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Original Paper

Therapist-Assisted Web-Based Intervention for Prolonged Grief Disorder After Cancer Bereavement: Randomized Controlled Trial

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Abstract

Background: Bereavement due to cancer increases the risk of prolonged grief disorder. However, specialized treatment options for prolonged grief after a loss due to illness are still scarce.

Objective: The aim of this study is to extend previous findings by evaluating a web-based cognitive behavioral intervention with asynchronous therapist support, consisting of structured writing tasks adapted specifically for prolonged grief after cancer bereavement.

Methods: The intervention was evaluated in a purely web-based randomized waitlist-controlled trial. Open-access recruitment of participants was conducted on the web. Prolonged grief (Inventory of Complicated Grief), depression, anxiety, posttraumatic stress, posttraumatic growth, somatization, sleep quality, and mental and physical health were assessed on the web via validated self-report measures.

Results: A total of 87 participants were randomized into the intervention group (IG; 44/87, 51%) or the waitlist control group (43/87, 49%). Of the participants, 7% (6/87) dropped out of the study (5/44, 11%, in the IG). Of the 39 completers in the IG, 37 (95%) completed all intervention tasks. The intervention reduced symptoms of prolonged grief (intention-to-treat: $P<.001$; $\eta^2=0.34$; Cohen $d=0.80$) to a clinically significant extent. It had favorable effects on depression, anxiety, posttraumatic stress, posttraumatic growth, and overall mental health but not on somatization, sleep quality, or physical health.

Conclusions: The web-based intervention for prolonged grief after cancer bereavement is effective in reducing symptoms of prolonged grief disorder and accompanying syndromes in a timely, easily realizable manner and addresses specific challenges of bereavement to illness. Considering web-based approaches in future mental health care policy and practice can reduce health care gaps for those who are bereaved to cancer.

Trial Registration: German Clinical Trial Register U1111–1186-6255; https://www.drks.de/drks_web/navigate.do?navigationId=trial.HTML&TRIAL_ID=DRKS00011001

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KEYWORDS

digital interventions; grief; traumatic loss; treatment effectiveness evaluation; cognitive behavioral therapy; neoplasms

Introduction

The loss of a loved one initiates a grief reaction, which is considered normal and healthy and enables adjustment to the loss and coping with new life realities. Although a normal grief reaction can be accompanied by significant emotional distress, the intensity of grief often decreases over a period that varies from culture to culture [1,2]. However, some bereaved persons show a grief reaction that is unusually long, intense, or complicated and can lead to significant impairment [2].

Pathological grief is included in the Diagnostic and Statistical Manual of Mental Disorders as persistent complex bereavement

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disorder (a diagnosis requiring further research) [3] and in the International Classification of Diseases (ICD-11) as prolonged grief disorder (PGD) [4]. With a conditional prevalence of 9.8% [5], PGD poses a considerable mental health risk for those who are bereaved of a loved one. The core symptoms of PGD include persistent and pervasive longing for or persistent preoccupation with the deceased and intense emotional pain, which may be reflected by sadness, anger, blame, guilt, numbness, the feeling of having lost a part of one's self, and an inability to accept the loss, experience positive mood, or engage in social and other activities [4]. The grief reaction must persist for at least 6 months; exceed social, cultural, and religious norms for the bereaved person's context; and cause significant impairment [4]. Persons with PGD report a reduction in quality of life, work and social functioning, energy levels, and overall mental health [6-8]. Risk factors for PGD include exposure to previous losses or trauma, previously impaired mental and physical health, low perceived social support, and low help-seeking [9,10].

A loss due to illness may cause specific additional strains for the bereaved, which increases the risk of developing PGD. Bereavement due to cancer has been identified as a risk factor for PGD [11,12]. Cancer is one of the leading causes of death in Germany. In 2016, a total of 229,827 persons died because of cancer, and 492,090 were diagnosed with cancer [13]. The diagnosis of a significant other is associated with a lower quality of life [14], increased distress [15,16], depression, and anxiety [17,18]. Such impairment of mental well-being during the time of illness was shown to predict further impairment of mental health in the case of bereavement [19,20]. Among bereaved caregivers, PGD is associated with preloss grief [20-23], preloss depression [20], the notion of not having coped well during the illness [23], poor family functioning [21], high caregiver burden [24], low preparedness, and low perceived social support [20,22]. A depletion of resources during the time of illness may impede bereavement adjustment [11,24] and put those who have a burdensome caregiving experience at increased risk of developing PGD after bereavement. A low perceived quality of death (agreement between preferences concerning the death and perceived actual circumstances of the death) [25], low preparedness for death, and death in a hospital [9,10] were further risk factors for PGD. The time of illness and the dying process, which are often experienced as burdensome or traumatic, influence the grieving process and should be specifically addressed in grief interventions.

Interventions targeting PGD have been proven effective [26]. Not all individuals with PGD, however, actually access treatment. Stigmatization [27] and low accessibility caused by conflicting schedules, long distances between client and therapist, or long waiting times may be barriers to treatment for the bereaved. Although caregiving and bereavement due to cancer pose a serious psychological strain, and studies examining interventions that specifically target cancer bereavement (eg, the studies by Kissane et al [28] and Lichtenthal et al [29]) have shown promising results, Guldin et al [30] reported that bereavement services in standard care do not target these aspects efficiently enough and therefore do not benefit those affected in a sufficient manner. This leaves bereaved relatives of persons with cancer at a high risk for adverse mental health outcomes, and their need for mental health care is often unmet.

Internet-based treatments offer an effective, flexible, and more anonymous approach for addressing mental health issues [31-33], which may help overcome treatment barriers for those with PGD. Internet-based treatment in general was shown to be as effective as conventional face-to-face treatment [34]. Internet-based interventions for grief have medium to large effect sizes [35]. Specific internet-based support for relatives of persons with cancer revealed promising results but, to date, mainly focused on caregiving during the time of illness (eg, the study by Applebaum et al [36]). There is a lack of evidence on internet-based interventions specifically addressing cancer bereavement and providing support beyond the time of illness. Web-based bereavement care targeted specifically at those with PGD after a cancer experience should be further examined.

Asynchronous web-based interventions that use cognitive behavioral techniques and rely on structured writing tasks and therapist feedback have proven effective in reducing syndromes such as prolonged grief, posttraumatic stress, or anxiety in the past (eg, the studies by Hedman et al [37] and Kersting et al [38]). They are often short and therefore economic and offer high flexibility for patients.

An asynchronous web-based intervention designed for the treatment of posttraumatic stress and PGD [39,40] has been successfully adapted by the research group to several specific bereavement situations such as pregnancy loss [38] or suicide bereavement [41]. To address the research gap concerning bereavement care after cancer, the intervention was adapted to suit the specific situation of those affected: difficult loss experiences are often preceded by a burdensome and possibly traumatic time of illness. The current intervention was designed to address the interlinking between grief and traumatic experiences, preloss grief and preparedness for the loss, and role conflicts and interpersonal conflicts. As a stand-alone, fully web-based intervention, it is suitable to overcome treatment barriers such as geographic and schedule restrictions and stigma. The effectiveness of the resulting therapist-assisted web-based intervention was evaluated in a randomized controlled trial to extend previous findings on bereavement care to the specific situation of cancer bereavement.

Methods

Study Design

The evaluation of the web-based cognitive behavioral therapy intervention for prolonged grief after bereavement due to cancer took place in a randomized waitlist-controlled trial. The primary outcome measure was prolonged grief. Prerandomization measurement points were screening (T-1) and baseline (T0), and postrandomization measurement points were posttreatment (T1) and follow-up (T2-T4).

The study was registered with the German Clinical Trial Register (Universal Trial Number U1111–1186-6255) and approved by the University of Leipzig Ethics Committee (no 450–15-21,122,015, January 20, 2017). The study was conducted in 2 waves with recruitment from November 2017

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to April 2018 and from May 2018 to June 2019. The first wave was funded by *Deutsche José Carreras Leukämie-Stiftung* (German José Carreras Leukemia Foundation, DJCLS R15/22) and is thoroughly described in a study protocol [42]. The second wave followed the same methodology, except for more liberal inclusion criteria concerning the cause of bereavement, as specified in the next section. The recruitment duration of the first wave was determined by the duration of funding. The second wave was set to 1 year in advance.

Participants

Individuals were eligible as participants if they:

- Were bereaved to hematological cancer (first wave) or any type of cancer (second wave),
- Reached a score of >25 on the Inventory of Complicated Grief (ICG) [43,44],
- Were ≥18 years, and
- Were fluent in the German language and had sufficiently stable web access.

The exclusion criteria were as follows:

- Current psychotherapy or change in psychopharmacological therapy within the last 6 weeks,
- Cognitive or physical impairment that would impede treatment participation, and
- Severe depression (Patient Health Questionnaire 9 [PHQ-9]; [45,46]), suicidal ideation (Beck Suicide Ideation Scale [47]; clinical assessment in telephone interview), dissociative tendency (Somatoform Dissociation Questionnaire [48]; clinical assessment in telephone interview), psychosis (Dutch Screening Device for Psychotic Disorder [49]; clinical assessment in telephone interview), posttraumatic stress disorder due to an event other than the loss (Impact of Event Scale–Revised [IES-R]; [50,51]), or substance use disorder [52].

Procedure

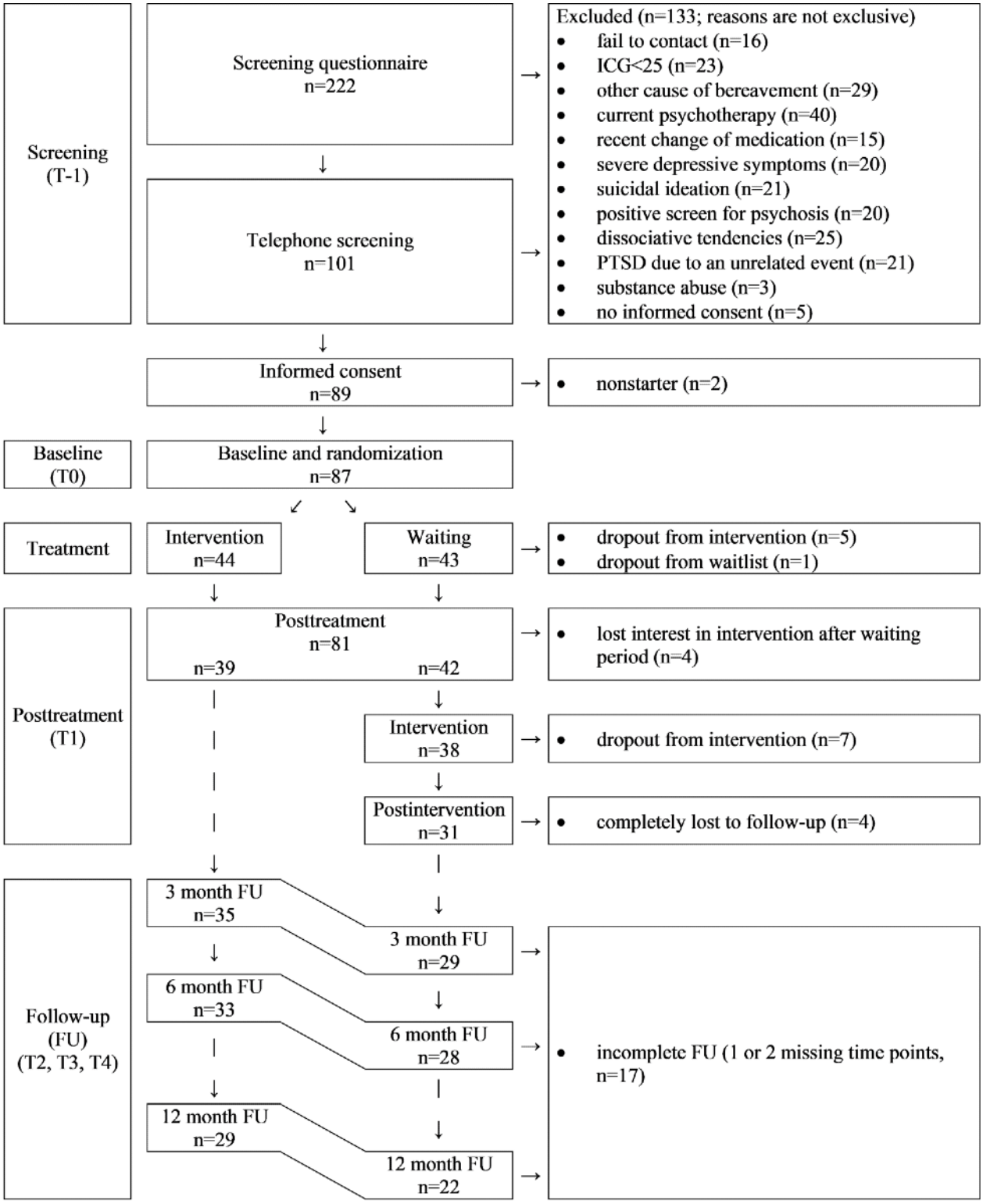
Open-access recruitment was carried out from November 2017 to June 2019 via social networks, relevant websites, and stakeholders such as support groups, clinics, medical practices, charities, and insurance companies. Study information forms were presented on the website and again upon inclusion. Participants could apply for the study by taking the open-access web-based screening questionnaire (T-1) (see the study protocol by Hoffmann et al [42]). A subsequent telephone screening was carried out by the participant's prospective therapist to clear any ambiguities concerning eligibility criteria (eg, to validate a possible positive screen for suicidality, psychosis, or dissociation) and to administer the Prolonged Grief Disorder Interview 13 [53,54] (not analyzed in this study). Informed consent was acquired as a signed form (mailed or scanned) from those who were included, and a baseline questionnaire (T0) was administered. Subsequently, randomization into either the intervention group (IG) or the waitlist control group (WCG) was conducted as described in the next section. Therefore, participants, as well as study personnel, were blinded to group allocation up to this point. After a treatment period of 5 weeks, a posttreatment measurement (T1) was administered to both groups. Afterward, participants in the WCG received the intervention and a second version of the posttreatment questionnaire (postintervention, T1.1). Follow-up measurements were administered at 3, 6, and 12 months after intervention completion. The entire study process was web based, except for 1 mandatory phone call per participant. All the data were stored in encrypted servers with password protection.

Measures to prevent multiple identities were informed consent forms, email confirmations, and phone calls. Participants did not pay for the intervention; neither were they paid.

The participant timeline is depicted in Figure 1.

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Figure 1. Participant flow. FU: follow-up; ICG: Inventory of Complicated Grief; PTSD: posttraumatic stress disorder.



Randomization

Randomization was conducted with the software *Randomization in Treatment Arms* via permutated block randomization with a block size of 4 and equal probabilities to be sampled into either group (pseudoseeds, MersenneTwister). The allocation sequence was generated by a research assistant and stored separately from other study materials. Participants were automatically assigned to the treatment conditions after completing the baseline measurement.

Intervention

The intervention *Online-Trauertherapie* (*Online Grief Therapy*) was conducted remotely via a secure website using the software *beranet* and consisted of 10 structured writing tasks that participants worked on independently in 2 self-scheduled 45-minute writing sessions per week. Participants received

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individualized therapist feedback from trained psychologists on all writing assignments within 24 hours, alternating between short and thorough feedback. If participants missed a scheduled session, they were reminded up to 2 times and called once if they did not respond. Participants could proactively contact their therapists via the website in case of questions or problems.

The structured writing tasks are organized into three modules (Table 1) that aim to work through grief and cope with the new situation: (1) *self-confrontation*, (2) *cognitive reappraisal*, and (3) *social sharing*.

Table 1. Intervention overview.

Phase and week	Procedure[a]		
	Pretask monitoring	Task	Posttask monitoring
Phase 1: self-confrontation			
1			
	SAM[b]	1	SAM
	SAM and PHQ-9[c]	2	SAM
2			
	SAM	3	SAM
	SAM and PHQ-9	4	SAM and WAI-S[d]
Phase 2: cognitive reappraisal			
3			
	SAM	5	SAM
	SAM and PHQ-9	6	SAM
4			
	SAM	7	SAM
	SAM and PHQ-9	8	SAM and WAI-S
Phase 3: social sharing			
5			
	SAM	9	SAM
	SAM and PHQ-9	10	SAM and WAI-S

[a]At the end of every week, thorough therapist feedback was provided.

[b]SAM: Self-assessment Manikin.

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

[d]WAI-S: Working Alliance Inventory–Short Form.

In the first module, *self-confrontation*, participants received information on prolonged grief, the treatment rationale, and the treatment platform. They were then asked to describe their loss experiences repeatedly in multiple sessions to reprocess traumatic memories and reduce avoidance behavior. Emphasis on emotional, cognitive, and bodily processes enables multimodal reprocessing. Addressed specifics of cancer bereavement included traumatic aspects of the illness experience, burdensome caregiving experiences, and ambiguity between hope for survival and preparation for the loss.

In the second module, *cognitive reappraisal*, participants were asked to write a letter to a hypothetical friend who shared the same loss experience. Participants were encouraged to focus on validating their counterparts' suffering as well as on building and reinforcing resources and coping strategies. Specific to cancer bereavement was the validation of one's own suffering, especially if the deceased's suffering was so far perceived as more important, addressing of guilt and anger, and reflection of one's role during the time of illness.

In the third module, *social sharing*, participants were asked to write (but not necessarily send) a letter to a real person involved in the loss experience (eg, themselves, the deceased, or a family member) to summarize and communicate their experiences, as well as new strategies and perspectives.

Instructions for all modules as well as psychoeducational material were standardized, and therapist feedback was highly structured but could be adapted to a specific patient's situation.

The patient's mood (Self-assessment Manikin [55]) and suicidality (PHQ-9 [45,46]) were monitored throughout the intervention to screen for increased distress and to provide information on emotional activation during the writing sessions. In addition, the Working Alliance Inventory–Short Form [56] was administered after every module. In case of increased

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distress, patients were contacted by their therapist via the platform or, if necessary, telephone.

Measurements

Overview

A detailed account of all measurement tools can be found in Hoffmann et al [42]. All constructs examined in this study were assessed using web-based self-report questionnaires, except for Prolonged Grief Disorder Interview 13 (telephone). Sociodemographic variables and characteristics of the loss were examined before randomization (T-1 and T0). All outcomes were assessed at T0, T1, and all follow-up times. Consistency and completeness checks were conducted. Questionnaires had 24 to 48 pages, depending on the time point, with up to 15 items per page.

Primary Outcome

This study examines the primary outcome of prolonged grief, as measured using the German version of the ICG [43,44]. At T0, the ICG had an internal consistency of Cronbach α=.82.

Secondary Outcomes

The 19 original items of the ICG were augmented by 3 additional items adapted from Xiu et al [57] to fully capture the ICD-11 criteria of PGD. They address feelings of guilt, difficulty accessing positive memories, and anhedonia. The augmented version of the ICG with 22 items is considered a secondary outcome in all analyses (Cronbach α=.85).

Further secondary outcomes were depression (PHQ-9 [45,46]; Cronbach α=.86), anxiety (Generalized Anxiety Disorder Screener 7 [58,59]; Cronbach α=.84), posttraumatic stress due to the loss (IES-R [50,51]; Cronbach α=.85), posttraumatic growth (Posttraumatic Growth Inventory [60,61]; Cronbach α=.90), somatization (Patient Health Questionnaire-15 [45,46]; Cronbach α=.65), sleep quality (Pittsburgh Sleep Quality Index [62,63]; Cronbach α=.75), and physical and mental health (12-item Short-Form Health Survey [64,65]).

Statistical Analyses

All statistical analyses were performed using R (R Foundation for Statistical Computing) [66]. Because both study waves were methodologically identical except for the cause of the bereavement inclusion criterion, a joint analysis was carried out for all participants across waves.

Descriptive analyses were used to provide means (SDs) or percentages of relevant variables. To test for baseline differences between treatment groups, between completers and dropouts, and between waves, 2-tailed *t* tests were used for numerical variables, and chi-square tests or the Fisher exact test for categorical variables.

The efficacy of the intervention was examined using linear mixed models for primary and secondary outcomes. This method allows for an intention-to-treat analysis under the assumption that data are missing at random. A restricted maximum-likelihood algorithm was applied. Analyses were performed in 2 steps. First, the appropriate base model was chosen by comparing the fit (Akaike information criterion and Bayesian information criterion) of three base models via analysis of variance: the unconditional means model (no random effects), random intercept model (unconditional growth model), and random intercept and random slope model. Second, fixed effects were added to the base model with the best fit to examine the effects of time, group, and time×group. Significance was assessed using *P* values approximated via Kenward–Roger approximations [67]. As there were 1 primary and 9 secondary outcomes, Bonferroni correction was applied, so that *P*=.05/10=.005 was deemed the threshold for significance in all linear mixed models. Effect sizes were calculated as Cohen *d* (between) and η^2, with the latter representing the percentage of variance explained by the model. Effect sizes were considered small if Cohen $d<0.5$ ($\eta^2<.06$), moderate if $0.5\leq$Cohen $d<0.8$ ($0.06\leq\eta^2<0.14$), and large if Cohen $d\geq0.8$ ($\eta^2\geq0.14$) [68]. In addition, Hedges *g* was computed to aid comparability across studies. To explore within-group effects, separate multilevel analyses were performed for each of the 2 treatment groups for all outcomes with time as a fixed effect.

Additional analyses were carried out for the primary outcome (ICG) as follows:

1. In addition to the intention-to-treat analysis, a completer analysis was conducted using a linear mixed model.
2. To test for differences in symptom trajectories across waves, a separate linear mixed model was run with wave×time as an additional fixed effect.
3. The clinical significance of the change in ICG scores was evaluated using three metrics: (1) The reliable change index (RCI) [26] weighs pretest–posttest differences by SE (in this case, derived from Cronbach α at baseline). By comparing the score with *z* scores, a dichotomous assessment (95% CI) to determine whether a participant exhibited clinically significant improvement between 2 measurement points was derived. (2) The cut-off criterion of the ICG (25 points [43]) was used to provide an additional approximation of clinical significance, and (3) as a more conservative measure, the intersection of both was chosen, indicating clinically significant improvement only if both the RCI and cut-off criteria were satisfied. Chi-square tests were carried out for all 3 dichotomous measures (RCI, cut-off, and their intersection) to examine differences between treatment groups posttreatment.
4. An analysis of follow-up data (T2-T4) was conducted with a linear mixed model with time as a factor (postintervention vs 3-month follow-up vs 6-month follow-up vs 12-month follow-up). The model included both the treatment groups.

Results

Sample Description

A total of 222 persons completed the screening questionnaire, 89 (40.1%) of whom fulfilled the eligibility criteria and provided informed consent. The baseline questionnaire was completed by 87 participants, who were randomized into the IG (44/87, 51%) or the WCG (43/87, 49%). Participant flow is depicted in Figure 1.

Participants were on average 47.32 (SD 14.01) years old, and 83% (72/87) were female. Approximately half of the participants

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(42/87, 48%) were in a relationship, and 49% (43/87) had children (mean number of children, if any, 1.86, SD 1.17). Most participants had high (60/87, 69%) or intermediate (21/87, 24%) levels of education.

Participants were most often bereaved of their parents (41/87, 47%), spouses (30/87, 34%), or children (9/87, 10%), and reported a very close relationship with the deceased (mean 4.93, SD 0.30; on a scale of 1 [not close at all] to 5 [very close]). The death occurred on average 28.73 months (2.4 years) ago (SD 40.3, median 16.93 months, or 1.4 years). The most commonly reported cancer types among the deceased were leukemia (8/21, 38%) and lymphoma (6/21, 29%) in the first wave and cancer of the respiratory and chest organs (16/66, 24%) and digestive organs (13/66, 20%) in the second wave.

On average, participants reported an intensity of prolonged grief of $mean_{total}$ 37.94 (SD_{total} 10.27; $mean_{IG}$ 38.98, SD_{IG} 9.87; $mean_{WCG}$ 36.88, SD_{WCG} 10.67; P=.35; on a scale of 0-76) at baseline.

The participants were assessed for secondary syndromes. Of all participants, 54% (47/87) scored above the threshold for at least moderate depression on the PHQ-9 (≥10), 39% (34/87) showed at least moderate anxiety (≥10), 17% (15/87) scored above the cut-off for likely posttraumatic stress disorder on the IES-R (>0), 44% (38/87) showed at least moderate somatization (≥10), and 32% (28/87) displayed severe sleep problems (>10). Overall, 76% (66/87) of the participants surpassed at least one of these thresholds. Of all participants, 86% (75/87) scored below the 20th percentile on the 12-item Short-Form Health Survey for mental health, whereas 35% (30/87) fell below the 20th percentile for physical health [69].

The treatment groups did not differ in sociodemographic variables, characteristics of the loss, or baseline mental health (Table 2). However, there was a significant difference in posttraumatic growth (P=.02), indicating that the IG reported significantly lower posttraumatic growth at baseline than did the WCG.

After randomization, 7% (6/87) of participants (5/44, 11% in the IG, 1/43, 2% in the WCG) dropped out of the study (ie, did not provide posttreatment data). Dropouts were exclusively female or nonbinary (P=.046) and reported slightly higher closeness to the deceased ($mean_{dropout}$ 5.00 vs $mean_{completer}$ 4.92; P=.03). Otherwise, there were no significant differences between completers and dropouts (Multimedia Appendix 1). Of the 39 completers in the IG, 37 (95%) completed all writing tasks, whereas 2 (5%) completed 7 and 9 tasks.

Participants recruited in the 2 waves did not differ, except for expected differences in the cause of loss (P<.001) and a smaller proportion of females among the deceased in the second wave (P=.01; Multimedia Appendix 1).

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Table 2. Demographic and clinical characteristics of the study sample at baseline.

	Total (N=87)	Intervention group (n=44)	WCG[a] (n=43)	*P* value[b]
Demographic characteristics				
Age (years), mean (SD)	47.32 (14.01)	47.80 (13.39)	46.84 (14.76)	.75
Gender, n (%)				.61
Female	72 (83)	36 (82)	36 (84)	
Male	14 (16)	7 (16)	7 (16)	
Other	1 (1)	1 (2)	0 (0)	
Relationship (yes), n (%)	42 (48)	19 (43)	23 (54)	.45
Has children (yes), n (%)	43 (49)	21 (47)	22 (51)	.92
Number of children (if any), mean (SD)	1.86 (1.17)	1.71 (0.9)	2 (1.38)	.43
School education, n (%)				.90
Low	6 (7)	4 (9)	2 (5)	
Intermediate	21 (24)	11 (25)	10 (23)	
High	60 (69)	29 (66)	31 (69)	
Characteristics of the loss				
Time since loss (months), mean (SD)	28.73 (40.3)	31.91 (50.65)	25.47 (26.02)	.46
Relationship to the deceased, n (%)				.86
Parent	41 (47)	21 (48)	20 (47)	
Child	9 (10)	3 (7)	6 (14)	
Spouse	30 (35)	16 (36)	14 (33)	
Sibling	3 (3)	2 (5)	1 (2)	
Other	4 (5)	2 (5)	2 (5)	
Gender of the deceased, n (%)				.45
Female	43 (49)	24 (55)	19 (44)	
Male	44 (51)	20 (45)	24 (56)	
Other	0 (0)	0 (0)	0 (0)	
Closeness to the deceased, mean (SD)	4.93 (0.30)	4.98 (0.15)	4.88 (0.39)	.15
Type of cancer, n (%)				.94
Hematological cancer	31 (36)	17 (39)	14 (33)	
Leukemia	10 (12)	5 (11)	5 (12)	
Lymphoma	7 (8)	3 (7)	4 (9)	
Plasmacytoma	6 (7)	4 (9)	2 (5)	
Other hematological	8 (9)	5 (11)	3 (7)	
Other types of cancer	56 (64)	27 (61)	29 (67)	
Respiratory and chest organs	16 (18)	9 (21)	7 (16)	
Digestive tract	13 (15)	5 (11)	8 (19)	
Breast	6 (7)	2 (5)	4 (9)	
Central nervous system and eyes	6 (7)	3 (7)	3 (7)	
Urinary tract	3 (3)	1 (2)	2 (5)	
Other	12 (14)	7 (16)	5 (12)	
Mental health at baseline, mean (SD)				
Prolonged grief	37.94 (10.27)	38.98 (9.87)	36.88 (10.67)	.35
Depression	10.72 (5.33)	10.77 (5.08)	10.67 (5.63)	.93

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	Total (N=87)	Intervention group (n=44)	WCG[a] (n=43)	*P* value[b]
Anxiety	8.39 (4.45)	8.68 (4.31)	8.09 (4.62)	.54
Posttraumatic stress	−0.83 (0.83)	−0.87 (0.83)	−0.80 (0.84)	.70
Posttraumatic growth	64.84 (18.13)	60.23 (18.3)	69.56 (16.89)	.02
Somatization	10.11 (4.51)	10.54 (4.66)	9.67 (4.36)	.37
Sleep quality	8.90 (3.71)	8.70 (3.54)	9.09 (3.91)	.62
Physical health	47.78 (10.13)	46.46 (10.66)	49.14 (9.5)	.22
Mental health	33.12 (9.44)	32.51 (8.63)	33.74 (10.26)	.55

[a]WCG: waitlist control group.

[b]Group difference.

Intervention Efficacy

Primary Outcome: Prolonged Grief

Baseline and posttreatment sum scores of prolonged grief measured with the ICG were used as outcomes of 3 base models (unconditional means, random intercept, random slope, and intercept), the fit of which was then compared via analysis of variance. A random intercept model provided the best fit (P<.001) and was used to examine the fixed effects of time, group, and the interaction of both (Table 3).

A significant group×time interaction effect indicated that prolonged grief decreased from baseline to posttreatment to a larger extent in the IG than in the WCG (P<.001; $F_{1,80.4}$=40.7; N=87). The effect size was large (η^2=0.34, 95% CI 0.20-0.46; Cohen d=0.80, 95% CI 0.35-1.25; Hedges g=0.79, 95% CI 0.34-1.24).

Separate random intercept models for each treatment group revealed a significant effect of time within the IG (P<.001; $F_{1,39.78}$=58.89; N=44), but not within the WCG (P=.34; $F_{1,41.11}$=0.92; N=43).

A random intercept model with inclusion of completers only revealed results similar to the intention-to-treat analysis (time×group interaction: P<.001; $F_{1,79.2}$=40.5), with large effect sizes (η^2=0.34; Cohen d=0.80; N=81).

A random intercept model with the intention-to-treat sample and inclusion of wave×time as a fixed effect did not lead to an increase in model fit (P=.09), and the wave had no significant impact on the ICG score trajectory (wave×time interaction: P=.15; N=87).

According to the RCI, 44% (17/39) of the IG and 2% (1/42) of the WCG displayed clinically significant improvements in the ICG from baseline to posttreatment (χ^2_1=17.6; P<.001). The ICG cut-off of 25 was undercut by 44% (17/39) of the IG and 14% (6/42) of the WCG at posttreatment (χ^2_1=7.2; P=.007). Both criteria were met by 33% (13/39) in the IG and 2% (1/42) in the WCG (χ^2_1=11.5; P<.001).

Follow-up analysis showed that ICG scores directly after the intervention and at 3, 6, and 12 months after the intervention differed (P<.001; $F_{3,174.31}$=6.48). Post hoc tests revealed that ICG scores were lower at follow-up (3 months vs postintervention, P=.009; 6 months vs postintervention, P<.001; 12 months vs postintervention, P<.001).

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Table 3. Results of mixed model analyses (intention-to-treat, N=87).

Outcome	Pre, mean (SD)	Post, mean (SD)	Within-group effects of time		Interaction effects (time×group)			
			F test (*df*)	*P* value[a]	*F* test (*df*)	*P* value[a]	η^2 (95% CI)	Cohen $d_{between}$ (95% CI)
Primary outcome								
Prolonged grief (ICG[b])					40.7 (1,80.4)	<.001	0.34 (0.20 to 0.46)	0.80 (0.35 to 1.25)
WCG[c]	36.9 (10.7)	36.0 (10.8)	0.9 (1,41.1)	.34				
IG[d]	39.0 (9.9)	27.5 (10.4)	58.9 (1, 39.8)	<.001				
Secondary outcomes								
Prolonged grief (ICGa[e])					44.4 (1,80.4)	<.001	0.36 (0.22 to 0.47)	0.84 (0.38 to 1.29)
WCG	42.4 (12.3)	41.5 (12.6)	0.8 (1,41.1)	.38				
IG	44.7 (11.5)	31.3 (11.9)	58.7 (1,39.6)	<.001				
Depression (PHQ-9[f])					21.0 (1,79.6)	<.001	0.21 (0.09 to 33)	0.69 (0.23 to 1.13)
WCG	10.7 (5.6)	9.4 (4.8)	4.4 (1,40.2)	.04				
IG	10.8 (5.1)	6.4 (3.9)	44.7 (1,39.8)	<.001				
Anxiety (GAD-7[g])					8.7 (1,80.4)	.004	0.10 (0.02 to 0.21)	0.43 (−0.01 to 0.88)
WCG	8.1 (4.6)	7.4 (3.9)	0.8 (1,40.5)	.39				
IG	8.7 (4.3)	5.9 (3.1)	20.6 (1,40.3)	<.001				
Posttraumatic stress (IES-R[h])					9.1 (1,80.4)	.003	0.10 (0.02 to 0.22)	0.65 (0.20 to 1.10)
WCG	−0.8 (0.8)	−1.0 (0.8)	5.4 (1,40.3)	.03				
IG	−0.9 (0.8)	−1.6 (0.8)	21.1 (1,40.6)	<.001				
Posttraumatic growth (PGI[i])					24.6 (1,79.7)	<.001	0.24 (0.11 to 0.36)	−0.29 (−0.73 to 0.15)
WCG	69.6 (16.9)	70.6 (16.7)	0.1 (1,40.4)	.75				
IG	60.2 (18.3)	76.1 (21.0)	42.4 (1,39.2)	<.001				
Somatization (PHQ-15[j])					1.9 (1,79.4)	.17	0.02 (0.00 to 10)	−0.03 (−0.47 to 0.41)
WCG	9.7 (4.4)	8.5 (3.7)	4.9 (1,40.4)	.03				
IG	10.5 (4.7)	8.6 (4.8)	13.2 (1,39.0)	<.001				
Sleep quality (PSQI[k])					0.02 (1,77.7)	.90	0.00 (0.00 to 0.02)	−0.01 (−0.46 to 0.43)
WCG	9.1 (3.9)	8.5 (3.6)	0.7 (1,39.7)	.41				
IG	8.7 (3.5)	8.6 (3.8)	0.3 (1,38.1)	.58				
Physical health (SF-12[l])					0.1 (1,79.6)	.77	0.00 (0.00 to 0.04)	0.23 (−0.21 to 0.67)
WCG	49.1 (9.5)	49.5 (8.1)	0.0 (1,40.4)	.95				
IG	46.5 (10.7)	47.5 (9.7)	0.2 (1,39.2)	.66				
Mental health (SF-12)					8.6 (1,80.8)	.004	0.10 (0.02 to 0.21)	−0.44 (−0.89 to 0.00)
WCG	33.7 (10.3)	34.8 (11.3)	0.4 (1,40.4)	.53				
IG	32.5 (8.6)	39.3 (8.8)	15.4 (1,41.2)	<.001				

[a]Values of *P*<.005 were considered to indicate significance.

[b]ICG: Inventory of Complicated Grief.

[c]WCG: waitlist control group.

[d]IG: intervention group.

[e]ICGa: augmented version of Inventory of Complicated Grief.

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

[g]GAD-7: Generalized Anxiety Disorder-7 scale.

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[h]IES-R: Impact of Event Scale–Revised.

[i]PGI: Posttraumatic Growth Inventory.

[j]PHQ-15: Patient Health Questionnaire-15.

[k]PSQI: Pittsburgh Sleep Quality Index.

[l]SF-12: 12-item Short Form Health Survey.

Secondary Outcomes

Prolonged grief as measured with the augmented version of the ICG, depression, anxiety, posttraumatic stress, somatization, mental and physical health, sleep quality, and posttraumatic growth were examined as secondary outcomes (Table 3). A random intercept model provided the best fit for all secondary outcomes. A significant group×time interaction was found for prolonged grief (augmented), depression, anxiety, posttraumatic stress, posttraumatic growth, and mental health with effect sizes from Cohen *d*=0.29 to 0.84 (small to large), but not for physical health, sleep quality, or somatization. A significant within-group effect of time was found in the IG for prolonged grief (augmented), depression, anxiety, posttraumatic stress, posttraumatic growth, mental health, and somatization and in the WCG for depression, posttraumatic stress, and somatization (Table 3). There was no deterioration in the mean scores of any secondary outcome. No unintended effects were observed.

Discussion

Principal Findings

In light of unmet mental health care needs among those bereaved by cancer, we adapted and evaluated a web-based intervention for PGD after cancer bereavement. Specifically, the intervention was designed to address the traumatic nature of the time of illness as well as difficulties in the bereavement phase. It exceeds the scope of previously evaluated web-based interventions for relatives of patients with cancer. The intervention proved effective in reducing symptoms of PGD to a clinically significant extent compared with a WCG.

A total of 87 participants were included and randomized. With 6 participants dropping out, 81 completed the posttreatment measurement. The dropout rate of 7% is in line with previous studies on web-based interventions for grief [35], which indicates sufficient acceptability.

With 76% of participants exceeding cut-offs for at least one secondary syndrome, and 86% scoring below the 20th percentile for mental health, our sample displayed considerable impairment before treatment, which illustrates the necessity of an accessible intervention.

A linear mixed model was used to examine the intervention's efficacy and revealed a significant interaction effect, indicating a greater decrease in PGD symptoms (ICG) in the IG than in the WCG. This effect proved robust in a completer analysis and in an analysis including the augmented version of the ICG with 3 additional items that reflect specifics of the ICD-11 criteria [57]. The intervention had a large effect on PGD symptoms (Cohen *d*=0.80; Hedges *g*=0.79) and led to clinically significant improvement. The effect size in this study exceeded the average pooled effect sizes from two recent meta-analyses examining (1) conventional and web-based interventions for prolonged grief (Hedges *g*=0.45) [26] and (2) only web-based grief interventions (Hedges *g*=0.54, 95% CI 0.30-0.78) [35]. Symptoms of PGD further decreased throughout the follow-up period of 12 months. These results indicate that the intervention is suitable for decreasing the symptoms of PGD to a relevant extent.

Small to moderate effects were found for depression, anxiety, posttraumatic stress, posttraumatic growth, and mental health. This shows that the intervention is suitable not only to decrease PGD but also to ameliorate accompanying syndromes and overall mental health. Some modules of the intervention are well suited to address syndromes besides PGD. Especially, (1) the module *self-confrontation* facilitates reprocessing of distressing memories and may therefore lead to a decrease in posttraumatic stress and related anxiety, and (2) the module *cognitive reappraisal* is set to improve coping skills and resource availability and may therefore influence depressive symptoms and posttraumatic growth. The effect size for depression in this study was comparable with the pooled effect size found by Wagner et al [35] for web-based grief interventions; the effect size for posttraumatic stress was slightly lower. The absence of an effect on physical health, somatization, and sleep is deemed conclusive, because these constructs are related to physical well-being, which was not targeted in the intervention.

We argue that this study is methodologically suitable for examining the effectiveness of a web-based intervention for PGD. However, some methodological aspects merit discussion.

As stated in the study protocol [42], a sample size of N=128 was intended to ensure enough power to detect a moderate effect. Although we did not meet this criterion, the achieved sample size of N=87 was sufficient to detect the large effect that the intervention had on PGD.

This study was conducted in 2 waves, with the second wave's (May 2018 to June 2019) inclusion criteria concerning the cause of bereavement being more liberal than the first wave's (November 2017 to April 2018). However, participants of both waves displayed similar amounts of distress, were from similar socioeconomic backgrounds, and had similar characteristics of their loss. Moreover, the PGD trajectories did not differ between the waves. Therefore, we deemed the groups homogeneous enough to be included in the joint analysis.

Treatment groups were considered mostly equal, as they differed only in that the WCG had more favorable values for posttraumatic growth at baseline than the IG. This may, to some extent, weaken the interpretability of the results concerning posttraumatic growth.

Females were overrepresented in this study, as is the case in many previous studies on web-based interventions [35] or caregiving and bereavement [24]. To some extent, this may reflect women in Germany being more often affected by

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bereavement than men. For example, women are more often widowed than men [70]. In addition, women do more often assume caregiver roles for sick relatives [71], which makes them more vulnerable to burdensome caregiving experiences and witnessing traumatic aspects of illness and death. This may lead to increased PGD levels among women compared with men. However, women may also be more likely to seek support via the internet or be open to therapist contact [72]. Therefore, our sample, which is not representative of the German population, may well be representative of those who have PGD after a loss due to illness and are willing to undergo web-based treatment.

This study relied on web-based self-report measures to assess the primary and secondary outcomes. Although the use of interviews would have provided added validity, our questionnaires comprised instruments that were designed and validated for administration as self-report assessments. Therefore, we deemed our assessments to be adequately valid.

Future research may examine the differential effects of the treatment modules used in this study, the role of therapist support, and the long-term effects of web-based interventions, especially in comparison with face-to-face approaches. In addition, it might be fruitful to explore the acceptability and effectiveness of web-based grief interventions when blended into existing health care structures (eg, primary care) and to examine economic aspects such as cost-effectiveness.

Conclusions

PGD has significant ramifications for individuals and society. As it has only recently been acknowledged as a mental illness, specialized treatment options are still scarce. A low-threshold, acceptable, and effective web-based intervention may reduce treatment barriers and improve the mental health care situation of those affected.

Our results extend previous findings by providing evidence for the efficacy of a web-based intervention that was specifically adapted for persons bereaved because of cancer. It proved effective in decreasing the symptoms of PGD and accompanying syndromes to a clinically significant extent in a relatively short treatment duration of 5 weeks. It addresses specific issues of cancer bereavement, such as traumatic aspects of the time of illness, preloss grief, and preparedness, and provides low-threshold access to specialized grief therapy. Therefore, it is suitable to reduce the treatment gap for those with PGD after a loss due to illness.

Alternatives and complements to conventional face-to-face psychotherapy are needed, as illustrated by the increased demand for remote treatment options during the COVID-19-pandemic. Web-based approaches should therefore be considered in future mental health care policies and practices.

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Authors' Contributions

AK, MN, and KL designed the study and acquired the funding. JK, RH, and MN administered the project, which was supervised by AK. JK conducted statistical analyses. The manuscript was prepared by JK, with review and consultation by MN, RH, and KL. AK reviewed and edited the manuscript. All authors have contributed to and approved the final manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Demographic and clinical characteristics of the study sample at baseline by dropout status and study wave.
[DOCX File , 42 KB - mental_v9i2e27642_app1.docx]

Multimedia Appendix 2
CONSORT-eHEALTH checklist (V 1.6.1).
[PDF File (Adobe PDF File), 1239 KB - mental_v9i2e27642_app2.pdf]

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Abbreviations

ICD-11: International Classification of Diseases
ICG: Inventory of Complicated Grief
IES-R: Impact of Event Scale–Revised
IG: intervention group
PGD: prolonged grief disorder
PHQ-9: Patient Health Questionnaire 9
RCI: reliable change index
WCG: waitlist control group

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Original Paper

In Search of State and Trait Emotion Markers in Mobile-Sensed Language: Field Study

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Abstract

Background: Emotions and mood are important for overall well-being. Therefore, the search for continuous, effortless emotion prediction methods is an important field of study. Mobile sensing provides a promising tool and can capture one of the most telling signs of emotion: language.

Objective: The aim of this study is to examine the separate and combined predictive value of mobile-sensed language data sources for detecting both momentary emotional experience as well as global individual differences in emotional traits and depression.

Methods: In a 2-week experience sampling method study, we collected self-reported emotion ratings and voice recordings 10 times a day, continuous keyboard activity, and trait depression severity. We correlated state and trait emotions and depression and language, distinguishing between speech content (spoken words), speech form (voice acoustics), writing content (written words), and writing form (typing dynamics). We also investigated how well these features predicted state and trait emotions using cross-validation to select features and a hold-out set for validation.

Results: Overall, the reported emotions and mobile-sensed language demonstrated weak correlations. The most significant correlations were found between speech content and state emotions and between speech form and state emotions, ranging up to 0.25. Speech content provided the best predictions for state emotions. None of the trait emotion–language correlations remained significant after correction. Among the emotions studied, valence and happiness displayed the most significant correlations and the highest predictive performance.

Conclusions: Although using mobile-sensed language as an emotion marker shows some promise, correlations and predictive R^2 values are low.

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KEYWORDS

depression; emotions; mobile sensing; language; LIWC; openSMILE; speech; writing; mobile phone

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Introduction

Background

Emotions are crucial to human survival, functioning, and well-being. They alert us to opportunities and challenges in our environment and motivate us to act on them to serve our goals and concerns [1]. As such, how people feel throughout their daily lives is an important determinant of their overall mental well-being [2,3]. On average, feeling higher levels of positive emotions and lower levels of negative emotions is generally considered to reflect better well-being, and mood disorders involve extreme instantiations of this [4]. Aside from average levels, emotions are in constant movement and fluctuation over time [1,3,5]. Small but repeated deviations in moment-to-moment emotion dynamics can accumulate over time into larger deviances in mood and, ultimately, episodes of mood disorders. Therefore, reliable and suitable methods to measure people's daily life emotions, in terms of both momentary fluctuations and average levels, are much needed to further improve the study of emotion and emotion disorder and help in the detection and prevention of maladaptive emotional functioning. One of the ways in which people convey emotions is language. In this paper, we will examine to what extent language-based data collected through mobile sensing can be instrumental in the prediction of emotions.

Experience Sampling Method

The current gold standard for researching emotion (dynamics) in daily life is the experience sampling method (ESM). Participants complete a short survey on how they feel multiple times a day, allowing data to be collected during their normal routine [6]. The momentary nature of the assessment helps mitigate memory biases, enhances ecological validity, and allows for within-person patterning and investigating of relationships [7-9].

However valuable, the ESM has some drawbacks. Interrupting daily activities for a survey multiple times a day can be burdensome [10]. Motivation loss may induce untruthful or superficial responses, compromising data quality [11]. Furthermore, thinking about emotions multiple times a day may influence their natural flow [9,12], and social desirability in self-reports is a known problem [9]. These drawbacks could be avoided if it were possible to collect equally informative data without having to rely on the participants' active involvement.

Mobile Sensing and Language

One such unobtrusive (passive) data collection method as an alternative to ESM is mobile sensing [13]. Whenever we use or carry our mobile devices, mobile sensors and user logs such as light sensors, accelerometers, and app use logs are registered as traces of our digital behavior [14,15]. Given the pervasiveness of smartphones, this continuous flow of information might enable the automatic and unobtrusive detection of behavioral features such as sleep, social behavior, or even mood disorder episodes to aid in research and clinical practice [14,16-19].

We need emotionally valid data that can be captured by a smartphone to be able to use mobile sensing in the detection of emotion and mood disorders. Language is one of the ways in which people (digitally) express their emotions [20]. Both language and emotions also serve as communication and cooperation tools and mutually influence each other [21]. People explicitly or implicitly convey emotions to their interaction partners through what they say and how they say it [22-26]. Therefore, in this paper, we will examine to what extent language-based data collected through mobile sensing can be instrumental for the prediction of momentary and trait emotion. We make a distinction, on the one hand, between what people communicate (content) and how they communicate it (form) and, in contrast, between speech and writing, resulting in 4 types of language data (Textbox 1).

Textbox 1. Types of language data.

Types of language data

- Speech content: spoken words
- Speech form: voice acoustics (eg, pitch and timbre)
- Writing content: written words
- Writing form: typing dynamics (eg, typing speed and key press duration)

Previous Related Work

Speech Content

Studies on speech and emotional word use have generally focused on positive or negative emotions. Induced positive emotions coincide with more positive and less negative emotions between persons [27,28]. In addition, in natural language snippets, a positive association between trait positive affectivity and positive emotion words was found [29]. Higher trait negative affectivity and higher within-person negative emotions coincided with more negative emotions and more sadness-related words in experimental and natural settings [27-29]. However, a recent study did not find any significant correlations between emotion words and self-reported emotions either within or between persons [30].

Because of these inconsistencies, *The Secret Life of Pronouns* supports the use of nonemotion words to assess emotional tone. In particular, depression and negative emotionality show a small correlation with first-person pronouns [31,32]. A larger variety of studies was conducted with writing, which will be further addressed in the *Writing Content* section.

Speech Form

Each voice has a unique sound because of age, gender, and accent. However, psychological features such as attitudes, intentions, and emotions also affect our sound [26]. Johnstone

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and Scherer [33] discern three types of features: time-related (eg, speech rate and speech duration), intensity-related (eg, speaking intensity and loudness), and features related to the fundamental frequency (F0; eg, F0 floor and F0 range). A fourth type could be timbre-related features (eg, jitter, shimmer, and formants). (Mobile-sensed) voice features have repeatedly been used in affective computing for the automatic classification of depression, bipolar disorder, and Parkinson disease [34-38].

Higher-arousal emotions (eg, fear, anger, and joy) generally induce a higher speech intensity, F0, and speech rate, whereas lower-arousal emotions (eg, sadness and boredom) induce a lower speech intensity, F0, and speech rate (Table 1) [33,39-43]. Other features include a harmonics to noise ratio, which was found unrelated to arousal [44], and jitter, which showed a positive correlation with depression [45]. Arousal has been easiest to detect based on voice acoustics [46]. Discrete emotion recognition based on these features in deep neural networks has also been successful [47]. It is not yet clear whether these features could also discriminate between discrete emotions in simple models [48].

Table 1. Expected emotion–speech form correlations.

Emotion	F0[a]-mean	F0-SD	F0-range	F0-rise	F0-fall	Loudness mean	Loudness rise	Loudness fall	Jitter[b]	Shimmer[c]	HNR[d]	Speech rate	Pause duration
Valence													
Arousal	(+)[e]	+	+	+	+	+	+	+				(+=)[f]	(−)[g]
Anger	+	+	+	+	+	+	+	+	+=	+=	+	(+−)[h]	−
Anxiety	+	+−	+	+−	+−	+			+	+	−	+−	+−
Sadness or depression	−	−	−	−	−	−	−	−	+		−	−	+
Stress	+	+	+	+	+	+	+	+				+	−
Happiness	+	+	+	+	+	+	+	+	+=	+=	+	+	−

[a]F0: fundamental frequency.

[b]Deviations in individual consecutive fundamental frequency period lengths.

[c]Difference in the peak amplitudes of consecutive fundamental frequency periods.

[d]HNR: harmonics to noise ratio (energy in harmonic components and energy in noise components).

[e]Positive correlation.

[f]Positive or no correlation.

[g]Negative correlation.

[h]Undirected correlation.

Writing Content

Higher valence has repeatedly been associated with more positive and less negative emotion words on a within- and between-person level, along with a higher word count in both natural and induced emotion conditions (Table 2) [28,49-51]. Other studies have demonstrated 1-time links between higher valence and more exclamation marks and fewer negations between persons and between higher valence and less sadness-related words within persons [50,51], although the latter 2 have also been found to be unrelated [28,49]. Pennebaker [52] states that people use more first-person plural pronouns when they are happy.

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Table 2. Expected emotion–speech and writing content correlations.

Emotion	WC[a]	I	We	You	Negate	Posemo[b]	Negemo[c]	Anx[d]	Anger	Sad	Certain[e]	Swear	Exclam[f]
Valence	(+)[g]	(−)[h]								+		+	+
Arousal													
Anger		+	+	+					+				
Anxiety		+	+	+	+	+	+	+			+		
Sadness		+	+		+			+					
Stress		+		+									
Happiness	+	−								+		+	+
Depression		+	+	+	+	+	+	+			+		

[a]WC: word count.

[b]Posemo: positive emotions.

[c]Negemo: negative emotions.

[d]Anx: anxiety.

[e]Certain: absolutist words.

[f]Exclam: exclamation marks.

[g]Positive correlation.

[h]Negative correlation.

Negative emotion, anxiety, and anger words recur as linguistic markers of anger within and between persons [49,51]. Pennebaker [52] adds to that the use of second-person pronouns. Recurrent linguistic markers of trait anxiety include negative emotion, sadness, and anger words [53,54]. The results with explicit anxiety words are mixed, and some isolated findings suggest a relationship with first-person, negation, swear, and certainty words [53,54]. Momentary and trait sadness have been linked to more negative emotion, sadness, and anger words in multiple studies [28,49,51]. In contrast, they were unrelated to sadness words in daily diaries [51]. A positive correlation existed between stress on one side and negative emotion and anger words between and within persons on the other [51,54]. Anxiety words have been related to stress both on a weekly and daily level [51], but this could not be replicated with trait stress [54]. Apart from the explicit emotion categories, several studies have linked depressive symptoms to the use of *I* words [23,55-58]. Other correlations include more negative emotion words, more swear words, and more negations [53,59,60]. More anxiety, sadness, and anger words were found in 1 study but were not significant in all studies [51,54]. In fact, Capecelatro et al [31] found depression to be unrelated to all Linguistic Inquiry and Word Count (LIWC) emotion categories.

Writing Form

Initially, studies concerning typing dynamics used external computer keyboards to predict stress and depression, among other emotions [61-65]. More recent studies have tried to use soft keyboards on smartphones for emotion, depression, and bipolar disorder detection [66-69]. It has been easier to distinguish between broad emotion dimensions—valence in 1 study and arousal in another [66,70].

Despite the high predictive accuracies of deep learning models, separate correlations between emotional states and typing dynamics are small (Table 3). They exist between increased arousal and decreased keystroke duration and latency [70]. The dynamics used in depression detection include a shorter key press duration and latency, with a medium reduction in duration for severe depression but a high reduction for mild depression [61]. No correlation was found between depression and the number of backspaces. For emotions, typing speed was the most predictive feature [66].

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Table 3. Expected emotion–writing form correlations.

Emotion	Number of characters	Typing speed	Average key press duration	Number of entries	Backspaces	Typing duration
Valence	(+)[a]					
Arousal		+	(–)[b]			–
Anger						
Anxiety						
Sadness						
Stress		+	–	–	–	–
Happiness	+					
Depression			–			

[a]Positive correlation.

[b]Negative correlation.

This Study

Despite this body of research, crucial questions remain. For instance, most research has focused on between-person relationships, whereas few studies have looked at state emotions within persons. Therefore, it is unclear to what extent mobile-sensed language can help predict moment-to-moment changes within individuals. Previous research has typically also examined particular language features in isolation. As a result, we do not know how the different types of language data compare in their predictive value nor to what extent combining them may enhance the prediction of moment-to-moment and trait emotions.

In this study, we will examine the separate and combined predictive value of 4 mobile-sensed language data sources for detecting momentary emotional experience as well as emotional traits and depression. A 2-week ESM study was designed, querying participants to indicate their valence, arousal, anger, anxiety, sadness, stress, and happiness on their smartphones 10 times a day. In addition, a custom-built app recorded data from several sensors. Relevant to this study, the participants were asked to use the provided custom keyboard software as often as possible and to make a voice recording regarding their emotional state at the end of each ESM survey. On the basis of these data, we will examine how self-reported emotional experience is correlated and can be predicted with spoken and written word use, acoustic voice features, and typing dynamics.

This study goes beyond previous work by comparing and combining all four sources of language behavior: speech, writing, content, and form. In addition, this study will examine the prediction of emotion traits as well as moment-to-moment emotional fluctuations in daily life, providing a comprehensive picture of the potential of language-based smartphone-sensing data for emotion detection.

Methods

Participants

Participants were recruited through notices on social media groups and notice boards around university buildings. In this notice, people were directed to a web survey for selection purposes. This web survey queried an email address, age, gender, and questions regarding the inclusion criteria. These entailed Dutch as mother tongue, availability for the duration of the study, ownership of an Android smartphone that supported the sensing app (not iPhone, Huawei, Wiko, Medion, or Xiaomi), always carrying that smartphone, and activating it at least 10 times a day. A total of 230 people completed the web survey, of whom 116 (50.4%) were excluded based on the aforementioned criteria. Of the remaining 114 people, 69 (60.5%) agreed to participate in the study. In the laboratory, 3% (2/69) of participants refused to sign the informed consent, and the installation of the apps failed with another 3% (2/69) of participants, leaving 65 actual participants. For the analyses, an extra inclusion criterion of having answered at least 30 surveys led to the exclusion of another 8% (5/65) of participants. Of the remaining 60 participants, 17 (28%) were men, and 43 (72%) were women (mean age 21.85 years, SD 2.31 years; range 17-32 years).

The participants were reimbursed depending on their cooperation in the study. A maximum of €50 (US $56) could be earned. A total of €10 (US $11.2) were earned after completing some baseline trait questionnaires at the start of the study. Another €5 (US $5.6) could be earned per 10% completed ESM surveys, ending at 80% completed surveys. This is a standard practice in ESM research. This study was approved by the Societal Ethical Commission of Katholieke Universiteit Leuven (G-2018 01 1095).

Materials

Mobile Sensing

A total of 2 apps were installed on each smartphone. The first one, a custom-built app called Actitrack, recorded data from multiple mobile sensors, such as screen locks, light sensors, and location. The software also provided a custom onscreen keyboard display that could be used instead of the default soft keyboard on the host smartphone. This way, the app could register all typing activity with the custom keyboard as it had no access to the default keyboard. Because of the precariousness of these data, privacy measures were taken. All data were

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securely sent over https to a central server of Katholieke Universiteit Leuven and stored in 2 different files.

This study solely focused on the sensed keyboard and voice data. The participants were asked to use the custom-made keyboard as often as possible to render enough writing data. While doing so, the following variables were stored: content of the message, number of backspaces, number of characters, typing speed, typing duration, average duration of a key press, number of positive emojis, and number of negative emojis.

After each ESM survey, the participants were redirected to the sensing app to record a voice message. In the app, there was a button to start and a button to decline, and the instruction read "Make a recording of about one minute about what you have done and how it made you feel. Good luck!" This meant that keyboard activity was passively sensed the entire time of the study, whereas voice recordings were actively prompted and initiated by the participants. As the keyboard messages and voice recordings might contain sensitive personal information, the files were encrypted separately and could only be stored and handled on computers with an encrypted hard drive.

ESM Approach

The second app, MobileQ, delivered the ESM surveys [71]. A total of 10 times a day for 2 weeks, the participants were prompted to answer some questions, including current levels of valence, arousal, anger, anxiety, sadness, stress, and happiness, using a visual analogue scale (0-100). The first notification of each day was sent randomly between 10 AM and 11 AM, including a question about sleep quality. The other 9 surveys were semirandom, dividing the time between 11 AM and 10 PM into 9 equal blocks and randomly programming a beep in each block. Other questions concerned where and with whom the participant was, what they were doing, if the app had worked without problems, and whether something positive or negative had happened since the last survey, but these questions are not analyzed in this paper.

Mental Health Survey

At the beginning of the study, each participant completed a mental health and personality survey. In this study, only the depression subscale of the Depression, Anxiety, and Stress Scale (DASS) was used [72]. The DASS contains 21 statements, and the participants must indicate how much these applied to them on a scale of 0 to 3. The depression subscale is an average score of 7 items.

Procedure

After meeting the inclusion criteria, the participants attended a session in the laboratory. During each session, an informed consent was first proposed and signed. Next, the 2 apps were installed on the participants' smartphones, and they received a booklet with user instructions and a unique participant number. The booklet included instructions to keep the phone turned on, charge it at night, not lend it to a friend, switch off the screen lock, and be connected to Wi-Fi as much as possible. It also included a guide on how to install and uninstall the apps. Finally, the participants were asked to complete the trait questionnaires. For each participant, the 2-week study began the day after the session, and the apps were automatically deactivated after 15 days. There was an optional feedback session at the end where the participants could receive a debriefing and help with uninstallation. The 60 participants that reached the cutoff of 30 completed surveys responded on average to 109.3 (SD 22) of the 140 notifications, yielding a compliance rate of 78% (mean compliance 0.78, SD 0.16; range 0.26-0.99).

Data Preprocessing

The voice samples were converted to text files to be able to analyze the words used in speech. The voice recordings were initially transcribed using the open-source transcriber software Kaldi (NVIDIA) [73]; however, as the transcripts contained many language errors, all of them were corrected by hand. These text files were then used for the automated word counting. All following data processing and analyses were performed using R (version 4.0.3; R Foundation for Statistical Computing) [74]. First, all voice recordings and keyboard activities were linked to their corresponding ESM surveys based on their timestamps. If the timestamps were not an exact match, voice recordings within 5 minutes of an ESM timestamp were linked to that corresponding survey. Keyboard activity was binned into intervals ranging from 30 minutes before to 30 minutes after an ESM survey by pooling all messages and summing the typing dynamics except for typing speed and average key press duration, for which the mean was taken. Second, all participants with <30 responses or without a single voice recording or keyboard activity were removed. This left 51 participants with a total of 1015 voice recordings and 59 participants with a total of 3929 keyboard bins. Finally, all used measures were prepared for the momentary- and trait-level analyses. For the momentary-level analyses, all observations were standardized within participants. For the trait-level analyses, all observations of a given participant were aggregated into 1 single observation to be used in a between-person context along with the DASS score. The momentary level thus reflects emotional states from one moment to another, whereas the trait level represents the average mood of the participant over the duration of the study. Standardization happened only over the observations with an ESM survey as well as keyboard or voice recordings.

Feature Extraction

Speech Content

The content of the voice recordings was analyzed using the LIWC software [75]. LIWC is a language processing tool that allows for the automated counting and labeling of words. LIWC counts and categorizes words going from pronouns to swear words to religion- or death-related words. Each category is then presented as a percentage of counted words on the total number of words. In this study, the automatically generated Dutch translation of the LIWC 2015 dictionary was used [76]. Twelve categories were selected based on the reviewed literature: *word count*, *i*, *we*, *you*, *negate*, *posemo*, *negemo*, *anxiety*, *anger*, *sad*, *certain*, and *swear* (Table 4).

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Table 4. Descriptive statistics of the speech data.

Item	Value, mean (SD; range)
Emotions[a]	
Valence	56.21 (11.3; 22.57 to 83.42)
Arousal	44.7 (11.35; 18.41 to 77.21)
Anger	10.63 (9.08; 1.7 to 52.05)
Anxiety	12.47 (12.62; 1.35 to 56.31)
Sadness	13.06 (9.38; 1.84 to 43.1)
Stress	27.58 (15.15; 5.08 to 74.16)
Happiness	56.44 (11.32; 21.41 to 80.68)
Depression	0.42 (0.45; 0 to 2.14)
Speech content[b]	
WC (word count)	60.72 (31.76; 4 to 125.63)
I (first-person singular)	9.44 (3.69; 0 to 19.09)
We (first-person plural)	0.58 (0.83; 0 to 3.7)
You (second-person singular)	0.06 (0.11; 0 to 0.41)
Negate (negations)	1.29 (0.75; 0 to 3.28)
Posemo (positive emotion words)	3.54 (2.04; 0 to 12.5)
Negemo (negative emotion words)	0.98 (0.72; 0 to 2.73)
Anx (anxiety-related words)	0.36 (0.52; 0 to 2.38)
Anger (anger-related words)	0.27 (0.35; 0 to 1.47)
Sad (sadness-related words)	0.16 (0.18; 0 to 0.76)
Certain (absolutist words)	1.59 (1.36; 0 to 7.71)
Swear (swear words)	0 (0.03; 0 to 0.19)
Speech form[c]	
F0[d] mean	29.93 (4.26; 20.25 to 40.63)
F0 SD	0.22 (0.05; 0.13 to 0.42)
F0 range	7.52 (3.63; 2.29 to 19.4)
F0 mean rising slope	303.85 (76.4; 126.97 to 556.56)
F0 mean falling slope	155.13 (50.45; 88.93 to 336.52)
Loudness mean	0.77 (0.37; 0.19 to 2.1)
Loudness mean rising slope	12.85 (5.01; 3.43 to 26.76)
Loudness mean falling slope	10.02 (4.08; 2.52 to 17.81)
Jitter mean	0.05 (0.01; 0.03 to 0.07)
Shimmer mean	1.29 (0.16; 1.02 to 1.75)
HNR[e] mean	4.61 (2.44; −4.16 to 8.6)
Voiced segments per second (speech rate)	2.12 (0.48; 0.55 to 3.38)
Mean unvoiced segment length (pause duration)	0.29 (0.56; 0.11 to 4.16)

[a]Emotions were rated on a visual analogue scale of 0-100, and depression was rated on a scale of 0-3.

[b]Except for word count, all Linguistic Inquiry and Word Count dimensions display percentages of the total word count.

[c]Fundamental frequency measures are logarithmic transformations on a semitone frequency scale starting at 27.5 Hz. Loudness measures are the perceived signal intensity. The harmonics to noise ratio displays an energy-related harmonics to noise ratio and is indicative of voice quality along with jitter and shimmer.

[d]F0: fundamental frequency.

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[e]HNR: harmonics to noise ratio.

Speech Form

The acoustic features of the voice recordings were extracted using the openSMILE software (audEERING GmbH) [77]. OpenSMILE is an open-source audio feature extraction toolkit with SMILE, which stands for speech and music interpretation by large-space extraction. The newest version, openSMILE 3.0, provides a simpler package for Python. We chose the Geneva Minimalistic Acoustic Parameter Set, which provides some basic statistics such as the mean and SD for a minor set of acoustic features [78]. Thirteen parameters were selected based on the reviewed literature: F0 mean, F0 range, F0 SD, F0 mean rising slope, F0 mean falling slope, loudness mean, loudness mean rising slope, loudness mean falling slope, mean jitter, mean shimmer, mean harmonics to noise ratio, voiced segments per second, and mean unvoiced segment length (Table 4). The first 5 relate to the pitch of the voice, the next 3 concern the loudness, the next 3 define the voice quality or timbre, and the last 2 can be interpreted as speech rate and mean pause duration.

Writing Content

The content of the writing was analyzed in the same way as the content of the voice recordings—by using the LIWC software and the 12 chosen categories, adding also *exclamation marks* (Table 5).

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Table 5. Descriptive statistics of the writing data.

Item	Value, mean (SD; range)
Emotions[a]	
Valence	56.07 (10.88; 22.57-83.42)
Arousal	44.34 (11.67; 9.27-77.21)
Anger	10.49 (8.8; 1.5-52.05)
Anxiety	12.14 (12.2; 0.15-56.31)
Sadness	12.82 (9.35; 1.84-43.1)
Stress	26.85 (15.12; 3.31-74.16)
Happiness	56.31 (10.97; 21.41-80.68)
Depression	0.45 (0.48; 0-2.14)
Writing content[b]	
Positive emojis	1.4 (5.94; 0-45.09)
Negative emojis	0.15 (0.26; 0-1.35)
WC (word count)	82.4 (58.45; 1.8-358.93)
I (first-person singular)	3.21 (1.22; 0-5.31)
We (first-person plural)	0.57 (0.34; 0-1.38)
You (second-person singular)	2.21 (0.82; 0.52-5)
Negate (negations)	1.44 (0.81; 0-3.83)
Posemo (positive emotion words)	0.1 (0.11; 0-0.38)
Negemo (negative emotion words)	3.48 (1.57; 0-8.25)
Anx (anxiety-related words)	0.85 (0.39; 0-1.68)
Anger (anger-related words)	0.12 (0.12; 0-0.55)
Sad (sadness-related words)	0.26 (0.2; 0-0.81)
Certain (absolutist words)	0.24 (0.15; 0-0.65)
Swear (swear words)	2.31 (1.06; 0-4.86)
Exclam (exclamation marks)	1.56 (1.8; 0-9.26)
Writing form[c]	
Characters, N	480.11 (293.67; 12.7-1764.5)
Typing speed (characters per second)	2.1 (0.55; 1.18-4.68)
Average key press duration (ms)	79.95 (16.48; 20.68-122.83)
Entries, N	15.37 (10.69; 1-71.92)
Total backspaces, N	0.17 (0.06; 0-0.3)
Total typing duration (seconds)	2.68 (2.18; 0.44-9.85)

[a]Emotions were rated on a visual analogue scale of 0-100, and depression was rated on a scale of 0-3.

[b]Except for word count, all Linguistic Inquiry and Word Count dimensions display percentages of the total word count.

[c]Number of backspaces and typing duration are divided by the total number of keystrokes (characters + backspaces).

Writing Form

The typing dynamics were immediately recorded during typing without any additional software. The variables extracted from the custom-made keyboard were the number of backspaces, typing duration, typing speed, number of characters, and average duration of a key press (Table 5). The absolute number of backspaces and typing duration were transformed into the relative number on the total number of keystrokes for that bin (characters + backspaces). After binning, the number of keyboard entries (eg, separate messages and notes) collected in that bin was also counted.

Correlation Analyses

After standardization, pairwise correlations were computed between the emotions on one side and the language features on the other. At the momentary level, this was done by extracting the slopes of multilevel simple linear regressions using the lme4

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and lmerTest packages in R with the restricted maximum likelihood modeling. At the trait level, Spearman correlations were applied to the aggregated data set. On each correlation table, a false discovery rate (FDR) correction was applied according to the step-down method by Holm [79].

Predictive Modeling

Next, we were interested in how well the language features would predict emotional states and traits. The total data set for voice and keyboard separately was divided into an 80% training and 20% test set. We used all the significant correlations of the previous analyses for the 4 language types separately as possible predictors for a given emotion in a linear regression model with a random intercept and varying slopes for participants at the momentary level, allowing predictors to have different values for each participant. When the correlation analysis yielded no significant correlations for an emotion, the 3 most highly correlated features were chosen as possible predictors. A 10-fold cross-validation on the training set was applied to determine which of the possible predictors had an average P value of <.05, and those were kept in the model. When there were no predictors with an average P value of <.05, the 2 best predictors were chosen to prevent overfitting of the training set. Finally, a model with the chosen predictors was fitted on the total training set, and then we calculated the predictive R^2 based on that model and the test set. The predictive R^2 is calculated as the mean squared error divided by the variance of the data, making it scale-independent:



As we noticed that a different split of the test and training sets yielded different results, especially for the trait level, we chose to perform a 50-fold variation of the training and test sets in a bootstrap-like manner. This means we randomly created 50 different splits of the observations into 80% training and 20% test sets.

Results

Descriptives

Speech

A total of 51 participants (51/60, 85%) recorded between 1 and 96 voice samples on the total number of ESM surveys they completed, with an average compliance rate of 19% (speech mean 0.19, SD 0.21; range 0.01-0.94). Within participants, there was a significant correlation between the day of the study (1 to 14) and the number of voice recordings (r=−0.36; P<.001), meaning that compliance decreased during the study. For the descriptive statistics of all speech measures, we looked at the distribution of the within-person averages (Table 4). The participants showed sufficient variability in their emotions. *I* and *posemo* were the most counted words, although, in general, the LIWC dimensions only accounted for a small share of the total amount of spoken words. When looking at depression, we saw a large cluster of DASS depression scores between 0 and 0.75 and then 6 sparse points reaching >0.75. The maximum of the scale was 3, which could mean that our sample lacked the sensitivity to register any significant relationships between depressive symptoms and the 4 language types.

Writing

A total of 59 participants (59/60, 98%) used the custom-made keyboard between 5 and 117 times in the hour around their completed ESM surveys, with an average use rate of 60% (writing mean 0.60, SD 0.21; range 0.07-0.95). Here, again, use declined throughout the study within participants (r=−0.23; P<.001). Similar to the speech data, for the descriptive statistics, we looked at the distribution of the within-person averages (Table 5). Overall, this sample showed the same depression and emotion distributions as the speech sample. *I*, *negemo*, and *swear* were the most counted words, although, again, the LIWC dimensions in general only accounted for a small share of the total amount of written words.

Correlation Analyses

Speech Content

After the FDR correction at the momentary level, P<.001 for all significant correlations mentioned here. Higher valence correlated with a lower word count; more *we* and positive emotion words; and fewer negations and negative emotion, anxiety, anger, and certainty words (Figure 1). Happiness showed the same relationships without word count and *we*. Arousal was only correlated with fewer negations and more positive emotion words. Anger showed positive correlations with negations, negative emotion words, and anger words. Anxiety was positively correlated with negative emotion, anger, and anxiety words. More sadness was associated with more negations and negative emotion, anger, and sadness words and with fewer positive emotion words. Finally, stress displayed the same correlations as sadness with anxiety instead of sadness words. At the trait level, some higher correlations arose at first but, after the FDR correction, no correlation was significant (Figure 2).

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Figure 1. Multilevel correlations between the state emotions and speech content variables (n=1015). *P<.05, **P<.01, ***P<.001. Italicized values are significant after false discovery rate correction. Anger: anger-related words; anx: anxiety-related words; certain: absolutist words; I: first-person singular; negate: negations; negemo: negative emotion words; posemo: positive emotion words; sad: sadness-related words; swear: swear words; WC: word count; we: first-person plural; you: second-person singular.

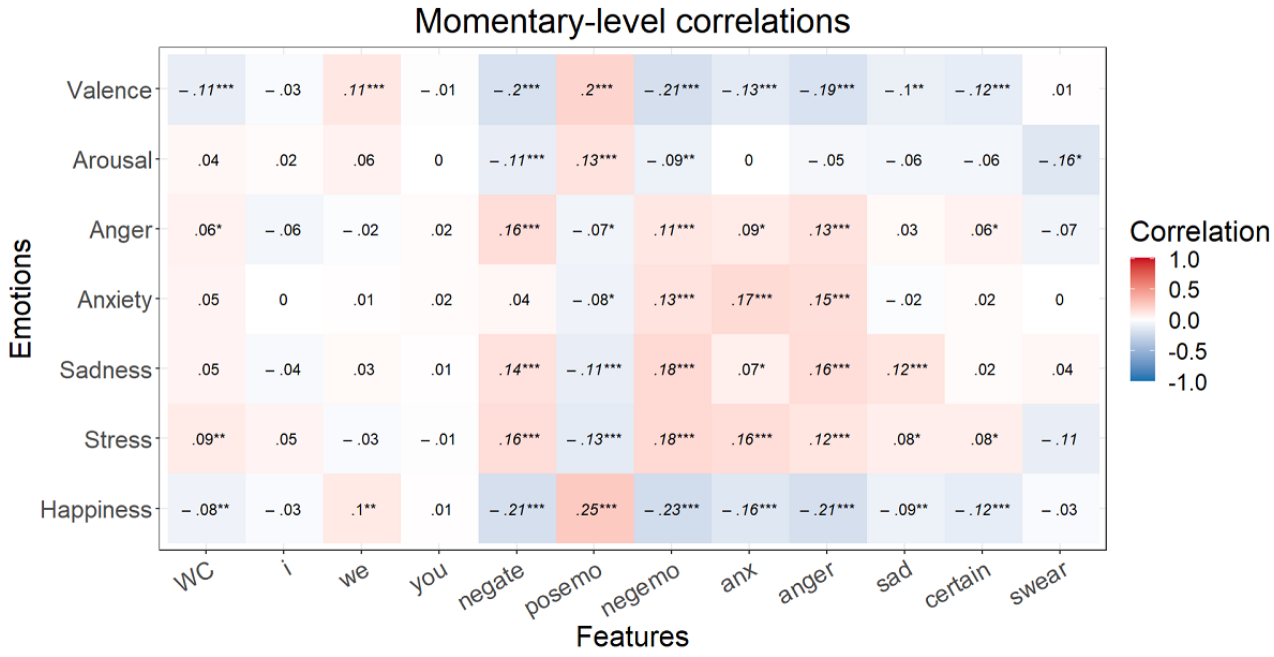
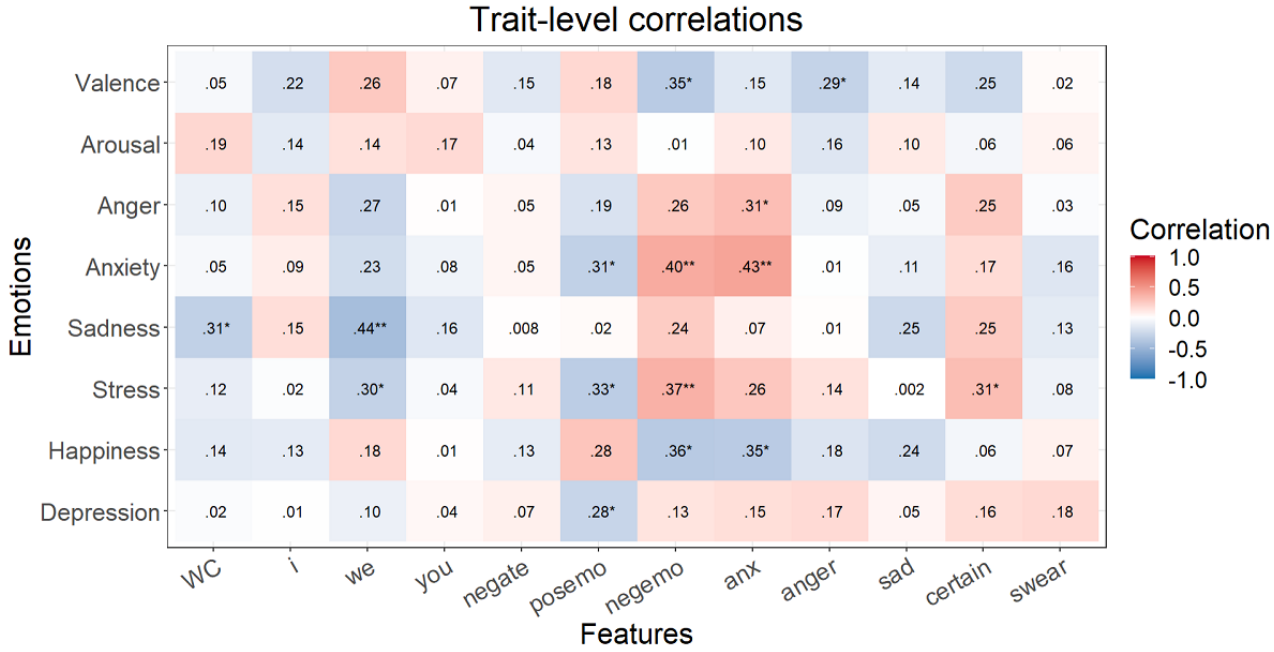


Figure 2. Spearman correlations between the trait emotions and speech content variables (n=51). *P<.05, **P<.01, ***P<.001. Italicized values are significant after false discovery rate correction. Anger: anger-related words; anx: anxiety-related words; certain: absolutist words; I: first-person singular; negate: negations; negemo: negative emotion words; posemo: positive emotion words; sad: sadness-related words; swear: swear words; WC: word count; we: first-person plural; you: second-person singular.



Speech Form

After the FDR correction at the momentary level, *P*<.001 for all significant correlations mentioned here. Higher valence correlated with a higher mean loudness, mean loudness rising slope, and mean loudness falling slope, and a lower mean unvoiced segment length (Figure 3). Happiness showed the same relationships. Arousal correlated with higher values of all 3 loudness measures and a lower mean unvoiced segment length. Anger and anxiety showed no significant correlations after FDR correction. More sadness was associated with a lower mean loudness rising slope and mean loudness falling slope. Finally, stress displayed a significant correlation with a lower F0 range. At the trait level, the correlation values again increased, but none of these were significant (Figure 4).

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Figure 3. Multilevel correlations between the state emotions and speech form variables (n=1015). *P<.05, **P<.01, ***P<.001. Italicized values are significant after false discovery rate correction.

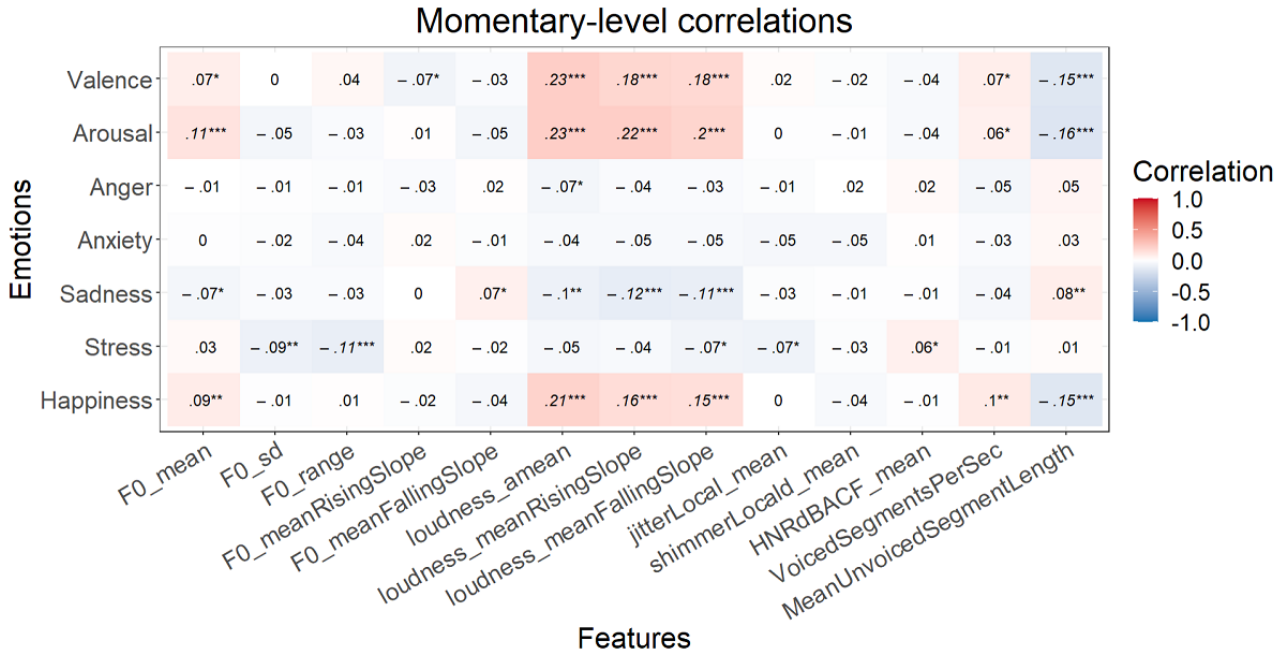
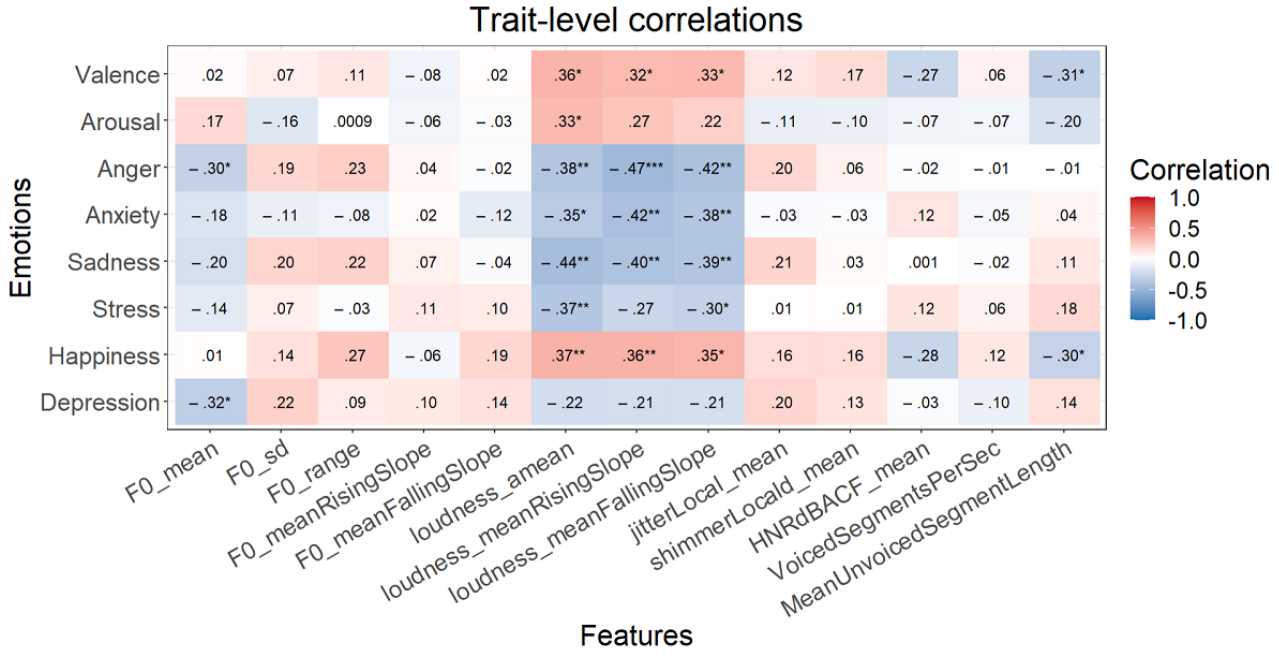


Figure 4. Spearman correlations between the trait emotions and speech form variables (n=51). *P<.05, **P<.01, ***P<.001. Italicized values are significant after false discovery rate correction.



Writing Content

After the FDR correction at the momentary level, *P*<.001 for all significant correlations mentioned here. Higher valence correlated with a lower word count and less first-person singular use (Figure 5). Happiness only correlated with a lower word count. Arousal, anxiety, and sadness showed no significant correlations after FDR correction. More anger was associated with a higher word count. Finally, stress displayed a correlation with a higher word count and first-person singular use. At the trait level, none of the correlations were significant (Figure 6).

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Figure 5. Multilevel correlations between the state emotions and writing content variables (n=3929). *P<.05, **P<.01, ***P<.001. Italicized values are significant after false discovery rate correction. Anger: anger-related words; anx: anxiety-related words; certain: absolutist words; exclam: exclamation marks; I: first-person singular; negate: negations; negemo: negative emotion words; posemo: positive emotion words; sad: sadness-related words; swear: swear words; WC: word count; we: first-person plural; you: second-person singular.

