Community Partnered Participatory Approach to Implement Depression Screening in Black Churches

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BACKGROUND

Study Purpose and Rationale

Depression is a leading cause of disability costing U.S. taxpayers $210 billion annually.[1] Significant racial disparities in depression exist with African American (AA) adults more disabled from the disease, and less likely to receive treatment compared to Whites.[2,3] These disparities have been linked to socio-economic, cultural, and contextual factors governing under-detection and under-treatment of depression.[4] For example, although most depression screening and treatment occurs in primary care settings, AAs are half as likely to be screened for depression in these settings compared to white adults.[5,6] Importantly, depression and anxiety disorders commonly co-occur. The current proposal seeks to test a novel "meet people where they are" engagement model for depression and anxiety screening and treatment referral among AAs, and evaluate its effect on detection of depression/anxiety and receipt of treatment. Churches are among the most trusted and influential institutions within AA communities.[7] AAs have the highest rates of church attendance among all racial/ethnic groups in the U.S., with over 60% attending church several times per month.[8] Approximately 72% of AAs with a serious personal problem, including depression, seek help in Black churches.[9] Indeed, in our prior work we found that 20% of adults in Black churches screened positive for depression using the Patient Health Questionnaire-9 (PHQ-9).[10] However, subjects with a positive depression screen (PHQ-910) universally declined treatment referral when offered by research coordinators.[11] Importantly, and relevant to the current study, a significant knowledge gap exists regarding effective strategies for linking church-based depression screening to engagement with clinical providers among AAs.[12]

Community Health Workers (CHWs) are trusted, culturally concordant lay health personnel from the local community with significant social capital.13 CHWs have proven effective at providing evidence-based screening and linkages to medical care for several chronic illnesses such as cancer and cardiovascular disease.[14] Although these conditions do not carry the same level of stigma as depression among AAs, we hypothesize that CHWs deployed for church-based depression screening can help overcome cognitive barriers and increase treatment engagement - defined as attending a depression-related clinical visit for which the subject reported receiving information, referral, counseling, or medication for depression.[15]

This proposal builds on extensive experience with depression and church-based research by the study team at Columbia University. Dr. Williams (Co-PI) completed a NIH-funded Randomized Controlled Trial targeting care-seeking behaviors for acute stroke, which involved 312 Black and Hispanic adults from 13 churches (Williams et al., 2019, JAMA Neurology).[16] In a separate NIMH-funded study (K23- MH102540), Dr. Hankerson (Contact-PI) trained 263 AA church members in an evidence-based mental health literacy intervention.[17] Through intramural funding, Drs. Williams and Hankerson created an 8-week CHW training program for Black churches in Harlem, NY, which includes an evidence-based program called Screening, Brief Intervention, and Referral to Treatment (SBIRT). The brief intervention in SBIRT is Motivational Interviewing (MI): an empirically tested, client-centered counseling approach.[18] The overarching aim of the current study is to expand the scope of these CHWs to include depression and anxiety screening, brief intervention, and referral.

Research Aims & Abstracts

Aim 1: To compare the effect of SBIRT (Intervention arm) to Referral As Usual (RAU) (Usual Care arm) on treatment engagement. We will randomize 15 churches to each study arm. Adults with a positive depression screen (n=600) will receive either SBIRT (Screening + Brief Intervention + Referral to Treatment) or RAU (list of treatment sites + depression education pamphlets). We hypothesize that SBIRT will lead to increased treatment engagement (primary outcome) compared to RAU at 6-months post-screening.

Aim 2: To assess changes in mental health outcomes at 3- and 6-months post-screening. We hypothesize that adults in the SBIRT arm will have better Mental Health-Related Quality of Life and fewer depressive and anxiety symptoms (secondary outcomes) compared to those in the RAU arm.

Aim 3: To identify contextual factors that act as facilitators or barriers of depression/anxiety screening and referral. Guided by the Consolidated Framework for Implementation Research (CFIR), we will conduct a mixed-methods process evaluation with key stakeholders (clergy, CHWs, and congregants with positive PHQ-9 screen) to understand multi-level influences on depression/anxiety screening and referral.

