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Original Paper

Conceptual Invariance, Trajectories, and Outcome Associations of Working Alliance in Unguided and Guided Internet-Based Psychological Interventions: Secondary Analysis of a Randomized Controlled Trial

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Abstract

Background: The role of working alliance remains unclear for many forms of internet-based interventions (IBIs), a set of effective psychotherapy alternatives that do not require synchronous interactions between patients and therapists.

Objective: This study examined the conceptual invariance, trajectories, and outcome associations of working alliance across an unguided IBI and guided IBIs that incorporated clinician support through asynchronous text messaging or video messaging.

Methods: Adults with high education attainment (n=145) with subclinical levels of anxiety, stress, or depressive symptoms were randomized to 1 of 3 treatment conditions for 7 weeks. All participants received treatments from MyCompass, an unguided IBI using cognitive behavior therapy. Participants in condition 2 and 3 received supplemental, asynchronous clinician support through text and video, respectively. Working alliance with the IBIs was measured weekly using select items from the 12-item version of the Agnew Relationship Measure. Symptom and functional outcomes were assessed at baseline, at the end of treatment, and 1-month follow-up.

Results: Working alliance with the IBIs was conceptually invariant across the 3 conditions. Working alliance followed a quadratic pattern of change over time for all conditions and declined significantly only in the text-support condition. After controlling for baseline symptoms, higher baseline levels of working alliance predicted less depression and less functional impairment at follow-up, whereas faster increases in working alliance predicted less worry at the end of treatment and at follow-up, all of which only occurred in the video-support condition.

Conclusions: Working alliance with the IBIs was generally established in the initial sessions. Although working alliance is conceptually invariant across IBIs with or without clinician support, the associations between working alliance and treatment outcomes among IBIs may differ depending on clinician involvement and the modalities of support.

Trial Registration: ClinicalTrials.gov NCT05122429; <https://clinicaltrials.gov/ct2/show/NCT05122429>

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KEYWORDS

working alliance; internet-based psychological interventions; video support; text support; trajectory; MyCompass

Introduction

Background

Working alliance is often conceptualized as a tripartite construct comprising agreement on therapeutic tasks and goals, as well as the bond between patients and therapists [1]. It has been identified as one of the most robust factors contributing to therapeutic change, with higher working alliance often associated with better treatment outcomes [2]. These effects have been consistently present in in-person psychotherapy as well as synchronous teletherapy, both of which feature direct, face-to-face interactions between clinicians and patients in real time [3]. However, the accessibility of in-person psychotherapy or synchronous teletherapy is limited by the shortage of clinicians, scheduling issues, difficulties with finding therapeutic space for both patients and therapists, transportation challenges (for in-person therapy), instability of internet connection (for synchronous teletherapy), perceived stigma of psychotherapy, and the financial cost of treatment. These barriers to in-person or synchronous teletherapy are especially salient during times of public health crisis, such as the COVID-19 pandemic, when the need for mental health services has surged despite limited supply.

Technology innovations have offered alternative options such as internet-based interventions (IBIs), which provide accessible mental health services that do not require synchronous communication. An unguided IBI, which is characterized by the delivery of a web-based therapeutic program with no support from clinicians, is an example of such interventions. Many unguided IBIs, also known as self-help programs, are based on cognitive behavior therapy (CBT) principles and involve components of psychoeducation, behavioral and cognitive practice, homework, and tracking-related activities for important variables (eg, mood and behaviors) [4,5]. In contrast to the absence of clinician involvement in unguided programs, guided IBIs often include a self-help program and asynchronous support from clinicians. Such integrated interventions are thought to improve treatment outcomes by leveraging the benefits of the therapeutic relationship between patients and clinicians. Clinicians in guided IBIs often provide low-intensity clinical guidance to facilitate the patient's independent work with the self-help program [6]. Empirical studies have shown effectiveness for both types of IBIs in treating issues such as anxiety, depression, and traumatic stress for a wide range of populations [3,7,8], supporting their flexible use in situations where in-person communication or real-time telecommunication may be limited. However, what remains unclear is the nature and function of working alliance in guided and unguided IBIs.

Conceptualization of Working Alliance and the Measurement Invariance Across IBIs

Previous studies have focused on understanding the level, trajectories, and outcome associations of working alliance in IBIs. A high level of working alliance has been reported by patients across guided IBIs with varying degrees of clinician involvement and different communication modalities [3,9], as well as across unguided programs [10]. Nonetheless, very few studies have directly compared the levels of working alliance

between guided and unguided IBIs [11]. Such direct comparisons are needed to clarify (1) the nature of the relationships that patients have established with unguided intervention programs and (2) whether guided IBIs are able to improve outcomes by leveraging the benefits of working alliance with additional clinician support compared with unguided programs [12]. Information regarding these questions will help to determine the contexts in which additional clinician support is needed to improve the outcomes and delivery of IBIs.

However, a conceptual question arises regarding whether we can quantitatively compare working alliance between guided interventions and unguided interventions. Most previous studies have directly taken measures of working alliance from studies of face-to-face therapy with minor adaptations to IBI contexts (eg, replacing the word *therapist* with the word *program* in items to refer to the relationship with therapeutic programs and clinicians together). The potential differences of working alliance in various IBI contexts remained unexamined in most cases (although there are exceptions [13-15]). The conceptual meaning and interpretation of working alliance for patients may be different for unguided interventions versus guided interventions; unless we verify that working alliance has the same conceptual meaning across different IBI contexts, quantitative comparisons of working alliance across IBIs are meaningless. The measurement invariance framework using multigroup confirmatory factor analysis [16] provides a strong methodological tool to examine the conceptual equivalence of working alliance across contexts. Therefore, the first aim of the study was to examine the measurement invariance of working alliance across guided versus unguided IBIs.

In addition to the potential differences in working alliance between guided and unguided interventions, the nature of working alliance may also vary for guided IBIs with different communication modalities. Clinician support can be delivered through video-based messages or text messages, both of which may have unique impacts on the development of working alliance. For example, video-based support is hypothesized to better facilitate the development of working alliance than text-based support because it allows for visual messages with facial expressions that facilitate nonverbal communication and relational bonding [3]. By contrast, text-based support may allow participants to develop more thorough, in-depth responses through words, which can facilitate the establishment of working alliance by enhancing deep emotional processing [3]. Understanding the impact of different communication modalities can help to improve the design of IBIs and maximize the influence of clinician support on the therapeutic process. Therefore, in this study, we aimed to examine the measurement invariance among (1) an unguided IBI (U-IBI), (2) a guided IBI with text-based clinician support (G-IBI-Text), and (3) a guided IBI with video-based clinician support (G-IBI-Video).

Trajectories of Working Alliance in IBIs

The literature on working alliance in face-to-face psychotherapy has consistently suggested that not only the levels but also the trajectories of working alliance matter. For example, studies show that varying trajectories of rupture repair-related patterns of working alliance in face-to-face therapy are differentially

related to therapy progress [17], suggesting that the trajectories of working alliance are important for treatment outcomes. However, little is known regarding the trajectories of working alliance in IBIs. The study by Jasper et al [18] examined working alliance in guided IBIs and found that working alliance seemed to be low in the initial weeks of treatment and gradually increased during and at the end of treatment. This suggests that working alliance may generally increase over time for guided IBIs [18]. More studies are needed to examine the trajectories of working alliance developed in both guided and unguided IBIs to understand the development of working alliance and its potential impact on treatment outcomes. Therefore, this study's second aim was to examine the trajectories of working alliance over the course of treatment in both guided and unguided IBIs.

Associations Between Working Alliance and Treatment Outcomes in IBIs

Many studies have examined the associations between working alliance and treatment outcomes, but the field has not yet reached a consensus regarding this relationship in the context of IBIs. Several systematic reviews suggest mixed relationships between working alliance and treatment outcomes assessed at the end of treatment [3,9,11] and emphasize that the heterogeneity in clinician involvement and support modalities may contribute to the inconsistent results. Nonetheless, a recent meta-analysis [19] that summarized associations between working alliance and treatment outcomes in IBIs across 20 studies found an average weighted effect size of $r=0.20$ (95% CI 0.14-0.26) for the associations. It also noted that there was no difference between clinician communication modalities (ie, written formats such as email or text compared with oral formats such as telephone or video) or between interventions with or without self-help components (ie, interventions with no self-help components versus interventions that incorporated clinician support and self-help programs). However, no comparisons of working alliance and treatment outcome associations between unguided and guided programs were included in the study. Furthermore, the meta-analysis found significant higher associations between working alliance and treatment outcomes when working alliance was measured at the end of treatment rather than during the early phase of treatment, which indicated that the working alliance trajectories may influence the associations between working alliance and treatment outcomes. In light of these results, our third study aim was to examine the associations between treatment outcomes and trajectories of working alliance in both unguided and guided IBIs.

Summary and Aims of This Study

In summary, there were 3 key aims of this study. First, we examined the measurement invariance of working alliance across 3 conditions of CBT-based IBIs (U-IBI, G-IBI-Text, and G-IBI-Video). We hypothesized that working alliance would be conceptually equivalent across the 3 conditions. Second, we examined the trajectories of working alliance over the course of the brief treatments in the 3 conditions. We expected to see increases in working alliance over time for all conditions. Finally, we examined the associations between working alliance trajectories and treatment outcomes (eg, mental health symptoms and functional impairment) across the 3 conditions. We

hypothesized that higher working alliance would predict better treatment outcomes in all 3 conditions.

Methods

Study Design

We conducted secondary data analysis of a randomized controlled trial of a 7-week internet-based psychological intervention. The original study was a 3-arm randomized controlled trial that was designed to approximate treatment situations for treatment-seeking adults in stressful occupations and with no resources for real-time communications (eg, astronauts). Condition 1 was the U-IBI condition in which participants used an unguided, self-help IBI called *MyCompass* without additional clinician support. Condition 2 was the G-IBI-Text condition in which participants used the same self-help IBI (*MyCompass*) and received additional asynchronous text-based support from a clinician. Condition 3 was the G-IBI-Video condition in which participants used the same self-help IBI (*MyCompass*) and received additional asynchronous video-based support from a clinician.

Ethics Approval

The study design and protocol were approved by the Stony Brook University Institutional Review Board (903034).

Interventions and Clinicians

The *MyCompass* program is a self-help IBI designed and shown to improve mild to moderate symptoms of depression, anxiety, and stress [20]. The program offers 14 self-management modules based on CBT principles, each of which comprises 3 sessions lasting 10 minutes each. The *MyCompass* program also includes homework tasks for each module as well as functions such as mood and symptom tracking, feedback from the program on patient performance, and psychoeducation (refer to Figures S1-S4 in [Multimedia Appendix 1](#) for the interface and examples of *MyCompass*).

Participants in all 3 conditions were asked to complete at least two modules of their choice on *MyCompass* during the 7-week treatment period. Participants in the U-IBI condition received automated email reminders to encourage them to use the program, track their symptoms, examine patterns and triggers related to changes in their mood and behaviors, and practice the skills they learned in real-world situations. No clinician support was provided in this condition.

Each participant in the G-IBI-Text condition was assigned to a clinician for additional, asynchronous text-based support. All clinicians ($n=10$) had master's or higher-level degrees and were trained and supervised weekly by 2 licensed psychologists (BM and AG). The clinicians initiated 1 weekly message through text at a prescheduled time to provide general support and positive reinforcement for program participation. This text-based contact typically involved encouraging participants to log on to *MyCompass* or to try a *MyCompass* module that was relevant to a stressor identified by the participant in a previous message to the clinician. Clinicians were instructed not to introduce skills or concepts not covered by the *MyCompass* program. Participants could respond to their clinician or initiate contact

with them at any time during the 7-week study but were informed that clinicians would only respond to messages during specified business hours. Clinicians were encouraged to use their own words rather than prefabricated responses to communicate with their patients.

The experience of participants in the G-IBI-Video condition was similar to that of participants in the G-IBI-Text condition, except that the clinicians initiated a weekly *video* message and communicated with participants through asynchronous video messages. Participants could initiate contact with clinicians or respond to clinicians by sending video messages on a communication platform that was specifically designed to receive asynchronous video messages for this study. As in the G-IBI-Text condition, clinicians in the G-IBI-Video condition were instructed not to introduce skills or concepts not covered by the *MyCompass* program.

Participants

Adults with high education attainment who sought treatment for subclinical levels of anxiety, depression, and stress were selected in the original study. The inclusion criteria were as follows: (1) aged ≥ 18 years; (2) English speaking; (3) enrolled in, or completed, a graduate-level education in science, technology, engineering, or math domains; (4) having a score of ≥ 5 on the depression subscale, ≥ 4 on the anxiety subscale, or ≥ 8 on the stress subscale of the 21-item version of the Depression, Anxiety, and Stress Scale [21], which indicates a moderate or higher level of clinical symptoms; and (5) having a score of ≥ 5 on any subscales or ≥ 6 on the global scale of the Sheehan Disability Scale (SDS), which indicates a moderate or higher level of functional impairment [22].

The exclusion criteria were as follows: (1) active suicidal ideation in the past month, (2) any history of suicide attempt within the past 5 years, (3) having a diagnosis of psychotic disorder or bipolar disorder, (4) alcohol or substance dependency in the past 6 months, (5) serious medical problems (eg, seizures or cancer), (6) pregnancy, (7) current participation in psychotherapy, and (8) having recently started a new psychoactive medication (ie, benzodiazepines for < 1 month or selective serotonin reuptake inhibitors, tricyclics, or serotonin-norepinephrine reuptake inhibitors for < 3 months). The Mini International Neuropsychiatric Interview [23] was used for assessing study eligibility.

Eligible participants completed a baseline assessment consisting of in-person or over-the-telephone clinical assessment and web-based questionnaires administered through Qualtrics. After this baseline assessment, participants were randomly assigned to a condition based on a pregenerated random assignment table—the procedure was weighted to favor assignment to the U-IBI condition. Participants in all 3 conditions received access to the *MyCompass* program and the study web-based portal.

A total of 300 individuals completed screening forms to indicate interest in the study between May 2018 and September 2018. Of the 300 individuals screened, 155 (51.7%) were excluded for the following reasons: they did not meet the inclusion criteria ($n=146$, 94.2%), were no longer interested when contacted by the research team ($n=4$, 2.6%), or met an exclusion criterion

($n=5$, 3.2%). Subsequently, of the 300 people screened, 145 (48.3%) were enrolled into the trial. These 145 participants were randomized to the U-IBI condition ($n=57$, 39.3%), the G-IBI-Text condition ($n=44$, 30.3%), or the G-IBI-Video condition ($n=44$, 30.3%; refer to [Multimedia Appendix 2](#) for the CONSORT [Consolidated Standards of Reporting Trials] flow diagram).

Most of the 145 participants were women ($n=99$, 68.3%), of heterosexual orientation ($n=125$, 86.2%), and identified as White ($n=99$, 68.3%) and non-Hispanic ($n=133$, 91.7%). The average age was 30 (SD 8.21) years. In total, 96.6% (140/145) of the participants were college graduates, with 59.3% (86/145) having at least a master's degree. The proportion of participants identifying as Hispanic was lower in the G-IBI-Text condition than in the other 2 treatment conditions; otherwise, no demographic differences in sex, age, sexual orientation, race, ethnicity, or education attainment were noted across the 3 conditions (refer to [Multimedia Appendix 3](#) for the demographic characteristics of the participants).

Measures

Working Alliance

In total, 4 items that were adapted from the Agnew Relationship Measure, 12-item version (ARM-12) were used to examine working alliance across the treatment conditions [24]. The ARM-12 has been widely used to examine working alliance in face-to-face therapy and has shown a strong reliability and good criterion validity with other working alliance measures [25,26]. The ARM-12 is one of the most commonly used questionnaires to assess working alliance in internet-based mental health interventions because of its conciseness and its full representation of the relevant concepts [27-30]. However, most studies have adapted the ARM-12 for IBIs by simply changing the term *clinician* to *program* or *app* in items [13]. Such alteration of wording may create issues with content validity (ie, an original item such as “the *clinician* seems bored or impatient with me” is modified to “the *program* seems bored or impatient with me”). Therefore, to enhance the measure's content validity across the treatment conditions, this study only included items that were assessed by experts' and users' consensus in previous qualitative studies as relevant for IBIs [13]. The 4 included items were as follows: “I feel friendly toward the program,” “I have confidence in the program and its techniques,” “I feel I can openly express my thoughts and feelings to the program,” and “The program is supportive.” Each item was rated using a 7-point Likert scale (from 1=*strongly disagree* to 7=*strongly agree*). The ARM-12 items were administered after each week of the intervention, starting from the first week and ending in the seventh week.