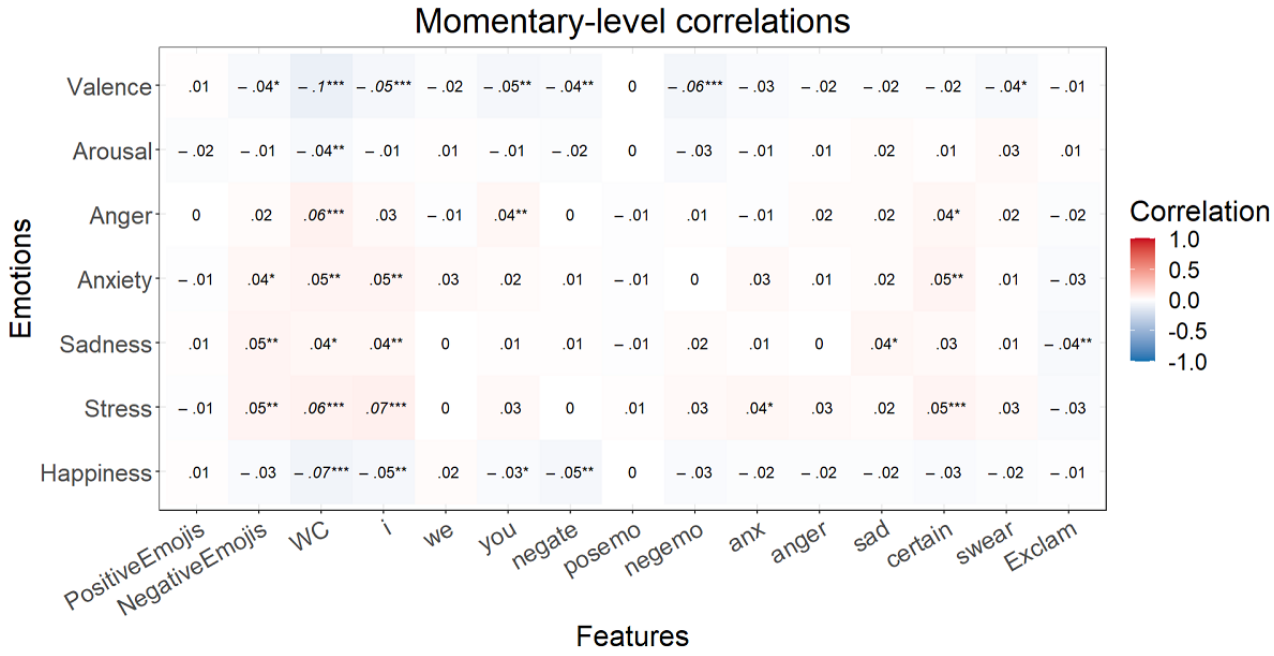
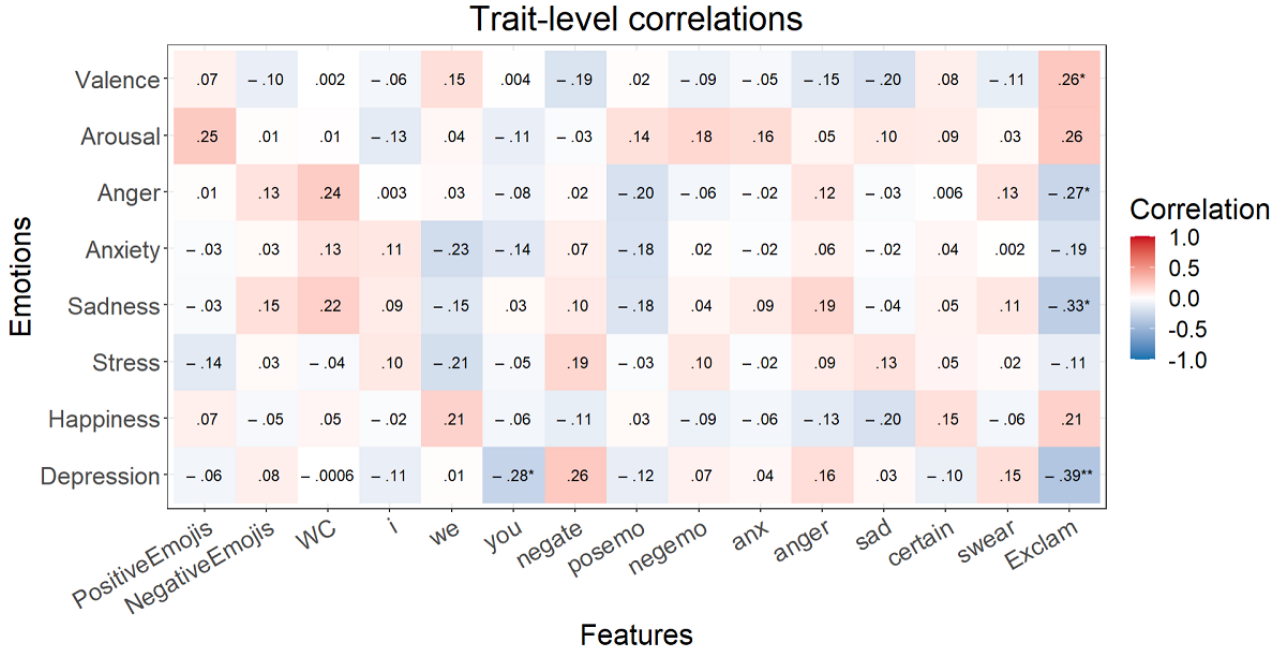


Figure 6. Spearman correlations between the trait emotions and writing content variables (n=59). *P<.05, **P<.01, ***P<.001. Italicized values are significant after false discovery rate correction. Anger: anger-related words; anx: anxiety-related words; certain: absolutist words; exclam: exclamation marks; I: first-person singular; negate: negations; negemo: negative emotion words; posemo: positive emotion words; sad: sadness-related words; swear: swear words; WC: word count; we: first-person plural; you: second-person singular.



Writing Form

After the FDR correction at the momentary level, P<.001 for all significant correlations mentioned here. Higher valence and happiness correlated with a lower number of characters and keyboard entries (Figure 7). Arousal displayed a correlation with a shorter average key press duration. Anger correlated with a higher number of characters. Anxiety, sadness, and stress showed no significant correlations. At the trait level, no correlations were significant after FDR correction (Figure 8).

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Figure 7. Multilevel correlations between the state emotions and writing form variables (n=3929). *P<.05, **P<.01, ***P<.001. Italicized values are significant after false discovery rate correction. AvgDurationKeyPress: average key press duration; Backspaces.Tot: backspaces divided by the total amount of keystrokes (characters + backspaces); nCharacters: number of characters; nEntries: number of entries; TypingDuration.Tot: typing duration divided by the total amount of keystrokes (characters + backspaces).

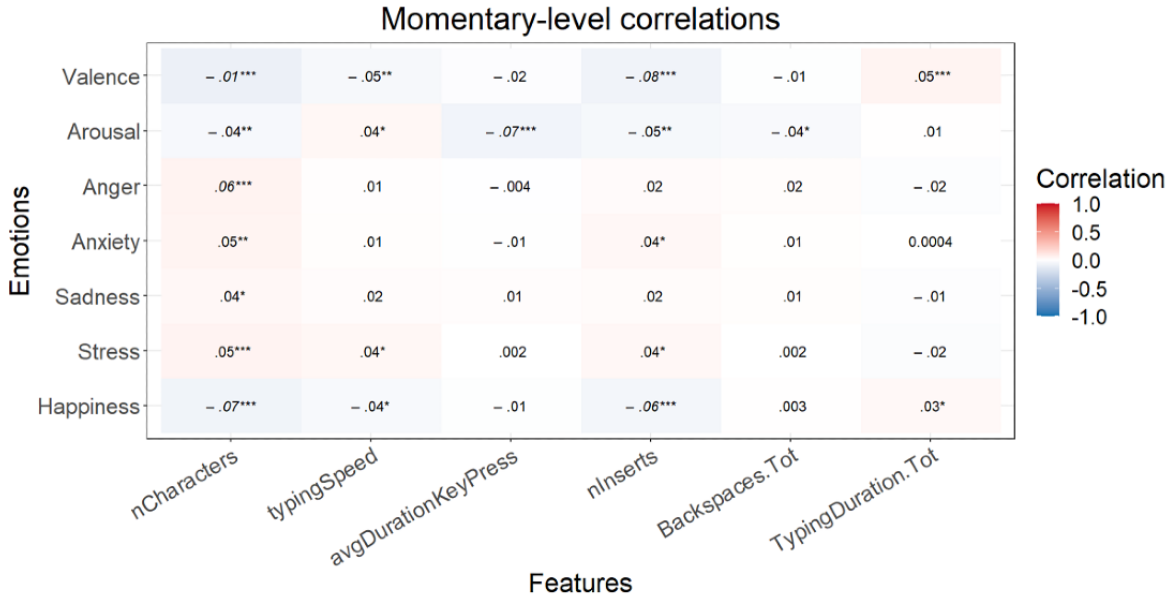
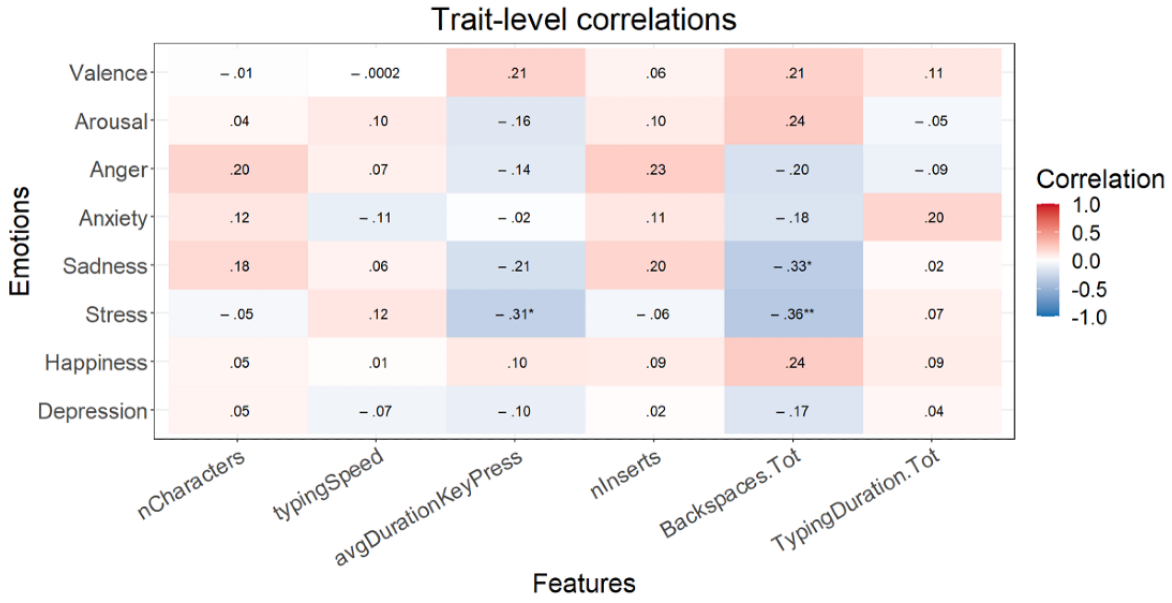


Figure 8. Correlations between the trait emotions and writing form variables (n=59). *P<.05, **P<.01, ***P<.001. Italicized values are significant after false discovery rate correction. AvgDurationKeyPress: average key press duration; Backspaces.Tot: backspaces divided by the total amount of keystrokes (characters + backspaces); nCharacters: number of characters; nEntries: number of entries; TypingDuration.Tot: typing duration divided by the total amount of keystrokes (characters + backspaces).



Predictive Modeling

The highest predictive R^2 at the momentary level was found for the prediction of happiness based on speech content (R^2 mean 0.10, SD 0.04; Figure 9) followed by the prediction of valence based on speech content (R^2 mean 0.06, SD 0.03) and speech form (R^2 mean 0.05, SD 0.03). The mean R^2 values of speech content models varied between 0.01 and 0.10, those of speech form varied between −0.01 and 0.05, those of writing content varied between 0 and 0.01, and those of writing form varied between −0.0002 and 0.01. At the trait level, the speech form models performed best, with the highest predictive R^2 for the predictions of valence (R^2 mean 0.16, SD 0.30), happiness (R^2 mean 0.14, SD 0.40), and arousal (R^2 mean 0.13, SD 0.25). All other mean predictive R^2 values were negative except for the speech form prediction of stress (R^2 mean 0.02, SD 0.25) and the speech content prediction of valence (R^2 mean 0.01, SD 0.39; Figure 10).

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Figure 9. Predictive R^2 of language data at the momentary level.

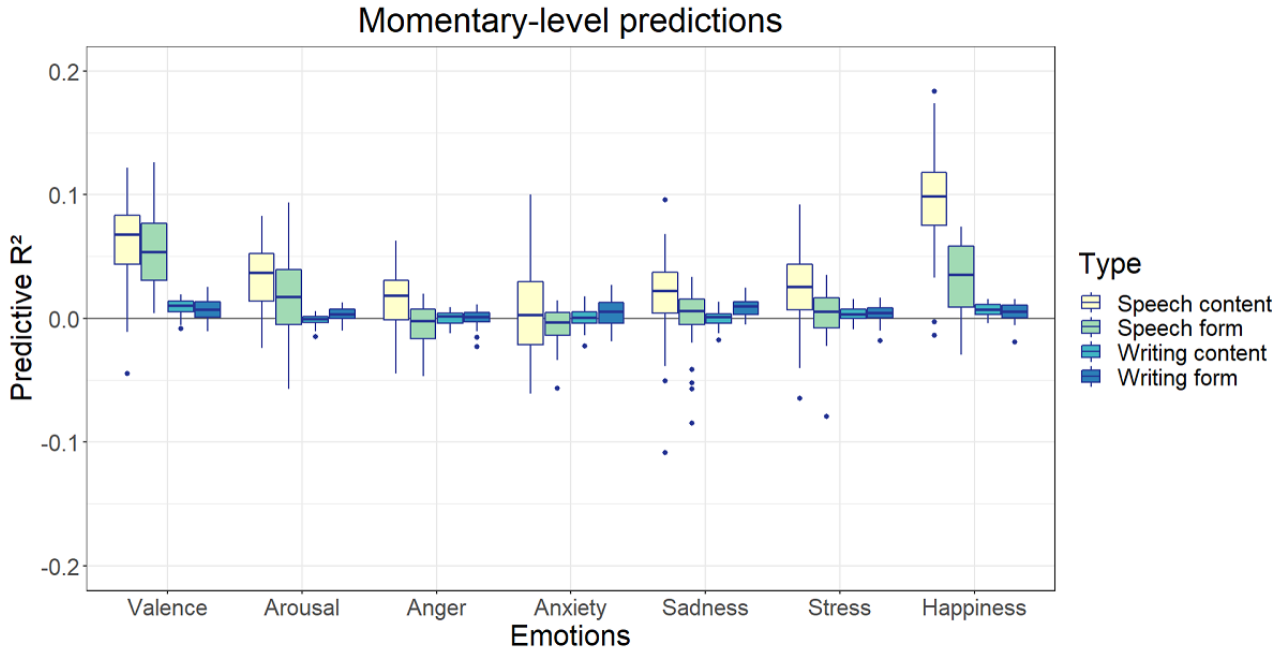
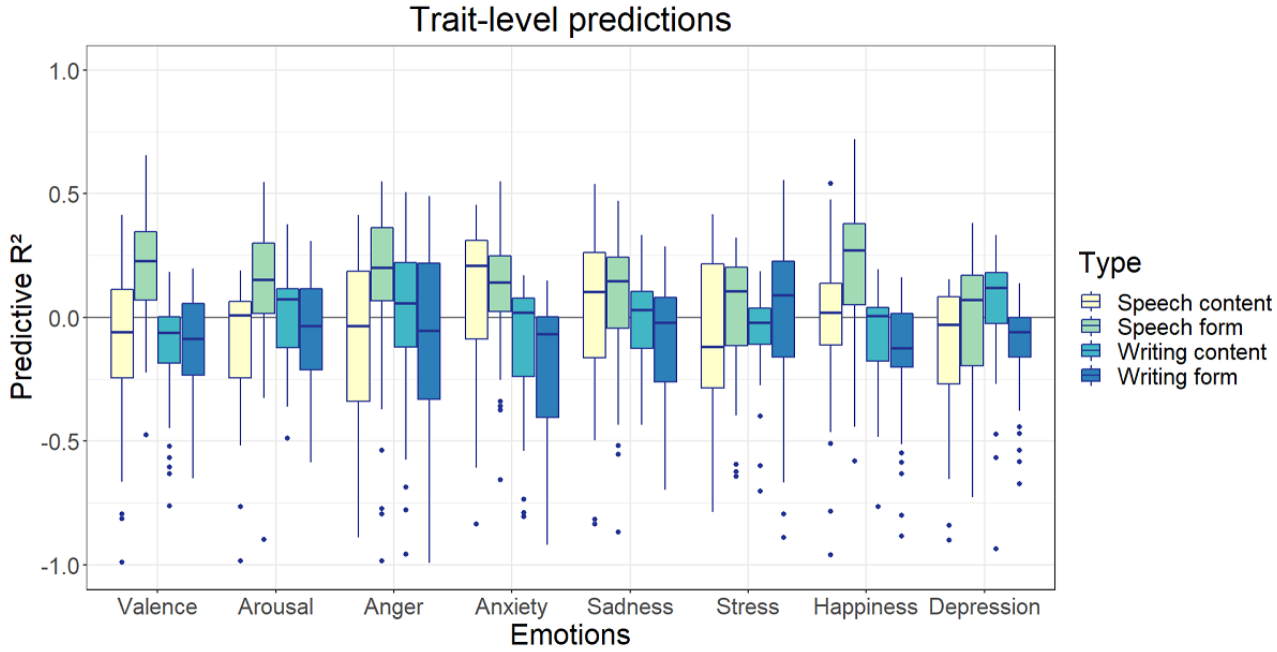


Figure 10. Predictive R^2 of language data at the trait level.



Afterward, this process was repeated for the speech content and form features combined in 1 model, the writing content and form features combined in 1 model, and all 4 language features combined in 1 model (Figures 11 and 12). The highest predictive R^2 at the momentary level was found for the prediction of happiness based on all language features (R^2 mean 0.11, SD 0.04) followed by the prediction of happiness based on speech features (R^2 mean 0.11, SD 0.06) and the prediction of valence based on all language features (R^2 mean 0.09, SD 0.05). The mean predictive R^2 values of speech models varied between −0.01 and 0.11, those of writing models varied between −0.02 and 0.02, and those of all features varied between −0.02 and 0.11. At the trait level, the speech models performed best, although only two of the mean predictive R^2 values were >0: the speech prediction of arousal (R^2 mean 0.08, SD 0.50) and the altogether prediction of arousal (R^2 mean 0.03, SD 0.49).

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Figure 11. Predictive R^2 of combined language data at the momentary level.

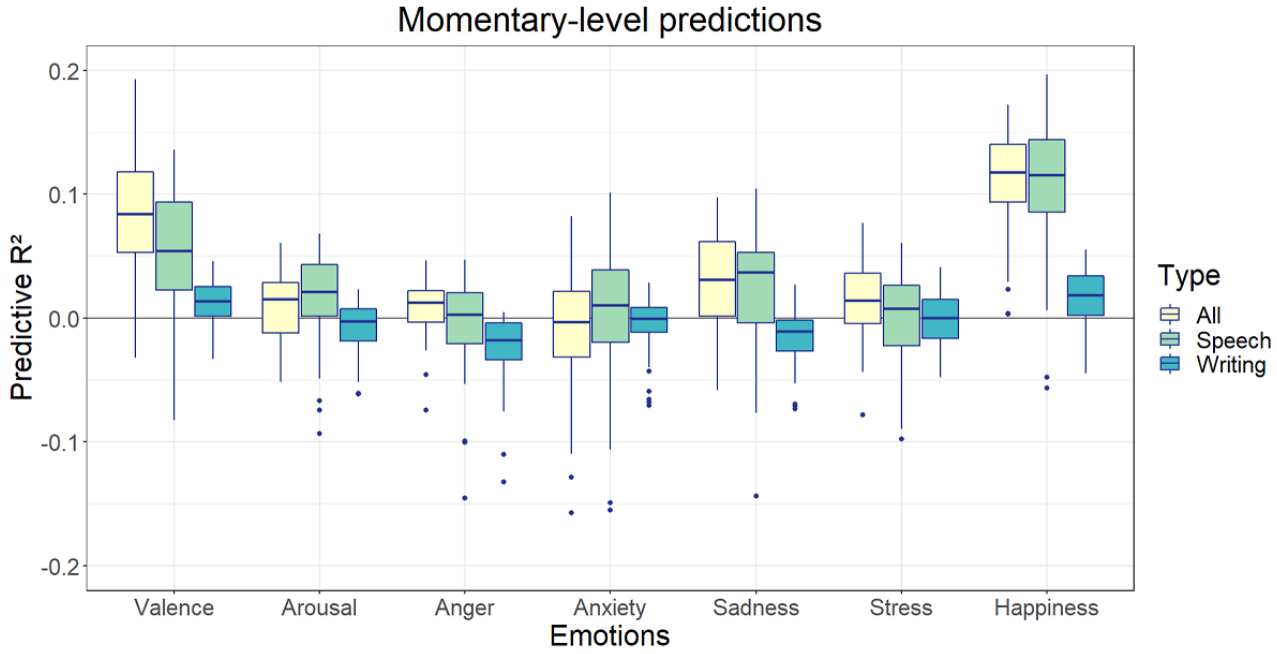
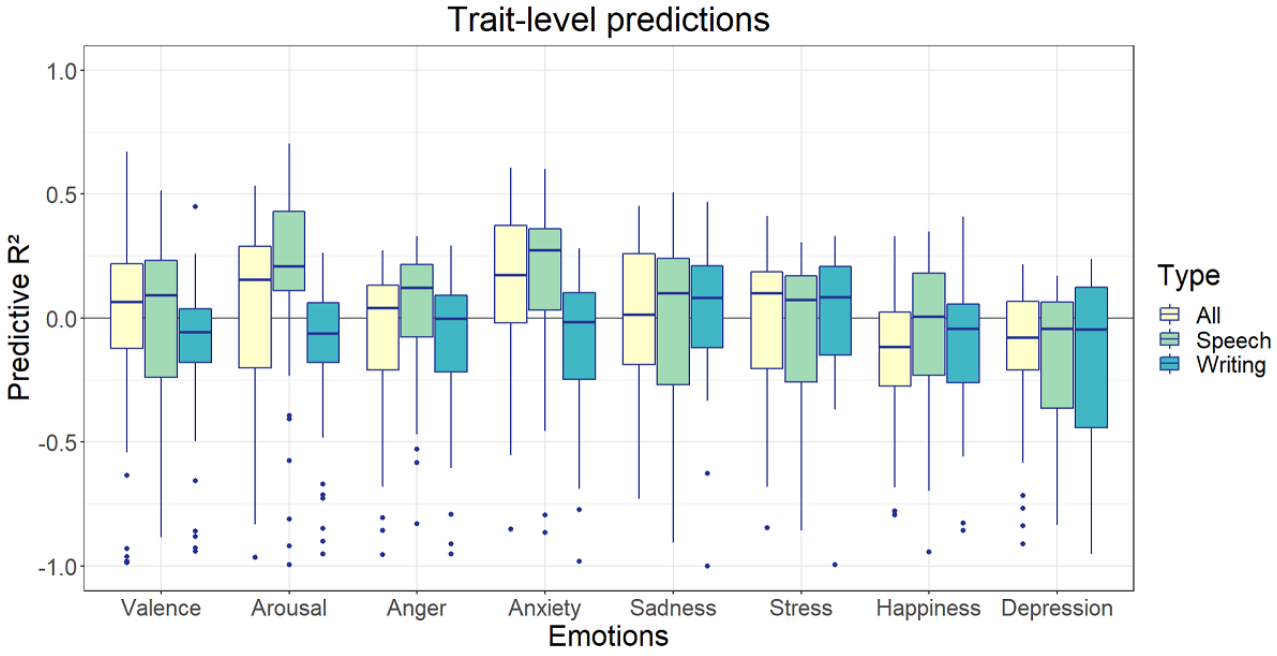


Figure 12. Predictive R^2 of combined language data at the trait level.



Discussion

In this study, we investigated the potential of mobile-sensed language features as unobtrusive emotion markers. We looked at pairwise multilevel correlations between emotions or mood and language features—distinguishing between speech content, speech form, writing content, and writing form—and at the (combined) predictive performance of those features in regression models.

Correlation Analyses and Predictive Modeling

Speech Content

Most of the significant correlations were found between speech content features and momentary emotions but were rather low, varying between |0.11| and |0.25|. However, they are in the range of those found in previous studies [30,32]. Most of these significant correlations were found for state valence and happiness, which is also in line with the literature. We found that the explicit emotion LIWC dimensions had the strongest correlations but did not find evidence of a relationship between pronoun use and emotion [52]. We expected to find at least some correlations with pronouns or negative emotion words at

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the trait level [28,29,31,32], but no correlations were significant after FDR correction.

Speech Form

Speech form and momentary emotions also displayed some significant correlations, ranging from |0.11| to |0.23|. Most of the literature has focused on discriminating high-arousal from low-arousal emotions [33,39-41]. In this study, arousal was indeed represented, but so were valence and happiness. However, anger was not. We expected F0, loudness, and speech rate to be important; however, in this study, only the loudness measures and pause duration were notable. At the trait level, nothing was significant. This is surprising given that most of the literature on speech form is based on between-person research.

Writing Content

Writing content features showed only a few weak significant correlations. Varying between |0.05| and |0.10|, these were lower than expected yet not entirely surprising given the mixed results throughout previous work [28,51]. Valence was again the best represented; however, in contrast to speech content, the first-person singular was most notable in writing along with word count. At the trait level, the exclamation marks seemed promising at first but turned nonsignificant after FDR correction, meaning this study was not able to replicate earlier findings with anxiety and depression [23,53,55-60].

Writing Form

Writing form showed the least amount of significant correlations, also in the range of |0.05| to |0.10|. In the literature, typing speed and average key press duration have been seemingly linked to emotions; however, in this study, the number of characters and the number of keyboard entries were the most telling. They followed the direction of the word count correlations. Here, again, valence and happiness showed the most correlations, and the complete trait level was nonsignificant.

Predictive Modeling

As could be expected based on the number of significant correlations, valence and happiness showed the highest predictive R^2 values at the momentary level. In addition, the speech content models performed best followed by the speech form models. The predictive R^2 estimations of the writing content and form models always stayed close to 0, although their variation was smaller (Figure 9). This is all in line with the previously found correlations. In addition, the size of the values followed the trend of the correlations and remained rather low—at most, 10% of peoples' state emotions can be predicted based on their momentary language.

When combining multiple types of momentary language data into the same models, writing does not contribute to better predictions. Combining speech content and form features yields more or less the same results as their separate models, whereas adding writing content and form features does not further improve the predictive performance. An important remark here is that not all ESM surveys with voice recordings had additional keyboard activity. Because of this, the data set was further reduced in size, which might contribute to the fact that the combined models seemingly have no added value.

No significant correlations were found at the trait level. In addition, by aggregating, the number of data points was reduced from multiple observations to a single observation per participant. As a result, our expectations for trait predictive performance were lower than those for the momentary models. As can be seen in Figures 10 and 12, the estimations of the predictive R^2 based on varying training and test sets show a larger variation than those of the momentary models. Moreover, they are clustered around 0 with numerous negative outliers, indicating regular overfitting of the training set. There was one type of data that performed better than the others: >75% of the predictive R^2 estimations based on the speech form models for valence, arousal, anxiety, and happiness performed >0, indicating at least some predictive value.

Overall, the found relationships were largely in the predicted direction but were very modest in size. For speech, these values are more or less in line with previously obtained results; however, writing performed below expectations. There are 3 main differences between voice recordings and keyboard activity that might account for this. One is the nature of collection—voice recordings were deliberately voiced, whereas keyboard activity was unobtrusively recorded. Second, keyboard activity was gathered without any instruction, whereas voice recordings came with the explicit instruction for the participants to say what they were doing and how they felt. Finally, although LIWC was able to categorize on average 87.17% (SD 38.83%) of the spoken words, it only recognized on average 54.23% (SD 25.81%) of the text messages because of typos and other distortions.

A second dichotomy exists between the momentary and trait values. Previous work has often focused on between-group designs; however, this study could only record significant within-person correlations. At the trait level, we found no significant correlations, and predictive trait models showed more variability and 0 or negative predictive R^2 values. Possibly, by aggregating the emotion and language data, important context data of their relationship were lost, and moment-to-moment tendencies were flattened out. For predictive modeling, trait level also meant a reduction in data points to train and test a model. The repeated redistribution of a small number of participants over the training and test sets will induce larger changes than a larger data set. Furthermore, momentary-level models are trained and tested within persons, whereas trait-level models are trained and tested between persons. The overfitting of predictive models at the trait level suggests that the participants' emotions and language use were too dissimilar to be encapsulated in 1 model (except perhaps for speech form).

Limitations and Future Directions

The first limitation entails that data collection was dependent on the participants' willingness to use the custom-made keyboard instead of their default one and to make recordings. This reduced the number of observations and created an unbalanced data set. Ideally, the smartphone's own keyboard and microphone could be activated and logged at will. This is

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impossible because of technical and ethical constraints. A solution might be to link reimbursement directly to the provision of valid data in the form of keyboard use or voice recordings, although this might lead too much to a perception of coercion.

A second limitation lies in the software used. We worked with LIWC as it is widely used in the literature and provides a fast and easy-to-use interface. A downside is that it only recognizes single words and not phrases. When the participants talked about feeling *not too happy*, LIWC scored this as a positive emotion and a negation. When looking at the correlations, this did not seem to pose a direct problem in this study, although it could add noise and reduce statistical significance. What might be more problematic is the language the participants used in their texting: abbreviations, typos, and neologisms. Although LIWC 2015 has a netspeak dimension, the average word recognition of writing was only 54.23% (SD 25.81%). In future studies, one might consider preprocessing all writing by hand, although this will be a very time-consuming task.

A third limitation is inherent to the sample of participants. Despite the strong representation of depression and language use in the literature, this study was not able to link depressive symptoms to any language feature. Replicating this study in a more diverse or clinical population might yield other results for depression.

Finally, language is strongly dependent on the chosen medium. Talking to a smartphone with a specific instruction restrains the natural flow of language and can compromise the generalizability of these findings. More technically, this also means that the participants would sometimes talk softly in a quiet room, whereas they might be screaming over the noise in another recording. We should keep in mind the fact that loudness is as much a factor of the environment as it is of the voice. Then again, this context might also say something about the emotional experience in itself.

Conclusions

This study investigated the relationship between self-reported emotions and 4 types of mobile-sensed language. The found correlations and predictive performances were overall weak, remaining <0.25. The best-performing language type was speech content, which displayed the largest number of significant correlations and the largest predictive R^2 values at the momentary level, followed by speech form. At the trait level, no significant correlations were found, resulting in unreliable predictive models. Only speech form models were able to reach a mean predictive R^2 value >0 at the trait level. Among the studied emotions, valence and happiness showed the most significant correlations and predictability. In conclusion, this means that the potential of this particular set of mobile-sensed language features as emotion markers, although promising, remains rather low.

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Authors' Contributions

CC contributed to writing and analysis. KN contributed to writing and analysis. MM contributed to the methodology and investigation. MB contributed to review, editing, and data curation. PV contributed to review, editing, and data curation. LG contributed to review and editing, methodology, and investigation. TvW contributed to review and editing, methodology, and investigation. PK contributed to writing and analysis.

Conflicts of Interest

None declared.

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Abbreviations

DASS: Depression, Anxiety, and Stress Scale
ESM: experience sampling method
F0: fundamental frequency
FDR: false discovery rate
LIWC: Linguistic Inquiry and Word Count

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Original Paper

A Web-Based Cognitive Behavioral Therapy, Mindfulness Meditation, and Yoga Intervention for Posttraumatic Stress Disorder: Single-Arm Experimental Clinical Trial

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Abstract

Background: Posttraumatic stress disorder (PTSD) is a debilitating, undertreated condition. The web-based delivery of cognitive behavioral therapy supplemented with mindfulness meditation and yoga is a viable treatment that emphasizes self-directed daily practice.

Objective: This study aims to examine the effectiveness of a web-based cognitive behavioral therapy, mindfulness, and yoga (CBT-MY) program designed for daily use.

Methods: We conducted an 8-week, single-arm, experimental, registered clinical trial on adults reporting PTSD symptoms (n=22; aged 18-35 years). Each participant received web-based CBT-MY content and an hour of web-based counseling each week. Pre-post outcomes included self-reported PTSD symptom severity, depression, anxiety, chronic pain, and mindfulness. Pre-post psychophysiological outcomes included peak pupil dilation (PPD) and heart rate variability (HRV). HRV and PPD were also compared with cross-sectional data from a non-PTSD comparison group without a history of clinical mental health diagnoses and CBT-MY exposure (n=46).

Results: Pre-post intention-to-treat analyses revealed substantial improvements in PTSD severity (d=1.60), depression (d=0.83), anxiety (d=0.99), and mindfulness (d=0.88). Linear multilevel mixed models demonstrated a significant pre-post reduction in PPD (B=−0.06; SE=0.01; P<.001; d=0.90) but no significant pre-post change in HRV (P=.87). Overall, participants spent an average of 11.53 (SD 22.76) min/day on self-directed mindfulness practice.

Conclusions: Web-based CBT-MY was associated with clinically significant symptom reductions and significant PPD changes, suggesting healthier autonomic functioning. Future randomized controlled trials are needed to further examine the gains apparent in this single-arm study.

Trial Registration: ClinicalTrials.gov NCT03684473; https://clinicaltrials.gov/ct2/show/NCT03684473

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KEYWORDS

posttraumatic stress disorder; cognitive therapy; internet delivery; pupillometry; psychophysiology; PTSD; therapy; cognitive behavioral therapy; mindfulness; intervention

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Introduction

Background

Posttraumatic stress disorder (PTSD) is a complex, disabling condition prevalent in 6.1% to 9.2% of the North American population [1-4]. PTSD is associated with distressing memories of traumatic events, persistent avoidance, negative mood, and hyperarousal [5]. Severe symptoms are often comorbid with depression and chronic pain [6-8].

The hyperarousal of PTSD reflects sympathetic nervous system dominance [9-13] in contrast to sympathetic–parasympathetic states typical of regulated autonomic functioning [14]. Pupillometry assesses pupil constriction and dilation changes that reflect autonomic nervous system (ANS) alterations relevant to ANS balance–imbalance [15-21]. Another physiological marker, heart rate variability (HRV), also reflects ANS status [22], with high HRV indicative of healthy states and low HRV signaling chronic disruption and pathology [23,24]. This study used both physiological markers to assess PTSD treatment efficacy.

Therapeutic Treatment Approaches for PTSD

Cognitive behavioral therapy (CBT) for PTSD is a psychotherapeutic intervention aimed at challenging dysfunctional thoughts and beliefs about the self and the world, and addressing emotional and behavioral patterns that impair social and emotional function [25,26]. Although CBT is one of the best-validated treatments for PTSD [25-31], current data suggest that certain PTSD subgroups (eg, severe symptom severity) are treatment resistant to cognitive-focused therapies [32,33]. As PTSD is associated with dysregulated bottom-up processes (eg, ANS dysregulation), mindfulness meditation (MM), with its emphasis on body awareness, has been identified as a promising adjunct to treatment. Mindfulness is defined as the nonjudgmental, moment-to-moment awareness of thoughts, emotions, and bodily sensations [34-36]. The most empirically supported mindfulness-based therapies include mindfulness-based stress reduction [35,37], mindfulness-based cognitive therapy [38], acceptance and commitment therapy [39], and mindfulness-based CBT via the web [40]. Meta-analytic findings suggest that stand-alone mindfulness-based interventions have a moderate effect (Hedges g=−0.44) on PTSD symptoms, with longer intervention duration associated with greater PTSD symptom reduction [41].

MM combined with CBT involves reframing habitual cognitive distortions and dysfunctional thought patterns while learning to experience emotions and bodily sensations with nonjudgmental acceptance [38,42]. Interventions of this kind have received the most validation in populations with major depression and comorbid anxiety and are known to be better than usual care in reducing major depression relapse and anxiety symptoms [42]. MM combined with CBT has also shown promise in treating PTSD symptoms [43-45], although trauma-related thoughts or emotions that surface during meditation can trigger or retraumatize patients, disrupting treatment efficacy [46-48].

Yoga is increasingly being recognized as a complementary therapeutic modality for a wide variety of mental health conditions because of its ANS effects and stimulation of the limbic system [49]. Yoga-based integration of breath awareness with sequenced physical movements can promote autonomic regulation [46,47] and interoceptive awareness, which are especially relevant to survivors of PTSD who dissociate physically to cope with uncomfortable visceral sensations [50,51]. Interoceptive awareness is crucial for self-regulation and the integration of unprocessed aspects of trauma connected to bodily experience [51]. Therefore, yoga can further supplement cognitive therapy and MM to help restore self-regulation [47,51]. Although yoga, mindfulness, and their combined application as PTSD treatment have been investigated with proven efficacy [52], this is the first known study that has investigated the fuller combination of CBT, MM, and yoga for PTSD on both psychometric and psychophysiological outcomes.

Other promising CBT developments involve web-based applications that enable 24/7 accessibility [40]. Notably, meta-analytic findings provided evidence of web-based CBT as a clinically meaningful treatment for PTSD and comorbid depression and anxiety [53,54] with equal efficacy relative to in-person CBT [53]. Web-based CBT has the potential to be effective in the post-COVID-19 era, given the benefits of wide accessibility and scalability, and the possibility of reduced treatment costs.

This study examined the effectiveness of an 8-week intervention combining web-based CBT, mindfulness, and yoga (CBT-MY) for PTSD. Analyses assessed psychometric improvement and psychophysiological changes via pupillometric and HRV indicators of autonomic function. Our hypotheses were the following:

1. Hypothesis 1: Clinically significant reductions in PTSD Clinician-Administered Posttraumatic Stress Scale (CAPS-5) scores, defined as a minimum reduction of 10 points, were predicted at postintervention.
2. Hypothesis 2: Clinically significant improvements in comorbid mental health outcomes of depression, anxiety, pain, and mindfulness were predicted at postintervention.
3. Hypothesis 3: Reductions in peak pupil dilation (PPD) and increases in HRV were predicted at postintervention.

Methods

Study Design

This study was a registered, single-arm, experimental clinical trial (ClinicalTrials.gov NCT03684473) approved by the York University human participants research and ethics committee.

Population

Participants (aged 18-35 years) were full-time students enrolled at York University, Toronto, Canada, and recruited through classroom announcements, flyers, and an undergraduate research pool. Eligibility criteria included exposure to trauma and a clinical diagnosis of threshold PTSD symptoms measured by the CAPS-5 or threshold symptoms on the PTSD Checklist for the Diagnostic and Statistical Manual of Mental Disorders, fifth edition (DSM-5) civilian version. Exclusion criteria were (1)

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current trauma exposure within the past 30 days, (2) significant suicide risk, (3) substance abuse, and (4) active psychological treatment. A cross-sectional convenience sample of students (aged 18-35 years) with no prior history of diagnosed mental health disorders or treatment were recruited for PPD and HRV autonomic function comparisons, which were collected during a modified 25-minute validated computer-based protocol of rest, stress, and guided meditation (GM) [55,56].

Sample Size

A power calculation was conducted based on hypothesis 1 to detect a minimal clinically important difference in PTSD symptom severity, defined as a CAPS-5 symptom reduction of ≥10.4 points or a z score change of ≥0.8 SDs [57]. On the basis of Cohen [58] large effect size (d=0.80), power of 0.8, and α<.05 (correlation among factors, r=0.50), it was estimated that a minimum sample of N=15 would provide ample testing power [58,59]. We anticipated 20% attrition (n=3), and planned to over enroll (N=18) to detect pre-post, within-group differences for hypothesis 1 [59,60].

Procedure

Interested participants emailed the study coordinator and were sent a prescreen survey (eg, trauma exposure, current symptoms, and suicidal ideation). Participants who met the inclusion criteria attended a 90-minute in-person meeting to further assess symptoms and provide written informed consent. Participants were screened for trauma exposure using the Life Events Checklist for DSM-5 to establish the DSM-5 Criterion A and underwent the CAPS-5 interview with a trained clinician. Participants suspended current psychological but not psychiatric treatment during the 8-week intervention period. Within 1 week of the CAPS-5 interview, participants completed demographic and psychometric questionnaires and laboratory assessment of psychophysiological variables (time point 1 [T1]; baseline [BL] measurements).

Intervention

The 8-week CBT-MY intervention was initiated after the laboratory assessment, where each participant received password-protected web-based program access. The program comprised eight CBT-themed modules (eg, cognitive distortions, negative self-talk) containing (1) 56 unique daily MM exercises focused on breath awareness, progressive relaxation, and nonjudgmental body awareness; (2) eight 20-minute trauma-informed yoga videos [61]; and (3) 10 mindfulness-of-breath practices (Multimedia Appendix 1). Participants had access to the prerecorded CBT-MY content 24 hours a day between the counseling sessions. Participants met weekly for a 60-minute web-based session with a CBT counselor, who attended weekly supervision sessions with a clinical psychologist (PR). Participants were instructed to engage in 90 minutes of self-directed CBT-MY practice per week. All psychological and psychophysiological variables were reassessed at postintervention (time point 2 [T2]; postintervention measurements).

Primary Outcome Measures

Life Events Checklist for DSM-5

The Life Events Checklist for DSM-5 was used to establish trauma exposure to 17 stressful events associated with PTSD [62]. Respondents self-reported exposures based on 6 responses: (1) *happened to me*, (2) *witnessed it*, (3) *learned about it*, (4) *part of job*, (5) *not sure*, (6) *doesn't apply*.

CAPS-5 Interview

PTSD symptom severity was assessed using the CAPS-5, a 30-item structured in-person interview that confirmed the current (ie, past month) diagnosis of PTSD [63]. All CAPS-5 interview notes and scoring were independently assessed by a second clinician with no study relationship. Discrepancies were resolved through consultation with a supervising clinical psychologist. The CAPS-5 total severity score had a high internal consistency (α=.88) with strong interrater reliability (intraclass correlation coefficient=0.91) and good test–retest reliability (intraclass correlation coefficient=0.78 [63]).

PTSD Checklist for the DSM-5 Measure

The PTSD Checklist for DSM-5 (PCL-5), a 20-item self-report measure of DSM-5 PTSD symptoms, was used as an additional measure of PTSD symptom severity [64]. The PCL-5 has demonstrated good internal consistency (α=.94) and test–retest reliability (r=0.66-0.82 [64,65]).

Secondary Outcome Measures

Beck Depression Inventory-2

The Beck Depression Inventory-2 (BDI-2 [66]), a 21-item self-report survey, was used to assess depression symptom severity and has demonstrated internal consistency [67] and test–retest reliability [68-70].

Beck Anxiety Inventory

The Beck Anxiety Inventory (BAI [71,72]), a 21-item self-report inventory, was used to assess symptoms of anxiety and has demonstrated internal consistency and test–retest reliability [71-74].

Pain Catastrophizing Scale

The Pain Catastrophizing Scale (PCS [75]) is a self-report measure of pain catastrophizing through pain-related thoughts, perceived helplessness, and exaggerated attentional focus on the threat of pain stimuli [75]. The PCS comprises rumination (α=.87), magnification (α=.60), and helplessness (α=.79) subscales [75].

Brief Pain Inventory

The Brief Pain Inventory (BPI [76,77]) is a 16-item, self-report questionnaire that measures the severity of *worst* and *least* pain in the past 24 hours, as well as participants' *average* and present pain (*right now*). It has demonstrated reliability and validity in patients with chronic nonmalignant pain [78].

Five Facet Mindfulness Questionnaire

The Five Facet Mindfulness Questionnaire (FFMQ [79]) is a valid 39-item survey that measures five mindfulness subscales: (1) *observing*, (2) *describing*, (3) *acting with awareness*, (4)

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nonjudging of experience, and (5) *nonreactivity to inner experience*. The subscales have demonstrated good construct validity and internal consistency, with α values ranging from .75 to .91 [80-82].

Demographic characteristics and intervention adherence variables were assessed via an investigator-initiated questionnaire.

Objective Outcome Measures

Autonomic Function

Autonomic function was assessed via PPD and HRV using a modified version of a validated 25-minute computer protocol [55,56]. A 5-minute BL rest phase was followed by a 10-minute artificial stress task (stress phase) and a 10-minute GM (recovery phase). During BL and GM, participants viewed a moving fixation cross on a computer screen that randomly changed locations in a 9-square grid every 10 seconds. The modified stress task (emotional stress task) comprised 60 International Affective Picture System (IAPS [83]) images depicting fear, sadness, anger, or frustration to evoke stress responses (Multimedia Appendix 2). Images were presented one at a time for 10 seconds [17,18]. The IAPS provides normative ratings of affect for images based on the Self-Assessment Manikin 9-point rating scale: 9 represents a high rating (ie, high pleasure and high arousal), 5 indicates a neutral rating, and 1 represents a low rating (ie, low pleasure and low arousal [84]). All images were carefully screened for acceptability and approved by a clinical psychologist who supervised the trial. The 60 selected images had a moderately low pleasure rating (mean 3.05, SD 1.63, range 1.79-4.31) and a moderately high arousal rating (mean 5.52, SD 2.13, range 3.93-6.96) [84]. The protocol was conducted in a standardized dimly lit, sound-attenuated room. A chin rest at 65 cm from the computer screen was used to optimize the pupillometric measurement.

Pupillometry

The PPD response was used to assess autonomic balance in conjunction with high-frequency HRV (HF-HRV) using the TobiiPro Glasses 2.0 eye tracking device [85]. PPD was assessed while participants viewed negative images on a computer screen. The data were cleaned using the recommendations of Siegle et al [86]. Trials with >50% blinks resulted in exclusion (1/18, 6%). Changes in PPD were recorded every 20 milliseconds (60 Hz) for 10 seconds following the onset of an image stimulus using Tobii Pro Software [85]. The BL pupil diameter for both the left and right pupils was calculated as the mean pupil size during the 200 milliseconds preceding the onset of the fixation crosses at BL. The resting pupil diameter was calculated as the weighted sum of both pupils. Autonomic PPD was calculated as the maximum pupil response in the first 500 milliseconds after image onset and averaged across 60 images. The first 300 to 500 milliseconds of measurement is recommended for pupillary response to stimuli where no saccades (eg, ballistic fast movements of the eyes and image avoidance) could be initiated [87,88]. Data were inspected for noise and outlier samples using Python software before analysis. Artifacts were identified and removed based on the guidelines of Kret and Sjak-Shie [89]. After the eyeblinks and artifacts were removed, a linear interpolation function was applied to the data to accommodate for missing values. To increase the temporal resolution and smoothness of the data, the data points were resampled with interpolation to a high sampling rate (1000 Hz) based on recommendations [89]. The resulting time-series signal was then smoothed using a zero-phase low-pass filter with a cutoff frequency of 4 Hz [90]. The final step was to calculate the relative pupil size change (percentage change) from the calculated resting pupil size based on recommendations by the Tobii Pro Studio software [81,91]. The Tobii Pro 2.0 glasses have optical sensors that calculate the PPD measure based on eye model algorithms. As the glasses do not report the actual physical pupil diameter, relative change measures such as percentage change in dilation were used to indicate physiological arousal [81,91].

HF-HRV Measure

HF-HRV is an established measure of parasympathetic control [92] and was acquired using a 3-lead electrocardiography (ECG) machine. ECG signals were digitized using a PowerLab 4/35 acquisition system (ADInstruments). LabChart 8 software was used to record and analyze the digitized signals at a sampling rate of 1000 Hz. ECG data were collected and prepared in accordance with the standards set by the 1996 Task Force of the European Society of Cardiology and the North American Society of Pacing and Electrophysiology [92]. LabChart 8 uses automated ECG interpretation, which indicates ectopic and normal beats. ECG recordings were visually inspected to ensure clear PQRST heart beat wave formations free of artifacts, arrhythmias, and ectopic beats and were manually adjusted if beat markers were missing or misplaced. HF-HRV (0.15-0.40 Hz) is conventionally an estimate of short-term (5-minute) recordings of vagal modulation and parasympathetic nervous system activity in HRV [92] and was the primary outcome variable measured in this analysis. Respiration was collected using a respiratory belt and was controlled for in the analyses. The average cyclical rate was calculated using LabChart 8.

Program Adherence and Satisfaction

The attendance rate and duration of counseling calls were tracked, as was the self-reported 7-day recall of time spent in self-directed practice. Google Analytics was linked to the intervention website to monitor the web-based website analytics of visitors during the treatment period. Program usefulness and satisfaction were assessed at postintervention.

Statistical Analysis

Analyses were performed using SPSS Statistics version 23.0 (IBM Corporation).

Hypotheses 1 and 2

The exposure variable was time (BL and postintervention, ie, T1 and T2). The outcomes were PTSD severity, PTSD comorbidities, mindfulness, HF-HRV, and PPD. All outcome variables were treated as continuous.

Hypotheses 1 and 2 Testing: Improvement in Psychometric Outcomes Individually

Paired-sample *t* tests (2-tailed; comparing T1 and T2) were conducted to assess changes in psychometric outcomes using

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intention-to-treat (ITT) analysis (last observation carried forward) and per-protocol (PP) analysis. Cohen *d* was used to evaluate effect size. Box plots were used to check for outliers. Extreme outliers were those located at >3 box lengths from the upper and lower quartiles. The Shapiro-Wilk test was used to assess the normality of the difference scores.

Hypothesis 3: Pre-Post Improvement in Psychophysiological variables of HF-HRV and PPD

Before the analyses, raw HF-HRV and PPD data were examined for normality. HF-HRV was natural log transformed to adjust for positively skewed data (Shapiro-Wilk test; $P<.001$). The study did not have a control group that completed pre-post measurements; instead, comparisons were undertaken with a convenience sample of BL-only participants without PTSD who did not receive the intervention.

Linear mixed effects (LME) models using multilevel regression allows for the inclusion of all cases in unbalanced data [93]. Thus, the non-PTSD convenience sample that completed only the initial BL time point could be entered into the model [93]. Entering all data into one model represents a more parsimonious and accurate analytic approach [93]. A 2-level LME was conducted with the HF-HRV (natural log transformed) or PPD set as the outcome variable. The LME had two levels; level 1 included the individual measurements on a given participant at a given time (eg, only BL for some participants), and level 2 was the participant. The fixed factors were coded as follows: treatment group (0=participants with PTSD who received intervention and 1=convenience, BL-only participants without PTSD), time (0=BL vs 1=postintervention), and protocol condition (eg, 0=BL rest 0-5 minutes, 1=emotional image stress task [EST] 0-5 minutes, 2=EST 5-10 minutes, 3=GM 0-5 minutes, and 4=GM 5-10 minutes). For the within-person repeated measures, participants with PTSD had two repeated measures: time (BL vs postintervention) and protocol condition (BL, EST 0-5 minutes, EST 5-10 minutes, GM 0-5 minutes, and GM 5-10 minutes). The participants without PTSD had one repeated measure: protocol condition (BL, EST 0-5 minutes, EST 5-10 minutes, GM 0-5 minutes, and GM 5-10 minutes). Participants without PTSD were coded for time as 0=BL and for treatment group as 0=did not receive intervention. The model included a subject intercept slope to account for random effects. Significant main effects of treatment group, time, and protocol conditions were evaluated with pairwise comparisons using a Bonferroni type 1 error rate correction. Post hoc analyses using independent and paired-sample *t* tests (2-tailed) were conducted to ascertain where significant differences emerged. Objective outcome measures were conducted using PP analysis to determine the treatment effect on the psychophysiology of participants who complied with the protocol. Exploratory bivariate correlations were examined between psychometric and psychophysiological data to analyze possible associations.

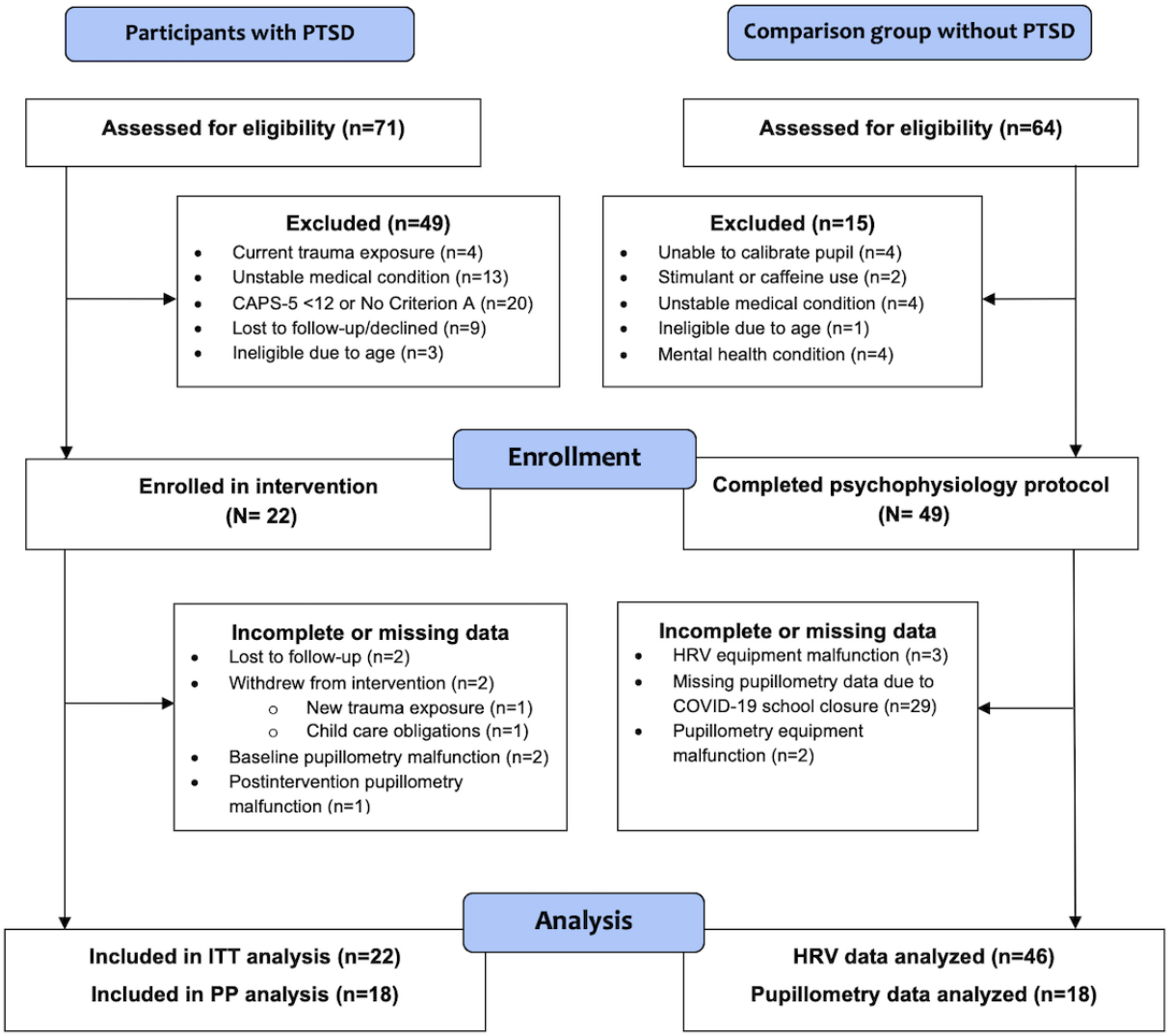
Results

Overview

Overall, 71 adults aged 18 to 35 years were screened for eligibility from October 2018 to December 2019 (Figure 1). Of the 71 adults, 49 (69%) were excluded. The reasons for exclusion were current exposure to trauma (4/49, 8%), high suicide risk or an unstable medical condition (14/49, 29%), a CAPS-5 score <12 or no clear trauma exposure (Criterion A; 20/49, 41%), unable to be contacted (9/49, 18%), or ineligible age (3/49, 6%). On the basis of the inclusion criteria, of the 71 adults, 22 (31%) adults with PTSD provided consent and were enrolled in the study. Of the 22 participants, 2 (9%; 1/2, 50% in week 2 and 1/2, 50% in week 7) withdrew from the study, and an additional 2 (9%; 1/2, 50% in week 2 and 1/2, 50% in week 8) were lost to follow-up. We compared the HF-HRV data of participants with PTSD with the HF-HRV data of 46 participants without PTSD and pilot pupillometry data findings for 18 participants without PTSD.

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Figure 1. CONSORT (Consolidated Standards of Reporting Trials) flow diagram of participant enrollment, follow-up, and analysis. CAPS-5: Clinician-Administered Posttraumatic Stress Scale; HRV: heart rate variability; ITT: intention-to-treat; PP: per-protocol; PTSD: posttraumatic stress disorder. Unstable medical condition (ie.current suicide ideation, substance abuse, current medical treatment).



Demographics of Participants With PTSD

The demographic characteristics of the participants with PTSD are presented in Table 1. Participants were aged 26.4 (SD 4.45) years on average, and most were female (18/22, 82%). Most reported a clinical mental health diagnosis confirmed by a clinical mental health professional (18/22, 82%). Of the 22 participants, 14 (64%) disclosed ≥2 diagnoses, and 11 (50%) reported currently taking prescription medication for a mental health condition.

Table 2 presents a summary of the clinical mental health and trauma exposure variables. Anxiety (14/22, 64%), depression (13/22, 59%), and PTSD (12/22, 55%) were the most common diagnoses. Participants reported an average of 3.5 (SD 2.89) years since the last trauma exposure, with a mean of 11.5 (SD 5.92) lifetime trauma exposures. Most participants experienced direct trauma (mean 5.14, SD 1.86), with physical assault being the most common trauma (19/22, 86%), followed by sexual assault (17/22, 77%). Most participants experienced direct childhood trauma exposure (19/22, 86%) that, on average, occurred as early as the age of 6.66 (SD 4.40) years and persisted for 9.97 (SD 4.62) years. Most childhood abuses were perpetrated by a parent (14/22, 64%), multiple family members (6/22, 27%), or a single family member (4/22, 18%).

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Table 1. Demographic characteristics of posttraumatic stress disorder intervention participants (N=22).

Variables	Values
Age (years), mean (SD)	26.4 (4.45)
Gender, n (%)	
Female	18 (82)
Male	3 (14)
Nonbinary	1 (5)
Ethnicity, n (%)	
White (North American or European)	13 (59)
Black (African American or Caribbean)	1 (5)
Middle Eastern (Persian or Arabian)	3 (14)
Asian (Chinese)	1 (5)
South Asian (Pakistani or Indian)	1 (5)
Mixed race	3 (14)
Immigration status, n (%)	
Landed immigrant	10 (46)
Canadian citizen	12 (55)
Education status, n (%)	
Undergraduate degree in progress (BA[a] and BSc[b])	16 (73)
Second degree in progress (MA[c], PhD, and second bachelor's degree)	6 (27)
Marital status, n (%)	
Single	12 (55)
Dating	6 (27)
Common law or married	4 (17)
Employment status, n (%)	
Unemployed	5 (23)
Part time (0-35 hours/week)	15 (68)
Full time (≥35 hours/week)	2 (9)
Pre-existing physical health condition, n (%)	
None	11 (50)
Obesity or overweight	4 (17)
Fibromyalgia or chronic fatigue syndrome	2 (11)
Autoimmune disorder	2 (11)
Other (ie, Tinnitus, IBS[d], and PCOS[e])	5 (28)
Prediabetes	1 (5)
≥2 conditions	4 (22)
Mental health diagnosis	
Clinical diagnosis, n (%)	18 (82)
≥2 diagnoses, n (%)	14 (64)
Total diagnoses, mean (SD)	2.27 (1.75)
Prescription medications for mental health	
None, n (%)	11 (50)
1 medical prescription, n (%)	6 (27)

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Variables	Values
≥2 medical prescriptions, n (%)	5 (23)
Total medications, mean (SD)	1.41 (2.02)
Mindfulness practice (min/day), n (%)	
0	16 (73)
<10	6 (27)
>10	0 (0)

[a]BA: bachelor of arts.

[b]BSc: bachelor of science.

[c]MA: master of arts.

[d]IBS: irritable bowel syndrome.

[e]PCOS: polycystic ovary syndrome.

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Table 2. Clinical mental health and trauma exposure variables of participants with posttraumatic stress disorder (PTSD; N=22).

Mental health and trauma exposure variables	Values
DSM-5[a] clinical mental health diagnosis, n (%)	
PTSD	12 (55)
Depression	13 (59)
Anxiety	14 (64)
Borderline personality disorder	3 (14)
Addiction or self-harm	3 (14)
Multiple diagnoses (≥2 diagnoses)	14 (64)
Other (ie, attachment disorder)	1 (5)
Trauma exposure (LEC-5)[b], mean (SD)	
Happened to me (directly)	5.14 (1.86)
Witnessed it	2.27 (1.96)
Learned about it	3.55 (3.61)
Part of job	0.55 (2.35)
Total trauma exposures	11.50 (5.92)
Time since last trauma exposure (years)	3.50 (2.89)
Direct trauma exposure category, n (%)	
Physical assault	19 (86)
Sexual assault (eg, rape or attempted rape)	17 (77)
Unwanted sexual experience (eg, groping or sexual harassment)	17 (77)
Transportation accident	10 (46)
Repeated trauma exposure[c]	20 (91)
Other (eg, psychological abuse)	18 (82)
Childhood trauma exposure	
Happened to me, n (%)	19 (86)
Age of first memory (years), mean (SD)	6.66 (4.40)
Duration of childhood trauma (years), mean (SD)	9.97 (4.62)
Childhood abuser, n (%)	
Parent	14 (74)
Family member	4 (21)
Multiple family members	6 (27)
Friend or acquaintance	2 (11)
Stranger	1 (5)
Type of childhood trauma, n (%)	
Physical abuse only	9 (47)
Sexual assault	9 (47)
Verbal emotional or psychological abuse	16 (84)
Past mental health treatment, n (%)	
Pharmacotherapy	11 (50)
Talk therapy	20 (91)
EMDR[d]	4 (18)
Hospitalization	3 (14)

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Mental health and trauma exposure variables	Values
Alternative or complementary medicine	4 (18)
Family history of mental health, n (%)	
Yes	15 (68)
No	7 (32)

[a]DSM-5: Diagnostic and Statistical Manual of Mental Disorders, fifth edition.

[b]LEC-5: Life Events Checklist for Diagnostic and Statistical Manual of Mental Disorders, fifth edition.

[c]Repeated by the same perpetrator or abuser or repeated type of trauma exposure.

[d]EMDR: eye movement desensitization and reprocessing.

Treatment Response on Psychometric Outcomes

Hypothesis 1

Table 3 shows the mean and SD for each psychometric measure at T1 and T2, as well as the mean percentage change from T1 to T2 for ITT and PP approaches. Pre-post analysis revealed a significant reduction in CAPS-5 PTSD symptom severity from BL to postintervention for both ITT (Δmean=−19.18, SD 12.38; t_{21}=7.27; P<.001) and PP (Δmean=−23.44, SD 9.14; t_{17}=10.88; P<.001). Cohen d was calculated as 1.42 (ITT), which equates to a large effect size [58]. The largest symptom severity reduction was in Criterion D: negative cognition and mood symptoms (Δmean=−7.59, SD 5.23; t_{21}=6.81; P<.001; d=1.39). Overall, the ITT results indicated that the 8-week intervention reduced PTSD symptom severity (Table 3) by 37.9%. This approximately 2-fold reduction in symptom severity surpassed the hypothesized minimal clinically important difference of a 10-point reduction.

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Table 3. Pre- (time point 1 [T1]; baseline measures) and postintervention (time point 2 [T2]) psychometric outcomes for intention-to-treat (ITT; N=22) and per-protocol (PP; N=18) analyses*a*.

Psychometric measure	ITT (N=22)				PP (N=18)			
	T1, mean (SD)	T2, mean (SD)	Δ score (%)	Cohen *d*	T1, mean (SD)	T2, mean (SD)	Δ score (%)	Cohen *d*
PTSD[b] (CAPS-5[c])								
Criterion B (intrusion)	12.23 (2.86)	*7.77* (*3.61*)[d]	–36.5	*1.37*	12.39 (2.39)	*6.94* (*3.23*)	–44.0	*1.92*
Criterion C (avoidance)	5.18 (1.89)	*2.86* (*2.21*)	–44.8	*1.13*	5.06 (2.01)	*2.22* (*1.83*)	–56.1	*1.48*
Criterion D (cognition or mood)	17.41 (4.62)	*9.82* (*6.95*)	–43.6	*1.29*	16.50 (4.50)	*7.22* (*4.39*)	–56.2	*2.09*
Criterion E (arousal or reactivity)	12.27 (4.32)	*7.73* (*4.63*)	–37.0	*1.01*	12.22 (4.49)	*6.67* (*4.13*)	–45.4	*1.29*
Total symptom severity	47.09 (9.09)	*27* (*15.22*)	–42.7	*1.60*	46.17 (9.56)	*21.61* (*10.54*)	–53.2	*2.44*
Total symptoms (out of 20)	15.68 (2.10)	*9.73* (*5.32*)	−37.9	*1.47*	15.33 (2.14)	*8.11* (*4.40*)	–47.1	*2.09*
PTSD (PCL-5[e])	48.14 (11.94)	*28.95* (*17.67*)	–39.9	*1.27*	45.56 (11.35)	*22.11* (*10.23*)	–51.5	*2.01*
Depression (BDI-2[f])	28.14 (13.70)	*16.27* (*15.02*)	–42.2	*0.83*	25.78 (13.39)	*11.28* (*10.65*)	–56.2	*1.34*
Anxiety (BAI[g])	29.68 (9.54)	*19.36* (*11.32*)	–34.8	*0.99*	28.33 (8.88)	*15.72* (*7.61*)	–44.5	*1.60*
Pain catastrophizing (PCS[h,i])	20.00 (13.73)	*10.85* (*8.59*)	–45.6	*0.80*	22.00 (13.59)	*11.18* (*8.66*)	−49.2	*0.82*
Pain severity (BPI[j])[i]	4.10 (1.01)	*2.48* (*1.68*)	–39.5	*1.17*	4.10 (1.01)	*2.48* (*1.68*)	–39.5	*1.17*
Pain interference (BPI)[i]	3.29 (1.39)	*2.10* (*1.74*)	–36.2	*0.75*	3.29 (1.39)	*2.10* (*1.74*)	–36.2	*0.75*
Five-facet mindfulness (FFMQ[k])								
FFMQ observing	25.09 (8.31)	27.45 (5.86)	9.4	—[l]	24.61 (8.79)	27.50 (5.98)	11.7	—
FFMQ describing	25.73 (7.16)	27.49 (6.54)	6.8	—	25.75 (7.30)	28.06 (6.45)	9.0	—
FFMQ awareness	20.95 (6.89)	*25.18* (*6.37*)	20.2	*0.64*	21.33 (6.86)	*26.50* (*5.42*)	24.2	*0.84*
FFMQ nonjudging	20.55 (5.16)	*26.41* (*6.95*)	28.5	*0.96*	20.33 (5.57)	*27.50* (*7.16*)	35.3	*1.12*
FFMQ nonreactivity	15.87 (5.17)	*20.55* (*6.05*)	29.6	*0.83*	16.56 (5.11)	*22.28* (*4.87*)	34.5	*1.15*
FFMQ total score	108.18 (19.12)	*127.18* (*23.84*)	17.6	*0.88*	108.61 (20.32)	*131.83* (*23.20*)	21.4	*1.06*

[a]Cohen *d* values are reported in absolute values, and intention-to-treat using the last observation was carried forward.

[b]PTSD: posttraumatic stress disorder.

[c]CAPS-5: Clinician-Administered Posttraumatic Stress Scale.

[d]Italicized values indicate significant differences.

[e]PCL-5: Posttraumatic Stress Disorder Checklist for the Diagnostic and Statistical Manual of Mental Disorders, fifth edition.

[f]BDI-2: Beck Depression Inventory-2.

[g]BAI: Beck Anxiety Inventory.

[h]PCS: Pain Catastrophizing Scale.

[i]n=13 because of the addition of scale after 6 months from recruitment.

[j]BPI: Brief Pain Inventory.

[k]FFMQ: Five Facet Mindfulness Questionnaire (in this subscale, higher values indicate improvement).

[l]Nonsignificant values are not reported.

Hypothesis 2

There were significant reductions in symptom severity for PCL-5 (t_{21}=6.44; *P*<.001), BDI-2 (t_{21}=5.59; *P*<.001), BAI (t_{21}=4.94; *P*<.001), PCS (t_{12}=3.22; *P*=.01), BPI severity (t_6=2.71; *P*=.04) and BPI interference (t_6=3.20; *P*=.02), and FFMQ (t_{21}=−5.00; *P*<.001). As shown in Table 3, effect sizes (Cohen *d*) of significant improvements ranged from 0.75 to 1.27, indicating a large effect, with PCL-5 exhibiting the largest reductions (*d*=1.27), followed by BAI (*d*=0.99), FFMQ (*d*=0.88), and BDI-2 (*d*=0.83). All secondary psychometric data

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demonstrated 17.5% to 45.6% symptom reduction supporting hypothesis 2.

Treatment Effect on Psychophysiology Outcomes

HRV Analysis

Tables 4 and 5 present the descriptive statistics of ECG variables and HF-HRV among the participants with PTSD (n=18) and those without PTSD (n=46). Figure 2 depicts the HF-HRV across the 25-minute laboratory protocol. Participants without PTSD were, on average, significantly younger than the participants with PTSD (d=1.41; P<.001). Resting heart rate (HR) was significantly lower in participants without PTSD (mean 76.45, SD 11.09) than in participants with PTSD at BL (mean 86.43, SD 13.98; d=0.88; P=.002) and postintervention (mean 84.95, SD 10.76; d=0.71; P=.02).

Multilevel LME modeling on HF-HRV was performed with all 64 participants (eg, 18/64, 28% participants with PTSD and 46/64, 72% participants without PTSD) and revealed significant differences in HF-HRV (Table 6). The results revealed a significant main effect of treatment (eg, participants with PTSD vs participants without PTSD) group ($F_{1,65}$=14.54; P<.001; ^{2}=0.10) and protocol (eg, BL, EST, GM) phase condition ($F_{4, 240}$=6.33; P<.001; ^{2}=0.18) on HF-HRV. No significant main effect of time was found between BL and postintervention among participants with PTSD (P=.87), indicating no significant intervention effect on HF-HRV among participants with PTSD.

For the main effect of the treatment group, pairwise comparisons using Bonferroni type 1 correction revealed that the participants without PTSD had a significantly higher overall mean HF-HRV than participants with PTSD (B=0.55, SE 0.14; $t_{65.16}$=3.81; P<.001) at *both* BL and postintervention. Furthermore, the differences in HF-HRV between participants with PTSD and participants without PTSD remained significant ($F_{4, 238}$=7.70; P<.001; ^{2}=0.11) after controlling for respiration, indicating that the differences found were not because of the influence of respiration rate. Post hoc analyses for the main effect of protocol condition using BL rest phase as the reference indicated that HF-HRV was significantly higher during the first 5 minutes of the EST phase compared with BL rest phase for participants without PTSD (Δmean=0.104, SE 0.03; d=0.20; P=.002) and participants with PTSD at T1 (Δmean=0.14, SE 0.04; d=0.20; P=.002) but not for participants with PTSD at T2 (P=.26). Additionally, HF-HRV was significantly higher during the first 5 minutes of GM compared to BL rest phase for participants without PTSD (Δmean=0.09, SE 0.04; d=0.26; P=.02) and participants with PTSD at T1 (Δmean=0.14, SE 0.05; d=0.32; P=.09) and at T2 (Δmean=0.19, SE 0.07; d=0.30; P=.02).

Table 4. Estimated marginal means and log-transformed high-frequency heart rate variability comparisons among participants with posttraumatic stress disorder (PTSD; N=18) and a non-PTSD convenience sample cohort (N=46).

Variable	Participants with PTSD, mean (SD)		Participants without PTSD, mean (SD)
	T1[a]	T2[b]	T1
Age (years)	26.39 (4.23)	26.39 (4.23)	20.78 (3.64)[c,d]
BL[e] heart rate (bpm[f])	86.43 (13.98)	84.95 (11.76)	76.45 (11.09)[c,d]
BL respiration	16.32 (4.09)	16.30 (4.48)	16.93 (2.72)
BL RMSSD[g]	30.89 (26.02)	30.14 (19.54)	49.04 (25.69)
BL LF:HF[h]	1.84 (1.30)	2.87 (4.08)	1.43 (2.01)

[a]T1: time point 1 (baseline).

[b]T2: time point 2 (postintervention).

[c]Significant difference (P<.05) between participants without posttraumatic stress disorder and participants with posttraumatic stress disorder at time point 1 (baseline).

[d]Significant difference (P<.05) between participants without posttraumatic stress disorder and participants with posttraumatic stress disorder at time point 2 (postintervention).

[e]BL: baseline.

[f]bpm: beats per minute.

[g]RMSSD: root mean square of successive differences (between normal heartbeats).

[h]LF:HF: low-frequency to high-frequency heart rate variability ratio.

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Table 5. Estimated marginal means (EMMs) and log-transformed high-frequency heart rate variability comparisons among participants with posttraumatic stress disorder (PTSD; N=18) and a non-PTSD convenience sample cohort (N=46) for the 25-minute protocol condition.

Variable	Participants with PTSD				Participants without PTSD	
	T1[a]		T2[b]		T1	
	EMM (SE)	Log_{10} (SE)	EMM (SE)	Log_{10} (SE)	EMM (SE)	Log_{10} (SE)
Baseline rest phase (5 minutes)	708.05 (224.96)	2.31 (0.19)	559.79 (147.12)	2.31 (0.18)	1467.45 (243.20)	2.90 (0.08)
EST[c] 1 (0-5 minutes)	995.50 (344.73)	2.45 (0.19)	490.12 (131.23)	2.40 (0.13)	1827.16 (310.67)	3.00 (0.08)
EST 2 (5-10 minutes)	810.08 (264.90)	2.40 (0.18)	460.78 (103.26)	2.38 (0.14)	1446.24 (232.66)	2.94 (0.07)
GM[d] 1 (0-5 minutes)	774.59 (207.90)	2.45 (0.18)	810.19 (357.26)	2.50 (0.14)	1547.99 (217.75)	3.00 (0.07)
GM 2 (5-10 minutes)	580.94 (150.65)	2.42 (0.16)	408.61 (87.78)	2.44 (0.10)	1220.34 (175.18)	2.90 (0.07)

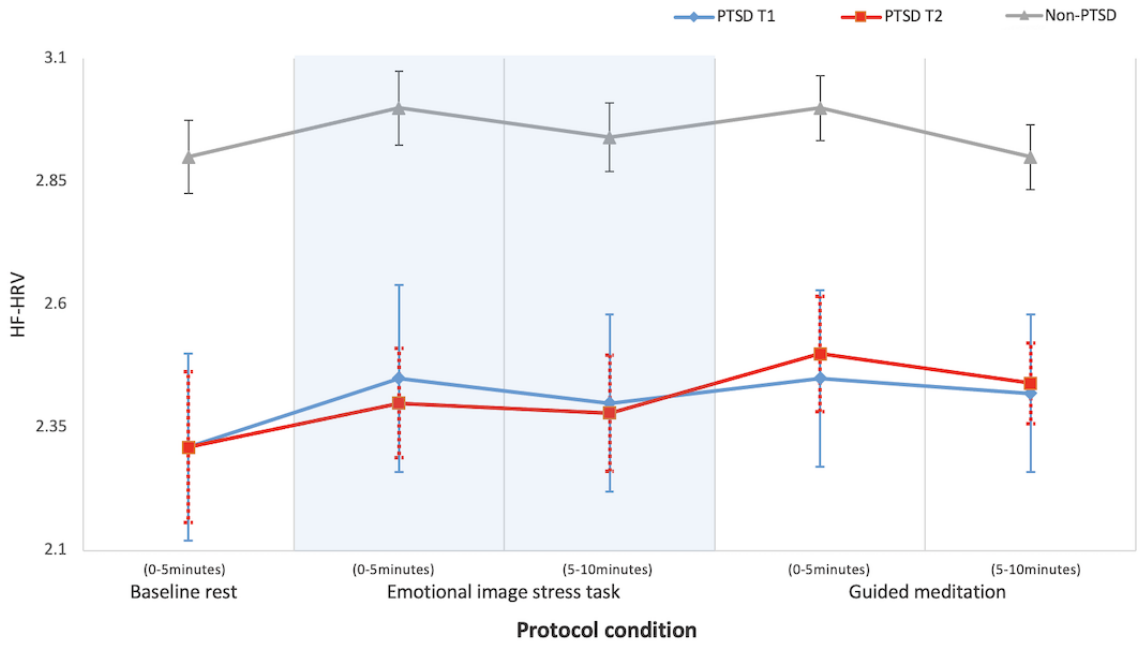
[a]T1: time point 1 (baseline).

[b]T2: time point 2 (postintervention).

[c]EST: emotional image stress task phase.

[d]GM: guided meditation phase.

Figure 2. The HF-HRV of participants with PTSD at baseline (T1) and postintervention (T2) compared with participants without PTSD during the 25-minute protocol conditions of rest, stress, and guided meditation. HF-HRV is presented as a log10-transformed plot with SE bars. HF-HRV: high-frequency heart rate variability; PTSD: posttraumatic stress disorder; T1: time point 1; T2: time point 2.



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Table 6. Linear mixed effects model parameter estimates for heart rate variability among participants with posttraumatic stress disorder (PTSD) and participants without PTSD*a*.

Parameter	B (SE; 95% CI)	*t* test (*df*)	*P* value	Wald *Z*	*P* value
Fixed effects				—[b]	—
Intercept	*2.32 (0.12; 2.07 to 2.56)* [c]	*18.77* (*67.74*)	<.001		
Treatment group					
Participants with PTSD	Reference	Reference	Reference		
Participants without PTSD	*0.55* (*0.14; 0.26 to 0.84*)	*3.81* (*65.16*)	<.001		
Time period					
BL[d]	Reference	Reference	Reference		
Postintervention	0.02 (0.06; –0.09 to 0.16)	0.411 (57.23)	.68		
Protocol condition					
BL	Reference	Reference	Reference		
EST[e] 1 (0-5 minutes)	*0.11* (*0.03; 0.05 to 0.16*)	*3.59* (*238.47*)	*<.001*		
EST 2 (5-10 minutes)	0.05 (0.03; 0.00 to 0.11)	1.82 (257.16)	.07		
GM[f] 1 (0-5 minutes)	*0.14* (*0.03; 0.08 to 0.20*)	*4.67* (*257.86*)	*<.001*		
GM 2 (5-10 minutes)	*0.08* (*0.03; 0.02 to 0.14*)	*2.64* (*286.98*)	*.009*		
Random effects (intercept)	*0.25* (*0.05; 0.17 to 0.36*)	—	—	*5.35*	*<.001*
Repeated measures		—	—		*<.001*
AR[g] 1 diagonal	*0.06* (*0.01; 0.05 to 0.07*)			*10.52*	
AR 1 rho	*–0.51* (*0.06; –0.61 to –0.39*)			*9.45*	

[a]Akaike Information Criterion value of 179.93.

[b]Not available (no data).

[c]Italicized values indicate significant findings (*P*<.01; 2-tailed).

[d]BL: baseline (rest phase; 5 minutes).

[e]EST: emotional image stress task phase.

[f]GM: guided meditation phase.

[g]AR: autoregressive covariance structure.

Pupillometry Analysis

Figure 3 presents the mean fluctuations in the relative pupil diameter size across the entire 25-minute protocol. Changes in relative pupil size were significant across the protocol phases, with the EST phases (eg, 0-5 minutes, 5-10 minutes) showing the greatest increases in relative PPD, reflecting higher autonomic reactivity responses.

Descriptive statistics of the mean PPD outcome variables in participants with PTSD (18/64, 28%) and participants without PTSD (18/64, 28%) are reported in Table 7. LME analysis was conducted to determine where significant differences in PPD emerged.

As seen in Table 8, multilevel LME modeling revealed a significant main effect of protocol condition ($F_{4,148}$=139.33; *P*<.001; ^{2}=0.79), time ($F_{1,54}$=31.14; *P*<.001; ^{2}=0.37), and treatment group ($F_{1,35}$=6.33; *P*=.02; ^{2}=0.15) on PPD. In terms of comparing participants with PTSD with participants without PTSD, pairwise comparisons revealed that participants without PTSD had a significantly lower overall PPD compared with participants with PTSD (B=−0.07; t_{35}=–2.52; *P*=.02), reflecting reduced pupillary reactivity. Post hoc analyses to determine where significant differences emerged revealed that participants without PTSD had significantly lower PPD (mean 0.007, SD 0.06) during BL rest protocol condition compared with participants with PTSD (mean 0.05, SD 0.05) at T1 (t_{34}=2.40; *P*=.02), indicating a large effect (*d*=0.78). Participants without PTSD also had significantly lower PPD during the first 5 minutes of GM (mean –0.04, SD 0.09) compared with participants with PTSD at T1 (mean 0.02, SD 0.07; t_{34}=2.41; *P*=.02; *d*=0.74), which yielded a moderate to large effect size. At postintervention, no significant differences in PPD between participants with PTSD and participants without PTSD were found across any protocol condition, which supports our hypothesis and suggests that there was an intervention effect on reduced PPD reactivity among participants with PTSD.

For the main effect of time among participants with PTSD only, pairwise comparisons using Bonferroni type 1 correction revealed a significant reduction in overall PPD among participants with PTSD at postintervention compared with BL

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(Δmean=0.06, SE 0.01; *P*<.001), which equated to a large effect (*d*=0.90).

Figure 3. Mean change in relative PPD size across the 25-minute protocol. PPD is presented as relative pupil size and expressed as a ratio (0.10=10%) with 95% CI bars. PPD: peak pupil dilation; PTSD: posttraumatic stress disorder; T1: time point 1; T2: time point 2.

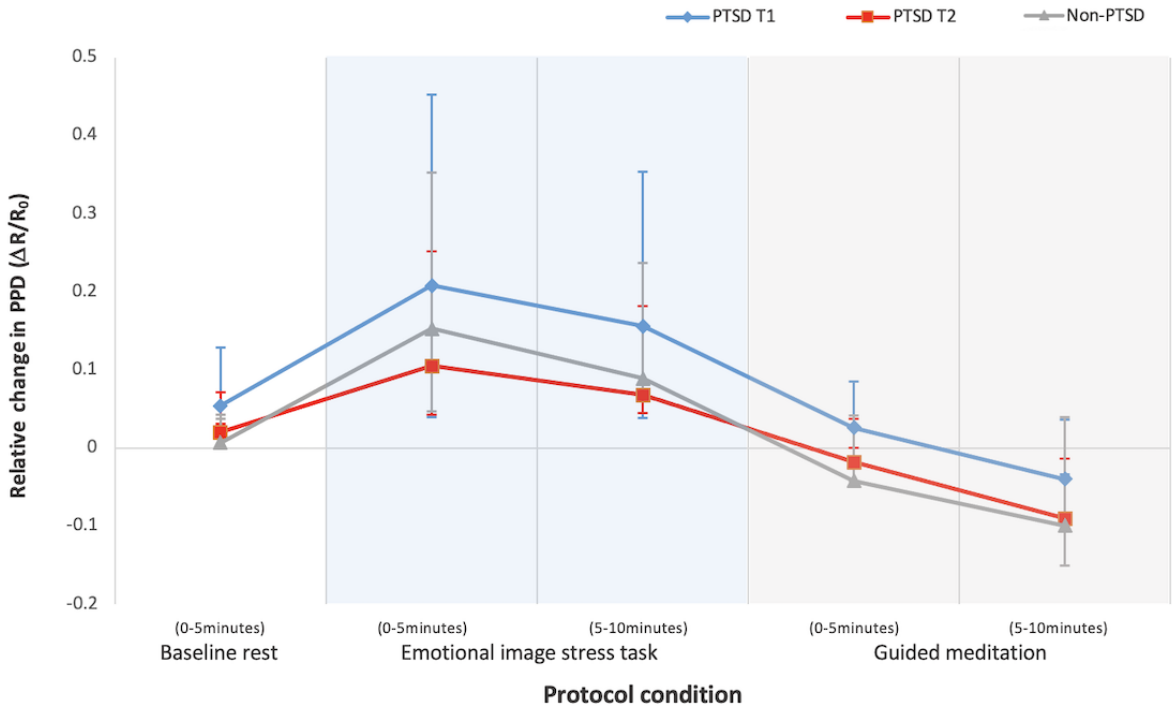


Table 7. Relative peak pupil dilation (PPD) across a 25-minute protocol among participants with posttraumatic stress disorder (PTSD) and participants without PTSD[a].

PPD 25-minute protocol phases	Participants with PTSD, mean (SD)		Participants without PTSD, mean (SD)
	T1[b] (n=18)	T2[c] (n=17)	T1 (n=18)
Baseline (rest phase)	0.05 (0.05)	0.02 (0.07)	*0.00 (0.06)*[d]
EST[e] 1 (0-5 minutes)	0.21 (0.09)	0.10 (0.09)	0.15 (0.10)
EST 2 (5-10 minutes)	0.16 (0.10)	0.07 (0.10)	0.09 (0.13)
GM[f] 1 (0-5 minutes)	0.03 (0.07)	−0.02 (0.08)	*−0.04 (0.09)*[d]
GM 2 (5-10 minutes)	–0.04 (0.10)	−0.09 (0.08)	−0.10 (0.10)

[a]Peak pupil dilation values are presented as relative change from 0; a 0.10 change reflects a 10% increase in peak pupil dilation.

[b]T1: time point 1.

[c]T2: time point 2.

[d]Italicized values indicate significant difference (*P*<.05) between participants with and without posttraumatic stress disorder at time point 1.

[e]EST: emotional image stress task phase.

[f]GM: guided meditation phase.

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Table 8. Linear mixed effects model parameter estimates for peak pupil dilation among participants with posttraumatic stress disorder (PTSD) and participants without PTSD[a].

Parameter	Estimate (SE; 95% CI)	*t* test (*df*)	*P* value	Wald *Z*	*P* value
Fixed effects				—[b]	—
Intercept	*0.07* (*0.02*; *0.03 to 0.11*)[c]	*3.41* (*43.83*)	*.001*		
Treatment group					
Participants with PTSD	Reference	Reference	Reference		
Participants without PTSD	*–0.07* (*0.03; 0.12 to –0.01*)	–2.52 (34.65)	*.02*		
Time period					
BL[d]	Reference	Reference	Reference		
Postintervention	*–0.06* (*0.01; 0.08 to –0.04*)	*–5.58* (*53.72*)	*<.001*		
Protocol condition					
BL	Reference	Reference	Reference		
EST[e] 1	*0.13* (*0.01; 0.11 to 0.15*)	*11.37* (*162.12*)	*<.001*		
EST 2	*0.08* (*0.01; 0.05 to 0.10*)	*6.80* (*144.07*)	*<.001*		
GM[f] 1	*−0.04* (*0.01; 0.06 to –0.02*)	*–3.58* (*145.74*)	*<.001*		
GM 2	*–0.10* (*0.01; 0.12 to –0.08*)	*–9.13* (*153.38*)	*<.001*		
Random effects (intercept)	0.005 (0.00; 0.003 to 0.009)	—	—	*3.57*	*<.001*
Repeated measures		—	—		
AR[g] 1 diagonal	0.004 (0.00; 0.003 to 0.005)			*10.25*	*<.001*
AR 1 rho	–0.21 (0.08; 0.36 to –0.04)			*–2.50*	*.01*

[a]Akaike Information Criterion –577.92.

