A mobile health app to increase engagement in mental health services: Protocol for a pilot randomized controllled trial

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Abstract

Background: Major depressive and anxiety disorders affect 57.3 million adults in the U.S.. People living with mental illness, including depression and anxiety experience stigma associated with the illness and receiving treatment for their illness. Stigma -- which refers to negative attitudes or beliefs about mental illness, or negative behaviors directed toward persons with mental illness (PWMI) -- is a leading and fundamental cause of health inequities. Contact interventions, which are premised on the idea that positive and voluntary contact with PWMI can effectively reduce mental illness stigma, are aimed at reducing stigma and improving health outcomes. Video-based interventions improve knowledge, attitudes and behavior in the short term, there is a need for randomized controlled trials of indirect contact or video based contact interventions to address stigma and engagement in mental health services.

Objective: The main study objective is to assess the feasibility and acceptability, and test the preliminary efficacy, of a self-administered, video-based mobile app in reducing mental illness stigma among Black adults with moderate to severe depression or anxiety.

Methods: The intervention will involve short videos (6-12 minutes in length) of patients describing personal narratives of mental illness, treatment and recovery; and will be delivered over 4 weeks, with two booster sessions in week 6 and 12. Study participants will be randomly assigned to one of 3 treatment arms: a standard video-based app (n=30), a video-based app modified with a concordant patient video (n=30), and a waitlist control (n=30).

Results: We hypothesize the concordant and standard intervention group will have greater mental health service utilization, lower stigma and lower mistrust compared to the waitlist arm. As a feasibility study, we will pilot the outcome analyses (to detect a signal and estimate direction of analysis. Based on the sample size of 90 (n=30 in each treated group and control group) and power at 72%, we will be able to detect a medium effect size of Cohen’s d=0.49 at alpha=0.05 using a paired Fisher-exact test for comparing the intervention vs. control proportions for any engagement in mental health care services.

Conclusions: Given the low uptake of mental health services for people experiencing early signs and emerging symptoms of mental illness, efforts to increase early access to mental health services will be met with ongoing significant barriers to mental health care utilization if stigma and medical mistrust are left unaddressed. Data from this pilot and feasibility randomized trial will provide critical information about the feasibility and acceptability of this intervention, and preliminary efficacy estimates. This study will fill a critical public health gap created by the stigma that leads to delayed diagnosis, delayed entry into mental health treatment, and increased morbidity and mortality related to mental illness. Clinical Trial: NCT06316804

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A mobile health app to increase engagement in mental health services: Protocol for a pilot randomized controllled trial.

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Introduction

Major depressive and anxiety disorders affect 57.3 million adults in the U.S. [1-3]. People living with mental illness, including depression and anxiety experience stigma associated with the illness and receiving treatment for their illness [4,5]. Stigma -- which refers to negative attitudes or beliefs about mental illness, or negative behaviors directed toward persons with mental illness (PWMI) [6] -- is a leading and fundamental cause of health inequities [7] [8,9]. The primary mechanisms through which stigma worsens mental health outcomes include delayed treatment seeking and limiting access to care [4]. Contact interventions, which are premised on the idea that positive and voluntary contact with PWMI can effectively reduce mental illness stigma [10], are aimed at reducing stigma and improving health outcomes. Past studies show face-to-face contact is superior to video-based contact; however, more recent randomized controlled trials show that video-based contact has a comparable effect in reducing stigma [4,11-14]. Video-based interventions improve knowledge, attitudes and behavior in the short term, there is a need for randomized controlled trials of indirect contact or video based contact interventions to address stigma and engagement in mental health services [4,14].

Interventions to reduce mental illness stigma among Black adults remain understudied [4,15], and the role of mistrust is rarely examined [16]. There is a need for methodologically strong research to develop scalable interventions to reduce stigma and address medical mistrust, thus potentially increasing mental health service use [4,14]. Concomitant with these known gaps in the current literature, we developed iteratively and using a co-design user centered design model, a mobile intervention platform to reduce stigma, address medical mistrust and increase mental health service engagement among Black adults. In this study protocol manuscript, we present on the planned protocol for a

novel randomized controlled interventing, testing the feasibility and preliminary efficacy of an anti-stigma mental health intervention delivered remotely on a digital mental health platform.