The Cronbach α values were .78 and .91 for the 4 items assessed at week 1 and at the end of treatment, respectively. We also examined factorial validity in confirmatory factor analysis for a single common factor of these 4 items at baseline and at the end of treatment, given the previous finding of a core working alliance factor for short versions of the ARM [24]. The single common factor model fit perfectly for the 4 items assessed at week 1 and at the end of treatment ($\chi^2_2=1.2$ and $\chi^2_2=1.3$,

respectively; comparative fit index=1.00, Tucker-Lewis Index=1.00, and root mean squared error of approximation (RMSEA)=0.00 in models at week 1 and at the end of treatment), suggesting that a single common factor of the working alliance underlay the 4 items.

Treatment Outcomes

The Patient Health Questionnaire-9 (PHQ-9) [31], Penn State Worry Questionnaire (PSWQ) [32], and SDS [22] were used as treatment outcome measures to assess depression, anxiety, and social functioning impairment, respectively, at baseline, at the end of treatment, and 1-month follow-up. The PHQ-9 is a self-report measure for general depression symptoms, with higher scores indicating more depressive symptoms. The Cronbach α values for the internal consistency were .79, .87, and .88 in our sample at baseline, at the end of treatment, and 1-month posttreatment follow-up, respectively. The PSWQ is a 21-item measure for worry symptoms, with higher scores indicating higher levels of worry. The Cronbach α values for the internal consistency were .76, .82, and .79 in our sample at baseline, at the end of treatment, and 1-month posttreatment follow-up, respectively. The SDS is a 3-item measure for social functioning impairment. The Cronbach α values for the internal consistency were .73, .89, and .89 in our sample at baseline, at the end of treatment, and 1-month posttreatment follow-up, respectively.

Data-Analytic Strategy

Overview

Multigroup confirmatory factor analysis and multigroup longitudinal structural equation modeling were used to assess the conceptual invariance, trajectories, and treatment outcome associations across treatment conditions. Data were modeled with Mplus (version 8.2; Muthén & Muthén) [33]. Full information maximum likelihood estimation [34] was used to handle missing data. We evaluated and compared the model fit for all models based on 6 model indices: chi-square [35], comparative fit index [36] (values >0.90 indicate acceptable fit), Tucker-Lewis Index [36] (values >0.90 indicate acceptable fit), RMSEA [37] (values <0.08 indicate acceptable fit), Akaike information criterion (lower values indicate better fit), and Bayesian information criterion (lower values indicate better fit). We compared nested models by calculating a chi-square difference test such that a nonsignificant chi-square difference indicates a preference for the nested, more parsimonious model.

Conceptual Invariance of Working Alliance

Confirmatory factor analysis was used to evaluate measurement invariance and determine whether working alliance was conceptually comparable across the 3 IBI conditions. In the multigroup invariance analyses, baseline models with no constraints requiring equality among the groups were compared with various invariance models to determine the best modeling fit to the data [38]. We used a single-factor baseline model with no restraints, requiring equality among the groups as the baseline model, and compared this model with three types of alternative, invariance models: (1) a configural invariance model (testing a single-factor model in all treatment groups without constraining the factor loadings or intercepts), which indicates

the same conceptual factor structure across treatment groups; (2) a metric invariance model (constraining the factor loadings to be equivalent across groups), which indicates that in addition to the same factor structure of the single-factor model, these groups have the same factor loadings on the single factor; and (3) a scalar invariance model (constraining both factor loadings and intercepts to be equivalent), which indicates that the 3 conditions have the same factor structure as the single-factor model, the same factor loadings, and the same true values on the latent factor. If the scalar invariance model is the best-fitting model, it indicates that the working alliance is conceptually invariant and that the latent values can be compared across treatment conditions [39]. We examined measurement invariance separately for working alliance assessed at the first week of treatment and at the end of treatment.

Trajectories of Working Alliance

Once we determined that working alliance was conceptually invariant (refer to the *Results* section), we fit a series of univariate latent growth curve models to identify the appropriate change pattern of working alliance for the entire sample. Data were modeled with multiple types of trajectories, including (1) a no-change, intercept-only model where we only estimated means and variance for all measurement points without a slope; this model indicates no change in working alliance over time; (2) a linear change model where we estimated both intercept and slope for the trajectories; this model indicates that working alliance changes in a linear fashion over time; (3) a latent basis model, where an intercept and a slope were estimated but the loading on the slope was not based on the temporal time and is freely estimated; this model indicates that working alliance may change at a nonlinear rate with time; and (4) a quadratic model where we estimated the intercept, a linear slope, and a quadratic slope; this model indicates that working alliance may change in a quadratic pattern. We used the model fit indices to determine the best-fitting model that depicted the trajectories of working alliance among the aforementioned models.

After identifying the best-fitting model in which everything was set as equal across treatment conditions (ie, the fully constrained model), we created alternative models in which the 3 conditions may not be equal (by gradually loosening the constraints of the parameters) and compared the model fit between alternative models and the fully constrained model. The following parameters (if they existed in the best-fitting model) were loosened to be uniquely estimated in each group one at a time: mean of intercept, mean of linear slope, quadratic slope, mean of autoregressive coefficient (if it existed), variance of intercept, variance of linear slope, variance of quadratic slope, and residual variance. In case of model misspecifications, the cause of misspecification was examined through modification indices. Model modifications were used with caution and applied only if supported by possible theoretical explanations. If any of the alternative models yielded better model fit than the fully constrained model, it indicated differences in the trajectories of working alliance across treatment conditions.

Associations Between Working Alliance and Treatment Outcomes

We examined whether the trajectories of working alliance contributed to treatment outcomes in each condition by examining whether the intercept (the initial level) or the change rates (linear or quadratic slope, if identified in previous steps) of the working alliance would predict treatment outcomes on depression (PHQ-9), worry (PSWQ), and social functioning impairment (SDS). We did so by including each outcome and the associations between each outcome and the intercept and slope of working alliance in the best-fitting multigroup structural equation modeling models that were identified from the previous step. We ran separate models for each outcome and controlled

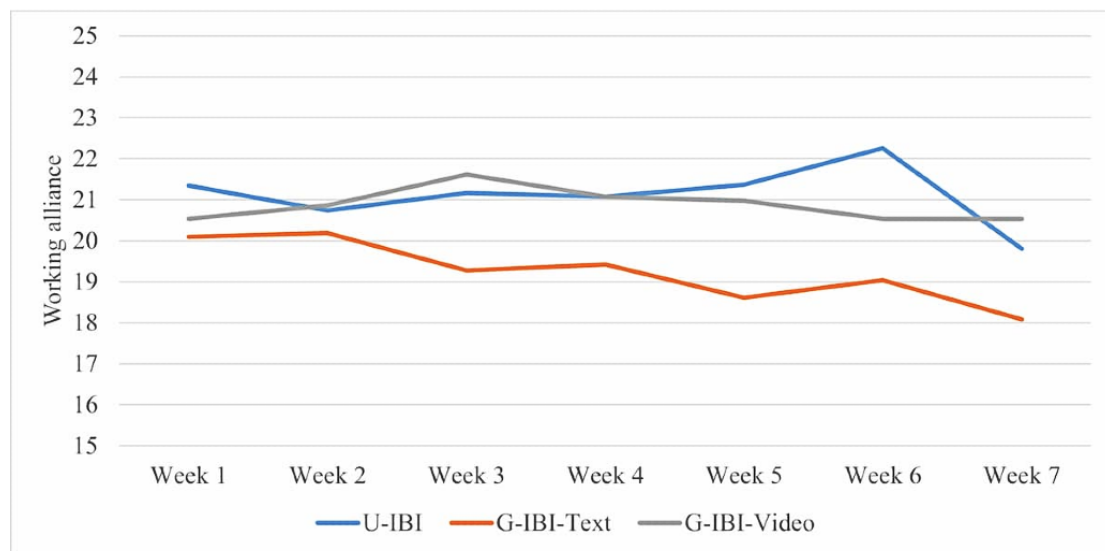
for the baseline level of each treatment outcome measure in each model.

Results

Overview

The levels of working alliance based on the selected items of ARM-12 for week 1 to week 7 are presented in [Figure 1](#). The treatment outcome variables were moderately correlated concurrently in the range of 0.48 to 0.66 between social functional impairment and depression and in the range of 0.43 to 0.50 between worry and depression and between worry and functional impairment.

Figure 1. The weekly working alliance ratings across treatment for each treatment condition. U-IBI: unguided internet-based intervention; G-IBI-Text: guided internet-based intervention with text-based clinician support; G-IBI-Video: guided internet-based intervention with video-based clinician support.



Conceptual Invariance of Working Alliance

The model fit indices for configural, metric, and scalar invariance models for the selected working alliance items at week 1 and week 7 are presented in [Table 1](#). Overall, the scalar invariance model across the 3 treatment conditions reached an excellent model fit at both week 1 and week 7 (chi-square test

for model fit; $P=.56$ and $P=.05$ in scalar invariance models for week 1 and for week 7, respectively). This suggests that the selected 4 items of the ARM-12 had measurement invariance across treatment groups, indicating that it is appropriate to compare scores across conditions to detect differences on the latent construct of working alliance.

Table 1. The model fit indices for configural, metric, and scalar invariance of working alliance (selected items from the Agnew Relationship Measure, 12-item version) across the 3 conditions at week 1 and week 7.

Assessment week and model	Free parameters, n	Chi-square (<i>df</i>)	<i>P</i> value	RMSEA ^a	CFI ^b	TLI ^c
Week 1						
Configural invariance	25	18.9 (17)	.34	0.05	0.99	0.99
Metric invariance	19	22.0 (23)	.52	0.00	1.00	1.00
<i>Scalar invariance^d</i>	<i>11</i>	<i>29.2 (31)</i>	<i>.56</i>	<i>0.00</i>	<i>1.00</i>	<i>1.00</i>
Week 7 (at the end of treatment)						
Configural invariance	25	29.5 (17)	.03	0.13	0.96	0.96
Metric invariance	19	35.8 (23)	.04	0.11	0.96	0.97
<i>Scalar invariance^d</i>	<i>11</i>	<i>44.8 (31)</i>	<i>.05</i>	<i>0.10</i>	<i>0.96</i>	<i>0.98</i>

^aRMSEA: root mean squared error of approximation.

^bCFI: comparative fit index.

^cTLI: Tucker-Lewis Index.

^dText in italics indicates the best-fitting model selected.

Trajectories of Working Alliance

The model fit indices for latent curve models are presented in [Table 2](#). When we constrained the treatment groups to be fully equal (ie, assuming no group differences), the quadratic model was the best model for the entire sample with acceptable fit, except for a slightly elevated index with RMSEA.

This quadratic model for all groups was then used as the baseline model in the multigroup modeling comparison to examine whether there were any group differences in trajectories. We compared this model with alternative models where we allowed 1 parameter to be different at a time. We identified the best-fitting model based on the chi-square difference test, acceptable model fit indices (comparative fit index=0.95, Tucker-Lewis Index=0.97, RMSEA=0.09), and the lowest Akaike information criterion and Bayesian information criterion. The best-fitting model allowed the linear slope to be different

in the G-IBI-Text condition but not in the other 2 conditions. In addition, the best-fitting model allowed the residual variance to be different in the G-IBI-Text condition. This indicated that for the best-fitting model, there was a significantly different linear change rate in the G-IBI-Text condition compared with the other 2 conditions.

The estimations for the parameters are presented in [Table 3](#). Specifically, the G-IBI-Text condition had a significant linear slope that was negative (linear slope estimation=-0.44; $P=.04$) compared with the nonsignificant linear slope for the other 2 conditions (linear slope estimation=0.19; $P=.35$). This indicates that the working alliance followed a different quadratic pattern in the G-IBI-Text condition compared with the other 2 conditions, in that there was a significant linear decrease only in the G-IBI-Text condition and no significant linear change in working alliance for the U-IBI or G-IBI-Video conditions.

Table 2. Model fit indices for multigroup latent curve modeling of working alliance (selected items from the Agnew Relationship Measure, 12-item version).

Model	Free parameters, n	AIC ^a	BIC ^b	Chi-square (df)	RMSEA ^c	CFI ^d	TLI ^e	Δ Chi-square ^f (Δ df)	P value for Δ chi-square (Δ df)
Fully constrained models for the entire sample as 1 group									
Intercept only	3	3879.21	3888.07	183.5 (32)	0.18	0.79	0.86	N/A ^g	N/A
Linear	6	3797.86	3815.59	96.1 (29)	0.13	0.91	0.93	87.4 (3)	<.001
Latent basis	11	3793.24	3825.76	81.5 (24)	0.13	0.92	0.93	102.0 (8)	<.001
<i>Quadratic^h</i>	<i>10</i>	<i>3762.95</i>	<i>3792.51</i>	<i>53.2 (25)</i>	<i>0.09</i>	<i>0.96</i>	<i>0.97</i>	<i>130.3 (7)</i>	<i><.001</i>
Multigroup modeling allowing for group differences									
Baseline, fully constrained quadratic model	10	3762.95	3792.51	143.0 (95)	0.10	0.94	0.96	N/A	N/A
Free intercept	12	3765.32	3800.79	141.3 (93)	0.11	0.94	0.96	1.4 (2)	.50
Free linear slope	12	3762.08	3797.55	138.1 (93)	0.10	0.94	0.96	4.9 (2)	.09
Free linear slope and quadratic slope	14	3765.39	3806.78	137.4 (91)	0.10	0.94	0.96	5.6 (4)	.23
Free quadratic slope	12	3762.91	3798.37	138.9 (93)	0.10	0.94	0.96	4.0 (2)	.14
Free variance and covariance	22	3777.70	3842.73	133.7 (83)	0.11	0.93	0.95	9.3 (12)	.68
Free residual variance	12	3753.00	3788.62	129.2 (93)	0.09	0.95	0.97	13.8 (2)	.001
Free residual variance and linear slope	14	3752.42	3793.80	124.0 (91)	0.09	0.96	0.97	19.0 (4)	<.001
<i>Free residual and linear slope only for the text group^h</i>	<i>12</i>	<i>3751.22</i>	<i>3786.69</i>	<i>127.2 (93)</i>	<i>0.09</i>	<i>0.95</i>	<i>0.97</i>	<i>15.7 (2)</i>	<i><.001</i>
Free linear slope only for the text group	11	3760.92	3793.43	138.9 (94)	0.10	0.94	0.96	4.0 (1)	.05
Free residual variance only for the text group	11	3753.08	3785.59	131.1 (94)	0.09	0.95	0.97	11.9 (1)	<.001

^aAIC: Akaike information criterion.

^bBIC: Bayesian information criterion.

^cRMSEA: root mean squared error of approximation.

^dCFI: comparative fit index.

^eTLI: Tucker-Lewis Index.

^f Δ Chi-square: chi-square difference test.

^gN/A: not applicable (the chi-square difference test is not applicable to the baseline models).

^hThe models presented in italics indicated the best-fitting models in each category. We first fit models for the entire sample and identified the quadratic model as the best-fitting model. Next, we fit the quadratic model to the 3 conditions in multigroup structural equation modeling, constraining the parameters to be the same for each group. We then gradually loosened the constraints to examine alternative models. The best-fitting model for multigroup modeling indicated a model in which the residual variance and linear slope were set to be different for the guided internet-based intervention with text-based clinician support condition only.

Table 3. Parameter estimation in the best-fitting model.

Parameters	U-IBI ^a		G-IBI-Text ^b		G-IBI-Video ^c	
	Estimate (SE)	<i>P</i> value	Estimate (SE)	<i>P</i> value	Estimate (SE)	<i>P</i> value
Level factor means	20.65 (0.30)	<.001	20.65 (0.30)	<.001	20.65 (0.30)	<.001
Linear slope factor means	-0.19 (0.20)	.35	<i>-0.44^d</i> (0.22)	<i>.04</i>	-0.19 (0.20)	.35
Quadratic slope factor means	0.01 (0.03)	.72	0.01 (0.03)	.72	0.01 (0.03)	.72
Level factor variance	9.42 (1.52)	<.001	9.42 (1.52)	<.001	9.42 (1.52)	<.001
Linear slope factor variance	2.68 (0.63)	<.001	2.68 (0.63)	<.001	2.68 (0.63)	<.001
Quadratic slope factor variance	0.06 (0.01)	<.001	0.06 (0.01)	<.001	0.06 (0.01)	<.001
Residual variance	3.05 (0.27)	<.001	<i>4.98 (0.61)</i>	<i><.001</i>	3.05 (0.27)	<.001
Covariance between level factor and linear slope factor	0.74 (0.69)	.29	0.74 (0.69)	.29	0.74 (0.69)	.29
Covariance between level factor and quadratic slope factor	-0.11 (0.10)	.28	-0.11 (0.10)	.28	-0.11 (0.10)	.28
Covariance between linear slope factor and quadratic slope factor	-0.37 (0.09)	<.001	-0.37 (0.09)	<.001	-0.37 (0.09)	<.001

^aU-IBI: unguided internet-based intervention.

^bG-IBI-Text: guided internet-based intervention with text-based clinician support.

^cG-IBI-Video: guided internet-based intervention with video-based clinician support.

