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Comparative effectiveness of two versions of a caring contacts intervention in healthcare providers, staff, and patients for reducing loneliness and mental distress: A randomized controlled trial

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Abstract

Background—Caring Contacts can effectively reduce suicide ideation, attempts, and death. In published clinical trials, Caring Contacts were sent by someone who knew the recipient. At scale, Caring Contacts programs rarely introduce the recipient and sender. It is not known whether receiving Caring Contacts from someone unknown is as effective as messages from someone the recipient has met.

Methods—Pragmatic randomized controlled trial comparing Caring Contacts with (CC+) versus without an introductory phone call (CC). Recruitment occurred January-July 2021, with outcomes

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Contributors

Study design and grant application: AR, KAC, JS, HF, SB, KCGC; Trial coordination & informed consent: JS, TF, BM, CP, AS, JY; Trial supervision: AR; Clinical/medical trial supervision: KAC, AD-J, JW, MW; Project Management: AR, JS; Intervention training: AK; Intervention oversight & fidelity monitoring: JT, LF, GA, AR; Data management: BM, SB, ZZ, KCGC; Statistical analysis: SB, KCGC; Writing first draft of the manuscript: AR with input from SB; critically revising the manuscript: all authors.

Trial Registration

The Mental Health Among Patients, Providers, and Staff (MHAPPS) Trial is registered at ClinicalTrials.gov (https://clinicaltrials.gov/ct2/show/NCT04700137), with the following identifier: NCT04700137. The full trial protocol can be accessed at the link above.

Declaration of Interests

The authors declare no competing interests.

assessed at 6 months. Participants were primary care patients or healthcare providers/staff reporting adverse mental health outcomes on a qualifying survey. Participants were sent 11 standardized caring text messages over 6 months; when participants replied, they received personalized unscripted responses. CC+ calls were semi-structured. The primary outcome was loneliness (NIH Toolkit).

Results—Participants included 331 patients (mean [SD] age: 45.5 [16.4], 78.9% female) and 335 healthcare providers/staff (mean [SD] age: 40.9 [11.8], 86.6% female). There were no significant differences in loneliness at 6 months by treatment arm in either stratum. In patients, mean (SD) loneliness was 61.9 (10.7) in CC, and 60.8 (10.3) in CC+, adjusted mean difference of −1.0 (95% CI: −3.0, 1.0); p-value=0.31. In providers/staff, mean (SD) loneliness was 61.2 (11) in CC, and 61.3 (11.1) in CC+, adjusted mean difference of 0.2 (95% CI: −1.8, 2.2); p-value=0.83.

Limitations—Study population was 93% white which may limit generalizability.

Conclusions—Including an initial phone call added operational complexity without significantly improving the effectiveness of a Caring Contacts program.

Keywords

Caring Contacts; Loneliness; Depression; Suicide; Mental Health; Brief Contact Intervention

Introduction

Background

The COVID-19 pandemic began amid a high prevalence of adverse mental health conditions.[1] The lived experience of the pandemic exacerbated social isolation, loneliness, and mental health disorders.[2,3] During the first year of the pandemic, 41% of US adults reported adverse mental health conditions, with healthcare providers and staff at disproportionately high risk.[4] This study compared the effectiveness of two versions of a Caring Contacts intervention in patients and healthcare providers and staff experiencing mental distress during the COVID-19 pandemic to determine whether knowing the person sending caring messages is necessary to optimize reductions in loneliness, depression, and suicidal ideation and behavior.

Caring Contacts is one of the only brief interventions with demonstrated effectiveness in reducing suicidal ideation, attempts, and death in randomized clinical trials.[5–10] Caring Contacts is recommended as part of standard suicide prevention care by the Joint Commission, [11] the US Department of Veterans Affairs (VA), [12] the US Department of Defense, [12] and the National Action Alliance for Suicide Prevention.[13] Caring Contacts involves brief, non-demanding caring messages sent via letters, [5,6] postcards, [7,8] or text messages[9]. Published trials sent Caring Contacts from someone who knew the recipient, but in practice messages are often sent from someone unknown to the recipient. [14,15] It is unknown whether the intervention is more effective if the recipient knows the person sending the caring messages.

Objective & Hypothesis

The study compared the effectiveness of Caring Contacts sent following an introductory phone call (CC+) versus Caring Contacts without an introductory call (CC). The authors hypothesized that CC+ would improve loneliness, depression, and suicidal ideation and behavior compared to CC. Loneliness was selected as the primary outcome because it is a hypothesized mechanism of the causal pathway for Caring Contacts.

Methods

Design

This study is a pragmatic randomized controlled comparative effectiveness trial, with a parallel design and 1:1 assignment stratified by patients, and healthcare providers/staff. Study objectives, interventions, and outcomes pertain to the individual level.

The St. Luke's Health System Institutional Review Board approved and oversaw the study. A Data and Safety Monitoring Board monitored the safety and scientific integrity of the trial. The research protocol and statistical analysis plan are available at ClinicalTrials.gov.

Setting

St. Luke's Health System (St. Luke's) in Idaho is a private, regional not-for-profit health system that employs over 16,000 healthcare providers and staff and had 1.87 million clinic visits in 2021. All data for this study were collected virtually.