[b]Not available (no data).

[c]Italicized values indicate significant findings (*P*<.01; 2-tailed).

[d]BL: baseline rest phase.

[e]EST: emotional image stress task phase.

[f]GM: guided meditation phase.

[g]AR: autoregressive covariance structure.

Exploratory Correlations Between PPD, HF-HRV, and PTSD Symptom Severity

Baseline resting PPD at T1 was significantly associated with CAPS-5 symptom severity score at postintervention (r_p=0.54; *P*=.20) suggesting that a higher resting PPD (increased autonomic reactivity) is associated with a higher CAPS-5 symptom severity score at postintervention. HF-HRV at T1 (*P*=.21) or T2 (*P*=.69) was not significantly correlated with the CAPS-5 or PCL-5 PTSD symptom severity scores.

Intervention Program Adherence

Overall, 94% (17/18) of participants had a 100% attendance rate on the weekly CBT calls, with one of the participants completing 88% (7/8) of the scheduled calls. In terms of weekly self-directed practice, the time spent in GM was highest (mean 38.89 min/week, SD 28.16 min/week), followed by yoga (mean 31.94 min/week, SD 28.24 min/week), and breathing techniques (mean 9.89 min/week, SD 11.87 min/week). Overall, participants spent 11.53 (SD 22.76) min/day in self-directed mindfulness (eg, meditation, yoga, breath awareness) practice. Combining all program intervention components (eg, CBT-MY), participants spent an average of 145 (SD 40.82) minutes (approximately 3 hours) per week engaging with the intervention, which is equivalent to 20 min/day. In total, 837 (SD 228.17) minutes of program engagement were recorded across the entire intervention equating to a total of 14-hours of program participation.

Discussion

Principal Findings

PTSD impedes daily function in multiple health domains [3,94]. Although significant findings support stand-alone CBT [95], mindfulness [41], and yoga treatment for PTSD [52], a paucity of research assesses integrated web-based approaches. This study investigated the psychometrics and objective measures of pupillometry and HF-HRV before and after an 8-week CBT-MY intervention. The results demonstrated significant self-reported improvements with large effect size reductions in PTSD (CAPS-5, *d*=1.60; PCL-5 *d*=1.27), depression (*d*=0.83), and anxiety (*d*=0.99) and increases in mindfulness (*d*=0.88). In

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objective measures, there were large effect size reductions for PPD (Δmean=–0.06, SE 0.01; *P*=.001), which were theoretically discrepant with the nonsignificant effects for HF-HRV (*P*=.87).

We found a large (*d*=1.60), clinically significant (≥10 points) reduction in CAPS-5 total symptom severity that exceeded the meta-analytic effect sizes referenced for psychotherapy for PTSD (*d*=1.43 [32]), web-based trauma-focused CBT (*d*=1.04 [54]), and web-based PTSD psychotherapy (*d*=1.05 [96]). The observed improvement was larger than the pre-post PCL-5 improvements associated with therapist-guided web-based PTSD therapy (*d*=1.40) [97]. The results compare favorably to a study of mindfulness and yoga in an intensive 3-week program for veterans diagnosed with PTSD associated with a pre-post effect size of Cohen *d*=1.12 [98]. In our study, BL depression severity moderate (mean 25.78, SD 13.39) and anxiety was severe (mean 28.33, SD 8.88). Postintervention scores reflected minimal depression (mean 11.28, SD 10.65) and mild to moderate anxiety (mean 15.72, SD 7.61 [99]). These reductions in depression and anxiety found in our study were consistent with previous trials showing comorbidity changes after effective PTSD treatment [54,98,100].

Although notable symptom improvements were observed in our study, they were partial improvements. At postintervention, 33% (6/18) of participants (compared with 20/22, 91% at BL) met the CAPS-5 PTSD diagnostic criteria, reflecting a reduction of 57.6%. Only one participant (1/18, 6%) reported being symptom-free at postintervention, whereas the remaining 61% (11/18) of participants reported subsyndromal PTSD [101]. McFarlane et al [102] proposed that varied PTSD symptom trajectories (eg, subsyndromal or partial PTSD vs severe or full PTSD) impact care provision and suggested that a clinical staging treatment strategy may be helpful to determine where specific treatment modalities are most effective. Symptom reductions based on PTSD trajectory can inform future clinical efforts by differentiating the stages of recovery [102]. With improved staging of PTSD recovery, clinical efforts can be targeted toward the specified participants most likely to achieve specific improvements [102]. Thus, the symptom improvements resulting from our CBT-MY intervention suggests a particular utility for a certain PTSD trajectory, but not necessarily appropriate for the most severe PTSD symptom trajectory. As noted in our findings, participants who scored *severe to extreme* PTSD symptom presentation in *Criterion D: negative cognition and mood symptoms* (CAPS-5) were the least likely to have reduced PTSD symptoms (to a subsyndromal stage) and most likely to withdraw from the intervention. On the basis of the recommendations by McFarlane et al [102], CBT-MY appears best suited for the less severe stages of clinical PTSD progression.

Participants exhibited substantial increases in 3 mindfulness facets (FFMQ), supporting the initial hypotheses. Specifically, improvements in *nonjudging* (*d*=0.96), *nonreactivity* (*d*=0.83), and *acting with awareness* (*d*=0.64) suggest participant integration of foundational mindfulness–yoga concepts (eg, *impermanence* and the appraisal of distressing events) [103]. For instance, more acceptance of change may facilitate *neutral judgments* of transient phenomena (memories and feelings) and *lesser reactivity* to associated distress [103,104].

The lack of FFMQ *observing* and *describing* improvements may be explained by a plausible interaction with hyperarousal symptoms [105]. This view is supported by research suggesting that articulating and communicating emotions becomes easier when amygdala hyperactivity, a PTSD neurocorrelate, is reduced [105,106]. Combined with the nonsignificant HF-HRV finding, it is possible that improvements in FFMQ *observing* and *describing* occur at a later stage in the PTSD recovery process [13].

Another plausible explanation is the presence of severe dissociative symptoms may have limited participants' capacities for mindful attention [107]. Virtually all participants (21/22, 95%) disclosed clinical symptoms of dissociation (eg, depersonalization). Trauma-related dissociation involves avoidance, numbing, and the compartmentalization of psychological functioning and is often expressed in victims of childhood abuse with repeated exposure [108]. In turn, survivors of childhood abuse often experience difficulties in labeling and downregulating emotions [108]. Mindfulness practices aim to counteract such dissociative processes by promoting experiential integration through nonjudgmental, present moment awareness [35,51,107-110].

Psychophysiology Outcomes

We found large effect size reductions for PPD (*d*=0.90) in contrast with nonsignificant HF-HRV effects (*P*=.87). Postintervention PPD and PTSD symptom outcomes (CAPS 5 and PCL-5) were correlated (*P*=.05), suggesting associations between self-report and PPD indicative of improved autonomic balance. HF-HRV results were discrepant, apparently unaffected by the intervention, and uncorrelated with self-reported benefits.

Participants with PTSD, compared with participants without PTSD, had significantly lower (pre- and postintervention) HF-HRV across all protocol phases. The mean BL resting HR in participants without PTSD was significantly lower than that in participants with PTSD. This finding is congruent with prior research examining the impact of trauma exposure and PTSD on autonomic dysregulation via HR and HF-HRV [111,112] and the findings of reduced capacities to psychophysiologically modulate in response to environmental changes [113,114]. During the lab procedure, the participants without PTSD exhibited significantly higher HF-HRV during stress onset (0-5 minutes) compared with that at rest, suggesting self-regulatory effectiveness and the mobilization of parasympathetic activity during negative image exposures [115]. In contrast, there were no significant changes in HF-HRV among participants with PTSD from rest to stress at BL or postintervention.

PTSD is often associated with comorbidities related to low and invariant HF-HRV [116-118]. It is possible that the chronicity of childhood trauma exposure (9.97 years duration) and severity of depression at BL had a blunting effect on HF-HRV during the protocol. Nonresponsive HF-HRV to a therapeutic intervention has been observed in patients with major depressive disorder [119,120]. Research examining the link between childhood emotional abuse and HF-HRV among women indicated that depressed women with histories of childhood emotional abuse exhibited significant HF-HRV decrements compared with depressed women without childhood abuse

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(d=0.90) and controls (d=0.87) [121]. These findings suggest that childhood emotional abuse is a strong predictor of impaired parasympathetic control.

Although PPD reductions across the 25-minute protocol were predicted, it is unclear why significant reductions were observed in PPD but not HF-HRV. An explanation involves mechanisms unique to ocular versus cardiac functioning. Theoretically, PPD reflects a more proximal and immediate form of threat reactivity than HF-HRV, as PPD responses appear to precede the autonomic reactions assessed by HF-HRV [21,113,122]. Although HF-HRV changes apparently reflect autonomic responses heavily influenced by cognitive–emotive responses, PPD changes reflect precognitive hypervigilance, hypothesized as prevalent in PTSD [21,113,122]. The varying foci of PPD and HF-HRV measurements in this study also substantially differed. PPD, representing autonomic function, was measured within the first 300 to 500 milliseconds of the onset of an image stimulus. This represents a significant duration difference from the recommended HF-HRV measurement of 5-minute epochs [92]. Not only does this indicate that PPD and HF-HRV measurement differences were, retrospectively, predictable as the observation period differed but also suggests that the physiological responses of participants differed significantly *during* image exposure. In the PPD response, participants were apparently less reactive to images at postintervention than at BL, whereas HF-HRV remained invariant and indicated sustained autonomic dysregulation at postintervention. Theoretically, the *ability* to *sustain* a less threatened response via HF-HRV is unlikely as participants are highly vulnerable to the more habit-based cognitive rumination and catastrophizing responses that *kick in* after an initially less disturbed image response [23]. Prior research has indicated an indirect relationship between HF-HRV and PPD, with low HF-HRV linked with perseverative cognition symptoms [123,124], which has been shown to be linked with greater pupil dilation to negative stimuli [125,126].

Few studies have explored the direct associations between HRV and the associated pupil response during rest, stress-induced, and meditation phases in clinical samples. Our findings are supported by a recent study by Macatee et al [127] that examined emotional processing indications of pupillary response and vagally mediated HRV in a nonclinical sample exposed to positive, negative, and neutral stimuli. HRV was unrelated to negative emotional processing and was not significantly associated with the pupillary indices of negative stimuli [127]. In contrast, low HRV predicted decreased pupil dilation to *positive* stimuli after a stress phase, reflecting altered *positive* emotional processing following stress induction [127]. As our study did not include positive emotional stimuli, a direct comparison was not possible. Future versions of our study should include positive emotional stimuli to better assess emotional processing in adults with PTSD via HRV and PPD and their associations.

A number of critical questions in our study merit further consideration. The first question is whether the selected negative emotional images were sufficiently evocative to elicit an autonomic stress response during the stress phase of the lab protocol. Our findings contrast with similar research conducted by Cascardi et al [128] that indicated that individuals who met PTSD diagnostic criteria showed large effect size differences (d=0.75) in pupil dilation to threatening stimuli compared with that of trauma-exposed controls without PTSD (P<.015). All the threatening images used by Cascardi et al [128] had an IAPS arousal rating of >6 [83]. The mean arousal rating of the images in our study was 5.51, and only 28% (17/60) of the selected images had an arousal rating of >6 [83,84]. Our preference for milder images, because of concern for the welfare of traumatized participants, may explain the nonsignificant PPD differences during the emotional image stress condition with the convenience sample of participants without PTSD.

However, another critical question is the extent to which the addition of positive stimuli might identify additional relationships between HRV and pupil response in participants with PTSD. In a recent cross-sectional study that examined pupil response to negative *and* positive images in individuals diagnosed with PTSD, McKinnon et al [21] found significantly larger pupil dilation in both threatening and positive (happy) images among individuals with PTSD than in controls exposed to trauma with no diagnosed PTSD (threatening, d=0.87; happy, d=0.73) and controls with no trauma exposure (threatening, d=0.85; happy, d=0.97). These findings suggest that autonomic function in PTSD is sensitive to *both* negative and positive image stimuli. Future studies of autonomic responses to a variety of emotional stimuli would advance the use of pupillometry as a PTSD biomarker. McKinnon et al [21] used a shorter image presentation (2000 ms) than our study (10 seconds), and each image was preceded and followed by a gray screen with a neutral fixation cross to allow the pupil to return to BL. Additional variations in used equipment and analysis procedures make precise comparisons difficult; however, the results from the McKinnon et al [21] study and our study findings lend support to further use of pupillometry in the assessment of emotional dysregulation and treatment of PTSD.

Our sample of participants reported spending an average of 12 min/day in self-directed mindfulness-based practice, which may have been sufficient to alter PPD-assessed precognitive autonomic function but insufficient to improve the autonomic regulation measured by HF-HRV. Prior controlled trials examining the effects of mindfulness on precognitive autonomic function have found significantly higher gray matter concentrations in the left hippocampal region of the brain in generally healthy meditators who spent 27 min/day in mindfulness [129] and changes in the connectivity of white matter fibers adjacent to the thalamus among long-term meditators (>15 years [130]). The thalamus relays immediate sensory information (as implicated in pupil dilation) and the hippocampal region modulates cortical arousal and emotional response [129,130]. Unfortunately, none of the referenced studies involved PPD measurements of autonomic function. Nonetheless, the reductions in PPD in our study, despite invariant HF-HRV, provide partial support for our hypothesized changes toward normative autonomic function after 8 weeks of the CBT-MY intervention. Given the known toxic effects of PTSD psychopathology on select brain regions (eg, decreased density of hippocampus), the lack of HF-HRV improvement is possibly explained by such effects [129].

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Achieving states of safety, autonomic regulation via HF-HRV, and relaxation are challenging for individuals who are traumatized, and recovery rates vary in association with severity of PTSD symptoms, comorbidities, duration of trauma exposure, and time since last exposure [46,118,131,132]. Our sample of participants reported approximately double the number of direct trauma exposures than the national average [2] and disclosed childhood trauma that extended for a mean duration of 9.97 years, which has been associated with significant pathology across the life span and long-term deficits to health and overall functioning [118]. Nonetheless, the significant reductions in PPD found in this study appear to reflect positive intervention responses.

With positive changes in PPD, individuals with PTSD could experience environments as less dangerous and assess potential threats more normatively. Over time, such changes might be accompanied by positive responses in autonomic balance. Future randomized controlled trials (RCTs) examining longer intervention periods would help ascertain the ideal dosage of self-directed learning required to improve HRV. In this 8-week study, the effects appear sufficient to reduce hypervigilance, although not yet sufficient for improvements in HF-HRV.

Strengths and Limitations

The strengths of this study include the rigorous clinical PTSD screening and assessment. The CAPS-5, a clinician-administered structured interview, is labor intensive but intended to be flexible and precise [63]. In addition, the PCL-5, a self-rated PTSD assessment, was used to precisely define and measure PTSD in conjunction with objective markers of autonomic function. The autonomic function of participants with PTSD and direct comparisons with a convenience cohort of relatively normative participants without PTSD were also conducted to assess psychophysiological differences.

There was a notable risk of experimenter bias with respect to PTSD assessments, as the CAPS-5 interview was conducted by a researcher who intervened with participants. However, there was a review process in which a trained second researcher with no relation to the study examined and verified all the scoring. As therapeutic alliances can significantly influence therapeutic outcomes, especially in the presence of childhood abuse [133], there was a possible confounding factor in the interview-based assessment. This issue was addressed through the additional use of the PCL-5, the self-rated counterpart to the CAPS-5, and the objective measures of autonomic function, especially PPD.

The attrition rate of the single-arm experimental trial was 18.2%, with 18% (4/22) of participants with PTSD not completing the postintervention follow-up measures, which limited a full understanding of the intervention effect. Of the 4 participants, 2 (50%) withdrew at week 2 and week 7, self-reporting child care obligations (week 2) and current trauma or stress exposure (week 7) as reasons, and the remaining 2 (50%) were lost to follow-up without providing any reason. On the basis of the CAPS-5 outcomes, the 4 participants who withdrew had significantly higher symptom severity for *Criterion D: negative cognition and mood symptoms*, suggesting that the intervention may be best implemented as an adjunctive treatment in combination with clinical psychological treatment addressing low mood or as a stand-alone program after acute mood symptoms and cognitions have improved. Other considerations such as time barriers and work or parenthood demands may be key factors to consider for future RCTs.

Although we controlled for multiple health factors in our research, our models did not account for the influence of pharmacotherapy on PPD and HF-HRV because of the small sample size and substantial heterogeneity in prescription type and dosage, as well as the lack of randomization. Evidence suggests that patients with a psychiatric diagnosis treated with tricyclic antidepressants demonstrate decreased HRV [134] as they contain anticholinergic compounds observed to reduce HRV. Tricyclic use could partially explain our nonsignificant HF-HRV results [134].

The results of this study must be interpreted with caution as they may not generalize to larger, more diverse samples. In addition to our small sample, the participants were mostly White, female, and highly educated. Nonetheless, these data provide a unique departure from the focus on war veterans in existing PTSD research. Other clear limitations include the lack of a randomly allocated waitlist control group, measurement blinding, and assessment of long-term changes and intervention effect maintenance.

Conclusions

This study provides preliminary support for the effectiveness of web-based CBT-MY in the treatment of PTSD. The combination of CBT with mindfulness and yoga practice appears to summatively contribute to PTSD recovery. Future RCTs should examine whether the present findings extend to larger and more diverse samples and whether gains achieved are maintained over time. Undertreated populations with PTSD may be treated more effectively with web-based treatment and delivery methods that are more accessible, reducing the social and human costs of PTSD.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Weekly program modules in the 8-week cognitive behavioral therapy, mindfulness, and yoga program.
[PDF File (Adobe PDF File), 91 KB - mental_v9i2e26479_app1.pdf]

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Multimedia Appendix 2
International Affective Picture System protocol images with emotional valence and arousal ratings.
[XLSX File (Microsoft Excel File), 14 KB - mental_v9i2e26479_app2.xlsx]

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Abbreviations

ANS: autonomic nervous system
BAI: Beck Anxiety Inventory
BDI-2: Beck Depression Inventory-2
BL: baseline
BPI: Brief Pain Inventory
CAPS-5: Clinician-Administered Posttraumatic Stress Scale
CBT: cognitive behavioral therapy
CBT-MY: cognitive behavioral therapy, mindfulness, and yoga
DSM-5: Diagnostic and Statistical Manual of Mental Disorders, fifth edition
ECG: electrocardiography
EST: emotional image stress task
FFMQ: Five Facet Mindfulness Questionnaire
GM: guided meditation
HF-HRV: high-frequency heart rate variability

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HR: heart rate
HRV: heart rate variability
IAPS: International Affective Picture System
ITT: intention-to-treat
LME: linear mixed effects
MM: mindfulness meditation
PCL-5: Posttraumatic Stress Disorder Checklist for the Diagnostic and Statistical Manual of Mental Disorders, fifth edition
PCS: Pain Catastrophizing Scale
PP: per-protocol
PPD: peak pupil dilation
PTSD: posttraumatic stress disorder
RCT: randomized controlled trial
T1: time point 1
T2: time point 2

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Review

Web-Based Interventions to Help Australian Adults Address Depression, Anxiety, Suicidal Ideation, and General Mental Well-being: Scoping Review

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Abstract

Background: A large number of Australians experience mental health challenges at some point in their lives. However, in many parts of Australia, the wait times to see general practitioners and mental health professionals can be lengthy. With increasing internet use across Australia, web-based interventions may help increase access to timely mental health care. As a result, this is an area of increasing research interest, and the number of publicly available web-based interventions is growing. However, it can be confusing for clinicians and consumers to know the resources that are evidence-based and best meet their needs.

Objective: This study aims to scope out the range of web-based mental health interventions that address depression, anxiety, suicidal ideation, or general mental well-being and are freely available to Australian adults, along with their impact, acceptability, therapeutic approach, and key features.

Methods: The PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines for scoping reviews (PRISMA-ScR [PRISMA extension for Scoping Reviews]) guided the review process. Keywords for the search were depression, anxiety, suicide, and well-being. The search was conducted using Google as well as the key intervention databases Beacon, Head to Health, and e-Mental Health in Practice. Interventions were deemed eligible if they targeted depression, anxiety, suicidal ideation, or general mental well-being (eg, resilience) in adults; and were web-based, written in English, interactive, free, and publicly available. They also had to be guided by an evidence-based therapeutic approach.

Results: Overall, 52 eligible programs were identified, of which 9 (17%) addressed depression, 15 (29%) addressed anxiety, 13 (25%) addressed general mental well-being, and 13 (25%) addressed multiple issues. Only 4% (2/52) addressed distress in the form of suicidal ideation. The most common therapeutic approach was cognitive behavioral therapy. Half of the programs guided users through exercises in a set sequence, and most programs enabled users to log in and complete the activities on their own without professional support. Just over half of the programs had been evaluated for their effectiveness in reducing symptoms, and 11% (6/52) were being evaluated at the time of writing. Program evaluation scores ranged from 44% to 100%, with a total average score of 85%.

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Conclusions: There are numerous web-based programs for depression, anxiety, suicidal ideation, and general well-being, which are freely and publicly available in Australia. However, identified gaps include a lack of available web-based interventions for culturally and linguistically diverse populations and programs that use newer therapeutic approaches such as acceptance and commitment therapy and dialectical behavior therapy. Despite most programs included in this review being of good quality, clinicians and consumers should pay careful attention when selecting which program to recommend and use, as variations in the levels of acceptability and impact of publicly available programs do exist.

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KEYWORDS

web-based interventions; depression; anxiety; suicide; well-being; mental health; technology; access to health care

Introduction

Background

Approximately half of the Australian population experiences a common mental disorder (eg, anxiety and depression) at some point in their lives [1]. Mental and substance use disorders are the fourth highest contributor to total disease burden after cancer, cardiovascular disease, and musculoskeletal conditions [2], whereas suicide is the leading cause of death among young people aged between 15 and 44 years and the fourth leading cause of death in those aged between 45 and 64 years [2]. Despite these alarming statistics, only one-third of people experiencing mental illness will access support services [3]. The reasons for this may be structural (eg, availability of suitable services), knowledge-related (eg, limited awareness of the benefits of accessing mental health services), or attitudinal (eg, stigma and stoicism).

When people do seek help for mental health issues, 71% will contact their general practitioner (GP) at the first instance [3]. GPs play a crucial role in suicide prevention; approximately 45% of people who die by suicide have had contact with primary care in the preceding month and 77% in the preceding year [4]. However, GPs report the lack of tools needed to administer psychological care, including a lack of time, resources, and confidence [5]. Although GPs and their patients increasingly value psychological support, a shortage of professionals and time on wait lists, averaging between 2 and 6 months, is both frustrating and distressing for GPs and their patients.

There is a pressing need to bridge the gap between primary health and mental health care, particularly for Australians facing greater difficulties in accessing mental health care and who are at particular risk of suicide, such as those in rural areas. Fortunately, Australians are increasingly willing to use the internet to search for health-related information [6], with at least 86% of Australian households now having access to the internet [7]. Therefore, web-based resources and interventions may supplement face-to-face services, providing support to people as they wait for appointments [8] and new avenues to reach those who face structural or attitudinal barriers to accessing face-to-face mental health services [9]. Web-based resources have the advantage of enabling consumers' anonymity and access at any time of the day or night, from the privacy and convenience of their own homes [8].

Across the globe, web-based interventions have been shown to effectively reduce the severity of symptoms of depression [10], anxiety [11], and social anxiety [12] and increase mental health literacy [13] and the ability to recognize, accept, deal with, and help prevent mental health issues [14]. The quality of this evidence is high, with a number of randomized controlled trials (RCTs; eg, the studies by McDermott et al [10], Powell et al [12], and Kiropoulos et al [13]) and systematic reviews (eg, the studies by Renton et al [15] and Ashford et al [16]) illustrating their value. Participation has also been associated with decreases in personal stigmatizing attitudes toward depression in the mainstream population [17] and among immigrants [13], as well as decreases in stigmatizing attitudes toward suicide [18] and help seeking [19]. Importantly, web-based interventions have been identified as acceptable in difficult-to-reach populations such as farmers [20], young people [21], and culturally and linguistically diverse groups [22,23]. They can be successfully integrated into routine primary care [24,25], and many Australian GPs support the notion of aiding their patients' mental well-being through these resources [26]. In addition, web-based interventions have been found to be cost-effective for development and delivery; many are offered for free to consumers [8]. However, with the plethora of interventions emerging on the internet [27], there is a need for reliable and clear recommendations to help clinicians and consumers select web-based interventions that are based on evidence-based therapeutic approaches and meet their needs. The e-Mental Health in Practice (eMHPrac) project, funded by the Australian Government, has a range of resources to help Australian health practitioners find digital mental health programs for use with their patients [28]. This provides an excellent quick reference guide for clinicians. However, it does not outline the types of therapeutic approaches and tools used or indicate whether resources are evidence-based.

A total of 2 existing international scoping reviews summarize the characteristics of web-based interventions available for the treatment of depression in Canada in 2014 [15] and anxiety in the United Kingdom in 2016 [16]. The review of programs for depression by Renton et al [15] identified 32 programs, with only 12 having published evidence of efficacy. Furthermore, the review of programs for anxiety by Ashford et al [16] identified 34 programs, with only 17 having published evidence of efficacy. Given the rapid creation of web-based mental health resources in recent years [27] and the tendency for web-based mental health programs to change, arise, and disappear with the provision or withdrawal of funding, there is a need for updated information on interventions that consumers and clinicians are likely to come across via search engines in the Australian context. Of particular benefit to clinicians would be a focus on

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free and publicly available interventions, based on evidence-based therapeutic approaches, that Australians can immediately find or be referred to. Clinicians have also indicated that it would be useful to include web-based interventions for adults seeking help for *general mental well-being* and *suicidal ideation*, which are issues commonly encountered in clinical practice but not covered by past reviews. We note that many reviews of the evidence for web-based interventions for specific disorders (eg, depression [29-31]) and for specific populations (eg, adolescents and young adults [32,33]) have been undertaken in recent years. Although these are helpful for researchers and intervention developers, they are less likely to meet the practical information needs of consumers and clinicians, as many of the interventions contained in the reviews are not available outside research settings, and others that are publicly accessible, have not been evaluated and therefore are not included in the reviews.

Objectives

The purpose of this research is to identify the scope of and evidence for web-based mental health interventions addressing depression, anxiety, suicidal ideation, or general mental well-being that are currently available for free to Australian adults, and in doing so, develop a quick reference guide for GPs and mental health clinicians. It seeks to answer the following questions [34]:

1. What web-based interventions addressing depression, anxiety, suicidal ideation, or general mental well-being are currently freely available (ie, at no cost and open to Australians) in Australia?
2. What are the key gaps?
3. What are the characteristics, including evidence of impact, credibility, and accessibility, of the interventions that are available?

Methods

This scoping review was conducted in accordance with the PRISMA-ScR (Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews) [35]. The study protocol was registered in the Open Science Framework [36].

Eligibility Criteria

Eligible interventions were those that (1) targeted depression, anxiety, suicidal ideation, or general mental well-being (eg, resilience and stress); (2) were web-based; (3) had an interactive component (ie, the delivery of content was not entirely in a passive manner); (4) were designed for adults; (5) were free (ie, at no cost) and publicly available (including via registration, application, or referral from a health care professional); (6) were available in English; and (7) were based on an evidence-based therapeutic approach.

Interventions were excluded if (1) they were targeted at consumers with a primary general medical condition (eg, survivors of cancer); (2) solely provided reading materials on one of the inclusion outcomes (ie, psychoeducation) or only offered a single tool (eg, diary-keeping, mood-monitoring, and meditation) without relevant psychoeducation or explanation of a broader evidence-based therapeutic approach; (3) were targeted at health professionals for training purposes; (4) were part of a research project *that restricted access* or limited program availability; or (5) included classes that had to be attended in person.

Search Strategy

A search was conducted in October 2020 for key terms using Google (Australian version). As the previously published scoping review on web-based interventions for depression only found 1 additional website when searching Yahoo and Bing [15], only Google was searched for this review. A total of 4 searches were conducted by searching the following keywords: *depression*, *anxiety*, *suicide*, and *wellbeing*. A search log was kept to record the number of hits for each search, as well as the number of websites that were included or excluded (Multimedia Appendix 1). The search was terminated for the terms after searching the first 10 pages of results (ie, approximately 100 hits per keyword). Cookies and existing search histories were deleted before the start of each search, and the search results were downloaded into a Microsoft Excel file using a Chrome extension (ie, Export Search Results).

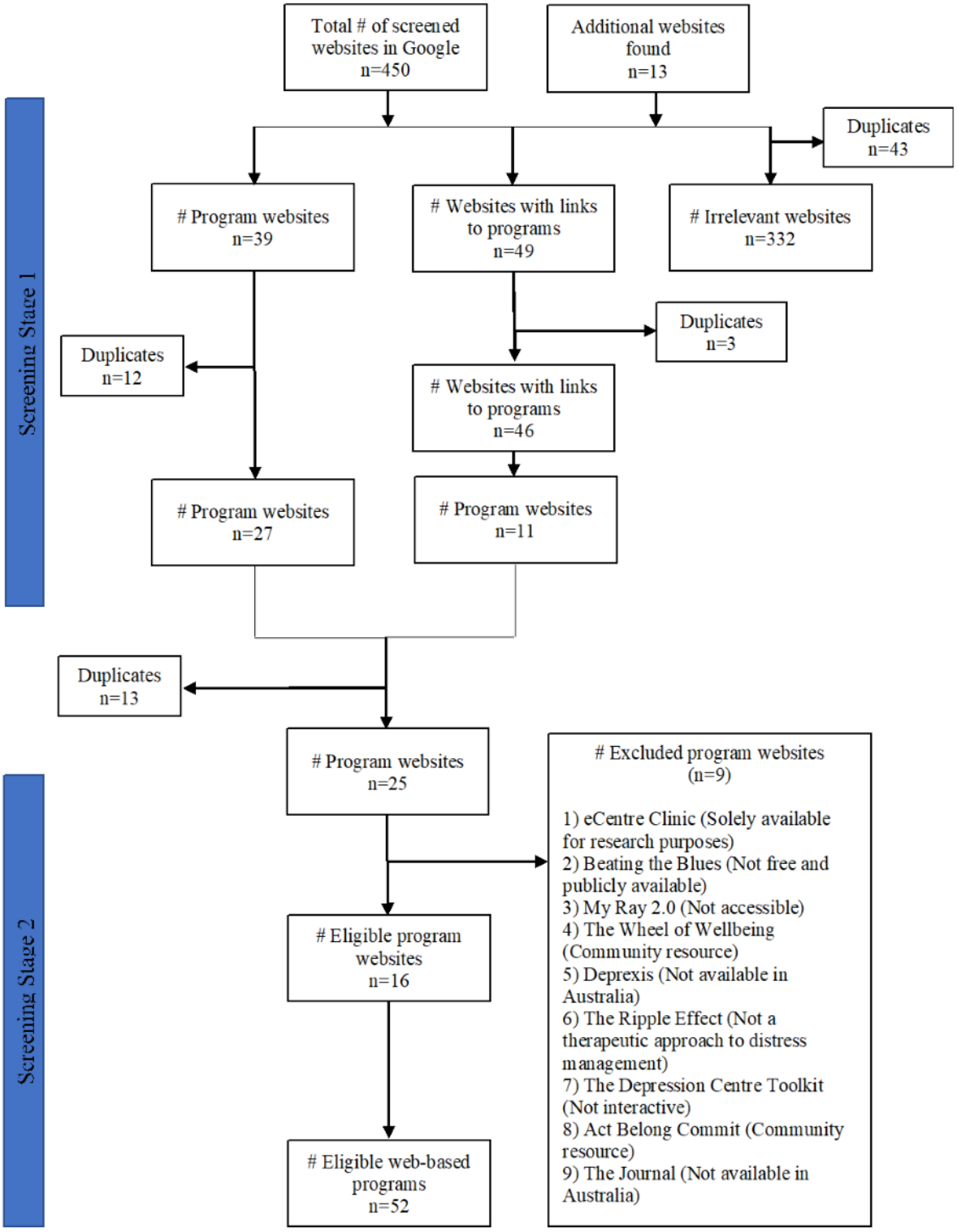
In addition, key intervention databases were searched by 2 reviewers (SvdK and SL). These included Beacon [37], Head to Health [38], and eMHPrac websites [39]. Finally, the reference lists and programs listed in the 2 existing scoping reviews on web-based depression [15] and anxiety [16] resources were searched by 2 reviewers (SvdK and SL) to identify any programs not included in the searches outlined. An overview of program developers and website links is provided in Multimedia Appendix 2.

Selection of Web-Based Programs

Screening of the search results to identify eligible web-based programs was completed in 2 stages. The first stage involved screening all search hyperlinks by 1 reviewer (SvdK) to eliminate websites that solely provided information on 1 of the outcomes or those that were clearly irrelevant (eg, mental health information only websites, YouTube videos, or blogs). The remainder of the websites was then divided into those that directly offered web-based programs and those that linked to web-based programs. Any duplicate websites were removed. The second stage involved screening potential eligible programs against the eligibility criteria by 2 reviewers (SvdK and SL; Figure 1).

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Figure 1. PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flow diagram of program selection.



Data Extraction

A data extraction form was created to systematically evaluate each identified program. The extraction tool was adapted from a previously published framework designed to evaluate and report internet intervention studies [40]. This framework has been used in 2 recent scoping reviews examining web-based interventions for depression [15] and anxiety [16]. The main categories and subcategories of investigation were adapted from these studies (Table 1).

Websites were trialed and data extraction was undertaken by 3 reviewers (SvdK, SL, and GS) in November to December 2020, with the reviewers independently extracting data for each website so that the data extraction was performed in duplicate. Discrepancies in coding were resolved by discussion and, where necessary, investigated by the third reviewer. Where necessary, program authors were contacted to request access to the

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program. For 2 websites (MindSpot and Evolution Health), information was extracted from the public-facing pages where possible, and the remaining information was requested from the website authors or developers because of time and administrative constraints.

Table 1. Data extraction categories.

Main categories and subcategories	Evaluation focus
Website characteristics	
Accessibility and credibility	• How is the website accessed (free, via assessment, or via referral from a health care professional)? • Registration requirement (if yes, what information is collected?) • Mobile phone rendering (yes or no) • Advertisements (if yes, relevant or irrelevant?)
Authorship details	• Presented contact details of authors or developers? (yes or no) • Country of origin
Program characteristics	
Focus and target population	• Target issue • Target audience
Professional support	• Therapist support (within the intervention, ability to link independent clinicians with the program)
Other support	• Peer support (did the program offer peer support, eg, forums? Was this monitored)?
Program interactivity	• This facet is addressed by type and dose of intervention
Multimedia channel of delivery	• Presentation format or mode of delivery (eg, how the content was delivered; text, audio, or video offered; use of character examples; and case scenarios)?
Degree of synchronicity	• Were email or SMS text message reminders or follow-up offered?
Audience reach	• This facet is addressed in focus and target population
Intervention characteristics	
Model of change	• Therapeutic approach
Type and dose of intervention	• Was the program structured or unstructured? • Number of modules • Suggested or set treatment length • Self-assessments (were these mandatory or optional)?
Intervention features	• Worksheets (yes or no) • Mood or symptom monitoring (yes or no) • Diary (yes or no) • Forums (yes or no) • Other features (if yes, specify)
Empirical evidence	
Program evaluation	• Usability (did the program provide users with statistics on registered users, completion rates, attrition rates? Testimonial videos or case studies?) • Empirical evidence (searched program website and Beacon[a] database and contacted authors) • Type of evidence (eg, RCT[b], pre, or post?)
Ethical issues	
Website	• Privacy notice specified? • Terms and conditions specified?
Emergency	• Does the program offer links to crisis or emergency contacts?

[a]Beacon is an Australian clinical web-based platform that describes different web-based self-help treatment programs.

[b]RCT: randomized controlled trial.

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To identify relevant peer-reviewed papers and thereby explore the empirical evidence behind each program, we checked the program websites and the Beacon directory and contacted the program authors. A total of 3 reviewers (SvdK, DHB, and GS) then conducted a rapid review of the peer-reviewed evidence for each program. This was limited to evaluations of the complete web-based program rather than individual program elements or individual modules. In addition, the level of evidence was determined for each peer-reviewed study [41].

Evaluation of Programs

A program evaluation scoring system was adapted from previously published guidelines for evaluating and reporting web-based intervention research [40], similar to Ashford et al [16]. The scale comprised 17 yes or no closed-ended questions (Textbox 1). Questions that were answered *yes* were given a score of 1 and questions that were answered *no* were scored 0. Questions that could not be evaluated were given a score of 0. Questions that were not relevant to the website were excluded from the final score (listed as "NA"). The final scores were calculated as a percentage of the number of relevant items for that website. A total of 3 reviewers (SvdK, SL, and GS) independently assessed the programs against the evaluation scoring system. Discrepancies were resolved through discussion.

Textbox 1. Program evaluation criteria (subcategories and questions).

Authorship details

- Were the names and credentials of authors or organizations present?
- Were contact details provided?
- Was country of origin stated?

Focus and target population

- Was the primary focus, goals, or objectives of the intervention stated?
- Was the target audience or mental health issue defined?

Professional support

- Was there a statement of professional support (ie, clinicians involved in website development)?

Multimedia channel of delivery

- Did the program offer a multimedia content delivery (ie, a combination of text, video, graphics, and audio formats)?

Model of change

- Was the model of change (ie, type of therapy used) defined or stated?

Type and dose of intervention

- Were the number of modules or time to complete each module stated?
- Was the intervention tailored to the user or was it generic for all users (ie, was the program content individualized with username, characteristics, previous responses)?
- Was the program easy to navigate (eg, clear links to the home page and easily able to stop or start the program)?
- Was the information on what is covered in the intervention modules provided (ie, names of modules or a short description)?

Program evaluation

- Was evidence for the program provided to the user (ie, attrition data, success rate, completion rate, or number of users in the program or testimonials)?
- Has the program been empirically evaluated?

Ethical issues

- Was a unique username or password provided to users?
- Was a privacy notice specified?
- Were the terms and conditions specified?

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Synthesis of Results

The results were summarized quantitatively by main categories and subcategories, as displayed in Table 1. Where possible, descriptive statistics were used to summarize these findings.

Results

Selection of Web-Based Programs

As seen in Figure 1, 450 websites were screened through Google search, and an additional 13 websites were identified through database searches. Approximately 10.6% (49/463) of websites with links to potentially eligible programs and 39 potentially eligible programs were identified. Of the 49 websites, 25 (51%) program websites were screened for eligibility, of which 16 (64%) websites (leading to 52 programs) were included in the review. Of the 52 programs, 20 (39%) programs were classified as *web-based interactive*, and 32 (62%) programs were classified as *web-based with downloadable worksheets/resources*. These 2 types of programs were separated in the summary tables.

We only found 2 programs (BeyondNow and My Digital Health iConsider Life) designed to address distress in the context of suicidal ideation. It should be noted that the inclusion of BeyondNow was debated between team members, as we experienced difficulty in determining whether it fully fulfills the criteria of using an evidence-based therapeutic approach. Nonetheless, it is considered a valuable tool for the management of suicide ideation; therefore, it was included in this review.

Website Characteristics

Accessibility and Credibility

Of the 52 programs, 36 (69%) were available at no cost and open to all Australians, 9 (17%) were accessible via referral from a health care professional (via This Way Up), 4 (8%) required an assessment before registration (via MindSpot), and 3 (6%) required sign-up to a research project (via My Digital Health; Tables 2 and 3). A free website (with 5/52, 10% programs) provided users with access to the basic course content without payment but required a paid upgrade to access additional features (Living Life to the Full). In total, 8% (4/52) of courses from Evolution Health were free to users. In addition, Evolution Health is a technology provider that licenses paid white label versions of its platform to organizations that contain only the course that the organization wants (eg, the smoking cessation course), thereby creating a *tailored* version of the platform for those organizations to distribute freely to their members.

Registration was required by 83% (43/52) of programs and most often required users' names, emails, location (country, city, or postcode), and age. Approximately 6% (3/52) of programs created by My Digital Health were offered as part of a research study; of these, 2 programs, Life Flex and Life Flex–LGBQ (lesbian, gay, bisexual, and queer), required the completion of comprehensive demographic, mental health, and well-being questionnaires before access was granted. Approximately 17% (9/52) of programs did not require registration and allowed users anonymous access. All websites were accessible via mobile phones and did not contain advertisements, except for the 5 Living Life to the Full programs, which contained advertisements for e-books related to the course content.

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Table 2. Program characteristics of web-based interactive programs.

Program	Focus and target population (if specified)	Access	Therapist support	Presentation format
Depression				
eCouch—Depression Program	Depression, ≥16 years	Free	No	• Text-based • Graphics • Characters or case scenarios • Audio or video • Comic slideshow format
Mum2B—MoodBooster	Depression during pregnancy, expectant mothers	Free	No	• Text-based • Graphics • Audio or video
MumMood—Booster	Postnatal depression, women with postnatal depression	Free	Yes, optional	• Text-based • Graphics • Audio or video
OnTrack—Depression	Depression, ≥18 years	Free	No	• Text-based • Graphics • Audio or video
Anxiety				
eCouch—Anxiety and Worry Program	Anxiety and worry, ≥16 years	Free	No	• Text-based • Graphics • Characters or case scenarios • Audio or video • Comic slideshow • Format
eCouch—Social Anxiety Program	Social anxiety, ≥16 years	Free	No	• Text-based • Graphics • Characters or case scenarios • Comic slideshow format
Multi-issue				
MindSpot—Indigenous Wellbeing	Managing depression and anxiety, Aboriginal and Torres Strait Islanders, ≥18 years	Free following mandatory assessment and contact with MindSpot therapist	Yes, optional access to MindSpot therapist	• Text-based • Graphics • Audio or video
MindSpot—Mood Mechanic	Managing depression and anxiety, young adults, 18-25 years	Free following mandatory assessment and contact with MindSpot therapist	Yes, optional access to MindSpot therapist	• Text-based • Graphics • Audio or video
MindSpot—Wellbeing	Managing depression and anxiety, 26-65 years	Free following mandatory assessment and contact with MindSpot therapist	Yes, optional access to MindSpot therapist	• Text-based • Graphics • Audio or video
MindSpot—Wellbeing Plus	Managing depression and anxiety, ≥60 years	Free following mandatory assessment and contact with MindSpot therapist	Yes, optional access to MindSpot therapist	• Text-based • Graphics • Audio or video
MoodGym	Anxiety and depression	Free	No	• Text-based • Graphics • Audio or video
MyCompass	Mild to moderate depression, anxiety and stress, ≥18 years	Free	No	• Text-based • Graphics • Audio or video

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Program	Focus and target population (if specified)	Access	Therapist support	Presentation format
My Digital Health—Life Flex	Anxiety or depression, ≥18 years	Free (via research study participation)	Yes, ability to connect independent clinician to program	• Text-based • Graphics • Audio or video
My Digital Health—Life Flex LGBQ[a]	Anxiety or depression, ≥18 years who are part of the LGBQ community	Free (via research study participation)	Yes, ability to connect independent clinician to program	• Text-based • Graphics • Audio or video
General well-being				
eCouch—Bereavement and Loss Program	Bereavement and loss, ≥16 years	Free	No	• Text-based • Graphics • Characters or case scenarios • Audio or video • Comic slideshow format
eCouch—Divorce and separation	Divorce and separation, ≥16 years	Free	No	• Text-based • Graphics • Characters or case scenarios • Comic slideshow format
ifarmwell	Well-being, farmers, ≥18 years	Free	No	• Text-based • Graphics • Audio or video
The Desk	Well-being, Australian tertiary students	Free	No	• Text-based • Graphics • Audio or video
Suicidal ideation				
My Digital Health—iConsider-Life	Decision support crisis digital health program, ≥18 years	Free (via research study participation)	No	• Text-based • Audio or video
BeyondNow	Suicide safety planning	Free	N/A[b]	• Text-based • Workbook or planner

[a]LGBQ: lesbian, gay, bisexual, and queer.

[b]N/A: not applicable.

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Table 3. Program characteristics of web-based programs with downloadable worksheets or resources.

Program	Focus and target population (if specified)	Access	Therapist support	Presentation format
Depression				
CCI[a]—Depression	Depression	Free	No	• Text workbook with images
Evolution Health—Overcoming Depression	Depression, ≥16 years	Free	Not in free version	• Text • Gamified quiz
Mental health Online—Depression Online Program	Depression, ≥18 years	Free	Yes, optional access to e-therapists	• Text-based • Graphics • Audio or video • Characters or case scenarios
This Way Up—The Depression Course	Depression, ≥18 years	Free when referred by clinician	Yes, independent clinician allowed access	• Text-based • Graphics • Audio or video • Characters or case scenarios • Comic slideshow format
Students Against Depression	Depression, students	Free	No	• Text-based
Anxiety				
CCI—Health and Anxiety	Health anxiety	Free	No	• Text workbook with images
CCI—Panic	Panic attacks	Free	No	• Text workbook with images
CCI—Social Anxiety	Social anxiety	Free	No	• Text workbook with images
CCI—Worry and Rumination	Worry	Free	No	• Text workbook with images
Evolution Health—Overcoming Anxiety	Anxiety, ≥16 years	Free	Not in free version	• Text • Gamified quiz
Evolution Health—Managing Anxiety Course	Anxiety, ≥16 years	Free	Not in free version	• Text • Gamified quiz
Mental Health Online—GAD[b] program	GAD, ≥18 years	Free	Yes, optional access to e-therapists	• Text-based • Graphics • Audio or video • Characters or case scenarios
Mental Health Online—Panic STOP!	Panic attacks, ≥18 years	Free	Yes, optional access to e-therapists	• Text-based • Graphics • Audio or video • Characters or case scenarios
Mental Health Online—Social Anxiety Online Program	Social anxiety, ≥18 years	Free	Yes, optional access to e-therapists	• Text-based • Graphics • Audio or video • Characters or case scenarios
This Way Up—Health Anxiety Course	Worry about health, ≥18 years	Free when referred by clinician	Yes, independent clinician allowed access	• Text-based • Graphics • Audio or video • Characters or case scenarios • Comic slideshow format
This Way Up—Panic Attacks Course	Panic attacks, ≥18 years	Free when referred by clinician	Yes, independent clinician allowed access	• Text-based • Graphics • Audio or video • Characters or case scenarios • Comic slideshow format

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Program	Focus and target population (if specified)	Access	Therapist support	Presentation format
This Way Up—Social Anxiety Course	Social anxiety, ≥18 years	Free when referred by clinician	Yes, independent clinician allowed access	• Text-based • Graphics • Audio or video • Characters or case scenarios • Comic slideshow format
This Way Up—Worry Course (GAD)	GAD, ≥18 years	Free when referred by clinician	Yes, independent clinician allowed access	• Text-based • Graphics • Characters or case scenarios • Comic slideshow format
Multi-issue				
Mental Health Online—Made-4-Me Program	Can pick up to 3 areas: depression, GAD, panic disorder, PTSD[c], social anxiety, OCD[d], ≥18 years	Free	Yes, optional access to e-therapists	• Text-based • Graphics • Audio or video • Characters or case scenarios
This Way Up—Mindfulness-Based CBT[e] Course	Depression and anxiety, ≥18 years	Free when referred by clinician	Yes, independent clinician allowed access	• Text-based • Graphics • Audio or video • Characters or case scenarios • Comic slideshow format
This Way Up—Mixed Depression and Anxiety Course	Depression and anxiety, ≥18 years	Free when referred by clinician	Yes, independent clinician allowed access	• Text-based • Graphics • Audio or video • Characters or case scenarios • Comic slideshow format
This Way Up—MUMentum Pregnancy	Anxiety and low mood, adults <36 week pregnant	Free when referred by clinician	Yes, independent clinician allowed access	• Text-based • Graphics • Characters or case scenarios • Comic slideshow format
This Way Up—MUMentum Postnatal	Anxiety and low mood, adults >36 weeks pregnant or have given birth within the last 12 months	Free when referred by clinician	Yes, independent clinician allowed access	• Text-based • Graphics • Characters or case scenarios • Comic slideshow format
General well-being				

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Program	Focus and target population (if specified)	Access	Therapist support	Presentation format
CCI—Tolerating Distress	Distress	Free	No	• Text workbook with images
Evolution Health—Grief and Loss	Grief, ≥16 years	Free	Not in free version	• Text • Gamified quiz
Living Life to the Full for Adults	Emotional well-being, adults	Free for the basic course; can upgrade for a fee	No	• Text-based • Graphics • Audio or video • Comic slideshow format
Living Life to the Full for Farming Communities	Emotional well-being, farming communities	Free for the basic course; can upgrade for a fee	No	• Text-based • Graphics • Audio or video • Comic slideshow format
Living Life to the Full with God	Emotional well-being, people of faith	Free for the basic course; can upgrade for a fee	No	• Text-based • Graphics • Audio or video • Comic slideshow format

[a]CCI: Center for Clinical Interventions.

[b]GAD: generalized anxiety disorder.

[c]PTSD: posttraumatic stress disorder.

[d]OCD: obsessive compulsive disorder.

[e]CBT: cognitive behavioral therapy.

Authorship Details

The review was limited to programs that were *accessible* to Australians. Unsurprisingly, most of these programs identified Australia as their country of origin (40/52, 77%), although other countries of origin were Scotland (5/52, 10%), Canada (4/52, 8%), the United States (in collaboration with Australia; 2/52, 4%) and the United Kingdom (1/52, 2%). Contact details for the authors or developers were provided by almost all websites (51/52, 98%). An overview of program developers and website links is provided in Multimedia Appendix 2.

Program Characteristics

Table 2 provides an overview of program characteristics for web-based interactive programs and Table 3 for web-based programs with downloadable worksheets or resources.

Focus and Target Population

Overall, 17% (9/52) of programs specifically addressed depression, 29% (15/52) of programs addressed anxiety, 25% (13/52) of programs addressed multiple issues, 25% (13/52) of programs addressed general well-being, and 4% (2/52) of programs addressed suicidal ideation. Most programs specifically stated that their target audience was the general adult population (aged ≥16 years or ≥18 years; 26/52, 50%), with other (9/52, 17%) programs not specifying a target group but appearing to be designed for adults, based on content. Several programs were designed for specific target populations, including expectant mothers or new parents (6/52, 12%), tertiary students (3/52, 6%), farmers or rural communities (2/52, 4%), church-going adults (1/52, 2%), the LGBQ community (1/52, 2%), Aboriginal and Torres Strait Islander people (1/52, 2%), young adults (1/52, 2%), adults aged 26 to 65 years (1/52, 2%), and older adults (1/52, 2%).

Support and Features

Approximately 88% (46/52) of programs provided a statement of professional support, that is, mental health clinicians or researchers were involved in the programs' development. Of the 52 programs, 11 (21%) programs allowed users to invite their independent clinician to monitor their progress in the course, and a further 10 (19%) programs offered optional therapist support while engaging in the program. Approximately 8% (4/52) of programs (Evolution Health) did not offer therapist support through the free version of their programs; however, therapist support was an optional inclusion for paid versions of the program licensed to organizations. Only 8% (4/52) of programs (Evolution Health) enabled peer support, such as through forums, and in all cases, this was expert-moderated. Most programs offered multiple forms of information delivery, with text, graphics, audio or video, characters, and case scenarios as common features. Email or SMS text message reminders were available 60% (31/52) of the programs.

Intervention Characteristics

Overview

The intervention characteristics of web-based interactive programs and web-based programs with downloadable worksheets or resources are shown in Tables 4 and 5, respectively.

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Table 4. Intervention characteristics of web-based interactive programs.

Program	Therapeutic approach	Program structure	Modules (length)	Intervention features
Depression				
eCouch—Depression Program	CBT[a]+IPT[b]	Structured	3 sections	• Worksheets • Mood or symptom monitoring • Diary
Mum2B—MoodBooster	CBT	Structured	6 modules (6 weeks)	• Worksheets • Mood or symptom monitoring
MumMood—Booster	CBT	Structured	6 modules (6 weeks)	• Worksheets • Mood or symptom monitoring
OnTrack—Depression	CBT	Structured	6 modules (8 weeks)	• Worksheets • Mood or symptom monitoring • Diary • Reminder or calendar feature
Anxiety				
eCouch—Anxiety and Worry Program	CBT+IPT	Structured	3 sections	• Worksheets • Mood or symptom monitoring • Diary
eCouch—Social Anxiety Program	CBT+IPT	Unstructured	6 sections	• Worksheets
Multi-issue				
MindSpot—Indigenous Wellbeing	CBT	Structured	5 modules (8 weeks)	• Worksheets
MindSpot—Mood Mechanic	CBT	Structured	5 modules (8 weeks)	• Worksheets
MindSpot—Wellbeing	CBT	Structured	5 modules (8 weeks)	• Worksheets
MindSpot—Wellbeing Plus	CBT	Structured	5 modules (8 weeks)	• Worksheets
MoodGym	CBT	Structured	5 modules	• Worksheets • Mood or symptom monitoring
MyCompass	CBT+ IPT+positive psychology	Unstructured	14 activities (recommend 7 weeks)	• Worksheets • Mood or symptom monitoring • Diary
My Digital Health—Life Flex	Biopsychosocial approach+CBT+positive psychology	Structured (optional or mandatory depending on RCT[c] arm)	7 modules (scheduled release over 7 weeks in 1 RCT arm)	• Worksheets • Mood or symptom monitoring • Diary • Option to connect Fitbit or other health monitoring tools • Safety planning tool
My Digital Health—Life Flex LGBQ[d]	Biopsychosocial approach+CBT+positive psychology	Structured (optional or mandatory depending on RCT arm)	7 modules (scheduled release over 7 weeks in 1 RCT arm)	• Worksheets • Mood or symptom monitoring • Diary • Option to connect Fitbit or other health monitoring tools • Safety planning tool
General well-being				
eCouch—Bereavement and Loss Program	CBT	Structured	2 sections	• Worksheets • Mood or symptom monitoring • Diary

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Program	Therapeutic approach	Program structure	Modules (length)	Intervention features
eCouch—Divorce and Separation	CBT	Structured	3 sections	• Worksheets • Mood or symptom monitoring • Diary
ifarmwell	ACT[e]	Structured	5 modules (10 weeks)	• Worksheets • Personalized script
The Desk	CBT+mindfulness+positive psychology	Unstructured	4 modules	• Mood or symptom monitoring • Reminder or calendar feature
Suicidal ideation				
My Digital Health—iConsiderLife	No	Structured	6 pathways	• Worksheets
BeyondNow	N/A[f]	Unstructured	No modules	• Process of completing plan is like a worksheet

[a]CBT: cognitive behavioral therapy.

[b]IPT: interpersonal psychotherapy.

[c]RCT: randomized controlled trial.

[d]LGBQ: lesbian, gay, bisexual, and queer.

[e]ACT: acceptance and commitment therapy.

[f]N/A: not applicable.

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Table 5. Intervention characteristics of web-based programs with downloadable worksheets or resources.

Program	Therapeutic approach	Program structure	Modules (length)	Intervention features
Depression				
CCI[a]—Depression	CBT[b]	Structured, optional	9 modules	• Worksheets • Mood or symptom monitoring • Diary
Evolution Health—Overcoming Depression	CBT+motivational interviewing	Structured but not mandatory to follow structure	9 modules	• Worksheets • Experiments to try • Symptom tracker diary • Optional self-assessments • Member forum • Messaging with others • Goal setting
Mental Health Online—Depression Online Program	CBT	Structured, optional	11 modules (recommend 12 weeks)	• Worksheets • Mood or symptom monitoring
This Way Up—The Depression Course	CBT	Structured	6 modules (3 months)	• Worksheets • Mood or symptom monitoring • Reminder or calendar feature
Students Against Depression	CBT	Structured, optional	6 modules (recommend 6 weeks)	• Worksheets • Diary • Safety planning tool
Anxiety				
CCI—Health and Anxiety	CBT	Structured, optional	9 modules	• Worksheets • Diary
CCI—Panic	CBT	Structured, optional	12 modules	• Worksheets • Mood or symptom monitoring • Diary
CCI—Social Anxiety	CBT	Structured, optional	10 modules	• Worksheets • Mood or symptom monitoring • Diary
CCI—Worry and Rumination	Metacognitive therapy	Structured, optional	10 modules	• Worksheets • Mood or symptom monitoring • Diary
Evolution Health—Overcoming Anxiety	CBT+motivational interviewing	Structured but not mandatory to follow structure	9 modules	• Worksheets • Experiments to try • Mood tracker diary • Optional self-assessments • Member forum • Messaging with others • Goal setting
Evolution Health—Managing Anxiety Course	CBT+motivational interviewing	Structured but not mandatory to follow structure	1 module	• Worksheets • Experiments to try • Optional self-assessments • Member forum • Messaging with others • Goal setting
Mental Health Online—GAD[c] Program	CBT	Structured, optional	12 modules (recommend 12 weeks)	• Worksheets • Mood or symptom monitoring
Mental Health Online—Panic STOP!	CBT	Structured, optional	12 modules (recommend 12 weeks)	• Worksheets • Mood or symptom monitoring

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Program	Therapeutic approach	Program structure	Modules (length)	Intervention features
Mental Health Online—Social Anxiety Online Program	CBT	Structured, optional	12 modules (recommend 12 weeks)	• Worksheets • Mood or symptom monitoring
This Way Up—Health Anxiety Course	CBT	Structured	6 modules (3 months)	• Worksheets • Mood or symptom monitoring • Reminder or calendar feature
This Way Up—Panic Attacks Course	CBT	Structured	6 modules (3 months)	• Worksheets • Mood or symptom monitoring • Reminder or calendar feature
This Way Up—Social Anxiety Course	CBT	Structured	6 modules (3 months)	• Worksheets • Mood or symptom monitoring • Reminder or calendar feature
This Way Up—Worry Course (GAD)	CBT	Structured	6 modules (3 months)	• Worksheets • Mood or symptom monitoring • Reminder or calendar feature
Multi-issue				
Mental Health Online—Made-4-Me Program	CBT	Structured, optional	11 modules (recommend 12 weeks)	• Worksheets • Mood or symptom monitoring
This Way Up—Mindfulness-based CBT Course	CBT+mindfulness	Structured	6 modules (3 months)	• Worksheets • Mood or symptom monitoring • Reminder or calendar feature
This Way Up—Mixed Depression and Anxiety Course	CBT	Structured	6 modules (3 months)	• Worksheets • Mood or symptom monitoring • Reminder or calendar feature
This Way Up—MUMentum Pregnancy	CBT	Structured	3 modules (4-6 weeks)	• Worksheets • Mood or symptom monitoring • Reminder or calendar feature
This Way Up—MUMentum Postnatal	CBT	Structured	3 modules (4-6 weeks)	• Worksheets • Mood or symptom monitoring • Reminder or calendar feature
General well-being				

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Program	Therapeutic approach	Program structure	Modules (length)	Intervention features
CCI—Tolerating Distress	DBT[d]	Structured, optional	4 modules	• Worksheets • Mood or symptom monitoring • Diary
Evolution Health—Grief and Loss	CBT+motivational interviewing	Structured but not mandatory to follow structure	1 module	• Worksheets • Experiments to try • Optional self-assessments • Member forum • Messaging with others • Goal setting
Living Life to the Full for Adults	CBT	Structured, optional	8 modules (recommend 8 weeks)	• Worksheets • Mood or symptom monitoring • Blog • Reminder or calendar feature
Living Life to the Full for Farming Communities	CBT	Structured, optional	5 modules	• Worksheets • Mood or symptom monitoring • Diary • Blog • Reminder or calendar feature
Living Life to the Full with God	CBT	Structured, optional	8 modules (recommend 8 weeks)	• Worksheets • Mood or symptom monitoring • Diary • Blog • Reminder or calendar feature
Living Life to the Full —Enjoy Your Baby	CBT	Structured, optional	5 modules	• Worksheets • Blog • Reminder or calendar feature
Living Life to the Full —Enjoy Your Bump	CBT	Structured, optional	5 modules	• Worksheets • Mood or symptom monitoring • Blog • Reminder or calendar feature
This Way Up—Coping with Stress Course	CBT	Structured	4 modules (3 months)	• Worksheets • Mood or symptom monitoring • Reminder feature • Calendar feature
This Way Up—The Student Well-being Course	CBT	Structured	8 modules (3 months)	• Worksheets • Mood or symptom monitoring • Reminder or calendar feature

[a]CCI: Centre for Clinical Interventions.

[b]CBT: cognitive behavioral therapy.

[c]GAD: generalized anxiety disorder.

[d]DBT: dialectical behavior therapy.

Therapeutic Approach or Model of Change

On the basis of either self-descriptions or the clinical judgment of the authors, 90% (47/52) of programs were based on cognitive behavioral therapy (CBT), either with 21% (11/52) or without 69% (36/52) other therapeutic approaches. In combination with CBT, some programs included motivational interviewing (4/52, 8%), interpersonal therapy (4/52, 8%), or mindfulness (1/52, 2%). Only 2% (1/52) of programs (ifarmwell) was based on acceptance and commitment therapy (ACT), 2% (1/52) of programs (Centre for Clinical Interventions [CCI]: Tolerating Distress) on dialectical behavior therapy (DBT), and 2% (1/52) of programs (BeyondNow) on problem solving (ie, how to keep self safe or safety planning).

Type and Dose of Intervention

In total, 48% (25/52) of programs were structured or *tunneled*, where participants were led through a series of modules or sessions in a specific order. A further 42% (22/52) of programs recommended to follow the program in a specific order but allowed users to choose the order in which they completed them. Approximately 4% (2/52) of programs were part of an RCT

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research project that had open access and allocated participants to 1 of 2 *therapy structure* conditions: mandatory (participants did not choose the order) or optional (participants were given the freedom to choose the order of completion). Approximately 6% (3/52) of programs were unstructured.

The number of modules or activities offered within a program ranged from 1 to 14 (mean 6.51, SD 3.03), except for 1 program (BeyondNow), which offered a safety planner instead of modules. The recommended time to complete the modules ranged from 1 week to 3 months (specified for 34/52, 65% of programs). Approximately 33% (17/52) of programs did not recommend a set treatment length. Self-assessments were included in 79% (41/52) programs, and it was mandatory in 56% (29/52) of programs and optional in 23% (12/52) of programs.

Intervention Features

All programs, except 4% (2/52; The Desk and iConsider Life), featured worksheets, either within the web-based intervention or as downloadable forms to be completed offline. Diaries were featured in 46% (24/52) of programs, and 75% (39/52) of programs included some type of mood or symptom monitoring.

Empirical Evidence: Program Evaluation

Out of 17 possible evaluation items, 75% (39/52) of programs could be evaluated against all 17 items, 15% (8/52) against 94% (16/17) of items, and 10% (5/52) against 76% (13/17) of items (Table 6). In total, scores ranged from 44% to 100%, with an average score of 85% (SD 10.7%). More specifically, of the 75% (39/52) of programs that provided values for all 17 items, scores varied between 65% and 94%, with an average score of 87% (SD 7%). This was between 44% and 81%, with an average of 69% (SD 11%), for programs that provided values for 16 items, and between 85% and 100%, with an average of 95% (SD 7%), for programs that provided values for 13 items. Individual answers to the program evaluation criteria are shown in Multimedia Appendix 3.

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Table 6. Type of research conducted to evaluate eligible programs, including the level of evidence and process evaluation scores (N=52).

Program	Type of research evaluation studies	Level of evidence[a]	Total number of relevant evaluation items, N	Process evaluation score, n (%)[b,c]
BeyondNow	• Feasibility and effectiveness study [42]	• Level III-3	13	11 (85)
CCI[d]—Depression	• Website: not specified • Beacon[e]: not reviewed	—[f]	16	11 (69)
CCI—Health Anxiety	• Preliminary pre–post study [43]	• Level IV	16	12 (75)
CCI—Panic	• Website: not specified • Beacon: not reviewed	—	16	11 (69)
CCI—Social Anxiety Course	• Website: not specified • Beacon: not reviewed	—	16	11 (69)
CCI—Tolerating Distress	• Website: not specified • Beacon: not reviewed	—	16	11 (69)
CCI—Worry and Rumination	• Preliminary pre–post study [43]	• Level IV	16	12 (75)
eCouch—Anxiety and Worry	• Adapted from MoodGym • RCT[g] [44,45]	• Level II	17	13 (76)
eCouch—Bereavement and Loss	• Adapted from MoodGym	—	17	11 (65)
eCouch—Depression	• Adapted from MoodGymRCT [46-50]	• Level II	17	13 (76)
eCouch—Divorce and Separation	• Adapted from MoodGym	—	17	12 (71)
eCouch—Social Anxiety	• Adapted from MoodGym • 2-group RCT and to assess effectiveness and cost-effectiveness [12] • Pre–post with control group and randomized [51]	• Level II • Level II	17	14 (82)
Evolution Health—Overcoming Anxiety	• Pre–post longitudinal study [52] • Pilot RCT [53] • User characteristics [54]	• Level IV • Level IV • Level IV	17	15 (88)
Evolution Health—Overcoming Depression	• Website: not specified • Beacon: not reviewed	—	17	14 (82)
Evolution Health—Grief and Loss	• Website: not specified • Beacon: not reviewed	—	17	14 (82)
Evolution Health—Managing Anxiety	• Pre–post longitudinal study [52]	• Level IV	17	15 (88)
ifarmwell	• Website: currently being evaluated • Beacon: not reviewed	—	17	15 (88)
Living Life to the Full for Adults	• Comparative clinical feasibility study [55] • Feasibility [56]	• Level III-3 • Level III-3	17	16 (94)
Living Life to the Full for Farming Communities	• Website: not specified • Beacon: not reviewed	—	17	15 (88)
Living Life to the Full with God	• Website: not specified • Beacon: not reviewed	—	17	15 (88)

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Program	Type of research evaluation studies	Level of evidence[a]	Total number of relevant evaluation items, N	Process evaluation score, n (%)[b,c]
Living Life to the Full—Enjoy Your Baby	• Website: not specified • Beacon: not reviewed	—	17	15 (88)
Living Life to the Full—Enjoy Your Bump	• Website: not specified • Beacon: not reviewed	—	17	15 (88)
Mental Health Online—Depression Online	• Uncontrolled pre–post treatment study [57,58]	• Level IV	17	15 (88)
Mental Health Online—Generalized Anxiety Disorder	• Uncontrolled pre–post treatment study [57] • Pre–post treatment [59] • Pre- to posttreatment quasi-experimental (participant choice) [60]	• Level IV • Level IV • Level IV	17	15 (88)
Mental Health Online—Made 4 Me	• Website: not specified • Beacon: not reviewed	—	17	15 (88)
Mental Health Online—Panic STOP!	• Uncontrolled pre–post treatment study [57] • Pre–post treatment [59] • Participant choice quasi-experimental trial [60]	• Level IV • Level IV • Level IV	17	15 (88)
Mental Health Online—Social Anxiety Online	• Pre–post treatment study [59] • Participant choice quasi-experimental trial [60]	• Level IV • Level IV	17	15 (88)
MindSpot—Indigenous Wellbeing Course	• Prospective uncontrolled observational cohort study [61]	• Level IV	13	13 (100)
MindSpot—Mood Mechanic Course	• Single-arm, open trial [62] • RCT [63]	• Level III-3 • Level II	13	13 (100)
MindSpot—Wellbeing	• Cost-effectiveness [64] • Feasibility trial [65] • RCT [66-73] • 12-month follow-up RCT [62] • Single group open trial [74]	• Level III-3 • Level II • Level II • Level III-3	13	13 (100)
MindSpot—Wellbeing Plus	• Cost-effectiveness [75,76] • Feasibility study [75,77] • Implementation [78] • RCT [75,76,79,80]	• Level II • Level II and III-3 • Level II • Level II	13	13 (100)
MoodGym	• Acceptability study [81] • Implementation [82] • Follow-up outcome analysis [83] • Program use [84] • RCTs [10,17,81,82,85-99] • School or class trials [100,101] • Compliance [102]	• Level II • Level II • Level II • Level II • Level III-2 • Level II	17	15 (88)
Mum2BMoodBooster	• Website: currently being evaluated • Beacon: not reviewed	—	17	14 (82)
MumMoodBooster	• Acceptability study [103,104] • Feasibility study [104] • RCT [105]	• Level III-3 • Level III-3 • Level II	17	15 (88)
myCompass			17	16 (94)

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Program	Type of research evaluation studies	Level of evidence[a]	Total number of relevant evaluation items, N	Process evaluation score, n (%)[b,c]
	• Feasibility study [106] • Open trial [107] • RCT [108-110]	• Level II-3 • Level III-3 • Level II		
My Digital Health—iConsiderLife	• Website: currently being evaluated • Beacon: not reviewed	—	16	13 (81)
My Digital Health—Life Flex	• Website: currently being evaluated • Beacon: not reviewed	—	17	15 (88)
My Digital Health—Life Flex LGBQ[h]	• Website: currently being evaluated • Beacon: not reviewed	—	17	15 (88)
OnTrack—Depression	• Website: not specified • Beacon: not reviewed	—	17	13 (76)
The Desk	• Website: not specified • Beacon: not reviewed	—	17	14 (82)
This Way Up—Coping with Stress Course	• Website: not specified • Beacon: not reviewed	—	17	15 (88)
This Way Up—The Depression Course	• Nonrandomized comparison study [111] • Open trial [112-117] • RCT [111,118-124] • Adherence [125]	• Level III-2 • Level III-3 • Level II-3 • Level III-3	17	16 (94)
This Way Up—Health Anxiety Course	• Open trial [126,127] • RCT [128]	• Level III-3 • Level II	17	16 (94)
This Way UpMindfulness-based CBT[i] Course	• Open trial [129] • RCT [130]	• Level III-3 • Level II	17	16 (94)
This Way Up—Mixed Depression and Anxiety Course	• Open trial [74,111,131-133] • RCT [72,131,134]	• Level III-3 • Level II	17	16 (94)
This Way Up—MUMentum Pregnancy	• RCT [135]	• Level II	17	16 (94)
This Way Up—MUMentum Postnatal	• RCT [136]	• Level II	17	16 (94)
This Way Up—Panic Attacks Course	• Open trial [137] • RCT [71,72,138-140]	• Level III-3 • Level II	17	16 (94)
This Way Up—Social Anxiety Course	• Open trial [141] • RCT [71,72,138,142-146]	• Level III-3 • Level II	17	16 (94)
This Way Up—Student Wellbeing Course	• Website: not specified • Beacon: not reviewed	—	17	15 (88)
This Way Up—Worry Course (GAD[j])	• Nonrandomized comparison study [111] • Open trial [112,133,147,148] • RCT [71,72,138,149-151]	• Level III-2 • Level III-3 • Level II	17	16 (94)
Students Against Depression	• Website: currently being evaluated • Beacon: not reviewed	—	16	7 (44)

[a]Level of evidence determined from the National Health and Medical Research Council evidence hierarchy by intervention studies [41]; level I: systematic review; level II: randomized controlled trials; level III-1: pseudorandomized controlled trial; level III-2: comparative study with controls; level III-3: comparative study without controls; and level IV: case series.

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[b]A program evaluation scoring system was adapted from previously published guidelines for evaluating and reporting web-based intervention research [40].

[c]Owing to access restrictions, not all programs could be evaluated against all 17 items, which may have resulted in higher scores.

[d]CCI: Centre for Clinical Interventions.

[e]Beacon is an Australian clinical web-based platform that describes different web-based self-help treatment programs.

[f]Evaluation studies are not available.

[g]RCT: randomized controlled trial.

[h]LGBQ: lesbian, gay, bisexual, and queer.

[i]CBT: cognitive behavioral therapy.

[j]GAD: generalized anxiety disorder.

Evidence of the program's usability (ie, attrition data, success rate, completion rate, or number of users in the program or testimonials) was provided for 52% (27/52) of programs. In many cases, where a website offered ≥1 program, these results were provided for the suite of programs listed on the website generally rather than for the specific programs (eg, Evolution Health and This Way Up). Approximately 56% (29/52) of programs were supported by some type of evaluation; 59% (17/29) had undergone effectiveness trials, and 41% (12/29) had empirical evidence of both effectiveness and acceptability (ie, level III and level IV evidence). Approximately 68% (19/29) of the evaluated programs had undergone evaluation via RCT (ie, level II evidence). Of the 23 programs without evaluation data, 6 (26%) are currently in the process of being evaluated. All 52 programs and the type of evaluation studies conducted, including the level of evidence, are shown in Table 6 [41]. A rapid review of the evidence for each of these programs' evaluations is provided in Multimedia Appendix 4 [10,12,17,42-151].

Legal and Ethical Issues

The vast majority of programs provided privacy notices (50/52, 96%) and terms and conditions (51/52, 98%). Approximately 88% (46/52) of programs provided crisis links in the form of telephone numbers for emergency services, numbers of helplines or links to websites, and other resources. Only 1 website did not offer crisis links for its programs (CCI); this website was developed by the Western Australian Department of Health to provide evidence-based web-based resources to support practitioners, as well as to provide self-help materials for individuals. The terms and conditions of the website state that the information is provided for information purposes only.

Discussion

Principal Findings

The purpose of this scoping review was to summarize the freely available web-based resources based on an evidence-based therapeutic approach for Australian adults seeking self-help for depression, anxiety, suicidal ideation, or general well-being. We sought to describe their characteristics, including therapeutic approaches, key features, and the quality of evidence behind them and thereby produce an accessible summary to inform clinicians' selection of web-based interventions for their patients. This review builds on past reviews of web-based resources for depression [15] and anxiety [16]. To our knowledge, this is the first review of publicly available interventions that includes both suicidal ideation and general well-being.

A total of 52 web-based programs were identified, of which 20 (39%) were classified as web-based interactive programs, and 32 (62%) were classified as web-based programs with downloadable worksheets or resources. Of these 52 programs, 29 (56%) had been empirically evaluated, and most of the evidence was assessed as level II or III studies. This is similar to past reviews, which found that 50% of the programs addressing anxiety had undergone empirical evaluation [16], and 38% of programs addressing depression had been evaluated via an RCT (ie, level II studies) [15]. A total of 6 additional programs in this review were also currently undergoing evaluation at the time of writing (ifarmwell, My Digital Health programs, Mum2BMoodBooster, and Students Against Depression).

The evaluation of the included programs showed that, on average, programs scored 85%, indicating that the included web-based programs are generally of good quality. The lowest score was for Students Against Depression (44%) as it did not include information about the developers or the evidence behind the program, privacy notices, terms and conditions. However, Students Against Depression was one of the programs that offered downloadable modules, similar to the CCI programs, and it is currently undergoing evaluation, which may lead to a higher evaluation score once completed. The CCI programs, which scored third to last but are highly regarded by clinicians, included a privacy notice and terms and conditions, and their scores ranged between 69% and 75%. The highest scores were given to the 4 programs by MindSpot, which could only be evaluated against 77% (13/17) of the items. These programs could not be evaluated on more of the items because of restrictions on accessing the program, which may have resulted in higher scores.

Almost all programs reported that they were based on CBT, either with or without other therapeutic approaches. Only 1 program, ifarmwell, was based on ACT. Although traditional CBT focuses on challenging unhelpful thoughts, ACT focuses on defusing from and accepting them and finding value-consistent ways of living despite the circumstances to build *psychological flexibility* [152]. A recent international systematic review and meta-analysis of internet-based ACT programs between 2009 and 2019 [153] found 25 efficacy studies in a variety of clinical and nonclinical populations. Overall, the pooled results showed a reduction in symptoms of depression and anxiety and an improvement in quality of life

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and psychological flexibility at postassessment, with results maintained at follow-up assessments. Given this evidence, it is surprising that not more ACT-based web- interventions are available in Australia. However, that review focused on research-driven studies and not publicly available programs; therefore, none of the studies examined by Thompson et al [153] overlapped with this review. Similarly, only 1 program was based on DBT, which differs from CBT in that its main focus is on helping people change their behavior patterns instead of changing dysfunctional beliefs [154,155]. It also focuses on distress tolerance, which is more like ACT than CBT, and includes mindfulness and interpersonal skills training. A review of clinical effectiveness and guidelines showed that DBT is not statistically significantly greater than comparators in reducing depressive and anxiety symptoms [156].

The results of the current review found that 19% (10/52) of programs provided free therapist support, and 21% (11/52) allowed users to link in their existing clinicians. Research examining whether therapist-guided versus self-guided web-based interventions are more, less, or equally effective has produced mixed results. A recent meta-analysis of 21 studies of web-based programs targeting depression found no significant differences in the effectiveness of the programs to prevent depression based on whether they were guided or not [31]. In contrast, another meta-analysis of studies reported greater effect sizes for outcomes from interventions for depression and anxiety that were guided compared with effect sizes for those that were not [153]. However, these differences may be because of the type of therapy given, as the former was based on CBT and the latter on ACT. In addition, the use of email or SMS text message reminders or messages of encouragement may compensate for the lack of guidance in some programs. Guided interventions are not always practical to implement and may be expensive and hard to sustain and limit the accessibility of the program. Therefore, future research should continue to examine the impact of incorporating, or not incorporating, these program components and alternatives.

This review found that roughly half of the programs were structured or tunneled; a further 22 programs provided a recommended structure (but did not require that the user follow this), and 3 programs were unstructured, allowing the user choice in how and when they completed different modules. Research evidence is inconclusive on the manner in which web-based materials are best organized [157]. A recent systematic review found inconclusive evidence linking website structure and behavioral or health outcomes [158]. They reported that the number of peer-reviewed studies that manipulated website structure to examine its effects on outcome measures was too few to enable conclusive comments to be made. Other studies have provided evidence that allowing unstructured use of websites may increase engagement with the website; however, this may or may not translate into behavior change [159]. Therefore, more empirical evidence is required.

Most resources were designed for adults generally, although a few included programs were designed for specific populations such as farmers, tertiary students, and expectant or new mothers. There were no programs identified in our searches that were designed for hard-to-reach groups such as culturally and linguistically diverse populations or men, and there was only 1 for people from an Aboriginal or Torres Strait Islander cultural background. Web-based interventions provide a useful avenue for administering targeted mental health support to populations who may face barriers to accessing traditional services for cultural reasons. These results highlight the need for more research and development of programs that meet the needs of these at-risk and underserved groups.

Limitations

The use of a scoring system to evaluate and compare programs was based on a framework for evaluating internet-based interventions [40], as adapted in subsequent research [15,16]. This is a useful tool for comparisons across programs and between this research and past studies. However, items may not reflect the overall true value of a program to a particular consumer, with many elements of the program not being included in this scale and not necessarily being quantifiable as a yes or no item. Future research could extend this by examining how consumers and practitioners select an appropriate resource and the factors that they consider to be important in this choice. In addition, although we evaluated the usability of the programs, no completion rates of the included studies were investigated. Future studies should consider examining the completion rate of programs, as program attrition and nonuse attrition are persistent problems with digital interventions [160,161].

At the time of the literature search, there were no national standards for website developers and users to refer to when considering the selection of Australian web-based interventions for mental health. However, on November 30, 2020, the Australian Government released the National Safety and Quality Digital Mental Health Standards for health care providers to refer to when selecting digital media (including web-based programs) for the delivery of high-quality mental health care and suicide prevention (counseling or peer-based support) [162]. The purpose of the National Safety and Quality Digital Mental-Health Standards is to provide consumers and practitioners with information on which to base their selection of trustworthy resources and guide resource developers by providing quality standards. Familiarity and use of the standards, along with the findings from the present research, may help GPs and consumers select the most suitable web-based program for their needs. Although standards are now publicly available, an independent assessment tool to identify where a digital mental health service is meeting the standards or where it can improve is currently being developed and will not be available until late 2021. Similar reviews of this type in the future should include information on whether interventions have met these standards and whether this is a self- or independent assessment.

Comparison With Prior Work

Overall, of the 52 programs, 9 (17%) addressed depression, 15 (29%) addressed anxiety, 13 (25%) addressed general mental well-being, and 13 (25%) addressed multiple issues. This is substantially lower than the 32 programs for depression and the 34 programs for anxiety identified by Renton et al [15] and Ashford et al [16], respectively. In part, this is because of the restriction of the current review to programs that were (1) free and (2) accessible to Australians, which excluded several

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currently available international programs such as Beating the Blues or Deprexis, which offer interventions for a fee or are not available to Australians. In addition, the results may highlight the difficulties consumers face in finding suitable programs through search engines [163]. Search engine results were based on the Australian version of Google; however, these results are likely to change over time, as do programs, and the same search conducted at a later date may yield different results. Our search terms were intentionally broad, and we did not require the terms to be used in conjunction with terms describing *therapy* or *self-help*. The purpose of broadening the search in this way was to mirror the type of search that a consumer is likely to perform (focused on the issue and not the intervention type).

Conclusions

A total of 52 web-based programs and web-based programs with downloadable worksheets or resources programs are currently freely available to help Australians with the management of depression, anxiety, suicidal ideation, or general mental well-being. Careful attention is needed by clinicians and consumers to determine whether the interventions they refer to, or access, are evidence-based and considered acceptable by other users, given the varied levels of acceptability and impact. This review complements existing resources by providing website summaries and a clear comparison of website features to inform clinicians and consumers and assist in the selection of the most suitable program for the individual. It also identified important gaps in the availability of free web-based interventions in Australia (eg, for culturally and linguistically diverse populations and based on ACT), which may inform future research and program development initiatives.

Acknowledgments

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Authors' Contributions

This project was overseen by GS and KG. GS and KG devised the concept for the review, with input from CH, NJ, DT, and MS. The grant was applied for and won by GS, CH, KG, NJ, and DT. GS wrote the initial draft. GS, SvdK, and SL conducted the searches. GS, SvdK, SL, and DHB conducted the rapid review. All authors contributed to the final manuscript.

Conflicts of Interest

The authors KG, DT, and GS are involved in the development and evaluation of ifarmwell (a web-based intervention described in this paper).

Multimedia Appendix 1
Google search results.
[XLSX File (Microsoft Excel File), 18 KB - mental_v9i2e31018_app1.xlsx]

Multimedia Appendix 2
Program developers and website links.
[DOCX File , 20 KB - mental_v9i2e31018_app2.docx]

Multimedia Appendix 3
Program evaluation scores.
[XLSX File (Microsoft Excel File), 16 KB - mental_v9i2e31018_app3.xlsx]

Multimedia Appendix 4
Types of research evaluations of eligible programs and summary of evidence.
[DOCX File , 35 KB - mental_v9i2e31018_app4.docx]

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Abbreviations

ACT: acceptance and commitment therapy
CBT: cognitive behavioral therapy
CCI: Centre for Clinical Interventions
DBT: dialectical behavior therapy
eMHPrac: e-Mental Health in Practice
GP: general practitioner
LGBQ: lesbian, gay, bisexual, and queer
PRISMA-ScR: Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews
RCT: randomized controlled trial

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Review

Digital and Mobile Health Technology in Collaborative Behavioral Health Care: Scoping Review

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Abstract

Background: The collaborative care model (CoCM) is a well-established system of behavioral health care in primary care settings. There is potential for digital and mobile technology to augment the CoCM to improve access, scalability, efficiency, and clinical outcomes.

Objective: This study aims to conduct a scoping review to synthesize the evidence available on digital and mobile health technology in collaborative care settings.

Methods: This review included cohort and experimental studies of digital and mobile technologies used to augment the CoCM. Studies examining primary care without collaborative care were excluded. A literature search was conducted using 4 electronic databases (MEDLINE, Embase, Web of Science, and Google Scholar). The search results were screened in 2 stages (title and abstract screening, followed by full-text review) by 2 reviewers.

Results: A total of 3982 nonduplicate reports were identified, of which 20 (0.5%) were included in the analysis. Most studies used a combination of novel technologies. The range of digital and mobile health technologies used included mobile apps, websites, web-based platforms, telephone-based interactive voice recordings, and mobile sensor data. None of the identified studies used social media or wearable devices. Studies that measured patient and provider satisfaction reported positive results, although some types of interventions increased provider workload, and engagement was variable. In studies where clinical outcomes were measured (7/20, 35%), there were no differences between groups, or the differences were modest.

Conclusions: The use of digital and mobile health technologies in CoCM is still limited. This study found that technology was most successful when it was integrated into the existing workflow without relying on patient or provider initiative. However, the effect of digital and mobile health on clinical outcomes in CoCM remains unclear and requires additional clinical trials.

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KEYWORDS

collaborative care; integrated care; augmented care; digital health; mobile health; behavioral health; review

Introduction

Background

There are more people who could benefit from behavioral health services than can be served by the currently existing resources for care [1,2]. Mood and anxiety disorders are highly prevalent in the general population [3,4]. These disorders are disabling to individuals and burdensome to communities, resulting in increased service use, loss of productivity, and poorer outcomes for pre-existing medical conditions [5-7]. Common behavioral health problems are frequently treated in primary care settings because of the relative scarcity of behavioral health specialists in many areas [8,9]. However, primary care providers (PCPs) often lack the training and resources to manage these problems

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effectively, resulting in overstrained primary care practices and the potential for suboptimal care [8,10]. Novel approaches are needed to improve the scale, delivery, and cost efficiency of behavioral health care.

The collaborative care model (CoCM) aims to meet this vast need [11]. The CoCM is a well-established mode of treatment for common behavioral health disorders in primary care settings. Briefly, in this model, a PCP systematically screens patients for common behavioral health disorders and refers those in need to a behavioral health care manager (BHCM). The BHCM, typically colocated with the PCP, sees patients for an initial assessment and provides time-limited psychotherapy and ongoing evaluation. The BHCM liaises with a consulting psychiatrist who provides treatment recommendations. The psychiatrist may supervise multiple BHCMs at multiple primary care sites, thus significantly extending their reach. The BHCM tracks patient outcomes with regularly administered symptom rating scales (eg, the Patient Health Questionnaire-9 or the Generalized Anxiety Disorder-7 [12,13]) in conjunction with clinical evaluation. The BHCM communicates recommendations to the PCP, who prescribes any necessary medications and remains the clinician of record. This model is effective, widely regarded as the best practice, and has been adopted by many health systems across the world since its introduction in the 1990s [11,14-18].