^dThe parameters in the 3 conditions were fixed to be the same, except for the ones in italics, which were estimated separately for the guided internet-based intervention with text-based clinician support condition.

Associations Between Working Alliance and Treatment Outcomes

We examined how the intercept (ie, initial level) and the linear slope (ie, the linear change rate) of the working alliance trajectories predicted each treatment outcome (depression,

worry, and functional impairment) at the end of treatment and at 1-month follow-up after controlling for each treatment outcome variable at baseline separately. The model fit indices are presented in [Table 4](#). All models reached acceptable fit. The parameter estimations are shown in [Table 5](#).

Table 4. Model fit indices for multigroup models with outcomes^a at the end of treatment and 1-month follow-up.

Model	Outcome	Assessment	Free parameters, n	Chi-square (<i>df</i>)	RMSEA ^b	CFI ^c	TLI ^d
Model 1	PHQ-9 ^e	the end of treatment	27	168.4 (129)	0.08	0.95	0.96
Model 2	PHQ-9	1-month follow-up	27	176.4 (129)	0.09	0.94	0.95
Model 3	PSWQ ^f	the end of treatment	27	172.6 (129)	0.09	0.95	0.96
Model 4	PSWQ	1-month follow-up	27	171.1 (129)	0.08	0.95	0.96
Model 5	SDS ^g	the end of treatment	27	182.4 (129)	0.09	0.93	0.94
Model 6	SDS	1-month follow-up	27	163.8 (129)	0.08	0.95	0.96

^aThe parameters indicated a good fit for all the models incorporating outcome measures.

^bRMSEA: root mean squared error of approximation.

^cCFI: comparative fit index.

^dTLI: Tucker-Lewis Index.

^ePHQ-9: Patient Health Questionnaire-9.

^fPSWQ: Penn State Worry Questionnaire.

^gSDS: Sheehan Disability Scale.

Table 5. The parameter estimations for alliance-outcome associations.

SEM ^a model and predictors	Outcomes	U-IBI ^b		G-IBI-Text ^c		G-IBI-Video ^d	
		Estimate	<i>P</i> value	Estimate	<i>P</i> value	Estimate	<i>P</i> value
PHQ-9^e							
Model 1							
Intercept of alliance	PHQ-9 at the end of treatment	-0.06	.77	-0.1	.71	-0.02	.91
Linear slope of alliance	PHQ-9 at the end of treatment	-0.44	.35	0.28	.65	-0.8	.09
Model 2							
Intercept of alliance	PHQ-9 at 1-month follow-up	0.05	.86	0.004	.99	<i>-0.62^f</i>	.04
Linear slope of alliance	PHQ-9 at 1-month follow-up	-0.82	.14	0.43	.42	0.04	.95
PSWQ^g							
Model 3							
Intercept of alliance	PSWQ at the end of treatment	0.59	.14	0.01	.99	0.83	.18
Linear slope of alliance	PSWQ at the end of treatment	-1.8	.05	0.82	.46	-2.85	.03
Model 4							
Intercept of alliance	PSWQ at 1-month follow-up	0.18	.62	-0.95	.08	0.67	.29
Linear slope of alliance	PSWQ at 1-month follow-up	-0.67	.40	2.17	.08	<i>-3.61</i>	.01
SDS^h							
Model 5							
Intercept of alliance	SDS at the end of treatment	-0.42	.16	-0.47	.14	-0.55	.17
Linear slope of alliance	SDS at the end of treatment	0.59	.36	0.48	.51	-0.34	.72
Model 6							
Intercept of alliance	SDS at 1-month follow-up	0.07	.82	-0.62	.14	<i>-0.76</i>	.04
Linear slope of alliance	SDS at 1-month follow-up	-0.004	.99	0.85	.39	0.64	.43

^aSEM: structural equation modeling.

^bU-IBI: unguided internet-based intervention.

^cG-IBI-Text: guided internet-based intervention with text-based clinician support.

^dG-IBI-Video: guided internet-based intervention with video-based clinician support.

^ePHQ-9: Patient Health Questionnaire-9.

^fItalicized items indicate significance at $P < .05$ level.

^gPSWQ: Penn State Worry Questionnaire.

^hSDS: Sheehan Disability Scale.

After controlling for baseline severity, the associations between treatment outcomes and working alliance seemed to vary across conditions. In the G-IBI-Video condition, the intercept of working alliance significantly predicted depression (PHQ-9) and functioning impairment (SDS) negatively at 1-month follow-up ($P = .04$ for both models) such that a higher initial level of working alliance predicted lower depression and lower functional impairment for the participants at 1-month follow-up after controlling for their baseline levels of depression or functional impairment. In addition, for the G-IBI-Video condition, the linear slope of working alliance negatively predicted worry (PSWQ) at the end of treatment and at 1-month follow-up ($P = .03$ and $P = .009$, respectively), which means that a faster increase of working alliance over time would predict less worry at the end of treatment and at 1-month follow-up, after controlling for baseline levels of worry.

By contrast, neither the intercept nor the linear slope of working alliance was associated with any treatment outcomes at either time points for the U-IBI condition or the G-IBI-Text condition, with 1 exception: the linear slope of working alliance was negatively associated with worry (PSWQ) at the end of the treatment ($P = .049$) in the U-IBI condition. However, this significant effect disappeared at 1-month follow-up.

Discussion

Summary

Internet-based psychological interventions promise to overcome accessibility-related issues associated with face-to-face, synchronous interventions while also embracing a patient-centered and stepped-care approach to mental health services. Despite a growing body of research supporting the

efficacy and effectiveness of IBIs, little is known regarding the relevance of psychotherapy relationship factors, such as working alliance, which are known to account for a significant portion of in-person treatment outcomes. Moreover, although some studies have examined the effects of the inclusion of clinician support services in IBIs, to our knowledge, no existing investigation has directly compared the effects of varying degrees of clinician involvement in IBIs on working alliance. This study was designed to address this knowledge gap by examining the measurement invariance and trajectories of working alliance, as well as the associations between working alliance and treatment outcomes across an unguided IBI and guided IBIs with text-based or video-based clinician support. We found that although the conceptual interpretation and the trajectories of working alliance was relatively similar across the 3 conditions, higher working alliance predicted better treatment outcomes only in the video-support (G-IBI-Video) condition.

Conceptual Invariance of Working Alliance

The results indicated that participants' ratings of their working alliance with the IBIs were conceptually invariant across the U-IBI condition and the asynchronous G-IBI-Text and G-IBI-Video conditions. This result was consistent with our hypothesis, supporting the equivalence of the underlying construct of working alliance for IBIs and allowed for further between-group comparisons across conditions. A growing number of studies [14,40] have explored the applicability of the tripartite construct of alliance formulated by Bordin [1] to IBIs. This study relied on the administration of a modified version of the ARM-12, which featured selected, reworded items measuring participants' perceived working alliance with IBIs. The methodological invariance suggests that the varying degrees of clinician involvement did not significantly affect participants' interpretation of the construct of working alliance with the IBIs. This also indicates that quantitative comparisons of working alliance with the IBIs across the unguided and guided interventions are possible and meaningful. It is worth noting that working alliance with IBIs may be different from working alliance with only clinicians [41]; thus, additional research is needed to further elucidate the nature of patients' ratings of working alliance with IBIs and their comparability to working alliance ratings for clinicians in face-to-face psychotherapy.

Trajectories of Working Alliance

We hypothesized that working alliance would increase over time but found that working alliance followed a quadratic pattern and remained relatively stable in the U-IBI and the G-IBI-Video conditions while displaying significant deterioration in the G-IBI-Text condition. This indicated that working alliance with the IBIs may have been established quickly in the initial weeks. The stable, quadratic pattern of working alliance also corresponds to patterns reported in the literature on face-to-face therapy, suggesting that these patterns may not be unique to IBIs [17].

Nonetheless, the linear decrease in working alliance in the G-IBI-Text condition was surprising. Although deteriorating patterns have been documented in previous studies examining the development of working alliance over the course of

face-to-face interventions [42], this trajectory had been rarely detected in working alliance in IBIs. Participants in the G-IBI-Text condition may have established higher expectations for human connection than participants in the U-IBI program; nonetheless, they received less visual and vocal communication with clinicians than participants in the G-IBI-Video condition. The gap between expectation for human connection and the lack of video-based communication may contribute to decreases in feelings connected in the G-IBI-Text condition. Future studies could shed additional light on this finding by examining whether text-based clinician support may interact with changes in treatment expectations, patient role expectation, or other relationship factors to contribute to decreases in working alliance over time.

Associations Between Working Alliance and Treatment Outcomes

Our results indicated that working alliance mattered in the G-IBI-Video condition. After controlling for baseline levels of symptoms, higher initial levels of working alliance predicted lower depressive symptoms and less functional impairment at 1-month follow-up. In addition, greater increases in working alliance over time predicted lower worry at the end of treatment and at 1-month follow-up. These results are consistent with the extensive literature on face-to-face therapy [2] as well as the literature on IBIs [11], supporting the robust positive relationship between working alliance and positive treatment outcomes. Our novel design allowed us to show that both the initial levels and the trajectories of working alliance contributed to better treatment outcomes separately for different treatment outcomes. In addition, these prospective associations between working alliance and treatment outcomes were detected at the 1-month follow-up, suggesting at least some level of sustainability for these treatment effects.

By contrast, working alliance was not consistently associated with treatment outcomes in the U-IBI or the G-IBI-Text conditions. These findings were unexpected, although not completely inconsistent with previous studies that did not find significant relationships between CBT-based IBIs and working alliance [43-45]. It is possible that the associations between working alliance and treatment outcomes are only present when clinician support is delivered through video-based modalities, the condition most closely aligned with traditional psychotherapy, which includes visual images, nonverbal facial expressions, and varying voice tones. These findings raise an important issue about the function of working alliance in asynchronous IBIs—although the interpretation and ratings of working alliance were similar across IBIs with or without clinician support, working alliance may only help reduce mental health symptoms when clinician support is present through video-based channels (vs text-based channels or no clinician support). Such findings should be replicated in future studies to compare how different communication modalities may influence the associations between working alliance and treatment outcomes.

Limitations and Future Directions

The study's findings should be considered in light of the following limitations. First, our sample was composed of

individuals with high educational achievement, which may limit the generalizability of these findings. Future research should attempt to replicate these findings with a sample representative of the general clinical population. Second, working alliance in IBIs may be particularly important for individuals with more moderate to severe levels of psychopathology; hence, future studies should examine whether the associations between working alliance and treatment outcomes among IBIs may vary depending on clinical populations. Third, the *MyCompass* program delivered in this study is a 7-week intervention. The brief duration of the interventions may have interfered with participants' ability to display more complex trajectories of working alliance, which may have been observed in longer interventions. Fourth, this study focused on using CBT-based IBIs to treat subclinical levels of depression, anxiety, and stress; therefore, the findings may not be generalizable to other IBIs using different theoretical frameworks or targeting other symptoms. In addition, this study selected 3 treatment outcomes that were moderately to highly correlated to each other. Future studies should select treatment outcome measures to reduce multicollinearity and examine whether the predictions of working alliance on treatment outcomes may differ depending on the outcome variables.

Future studies should also examine the potential mediators through which the initial level or the change rate of working alliance may affect treatment outcomes. For example, it is possible that an initial high level of working alliance would

help the patient to use IBIs more frequently or complete the homework more often, which may result in greater symptom reduction. Finally, the study is limited to assessing working alliance with IBIs; future studies are needed to understand similarities and differences between working alliance with only clinicians and working alliance with IBIs.

Conclusions

This study examined the conceptual equivalence, trajectories, and outcome associations of working alliance in a randomized controlled trial with 3 conditions, including unguided IBIs as well as guided IBIs with text-based and video-based support. We found conceptual equivalence of working alliance with the IBIs across the 3 conditions. Our results also revealed a quadratic pattern of working alliance over time in the U-IBI and G-IBI-Video conditions, but a deterioration pattern was revealed in the G-IBI-Text condition. Higher initial-level and faster increases of working alliance in the G-IBI-Video condition predicted lower mental health symptoms and functional impairment at the end of treatment and 1-month follow-up compared with the other 2 conditions. Working alliance was also not consistently associated with treatment outcomes in the U-IBI or G-IBI-Text conditions. Our results suggested that despite similar conceptual interpretation and trajectories, the function of working alliance may differ among IBIs with varying degrees and types of clinician support for high-functioning populations with subclinical levels of distress.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

MyCompass interface examples.

[\[DOCX File, 1476 KB - mental_v9i6e35496_app1.docx\]](#)

Multimedia Appendix 2

CONSORT(Consolidated Standards of Reporting Trials) flow chart of participants.

[\[DOCX File, 108 KB - mental_v9i6e35496_app2.docx\]](#)

Multimedia Appendix 3

Participants' demographic information.

[\[DOCX File, 17 KB - mental_v9i6e35496_app3.docx\]](#)

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Abbreviations

ARM-12: Agnew Relationship Measure, 12-item version

CBT: cognitive behavioral therapy

CONSORT: Consolidated Standards of Reporting Trials

G-IBI-Text: guided internet-based intervention with text-based clinician support

G-IBI-Video: guided internet-based intervention with video-based clinician support

IBI: internet-based intervention

PHQ-9: Patient Health Questionnaire-9

PSWQ: Penn State Worry Questionnaire
RMSEA: root mean squared error of approximation
SDS: Sheehan Disability Scale
U-IBI: unguided internet-based intervention

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Original Paper

The Effectiveness of a Brief Telehealth and Smartphone Intervention for College Students Receiving Traditional Therapy: Longitudinal Study Using Ecological Momentary Assessment Data

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Abstract

Background: Brief interventions such as mental health apps and single-session interventions are increasingly popular, efficacious, and accessible delivery formats that may be beneficial for college students whose mental health needs may not be adequately met by college counseling centers. However, no studies so far have examined the effectiveness of these modes of treatment for college students who are already receiving traditional therapy, despite it being common among this population.

Objective: The aim of this study was to compare the differences in self-reported momentary negative affect between college students in therapy and not in therapy who received a brief single-session intervention delivered by counseling center staff and a supplemental mobile app.

Methods: Data for this study were drawn from E-Manage, a brief mobile health intervention geared toward college students. Participants in the study were 173 college students who indicated whether they had received therapy. We conducted a multilevel model to determine whether there were differences between those in therapy versus not in therapy in negative affect reported throughout the study. Following this, we conducted multilevel models with therapy status as the predictor and negative affect as the outcome.

Results: Results of the multilevel model testing showed that the cross-level interaction between the time point (ie, pre- vs postexercise) and therapy status was significant ($P=.008$), with the reduction in negative affect from pre- to postexercise greater for those in therapy ($b=-0.65$, 95% CI -0.91 to -0.40 ; $P<.001$) than it was for those not in therapy ($b=-0.31$, 95% CI -0.43 to -0.19 ; $P<.001$). Therapy status was unassociated with both the pre-exercise ($b=-1.69$, 95% CI -3.51 to 0.13 ; $P=.07$) and postexercise ($b=-1.37$, 95% CI -3.17 to 0.43 ; $P=.14$) ratings of negative affect.

Conclusions: These findings suggest that app-based and single-session interventions are also appropriate to use among college students who are receiving traditional therapy. A randomized controlled trial comparing students receiving therapy to students receiving therapy and E-Manage will be necessary to determine to what extent E-Manage contributed to the reductions in negative affect that therapy-attending college students experienced.

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KEYWORDS

college students; digital mental health; brief interventions

Introduction

It has been well established that traditional models of mental health care are inaccessible to many of those who need it [1]. Various factors contribute to this inaccessibility, including an insufficient number of providers to meet demands [2], lack of affordability [3], and stigma [4]. Furthermore, traditional models of mental health care do little to decrease strain on overburdened mental health care systems [5]. Thus, there is a distinct need for innovative and scalable interventions that can increase access to mental health care and reduce burden on service providers.

Brief interventions using mobile technology (ie, apps) and interventions designed to be completed in one sitting (ie, single-session interventions) are becoming popular and efficacious delivery formats for mental health needs that help make mental health care more accessible [6-9]. These accessible modes of treatment may be particularly beneficial for college students, who experience high levels of mental disorders [10,11]. Worldwide, about 1 in 4 college students meet the diagnostic criteria for a mental disorder within a given year [12], with the rates for some disorders having doubled over the past decade [13]. Despite these upward trends, college counseling centers have struggled to keep up with the growing demands for individual therapy due to institutional constraints, such as using insufficient amounts of staff members to meet student needs [11,14]. In light of the budgetary constraints on college counseling centers, efficient delivery formats such as mental health apps and single-session interventions are appealing to address increased student demand, especially due to growing evidence of their effectiveness for and ease of dissemination to college students [15-20].