Several forms of stigma are prominent among PWMI and contribute to increased psychological distress [8,17-21]: enacted stigma -- the behavioral manifestations of negative attitudes about PWMI, including stereotyping, social distancing, prejudice, and discrimination [22,23]; anticipated stigma -- the expectation that one will be devalued for having mental illness and/or being subjected to stereotyping, prejudice or discrimination if one's mental illness were to become known by others [8,17,24]; and internalized stigma -- endorsing the negative attitudes and beliefs as valid, thereby developing self-defacing beliefs about oneself [24]. Among Black adults, the content of mental health stigma includes beliefs that mental illness is attributed to lack of faith in God, weakness, or lack of self-control [25-28]. However, current research studies approach Black adults as a homogenous group, and this assumption of homogeneity limits the efficacy of programs that seek to reduce mental illness stigma among Black adults in the United States[29]. Previous studies show that concordance in sociodemographic factors including race, ethnicity and religiosity may improve the efficacy of anti-stigma contact interventions [28].

Mobile mental health offers a mechanism to deliver interventions that can be modified in real time to align with user characteristics (such as race, ethnicity, or religious background) [30-35]. The largest systematic reviews and meta-analysis on stigma interventions to date have called for more culturally-informed approaches to the design of stigma interventions [4,6,14]. In addition, concordance (e.g. in racial or ethnicity) between patients and providers is associated with higher trust, improved communication, and higher intent to adhere to health services [36-38]. Medical mistrust may be directed towards health professionals or health systems, and is a known barrier to engagement in mental health

services for the Black population [16,39]. Anti-stigma interventions that simultaneously address medical mistrust may have enhanced efficacy [16,40,41]. Previous studies show that having health professionals of shared racial/ethnic/religious background would reduce their hesitancy towards accessing mental health services[37,42,43].

The main study objective is to address mental health gaps around the role of stigma in reducing mental health service engagement by assessing a mobile app, co-developed with end users. The user centered design phase involved usability testing to refine intervention components to meet the needs and preferences of end-users through an iterative, stepwise design process. Given the high stigma among underserved populations including Black adults with mental illness, screened participants in the user centered design study reported a preference for key informant interviews over focus groups. A separate paper has been published on the app development of the intervention that is being tested and reported on in this protocol study manuscript. This paper describes the protocol for a three arm randomized controlled waitlist trial to assess the feasibility and preliminary efficacy of an anti-stigma mobile mental health app, that integrates components that address mistrust of health systems.

Conceptual Framework

The conceptual model for stigma reduction is based on well-established sociological and psychological theories of behavior change. This model predicts that positive and voluntary contact with people living with mental illness can effectively reduce stigmatizing attitudes and stigmatizing behaviors [10,11]. Based on extensive research conducted by Corrigan, successful contact interventions have the following characteristics: Targeted (i.e., at a specific outcome, such as use of mental health services), local (within a geographical region such as an urban setting), credible (i.e., to the target group), continuously delivered

(i.e., not a single point of contact), involve contact (closing the social gap between people with stigma and people living with mental illness through direct (in person) or indirect (video based or virtual).

Meta-analyses have consistently shown that both face-to-face and video based contact with people living with mental illness can reduce stigma. Face-to-face interventions require intensive professional or peer facilitators, which significantly limits scaling, dissemination, and implementation goals [44]. Delivery of face-to-face stigma-reducing interventions can potentially be addressed by use of mobile mental health technology to deliver video-based interventions. Recent randomized trials of interventions that optimize the core underpinnings of video contact show that video-based contact has similar efficacy as face-to-face contact [12,13,45].

Methods

Study Objectives

The primary ojective is to assess the feasibility and acceptability, and test the preliminary efficacy, of a self-administered, video-based mobile app in reducing mental illness stigma among Black adults with moderate to severe depression or anxiety. The intervention will involve short videos (6-12 minutes in length) of patients describing personal narratives of mental illness, treatment and recovery; and will be delivered over 4 weeks, with two booster sessions in week 6 and 12. Study participants will be randomly assigned to one of 3 treatment arms: a standard video-based app (n=30), a video-based app modified with a concordant patient video (n=30), and a waitlist control (n=30).