Pitfalls along every aspect of collaborative care (CC) may contribute to unsuccessful implementation. For example, as the CoCM is a specialized multicomponent service, robust adoption requires provider training and stakeholder buy-in [19]. However, local expertise may be scarce. The colocation of the PCP and BHCM may also be a logistical challenge in some settings. To maximize reach, screening for behavioral health disorders within the primary care population must be systematic [20]; subsequent referrals to the BHCM should be streamlined in the clinical workflow. Monitoring symptoms within a large caseload requires efficient tracking mechanisms. The scope of interventions traditionally available to patients includes brief psychotherapy and limited pharmacotherapy [11]. Even under trial conditions, these options may not meet the needs of some patients [17]. Moreover, there are potential financial challenges to implementation [21].

Digital and mobile health technologies have the potential to support multiple components of CoCM [22]. Technologies such as mobile apps, wearable and ambient sensors, social media, and web-based platforms and devices can improve implementation by supporting provider training, patient screening and referral, monitoring, and treatment. For example, improving live and asynchronous communication technology can link novices with experts who can support the development of a CC program. Technologies can continuously collect interpretable patient data and potentially enable quick, flexible, and targeted care [23]. These resources can act as extenders, decreasing provider workload by automating tasks previously required of clinicians in the CoCM and supporting clinician decision-making by providing actionable clinical information in real time [22,24]. Digital and mobile health technologies can also support patients by providing education and real-time feedback from clinicians, reinforcing concepts learned in therapy, and tracking progress [22]. Emerging research has examined the potential of digital solutions for common behavioral disorders in primary care settings [25-27].

Technology has been recognized as important for the optimal functioning of the CoCM from an early stage. For example, clinicians and researchers recognized the necessity of using caseload registries to manage patient information, track outcomes, and have easy access to information from assessments and follow-up appointments [28-32]. In addition, telephone- and 2-way video-based remote care emerged in the 2000s as a viable method of providing CC [33-36]. Thus, there is extensive precedent and continuous interest in the use of technology to augment CC, which is unsurprising, given the model's spirit of innovation and dissemination.

This review aims to summarize the current state of research into the ability of digital and mobile health to augment the CoCM, highlight important challenges and limitations, and explore areas for further investigation.

Objective

The primary aim of this review is to synthesize the evidence available on digital and mobile health technology in CC settings.

Methods

Scoping Review

The topic of CC augmented with technology includes a wide variety of potential interventions, both patient-facing and provider-facing, and a wide variety of psychiatric disorders, including depression, anxiety, posttraumatic stress disorder (PTSD), bipolar disorder, and others. Thus, we chose to conduct a scoping review on this broad and emerging topic using the methodology recommended by Arksey and O'Malley [37] and refined by Levac et al [38]. To this end, we conducted six stages of review development: defining the research questions to broadly capture the relevant literature in this emerging field; balancing breadth and feasibility in the search strategy; identifying and selecting studies; extracting and charting data; and synthesizing and reporting the findings, including a forward-looking discussion that could guide future research or quality improvement efforts.

Research Question

We attempted to answer 3 research questions with this scoping review. First, what digital and mobile health technologies have been studied in CC, and at what levels have they been implemented (patient- vs provider-facing)? Second, what is known about the acceptability and feasibility of digital and mobile health use in the CC context? Third, what, if anything, is known about the impact of these technologies on clinical outcomes in this setting?

Search Strategy

We searched 3 web-based databases (Web of Science, MEDLINE, and Embase) during February 2020 with search terms related to CC (sometimes termed integrated care) and various technology interventions, including mobile apps, sensors, social media, and wearable devices. Scans of dark

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literature from Google Scholar were also completed. Scoping reviews on similar topics were consulted in the search strategy development [39,40]. Additional searches with the same search criteria were conducted in December 2020 and September 2021 to fully capture the status of this rapidly growing field of research. A full list of the search criteria is presented in Multimedia Appendix 1.

Inclusion and Exclusion Criteria

Articles were determined eligible for inclusion if they described original research on digital and mobile health to augment the CoCM for the treatment of common behavioral health conditions. Novel technologies such as mobile apps, web-based platforms, ambient or wearable sensors, and social media were included. Technologies that are already well-established in the CoCM and in medicine broadly, such as electronic medical records, caseload registries, or telemedicine, were excluded. Opinion pieces, reviews, books, book chapters, protocols, and commentaries were excluded. Post hoc analyses of the trials included in this review were only included if they helped answer the questions posed by this review; otherwise, they were excluded. Articles written in languages other than English were also excluded. Studies were excluded if they recruited patients from a primary care population or other general medical populations that did not participate in a CoCM, as described previously in this paper. Studies in which substance abuse was the primary diagnosis were excluded.

Study Screening Process

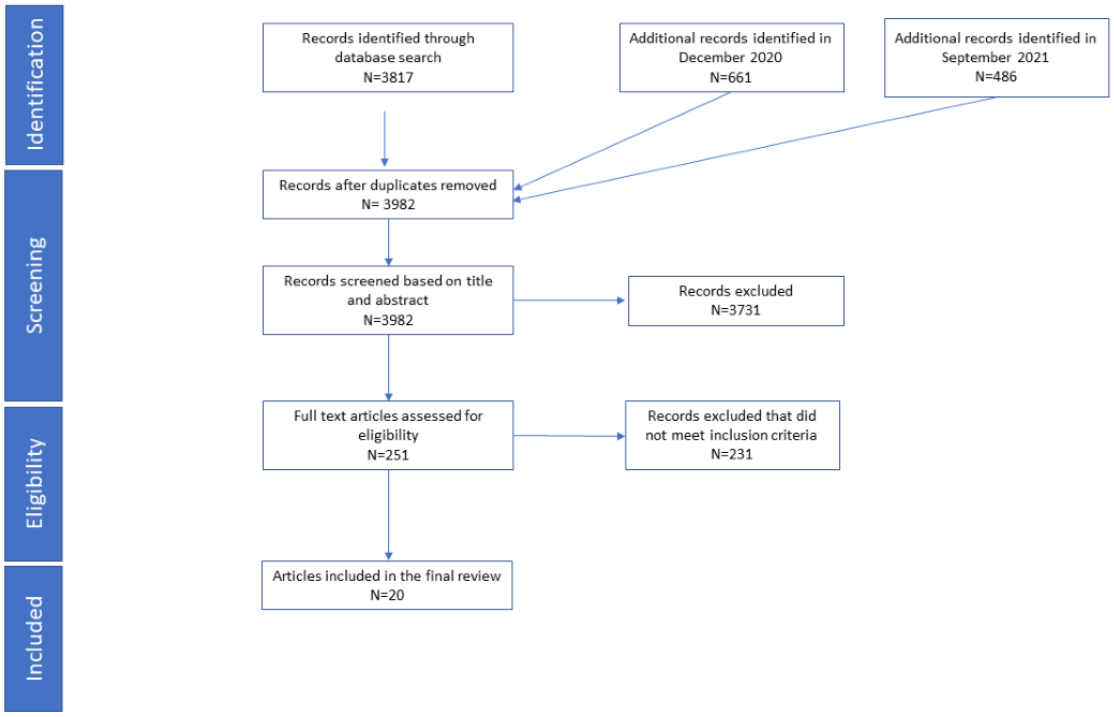
Owing to the large volume of articles obtained in the initial screening, the articles were divided and screened by 2 independent reviewers (KM and MS). In the initial stage of screening, articles were excluded based on the title and abstract. In the second stage, the remaining papers were excluded based on their full text. At the stage of full-text screening, conflicts were resolved by consensus between the reviewers.

Results

Summary of Studies

The initial search identified 3817 reports; 661 additional reports were identified in December 2020, and 489 were identified in September 2021. The study selection process is summarized in Figure 1. A total of 20 studies were included in this review. The characteristics of the studies are summarized in Table 1, and more details on individual studies are provided in Multimedia Appendix 2 [15,35,41-58]. The 20 studies included a comparative effectiveness trial of an interactive voice recording (IVR) intervention in a safety net population and a series of post hoc analyses on the same study population [41-44], a randomized trial of an internet support group with an associated subgroup analysis [45,46], 30% (6/20) other randomized trials [35,47-52], a nonrandomized trial [53], 25% (5/20) implementation trials without a comparator [15,54-57], and a qualitative exploratory study [58].

Figure 1. Study selection diagram.



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Table 1. Characteristics of the included studies (N=20).

Characteristics	Studies, n (%)
Study metadata	
Study design	
Randomized trial	8 (40)
Quasi-experiment or nonrandomized trial with comparator group	2 (10)
Qualitative or mixed methods	6 (30)
Post hoc analysis	4 (20)
Year of publication	
2018 or newer	15 (75)
2015-18	4 (20)
2014 or before	1 (5)
Population characteristics	
Size	
≤10	1 (5)
10-50	5 (25)
50-200	2 (10)
200-500	4 (20)
>500	7 (35)
Not specified	1 (5)
Diagnosis	
Anxiety disorders	4 (20)
Depressive disorders	14 (70)
Bipolar disorder	1 (5)
Posttraumatic stress disorder	3 (15)
Patient- vs provider-facing	
Patient-facing	13 (65)
Provider-facing	3 (15)
Combination	5 (25)
Digital and mobile health intervention used to augment collaborative care	
SMS text messaging	3 (15)
Interactive voice recording	5 (25)
Mobile app	5 (25)
Web-based platform	7 (35)
Videoconferencing	1 (5)
Other	4 (20)
Outcome measured	
Adherence	3 (15)
Acceptability	7 (35)
Feasibility	9 (45)
Clinical improvement	10 (50)
Other	3 (15)
Comparator	
Collaborative care	4 (20)

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Characteristics	Studies, n (%)
Primary care	3 (15)
Collaborative care and primary care	4 (20)
Other	2 (10)
No comparator	7 (35)

Synthesis of Findings

Overview

We have summarized the results of our review in light of the research questions that we posed. We first describe which digital and mobile health technologies have been studied in CC and the nodes of the CC workflow that have been implemented. Next, we describe what is known about the acceptability and feasibility of digital and mobile health use in CC settings. Finally, we describe what is known about the impact of these technologies on the clinical outcomes in this setting.

Digital and Mobile Health Technologies in CC

Most studies identified by this review implemented or assessed multiple technologies at once rather than a single intervention. Of the 20 studies, 5 (25%) [15,50,53,54,57,58] assessed mobile apps, and 5 (25%) used a web-based platform [46,49-52]. Adewuya et al [47] and Jin and Wu [48] used SMS text messaging as a core feature of the intervention, although other investigators used SMS text messaging as an adjunctive tool [51,53,59]. Of the 20 research groups, 2 (10%) used IVR [49,60]. No studies identified in this review investigated social media, web-based search activities, or wearable devices.

The studies considered in this review encompassed all aspects of the CC workflow. Of the 20 studies, 3 (15%) used technology to augment BHCM training in the skills and implementation of the model [35,55,56]. One of the research groups [41-44,48] used technology to facilitate the screening of patients into CC by SMS text messages and IVR. Of the 20 studies, 1 (5%) described a decision support tool to triage patients into different levels of care [52]. Studies also used technology to facilitate measurement-based care by collecting clinical assessments [48,51,53,54]. Most studies provided participants with self-management modules and psychoeducational materials [15,35,46,49-51,53,54,57]. Several studies used technology to promote communication with the BHCM via asynchronous messaging [15,53,57]. Of the 20 studies, 1 (5%) used app-based therapy [57] and another assessed patient and provider attitudes toward app-based depression management [58]; 1 (5%) study used a web-based intervention in the form of web-based cognitive behavioral therapy and web-based group therapy [46]. Several studies had a patient-facing information collecting system that fed directly into a caseload management system [15,48,49,51,54,60].

Acceptability and Feasibility of Digital and Mobile Health in CC

The overall response to the technology presented in these studies was positive for both patients and providers. Patients enjoyed having the option of using technology for psychoeducation as therapy extenders and ways of communicating with their providers [15,41,49,50,54,57,58]. However, some of the technologies had limited sustainability, especially if they required sustained engagement from either patients or providers. Meglic et al [51] cited high dropout rates, and Bauer et al [54] had few participants who continued to use the app at 8 weeks. Less than half of the participants met the threshold for engagement in the study by Carleton et al [53]. Participation in IVR-based phone calls decreased after 6 months in the study by Vidyanti et al [44]. Fletcher et al [52] saw limited differences in intervention groups at 1 year. Participants cited privacy about the data collected in the apps as a concern in 15% (3/20) of studies [54,57,58]. Bhat et al [56] struggled with inconsistent attendance at meetings, which made it difficult for the provider training intervention to be effective. Meanwhile, staff cited concerns over increased workload if the technology intervention was not integrated into the usual medical record and required consulting a separate resource to see the results of data collection [54,58]. Providers also expressed concern over having little time to address the apps with patients and being uncomfortable or unfamiliar with the apps [57,58]. Usability and functionality of web- and app-based interventions were noted as concerns in the studies by Meglic et al [51] and Dinkel et al [58]. The potential cost of apps was noted as a barrier by Dinkel et al [58]. Meanwhile, studies that examined automated interventions such as IVR and automated SMS text messaging enjoyed higher levels of acceptability and feasibility [41,47,49]. The IVR-based screening trial for depression was noted to be cost-effective [42] and acceptable to patients [43]; providers reported feeling that they could spend more time focusing on clinical management if they knew that screening had already been completed [44]. Jin and Wu [48] found that participants with a high degree of depression stigma who were screened for depression using SMS text messaging were more likely to report certain symptoms when compared those screened with telephone interviews.

Clinical Outcome of Digital and Mobile Health in CC

Of the 20 studies, 8 (40%) studies examined clinical outcomes [35,41,45,46,49,51,53]. Of these 8 studies, 7 (88%) focused on depression or anxiety outcomes [41,45,46,49,51-53], whereas 2 (25%) focused on PTSD outcomes [35,50]. Of the 20 studies, the following 3 (15%) focused on patients with specific comorbid medical conditions: Zatzick et al [50] on combat-related injury, Wu et al [41] on diabetes mellitus, and Kroenke et al [49] on chronic musculoskeletal pain. Rollman et al [46] found that clinical outcomes were improved between the 2 intervention arms (which both used CoCM and technological interventions) compared with that of usual primary care. Zatzick et al [50] found a reduction in PTSD symptoms but not in depression symptoms in the information technology–enhanced CC group compared with that of usual

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primary care. However, these 2 studies had important limitations: they did not compare technology-enhanced CC with CC alone. Thus, it is not known whether the components of the CoCM or the technological intervention itself were associated with improvement. Of the 20 studies, 4 (20%) compared technology-enhanced CC with CC alone [41,49,51,53]. The study by Meglic et al [51] had small sample sizes but found an improvement in the clinical outcomes of the intervention group when compared with that of usual care. Both IVR-based studies (Wu et al [41] and Kroenke et al [49]) found modest improvements in clinical depression outcomes compared with CC alone. In the study by Carleton et al [53], which is the largest included study to investigate a mobile app, depression outcomes were similar between the app-augmented group and the usual CC group; however, the baseline depression severity was greater in the intervention group. Therefore, the authors speculated that the app may have improved outcomes beyond what might have been initially expected by facilitating communication and more frequent contact between patients and providers, given the baseline depression severity in this group. Fletcher et al [52] found that patients with both mild and severe illness showed improvement after using the decision support tool compared with usual care; however, these differences were modest.

Discussion

Principal Findings

In this scoping review, we investigated the use of digital and mobile health technology in CC settings. This study builds on previous research highlighting the potential of technology in improving behavioral health care [22,23,27].

Our results suggest that the implementation of digital and mobile health technology in CC is currently in its early stages in both clinical research and practice. For example, of the 20 studies, only 1 (5%) study using an app was a large trial [53]. Mobile apps were among the most novel technologies used by studies in this review; no studies using social media, wearable devices, ambient sensors, or other more innovative technologies were identified. Overall, there is more to learn about the use of technologies in this setting.

We believe that digital technology has the potential to support the delivery and scale of the CoCM by mitigating several common challenges to their effective implementation, ranging from provider training, patient screening and referral, monitoring and treatment, and sustainability of the practice. We also believe that the CoCM is especially suited to absorb such changes because of its forward-looking, team-based, and measurement-guided approach. We have used the results of our review to scope future directions for augmenting CC with digital and mobile health technologies focusing on provider training, screening, monitoring, treatment, and sustainability.

Future of Digital and Mobile Health Technologies in Collaborative Care

Training and Adoption

Despite widespread recognition of the merits of the CoCM, adoption may continue to lag in part because of the lack of local expertise and provider training in the implementation of this complex, multicomponent service [11,19]. Of the 20 studies identified in this review, 3 (15%) addressed adoption and quality improvement challenges from several angles: remote coaching with videoconferencing, web-based self-guided modules for providers, and telephone-based training in behavioral health skill delivery [35,55,56]. These data suggest that a combination of premade self-guided materials and remote live coaching by experts can mitigate the need for local expertise in CC. The availability of these strategies, and, in the future, more robust evidence for their success, can also mitigate stakeholder hesitancy. In our review, longitudinal remote coaching was shown to experience lagging attendance at regularly scheduled coaching meetings that hindered clinical progress [56]. Digital tools such as asynchronous chat may alleviate this by encouraging providers to troubleshoot challenges in real time. In the future, other strategies, such as automated monitoring of caseload registries to measure faithfulness to the model, can further guide quality improvement and adoption efforts.

Screening and Referral

Increasing access to behavioral health care through systematic screening and referral is a core mission of the CoCM, one that technology has a great potential to support. Of the 20 studies, our review identified 1 (5%) research group that successfully used SMS text messaging and IVR to scale the screening of behavioral health disorders [44,48,61] and 1 (5%) study that used a patient-completed decision support tool to triage patients to different levels of care within an integrated, stepped-care system [52]. Surprisingly, most of the reviewed studies did not use technology for screening. However, the available data suggest that IVR, SMS text message, and other remote strategies can provide several benefits compared with traditional screening methods. For example, they could allow enrollment into the CoCM via the web or phone without attending a physical clinic, expanding access to people with mobility and engagement challenges [44,62]. They met the needs of a diverse population by being adapted relatively easily to languages other than English. Automated screening freed up provider time to address patient concerns [44]. Finally, as shown by Jin and Wu [48], automated screening may even be preferable because of its potential to identify individuals who may be unlikely to report symptoms in a traditional clinical interview. One of the advantages of IVR and SMS text messaging is that they do not require the patient to install any software or receive any education on the use of the technology, such as might be required by a mobile app or sensing device. Therefore, these tools may be especially well-suited to the screening process.

Although much further into the future, technology has the potential to facilitate screening by using digital biomarkers rather than self-report [63]. For example, the diagnosis of behavioral health disorders can be automatically assessed using speech processing and voice biomarkers. This technology can intuitively fit with existing voice technologies such as IVR [64]. For such data to be clinically meaningful, digital phenotypes of common behavioral health disorders will need to be well-established and validated; such research is currently in its infancy [65,66]. Although the CoCM was initially designed for depression, our review suggests that a diversity of disorders can

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be addressed in this context [17,50,55,67]. Automation can facilitate this by screening for a wider range of common behavioral disorders than is currently feasible in traditional, in-person, provider-administered screening processes [68]. This can then facilitate more targeted referral and earlier interventions [52]. Taken together, integrating these diverse data sources can enhance multimodal assessment and diagnosis of behavioral health disorders.

Remote Monitoring

Another core CoCM feature is its reliance on measurement-based care and systematic monitoring to guide clinical decisions. Our results suggest that technology can support this, particularly with the use of mobile apps, which can solicit symptom rating scales from patients at regularly set intervals [53]. This method supports measurement-based care by allowing a much more frequent collection of patient-reported outcomes than is currently possible in the interval clinical assessment model. If funneled into the electronic medical records, these data can then generate alerts to PCPs that would trigger an intervention from the BHCM if indicated [46]. Our results reinforce the idea that without integration into existing medical records and workflows, these data can actually be burdensome to staff, who would now have to consult multiple platforms to obtain clinical information [15,58]. Measurement-based care can be further enhanced by technology that allows for asynchronous communication between patients and the BHCM. Chat communication can reinforce therapeutic alliances, increase adherence to symptom reporting, and reduce the likelihood of treatment failure, thus improving clinical outcomes [22,57,58].

A future direction for digital and mobile health technologies in measurement-based care involves unobtrusive monitoring with connected devices, in particular mobile phones and wearable devices [69]. Patient-generated data can help measure clinical variables such as activity, sleep, and socialization, supporting measurement-based care and clinical decision-making and ultimately delivering personalized interventions when needed [66,70,71]. To date, these technologies have not been investigated as part of the CoCM but provide opportunities for future research and practice.

Treatment

Digital and mobile health technology can facilitate and scale treatment as part of the CoCM. For example, providing psychoeducational material is a basic intervention that was implemented in most of the studies in this review [15,35,46,49-51,53,54,57]. Mobile apps can allow the BHCM to monitor and nudge patients to engage with psychoeducational materials or provide automatic reminders. Higher engagement can be achieved by personalizing the technological solutions to deliver the right treatment, in the right amount, and at the right time [72-74]. This would require future research to identify the pathways for personalization. Most of the studies in this review showed improvement in clinical outcomes; however, most also implemented multiple technologies at once. To help personalize treatment, future research can more systematically identify therapeutic elements that directly relate to outcomes.

Digital and mobile health technologies can also help to facilitate more active treatment modules. For example, our review identified the preliminary use of cognitive behavioral therapy–based web-based treatments as part of technological implementation in CC [57,75]. Although a large number of therapy-based apps exist in commercial marketplaces, there is a dearth of research evaluating these apps in clinical practice [76,77]. If research were to show that these tools have meaningful clinical applications, their use could significantly scale the ability of CC to provide psychotherapy as treatment. There is also an opportunity to explore more novel treatment options that include virtual reality and other digital therapeutics and mindfulness-based interventions [27]. Future research should uncover which of these potential technologies are feasible and effective in CoCM settings.

Sustainability and Challenges in Implementation of Digital and Mobile Health Technology

Research suggests that the implementation of digital and mobile health technologies in behavioral health care requires the addition of a new team member—a digital health coach—who might help patients and providers navigate digital interventions [78]. This can pose a challenge to the cost-effectiveness of digital technology. The structure of the CoCM has an advantage over standard primary care settings because of the existence of the BHCM, who could potentially act as a digital health navigator, and because of the infrastructure that already exists for collaboration between team members in this model.

There are several challenges in the implementation of digital and mobile interventions in CC. To provide evidence for efficacy, clinical outcomes in technology-augmented care should be superior to the clinical outcomes of traditional CoCM. The most comprehensive study of app-augmented care to date, by Carleton et al [53], found comparable effectiveness for both traditional (46%) and augmented CC (47%), as measured by improvement in Patient Health Questionnaire-9 scores [53]. To compensate for the lack of improvement in clinical outcomes, augmented care can be designed to save the cost of care and provider time. Currently, there is a relative lack of evidence on the effect of augmented care on cost and time, with only 5% (1/20) of the studies in this review addressing this issue [42]. In fact, digital and mobile health technologies may come with an additional cost to the providers as they require investment in the technology itself and in the implementation of its use. From this perspective, relatively low-cost interventions such as SMS text messaging and IVR, such as those implemented by Kroenke et al [62], Wu et al [61], and Adewuya et al [47], may be preferred.

Another common challenge in mobile health technology is the lack of engagement and high attrition rates, as demonstrated in several of the reviewed studies [15,53,56]. In augmented CC, the introduction of a mobile app or other technology for remote monitoring and treatment will require compliance with assessment modules and engagement with psychoeducational materials and chat communication. Our results show difficulties with engagement, especially in technologies that were not automated and required user-initiated actions to work [15,44,51]. In initial implementations, encouraging engagement and

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preventing attrition can become a function of the BHCM or digital health navigator. Future research should address these challenges through the lens of implementation science.

Finally, implementation of many of the discussed technologies requires addressing challenges with legal, ethical, and privacy concerns about the use of these data at both the patient and provider levels. This is a common challenge in technology, especially in the clinical context of behavioral health. Our review identified early reports of privacy concerns with regards to tracking [49,52]. These concerns might be amplified when additional tracking technologies for remote monitoring and treatment are introduced. Therefore, novel strategies must be implemented with the utmost concern for privacy in a cooperative and transparent manner.

Limitations

Our review has several limitations. Methodologically, we did not use a librarian as part of the search strategy or calibration of the exclusion and inclusion criteria. Although improving the feasibility of our review, these strategies may have limited the breadth of our search and screening process. In a few years, as more technologies are implemented in CoCM, we expect a systematic review of the literature to be conducted to assess the evidence. In this review, we focused on the treatment of common behavioral health disorders in the CC setting specifically because of the unique approach and structure of this model. Therefore, we excluded studies of digital and mobile health technologies in related settings, such as primary care and substance abuse treatment. Nevertheless, as digital and mobile health technologies are used both in primary care and substance abuse, we drew and built on this research in our discussion.

Conclusions

The use of digital and mobile health technologies in the CoCM is still limited. Digital technology was the most successful when it was integrated into the existing workflow without relying on the patient or provider initiative. The effect of digital and mobile health on clinical outcomes in CoCM remains unclear and requires additional clinical trials. To advance the use of digital and mobile health in CoCM, we have introduced a forward-looking discussion for augmenting CC with a focus on improving access to care, remote patient monitoring, and enhancing treatment.

Conflicts of Interest

JMK has received fees for consultation or honoraria for lectures from Alkermes, Dainippon Sumitomo, H Lundbeck, Intracellular Therapies, Janssen, Karuna, LB Pharma, Lyndra, Merck, Minerva, Neurocrine, Otsuka, Roche, Saladex, Sunovion, Takeda, and Teva. He is also a shareholder of LB Pharma and The Vanguard Research Group.

Multimedia Appendix 1
Search terminology.
[DOCX File , 47 KB - mental_v9i2e30810_app1.docx]

Multimedia Appendix 2
Summary of selected studies.
[DOCX File , 75 KB - mental_v9i2e30810_app2.docx]

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Abbreviations

BHCM: behavioral health care manager
CC: collaborative care
CoCM: collaborative care model
IVR: interactive voice recording
PCP: primary care provider
PTSD: posttraumatic stress disorder

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Review

The Associations Between Gaming Motivation and Internet Gaming Disorder: Systematic Review and Meta-analysis

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Abstract

Background: There has been a surge in interest in examining internet gaming disorder (IGD) and its associations with gaming motivation. Three broad components of gaming motivation have been proposed: achievement, immersion, and social. Achievement-oriented players are motivated by gaining in-game rewards, immersion-oriented players are motivated by the experience of immersion in the virtual world, and social-oriented players are motivated by the need to socialize with other players through gaming.

Objective: This study aimed to (1) quantitatively synthesize the growing body of literature to systematically examine the discrepancies in the magnitude of associations between various components of gaming motivation and IGD and (2) examine the moderating role of cultural dimension on the association between escapism gaming motivation and IGD.

Methods: We conducted a systematic search of multiple databases between 2002 and 2020. Studies were included if they (1) included quantitative data, (2) used measures assessing both gaming motivation and IGD, and (3) contained sufficient information for effect size calculation.

Results: The findings revealed IGD to have a stronger association with achievement motivation (r=0.32) than with immersion (r=0.22) or social motivation (r=0.20), but the strongest such association was found to be with escapism motivation (r=0.40), a subcomponent of immersion motivation. Our cross-cultural comparison further showed a stronger association between escapism motivation and IGD in studies conducted in individualistic (vs collectivistic) regions.

Conclusions: This meta-analysis highlights the importance of acknowledging the discrepancies among different components of gaming motivation with respect to their role in the development of IGD, as well as the potential cultural variations in the strength of such associations.

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KEYWORDS

gaming motivation; problematic gaming; gaming disorder; video gaming; online gaming; compulsive gaming; escapism; culture; cross-cultural comparison, cultural individualism

Introduction

Background

Internet gaming is a popular leisure activity in the present digital age. However, gaming can become problematic when it interferes with a player's psychological and social functioning [1,2]. Considering the prevalence of this emergent problem worldwide [3,4], problematic gaming was included as a "condition for further study" in the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5), under the label of "*Internet Gaming Disorder*" (IGD) [5], and considerable research efforts have been made to conceptualize and assess IGD [6,7]. After IGD was listed as a "condition for further study" in the DSM-5 in 2013, *gaming disorder* was also officially included in the International Classification of Diseases, Eleventh Revision (ICD-11) in 2018. Thus far, only 1 measure has been developed based on the ICD-11 criteria, but none of

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the studies retrieved in this meta-analysis used this measure. This work thus focuses on IGD because several measures included in the present meta-analysis were constructed based on the DSM criteria.

Some scholars conceptualize this disorder to be a form of behavioral addiction because some of its symptoms are similar to those of other behavioral addictions (eg, gambling disorder) and substance use disorder [8]. Based on the criteria for other behavioral addictions, several recurring symptoms of IGD have been identified, including preoccupation with gaming activities and withdrawal symptoms such as irritability when individuals are kept from playing [9,10]. Studies have revealed that IGD was positively associated with mental health issues such as depression, social anxiety, and psychological distress [11-16].

Gaming Motivation as an Underlying Factor of IGD

As gaming is generally regarded as a healthy leisure activity, scholars have advocated for an examination of IGD from the viewpoint of etiological factors such as gaming motivation [17,18]. Although the specific gaming motivation differs considerably among players, the driving force behind IGD stems from players' over-reliance on gaming to fulfill certain psychological needs [19], a postulation corroborated by evidence on the positive associations between various types of gaming motivation and IGD [20,21]. Nevertheless, several issues remain unexplored, and we conducted a meta-analysis to quantitatively synthesize the available evidence to address 2 of these important but unresolved issues.

The first issue is the empirical inconsistencies regarding the associations between gaming motivations and IGD. For instance, some studies indicate that certain types of gaming motivation, such as the desire to achieve in-game success, are more strongly associated with IGD than are other types of gaming motivation, such as the motivation to form social relations through gaming [22,23]. However, the evidence remains inconclusive because many studies in this area have examined only a single type of gaming motivation, thereby rendering between-motivation comparisons impossible [20]. Second, cross-cultural comparisons are essential for studying IGD as a global phenomenon [24]. For instance, although intervention programs for IGD are more commonly observed in Asian countries characterized by collectivistic orientations [25-27], the implications and the potential influence of such cultural differences on the association between gaming motivation and IGD has yet to be empirically investigated.

Components of Gaming Motivation

To identify specific components of gaming motivation that play an influential role on IGD, we adopted Yee's categorization [28] as our theoretical foundation for a systematic analysis. Among the various frameworks available in the literature, we chose Yee's framework [28] because it is the most comprehensive one that adopts a hierarchical structure encompassing both components and subcomponents and is also by far the most widely adopted framework in the literature of gaming motivation. This tridimensional framework categorizes gaming motivation into 3 broad components. First, achievement motivation comprises gaming motivations pertaining to the desire to achieve in-game recognition, power, and status. Second, social motivation refers to gaming motivations related to the urge to build connections and interact with other players. Third, immersion motivation includes those motivations pertaining to the desire to experience the virtual in-game world.

The hypothesized discrepancies among the achievement, social, and immersion motivation components are corroborated by prior studies indicating that the 3 components have distinct magnitudes of associations with IGD. For instance, the achievement component has been consistently identified as a robust indicator of IGD, with a moderately positive association between the 2 constructs [22,29]. Specifically, scholars have postulated that players who lack success in real life often choose to compensate for such deficiencies with their achievements in the gaming world [30]. Hence, players who overvalue their in-game achievements often need to endure extensive gameplay to achieve the occasional moments of success, which in turn increases their propensity to develop IGD [30].

Another body of studies has revealed weak to moderate positive associations between immersion motivation and IGD [23,31]. Immersion motivation entails the incentive to immerse oneself in gaming, as the highly immersive nature of internet games may serve as a refuge for players to escape from real-life difficulties (eg, social anxiety, loneliness) [32,33]. Although gaming may provide temporary relief from such difficulties, it can also create problematic beliefs about the maladaptive use of gaming to constantly avoid real-life issues [19].

Mixed findings, however, have been reported for the association between social motivation and IGD. Although some studies have documented weak to moderate positive associations between the 2 constructs [29,34], others have reported null or even contradictory findings [22,35]. Such inconsistencies may be related to the complex social outcomes of gaming. For instance, although players with a stronger social motivation are more likely to receive online social support through gaming [36,37], these online relations have also been linked to the social "obligation" of gaming [38]. More specifically, players who want to become core members of a gaming team are often obligated to play for as long as other team members want to play. This perceived obligation of gaming often increases players' gameplay time and gaming-related distress, both of which contribute to the onset of IGD [30,39].

Studies examining all 3 motivation components have compared the associations of these components with IGD. For example, studies investigating both achievement and immersion motivations have revealed IGD to be more strongly associated with the former than the latter [22,29]. Moreover, IGD has also been consistently shown to have a weaker association with social motivation than with achievement motivation [40] or immersion motivation [23].

Based on these empirical findings, we hypothesize that the 3 components of gaming motivation are differentially associated with IGD. More specifically, we predict that this meta-analysis may reveal the association between achievement motivation and IGD to be stronger than that between immersion motivation and IGD. Moreover, social motivation is expected to have a

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weaker association than achievement or immersion motivation with IGD.

Subcomponents of Gaming Motivation

In addition to the 3 motivation components conceptualized in the tridimensional gaming motivation framework, each motivation component also comprises multiple subcomponents. Moreover, prior studies have revealed sizable differences among specific subcomponents of the same motivation component with respect to their association with IGD [41,42]. To empirically evaluate these within-component variations, we adopted Yee's 10-factor motivation taxonomy [43] that includes 10 motivation subcomponents, each of which is classified under 1 of the 3 aforementioned gaming motivation components (ie, achievement, immersion, and social).

According to the 10-factor taxonomy, immersion gaming motivation comprises 4 subcomponents: discovery, role-play, customization, and escapism. Discovery motivation refers to players' interest in exploring the virtual in-game world, whereas role-play motivation reflects players' incentive to create and identify with their in-game avatars. Customization motivation refers to players' desire to alter various aspects of their in-game characters as they wish, whereas escapism motivation reflects their urge to use gaming activities to escape from real-life difficulties. Studies have revealed considerable differences in the association of each of the 4 subcomponents with IGD. For example, escapism motivation has been consistently documented to have a moderate to strong association with IGD [43], whereas the discovery and customization motivation subcomponents display a much weaker such association [44,45].

These within-component variations have been attributed to the stronger conceptual connections between escapism motivation and IGD than between the other subcomponents and IGD [32]. According to Baumeister's escape-from-self theory [46], the assertion that immersion-oriented players use gaming to evade real-life adversities is more applicable to escapism motivation [47], primarily because that subcomponent refers explicitly to such desire [48]. In contrast, the other subcomponents, such as discovery and customization motivations, do not entail similar incentives to use gaming as a means to escape. It is thus important to disentangle the distinctions between escapism motivation and the other subcomponents of immersion motivation in this meta-analysis.

In contrast to the substantial differences among the subcomponents of immersion motivation, there are fewer distinctions among the subcomponents of achievement motivation and social motivation with respect to their association with IGD. There are 3 subcomponents of achievement motivation. Advancement motivation refers to the desire to accumulate in-game rewards, mechanics motivation describes the urge to understand the gameplay mechanism, and competition motivation refers to the incentive to challenge and outcompete other players. Studies have shown moderately positive associations between all 3 subcomponents and IGD [42,49].

Social motivation also comprises 3 subcomponents. Socializing motivation describes players' intention to establish casual social relations with other players, relationship motivation refers to players' desire to maintain long-term social relations through gaming, and teamwork motivation describes players' interest in collaborating with other players during gameplay. Past studies have revealed few differences among the 3 social motivation subcomponents with respect to their associations with IGD [50,51].

Considering these findings, we hypothesize that there will be significant differences among the immersion motivation subcomponents in terms of their associations with IGD, but there will be no such significant differences among the subcomponents of achievement motivation or those of social motivation.

Cultural Dimensions

We further posited that the magnitude of the association between gaming motivation and IGD varied by some cultural factors. Cross-cultural psychologists have maintained that people's thoughts and behaviors are often shaped by the culture in which they reside [52,53]. Specifically, one of the most widely studied cultural dimensions is individualism-collectivism [54,55]. In individualistic cultures, the self-interest of individuals is generally regarded to be of greater importance than the collective interests of the group, whereas in collectivistic cultures, it is the collective interests of the group that take precedence [56,57].

We hypothesize that the cultural dimension of individualism-collectivism may also explain the differential magnitudes of the association between IGD and gaming motivation, escapism motivation in particular. Such assertion is made based on past studies that documented cross-cultural differences in the way that members of a society interpret the non-normative behaviors such as excessive gaming. For instance, members of individualistic societies tend to view behavioral addiction or substance addiction as a consequence of one's own choices or personality, whereas members of collectivistic societies tend to attribute it to such interpersonal factors as the influence of the social environment or such institutional factors as government policy [58].

In the context of IGD, such cultural differences are reflected in the preventive approaches implemented in different regions. For example, legislation concerning prevention programs for IGD is more commonly observed in collectivistic countries such as Japan and South Korea [59]. These regions place stronger emphasis on the need for parental and teacher supervision of youngsters' gaming activities [60,61]. Such policies are less common in Western individualistic countries. Hence, in societies emphasizing collectivistic values, players with stronger escapism motivation may more likely receive attention from their parents or teachers and benefit from prevention programs before their gaming activities evolve into problematic or addictive gaming. In individualistic societies, where similar prevention programs are less accessible, players who wish to escape real-life issues through gaming may not receive sufficient social support and attention to prevent the onset of IGD. In summary, we hypothesize that the association between escapism motivation and IGD may be stronger in studies conducted in individualistic (vs collectivistic) regions.

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Methods

Literature Search

The PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines were adhered to when this meta-analysis was performed and when the findings were reported. To identify relevant reports for this meta-analysis, we performed a multistage literature search using diverse methods in April 2019 with an update in March 2020. In the first stage, electronic bibliographic searches were conducted using 3 meta-databases: ProQuest, EBSCOhost, and Scopus. The following Boolean string was used in the search for relevant articles: ("Internet gam*" OR "online gam*" OR "digital gam*") AND ("disorder" OR "abuse" OR "addict*" OR "compulsi*" OR "dependenc*" OR "excess*" OR "pathologic*" OR "problematic").

In the next stage, we manually located reports that could not be identified in the first stage. First, the reference sections of previous meta-analyses related to the topic of IGD were scanned [3,6]. Second, bibliographic searches were performed on the aforementioned meta-databases for studies citing instruments of IGD and gaming motivation. Third, a review of the "gray literature" was performed to identify relevant unpublished reports (eg, regional literature databases, online archives). In the final stage, we contacted authors of some reports identified for further clarification and the provision of missing data.

Study Inclusion and Exclusion Criteria

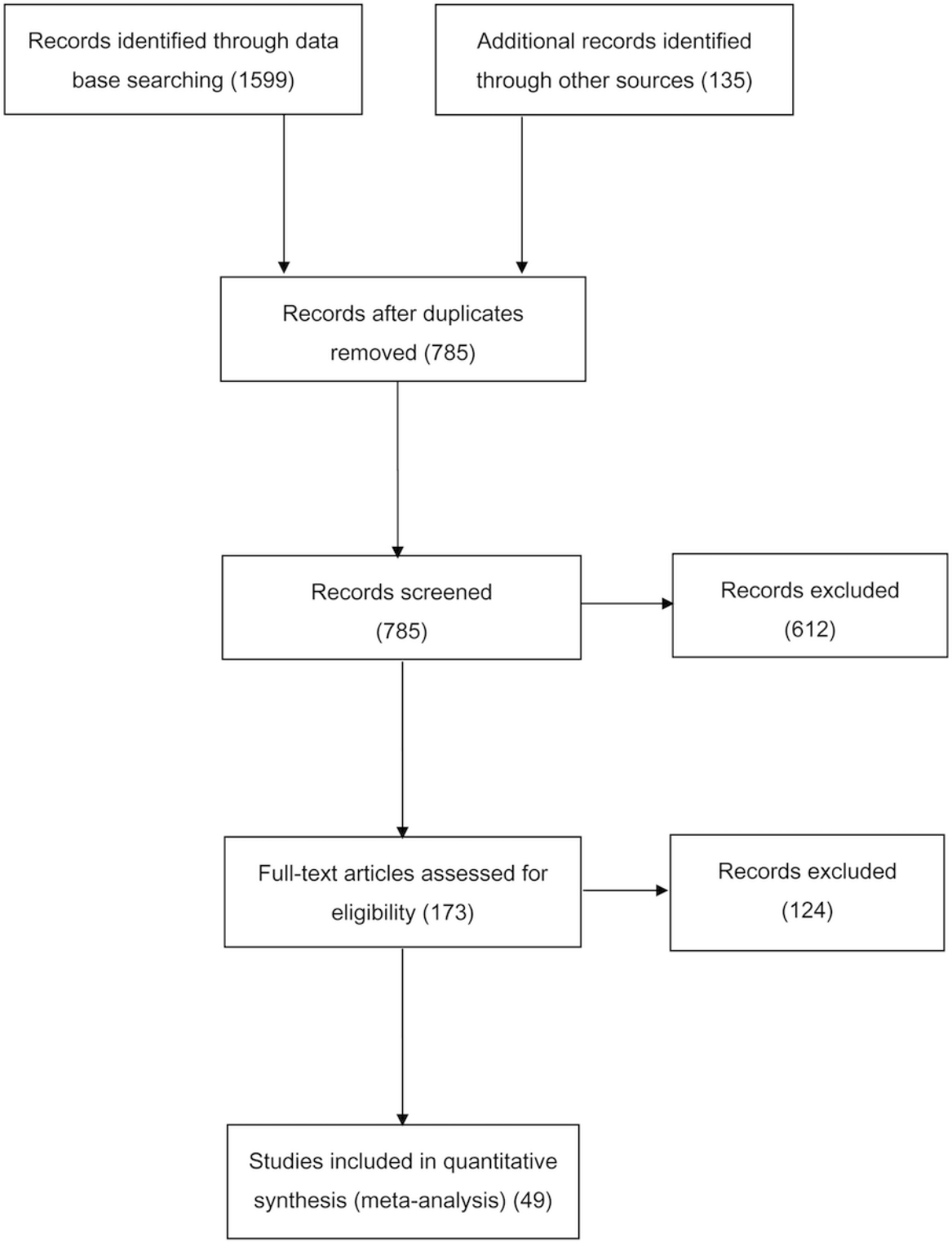
To be included in this review, reports identified in the literature search had to contain at least one quantitative measure of IGD and at least one quantitative measure of gaming motivation. Reports were excluded if they (1) included qualitative data alone, (2) used measures assessing only the problematic use of internet activities or offline gaming but not internet gaming, (3) employed a measure of either IGD or gaming motivation but not both, or (4) lacked sufficient information for effect size calculation. No exclusions were made based on language.

Report Selection Process

Two independent reviewers performed the initial screening of the reports based on their titles, abstracts, keywords, or a combination thereof. After the initial screening, the full text of the remaining reports was retrieved for data extraction. Figure 1 presents a PRISMA flow diagram illustrating the report selection process, which yielded the final pool of 49 eligible reports.

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Figure 1. PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) diagram illustrating the procedures of report selection in the meta-analysis.



Coding of Effect Sizes and Moderators

Data Extraction Process

The 2 reviewers who performed the screening task also independently extracted the following data: number of participants, sex and age composition, research design, geographical location of the study, measures of IGD and gaming motivation used, gaming motivation components and subcomponents, and the corresponding effect size estimates for the associations between IGD and gaming motivation. Any discrepancies in coding were resolved by a discussion with the senior author who was not involved in the coding process. The interrater reliability index of Krippendorff α coefficient was .92 [62], indicating a high level of interreviewer reliability.

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Effect Size Metric

The Pearson product-moment correlation coefficient (*r*) was selected as the effect size metric for its ease of interpretation. When such an effect size could not be found, other relevant statistics (ie, chi-square, Cohen *d*) were extracted and then converted into *r* using the "compute.es" statistical package in the R programing environment (version 4.0.0; R Foundation for Statistical Computing) [63,64].

Coding of Effect Size Estimates

The reviewers extracted all relevant effect size estimates pertaining to the associations between gaming motivation and IGD. We extracted all effect size estimates of the associations of IGD with the 3 gaming motivation components (ie, achievement, immersion, and social) and IGD and with the gaming motivation subcomponents and IGD based on the aforementioned 10-factor motivation model [28]. For the studies that used instruments based on this model or other conceptually similar models, effect size estimates were extracted.

A Priori Moderators

All the a priori moderators described in the Introduction were coded during data extraction. First, the motivation component was coded as a 3-level categorical variable (ie, achievement, immersion, and social). Second, the subcomponents categorized under each motivation component were coded as a categorical variable. For instance, the subcomponents related to achievement motivation were coded as advancement, mechanics, and competition, and those related to social motivation were coded as socializing, relationship, and teamwork. Those related to immersion motivation were coded as a 4-level categorical variable: discovery motivation, role-playing motivation, customization motivation, and escapism motivation.

Finally, the moderator variable of individualism was defined as a continuous variable, with higher scores assigned to regions with higher individualistic cultural values. We first recorded the geographical locations in which individual samples were recruited and then ascribed a national individualism score to each sample based on Hofstede's data matrix [65].

Meta-analytic Procedures

Three-level mixed-effects meta-analysis was adopted in this study. Conventional meta-analytic methods may generate biased effect size estimates when effect sizes are not independent. In this meta-analysis, there were many reports (77%) with multiple effect sizes for the associations between the various components of gaming motivation and IGD. It was thus necessary to perform 3-level meta-analysis using the structure of a multilevel model, with level 1 analyzing effect sizes, level 2 analyzing independent samples, and level 3 analyzing individual reports [66].

Main effect analysis was conducted using the metaSEM package version 1.2.0 [67] and metafor package version 2.4.0 [68] in the R programming environment [64]. Such analyses examined the magnitude and direction of the association of IGD with the various gaming motivation components and subcomponents. Maximum likelihood estimation was performed to estimate 95% CI.

The Cochran *Q* statistic was examined to evaluate the presence of heterogeneity and determine whether the effect size was consistent across reports. In addition, the I^2 index was also calculated to evaluate between-study heterogeneity. If both the *Q* statistic and I^2 index indicated a significant level of heterogeneity, 3-level mixed-effects meta-analysis was performed to further examine the variability across reports using the metaSEM package.

Detection of Possible Bias Risks (Omnibus Analysis)

Study Quality

The quality of each report was evaluated based on 8 indicators [69,70]: sampling method, sample heterogeneity, statistical power, sample description, measurement validity, measurement reliability, study methodology, and study design. The criteria used for coding the various indicators are summarized in Table 1. An individual report was assigned a value of 1 for meeting the criteria of each indicator and a value of 0 for failing to do so, except for scale reliability and scale validity, both of which were coded as continuous variables. To determine whether the quality of individual reports exerted an influence on the magnitude of a correlation, we tested the moderating effects of study quality using the 8 individual indicators and the composite score.

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Table 1. Coding criteria for study quality indicators.

Quality indicators[a]	Criteria met (score=1)	Criteria not met (score=0)
Sampling method	Sampling involved random selection of participations	Sampling involved nonrandom methods
Sample heterogeneity	Sample comprised 2 or more demographic groups	Sample included only a single group
Statistical power	Sample size was large enough to yield adequate statistical power	Sample size was not sufficient to yield adequate statistic power
Sample description	Demographic information was clearly described	Demographic information was not clearly described
Measurement validity	All scales used in the study were validated	None were validated
Measurement reliability	All scales were reliable (Cronbach $\alpha \geq .70$)	No scales were reliable (Cronbach $\alpha \geq .70$)
Study methodology	Study adopted 2 or more methodologies	Study adopted only 1 methodology
Study design	Data were collected at 2 or more time points	Data were collected at only 1 time point

[a]The indicators of scale reliability and scale validity were coded as continuous variables (ie, percentage of scales that were reliable or valid, respectively). The other indicators were all coded as dichotomous variables.

Publication Bias

To address the potential issues of publication bias, we adopted several common methods. First, the fail-safe *N* was employed to estimate the number of unpublished or missing reports with an effect size averaging 0 that would nullify the effect observed in the meta-analysis. Publication bias was a potential concern if the fail-safe *N* was smaller than $5k + 10$ (k = the number of studies) based on established criteria [71]. Second, publication bias was evaluated by funnel plots and Egger tests derived from weighted regression [72], with asymmetrical funnel plots indicating publication bias. The potential issue of asymmetry was also indicated by significant Egger test results. Finally, we employed the trim-and-fill technique, which estimates the number of missing reports and provides an estimate of the effect size after publication bias has been taken into account [73]. If the adjusted effect size is vastly different from that yielded prior to such adjustment, publication bias is a likely concern. These analyses were performed using the metafor package in the R programming environment.

Results

Descriptions of the Data Set

The majority of the 49 studies included in this analysis were published in academic journals (89%), and the remainder included 6 unpublished dissertations and 2 conference proceedings. Most were published after 2008, when studies on IGD began to be seen. Moreover, 74% were published after 2014, when the American Psychiatric Association listed IGD in the DSM-5 as a condition for further study [74].

The aggregate number of participants in the meta-analysis of this study was 52,254 (mean 1022, *SD* 1249.37, range 59-5222). The participants were recruited from 86 independent samples. The mean age across the samples was 26.51 (*SD* 5.03, range 12.90-34.23), and 68% of the participants were men. The samples were recruited from 23 countries across multiple geographical regions, including Europe (54%), Asia (25%), North America (16%), and other regions (5%).

To assess IGD symptoms, some of the included studies adopted the DSM criteria [74]. Other popular such measures included the Addiction-Engagement Questionnaire [75], Game Addiction Scale [76], Internet Gaming Disorder Test [7], and Problematic Online Gaming Questionnaire [77]. Moreover, some studies adapted Young's Internet Addition Test [78] to measure IGD symptoms. To assess gaming motivation, most of the included studies employed the Motivation to Play in Online Games Questionnaire [28], followed by the Motives for Online Gaming Questionnaire [79] and Online Gaming Motivations Scale [80]. All the subscales of these gaming motivation measures can be mapped onto Yee's hierarchical model [28], except for the "fantasy" subscale. The results involving this subscale were omitted in this meta-analysis.

Main-Effect Meta-analysis

Gaming Motivation Components and IGD

To examine the associations between the 3 gaming motivation components (ie, achievement, social, and immersion) and IGD, 3 sets of 3-level meta-analysis were performed based on 64 effect size estimates extracted from 22 reports. The results are summarized in Table 2. Significant positive correlations were identified for the association between each gaming motivation component and IGD. The correlation between the achievement motivation and IGD was 0.32, indicating a medium effect size, whereas that between the other 2 types of motivation and IGD was small to medium in magnitude (r=0.20 and r=0.22).

As shown in Table 2, the Cochran's Q test results revealed significant heterogeneity in the effect size estimates of all 3 gaming motivation components. In addition, the I^2 statistics indicated a moderate to high degree of between-study heterogeneity [81]. Accordingly, 3-level mixed-effects meta-analysis was performed to examine the hypothesized moderating effects of the 4 a priori moderators.

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Table 2. Correlation coefficients of problematic gaming with gaming motivation components and subcomponents. Subscripts that do not share a common number (for comparisons among components) or symbol (for comparisons among subcomponents) differ significantly at $P<.05$.

Gaming motivation	k[a] value	r[b] value	95% CI value	Q[c] value	I^2[d] value	I^2[e] value
Achievement component[f]	21	0.32[g]$_1$	0.27 to 0.36	182.21[g]	0.91	0.03
Advancement subcomponent	10	0.29[g]$_*$	0.25 to 0.35	310.14[g]	0.52	N/A[h]
Mechanics subcomponent	9	0.28[g]$_*$	0.25 to 0.33	11.01	0.36	N/A
Competition subcomponent	24	0.31[g]$_*$	0.23 to 0.42	1341.25[g]	0.74	0.11
Social component[i]	27	0.20[g]$_2$	0.14 to 0.29	844.90[g]	0.78	0.18
Socializing subcomponent	27	0.17[g]$_\#$	0.09 to 0.26	1291.76[g]	0.84	0.12
Relationship subcomponent	11	0.25[g]$_*$	0.13 to 0.32	101.42[g]	0.88	N/A
Teamwork subcomponent	8	0.08$	−0.09 to 0.22	145.01[g]	0.49	N/A
Immersion component[j]	16	0.22[g]$_2$	0.13 to 0.30	341.22[g]	0.80	0.13
Discovery subcomponent	8	0.07$	−0.01 to 0.17	40.87[g]	0.41	N/A
Role-play subcomponent	24	0.22[g]$_\#$	0.14 to 0.32	2143.22[g]	0.54	N/A
Customization subcomponent	8	0.21[g]$_\#$	0.15 to 0.30	50.41[g]	0.41	N/A
Escapism subcomponent	44	0.40[g]$_*$	0.35 to 0.45	1510.22[g]	0.70	0.21

[a]*k:* number of tested correlations.

[b]*r:* pooled correlation coefficient.

[c]*Q:* Cochrane heterogeneity statistic.

[d]I^2: level 2 heterogeneity index.

[e]I^2: level 3 heterogeneity index.

[f]Comprises the advancement, mechanics, and competition subcomponents.

[g]$P<.001$.

[h]N/A: not applicable.

[i]Comprises the socializing, relationship, and teamwork subcomponents.

[j]Comprises the discovery, role-play, customization, and escapism subcomponents.

Gaming Motivation Subcomponents and IGD

As summarized in Table 2, significant positive correlations were identified for 8 of the subcomponents (r ranging from 0.17 to 0.40), but those for the teamwork and the discovery subcomponents were not significant (r=0.08 and r=0.07, respectively).

The magnitude of the correlations between all 3 subcomponents of achievement motivation and IGD was moderate (r= 0.29 for advancement, r=0.28 for mechanics, and r=0.31 for competition). For the subcomponents of social motivation, the magnitude of the correlations with IGD was small to moderate for socializing and relationship motivation (r=0.17 and r=0.25, respectively) but not significant for teamwork motivation (r=0.08). The results for the subcomponents of immersion motivation were more diverse. The association between escapism motivation and IGD showed the strongest correlation (r=0.40), whereas the magnitude of the correlations with IGD was small to moderate for the role-play and the customization subcomponents (r=0.22 and r=0.21, respectively). The discovery motivation subcomponent was found to have no significant association with IGD (r=0.07).

The Cochran Q heterogeneity statistics indicated significant between-study heterogeneity for all the gaming motivation subcomponents except mechanics motivation (Q=20.14, P=.08). Similarly, the I^2 statistics also revealed a moderate to high degree of between-study heterogeneity in the effect size estimates [81].

Moderator Analysis

Moderating Role of Gaming Motivation Components

For the moderator of the gaming motivation component, the findings from the 3-level mixed-effects meta-analysis supported our hypothesis that this variable moderated the association between gaming motivation and IGD (Q_M=1199.27, $P<.001$). Pairwise comparisons indicated IGD to have a significantly stronger correlation with achievement motivation than with social or immersion motivation (all $P<.001$). However, only a marginally significant difference between the social

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motivation–IGD correlation and the immersion motivation–IGD correlation was identified (P=.15).

Moderating Role of Gaming Motivation Subcomponents

A series of 3-level mixed-effects meta-analysis was performed to examine the moderating effects of the gaming motivation subcomponents of the 3 motivation components.

In the first set, the results corroborated our hypothesis that the subcomponents of achievement motivation were not a significant moderator (Q_M=9.81, P=.09). In the second set, however, the results were contrary to our hypothesis concerning the subcomponents of social motivation, indicating that they significantly moderated the association of social motivation with IGD (Q_M=45.94, P=.01). Pairwise comparisons indicated significantly stronger correlations of IGD with socializing motivation than with relationship or teamwork motivation (all P<.01), and significant differences were identified between the relationship motivation–IGD correlation and the teamwork motivation–IGD correlation (P<.001).

In the third set, the results supported the hypothesized moderating effect of the subcomponents of immersion motivation (Q_M=602.84, P<.001). Further analysis based on pairwise comparisons revealed the correlation of IGD with escapism motivation to be significantly stronger than that with discovery, role-play, or customization motivations (all P<.001). Although no significant differences were identified between the role-play motivation–IGD correlation and the customization motivation–IGD correlation (P=.23), the correlation of IGD with the role-play and customization motivation subcomponents was significantly stronger than that with the discovery motivation subcomponent (P<.001).

Moderating Role of Individualism (vs Collectivism)

Three-level mixed-effects meta-analysis was also conducted to examine the hypothesized moderating role of individualism. The results supported our hypothesis that the cultural dimension of individualism had a significant moderating effect (b=−.0023, SE .0015; P<.001) on the correlation between the escapism subcomponent of immersion motivation and IGD. Simple slope analysis further revealed the positive correlation between IGD and escapism motivation to be stronger among the samples recruited from regions higher versus lower in individualism (r=0.47 vs r=0.25).

Detection of Possible Bias

Study Quality

Moderator analysis was performed to examine the potential influence of study quality on the meta-analysis results based on 8 indicators. The nonsignificant results revealed that study quality did not exert a significant influence on the association between any of the components or subcomponents of gaming motivation and IGD (all P ranging from .16 to .47).

Publication Bias

The various analyses similarly revealed no evidence of publication bias. First, the fail-safe N estimations computed based on the revisited file-drawer test (N ranging from 583 to 12,770) all exceeded the suggested cutoff value ($5k + 10 = 255$). Moreover, the trim-and-fill technique showed no evidence to suggest that publication bias would substantially alter the effect size estimates after the corresponding adjustments. Finally, the Egger regression test revealed no significant asymmetry (all P ranging from .09 to .68), indicating that the effect size estimates were unrelated to sample size.

Discussion

Summary of Findings

This meta-analysis synthesized the growing body of literature and addressed several unresolved research issues in the study of gaming motivation and IGD. First, the findings partially support the hypothesized discrepancies among the 3 gaming motivation components (ie, achievement, social, and immersion) with regard to their associations with IGD. Specifically, IGD tends to have a stronger association with achievement motivation than with immersion motivation or social motivation. However, there is no significant difference between immersion motivation and social motivation, with both showing a weak to moderate positive correlation with IGD. Hence, social motivation should also be acknowledged in the treatment of this emergent disorder.

Regarding the within-component variations, there are no significant differences among the subcomponents of achievement with regard to their associations with IGD. The results for the immersion motivation component are consistent with the escape-from-self theory [46], with the escapism motivation subcomponent demonstrating a considerably stronger association than the other subcomponents (ie, discovery, customization, and role-play motivations) with IGD. Moreover, interest in experiencing the virtual world (ie, discovery motivation) is not identified as a risk factor for IGD. This meta-analysis thus highlights the importance of distinguishing between motivation to explore the virtual world and motivation to use gaming to escape from various real-life issues.

The results for the social motivation component contradict our hypothesis. Our findings show that the relationship subcomponent has a considerably stronger association than the socializing or the teamwork subcomponent with IGD. These findings substantiate the postulation that “social obligation” can contribute to excessive gameplay in socially oriented players [38]. Although the collaborative gameplay design of many online games may increase players’ online social capital [37,82], it can require players to unwillingly engage in gaming for the collective benefit of the gaming team [83]. Such obligation can lead to excessive gameplay and decrease the resources needed to maintain offline social relations [84,85]. Moreover, the nonsignificant association between the teamwork subcomponent and IGD further indicates that collaborative gameplay itself does not directly influence the onset of IGD. Thus, only the socializing and the relationship motivation subcomponents should be acknowledged as relevant to IGD and its treatment.

Implications for Assessment and Treatment

This meta-analysis has implications for researchers. Specifically, the considerable discrepancies identified among the subcomponents of social motivation and immersion motivation highlight the importance of assessing gaming motivation at the

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subcomponent level. The 3 broad components of gaming describe 3 distinct domains of motivation for gameplay, but these domains also encompass multiple subcomponents that need to be evaluated in diverse ways. For instance, exclusive examination of the social motivation component may lead to neglect of the differences between players' interest in forming social relations and their interest in collaborating with other players. To provide a more comprehensive examination of gaming motivation, future studies should investigate gaming motivation at both the component and subcomponent levels.

Our meta-analysis also has implications for clinicians and practitioners. Some scholars have maintained that a shortcoming of current cognitive therapy–based interventions is the lack of measures to evaluate the cognitions associated with IGD [86,87]. To bridge this knowledge gap, discerning among the multiple motivations for gaming may help practitioners identify the underlying problematic cognition and use specific treatment programs. For example, clients with a stronger social gaming motivation may more likely believe gaming to be the only means of forming social relations; thus, it may be helpful to incorporate programs that strengthen their social skills in face-to-face interactions [27,88]. However, reviews of IGD treatment programs indicate that gaming motivation is rarely considered [86]. Thus, practitioners should consider evaluating their clients' gaming motivation and then tailor treatment programs to specifically address the corresponding problems.

Research Caveats and Directions for Future Research

As our findings are limited by the available studies, there are several research caveats. First, it is noteworthy that Yee's motivation taxonomy [28] was originally developed from samples of massively multiplayer online role-playing game players, so some of its motives (eg, role-play, customization) are specifically related to this game genre. Some studies have revealed certain genres (eg, massively multiplayer online role-playing game, first-person shooter) to have a stronger tendency to elicit IGD among players with specific types of gaming motivation, including social and immersion motivation [21]. In response to the increasingly diversified gameplay designs, some scholars have called for greater effort in investigating the role of game genre in the motivation and behavior across players of various game genres [89,90]. Moreover, although most subscales of the included gaming motivation measures are covered in Yee's framework [28], there are a few exceptions (eg, fantasy) that cannot be mapped onto the framework. Researchers may integrate Yee's framework with other existing ones to broaden coverage.

Second, a large number of studies included in our meta-analysis recruited players who are highly committed to gaming, so our findings are not necessarily generalizable to the increasing number of casual players who play occasionally, as these players may have distinct interpretations of gaming motivations [91]. For example, committed players tend to perceive social gaming motivation as their desire to build and maintain online social relations through gaming activities [92]. For casual players, however, this type of gaming motivation primarily indicates their interest in playing with members of their offline social circle in a group context [91]. Thus, the scope of future studies should be expanded to include different types of players (eg, committed vs casual players) to allow comparisons of their potentially distinct interpretations of gaming motivation.

Third, as our meta-analysis mainly included studies that examined IGD based on composite scores for multiple symptoms, our findings may not be generalizable to specific symptoms of IGD [24,93] such as preoccupation with gaming activities or unsuccessful attempts to control gaming activities. Studies using composite scores for multiple symptoms may be unable to distinguish among the varying magnitudes of the association of gaming motivation with different symptoms of IGD. For example, the associations between social gaming motivation and preoccupation with gaming activities and a deterioration in interpersonal relations were found to be stronger than the association between such motivation and academic problems [94]. Future studies should thus investigate the specific symptoms of IGD to allow comparisons of their potential differing associations with gaming motivation.

Finally, all the studies included in this systematic review adopted self-report questionnaires to assess both gaming motivation and IGD symptoms. The survey method is susceptible to various methodological biases in responding and recall [95], and no causal links can be inferred. Greater effort should be expended to the design of experiments or quasi-experiments to test the causal relationships between gaming motivation and IGD.

Conclusions

This meta-analysis explores several issues in the study of gaming motivation and IGD. First, IGD was found to be more strongly associated with achievement motivation than with immersion motivation or social motivation; however, both of the latter components had weak positive associations with IGD. Second, our analysis at the subcomponent level strongly corroborates escape-from-self theory, with escapism motivation demonstrating a significantly stronger association than the other conceptually related subcomponents with IGD. Finally, our cross-cultural analysis identified the individualism-collectivism dimension to be a significant moderator of the association between escapism motivation and IGD, with a stronger such association found for studies conducted in individualistic countries than in those conducted in collectivistic countries.

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Conflicts of Interest

None declared.

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Abbreviations

DSM-5: Diagnostic and Statistical Manual of Mental Disorders

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ICD-11: International Classification of Diseases, Eleventh Revision
IGD: internet gaming disorder
PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses

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Review

Feasibility and Efficacy of Virtual Reality Interventions to Improve Psychosocial Functioning in Psychosis: Systematic Review

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Abstract

Background: Functional recovery in psychosis remains a challenge despite current evidence-based treatment approaches. To address this problem, innovative interventions using virtual reality (VR) have recently been developed. VR technologies have enabled the development of realistic environments in which individuals with psychosis can receive psychosocial treatment interventions in more ecological settings than traditional clinics. These interventions may therefore increase the transfer of learned psychosocial skills to real-world environments, thereby promoting long-term functional recovery. However, the overall feasibility and efficacy of such interventions within the psychosis population remain unclear.

Objective: This systematic review aims to investigate whether VR-based psychosocial interventions are feasible and enjoyable for individuals with psychosis, synthesize current evidence on the efficacy of VR-based psychosocial interventions for psychosis, and identify the limitations in the current literature to guide future research.

Methods: This research followed the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines. Literature searches were conducted in PubMed and PsycINFO in May 2021. We searched for peer-reviewed English articles that used a psychosocial intervention with a VR component. Participants in the included studies were diagnosed with schizophrenia, schizoaffective disorder, or another psychotic disorder. The included studies were divided into four categories as follows: cognitive remediation interventions, social skills interventions, vocational skills interventions, and auditory verbal hallucinations and paranoia interventions. The risk of bias assessment was performed for each study.

Results: A total of 18 studies were included in this systematic review. Of these 18 studies, 4 (22%) studies used a cognitive remediation intervention, 4 (22%) studies used a social skills intervention, 3 (17%) studies used a vocational skills intervention, and 7 (39%) studies implemented an intervention aimed at improving auditory verbal hallucinations or paranoia. A total of 745 individuals with psychosis were included in the study. All the studies that evaluated feasibility showed that VR-based psychosocial interventions were feasible and enjoyable for individuals with psychosis. The preliminary evidence on efficacy included in this review suggests that VR-based psychosocial interventions can improve cognitive, social, and vocational skills in individuals with psychosis. VR-based interventions may also improve the symptoms of auditory verbal hallucinations and paranoia. The skills that participants learned through these interventions were durable, transferred into real-world environments, and led to improved functional outcomes, such as autonomy, managing housework, and work performance.

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Conclusions: VR-based interventions may represent a novel and efficacious approach for improving psychosocial functioning in psychosis. Therefore, VR-based psychosocial interventions represent a promising adjunctive therapy for the treatment of psychosis, which may be used to improve psychosocial skills, community functioning, and quality of life.

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KEYWORDS

auditory verbal hallucinations; cognitive remediation; functional outcomes; neurocognition; paranoia; psychosis; schizophrenia; social skills; virtual reality (VR); vocational skills

Introduction

Background

Psychosis is a mental state characterized by hallucinations, delusions, disorganized thoughts, disorganized speech, and disorganized or catatonic behavior [1]. People with psychosis often experience social and cognitive impairments [2,3]. This panoply of symptoms is associated with widespread debilitating effects on functioning in people with psychosis [4-6]. Although current pharmacological treatments (ie, antipsychotic medications) are often successful in remediating the positive symptoms related to psychosis, some individuals experience persistent symptoms, including auditory verbal hallucinations and paranoia [7,8]. Furthermore, antipsychotic medications have shown limited efficacy in improving cognitive and psychosocial functioning [9-12]. Hence, adjunctive interventions aimed at improving psychosocial outcomes are critical for the comprehensive and holistic treatment of psychosis [13,14].

Existing psychosocial interventions used in patients with psychosis typically focus on improving cognitive, social, or vocational skills [15,16]. Cognitive interventions target improvements in various cognitive domains, including attention, executive function, and working and verbal memory [17,18]. Social skills interventions target social cognition and social skills through technology, cognitive behavioral techniques, psychoeducation, and life management skills [15]. Finally, vocational skills interventions specifically aim to improve employment rates for individuals with psychosis [16,19]. These interventions have been shown to improve symptomatic *and* functional outcomes in individuals with psychosis [15,16]. However, the long-term maintenance of these positive outcomes, along with the generalizability and transfer of learned skills to real-world environments, remains a challenge [14,15,20]. For instance, current psychosocial interventions for individuals with psychosis are often offered in clinical settings, which may restrict the transfer of learned skills outside of the clinic [21,22]. Therefore, the development of more ecological interventions is needed.

Over the past decade, advancements in virtual reality (VR) technology have expanded the types of psychosocial interventions that can be offered to patients with psychosis [23,24]. VR involves computer technology that enables the perception of multisensory stimuli within immersive, 3D, complex environments [25,26]. With VR, patients can practice functioning in familiar settings, which may allow them to develop skills that are more generalizable to real-world situations [27,28]. Furthermore, health care providers can interact with patients in the VR environment in real time, offering in situ therapy, support, and guidance [27]. These features of VR technology have previously been used in the treatment of several psychiatric and medical conditions, including anxiety disorders (where VR has been integrated with cognitive behavioral therapy and exposure therapy) [29], traumatic brain injury [30], multiple sclerosis [31], and stroke [32]. More recently, VR-based interventions have been implemented to improve auditory verbal hallucinations and paranoia in psychosis, where traditional treatment approaches for these symptoms are limited to cognitive behavioral therapy, electroconvulsive therapy, or transcranial magnetic stimulation [33,34]. Hence, VR represents a promising tool for psychosocial interventions in psychosis because of its increased capacity for ecological validity and its potential to be more engaging than traditional interventions [24,32,35,36].

Although there is some empirical evidence suggesting that VR-based psychosocial interventions may improve symptoms and community functioning in individuals with psychosis [37,38], there are no systematic reviews focusing on this topic. Furthermore, there are known possible risks and side effects associated with the use of VR, including fatigue and simulator sickness [36]. However, the adverse effects of VR-based psychosocial interventions on psychosis have not been systematically investigated. Therefore, to fill these knowledge gaps, this study systematically reviewed the literature to explore the effects of VR-based psychosocial interventions in individuals with psychosis.

Objectives

This systematic review aims to (1) investigate whether VR-based psychosocial interventions are feasible and enjoyable for individuals with psychosis, (2) synthesize current evidence on the efficacy of VR-based psychosocial interventions for psychosis, and (3) identify the limitations in the current literature to guide future research.

Methods

This systematic review followed the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines [39].

Search Strategy

We conducted a broad search of the published literature using the following search strategy: (*treatment* OR *therapy* OR *intervention* OR *training* OR *rehabilitation*) AND (*schizophrenia* OR schizoaffective OR *psychosis*) AND (*virtual reality*). Searches were executed in PubMed and PsycINFO on May 20, 2021. Searches were limited to English language

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sources with no limits on setting, date, age group, or geographical restrictions. The reference lists of the included studies were reviewed to identify additional potential records.

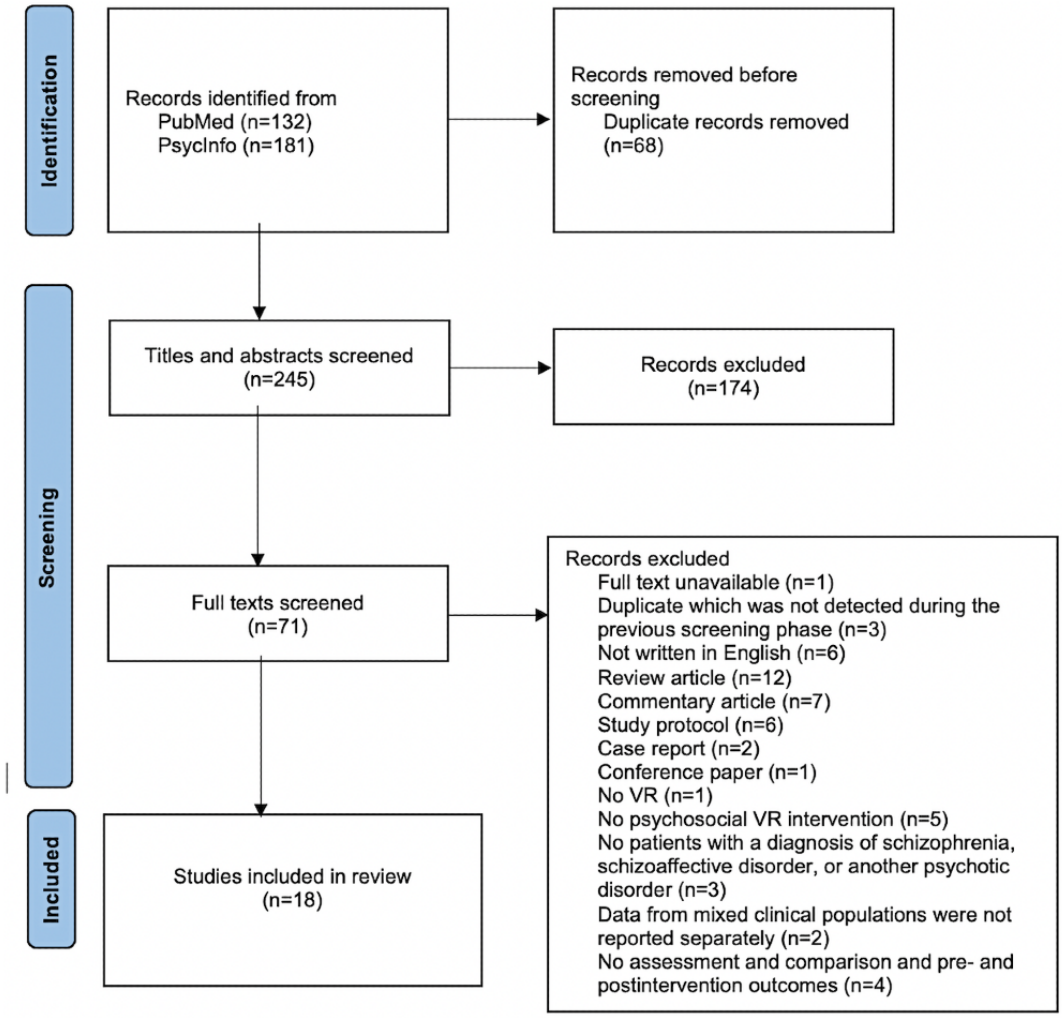
Eligibility Criteria

Studies were included if they (1) were a randomized controlled trial (RCT), randomized comparative trial, randomized partial crossover trial, nonrandomized controlled trial, or single-arm study; (2) used a psychosocial intervention with a VR component; and (3) included participants with schizophrenia, schizoaffective disorder, or other psychotic disorders. The inclusion of a control group was not an eligibility criterion. Studies were excluded if they (1) were not available in English; (2) were a review article, commentary, study protocol, case report, or conference paper; (3) included a mixed clinical population (eg, combined participants with a psychotic disorder and participants with a mood disorder); or (4) did not assess and compare pre- versus postintervention outcomes.

Study Selection

Figure 1 summarizes the study selection process. We identified 313 records from our literature search (PubMed=132; PsycINFO=181). Once duplicates were removed, at least 2 authors (AHS, BJMB, TTR, AT, or HM) screened the titles and abstracts of the remaining 245 (78.3%) studies (disagreements were resolved through discussion until consensus was reached). A total of 71 (29%) studies met the eligibility criteria and subsequently underwent full-text review. At least two authors (AHS, BJMB, TTR, AT, or HM) screened each study (disagreements were resolved through discussion until consensus was reached). A total of 18 (25%) studies were included in the final narrative synthesis of this systematic review.

Figure 1. PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flow diagram. VR: virtual reality.



Data Extraction

The following information was extracted from the included studies: author, year of publication, country, sample size, diagnosis of participants, mean age of participants, study design, blinding protocol, VR condition, control condition, number and duration of VR sessions, type of VR system, type of VR-based psychosocial interventions and exercises, feasibility, measured outcomes, and main findings. The extracted information was independently cross-checked by at least 2 authors (AHS, BJMB, TTR, AT, or HM).

Risk of Bias Assessment

Risk of bias assessments for the included RCTs and the single randomized comparative trial was performed using the Cochrane risk-of-bias tool for randomized trials (version 2) [40]. Modified versions of the Cochrane risk-of-bias tool for randomized trials (version 2) were used to assess the risk of bias in a single

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randomized partial crossover trial [41] and single-arm studies [42]. Finally, the Newcastle-Ottawa Quality Assessment Scale was used to assess the risk of bias in nonrandomized controlled trials [43]. The risk of bias assessment for each study was independently evaluated by 2 authors (AHS, BJMB, AT, or HM). Disagreements were resolved through discussion until a consensus was reached. Multimedia Appendix 1 [40,42-61] provides more information on each tool used to assess the risk of bias in the included studies.

Results

General Characteristics of the Included Studies

Of the 18 studies included in this systematic review, 4 (22%) studies used a cognitive remediation intervention, 4 (22%) studies used a social skills intervention, 3 (17%) studies used a vocational skills intervention, and 7 (39%) studies used an intervention aimed at improving auditory verbal hallucinations or paranoia. Table 1 provides a general summary of the included studies. Table S1 in Multimedia Appendix 2 [44-61] provides further details of the studies included in this systematic review.

A total of 3 of the 4 (75%) cognitive remediation studies required participants to complete daily life tasks in VR, which involved the use of common cognitive skills, such as shopping using a list or navigating in public transit [44,46,47]. The other cognitive remediation intervention used VR games to train the fluid intelligence [45]. Figure 2 provides an example of a VR environment used in a cognitive remediation intervention [47].

All social skills interventions required participants to interact socially with the avatars. Feedback was provided to the participants by the avatars or the therapist during the VR intervention [48-51]. Figures 3 and 4 provide examples of VR environments used in social skills interventions [48,50].

In all, 2 (67%) of the vocational skills intervention studies focused on developing work-related skills in specific job environments, such as in a boutique [54], convenience store, and supermarket [53]. The other vocational skills intervention study trained participants on job interviewing skills [52]. The VR scenarios were chosen based on common settings in which individuals with mental illness might find employment [53,54].

Within the auditory verbal hallucinations or paranoia category, 3 studies used the same intervention in which participants created avatars that most accurately resembled the entity they believed was the source of their hallucinations [55-57]. Participants then engaged in a dialogue with these avatars, which were animated in real time by a therapist. Within this category, 3 other studies also used the same intervention that involved VR-based cognitive behavioral therapy to reduce paranoia and improve social participation [58,60,61]. In these studies, participants interacted with avatars in VR-based social environments while simultaneously communicating with a therapist. Finally, the remaining study used an intervention in which participants met pedestrians while navigating through a virtual street [59]. Participants subsequently had to recollect the pedestrians' facial affect. Participants graded their confidence in their responses and received feedback on the accuracy of their memory performance. The feedback served to induce doubt in the participants about their false judgments or errors from the memory task, which was hypothesized to affect the participants' overall judgment process. The aim of this study was to assess the effect of this intervention on delusion severity (ie, the severity of false, fixed beliefs that are resistant to counterevidence).

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Table 1. Summary of included studies.

Study (country)	Sample	Diagnosis of participants	Study design	Control condition	VR[a] exercises	Main findings
Cognitive remediation interventions						
Amado et al [44] (France)	N[b]=7, *k*[c]=1	Schizophrenia or schizoaffective disorder	Single-arm, unblinded, pilot study	N/A[d]	Participants acted as pedestrians in a virtual town and completed tasks that were difficult for them in real life (eg, memorizing an itinerary, shopping, or being on time at a meeting point). After the exercise, participants discussed the possible transfer of skills to their real lives and were assigned a task to perform at home.	Pre- and postintervention assessments: the VR group showed improvements in attention, working memory, prospective memory, retrospective memory, and autonomy. There were no improvements in planning. Postintervention qualitative findings: the VR group reported improvements in their amount of energy to develop concrete plans to look for employment or to return to community activities, sparing time, planning, enriched relatedness, and management of their housework.
Chan et al [45] (Hong Kong)	N=27, *k*=2; experimental: n[e]=12; control: n=15	Schizophrenia	Randomized controlled trial, pilot study	Treatment as usual (attended the usual program in the long-term care facility; did not include VR)	The (1) ball and bird and (2) shark bait activities were chosen to train fluid intelligence. Ball and bird activity: balls of different colors fly toward participants, and they must contact the ball using any part of their body, making the ball "burst" or "transform" into doves. Shark bait activity: participants navigate in the sea and chase a yellow star while avoiding distracters.	Compared with the control group, the VR group showed significant improvements in overall cognitive function, repetition, and memory.
La Paglia et al [46] (Italy)	N=12, *k*=2; experimental: n=6; control: n=6	Schizophrenia	Nonrandomized controlled trial, pilot study	IPT[f] and pharmacological therapy	Tasks to train attention and executive function in VR environments such as a park, valley, beach, and supermarket. For example, participants collected and bought products from a shopping list in a supermarket setting to train executive function.	Pre- and postintervention assessments: both groups showed significant benefits in divided attention. The VR group also showed reduced cognitive deficits and improved planning. After the executive function training (VR supermarket), the experimental group showed improvements in decreased errors, reduced time of execution, and increased observance of rules. After the attention training (VR park, valley, and beach), the experimental group showed improvements in reduced time of execution, decreased perseverative errors, and improved sustained attention.
La Paglia et al [47] (Italy)	N=15, *k*=2; experimental: n=9; control: n=6	Schizophrenia	Nonrandomized controlled trial, pilot study	IPT and pharmacological therapy	Three different virtual environments (park, valley, and beach) featured hierarchical sequences of tasks designed to train attention (eg, catching footballs that were presented at irregular time intervals, identifying and picking a specific type of flower, or picking up specific types of bottles while being alerted to calls and loudspeaker announcements).	Pre- and postintervention assessments: both groups showed improvements in divided attention. The VR group showed improvements in general cognitive functioning, planning, sustained attention, reduced time of execution, decreased requests for assistance, decreased needs of the therapist's intervention, and decreased number of omissions.

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Study (country)	Sample	Diagnosis of participants	Study design	Control condition	VR[a] exercises	Main findings
Social skills interventions						
Adery et al [48] (United States)	N=16, *k*=1	Schizophrenia	Single-arm, single blind, feasibility study	N/A	Three different VR environments were used (bus stop, shop, and cafeteria) to train participants in both microlevel social skills (ie, eye contact and facial expression) and macrolevel social skills (ie, starting conversations and requesting help). Tasks were administered without time constraints.	Pre- and postintervention assessments: the VR group showed improvements in overall clinical symptoms and negative symptoms.
Park et al [49] (Republic of Korea)	N=64, *k*=2; SST-VR[g]: n=33; SST-TR[h]: n=31	Schizophrenia	Randomized controlled trial, single blind, efficacy study	Social skills training using traditional role-playing (in-person with the social skills training therapist as the role-play actor instead of using VR)	Role-play with virtual avatars in environments such as a restaurant or walking down a street. Participants were trained in conversation skills, assertive skills, and emotional expression skills. Helper avatars provided positive and corrective feedback as needed.	Compared with the control group, the VR group showed improvements in conversational skills and assertiveness. Compared with the VR group, the control group showed improvements in nonverbal skills.
Rus-Calafell et al [50] (Spain)	N=12, *k*=1	Schizophrenia or schizoaffective disorder with a deficit in social skills or social functioning	Single-arm, unblinded, pilot study	N/A	The VR program comprised 7 activities that each targeted different social skills. Participants received positive or negative reinforcement from virtual avatars based on their performance in a bar or supermarket environment.	Pre- and postintervention assessments: the VR group showed improvements in negative symptoms, psychopathology, social anxiety and discomfort, avoidance, social functioning, learning in emotion perception, assertive behaviors, and time spent in a conversation.
Vass et al [51] (Hungary)	N=17, *k*=2; VR-ToMIS[i]: n=9; control: n=8	Schizophrenia	Randomized controlled pilot study	Passive VR control condition (participants used the same VR software as the experimental group but without any intervention)	The VR-based targeted theory of mind (ToM) intervention (VR-ToMIS) used cognitive and behavioral therapeutic techniques. Participants engaged in social interactions with an avatar with prerecorded dialogue that was designed to induce ToM impairment (double meaning sentences, overstatements, and irony). After the interaction, participants visualized the inferred emotions of the avatar. The task was also discussed with a therapist.	Pre- and postintervention assessments: VR-ToMIS was associated with improvements in negative symptoms, in 1 neurocognitive field (immediate memory), ToM, and pragmatic language skills, but no significant change in quality of life was detected. These findings were also significantly greater in the VR-ToMIS group compared with the control group.
Vocational skills interventions						
Smith et al [52] (United States)	N=32, *k*=2; VR-JIT[j]: n=21; control: n=11	Schizophrenia or schizoaffective disorder	Randomized controlled trial, single blind, efficacy study	Treatment as usual (which did not include a VR component)	The VR-JIT was designed to improve interviewing skills. Participants completed virtual job interview role plays with a virtual human resources representative that were each approximately 20 minutes in duration.	Pre- and postintervention assessments: the VR group showed improvements in role-play job interview scores. Compared with the control group, the VR group showed improvements in the odds of receiving a job offer at a 6-month follow-up. There was also an association between more training and waiting fewer weeks to receive a job offer.

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Study (country)	Sample	Diagnosis of participants	Study design	Control condition	VR[a] exercises	Main findings
Sohn et al [53] (Republic of Korea)	N=9, *k*=1	Schizophrenia	Single-arm, feasibility study	N/A	The virtual reality-based vocational rehabilitation training program included scenarios with a convenience store employee and supermarket clerk. Each scenario included various situations that trained participants on how to manage problems they may encounter in real life. For example, the convenience store situations included training on the arrangement of goods and training for problematic situations.	Pre- and postintervention assessments: the VR group showed improvements in individual and social performance, general symptoms, verbal memory, and immediate and delayed recall on visual memory. Improvements in positive symptoms showed a trend toward significance.
Tsang and Man [54] (Hong Kong)	N=75, *k*=3; experimental: n=25; TAG[k]: n=25; CG[l]: n=25	Schizophrenia	Randomized controlled trial, single blind, efficacy study	TAG (received therapist-administered vocational training) and conventional treatment group (CG). Neither control group experienced a VR intervention.	The 3D nonimmersive VR training was set in a boutique. The training involved a hierarchical structure divided into levels in which problem-solving competence tests had to be passed to advance levels (pretrainee level, trainee level, and sales level).	Compared with both control groups, the VR group showed improvements in cognitive functioning and executive functioning performance. Compared with the CG, the VR group showed improvements in self-efficacy. Compared with the CG, the VR and TAG groups showed improvements in work performance during an on-site test.
Auditory verbal hallucinations and paranoia interventions						
Dellazizzo et al [55] (Canada)	N=10, *k*=1	Schizophrenia or schizoaffective disorder	Single-arm study	N/A	Participants who had already undergone CBT[m] as part of the study by Dellazizzo et al [56] were invited to complete the VR intervention (ie, after finishing CBT). The VR intervention was identical to that used in Dellazizzo et al [56], which is described further in the table.	The VR group showed improvements in auditory verbal hallucinations, beliefs about voices, depressive symptoms, symptoms of schizophrenia, and quality of life.
Dellazizzo et al [56] (Canada)	N=74, *k*=2; experimental: n=37; control: n=37	Schizophrenia or schizoaffective disorder	Randomized comparative trial, pilot study	CBT with no VR component	Participants created avatars which they believed most resembled the entity which was the source of their most distressing or dominant auditory verbal hallucination. Participants were encouraged to enter a dialogue with their avatar (which was animated in real time by a therapist). The interaction with the avatar became more supportive and less abusive as the intervention progressed. The conversations were designed to target participants' emotional regulation, assertiveness, and self-esteem.	Both groups showed improvements in the severity of their auditory verbal hallucinations and depressive symptoms. The VR group also showed improvements in persecutory beliefs and quality of life. Although the results did not show a statistically significant superiority of the VR intervention over CBT in improving auditory verbal hallucinations, the VR intervention did achieve larger effect sizes, particularly on improving overall auditory verbal hallucinations. The VR intervention was superior to CBT at improving affective symptoms.