Study Population

Participants were St. Luke's providers/staff or primary care patients, recruited based on severity of mental distress reported through an initial survey. Eligibility criteria were intentionally broad for the initial survey and included: proficiency in English, willingness to provide informed consent; for providers/staff: (a) 18+ years old and (b) a current provider or employee at St. Luke's; for patients: (a) ≥12years old, (b) completed primary care visit in last 12 months; and (c) current mobile electronic health record account user. Inclusion criteria for the clinical trial included (1) moderate or high score for loneliness, suicidal ideation, psychological stress, anxiety, and/or depression[2] on the initial survey; and (2) access to a phone with call and texting capabilities.

Study Procedures

Individuals were invited to participate in the initial survey via email (providers/staff) or mobile electronic health record message (patients). REDCap (Research Electronic Data Capture) was used for surveys and informed consent. [16,17] Eligible survey participants were contacted by text message to schedule a study enrollment call; informed consent was conducted over the phone written consent in REDCap. Randomization was stratified by stratum and the assigned treatment was displayed on individuals' informed consent forms.

[2]Moderate or high risk was defined as follows: NIH Toolkit Loneliness raw score of 13 or greater for adults or 16 or greater for adolescents; or C-SSRS score of 3 or greater; or GAD7 score of 11 or greater; or PHQ9 score of 10 or greater; or NIH Toolkit Stress raw score of 31 or greater for adults or 33 or greater for adolescents.

Trial participants completed a pre-intervention baseline survey immediately following consent. Two non-clinician follow-up specialists at the Idaho Crisis and Suicide Hotline (Hotline) were trained on the Caring Contacts intervention and sent caring texts, monitored and responded to incoming text messages and completed introductory phone calls with CC+ participants. Outcomes surveys were sent at 6 months via text or email per participant preference.

Description of Interventions

Participants in both intervention arms received medical and behavioral health services including medications and psychosocial treatment as usual.

Caring Contacts (CC)—The CC intervention comprised 11 standardized caring texts sent over 6 months according to the following schedule: weeks 1, 2, 3, 4, 6, 8, 10, 12, 16, 20, and 24, plus a birthday text if their birthday occurred during follow-up. The schedule and content of outgoing texts was uniform across participants and was developed in consultation with a local lived experience with suicide advisory board. A HIPAA-compliant program called Mosio was used for calls and texting. Participants could choose whether to reply to the caring texts. Hotline follow-up specialists reviewed and responded to incoming text messages with unscripted individually tailored replies, similar to previous text-based Caring Contacts studies.[9] Replies adhered to the principles of Caring Contacts (non-demanding, unconditional care) except in instances of suicidal crisis when follow-up specialists asked questions to assess safety.

Caring Contacts with Introductory Call (CC+)—CC+ was the same as CC, plus one introductory phone call to connect the participant and follow-up specialist before texting began. Phone calls were unscripted but generally included: an introduction; a safety/wellbeing check; a discussion of the participants' mental health and contributing stressors; a review of relevant resources; and a description of the caring text messages. Caring texts were initiated without a phone call if the call was not completed within 2 weeks of enrollment.

Fidelity Monitoring

The Mosio texting platform facilitated real-time oversight of call and texting activity, tracking incoming and outgoing texts with dates and timestamps. Study staff reviewed the content of call notes and text messages and monitored the date and time of outgoing texts to ensure fidelity with the research protocol.

Measures

Primary Outcome—The primary outcome was loneliness. Loneliness is a well-established risk factor for suicide, [18,19] depression, [20–23] stress, [22,24] and anxiety. [20,23] The authors hypothesized that by reducing loneliness, Caring Contacts may also reduce depression, stress, anxiety, and suicidality. Loneliness was measured at baseline and at 6 months using the NIH Toolbox Social Relationship Scales Emotion Battery Loneliness measure, which is validated and psychometrically sound.[25] The loneliness measure comprises five items (adults) or seven items (adolescents) rated on a Likert scale. Responses were used to calculate a raw score which was converted to a t-score.

Secondary Outcomes—Secondary outcomes were measured at baseline and 6 months. Suicidal ideation and behavior were assessed using the 6-item Columbia Suicide Severity Rating Scale (C-SSRS) self-assessment screener.[26–28] Depression was assessed using the Patient Health Questionnaire-9 (PHQ-9).[29,30] Perceived Burdensomeness and thwarted belongingness were measured using the 15-item Interpersonal Needs Questionnaire.[19,31]

Exploratory Outcomes—Stress, [32] anxiety, [33] alcohol use, marijuana use, illicit drug use,[34] and use of outpatient mental healthcare services were exploratory outcomes.

Power & Sample Size

For each stratum, a sample of 330 participants (165 in each arm) was planned to provide 80% power to detect a difference of 5 units in the loneliness outcome, assuming at least 70% of participants would be retained. The minimum clinically important difference (MCID) was defined a priori as 5 T-score units on the loneliness scale.