However, no studies so far have examined the effectiveness of these brief mobile interventions for college students who are already receiving mental health treatment. Approximately 9% of college students use counseling center services within a given year [10], and 15% of students have received therapy at some point in their lives [21]. Understanding the effectiveness of mental health apps and single-session interventions in college students who have received therapy is important for determining how these tools may be disseminated among college students. There are two possibilities that could arise. If mental health apps and single-session interventions are found to be just as effective or more effective for students who are currently receiving (or have previously received) therapy (compared to those never in therapy), these treatment modalities could be offered as a beneficial adjunct to their care. Mental health apps may add some benefit to those who have had therapy because they have prior experience both in terms of socialization (ie, familiarity with what therapy is like) and familiarity with specific content. If these modes of treatment modalities are not as effective for students currently or previously in therapy, counseling centers may want to direct their dissemination to students who have not sought out traditional treatment.

The purpose of this study is to examine if there were any differences in the effectiveness of a brief single-session intervention delivered by counseling center staff and mobile app between college students in therapy and those not in therapy.

To accomplish this, we analyzed data collected from 173 participants in E-Manage [22], a brief 90-minute workshop based on the Unified Protocol [23] with a supplemental mobile app implemented in a northeastern public university's counseling center. We compared the differences in self-reported momentary negative affect across 8 weeks post workshop between students reporting attending therapy and students reporting not attending therapy. We also examined whether or not these differences were due to differences in baseline negative affect. We hypothesized that there would be differences in the change in negative affect between the two groups. More specifically, we hypothesized that students attending therapy would have greater reductions in negative affect from E-Manage than those not in therapy due to prior socialization to the skills introduced in E-Manage through their therapy treatment.

Methods

Participants

Data for this study were drawn from a Registered Clinical Trial (NCT04636151) of E-Manage, a brief mobile health intervention geared toward college students [18]. Participants in the study were 173 college students, of the original study sample of 177, since 4 participants did not indicate whether they had received therapy previously and were thus excluded from these analyses. Regarding gender, 78.6% (n=136) of the sample identified as cisgender female, 16.8% (n=29) as cisgender male, and the remainder identified as nonbinary or gender nonconforming. Regarding race, the sample was 42.8% (n=74) White, 34.1% (n=59) Asian, 10.4% (n=18) Black/African American, 8.7% (n=15) more than one race, and the remainder chose not to disclose race. Regarding ethnicity, 13.3% (n=23) identified as Hispanic or Latinx. Regarding prior therapy exposure, 31.8% (n=55) of the sample reported previously attending therapy.

Ethics Approval

All study materials and procedures were approved by Rutgers, The State University of New Jersey's Institutional Review Board (Federal Wide Assurance Identifier FWA00003913).

Analytic Strategy

We first created a negative affect composite variable using the four negative affect variables asked at both pre- and postexercise (agitated, angry, hopeless, burdensome). We then conducted two sets of multilevel models in the *lme4* R package. The first set of models was conducted to determine whether there were differences between those in therapy versus not in therapy in negative affect reported throughout the study. We conducted multilevel models with therapy status as the predictor and negative affect as the outcome. We conducted separate models for the pre-exercise ratings and the postexercise ratings, given that we were hypothesizing differences in pre-post ratings of negative affect between groups and did not want to introduce this expected difference as a confound to these analyses. The second analysis tested our primary hypothesis. We conducted another multilevel model that included a time point (ie, pre- vs postexercise rating) at the observation level, therapy status at the person level, and the cross-level interaction between the

two. We probed the simple slopes of the significant interaction using the *reghelper* package.

Results

Results of the multilevel models exploring whether those in therapy reported more negative affect than those not in therapy suggested that this was not the case. Therapy status was unassociated with both the pre-exercise ($b=-1.69$, 95% CI -3.51

to 0.13 ; $P=.07$) and postexercise ($b=-1.37$, 95% CI -3.17 to 0.43 ; $P=.14$) ratings of negative affect.

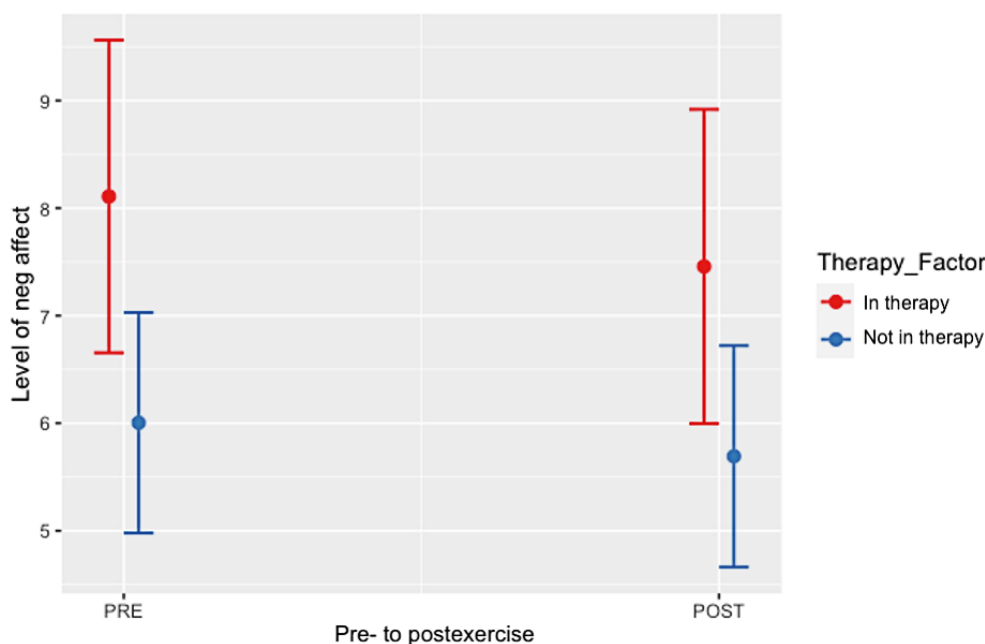
Results of the multilevel model testing our primary hypothesis showed (Table 1) that the cross-level interaction between the time point (ie, pre- vs postexercise) and therapy status was significant. When we further plotted (Figure 1) and probed the model, we found that the reduction in negative affect from pre- to postexercise was greater for those in therapy ($b=-0.65$, 95% CI -0.91 to -0.40 ; $P<.001$) than it was for those not in therapy ($b=-0.31$, 95% CI -0.43 to -0.19 ; $P<.001$).

Table 1. Results of the multilevel model predicting negative affect.

Predictors	Estimates (95% CI)	P value
(Intercept)	8.11 (6.65 to 9.56)	<.001
Pre vs post (ref=pre)	-0.65 (-0.86 to -0.44)	<.001
In therapy (ref=in therapy)	-2.10 (-3.88 to -0.33)	.02
Pre/post X therapy	0.34 (0.09 to 0.59)	.008
Random effects		
Within-person residual variance (σ^2)	16.64	N/A ^a
Between-person residual variance (τ_{00})	29.66	N/A
Intraclass correlation coefficient	0.64	N/A
N _{ID}	166	N/A
Observations, n	22,846	N/A
Marginal R^2 (conditional R^2)	0.020 (0.648)	N/A

^aN/A: not applicable.

Figure 1. Changes in negative affect from pre- to postexercise for college students in therapy versus not in therapy. neg: negative.



Discussion

Principal Findings

Mental health apps and single-session interventions show promise as solutions to the growing mental health demands of

college students. However, little has been done prior to this study to examine the effectiveness of these modes of treatment for the sizeable amount of college students who are already receiving therapy. The aim of this study was to compare the effectiveness of a brief workshop with a supplemental mobile app between college students who were concurrently attending

therapy and students who were not. We found that both college students who had prior exposure to therapy and those who did not reported significant reductions in negative affect over the 8-week period. These reductions are in line with the results of prior studies examining digital mental health interventions in college students, which have found such interventions to be effective in reducing depression, anxiety, and stress for students seeking services at college counseling centers [17,18]. Those who did have exposure to therapy reported a greater reduction in negative affect in the 8 weeks following the workshop than students who were not currently in therapy. Additionally, there were no between-group differences in the level of negative affect across the study, suggesting that the greater reduction in negative affect that college students in therapy experienced cannot be explained by having a higher average level of negative affect.

One explanation for these findings is that students who have exposure to therapy are familiar with thinking about and addressing uncomfortable and sometimes distressing feelings while receiving treatment. Since some of the skills taught in the workshop may cause distress (eg, reflecting on negative thoughts while addressing cognitive distortions), college students with prior exposure to therapy may have been better equipped to handle this distress, allowing them to benefit more. Since we did not measure familiarity with therapy in this study, we are not able to examine if it is responsible for this difference. Future studies could assess familiarity with therapy to college students before they begin treatment to see if socialization to therapy is a mechanism of action. If it is a mechanism of action, future iterations of E-Manage and other mental health apps or single-session interventions could consider adding psychoeducation on what to expect in therapy at the beginning of the program to improve outcomes for students not attending therapy.

Additionally, college students with prior therapy exposure may have been previously exposed to the specific skills provided in this treatment. The skills taught in the E-Manage workshop and mobile app were based off the Unified Protocol, a form of therapy that combines elements of cognitive therapy, behavioral therapy, and mindfulness to help clients improve their ability to regulate distressing emotions [23]. Given the prevalence of cognitive behavioral therapy and mindfulness elements in therapy [24,25], it is highly possible that the prior therapy students received introduced them to the therapeutic content we provided. This familiarity could have led students with prior therapy exposure to be more receptive and engaged. We did not evaluate the content of the therapies students in this study were receiving. This makes us unable to determine if students in therapy learned skills similar to those they learned in the workshop/app, and thus if they were truly socialized to these skills prior to their participation in this study.

Limitations

There are some additional limitations and future directions to consider when interpreting the findings of this study. First, due

to lacking a therapy-only control group, we are unable to determine to what extent the reductions in negative affect that therapy-attending college students experienced were due to receiving E-Manage rather than changes resulting from receiving additional therapy. A randomized controlled trial comparing reductions in negative affect for students in therapy versus those in therapy with the workshop and app is still necessary to resolve this question. We are also unable to assess if E-Manage was able to lessen the time college students attending therapy needed to spend in treatment. This could also be addressed in a future randomized controlled trial comparing students attending therapy and receiving E-Manage with college students only attending therapy.

Additionally, several studies have noted ongoing concerns over the lack of fidelity monitoring and quality assurance when implementing mobile treatments into clinical settings, potentially hampering the scalability of these treatments post study [26,27]. While such measures were not the focus of this study, future work on E-Manage should focus on examining the treatment's fidelity to the Unified Protocol when being delivered by college counselors to ensure the scalability of E-Manage. Finally, because we did not recruit from a clinical population, participants in the study likely had a range of symptom severity. Future studies will be needed to determine the effectiveness of E-Manage for different levels of symptom severity in college students.

Conclusions

These findings suggest that brief single-session interventions and apps like E-Manage may be appropriate to use for college students receiving therapy as well as those not receiving therapy. This suggests that programs like E-Manage could be useful as a broader prevention framework in the college community. As more college students attend therapy prior to their freshman year [11], some students may have to terminate with their current therapist to relocate to their college, resulting in a gap in their mental health treatment. Due to its ease of dissemination, one practical application for brief technology-based treatments like E-Manage could be implementing them in programs for incoming freshmen, helping to bridge the gap for these students as they transition into college and locate new therapists. Another practical application for E-Manage, given the reductions in negative affect for students in therapy, could be to serve as a treatment adjunct in college counseling centers. It is possible that giving students in counseling centers access to programs like E-Manage could lead to more substantial gains during traditional treatment in a shorter period of time, improving counseling center's ability to provide individual therapy services to other students. Integrating mental health apps and single-session interventions like E-Manage into routine care in counseling centers could ultimately lead to meaningful reductions in the burden placed on counseling centers.

Conflicts of Interest

None declared.

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Review

Human-Centered Design Approaches in Digital Mental Health Interventions: Exploratory Mapping Review

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Abstract

Background: Digital mental health interventions have a great potential to alleviate mental illness and increase access to care. However, these technologies face significant challenges, especially in terms of user engagement and adoption. It has been suggested that this issue stems from a lack of user perspective in the development process; accordingly, several human-centered design approaches have been developed over the years to consider this important aspect. Yet, few human-centered design approaches to digital solutions exist in the field of mental health, and rarely are end users involved in their development.

Objective: The main objective of this literature review is to understand how human-centered design is considered in e-mental health intervention research.

Methods: An exploratory mapping review was conducted of mental health journals with the explicit scope of covering e-mental health technology. The human-centered design approaches reported and the core elements of design activity (ie, object, context, design process, and actors involved) were examined among the eligible studies.

Results: A total of 30 studies met the inclusion criteria, of which 22 mentioned using human-centered design approaches or specific design methods in the development of an e-mental health solution. Reported approaches were classified as participatory design (11/27, 41%), codesign (6/27, 22%), user-centered design (5/27, 19%), or a specific design method (5/27, 19%). Just over half (15/27, 56%) of the approaches mentioned were supported by references. End users were involved in each study to some extent but not necessarily in designing. About 27% (8/30) of all the included studies explicitly mentioned the presence of designers on their team.

Conclusions: Our results show that some attempts have indeed been made to integrate human-centered design approaches into digital mental health technology development. However, these attempts rely very little on designers and design research. Researchers from other domains and technology developers would be wise to learn the underpinnings of human-centered design methods before selecting one over another. Inviting designers for assistance when implementing a particular approach would also be beneficial. To further motivate interest in and use of human-centered design principles in the world of e-mental health, we make nine suggestions for better reporting of human-centered design approaches in future research.

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KEYWORDS

design; human-centered design; user experience; mental health; digital mental health

Introduction

Background

E-mental health research is expanding around the world [1]. This area of mental health research and intervention relies on digital technologies to deliver complementary care, support, and information [2]. Over the past ten years, digital mental health interventions have appeared at an unprecedented rate, largely in the form of mobile apps, social media, chatbots, and virtual reality [3]. Since the beginning of the COVID-19 pandemic, the digital health world has expanded at an unprecedented rate [4], and its potential to improve access to care has never been greater [5]. However, some important challenges remain in the field. Several issues raised in recent years have not been resolved: there is some distrust in the field that is not served by the lack of empirical validation of its benefit [6-9]; it raises privacy and data security concerns [9,10]; it presents commercial issues (eg, financial interest, user access, advertising) [11,12]; and the solutions often lack usability and show low user engagement [13,14].

The Problem of Adoption

The promise of digital technology still far outweighs the reality of its use. This is particularly evident in the field of digital mental health, in which designs must survive successive waves of adoption: phases of preuse, first use, and sustained use [15]. A study of 93 mobile mental health apps showed that the overall user retention is very low, with a 15-day retention rate of 3.9% and a 30-day retention rate of 3.3% [16]. Another study with 77 participants in two randomized controlled trials demonstrated how difficult it is to motivate people to begin using an e-mental health solution [17]. Any digital health trial will see a significant proportion of users drop out or cease using the app before completion. Eysenbach [18] calls this phenomenon “the law of attrition.” Data on the health app market are scarce but do converge on two findings: the majority of health apps are downloaded fewer than 5,000 times, and 46% of apps have less than one monthly active user [19]. While usage is only one indicator of engagement [20], these statistics are consistent with adoption issues commonly reported among users, such as a lack of awareness of the app or lack of time and motivation to use one [21,22]. This is concerning because the use of these apps may not be associated with a significant decrease in mental disorders if they are not used for the intended period of time [14]. The average cost of developing a mobile health app is US \$425,000 [19]—a cost-benefit ratio too high and unsustainable in the long run if we do not change how they are developed.

Lack of Attention to User Perspectives During the Design Process

Research has shown that most people are willing to adopt and use some form of new technology in the interest of improving their mental health [23]. So why the low utilization rates? Given the already significant barriers to adoption that users face (eg, privacy concerns, commercial issues), we seek to underscore the importance of user-centric design approaches for the development of e-mental health solutions, of which a solid notion is lacking in the digital mental health design sphere [14]. Based on the existing literature [13], we hypothesize that the

lack of adoption of digital mental health solutions could be largely due to a lack of attention to user perspective in the design of these technologies, or at the very least, a lack of understanding of design approaches that accommodate user perspectives. In the field of mental health, there are very few examples of involving real people with mental disorders in the development and design of mobile apps intended for them [14]. The most common development approaches seem primarily researcher- and expert-driven, top-down in style, and to rely mainly on a bilateral partnership between clinicians and engineers [24]. This is not adapted to the challenges of contemporary digital culture that places the user at the center of these platforms by empowering them [25].

Design Principles and Human-Centered Design Approaches

In this section, we recall some fundamental principles of design culture and explain how they can help actors better account for the needs of users and integrate their perspective early on in the e-mental health design process.