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Study (country)	Sample	Diagnosis of participants	Study design	Control condition	VR[a] exercises	Main findings
du Sert et al [57] (Canada)	N=15, *k*=1	Schizophrenia or schizoaffective disorder	Randomized, partial crossover trial, pilot study	Treatment as usual (antipsychotic treatment and meetings with clinicians; no VR component).[n]	Participants created avatars which they believed most resembled the entity which was the source of their most distressing or dominant auditory verbal hallucination. Participants were encouraged to enter a dialogue with their avatar (which was animated in real time by a therapist). The interaction with the avatar became more supportive and less abusive as the intervention progressed. The conversations were designed to target participants' emotional regulation, assertiveness, and self-esteem. [n]	Pre- and postintervention assessments: the VR group showed improvements in auditory verbal hallucinations, beliefs about voices, general symptoms (however, positive and negative symptoms did not significantly improve), and quality of life.
Geraets et al [58] (Netherlands)	N=91, *k*=2; experimental: n=43; control: n=48	Schizophrenia, schizoaffective disorder, or not-otherwise specified psychotic disorder	Randomized controlled trial, single blind	Treatment as usual with no VR component	VR-based CBT for reducing paranoia and improving social participation was used in this study. Evidence-based CBT elements were used by trained psychologists and exercises and behavioral experiments were completed in VR. Participants interacted with human avatars in social environments (a street, bus, café, and supermarket). Characteristics of the social environments (number of avatars and avatars' responses to the participant) could be edited by the therapist, and they communicated with the participant during the VR sessions.	Pre- and postintervention assessments (baseline vs 3-month follow-up): compared with the control group, the VR group showed improvements in average levels of paranoia (feeling suspicious, disliked, and hurt) and negative affect (feeling anxious). Pre- and postintervention assessments (baseline vs 6-month follow-up): compared with the control group, the VR group showed improvements in average levels of paranoia (feeling disliked and hurt) and negative affect (feeling down and insecure). Positive affect did not improve more in the VR group than in the control group. The VR intervention did not change the interplay between affective states and paranoia.
Moritz et al [59] (Germany)	N=33, *k*=1	Schizophrenia	Single-arm, proof of concept study	N/A	Participants met 6 different pedestrians while navigating through a virtual street on 2 occasions (in addition to 1 practice trial) in either a noise or no noise condition. Then, participants participated in a recognition task graded for confidence where they were asked to recollect the pedestrians and their corresponding facial affect. Participants also received feedback on the accuracy of their recall.	Pre- and postintervention assessments: the VR group showed improvements in paranoia. Improvement was associated with lower confidence ratings (both during the experiment, particularly for incorrect responses, and according to retrospective assessment).

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Study (country)	Sample	Diagnosis of participants	Study design	Control condition	VR[a] exercises	Main findings
Pot-Kolder et al [60] (Netherlands)	N=116, *k*=2; experimental: n=58; control: n=58	Schizophrenia, schizoaffective disorder, delusional disorder, or not-otherwise specified psychotic disorder	Randomized controlled trial, single blind	Treatment as usual with no VR component	VR-based CBT for reducing paranoia and improving social participation was used in this study. Evidence-based CBT elements were used by trained psychologists and exercises and behavioral experiments were completed in VR. Participants interacted with human avatars in social environments (a street, bus, café, and supermarket). Characteristics of the social environments (number of avatars and avatars' responses to the participant) could be edited by the therapist and, they communicated with the participant during the VR sessions.	Pre- and postintervention assessments (baseline vs 3-month follow-up): compared with the control group, the VR group showed improvements in momentary paranoid ideation when in the presence of others and momentary anxiety when in the presence of others. The VR group did not show a significant improvement in the amount of time spent with others. Pre- and postintervention assessments (baseline vs 6-month follow-up): the improvements shown at the 3-month follow-up were maintained at the 6-month follow-up. At the postintervention and follow-up time points, quality of life did not differ significantly among groups.
Pot-Kolder et al [61] (Netherlands). [o]	See Pot-Kolder et al [60]	See Pot-Kolder et al [60]	See Pot-Kolder et al [60]	See Pot-Kolder et al [60]	See Pot-Kolder et al [60] for the specific VR exercises used in this study. The main outcomes of this study related to the feasibility of the VR intervention.	Feasibility of the VR intervention: the average incremental cost per quality-adjusted life year was €48,868 (US $55,220.84). When relevant baseline differences were included, the average cost per quality-adjusted life year gained was €42,030 (US $47,493.9).

[a]VR: virtual reality.

[b]N: total sample size.

[c]k: number of groups.

[d]N/A: not applicable.

[e]n: group sample size.

[f]ITP: integrated psychological treatment.

[g]SST-VR: social skills training using VR role-playing.

[h]SST-TR: social skills training using traditional role-playing.

[i]VR-ToMIS: virtual reality-based targeted theory of mind intervention.

[j]VR-JIT: virtual reality job interview training.

[k]TAG: therapy administered group.

[l]CG: conventional group.

[m]CBT: cognitive behavioral therapy.

[n]The group comprised participants who received an "immediate" VR intervention as well as participants who received "delayed" VR intervention (that is, after they participated within a control, treatment as usual group). Both VR interventions were identical.

[o]This study used the same sample as Pot-Kolder et al [60]. This study reported novel outcomes.

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Figure 2. Virtual reality environments developed via the NeuroVr 2.0 software for a cognitive remediation intervention in schizophrenia. The environments include a park (A), valley (B), beach (C), and supermarket (D). Images reproduced with author permission from La Paglia [46].

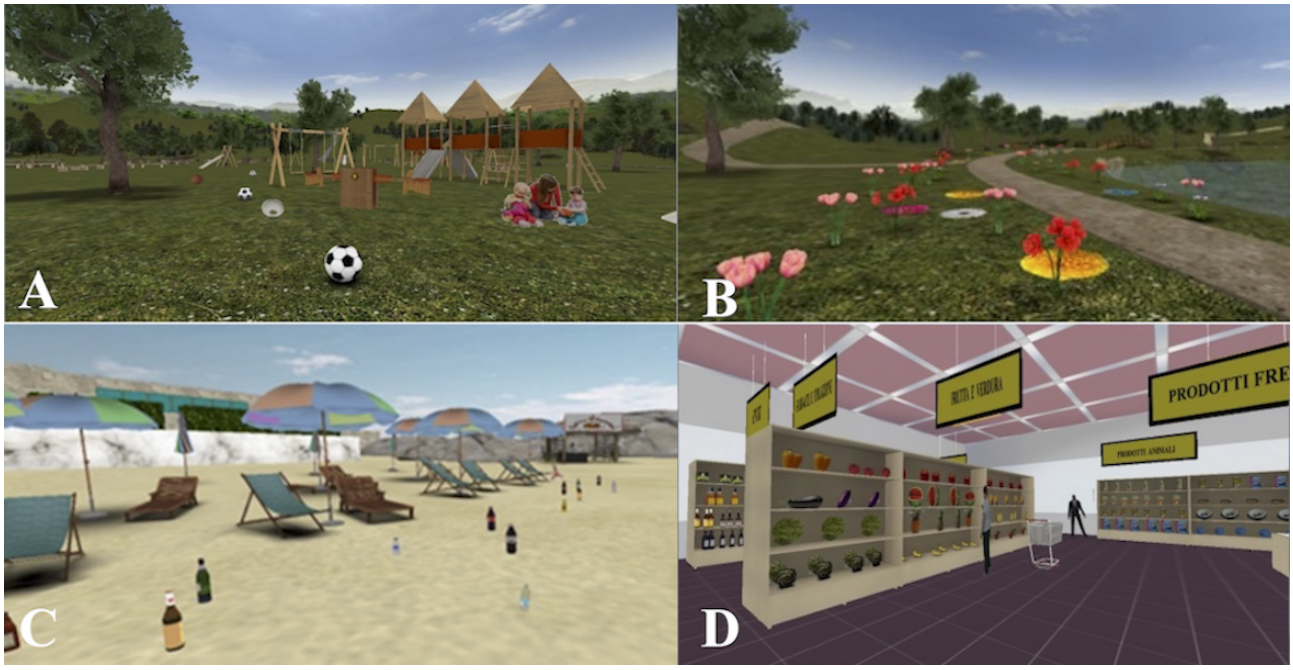
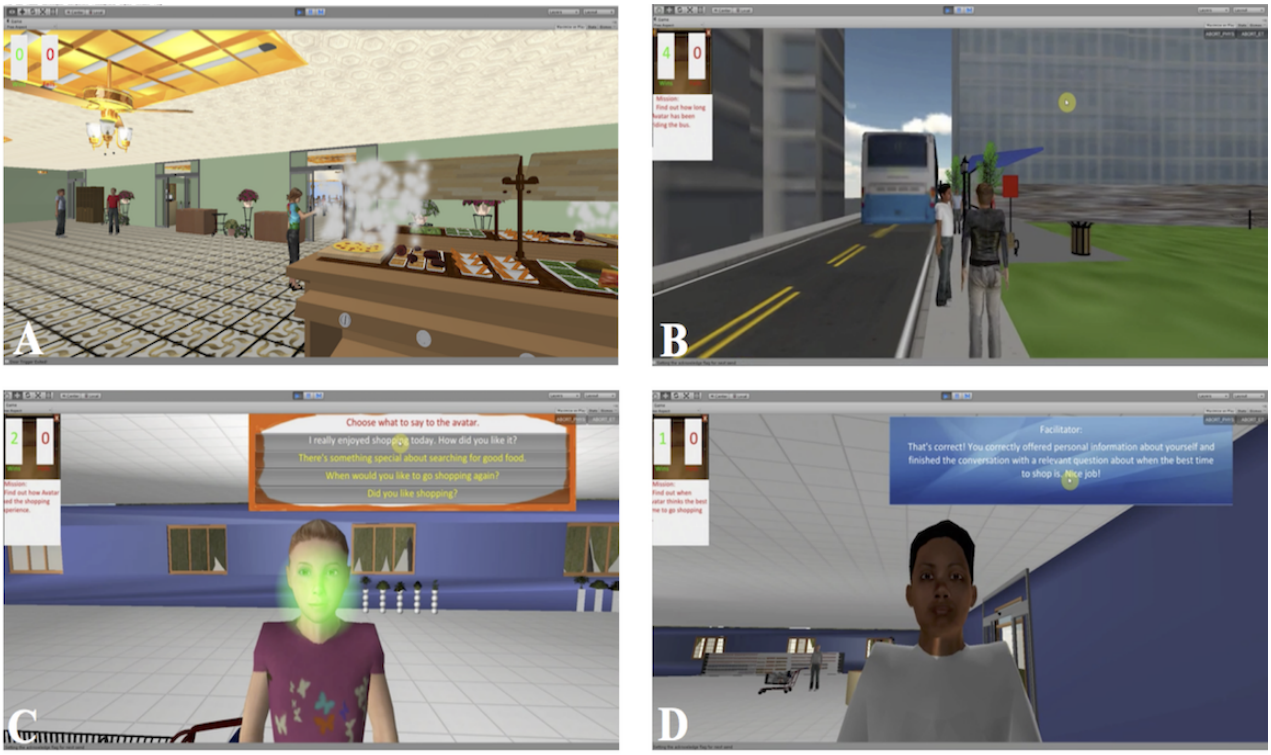


Figure 3. Virtual reality environment used in the Multimodal Adaptive Social Intervention in virtual reality. (A) The cafeteria environment and (B) the bus stop environment where participants can practice "small talk" and interact with the avatars. (C) The participant chooses what to say to the avatar from a multiple-choice menu. (D) The avatar provides feedback after the exchange with the participant. Reprinted from Psychiatry Research, Adery et al [48], Copyright 2018, with permission from Elsevier.



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Figure 4. Virtual reality environment used in the Soskitrain virtual reality integrated program for improving social skills in patients with schizophrenia. Participants can practice social interactions with avatars, such as (A) a bartender and (B) a security guard in a museum. Unpublished images reproduced from the Soskitrain program with author permission from Rus-Calafell [50].



Feasibility

Overall, the VR-based psychosocial interventions included in this systematic review were associated with positive acceptability and feasibility profiles. For example, most participants in the VR-based cognitive remediation studies were largely satisfied with the interventions as shown through high attendance, punctuality, and participant questionnaire data [44,45]. Dropout rates ranged from 0% to 20% [44,45]. However, it should be noted that 2 of the 4 studies within this category did not specifically evaluate the feasibility of their intervention [46,47]. For the VR-based social skills interventions, participants reported positive feedback after using the VR system [48-51]. Dropout rates during VR-based social skills interventions ranged from 8% to 20% [48,50]. One study also showed higher attendance in the VR group than in the traditional social skills control group [49]. Most participants found VR-based vocational skills interventions helpful [52,54] and interesting [54]. One participant in a VR-based vocational skills intervention experienced simulator sickness, but this was not a problem throughout the rest of the training [54]. In the same study, some participants (particularly those who were less educated, chronically ill with long-term deinstitutionalization, and who rarely used computers) experienced different degrees of computer phobia [54]. Finally, in one of the studies that implemented an intervention aimed at improving auditory verbal hallucinations or paranoia, participants dropped out because they were too afraid of the intervention (n=1), found the head-mounted display too uncomfortable (n=2), or because they felt nauseous (n=1) [60]. The remaining studies that evaluated feasibility within this category reported positive feasibility profiles (Table S1 in Multimedia Appendix 2).

Initial Evidence of Efficacy

The most commonly reported benefits following VR-based cognitive remediation interventions were improved memory [44,45], attention [44,46,47], and planning [44,46,47]. The single RCT and both nonrandomized controlled trials included within this category showed improvements in overall cognitive functioning in the VR group compared with the control group (treatment as usual, pharmacological therapy, and integrated psychological treatment) [45-47].

Improvements in conversational or communication skills [49,50], assertiveness [49,50], and negative symptoms [48,50,51] were observed following VR-based social skills interventions. In 1 RCT, the VR group showed more improvement in conversational skills and assertiveness but less improvement in nonverbal skills, compared with the active control group (social skills training using traditional role-playing) [49]. In the same RCT, the scores for generalization of skills were also higher in the VR group than in the active control group [49]. Another RCT, which targeted theory of mind (ToM), reported that the VR group displayed improved ToM, immediate memory, and pragmatic language skills compared with the passive VR control condition (wherein participants used the same VR system as the experimental group without the therapeutic intervention) [51].

One RCT showed that participants in the VR-based vocational skills intervention group displayed greater improvements in cognitive and executive functioning compared with both control groups (a therapist-administered training group and a conventional group) [54]. The other RCT showed that participants in the VR-based vocational skills intervention group had increased odds of receiving a job offer compared with the waitlist or treatment as usual control group [52]. The remaining study found that the VR-based intervention produced benefits in individual and social performance, general symptoms, verbal memory, and visual memory [53].

Finally, all VR-based psychosocial interventions for auditory verbal hallucinations or paranoia symptoms reported postintervention improvements. These improvements included reductions in the severity of auditory verbal hallucinations and persecutory beliefs [55,56], average levels of paranoia [58,59], momentary paranoid ideation [60], depressive symptoms [55,56], negative affect [58], and anxiety symptoms [60]. In the RCTs included within this category, the VR groups showed significant improvements compared with the control groups (treatment as usual) in the abovementioned outcomes [56,58,60,61]. However, in the randomized comparative trial included within this category [55], the VR-based intervention

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was not significantly better than cognitive behavioral therapy in improving the symptoms of auditory verbal hallucinations.

Functional Outcomes

All types of VR-based interventions showed some efficacy in improving the functional outcomes. For instance, the VR-based cognitive skills intervention used by Amado et al [44] yielded postintervention benefits in several functional outcomes relating to autonomy. More specifically, qualitative participant reports revealed postintervention increases in energy with respect to developing plans, looking for employment, returning to community activities, and managing housework.

Studies by Park et al [49] and Rus-Calafell et al [50] showed improvements in functional outcomes following the VR-based social skills intervention, specifically on social functioning and conversation skills. However, the study by Vass et al [51] found no significant changes in quality of life following the VR-based targeted ToM intervention.

All 3 (100%) vocational rehabilitation studies showed improvements in functional outcomes [52-54], including benefits in work performance during an on-site test [54], role-play job interview scores [52], and social performance [53]. The study by Smith et al [52] conducted a 6-month follow-up to their intervention and observed that individuals who completed the job interview training in VR had increased odds of receiving a job offer compared with waitlist controls that received treatment as usual [52].

Finally, of the 5 studies that assessed quality of life in the auditory verbal hallucinations or paranoia studies category [55-57,60,61], 4 (80%) studies reported significant improvements in quality of life or quality-adjusted life years following the VR-based intervention [55-57,61]. The study by Pot-Kolder et al [60] also reported a significant improvement in social function in the VR group during a 6-month follow-up assessment.

Durability

Of the included studies, 8 (44%) studies performed postintervention follow-up assessments or postintervention assessments in real-life environments to assess the durability of the interventions [49,50,52,54,56-58,60]. All 8 (100%) studies that assessed durability reported positive outcomes. For example, most of the skills that participants gained through the VR-based social skills interventions (eg, interpersonal communication skills and emotion perception skills) were maintained at a 4-month follow-up assessment [50]. In one of the RCTs included within the VR-based social skills intervention category, the generalization of skills was higher in the VR group than in the active control intervention (social skills training using traditional in-person role-playing with the therapist as the role-play actor instead of using VR) [49]. Similarly, at a 6-month follow-up, participants who received a VR-based vocational skills intervention had increased odds of receiving a job offer compared with controls who received treatment as usual [52]. The VR group also demonstrated stronger performance in sales-related activities (such as the ability to identify different items and the ability to sort clothes based on gender) compared with the control group during an on-site assessment [54]. Finally, participants who completed VR-based auditory verbal hallucinations or paranoia interventions showed reduced average levels of paranoia [58], negative affect [58], auditory verbal hallucinations [57], and severity of auditory verbal hallucinations [56] at follow-up time points (ranging from 3 to 12 months after the intervention).

Overall Quality of the Included Studies

For the RCTs, the overall bias was low for 2 studies [52,54], some concerns were identified in 6 studies [45,49,51,58,60,61], and high concerns were identified in 1 study [56] (Table S1 in Multimedia Appendix 1). One nonrandomized controlled trial had a score of 5 out of 9 on the Newcastle-Ottawa Risk of Bias Scale [46], whereas the other had a score of 7 out of 9 [47] (Table S2 in Multimedia Appendix 1). In total, 5 single-arm studies had a low risk of bias [44,48,50,53,59], whereas 1 single-arm study had a high risk of bias [55] (Table S3 in Multimedia Appendix 1). Finally, there was a high risk of bias in the randomized partial crossover trial [57] (Table S4 in Multimedia Appendix 1). All studies identified as having a high risk of bias were included within the auditory verbal hallucinations or paranoia category.

Discussion

Principal Findings

The main finding of this systematic review was that VR-based interventions can be used as a feasible approach to improve psychosocial functioning in individuals with psychosis. All included studies showed significant improvements in at least one measured outcome after a VR-based psychosocial intervention was used. The RCTs included in this systematic review demonstrated significant improvements in overall cognitive function [45,54], conversational skills [49], and odds of receiving a job offer [52] following a VR-based intervention compared with a control condition. Within the included studies comparing a VR-based intervention to a traditional in-person rehabilitation condition, the VR interventions resulted in greater improvements in planning, cognitive function, sustained attention, conversational skills, assertiveness, and executive functioning (ie, the cognitive processes required for the cognitive control of goal-directed behavior) [47,49,54].

Feasibility of VR-Based Psychosocial Interventions

Although VR technology has historically been an expensive and rare commodity, it is now affordable and can be administered in a cost-effective manner [61,62]. Our results suggest that VR is a safe and well-tolerated intervention that can be easily integrated into the treatment plan for individuals with psychosis. The studies included in this systematic review reported positive feasibility outcomes, such as high retention rates, participant satisfaction and motivation, and a low incidence of simulator sickness. Moreover, the study by Pot-Kolder et al [61] specifically examined the cost-effectiveness of VR-based cognitive behavioral therapy for psychosis and found that the intervention improved participant outcomes in a cost-effective manner. Therefore, the positive feasibility profiles of VR-based interventions support

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their integration into psychiatric clinics for individuals with psychosis.

Impact of VR-Based Psychosocial Interventions for Individuals With Psychosis

The specific VR-based interventions evaluated within this systematic review included cognitive, social, and vocational skills interventions as well as interventions aimed at improving auditory verbal hallucinations or paranoia. We found that cognitive skills interventions were associated with improved memory [44,45], attention [44,46,47], planning [44,46,47], and overall cognitive functioning [45,47]. Findings from these studies suggest that individuals with psychosis can rehabilitate several cognitive domains in an ecologically valid environment through VR-based psychosocial interventions. Furthermore, we found that the most common benefits of VR-based social skills interventions were improvements in conversational skills [49,50], assertive behaviors [49,50], and negative symptoms [48,50,51]. Studies investigating VR-based vocational skills interventions varied in their methodology and trained either vocational skills or job interview skills. Nevertheless, all studies within this category have demonstrated significant improvements in vocational skills [52-54]. Finally, the interventions aimed at improving auditory verbal hallucinations or paranoia reported a reduction in the severity of auditory verbal hallucinations [55,56], average levels of paranoia [58,59], and momentary paranoid ideation [60].

Previous studies on rehabilitation interventions for individuals with psychosis have shown limitations in the generalizability and maintenance of skills in real-world environments [14,15,20]. Interestingly, in our current synthesis of the literature, we showed that generalizability, along with maintenance and transference of skills, to real-world environments is possible through the use of VR-based psychosocial interventions. Indeed, all 8 (100%) studies that assessed durability reported positive postintervention outcomes [49,50,52,54,56-58,60]. These findings demonstrate that the positive effects of VR-based interventions can be maintained months after the intervention has ended and that the skills gained during the intervention can be generalized to real-world environments. Given that cognitive, social, and vocational skills are strong predictors of quality of life, improving these skills in real-world environments may greatly enhance the lives of individuals with psychosis [3,20,63-65]. Further research on the generalizability and transference of skills to real-world environments must be conducted.

Limitations

Limitations of This Systematic Review

This systematic review only assessed articles published in English, which limited the number of studies included. Furthermore, we only included peer-reviewed articles and did not examine any preprint servers for upcoming papers on the topics of interest.

Limitations of the Reviewed Literature

There are several limitations to the reviewed literature that must be noted. The number of identified studies within each VR-based intervention category was modest, and the sample sizes of the included studies were relatively small. There were also limitations in the number of studies that included active control conditions. This limited our ability to compare the efficacy of VR-based psychosocial interventions with that of their traditional counterparts. Furthermore, there was large heterogeneity across the VR environments (ie, immersive vs nonimmersive) and image quality used in the included studies. Immersiveness and image quality of the VR environment both influence user presence and emotional arousal, which may have affected the efficacy of the VR-based intervention as well as the transfer of skills to real-world settings [66,67]. There were also variations in the length and number of sessions used in each study, which could have affected the efficacy of the VR-based intervention. It is possible that longer VR sessions can result in participant fatigue and therefore reduce the efficacy of the intervention [68,69]. However, if the VR sessions are too short, the participant may not have sufficient time to become comfortable using the VR tool or to practice the desired skills, which may reduce the overall efficacy of the intervention [70]. Various methodological inconsistencies across the included studies prevented meta-analysis of the studies in this review.

Recommendations for Future Research

On the basis of the methodological limitations identified in the current literature, future studies investigating the feasibility or efficacy of VR-based psychosocial interventions should aim to perform RCTs that compare a VR-based intervention to a traditional rehabilitation or active VR control condition. This would allow for direct comparisons of the efficacy of VR-based interventions to traditional rehabilitation interventions with respect to improvements in cognitive, social, and vocational skills as well as symptoms such as auditory verbal hallucinations and paranoia. Furthermore, the comparison of a VR experimental condition to a VR control condition would enable researchers to isolate the impact of the intervention in VR. Methodological consistency across future RCTs would also facilitate meta-analysis of the current evidence.

Future research should also include a varied duration and number of VR sessions to help determine the optimal number and duration of VR sessions to impact rehabilitation outcomes [71]. Finally, future research should include follow-up assessments to ensure that the skills gained during the intervention are maintained and transferred into the real world, especially, because the generalizability and maintenance of skills remain a concern for traditional rehabilitation interventions for individuals with psychosis [14,15,20].

A summary of the limitations of the reviewed literature and our recommendations for future research is shown in Table 2.

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Table 2. Summary of the limitations in the current literature on virtual reality (VR)–based psychosocial interventions for individuals with psychosis and recommendations for future research.

Limitations in the current literature	Recommendations for future research	Impact of recommendation for future research
Limited number of studies comparing VR-based psychosocial interventions to traditional psychosocial interventions.	Perform RCTs[a] that compare a VR-based intervention to traditional psychosocial intervention.	Efficacy of VR-based interventions could be compared with traditional psychosocial interventions for improving cognitive, social, and vocational skills as well as auditory verbal hallucinations or paranoia.
No studies included a VR control condition.	Perform RCTs that compare a VR experimental intervention to a VR control condition.	Isolate the impact of the intervention in VR vs the effects of using VR recreationally.
Inconsistency in the number and duration of VR-based sessions across studies.	Including various numbers and durations of VR-based sessions.	Determine the optimal number and duration of VR sessions to impact rehabilitation outcomes.
Sample sizes of the included studies were relatively small.	Use larger sample sizes.	More accurate results on the impact of VR-based interventions for individuals with psychosis.
Limited number of studies featuring follow-up assessments of the skills gained during the VR intervention.	Perform follow-up assessments.	Ensure that skills gained during the VR-based interventions are maintained and transferred into the real world.

[a]RCT: randomized controlled trial.

Conclusions

This systematic review provided preliminary evidence that VR-based interventions may represent a novel and efficacious approach to improving psychosocial functioning in psychosis. VR-based psychosocial interventions were found to be safe and feasible. The VR-based interventions included in this review were shown to improve cognitive, social, and vocational skills as well as symptoms of auditory verbal hallucinations and paranoia in individuals with psychosis. The psychosocial skills learned from these interventions were also durable, with evidence supporting the maintenance and transfer of learned skills to real-world environments. Taken together, these findings reveal the potential of VR-based interventions to improve the persistent and debilitating symptoms of psychosis, which may be resistant to current pharmacotherapy. VR-based psychosocial interventions represent a promising adjunctive therapy for the treatment of psychosis, which may be used to improve psychosocial skills, community functioning, and quality of life in individuals with psychosis.

Acknowledgments

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Summary of the risk of bias assessment scores of the studies included in this systematic review.
[DOCX File , 24 KB - mental_v9i2e28502_app1.docx]

Multimedia Appendix 2
Detailed summary of the studies included in this systematic review.
[DOCX File , 35 KB - mental_v9i2e28502_app2.docx]

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Abbreviations

RCT: randomized controlled trial
ToM: theory of mind
VR: virtual reality

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Review

eHealth Interventions for Treatment and Prevention of Depression, Anxiety, and Insomnia During Pregnancy: Systematic Review and Meta-analysis

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Abstract

Background: Pregnancy is associated with an increased risk for depression, anxiety, and insomnia. eHealth interventions provide a promising and accessible treatment alternative to face-to-face interventions.

Objective: The objective of this systematic review and meta-analysis is to determine the effectiveness of eHealth interventions in preventing and treating depression, anxiety, and insomnia during pregnancy. Secondary aims are to identify demographic and intervention moderators of effectiveness.

Methods: A total of 5 databases (PsycINFO, Medline, CINAHL, Embase, and Cochrane) were searched from inception to May 2021. Terms related to eHealth, pregnancy, randomized controlled trials (RCTs), depression, anxiety, and insomnia were included. RCTs and pilot RCTs were included if they reported an eHealth intervention for the prevention or treatment of depression, anxiety, or insomnia in pregnant women. Study screening, data extractions, and quality assessment were conducted independently by 2 reviewers from an 8-member research team (KAS, PRS, Hangsel Sanguino, Roshni Sohail, Jasleen Kaur, Songyang (Mark) Jin, Makayla Freeman, and Beatrice Valmana). Random-effects meta-analyses of pooled effect sizes were conducted to determine the effect of eHealth interventions on prenatal mental health. Meta-regression analyses were conducted to identify potential moderators.

Results: In total, 17 studies were included in this review that assessed changes in depression (11/17, 65%), anxiety (10/17, 59%), and insomnia (3/17, 18%). Several studies included both depression and anxiety symptoms as outcomes (7/17, 41%). The results indicated that during pregnancy, eHealth interventions showed small effect sizes for preventing and treating symptoms of anxiety and depression and a moderate effect size for treating symptoms of insomnia. With the exception of intervention type for the outcome of depressive symptoms, where mindfulness interventions outperformed other intervention types, no significant moderators were detected.

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Conclusions: eHealth interventions are an accessible and promising resource for treating symptoms of anxiety, depression, and insomnia during pregnancy. However, more research is necessary to identify ways to increase the efficacy of eHealth interventions for this population.

Trial Registration: PROSPERO (International Prospective Register of Systematic Reviews) CRD42020205954; https://www.crd.york.ac.uk/prospero/display_record.php?RecordID=205954

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KEYWORDS

eHealth; pregnancy; depression; anxiety; insomnia; mobile phone

Introduction

Background

Meta-analyses show high rates of depression [1] and anxiety disorders [2] during pregnancy. Sleep problems are also common during pregnancy; they increase as the pregnancy progresses and are often comorbid with other mental health problems [3-6]. Untreated antenatal mental health problems are associated with an increased risk for poor birth outcomes, such as miscarriage [7], preterm birth [2,8], and low birth weight [2,8]. Similarly, poor sleep during pregnancy is a predictor of poor birth outcomes [9], such as shorter gestational age in addition to increased risk for developing postpartum depression [6].

Symptoms of antenatal depression, anxiety, and insomnia, if left untreated, can persist long into the postpartum period as many symptoms postpartum begin antenatally [6,10,11]. Furthermore, the effects of psychological distress during pregnancy can have long-lasting developmental [12,13], emotional [14], behavioral [14], and cognitive impairments [14] on the child. Prenatal and postpartum maternal mental health concerns have been linked to altered brain structure in preschool children [15]. Together, these findings emphasize the importance of providing pregnant women with timely, accessible, and culturally safe interventions to better treat and support the mental health of all women or birth parents.

A confluence of evidence now shows that depression, anxiety, and insomnia can be effectively treated using in-person individual or group psychotherapy for the perinatal period [16,17]. On the basis of this evidence and the clear harm of untreated antenatal mental health problems, public health and medical agencies around the world are recommending routine screening and treatment for depression and anxiety during pregnancy [18-20]. Studies have found that women who are screened for depression during pregnancy, as opposed to the postpartum period, are more likely to follow up with treatment [21], which can lead to the prevention of further adverse outcomes [17].

Despite the strong arguments for antenatal screening and treatment of mental health problems, resources for the treatment of these concerns are limited, leaving mental health needs unrecognized and contributing to fetal risk along with persistent postpartum mental health problems [22]. Owing to the high rates of mental health and sleep problems during pregnancy, limited screening, and limited treatment resources, researchers and hospital administrators are increasingly looking to eHealth as a way to address unmet needs [23,24]. Screening alone, even without further treatment, has shown significant reductions in depression during the perinatal period [25]. Even in the presence of simple and effective screening tools, it is estimated that health care professionals detect only 25% of women with postpartum depression and even less with other perinatal mental health disorders [26] and up to 70% of pregnant or postpartum women will fail to seek treatment [27]. As a result, only 15% of women with a perinatal mental health disorder will receive evidence-based care [28] and these rates are lower in marginalized groups [29] and in fathers and partners [30].

eHealth is a new area in health care that focuses on the delivery of health services and information through web-based programs, remote monitoring, teleconsultation, and mobile device–supported care [31]. eHealth's accessible nature aids in providing treatment to rural or remote areas, where patients otherwise would not have access to treatment and can involve lower intensity and more cost-effective delivery of services than in-person intervention, meaning that it may reach a larger number of patients [32].

The relevance of the use of eHealth interventions has only increased given that the COVID-19 pandemic has heightened psychological distress and sleep problems around the world. Pregnancy is already a period of vulnerability for mental health concerns [33-36] and a recent rapid review and meta-analysis of depression and anxiety during pregnancy during the COVID-19 pandemic reported that rates of depression and anxiety in pregnant women across the world are elevated compared with prepandemic levels [37]. The prevalence of insomnia has also increased during the COVID-19 pandemic [38], including during pregnancy. In addition to the need to investigate anxiety and depressive symptoms, insomnia is also important to be investigated as it is considered to be a transdiagnostic mechanism for various mental health concerns [39]. The elevation of mental health concerns during pregnancy has highlighted the need for accessible and timely solutions.

Although many eHealth interventions already exist, such as mobile health app for smartphones, very few are evidence-based [40,41]. Moreover, meta-analyses evaluating the effectiveness of eHealth interventions demonstrate mixed findings [42]. For example, prevention and treatment effects for depression appear to be small and dropout rates are high when there is no human monitoring and mood feedback. In contrast, moderate to large effect sizes are seen for eHealth interventions for insomnia [43,44]. The field of eHealth in the context of pregnancy is relatively new. Consequently, a systematic review and meta-analysis are needed to determine the effectiveness of

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eHealth interventions during pregnancy for the treatment of depression, anxiety, and insomnia symptoms.

Aims of the Study

This study is a systematic review and meta-analysis of the data from available randomized controlled trials (RCTs) published to date on eHealth interventions delivered during pregnancy to prevent or treat depression, anxiety, and insomnia. Meta-estimates are conducted separately for each outcome (anxiety, depression, and insomnia). A secondary goal of the review is to identify moderators of treatment effects. Potential moderators investigated include frequency of treatment (less frequent or more frequent), method of eHealth delivery (SMS text messaging, app, internet, and computer), treatment provider (health care provider, researcher, and self), risk of bias, type of control group (active and nonactive), treatment goal (treatment and prevention), baseline mental health symptoms (above or below clinical threshold), number of sessions, structure of the intervention (guided or unguided), and intervention type (hybrid or asynchronous). To clarify further, hybrid eHealth interventions refer to eHealth interventions where a component of the intervention was completed in person, if there was in-person contact. Asynchronous interventions refer to eHealth interventions, which were delivered completely via the web.

Methods

Search Strategy

A total of 5 electronic databases (ie, CINAHL with full text, PsycINFO, Medline or PubMed, Cochrane CENTRAL, and Embase) were searched using key terms to capture eHealth or digital interventions, RCTs, depression, anxiety, and insomnia during pregnancy to retrieve all relevant peer-reviewed articles from 1957 to May 2021. Subject headings were used in databases when appropriate. No filters or limits were applied to ensure that no articles were missed. Recognized articles were exported to a web-based systematic review program, Covidence (Veritas Health Innovation) [45] and duplicates were removed. This investigation followed the methods outlined by the Cochrane Collaboration Handbook [46] and the standards set by PRISMA (Preferred Reporting Items for Systematic Review and Meta-Analysis) [47,48]. The remaining articles were reviewed for inclusion using Covidence [45]. The study was registered with PROSPERO through the University of York Center for Reviews and Dissemination (CRD42020205186). The full search is available in Multimedia Appendix 1.

Study Selection

The initial abstract review was calibrated to ensure that the interrater reliability was >85%. Abstract eligibility was determined independently by each reviewer for all the identified articles. Conflicts were resolved by consensus with the first (KS) and second (PS) authors along with the research assistants (Roshni Sohail, Jasleen Kaur, Beatrice Valmana, Hangsel Sanguino, Makayla Freeman, and Songyang (Mark) Jin). Reference lists of the included articles and related review articles were inspected for any missed or relevant articles.

Inclusion and Exclusion Criteria

To be included in the review, studies had to be written in English and evaluate an eHealth intervention for anxiety, depression, or insomnia. eHealth interventions were defined and restricted to interventions that were delivered in an electronic capacity (eg, video therapy sessions, telephone, SMS text messaging, self-help interventions, and recorded therapy sessions). Studies had to be an RCT by study design. The intervention was required to occur before labor; however, the assessment of outcomes could occur in the postpartum period. Studies were excluded if (1) were not an RCT, (2) they did not have a control group, (3) they included a nonpregnant sample, (4) the interventions were not delivered electronically, (5) they were review articles, (6) they were case reports, (7) they used a previously included sample, or (8) they did not include continuous scores on a symptom measure of depression, anxiety, or insomnia. A flow chart of article inclusion and exclusion is shown in Figure 1.

Data Extraction

The remaining articles were divided and extracted independently by 2 reviewers from an 8-member research team (KAS, PRS, Hangsel Sanguino, Roshni Sohail, Jasleen Kaur, Songyang (Mark) Jin, Makayla Freeman, and Beatrice Valmana). Conflicts were resolved by consensus with the coders and the first and second authors. Extracted data included authors' names; publication year; country in which the research was conducted; sample demographics; pregnancy characteristics; intervention characteristics; administration details; and assessment information of depression, anxiety, or insomnia for all groups. Additional sample characteristics that were extracted when possible included sample size, age, gestational age during intervention baseline, ethnicity and race, sex, and gender breakdown of participants within the invention. The name of the intervention (when applicable), description, method of administration, degree of interaction and guidance from the provider (if applicable) during the intervention, and time spent by participants on the intervention were extracted. Information about depression, anxiety, and insomnia outcomes extracted included rates or effect sizes of all groups postintervention. Authors of included articles were contacted for additional information if studies had missing or incomplete data that precluded them from the analyses. If author contact was unsuccessful (ie, the author did not respond to an email request or no longer had access to data), the studies were excluded from the full-text review.

Data Analysis

Meta-analyses were conducted using the Comprehensive Meta-Analysis Software [49]. Sample sizes for each group (control and intervention), along with means and SDs of mental health symptoms for all study groups following the intervention (postintervention assessments, follow-ups, etc) were used to calculate meta-estimates of levels of depression, anxiety, or insomnia postintervention using random-effects meta-analyses. The overall meta-analysis computed a pooled Hedges *g* effect size, along with 95% CIs, for eHealth interventions across all included studies. A Hedges *g* of 0.20, 0.50, and 0.80 can be interpreted as small, moderate, and large effect sizes, respectively [50]. Stratified analyses were conducted according

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to the outcome (anxiety, depression, and insomnia). Separate meta-regression analyses with random-effects models were conducted when there were enough studies (3/17, 18%) that included at least one of the moderators of interest.

Quality Assessment

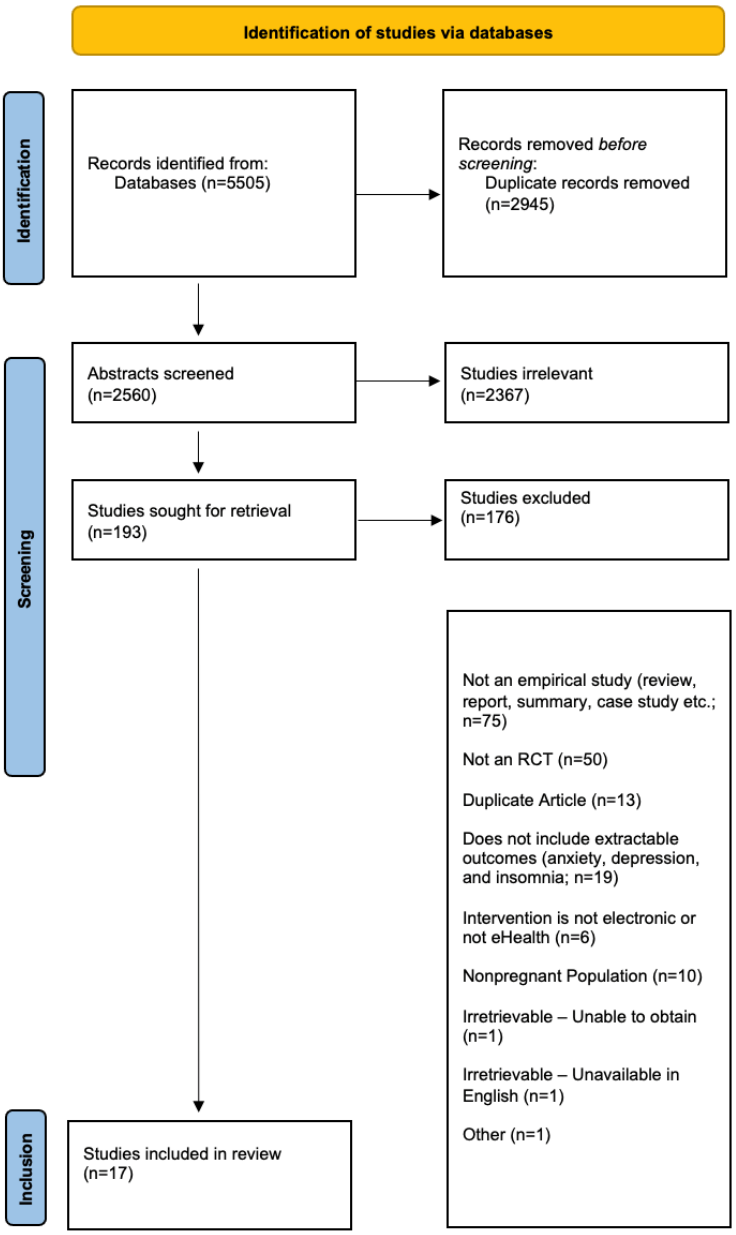
To assess the quality of the studies, the Cochrane Collaboration's Risk of Bias Tool was used. The tool assesses seven criteria common to RCTs (random sequence generation, allocation concealment, selective reporting, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, and other sources of bias) in which bias could occur. Quality indicators from the studies were extracted by 2 reviewers. Discrepancies in quality indicator scores were resolved by the first author (KS). Total scores ranged from 0 to 7, with higher scores indicating a greater risk of bias.

Results

Study Selection

The search returned 5505 results, which were reduced to 2560 (46.50%) after duplicates were removed. Of the 2560 articles, 2367 (92.46%) articles were excluded after reviewing the titles and abstracts. At the full-text level, 7.54% (193/2560) of the articles were retrieved. From these 193 articles, 23 (11.9%) were included for extraction and, of them, 17 (89%) were included in this review. In all, 3 authors were contacted for additional information; 2 of whom replied and were included in the review. No additional articles were retrieved from additional searches of the reference lists. The article screening process is detailed in Figure 1.

Figure 1. PRISMA (Preferred Reporting Items for Systematic Review and Meta-Analysis) flow chart. RCT: randomized controlled trial.



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Characteristics of Included Studies

Full details of each study are presented in Table 1. Mean participant age ranged from 25.97 (SD 6.01) to 37.80 (SD 2.31) years and 100% of the participants were women. None of the included studies assessed fathers. Mean gestational age ranged from 15.9 (SD 6.3) to >30 weeks at the start of the trial. Of the 71% (12/17) of the studies where data about ethnicity were reported, 10 (83%) studies included 50-80% of participants who identified as White [51-60] and 6 (50%) studies had >80% of the total sample identified as White [51-56].

No studies required a formal diagnosis of anxiety, depression, or insomnia at baseline. Studies primarily delivered the eHealth intervention through the computer or internet (12/17, 71% of the included studies) [51-57,59-61,65,66]. Of these 12 studies, 4 (33%) were delivered via a mobile app on a smartphone [58,62-64] and 1 (8%) was delivered through SMS text messages [67]. It should be noted that although telephone-based studies were also eHealth interventions of interest, the review did not identify any telephone-based studies. Regarding the frequency at which the intervention was delivered, 12% (2/17) of the studies were considered to be low frequency (defined as an intervention that was accessed once, twice, or monthly) [52,66] and 88% (15/17) of the studies were considered to be high frequency (defined as an intervention that was delivered weekly or daily) [51,53-65,67]. In considering who delivered the intervention, treatment providers varied, as 12% (2/17) of the studies used health care [62,64] providers to deliver the intervention, 24% (4/17) of the studies used researchers to deliver the intervention [51,65-67], and 65% (11/17) of the studies used other means [52-57,59-61,63]. *Other* was subjectively defined as an intervention that was self-administered, but indirectly provided or developed by another organization, researcher, or clinician.

Interventions used to treat or prevent depression included cognitive behavioral therapy (CBT; 3/17, 18%) [54,56,65], psychoeducation (4/17, 24%) [52,55,59,62], mindfulness (3/17, 18%) [53,63,64], and attention bias modification training (1/17, 6%) [58].

Interventions used to treat or prevent anxiety included CBT (2/17, 12%) [51,54], general education about the perinatal period (2/17, 12%) [66,67], psychoeducation (2/17, 12%) [52,62], mindfulness (3/17, 18%) [53,63,64], and attention bias modification training (1/17, 6%) [58]. CBT for insomnia (CBT-I) was the only type of intervention used to improve symptoms of insomnia.

Symptoms of anxiety, depression, or insomnia were assessed by using validated questionnaires. Of the 17 included studies, 10 (59%) studies measured anxiety symptoms, 11 (65%) studies measured depressive symptoms, and 3 (18%) studies measured insomnia symptoms.

Of the 59% (10/17) studies that measured anxiety, 1 (10%) study measured anxiety using the Spielberger Trait Anxiety Inventory [51], 2 (20%) studies used the Depression Anxiety Stress Scale–Anxiety [58,62], 1 (10%) study used the Hamilton Anxiety Rating Scale [58], 1 (10%) study used the Visual Analogue Scale for Anxiety [66], 1 (10%) study used the Hospital Anxiety Depression Scale–Anxiety [52], 4 (40%) studies used the Generalized Anxiety Disorder-7 [53,54,63,64], and 1 (10%) study used an unspecified anxiety measure [67] (Table 2).

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Table 1. Characteristics of included studies (N=17).

Study; country	Name of intervention	Intervention, N; control, N	Age of sample (years), intervention, mean (SD); control, mean (SD)	Gestational age (weeks)[a], intervention, mean (SD); control, mean (SD)	Type of control group	Type of eHealth	Type of intervention	Outcome
Cain et al [61]; United States	Go To Sleep! internet-based CBT-I[b]	27; 26	28.5 (5.8); 29.8 (5.3)	19.6 (3.6); 22.8 (2.6)	Waitlist condition	Internet	CBT	Insomnia
Felder et al [57]; United States	Sleepio: Big Health; digital CBT-I	105; 103	33.9 (3.38); 33.2 (4)	17.1 (6.4); 18.1 (6.3)	Psychoeducation	Internet	CBT	Insomnia
Kalmbach et al [60]; United States	Sleepio: Big Health; digital CBT-I	46; 45	28.91 (4.21); 29.16 (4.11)	N/A[c]	Psychoeducation	Internet	CBT	Insomnia
Heller et al [52]; Netherlands;	MamaKits Onling: internet-based intervention	79; 80	32.08 (4.61); 31.94 (4.83)	<30; <30	TAU[d]	Internet	Psychoeducation	Anxiety and depression
Chan et al [62]; China	iParent app	330; 330	31.3 (4.6); 31.2 (4.5)	N/A	TAU	Mobile app	Psychoeducation	Anxiety and depression
Duffecy et al [56]; United States	Sunnyside Cognitive Behavioral Therapy e-Intervention	17; 6	30.5 (4.05; total sample)	20-28	eHealth intervention of reduced intensity	Internet	CBT	Depression
Haga et al [55]; Norway	Mamma Mia: web-based program	678; 664	31.0 (4.6); 31.1 (4.5)	21-25	TAU	Internet	Psychoeducation	Depression
Yang et al [63]; China	WeChat (mobile) Messages: mobile app	62; 61	31.31 (4.87); 30.38 (3.91)	25.52 (1.84); 26.33 (3.45)	TAU	Mobile app	Mindfulness	Anxiety and depression
Krusche et al [53]; United Kingdom	Be Mindful: website	107; 78	32.7 (mode=34; total sample)	>12	Waitlist condition	Internet	Mindfulness	Anxiety and depression
Loughnan et al [54]; Australia	MUMentum Pregnancy program: internet-delivered CBT	36; 41	31.69 (4.44); 31.54 (3.63)	20.54 (6.01); 22.63 (5.76)	TAU	Internet	CBT	Anxiety and depression
Dennis-Tiwary et al [58]; United States	ABMT[e]	15; 14	34.67 (4.39); 31.14 (6.16)	22.44 (2.43); 20-28	Placebo condition	Mobile app	ABMT	Anxiety and depression
Sun et al [64]; China	WeChat (mobile) Messages; mobile app	84; 84	30.27 (3.80); 29.55 (4.21)	13.82 (2.0); 14.41 (2.2)	eHealth intervention of reduced intensity	Mobile app	Spirits Healing app and mindfulness	Anxiety and depression
Forsell et al [65]; Sweden	Internet-delivered CBT	22; 20	31.2 (3.7); 30.8 (5.3)	15.9 (6.5); 18.6 (6.5)	TAU	Internet	CBT	Depression
Scherer et al [51]; Switzerland	Internet-based cognitive behavioral stress management; internet	31; 27	32.90 (3.49); 31.11 (3.50)	28.32 (2.96); 29.11 (2.47)	Placebo condition	Internet	CBT	Anxiety
Barrera et al [59]; United States	Internet-based mood management intervention	57; 54	29.81 (6.09); 30.59 (4.99)	20.51 (10.37); 19.42 (10.42)	eHealth intervention of reduced intensity	Internet	Psychoeducation	Depression

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Study; country	Name of intervention	Intervention, N; control, N	Age of sample (years), intervention, mean (SD); control, mean (SD)	Gestational age (weeks)[a], intervention, mean (SD); control, mean (SD)	Type of control group	Type of eHealth	Type of intervention	Outcome
Hanprasertpong et al [66]; Thailand	Computer-assisted instruction	157; 164	37.8 (2.31); 37.5 (2.62)	16-20; 16-20	Paper version of the intervention	Computer or internet	General education	Anxiety
Jareethum et al [67]; Thailand	SMS text messaging intervention	32; 29	28.72 (4.9); 25.97 (6.1)	<28; <28;	TAU	SMS text message	General education	Anxiety

[a]The deviation from *mean (SD)* format in few studies is owing to unavailability of data.

[b]CBT-I: cognitive behavioral therapy for insomnia.

[c]N/A: not applicable.

[d]TAU: treatment as usual.

[e]ABMT: attention bias modification training.

Table 2. Anxiety outcome measures used by each study (N=10).

Study	Anxiety measure						
	STAI[a]	DASS-A[b]	HAMA[c]	VAS[d]	HADS[e]	GAD-7[f]	Unspecified
Heller et al [52]					✓		
Chan et al [62]		✓					
Yang et al [63]						✓	
Krusche et al [53]						✓	
Loughnan et al [54]						✓	
Dennis-Tiwary et al [58]		✓	✓				
Sun et al [64]						✓	
Scherer et al [51]	✓						
Hanprasertpong et al [66]				✓			
Jareethum et al [67]							✓

[a]STAI: State Trait Anxiety Inventory.

[b]DASS-A: Depression Anxiety Stress Scale–Anxiety.

[c]HAMA: Hamilton Anxiety Rating Scale.

[d]VAS: Visual Analogue Scale.

[e]HADS: Hospital Anxiety Depression Scale.

[f]GAD-7: Generalized Anxiety Disorder–7.

For symptoms of depression, of the 65% (11/17) of the studies, 7 (64%) studies used the Edinburgh Postnatal Depression Scale [52-55,62,64,65], 4 (36%) studies used the Patient Health Questionnaire-9 [53,54,56,63], 2 (18%) studies used the Center for Epidemiologic Studies Depression Scale [52,59], 1 (9%) study used the Hamilton Depression Rating Scale [56], 1 (9%) study used the Inventory of Depression and Anxiety Scale [56], 1 (9%) study used the Depression Anxiety Stress Scale–Depression [58], 1 (9%) study used the Montgomery-Asberg Depression Rating Scale [65], and 1 (9%) study used the Work and Social Adjustment Scale–Depression [65] (Table 3). For symptoms of insomnia, all 3 (100%) studies used the Pittsburgh Sleep Quality Index and the Insomnia Severity Index [57,60,61] (Table 4).

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Table 3. Depression outcome measures used by each study (N=11).

Study	Depression measure							
	EPDS[a]	PHQ-9[b]	CES-D[c]	HDRS[d]	IDAS[e]	DASS-D[d]	MADRS[g]	WSAS[h]
Heller et al [52]	✓		✓					
Chan et al [62]	✓							
Duffecy et al [56]		✓		✓	✓			
Haga et al [55]	✓							
Yang et al [63]		✓						
Krusche et al [53]	✓	✓						
Loughnan et al [54]	✓	✓						
Dennis-Tiwary et al [58]						✓		
Sun et al [64]	✓							
Forsell et al [65]	✓						✓	✓
Barrera et al [59]			✓					

[a]EPDS: Edinburgh Postnatal Depression Scale.
[b]PHQ-9: Patient Health Questionnaire-9.
[c]CES-D: Center for Epidemiologic Studies Depression Scale.
[d]HDRS: Hamilton Depression Rating Scale.
[e]IDAS: Inventory of Depression and Anxiety Scale.
[f]DASS-D: Depression Anxiety Stress Scale–Depression.
[g]MADRS: Montgomery-Asberg Depression Rating Scale.
[h]WSAS: Work and Social Adjustment Scale.

Table 4. Insomnia outcome measures used by each study (N=3).

Study	Insomnia measure	
	ISI[a]	PSQI[b]
Cain et al [61]	✓	✓
Felder et al [57]	✓	✓
Kalmbach et al [60]	✓	✓

[a]ISI: Insomnia Severity Index.
[b]PSQI: Pittsburgh Sleep Quality Index.

Of the 17 studies, 7 (41%) studies assessed both anxiety and depressive symptoms [52-54,58,62-64]. Most of the control conditions specified that control participants received treatment as usual (TAU) from their health care providers (7/17, 41%) [52,54,55,62,63,65,67]. Some studies defined their control group as a waitlist condition (2/17, 12%) [53,61], a placebo condition (2/17, 12%) [51,58], an eHealth intervention of reduced intensity (3/17, 18%) [56,59,64], a paper version of the intervention (1/17, 6%) [66], or psychoeducation (3/17, 18%) [57,60,63].

Risk of Bias in the Included RCTs

The results of bias assessments are shown in Table 5. Risk was rated as low for the 17 studies that were included. The most common risk of bias was owing to other biases, which were not explicitly mentioned in the quality assessment tool (ie, sampling bias). In general, the risk of selection, reporting, and attrition biases were low. The presence of other biases was judged as high in 10 (59%) of the 17 studies. Of the 17 included studies, 15 (88%) were judged to have a high risk of bias in at least one domain.

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Table 5. Outcomes from included studies (N=17).

Study	Outcome	Study quality rating	Hedges *g*	*P* value	Intervention effect
Cain et al [61]	Insomnia	3	0.576	.06	The study was marginally significant in reducing insomnia symptoms following the intervention for women in the CBT-I[a] group.
Felder et al [57]	Insomnia	3	0.688	<.001	Results from the study found those who received digital CBT-I experienced significantly greater reductions in insomnia symptom severity compared with women in the control group.
Kalmbach et al [60]	Insomnia	1	0.403	.06	CBT-I patients reported lower insomnia symptoms on the ISI[b] and PSQI[c] after treatment than controls; however, this was marginally significant.
Heller et al [52]	Anxiety and depression	1	Anxiety: 0.076; depression: –0.10	Anxiety: .70; depression: .96	No significant differences were found between the intervention group and the control group for both anxiety and depression.
Chan et al [62]	Anxiety and depression	1	Anxiety: –0.045; depression: 0.219	Anxiety: .56; depression: .02	Scores of depression significantly decreased in the intervention group when compared with the control group; however, scores of anxiety did not significantly decrease when comparing the intervention group with the control group.
Duffecy et al [56]	Depression	3	0.696	.29	Study results participants in the web-based intervention had reduced scores of depression when compared with the control group; however, this was not significant.
Haga et al [55]	Depression	1	0.121	.03	At all 4 follow-up time points of this study, pregnant people participating in the *Mamma Mia* had significantly lower depressive scores in comparison with the control group.
Yang et al [63]	Anxiety and depression	2	Anxiety: 0.868; depression: 0.933	Anxiety: <.001; depression: <.001	In comparison with the control group who had received in-person treatment, the participants belonging to the WeChat intervention reported significant reduction in anxiety and depressive scores.
Krusche et al [53]	Anxiety and depression	1	Anxiety: 0.641; depression: 0.677	Anxiety: .02; depression: .01	There was a significant reduction in scores between intervention and waitlist groups, regarding anxiety and depressive symptoms.
Loughnan et al [54]	Anxiety and depression	0	Anxiety: 0.588; depression: 0.300	Anxiety: .01; depression: .19	The analysis indicates that the iCBT[d] group demonstrated no significant group by time interactions for depression symptom reduction. However, the iCBT group showed significantly reduced anxiety symptoms.
Dennis-Tiwary et al [58]	Anxiety and depression	1	Anxiety: –0.305; depression: 0.068	Anxiety: .40; depression: .85	Results found that individuals in the ABMT[e] group did not show significant improvements in anxiety and depression.

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Study	Outcome	Study quality rating	Hedges *g*	*P* value	Intervention effect
Sun et al [64]	Anxiety and depression	2	Anxiety: 0.182; depression: 0.155	Anxiety: .24; depression: .08	Mindfulness training participants reported a decreased risk of positive depressive symptoms and anxiety symptoms in comparison with controls; however, this was not significant.
Forsell et al [65]	Depression	1	0.739	.02	Depression symptoms significantly decreased in the intervention group compared with the control group.
Scherer et al [51]	Anxiety	0	0.096	.71	Levels of stress and anxiety did not significantly decrease in the intervention group when compared with the control group.
Barrera et al [59]	Depression	3	–0.425	.16	Following the intervention, depression scores in the intervention group did not statistically differ from the control group.
Hanprasertpong et al [66]	Anxiety	3	0.010	.93	Anxiety following the intervention was reduced significantly in both groups in comparison with baseline; however, no significant differences existed among groups after the intervention.
Jareethum et al [67]	Anxiety	3	0.624	.02	In comparison with the control group who received treatment as usual, women receiving SMS text messages during the antenatal period demonstrated significantly decreased levels of anxiety.

[a]CBT-I: cognitive behavioral therapy for insomnia.

[b]ISI: Insomnia Severity Index.

[c]PSQI: Pittsburgh Sleep Quality Index.

[d]iCBT: internet-based CBT.

[e]ABMT: attention bias modification training.

Effectiveness of eHealth Interventions for Treatment of Depressive Symptoms During Pregnancy

Overview

A random-effects model was used to analyze the 65% (11/17) of the studies that assessed the effectiveness of eHealth interventions for the treatment of depressive symptoms. There were 2458 participants included in total (intervention: 1221, 49.67% and control: 1237, 50.32%). The pooled effect size reflected a significant effect of eHealth interventions on depressive symptoms with a small effect size (Hedges g=0.293, 95% CI 0.207-0.478; Z=3.090; P=.002; Figure 2). Significant heterogeneity was observed among the studies (Q=29.789; P=.001; I^2=66.431). The test of asymmetry funnel plot is displayed in Figure 3. Egger regression test found no evidence of publication bias (b=1.02; t_9=1.23; SE 0.831; P=.25). The Begg and Mazumdar rank correlation was nonsignificant (Kendall S statistic=9; T=0.163; Z=0.701; P=.48).

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Figure 2. Depression–forest plot [52-56,58,59,62,64-66].

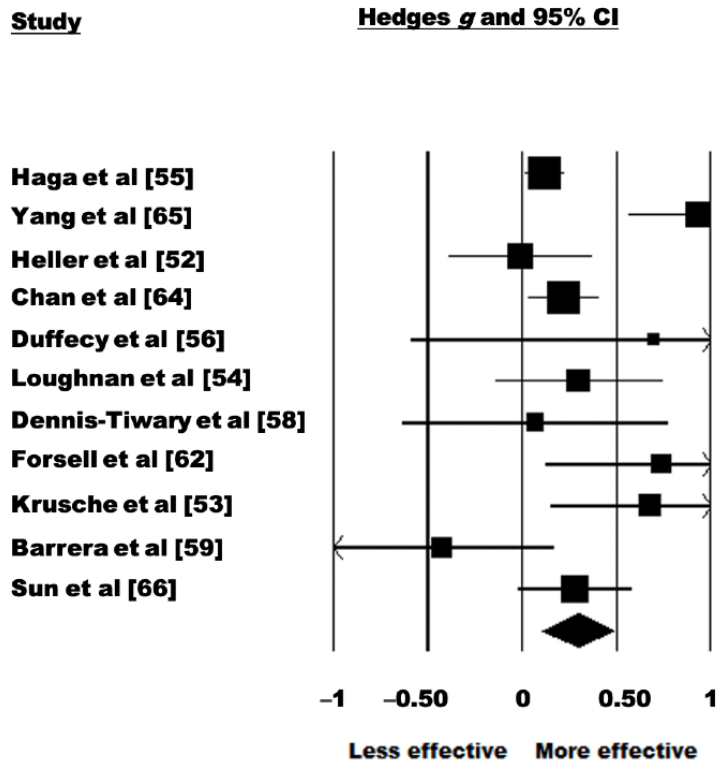
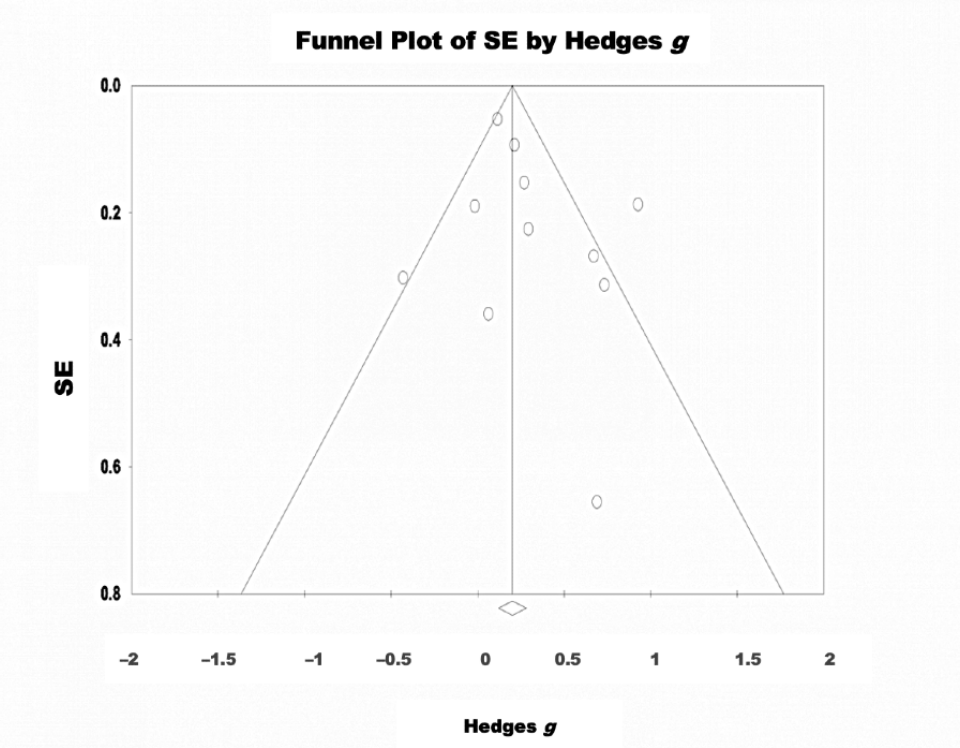


Figure 3. Depression–funnel plot.



Sensitivity Analyses

After systematically removing one study at a time, it was observed that 64% (7/11) of the studies affected the meta-estimate of the effect size of eHealth intervention during pregnancy by >5% [52,53,55,58,59,62,63]. Of the 11 studies, 5 (45%) studies affected the meta-estimate such that it made the estimate larger, however, a significant association was still noted without the studies included (P<.001-.009) [52,55,58,59,62]. Of the 11 studies, 2 (18%) studies affected the meta-estimate such that they made the estimate smaller; however, a significant association was still noted when each individual study was excluded (P=.004-.006) [53,63].

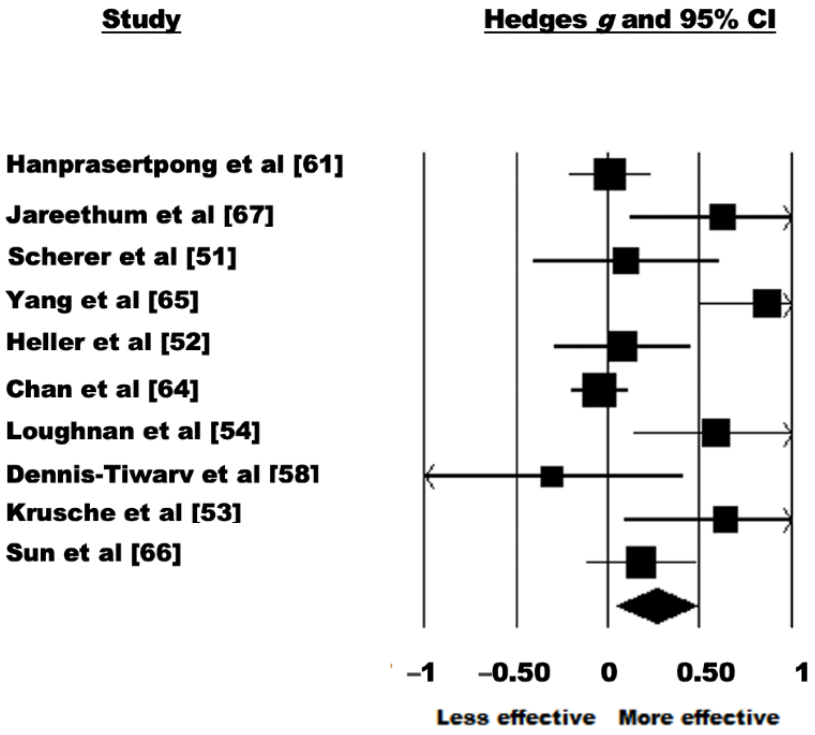
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Effectiveness of eHealth Interventions for Treatment of Anxiety Symptoms During Pregnancy

Overview

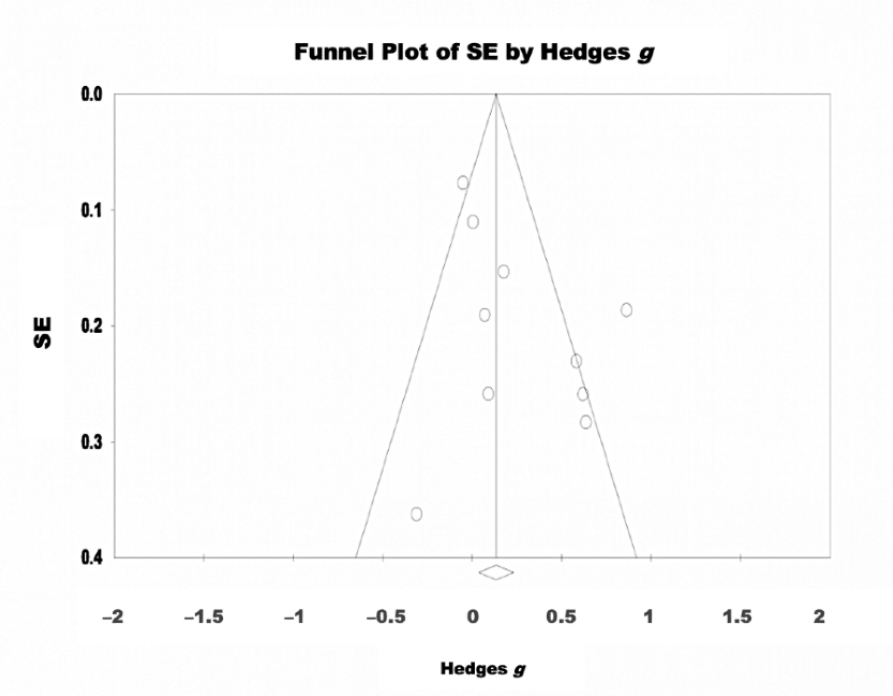
A random-effects model was used to analyze the 59% (10/17) of the studies that assessed the effectiveness of eHealth interventions for the treatment of anxiety symptoms. There were 1668 participants included in total (intervention: 816, 48.92% and control: 852, 51.08%). The pooled effect size reflected a significant effect of eHealth interventions on anxiety symptoms with a small effect size (Hedges g=0.262, 95% CI 0.046-0.478; Z=2.379; P=.02; Figure 4). Significant heterogeneity was observed among the studies (Q=34.103; P<.001; I^2=73.609). The test of asymmetry funnel plot is displayed in Figure 5. Egger regression test found no evidence of publication bias among the studies (b=2.33; t_8=1.98; SE 1.18; P=.08). The Begg and Mazumdar rank correlation was nonsignificant (Kendall S statistic=9; T=0.200; Z=0.805; P=.42).

Figure 4. Anxiety–forest plot [51-54,58,61,64-67].



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Figure 5. Anxiety–funnel plot [57,60,63].



Sensitivity Analyses

After systematically removing one study at a time, it was observed that all studies affected the meta-estimate of the effect size of eHealth interventions during pregnancy by >5%. Of the 10 studies, 6 (60%) studies affected the meta-estimate such that their removal made the estimate larger, where a significant association was noted when individual studies were excluded (*P*=.01-.03) [51,52,58,62,64,66]. Of the 10 studies, 3 (30%) studies affected the meta-estimate such that their (individual) removal made the estimate smaller; however, the effect of the intervention remained significant (*P*=.04) [53,54,67]. Of the 10 studies, 1 (10%) study affected the meta-estimate such that its removal made the estimate smaller and nonsignificant [62].

Effectiveness of eHealth Interventions for Treatment of Insomnia Symptoms During Pregnancy

Overview

A random-effects model was used to analyze the 18% (3/17) of the studies that assessed the effectiveness of eHealth interventions for the treatment of insomnia symptoms. There were 343 participants in total (intervention: 174, 50.7% and control: 169, 49.3%). The pooled effect size showed a significant effect of eHealth interventions on insomnia symptoms with a moderate effect size (Hedges *g*=0.595, 95% CI 0.379-0.811; Z=5.406; *P*<.001; Figure 6). No significant heterogeneity was observed among the studies (Q=1.259; *P*=.53; I^2<0.001). The test of asymmetry funnel plot is displayed in Figure 7. Egger regression test found no evidence of publication bias among the studies (b=–1.27; t_1=0.709; SE 1.80; *P*=.61). The Begg and Mazumdar rank correlation was nonsignificant (Kendall *S* statistic=–1; T=–0.33; Z=0.522; *P*=.60).

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Figure 6. Insomnia–forest plot.

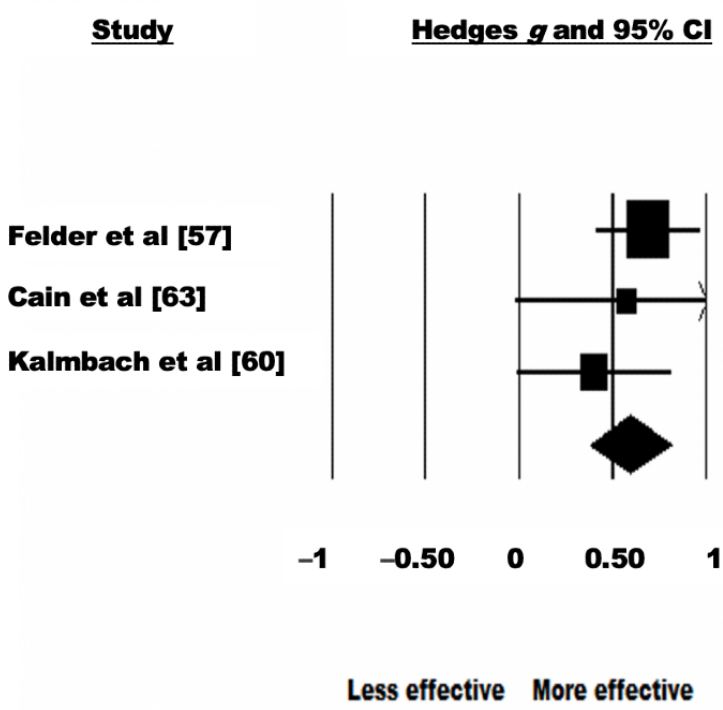
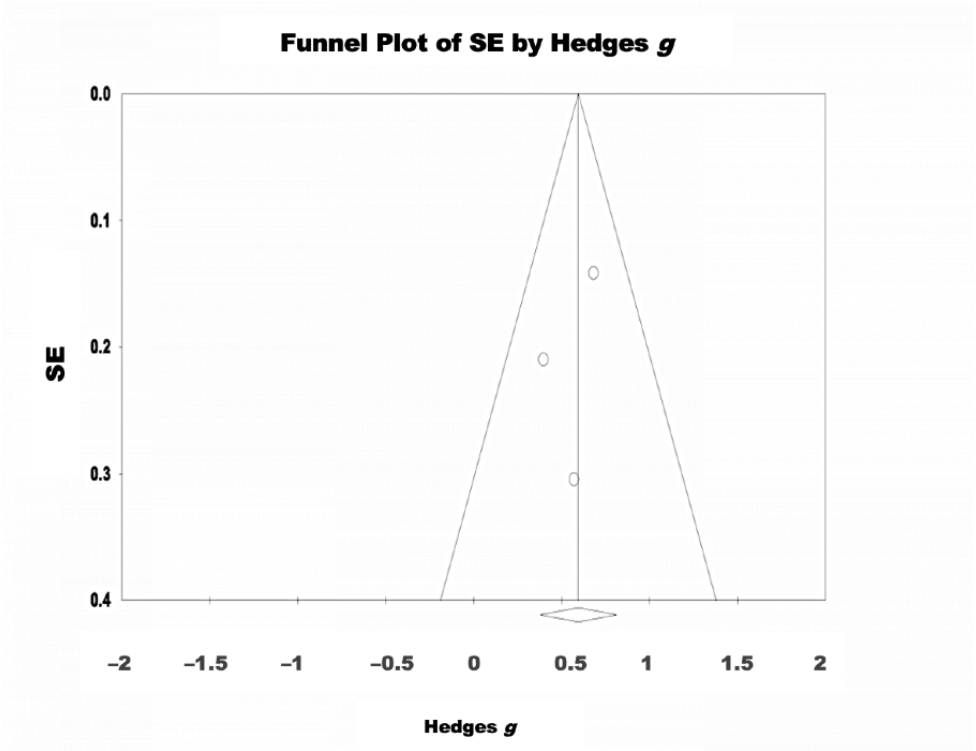


Figure 7. Insomnia–funnel plot.



Moderator Analyses

Using a meta-regression analysis, variables such as human monitoring (yes or no), risk of bias, type of control group used (active control vs nonactive control), treatment goal (treatment or prevention), baseline mental health symptoms (above or below), number of sessions, level of interactivity (web-based or hybrid), type of intervention (ie, CBT and mindfulness), structure (guided vs unguided), frequency (low or high), provider type (health care provider, researcher, or other), and eHealth type (internet or computer, text, and app) were noted as possible moderator variables for the observed effect sizes for both depressive and anxiety symptoms. Moderator analyses were not conducted for insomnia symptoms as there were not enough studies included to run the meta-regression. No

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significant moderators were detected for anxiety outcomes. However, for depressive outcomes, the meta-regression revealed that intervention type (mindfulness) significantly moderated depressive symptoms, where mindfulness interventions lead to better treatment outcomes in comparison with other intervention types (Tables 6 and 7).

Table 6. Moderators of eHealth intervention effectiveness on depressive symptoms using meta-regression analyses.

Moderator	Depression measure						
	N	β	SE	95% CI	Z value	Q	*P* value
Human monitoring[a]	11	.317	0.201	–0.077 to 0.711	1.58	2.49	.12
Risk of bias	11	–.023	0.131	–0.280 to –0.234	–0.18	0.03	.86
Type of control group[b]	11	–.254	0.248	–0.741 to 0.232	–1.02	1.05	.31
Treatment goal[c]	11	.104	0.234	–0.358 to 0.566	0.44	0.20	.66
Baseline symptoms[d]	11	–.018	0.228	–0.465 to 0.429	–0.08	0.01	.94
Number of sessions	9	–.006	0.010	–0.026 to 0.014	–0.57	0.33	.57
Interactivity (web-based or hybrid)[e]	11	.247	0.205	–0.156 to 0.649	1.20	1.44	.23
Guided versus unguided[f]	11	–.089	0.233	–0.544 to 0.367	–0.38	0.15	.70
Intervention type[g]							
ABMT[h]	11	–.0124	0.405	–0.805 to 0.781	–0.03	9.86	.98
CBT[i]	11	.4065	0.229	–0.042 to 0.855	1.78	9.86	.08
Mindfulness	11	.510	0.176	0.166 to 0.854	1.91	9.86	.004
Frequency[j]	11	.339	0.319	–0.286 to 0.964	1.06	1.13	.39
Type of provider[k]							
Health care provider	11	–.030	0.250	–0.520 to 0.460	–0.12	1.21	.90
Researcher	11	.464	0.438	–0.394 to 1.322	1.06	1.21	.29
eHealth type[l]							
App	11	.169	0.206	–0.235 to 0.573	0.82	0.67	.41

[a]No human monitoring was used as the reference group.

[b]Nonactive control group was used as the reference group.

[c]Prevention was used as the reference group.

[d]Below clinical cutoff was used as the reference group.

[e]Web-based interactivity was used as the reference group.

[f]Unguided was used as the reference group.

[g]Psychoeducation was used as the reference group.

[h]ABMT: attention bias modification training.

[i]CBT: cognitive behavioral therapy.

[j]Low frequency was used as the reference group.

[k]*Other* was used as the reference group.

[l]Internet was used as the reference group.

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Table 7. Moderators of eHealth intervention effectiveness on anxiety symptoms using meta-regression analyses.

Moderator	Anxiety measure						
	N	β	SE	95% CI	Z Value	Q	*P* value
Human monitoring[a]	10	.110	0.238	–0.357 to 0.577	0.46	0.21	.64
Risk of bias	10	.034	0.119	–0.200 to 0.267	0.28	0.08	.78
Type of control group[b]	10	–.262	0.262	–0.776 to 0.252	–1	1.00	.32
Treatment goal[c]	10	.142	0.212	–0.275 to 0.558	0.67	0.44	.51
Baseline symptoms[d]	10	.0645	0.289	–0.501 to 0.630	0.22	0.05	.82
Number of sessions	8	.017	0.020	–0.022 to 0.055	0.84	0.71	.40
Interactivity (web-based or hybrid)[e]	10	–.073	0.240	–0.543 to 0.398	–0.30	0.09	.76
Guided versus unguided[f]	10	–.213	0.258	–0.719 to 0.294	–0.82	0.68	.41
Intervention type[g]							
ABMT[h]	10	–.311	0.504	–1.299 to 0.677	–0.62	5.06	.54
CBT[i]	10	.349	0.339	–0.315 to 1.012	1.03	5.06	.30
Mindfulness	10	.534	0.293	–0.041 to 1.109	1.82	5.06	.07
General health	10	.233	0.318	–0.386 to 0.861	0.75	5.06	.46
Frequency[j]	10	.295	0.284	–0.263 to 0.852	1.04	1.08	.30
Type of provider[k]							
Health care provider	10	–.370	0.263	–0.885 to 0.145	–1.41	2.11	.16
Researcher	10	–.225	0.254	–0.722 to 0.272	–0.89	2.11	.38
eHealth type[l]							
Smartphone app	10	–.041	0.256	–0.543 to 0.459	–0.16	0.84	.87
SMS text message	10	.372	0.449	–0.508 to 1.252	0.83	0.84	.41

[a]No human monitoring was used as the reference group.
[b]Nonactive control group was used as the reference group.
[c]Prevention was used as the reference group.
[d]Below clinical cutoff was used as the reference group.
[e]Web-based interactivity was used as the reference group.
[f]Unguided was used as the reference group.
[g]Psychoeducation was used as the reference group.
[h]ABMT: attention bias modification training.
[i]CBT: cognitive behavioral therapy.
[j]Low frequency was used as the reference group.
[k]*Other* was used as the reference group.
[l]Internet was used as the reference group.

Discussion

Principal Findings

This systematic review and meta-analysis found that eHealth interventions reduced symptoms of anxiety and depression during pregnancy; however, the effect sizes for the treatment of depression and anxiety symptoms were small. eHealth, specifically CBT-I, was associated with improved insomnia symptoms during pregnancy, with a moderate effect size. None of the moderators of treatment response that we investigated emerged as significant, with the exception of intervention type being a significant moderator for depressive outcomes.

Findings showing a small effect size across eHealth interventions are consistent with the findings of other meta-analyses in this area. For instance, a study on the effectiveness of computer-based CBT for the treatment of depressive and anxiety symptoms in adolescent populations reported small to moderate effect sizes [68]. Another meta-analysis that investigated the efficacy of smartphone-based mental health interventions [69] found a small positive effect for individuals within the general population with depressive

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symptoms. In a meta-analysis that observed eHealth interventions for depression and anxiety in the general population, the overall effect size between intervention and control for depression and anxiety outcomes was small [42]. The consistent findings of small effect sizes for eHealth interventions targeting anxiety and depressive symptoms highlight the need for additional modifications that could increase effectiveness.

The small effect sizes observed for the use of eHealth interventions may be owing to the lack of factors theorized to improve program impact, including human monitoring, mood feedback, and high dropout rates in eHealth studies [70]. In this study, only 29% (5/17) of the studies included used human monitoring [51,52,63,65,66]. Furthermore, studies reported moderate to high attrition rates, which were as high as 75% [59]. As noted during the sensitivity analysis for the anxiety meta-estimate, the removal of the study by Chan et al [62] made the meta-estimate nonsignificant. Part of what may differentiate the study by Chan et al [62] from the other studies included in this meta-analysis is that participants were sent multiple prompts via email if it was noticed that they were not logging into the app. Another helpful component noted in the study by Chan et al [62] was that participants could directly message their obstetrics and gynecology physicians for any questions that they may have—again highlighting the importance of reminders and human monitoring throughout eHealth interventions.

There was also variability in the type of control groups used across the included studies, where some studies used a TAU control group, some used a waitlist control group, and others used an *active* control group (where control participants receive some sort of intervention that differs from the actual treatment). For example, in some studies, participants assigned to the control group were provided psychoeducation [61,63]. Although the use of an active control tends to reduce the observed effect sizes, moderator analyses found that the type of comparison group did not moderate the effectiveness of eHealth interventions. Furthermore, it should be noted that most studies included in the review used control conditions that were *TAU* and comparing with TAU may inflate effect sizes, as any sort of intervention is expected to be more helpful than no intervention. eHealth interventions do not necessarily need to outperform pre-existing face-to-face visits for them to be implemented in regular practice and these findings show that they likely outperform TAU.

For depression, the type of intervention emerged as a significant moderator of treatment effect (b=0.510; P=.004). Specifically, studies using mindfulness eHealth interventions had significant treatment outcomes compared with other interventions including CBT, attention bias modification training, and psychoeducation. Other intervention types did not significantly moderate the treatment effect, though CBT was approaching significance (b=0.407; P=.08). This finding could suggest that mindfulness eHealth interventions are more effective than CBT eHealth interventions under certain circumstances. For example, a study comparing CBT and mindfulness-based cognitive therapy to treat anxiety and depression in a diabetic population found that individuals with higher educational attainment responded better to mindfulness-based cognitive therapy compared with CBT [71].

Regarding anxiety, results from the moderator analyses showed that none of the hypothesized moderators influenced the effectiveness of the eHealth intervention on anxiety symptoms. Potentially, the null results in this study may be owing to the small number of studies included, thus limiting the statistical power of the study. However, the overall lack of significant moderators in this review is similar to results from recent meta-analyses, which also found that risk of bias, number of sessions, and therapist guidance (guided or unguided) did not significantly moderate depression and anxiety outcomes in eHealth intervention [72]. In contrast, findings from other meta-analyses on eHealth interventions in the general population suggest that intervention-level variables such as whether the intervention was guided or unguided, number of sessions, and the type of comparison group chosen significantly influenced the outcome [73,74]. Future researchers should continue to examine the possibility of moderators that were not investigated in this review, which may moderate treatment outcomes. For instance, experiences of poverty, racism, medical system marginalization, and single parent status are all moderators, which are known to contribute to elevated risk for maternal–child outcomes [75,76]. For example, in a study by Giscombé and Lobel [76] the authors found that compared with European Americans, African American infants show disproportionately higher rates of low birth weight, preterm delivery, and death during the first year of life. The review of the literature reveals that these outcomes are explained partly by various factors including socioeconomic status, higher levels of stress in African American women, racism, and ethnic differences in certain stress-related processes [76]. Similarly, another review revealed higher odds of low birth weight, preterm birth, stillbirth, and infant mortality among various indigenous populations [77]. Consequently, these various types of experiences can have a negative impact on treatment outcome. As such, these experiences should be taken into consideration when generalizing treatment efficacy to a heterogeneous population of women of various racial and socioeconomic backgrounds.

The eHealth intervention treatment of antenatal insomnia produced the largest effect size. However, this finding should be interpreted with caution, because only 3 studies on insomnia were included in this analysis. However, all of the included insomnia studies were evidence-based psychological interventions and this finding is in line with the general CBT-I literature, which has shown moderate to large effect sizes when treatment is delivered digitally [78]. The moderate effect sizes observed in eHealth interventions treating insomnia in comparison with the small effect sizes for eHealth interventions treating anxiety and depression may be owing to the use of standardized and highly behavioral treatment protocols that are established to work in person. Presentation of anxiety and depression may arise owing to myriad factors (ie, genetics, work, social support, partner support, and socioeconomic status), some of which may not be adequately targeted through digital intervention.