STUDY DESIGN

Using a Hybrid Type 1 Effectiveness-Implementation design,[19] we propose a 2-arm, mixed-methods Cluster-Randomized Controlled Trial within 30 Black churches our CHWs currently attend. Guided by the Consolidated Framework for Implementation Research (CFIR), we will assess key implementation variables related to depression screening uptake. We will also assess patient-level barriers and facilitators of help-seeking behaviors for depression. Data collection will be prospective. We will randomize 15 churches to the intervention arm (SBIRT) and 15 churches to the control arm (Referral as Usual). The TRIUMPH Instagram, Facebook, and Twitter websites will be monitored daily by Project Coordinators and Research Assistants. Monitoring of the social media websites will ensure accuracy of information posted about the study as well as prompt action if someone expresses suicidal ideation or behavior with imminent risk of harm to self or other themselves through a post comment or Direct Message (DM).

Suicidality De-escalation Plan

Plan for Non-Participant Comment or DM: When a comment or DM of concern is received from a non-participant, one of the Study's IRB-approved research personnel will respond to the individual via Direct Message with the following: "Hello, thank you for reaching out to the TRIUMPH Research Study team. We saw your comment/DM and are concerned for your safety and well-being. If you or someone you know is struggling or in crisis and need immediate support, please reach out to the National Suicide Prevention Lifeline by calling or texting '988'. You can also reach out to the NYC WELL Hotline by sending the text "WELL" to 65173 or call 1-888-NYC-WELL for support with problems like stress, depression, anxiety, or drug and alcohol use. Both services are available 24/7."

Plan for Study Participant Comment or DM of Concern: When a comment or DM of concern is received from a TRIUMPH Research Study participant, one of the Study's IRB-approved research personnel will respond to the individual via Direct Message with the following: "Hello, thank you for reaching out to the TRIUMPH Research Study team. We saw your comment/DM and are concerned for your safety and well-being. A member of our staff will be reaching out to you shortly via phone call to follow up. If you or someone you know is struggling or in crisis and need immediate support, please reach out to the National Suicide Prevention Lifeline by calling or texting '988'. You can also reach out to the NYC WELL Hotline by sending

"WELL" to 65173 or calling 1-888-NYC-WELL for support with problems like stress, depression, anxiety, or drug and alcohol use. Both services are available 24/7." The Program Coordinator will also immediately initiate the current IRB-approved safety assessment protocol. Dr. Hankerson, Dr. Waller, Dr. Williams, or other on-call personnel will assess and quantify safety risk with the Columbia-Suicide Severity Rating Scale (C-SSRS). The on-call clinician will then review the score on the C-SSRS and quantify the specific suicidal plans and access to lethal means (e.g., firearms). For participants with active suicidal ideation or behavior with imminent risk of harm to self or others, severe disability, or psychosis, the Study participant's assigned CHW or a member of the assessment team will immediately collaborate with church staff and the participant's family for transfer to a local Emergency Room or Mobile Crisis. For participants with non-active suicidal ideation/behavior, the Study participant's assigned CHW or a member of the assessment team will inform the study's PIs within 24 hours and complete the Stanley-Brown Safety Plan. The Study participant's assigned CHW will inquire to see if the subject is currently in treatment, and if so, he/she will attempt to contact the participant's mental health provider. If the subject does not attend or refuses the in-person assessment, Mobile Crisis will be dispatched to the residence. Dr. Hankerson or one of the Project Coordinators will report any adverse events to the IRB and inform them of the actions taken to address the event. Any further action will be taken at the direction of the IRB.

Study procedures

The Columbia University Community Health Worker (CHW) Program has trained and certified 102 CHWs from 42 Black churches in Harlem. These CHWs will serve as interventionists in the current protocol.

We will conduct a two-arm, cluster Randomized Controlled Trial in 30 Black churches that will compare the effectiveness of CHW-delivered Screening, Brief Intervention, and Referral to Treatment (SBIRT, n=15 churches) to Referral as Usual (RAU, n=15 churches) on treatment engagement (primary outcome). We will assess change in Mental Health-Related Quality of Life (QoL) and depressive symptoms at 3- and 6-months post-screening (secondary outcomes).

Prior to participant enrollment, CHWs will receive an additional 18 hours of booster training sessions prior to screening implementation. Training will take place at Columbia University's Wellness Center or virtually. We have added a training module on human subjects,

including CITI and HIPAA certifications. The booster training curriculum will be reviewed by our Community Coalition for cultural appropriateness prior to implementation. Dr. Hankerson or a designee will facilitate each booster training session. Based on our experience with cultural and faith-based curriculum tailoring, our CHWs will not only be instructed on what to say, but also on what not to say, such as suggesting that depression or trauma was due to a person's moral failure. We have also included a module on trauma, informed by our pilot work, which revealed that a large proportion of adults in our target population have been exposed to some type of traumatic event. Guided by the information-motivation-behavioral skills (IMB) model, all CHWs will complete measures of knowledge (mental health literacy – Information), attitudes towards people with mental illness (Motivation), and self-efficacy (Skills) in providing services to people with mental illness prior to and after completion of the training. CHWs will also be observed for comfort and skill during booster sessions.