Statistical Analysis

The analysis population included all randomized, consented participants who completed the baseline survey. Data were analyzed using an intention to treat protocol. Linear regression with robust standard errors was used to determine whether mean loneliness differed between intervention arms, adjusted for the baseline score as a precision variable. The comparative effectiveness of the interventions was modeled separately by stratum. With two active treatment arms, this study's results show the difference in effectiveness between the interventions, not the efficacy of either intervention compared to an inactive control. Hot deck multiple imputation was used for missing outcome data; missing 6-month primary and secondary outcomes were sampled from complete cases in the same treatment arm, baseline loneliness tertile, and stratum. Twenty complete data sets were imputed, and results were combined across imputations using Rubin's rule. [35]

For secondary outcomes, linear regression was used to estimate the difference in means. Robust/sandwich standard errors were used to allow for departures of the observed standard errors from classic model assumptions, such as heteroskedasticity. Inference is based on a two-sided significance threshold of 0.05; confidence intervals are correspondingly 95%. Analyses were performed in R version 4.1.2 (R Foundation for Statistical Computing). Post-hoc sensitivity analyses used Chi-squared tests for binary outcomes and the Mann-Whitney test for ordinal outcomes.

Randomization & Masking—Randomization occurred at the individual level and was stratified. The study statistician generated a random list of treatment assignments for each stratum with varying block sizes. REDCap pulled the next treatment assignment from the list at the time of randomization. The list was concealed from the study staff conducting enrollment.

This trial was single masked, with most members of the study team including the lead statistician masked to treatment assignment for individuals and aggregate data by treatment arm. Participants were aware of the treatment arm to which they were assigned but were

unaware of the alternative treatment arm. Masking interventionists or study participants to the assigned intervention was not feasible due to the nature of the intervention.

Role of the Funder

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Results

Demographic & Baseline Characteristics

3,646 individuals completed the initial survey. Of those, 331 patients and 335 healthcare providers/staff were enrolled in the clinical trial. Table 1 describes participant demographics and baseline characteristics by stratum and treatment arm. Participants were mostly female (82.7%), white (93.2%), and non-Hispanic (91.3%), with a mean age of 43.1 years (SD: 14.4). Less than 1% of the study population was under age 18. Unemployment was common (40%) among patients. Baseline clinical characteristics are reported in Table 2 and Table 3 and were similar across treatment arms within strata.

Timing of the study and COVID-19 Pandemic

The study took place from January 2021 – January 2022. Recruitment occurred between January 18, 2021, and July 6, 2021. Participants were followed for 6 months. All outcome assessments were completed by January 6, 2022. During the outcome assessment period, Idaho was severely impacted by the Delta variant of COVID-19. All health systems in Idaho operated under crisis standards of care from September – November, 2021.

Participant Flow

Figure 1 is the participant flow diagram. Retention was high with over 98% of participants completing the 6-month outcome survey.

Primary Outcome

There was no significant difference in loneliness by treatment arm in either patients (−1.0 difference, 95% CI: (−3.0, 1.0), p=0.31) or providers/staff (0.2 difference, 95% CI: (−1.8, 2.2), p=0.83). Including an introductory phone call did not significantly improve loneliness among Caring Contacts recipients with mental distress over a 6-month period. Results for loneliness are summarized in Table 2.

Secondary Outcomes

There was a statistically significant difference in suicidality by treatment arm in patients, but the magnitude of difference was small (0.2 difference, 95% CI: (0.002, 0.5), p=0.048). Post hoc sensitivity analyses were conducted in the patient cohort to further explore this finding. A Mann-Whitney test did not find a difference in C-SSRS between intervention arms (p=0.38), and a Chi-squared test of the difference in proportions of participants with a moderate or high C-SSRS score was not significant (p=0.53). There was no

significant difference in suicidality in providers/staff (−0.2 difference, 95% CI: (− 0.4, 0.1), p=0.20). There was no significant difference in depression by treatment arm in patients (−0.4 difference, 95% CI: (−1.5, 0.7), p=0.45) or providers/staff (0.3 difference, 95% CI: (−0.7, 1.3), p=0.51). Neither perceived burdensomeness nor thwarted belongingness differed significantly by treatment arm in either stratum. Results for secondary outcomes are summarized in Table 2.

Other Exploratory Outcomes

Anxiety, stress, recent mental health treatment, increased substance use, and safety outcomes including death, death by suicide, and attempted suicide were assessed as exploratory outcomes. Results are summarized in Table 3. Anxiety was statistically significantly higher among CC+ recipients compared to CC in providers/staff (1.0 difference, 95% CI: (0.1, 2.0), p=0.04) but there was no significant difference among patients (−0.3 difference, 95% CI: (−1.3, 0.7), p=0.54). In a post-hoc sensitivity analysis, a Chi-squared test did not find a difference by study arm in the proportion of employees reporting moderate or high levels of anxiety (p=0.22). No other exploratory outcomes differed significantly by treatment arm.

Participant Satisfaction & Engagement

Participant satisfaction with the interventions was high and similar by treatment arm and stratum. Of CC+ participants who reported receiving a phone call, at least 97% in each stratum were strongly or somewhat satisfied with the phone call. Most participants agreed strongly or somewhat agreed that the caring text messages were helpful, and they were glad to receive them (86.7% in CC and 86.7% in CC+ (providers/staff)) and (92.4% in CC and 90.7% in CC+(patients)). Table 4 summarizes the number of CC+ recipients who received an initial phone call and the number of incoming and outgoing text messages by intervention arm and stratum.