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Limitations

These findings should be interpreted in the context of several limitations. First, the sample sizes of the selected studies were small. In addition, most of the studies had moderate to high levels of participant attrition—a problem that is commonly identified in the eHealth literature [79]. High levels of attrition are attributed to the lack of human interactions in some eHealth interventions [80]. There was also high heterogeneity among interventions treating symptoms of anxiety and depression. Methodological variations within selected studies included variability in intervention, intervention intensity, duration of the intervention, and mode of eHealth delivery (ie, app, SMS text message, and internet). It should be noted that although telephone-based studies were also eHealth interventions of interest, the review did not identify any telephone-based studies, which may be owing to the rise in technology, which is supported by the fact that most of the interventions were delivered through the internet (12/17, 71%). Another limitation of this research is that most of the studies included in the review were conducted in the context of a high-income country rather than low-income countries, which may limit the generalizability of the findings. Fathers have significantly elevated rates of depression and anxiety during pregnancy and the postpartum period [81,82]; however, this meta-analysis found no studies that focused on men and partners during pregnancy, despite this having been an initial goal in the search. Research concerning fathers and partners during pregnancy is a future direction for eHealth research. Participants' race and ethnicity were also rarely reported in the included studies, limiting our ability to examine moderation by race and ethnicity. This is a common limitation of RCTs and should be addressed in future studies [83,84].

Future Directions

The accessibility to rural or underserved areas and flexibility of eHealth interventions makes eHealth an important part of health care beyond the pandemic. Given that eHealth interventions can take the form of web-based programs, remote monitoring, teleconsultation, and mobile device–supported programs, eHealth interventions provide many potential avenues for pregnant women to receive care for mental health problems. Future eHealth trials should consider a stepped model for mental health interventions [85-87], whereby mild mental health symptoms can be matched with lower-resourced interventions, such as eHealth. More significant symptoms are matched with face-to-face intervention, longer sessions, and more clinician interaction [87]. eHealth could also be used to track patient symptoms, which could be a promising way to detect worsening mental health and prevent future symptom deterioration. In addition, partners and fathers are also subject to symptoms of anxiety and depression perinatally. As such, during pregnancy, fathers and partners may benefit from adapted eHealth treatments [81].

eHealth intervention trials should also consider implementing conditions that have asynchronous activities (ie, video modules) compared with synchronous activities (intensive guidance via the web) [86]. Comparison of these modes of delivery would indicate which mode successfully implements adherence to the app or intervention. This could inform future interventions for methods to decrease attrition and increase engagement.

In addition, further emphasis should be placed on understanding the potential that eHealth interventions may have for communities that have faced medical marginalization and maternal–child health disparities. It is important to consider that health disparities and inequities are often the result of adverse social determinants (including issues related to service access, racism, colonialism, and stigmatization) [88]. For example, research has found that indigenous women do not seek help owing to stigma, racism, fear of being blamed or labeled as a bad parent, and for fear of child apprehension [89]. As such, future research can investigate how eHealth interventions can be tailored to be more culturally sensitive, and thus, more appealing to marginalized groups.

Moreover, it should be noted that not everyone in Canada and other parts of the world have access to the means necessary to engage in eHealth interventions. For example, not everyone has reliable internet or access to computers, telephones, or smartphones. Therefore, health care systems should consider how to provide better support for infrastructure and equipment, specifically for those in rural, remote, and indigenous communities. For instance, only 24% of First Nation reserves in Canada have access to reliable internet [90]. Furthermore, in the United States, low-income Hispanics are the most digitally underserved population and this is not owing to a lack of interest in using internet health services [91]. Rather, this finding stems from barriers including low income, poor digital competence, and limited English proficiency [91]. Furthermore, often, devices are also shared among family members, which also limits internet access. Thus, research should focus on determining how eHealth interventions can be streamlined into the current health care system to increase accessibility to mental health services.

In addition, the finding that none of the included studies required a formal diagnosis of anxiety, depression, or insomnia at baseline is also common in the larger literature of nonspecialist-delivered interventions in high-income countries. This finding may be related to some of the barriers in the delivery of psychological treatment, which include the lack of skilled providers who can provide a formal diagnosis [92]. However, this barrier may be overcome if current trends in global mental health move toward transdiagnostic approaches, which focus on common elements of mental health rather than focusing on any 1 specific disorder [92]. This is because recent evidence suggests that targeting *common elements* including behavioral activation, communication, and problem solving can reduce the complexity of needing to learn diverse psychological treatment packages for specific clinical phenotypes (such as depression, anxiety, and stress‐related disorders) [92]. Moreover, we see that most of the included studies had interventions that were facilitated by clinicians and peers. However, recent research suggests that a potential solution to increasing accessibility of mental health services is to use nonspecialist providers (ie, nurse practitioners and nurses) and train them in the delivery of brief and low-intensity interventions, which has consistently been found to have

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moderate to strong effects in reducing distress associated with mental health concerns [23].

Finally, future research on eHealth can be directed toward determining how eHealth interventions can be smoothly integrated into the current health care system to streamline patient care and increase patient accessibility to mental health services.

Conclusions

In conclusion, this review demonstrated that eHealth interventions reduced symptoms of anxiety, depression, and insomnia in individuals during pregnancy in comparison with controls. eHealth interventions for anxiety, depression, and insomnia symptoms hold promise as adjuncts to other clinical approaches and as a component to stepped-care models of treatment for mental health problems [93,94].

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Search strategy used for the review.
[PNG File , 244 KB - mental_v9i2e31116_app1.png]

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Abbreviations

CBT: cognitive behavioral therapy
CBT-I: cognitive behavioral therapy for insomnia
PRISMA: Preferred Reporting Items for Systematic Review and Meta-Analysis
PROSPERO: International Prospective Register of Systematic Reviews
RCT: randomized controlled trial
TAU: treatment as usual

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Review

Methods and Applications of Social Media Monitoring of Mental Health During Disasters: Scoping Review

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Abstract

Background: With the increasing frequency and magnitude of disasters internationally, there is growing research and clinical interest in the application of social media sites for disaster mental health surveillance. However, important questions remain regarding the extent to which unstructured social media data can be harnessed for clinically meaningful decision-making.

Objective: This comprehensive scoping review synthesizes interdisciplinary literature with a particular focus on research methods and applications.

Methods: A total of 6 health and computer science databases were searched for studies published before April 20, 2021, resulting in the identification of 47 studies. Included studies were published in peer-reviewed outlets and examined mental health during disasters or crises by using social media data.

Results: Applications across 31 mental health issues were identified, which were grouped into the following three broader themes: estimating mental health burden, planning or evaluating interventions and policies, and knowledge discovery. Mental health assessments were completed by primarily using lexical dictionaries and human annotations. The analyses included a range of supervised and unsupervised machine learning, statistical modeling, and qualitative techniques. The overall reporting quality was poor, with key details such as the total number of users and data features often not being reported. Further, biases in sample selection and related limitations in generalizability were often overlooked.

Conclusions: The application of social media monitoring has considerable potential for measuring mental health impacts on populations during disasters. Studies have primarily conceptualized mental health in broad terms, such as distress or negative affect, but greater focus is required on validating mental health assessments. There was little evidence for the clinical integration of social media–based disaster mental health monitoring, such as combining surveillance with social media–based interventions or developing and testing real-world disaster management tools. To address issues with study quality, a structured set of reporting guidelines is recommended to improve the methodological quality, replicability, and clinical relevance of future research on the social media monitoring of mental health during disasters.

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KEYWORDS

social media; SNS; mental health; disaster; big data; digital psychiatry

Introduction

Disaster mental health has emerged as a critical public health issue, with increasing rates of both disasters and mental health impacts on affected communities [1,2]. Disasters are natural (eg, earthquakes), technological (eg, industrial accidents), or human-caused events (eg, mass shootings) that have an acute and often unpredictable onset, are time delimited, and are experienced collectively [3]. The unexpected and evolving nature of disasters makes it challenging to monitor the population's mental health in real time. Capturing current, accurate, and representative information about a population's mental health during a disaster can assist in directing support to where it is most needed, monitoring the impact of response efforts, and enabling the delivery of targeted intervention. However, traditional methods of population-level mental health monitoring, such as large surveys of representative samples, can be logistically difficult to implement at short notice in an evolving and potentially deteriorating emergency context [4].

Research has investigated the potential benefits of social media (also known as social networking sites) data to capture the mental health status of affected population groups during a disaster, and monitor their recovery over time [5,6]. Social media data are advantageous because of their low cost of implementation; their ubiquity in the general population; the rich, real-time information that is shared by users (eg, photos, text, and video); and longitudinal assessment, which permits modeling of time trends and the temporal sequencing of target variables including events from the past [7]. Social media data also have particular strengths over traditional survey–based mental health monitoring [7,8]. This includes its ability to rapidly assess whole or specific populations to inform clinical decision-making, such as individuals in proximity to the disaster, those with pre-existing mental health conditions, or emergency responders. Further, social media data can support the real-time updating of mental health assessments, enabling administrators to identify and respond to shifting population needs, and transitions to new phases of the disaster event that may require a change in response strategy. Finally, social media data uniquely offer 2-way, synchronous communication opportunities, which can allow for rapid and scalable responses to misinformation, rumors, and stigma that may be harmful to mental health and the deployment of digital mental health support as required. However, the large quantity and unstructured nature of social media data also poses difficulties in terms of managing and extracting meaningful mental health information that is suitable for informing emergency response efforts.

A review capturing the strengths and weaknesses of the literature on disaster mental health monitoring via social media is both pertinent and timely, given the availability of social media analytic tools and the current COVID-19 crisis [9]. Previous reviews [10,11] have taken a narrower focus by examining the health literature; however, substantial research has been published in other interdisciplinary areas [12]. Notably, research from computer science and engineering is particularly relevant, and may offer sophisticated methodological advances to address challenges specific to large, unstructured data sets obtained from social media to indicate mental health outcomes [12,13]. This study aims to conduct a scoping review of the interdisciplinary literature assessing mental health in disasters using social media. Thus, this review aims to (1) identify how social media data have been applied to monitor mental health during disasters, including the type of social media and mental health factors that have been investigated; (2) evaluate the methods used to extract meaningful or actionable findings, including the mental health assessment, data collection, feature extraction, and analytic technique used; and (3) provide structured guidance for future work by identifying gaps in the literature and opportunities for improving methodologies and reporting quality.

Methods

Overview

A scoping review methodology was selected to map the key concepts, main sources, and types of evidence available in the literature on mental health using social media during disasters [14]. The review was performed adhering to the PRISMA-ScR (Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews) guidelines [15] and presents a subset of findings related to disaster mental health under a prospectively registered protocol (PROSPERO2020 CRD42020166421). The PRISMA-ScR Checklist is provided in Multimedia Appendix 1.

Data Sources and Analysis

The following health and computer science databases were searched for relevant literature: PubMed or MEDLINE, PsycINFO, Cochrane Library, Web of Science, IEEE Xplore, and the ACM Digital Library. Details of the search strategy and variations of the key search terms can be found in Multimedia Appendix 2. Data were extracted using a standardized template adapted from similar reviews [10,12,13], which collated the following: (1) the aim and key findings of the research; (2) the disaster event details; (3) social media platform, data collection methods, and sample size; (4) area of mental health focus and assessment methods; and (5) analytic methods used, including preprocessing steps, feature extraction, and algorithm details. To analyze the data, a narrative review synthesis method was selected to best capture the methods and applications in the identified studies. A meta-analysis was not considered appropriate for this review given the broad range of mental health issues and analytic techniques used in the studies identified. As scoping reviews aim to provide an overview of the existing evidence regardless of methodological quality or risk of bias, no critical appraisal was performed [14,15]. However, missing information in articles was recorded in the data extraction template to assess overall methodological reporting quality.

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Search Strategy and Selection Criteria

A broad search strategy was adapted from the review of machine learning applications in mental health by Shatte et al [12]. Both health and information technology research databases were selected, including PubMed or MEDLINE, PsycINFO, Cochrane Library, Web of Science, IEEE Xplore, and the ACM Digital Library. Search terms were relevant to 3 themes—(1) mental health, (2) social media, and (3) big data analytic techniques—and the search was adapted to suit each database (Multimedia Appendix 2). The reference lists of all articles selected for review were manually searched for additional articles. The search was conducted on April 20, 2021, with no time or language delimiters.

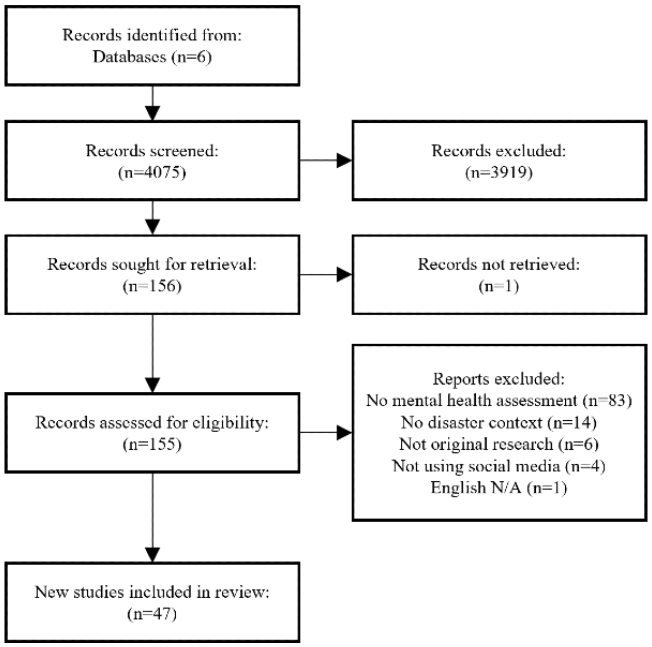
The inclusion criteria were (1) articles that reported on a method or application of assessing mental health symptoms or disorders in a disaster, crisis, or emergency event; (2) articles that used social media data, with social media defined as any computer-mediated technology that facilitates social networks through user-generated content; (3) articles published in a peer-reviewed publication; and (4) articles available in English. Articles were excluded if they (1) did not report an original contribution to the research topic (eg, commentaries and reviews); (2) did not focus on a mental health application; (3) did not have full text available (eg, conference abstracts); and (4) solely used other internet-based activities, such as web browser search behaviors. Articles were screened by the lead author (SJT), with the second author (ABRS) blindly double-screening 5% of title and abstract articles and 10% of full-text articles, obtaining a 100% agreement rate.

Results

Overview of Article Characteristics

The search strategy identified 4075 articles, of which 47 were included in the review (Figure 1). The mean publication year was 2018 (*SD* 2.44 years), with the earliest article published in 2013. Health crises were the most commonly researched disaster events (24/47, 51%, including COVID-19, Middle East respiratory syndrome, and SARS) followed by human-made disasters (15/47, 32%, including terrorist attacks, school or mass shootings, technological and transportation accidents, and war), and natural disasters (12/47, 26%, including hurricanes, storms, floods, fires, earthquakes, tsunamis, and drought). Notably, the most commonly studied single disaster event was the COVID-19 pandemic (22/47, 47%), with human-made disasters being the most frequently studied disaster category before 2020. Disasters were reported most frequently in Asia (17/47, 36%), followed by North America (15/47, 32%), Europe (6/47, 13%), and South America (1/47, 2%). An additional 9 studies used social media data without any geographic restrictions. A total of 31 mental health issues were examined across the articles, with the most frequent being social media users' affective responses (24/47, 51%), followed by anxiety (8/47, 17%), depression (7/47, 15%), stress (3/47, 4%), and suicide (3/47, 4%). The most common social media platform was Twitter (34/47, 72%), followed by Sina Weibo (6/47, 13%), Facebook (5/47, 11%), YouTube (4/47, 8%), Reddit (2/47, 4%), and other platforms (8/47, 17%). Overwhelmingly, the articles used an unobtrusive observational research design, with only 2 articles including any direct participation from users. Most articles reported the number of social media posts (44/47, 94%); in contrast, few studies reported the unique number of users included in the analysis (16/47, 34%). The mean number of posts in the included studies was 1,644,760.58 (SD 3,573,014.84, range 17-18,000,000), and the mean number of unique users was 164,318 (SD 250,791.27, range 49-826,961).

Figure 1. Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) Flowchart.



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Disaster Mental Health Applications

Overview

Three disaster mental-health application themes emerged: (1) estimating mental health burden (33/47, 70%; Table 1), which included articles that identified posts from the affected disaster region to track or predict changes to mental health over the disaster duration; (2) planning or evaluating interventions or policies (9/47, 19%; Table 2), which included articles that monitored mental health via social media as part of an intervention or policy evaluation; and (3) knowledge discovery (5/47, 11%; Table 3), which included a small number of articles that aimed to generate new insights into human behavior using social media in disaster contexts by developing theory and evaluating new hypotheses.

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Table 1. Summary of articles estimating mental health burden from social media during a disaster.

Disaster category and reference	Disaster type	Disaster year	Disaster location	Mental health issue	Social media platform	Number of posts (number of users)	Analysis
Natural disaster							
Gruebner et al [16]	Meteorological	2012	United States	Affective response	Twitter	344,957 (NR[a])	GIS[b] analysis
Gruebner et al [17]	Meteorological	2012	United States	Affective response	Twitter	1,018,140 (NR)	GIS analysis
Karmegam and Mappillairaju [18]	Hydrological	2015	India	Affective response	Twitter	5696 (NR)	Mixed effect model, spatial regression model, thematic analysis
Li et al [19]	Geophysical, biological	2009-2011	Japan, Haiti	Affective response	Twitter	50,000 (NR)	*t* test
Shekhar and Setty [20]	Geophysical, climatological, and hydrological	2015	Global	Affective response	Twitter	60,519 (NR)	Text mining; k-means clustering
Vo and Collier [21]	Geophysical	2011	Japan	Affective response	Twitter	70,725 (NR)	Naive Bayes, support vector machine, MaxEnt, J48, multinomial naive Bayes; Pearson correlation
Human-made disaster							
Doré et al [22]	Active shooter	2012-2013	United States	Affective response	Twitter	43,548 (NR)	Negative binomial regression
Glasgow et al [23]	Active shooter	2012-2013	United States	Grief	Twitter	460,000 (NR)	Multinomial naive Bayes; support vector machine
Gruebner et al [5]	Terrorist attack	2015	France	Affective response	Twitter	22,534 (NR)	GIS analysis
Jones et al [24]	Active shooter	2014-2015	United States	Affective response	Twitter	325,736 (6314)	Piecewise regression
Jones et al [25]	Terrorist attack	2015	United States	Affective response	Twitter	1,160,000 (25,894)	Time series, topic analysis
Khalid et al [26]	Terrorist attack	NR	NR	Trauma	Unspecified blogs and discussion boards	17 (NR)	Semantic mapping and knowledge pathways
Lin et al [27]	Terrorist attack	2015-2016	France, Belgium	Affective response	Twitter	18 Million (NR)	Multivariate regression analysis, survival analysis
Sadasivuni and Zhang [28]	Terrorist attack	2019	Sri Lanka	Depression	Twitter	51,462 (NR)	Gradient-based trend analysis methods, correlation, learning quotient, text mining
Saha and De Choudhury [29]	Active shooter	2012-2016	United States	Stress	Reddit	113,337 (NR)	Support vector machine classifier of stress, time-series analysis
Woo et al [30]	Accident	2011-2014	Korea	Suicide	Twitter	NR	Time-series analysis
Epidemic or pandemic							
Da and Yang [31]	Epidemic or pandemic	2020	China	Affective response	Sina Weibo	340,456 (NR)	Linear regression
Gupta and Agrawal [32]	Epidemic or pandemic	2020	India	Anxiety, depression, panic attacks, stress, suicide attempts	Twitter, Facebook, WhatsApp, and blogs	NR	Thematic analysis

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Disaster category and reference	Disaster type	Disaster year	Disaster location	Mental health issue	Social media platform	Number of posts (number of users)	Analysis
Hung et al [33]	Epidemic or pandemic	2020	United States	Psychological stress	Twitter	1,001,380 (334,438)	Latent Dirichlet allocation
Koh and Liew [34]	Epidemic or pandemic	2020	Global	Loneliness	Twitter	NR (4492)	Hierarchical clustering
Kumar and Chinnalagu [35]	Epidemic or pandemic	2020	NR	Affective response	Twitter, Facebook, YouTube, and blogs	80,689 (NR)	Sentiment analysis bidirectional long short-term memory
Lee et al [36]	Epidemic or pandemic	2020	Japan, Korea	Affective response	Twitter	4,951,289 (NR)	Trend analysis
Li et al [37]	Epidemic or pandemic	2020	China	Anxiety, depression, indignation, and Oxford happiness	Sina Weibo	NR (17,865)	*t* test
Low et al [38]	Epidemic or pandemic	2018-2020	Global	Eating disorder, addiction, alcoholism, ADHD[c], anxiety, autism, bipolar disorder, BPD[d], depression, health anxiety, loneliness, PTSD[e], schizophrenia, social anxiety, suicide, broad mental health, COVID-19 support	Reddit	NR (826,961)	Support vector machine, tree ensemble, stochastic gradient descent, linear regression, spectral clustering, latent Dirichlet allocation
Mathur et al [39]	Epidemic or pandemic	2019-2020	Global	Affective response	Twitter	30,000 (NR)	Sentiment analysis
Oyebode et al [40]	Epidemic or pandemic	2020	Global	General mental health concerns	Twitter, YouTube, Facebook, Archinect, LiveScience, and PushSquare	8,021,341 (NR)	Thematic analysis
Pellert et al [41]	Epidemic or pandemic	2020	Austria	Affective response	Twitter and unspecified chat platform for students	2,159,422 (594,500)	Trend analysis
Pran et al [42]	Epidemic or pandemic	2020	Bangladesh	Affective response	Facebook	1120 (NR)	Convolutional neural network and long short-term memory
Sadasivuni and Zhang [43]	Epidemic or pandemic	2020	Global	Depression	Twitter	318,847 (NR)	Autoregressive integrated moving average model
Song et al [44]	Epidemic or pandemic	2015	South Korea	Anxiety	Twitter, Unspecified blogs and discussion boards	8,671,695 (NR)	Multilevel analysis, association analysis
Xu et al [45]	Epidemic or pandemic	2019-2020	China	Affective response	Sina Weibo	10,159 (8703)	Content analysis, regression
Xue et al [46]	Epidemic or pandemic	2020	Global	Affective response	Twitter	4,196,020 (NR)	Latent Dirichlet allocation, sentiment analysis
Zhang et al [47]	Epidemic or pandemic	2020	United States	Depression, anxiety	YouTube	294,294 (49)	Regression, correlation, feature vector

[a]NR: not reported.

[b]GIS: geographic information system.

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

[d]BPD: borderline personality disorder.

[e]PTSD: posttraumatic stress disorder.

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Table 2. Summary of articles planning or evaluating interventions or policies from social media during a disaster.

Disaster category and reference	Disaster type	Disaster year	Disaster location	Mental health issue	Social media platform	Number of posts (number of users)	Analysis
Natural disaster							
Baek et al [48]	Geophysical, accident	2011	Japan	Anxiety	Twitter	179,431 (NR[a])	Time-series analysis
Human-made disaster							
Budenz et al [49]	Active shooter	2017	United States	Mental illness stigma	Twitter	38,634 (16,920)	Logistic regression
Glasgow et al [50]	Active shooter	2011-2012	United States	Coping and social support	Twitter	NR	Classifier (unspecified), qualitative coding analysis
Jones et al [6]	Active shooter	NR	United States	Psychological distress	Twitter	7824 (2515)	Time-series analysis
Epidemic or pandemic							
Abd-Alrazaq et al [51]	Epidemic or pandemic	2020	Global	Affective response	Twitter	167,073 (160,829)	Latent Dirichlet allocation
He et al [52]	Epidemic or pandemic	2020	Americas and Europe	Depression, mood instability	YouTube	255 (NR)	Touchpoint needs analysis
Massaad and Cherfan [53]	Epidemic or pandemic	2020	Undisclosed	Service access/needs	Twitter	41,329 (NR)	Generalized linear regression, k-means clustering
Wang et al [54]	Epidemic or pandemic	2020	China	Subjective well-being	Sina Weibo	NR (5370)	Regression, analysis of variance
Zhou et al [55]	Epidemic or pandemic	2020	China	Affective response	Sina Weibo	8,985,221 (NR)	Latent Dirichlet allocation

[a]NR: not reported.

Table 3. Summary of articles discovering new knowledge and generating hypotheses from social media during disasters.

Disaster category and reference	Disaster type	Disaster year	Disaster location	Mental health issue	Social media platform	Number of posts (number of users)	Analysis
Natural disaster							
Gaspar et al [56]	Biological	2011	Germany	Coping	Twitter	885 (NR[a])	Qualitative coding analysis
Shibuya and Tanaka [57]	Geophysical	2011	Japan	Anxiety	Facebook	873,005 (16,540)	Hierarchical clustering
Human-made disaster							
De Choudhury et al [58]	War	2010-2012	Mexico	Anxiety, PTSD[b] symptomatology, affective response	Twitter	3,119,037 (219,968)	Pearson correlation, *t* test
Epidemic or pandemic							
Van Lent et al [59]	Epidemic or pandemic	2014	Netherlands	Affective response	Twitter	4500 (NR)	Time-series analysis
Ye et al [60]	Epidemic or pandemic	2020	China	Prosociality, affective response	Sina Weibo	569,846 (387,730)	Regression

[a]NR: not reported.

[b]PTSD: posttraumatic stress disorder.

Estimating Mental Health Burden

Articles that estimated the mental health burden after a disaster typically examined the presence of any negative affect in posts using sentiment or affect dictionaries over the duration of the disaster. For example, Gruebner et al [16] monitored the mental health of New Yorkers during the Hurricane Sandy disaster of 2012 using sentiment analysis of Twitter posts. Over 11 days surrounding the hurricane's landfall, 24 spatial clusters of basic emotions were identified: before the disaster, clusters of anger,

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confusion, disgust, and fear were present; a cluster of surprise was identified during the disaster; and finally a cluster of sadness emerged after the disaster. Expanding on this, Jones et al [24] examined the mental health trauma impact of school shooting events across 3 US college campuses using a quasi-experimental design. Specifically, an interrupted time series design was used with a control group and a reversal when the next shooting event occurred in the original control group's college. Increased negative emotion was observed after all 3 shooting events, particularly among users connected to the affected college campus within 2 weeks of the shooting. Finally, a few articles explored specific mental health conditions rather than general negative sentiments (eg, depression [28], stress [29], and anxiety [30]). One notable study by Low et al [38] examined mental health during the impact of the initial stages of the COVID-19 pandemic on 15 mental health support groups on Reddit, allowing for disorder-specific monitoring and comparison. An increase in health anxiety and suicidality was detected across all mental health communities. In addition, the attention deficit hyperactivity disorder, eating disorder, and anxiety subreddits experienced the largest change in negative sentiment over the duration of the study and became more homogeneous to the health anxiety subreddit over time.

Planning or Evaluating Interventions or Policies

Articles evaluating the mental health impact of disaster interventions or policies focused primarily on the association between public health measures during the COVID-19 crisis, such as lockdowns, personal hygiene, and social distancing, with social media users' mental health. For example, Wang et al [54] compared the subjective well-being of Sina Weibo users in China during lockdown versus those who were not, finding that lockdown policy was associated with an improvement in subjective well-being, following very low initial levels recorded earlier in the pandemic. Next, 2 studies examined the relationship between crisis communication and the mental health of social media users impacted by a disaster, including government communication during the 2011 Great East Japan Earthquake or Fukushima Daiichi Nuclear Disaster and a school shooting event in the United States [6,48]. Both studies found that unclear or inconsistent official communication delivered via social media was associated with a proliferation of rumors and public anxiety. Finally, 3 studies examined the mental health service needs of social media users following disasters, including telehealth needs during the COVID-19 pandemic, mental illness stigma following a mass shooting, and the support offered to disaster victims after a tornado and mass shooting [49,50,53]. Combined, these studies identified potential methods to assess the need for policies or interventions for mental health issues following a disaster by examining the access and availability of services to social media users.

Knowledge Discovery

The 5 articles that were classified as knowledge discovery aimed to evaluate theories of human behavior and mental health during disasters using social media data. This included examining the impact of psychological distance on the attention a disaster receives from social media users [59], prosocial behavior, coping, and desensitization to trauma during the disaster [56,58,60] and predicting recovery from social media users' purchasing behaviors and intentions [57].

Disaster Mental Health Methods

Assessing Mental Health

A total of 4 methods were identified to assess mental health using social media data. First, linguistic methods were the most frequently used (26/47, 55%), such as the presence of keywords generated by the study authors (eg, *loneliness* and synonyms [34]) applying established dictionaries (eg, the Linguistic Inquiry and Word Count (LIWC) dictionary [27]), or pretrained language models (eg, Sentiment Knowledge Enhanced Pre-training [31]). Second, human assessment was used in 18 studies, with 61% (11/18) using human annotators to conduct qualitative coding, typically for nuanced mental health information (eg, type of social support received [50]), and 39% (7/18) of studies interpreting a mental health topic from a topic modeling analysis. Next, 2 studies used mental health forum membership to indicate mental health problems [29,38], with Saha and De Choudhury [29] using a novel method of transfer learning from a classifier trained on a mental health subreddit (r/stress) and a random sample of Reddit posts to identify posts with high stress on college-specific subreddits following gun-related violence on campus. Finally, mental health questionnaires were used in 2 studies, specifically, the Patient Health Questionnaire-9 item and 7-item Generalized Anxiety Disorder scale [47], and Psychological Wellbeing scale [54].

Very few studies had implemented methods to improve data quality and validity of mental health assessments. A total of 3 studies included direct coding of posts using validated mental health measures. For example, Saha et al [29] directly annotated r/stress Reddit posts for high or low stress using the Perceived Stress Scale to develop a classifier. Gaspar et al [56] directly coded 885 tweets for coping during a food contamination crisis in Germany with a coping classification framework by Skinner et al [61]. Furthermore, very few studies had included a control or comparison group to delineate the relationship between the disaster and mental health. Comparison groups were identified in 8 studies: 63% (5/8) studies used a between-groups design typically selecting users from a different location to the disaster event as a comparison [23,31,38,49,54], and 38% (3/8) used a within-subjects comparison by comparing social media users against their own data from a different point in time [27-29].

Data Collection and Preprocessing

Data were primarily collected via the platform's public streaming application programming interface (API) (20/47, 42%); for example, the Twitter representational state transfer (REST) API. Digital archives and aggregation services of social media data were the next most commonly used method (10/47, 21%), such as the Harvard Center for Geographic Analysis Geotweet Archive [5,17] and the TwiNL archive [59]. Finally, a few studies used other techniques, including web crawlers (8/47, 17%), third-party companies (2/47, 4%), and other novel methods (2/47, 4%) such as having participants download and share their use patterns via Google Takeout [47]. A handful of studies did not report their data collection method (6/47, 13%). In most studies (39/47, 83%), individual posts were the unit of

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analysis, rather than the user contributing to those posts (8/47, 17%). Sampling methods typically involved selecting posts or users with location data and key terms related to crisis events. Identifying the location of users or posts included extracting location data from profile pages [57], selecting users or posts with geotagged posts [53], or identifying users or posts with hashtags of the crisis location [58]. A few studies selected users that followed organizations local to the crisis event, including college campus subreddits or Twitter profiles [24,29]. Key terms related to the crisis event included hashtags or key terms of the event (eg, #Ebola [59]) or mental health keywords (eg, suicide or depression synonyms [30]).

Preprocessing steps to prepare the data for analysis were reported in 36 articles, and typically involved translating posts into a single language (typically English) or removing posts in other languages, identifying and removing posts containing advertising or spam, and removing duplicate posts (eg, retweets). Usernames, URLs, and hashtags were either removed or normalized. Many studies have also removed posts without keywords related to crisis events, such as location or crisis-specific terms. Studies using natural language processing methods have conducted additional preprocessing steps to clean the data before machine analysis, including removing punctuation, stopwords, and nonprintable characters, and stemming, lemmatizing, and tokenizing words. No studies reported how missing data were handled, or evidence of strategies to improve data quality, such as minimum thresholds of engagement with social media or mental health disclosure.

Feature Extraction

Several features were extracted across studies, which have been grouped into linguistic, psycholinguistic, demographic, and behavioral features. Psycholinguistic features were the most frequently identified (34/47, 72%), and included sentiment (positive, negative, or neutral), affect (positive or negative), time orientation (past, present, or future tense), personal concerns (eg, LIWC's work, money, and death dictionaries), humor, valence, arousal, and dominance. These features were typically extracted using established lexicons, such as Stanford CoreNLP and LIWC. Some studies used direct coding of posts for psycholinguistic features, for example, attitudes toward vaccinations [62], and whether the post contained fear for self or others [59]. Linguistic features were present in 24 studies and included n-grams, term frequency–inverse document frequency statistics, bag of words, usernames, hashtags, URLs, and grammar and syntax features. Demographic features were less commonly used (12/47, 26%), but typically involved the location associated with the social media post. Some studies engineered location data into new metrics, for example, negative emotion rate per local area surrounding the disaster [18]. A few studies identified the age and gender of users by extracting the information from user profiles [37] or via age and gender lexicons (eg, Genderize API [27]).

Although most studies used linguistic, psycholinguistic, and demographic features only, a few studies also extracted additional features about users' behaviors. Behavioral features were identified in 7 studies and included metrics such as a user's social media post rate [22], sharing of news site URLs [27], and directly coded behaviors such as handwashing and social distancing [44]. Behavioral features also included the aspects of the user' social network (identified in 3 studies), including the user's friend and follower counts [53,63], and social interaction features (identified in 4 studies), such as the use of @mentions [27,63] and retweets [6].

Analytic Methods

A range of analytic methods have been used across studies, including machine learning, statistical modeling, and qualitative techniques. The most common approach was trend analysis to examine temporal changes in mental health before, during, and/or after a disaster event (24/47, 51%). Geospatial analytic methods were also identified (4/47, 8%), including geographic information system methods to examine location-based differences in mental health factors during disasters [18]. A few studies have used machine learning classifiers to categorize posts or users into groups (eg, high vs low stress in study by Saha et al [29]), namely support vector machine (6/47, 13%), maximum entropy classifier (1/47, 2%), multinomial naïve Bayes (2/47, 4%), long short-term memory (2/47, 4%), naive Bayes (1/47, 2%), J48 (1/47, 2%), convolutional neural network (1/47, 2%), tree ensemble (1/47, 2%), and stochastic gradient descent classifier (1/47, 2%). Validation metrics for these studies involved train-test splits and k-folds cross-validation, with k ranging from 5 to 10. Finally, a number of studies implemented topic modeling (12/47, 25%) and qualitative analytic approaches (8/47, 17%) to identify themes in social media discussions during the disaster. Topic modeling included latent Dirichlet allocation (5/12, 42%) (eg, [33]), k-means clustering (3/12, 25%) (eg, [20]), hierarchical cluster analysis (2/12, 17%) (eg, [34]), and other clustering methods (3/12, 25%) (eg, [19]). Qualitative analyses included topic analysis (1/8, 12%) [25], thematic analysis (2/8, 25%) (eg, [64]), touchpoint needs analysis (1/8, 12%) [52], content analysis (1/8, 12%) [45], and other coding techniques (3/8, 37%) (eg, [26]).

Ethical Considerations

There was limited discussion of the ethics of pervasive mental health monitoring in the identified studies (18/47, 38%). A total of 7 studies noted that their research protocol was reviewed and approved by an institutional review board, and 5 stated that their research was exempt from ethical review. A total of 8 studies noted participant privacy concerns, addressing this by anonymizing usernames or handles, accessing only public information about users, and not publishing verbatim quotes from posts. Furthermore, 5 articles provided information capable of reidentifying social media users involved in their study, such as direct quotes from users and social media post IDs. In addition, 2 studies noted that their work complied with the platform's data use policy. Only 1 study sought direct consent from social media users to access their data.

Methodological Reporting

As noted previously, the included literature was inconsistent in its reporting of key factors, such as the place, date, and type of the disaster; social media platform used; number of unique users within the data set; handling of missing data; preprocessing steps; data quality requirements; final feature set included in

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the analysis; rationale for mental health assessment methods, analysis plan, overall study design; and ethical considerations. These details are important for accuracy in the interpretation and reproduction of research findings. To assist researchers in improving their study quality and reporting, Textbox 1 presents a checklist of key methodological decisions to be considered and reported, where appropriate. The checklist was based on the data extraction template used for the current review and is intended as a guide for key study design and reporting considerations. None of the included studies met all of the reporting criteria.

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Textbox 1. Reporting checklist for the social media analysis of mental health during disasters.

Research design and theoretical formulation

- Type, place, and dates of disaster event
- Use and selection of control or comparison group (eg, between or within subject design with comparison users at a different time point, geographic location, and social media platform)
- Consideration of causal inference methods (eg, natural experiment design, positive and negative controls)
- Theoretical justification of research question (eg, theories of mental health onset or progression and web-based social interaction)

Data collection

- Social media platforms targeted (eg, Twitter, Reddit)
- Data collection method specified (eg, application programming interface, scraping, and data provided by user directly)
- Sampling frame restrictions (eg, dates, geolocation, keyword requirements)
- Number of unique social media posts and users
- Consideration of sampling biases and confounding factors (eg, matching demographics to census data)

Mental health assessment

- Methods for assessing mental health status (eg, sentiment analysis, human annotation)
- How ground truth was obtained (eg, manual coding of social media posts, participant completion of validated psychological measures)
- Clinical justification for assessment method (ie, evidence to support the clinical validity and reliability of the assessment method)

Preprocessing and feature extraction

- Details of any manipulations to the data (eg, text translation)
- Criteria for removed social media posts or users (eg, spam or advertisements)
- Use of minimum engagement thresholds (eg, users were required to have >1 post per week)
- Handling of missing data (eg, multiple imputation)
- Transformation of data (eg, tf-idf or word to vector)
- Explicit number of features extracted and used in analysis

Analysis

- Analytic technique or algorithm selection justification (ie, techniques suitability to address the research question)
- Consideration of statistical techniques for causal inference (eg, propensity scores)
- Validation technique and metrics (eg, k-fold cross-validation; test or train split)
- Performance or fit of algorithm (eg, F1-score, accuracy)
- Number of data points
- Error analysis and explanation (eg, sensitivity analysis)
- Feature reduction techniques (eg, principal-component analysis, forward feature selection)

Ethical considerations

- Compliance with social media platform's data policy (eg, Twitter terms of use)
- Consideration of ethical research obligations (eg, ethical review board approval)
- Minimizing human exposure to participant data where possible (eg, restricting human researcher access to data when not required, use of machine-based analyses)
- Individual participant data not reported without consent (ie, aggregate results reported only)
- Use of public social media data only (ie, no login or interaction with users required to access the data)
- Anonymization of data to maintain participant privacy (eg, removing usernames or identifiable photos, natural language processing techniques such as named entity recognition, publishing metadata only in data repositories)

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Discussion

Principal Findings

This study synthesized the literature assessing mental health in disasters using social media, highlighting current applications and methods. Research has predominantly focused on retrospectively monitoring the negative affect of social media users local to a disaster area using established psycholinguistic dictionaries. Emerging research has assessed other public mental health issues, including the impact of news and government messaging, telehealth access, and mental health stigma. Analytic techniques are sophisticated in identifying relevant social media users and modeling their changing mental health after a disaster. Overall, social media offers a promising avenue to efficiently monitor public mental health during disasters and is capable of overcoming many logistical challenges of traditional methods such as large sample sizes, before, during, or after event data, and collection of comparison or control data.

As an emerging field, there are understandably significant gaps for future research to address. It is evident that mental health is broadly conceptualized by researchers as negative affect or distress, assessed using sentiment or affect dictionaries. However, it remains unclear whether spikes in posts with negative affect detected during and after disasters are clinically meaningful changes warranting intervention or the natural course of psychopathology following a distressing event [65]. More participatory research could address this issue by combining passive social media monitoring with validated psychological measures capable of capturing both distress and dysfunction in the affected population [47]. Furthermore, few studies have examined the use of social media to assess the impact of disasters on the mental health of vulnerable populations, including those with pre-existing mental health issues. Only one identified study compared how different mental health communities were affected following a disaster [38], finding both similarities and differences in responses between disorder-specific communities. Researchers may consider investigating how specific mental health conditions can be detected and monitored using social media, particularly focusing on disorders that are likely to experience exacerbated symptomatology during disasters.

Beyond community mental health assessment, it is also clear that there is scope to improve the field by using more robust research methods. Most studies used an observational pre-post crisis event design, with few studies including a control or comparison group or causal inference methods. Social media data offer many opportunities for rich study designs, including natural experiments or positive and negative control designs. Such designs would assist in delineating the impact of crisis events and response efforts on mental health. Researchers should consider how to collect representative samples or control for demographic differences in analyses, for example, by matching sample data with census information, with very few studies considering the generalizability of results. Notably, researchers in this field should be mindful of differences between measures of association (eg, *lockdown measures were associated with increased loneliness on Twitter)* and causal claims (eg, *the terrorist attack increased anxiety on Reddit*) in observational studies. Causal claims should not be inferred outside of causal models, as there may be multiple possible causes to the observed effects that are not able to be measured and controlled in observational research designs. Importantly, controlled studies may be infeasible when modeling unforeseen events such as disasters or large, varied populations over time; therefore, finding associations through public health monitoring could be incredibly useful.

Further, few studies have considered the ethical implications of their research. Current ethical guidelines state that the large-scale and public nature of social media data may enable such research to be exempt from review by ethics committees. Nevertheless, researchers need to be mindful of the sensitive nature of inferring mental health states using unvalidated methods from social media data that may not be anonymous. The community needs to develop protocols for managing social media users' privacy while maintaining high-quality research practices, including balancing participant privacy with open science principles of data sharing [66]. Researchers should be mindful that, despite the public nature of the collected data, social media users may have privacy concerns about their data being aggregated into a permanent, curated data set to enable inferences about their mental health, without their knowledge or consent [67]. Ethical data sharing protocols could include sharing the data with qualified researchers to improve reproducibility and open science practices and removing ties between a user's posts and profile in publications, such as paraphrasing quotes and publishing meta data rather than identifiable profiles or posts. Researchers also need to ensure that their study complies with the data use policies of the platforms they are accessing, including user privacy requirements and the platform's preferred data access methods.

Finally, there are exciting avenues for future research that will greatly progress the field. Emerging research has developed and evaluated new theories and hypotheses of mental health during disasters using social media data, providing exciting advances in our understanding of how social media data can be capitalized for knowledge discovery [58,60]. Such research should be encouraged by both computer and mental health scientists, given that other public health applications can be achieved by government organizations as part of their disaster response efforts [65]. No study has evaluated the clinical utility of social media mental health monitoring by developing and testing real-world disaster management tools. Creating simple tools for disaster mental health monitoring and translating them into real-world settings will likely elicit new challenges that may not be present in the laboratory, particularly when applied across different clinical and emergency contexts. Another promising avenue for future research is to combine social media mental health monitoring with interventions. This could be achieved by detecting individuals in need of support and directing them toward available interventions, including those designed for disaster contexts (eg, psychological first aid or debriefing and crisis counseling), tailored mobile health and eHealth tools, or broader social media–based interventions [68]. Finally, the field would greatly benefit from more collaboration between mental health and computer science experts to bring nuance to the

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conceptualization of mental health and its assessment alongside sophisticated analytic methods.

There are 2 key limitations to this review that should be considered along with the study findings. First, the scoping review methodology entails a rapid and broad search to identify and map relevant literature. To balance these requirements, the search strategy used broad search terms and excluded non-English and non–peer reviewed literature [69]. A more in-depth review would potentially capture additional relevant studies, but would be less feasible to complete and would date quickly given the rapidly evolving nature of the field. Second, this study did not delineate how effectively social media can be used to capture mental health impact during a disaster event, as validation of mental health assessments against other measures was limited. To address both limitations, future work could conduct an in-depth review of specific mental health issues, social media, or disaster contexts, guided by the framework developed in this study.

Conclusions

In conclusion, there have been exciting advances in research aimed at monitoring mental health during disasters using social media. Overall, social media data can be harnessed to infer mental health information useful for disaster contexts, including negative affect, anxiety, stress, suicide, grief, coping, mental illness stigma, and service access. Sophisticated analytic methods can be deployed to extract features from social media data and model their geospatial and temporal distribution over the duration of the crisis event. As an emerging field, there are substantial opportunities for further work to improve mental health assessment methods, examine specific mental health conditions, and trial tools in real-world settings. Combined, such platforms may offer a useful avenue for monitoring mental health in contexts where formal assessments are difficult to deploy and may potentially be harnessed for response effort monitoring and intervention delivery.

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Authors' Contributions

SJT conceived the study, participated in its design and coordination, performed the search and data extraction, interpreted the data, and drafted the manuscript. ABRS conceived the study, participated in its design and coordination, contributed to the data extraction, contributed to the interpretation of the data, and helped to draft and revise the manuscript. EW and MFT assisted with the interpretation of the data and helped draft and revise the manuscript. DMH participated in the study's design and coordination, contributed to the interpretation of the data, and helped to draft and revise the manuscript. All authors read and approved the final manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) extension for Scoping Reviews checklist.
[PDF File (Adobe PDF File), 66 KB - mental_v9i2e33058_app1.pdf]

Multimedia Appendix 2
Search details.
[DOCX File , 13 KB - mental_v9i2e33058_app2.docx]

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Abbreviations

API: application programming interface
LIWC: Linguistic Inquiry and Word Count
PRISMA-ScR: Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews

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Original Paper

International Technologies on Prevention and Treatment of Neurological and Psychiatric Diseases: Bibliometric Analysis of Patents

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Abstract

Background: Neurological and psychiatric disorders are serious and expensive global public health problems. Therefore, exploring effective intervention technologies plays an important role in improving patients' clinical symptoms and social functions, as well as reducing medical burden.

Objective: The aim of this study is to analyze and summarize the key new technologies and innovative development trends witnessed globally for neurological illness and psychiatric disorders by mining the relevant patent data.

Methods: A bibliometric analysis was conducted on patent applications, priority countries, main patentees, hot technologies, and other patent information on neurological and psychiatric disorders, revealing the current situation along with the trend of technology development in this field.

Results: In recent years, inventions and innovations related to neurological and psychiatric diseases have become very active, with China being the largest patent priority country. Of the top patent holders, Visicu (headquartered in the United States) is the leader. The distribution of patent holders in China remains relatively scattered, with no monopoly organization at present. Global technologies on neurological illness and psychiatric disorders are mainly concentrated around A61B (diagnosis, surgery, and identification).

Conclusions: This paper analyzed and summarized the key new technologies and global innovative development trends of neurological and psychiatric diseases by mining the relevant patent data, and provides practical references and research perspectives for the prevention and treatment of the aforesaid diseases.

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KEYWORDS

neurological diseases; psychiatric diseases; patent; bibliometric analysis; prevention; treatment

Introduction

Neurological diseases mainly include diseases of the central nervous system, peripheral nervous system, skeletal muscle, among others, whereas mental diseases pertain to obstacles in mental development, emotion, volition, and behavior, etc. Although neurological illness and psychiatric disorders [1-3] cross each other, they are neither fully inclusive nor completely distinguishable. Studies based on neurological and psychiatric diseases can promote the generation and progress of related technologies, which can also further improve the prevention, diagnosis, and treatment of these diseases. Since the mid-20th century, many countries have performed studies on neurological and psychiatric diseases [1-3]. The United States, the European

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Union, Japan, Australia, and other developed countries have commenced long-term projects and increased financial support for scientific studies on neurological illness and psychiatric disorders [1-3] by proposing special and strategic plans to constantly expand research (both studies and teams) in this area. The United States plays a leading role in the investigation of neurological and psychiatric diseases. The National Institute of Medicine (NIH) and the National Science Foundation (NSF) are the main management and funding agencies in this field. The most prominent area of research in the field is *brain science*. The "Brain Research Through Advancing Innovative Neurotechnologies" (BRAIN) focuses on the construction of brain maps and new related medical treatments [4,5]. European Union's "Human Brain Project" (HBP) puts emphasis on simulating brain functions via supercomputer technologies to realize artificial intelligence [6]. The Brain/MINDS (Brain Mapping by Integrated Neurotechnologies for Disease Studies) Program of Japan is focused on establishing animal models of brain development and diseases for studying the treatment of neurological and psychiatric diseases [7]. The Australian Brain Initiative lays stress on developing new treatment methods, new drugs, medical equipment, and wearable technologies by revealing the abnormal brain mechanisms of neuropsychiatric diseases [8]. As for China, financial support for studies on neurological and psychiatric diseases mainly comes from the National Natural Science Foundation (NSFC), the National Key Research and Development Plan, the National Key Basic Research and Development Plan of the Ministry of Science and Technology (973 Plan), and the National High-tech Research and Development Plan (863 Plan). Chinese studies were mainly performed on basic neurobiology techniques, neuropsychiatric diseases, brainlike artificial intelligence, transformative neuroscience, and supporting platform construction. Besides, China has strengthened the cultivation and support of neurological and psychiatric medication, neurobiomedical engineering, and artificial intelligence industries [9].

Many of the aforementioned technological achievements have successfully clarified the causes of several neurological and psychiatric diseases and reported the prevention and treatment measures. For example, the development of neural networks, internet, and big data technologies has enabled the prevention and treatment of related diseases at both population and individual levels. Analysis of the technological achievements concerning neurological and psychiatric diseases worldwide can reveal the progress and achieved cure level of each country in this field. Patent databases, an important analysis object, include more than 90% of the latest and most detailed technical information, and thus can accurately reflect the overall situation and development trend of technological innovation in global neurological and psychiatric diseases. Moreover, by performing patent bibliometric analysis, the internal information about technologies on neurological and psychiatric diseases such as distribution structure, quantitative relationship, and change rules can be clarified. Therefore, this study applied patent bibliometric analysis to explore the global research status and development trend of neurological and psychiatric diseases to provide valuable references for promoting the prevention and treatment of neurological and psychiatric diseases from an information science perspective.

Methods

Data Sources

Information about technologies on neurological and psychiatric diseases (IPC A61B5, G16 and H04, LOC 24) was retrieved and collected by International Patent Classification (IPC) and Locarno Classification (LOC). The date of data retrieval and download was September 1, 2019, and a total of 328 valid relevant patents were obtained.

Data Collection and Analysis

The search keywords were psychosis, rehabilitation, psychology, rehabilitation training, rehabilitation resource survey, mental illness, mental trauma, psychological care, alzheimer's, schizo, autism, anxiety, depressed, paranoid, manic, commit suicide, and so on. The retrieval type was "or." First, all patent data were converted into plain text format and directly imported into a professional data analyzer (Thomson Data Analyzer [TDA]). The data were then cleaned, integrated, and analyzed. We adopted patentometric analysis and visualization to investigate the global technology development trends in the field of neurological and psychiatric disorders based on the following: patent application, distribution of patent priority countries, major patentees, hot technologies, patent citations, and so on.

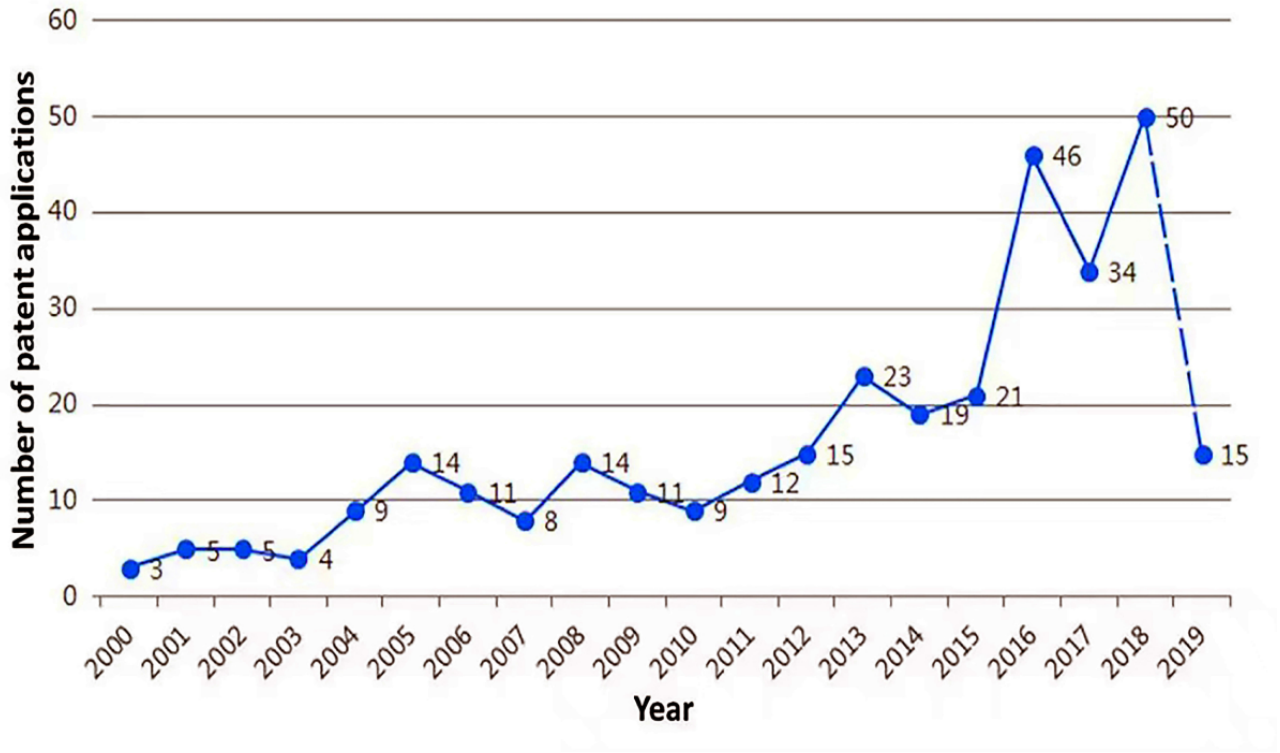
Results

Global Patent Application and Authorization

A total of 328 patents related to neurological and psychiatric diseases were retrieved from 16 countries (regions), including 191 applications for inventions, 104 grants for inventions, 16 designs, and 17 utility models. Trend analysis was performed on the number of patent applications submitted annually (Figure 1). In the past 10 years, the number of patent applications related to the prevention and treatment of neurological and psychiatric disorders has generally increased year by year. However, the number of relevant patent applications was relatively small and the growth rate was relatively low (Figure 1). From 2015 onward, the growth rate began to accelerate and subsequently the number of applications submitted began to rise rapidly. From 2000 to 2004, the number of patent applications for neurological and psychiatric diseases was relatively low and was in the first stage (Figure 1). The second phase was from 2004 to 2015, and the number of applications increased to a certain extent. Since 2015, it has been in the third stage, and the number of applications has doubled from the previous stage.

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Figure 1. Trend chart of patent application.

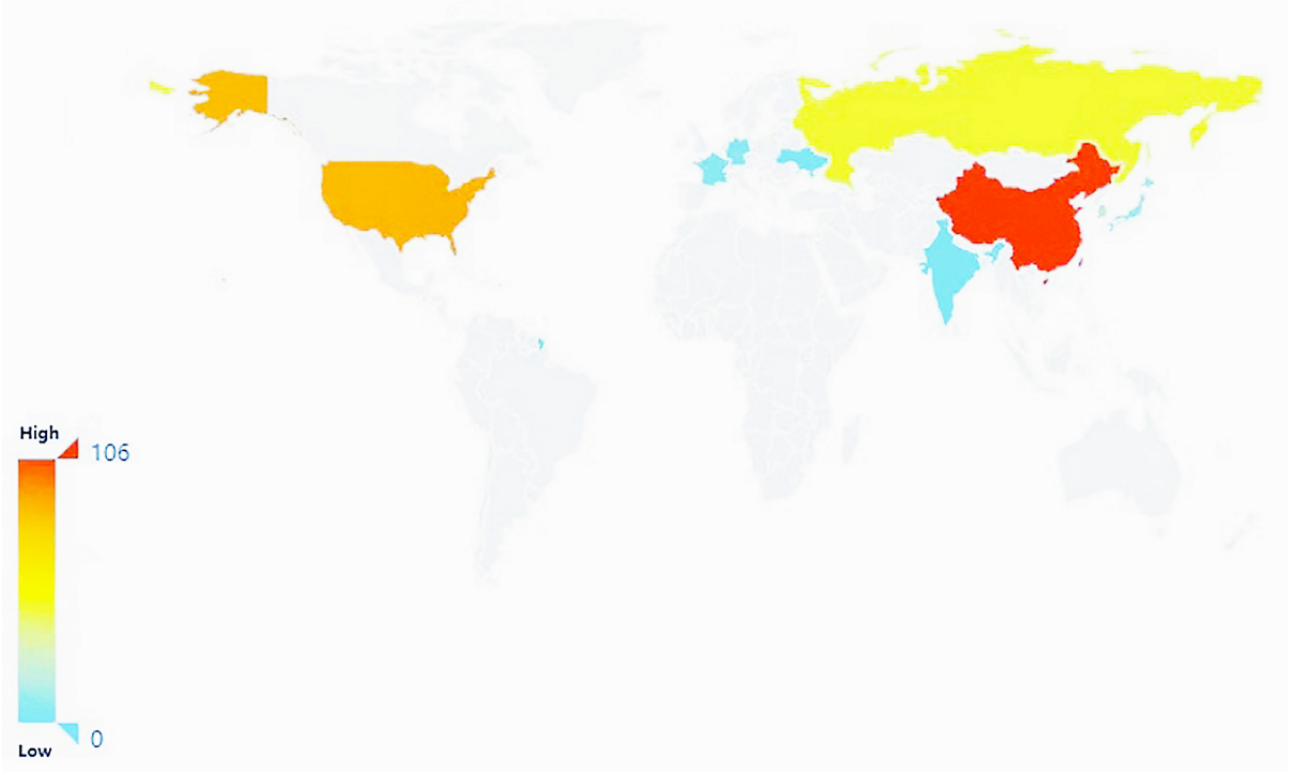


Analysis of Regional Competition Situation

If an applicant files a patent application for his invention in one country for the first time and then files a patent application for the same subject matter in another country within the statutory period, the date of the first patent application shall be used as the filing date for the subsequent application according to the relevant law, so as to exclude the possibility of copying the patent in other countries and filing a pre-emptive application to obtain registration. By analyzing the distribution of patent priority countries, the attention and technical strength of various countries in this field can be deduced. Figure 2 shows the global regional distribution of the patent applications for neurological illness and psychiatric disorders. Since 2000, patent applications in this area have mainly come from China, the United States, and Russia. Among them, China and the United States are the front runners (or form the first echelon). The United States, which was the first country to introduce community-based prevention and treatment for patients with psychiatric disorders, developed community psychiatric rehabilitation technologies earlier than China and other countries. After more than 40 years of practice, community service has developed rapidly and achieved good results. China followed suite, occupying the second place, and currently has the largest number of patents. Russia, South Korea and Japan, as the second echelon, have submitted relatively few applications. France, Germany, India, Ukraine, the Soviet Union, Brazil, Canada, Europe, and the United Kingdom are in the third tier with even fewer applications. As for the distribution of patent priority countries, China leads the race and currently holds many core patents. As neurological and psychiatric disorders are common chronic noncommunicable diseases, and because China emphasizes on chronic disease management and continuous improvement of the medical security system, Chinese technologies for neurological and psychiatric diseases are showing a trend of continuous progress.

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Figure 2. Global regional distribution of patent applications.



Major Patentee

An analysis of those holding patents (ie, patent holders) on technologies useful for treating neurological and psychiatric disorders and the identification of major application agencies in this field can provide a strategic basis for interagency cooperation and competition. Visicu headquartered in Baltimore, Maryland, ranks second in the number of applications submitted and is the largest transferee of related patents in the world. As a clinical IT service provider and medical monitoring system developer, the company mainly develops and applies remote patient monitoring and diagnostic support technologies. Visicu was acquired by Royal Philips in 2008 (with the acquisition estimated to be 30 times the income before interest, taxes, depreciation, and amortization calculation). As can be seen from Table 1, Visicu's applications are all US patents, most of which were filed in 2005 [10-19]. The major applications were A61B (diagnosis, surgery, and identification), G06F (electric digital data processing), and G08B (signaling or calling systems, order telegraphs, and alarm systems), which refer to electric digital data processing for diagnosis or surgery, and identification of medical and hygienic human necessities. Those are basically consistent with the technical distribution of relevant US patents.

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Table 1. Patent form of Visicu (United States).

Patent name	Publication number	Application date	Reference
Remote command center for patient monitoring	US8175895B2	March 4, 2005	[10]
System for providing expert care to a basic care medical facility from a remote location	US7991625B2	May 31, 2006	[11]
System and method for displaying a health status of hospitalized patients	US7433827B2	February 18, 2005	[12]
Using predictive models to continuously update a treatment plan for a patient in a health care location	US7395216B2	May 31, 2006	[13]
System and method for displaying a health status of hospitalized patients	US20060161459A9	March 31, 2005	[14]
System and method for standardizing care in a hospital environment	US20060122869A9	February 18, 2005	[15]
Remote command center for patient monitoring relationship to other applications	US20060085229A9	March 4, 2005	[16]
System and method for displaying a health status of hospitalized patients	US20050187796A1	March 31, 2005	[17]
Remote command center for patient monitoring relationship to other applications	US20050177400A1	March 4, 2005	[18]
System and method for standardizing care in a hospital environment	US20050159987A1	February 18, 2005	[19]

The most frequently cited patent of Visicu is US7395216B2 [13], which uses predictive models to continuously update treatment plans for patients in different health care locations. The system comprises a database of patient data elements indicative of a medical condition associated with a patient. A predictive model is applied to patient assessment data and used to prepare a treatment plan. A rules engine applies a patient rule consistent with the treatment plan to selected data elements stored in the database to produce an output indicative of a change in the medical condition of the patient. The output from the rules engine is used to determine whether intervention is warranted. The predictive model is applied continuously to determine whether to update the treatment plan and, if necessary, the patient rule.

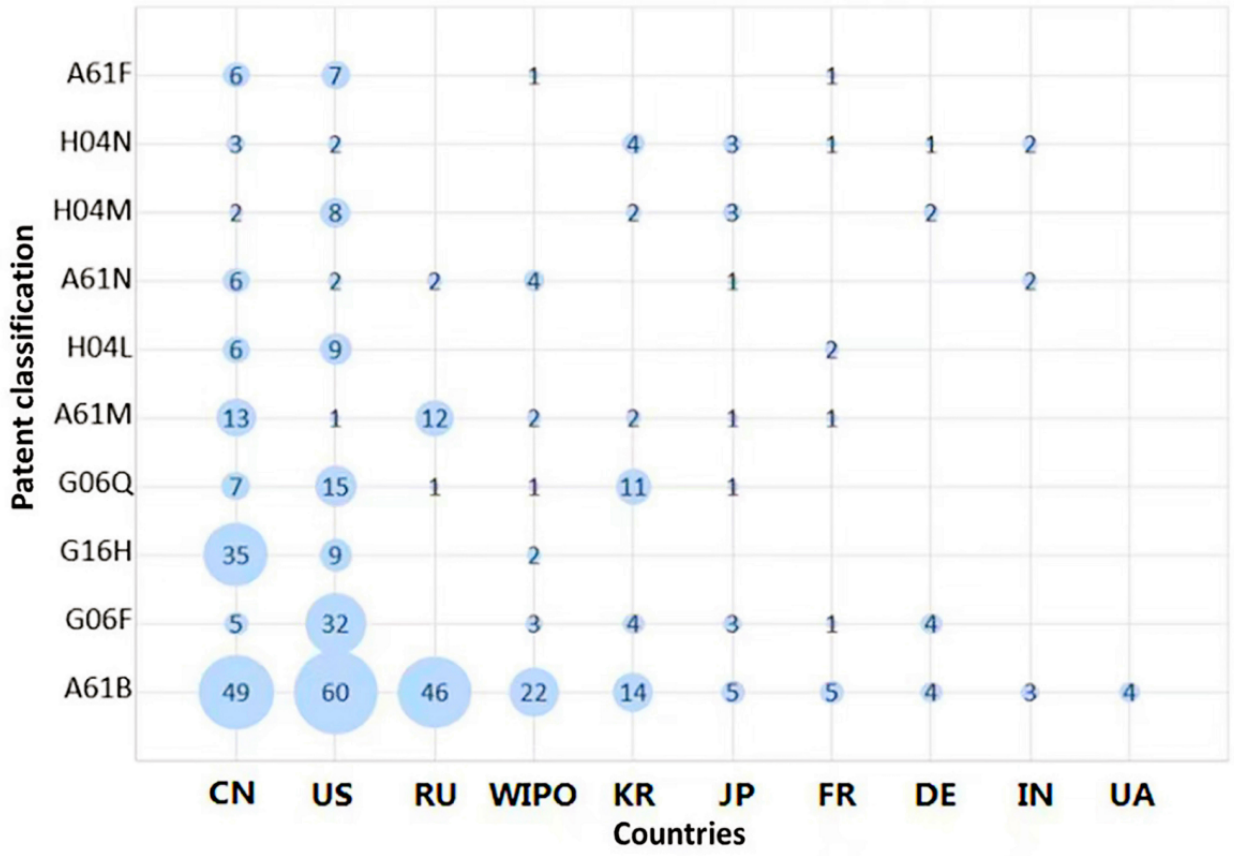
Analysis of Technological Competition Situation

Analysis of Global Patent Hotspots

An analysis of the hotspots of patents related to neurological and psychiatric diseases indicated that researchers in the field are making continuous efforts to identifying new therapies and drugs, to further improve the effect of treatment and reduce the recurrence rate. Among the patents related to neurological illness and psychiatric disorders, most countries, especially the United States, have focused on A61B (ie, diagnosis, surgery, and identification; Figure 3). US A61B patents have been cited and transferred more frequently than those of other countries. For example, the patent named *Medical Emergency Alert System and Method* applied by Hwang et al [20] has been cited 286 times in various patents submitted by different countries. The medical emergency reporting system and its methodology utilizes a wearable monitoring device to continuously monitor key physiological parameters of a person, and when measurements exceed programmed threshold levels, it will automatically issue a medical emergency alert along with location information to a remote monitoring center via a wireless network and the internet for immediate local response. This system also provides manual emergency alert activation, continuous updates with key physiological measurements to the emergency response personnel along with the medical history of the individual as well as redundancy in emergency alert reporting and malfunction diagnosis to ensure accuracy, immediacy, and reliability for the person that requires medical assistance.

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Figure 3. Patent technical distribution. CN, China; DE, Germany; FR, France; IN, India; JP, Japan; KR, Korea; RU, Russia; UA, Ukraine; US, United States; WIPO, World Intellectual Property Organization.



The US patents also concentrate on electric digital data processing (G06F), mainly the technologies related to internet big data. Among the US G06F patents, the latest trend pertains to computer-aided patient navigation and information systems. Such a system scans a patient's electronic and oral communication to determine the medical needs of the patient, and then displays relevant information to appropriate medical personnel who can immediately advise the patient of the most appropriate source of medical assistance based on the identified symptoms.

China pays increased attention to the G16H (2018) class of patents, which pertains to psychotherapy research, and involves mainly psychotherapy, self-training, or computer-aided diagnosis. For example, the Medical Expert System [21], which comprises a mental retardation drug recommendation method and a system based on subtype classification of mental disorders, applied by Fudan University utilizes artificial intelligence and machine learning techniques to classify mental disorders by data mining and analysis of mental disorder diagnosis and treatment scale. The method specifically includes preliminary disease judgment, biclustered subtype classification, a posttreatment evaluation prediction model, and schizophrenia drug recommendations. The method can realize accurate and objective disease auxiliary diagnosis and treatment. Another example is Personal Health Risk Assessment [22], which includes a system and a device for evaluating the health status and rehabilitation progress. It is able to acquire physiological and psychological data, and then respectively perform feature selection/extraction on the data by mining and machine learning technologies. This method can provide more accurate health state evaluation, along with more rapid and effective treatment. Besides, there is information and communication technology. The Shenzhen Nanshan District Chronic Disease Prevention and Treatment Hospital has applied for a quality management system of community mental health service based on big data analysis. The system comprises an internet terminal module for mental health service, work management, and health education; a mental health service module for doctor follow-up, medical referral, and patient consultation; and a work management module for supervision and quality control. All kinds of information are collected into the subsystem and sent to the general system. Subsequently, the general system comprehensively evaluates the quality of community mental health services based on these big data. This tool assists doctors and assesses their work, to more comprehensively check for deficiencies and continuously improve mental health services.

Analysis of Global Application Types

The global patents for neurological and psychiatric disorders were mainly invention patents (Multimedia Appendix 1), which shows that the novelty and creativity of the patents in this field are relatively high and the quality of the patents is quite good.

Chinese invention patent grants related to neurological and psychiatric disorders were relatively few (Table 2). This is because the related technologies in China have only begun to sprout in recent years. Those concerned have just begun to apply

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for patent filing, and there is not enough time for examination and authorization. However, from the analysis of the number of applications and authorizations for invention patents in the United States, we can see that, after a period of development, the number of grants in the United States has started to increase. By contrast, Russia has a very large number of grants and a relatively high authorization rate.

Table 2. Types of global patents on neurological and psychiatric diseases.

Countries and regions	Invention/patent application, n	Invention patent grants, n	Design patents, n	Utility models, n
China	72	9	16	12
United States	52	33	0	0
Russia	4	40	0	2
World Intellectual Property Organization	24	0	0	0
Korea	10	12	0	0
Japan	8	3	0	0
France	4	3	0	0
Germany	5	1	0	0
India	4	1	0	0
Ukraine	0	2	0	2
Union of Soviet Socialist Republics	3	0	0	0
Brazil	1	0	0	1
Canada	2	0	0	0
European Patent Office	1	0	0	0
United Kingdom	1	0	0	0

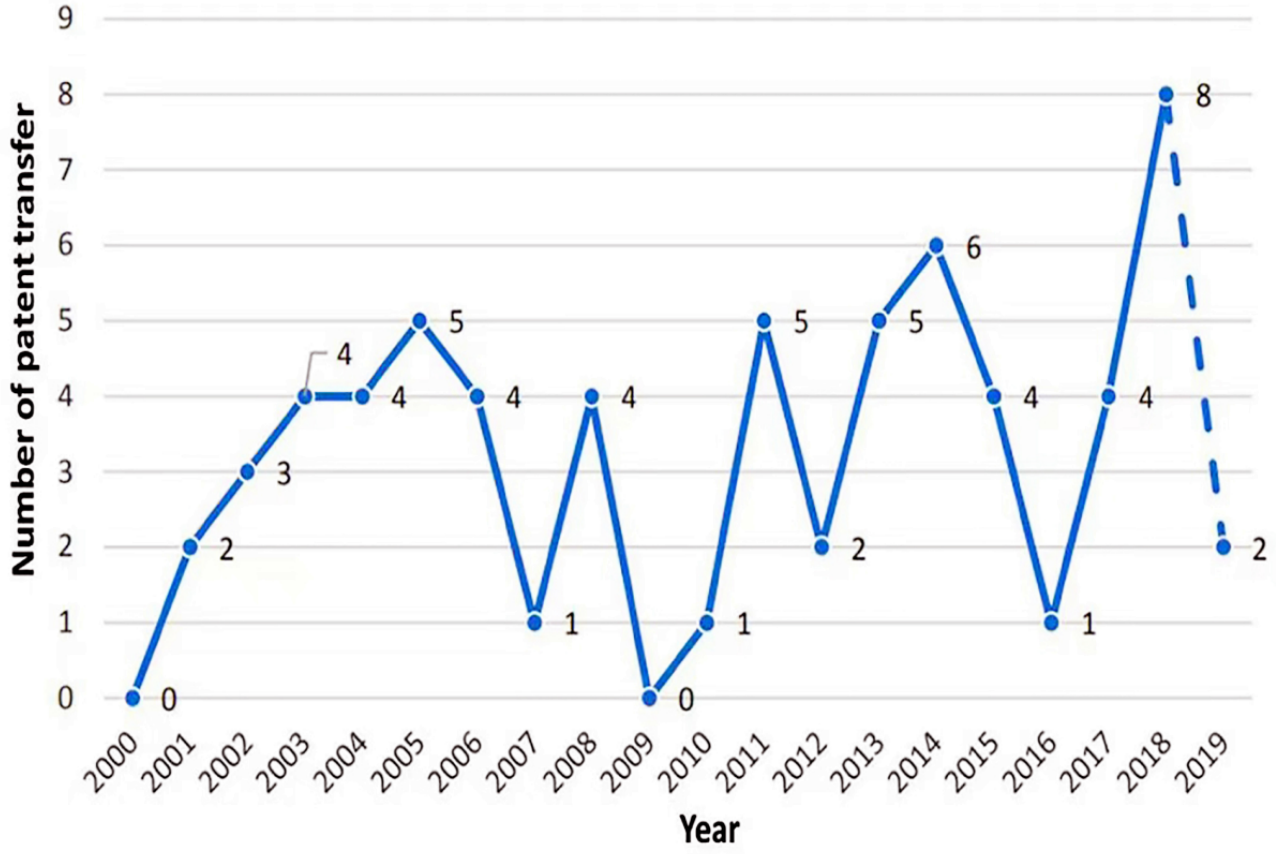
Besides invention patents, China, Russia, Ukraine, Brazil, and other countries (regions) have utility model patents, but their number is very small, which indicates that most technologies in this field are protected by invention patents. Because this field is mainly concerned with methods such as medicine, the relevant patents are difficult to be protected with utility models. Moreover, China has design patents on equipment and instruments.

Hot Technology Analysis

Generally, the higher the value of a patent, the more it will be transferred, and the more likely it will involve hot technologies in this field. The global trend of patent transfer is shown in Figure 4. Although patents related to neurological and psychiatric diseases have been transferred since the beginning of its application, the overall transfer trend remains stable. The number of transferred patents has fluctuated within 10, involving 65 transfers.

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Figure 4. Global trend of patent transfer.



As can be seen from the global transferor ranking (Multimedia Appendix 2), Breslow and Rosenfeld, both of whom are medical doctors, have transferred the most relevant patents in the field of neurological and psychiatric disorders. Most of their transferred patents are methods for analyzing patient information and predicting treatment plans, including predictive models for treatment plan, methods for displaying patient health status, remote command centers for patient monitoring, among others.

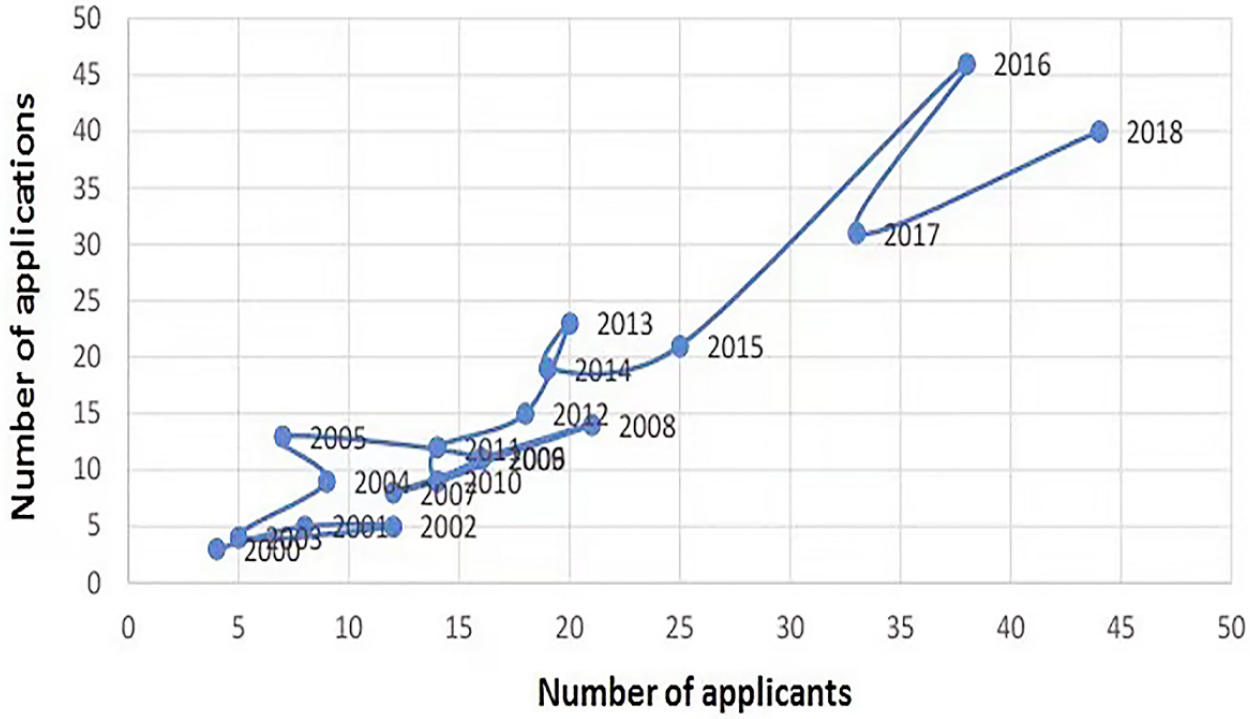
Visicu has received 9 patents, which is the largest assignee (Multimedia Appendix 3), and also an important applicant in this field.

Analysis of Technology Life Cycle

According to the life cycle diagram of patents (Figure 5), since 2000, neurological and psychiatric disorders have not been an important area of focus. From 2000 to 2005, the number of patent applications and applicants in this field were relatively small, hovering up and down. At this time, few people showed solicitude for this field. Earlier patent applications in the United States related to methods and apparatuses for measuring indices of brain activity during motivational and emotional functions, which directly determines the composition and degree of the motivational and emotional brain circuitry response. This circuitry response answered questions focusing on normal and abnormal behavior, along with questions regarding the normal and abnormal functions of the circuitry. The results obtained by interrogating the motivational and emotional circuitry can be used for objectively measuring, in human or animal individuals, one's preferences toward or responses to motivationally salient stimuli including but not limited to those that are internal or external, conscious or nonconscious, pharmacological or nonpharmacological therapies, disease- or non-disease–based processes, financial or nonfinancial, etc.

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Figure 5. Life cycle diagram of patents.



Between 2005 and 2015, the number of patent applicants has increased to a certain extent, but the number of patents has not risen significantly, suggesting that although more applicants paid attention to neurological and psychiatric diseases, the technology has not made much progress. Since 2015, with increasing public concerns for this field, and based on the development of big data and internet platform technologies, the patent field has begun to undergo certain transformations. Therefore, the number of applicants and applications for related patents has witnessed a sharp rise since. The most recent application (US20190200915) was on digital biomarkers for cognition and movement diseases or disorders, which assessed a cognition and movement disease or disorder in an individual suspected to have one [23]. A cognitive or fine motoric activity parameter was determined from a data set of activity measurements obtained from the individual using a mobile device. The determined activity parameter was compared with a reference, and the cognition and movement disease or disorder was assessed. A method for identifying whether an individual will benefit from a therapy for a cognition and movement disease or disorder was also disclosed. The steps just described are performed along with the step for identifying the individual as one who will benefit from the therapy if the cognition and movement disease or disorder is assessed. A mobile device was revealed as well, comprising a processor, at least one sensor, a database, and software that is tangibly embedded in the said device and when installed on the said device performs the disclosed methods.

Research and development on patents for neurological and psychiatric disorders are significantly influenced by government policies and the market. Therefore, the number of applications and applicants will grow each time when this field is favorably affected. This means that neurological and psychiatric diseases remain in the focus of scientific and technological development, and professionals are still very much interested in it.

Discussion

Principal Findings

China, as the country with the largest number of patents related to technologies on neurological and psychiatric diseases, has 107 related patents, which mainly focus on A61B and G16H. Jilin Longjin Technology Co., Ltd., the applicant with the most patents on this topic in the world, is headquartered in China. China has not only applied for many invention patents, but also applied for 11 utility model patents and 15 appearance designs. Most global utility models and appearance design patents for community psychiatric rehabilitation are in fact Chinese patents. However, the authorization rate of invention patents in China remains very low, which may be because most patents in China were only proposed after 2015 and are thus still in the substantive examination stage. Although China had put forward relevant theories later than the United States and other Western countries, it has caught up and currently occupies a large market. The number of patents for neurological illness and psychiatric disorders in the United States is second only to that in China, with a total of 85, but all of these are invention applications with a high authorization rate. Besides A61B, the United States focuses on G06F, which is slightly different from that of China. Russia closely follows the United States, being the third country with 46 related patents, which is only about half of the number of US patents. The per-capita patent applications of Russian applicants are extremely low, with only 1 applicant applying for 3 patents and the rest applying for only 1 patent. Furthermore, unlike China and the United States, Russia's

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patents are mainly focused on medical diagnosis and medical devices. There are no patents involving mobile devices.

The global development of technologies on neurological and psychiatric disorders shows the following characteristics: (1) The technology is increasingly mature. The number of patent applications in recent years has remained at a high level. Inventions and innovations are very active, with China currently being the largest patent priority country. (2) European and American companies, with a strong independent innovation capability, have considerable advantages in the area of research and development. The distribution of patent holders in China remains relatively scattered, with no technology monopoly organization at present. It is thus necessary to strengthen the collaboration between production, teaching, and research. (3) The types of patent applications worldwide are mainly invention patents. A few countries such as China and Russia have applied for a small number of utility model patents. (4) Patents mainly pertain to A61B (ie, medical and hygienic fields). By 2011, the classification number G16H (ie, health care informatics) was added, and eventually patents about internet-related mobile terminal platforms began to appear. The number of applications has increased year by year. As a newly emerging technology, there is still however great room for its development. From the special perspective of patents, this paper investigated the key technologies and development directions of industries as well as the technology combination and technology investment trends of major competitors for enterprises or countries, so as to establish technology research and application strategies on neurological and psychiatric diseases.

This paper had certain limitations. Because of the large number of patents involving neurological and psychiatric diseases, it is impossible to make a detailed interpretation of the contents of each document. Therefore, this study focused on the key technical points, categories, and regions of the patents, and illustrated the layout of the patents based on the primary and secondary technical points of the cluster diagram.

Conclusions

Based on this analysis, we concluded the following: (1) The United States, as a relatively mature country in the development of existing technologies, can focus its attention on further development in this area. (2) Technologies on neurological and psychiatric disorders in China have a low authorization rate for invention patents. It is thus suggested to improve the quality of Chinese patent applications and submit high-value patents. (3) In Russia, the number of patent applications on neurological and psychiatric diseases is generally small, but the authorization rate is extremely high, and therefore these need to be tracked.

Authors' Contributions

FZ developed the study design under the guidance of SW. LW and ZZ collected records and formulated the query with assistance from FZ. All authors provided contributions to the final version of the paper and approved it.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Global patent type.
[PNG File , 315 KB - mental_v9i2e25238_app1.png]

Multimedia Appendix 2
Global ranking of patent transferors.
[PNG File , 424 KB - mental_v9i2e25238_app2.png]

Multimedia Appendix 3
Global ranking of patent assignees.
[PNG File , 352 KB - mental_v9i2e25238_app3.png]

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Abbreviations

BRAIN: Brain Research Through Advancing Innovative Neurotechnologies
Brain/MINDS: Brain Mapping by Integrated Neurotechnologies for Disease Studies
HBP: Human Brain Project
IPC: International Patent Classification
LOC: Locarno Classification
NIH: National Institute of Medicine
NSF: National Science Foundation
NSFC: National Natural Science Foundation
TDA: Thomson Data Analyzer

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Original Paper

Crowdsourced Community Support Resources Among Patients Discharged From the Emergency Department During the COVID-19 Pandemic: Pilot Feasibility Study

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Abstract

Background: The COVID-19 pandemic has placed strains on communities. During this public health crisis, health systems have created remote methods of monitoring symptom progression and delivering care virtually.

Objective: Using an SMS text message-based system, we sought to build and test a remote model to explore community needs, connect individuals to curated resources, and facilitate community health worker intervention when needed during the pandemic. The primary aims of this pilot study were to establish the feasibility (ie, engagement with the text line) and acceptability (ie, participant ratings of resources and service) of delivering automated well-being resources via smartphone technology.

Methods: Eligible patients (aged 18 years or older, having a cell phone with SMS text messaging capability, and recently visited the emergency department) were identified using the electronic health record. The patients were consented to enroll and begin receiving COVID-19–related information and links to community resources. We collected open-ended and close-ended resource and mood ratings. We calculated the frequencies and conducted a thematic review of the open-ended responses.

Results: In 7 weeks, 356 participants were enrolled; 13,917 messages were exchanged including 333 resource ratings (mean 4) and 673 well-being scores (mean 6.8). We received and coded 386 open-ended responses, most of which elaborated upon their self-reported mood score (29%). Overall, 77% (n=274) of our participants rated the platform as a service they would highly recommend to a family member or friend.

Conclusions: This approach is designed to broaden the reach of health systems, tailor to community needs in real time, and connect at-risk individuals with robust community health support.

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KEYWORDS

COVID-19; mHealth; CHW; digital health; platform; crowdsource; support; community; health system; monitoring; virtual care; text message; model; community health worker; pilot study; feasibility

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Introduction

Background

The COVID-19 pandemic continues to disrupt the health and well-being of communities. An immediate call to address clinical issues has been followed by a call to public health and community action [1]. Prior to COVID-19, underserved and vulnerable communities were struggling with basic "life needs," and a high disease burden (which led to public health actions needed to curb the epidemic) placed further strain on access tied to community resources [2]. Despite new concerns such as emerging variants [3] and reaching herd immunity to prevent wider spread in the community [4], all 50 states have reopened public spaces, businesses, and the larger economy. Although public health policies in place, such as social distancing and self-quarantines, are meant to curb the epidemic, they also can lead to social isolation and loneliness. [5]. Prior to COVID-19, communities and individuals were already struggling with loneliness and well-being, which have been shown to negatively impact physical and mental health [6].

Health care institutions are woven into the fabric of communities and serve as a critical hub of information, resources, and care. These systems will continue to play an integral part in supporting communities throughout the prolonged response to, and recovery from, the pandemic [7]. However, community members themselves are likely best equipped to identify areas of focus and what nonclinical needs should be addressed. The pandemic impacted not only the health of individuals but all aspects of society, including the climate, workplaces, and education, as well as global, national, and local economies [8].

An emerging and critical health care professional is the community health worker (CHW). The American Public Health Association defines CHWs as "frontline public health worker who is a trusted member of and/or has an unusually close understanding of the community served" [9]. The CHW has a trusting relationship with community members, which can improve access to health care and other social services [9]. The Centers for Disease Control and Prevention reported that the use of CHWS for home-based care during the COVID-19 pandemic can alleviate overburdened health care institutions. In parallel, the use of technology to adapt health care has rapidly changed during the COVID-19 pandemic [10]. Clinical providers shifted to virtual visits and text messaging-based communication to care for patients and limit physical interactions [11]. Virtual support networks have been created to rapidly shift care, and health systems remain uniquely positioned to also serve as stewards of health information and mental health or well-being support for broader communities. Emotional disaster models highlight the need for persistent vigilance and monitoring to ensure that well-being is prioritized, monitored, and proactively supported [12]. As many health systems quickly implemented clinical remote monitoring, contact tracing mechanisms, and testing and vaccination sites [13], the challenge remains in developing a scalable, remote approach toward engaging at-risk groups, identifying needs and providing tailored community mental health and well-being support.

