

Protocol

# An mHealth App to Increase Engagement in Mental Health Services for Depression and Anxiety: Protocol for a Pilot Randomized Controlled Trial

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## Abstract

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**Background:** Major depressive and anxiety disorders affect 61 million adults in the United States. People living with mental illness, including depression and anxiety, experience stigma associated with the illness and receiving treatment for their illness. Stigma refers to negative attitudes or beliefs about mental illness or negative behaviors directed toward persons with mental illness. Stigma is a leading and fundamental cause of health inequities. Contact interventions, which are premised on the idea that positive and voluntary contact with persons with mental illness 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, and 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 aim 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 2 booster sessions in weeks 6 and 12. Study participants (N=90) will be randomly assigned to 1 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 use, 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). On the basis of 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  $d=0.49$  at  $\alpha=.05$  for comparing the intervention versus 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 substantial barriers to mental health care use if stigma and medical mistrust are left unaddressed. Data from this pilot and feasibility randomized controlled 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.

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**KEYWORDS**

stigma; mental health; interventions; illness; mental; services; mobile phone

## Introduction

### Background

Major depressive and anxiety disorders affect 61 million adults in the United States [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 [6,7], is a leading and fundamental cause of health inequities [8-10]. The primary mechanisms through which stigma worsens mental health outcomes include delayed treatment seeking and limited access to care [4,11]. Contact interventions, which are premised on the idea that positive and voluntary contact with persons with mental illness can effectively reduce mental illness stigma [9,11,12], 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 (RCTs) show that video-based contact has a comparable effect in reducing stigma [4,7,13-16]. Video-based interventions improve knowledge, attitudes, and behavior in the short term, and there is a need for RCTs of indirect contact or video-based contact interventions to address stigma and engagement in mental health services [4,7,15,16].

Interventions to reduce mental illness stigma among Black adults remain understudied [4,17-19], and the role of mistrust is rarely examined [20]. 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 [4,15,21]. 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 intervention, testing the feasibility and acceptability of an antistigma mental health intervention delivered remotely on a digital mental health platform.

Several forms of stigma are prominent among persons with mental illness and contribute to increased psychological distress [8,9,11,22-24]: enacted stigma—the behavioral manifestations of negative attitudes about persons with mental illness, including stereotyping, social distancing, prejudice, and discrimination [25,26]; 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 [8,27-29]; and internalized stigma—endorsing the negative attitudes and beliefs as valid, thereby developing self-defacing beliefs about oneself [28,29]. Among Black adults, the content of mental health stigma includes beliefs that mental illness is attributed to a lack of faith in God, weakness, or lack of self-control [30-33]. 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 [34-37]. Previous studies show that concordance in sociodemographic factors including race, ethnicity, and religiosity may improve the acceptability and efficacy of antistigma contact interventions [33].

Mobile mental health apps offer a mechanism to deliver interventions that can be modified in real time to align with user characteristics (such as race, ethnicity, or religious background) [38-42]. 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 [4,6,15,19,43]. In addition, concordance (eg, in race or ethnicity) between patients and providers is associated with higher trust, improved communication, and higher intent to adhere to health services [44-46]. Medical mistrust may be directed toward health professionals or health systems and is a known barrier to engagement in mental health services for the Black population [20,47,48]. Antistigma interventions that simultaneously address medical mistrust may have enhanced efficacy [20,49-51]. Previous studies show that having health professionals of shared racial, ethnic, or religious backgrounds would reduce their hesitancy toward accessing mental health services [46,52,53].

### Study Objective

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, codeveloped 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 3-arm randomized controlled waitlist trial to assess the feasibility and preliminary efficacy of an antistigma mobile mental health app, which integrates components that address the mistrust of health systems, in reducing mental illness stigma among Black adults with moderate to severe depression or anxiety.

### 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 [9,12,13]. On the basis of extensive research conducted by Corrigan et al [6], successful contact interventions have the following characteristics: targeted (ie, at a specific outcome, such as the use of mental health services); local (within a geographical region such as an urban setting); credible (ie, to

the target group); continuously delivered (ie, not a single point of contact); and involves 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] means).

Meta-analyses have consistently shown that both face-to-face and video-based contact with people living with mental illness can reduce stigma. In contrast to video-based contact, face-to-face interventions require intensive professional or peer facilitators, which significantly limits scaling, dissemination, and implementation goals [7,54,55]. The 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 RCTs of interventions that optimize the core underpinnings of video contact show that video-based contact has similar efficacy as face-to-face contact [7,14,55-57].