Designers and Engineers

According to Cumulus [26], an international association of art and design education and research, a designer is someone who has acquired professional design expertise at a “design school.” For instance, Jony Ive, former chief design officer at Apple, is an industrial designer who graduated from the Northumbria School of Design in the United Kingdom. Although engineers might be considered designers (according to the broad sense of the word “design” in English), design and engineering are two separate fields that correspond to two different professions, methods, and cultures. Nevertheless, they share some similarities; for instance, both interaction designers and software engineers follow an iterative process [27].

However, design must not be confused with engineering design, as differences in the way engineers and designers tackle the design of a technology are well documented [28]. In the initial prototyping phases, engineers seek to define specific goals to be achieved and, following a linear way of thinking, focus on technical functioning. Designers, on the other hand, use prototypes to creatively explore the design space for novel possibilities [29]. In health care, designers tend to focus attention on unmet needs and ways to improve care and are sensitive to how care is received through user-centered practices [30]. In this paper, we use the term “human-centered design” to distinguish the field of design from engineering, and when we say “design,” we mean human-centered design.

Core Elements of Design Activity: Actor, Object, Context, Process

It is generally admitted in the field of design studies that the core elements of design activity are the following: (1) a design problem and its coevolving design solution are its *objects*; (2) the environment in which design activity takes place is the design *context*; (3) the structure and dynamics of design activity are the *process*; and (4) a designer (person, team, organization) is an *actor* [31-33]. To be clear, let us consider the example of Temstem, an app developed in the Netherlands based on language games intended to help people experiencing psychosis

distract themselves from voices they hear in their minds [34]. Temstem was co-designed by a group of designers, psychotherapists, and people living with psychosis—all of whom constitute *actors* (4). In collaboration with Parnassia Group, a private nonprofit mental health institution, a group of industrial design students from the Delft University of Technology spent a day in the life of people with psychosis. This led to a solution fully designed by the Amsterdam-based Reframing Studio design firm—all of which constitute the *context* (2). Design students were asked to come up with a product that would promote the recovery of psychosis—which constitutes the “problem” aspect of the *object*—and this product turned into an app called Temstem (“tame voices” in Dutch) to help people cope with “hearing voices”—constituting the “solution” aspect of the *object* (1). The main methods used to imagine and build this solution were co-design, user experience design, interaction design, game design, and ethnographic approach — the core components of the *process* (3).

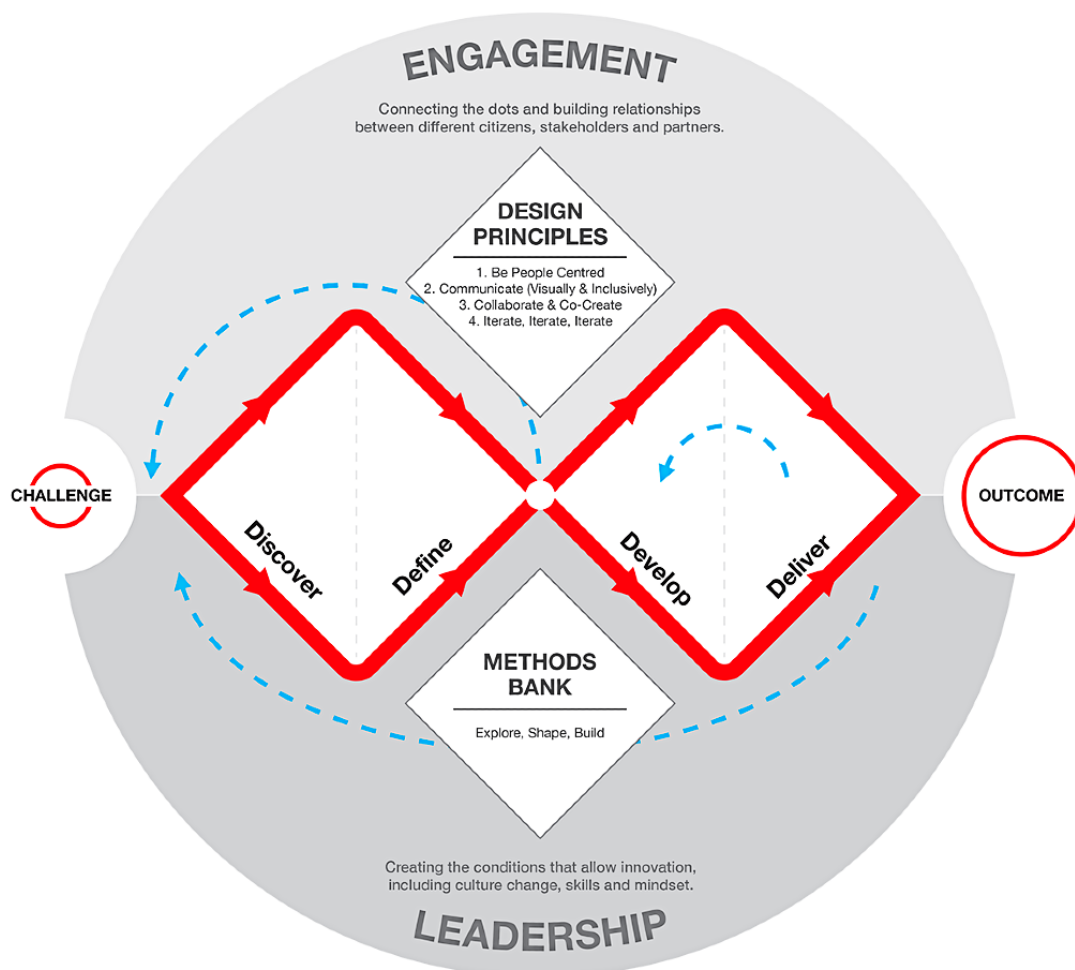
Typical Process of a Design Activity

Design research is a relatively young field that appeared in the 1960s and is represented today by the International Association of Societies of Design Research [35]. Since its inception, this

field has focused on the study of the design process [31]. The design process has also been the subject of research outside of academia to help the profession structure its methods. In 2005, the Design Council in the United Kingdom published the first version of its Double Diamond model, which was updated in 2019 and renamed the Framework for Innovation [36]. This internationally recognized model proposes a schematic representation of the typical process of any human-centered design activity (Figure 1).

The framework comprises 4 steps: (1) *discover* (ie, gather information, understand the problem, make sense of them, and broaden the possibilities); (2) *define* (ie, narrow down the possible paths and define the main challenge); (3) *develop* (ie, give different answers to the clearly defined problem and push further the most promising solution, mostly by prototyping); and (4) *deliver* (ie, test and refine different versions of the solution at different scales). Each step is associated with specific and relevant methods. For instance, the design methods for step 1 include user diaries and quantitative surveys, whereas the design methods for step 2 employ techniques such as focus groups and customer journey mapping. The value of the Double Diamond is that it captures what all human-centered design approaches have in common from the perspective of the *process*.

Figure 1. Framework for Innovation (used with permission from Design Council 2019).



Human-Centered Design Approaches

There are several human-centered design approaches that allow end users to significantly and positively impact the design of technologies. The most used are user-centered design, user experience design, design thinking, participatory design, and co-design. These design methods stem from industry practice rather than academia and are very advanced there. They are used by design agencies, communications agencies, and large technological companies. These methods are historically derived from the disciplines of industrial and graphic design and from the evolution of the latter in contact with digital technologies [37]. Supported by the works of influential authors in design studies, we present how the five differ from each other and for what purpose each is generally used.

User-centered design, also called human-centered design, was defined in the late 1980s by Don Norman in his book *The Design of Everyday Things* [38]. It is used to design products that are readily usable and immediately understandable thanks to the observance of certain design principles, such as the salience of affordances (ie, when the user understands what to do just by looking). Enriched by the work of J Nielsen on web usability [39] and JJ Garrett on user experience [40], user-centered design has become the standard for best practices in web design. Garrett defines it as “the practice of creating engaging and effective user experiences,” which involves considering the user at every stage of product development [40]. User-centered design is the fundamental basis of many current practices in modern industrial design, UX design, and interaction design. It is used to gain the best possible knowledge of end users’ needs and desires and to transform this knowledge into the best possible design of a product through usability testing. User-centered design should be used to validate the product’s utility, efficiency, and desirability.

User experience design, also known as UX design, is about optimizing the experience that arises from interacting with a product, service, or technology [41]. User experience is defined as “the experience that the product creates for the people who use it in the real world,” meaning not its internal workings but “the way it works externally, where a person comes into contact with it” [40]. In the case of an app, it is the cognitive and emotional experience that the user has in front of the screen. In the field of digital technologies, the expression “UX design” has now largely replaced “user-centered design.” UX design should be used to create meaningful interfaces and engaging interactive experiences: it will make it more useful, more attractive, and more engaging for the end user.

Design thinking as a human-centered method has been widely theorized, practiced, and popularized by the IDEO design agency and its founders. It can be defined as “a creative method of innovation, based on design-like culture and designer-like methods, whose main focus is on the needs of its end users,” and it has three dimensions: the desirability, feasibility, and viability of the future product or service [42]. There are important similarities between user-centered design and design thinking approaches—two terms that appeared around the same time—mainly the central place given to empathy and listening to the user's needs. Design thinking is recognized worldwide

for its ability to foster the emergence of user-centered innovative solutions through cocreation, including in the field of health care [43]. It is generally used to implement transformations inside an organization, stimulate creativity within a team, or devise new solutions in a specific sector. Design thinking should be used to drive innovation in an organization or a team to make them more creative and empathetic with end users and to build better products and technologies.

Participatory design was first defined in Norway and Sweden in the 1970s and 1980s by Kristen Nygaard and Pelle Ehn, respectively. Its original objective was to involve users in every stage of the design and development process of a complex computer system by using low-tech mediation techniques that are easy to handle by nonexperts (colored notes hung on the wall, cardboard mock-ups, decks of design cards) [44]. Participatory design is used to involve users in design activities such as ideation or prototyping. The approach is often implemented partially or even incorrectly, typically reduced to inviting end users to participate during the beginning of the process for research needs or at the end for usability testing [45,46]. Gathering feedback from users via usability testing is not a form of participatory design since users are not involved in the actual designing act of the design process.

Co-design is often used as a synonym for “participatory design.” However, the term actually refers to a specific form of participatory design that is much closer to cocreation. Co-design refers to the creativity of designers and people not trained in design combined during the design development process. It is “collective creativity as it is applied across the whole span of a design process” [47]. It is a truly participatory approach in which the user is engaged from the start as an equal partner and has been widely recognized as a lever for social innovation [48].

Participatory design and co-design are generally used to better consider the needs and desires of users in the design of a product and to make the design process less top-down and more democratic. These two approaches aid in developing an idea early that is in line with users' realities and to engage them in the product before it even exists. Co-design, in particular, should be used when the team is faced with a complex problem and seeks to improve and evolve its initial idea, provided that it accepts that the participants can transform this idea in a meaningful way.

All these human-centered design approaches must become more familiar, better understood, and more widely implemented in the field of mental health in general and e-mental health in particular.

Objective and Research Questions

The main objective of this literature review was to understand how human-centered design is considered in e-mental health intervention research. The following research questions were considered:

1. Which human-centered design approaches are reported in the development of e-mental health interventions?
2. How are these approaches used in light of the generally accepted core elements of a design activity?

3. How are designers involved in the process and what roles are they given?

Through our efforts, we seek to open the discussion on the place of human-centered design methods in e-mental health research.

Methods

Study Design

To answer the 3 questions, an exploratory mapping review was conducted by researchers from the fields of design and mental health. The aim of mapping reviews is to map out and categorize existing literature on a particular topic to identify gaps in knowledge or opportunities for further research [49]. It focuses less on findings and more on activities related to the findings, such as the quantity and quality of the literature [49,50]. To streamline the process and identify a relevant sample of articles for this interdisciplinary exploratory review, a search was conducted among journals in mental health whose explicit scope covers technology. The following journals were identified: *JMIR Mental Health*, *Frontiers in Psychiatry*, *Internet Interventions*, and the *Journal of Technology in Behavioral Science*. Articles published between 2015 and 2020 were examined using the search terms “design” and “design*” to narrow down the results.

Given the interdisciplinary nature of this work, extensive discussions were conducted among the coauthors to agree on a common understanding of the concept of design. The following inclusion criteria were defined: articles reporting original research on the development of a digital technology in mental health and those addressing the concept of design (at least one explicit use of the term design) in connection with at least one core element of a design activity.

The use of the term “design” in research (eg, “study design”) or in its common sense was excluded.

Study Selection

The third author (MD) screened all titles and abstracts for potential articles. Then, the second (SB) and third (MD) authors independently assessed the full text of the articles for eligibility. There was an initial level of agreement of 80.7% (42/52) between the two authors (SB and MD), which is usually considered acceptable in the literature [51]. When there was discrepancy, the first author (SV) made the final decision.

Data Extraction and Analysis

For each article selected, data regarding the design approaches and the four core elements of a design activity (ie, the object, the context, the actor, and the process) were extracted. This included the type of solution created, the design approaches reported, the setting in which the project took place, and the type of actors involved throughout the design process. The design process was examined according to the steps defined in the UK Design Council’s framework for innovation [36]. The design methods reported in the articles were used to define the

steps addressed in the development of the digital solutions. The analysis process was conducted jointly by the second (SB) and third (MD) authors.

Results

Overview

Of the 1035 articles initially found, 51 full-text articles were assessed for eligibility. Of these, 30 studies met the inclusion criteria. The articles came from *JMIR Mental Health* (22/30, 73%), *Frontiers in Psychiatry* (4/30, 13%), *Internet Interventions* (2/20, 7%), and the *Journal of Technology in Behavioral Science* (2/30, 7%). [Multimedia Appendix 1](#) presents the characteristics of the included studies, indicated from left to right: the specific research domain (eg, depression and anxiety, psychosis, well-being, etc), the synthesized naming of the adopted approach, and the 4 core elements of a design activity (object, context, process, and actors). Process is presented according to the 4 steps in the Double Diamond (coding each actor type with a number across the steps). Finally, we reported whether the study indicated that the process was iterative or not.

Design Approaches

To develop the digital solutions, 22 studies mentioned using human-centered design approaches or specific design methods. Various design approaches were reported, and there were many variations in the names given to these approaches. After several rounds of discussions between all authors, different approaches were classified under the 3 common names used in design studies, as listed in [Table 1](#): participatory design (11/27, 41%), co-design (6/27, 22%), and user-centered design (5/27, 19%). Under the term “participatory design,” generally named as such in the studies, we considered alternative names such as “user involvement” [52]. Under the term “user-centered design,” we included other names like “person-based approach” or “person-centered approach.” Other studies reported specific design methods (5/27, 19%) that did not correspond to these 3 common names. Those methods are not common in the design studies field, except for the UK Design Council’s Double Diamond method. Among the studies included in this review, 8 (27%) did not refer to any human-centered design approach, so they are not listed in [Table 1](#) [53-60]. Five studies reported more than one approach, mixing 2 common approaches or 1 common approach with 1 specific design method, and these studies are demarcated with a superscript in [Table 1](#). Only 16 studies provided a definition of the reported approach(es), either by referring to other studies (15/16, 94%) or by offering their own definition (1/16, 6%). This means that about half (14/30, 47%) of the studies did not cite or provide a definition for their chosen approach, include references, or mention the theoretical underpinnings of the design approach. Although it was the second most reported approach, co-design was never defined in the 6 studies that mentioned it.

Table 1. Classification of the reported approaches.

Reported approaches	Authors	Reported definition
Participatory design approach		
Participatory design	Peters et al [61]	Yes
Participatory design (explore, approximate, refine framework)	Buitenweg et al [62]	Yes
Participatory design thinking and methods	Terp et al [63]	Yes
Participatory design (using research and development cycle)	Ospina-Pinillos et al [64]	Yes
User-involvement processes	Buus et al [52]	Yes
Participatory design process	Cheng et al [65]	Yes
Participatory design approach	Reupert et al [66]	Yes
Participatory design methods	Gulliver et al [67]	Not reported
Participatory design	Werner-Seidler et al [68]	Not reported
Participatory design process	Peck et al [69]	Not reported
Participatory design	Povey et al [70] ^a	Not reported
Co-design approach		
Co-design approach	Yoo et al [71] ^a	Not reported
Iterative co-design process	Christie et al [72]	Not reported
Co-design process	Povey et al [70] ^a	Not reported
Co-design	Torous et al [73]	Not reported
Co-design	Bevan Jones et al [74] ^a	Not reported
Human-centered co-design	Hetrick et al [75] ^a	Not reported
User-centered approach		
User-centered approach	Honary et al [76]	Yes
(Aligned with) person-based approach	Abraham et al [77]	Yes
User-centered approach	Stawarz et al [78]	Yes
Person-based/person-centered approach; user-centered approach	Bevan Jones et al [74] ^a	Yes
User-centered design research	Hardy et al [79] ^a	Not reported
Specific design methods		
Design research framework	Terlouw et al [80]	Yes
Iterative approach informed by the ADDIE ^b framework	Khan et al [81]	Yes
UK Design Council's Double Diamond method	Hardy et al [79] ^a	Not reported
Agile design development/design studio methodology	Hetrick et al [75] ^a	Yes
Needs-affordances analysis framework	Yoo et al [71] ^a	Yes

^aAuthors who reported using more than one approach.