Objective

This pilot study's purpose was two-fold. First, to identify patients with an initial health system encounter (emergency department [ED] discharge) early in the pandemic (April-June 2020) and engage them via SMS text messaging to understand collective community and well-being needs. Second, to curate a community-driven repository of community resources and connect individuals experiencing emotional distress or those who express other social support needs to CHWs for urgent nonclinical needs.

Hypotheses

We hypothesize that we will be able to connect high-risk individuals to CHWs for urgent social support and nonclinical needs. Second, we will be able to collect community-identified resources and better understand collective community and well-being needs.

Methods

Recruitment

Our team deployed a text message-based script, and using an automated text messaging platform, the patients were consented to enroll and begin receiving COVID-19–related information and links to community resources (eg, social services, resources for families with children, mental health and well-being, and virtual, hyperlocal cultural events). The text messaging script sought to engage participants and elicit feedback on all resource content in order to prioritize the content driven by community members [14]. This study employed an iterative design approach to test assumptions and gather continuous descriptive feedback. Further details regarding the pilot design have been reported previously [15].

The participants were identified using the electronic health record (EHR) and sent an initial message if they met the following inclusion criteria: adult (>18 years of age); mobile number in EHR; and recent ED discharge. Enrollment occurred between April through May 2020. We defined this study sample as high-risk due to their ED use during the COVID-19 pandemic in Spring 2020. The participants were recruited through a Health Insurance Portability and Accountability Act (HIPAA)-compliant technology platform (Mosio), to invite eligible participants and engage in 2-way text messaging. The participants received a text message about the pilot and were asked if they wanted to opt in with a simple "yes" reply. Potential participants who did not respond or replied "stop" were no longer contacted. The entire process of approaching, enrolling, and engaging participants was completed through text messaging.

Measures

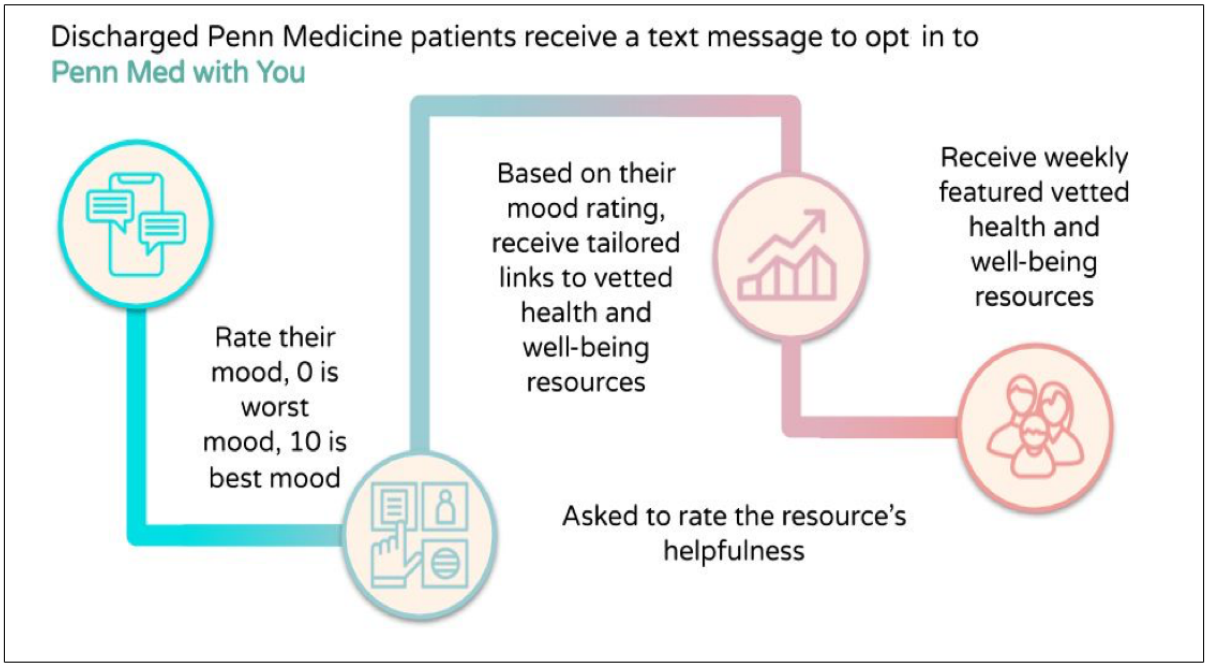
The participants were asked to provide quantitative ratings on resource links, mood ratings, and open-ended narrative feedback. Participants were asked to provide quantitative ratings (1-5 scale, 5=very helpful) on resource links, mood ratings, and open-ended narrative feedback weekly. Participant feedback and ratings of the resources guided the content of the mobile web-based resource hub. This allowed the content to be curated

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and defined by community members. This created a mechanism to continuously tailor content and create a living, community-driven resource hub.

The participants self-reported well-being on a weekly basis on a numeric scale (0-10, with 0 representing the worst mood and 10 as the best mood) [16]. A "high" mood rating was assigned for ratings between 7 and 10, "medium" mood rating between 4 and 6, and "low" mood between 0 and 3. The participants who reported a low mood (0-3) were sent a follow-up message to assess their mood compared to the previous day, "Good morning, I wanted to see how you're doing compared to yesterday. How is your mood today? Please text back a number between 0 and 10, 0 is the worst mood and 10 is the best mood." If the participants reported consistent low well-being scores (up to 3 days) or responded with an urgent social support need (eg, mental health issue and accessing services) they were contacted by our team and connected to a trained CHW (Figure 1). Moreover, there were open-ended and closed-ended acceptance measures such as how to improve the text line and the Net Promote Score (NPS) [17], a commonly used single-survey question about an individual's willingness to recommend a product or service. NPS was asked midway (2-week mark) and at the end of the pilot study (4-week mark). The NPS asks, "on a scale of 1-10, how likely would you recommend this text message service to a friend? 1 is very unlikely to recommend and 10 is very likely." NPS is scored by segmenting the respondents into 3 groups: promoters (scored 9 or 10), passives (scored 7 or 8), and detractors (scored 6 or below) and subtracting the proportion of detractor respondents from promoters. Historically, NPS scores are used in business as a predictor of growth in sales and revenue [17].

Figure 1. Penn Med with You participant flow.



Procedures and SMS Text Messaging System

Figures 2-4 display the automated messaging interface and the flow of engagement to connect with individuals. Of note, 90% of the text messages were automated; however, the study team manually reviewed all text messages for quality control and safety audits. For example, after 3 days of low mood ratings, the research team would reach out to the participant to further assess their well-being needs and escalate to a CHW if needed. Messages were sent on weekdays at 10 AM. On weekends, the participants received an out-of-office message. Demographic data were extracted from the participants' EHR records.

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Figure 2. Automated text messaging engagement.

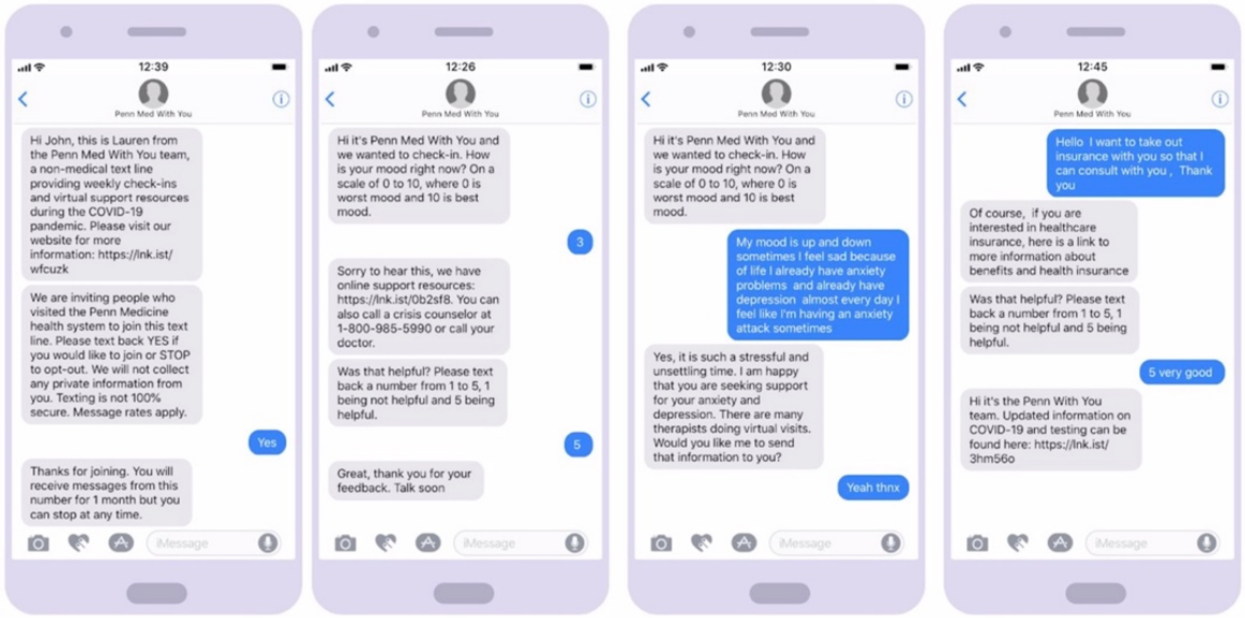
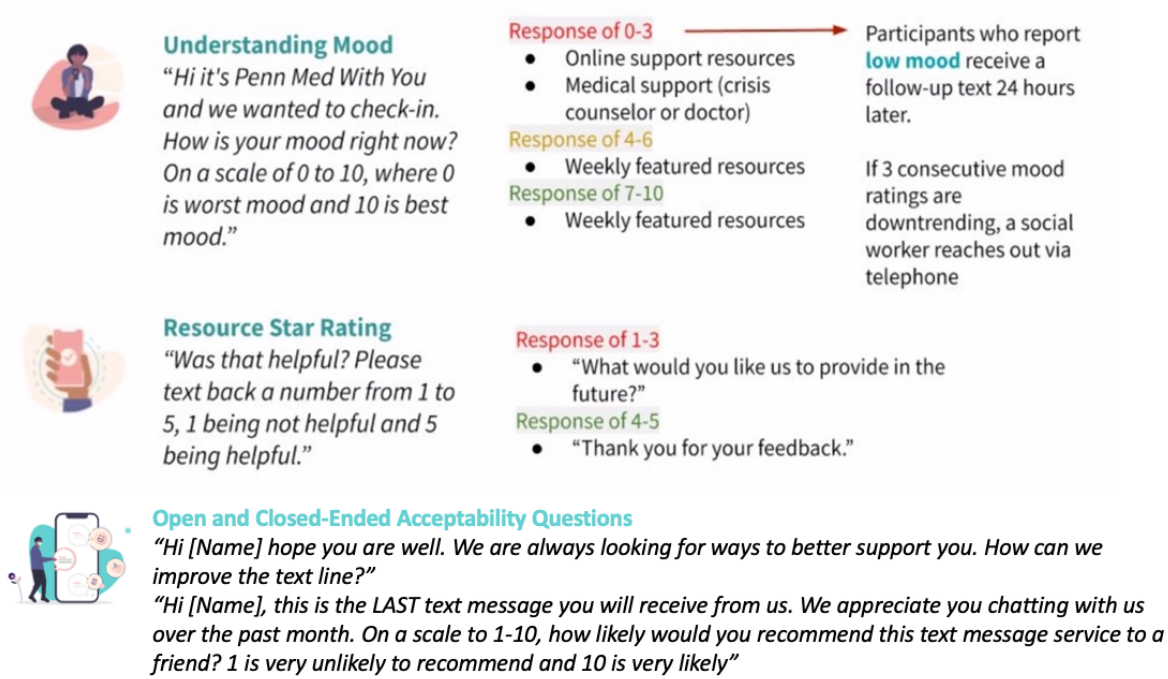
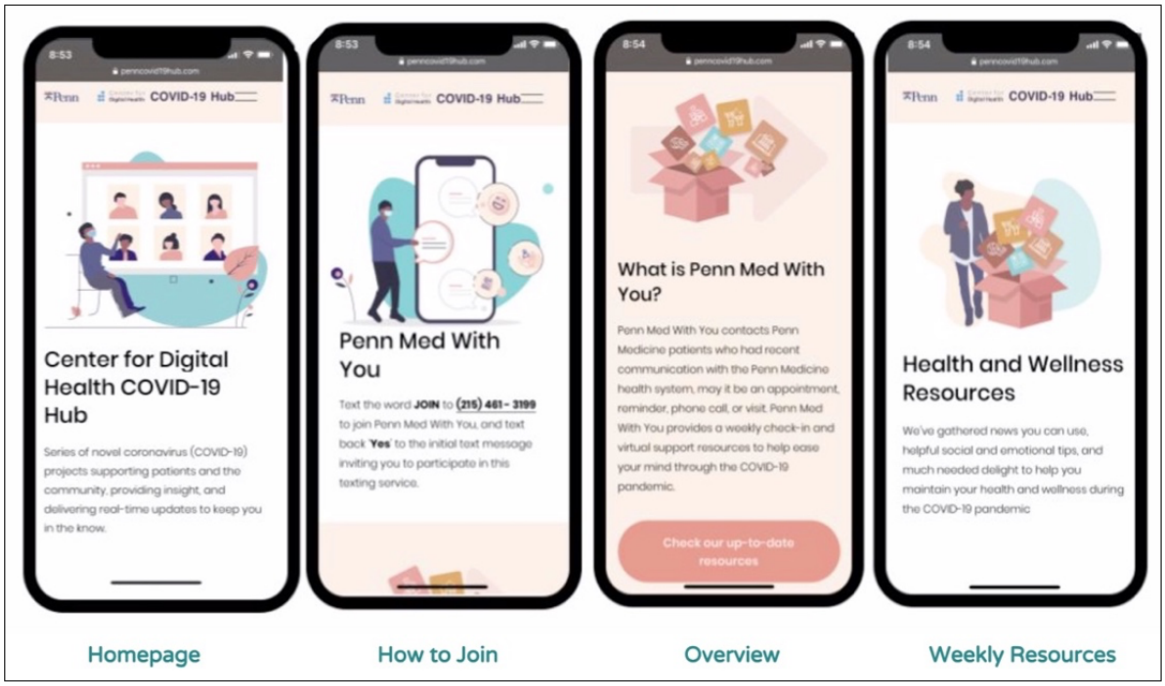


Figure 3. Tailored messaging schematic for well-being.



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Figure 4. Community-tailored resource hub.



Ethical Approval

This study was approved by the University of Pennsylvania Quality Improvement Institutional Review Board. A protocol for identifying risk of emotional and psychological harm was established. We built automated notifications to hover over self-reported well-being scores and free text input. We built automated responses for any messaging that the system could not interpret as an answer and keyword phrases that triggered immediate human intervention (eg, “death,” “kill,” “suicide,” “hang”). This automated messaging directed the participants to seek medical care if needed and directed them to a website for a comprehensive list of other resources. We ultimately established a human mechanism in place to identify the participant, connect with them via telephone, and route them to the appropriate professional.

Team

Our team is multidisciplinary, spanning from clinician and nonclinical members. It includes Penn Medicine Center for Digital Health, Center for Healthcare Innovation, department chair and faculty from Emergency Medicine, medical students from the Perelman School of Medicine, data analysts, graphic design students from the University of Pennsylvania, the text messaging platform, and the Individualized Management for Patient-Centered Targets team. The latter is a nationally recognized community health worker program that hires and trains trusted neighborhood residents to become CHWs to carry out culturally appropriate outreach activities, social support, patient advocacy, and health system navigation, with the goal of improving health in underserved populations [18]. The partnership with virtual CHWs provided a robust and well-rounded approach to community health and well-being.

Statistical Analysis

Descriptive statistics were used to summarize demographic variables. Authors LS and RO categorized the open-ended responses; they reviewed 50 responses to identify common themes and applied a thematic analysis approach [19]. Once categorized, the responses were coded, and a third reviewer adjudicated any discrepancies.

Results

User Statistics

The 409 individuals who opted into the “With You” program were asked to self-report their well-being. A total of 286 (70%) individuals responded with a well-being rating. The majority of participants were Black (275/409, 73.5%) and female (264/409, 70.1%) (Table 1). Additional participant demographics and intervention details have been reported previously [15].

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Table 1. Participant demographics.

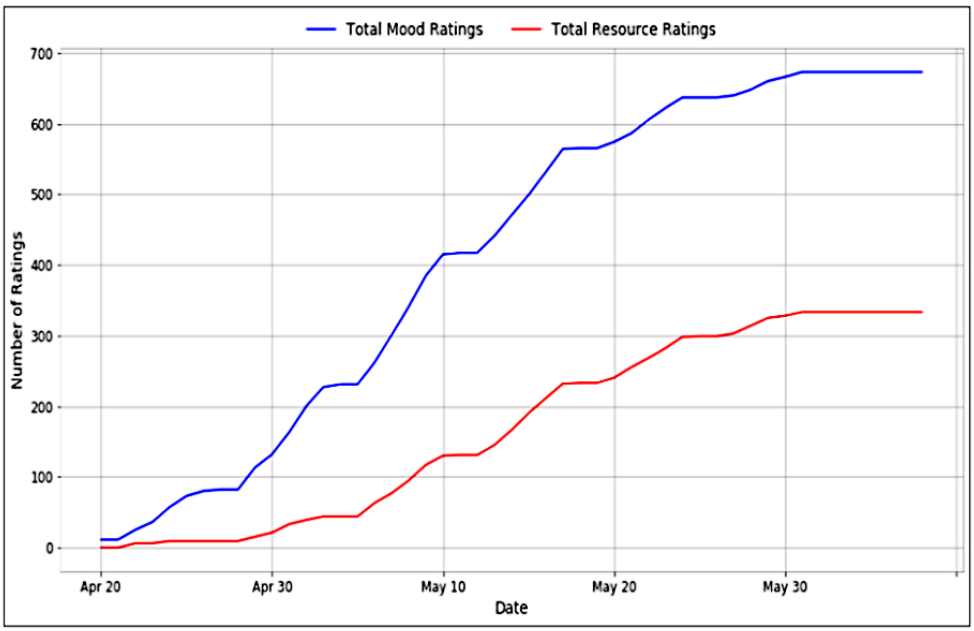
Characteristics	Values[a]
Age (years), mean (SD)	46.9 (16.8)
Female, n (%)	264 (70.1)
Race or ethnicity, n (%)	
Black	275 (73.5)
White	69 (18)
Asian	14 (3)
Hispanic Latino	14 (3)
Other	16 (4)
Emergency department, n (%)	
Hospital A	225 (60.2)
Hospital B	149 (39.8)

[a]Of the total study sample (n=383), demographic data were missing for 9 (2.3%) participants.

Evaluation Outcomes

Over the course of 7 weeks, we exchanged 13,917 text messages, elicited 673 self-reported well-being ratings (mean 6.8), and received 333 resource ratings (mean 4) (Figure 5). For those who reported low mood scores, we sent 209 follow-up mood questions. From the follow-up mood questions, only 2% (n=9) of the participants were escalated to CHWs. The website received over 6400 views, and most visits (91.5% [n=5856]) originated from a direct link.

Figure 5. Initial community engagement and mood ratings.



We received 368 open-ended participant responses (Table 2). Most responses were by participants elaborating on their self-reported mood score (132/368, 36%). For example, the system would ask the participants to rate their mood from 0 to 10 (best mood), and a participant followed their score with a message as such:

> *I am in a good space. Praying for this attack on America to end so that we can get back to a normal existence. On a scale from 1-10 my mood is a 10.* [Participant #1, female, aged 58 years]

or

> *My mood is good I say it about 9 thank you for being concerned.* [Participant #2, female, aged 56 years]

Additionally, after describing one's mood, most participants (125/368, 34%) would include pleasantries such as the following:

> *thank you for looking out.* [Participant #3, female, aged 35 years]

or

> *I appreciate the text messages, keep them coming!* [Participant #4, female, aged 49 years]

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Table 2. Qualitative codes demonstrating themes.

Codes	Operational definition	Frequency, n (%)
Administrative	Question or concern related to text line logistics	55 (15)
Health	Physical and mental health-related question	53 (14)
Mood	Elaborates on mood score response	135 (36.6)
Pleasantries	Responds to automated message	125 (34)

Measure of Acceptability

Overall, 77% (164/213) of our participants rated the platform as a service they would highly recommend to a family member or friend. Moreover, 67% (143/213) of unstructured feedback on the platform and content were positive. Through open-ended questions, the participants made the following remarks:

> *The line is good…Enjoying the information you're directing to me.* [Participant #5, female, aged 55 years]
>
> *Keep the texting line active. Folks like myself appreciate a caring text and health information/resources. Thank you so much. Be safe….* [Participant #5, female, aged 61 years]
>
> *Thanks, you for crisis info your help is right on time at times I just got to talk to someone thank you once again.* [Participant #6, male, aged 29 years]

The participants also provided constructive feedback and recommendations through the open-ended questions. This feedback helped guide our platform development. Some examples of unstructured and open feedback are as follows:

> *Live counselors would be awesome.* [Participant #7, female, aged 33 years]
>
> *More resources for anxiety.* [Participant #8, female, aged 40 years]
>
> *Text at different times of the day to check in.* [Participant #9, male, aged 54 years]

As we enrolled more participants, we obtained additional feedback on resources and the platform itself as a means to institute continuous and real time quality improvement. For example, a participant requested information on better sleep in the qualitative resource feedback. The following week, we featured recommendations for healthy sleeping habits during COVID-19. The participants also reported feelings of isolation and disconnection; in response, we included content featuring how several neighborhoods were banding together to create outdoor socially distanced events for children.

Feasibility and Sustainability

After the pilot study concluded, the research team met twice virtually for approximately 30-45 minutes to elucidate feasibility and sustainability factors. Below are key factors for feasibility and sustainability:

1. Form an interdisciplinary team to frame out the engagement strategy and overarching method of connecting at-risk groups to urgent medical and social needs.
2. Design an approach that learns early and often to inform and adapt growth to needs.
3. Create a central, easy-to-access hub for social resources that currently exist. This includes content for those with low and high self-reported well-being.
4. Build a team and schedule to allow for intermittent but daily monitoring of responses for quality and safety assessment.
5. Recognize that content and resources will need to be tailored to the local community and environments and be open to change.
6. Partner with local champions and resources so as to not reinvent the wheel and lean on the expertise of existing networks.

Discussion

Principal Results

This pilot study aimed to determine the acceptability and feasibility of a health system-driven community engagement for health and wellness line. This pilot study engaged discharged ED patients with a visit during the early phase of the pandemic via SMS text messaging to understand their well-being needs, curated a participant-driven repository of community resources, and proactively connected individuals with CHWs to support their well-being and connection to needed resources. In other health systems, CHWs were essential in addressing social determinants of health in vulnerable populations [20]. The pilot demonstrated that health systems are uniquely positioned to serve as hubs and sources of credible information, resources, and connections to community needs. The participants found the SMS text messaging-based line to help with "life needs" and interacted with the text line as if it were a friend, such as asking, "how are you?" saying "stay safe," and "have a blessed day." This is noteworthy as these types of responses suggest that health systems are well positioned to remotely address and support community well-being.

The text line also filled an important gap in mental health access. Earlier research found that rates of anxiety and depression are on the rise during the pandemic, and resources are needed [21]. In addition to the emerging mental health concerns, individuals are experiencing an infodemic, ''an overabundance of information—some accurate and some not—that makes it hard for people to find trustworthy sources and reliable guidance when they need it" [22]. Early in the pandemic, the World Health Organization coined a new term and cautioned users about misinformation. Our response was this text line, which focused on providing timely and scientifically accurate information to the participants.

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This pilot study demonstrated that digital engagement through simple options such as SMS text messaging provides a means to engage and interact with communities through COVID-19 and other crises. Automated hovering [23], resource sharing, and well-being monitoring act as means to extend the network and expertise of medical centers and can work to support broader community mental health and well-being. As health systems prepare for subsequent waves, additional attention is needed on how to support health care workers (including CHWs) facing the psychological impacts of COVID-19 [24]. As we work to continue to live through and fight COVID-19, health systems are uniquely positioned and can implement rapid, remote, population-level efforts to address and support community health and well-being. The early results from our work provide essential insights toward understanding how health systems can remotely engage and use automated digital technology to explore and react to community needs during times of need. Further research is warranted to explore how individuals navigate social distancing, isolation, health, and well-being throughout the prolonged response to, and recovery from, the pandemic.

Limitations

This pilot study has limitations. First, it was limited by its enrollment and retention. Overall, 20% of the participants opted into the text messaging line, and 70% were retained. Despite the high rates for a pilot study, it is possible that this contributes to a selection bias. Second, the pilot study only assessed mood and resource ratings from participants who opted in; it did not have comparison or control groups. Our findings only represent community members who are engaged in care at 2 hospitals; these results do not represent those who receive care at other hospitals and most importantly, those who are not engaged in health care at all, which comprises some of the highest need populations. Third, we could not assess how many participants used the resources over the course of the pilot study. This is because the website was publicly available, and nonparticipants might have accessed it. Fourth, we defined our study sample as high-risk due to their ED use during the COVID-19 pandemic. We posit that there are other key variables such as chief complaint and housing stability that would be helpful in further classification. Lastly, we assessed feasibility of a health system implementing a community line; further research can delve into the acceptability of community perspective of the service. Our evaluation methods elicited feedback; however, future research can use frameworks such as the RE-AIM (reach, effectiveness, adoption, implementation, and maintenance) [25] or validated instruments such as Participant Feedback Questionnaire used in other pilot studies [26].

Comparison With Prior Work

Our pilot study can be compared with prior work, such as the Thought Spot, a randomized controlled trial aimed at optimizing and evaluating a web-based and mobile-based platform designed to improve the ability of students to access mental health and substance use services [27]. Despite the participant demographic differences, both studies employed crowdsourced materials to codesign and cocreate content and focused on participants having an active role in the program to share their knowledge about services and discover wellness tools and resources in their community. Importantly, our pilot study was not a randomized controlled trial and was executed within a short period of 3 months to rapidly respond to mental health and well-being early in the COVID-19 pandemic. Thus, we cannot isolate how seasonal and sociocultural factors in Spring 2020, such as the murder of George Floyd and other African Americans, had an impact on our findings. Interestingly, the topic of CHWs employing digital tools during the COVID-19 is discussed within the context of low-to-middle income countries [28,29]. For example, Feroz, Khoja, and Saleem [29] note how there is some resistance to adopting digital tools among CHWs. Most notably, there is a lack of training on new technologies, weak technical support, and persistent issues of stable internet access.

Conclusions

This study suggests that health systems are well positioned to support community well-being. It is feasible and acceptable to proactively text health system patients and provide robust, wraparound support during a pandemic. The expanding use of digital technology offers an opportunity to engage community members throughout the stages of the COVID-19 pandemic.

Acknowledgments

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Conflicts of Interest

None declared.

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Abbreviations

CHW: community health worker
ED: emergency department
EHR: electronic health record
HIPAA: Health Insurance Portability and Accountability Act
NPS: net promote score
RE-AIM: reach, effectiveness, adoption, implementation, and maintenance

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Viewpoint

Attentional Harms and Digital Inequalities

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Abstract

Recent years have seen growing public concern about the effects of persuasive digital technologies on public mental health and well-being. As the draws on our attention reach such staggering scales and as our ability to focus our attention on our own considered ends erodes ever further, the need to understand and articulate what is at stake has become pressing. In this ethical viewpoint, we explore the concept of attentional harms and emphasize their potential seriousness. We further argue that the acknowledgment of these harms has relevance for evolving debates on digital inequalities. An underdiscussed aspect of web-based inequality concerns the persuasions, and even the manipulations, that help to generate sustained attentional loss. These inequalities are poised to grow, and as they do, so will concerns about justice with regard to the psychological and self-regulatory burdens of web-based participation for different internet users. In line with calls for multidimensional approaches to digital inequalities, it is important to recognize these potential harms as well as to empower internet users against them even while expanding high-quality access.

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KEYWORDS

digital inequalities; attentional harms; excessive internet use; persuasive technologies; internet ethics; attention economies

Introduction

Over the past 3 decades, as the internet has become an increasingly indispensable tool for economic, social, and political inclusion, there has been extensive and warranted concern about the sorts of social inequalities, or stratifications, that are generated or exacerbated by digital exclusion.

Initially, first-level research on these digital divides focused predominantly on the issue of access or nonaccess to the internet. However, as access has widened and as the field has developed, it has become clear that more complex and multidimensional analyses of digital inequalities are necessary. In turn, focus has shifted from access alone to include the quality of access; questions regarding digital literacy and proficiency (referred to as *second-level digital divides*) [1]; and, more recently, the ability to generate concrete social and economic benefits via the internet (referred to as *third-level digital divides*) [2,3].

Increasingly, there has been growing concern about the prejudicial nature of the *harms*, and not only the benefits, that can accompany web-based participation, particularly with regard to surveillance, algorithmic bias, and predatory marketing [4-14]. Among the potential harms associated with digital access, which can be exacerbated by socioeconomic forces and factors, are what we will be calling *attentional harms*. The present nature of the internet has made it an extraordinary draw on human attention, which has been amplified by the internet's design and commodification. The growing awareness of design features that encourage excessive use has necessitated an ethical reckoning regarding what is at stake when we introduce powerful forces of distraction into our lives at such an enormous scale or when human attention is treated as a commodity by the world's most powerful corporations.

The acknowledgment of these factors has serious implications within multidimensional analyses of digital divides, especially insofar as our goal ought to be to provide digital access that

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empowers individuals and enriches their lives. In countries that have addressed earlier digital divides, the issue of attentional harms has become more pressing, and in some tech-heavy societies, being empowered to disconnect or having the option of "tech-lite" environments is increasingly seen as a privilege [15].

In many other countries, particularly those in the Global South, the issue of digital divides is understudied and underresearched, with the focus remaining predominantly on enduring first-level divides [16]. However, countries that are still addressing earlier digital divides now have the opportunity to do so in a more complex and multidimensional way, including by recognizing the potential harms and agential costs that can be generated by internet use, particularly when we are not adequately informed about and empowered against them.

Attention Economies

Broadly speaking, persuasive design is the process of creating technologies in order to generate behavioral change. One can distinguish between the intended and unintended effects of persuasive design [17] and between persuasive design and outright manipulative, deceptive, or coercive design [18,19], though in some cases these distinctions will be vague. Fogg [20] famously founded the Stanford Persuasive Technology Lab (now the Behavior Design Lab) and developed a behavior model for persuasive design. Concern about the ethics of persuasive design has accompanied the field from the outset. Fogg [21] himself has been careful to say that these techniques should not be used for ignoble purposes and has proposed that education is key to empowering individuals against nefarious forms of persuasive design. Recent ethical debates concerning design principles have emphasized the roles of participatory design and design justice as ways of overcoming marginalization and oppression [6,22-25] as well as advancing design that is aligned with, rather than opposed to, human well-being and flourishing (a point to which we will soon return) [26].

The so-called *attention economy* has come to dominate the provision of many web-based services. As such, success and profitability often relies on maximizing user engagement; the more often and the longer users engage with products, the more data manufacturers are able to collect on them and the longer manufacturers have them as an audience for advertisers. In turn, the goal of many software developers has been to design products that generate habitual engagement and maximize use, drawing on techniques from applied psychology, neuroscience, and behavioral economics in their efforts.

Certain pervasive design features, such as "like" buttons (or their equivalents), push notifications, streaks, auto-play, and infinite scroll, have been especially successful in this regard and have proliferated across platforms. The success of some of these features in terms of maximizing use have often been attributed to intermittent variable rewards, which have long been linked to addictive behavior and are also associated with the addictive quality of slot machines [27,28]. At the level of our neural reward system, an uncertain reward generates a more significant dopamine response than those generated by a reliable reward. On prominent internet platforms, sophisticated machine learning technologies now endeavor to randomize rewards for each user. Insofar as these content "rewards" involve high arousal and extreme or divisive material, there are related concerns about social harms [29,30].

The effect of these design features on our behavior, and their draw on our attention, is patent. The habitual checking of certain internet platforms and incessant engagement with smartphones have become facts of life in many parts of the world. One report indicates that the average smartphone user checks their device over 70 times per day and swipes and interacts with it thousands of times [31]. Efforts to limit or reduce the time spent on devices, even among "ordinary" users, can require significant self-control and often results in failure [32]. The difficulty of focusing one's attention while having ready access to the internet has also become renowned, with many people investing in internet and site-blocking software in order to aid concentration. The mere presence of a smartphone has been reported to adversely affect working memory and functional fluid intelligence [33].

Persuasive design focused on maximizing use has come under increased scrutiny in recent years. Public interest about the effects of persuasive technologies on our behavior, mental health, and well-being has grown significantly, informed by a public conversation featuring tech insiders (notably the former Google design ethicist Tristan Harris), policy makers, health specialists, and educators, among others [34]. Some have argued that the increasing sophistication of persuasive digital technologies and their personalized nature makes them a far deeper and more considerable threat to autonomy than more long-standing and familiar forms of persuasive design [35].

Attentional Harms

The value of our attention, that is, our ability to direct our attention in meaningful ways and our capacity for sustained attention, is as yet underexplored and undertheorized territory [15,35]. However, as the draws on our attention and the power of digital distractions reach such staggering scales and as our ability to focus our attention on our own considered ends erodes ever further, the need to understand and articulate what is at stake has become pressing. Yet, the necessary ethical frameworks (and even vocabularies) for understanding the significance of these forces are presently underdeveloped. Williams [35] writes:

> *To date, the problems of "distraction" have been minimized as minor annoyances. Yet the competition for attention and the "persuasion" of users ultimately amounts to a project of the manipulation of the will. We currently lack a language for talking about, and thereby recognizing, the full depth of these problems. At individual levels, these problems threaten to frustrate one's authorship of one's own life.*

Amplifying this sentiment, Dennett [36] has said that "this is perhaps the greatest risk to human political freedom that we've ever seen," and that "an agent who controls your attention controls you."

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It is clear that what we pay attention to is closely related to our conscious awareness and, therefore, to deep aspects of our individual identity and what constitutes our experience of life. How we direct our attention has both voluntary and involuntary aspects, and our attention can be drawn and held in ways that are by no means indicative of our assessments of worth, including via persuasion, manipulation, and coercion. Insofar as we are compelled to direct ever more significant amounts of our attention in ways that we do not relate to on a deeper level or in ways that we would not reflectively endorse, there are elements of our very selfhoods that are at stake.

An emerging philosophical conversation has sought to situate attentional harms within existing paradigms for understanding what is necessary for human well-being. For the purposes of this viewpoint, we only summarize some of the approaches that have been taken and gesture to other moral frameworks that might be applicable to the issue of attentional harms. As seen above, in exploring the harms implicit in pervasive attentional loss, some philosophers have focused on personal autonomy [35,36]. Other philosophers, drawing on Wolf [37], have emphasized the importance of the construction of worth and meaning to human well-being and have argued that persistent distraction undermines the pursuit of this goal [38]. Still others have drawn on Nussbaum's [39] capabilities approach, which asserts the moral importance of the freedom to achieve well-being and understands well-being in terms of an individual's capabilities, to argue that the harms of excessive time spent on the internet can undermine the capabilities central to human dignity [40].

An enduring difficulty within this debate concerns how to distinguish between beneficial and harmful co-options of our attention. After all, sometimes our attention is drawn precisely because we are highly invested in something and consider it enduringly worthwhile and meaningful. This can also be true of the time we spend on the internet; there is no end to what can be pursued on the internet, including essential and otherwise worthwhile undertakings, and therefore no straightforward relationship between the time spent on the internet and the sorts of attentional harms with which we are concerned. Further, within certain parameters, escapism itself can be stress relieving and curative. Given this: how can we recognize the harmless aspects, and even the beneficial aspects, of attentional loss while simultaneously recognizing where our attention is being co-opted in harmful ways and where we are giving over large swathes of our lives and receiving little in return but angst, regret, and alienation from our web-based pursuits?

A deontological framework is potentially useful here; we can distinguish between cases where our attention is being used as a mere means to the ends of others and cases where it is being treated as an end in itself. Per this framework, in cases where our attention is used as a mere means, the sustained co-option of our attention can be construed as harmful. In cases where our attention is also treated as an end in itself—cases where our engagement is ultimately something we would reflectively endorse—the sustained co-option of our attention need not be harmful and may even be beneficial.

Another important consideration in appraising these attentional harms is what has been called the *indispensability thesis* [15]. The all-purpose nature of digital devices, which include a range of essential and work-related functions, has resulted in the use of such devices increasingly becoming a requirement in both our personal and professional lives (and never more so than during the COVID-19 pandemic). This increasing indispensability has long motivated concern about digital inequalities in terms of the quality of access. However, the fact of indispensability also raises different ethical questions, and there is a sense in which the indispensability of (near-constant) internet access undermines full-fledged consent to the risks and deleterious effects associated with such access and engagement, given that there is increasingly no realistic alternative [15].

The current nature of the internet exacerbates this difficulty. In most cases, people cannot keep only the "essential" internet on them (ie, the parts they need to function or pursue their goals); people must always have access to the whole thing, including parts that might be sources of compulsion and regret. As Hanin [15] puts it:

> *Whereas no sane adult must smoke, use drugs, consume sugary foods, or gamble as a precondition to leading a fulfilling life or excelling in a profession, many sane adults have no practical way of avoiding often prolonged entanglement with digital ecosystems in the workplace and their personal lives. This entanglement poses formidable psychological challenges for self-regulation.*

We agree with scholars who argue that widespread and systemic attentional harms should not be downplayed or dismissed and that they can potentially be deeply undermining to human agency and well-being. Respect for individuals ought to include respect for their attention, and any aspirational notion of the value of human life and the conditions for human flourishing ought to recognize the importance of our engaged presence and the ideal of achieving a sense of meaning and worth within our lives [26,41]. Insofar as digital distractions stymie these pursuits—often intentionally and on an utterly unprecedented scale—we are warranted in resisting or seeking to alter the forms these technologies take within our lives.

Attentional Inequalities

As research into digital inequalities has emphasized, in expanding access to web-based services, it is crucial to acknowledge that not all internet access is equal. This inequality also pertains to attentional harms. The potential burdens of internet access, including the psychological and self-regulatory burdens that we have been describing, are very differently felt by different users depending on their device, their digital literacy, their awareness of these potential harms, and their recourse to strategies for avoiding them.

In societies where inequalities related to internet access have largely been overcome, socioeconomic vulnerability sometimes correlates with more time, rather than less time, on certain platforms, including social media and digital games [8,42]. In some places, "tech-lite" environments are becoming the ultimate

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privilege. For example, it is a much-reported fact that many Silicon Valley insiders send their children to the deliberately "tech-lite" Waldorf School [43]. Advocating for government-provided "tech-lite" environments, Hanin (writing from the United States of America) emphasizes that "poor and rich alike should have access to such settings, which may otherwise risk becoming a luxury for the few" [15].

Societies that are addressing earlier digital divides, including those in the Global South, should do so with cognizance of the emerging complexities and new stratifications regarding the potential attentional costs and burdens of access. In other words, the most empowering forms of connectivity are those that also empower us with strategies and effective methods for disengaging and disconnecting when we recognize, and are enabled to recognize [44], that time spent on the internet is impeding our own considered ends rather than serving them.

Research has also suggested that socioeconomic vulnerability is a risk factor for developing clinically significant internet addiction [45]. Our earlier points about indispensability are relevant here too. One important consideration is determining how feasible it is for individuals to control their access, especially among those who are vulnerable to internet addiction or problematic use. As Christakis [46] writes:

> *Cultural influences both mandate and facilitate that we spend time "online," meaning that teetotalism is not an option. Given our current understanding that there is a genetic predisposition to behavioral addictions, we may be going a long way toward ensuring that the entire susceptible population develops them.*

There are a range of straightforward socioeconomic factors that potentially contribute to attentional harms. Low-income internet users are much more likely to go on the internet by using their phone rather than a computer [8,47], which increases data vulnerability and, in many cases, limits control. Moreover, the ability to afford a more expensive smartphone provides a far higher degree of data privacy and greater control over which apps and services can be removed from a device or controlled within it, including those that someone might find to be compulsive or habit forming. A person who can afford to buy an iPhone (Apple Inc) or a parent who can afford to buy one for their child therefore has a far greater range of control over the time spent on their device and other use limits compared to that of someone who cannot afford to buy one [34]. Android phones (which cost one-third of the price of iPhones) have also been reported to collect significantly more personal data [48].

Data vulnerability has primarily been assessed through the lens of privacy and security [8,11]. However, another aspect of this vulnerability relates to attentional harms and the efficacy of targeted content. Increased data collection can generate a vicious cycle in which data can be deployed to better maximize use (through artificial intelligence–driven personalized recommendations and randomized rewards), which in turn allows more data to be gathered [8,15]. Relatedly, these factors increase vulnerability to predatory marketing tactics [13,49].

Socioeconomic inequalities in the burdens of attentional harms are liable to increase in coming years as divisions concerning who is aware of these harms emerge and as wealthier internet users buy their way out of some of the more noxious aspects of the web-based attention economy [44]. In considering ways to move away from the attention economy model, the most obvious suggestion is to require users to pay for services. In recommending regulations on persuasive technologies, Williams [35] suggests that "companies could be expected (or compelled, if necessary) to give users a choice about how to 'pay' for content online – that is, with their money or with their attention." Aspects of this choice are already prevalent on the internet, with the distinction between free and premium services. As Roose writes [50]:

> *Today's internet is full of premium subscriptions, walled gardens and virtual VIP rooms, all of which promise a cleaner, more pleasant experience than their free counterparts.*

At present, available methods for mitigating attentional harms require significant digital literacy. In the first place, one must recognize such forces and the designs that exacerbate them, and one must further recognize the available means for resisting them. One study, which used education as a proxy for socioeconomic status, found that while internet users with both low and high education levels recognize the attentional burdens of being on the internet, especially with regard to wasted time, highly educated users were much more likely to intervene or to consider that time spent on the internet is potentially detrimental to their self-actualization [51]. Provided that one is aware of these options and, in many cases, is also able to pay for them, one can partially mitigate digital distraction by investing in site-blocking software, ad-blocking software, apps that generate screen time alerts, or devices that disable one's internet connection for certain hours. People can also hide more of their personal information, encrypt their browsing history, and invest in apps and plug-ins that overwrite certain persuasive design features and shift default settings to those that reduce use rather than amplify use [52].

If the goal of overcoming digital inequalities is to empower individuals and enhance their well-being and their access to opportunities, we have to be cognizant of aspects of digital access that are deliberately *disempowering*, undermine our pursuit of meaning and worth within our lives, and ultimately serve powerful corporate interests that might well conflict with the interests of individual users.

The fact that these burdens can be compounded by socioeconomic factors generates further moral reasons to support decent minimum standards for design regulation and user controls (regardless of the cost of a device and regardless of whether services are free or paid for), since these burdens raise issues of justice with regard to the distribution of these essential controls and, in turn, raise issues of justice with regard to who will be empowered to better safeguard their attention as an end in itself and whose attention will be treated as a mere means to the ends of others.

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Acknowledgments

A portion of the material within this viewpoint overlaps with a chapter that we have written for *Mental Health in a Digital World* [53], which overviewed some of the ethical implications of the addictive qualities of the internet.

Conflicts of Interest

None declared.

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Original Paper

Depressive Symptoms and Anxiety During the COVID-19 Pandemic: Large, Longitudinal, Cross-sectional Survey

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Abstract

Background: The COVID-19 pandemic has influenced the mental health of millions across the globe. Understanding factors associated with depressive symptoms and anxiety across 12 months of the pandemic can help identify groups at higher risk and psychological processes that can be targeted to mitigate the long-term mental health impact of the pandemic.

Objective: This study aims to determine sociodemographic features, COVID-19-specific factors, and general psychological variables associated with depressive symptoms and anxiety over 12 months of the pandemic.

Methods: Nationwide, cross-sectional electronic surveys were implemented in May (n=14,636), July (n=14,936), October (n=14,946), and December (n=15,265) 2020 and March/April 2021 (n=14,557) in the United States. Survey results were weighted to be representative of the US population. The samples were drawn from a market research platform, with a 69% cooperation rate. Surveys assessed depressive symptoms in the past 2 weeks and anxiety in the past week, as well as sociodemographic features; COVID-19 restriction stress, worry, perceived risk, coping strategies, and exposure; intolerance of uncertainty; and loneliness.

Results: Across 12 months, an average of 24% of respondents reported moderate-to-severe depressive symptoms and 32% reported moderate-to-severe anxiety. Of the sociodemographic variables, age was most consistently associated with depressive symptoms and anxiety, with younger adults more likely to report higher levels of those outcomes. Intolerance of uncertainty and loneliness were consistently and strongly associated with the outcomes. Of the COVID-19-specific variables, stress from COVID-19 restrictions, worry about COVID-19, coping behaviors, and having COVID-19 were associated with a higher likelihood of depressive symptoms and anxiety.

Conclusions: Depressive symptoms and anxiety were high in younger adults, adults who reported restriction stress or worry about COVID-19 or who had had COVID-19, and those with intolerance of uncertainty and loneliness. Symptom monitoring as well as early and accessible intervention are recommended.

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KEYWORDS

COVID-19; depression; anxiety; pandemic; mental health; public health; psychological variables; younger adults; symptom monitoring; health intervention

Introduction

As a prolonged, multidimensional stressor, COVID-19 has affected global mental health [1,2]. Sociodemographic and psychological correlates of elevated anxiety and depressive symptoms in early 2020 after pandemic onset are well documented [3]; a younger age, female gender, lower income/unemployment, uncertainty intolerance, and loneliness are associated with worse mental health during the pandemic. These findings primarily are from cross-sectional or short-term longitudinal studies (eg, 4-8 weeks) early in the pandemic. Less is known about contributors to mental health across the pandemic and as it wanes in the United States. Accordingly, this study was designed to examine hypothesized contributors to depressive symptoms and anxiety from 5 waves of data collected over 12 months.

The nature of the expected associations of sociodemographic, psychological, and COVID-19-specific variables with mental health outcomes were hypothesized to change from earlier to later phases of the pandemic. We focused on findings that are robust and consistent and are most pertinent to how the population will emerge from the pandemic.

Methods

Data Collection

Data were obtained from 5 national online surveys from May 2020 to April 2021 involving a total of 74,340 adults in the University of California, Los Angeles (UCLA) COVID Health and Politics Project, after institutional review board approval (IRB #20-000786). The samples were provided by Lucid, a market research platform. Prior to survey completion, respondents were informed of the following: the name and contact information of the principal investigator, that completion of the survey was voluntary, that the survey would take approximately 15 minutes, that no personally identifiable information would be asked within the survey, that any identifying information in connection with the study would remain confidential, and that the study was being performed to understand the impact of the COVID-19 pandemic on daily life. Project staff set quotas for sample acquisition and generated weights to produce representative samples of the adult US population. The response rate was approximately 69% on average across waves. Additional details regarding sampling and survey methods are available. [4].

Outcome Variables

Depressive symptoms were assessed using the Patient Health Questionnaire-8 (PHQ-8) [5], which contains 8 of the 9 *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition* (DSM-5), major depressive disorder (MDD) symptom criteria. Scores ranged from 0 to 24. Based on recommended cut-offs [5], severity categories were no significant symptoms (0-4), mild symptoms (5-9), and moderate-to-severe symptoms (10).

The 4-item Patient-Reported Outcome Measurement Information System (PROMIS) short form [6] assessed anxiety. Total scores ranged from 4 to 20. Following PROMIS scoring guidelines and established severity cut-offs, raw scores were converted to T scores, and established cut-off points yielded 3 categories: normal, mild, and moderate-to-severe anxiety.

Independent Variables

Table 1 displays categorical sociodemographic, COVID-19-related, and psychological variables. All independent variables were coded as categorical variables for inclusion in logistic regressions. Respondents were asked to indicate their age, gender (male or female), race/ethnicity, education level, household income, living status, presence of children in the home, employment status in the past 2 months prior to assessment, political identification, and health status (eg, presence or absence of a “significant medical problem or ailment,” including heart disease, cancer, or diabetes). Respondents’ geographical region and urban/rural living status were determined using the respondents’ zip code. Levels of categorical sociodemographic variables and referent categories are displayed in Table 1.

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Table 1. Characteristics of survey respondents.

Variable level	Weighted percentage, %					
	Wave 1 (N=14,636)	Wave 2 (N=14,936)	Wave 3 (N=14,946)	Wave 4 (N=15,265)	Wave 5 (N=14,557)	Overall (N=74,340)
Age (years), n (%)						
18-29	2975 (20.3)	3036 (20.3)	3046 (20.4)	3100 (20.3)	2958 (20.3)	15,115 (20.3)
30-44	3703 (25.3)	3798 (25.4)	3911 (26.2)	3866 (25.3)	3922 (26.9)	19,119 (25.8)
45-64	4953 (33.8)	5106 (34.2)	5054 (33.8)	5114 (33.5)	4925 (33.8)	25,151 (33.8)
65+[a]	3006 (20.5)	2996 (20.1)	2936 (19.6)	3185 (20.9)	2752 (18.9)	14,875 (20.0)
Gender, n (%)						
Male	7067 (48.3)	7211 (48.3)	7225 (48.3)	7367 (48.3)	7028 (48.3)	35,898 (48.3)
Female[a]	7569 (51.7)	7725 (51.7)	7721 (51.7)	7898 (51.7)	7529 (51.7)	38,443 (51.7)
Race/ethnicity, n (%)						
White[a]	9266 (63.3)	9456 (63.3)	9512 (63.6)	9666 (63.3)	9222 (63.3)	47,122 (63.4)
Black	1641 (11.2)	1670 (11.2)	1638 (11.0)	1736 (11.4)	1633 (11.2)	8318 (11.2)
Asian	8318 (6.9)	1029 (6.9)	1032 (6.9)	1051 (6.9)	1003 (6.9)	5123 (6.9)
Hispanic	2264 (15.5)	2325 (15.6)	2292 (15.3)	2338 (15.3)	2256 (15.5)	11,475 (15.4)
Other	457 (3.1)	456 (3.1)	472 (3.2)	475 (3.1)	444 (3.0)	2304 (3.1)
Education, n (%)						
High school or less[a]	4771 (32.6)	4861 (32.5)	4610 (30.8)	5011 (32.8)	4825 (33.1)	24,086 (32.4)
Some college	5350 (36.6)	5467 (36.6)	5711 (38.2)	5541 (36.3)	5239 (36.0)	27,283 (36.7)
College and above	4515 (30.8)	4608 (30.8)	4626 (30.9)	4713 (30.9)	4493 (30.9)	22,971 (30.9)
Heath status, n (%)						
Generally healthy[a]	8260 (56.4)	8347 (55.9)	8078 (54.0)	8196 (53.7)	7446 (51.1)	40,326 (54.2)
Significant diagnosis	6376 (43.6)	6589 (44.1)	6868 (46.0)	7070 (46.3)	7111 (48.9)	34,014 (45.8)
Household income[b], n (%)						
34,999 or less	2968 (20.3)	3029 (20.3)	3018 (20.2)	3095 (20.3)	2950 (20.3)	15,060 (20.3)
35,000-79,999	5228 (35.7)	5336 (35.7)	5339 (35.7)	5462 (35.7)	5200 (35.7)	26,565 (35.7)
80,000 or more	6440 (44.0)	6571 (44.0)	6589 (44.1)	6708 (44.0)	6407 (44.0)	32,715 (44.0)
Lives alone, n (%)						
Yes	2254 (15.4)	2305 (15.4)	2305 (15.4)	2440 (16.0)	2544 (17.5)	11,850 (15.9)
No[a]	12,347 (84.4)	12,596 (84.3)	12,597 (84.3)	12,720 (83.3)	11,955 (82.1)	62,215 (83.7)
Missing[c]	34 (0.2)	35 (0.2)	44 (0.3)	105 (0.7)	58 (0.4)	276 (0.4)
Children living at home, n (%)						
Yes	5552 (37.9)	5787 (38.7)	5863 (39.2)	5948 (39.0)	5297 (36.4)	28,447 (38.3)
No[a]	9013 (61.6)	9088 (60.8)	9012 (60.3)	9187 (60.2)	9189 (63.1)	45,488 (61.2)
Missing	71 (0.5)	61 (0.4)	72 (0.5)	130 (0.9)	72 (0.5)	376 (0.5)
Employment in the past 2 months[d], n (%)						
Working in person	3175 (21.7)	4012 (26.9)	4414 (29.5)	N/A[e]	N/A	N/A
Working remotely	3239 (22.1)	2937 (19.7)	2699 (18.1)	N/A	N/A	N/A
Not working due to COVID	1974 (13.5)	1555 (10.4)	1364 (9.1)	N/A	N/A	N/A
Not working for other reason	244 (1.7)	464 (3.1)	489 (3.3)	N/A	N/A	N/A

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Variable level	Weighted percentage, %					
	Wave 1 (N=14,636)	Wave 2 (N=14,936)	Wave 3 (N=14,946)	Wave 4 (N=15,265)	Wave 5 (N=14,557)	Overall (N=74,340)
Not working prior to COVID[a]	5982 (40.9)	5949 (39.8)	5941 (39.8)	N/A	N/A	N/A
Missing	21 (0.1)	18 (0.1)	39 (0.3)	N/A	N/A	N/A
Political identification, n (%)						
Democrat	6575 (44.9)	6685 (44.8)	6548 (43.8)	7199 (47.2)	6218 (42.7)	33,225 (44.7)
Republican[a]	5374 (36.7)	5416 (36.3)	5785 (38.7)	5375 (35.2)	5515 (37.9)	27,465 (36.9)
Independent	2676 (18.3)	2818 (18.9)	2596 (17.4)	2655 (17.4)	2795 (19.2)	13,540 (18.2)
Missing	12 (0.1)	17 (0.1)	17 (0.1)	37 (0.2)	29 (0.2)	111 (0.1)
Region, n (%)						
Northeast	2653 (18.1)	2605 (17.4)	2607 (17.4)	2663 (17.4)	2539 (17.4)	13,067 (17.6)
Midwest	3075 (21.0)	3107 (20.8)	3109 (20.8)	3179 (20.8)	3028 (20.8)	15,499 (20.8)
South	5695 (38.9)	5664 (37.9)	5668 (37.9)	5786 (37.9)	5521 (37.9)	28,334 (38.1)
West[a]	3213 (22.0)	3560 (23.8)	3561 (23.8)	3637 (23.8)	3469 (23.8)	17,441 (23.5)
Urban-rural, n (%)						
Rural	3530 (24.1)	3602 (24.1)	3614 (24.2)	3677 (24.1)	3512 (24.1)	17,936 (24.1)
Suburban	3554 (24.3)	3627 (24.3)	3710 (24.3)	3709 (24.3)	3535 (24.3)	18,054 (24.3)
Urban-suburban	6183 (42.2)	6309 (42.2)	6311 (42.2)	6450 (42.2)	6149 (42.2)	31,401 (42.2)
Urban[a]	1369 (9.4)	1397 (9.4)	1393 (9.3)	1428 (9.4)	1361 (9.3)	6949 (9.4)
COVID-19 infection in the past 2 months, n (%)						
Believes no exposure[a]	13,348 (91.2)	13,403 (89.7)	13,409 (89.7)	12,989 (85.1)	12,039 (82.7)	65,188 (87.7)
Tested positive for COVID-19	209 (1.4)	447 (3.0)	553 (3.7)	794 (5.2)	1211 (8.3)	3213 (4.3)
Believes had COVID-19	802 (5.5)	730 (4.9)	687 (4.6)	960 (6.3)	651 (4.5)	3831 (5.2)
Believes household had COVID-19 (but not self)	250 (1.7)	323 (2.2)	271 (1.8)	462 (3.0)	620 (4.3)	1926 (2.6)
Missing	27 (0.2)	32 (0.2)	27 (0.2)	60 (0.4)	36 (0.2)	182 (0.2)
COVID-19 restriction stress in the past 2 weeks, n (%)						
Not at all[a]	4145 (28.3)	4666 (31.2)	5402 (36.1)	4904 (32.1)	6231 (42.8)	25,348 (34.1)
Slightly	5389 (36.8)	5386 (36.1)	5085 (34.0)	5126 (33.6)	4227 (29.0)	25,213 (33.9)
Moderately	2992 (20.4)	2890 (19.3)	2724 (18.2)	3022 (19.8)	2414 (16.6)	14,041 (18.9)
Very	1354 (9.3)	1227 (8.2)	988 (6.6)	1319 (8.6)	909 (6.2)	5797 (7.8)
Extremely	718 (4.9)	735 (4.9)	734 (4.9)	843 (5.5)	712 (4.9)	3742 (5.0)
Missing	38 (0.3)	33 (0.2)	13 (0.1)	50 (0.3)	65 (0.4)	199 (0.3)
COVID-19 worry in the past month, n (%)						
Not worried[a]	3982 (27.2)	3856 (25.8)	4234 (28.3)	3965 (26.0)	5586 (38.4)	21,623 (29.1)
Mild	5912 (40.4)	6057 (40.6)	6118 (40.9)	6188 (40.5)	5036 (34.6)	29,311 (39.4)
Moderate-severe	3843 (26.3)	4098 (27.4)	3708 (24.8)	4220 (27.6)	3204 (22.0)	19,073 (25.7)
Missing	899 (6.1)	925 (6.2)	887 (5.9)	892 (5.8)	731 (5.0)	4333 (5.8)
COVID-19 risk in the next 30 days, n (%)						
Very low[a]	4736 (32.4)	4680 (31.3)	4915 (32.9)	5496 (36.0)	6352 (43.6)	26,180 (35.2)
Moderately low	4114 (28.1)	4193 (28.1)	4078 (27.3)	3804 (24.9)	3595 (24.7)	19,785 (26.6)
Neither high nor low	4081 (27.9)	4241 (28.4)	4178 (28.0)	4150 (27.2)	3212 (22.1)	19,862 (26.7)

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Variable level	Weighted percentage, %					
	Wave 1 (N=14,636)	Wave 2 (N=14,936)	Wave 3 (N=14,946)	Wave 4 (N=15,265)	Wave 5 (N=14,557)	Overall (N=74,340)
Moderately or very high	1686 (11.5)	1797 (12.0)	1761 (11.8)	1796 (11.8)	1375 (9.4)	8414 (11.3)
Missing	19 (0.1)	25 (0.2)	14 (0.1)	19 (0.1)	22 (0.2)	100 (0.1)
COVID-19 deaths per 1000 in the past 14 days (terciles)[f], n (%)						
Low density of deaths	4862 (33.2)	4942 (33.1)	4959 (33.2)	5014 (32.8)	4851 (33.3)	24,628 (33.1)
Medium density of deaths	4827 (33.0)	5011 (33.5)	4990 (33.4)	5176 (33.9)	4860 (33.4)	24,864 (33.5)
High density of deaths	4947 (33.8)	4983 (33.4)	4997 (33.4)	5075 (33.2)	4846 (33.3)	24,848 (33.4)
Known COVID-19 deaths[g], n (%)						
0[a]	N/A	N/A	N/A	N/A	8046 (55.3)	N/A
1	N/A	N/A	N/A	N/A	2277 (15.6)	N/A
≥2	N/A	N/A	N/A	N/A	4141 (28.4)	N/A
Missing	N/A	N/A	N/A	N/A	93 (0.6)	N/A
Vaccination status[g], n (%)						
Fully vaccinated	N/A	N/A	N/A	N/A	4745 (32.6)	N/A
Partially vaccinated	N/A	N/A	N/A	N/A	2355 (16.2)	N/A
Not vaccinated[a]	N/A	N/A	N/A	N/A	7457 (51.2)	N/A
Loneliness, n (%)						
No loneliness[a]	9211 (62.9)	9204 (61.6)	9162 (61.3)	9045 (59.2)	8909 (61.2)	45,531 (61.3)
Any loneliness	5271 (36.0)	5577 (37.3)	5611 (37.5)	6024 (39.5)	5281 (36.3)	27,764 (37.3)
Missing	153 (1.0)	155 (1.0)	173 (1.2)	197 (1.3)	367 (2.5)	1045 (1.4)
Uncertainty tolerance, n (%)						
High tolerance[a]	5957 (40.7)	6089 (40.8)	6064 (40.6)	6042 (39.6)	6024 (41.4)	30,175 (40.6)
Medium tolerance	5230 (35.7)	5226 (35.0)	5262 (35.2)	5532 (36.2)	4987 (34.3)	26,238 (35.3)
Low tolerance	3112 (21.3)	3351 (22.4)	3281 (21.9)	3451 (22.6)	3308 (22.7)	16,503 (22.2)
Missing	337 (2.3)	270 (1.8)	339 (2.3)	241 (1.6)	238 (1.6)	1424 (1.9)
Avoidance coping (past 2 weeks), n (%)						
No avoidance[a]	7917 (54.1)	8475 (56.7)	8795 (58.8)	8663 (56.8)	9103 (62.5)	42,954 (57.8)
Any avoidance	6719 (45.9)	6461 (43.3)	6151 (41.2)	6602 (43.2)	5454 (37.5)	31,387 (42.2)
Approach coping (past 2 weeks), n (%)						
Low approach	5177 (35.4)	5476 (36.7)	6134 (41.0)	6022 (39.4)	7205 (49.5)	30,015 (40.4)
Moderate approach	4116 (28.1)	4222 (28.3)	4175 (27.9)	4464 (29.2)	3804 (26.1)	20,781 (28.0)
High approach[a]	5343 (36.5)	5238 (35.1)	4637 (31.0)	5780 (31.3)	3547 (24.4)	23,545 (31.7)
Anxiety (past 7 days), n (%)						
No anxiety[a]	6371 (43.5)	6384 (42.7)	6674 (44.7)	6418 (42.0)	7274 (50.0)	33,122 (44.6)
Mild	3540 (24.2)	3569 (23.9)	3478 (23.3)	3500 (22.9)	2864 (19.7)	16,951 (22.8)
Moderate to severe	4616 (31.5)	4905 (32.8)	4661 (31.2)	5233 (34.3)	4309 (29.6)	23,723 (31.9)
Missing	109 (0.7)	78 (0.5)	133 (0.9)	114 (0.7)	110 (0.8)	544 (0.7)
Depression (past 2 weeks), n (%)						
No depression[a]	7751 (53.0)	7712 (51.6)	7688 (51.4)	7702 (50.5)	7560 (51.9)	38,413 (51.7)
Mild	3493 (23.9)	3578 (24.0)	3301 (22.1)	3372 (22.1)	3044 (20.9)	16,789 (22.6)

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Variable level		Weighted percentage, %					
		Wave 1 (N=14,636)	Wave 2 (N=14,936)	Wave 3 (N=14,946)	Wave 4 (N=15,265)	Wave 5 (N=14,557)	Overall (N=74,340)
	Moderate to severe	3186 (21.8)	3407 (22.8)	3705 (24.8)	3936 (25.8)	3684 (25.3)	17,918 (24.1)
	Missing	205 (1.4)	239 (1.6)	253 (1.7)	255 (1.7)	269 (1.8)	1221 (1.6)

[a]Referent category for regressions presented in Table 2.

[b]Income was included in the regression in terciles, with the first tercile as the reference group.

[c]Cases with missing responses were excluded from the regression models in Table 2.

[d]Current employment status was not assessed at waves 4 and 5.

[e]N/A: not applicable.

[f]COVID-19 deaths by respondent county were included in the regressions in terciles, with the first tercile as the reference group.

[g]Known COVID-19 deaths and vaccination status were assessed at wave 5 only.

Variables specific to COVID-19 were also collected. Respondents were asked to indicate their level of exposure to COVID-19 in the past 2 months ("tested positive for COVID-19," "believes had COVID-19 but did not test positive," "believes someone in their household had COVID-19," or "does not believe had COVID-19"), stress related to COVID-19 "shelter-in-place" orders, worry about contracting COVID-19, perceived risk of contracting COVID-19 in the next 30 days, and COVID-19-specific coping behaviors (eg, approach coping [broken into low, medium, and high terciles of approach behaviors] and avoidance coping [broken into "any avoidance behaviors" and "no avoidance behaviors]). COVID-19-related coping was assessed using yes/no items based on commonly used measures of coping [7,8]. Exposure to COVID-19-related deaths was calculated using the respondents' zip code in combination with data from the *New York Times* reporting deaths per 1000 residents to determine low, medium, and high death rates by tercile at each wave. Thus, the level of exposure to COVID-19 deaths was relative to a nationally representative US sample by wave. At wave 5 only, "known COVID-19 deaths" was assessed by asking respondents to indicate how many individuals they personally knew who had died from COVID-19. Levels of categorical COVID-19-related variables and referent categories are displayed in Table 1.

General psychological variables were collected at each wave. Loneliness was assessed with a 3-item scale adapted from the UCLA Loneliness Scale Revised [9], which asked how often respondents feel "lack of companionship," "left out," and "isolated from others." Response options included "hardly ever," "some of the time," and "often." Raw scores ranged from 3 to 9, with scores of 3-5 categorized as "not lonely" and scores of 6-9 categorized as "lonely." Uncertainty tolerance was assessed with 3 items from the Intolerance of Uncertainty Scale [10], summed and categorized by tercile (low, medium, and high tolerance of uncertainty).

Analysis

The data included 14,636 interviews conducted on May 11-24, 2020; 14,936 on July 9-22, 2020; 14,946 on October 1-17, 2020; 15,265 on December 4-16, 2020; and 14,557 on March 25-April 13, 2021. Missingness varied by wave in the logistic regressions. Weighted proportions (Table 1) were calculated using R statistical software version 3.6.1. Weighted ordinal logistic regression in SPSS version 27.0 was used to calculate the odds ratios (ORs) for anxiety and depression independently at each wave. Separate wave-by-wave regressions were conducted to test differences in independent variable associations with outcomes across approximately 1 year of the COVID-19 pandemic.

Results

Descriptive Statistics

On average, from May 2020 to April 2021, 17,918 of 73,120 (24.1%; n=1221 [1.6%] missing) adults reported moderate-to-severe depression, which increased from waves 1 and 2 (3186-3407 [21.8%-22.8%]) to waves 3 to 5 (3705-3684 [24.8%-25.3%]). On average, 23,723 of 73,796 (31.9%; n=544 [0.7%] missing) reported moderate-to-severe anxiety, with some evidence of decline at wave 5 (waves 1-4=4616-5233 [31.5%-34.3%] vs wave 5=4309 [25.3%]). Descriptive statistics are displayed in Table 1.

Logistic Regressions

Table 2 displays ORs and 95% CIs from logistic regressions on depression and anxiety at each wave.

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Table 2. Depression and anxiety full regression models[a] by wave.

Variable	Depression[b]					Anxiety[b]				
	Wave 1 OR[c] (95% CI)	Wave 2 OR (95% CI)	Wave 3 OR (95% CI)	Wave 4 OR (95% CI)	Wave 5 OR (95% CI)	Wave 1 OR (95% CI)	Wave 2 OR (95% CI)	Wave 3 OR (95% CI)	Wave 4 OR (95% CI)	Wave 5 OR (95% CI)
Age 18-29 years	*3.57 (3.06-4.18)*	*3.62 (3.10-4.23)*	*4.36 (3.70-5.15)*	*4.39 (3.76-5.11)*	*4.78 (4.01-5.69)*	*2.12 (1.83-2.46)*	*1.72 (1.49-1.99)*	*2.06 (1.76-2.40)*	*2.66 (2.30-3.06)*	*2.78 (2.35-3.28)*
Age 30-44 years	*2.13 (1.82-2.48)*	*2.57 (2.21-3.0)*	*2.63 (2.24-3.10)*	*3.01 (2.59-3.50)*	*2.55 (2.14-3.03)*	*1.98 (1.71-2.29)*	*1.45 (1.26-1.67)*	*2.10 (1.81-2.43)*	*2.13 (1.85-2.45)*	*2.05 (1.74-2.41)*
Age 45-64 years	*1.49 (1.30-1.70)*	*1.64 (1.44-1.88)*	*1.80 (1.55-2.08)*	*1.78 (1.56-2.02)*	*2.00 (1.71-2.33)*	*1.42 (1.25-1.61)*	*1.36 (1.20-1.53)*	*1.61 (1.41-1.83)*	*1.64 (1.46-1.84)*	*1.56 (1.35-1.80)*
Male	1.03 (0.94-1.12)	0.91 (0.84-.99)	0.90 (0.82-.98)	1.0 (0.92-1.09)	0.87 (0.79-.95)	*0.85 (0.78-.92)*	*0.75 (0.70-.82)*	*0.79 (0.72-.85)*	*0.86 (0.79-.93)*	*0.78 (0.71-.85)*
Black	0.81 (0.70-0.93)	0.89 (0.77-1.02)	*0.70 (0.60-0.81)*	1.09 (0.95-1.25)	0.87 (0.75-1.01)	0.88 (0.78-1.01)	0.79 (0.69-0.91)	*0.72 (0.62-0.82)*	0.89 (0.78-1.02)	*0.72 (0.62-0.84)*
Asian/Pacific Islander	*0.59 (0.50-0.70)*	0.79 (0.67-0.94)	0.97 (0.83-1.15)	0.86 (0.73-1.02)	0.84 (0.71-1.0)	0.95 (0.82-1.11)	*1.33 (1.14-1.56)*	*1.40 (1.20-1.63)*	0.91 (0.78-1.06)	1.18 (1.0-1.39)
Hispanic	0.97 (0.86-1.10)	0.82 (0.72-0.93)	0.97 (0.86-1.10)	1.07 (0.95-1.21)	*1.34 (1.18-1.52)*	1.01 (0.90-1.14)	0.96 (0.85-1.09)	0.95 (0.84-1.07)	0.96 (0.85-1.08)	0.90 (0.80-1.02)
Other	1.44 (1.13-1.84)	1.25 (0.99-1.58)	1.25 (0.98-1.59)	*1.56 (1.24-1.97)*	1.31 (1.02-1.68)	1.07 (0.84-1.37)	0.96 (0.77-1.21)	1.08 (0.86-1.37)	1.25 (0.99-1.57)	1.14 (0.89-1.46)
Some college	0.98 (0.88-1.08)	*0.80 (0.72-0.89)*	1.09 (0.99-1.21)	0.85 (0.77-0.94)	*0.82 (0.74-0.91)*	0.93 (0.84-1.03)	1.00 (0.91-1.11)	1.01 (0.92-1.12)	0.95 (0.86-1.04)	*0.81 (0.73-0.90)*
College and above	0.84 (0.75-0.95)	*0.80 (0.71-0.91)*	0.89 (0.78-1.01)	*0.77 (0.69-0.87)*	*0.71 (0.63-0.80)*	0.95 (0.84-1.07)	1.06 (0.95-1.19)	0.90 (0.79-1.01)	0.86 (0.77-0.96)	0.88 (0.78-0.99)
Significant diagnosis	*1.53 (1.40-1.68)*	*1.38 (1.26-1.51)*	*1.57 (1.43-1.72)*	*1.49 (1.36-1.63)*	*1.65 (1.50-1.81)*	*1.33 (1.21-1.45)*	*1.21 (1.11-1.31)*	*1.19 (1.09-1.30)*	1.08 (0.99-1.17)	*1.26 (1.15-1.38)*
2nd tercile income	0.84 (0.76-0.94)	0.97 (0.87-1.08)	*0.77 (0.69-0.86)*	0.95 (0.86-1.06)	0.89 (0.80-0.99)	*0.82 (0.73-0.91)*	0.89 (0.80-0.99)	0.91 (0.82-1.01)	0.97 (0.88-1.08)	*0.82 (0.74-0.91)*
3rd tercile income	*0.78 (0.69-0.88)*	0.88 (0.78-1.00)	*0.70 (0.62-0.80)*	*0.80 (0.71-0.90)*	*0.74 (0.65-0.84)*	*0.72 (0.64-0.81)*	*0.74 (0.66-0.83)*	*0.74 (0.65-0.83)*	*0.81 (0.73-0.91)*	*0.74 (0.65-0.84)*
Going into the workplace	1.10 (0.98-1.23)	0.89 (0.79-0.99)	*0.70 (0.62-0.78)*	N/A[d]	N/A	0.86 (0.76-0.96)	1.12 (1.01-1.24)	0.92 (0.83-1.03)	N/A	N/A
Remote work	1.15 (1.02-1.30)	0.87 (0.77-0.99)	0.90 (0.80-1.03)	N/A	N/A	1.04 (0.93-1.17)	*1.26 (1.12-1.41)*	1.09 (0.96-1.23)	N/A	N/A
Not working (COVID-19)	1.17 (1.03-1.34)	1.26 (1.10-1.46)	1.17 (1.01-1.37)	N/A	N/A	1.16 (1.02-1.32)	*1.28 (1.11-1.46)*	1.03 (0.88-1.19)	N/A	N/A
Not working (other reason)	1.16 (,85-1.60)	1.36 (1.07-1.72)	1.24 (0.98-1.58)	N/A	N/A	1.13 (0.83-1.54)	0.96 (0.76-1.21)	0.97 (0.77-1.22)	N/A	N/A
Lives alone	1.09 (0.96-1.23)	0.99 (0.87-1.12)	0.99 (0.88-1.12)	1.08 (0.96-1.22)	1.23 (1.10-1.39)	0.82 (0.72-0.92)	*0.78 (0.70-0.88)*	1.06 (0.94-1.19)	0.86 (0.77-0.97)	0.85 (0.76-0.96)
Living with children	1.05 (0.95-1.15)	1.04 (0.95-1.14)	*1.28 (1.16-1.41)*	0.94 (0.86-1.03)	1.14 (1.03-1.27)	1.06 (0.97-1.16)	*1.23 (1.12-1.34)*	1.16 (1.06-1.27)	0.91 (0.83-0.99)	0.94 (0.85-1.04)
Democrat	1.10 (1.0-1.21)	0.93 (0.84-1.02)	1.04 (0.94-1.15)	1.16 (1.05-1.27)	1.14 (1.03-1.27)	*1.31 (1.19-1.43)*	1.17 (1.07-1.28)	*1.25 (1.14-1.38)*	*1.21 (1.11-1.33)*	1.07 (0.97-1.18)
Independent	1.16 (1.03-1.31)	1.08 (0.96-1.22)	1.06 (0.93-1.20)	1.01 (0.90-1.15)	1.21 (1.07-1.37)	1.08 (0.96-1.22)	1.17 (1.04-1.31)	1.11 (0.99-1.25)	*1.24 (1.10-1.39)*	1.05 (0.93-1.18)
Rural	1.17 (0.99-1.39)	0.81 (0.68-0.96)	*1.38 (1.16-1.64)*	1.28 (1.08-1.50)	0.95 (0.79-1.14)	0.99 (0.83-1.17)	0.83 (0.71-0.98)	1.20 (1.02-1.42)	1.0 (0.85-1.17)	0.88 (0.74-1.04)
Suburban	1.18 (1.0-1.38)	0.82 (0.69-0.96)	1.28 (1.09-1.51)	1.27 (1.08-1.50)	0.92 (0.77-1.09)	1.01 (0.87-1.19)	1.07 (0.92-1.25)	1.22 (1.04-1.42)	1.21 (1.21-1.03)	0.94 (0.80-1.11)

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Variable	Depression[b]					Anxiety[b]				
	Wave 1 OR[c] (95% CI)	Wave 2 OR (95% CI)	Wave 3 OR (95% CI)	Wave 4 OR (95% CI)	Wave 5 OR (95% CI)	Wave 1 OR (95% CI)	Wave 2 OR (95% CI)	Wave 3 OR (95% CI)	Wave 4 OR (95% CI)	Wave 5 OR (95% CI)
Urban-suburban	1.23 (1.05-1.43)	0.85 (0.73-0.99)	1.17 (1.0-1.37)	1.13 (0.97-1.32)	1.02 (0.87-1.20)	1.01 (0.87-1.17)	0.95 (0.82-1.09)	1.19 (1.03-1.38)	1.14 (0.98-1.32)	1.06 (0.90-1.23)
Northeast	0.93 (0.80-1.08)	0.93 (0.81-1.06)	0.97 (0.84-1.11)	0.91 (0.80-1.03)	0.83 (0.73-0.96)	1.04 (0.90-1.20)	1.09 (0.97-1.24)	1.23 (1.08-1.40)	0.91 (0.81-1.03)	*0.78 (0.68-0.89)*
Midwest	0.86 (0.75-0.99)	0.93 (0.82-1.06)	1.11 (0.97-1.26)	1.00 (0.88-1.15)	1.08 (0.95-1.24)	0.82 (0.72-0.93)	1.12 (0.99-1.27)	1.04 (0.92-1.18)	0.96 (0.85-1.09)	*0.72 (0.63-0.82)*
South	1.03 (0.92-1.15)	0.88 (0.79-0.98)	0.99 (0.89-1.11)	1.11 (0.99-1.24)	0.96 (0.85-1.08)	0.94 (0.84-1.05)	1.18 (1.06-1.31)	*1.24 (1.11-1.38)*	1.0 (0.90-1.11)	0.95 (0.84-1.06)
Tested positive for COVID-19	*2.50 (1.75-3.58)*	*2.75 (2.13-3.55)*	*3.05 (2.38-3.92)*	*2.59 (2.12-3.17)*	*1.76 (1.47-2.10)*	1.32 (0.92-1.89)	*1.81 (1.40-2.33)*	*1.84 (1.44-2.35)*	*1.54 (1.27-1.88)*	0.96 (0.81-1.14)
Believes had COVID-19	*2.26 (1.89-2.69)*	*1.79 (1.48-2.15)*	*2.38 (1.93-2.93)*	*2.07 (1.75-2.45)*	1.02 (0.83-1.24)	1.08 (0.91-1.30)	0.86 (0.72-1.04)	*2.01 (1.63-2.47)*	*1.57 (1.32-1.86)*	1.12 (0.91-1.37)
Believes household (but not self) had COVID-19	1.08 (0.80-1.46)	1.12 (0.86-1.47)	1.13 (0.85-1.52)	*1.69 (1.34-2.13)*	0.94 (0.76-1.16)	0.65 (0.48-0.88)	0.81 (0.62-1.06)	0.79 (0.59-1.06)	1.28 (1.02-1.62)	0.92 (0.75-1.13)
COVID-19 restriction stress: slight	*1.65 (1.46-1.87)*	*1.41 (1.26-1.58)*	*1.88 (1.68-2.11)*	*1.48 (1.32-1.66)*	*1.60 (1.43-1.79)*	*1.95 (1.75-2.18)*	*1.54 (1.39-1.70)*	*1.61 (1.46-1.78)*	*1.87 (1.69-2.07)*	*1.92 (1.73-2.14)*
COVID-19 restriction stress: moderate	*2.83 (2.48-3.23)*	*2.65 (2.33-3.01)*	*2.84 (2.50-3.24)*	*2.56 (2.26-2.90)*	*2.83 (2.48-3.22)*	*3.77 (3.33-4.28)*	*2.95 (2.62-3.33)*	*3.33 (2.94-3.76)*	*2.78 (2.47-3.13)*	*3.22 (2.83-3.66)*
COVID-19 restriction stress: very	*3.98 (3.36-4.70)*	*3.80 (3.22-4.50)*	*3.74 (3.11-4.50)*	*3.90 (3.31-4.61)*	*3.50 (2.89-4.23)*	*5.63 (4.74-6.69)*	*3.42 (2.88-4.05)*	*3.41 (2.84-4.10)*	*3.44 (2.91-4.06)*	*4.29 (3.53-5.21)*
COVID-19 restriction stress: extreme	*6.24 (4.99-7.80)*	*5.95 (4.74-7.47)*	*6.93 (5.45-8.82)*	*6.75 (5.44-8.39)*	*8.63 (6.68-11.14)*	*6.73 (5.30-8.53)*	*4.33 (3.43-5.48)*	*4.85 (3.84-6.14)*	*4.88 (3.92-6.09)*	*6.62 (5.19-8.45)*
COVID-19 worry: mild	*1.69 (1.50-1.90)*	*1.49 (1.33-1.68)*	*1.61 (1.43-1.81)*	*1.56 (1.39-1.75)*	*1.80 (1.61-2.02)*	*3.37 (3.02-3.76)*	*3.08 (2.76-3.43)*	*2.64 (2.37-2.95)*	*2.98 (2.68-3.33)*	*2.27 (2.03-2.52)*
COVID-19 worry: moderate to severe	*2.48 (2.18-2.82)*	*2.16 (1.89-2.47)*	*2.96 (2.60-3.39)*	*2.38 (2.09-2.70)*	*3.52 (3.09-4.01)*	*6.23 (5.50-7.05)*	*6.39 (5.59-7.19)*	*5.26 (4.63-5.96)*	*5.11 (4.52-5.77)*	*3.40 (2.99-3.86)*
COVID-19 risk: moderately low	1.0 (0.89-1.12)	0.98 (0.87-1.10)	*1.24 (1.10-1.39)*	*1.40 (1.25-1.57)*	0.97 (0.87-1.09)	1.09 (0.98-1.22)	1.05 (0.94-1.18)	1.19 (1.07-1.34)	*1.27 (1.14-1.42)*	1.18 (1.06-1.32)
COVID-19 risk: neither high nor low	1.02 (0.91-1.14)	1.0 (0.89-1.13)	1.09 (0.97-1.21)	1.19 (1.07-1.34)	0.83 (0.73-0.93)	*1.54 (1.38-1.72)*	*1.37 (1.23-1.53)*	*1.38 (1.23-1.54)*	*1.49 (1.34-1.66)*	*1.33 (1.19-1.49)*
COVID-19 risk: moderate or very high	1.15 (0.99-1.33)	1.21 (1.04-1.40)	1.11 (0.95-1.29)	*1.44 (1.24-1.66)*	*0.74 (0.63-0.88)*	*1.39 (1.20-1.62)*	1.27 (1.10-1.46)	1.28 (1.11-1.48)	*1.50 (1.30-1.73)*	*1.35 (1.15-1.59)*
Medium death density	1.08 (0.97-1.20)	1.06 (0.95-1.17)	1.09 (0.97-1.21)	1.15 (1.04-1.26)	1.07 (0.96-1.19)	1.08 (0.97-1.22)	1.0 (0.94-1.14)	0.98 (0.88-1.08)	1.09 (0.99-1.20)	1.0 (0.90-1.11)
High death density	0.97 (0.86-1.09)	1.0 (0.90-1.11)	0.85 (0.76-0.96)	0.88* (0.79-0.98)	0.86 (0.77-0.96)	1.05 (0.93-1.17)	1.11 (1.0-1.23)	*0.80 (0.72-0.89)*	1.05 (0.95-1.17)	0.88 (0.79-0.98)

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Variable	Depression[b]					Anxiety[b]				
	Wave 1 OR[c] (95% CI)	Wave 2 OR (95% CI)	Wave 3 OR (95% CI)	Wave 4 OR (95% CI)	Wave 5 OR (95% CI)	Wave 1 OR (95% CI)	Wave 2 OR (95% CI)	Wave 3 OR (95% CI)	Wave 4 OR (95% CI)	Wave 5 OR (95% CI)
1 death	N/A	N/A	N/A	N/A	1.08 (0.95-1.22)	N/A	N/A	N/A	N/A	1.08 (0.96-1.22
≥2 deaths	N/A	N/A	N/A	N/A	*1.27 (1.14-1.42)*	N/A	N/A	N/A	N/A	*1.38 (1.24-1.54)*
Fully vaccinated	N/A	N/A	N/A	N/A	1.17 (1.05-1.30)	N/A	N/A	N/A	N/A	0.84 (0.76-0.93)
Partially vaccinated	N/A	N/A	N/A	N/A	1.08 (0.95-1.23)	N/A	N/A	N/A	N/A	*0.79 (0.70-0.89)*
Any loneliness	*3.35 (3.07-3.66)*	*2.98 (2.73-3.26)*	*3.36 (3.07-3.67)*	*2.80 (2.57-3.06)*	*3.60 (3.28-3.95)*	*2.00 (1.83-2.18)*	*2.26 (2.07-2.47)*	*2.11 (1.93-2.31)*	*2.26 (2.07-2.46)*	*2.82 (2.57-3.09)*
Low tolerance of uncertainty	*7.36 (6.49-8.34)*	*8.51 (7.51-9.64)*	*6.84 (6.02-7.77)*	*7.08 (6.26-7.99)*	*6.09 (5.35-6.93)*	*7.23 (6.39-8.18)*	*7.93 (7.02-8.96)*	*7.94 (7.01-8.99)*	*7.84 (6.94-8.84)*	*7.40 (6.53-8.40)*
Medium tolerance of uncertainty	*3.14 (2.83-3.49)*	*3.52 (3.17-3.91)*	*2.73 (2.45-3.04)*	*2.98 (2.69-3.30)*	*2.93 (2.63-3.28)*	*3.03 (2.76-3.33)*	*3.28 (3.0-3.60)*	*2.85 (2.59-3.14)*	*2.67 (2.44-2.93)*	*3.45 (3.11-3.83)*
Any avoidance	*2.31 (2.12-2.52)*	*2.53 (2.32-2.75)*	*2.47 (2.26-2.69)*	*2.27 (2.09-2.46)*	*2.54 (2.32-2.79)*	*1.43 (1.32-1.55)*	*1.30 (1.19-1.41)*	*1.39 (1.28-1.52)*	*1.46 (1.35-1.59)*	*1.45 (1.33-1.59)*
Low approach coping	*1.67 (1.51-1.85)*	*1.78 (1.61-1.97)*	*1.84 (1.66-2.04)*	*1.58 (1.43-1.75)*	*2.19 (1.96-2.45)*	0.99 (0.90-1.09)	1.13 (1.03-1.24)	0.99 (0.89-1.09)	1.01 (1.35-1.59)	0.92 (0.82-1.02)
Medium approach coping	1.15 (1.04-1.28)	1.19 (1.07-1.32)	*1.24 (1.11-1.39)*	*1.45 (1.31-1.61)*	*1.65 (1.46-1.87)*	0.92 (0.84-1.02)	1.09 (0.99-1.21)	0.94 (0.84-1.04)	1.02 (0.93-1.13)	0.93 (0.83-1.04)

[a]Each column presents ORs (95% CIs) from separate regression models (for referent categories, see Table 1). *N* varied by model.

[b]Italicized OR (95% CI) values signify *P*<.001.

[c]OR: odds ratio.

[d]N/A: not applicable.