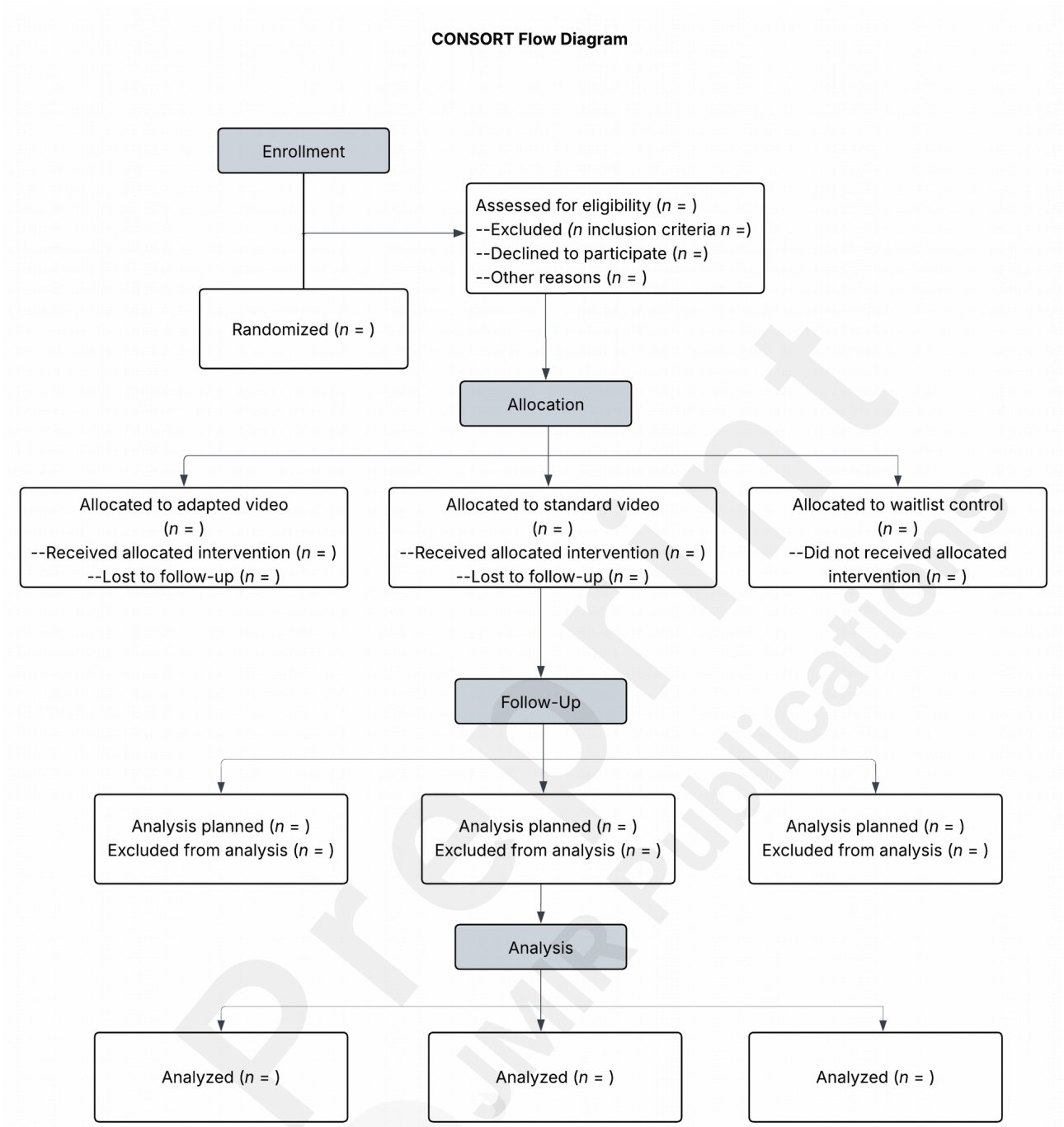
Hypotheses

We hypothesize the concordant and standard intervention group will have greater mental health service utilization, lower stigma and lower mistrust compared to the waitlist arm. We also hypothesize that among the two intervention groups, the concordant intervention group will have greater effects on the primary and secondary outcomes compared to the standard intervention group.