^bADDIE: Analyze, Design, Develop, Implement, and Evaluate.

Core Elements of the Design Activity

Object (Solution)

The digital technologies developed were mobile apps (15/30, 50%), web platforms (10/30, 33%), desktop apps (2/30, 7%), virtual reality (1/30, 3%), a serious game (1/30, 3%), and a digital comic creator (1/30, 3%). The solutions were most often used for applications related to anxiety and depression (8/30,

27%), well-being (5/30, 17%), access to and quality of care (5/30, 17%), and psychosis (4/30, 13%).

Context

Most (23/30, 77%) design activities were conducted exclusively in academic environments. Some studies (5/30, 17%) mentioned a collaboration with a private company. Two studies reported either a collaboration with community organizations (1/30, 3%) or public mental health services (1/30, 3%). The collaborative

work took place within projects using participatory design (3/11, 27%), co-design (3/6, 50%), or no identifiable approach (1/8, 13%).

Process

About two-thirds of the projects adopted an iterative process (21/30, 70%). Most of the studies (27/30, 90%) described methods including at least 3 out of the 4 steps of the Double Diamond framework. As one might expect, the studies that covered fewer steps were those not reporting any identified design approach. For 10 studies (indicated by superscript 'a' in [Multimedia Appendix 1](#)), the *discover* and *define* steps were not clearly differentiated. The most often missing step was *deliver*, which was planned but not carried out in 8 of the studies (at the time these papers were published).

Table 2. Distribution of the explicitly mentioned actors.

Actors	Explicitly mentioned in the 30 studies, n (%)
Designers	8 (27)
Software development company	14 (47)
Experts (including health professionals, consultants)	8 (27)
End users	30 (100)
Community of interest	1 (3)

Involvement of Designers

Although the 30 studies selected addressed the concept of design and reported a variety of human-centered design approaches, very few explicitly mentioned the presence of designers on their teams. Regardless of the step of the process, only 8 studies mentioned designers, representing about 27% of all included studies. For the 22 studies that did not mention them (74%), we do not know whether it is because no designer was involved or because the presence of designers was not considered important enough to be reported.

Looking at the few studies mentioning designers in their teams (8/30, 27%), it is interesting to note that some designers were

Actors

All 30 studies mentioned that end users were involved at some point in the process, but not necessarily in the act of designing ([Table 2](#)). Designers were explicitly mentioned in only 8 studies, whereas software development companies were mentioned in 14. We know from experience that software companies include few UX designers on their teams in proportion to the number of software engineers (eg, even in a small team of 5 software engineers, we can find at best 1 UX designer). However, there were no details about this in the 14 studies. A few studies reported involving other actors such as experts (consultants, health professionals; 8/30, 27%) and various stakeholders (eg, advocates, philanthropists; 1/30, 3%).

explicitly present for all steps but mostly just the first three: *discover* (4/8, 50%), *define* (3/8, 38%), and *develop* (7/8, 88%). Only 1 was explicitly present for *deliver*. It is also interesting to note that 3 of the 4 studies that included designers in the *discover* step also included them in the *define* and *develop* steps, reflecting their ongoing involvement in the process. These 3 studies represented a small proportion of the studies that reported using participatory design and co-design. Overall, designers were clearly more involved in the *develop* step (7/30, 23%) but much less involved here than software development companies ([Table 3](#)). The latter were exclusively present in this step (14/30, 47%). End users were the most present participants at each step of the design process ([Table 3](#)).

Table 3. Distribution of the explicitly mentioned actors according to the 4 steps of the Double Diamond (discover: n=27; define: n=27; develop: n=30; deliver: n=17).

Actors	Steps			
	Discover, n (%)	Define, n (%)	Develop, n (%)	Deliver, n (%)
Designers	4 (15)	3 (11)	7 (23)	1 (6)
Software development company	0 (0)	0 (0)	14 (47)	0 (0)
Experts (including health professionals, consultants)	3 (11)	5 (19)	5 (17)	1 (6)
End users	24 (89)	26 (96)	21 (70)	15 (88)
Community of interest	0 (0)	0 (0)	1 (3)	1 (6)

Discussion

Principal Results

In this initial exploratory research study, we investigated how design is considered in e-mental health research. Our results show that there have been attempts to integrate human-centered

design methods into the development of e-mental health solutions, but they are still rare and rely very little on designers or design research. Most reported design approaches such as user-centered design, participatory design, and co-design are well known and documented in the design research literature, but most of the included studies did not rely on them. Almost half of the included studies did not bring or report any existing

definition of the design approach they used. Moreover, it was not possible to link the use of an approach to its influence on the main core elements (steps conducted through the process or actors involved) and vice versa. The impact of each chosen approach on the whole process is not clear, nor is the reason behind the selection of a particular approach. This indicates that there is a lack of shareable knowledge on how design approaches are understood, and by extension, applied in the mental health field. This suggests that human-centered design methods are not fully integrated in e-mental health and that reported design approaches are still primarily used from the outside without a deep understanding of the design culture that is needed to fully leverage their power.

Comparison With Earlier Work

There has been very little research conducted on human-centered design methods in e-mental health and on how to guide the design of e-mental interventions. Thabrew et al [82] highlight the importance of active collaboration using co-design jointly between researchers, designers, developers, and users to develop more engaging and useful interventions. The results from this literature review show that such collaboration among all these stakeholders remains limited throughout the design process. While most design approaches reported were consistent with human-centered methods stemming from the design discipline, the choice and combination of the approaches varied greatly across studies. Orlowski et al [83] claim that the e-mental health development process must prioritize empathy and understanding over innovation, as proposed in participatory design and design thinking approaches. Torous et al [14] highlight the poor usability of mental health apps and the lack of user-centric design. Aryana et al [84] attempt to identify the key principles of the design process relevant to mobile mental health. Among the 6 principles identified, they mention “high quality user experience,” which is closely related to user-centered design, and an “empathic design process,” which is closely related to participatory design and co-design, and conclude that there are few examples of the implementation of several of these design principles in real-world products. This was also the case for the identified research projects. Bakker et al [85] note that design principles that have led to the huge success of many physical health and social networking apps have not been utilized in the mental health apps field. These findings are all consistent with our study and show that human-centered design methods are largely underutilized and neglected when their impact could be very important, especially on user engagement.

Limitations

This exploratory review offers significant insights into how design is considered in e-mental health. We consider it to show a fairly representative sample of the type of design-related

research currently being conducted on the development of digital technology in mental health. We do not think that additional studies would significantly change our main conclusions. However, this study does not meet the criteria for a systematic review and has a few limitations. First, when analyzing the core elements of design activity, we could only rely on the information reported in the articles, which was fairly heterogeneous. We had to conduct several rounds of interdisciplinary discussions among ourselves (the authors) to ensure its best interpretation. Second, to analyze the design process described in each study, we chose the Double Diamond framework, which is a global reference, but other frameworks could also be used and might yield additional results. Third, in all the studies selected, it was difficult to understand how end users influenced the design, especially in participatory approaches. User involvement can be informative, consultative, or fully collaborative [86]. Orlowski et al [46] have already concluded that it is difficult to track ongoing user participation and clearly determine the contribution of participatory design to the effectiveness of designed interventions.

Research Implications

Good Design Comes Before Effective Science

Health technologies are useless if they are not used, even if they are validated by science. We urge health researchers and technology developers in e-mental health to consider human-centered design methods not as the form-giving step of a technology development process but as a comprehensive approach integrated at an early stage in close relation to the research strategy and vision. Researchers and technology developers in e-mental health should consider systematically hiring interaction designers, user interface designers, user experience designers, and service designers in their teams to fully implement the human-centered design approach they need and then increase user engagement and technology acceptance. They should also include co-design workshops with end users conducted by trained designers from the beginning to the end of the development process. Design comes before science, which means that in the realm of apps, good design is a prerequisite for effective science.

Suggested Recommendations for Better Reporting of Human-Centered Design Approaches

This study suggests that researchers in e-mental health may not understand or value design principles enough to clearly describe them in their manuscripts. Without claiming to define a publication standard for reporting the design process and the outcomes of that process, we suggest 9 recommendations to be considered to further motivate interest in and adoption of design principles and human-centered design approaches (Textbox 1).

Textbox 1. Recommendations to motivate interest in and adoption of design principles and human-centered design approaches.

Name and definition of human-centered design approaches

1. Explicitly state which human-centered design approach was used.
2. Provide a definition or, at least, a reference for each human-centered approach.
3. Explain why a human-centered design approach is chosen (for which purpose).

Implementation of the core elements of a human-centered design activity

4. Describe each of the 4 core elements: object, context, process, and actors.
5. Clearly define the steps and the methods used in the design process. If necessary, use a framework such as the Framework for Innovation (Figure 1).
6. Explain when and to what extent actors were involved in the design process.

Involvement of designers

7. Indicate how many designers (not engineers or software developers) are involved.
8. Specify what design profession they practice (UX designer, interaction designer, service designer, design researcher, etc).
9. Indicate if the designers contribute on their own behalf or if they are employed by software development companies.

Future Work

Bridging the gap between design and e-mental health is our next research agenda. We are currently developing a health intervention research framework called Design For e-Mental

Health [87]. This framework refers to the broad range of human-centered design creative strategies that define the structure, function, and form of a digital mental health with a high quality of experience in terms of user experience, scientific validity, privacy, and viability.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Classification of the included studies.

[DOCX File, 24 KB - [mental_v9i6e35591_app1.docx](#)]

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Letter to the Editor

Urgency for Digital Technologies to Support Caregivers. Comment on “Telehealth-Based Psychoeducation for Caregivers: The Family Intervention in Recent-Onset Schizophrenia Treatment Study”

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schizophrenia; family psychoeducation; caregiver burden; recent-onset schizophrenia; telehealth

I read with great interest the article “Telehealth-Based Psychoeducation for Caregivers: The Family Intervention in Recent-Onset Schizophrenia Treatment Study” by Mueser et al [1].

First, I would like to congratulate the authors for raising awareness of telehealth-based psychoeducation for informal caregivers of people with mental illness. The results of their study present important understandings and hope for continued progress in the web-based delivery of valuable family interventions within the field of psychiatry. Although this study did not show the family psychoeducation intervention to be advantageous at the level of exposure reached, explorations of future caregiver-focused, telehealth-based interventions in mental health are still needed.

As we look toward future development in working with families and informal caregivers of people with mental illness, digital innovations, applications, and advancements in web-based interventions [2] suggest the importance of supporting more research, strategies, and exploration of sufficient and continuous caregiver engagement and involvement. Such approaches are critically desired and have the potential to engage more informal caregivers and families in a cost- and time-effective manner, offer prospects for online social networking, and provide more elasticity in informal caregiver decisions of where, when, and

how they choose to be involved with the intervention or application. Additionally, such innovations could make mental health resource allocation less challenging.

Compared to patient groups, telehealth-based interventions with family groups have been limited [3] despite the extensive existing quality research on family engagement and the effectiveness of family interventions in mental health services [4]. The findings of Mueser et al [1] imply that digital technology and engagement strategies can be used successfully to meet the needs of informal caregivers and families for psychoeducation and network support throughout a considerable geographical area and, therefore, have the potential to fill a significant gap in delivering high-quality interventions and support to informal caregivers of people with mental illness [5].

In light of accelerating digital interventions within the field of psychiatry, I call on the research community to also draw more attention to the potential of telehealth-based psychoeducation for informal caregivers of people with mental illness. With the expected growth in the caregiver population coupled with significant caregiver needs and demands for help and support, notwithstanding those who are unable to join or have no access to these mental health services or best practices, taking advantage of the future potential of digital technologies and interventions for caregivers is inevitable.

Conflicts of Interest

None declared.

Editorial Notice: The corresponding author of “Telehealth-Based Psychoeducation for Caregivers: The Family Intervention in Recent-Onset Schizophrenia Treatment Study” declined to respond to this letter as they agreed with the comment of the author of the Letter to the Editor.

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Original Paper

Impact of a Long Lockdown on Mental Health and the Role of Media Use: Web-Based Survey Study

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Abstract

Background: Due to the COVID-19 pandemic, the Czech population experienced a second lockdown lasting for about half a year, restricting free movement and imposing social isolation. However, it is not known whether the impact of this long lockdown resulted in habituation to the adverse situation or in the traumatization of the Czech population, and whether the media and specific media use contributed to these effects.

Objective: The aim of this study was to elucidate the effect of the long lockdown on the mental health of the Czech population, and the role of exposure to COVID-19 news reports and specific forms of media news use in mental health.

Methods: We conducted two consecutive surveys in the early (November 2020) and late (March/April 2021) phases of the nationwide lockdown on the same nationally representative group of Czech adults (N=1777) participating in a longitudinal panel study.

Results: Our findings showed that the self-reported symptoms of anxiety and depression increased in the second observation period, confirming the negative effect of the pandemic lockdown as it unfolded, suggesting that restrictive measures and continuous exposure to a collective stressor did not result in the strengthening of resilience but rather in ongoing traumatization. The results also suggest a negative role of the media's coverage of the COVID-19 pandemic in mental health during the early, and particularly late, phases of the lockdown. Furthermore, we found several risk and protective factors of specific media news use. The media practice in news consumption connected to social media use was the strongest predictor of exacerbated mental health symptoms, particularly in the late phase of the lockdown. Moreover, news media use characterized by internalization of information learned from the news, as well as negative attitudes toward media news, were associated with higher levels of anxiety and depression. Conversely, the use of infotainment, together with an in-depth and contextual style of reading news articles, were related to improvement of mental health.

Conclusions: Our study showed that the long lockdown resulted in traumatization rather than habituation, and in more pronounced effects (both negative and positive) of media use in mental health.

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KEYWORDS

mental health; COVID-19; lockdown; media use; anxiety; depression; nationally representative data; survey; longitudinal study; pandemic; social isolation; social media; psychological trauma; mental stress; media news

Introduction

The Role of Media Use During the COVID-19 Pandemic in Mental Health

As the global COVID-19 pandemic has gradually evolved since its inception early in 2020, it has been increasingly apparent that it constitutes not only an unprecedented epidemiological and medical emergency but also a major psychological, social, and political problem. Since the outbreak of the epidemic, numerous studies have examined its impact on measures of the mental health and well-being of the populations of many countries [1], including Czechia [2].

Early on, it was also recognized that perception of the pandemic and its impact on mental well-being were to a substantial extent determined by the ways the media covered the course of the epidemic [3,4]. To date, research on media use in relation to mental health has focused primarily on the exposure to traumatic news and the use of social media. Previous research established that exposure to media reporting of traumatic events such as terrorist attacks or wars exacerbates subjective measures of mental health, particularly posttraumatic stress disorder, anxiety, and depressive symptoms [5-8]. Analogous results were obtained in research examining the media effects in nonclinical populations in the context of the COVID-19 pandemic. Several studies analyzed participants' subjective measures of mental health in relation to certain aspects of their news consumption, primarily exposure to news reports or specifically to COVID-19 news reports [9-13]. Another large group of studies examined the use of social media [14-16]. Across these studies, higher frequencies of both news consumption and social media use were consistently found as factors connected to (self-reported) poorer mental health.

The inherent limitation of this body of research may be related to the fact that it examined the effects of only one or two chosen indicators of media use. Therefore, some important information on specific media effects on mental health, as well as internal relationships between particular dimensions of media behavior, may be lacking. Hence, when potentially adverse effects of media use on mental health are reduced to only one dimension of media behavior (such as the exposure to news reports), erroneous generalizations may ensue (eg, media news consumption as such is solely harmful to mental health).

In media theory, analogous limitations of the dominant quantitative approach to media research have been identified by the media repertoires approach [17]. This theory criticizes traditional media research methodology for being descriptive of only one single studied media type, thereby not being able to adequately analyze people's actual everyday practices. In contrast, the media repertoires approach aims at studying individual patterns of media use, including a composition of different media types or technologies, different content, the way they are consumed, and how these repertoires are interrelated [18]. In the context of the COVID-19 pandemic, Pahayahay et

al [19] used this approach to assess both the harms and benefits of screen media use as a coping mechanism for self-isolation. However, it is still unknown whether some forms of media news use have the potential to positively impact mental well-being or offer a possible remedy for "safer" media news use. Such an understanding is crucial in terms of developing recommendations for media coverage of a crisis and in terms of media hygiene recommendations for media users.