Sociodemographic Variables

Of the sociodemographic variables, a younger adult age evidenced the strongest associations with depression and anxiety across waves. The effect of a younger age (ie, age 18-29 years) on depression was nearly double that for anxiety (waves 1-5 depression ORs 3.57-4.78, all *P*<.001, vs waves 1-5 anxiety ORs 2.12-2.78, all *P*<.001). Respondents aged 18-29 years and aged 30-44 years evidenced increasing moderate-to-severe depression rates from wave 1 to wave 5 (age 18-29 years=5459-6871 [37.3%-47.2%]; age 30-44 years=4069-4673 [27.8%-32.1%-), while older age groups had stable or declining rates (age 45-64 years=2386-2576 [16.3%-17.7%]; age ≥65 years=1171-815 [8.0%-5.6%]). To explore why younger adults might be more prone to persistent depressive symptoms, post hoc analyses tested interactions of age (continuous) with COVID-19-specific and psychological variables of depression. Tests of interactions did not identify any variable consistently related more strongly to greater depression in younger relative to older adults.

Women reported more anxiety than men (waves 1-5 ORs 1.18-1.28, all *P*<.001). Being in the highest income tercile was associated consistently with lower depression and anxiety (waves 1-5 depression ORs 0.78-0.74, all *P*<.001; waves 1-5 anxiety ORs 0.72-0.74, all *P*<.001). Medical comorbidity was related to depression and anxiety at most waves, although effects were not large (waves 1-5 depression ORs 1.53-1.65, *P*<.001; waves 1-5 anxiety ORs 1.33-1.26, all *P*<.001). Other sociodemographic variables were not associated consistently with outcomes.

COVID-19-Specific Variables

Of the COVID-19-specific variables, perceived stress from COVID-19 restrictions evidenced the strongest, graded relationships with depression (waves 1-5 “slightly stressful” to “extremely stressful” ORs from 1.65-1.48 to 6.24-8.63, all *P*<.001) and anxiety (waves 1-5 “slightly stressful” to “extremely stressful” ORs from 1.95-1.92 to 6.73-6.62, all *P*<.001) across waves. COVID-19-related worry also evidenced a strong, graded relationship with anxiety, which diminished at wave 5 (waves 1-5 “mild” to “moderate to severe” ORs from 3.37-2.27 to 6.23-3.40, all *P*<.001); its relationship with depression was somewhat weaker. Testing positive for COVID-19 in the past 2 months (or believing one had COVID-19) was associated consistently with higher depression. Perceived COVID-19 risk was associated with higher anxiety,

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with small effects (waves 1-5 "moderately to very high" ORs 1.39-1.35, all *P*<.001). Knowing 2 or more people (vs knowing no one) who had died from COVID-19 (measured only at wave 5) was associated with both outcomes, with small effects (wave 5 depression OR=1.27, *P*<.001; wave 5 anxiety OR 1.38, *P*<.001). At wave 5, being partially vaccinated (vs no vaccination) was associated with less anxiety, with small effects (wave 5 OR 0.79, *P*<.001). With regard to COVID-19-related coping, reporting any (vs no) avoidance behaviors was associated consistently with more depression and anxiety, with small-to-moderate effect sizes, which were greater for depression than anxiety (waves 1-5 depression ORs 2.31-2.54, all *P*<.001; waves 1-5 anxiety ORs 1.43-1.45, all *P*<.001). Lower approach-oriented coping was associated consistently with greater depression (but not anxiety) across waves, with small effect sizes (waves 1-5 "low approach" depression ORs 1.67-2.19, all *P*<.001).

Psychological Variables

Of the general psychological variables, lower tolerance of uncertainty evidenced the strongest, graded relationships with depression (waves 1-5 "low" to "medium" ORs from 7.36-6.09 to 3.14-2.93, all *P*<.001) and anxiety (waves 1-5 "low" to "medium" ORs from 7.23-7.40 to 3.03-3.45, all *P*<.001). Respondents reporting any (vs no) loneliness also reported more depression (waves 1-5 ORs 3.35-3.60, all *P*<.001) and anxiety (waves 1-5 ORs 2.00-2.82, all *P*<.001) across waves, with moderate-to-large effect sizes, which were slightly larger for depression than anxiety.

Discussion

Principal Findings

Findings from 5 waves of large, nationally representative samples provided substantial evidence that the US population has experienced increased rates of clinically relevant depression and anxiety in response to the onset of the COVID-19 pandemic, which have been sustained across the majority of the first year of the pandemic. Rates of moderate-to-severe depression (n=17,918, 24.1%) and anxiety (n=23,723, 31.9%) were much higher than documented prepandemic levels of depression (n=7%) [11] and anxiety (6.1%) [12]. Logistic regression analyses revealed that in general, the magnitude of associations of sociodemographic and other variables with mental health outcomes did not evidence a consistent pattern of change over the year. Of the sociodemographic variables, age was most robustly and reliably associated with the outcomes. Consistent with other research, younger adults (age<44 years) demonstrated a substantially higher likelihood of reporting moderate-to-severe depression compared to adults ≥65 years old [13-15]. These findings contribute to the literature by demonstrating that the risk for depression to younger adults persisted late into the pandemic, whereas older adults began to decline in depression and anxiety. These findings have important implications for mental health both now and in the future. MDD is episodic in nature, and a documented risk factor for recurrent episodes is the frequency and duration of prior episodes [16]. Promoting mental health awareness and psychoeducation will be crucial to reaching young adults, as will making mental health care easily accessible through integration with primary care and leveraging technology to deliver remote care. Research is needed to identify novel methods to reach younger adults to assess for mental well-being as well as deliver mental health care that is sensitive to and able to address specific generational differences in the experience of the pandemic that may contribute to worse mental health outcomes [17].

Over and above sociodemographic factors, the strongest and most persistent COVID-19-related factors related to the outcomes were testing positive for COVID-19 (for depression), perceiving stress from pandemic-related restrictions, worry, and coping behaviors related to the pandemic. Presumably, the COVID-specific factors contributing to mental health outcomes will become less relevant as the pandemic wanes, with the exception of potentially chronic effects of having the disease. However, even in the light of efforts to manage the pandemic through vaccination and ongoing implementation of mask recommendations/mandates, COVID-19 continues to be diagnosed in the vaccinated and especially the unvaccinated, and research has emerged related to effects of long COVID-19 [18]. Thus, COVID-19-related stress, worry, and coping behaviors continue to be significant factors in COVID-19-related depression and anxiety that warrant long-term monitoring. Specifically, individuals who have been diagnosed with COVID-19 warrant long-term monitoring for symptoms of depression.

Among general psychological factors, a lower tolerance of uncertainty was the most potently and consistently associated with outcomes. Loneliness was also associated with a greater likelihood of moderate-to-severe depression and anxiety. Loneliness has been identified by numerous studies as an increasing contributor to mental health outcomes, such as depression and anxiety, as well as an indicator of diminished quality of life per se, especially following the onset of the COVID-19 pandemic. Evidence also suggests that interventions designed to improve social connection behaviorally and challenge patterns of thinking that contribute to loneliness (ie, cognitive behavioral therapy [CBT]) are effective at reducing perceived loneliness and associated depressive symptoms [19,20]. Recent research has explored digital applications of these CBT principles, a delivery method that is recognized as critical to intervention dissemination, particularly with the necessity of remote delivery of services in the context of the COVID-19 pandemic [21]. Similarly, CBT-based interventions for intolerance of uncertainty should also be emphasized and disseminated, given present findings. For example, mindfulness-based interventions that promote tolerance of psychological experiences [22] and CBT-based interventions that promote adaptive coping and disconfirmation of feared outcomes may be beneficial for individuals with chronic intolerance of uncertainty [23,24].

Conclusion

In summary, data from large, nationally representative samples of adults collected at 5 waves over a year's period reveal that symptoms of depression and anxiety are markedly elevated from shortly after COVID-19 was first diagnosed in the United States through more than 1 year later. Health care professionals

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should monitor at-risk groups, particularly younger adults, adults who evidence intolerance of uncertainty or loneliness, and those who have had the disease. This study identified both vulnerable groups and psychological processes that can be targeted to promote the psychological health of the population as the nation continues to move through profoundly challenging times.

Conflicts of Interest

None declared.

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Abbreviations

CBT: cognitive behavioral therapy
MDD: major depressive disorder
OR: odds ratio
PHQ-8: Patient Health Questionnaire-8
PROMIS: Patient-Reported Outcome Measurement Information System
UCLA: University of California, Los Angeles

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Original Paper

Risk Factors for COVID-19 in College Students Identified by Physical, Mental, and Social Health Reported During the Fall 2020 Semester: Observational Study Using the Roadmap App and Fitbit Wearable Sensors

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Abstract

Background: The COVID-19 pandemic triggered a seismic shift in education to web-based learning. With nearly 20 million students enrolled in colleges across the United States, the long-simmering mental health crisis in college students was likely further exacerbated by the pandemic.

Objective: This study leveraged mobile health (mHealth) technology and sought to (1) characterize self-reported outcomes of physical, mental, and social health by COVID-19 status; (2) assess physical activity through consumer-grade wearable sensors (Fitbit); and (3) identify risk factors associated with COVID-19 positivity in a population of college students prior to release of the vaccine.

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Methods: After completing a baseline assessment (ie, at Time 0 [T0]) of demographics, mental, and social health constructs through the Roadmap 2.0 app, participants were instructed to use the app freely, wear the Fitbit, and complete subsequent assessments at T1, T2, and T3, followed by a COVID-19 assessment of history and timing of COVID-19 testing and diagnosis (T4: ~14 days after T3). Continuous measures were described using mean (SD) values, while categorical measures were summarized as n (%) values. Formal comparisons were made on the basis of COVID-19 status. The multivariate model was determined by entering all statistically significant variables (P<.05) in univariable associations at once and then removing one variable at a time through backward selection until the optimal model was obtained.

Results: During the fall 2020 semester, 1997 participants consented, enrolled, and met criteria for data analyses. There was a high prevalence of anxiety, as assessed by the State Trait Anxiety Index, with moderate and severe levels in 465 (24%) and 970 (49%) students, respectively. Approximately one-third of students reported having a mental health disorder (n=656, 33%). The average daily steps recorded in this student population was approximately 6500 (mean 6474, SD 3371). Neither reported mental health nor step count were significant based on COVID-19 status (P=.52). Our analyses revealed significant associations of COVID-19 positivity with the use of marijuana and alcohol (P=.02 and P=.046, respectively) and with lower belief in public health measures (P=.003). In addition, graduate students were less likely and those with ≥20 roommates were more likely to report a COVID-19 diagnosis (P=.009).

Conclusions: Mental health problems were common in this student population. Several factors, including substance use, were associated with the risk of COVID-19. These data highlight important areas for further attention, such as prioritizing innovative strategies that address health and well-being, considering the potential long-term effects of COVID-19 on college students.

Trial Registration: ClinicalTrials.gov NCT04766788; https://clinicaltrials.gov/ct2/show/NCT04766788

International Registered Report Identifier (IRRID): RR2-10.2196/29561

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KEYWORDS

mHealth; mobile health; college student; mental health; wearable devices; wearable; student; risk factor; risk; COVID-19; physical health; observational; crisis; self-report; outcome; physical activity; wellbeing; well-being

Introduction

As SARS-CoV-2 spread throughout the United States and worldwide [1], the COVID-19 pandemic disrupted and transformed education overnight [2]. Reacting to the COVID-19 pandemic and subsequent quarantine and isolation measures [3], academic institutions across the nation adapted to virtual learning owing to closures of in-person schooling. The unprecedented changes included significant reduction in access to campus resources (eg, libraries, computing facilities, group study areas, mental health services, and exercise facilities), which upended the education landscape [2,4] and created intense stress across institutions. Several recent studies provide evidence for a high prevalence of mental health problems among college students who experienced virtual education [5-16].

Given the potential profound impact of the COVID-19 pandemic on the health and well-being of college students, our interdisciplinary team leveraged a positive psychology–based mobile health (mHealth) app, Roadmap 2.0, as a resilience-building platform for the student population. The Roadmap platform was initially developed to provide support to patients and their family caregivers in health care delivery (eg, information, education, and skills-based training) because of its accessibility and scalability [17-23]. This platform was iteratively enhanced to support the health and well-being of the user and to aggregate their raw step and sleep counts, which were collected through the Fitbit [24].

Herein, this Roadmap platform was leveraged to (1) characterize self-reported outcomes of physical, mental, and social health by COVID-19 status during the fall 2020 semester; (2) assess physical activity through consumer-grade wearable sensors (Fitbit) by COVID-19 status [25]; and (3) evaluate potential risk factors associated with COVID-19 positivity, including student demographics (eg, gender, race, and ethnicity), substance use, and physical, mental, and social health constructs [25]. This work is important because it may inform future mHealth design interventions for this population. Moreover, these data may be important factors to consider when developing future public health responses that include massive disruptions to mitigate spread of communicable diseases, particularly in emerging, young adults. By using the Roadmap platform, we sought to focus our findings on the nexus between mental and social health constructs with physical activity and COVID-19 status.

Methods

Study Site

The data coordinating site was a Midwestern academic institution (University of Michigan [U-M]). All study activities were conducted remotely with no in-person contact, and all study materials were mailed to participants' residences through a US shipping company.

Study Design, Recruitment, and Informed Consent

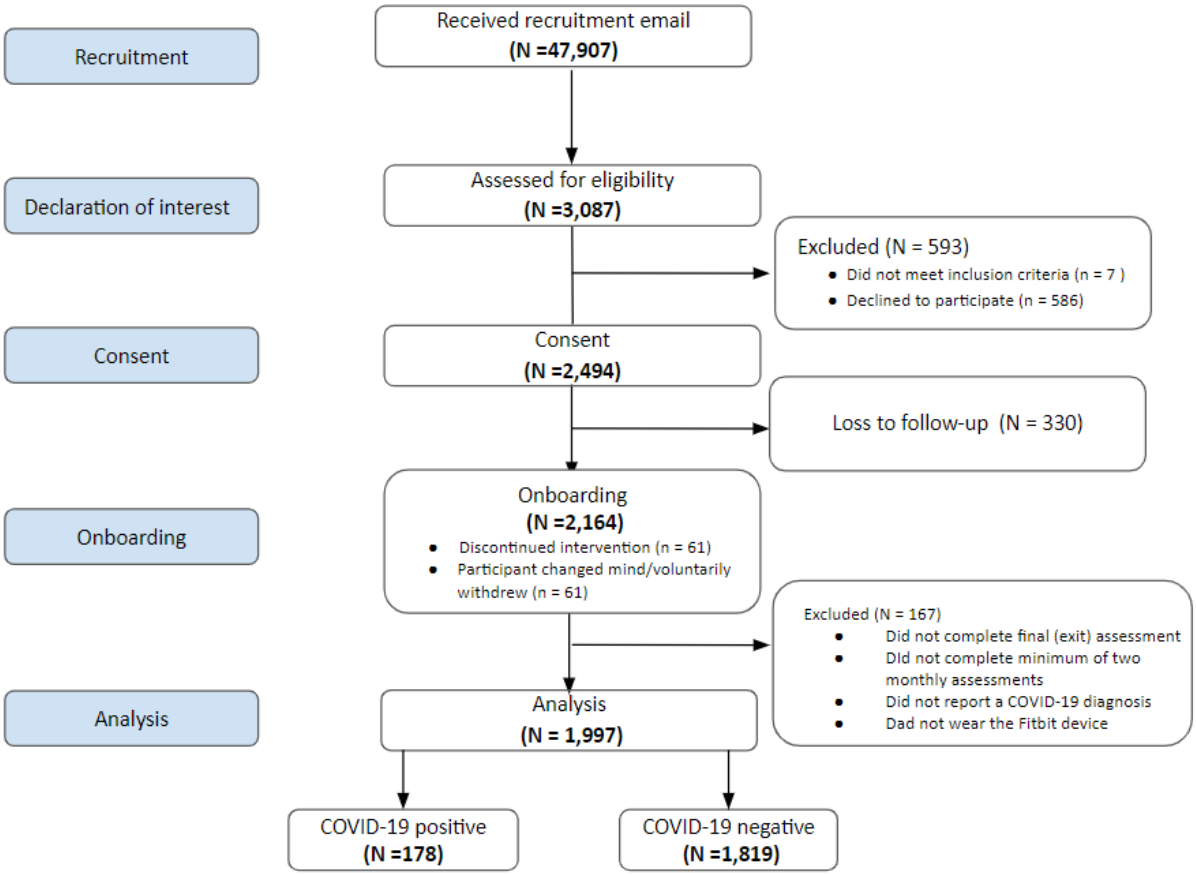
The study protocol has been previously published with more details [25]. Briefly, eligibility for study participation included the following: age ≥18 years, being a confirmed undergraduate or graduate U-M student (eg, on campus or at home). being able to provide digital informed consent, being comfortable with reading and speaking English, and having access to necessary

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resources for participating in an mHealth technology-based intervention (ie, smartphone or tablet device and internet access) while also being willing to use personal equipment or the internet for the study.

The recruitment period was between September 2020 and December 2020. While paper flyers and postings were distributed throughout the campus buildings, the primary mode of recruitment was by the "Targeted Email and Data Service," coordinated by the U-M Registrar's Office, with IRBMED approval (Figure 1).

Figure 1. CONSORT (Consolidated Standards of Reporting Trials) flow diagram [26] for participant recruitment and enrollment.



Interested participants who contacted the study team by telephone or email received additional study information (eg, overview of study procedures, risks, and benefits). Following confirmation of university student status, the research coordinator emailed the informed consent through the SignNow platform, and the participant signed the document electronically [27].

Study Procedures

The study procedures are outlined in Multimedia Appendix 1.

Wearable Device

The Fitbit was mailed to the participants' homes. They were instructed to use it continuously (at least ~40 hours/week) to measure their physical activity, heart rate, and sleep during the monitoring period. The Fitbit automatically generated accelerometer-based summary data (per proprietary algorithms) that were based on "activity counts" collected over the course of the day. We assessed participant compliance in wearing the Fitbit by identifying when heart rate data were present through the Roadmap platform using the Fitbit API [28]. We measured daily wear time using heart rate data with a minute-level resolution. Compliance was expressed both in hours (0-24 hours) and in percentages (ie, by dividing the number of hours spent wearing the device by 24) [29]. By assessing compliance, we calculated the average daily step count for participants who wore the Fitbit for more than 6 hours between 8 AM and 8 PM. We chose a cut-off of 6 hours because the distribution of average daily step count did not change significantly for higher cut-offs. No compliance cut-off was applied for calculating asleep hours because the daily average changed by only approximately .05 hours between a cut-off of 0 hours and a cut-off of 11 hours between 8 PM and 8 AM.

Roadmap and Fitbit Apps

Participants were instructed to download the Roadmap 2.0 (Multimedia Appendix 2) and Fitbit apps on their smartphone device (both free of charge and publicly available on Apple App Store and Google Play).

Self-reported Outcomes

All self-reported physical, mental, and social health data were collected using Roadmap 2.0, which used Qualtrics (Qualtrics), a web-based research tool that enables researchers to create study-specific websites for administering study surveys and storing participant data. The data were associated via a unique

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study participant ID and did not contain any identifying information. Data were stored in the cloud and regularly downloaded and saved on Health Insurance Portability and Accountability Act–compliant and password-protected university servers. Participants were instructed to complete surveys at baseline (preintervention: T0, monthly: T1, T2, T3, and upon study exit [T4] using the Roadmap platform). A list of the survey questionnaires is provided in the Research Protocol [25]. Psychometric properties of these measures are provided in Multimedia Appendix 3. Of note, only the preintervention (T0) mental health and health behaviors data were analyzed in this study. The 9-item Patient Health Questionnaire (PHQ-9; for depression) and the 7-item General Anxiety Disorder (GAD-7; for anxiety) scales were added into the study protocol after the study began, and only a subset of participants answered these items.

Statistical Analyses

For the descriptive statistics, continuous measures were described using mean (SD) values, while categorical measures were summarized as n (%) values. These data were analyzed using SAS software (SAS Institute). Formal comparisons were made on the basis of COVID-19 status (ie, positive or negative) with Cronbach α levels (statistical significance) set at $P<.05$.

Logistic regression models were fit in two stages. First, univariate associations of student demographics and characteristics, mental health, self-reported substance use and social health measures were assessed by COVID-19 status. Second, the multivariate associations of student demographics and characteristics, mental health, self-reported substance use, and social health measures were assessed by COVID-19 status. The multivariate model was developed by entering all statistically significant variables ($P<.05$) in univariable associations at once and then removing one variable at a time by backward selection until the optimal model was obtained (ie, the deviance of the model was minimized).

Next, to test the performance of the multivariate regression model, several receiver operating characteristic (ROC) curves were plotted for candidate models: Model 1 included only demographic variables; Model 2 included demographic and mental health measures; Model 3 included demographic, mental health measures, and self-reported substance use; and Model 4 (Full Model) included all the variables in Models 1 through 3 plus all other significant characteristics and social health variables from univariate associations; as well as Model 5 (Final Model), which was selected through backward stepwise regression from Model 4. Model 5 provided the minimal Akaike Information Criterion. The area under the ROC curve (AUC) represented the prediction accuracy of the current model. When we constructed our models, we observed an increase in accuracy as more variables were added from Model 1 to Model 4. Importantly, even though Model 5 included fewer variables than the Model 4, we did not observe a significant loss in prediction accuracy. Thus, Model 5 was selected as the final multivariate model owing to its simplicity. The univariate and multivariate logistic regression were analyzed using R (version 4.1.1). Figures and graphs were generated with GraphPad Prism (version 9.1.0 for Windows, GraphPad).

Ethics Approval

Ethical approval for this study was obtained by the U-M Medical School Institutional Review Board (IRBMED), and the study was registered on ClinicalTrials.gov (NCT04766788).

Results

Participant Demographics by COVID-19 Status

The majority of students consented and enrolled in the study during the months of October and November 2020 (Multimedia Appendix 4), which coincided with the peak number of confirmed cases of COVID-19 at the local, state, and national levels (Multimedia Appendix 5). As shown in Table 1, the student population (total N=1997) consisted of undergraduate (n=1312, 66%) and graduate students (n=670, 34%). The majority of the respondents were female (n=1367, 68%) and White (n=1150, 58%), followed by Asian (n=597, 30%), 2 or more races (n=107, 5%), and Black (n=85, 4%). In total, 10% of participants reported their ethnicity as Hispanic or Latinx, and 8% were international students. Approximately one-fourth of the participants were first-generation college students.

In this population, 178 (8.9%) students reported a positive COVID-19 diagnosis (COVID-19 positivity), which occurred either before or during the study period (ie, reported at the baseline, monthly, or the exit survey). These individuals were more likely to be non-Asian, non–multi-racial, domestic undergraduate students, living with ≥20 housemates, or owning iPhone devices.

The most common COVID-19 symptoms reported by students included body aches (n=93, 51%), loss of smell (anosmia; n=68, 37%), chills (n=67, 36.8%), and cough (n=64, 35%). Additionally, the most common clusters of associated dyadic symptoms were chills and body aches (Cluster 1: n=59) and loss of taste (ageusia) and anosmia (Cluster 2: n=49). The most common triad of symptoms were fever, chills, and body aches (Cluster 3: n=40). Not surprisingly, all respiratory symptoms (eg, cough, shortness of breath, and sore throat) were associated with each other (Figure 2). However, 53 participants (30% of the 178 COVID-19–positive participants) reported that they were asymptomatic.

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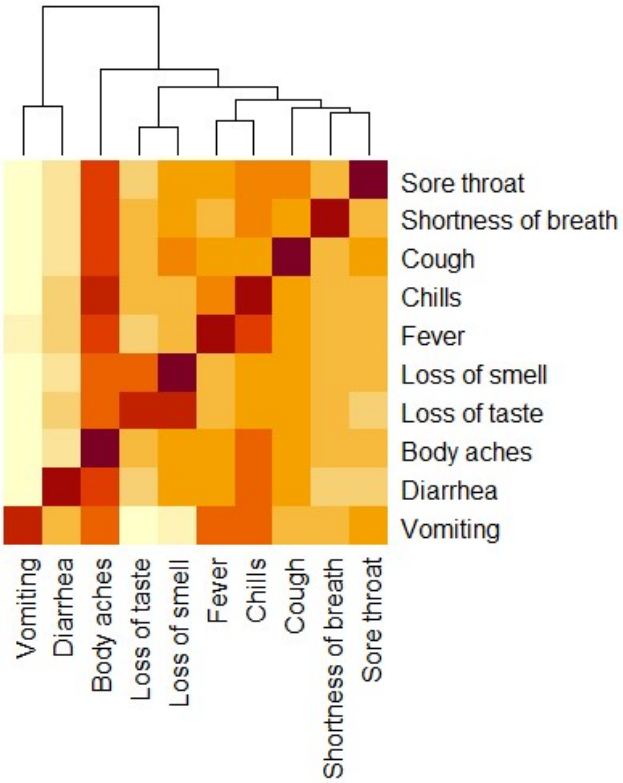
Table 1. Participant demographics and characteristics by COVID-19 status.

Demographics	Population, n (%)	COVID-19–negative students, n (%)	COVID-19–positive students, n (%)	*P* value[a]
School year				<.001
Freshman	231 (11.6)	209 (90.5)	22 (9.5)	
Sophomore	355 (17.8)	308 (86.8)	47 (13.2)	
Junior	338 (16.9)	299 (88.5)	39 (11.5)	
Senior	388 (19.9)	357 (92.0)	31 (8.0)	
First year graduate	238 (11.9)	218 (91.6)	20 (8.4)	
Second year or greater graduate	432 (21.6)	413 (95.6)	19 (4.4)	
Gender				.92
Female	1367 (68.5)	1244 (91.0)	123 (9.0)	
Male	613 (30.7)	559 (91.2)	51 (8.8)	
Other	16 (0.8)	15 (93.7)	1 (6.3)	
Race				<.001
White	1150 (58.1)	1016 (88.4)	124 (11.6)	
Black or African American	85 (4.3)	80 (94.1)	5 (5.9)	
American Indian/Alaska Native	4 (0.2)	3 (75.0)	1 (25.0)	
Asian	597 (30.2)	570 (95.5)	27 (4.5)	
Multiracial	107 (5.4)	102 (95.3)	5 (4.7)	
Other	37 (1.9)	32 (86.5)	5 (13.5)	
Ethnicity				.13
Hispanic or Latino	193 (9.7)	170 (88.1)	23 (11.9)	
Non-Hispanic or Latino	1800 (90.3)	1645 (91.4)	155 (8.6)	
Domestic or international				.01
Domestic	1843 (92.4)	1670 (90.6)	173 (9.4)	
International	151 (7.6)	146 (96.7)	5 (3.3)	
First or continuing generation				.60
First generation	503 (25.3)	461 (91.7)	42 (8.3)	
Continuing generation	1489 (74.7)	1353 (90.9)	136 (9.1)	

[a]*P* values are representative of a chi-square test performed for the entire study population.

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Figure 2. COVID-19 symptoms. The most common clusters of associated dyadic symptoms were chills and body aches (cluster 1, n=59), and loss of taste (ageusia) and anosmia (cluster 2, n=49). The most common triad of symptoms was fever, chills, and body aches (cluster 3, n=40). Body chills occurred most frequently, which was concurrently most frequent. All respiratory symptoms (eg, cough, shortness of breath, and sore throat) were associated with one another.



Self-reported Mental and Social Health by COVID-19 Status

A high prevalence of anxiety, as assessed by the State Trait Anxiety Index (STAI), was reported at moderate (n=465, 24%) and severe (n=970, 49%) levels in this student population (Table 2). These findings were consistent with those of self-reported anxiety (n=570, 28%), depression (n=373, 19%), or indication of any mental health disorder (n=656, 33%) when asked the question, “do you have any of the following health conditions?” However, there were no differences in these parameters in accordance with COVID-19 status. Similarly, there were no differences in levels of coping, compassion, or flourishing between the groups in accordance with COVID-19 status. Not surprisingly, this population reported high levels (mean 6.14, SD 0.88; maximum 7.0) of desire for academic success. Interestingly, lower levels of loneliness and higher social fitness were associated with COVID-19 positivity (Table 2).

Given the high prevalence of anxiety in our population, we were interested in examining their coping levels. Table 3 details the mean scores on the Brief Coping Orientation to Problems Experienced inventory based on problem-focused, emotion-focused, and avoidant coping subscales [30]. As a population, students had the highest mean scores for acceptance, followed by self-distraction, and the lowest mean scores for denial and substance use. Low levels of planning and higher use of humor and substance use were associated with COVID-19 positivity (Table 3). Pearson correlation analysis revealed a significant negative association between anxiety and compassion (r=–0.22) as well as anxiety and flourishing (r=–0.71). There was also a significant positive correlation between compassion and flourishing (r=0.22). There was no relationship between compassion and adherence to public health COVID-19 measures (r=–0.001; Multimedia Appendix 6).

Table 2. Self-reported mental health outcomes by COVID-19 status.

Mental health outcome	Population, mean (SD)	COVID-19–negative students, mean (SD)	COVID-19–positive students, mean (SD)	*P* value
State Trait Anxiety Index trait	44.49 (10.61)	44.55 (10.60)	43.86 (10.78)	.41
Compassion	3.46 (0.91)	3.46 (0.92)	3.46 (0.87)	.95
Flourishing	7.35 (1.47)	7.34 (1.46)	7.51 (1.54)	.14
Loneliness	1.94 (0.58)	1.95 (0.58)	1.83 (0.61)	<.001
Social fit	5.03 (1.14)	5.00 (1.13)	5.29 (1.13)	<.001
Academic success	6.14 (0.88)	6.13 (0.87)	6.21 (0.95)	.29

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Table 3. Outcomes on the Brief Coping Orientation to Problems Experienced inventory by COVID-19 status.

Coping mechanisms	Population, mean (SD)	COVID-19–negative students, mean (SD)	COVID-19–positive students, mean (SD)	*P* value
Problem-focused coping	2.46 (0.59)	2.47 (0.59)	2.40 (0.57)	.14
Active coping	2.45 (0.76)	2.45 (0.76)	2.37 (0.72)	.16
Instrumental support	2.39 (0.86)	2.40 (0.86)	2.34 (0.83)	.38
Positive reframing	2.48 (0.83)	2.47 (0.83)	2.54 (0.82)	.30
Planning	2.53 (0.80)	2.55 (0.80)	2.36 (0.80)	<.001
Emotion-focused coping	2.34 (0.42)	2.34 (0.42)	2.34 (0.40)	.92
Emotional support	2.64 (0.88)	2.64 (0.89)	2.60 (0.86)	.59
Venting	2.14 (0.72)	2.14 (0.73)	2.13 (0.69)	.79
Humor	2.29 (0.92)	2.28 (0.92)	2.44 (0.86)	.02
Acceptance	3.22 (0.68)	3.23 (0.67)	3.17 (0.67)	.21
Self-blame	2.04 (0.81)	2.04 (0.81)	2.07 (0.85)	.75
Religion	1.67 (0.89)	1.67 (0.90)	1.63 (0.83)	.51
Avoidant coping	1.77 (0.38)	1.76 (0.38)	1.84 (0.41)	.008
Self-distraction	2.96 (0.72)	2.95 (0.72)	2.99 (0.70)	.49
Denial	1.20 (0.44)	1.20 (0.43)	1.26 (0.48)	.10
Substance use	1.40 (0.69)	1.38 (0.66)	1.62 (0.84)	<.001
Behavioral disengagement	1.53 (0.65)	1.53 (0.64)	1.49 (0.68)	.47

Self-reported Substance Use by COVID-19 Status

Among all students, cigarette smoking was low (n=23, 1.2%), while the numbers of students who reported any marijuana use, vaping, and alcohol use were 847 (42.6%), 431 (21.6%), and 1600 (80.4%), respectively, which were all associated with COVID-19 positivity (Table 4). Moreover, students who reported a mental health problem were significantly more likely to use marijuana (odds ratio [OR] 1.76, 95% CI 1.46-2.13), consume alcohol (OR 2.22, 95% CI 1.70-2.90), engage in vaping (OR 1.64, 95% CI 1.32-2.04), or smoke cigarettes (OR 4.76, 95% CI 1.95-11.63; Multimedia Appendix 7).

Table 4. Health behaviors including substance use and exercise by COVID-19 status.

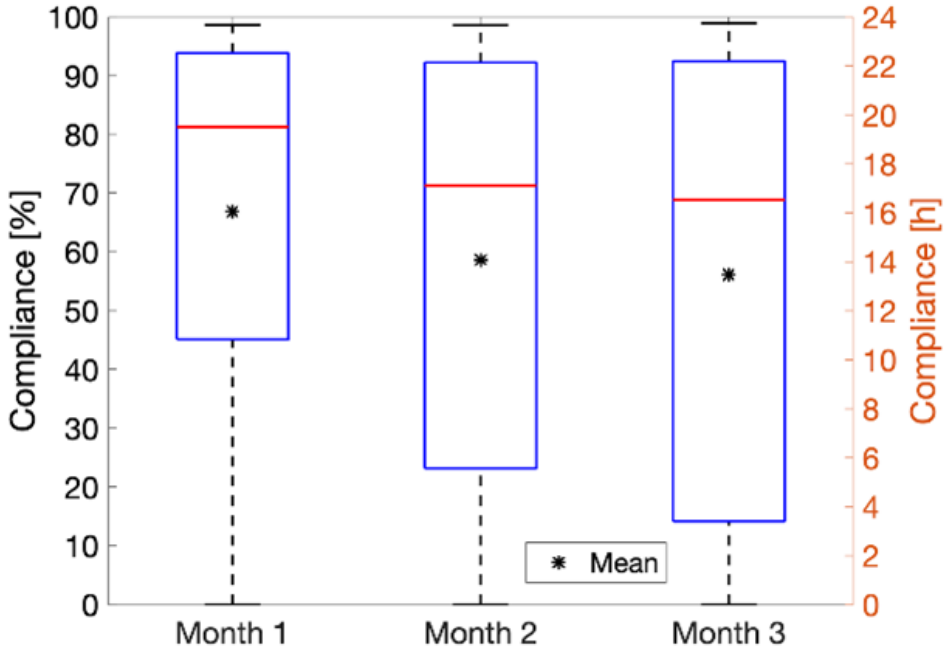
Health behaviors	Population, n (%)	COVID-19–negative students, n (%)	COVID-19–positive students, n (%)	*P* value
Marijuana				<.001
Yes	847 (42.6)	737 (87.0)	110 (13.0)	
No	1143 (57.4)	1076 (94.1)	67 (5.9)	
Smoking				.49
Yes	23 (1.2)	20 (87.0)	3 (13.0)	
No	1973 (98.8)	1798 (91.1)	175 (8.9)	
Vaping				<.001
Yes	431 (21.6)	359 (83.3)	72 (16.7)	
No	1563 (78.4)	1458 (93.3)	105 (6.7)	
Alcohol consumption				<.001
Yes	1600 (80.4)	1435 (89.7)	165 (10.3)	
No	391 (19.6)	379 (20.9)	12 (3.1)	
Exercise				.42
Yes	1917 (96.0)	1745 (91.0)	172 (9.0)	
No	79 (4.0)	74 (93.7)	5 (6.3)	

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Using Fitbit Data to Assess Physical Health in College Students by COVID-19 Status

In addition to completing longitudinal survey measures, students also provided continuous physiological data by wearing the Fitbit device throughout the study period. The average wear time of the device was 14.5 hours (in a 24-hour day), 7.4 hours during daytime (between 8 AM and 8 PM), and 7.1 hours during nighttime (between 8 PM and 8 AM). As shown in Figure 3, we observed a modest decline in compliance over the 90 days of the study, from an average of 16.1 hours for the first 30 days, to 13.5 hours for the last 30 days. Students who reported COVID-19 positivity had significantly lower average daily compliance (24 hours) than those who did not (P=.04). Multimedia Appendix 8 shows the distribution of average daily compliance by COVID-19 status. The average number of daily steps in this student population was approximately 6500 (mean 6474, SD 3371; Multimedia Appendix 9). There were no significant differences in average daily step counts in accordance with COVID-19 status (P=.52).

Figure 3. Fitbit compliance over time. Each boxplot represents the daily compliance averaged chronologically for each 30-day span of the 90-day study period for all participants. Error bars indicate the minimum and maximum values.



Multivariate Risk Factors for COVID-19 Positivity

In the final multivariate model of student demographics and characteristics, including physical, mental, and social health variables, individuals who reported marijuana or alcohol use and lived with a greater number of housemates (≥20) were at increased risk of COVID-19 positivity. However, being a graduate student and being an individual who aligned with public health measures were associated with COVID-19 negativity (Table 5). Graduate students' protection from COVID-19 may have resulted from their less dense living environments compared to those of undergraduate students (P<.001). Model 5 with an AUC of 85% is available in Multimedia Appendix 10. All models that were significant at the univariate level and included in the multivariate model are shown in Multimedia Appendix 11.

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Table 5. The final multivariate model.

Predictor	Estimate (SE)	*P* value
Demographics		
Intercept	–1.9116 (1.0022)	.06
Race		
Black or African American	0.0170 (0.5414)	.98
American Indian/Alaska Native	1.5975 (1.2206)	.19
Asian	–0.4895 (0.2723)	.07
Multiracial	0.9844 (0.5664)	.08
Other	–1.1114 (0.6125)	.07
Grade		
Sophomore	0.0873 (0.3488)	.80
Junior	–0.0834 (0.3512)	.81
Senior	–0.5921 (0.3686)	.11
Graduate student (first year)	–0.9850 (0.4520)	*.03* [a]
Graduate student (second year)	–1.1648 (0.4160)	*.01*
Other	–14.1032 (596.5290)	.98
Mental		
Coping: planning (planning)	–0.2215 (0.1269)	.08
Substance use		
Marijuana (binary usage)	0.5523 (0.2387)	*.02*
Alcohol (binary usage)	0.7483 (0.3756)	*.046*
Vaping (binary usage)	0.3807 (0.2342)	.10
Other		
Student social fit (numeric)	0.1774 (0.0988)	.07
Public health beliefs (numeric)	–0.2219 (0.0752)	*.003*
Loneliness (numeric)	–0.3217 (0.1902)	.09
Belief in COVID-19 likeliness		
Somewhat agree	0.1460 (0.5055)	.77
Neither agree nor disagree	0.3415 (0.4947)	.49
Somewhat disagree	0.5355 (0.4869)	.27
Strongly disagree	0.7695 (0.5485)	.16
Already had COVID-19	6.7463 (0.8943)	*<.001*
Number of housemates		
1-3	–0.1159 (0.2905)	.69
3-10	–0.4007 (0.3362)	.23
10-20	0.6635 (0.5937)	.26
>20	1.3433 (0.5160)	*.009*

[a]Italicized *P* values indicate significance at *P*<.05.

Discussion

Principal Results

A major finding in this study indicates concerns of adverse mental health symptoms reported by college students, confirming data from other recent studies [31-34]. When looking at the STAI trait, 73% of our study population had moderate or severe anxiety. Our study also used the GAD-7 and PHQ-9 assessments of anxiety and depression, respectively, in a subset of our students. The data not shown indicate that approximately 52% of participants (among those who completed the GAD-7,

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n=1366) reported having anxiety and 65% of participants (among those who completed the PHQ-9, n=1365) reported having depressive symptoms. These data further highlight the high prevalence of mental health problems in current college students [35]. Indeed, the upsurge in mental health problems among college students has escalated to alarming levels nationwide [32,34,36], which was likely amplified by the effects of the global pandemic [2,15].

Our study did not find a difference in mental health data reported by COVID-19 status, whereas substance use was significantly associated with COVID-19 positivity. It is possible that in some students who reported mental health problems, their coping strategies may have included substance use behaviors (eg, marijuana and alcohol consumption), which tend to be social activities occurring in groups (ie, more than one individual). Indirectly, this may have accounted for increased COVID-19 risk owing to less vigilant safety practices. Alternatively, among other students who reported mental health problems, those problems may be associated with (or be due to) isolation, thereby decreasing their COVID-19 risk. It is possible this competing process canceled out any significant total effect of mental health problems by COVID-19 status.

Comparison With Prior Work

This study leveraged mHealth technology to characterize the demographics and physical, mental, and social health of college students during a global pandemic. During a unique period in history where all in-person research activities were halted, the mHealth platform facilitated this type of data collection. The findings herein were self-reported by students prior to the availability of COVID-19 vaccines nationwide. Approximately 9% of students who participated in this study reported COVID-19 positivity. Across the nation, there were over 30 million cumulative reported positive COVID-19 cases by April 01, 2021 [37], which was approximately 9.2% of the US population. In the state of Michigan, where this study was conducted, ~750,000 COVID-19 cases were reported by this time (~7.5% of the population). In addition, cases in Michigan have been most prevalent in the 20-29–year age group [38], which may be owing to students living in close proximity during the pandemic.

In our sample of college students, the most common symptoms were body aches, anosmia, chills, and cough. Interestingly, in a large meta-analysis of 9 countries and 24,410 adults, the most commonly reported symptoms were fever (78%) and cough (58%) [39]. However, many of the studies contributing to this meta-analysis were focused on patients requiring hospitalization, which suggests that these symptoms may have been more common in infections with severe clinical phenotypes. Another recent study used an mHealth app that reported symptomology and COVID-19 test results in ~3.2 million users. Within the symptomatic population, 60.4% reported a cough, while only 42.7% reported a fever [40]. Those data were consistent with our findings in that 51.2% of our symptomatic population reported cough and 45.6% reported fever.

We found that second-year graduate students, Asians and multi-racial students, and international students were significantly less likely to report COVID-19 positivity. There was also an association between an increased number of roommates and an increased risk of COVID-19 positivity. Graduate students in our sample lived with significantly fewer people, presumably decreasing their risk of COVID-19. Marijuana and alcohol consumption were significant risk factors for COVID-19. Additionally, students who agreed or believed in public health measures were less likely to report COVID-19 positivity.

Not surprisingly, we observed a relatively modest decrease in Fitbit compliance over the study duration. This was likely due to decreased engagement with both the Fitbit device and the study over time. Despite the ease of use of consumer-grade wearable sensors, “wearables abandonment” is a well-documented issue [41]. Nonetheless, we observed a large proportion of highly compliant students (ie, daily wear time >14 hours) and a smaller proportion with lower levels of compliance (<2 hours). Students who reported COVID-19 positivity showed a bimodal-like distribution in their Fitbit compliance compared to COVID-19–negative students. The NetHealth study recorded overall higher levels of compliance for a longer period on using a similar Fitbit device in a college student population [29]. However, the NetHealth study was conducted from 2015 to 2017 (ie, prior to the one of the COVID-19 pandemic), which may help explain the different behaviors. Additionally, the differences may be attributed to the compensation model of the studies. The study herein did not incentivize regular data reporting outside of providing the Fitbit device, whereas the NetHealth study did (ie, it provided monetary compensation for regular Fitbit use and data reporting).

The average daily step count observed in this study population was 6474 (SD 3371), which was a relatively low level of physical activity [42]. The NetHealth study conducted with 692 college students reported an average prepandemic daily step count of 11258 (SD 5874) [43]. This large difference in physical activity was likely due to pandemic procedures and norms (eg, isolation, quarantine, and public health guidelines). Specifically, during that time the periodic walks to and from classes (on campus) were possibly limited by the virtual learning environment and strict isolation and quarantine guidelines mandated by the university when the number of COVID-19 cases had peaked Multimedia Appendix 5. Of note, data analyses are forthcoming in examining the impact of Roadmap’s resilience-based activities on physical, mental, and social health outcomes over time (pre- and post-), given the study’s longitudinal design. Moreover, we currently have a “Re-contact Student Study” (postvaccination era) in the same study population of students who participated in the initial 2020-2021 Student Study, which will allow us to compare data from the pre- and postvaccination eras in future analyses.

Limitations

We interpret the findings herein within the context of several limitations. Owing to the single-institution design, our findings are not generalizable outside of our student cohort. In the fall 2020 semester, the undergraduate U-M student population was represented by the following racial and ethnic categories: White (n=17,307, 55.2%), Asian (n=5111, 16.3%); international

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(n=2301, 7.4%); Hispanic or Latinx (n=2187, 7%); not indicated (n=1615, 5.2%); 2 or more (n=1508, 4.8%); Black or African American (n=1249, 4%); American Indian/Alaska Native (n=36, 0.11%); and Native Hawaiian/Other Pacific Islander (n=14, 0.04%). While our cohort recruited similar proportions of racial or ethnic categories that are reflective of the U-M student demographics, there was a greater percentage of Asian students. In addition, females were much more likely to participate in our study than males (68% vs 31%), despite a roughly equal percentage of gender types attending the U-M (50.3% female, 49.7% male).

Second, data attrition resulting from wearable abandonment or digital fatigue may have underestimated the student population's physical activity based on their daily step count. Future work involving emerging adults should consider types of compensation models to incentivize engagement [29] as well as study designs that are adaptive rather than a one-size-fits-all approach [44]. Lastly, COVID-19 diagnosis and symptoms were based on self-report. Our study was limited by resources that did not allow for routine surveillance testing during the study period or access to student medical records to confirm a COVID-19 diagnosis and symptoms reporting.

Despite these limitations, our study had robust recruitment during a period wherein face-to-face research activities were largely halted, indicating the feasibility and merit of conducting a longitudinal study of this nature during a global pandemic. Mobile health technology enabled the team to conduct a virtual and contactless study from recruitment, informed consent, enrollment, onboarding, and multiparameter data collection, including self-report measures and physiological data. The study design aligned with student preferences regarding their ease of use of technology, such as the use of Fitbits and smartphones.

Conclusions

In summary, our results provide initial data supporting the use of an mHealth platform during a global pandemic, while in-person activities were significantly altered. The most significant factors associated with the risk of COVID-19 positivity in this population included student demographics (eg, graduate student and number of roommates), behavioral factors (eg, marijuana use and alcohol consumption), and beliefs in public health measures. Soberingly, a substantial proportion of this student population was facing a mental health problem and substance use was common. Over the course of the COVID-19 pandemic, students' educational opportunities have been abruptly disrupted, which may have long-term, unintended consequences. Thus, attention to the current student mental health crisis is imperative with an urgent need to develop novel and timely interventions that address student health and well-being [2].

Acknowledgments

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Authors' Contributions

KNG drafted the manuscript, coordinated the study, carried out recruitment, provided consent, carried out onboarding, and curated the data and figures. LB and MY drafted the manuscript and curated the data and figures. IG and CB critically reviewed and edited the manuscript, selected the survey measurements, and designed the study methodology. NR critically reviewed and edited the manuscript and curated the data. C Cislo, MLR, and C Clingan critically reviewed and edited the manuscript, coordinated the study, carried out recruitment and onboarding, obtained consent, and curated the data. MSD critically reviewed and edited the manuscript, designed the study methodology, and curated the data and figures. TC critically reviewed and edited the manuscript. KB, NC, MC, JG, and RFZ critically reviewed and edited the manuscript and designed the study methodology. DF designed the study methodology, supervised the study, critically reviewed and edited the manuscript, and created the Social Rhythms app. JLC critically reviewed and edited the manuscript, selected the study measurements, and designed the study methodology. SC critically reviewed and edited the manuscript, supervised the study, and designed the study methodology. MT and SC curated the data, carried out the investigation, curated the resources, supervised the study, visualized the data, and drafted, edited, and critically revised the manuscript. SC created the Roadmap 2.0 app.

Conflicts of Interest

DF is the CSO of Arcascope, a company that makes circadian rhythms software. DF and the University of Michigan are part owners of Arcascope. The other coauthors of the manuscript have no conflicts of interest to declare.

Multimedia Appendix 1

Study Procedures. Recruitment occurred in college students that were 18 years or older through a targeted email and posted flyers. Interested participants reached out through email and study coordinators performed an informed consent process. Participants

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were then onboarded via HIPAA (Health Insurance Portability and Accountability Act)-approved teleconference (e.g., Zoom) or recorded video. Onboarding included downloading the Roadmap 2.0 and Fitbit apps as well as completing the baseline survey. Participants were instructed to continue Fitbit syncing and monthly surveys for the next 3 months. Two weeks after the final monthly survey, students took one more closing survey and Fitbit data were collected to the end of the academic year.
[PNG File , 1499 KB - mental_v9i2e34645_app1.png]

Multimedia Appendix 2
Main components of the roadmap app.
[PNG File , 218 KB - mental_v9i2e34645_app2.png]

Multimedia Appendix 3
Psychometric properties of self-report measures.
[DOC File , 49 KB - mental_v9i2e34645_app3.doc]

Multimedia Appendix 4
Student enrollment over time.
[PNG File , 41 KB - mental_v9i2e34645_app4.png]

Multimedia Appendix 5
COVID-19 Cases at the local (University of Michigan and Washtenaw County), state (Michigan), and national (U.S.) levels. University: UM Covid-19 data. Campus Maize and Blueprint. 2021. https://campusblueprint.umich.edu/dashboard. County and State: Michigan.gov. 2021. Coronavirus. https://www.michigan.gov/coronavirus. United States: Center for Disease Control. 2021. COVID data tracker. https://covid.cdc.gov/covid-data-tracker/#trends_dailytrendscases.
[PNG File , 136 KB - mental_v9i2e34645_app5.png]

Multimedia Appendix 6
Correlations of flourishing, compassion, State Trait Anxiety Index (STAI) trait, and public health beliefs.
[DOC File , 30 KB - mental_v9i2e34645_app6.doc]

Multimedia Appendix 7
Odds Ratios of substance use where no report of a mental health condition is the reference group compared to those who reported any mental health condition.
[DOC File , 28 KB - mental_v9i2e34645_app7.doc]

Multimedia Appendix 8
Distribution of compliance by COVID-Status – Distribution of the average daily compliance per participant by COVID-status. The mean and standard deviation of each distribution are given.
[PNG File , 497 KB - mental_v9i2e34645_app8.png]

Multimedia Appendix 9
Distribution of the average daily step count over the 90-day study period. The mean and standard deviation of each distribution are given.
[PNG File , 211 KB - mental_v9i2e34645_app9.png]

Multimedia Appendix 10
Model selection. Model (1) included only demographic variables; Model (2) included demographic and mental measures; Model (3) included demographic, mental measures, and self-reported substance use; and (4) the Full Model included all the variables in models (1) through (3) plus all other significant characteristics and social health variables from univariate associations as well as (5) the Final Model, which was selected by backward stepwise regression from the Full Model (4). The Final Model provided the minimal Akaike information criterion (AIC). The Area Under the receiver operating characteristic curve (AUC) represented the prediction accuracy of the current model. When we constructed our models, we observed an increase in accuracy as more variables were added from Model (1) to Model (4). Importantly, even though the Final Model (5) included fewer variables than the Full Model (4), we did not observe a significant loss in prediction accuracy. Thus, the Final Model (5) was selected as the final multivariate model due to its simplicity.
[PNG File , 86 KB - mental_v9i2e34645_app10.png]

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Multimedia Appendix 11
Univariate significant models.
[DOC File , 50 KB - mental_v9i2e34645_app11.doc]

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Abbreviations

AUC: area under the receiver operating characteristic curve
GAD-7: General Anxiety Disorder, 7 items
IRBMED: University of Michigan Medical School's Institutional Review Board
mHealth: mobile health
NIH/NHBLI: National Institutes of Health's National Heart, Lung, and Blood Institute
PHQ-9: Patient Health Questionnaire, 9 items
ROC: receiver operating characteristic
STAI: State Trait Anxiety Index
U-M: University of Michigan

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Original Paper

The Impact of Long COVID-19 on Mental Health: Observational 6-Month Follow-Up Study

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Abstract

Background: The psychological impact of COVID-19 can be substantial. However, knowledge about long-term psychological outcomes in patients with COVID-19 is scarce.

Objective: In this longitudinal, observational study, we aimed to reveal symptoms of posttraumatic stress disorder (PTSD) and symptoms of anxiety and depression up to 6 months after the onset of COVID-19–related symptoms in patients with confirmed COVID-19 and persistent complaints. To demonstrate the impact in nonhospitalized patients, we further aimed to compare these outcomes between nonhospitalized and hospitalized patients.

Methods: Demographics, symptoms of PTSD (Trauma Screening Questionnaire [TSQ] ≥6 points) and symptoms of anxiety and depression (Hospital Anxiety and Depression Scale [HADS] ≥8 points) were assessed at 3 and 6 months after the onset of COVID-19–related symptoms in members of online long COVID-19 peer support groups.

Results: Data from 239 patients with confirmed COVID-19 (198/239, 82.8% female; median age: 50 [IQR 39-56] years) were analyzed. At the 3-month follow-up, 37.2% (89/239) of the patients had symptoms of PTSD, 35.6% (85/239) had symptoms of anxiety, and 46.9% (112/239) had symptoms of depression, which remained high at the 6-month follow-up (64/239, 26.8%, P=.001; 83/239, 34.7%, P=.90; 97/239, 40.6%, P=.08, respectively; versus the 3-month follow-up). TSQ scores and HADS anxiety and depression scores were strongly correlated at the 3- and 6-month follow-ups (r=0.63-0.71, P<.001). Symptoms of PTSD, anxiety, and depression were comparable between hospitalized (n=62) and nonhospitalized (n=177) patients.

Conclusions: A substantial percentage of patients with confirmed COVID-19 and persistent complaints reported symptoms of PTSD, anxiety, or depression 3 and 6 months after the onset of COVID-19–related symptoms. The prevalence rates of symptoms of PTSD, anxiety, and depression were comparable between hospitalized and nonhospitalized patients and merely improved over time. Health care professionals need to be aware of these psychological complications and intervene on time in post-COVID-19 patients with persistent complaints.

Trial Registration: Netherlands Trial Register NTR8705; https://www.trialregister.nl/trial/8705.

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(JMIR Ment Health 2022;9(2):e33704) doi:10.2196/33704

KEYWORDS

SARS-CoV-2; corona; COVID-19; post-traumatic stress disorder; anxiety; depression; PASC

Introduction

A traumatic event is an incident that causes physical, emotional, spiritual, or psychological harm [1]. The impact of a traumatic event varies between individuals. Most individuals are resilient, develop appropriate coping strategies, and recover without long-term consequences. Nevertheless, some experience symptoms such as unwanted upsetting memories, flashbacks, nightmares, emotional distress, or physical reactivity after exposure to traumatic reminders. If symptoms last for more than 1 month, create distress, or interfere with daily functioning, posttraumatic stress disorder (PTSD) needs to be considered [2]. PTSD has major negative consequences for patients and their families [2,3] and is associated with long-term comorbid depression and substance abuse [2], underlining the need to detect and treat the disorder.

Severe illness or acute onset of severe illness can be experienced as a traumatic event [1]. Furthermore, isolation precautions for infection prevention have been shown to be associated with severe mental health problems [4]. Accordingly, COVID-19 might also lead to PTSD. Indeed, previous studies reported prevalences of symptoms of PTSD ranging from 10% to 30% in patients discharged from the hospital [5-12]. Prevalences of symptoms of anxiety and depression in these samples vary between 5% and 42% [7,9-12] and 14% and 31% [6,9,11,12], respectively. A recently published review also confirmed the persistence of symptoms and their physical and psychosocial impact following a COVID-19 infection [13]. However, the authors mainly summarized findings from studies including hospitalized patients and concluded that more research is needed in nonhospitalized patients [13]. Indeed, the impact of so-called "mild" COVID-19 can be substantial [14-16]. To date, knowledge about psychological long-term outcomes in these patients is scarce. Mazza and colleagues [11] studied PTSD, depression, and anxiety in COVID-19 patients who visited the emergency department (ED) and compared outcomes between patients who were hospitalized or managed at home 1 month after discharge or ED visit. Psychological outcomes, including PTSD, major depression, and anxiety, were comparable between both groups or even worse in nonhospitalized patients [11]. So, even "mild" COVID-19 may not only cause symptoms of anxiety and depression but also be a stressor leading to PTSD symptoms.

As symptoms of PTSD often develop after a period of time or get worse over time [17], longer follow-up is needed. Therefore, we aimed to explore the prevalence of PTSD and symptoms of anxiety and depression at 3 and 6 months after the onset of COVID-19 symptoms and to study the association between symptoms of PTSD, anxiety, and depression in patients with confirmed COVID-19. To demonstrate the impact of COVID-19 on mental health, especially in nonhospitalized patients, we aimed to compare these outcomes between nonhospitalized and hospitalized patients. As the number of reports demonstrating a substantial burden of psychological trauma in patients with less severe COVID-19 is increasing [18], we hypothesized in advance that the long-term impact of COVID-19 on mental health, even in nonhospitalized patients, is substantial.

Methods

Study Design, Setting, and Participants

Members from 2 Facebook groups for coronavirus patients with persistent complaints in The Netherlands (~11,000 members; "Corona ervaringen en langdurige klachten!") [19] and Flanders (Belgium, ~1200 members; "Corona patiënten met langdurige klachten (Vlaanderen)") [20] as well as ~1200 people who registered on the website of the Lung Foundation Netherlands (Coronaplein [21]) were invited to complete an online open survey between June 4, 2020 and June 11, 2020 and between August 31, 2020 and September 8, 2020. In total, 1939 members completed the first survey, of which 1556 consented to be approached for future research (see Multimedia Appendix 1).

Ethical Approval

The medical ethics committee of Maastricht University stated that the Medical Research Involving Human Subjects Act (WMO) did not apply for this study and that an official approval of this study by the committee was not required (METC2020-1978 and METC2020-2554). The medical ethics committee of Hasselt University formally judged and approved the study (MEC2020/041). All respondents gave digital informed consent at the start of both surveys. Without informed consent, the survey could not be continued. The study was registered in the Dutch trial register. Health status, care dependency, and other characteristics of this study sample have been described elsewhere [14-16,22-25].

Clinical Characteristics

Demographics (age, gender), marital status (yes, not married, or living with partner), educational level (low, middle, or high), BMI, and self-reported pre-existing comorbidities were assessed. Furthermore, the survey contained questions regarding the diagnosis of COVID-19: self-reported, polymerase chain reaction (PCR)-confirmed, and/or radiologic confirmed. A confirmed diagnosis was based on a computed tomography (CT) scan or reverse transcription PCR (RT-PCR). Self-reported health status (good, moderate, or poor), symptoms during the infection and during follow-up, as well as the date of the onset of these COVID-19 symptoms were assessed as previously described [15,23].

PTSD

The Trauma Screening Questionnaire (TSQ) was used as a screening instrument for PTSD [26]. The TSQ is a 10-item self-report scale consisting of 5 re-experiencing items and 5 arousal items from the Diagnostic and Statistical Manual of Mental Disorders IV (DSM-IV) criteria for PTSD.

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Re-experiencing items include (1) upsetting thoughts or memories about the event that have come into your mind against your will, (2) upsetting dreams about the event, (3) acting or feeling as though the event was happening again, (4) feeling upset by reminders of the event, and (5) bodily reactions (such as fast heartbeat, stomach churning, sweatiness, dizziness) when reminded of the event.

Arousal items include (1) difficulty falling or staying asleep, (2) irritability or outbursts of anger, (3) difficulty concentrating, (4) heightened awareness of potential dangers to yourself and others, and (5) feeling jumpy or being startled at something unexpected.

For the current study, the event was defined as a "corona infection." Participants were asked whether they experienced each symptom at least twice in the past week. In total, 10 questions could be answered with yes or no. A cut-off score of ≥6 points was used to identify patients at risk of having PTSD [26].

Anxiety and Depression

Symptoms of anxiety and depression were assessed using the Hospital Anxiety and Depression scale (HADS), which is divided into an anxiety subscale and a depression subscale [27]. Total scores for each subscale range from 0 (optimal) to 21 points (worst). A cut-off score of ≥8 points was used to identify the presence of clinically relevant symptoms of anxiety or depression [27,28].

Statistical Analyses

Continuous data are presented as mean (SD) or median (IQR), as appropriate. Categorical data are presented as absolute and relative frequencies.

Differences between 3- and 6-month follow-ups were evaluated with the McNemar test, paired sample *t* test, or Wilcoxon signed rank test, as appropriate. Differences between hospitalized (without admission to the intensive care unit) and nonhospitalized patients were tested with chi square tests, independent sample *t* tests, or Mann-Whitney *U* tests. Correlations between TSQ and HADS anxiety and depression scores were assessed with scatterplots and Spearman rho. Correlation coefficients of 0.00-0.19, 0.20-0.39, 0.40-0.59, 0.60-0.79, and 0.80-1.00 were defined as very weak, weak, moderate, strong, or very strong, respectively [29]. Statistics were performed using SPSS version 25.0. A priori, the level of significance was set at $P<.05$.

Results

Survey Completion

Of the 1556 patients who completed the first survey about 3 months after the onset of COVID-19–related symptoms and consented to be approached for future research, 1005 patients (65%) completed the second survey about 6 months after the onset of COVID-19–related symptoms (see Multimedia Appendix 1). For the current study, only patients who completed both surveys and who had a confirmed diagnosis based on CT/RT-PCR were included for analyses (n=239). Results from patients with suspected COVID-19 (ie, patients who did not have a formal COVID-19 test at the time of the suspected infection) who completed both surveys (n=766) are presented online and show similarities to those of patients with a confirmed COVID-19 diagnosis (see Multimedia Appendix 2). Time between symptom onset and completion of the questionnaire was 10.4 (2.4) weeks for the first survey and 22.6 (2.4) weeks for the second survey. As demonstrated in another analysis of the current data [23], the results of the first survey were comparable between patients who did and did not complete the second survey.

Patient Characteristics

Generally, patients were middle-aged women. The majority of patients were married or living with a partner (173/239, 72.4%) and had no pre-existing comorbidities (142/239, 59.4%). Self-reported health status was generally good before the infection, which was significantly worse 3 months after infection and during the 6 months of follow-up. During the infection, patients reported a median of 15 (IQR 11-18) different symptoms, which decreased to medians of 6 (IQR 4-9) and 6 (IQR 3-8) symptoms at the 3- and 6-month follow-ups, respectively (Table 1).

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Table 1. Patient characteristics.

Characteristics	All patients (n=239)	Hospitalized patients (n=62)	Nonhospitalized patients (n=177)	*P* value[a]
Women, n (%)	198 (82.8)	39 (62.9)	159 (89.8)	<.001
Age (years), median (IQR)	50.0 (39.0-56.0)	53.0 (47.8-60.0)	48.0 (37.5-54.5)	<.001
BMI (kg/m^2), median (IQR)	26.0 (23.4-30.5)	28.2 (24.8-32.6)	25.6 (23.0-29.4)	.005
Married/living with partner, n (%)	173 (72.4)	43 (69.4)	130 (73.4)	.51
Educational level, n (%)				
Low	6 (2.5)	6 (9.7)	0 (0)	<.001
Medium	126 (52.7)	32 (51.6)	94 (53.1)	.84
High	107 (44.8)	24 (38.7)	83 (46.9)	.27
Pre-existing comorbidities, n (%)				
None	142 (59.4)	28 (45.2)	114 (64.4)	.008
1	62 (25.9)	23 (37.1)	39 (22.0)	.02
≥2	35 (14.6)	11 (17.7)	24 (13.6)	.42
Good self-reported health status before infection, n (%)				
Before infection	208 (87.0)	49 (79.0)	159 (89.8)	.03
After 3 months	22 (9.2)	10 (16.1)	12 (6.8)	.03
After 6 months	40 (16.7)	12 (19.4)	28 (15.8)	.52
Number of symptoms, median (IQR)				
During infection	15 (11-18)	14 (10-17)	15 (12-18)	.20
After 3 months	6 (4-9)	6 (4-8)	6 (4-9)	.32
After 6 months	6 (3-8)	6 (2-8)	6 (3-8)	.62

[a]Hospitalized patients compared with nonhospitalized patients.

Symptoms of PTSD

At 3 months after the onset of symptoms, 37.2% (89/239) of the patients were at risk for PTSD, which decreased to 26.8% (64/239) at the 6-month follow-up (*P*=.001; Table 2).

At 3 months after the onset of symptoms, patients most frequently experienced problems with “difficulty concentrating” (202/239, 84.5%), “difficulty falling or staying asleep” (170/239, 71.1%), and “upsetting thoughts or memories about the event that have come into your mind against your will” (135/239, 56.5%). Of the TSQ items, 4 improved significantly over time (see Figure 1 for details).

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Table 2. Symptoms of posttraumatic stress disorder, anxiety, and depression.

Assessments	All patients (n=239)	*P* value[a]	Hospitalized patients (n=62)	*P* value[a]	Nonhospitalized patients (n=177)	*P* value[a]	*P* value[b]
Trauma Screening Questionnaire							
Total score after 3 months, mean (SD)	4.7 (2.5)	<.001	4.7 (2.9)	.02	4.7 (2.4)	0.001	.83
Total score after 6 months, mean (SD)	4.1 (2.5)		4.2 (2.8)		4.1 (2.4)		.89
Total score ≥6 points after 3 months, n (%)	89 (37.2)	.001	27 (43.5)	.02	62 (35.0)	.02	.23
Total score ≥6 points after 6 months, n (%)	64 (26.8)		19 (30.6)		45 (25.4)		.42
HADS[c] anxiety subscale							
Total score after 3 months, mean (SD)	6.5 (4.0)	.15	6.5 (4.5)	.06	6.5 (3.8)	.51	.92
Total score after 6 months, mean (SD)	6.2 (4.0)		5.7 (4.3)		6.3 (3.9)		.31
Total score ≥8 after 3 months, n (%)	85 (35.6)	.90	21 (33.9)	.55	64 (36.2)	.99	.75
Total score ≥8 after 6 months, n (%)	83 (34.7)		18 (29.0)		65 (36.7)		.27
HADS depression subscale							
Total score after 3 months, mean (SD)	7.2 (4.0)	.001	7.0 (4.1)	.19	7.3 (3.9)	.003	.59
Total score after 6 months, mean (SD)	6.5 (3.0)		6.4 (4.6)		6.6 (3.6)		.83
Total score ≥8 after 3 months, n (%)	112 (46.9)	.08	31 (50.0)	.33	81 (45.8)	.19	.57
Total score ≥8 after 6 months, n (%)	97 (40.6)		26 (41.9)		71 (40.1)		.80

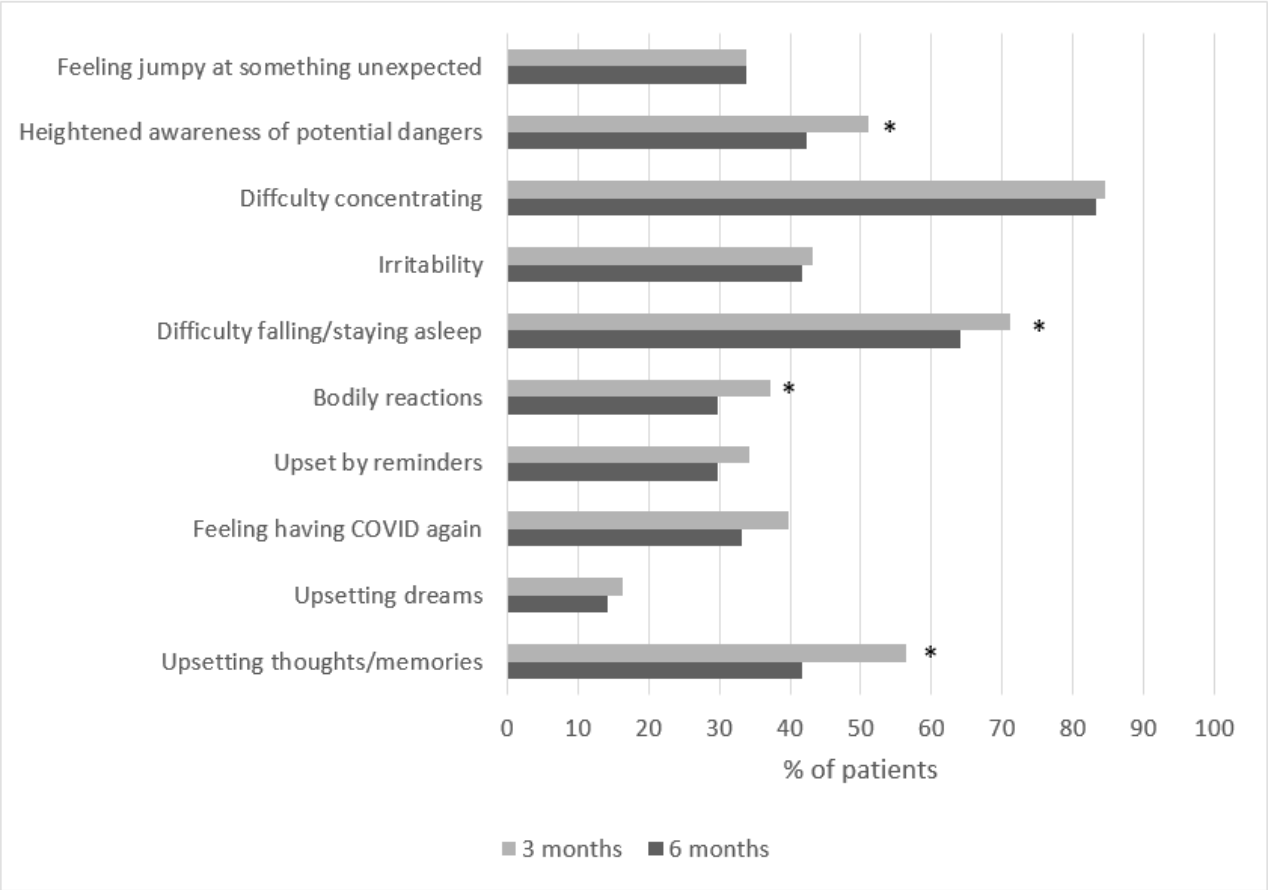
[a]3 months compared with 6 months.

[b]Hospitalized patients compared with nonhospitalized patients.

[c]HADS: Hospital Anxiety and Depression Scale.

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Figure 1. Percentage of patients reporting each item on the Trauma Screening Questionnaire (TSQ) at 3 and 6 months after the onset of COVID-19 symptoms (n=239). *P≤0.05 3 months versus 6 months.



Symptoms of Anxiety and Depression

Clinically relevant symptoms of anxiety and depression were detected in 35.6% (85/239) and 46.9% (112/239), respectively, of all patients at the 3-month follow-up. The prevalence of symptoms of anxiety and depression remained high at the 6-month follow-up (83/239, 34.7% for symptoms of anxiety, P=.90; 97/239, 40.6% for symptoms of depression, P=.08; Table 2).

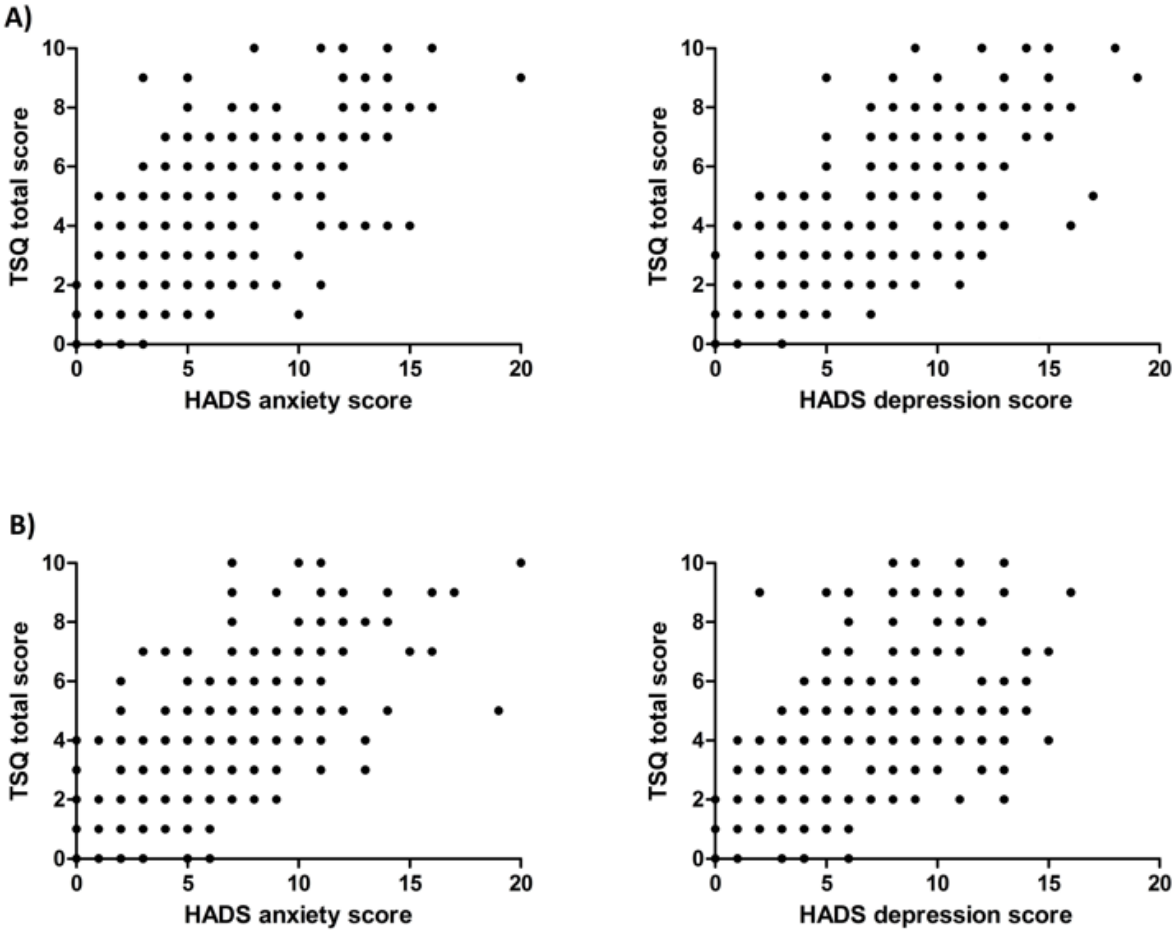
Associations Between Symptoms

TSQ scores and HADS anxiety and depression scores were strongly correlated at the 3- and 6-month follow-ups (P=0.631-0.714, P≤.001; Figure 2).

Of those patients who were at risk for PTSD at 3- and 6-month follow-ups, two-thirds had clinically relevant symptoms of anxiety and depression.

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Figure 2. Correlations between Trauma Screening Questionnaire (TSQ) scores and Hospital Anxiety and Depression Scale (HADS) scores at (A) 3 and (B) 6 months after the onset of COVID-19–related symptoms.



Differences Between Hospitalized and Nonhospitalized Patients

Compared with hospitalized patients (n=62), nonhospitalized patients (n=177) more often were women, were younger, had a lower BMI, and reported fewer pre-existing comorbidities. Nonhospitalized patients more often reported good health status before the infection, while more hospitalized patients reported good health status at the 3-month follow-up (Table 1). The prevalences of symptoms of PTSD were comparable between hospitalized and nonhospitalized patients (3-month follow-up: 27/62, 43.5% vs 62/127, 35.0%, *P*=.23; 6-month follow-up: 19/62, 30.6% vs 45/127, 25.4%, *P*=.42; Table 2). Prevalence distributions for the separate TSQ items at 3 and 6 months were generally comparable between hospitalized and nonhospitalized patients, except for "upsetting dreams about the event" (*P*=.04) and "feeling upset by reminders of the event" (*P*=.03), which were more prominent in hospitalized patients at the 6-month follow-up, and "irritability or outbursts of anger" (*P*=.04), which was more prominent in nonhospitalized patients at the 6-month follow-up (see Multimedia Appendix 3). Nonhospitalized patients reported a similar level of symptoms of anxiety and depression compared with hospitalized patients at the 3- and 6-month follow-ups (Table 2).

Patients With Suspected COVID-19

The results of the 766 patients with suspected COVID-19 are comparable to those of patients with a confirmed COVID-19 diagnosis (see Multimedia Appendix 4 and Multimedia Appendix 5).

Discussion

Principal Findings

A relevant percentage of nonhospitalized patients were at risk of PTSD and had clinically relevant symptoms of anxiety and depression at 3 and 6 months after the onset of COVID-19–related symptoms. The prevalence rates of symptoms of PTSD, anxiety, and depression were comparable between hospitalized and nonhospitalized patients and merely improved over time. A previous analysis of the current data demonstrated that 95% of the patients still experience 1 or more symptoms at the 6-month follow-up, which can affect work productivity, functional status, and quality of life [23]. This study indicates the long-term impact of COVID-19 on mental health, especially in nonhospitalized patients with COVID-19 with persistent complaints.

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Comparison With Prior Studies

This study supports the suggestion by Gu and colleagues [30] that the impact of COVID-19 is no less than the impact of other stressors (eg, natural disasters, technological accidents). The prevalence of patients at risk of PTSD (89/239, 37.2%) is nearly comparable with the prevalence (41%) found in 76 victims of violence and traffic accidents [31]. In addition, a meta-analysis suggested that around 20% of adult critical care survivors experience PTSD [32], while in previous coronavirus pandemics (SARS and MERS outbreaks), PTSD occurred in 32.2% of individuals who recovered from coronavirus infection [33]. This demonstrates the long-term impact of severe viral disease. Whether PTSD is also highly prevalent in the aftermath of different COVID-19 populations remains to be determined. Previous published studies reported prevalences of symptoms of PTSD ranging from 10% to 30% in patients discharged from the hospital [5-12], which is lower than the current prevalence rates from hospitalized as well as nonhospitalized patients. Hellemons and colleagues [12] reported an even lower prevalence for PTSD (4%) in patients with COVID-19 6 months after hospital discharge. With regards to anxiety and depression, a meta-analysis demonstrated pooled prevalences of 47% and 45% for anxiety and depression, respectively, in patients with COVID-19 [34]. In addition, Kong and colleagues [35] used the same assessment method (HADS) and the same cut-off score (≥8 points) as our study to evaluate symptoms of anxiety and depression in hospitalized patients with COVID-19 and showed prevalences of 35% and 29%, respectively. This study reported a comparable prevalence of anxiety symptoms, though a higher prevalence of depression symptoms, which might be explained by the fact that our study included patients with long COVID-19 symptoms. This study showed that symptoms of PTSD, anxiety, and depression merely improved over time. This is in line with a recent study demonstrating that anxiety and PTSD did not change between 1- and 3-month follow-ups in COVID-19 survivors after hospital discharge [10]. Our paper supports the authors' conclusion that patient follow-up is an essential component of disease management [10], especially in patients with persistent complaints.

Reasoning Behind Similar Outcomes Between Hospitalized and Nonhospitalized Patients

Notably, the impact of long COVID-19 on mental health was comparable between hospitalized and nonhospitalized patients, which might, in part, be explained by the following causes.

Lack of Care

Although the number of symptoms during the acute phase of the infection was comparable, hospitalized patients might have experienced a more severe clinical cause and manifestations of the disease. However, they probably learned to cope with the persistent symptoms of the disease during hospital admission or received aftercare immediately after discharge. Indeed, compared with nonhospitalized patients, hospitalized patients more often received any care from a physiotherapist, medical specialist (eg, pulmonologist), psychologist, dietician, or nurse during or after the onset of symptoms [15]. Moreover, not only during the infection but also in the months following the onset of symptoms, hospitalized patients received physiotherapy or rehabilitation substantially more often than nonhospitalized patients [23]. This might have contributed to the higher percentage of hospitalized patients reporting good self-reported health during the follow-up compared with nonhospitalized patients.

Unmet Needs

A previous analysis of the current data demonstrated that patients perceive a broad variety of unmet care and information needs, perceive lack of support and understanding from family members, and are worried about incomplete recovery [24]. They indicated the need for certainty and wanted clear information [24], which might further contribute to anxious or depressive feelings or add to "irritability" and "feeling jumpy or being startled at something unexpected." Indeed, in uncertain or frightening situations, clear and precise information is essential [36]. Furthermore, lacking knowledge of the pandemic and less family support were associated with increased risk of depression or anxiety [37].

In addition, patients indicated the need for a test to confirm their diagnosis or certainty that they have had COVID-19: "Without a test, it's all in your mind, it's a psychological thing" [24]. This study demonstrated once again the (mental) impact on patients with suspected COVID-19. We therefore underline the importance of also considering these patients for relevant interventions.

Social Isolation

The impact of COVID-19 on mental health is tremendous, not only in patients who have been infected with the disease: "Humans are social beings; hence, it is not surprising that extended periods of social isolation are so difficult to cope with" [38]. Being in lockdown can lead to feelings of confinement and loneliness [39]. Loneliness has been described as one of the greatest threats to our health, survival, and well-being [36]. Furthermore, besides the physical harm of COVID-19, periods of confinement can be associated with depression, anxiety, and PTSD [38]. Quarantine has been associated with increased rates of suicide, anger, acute stress disorder, depression, and PTSD, with symptoms continuing even years after quarantine ends [38].

Methodological Considerations

To the best of our knowledge, this study is one of the first investigating the mental impact of patients with confirmed COVID-19 and persistent complaints at 3- and 6-month follow-ups after the onset of COVID-19–related symptoms. In the following paragraphs, several strengths and limitations are discussed.

First, the majority of the study sample was middle-aged women, which may limit the external validity of the study. However, this needs to be discussed in a broader context: During the COVID-19 pandemic, female gender has been shown to be associated with an increased risk of anxiety or depression as well as PTSD [37], and women and younger age groups were at risk of poorer mental health [40,41]. Additionally, older age was associated with better mental health (ie, lower levels of anxiety and depression). However, the role of age during the

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recovery period is not known yet [42]. Nonetheless, the gender distribution is consistent with previous studies [43-47] and can partly be explained by the higher number of women in COVID-19 support groups [44,45]. Moreover, it has been suggested that long COVID is more common in women than in men [47]. Second, a comprehensive picture of the mental health status of the study sample before infection is not known. We do know that patients with psychiatric history were more likely to have PTSD as demonstrated by Kang and colleagues [48]. However, of those 239 confirmed cases included in our study, 2 (0.8%) patients reported that they had been treated for anxiety, while 5 (2.1%) patients reported that they had been treated for depressive mood before infection (see Multimedia Appendix 6), suggesting a limited influence of pre-existing mental health problems in this study. Third, a longer follow-up period might be relevant to detect even more patients with PTSD symptoms, as there can be a delay of months or even years before symptoms appear for some people [49]. Fourth, there is lack of data about other COVID-19–related stressors (such as death or serious illness [due to COVID-19] of a loved one, social isolation, or loss of work), which might have influenced mental health status. Finally, since the study sample consisted of selected participants recruited through online platforms and specifically targeted patients with persistent complaints, the external validity of our findings is limited.

Taking these considerations into account, this study sample still represents an important, as well as increasing, group of patients with a rising demand for health care services [18].

Recommendations

Patients with persistent complaints report clinically relevant symptoms of anxiety, depression, and PTSD, supporting the urgent call for rapid response to the mental health impacts of COVID-19 [36], not only for patients but also for the general population [50]. Health care professionals need to be aware that patients, especially women and younger age groups [40,41], are at risk of developing such symptoms and need to intervene on time (eg, prevention of onset of these symptoms during the acute phase or treatment and prevention of progression during follow-up). General practitioners and occupational physicians play a central role in the management of mental disorders during the COVID-19 pandemic, involving early detection, (risk) assessment, and referral [51-53]. Accordingly, psychological-behavioral interventions might be provided if needed, which has been shown to reduce symptoms of anxiety and depression in patients with COVID-19 [35]. Internet-based cognitive and behavioral therapy has been shown to be an effective and acceptable alternative to therapist-delivered treatments for anxiety and depression, while the efficacy for treating PTSD is uncertain [54]. Systemic and well-designed intervention trials with robust outcome evaluations are needed to reveal strategies and models of prevention for PTSD among individuals affected by epidemics of other infectious diseases, such as COVID-19 [50]. Additionally, creating opportunities for patients to access platforms and care team members through telehealth is recommended [55]. Finally, as the experienced distress is a normal human response to a serious crisis, it is therefore advised to recognize and accept these feelings to prevent them from turning into a disorder [36].

Conclusion

This study shows that a substantial percentage of hospitalized as well as nonhospitalized patients with persistent complaints after COVID-19 has clinically relevant symptoms of PTSD, anxiety, and depression. These symptoms were present at 3 months after the onset of COVID-19–related symptoms and remained high at the 6-month follow-up. Health care professionals as well as patients need to be aware of these symptoms and intervene on time.

Acknowledgments

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Authors' Contributions

SHW, JMD, AWV, YMJG, RM, FVCM, and MvH were responsible for the data collection. MAS is the principal investigator of this trial. SH-W, YMJG, and DJAJ drafted the manuscript. All authors interpreted the data as well as critically reviewed, revised, and approved the manuscript.

Conflicts of Interest

FMEF reports grants and personal fees from AstraZeneca, personal fees from Boehringer Ingelheim, personal fees from Chiesi, personal fees from GlaxoSmithKline, grants and personal fees from Novartis, and personal fees from TEVA, outside the submitted work. DJAJ has received lecture fees from Chiesi and Boehringer Ingelheim within the previous three years, outside the submitted work. MAS reports grants from Lung Foundation Netherlands, grants from Stichting Astma Bestrijding, grants from Boehringer Ingelheim, grants from Chiesi, grants from TEVA, and grants from AstraZeneca, outside the submitted work. SHW, JMD, AWV, YMJG, RM, FVCM, MvH, CB, RP, HV, YS, and AvH have nothing to declare.

Multimedia Appendix 1

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Study flow chart.
[DOCX File , 24 KB - mental_v9i2e33704_app1.docx]

Multimedia Appendix 2
Characteristics of patients with presumed COVID-19.
[DOCX File , 13 KB - mental_v9i2e33704_app2.docx]

Multimedia Appendix 3
Percentage of (a) hospitalized and (b) nonhospitalized patients for separate Trauma Screening Questionnaire (TSQ) items 3 and 6 months after the onset of COVID-19 symptoms.
[DOCX File , 30 KB - mental_v9i2e33704_app3.docx]

Multimedia Appendix 4
Symptoms of post-traumatic stress disorder, anxiety, and depression.
[DOCX File , 13 KB - mental_v9i2e33704_app4.docx]

Multimedia Appendix 5
Percentage of patients for separate Trauma Screening Questionnaire (TSQ) items 3 and 6 months after the onset of COVID-19 symptoms (patients with suspected COVID-19, n=766).
[DOCX File , 27 KB - mental_v9i2e33704_app5.docx]

Multimedia Appendix 6
Self-reported pre-existing comorbidities.
[DOCX File , 12 KB - mental_v9i2e33704_app6.docx]

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Abbreviations

CT: computed tomography
DSM-IV: Diagnostic and Statistical Manual of Mental Disorders
ED: emergency department

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HADS: Hospital Anxiety and Depression Scale
PTSD: posttraumatic stress disorder
RT-PCR: reverse transcription polymerase chain reaction
TSQ: Trauma Screening Questionnaire
WMO: Medical Research Involving Human Subjects Act

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