Study Design and Setting

The study is a single blind among two experimental arms and one waitlist control arm. Participants are unaware of which intervention arm they are assigned. It was not feasible to fully blind the participants to intervention versus waitlist but we are able to blind participants to the specific content of the two intervention arms.

Figure 1. CONSORT Diagram



Intervention overview

A self-administered, video-based stigma reduction app using a randomized controlled trial (RCT) design among Black adults (ages 18-45) from diverse ethnic backgrounds with moderate to severe depression and/or anxiety (PHQ9≥10 or GAD7≥10) who have not accessed mental health services in the past year.

The intervention videos involves 6-12 minute videos, offering narratives on treatment and recovery by people living with mental illness from diverse backgrounds including narratives of depression illness and recovery [46,47]. In the adapted (concordant) intervention arm, participants will be offered video content from someone with the same or similar sociodemographic background based on their reported characteristics at screening [48]. The standard (discordant) intervention arm will involve video contexnt from someone from a different sociodemographic background. The two intervention conditions will be delivered on a secure HIPAA-compliant platform. Content will be available in English at an 8th-grade reading level [49]. New sessions will be prompted each week based on the experimental condition arm, and usage data will be collected. The study will include individuals from various age groups, education and income levels and gender identities. Study participants will be randomly assigned to one of 3 arms: a standard video-based app (n=30), a video-based app modified with a concordant individual (n=30), and a waitlist control (n=30).

Setting and participants and eligibility criteria: Recruitment will take place through Massachusetts General Hospital Patient registry, online social media advertising and in partnership with community based organizations. All participants will be prescreened via phone call and/or online form. All participants will complete an orientation call prior to randomization. Inclusion criteria: 1) Black adults with moderate to severe depression (PHQ9$\geq$10) or anxiety (GAD7 $\geq$10) who are not receiving routine mental health care. 2) Ages 18-45 years at time of screening. 3) English speaking. 4) Own a smartphone and have internet access. Language variance and lack of access to a smartphone would prevent engagement in study procedures and impact feasibility assessment. Exclusion criteria: 1) Visual, hearing, voice, or motor impairments that would prevent engagement in

study procedures. 2) Diagnosis of psychotic disorder or severe suicidality for which participation would be inappropriate.

Procedure: At the initial visit, we will obtain baseline measurements of enacted, anticipated, and internalized stigma [8]. The self-administered intervention will be delivered over 4-weeks based on experimental condition, participants will each receive a standard video-based intervention or a concordant video based intervention. Each week, participants will be prompted with a notification (via text and/or email) to access each week's intervention components. The content of booster sessions in week 6 and 12 will be based on the experimental arm and will contain repeat sessions used in each experimental arm. The waitlist arm will receive the concordant video condition after 12 months.

Recruitment: Patients who present for general medical care at the selected MGB community clinic partners are routinely given screening tests (PHQ-9 and GAD-7). The Community Advisory Board (CAB) will support recruitment efforts. Flyers and announcements will be available in clinics and shared with community partners. Any participant who meets entry criteria on screening tests and may have declined mental health services will be offered the stigma intervention program. If a patient agrees to participate, a trained research assistant will contact the patient. In addition, using the EMR, patients who meet criteria within the last 12 months and have not received mental health services in the past year will be invited to participate in the eligibility screening. The waitlist arm will receive holiday cards, and text reminders to complete assessments. Incentives to participate in the stigma intervention include offering a low intensity, nonjudgmental and confidential option to patients who have screened positive for depression or anxiety but who are not receiving routine mental health care. To help with retention, starting at $20 for the initial baseline assessment, we offer a graded compensation schedule with $5-10

increments for subsequent assessments completed.

Assessments: Study recruitment and retention rates will be assessed to determine the feasibility of study procedures (Table 1). The feasibility outcomes will be measured based on acceptability of the study through measures of usability: System Usability Scale (SUS) and Usefulness, satisfaction, ease of use, and learning (USE) scales [52,53]. We will also document adherence based on time spent on the intervention program and app usage data to assess completion of video activities. Assessments will be completed using standardized measures (Table 1).