To address this gap, we decided to relate subjective measures of mental health to more realistic and comprehensive media news use patterns extracted from our data. Therefore, we performed a representative survey covering two periods of the pandemic lockdown, taking into account a number of indicators of media behavior, namely the total time of media news consumption, type of news content, frequency of social media use as a source of information, type of media, category of media (eg, public, commercial, antisystem), level of detail to which the news is read (eg, only headlines, full news articles), reading comments in discussions below news articles, subjective attitudes to the media, perceived stress from the media, and internalization of media news. Inspired by the media repertoires approach, we were further interested in whether there is a latent structure behind these forms of media use that would reveal interrelated practices of media news use, and whether some of them are risk or protective factors for mental health.

COVID-19 and its Media Representations as a Dynamic Stressor

At least as of late spring 2020, it became apparent that the COVID-19 pandemic represented a dynamically evolving stressor, and that the context of potential media impacts on mental health were changing over time in response to both global and locally specific patterns of pandemic development and the societal response to it. The next step in understanding the role of the media in the COVID-19 crisis was to determine whether media coverage of the COVID-19 pandemic played the same role in mental health of the population during the different phases of the pandemic to determine whether media representations of the pandemic represent a dynamic stressor. In addition, comparing associations between other specific media practices and mental health in two different phases would reveal the dynamic aspect of their negative/positive role in mental health. To the best of our knowledge, no previous research has examined the link between media news use and mental health in a longitudinal design on a representative sample. We set out to examine associations between mental health (depression, anxiety) and media use in a population-level representative survey using a longitudinal design, collecting responses in two subsequent waves from the same group of participants in Czechia.

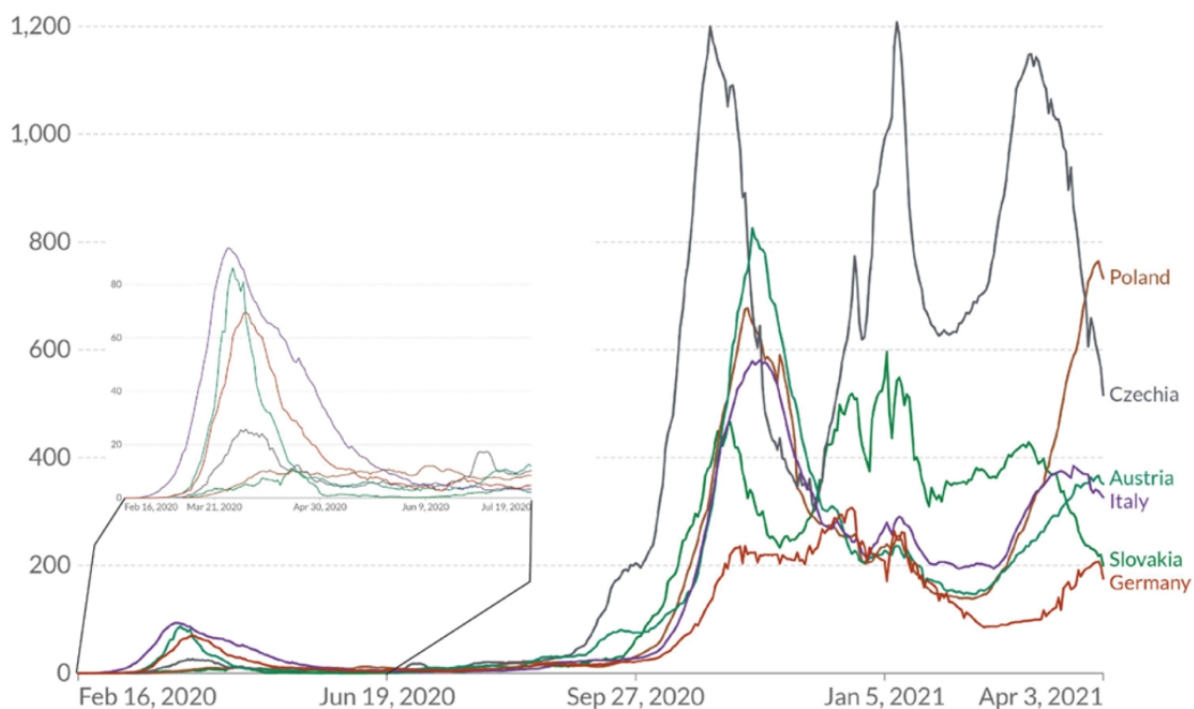
The first wave of our survey took place at the beginning of November 2020, the second week after a second nationwide lockdown was announced, imposing social isolation; restriction of free movement; and the closure of schools, restaurants, and

most shops. The lockdown was declared when Czechia became the worst affected country in the world, with the highest per capita incidence and mortality related to COVID-19 (Figure 1) [20]. The epidemiological situation deteriorated after the summer of 2020, when almost all protective measures maintained after the first nationwide lockdown in the spring of 2020 were abandoned to an extent without parallel elsewhere. Therefore, the first wave of our survey took place at the highest point of the crisis, in the week when the highest daily incidence had been reached with 15,726 newly reported cases, and the daily mortality count reached its peak with 261 reported fatalities [20]. The second wave of the survey took place at the end of March and beginning of April 2021, about 2 weeks after the peak of the third wave and roughly 5 months since the beginning of the lockdown in November 2020, with only a brief release of restrictive measures during a slight decline in the epidemic in December 2020. During the week of our second survey, the

highest daily incidence of the second wave had been reached, with 8664 newly reported cases, and the daily mortality count reached its peak with the 218 reported fatalities (Figure 1) [20]. Together, our survey covered two periods of maximal pandemic outbreak, characterized by comparable objective measures of the pandemic situation (extreme daily incidence and mortality); although the epidemiological situation was slightly more favorable in the second wave of the survey, this was not the case for the social climate and public mood.

Therefore, compared to previous longitudinal studies that examined the change in mental health between the period before and during the COVID-19 pandemic [21], or the effect of a nationwide lockdown lasting 1 or 2 months [22], the design of our study allowed us to observe the effect of a continuous 5-month-long lockdown spanning a continuing public health and social crisis.

Figure 1. Visualization of daily new confirmed COVID-19 cases per million people in Czechia. In comparison to surrounding countries (Poland, Germany, Austria, Slovakia) and Italy, Czechia was the worst affected European country at the peak of the first wave of the COVID-19 pandemic. Visualization and data retrieved from Johns Hopkins University [20].



Aims of the Research

The first aim of our study was to compare the levels of anxiety and depression of the Czech population between the early and late phases of the COVID-19 lockdown. We hypothesized that the continuing influx of traumatic news, along with the negative impact of long-term uncertainty, possible increasing frustration, and resistance toward government measures will result in an increase in self-reported symptoms of anxiety and depression. Second, we were interested in whether consumption of media

coverage of COVID-19 played a role in mental health and whether/how it changed between the two observation periods. The third aim was to specify more complex media use practices and their role in mental health in both observation periods.

Methods

Procedure

Data were collected during two phases of the nationwide pandemic lockdown in Czechia (first survey: November 2-8,

2020; second survey: March 29 to April 6, 2021). Our two surveys were completed by a representative cohort within the Czech National Panel [23] using a standardized computer-assisted web interviewing method. The mean completion time of the survey was 8 minutes 25 seconds. The survey comprised demographic data (gender, age, level of education, region of residence, and household income), standardized mental health measures, and our comprehensive Media Use Questionnaire (MUQ). Only self-reported measures were used.

Ethics Approval

The study was approved by the Ethics Committee of the National Institute of Mental Health, Czechia (project number 115/19), and all participants provided informed consent. The participation was voluntary with a financial reward within the Czech National Panel.

Participants

In the first and second waves of the survey, we obtained answers from 2214 (return rate 71%) and 2061 (return rate 67%) respondents, respectively, with 86% of the respondents in the second wave also participating in the first wave. Thus, the final study sample consisted of 1777 individuals (n=890 women,

50.08%) aged between 18 and 91 years (mean 53.06, SD 15.89 years). The distribution in educational level of the participants was 4.9% elementary school education, 26.3% certificate of apprenticeship, 37.5% high school education, and 31.3% university degree. The inclusion criteria were age above 18 years and knowledge of the Czech language.

Measures

Mental Health

The 8-item Patient Health Questionnaire Depression Scale (PHQ-8) [24] was used to measure depression severity within the past 2 weeks. The PHQ-8 score was standardly divided into five levels: no (0-4 points), mild (5-9), moderate (10-14), moderate to severe (15-19), and severe (20-24) depressive symptoms. The Generalized Anxiety Disorder questionnaire (GAD-7) [25] was used to quantify the degree of anxiety. The GAD-7 score was standardly divided into five levels: minimal (0-4), mild (5-9), moderate (10-14), and severe (15-21) anxiety symptoms.

Media Use

We developed a comprehensive Media Use Questionnaire (MUQ) mapping eight major indicators of media use within the past 2 weeks based on 33 items, as summarized in [Textbox 1](#).

Textbox 1. Main indicators of the Media Use Questionnaire (MUQ)

- *Exposure to media news*

Respondents were asked to estimate the time of daily consumption of news in the media in hours and minutes (television, radio, press, and internet, including social networks).

- *Media categories*

Thirty-six Czech media outlets with predominant news content were sorted into five categories: “public,” “mainstream,” “commercial,” “antisystem,” “information from official public sources” (such as the Ministry of Health), and “opinion online newspapers” claiming a specific political orientation. Participants indicated the frequency of use of each media category on a 5-point Likert scale ranging from “never” to “several times a day—more than two times.” These media categories were further divided into two types: *audiovisual/audio* (passive use: watching/listening) and *print/internet* (active use: reading). The frequency of their use was calculated as a mean of the summary of frequencies of the usage of each corresponding media category.

- *News content*

News was divided into several categories based on the content: politics, economics, COVID-19 pandemic, entertainment/show business, culture, sport, science and technologies, crime, transport, weather, environment, and health. Participants rated how much they were interested in each topic on a 4-point scale (from “I was not interested at all” to “I was very interested”).

- *Reading comments*

Participants were asked to rate how frequently they read online comments in discussions under web news articles on a 5-point scale from “never” to “very often.”

- *Social media as an information source*

Participants evaluated how often they use social media as a means of obtaining news information on a 5-point scale from “never” to “very often.”

- *Reading habits*

Participants rated how thoroughly they read the news reports on a 6-point scale (1: “I do not read news,” 2: “I usually read only headlines,” 3: “I usually read only headlines and first few sentences,” 4: “I usually read half of the article,” 5: “I usually read the whole article,” 6: “I usually read the whole article and I search for further information on the discussed issue”).

- *Perceived impact of media news*

(1) *Perceived stress* from the media news was evaluated using a questionnaire taken from Liu and Liu [3].

(2) *Internalization of media news* was assessed with four statements assessing whether the information one learns in the news was internalized in one’s thoughts, interactions with others, or whether it influences one’s attitudes or behavior.

Responses on both scales were rated on a 4-point scale from “strongly disagree” to “strongly agree.”

- *Attitudes to the media*

Participants were asked to rate various statements about media expressing *mistrust* (“I do not trust media”), *frustration* (“Media news usually frustrates or upsets me”), *annoyance* (“It seems that the news keeps saying the same thing over and over”), *stress avoidance* (“I do not want to be unnecessarily stressed by the news”), *lack of interest* (“I am not usually interested in the news”), *lack of concentration* (“I usually cannot concentrate on the news”), *lack of time* (“I don’t have time to watch/read/listen to the news”), *positive appreciation* (“The information I learn in the media news helps me find my way around today’s world”). The responses were rated on a 6-point scale from “strongly disagree” to “strongly agree.”

Statistical Analysis

All data were analyzed using R software [26]. The significance level was set to $P < .05$. Poststratification weighting was performed using a quadratic programming algorithm given the current population distributions of the following characteristics: gender, age, education, region and residence size, job status and description, interaction between age and education, and interaction between age and gender.

Descriptive statistics were used for demographics. As the Shapiro-Wilk test did not confirm a normal distribution, we used the nonparametric Wilcoxon signed-rank test with continuity correction to evaluate the differences in mental health and media use between the two waves of data collection. Exploratory factor analysis (EFA) was performed to reduce the

MUQ data and to show its latent structure based on interdependencies between the items. The Bartlett test of sphericity and the Kaiser-Meyer-Olkin measure of sampling adequacy indicated the suitability of our data for structure detection. Principal component analysis identified seven factors with an eigenvalue greater than 1. Direct Oblimin rotation not requiring orthogonality of the factors was used. Factor scores were computed for each observer. Confirmatory factor analysis was performed for media use data accessed from the MUQ from the second wave to confirm the first-wave EFA factors and to calculate the factor score.

Multiple linear regression models were used to reveal the relationships between media use factors and mental health. For the linear models, we used normalization of nonparametric right-skewed data by square-root transformation. Separate

models for anxiety and depression (dependent variables) in both observation periods of the pandemic lockdown were calculated and controlled for demographic characteristics (age, gender). The seven media factors extracted from EFA were further used in multiple linear regression models as predictors. Media variables that did not saturate any of the factors (COVID-19 news exposure, media news exposure, reading habits) were used in the linear models as separate explanatory variables.

Results

Mental Health

The majority of the sample reported no/minimal anxiety and depression during both waves of the survey (Table 1). The results of the Wilcoxon signed-rank test showed a significant increase in anxiety ($V=208,263$, $P=.005$) and depression ($V=256,681$, $P<.001$) levels between the two waves. Higher levels of anxiety and depression were associated with female gender and younger age in both waves. The anxiety and depression scores were highly correlated, showing a Pearson correlation coefficient of $r=0.889$ and $r=0.895$ in the first and second wave, respectively.

Table 1. Scores of the Generalized Anxiety Disorder questionnaire (GAD-7) and Patient Health Questionnaire Depression Scale (PHQ-8) in the first and second waves of the survey (N=1771).

Scale	First wave, n (%)	Second wave, n (%)
GAD-7		
Minimal symptoms	1420 (79.9)	1377 (77.75)
Mild	248 (14)	280 (15.8)
Moderate	77 (4.3)	66 (3.7)
Severe	32 (1.8)	54 (3.0)
PHQ-8		
No symptoms	1330 (74.8)	1308 (73.6)
Mild	300 (16.9)	304 (17.1)
Moderate	94 (5.3)	90 (5.1)
Moderate to severe	37 (2.1)	51 (2.9)
Severe	16 (1.4)	24 (1.4)

Media Use

The frequencies of the answers to the individual MUQ items are presented in Multimedia Appendix 1. We found significant differences between the two waves in several media variables (social media as news source; reading comments; use of commercial, mainstream, audio/visual, print/internet media; reading habits; perceived stress from media news; internalization of media news; positive appreciation of media news; negative attitude to the news: lack of interest; use of the following news sections: politics, economics, COVID-19-related news, entertainment/show business, culture, science and technologies, crime, transport, weather, environment, and health). The rates in these dimensions of media behavior

decreased except for the use of print/internet news and lack of interest in the news, which increased. In overall exposure to media news, we found no significant difference between the two waves.

Media Use Factors

EFA extracted seven factors with an eigenvalue greater than 1 (Table 2). The overall value of the Kaiser-Meyer-Olkin measure of sampling adequacy (0.83) indicated a good level of suitability for analysis. The Bartlett sphericity test ($\chi^2_{435}=16,995.02$, $P=.001$) also showed that the items in the MUQ are related and suitable for factor analysis. Multimedia Appendix 2 shows the factor loadings of the seven media factors.

Table 2. Media factors, factor items, and factor descriptions.

Media factor (MF)	Factor items	Factor description
MF1: Conscientious public news use	Lack of interest in news (negative factor loading), lack of time to follow news (negative factor loading), politics, economics, public media (audiovisual broadcast media)	Media practice characterized by interest in media news and determination to find time and follow information of great social significance (“hard news” other than pandemic-related) via public media (the media outlet commonly viewed as the most reliable)
MF2: News aversion	Frustration with news, annoyance with news, stress avoidance, mistrust in media, lack of concentration to news	The use of media that is characterized by various negative attitudes to the media: mistrust in the media; frustration, annoyance, and avoidance behavior toward the media news
MF3: News reading	Mainstream media, foreign media, antisystem media, official public sources, opinion online newspapers	Media practice characterized by the use of news from various media categories other than public and commercial (which are mostly audio/audiovisual). Media news reports in MF3 have a variety of journalistic styles but are almost exclusively of the print/internet type (requiring reading)
MF4: Social media practice in news consumption	Reading comments, social media as a news source, perceived stress from the media	Media practice of news consumption linked to social media use characterized by using social media as an information source, reading comments, and subjectively perceived stress from the media
MF5: Infotainment	Commercial media, entertainment, crime, sports	Media practice characterized by the use of commercial media news and the use of entertainment topics that are typical for commercial media (show business, sports, and crime)
MF6: Internalized use	Internalization of media news, positive appreciation of news	Media practice that attaches great importance to news information, which has a great impact on personal inner/social life and behavior. This practice also groups a positive appreciation of media news (the impact of information on one’s own life must necessarily be associated with some level of trust in the source of the information)
MF7: Use of practical news	Transport, weather, environment, health, culture, science and technologies	Media practice characterized by the use of news sections providing practical information, which helps to navigate daily life

Associations Between Media Use Factors and Mental Health

The results of multiple linear regression showed significant relationships between the seven media factors as regressors and anxiety (GAD-7 total score) as the explained variable (Table 3). The media factors news aversion, social media practice, news reading, internalized use factors, and COVID-19 news exposure predicted higher levels of anxiety, with social media practice having the strongest effect size. The associations were significant in both observation periods, except for news reading, which was found as a significant predictor only in the second wave of the survey. Therefore, most of the factors were found to be stable over time, while the strength of the associations increased in most cases. In particular, associations between three media factors (COVID-19-news use, social media practice, and infotainment) and anxiety were considerably stronger in the second wave than in the first wave. We also found two media factors, infotainment and reading habits, that predicted lower anxiety levels in both waves, although reading habits had much

smaller effect sizes compared to those of the other factors. The strength of the association between the factor infotainment and anxiety considerably increased in the second wave.