## Methods

### Hypotheses

We hypothesize the concordant and standard intervention group will have greater mental health service use, 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 follows a single blind design among 2 experimental arms and 1 waitlist control arm. Participants are unaware of which intervention arm they are assigned among the two experimental arms. It was not feasible to fully blind the participants to the intervention versus waitlist arms, but we are able to blind participants to the specific content of the two intervention arms.

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 2 booster sessions in weeks 6 and 12. Study participants (N=90) will be randomly assigned to 1 of 3 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).

The study team used the SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) checklist in the development of the study protocol and conceptualization of the study and as study activities were initiated. We have included

the page reference numbers for the SPIRIT checklist. The study team will follow the CONSORT (Consolidated Standards of Reporting Trails) checklist criteria throughout the study, including randomization scheme, study procedures, and planned analysis.

### Intervention Overview

#### *Intervention Format*

This study consists of a self-administered video-based stigma reduction app using an RCT design among Black adults (ages 18-45 years) from diverse ethnic backgrounds with moderate to severe depression and/or anxiety (9-item Patient Health Questionnaire <sup>3</sup>10 or 7-item generalized anxiety disorder <sup>3</sup>10) who have not accessed mental health services in the past year.

The intervention videos involve 6- to 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 [58,59]. 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 [60]. The standard (discordant) intervention arm will involve video content from someone from a different sociodemographic background. The 2 intervention conditions will be delivered on a secure HIPAA (Health Insurance Portability and Accountability Act)-compliant platform. Content will be available in English at an eighth-grade reading level [61,62]. 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 1 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, Participants, and Eligibility Criteria*

Recruitment will take place through the Massachusetts General Hospital patient registry, online social media advertising, and in partnership with community-based organizations. All participants will be prescreened via a phone call and/or an online form. All participants will complete an orientation call prior to randomization. To ensure representativeness of the sample, we will use a stratified random sampling of study participants to include equitable numbers of genders, migrant status, and ethnic origin (African Americans, African immigrants, Afro-Caribbean immigrants, and Afro-Latina). The participant eligibility criteria are shown in [Textbox 1](#).

**Textbox 1.** Participant eligibility criteria.

<p><b>Inclusion criteria</b></p> <ul style="list-style-type: none"><li>• Black adults with moderate to severe depression (9-item Patient Health Questionnaire <sup>3</sup>10) or anxiety (7-item generalized anxiety disorder <sup>3</sup>10) who are not receiving routine mental health care</li><li>• Aged 18 to 45 years at time of screening. This age range was chosen due to variability in technology across age groups, reducing the heterogeneity of technology use among participants.</li><li>• English speaking</li><li>• Own a smartphone and have internet access</li></ul> <p><b>Exclusion criteria</b></p> <ul style="list-style-type: none"><li>• Visual, hearing, voice, or motor impairments that would prevent engagement in study procedures</li><li>• Diagnosis of psychotic disorder or severe suicidality for which participation would be inappropriate</li></ul>
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Language variance and lack of access to a smartphone would prevent engagement in study procedures and impact feasibility assessment.

**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 the experimental condition, and 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 SMS text message and/or email) to access that week's intervention components. The content of booster sessions in weeks 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. At the orientation visit, for all participants, guidance on obtaining emergent or urgent services is provided, including reaching out to the study team (which includes a social worker, resource specialist, and psychiatrist) at any time.

**Recruitment**

Patients who present for general medical care at the selected Mass General Brigham community clinic partners are routinely given screening tests (9-item Patient Health Questionnaire and 7-item generalized anxiety disorder). The community advisory board will support recruitment efforts. Flyers and announcements will be available in clinics and shared with

community partners. Any participant who meets the entry criteria on screening tests and who 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 electronic medical records, patients who meet the 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 manage attrition in app use, which is common, we will send out weekly reminders using multiple methods such as email, text, and phone call reminders for participants missing study activities or assessments.

**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, and ease of use (USE) scales [63,64]. We will also document adherence based on time spent on the intervention program and app use data to assess the completion of video activities. Assessments will be completed using standardized measures (Table 1).