Study outcomes

Our study will assess our ability to recruit and retain study participants; and measure usability, satisfaction, and adherence. The *primary outcome* will be mental health service utilization, assessed 4 weeks post-intervention and at 3 months, 6 months, and 12 months. Secondary outcomes will include anticipated, enacted, and internalized stigma; medical mistrust; and help-seeking behavior.

Data collection and outcomes: Data collection will be done through a secure Research Electronic Data Capture (REDCap) database.

The *secondary outcomes* will be anticipated, enacted, and internalized stigma; medical mistrust; self-reported help-seeking behavior. Feasibility outcomes will be assessed including acceptability (USE and SUS), adherence (usage metrics), and retention in the study (online assessments completed).

Data Analysis and Power Calculation: As a feasibility study, we will pilot the outcome analyses (to detect a signal and estimate direction of analysis), recognizing that the trial may be underpowered. Based on the sample size of 90 (n=30 in each treated group and control group) and power at 72%, we will be able to detect a medium effect size of Cohen's d=0.49 at alpha=0.05 using a paired Fisher-exact test for comparing the intervention vs. control proportions for any engagement in mental health care services.

Randomization and Blinding

Participants will be randomized to one of three arms: a standard video contact arm, a concordant video contact arm and a waitlist control arm. Assignment to the 3 arms in a 1:1:1 allocation ratio will be determined centrally by the PI according to a computer-generated random schedule (i.e., in Stata). There is no practical way to fully blind the study participants to treatment assignment versus waitlist and accomplish the objectives of the study. However, the study participants will be blinded to the two intervention arms and will be unaware which intervention arm they were assigned. The research study staff and biostatistician (who will be conducting the outcome assessments and analysis respectively) will be blinded to treatment assignment status. To avert chance imbalances by ethnicity and sex, we will stratify randomization by ethnicity (African American, Afro-Caribbean/Afro-Latino/a/x and African immigrant) and sex. The regression models for the primary analysis include the stratification variables as covariates to ensure the estimated standard errors are accurate. We hypothesize that the concordant video arm will be superior to the standard video arm. The standard video arm is needed to test our hypothesis and understand the mechanistic effect of each therapeutic target.

Reliability and validity data for the study assessments (Table 2) [54-57]:

Table 2	
Variable	Reliability and Validity
4-item Reported and Intended Behavior scale (Evans-Lacko et al. 2011)	Reliability: Overall test–retest reliability was 0.75 and internal consistency, based on Cronbach's alpha among items 5–8 was 0.85.
29-item Internalized Stigma of Mental Illness (Boyd et al. 2014)	Reliability: The original ISMI reported test-retest reliability of 0.92
12-item Group-Based Medical Mistrust Scale (Shelton et al. 2010)	Reliability: Cronbach alpha for the full measure in previous studies (α=0.87–0.88). Validity: The total GBMMS score and its three subscales were positively correlated with avoidance of health care (total score: p<0.0001; r=0.344).
20-item General Help Seeking Questionnaire (Ibrahim et al. 2019)	Reliability: Cronbach alpha for the full measure in previous studies (α=0.91). Validity: The perceived quality of previous mental health care was positively related to intentions to seek help from a mental health professional for personal-emotional problems, *r*s(55) = 0.51, *p* < 0.001, and suicidal thoughts, *r*s(54) = 0.57, *p* < 0.001.

Missing Data: Data missing at follow-up could bias study findings. We plan to record the dropout reason. When dropout occurs completely at random, the statistical analyses stated will provide appropriate statistical inferences. The multiple imputation approach will be conducted for follow-up data that is missing at random.

Planned and Interim Analysis: We hypothesize that the contact based intervention arm that incorporates an approach using concordance will reduce stigma and lower medical mistrust, improving engagement in mental health services. Feasibility will be assessed by meeting our recruitment goals (90 participants), obtaining 80% of follow-up self-report data, and having a dropout rate of <20% in one or more treatment conditions, which is in line with previous mobile mental health intervention randomized controlled trials [58], and which would indicate the treatment format for future research. Recruitment and retention rates, acceptability, adherence to

study and treatment will be reported as percentages. The average USE and SUS scores will be reported.