Heterogeneity of Treatment Effects

The treatment effect for loneliness was analyzed for sub-groups (specified a priori) based on: age; patient-facing vs. non-patient-facing healthcare employees; baseline suicide risk; ethnicity; sex at birth; gender identity; sexuality; and rural vs. urban residence. Subgroup analysis results are summarized in Supplement table 1. The treatment effect varied significantly based on age category (p-value for the interaction: 0.03). Older adults (50+ years) were lonelier in CC+ compared to CC, though the difference was not statistically significant (2.1 difference, 95% CI: (−0.04, 4.3)). Loneliness was lower (but not statistically significant) in CC+ compared to CC in 12–24 year olds and 25–49 year olds. The treatment effect also varied significantly based on ethnicity (p-value for the interaction: 0.01). Hispanic participants reported significantly lower loneliness in CC+ compared to CC (−7.3 difference, 95% CI: (−12.4, −2.1). While the magnitude of difference was large, there were few Hispanic participants, and this finding should be considered hypothesis-generating.

Discussion

Summary of Results

We did not find evidence that including an introductory phone call significantly improves clinical outcomes or participant satisfaction in a two-way text message Caring Contacts intervention for patients and healthcare providers and staff with mental distress. There were two statistically significant findings: (1) suicidal ideation and behavior was higher among patients receiving CC+ compared to CC, and (2) anxiety was higher among providers/staff receiving CC+ compared to CC. In the context of the overall null findings of the trial across multiple mental health outcomes, the inconsistency of these findings across strata, and the non-significant findings from the post hoc sensitivity analyses, we believe there is insufficient evidence to conclude that there is any clinically meaningful difference in mental health outcomes between intervention arms.

Results in Context

This is the first study to examine Caring Contacts for participants not recruited for suicidality, the first to include loneliness as a primary outcome, and the first to provide Caring Contacts to health care providers and staff. Previously published efficacy trials have compared usual care to usual care plus Caring Contacts,[5–10] whereas this comparative effectiveness trial was designed to determine whether caring texts sent by someone the recipient has met improved clinical outcomes or satisfaction compared to caring texts sent by someone unknown to the participant. No such difference was found. In prior studies, Caring Contacts were sent by a clinician who was part of the recipient's care team. Having a single phone call to connect with an otherwise unknown follow-up specialist is not equivalent to having an established relationship with a caregiver. Additional research is needed to determine whether Caring Contacts from an unknown sender are as effective as messages from a known member of the care team.

While most clinical outcomes improved over time, suicidal ideation increased in both cohorts and intervention arms during the trial. The increase in suicidal ideation was statistically significant in providers/staff (mean change of 0.15, 95% CI: (0.02, 0.27), p=0.02) but not among patients (mean change of 0.02, 95% CI: (−0.11, 0.16), p=0.73). Without an inactive control arm, it is unknown how high rates of suicidal ideation may have been without Caring Contacts. The higher levels of suicidal ideation reported in the follow-up period may reflect regression to the mean or a cohort effect related to the Delta surge of COVID-19 and implementation of crisis standards of care. The increased suicidality was not consistent with changes in the other mental health outcomes, nor was it explained by participant satisfaction, which was very high, consistent with other Caring Contacts research.

Lessons for Scale-Up of Caring Contacts

The results from this study may inform the design and implementation of text message-based Caring Contacts interventions. Removing the requirement to meet or speak with the person to send caring texts makes the intervention easier to deliver at scale, reducing costs and operational complexity.

All states have at least one local suicide and crisis hotline. Health systems can feasibly partner with hotlines to deliver two-way Caring Contacts even in rural or low-resource settings. The nationwide rollout of 988 expands the role of state crisis and suicide prevention hotlines, with an emphasis on providing longer-term follow-up support. Caring Contacts is an evidence-based follow-up model that Hotlines can deliver effectively.

Staffing for two-way text message programs is a commonly cited barrier to scaling Caring Contacts. Because suicide prevention hotlines are typically staffed 24–7, they are well positioned to monitor and respond to incoming text messages. Our intervention team comprised two follow-up specialists tasked with calls and text replies for 666 participants. They communicated their working hours so participants knew when to expect text replies. Overnight and on weekends, Hotline phone room supervisors monitored incoming texts and could respond in true emergencies when participants were at imminent risk for suicide (none occurred during the trial). Other incoming texts waited for response until the follow-up specialists were working.

External Validity

This was a pragmatic clinical trial, conducted in a non-academic regional healthcare system with a local hotline delivering interventions – a model that could be realistically replicated. The study population was mostly female (83%), white (93%), and non-Hispanic (91%), and findings may not be generalizable to populations with different demographics. Few minors enrolled in the trial and the study cannot draw conclusions about adolescents.

Strengths

This trial demonstrated the feasibility of delivering an evidence-based mental health intervention in a largely rural state during a public health crisis without adding work to the healthcare system. The study successfully retained 98% of participants. The trial addresses an important gap in implementation science for Caring Contacts, demonstrating that it may not be necessary to introduce the Caring Contacts author and the recipient.

Limitations

This study has several limitations. A longer follow-up period would have allowed assessment of longer-term outcomes. Selection bias was likely present in (1) the patient sample, as 40% of enrolled patients were unemployed; and (2) the physicians and clinical providers, as they were about half as likely as other cadres of healthcare workers to participate in the study. This is the first time Caring Contacts has been rigorously evaluated in non-suicidal individuals, and without an inactive control arm conclusions about the efficacy of the intervention in this population cannot be made. With no inactive control arm, it is impossible to know whether changes in mental health observed in both intervention arms were due to regression to the mean or a cohort effect related to lived experience of the pandemic, which surged during the follow-up period, versus the effectiveness of the interventions. This is a limitation of all comparative effectiveness trials lacking inactive control arms.