**Table 1.** Intervention feasibility trial process and outcomes.

Domain, construct, and measure	Baseline	Each week	After the booster	Follow-up at 6-12 months
<b>Feasibility outcomes</b>				
<b>Acceptability</b>				
USE <sup>a</sup> and SUS <sup>b</sup>		✓	✓	✓
<b>Retention to intervention</b>				
Completed assessments		✓	✓	✓
<b>Adherence to intervention</b>				
App metrics		✓	✓	✓
<b>Primary outcomes</b>				
<b>Demographic</b>				
Survey	✓			
<b>Any engagement with mental health services</b>				
EMR <sup>c</sup>	✓			✓
<b>Secondary outcomes</b>				
<b>Sigma scores</b>				
RIBS <sup>d</sup> and ISMI <sup>e</sup>	✓	✓	✓	✓
<b>Help-seeking behavior</b>				
GHSQ <sup>f</sup>	✓	✓	✓	✓
<b>Medical mistrust scores</b>				
GBMMS <sup>g</sup>	✓	✓	✓	✓
<b>Targets</b>				
<b>Sigma and medical mistrusts</b>				
RIBS, ISMI, and GBMMS	✓	✓	✓	✓

<sup>a</sup>USE: usefulness, satisfaction, and ease of use.

<sup>b</sup>SUS: System Usability Scale.

<sup>c</sup>EMR: electronic medical record.

<sup>d</sup>RIBS: Reported and Intended Behavior Scale.

<sup>e</sup>ISMI: Internalized Stigma of Mental Illness.

<sup>f</sup>GHSQ: General Help-Seeking Questionnaire.

<sup>g</sup>GBMMS: Group-Based Medical Mistrust Scale.

### 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. On the basis of 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  $d=0.49$  at  $\alpha=.05$  comparing the intervention versus control proportions for any engagement in mental health care services.

For the continuous outcomes (such as Group-Based Medical Mistrust Scale), we will use generalized linear mixed models with a gamma distribution for continuous outcomes. If variables are not normally distributed, we will explore a transformation. For binary outcomes, we will use Poisson or negative binomial regression depending on the variance.

### Randomization and Blinding

#### Randomization Scheme

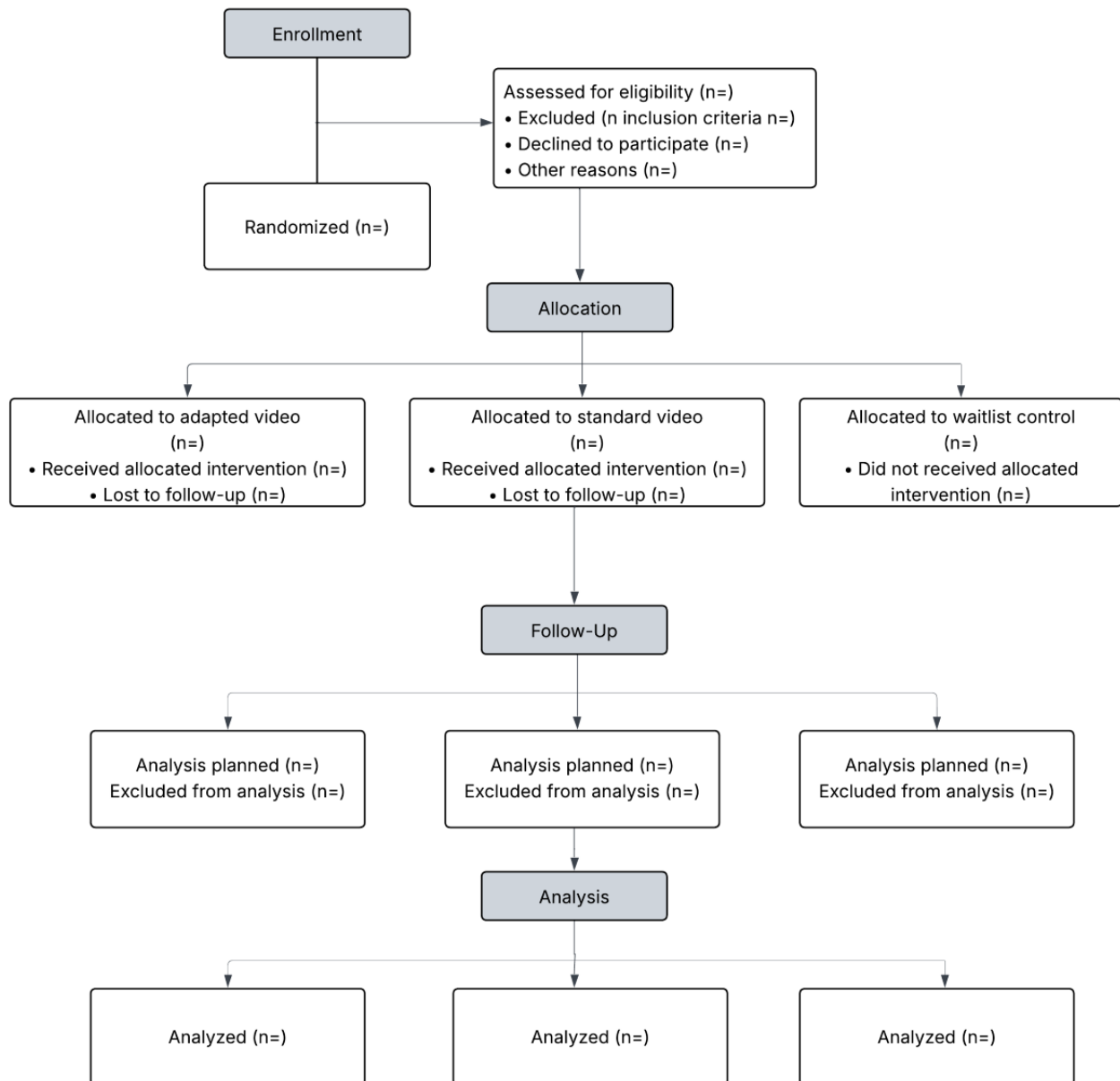
Participants will be randomized to 1 of 3 arms: a standard video contact arm, a concordant video contact arm, and a waitlist control arm as outlined in our CONSORT diagram (Figure 1). Assignment to the 3 arms in a 1:1:1 allocation ratio will be determined centrally by the principal investigator according to a computer-generated random schedule (ie, in Stata [StataCorp]). There is no practical way to fully blind the study participants to treatment assignment versus waitlist and accomplish the objectives of the study. To avoid bias among participants receiving the concordant or standard video assignment, we will conceal treatment arm allocation. We are testing the salience of concordance across sociodemographic characteristics; unblinding would prevent unbiased testing of the role of concordance. The study participants will be blinded to the two