Analyses will follow an “intention-to-treat" approach using all randomized participants. For the primary outcome of any engagement in mental health services, the proportion (and percentages) of engagement for each intervention condition will be reported and statistically compared using Fisher-exact tests. Primary outcome data will be collected at baseline pre-intervention, at 4 weeks post-intervention, at 6 and 12 weeks pre-booster sessions, and at 6 and 12 months). A linear mixed model adjusted for demographic covariates will model engagement in mental health care as the outcome and intervention condition as the explanatory variable of interest.

For the additional outcomes that are continuous such as GBMMS, means and standard deviations will be reported across the intervention conditions for each follow-up time. Paired Fisher-exact tests[59] will statistically compare the difference in the means for the intervention conditions from baseline to 6 months follow-up and from baseline to 12 months follow-up for each of the continuous outcomes. To evaluate the pre-post percentage differences between the categorical outcomes and the intervention conditions, McNemar’s tests will be performed. In addition, categorical outcomes such as RIBS will be reported as percentages and 95% confidence intervals for each intervention condition.

Ethical considerations

Full informed consent will be obtained by the principal investigator (a licensed physician) prior to study activities. A data safety monitoring board is not needed for a minimal risk

intervention (IRB determination).

Protocol deviations are documented and reported to the IRB and sponsor based on [BLINDED UNIVERSITY] IRB policy. Minor deviations are reported at continuing review based on designated timeline by the IRB. Any major deviations are reported at time of identifying the deviation based on IRB policy.

Data dissemination

The study results will be presented at conferences and in relevant journals. After data collection and initial analysis is completed and published, data will be managed based on sponsor (NIH) data management and privacy policy.

Discussion

Expected Findings

Black adults are known to have lower utilization of mental health services. In light of the increasing use of mobile devices, a self administered anti-stigma mobile app has the potential to enhance accessibility and scalability of traditionally difficult to access stigma reduction tools. This manuscript describes the study protocol for an ongoing RCT to assess two intervention arms (a concordant and standard video based stigma reducing mobile app) compared to a waitlist control group. We hypothesize that individuals assigned to the intervention groups will be more likely to choose to engage in mental health services, and report decreased stigma and decreased mistrust compared to the

waitlist control group. Additional secondary outcomes will allow use to estimate the extent to which changes in anticipated/enacted/internalized stigma and medical mistrust mediate the intervention's effect on the primary and secondary outcomes. Mediation analysis will be conducted to assess whether stigma (RIBS, ISMI) and medical mistrust (GBMMS) are potential mediators in the pathway between engagement in mental health care and the intervention [54,55,57,60,61]. Causal mediation analyses will be conducted to assess the relationships. The direct and indirect effects from the causal mediation analyses will be estimated. Percent of total mediation effect and 95% confidence interval from each causal mediation analysis will be provided. We will use the SAS procedure causalmed, based on methods developed by VanderWeele [62].

Study status

This is an ongoing randomized controlled clinical trial. Recruitment of participants started in July 2024 and is expected to be completed in July 2026 for the one-year surveillance follow-up. The study is currently under protocol version #3, with date December 2024.

Future directions

Given the low uptake of mental health services for people experiencing early signs and emerging symptoms of mental illness, efforts to increase early access to mental health services will be met with ongoing significant barriers to mental health care utilization if stigma and medical mistrust are left unaddressed. Data from this pilot and feasibility randomized trial will provide critical information about the feasibility and acceptability of this

intervention, and preliminary efficacy estimates.

Limitations

The sample size is insufficient to definitively test the effectiveness of the intervention for the primary outcomes. However, prior to making large investments in this line of study, delineating mechanistic targets, identifying key outcome assessments and measures will be critical to informing future investment in fully powered randomized controlled trials and implementation studies. The use of mobile technology varies across age groups, to address this limitation, we have chosen to include a narrow age group (18-45) while we test the preliminary efficacy of the mobile application.

Conclusion

Despite the limitations, the next step is to further refine the intervention (based on the current clinical trial) for testing in a fully-powered randomized controlled effectiveness trial. Future studies will be adequately informed on the refined approach in testing the effectiveness and implementation of this mobile app and other similar mobile health apps across disease conditions and across populations at risk of worsening of disease due to treatment hesitancy and high stigma. While the study is underpowered to test effectiveness, this study will fill a critical public health gap created by the stigma that leads to delayed diagnosis, delayed entry into mental health treatment, and increased morbidity and mortality related to mental illness.

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