Future Research

While this trial suggests that offering Caring Contacts to healthcare providers, staff, and patients experiencing mental distress is acceptable and feasible, additional research is needed to determine the efficacy of Caring Contacts to reduce mental distress in non-suicidal individuals compared to an inactive control arm. Determining whether results of this study would differ for Hispanic, and/or non-white populations is critical. Research is also needed to understand whether messages from a peer or clinical staff who have treated the patient would be received differently than those from someone unknown. It is unknown whether the findings from this study would be consistent in populations of suicidal individuals. Finally, research is needed to assess the comparative effectiveness of one-way versus two-way Caring Contacts, as the version being scaled often involves one-way communication, in which participants cannot interact with the person supporting them. [14,15]

Conclusions

Adding an introductory phone call did not significantly improve the effectiveness of a Caring Contacts intervention in a mostly White, mostly female population of healthcare providers, staff, and patients experiencing mental distress. Delivering the interventions in partnership with the state Crisis and Suicide Hotline facilitated provision of evidence-based mental health support during the peak of the COVID-19 pandemic without straining the healthcare system. Similar health system-community based partnerships could be replicated to deliver two-way text message Caring Contacts interventions elsewhere, including in settings with limited resources.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Study data were collected and managed using REDCap electronic data capture tools[3] hosted at the Institute of Translational Health Sciences. REDCap (Research Electronic Data Capture) is a secure, web-based application designed to support data capture for research studies, providing: 1) an intuitive interface for validated data entry; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for importing data from external sources.

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Highlights

- Evidence supports use of Caring Contacts to reduce suicidal ideation and behavior
- Important questions remain regarding how to deliver the intervention
- Introducing Caring Contacts recipients to the sender may not be necessary
- Outcomes were similar whether participants knew the person texting them or not
- Eliminating introductions could reduce the cost and complexity of the intervention

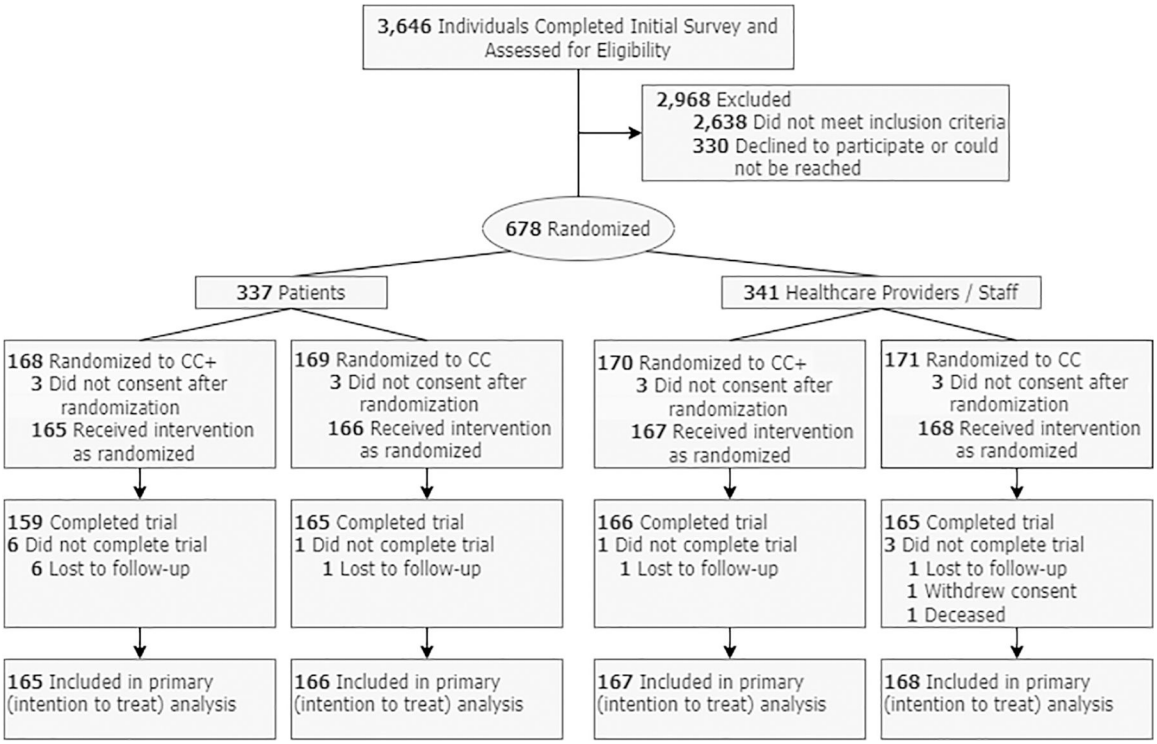

Fig. 1.
MHAPPD trial participant flow diagram.