intervention arms and will be unaware which intervention arm they were assigned throughout the study. The research study staff and biostatistician (who will be conducting the outcome assessments and analysis, respectively) will be blinded to treatment assignment status. The participants assigned to the waitlist will receive access to the concordant video contact intervention after they have completed their 12-month study assessment. To avert chance imbalances by ethnicity and sex, we will stratify randomization by ethnicity (African American,

Afro-Caribbean or Afro-Latino, 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 are shown in [Table 2 \[65-68\]](#).

**Figure 1.** CONSORT (Consolidated Standards of Reporting Trails) diagram.



**Table 2.** Reliability and validity data for the study assessments.

Variables	Reliability and validity	Estimated administration time
4-item Reported and Intended Behavior Scale (Evans-Lacko et al [66], 2011)	<ul style="list-style-type: none"> <li>Reliability: overall test-retest reliability was 0.75, and internal consistency, based on Cronbach <math>\alpha</math> among items 5-8, was 0.85.</li> </ul>	2 minutes
29-item Internalized Stigma of Mental Illness (Boyd et al [65], 2014)	<ul style="list-style-type: none"> <li>Reliability: the original ISMIa reported test-retest reliability of 0.92</li> </ul>	4-6 minutes
12-item Group-Based Medical Mistrust Scale (Shelton et al [67], 2010)	<ul style="list-style-type: none"> <li>Reliability: Cronbach <math>\alpha</math> for the full measure in previous studies (<math>\alpha=0.87-0.88</math>).</li> <li>Validity: the total GBMMSb score and its 3 subscales were positively correlated with avoidance of health care (total score: <math>P&lt;.001</math>; <math>r=0.344</math>).</li> </ul>	3-5 minutes
20-item General Help-Seeking Questionnaire (Ibrahim et al [68], 2019)	<ul style="list-style-type: none"> <li>Reliability: Cronbach <math>\alpha</math> for the full measure in previous studies (<math>\alpha=0.91</math>).</li> <li>Validity: the perceived quality of previous mental health care was positively related to intentions to seek help from a mental health professional for personal and emotional problems (<math>rs55=0.51</math>, <math>P&lt;.001</math>) and suicidal thoughts (<math>rs54=0.57</math>, <math>P&lt;.001</math>).</li> </ul>	3-5 minutes

<sup>a</sup>ISMI: Internalized Stigma of Mental Illness.

<sup>b</sup>GBMMS: Group-Based Medical Mistrust Scale.

### Missing Data

Data missing at follow-up could bias study findings. We plan to record the reason for dropout. 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 are 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 RCTs [69] 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.

We will assess the moderating role of sociodemographic factors (religiosity, migrant status, and socioeconomic status) by controlling for these variables in our pre-post assessments.

### Ethical Considerations

This study has been approved by the institutional review board (IRB) of Massachusetts General Brigham (2022P000580). 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). This study was registered on ClinicalTrials.gov (NCT06316804).