The multiple linear regression model for depression (total PHQ-8 score as explained variable) identified identical predictors as the model of anxiety (Table 4), except for news reading, which was not identified as a significant predictor in depression. The media factors also proved to be fairly stable over time. In the first wave of the survey, the media factors news aversion, social media practice, and internalized use, and COVID-19 news exposure predicted higher levels of depression, and the same was true in the second wave. Again, the same media factors as in the models explaining anxiety predicted lower rates of depression: infotainment in both waves and reading habits only in the second wave. The effect size of reading habits was smaller than that of the other media predictors. Social media practice and infotainment had the strongest effect sizes among all media factors in the second wave of the survey, following a considerable increase compared to the first wave of the survey.

Table 3. Results of the multiple linear regression model for anxiety.

Variable	First wave of the survey ($F=25.77$; $df=1764$; $R^2=0.1491$; $P<.001$)			Second wave of the survey ($F=37.67$; $df=1764$; $R^2=0.204$; $P<.001$)		
	Coefficient (SE)	<i>t</i> value	<i>P</i> value	Coefficient (SE)	<i>t</i> value	<i>P</i> value
Intercept	1.484 (0.176)	8.449	<.001	1.288 (0.146)	8.829	<.001
Conscientious public news use (MF ^a 1)	-0.016 (0.037)	-0.422	.67	0.041 (0.077)	0.532	.59
News aversion (MF2)	0.186 (0.032)	5.803	<.001	0.147 (0.070)	2.106	.04
News reading (MF3)	0.053 (0.033)	1.589	.11	0.092 (0.041)	2.257	.02
Social media practice (MF4)	0.263 (0.034)	7.773	<.001	0.584 (0.077)	7.618	<.001
Infotainment (MF5)	-0.071 (0.035)	-2.026	.04	-0.643 (0.166)	-3.880	<.001
Internalized use (MF6)	0.263 (0.033)	8.038	<.001	0.282 (0.067)	4.224	<.001
Practical use (MF7)	0.015 (0.032)	0.457	.65	0.193 (0.114)	1.689	.09
Media news exposure	-0.0004 (0.0004)	-0.914	.36	-0.001 (0.0004)	-1.263	.21
COVID-19 news exposure	0.090 (0.040)	2.249	.03	0.280 (0.035)	7.951	<.001
Reading habits	-0.042 (0.021)	-1.990	.05	-0.061 (0.020)	-2.969	.003
Age	-0.011 (0.002)	-6.011	<.001	-0.016 (0.002)	-8.440	<.001
Gender (women)	0.123 (0.061)	2.031	.04	0.203 (0.057)	3.584	<.001

^aMF: media factor.

Table 4. Results of the multiple linear regression model for depression.

Variable	First wave of the survey ($F=25.34$; $df=1764$; $R^2=0.147$; $P<.001$)			Second wave of the survey ($F=30.78$; $df=1764$; $R^2=0.173$; $P<.001$)		
	Coefficient (SE)	<i>t</i> value	<i>P</i> value	Coefficient (SE)	<i>t</i> value	<i>P</i> value
Intercept	1.273 (0.178)	7.137	<.001	1.533 (0.150)	10.223	<.001
Conscientious public news use (MF ^a 1)	0.001 (0.038)	0.025	.98	-0.100 (-0.099)	-1.259	.21
News aversion (MF2)	0.159 (0.032)	4.905	<.001	0.187 (0.072)	2.609	.009
News reading (MF3)	0.048 (0.034)	1.431	.15	0.048 (0.042)	1.161	.25
Social media practice (MF4)	0.265 (0.034)	7.723	<.001	0.503 (0.079)	6.368	<.001
Infotainment (MF5)	-0.122 (0.036)	-3.435	.001	-0.471 (0.170)	-2.767	.006
Internalized use (MF6)	0.229 (0.033)	6.901	<.001	0.254 (0.069)	3.696	<.001
Use of practical news (MF7)	-0.005 (0.033)	-0.165	.87	0.019 (0.117)	0.164	.87
Media news exposure	-0.00037 (0.0004099)	-0.919	.36	-0.0002904 (0.0004214)	-0.689	.49
COVID-19 news exposure	0.161 (0.041)	3.963	<.001	0.233 (0.036)	6.445	<.001
Reading habits	-0.021 (0.021)	-0.993	.32	-0.042 (0.021)	-1.997	.05
Age	-0.009 (0.002)	-4.978	<.001	-0.015 (0.002)	-7.856	<.001
Gender (women)	0.199 (0.061)	3.239	.001	0.259 (0.058)	4.439	<.001

^aMF: media factor.

Discussion

Principal Findings

The findings of our longitudinal representative study showed that the symptoms of anxiety and depression of the Czech population increased in the late phase of the COVID-19 lockdown compared to the early phase. We further identified

the negative role of media coverage of the COVID-19 pandemic in self-reported measures of mental health in both the early and late phases of the pandemic lockdown in Czechia. Moreover, other specific media practices were revealed as either risk or protective factors for mental health. Most of these media factors were found to be fairly stable and long-lasting characteristics associated with mental health, and some of them were more pronounced in the second observation period.

Impact of the Long Lockdown on Mental Health

Our finding of an overall increase of anxiety and depression symptoms between the two observation periods shows that the pandemic lockdown spanning 5 months had a negative impact on mental health of the Czech population, even when the objective measures of the epidemiological situation (daily incidence and mortality) in the two periods were comparable or slightly more favorable in the late phase compared to the early phase of the lockdown. Therefore, our data strongly suggest that severe restrictions and continuous exposure to the collective trauma did not result in a strengthening of resilience but rather in ongoing traumatization. This is in line with several previous longitudinal studies, which showed a higher level of mental health problems in response to a long, drawn-out lockdown, comparing an advanced stage of lockdown to its initial stage [27-29]. Our results also confirm a previous finding that the strict lockdown measures played a more significant role in mental health than the epidemiological situation itself [30]. The long period of the health emergency and restrictions on the normal life of society without any clear prospect of an end may have fostered frustration, uncertainty, fear of infection or death, loss of employment, and reduced household incomes, which have previously been associated with an increase in long-term psychological problems (anxiety, depression, insomnia, or posttraumatic stress symptoms) [31,32]. Therefore, we conclude that human well-being is at long-term risk during a long pandemic crisis addressed by a lockdown.

Our next finding, which associated higher levels of anxiety and depression with the female gender in both observation periods, is in accordance with previous studies on mental health during the COVID-19 pandemic [33-35]. One possible explanation for this may be related to the closing of schools during the protracted lockdown, when women largely had to bear with the additional burden of home childcare and teaching. The association of higher rates of anxiety and depression with younger ages that we found in both observation periods is also in line with other studies [36]. Possibly, younger people may be more affected by the pandemic restrictions, resulting in multifaceted uncertainties affecting their lives as well as social isolation from their peers.

Media Factors Associated With Poorer Mental Health

Our results confirmed a growing body of literature suggesting the negative impact of exposure to COVID-19 reports on mental health [3,9,11]. Additionally, by showing that exposure to specific COVID-19-related content (*COVID-19 news exposure*) predicted increased levels of anxiety and depression unlike exposure to news reports in general (*media news exposure*), we confirmed that not all media news consumption is solely negative for mental health, but specifically the consumption of topics related to a current (collective) stressor. Interestingly, the comparison of the predictive powers of COVID-19 news exposure between the two phases of the lockdown did not confirm a habituation to COVID-19 media reports. By contrast, exposure to COVID-19 news remained a stable predictor of depression, and the association strengthened for anxiety in the late phase of the lockdown. We may speculate that the missing association between COVID-19 news exposure and anxiety

levels in the early phase of the pandemic crisis may be due to the widespread conviction that the forthcoming wave of the epidemic would again be contained without major consequences and with a minimum of casualties, similar to the first peak in the pandemic in Czechia in the spring of 2020. However, after 5 months of continuous daily presentation of the life-threatening situation and unclear solutions, the exposure to COVID-19 news reports became a stronger risk factor for mental health. In summary, our finding provides further support for understanding COVID-19 media coverage as a traumatic stressor acting in the long term, as suggested by research associating the frequent use of media reports on COVID-19 with secondary traumatization [37,38].

In our search for specific media practices and their potential negative or protective role in mental health, we identified several predictors of mental health, which we first extracted from our comprehensive MUQ via a data-driven approach. The strongest predictor of mental health among all other media or demographic predictors was the media factor that we call *social media practice in news consumption*. The interconnection of three specific aspects of media use in this factor—use of social media as a news source, reading comments under web news articles, and perceived stress from the media—points to an existence of a media use practice linked to the social media environment, which prompts its users to read comments on posts. This social media practice seems to apply to news consumption as well, prompting media users to read comments under web news articles. Importantly, the social media practice factor suggests that such a media practice, including reading anonymized and therefore often highly negatively balanced, comments under web news articles [39], is connected to a subjective perception of stress induced by the media, which is in line with our other finding associating this factor to increased levels of anxiety and depression. These results are in accordance with previous research connecting social media use to stress and other mental health problems [14,40]. Identifying social media practice for news as a risk factor for mental health possibly links to the pandemic-related misinformation overload on Czech social media [41], and the spread of fear, panic, frustration, and other negative emotions [41-44], since social media has been confirmed to be a perfect platform for “emotional contagion” [45]. The increase in predictive powers of the social media factor for both anxiety and depression in the late phase of the lockdown (spring 2021) may be linked to the vaccination of the population, which began in Czechia at the end of December 2020. The vaccination rollout triggered an avalanche of misinformation and conspiracies on social media, resulting in a division of society into vaccine supporters and refusers. Moreover, the increased strength of the relationship may have been due to the prolonged exposure to traumatic content and emotive comments that circulated on social media during the long-lasting crisis.

The media use factor that we call *internalized use*, describing the personal engagement with information learned from media news, has not yet been described in the literature. This data-driven factor, grouping several indicators of a deep immersion in the media news [46], including ruminations on news content or its impact on one’s own decision-making and action, predicted increased anxiety and depression in both

waves, and may therefore be considered another risk factor for mental health. Hence, we confirmed that not only exposure to traumatic news is of significance but also the extent to which users internally engage with it and the importance they give to it. This finding offers possible ways to mitigate the negative impact of traumatic news on mental health. Psychotherapeutic techniques developed to stop negative thinking may be used to practice deliberate avoidance of traumatic topics in one's thoughts and further emotional engagement in the traumatic news.

Our next result that the *news aversion* factor predicted higher rates of anxiety and depression in both phases of the lockdown corresponds with the findings of a few studies that link mistrust in the media to mental health problems [12,47]. However, in addition to mistrust, the news aversion factor was constructed of further negative attitudes to media news (frustration, annoyance, avoidance). Negative attitudes to the information source associated with poorer mental health may be interpreted as a reaction to a failure to cope with ambiguous or frequently changing information, along with uncertainty of the epidemic situation and its possible consequences [46]. Avoidant reactions to media news contained in the news aversion factor may be seen as analogous to the depressive symptom of withdrawal from the external world, which is considered an avoidance response to a problematic stimulus. This factor must not be overlooked, as other types of problematic behavior have been related to negative attitudes to the media. Together with mistrust in public institutions, avoidant behavior has been previously connected to an inclination to extreme views or even extremism and aggression [48]. Previous research has also suggested that aversion is associated to detrimental media behavior such as searching for antisystem websites, endorsement of conspiracy theories [49], or following and sharing disinformation and extreme views on social media [50].

The *news reading* factor was revealed in our data to be a media practice common to users of a wide range of online and print media, whereas the use of audio/audiovisual media outlets contributed to other factors (conscientious public news use, infotainment). An association between the practice of reading and poorer mental health was found; however, this was only the case for anxiety in the late phase of the lockdown. This may be due to the escalating polarization of views on vaccination, which was more apparent in online media news than other media types, because of the greater diversity of views represented in the online environment, including the antisystem media. At the time of the second wave of our survey, the process of vaccination against COVID-19 was in full swing in Czechia, and so was the fear-inducing news published by the antisystem media [41].

In summary, we may interpret our media factors that played a negative role in mental health as indicators of four levels of the spread of negative mental states from traumatic news content: (1) behavioral level of the consumption of negative information contained in COVID-19 media news reports (*COVID-19 news exposure*); (2) subjective level of immersion in media news and its internalization; (3) level of attitudes, including refusal of the media, possibly due to negative information overload, manifesting in aversive reactions; and (4) a specific platform

of a social media environment that strengthens present emotional biases, and multiplies and accelerates the process of spreading of negative mental states in society [51,52].

Media Factors Associated With Improvement of Mental Health

The association between the *infotainment* factor, grouping consumption of entertainment topics and consumption of news from commercial media, and improvement of mental health contradicts some of the previous research [3], which found negative effects of using commercial media on mental health during the COVID-19 pandemic, although our infotainment factor contained further indicators of media use (interest in entertainment topics). Sports and show business or even crime news with an air of police drama may have distracted participants from otherwise stressful news focused almost exclusively on the COVID-19 pandemic. The discrepancy with the previous study [3] may be further due to the fact that our survey took place in a different situation (the previous study's data were collected during the first 2 weeks of April 2020), and also possibly due to the different characteristics of Czech commercial media.

The second protective factor found in our data, *reading habits* (contextual in-depth reading vs only headline browsing), did not have as a pronounced effect on mental health as other media factors (especially in depression); however, we still consider it an important finding, suggesting a possible remedy for the consumption of traumatic news. Receiving and processing contextual information may possibly be associated with "cold" cognition (ie, information processing in the absence of emotional influence), which is crucial to analytical thinking, whereas headline browsing may be associated with "hot" cognition (ie, fast and emotional). Impairment of "cold" cognition has previously been connected to both depression and anxiety [53,54]. Even though the method used in this study does not enable inferring causality, we suggest that contextual reading, as a slower and more analytical approach to consuming media news, thereby nurturing "cold" cognition, may lead to a more adaptive processing of a stressor, and may therefore be considered a protective factor to mental health. The weaker association in the early phase of the lockdown may be interpreted to indicate that quick headline browsing and employing "hot" cognition may be more damaging in the long run in terms of coping with the persisting collective stressor spread by the media.

Conclusions

The 5 months of the second pandemic lockdown in Czechia had a negative impact on mental health, and caused an increase in some of the negative, as well as positive, media use effects. Our results suggest that exposure to COVID-19 news played a negative role in mental health during the early and particularly the late phase of the lockdown in Czechia, while exposure to news media as such did not. The social media practice in news consumption was the strongest predictor of exacerbated mental health symptoms of all the examined factors, particularly in the late phase of the lockdown. Additionally, news media use characterized by internalization of information learned from the news, as well as negative attitudes to media news, were

associated with higher levels of anxiety and depression. Stability or strengthening of associations between these media factors and exacerbation of mental health symptoms in the late phase of the lockdown leads us to the conclusion that these factors had a long-term or even increasing negative effect on mental health. By contrast, the use of infotainment as well as the

in-depth and contextual practice of reading news articles were related to lower rates of anxiety and depression, thereby perhaps easing the burden of the crisis in terms of media use. These protective media use practices considerably strengthened in the late period of the lockdown.

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Authors' Contributions

LK conceived the project and was in charge of overall direction and planning. DG, PA, LK, VJ, JH, and IF designed the survey, and DG, PA, and VJ elaborated the technical details of the survey. EB and PA designed the statistical models, EB supervised the data analysis, and PA performed the calculations. DG, VJ, LK, and PA wrote the manuscript with input from the other authors.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Percentage of answers in media use questionnaire.

[[DOCX File, 28 KB - mental_v9i6e36050_app1.docx](#)]

Multimedia Appendix 2

Factor loadings of media factors resulting from exploratory factor analysis.

[[DOCX File, 18 KB - mental_v9i6e36050_app2.docx](#)]

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Abbreviations

EFA: exploratory factor analysis

GAD-7: Generalized Anxiety Disorder Questionnaire

MUQ: Media Use Questionnaire

PHQ-8: Patient Health Questionnaire Depression Scale

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