Table 1:

Demographic Characteristics of MHAPPS Trial Participants by Strata and Study Arm

	Patients		Providers/Staff		All Participants	
	CC N=166	CC+ N=165	CC N=168	CC+ N=167	CC N=334	CC+ N=332
Sex						
Female	130 (78.3%)	131 (79.4%)	140 (83.3%)	150 (89.8%)	270 (80.8%)	281 (84.6%)
Ethnicity						
Hispanic or Latino	9 (5.4%)	11 (6.7%)	12 (7.1%)	19 (11.4%)	21 (6.3%)	30 (9%)
Not Hispanic or Latino	156 (94%)	154 (93.3%)	153 (91.1%)	145 (86.8%)	309 (92.5%)	299 (90.1%)
Unknown	1 (0.6%)	0 (0%)	3 (1.8%)	3 (1.8%)	4 (1.2%)	3 (0.9%)
Age						
Mean (SD)	44.3 (17)	46.7 (15.7)	41.6 (12.2)	40.1 (11.4)	43 (14.8)	43.4 (14.1)
Median (min, ma)	43 (12,89)	46 (17,83)	39 (20,69)	39 (21,72)	41 (12,89)	42 (17,83)
Race						
American Indian/Alaska Native	2 (1.2%)	0 (0%)	0 (0%)	0 (0%)	2 (0.6%)	0 (0%)
Asian	3 (1.8%)	1 (0.6%)	1 (0.6%)	2 (1.2%)	4 (1.2%)	3 (0.9%)
Black or African American	2 (1.2%)	1 (0.6%)	1 (0.6%)	0 (0%)	3 (0.9%)	1 (0.3%)
Native Hawaiian or Pacific Islander	1 (0.6%)	0 (0%)	1 (0.6%)	0 (0%)	2 (0.6%)	0 (0%)
Caucasian or White	153 (92.2%)	156 (94.5%)	155 (92.3%)	157 (94%)	308 (92.2%)	313 (94.3%)
Other or multiple	4 (2.4%)	4 (2.4%)	7 (4.2%)	5 (3%)	11 (3.3%)	9 (2.7%)
Unknown	1 (0.6%)	3 (1.8%)	3 (1.8%)	3 (1.8%)	4 (1.2%)	6 (1.8%)
Employed at baseline	101 (60.8%)	96 (58.2%)	168 (100%)	166 (99.4%)	269 (80.5%)	262 (78.9%)
Healthcare employee type						
Providers (physicians & advanced practice providers)	--	--	8 (4.8%)	8 (4.8%)	--	--
Pharmacy, patient access specialists, lab, specialists, technicians, medical assistants	--	--	26 (15.5%)	20 (12%)	--	--
Trades & food service	--	--	1 (0.6%)	2 (1.2%)	--	--
Nursing	--	--	57 (33.9%)	67 (40.1%)	--	--
Office work & educators	--	--	62 (36.9%)	60 (35.9%)	--	--
Senior management	--	--	2 (1.2%)	2 (1.2%)	--	--
Social support services	--	--	11 (6.5%)	6 (3.6%)	--	--
Other	--	--	1 (0.6%)	1 (0.6%)	--	--

Table 2:

MHAPPS Trial Baseline Clinical Characteristics and Primary & Secondary Outcomes at 6 Month Follow-up

	Patients				Providers/Staff			
	CC N=166	CC+ N=165	Adjusted Mean Difference (95% CI)	p-value	CC N=168	CC+ N=167	Adjusted Mean Difference (95% CI)	p-value
Loneliness (NIH Loneliness Scale) [a]								
Baseline loneliness								
Mean (SD)	64.4 (9.9)	64.4 (10.3)			62.6 (9.3)	62.5 (9.5)		
Moderate/high loneliness, No. (%)	132 (79.5%)	128 (77.6%)			125 (74.4%)	121 (72.5%)		
Follow-up Loneliness								
Mean (SD)	61.9 (10.7)	60.8 (10.3)	−1.0 (−3.0, 1.0)	0.31	61.2 (11)	61.3 (11.1)	0.2 (−1.8, 2.2)	0.83
Moderate/high loneliness, No. (%)	98 (59%)	87 (52.7%)			103 (61.3%)	98 (58.7%)		
Suicidal Ideation & Behavior (C-SSRS) [b]								
Baseline suicidal ideation/behavior (SI)								
Mean (SD)	0.5 (1.3)	0.4 (1.1)			0.3 (0.9)	0.4 (1.1)		
Any suicidal ideation, No. (%)	39 (23.5%)	39 (23.6%)			28 (16.7%)	26 (15.6%)		
Moderate/high SI, No. (%)	12 (7.2%)	9 (5.5%)			7 (4.2%)	9 (5.4%)		
Follow-up suicidal ideation/behavior (SI)								
Mean (SD)	0.4 (0.9)	0.6 (1.3)	0.2 (0.002, 0.5)	0.048	0.5 (1.2)	0.4 (1.1)	−0.2 (−0.4, 0.1)	0.2
Any suicidal ideation, No. (%)	40 (24.1%)	46 (27.9%)			41 (24.4%)	32 (19.2%)		
Moderate/high SI, No. (%)	11 (6.6%)	15 (9.1%)			18 (10.7%)	11 (6.6%)		
Perceived Burdensomeness (PB) (INQ-15) [c]								
Baseline Perceived Burdensomeness (PB)								
Mean (SD)	10.1 (6.7)	9.2 (5.4)			7.9 (3.6)	8.0 (4.9)		
Moderate/high PB, No. (%)	16 (9.6%)	12 (7.3%)			7 (4.2%)	5 (3.0%)		
Follow-up Perceived Burdensomeness								
Mean (SD)	9.6 (6.8)	9.5 (6.7)	0.5 (−0.6, 1.6)	0.38	8.4 (5.1)	8.5 (5.1)	0.1 (−0.8, 1.0)	0.81
Moderate/high PB, No. (%)	13 (7.8%)	15 (9.1%)			10 (6.0%)	7 (4.2%)		