Protocol deviations are documented and reported to the IRB and sponsor based on Massachusetts General Brigham IRB

policy. Minor deviations are reported at continuing review based on the designated timeline by the IRB. Any major deviations are reported at time of identifying the deviation based on the IRB policy. All participants will complete a virtual orientation visit (prior to baseline assessment). At this visit, waitlist participants and intervention participants are provided guidance on obtaining emergent or urgent referral services, including reaching out to the study team (which includes a social worker, resource specialist, and psychiatrist) at any time throughout the study period.

All participants complete full informed consent prior to study activities. The study is voluntary and participants may discontinue participation at any time. The study team will ensure participants are able to safely discontinue participation. Only deidentified information is used for analysis and publication purposes. To help with retention, starting at US \$20 for the initial baseline assessment, we will offer a graded compensation schedule with US \$5 to US \$10 increments for subsequent assessments completed.

### Data Dissemination and Data Availability

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 (National Institutes of Health) data management and privacy policy. Deidentified data will be available in accordance with the National Institute of Mental Health Data Archive policy and timeline.

## Results

### Study Status

The study was funded on August 16, 2022. Initial activities involved app design. Following app design, clinical trial activities will be initiated. As of submission of the manuscript,

75 of 90 participants were successfully recruited. Study results will be published in March 2027.

### 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 use, assessed 4 weeks after the intervention and at 3 months after the booster sessions and again at 6 and 12 months, following booster sessions. Secondary outcomes will include anticipated, enacted, and internalized stigma; medical mistrust; and help-seeking behavior. The primary outcome is defined as any engagement with mental health services: this includes intake appointments, follow-up appointments, or scheduled appointments for mental health with a psychiatrist, physician or clinician, clinical psychologist, therapist, or self-report mental health service use (verified by electronic health records). At baseline, participants sign a release of information (ROI) form to allow the study team to obtain their medical records from their designated health system. The ROI form expires at 6 months, and a new ROI will be obtained to ensure the study team is able to retrospectively review use of mental health services at study completion at 12 months.

### Data Collection and Outcomes

Data collection will be done through a secure Research Electronic Data Capture (REDCap; Vanderbilt University) database. Our app platform allows us to track and collect data on app engagement and usage metrics.

The secondary outcomes will be anticipated, enacted, and internalized stigma; medical mistrust; and self-reported help-seeking behavior. Feasibility outcomes will be assessed, including acceptability (USE and SUS), adherence (use metrics), and retention in the study (online assessments completed). We define a priori targets for the SUS and USE scales as usability scores >70, indicating good to excellent usability and mean scores on the USE scales (comparing the two experimental arms). We will measure study adherence based on the number of app logins and target at least one video session and assessment completed.

## Discussion

### Expected Findings

Black adults are known to have lower use of mental health services. In light of the increasing use of mobile devices, a self-administered antistigma 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 2 intervention arms (a concordant and standard video-based stigma-reducing mobile app) compared with 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 with the waitlist control group. Additional secondary outcomes will allow an estimate of the extent to which changes in anticipated

or enacted or 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 (Reported and Intended Behavior Scale and Internalized Stigma of Mental Illness) and medical mistrust (Group-Based Medical Mistrust Scale) are potential mediators in the pathway between engagement in mental health care and the intervention [65,66,68,70,71]. 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% CI from each causal mediation analysis will be provided. We will use the SAS (SAS Institute) procedure CAUSALMED based on methods developed by Valeri and Vanderweele [72].

### 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 1-year surveillance follow-up. The study is currently under protocol version 3 (approved in 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 use 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 and identifying key outcome assessments and measures will be critical to informing future investment in fully powered RCTs 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 (aged 18-45 years) while we test the feasibility and acceptability of the mobile app.

### Conclusions

Despite the limitations, the next step is to further refine the intervention (based on this 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.

## Funding

ABP reports funding from US National Institutes of Health (K23MH128535).

## Authors' Contributions

ABP was responsible for conceptualization, data curation, formal analysis, funding acquisition, investigation, methodology, project administration, resources, software, supervision, validation, visualization, and writing of the paper.

## Conflicts of Interest

ABP reports receiving financial compensation for educational consultation from Otsuka, Apple Inc, and Quality Interactions.

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## Abbreviations

**CONSORT:** Consolidated Standards of Reporting Trails  
**HIPAA:** Health Insurance Portability and Accountability Act  
**IRB:** institutional review board  
**RCT:** randomized controlled trial  
**ROI:** release of information  
**SPIRIT:** Standard Protocol Items: Recommendations for Interventional Trials  
**SUS:** System Usability Scale  
**USE:** usefulness, satisfaction, and ease of use

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