	Patients				Providers/Staff			
	CC N=166	CC+ N=165	Adjusted Mean Difference (95% CI)	p-value	CC N=168	CC+ N=167	Adjusted Mean Difference (95% CI)	p-value
Thwarted Belongingness (TB) (INQ-15) [c]								
Baseline Thwarted Belongingness (TB)								
Mean (SD)	31.1 (11.1)	30.3 (11.4)			31.4 (10.0)	30.4 (11.8)		
Moderate/high TB, No. (%)	71 (42.8%)	62 (37.6%)			65 (38.7%)	62 (37.1%)		
Follow-up Thwarted Belongingness								
Mean (SD)	29.3 (12.2)	27.6 (12.3)	−0.4 (−2.6, 1.8)	0.73	27.8 (12.3)	28.6 (12.4)	1.2 (−0.8, 3.2)	0.24
Moderate/high TB, No. (%)	62 (37.3%)	47 (28.5%)			47 (28.0%)	58 (34.7%)		
Depression (PHQ-9) [d]								
Baseline Depression								
Mean (SD)	10.5 (6.1)	10.0 (6.0)			8.4 (5)	8.6 (5.4)		
Moderate/high depression, No. (%)	87 (52.4%)	82 (49.7%)			66 (39.3%)	66 (39.5%)		
Follow-up Depression								
Mean (SD)	8.6 (6.2)	7.9 (5.8)	−0.4 (−1.5, 0.7)	0.45	7.7 (5.1)	8.1 (5.4)	0.3 (−0.7, 1.3)	0.51
Moderate/high depression, No. (%)	65 (39.2%)	52 (31.5%)			59 (35.1%)	62 (37.1%)		

Note: bolded text indicates results at 6-month follow-up.

[a]The NIH Toolbox Social Relationship Scale for Loneliness is a validated method for measuring loneliness. Participants rate items on a 5-point scale, with options ranging from never (1) to always (5). This creates a raw score, which is then converted to a t-score, with higher scores indicating greater levels of loneliness. T-score of 50 represents the mean of the US general population (based on the 2010 Census) and 10 T-score units represents one standard deviation. A T-score of 60.7 or more (adults) or 60 or more (youth) indicates moderate to high levels of loneliness.

[b]The Columbia Suicide Severity Rating Scale (C-SSRS) 6-item screener (self-assessment lifetime-recent (baseline) and since last visit (6 months) for Primary Care settings versions will be used). The C-SSRS is a validated tool to assess suicidality. C-SSRS score is determined based on the highest question number to which the participant responds “yes”. For example, a score of 5 would be assigned to a participant who responded “yes” to Question 5 and any or all preceding questions. Higher scores are indicative of greater risk for suicide. C-SSRS screener scores range from 0 to 6, with higher scores indicative of higher suicide risk. Scores of 3 and higher indicate moderate to high risk for suicide.

[c]The Interpersonal Needs Questionnaire (INQ) was developed from the Interpersonal Theory of Suicide and the 15-item version (INQ15) is a validated tool to measure both perceived burdensomeness (PB) (6 items, scores range from 6 to 42) and thwarted belongingness (TB) (9 items; scores range from 9 to 63). Individuals provide a self-report response to each item ranging from 1 (Not at all true for me) to 7 (Very true for me). The appropriate items are reverse coded, and items are summed to calculate the TB and PB subscale scores with higher scores indicating greater TB and PB. Clinical Cutoff scores predicting desire for death (moderate/high as reported in table above) are 35 or greater for TB and 19 or greater for PB. Clinical cutoff scores predicting desire for suicide are 50 or greater for TB and 30 or greater for PB.

[d] The PHQ-9 is a widely used and validated tool to screen for depression in primary care and other non-psychiatric settings. The tool is composed of 9 questions each with a response of 0–3 which generate a score from 0–27 with higher scores indicating a greater degree of depression. Scores are categorized in the following manner: a score of 5–9 is considered minimal depression, 10–14 is considered mild major, 15–19 is moderate major, and ≥20 is severe major.

Table 3:

MHAPPS Trial Exploratory and Safety Outcomes & Baseline Clinical Characteristics

	Patients				Providers/Staff			
	CC	CC+	Adjusted Mean Difference (95% CI)	p-value	CC	CC+	Adjusted Mean Difference (95% CI)	p-value
Anxiety (GAD-7) [a]								
Baseline Anxiety	N=166	N=165			N=168	N=167		
Mean (SD)	9.3 (5.3)	8.8 (5.3)			7.8 (4.4)	8.4 (5)		
Moderate/high anxiety, No. (%)	62 (37.3%)	61 (37.0%)			44 (26.2%)	51 (30.5%)		
Follow-up Anxiety	N=165	N=159			N=165	N=166		
Mean (SD)	7.9 (5.6)	7.3 (5)	−0.3 (−1.3, 0.7)	0.54	6.8 (4.7)	8.2 (5.1)	1.0 (0.1, 2.0)	0.04
Moderate/high anxiety, No. (%)	44 (26.5%)	39 (23.6%)			38 (22.6%)	49 (29.3%)		
Stress (NIH Perceived Stress Scale) [b]								
Baseline Stress	N=166	N=165			N=168	N=167		
Mean (SD)	60.7 (8.7)	59.6 (8.6)			58.5 (7.3)	59.5 (7.7)		
Moderate/high stress, No. (%)	98 (59%)	85 (51.5%)			80 (47.6%)	94 (56.3%)		
Follow-up Perceived Stress	N=165	N=159			N=165	N=166		
Mean (SD)	56.5 (10.7)	55.3 (10.1)			55.1 (9.2)	57.6 (9.6)		
Moderate/high stress, No. (%)	64 (38.6%)	45 (27.3%)			59 (35.1%)	70 (41.9%)		
Change from baseline	−4.2 (9.3)	−4.4 (8)	−0.2 (−2.1, 1.7)	0.84	−3.3 (10.3)	−1.9 (9.9)	1.5 (−0.7, 3.7)	0.18
Recent mental health treatment [c]	N=164	N=158			N=164	N=166		
At follow-up, n (%)	119 (71.7%)	105 (63.6%)	−4.5% (−15.4%, 6.3%)	0.41	124 (73.8%)	123 (73.7%)	5.5% (−5.2%, 16.2%)	0.31
Increased substance use at follow-up [d]								
Increased Tobacco use, n/N (%)	23/163 (14.1%)	13/152 (8.6%)	−5.6% (−12.5%, 1.4%)	0.12	16/164 (9.8%)	6/164 (3.7%)	−6.1% (−11.5%, −0.7%)	0.03
Increased alcohol use, n/N (%)	42/162 (25.9%)	38/153 (24.8%)	−1.1% (−10.7%, 8.5%)	0.83	52/164 (31.7%)	55/162 (34%)	2.2% (−8.0%, 12.5%)	0.67
Increased marijuana use, n/N (%)	15/156 (9.6%)	19/152 (12.5%)	2.9% (−4.1%, 9.9%)	0.42	17/156 (10.9%)	14/159 (8.8%)	−2.1% (−8.7%, 4.5%)	0.53
Increased illicit drug use, n/N (%)	7/159 (4.4%)	3/157 (1.9%)	−2.5% (−6.3%, 1.4%)	0.2	3/159 (1.9%)	2/165 (1.2%)	−0.7% (−3.4%, 2.0%)	0.62
Safety Outcomes [e]	N=166	N=165			N=168	N=167		
Any death, n (%)	0 (0%)	0 (0%)			1 (0.6%)	0 (0%)		

	Patients				Providers/Staff			
	CC	CC+	Adjusted Mean Difference (95% CI)	p-value	CC	CC+	Adjusted Mean Difference (95% CI)	p-value
Death by suicide, n (%)	0 (0%)	0 (0%)			1 (0.6%)	0 (0%)		
Attempted suicide, n (%)	0 (0%)	0 (0%)			2 (1.2%)	0 (0%)		
Interrupted/aborted suicide attempt, n (%)	0 (0%)	1 (0.6%)			3 (1.8%)	3 (1.8%)		

[a] Symptoms of anxiety were assessed using the GAD-7, a brief self-report scale frequently used in the identification of Generalized Anxiety Disorder. The tool is composed of seven items, which are rated 0–3 to generate a score from 0–21. Higher scores indicate a greater severity of generalized anxiety symptoms. Scores of 11 and higher indicate moderate to high anxiety.

[b] The National Institute of Health (NIH) Toolbox Self-Efficacy Scales Perceived Stress measure is a validated tool to measure the stress and coping resources of an individual. The measure is comprised of ten items which are scored and granted a t-score specific to adult or adolescent participants. Higher t-scores are indicative of higher levels of stress. T-score of 50 represents the mean of the US general population (based on the 2010 Census) and 10 T-score units represents one standard deviation. A T-score of 60.5 or more for adults or 60.8 or more in adolescents indicates moderate to high levels of stress.

[c] Any counseling, therapy, or other mental health treatment in the last 6 months.

[d] Number of participants reporting increased alcohol, tobacco, marijuana, and illicit drug use, measured by questions adapted from Youth Risk Behavior Survey posed in relation to timing of COVID-19 pandemic.

[e] Three elements of the full version of the Columbia Suicide Severity Rating Scale (C-SSRS) (lifetime-recent (baseline) and since last visit (6 months)) were complied to create a Suicide Attempts Survey. These measured self-reported aborted or self-interrupted suicide attempts, interrupted suicide attempts, and actual suicide attempts. Non-lethal self-harm and lethal means used for attempts or completions were also collected. These elements were not included in the C-SSRS score but were compared across the intervention groups. Medical records were used to measure suicide completion.

Table 4:

MHAPPS Trial Summary of Ingoing and Outgoing Text Messages

		Patients		Providers/Staff	
		CC N=166	**CC+ N=165**	**CC N=168**	**CC+ N=167**
Initial call received	No. (%)	--	159 (96.4%)	--	157 (94%)
Number of text messages	mean (SD)	17.8 (6.3)	20.7 (5.8)	15.3 (4.5)	19 (5.3)
sent from Hotline	median (Q1, Q3)	16 (13, 20.8)	20 (16, 24)	14 (12, 17)	18 (15, 22)
Number of text messages	mean (SD)	9.9 (9.7)	11.4 (7.5)	6.2 (6.4)	9.9 (7.4)
sent from participant	median (Q1, Q3)	8 (3.2, 13)	11 (6, 15)	4 (2, 8)	9 (5, 14)