Church-based study procedures: Each CHW will collaborate with church leaders (see study sites and letters of support) to organize depression screening events at church health-focused programs. Two CHWs and at least one Project Coordinator (PC) or designee will be present at the church for each screening event to assist with scoring the Patient Health Questionnaire-9 (PHQ-9), Generalized Anxiety Disorder-7 (GAD-7), interpreting the results, and study enrollment. Eligibility for depression screening include: 1) Adults 18 years and older; and 2) English-speaking. There are no exclusion criteria for general depression screening. The screening will occur in a private space in the church to protect participant confidentiality. The screening survey will include the PHQ-9, GAD-7 and demographic information. Participants will submit their completed survey to the CHW in a private church space, who will quickly assess for suicidality by examining responses to Question #9 of the PHQ-9. Eligibility for the Randomized Controlled Trial (RCT) depends on the participants' total PHQ-9 score:

- Participants whose PHQ-9 4 (negative depression screen), are ineligible for the RCT and will receive a copy of Mental Health Resources.

- Participants whose PHQ-9 5 (positive depression screen), will be eligible for the RCT and invited to sign informed consent to participate in the study.

- Participants whose GAD-7 4 (negative anxiety screen), are ineligible for the RCT and will receive a copy of Mental Health Resources.

- Participants whose GAD-7 5 (positive anxiety screen), will be eligible for the RCT and invited to sign informed consent to participate in the study.

Safety Assessment and Quality Assurance. If a subject responds positively to Question #16 of the PHQ-9 or verbally endorses suicidality, the CHW will initiate a safety assessment protocol. The CHW will assess and quantify safety risk with the Columbia-Suicide Severity Rating Scale (C-SSRS). After administering the C-SSRS, the CHW or a member of the assessment team will immediately call the on-call study clinician (Drs. Hankerson or Williams or another licensed clinician). The on-call clinician will then conduct a brief, standardized clinical interview that reviews the score on the C-SSRS and quantifies the specific suicidal plans and access to lethal means (e.g., firearms). For participants with active suicidal ideation or behavior with imminent risk of harm to self or others, severe disability, or psychosis, the CHW or a member of the assessment team will immediately collaborate with church staff and the participant's family for transfer to a local Emergency Room or Mobile Crisis. For participants with non-active suicidal ideation/behavior, the CHW will inform the study PIs within 24 hours and complete the Stanley-Brown Safety Plan94,95 (see 'Safety Plan' in Appendix). The CHW will inquire to see if the subject is currently in treatment, and if so, he/she will attempt to contact the participant's mental health provider. The subject will be referred for an in-person clinical interview with the on-call study clinician within 48 hours. If the subject does not attend or refuses the in-person assessment, Mobile Crisis will be dispatched to the residence.

Eligibility for Participation in RCT among Participants with a Positive Depression Screen with the PHQ-9 OR a Positive Anxiety Screen with the GAD-7. Inclusion criteria are: 1) Adults 18 years and older; 2) English speaking; 3) PHQ-95; and/or 4) GAD-75. Exclusion criteria are reporting active suicidality, or verbally endorsing homicidal ideation or psychotic symptoms, and those actively receiving formal treatment for depression or mental health illness (e.g. with medications and/or psychotherapy).

Intervention arm: [(Screening + Brief Intervention + Referral to Treatment), n=15 churches]. CHWs will provide two Motivational Interviewing (MI) sessions in each of the first three months, for a maximum of 6-MI sessions over 3 months. The initial two sessions will be conducted in person at the church and follow-up sessions will occur either inchurch or over the phone. Data will be collected on method of delivery. MI sessions will create a non-judgmental and supportive environment for eligible participants to move through the various stages of change

associated with depression help-seeking. In the initial session, CHWs will focus on establishing rapport using open-ended questions, affirmations, reflections, and summary statements (OARS). They will then review depression symptoms based on the participants PHQ-9 score. The second session will focus on assessing motivation and confidence in seeking treatment and elicit barriers and facilitators for depression treatment. Follow-up sessions will involve summarizing the 'pros' and 'cons' of depression treatment; providing options for the participant based on the nature of barriers elicited from them; assessing participant's values and goals, to help them link their current mental health pattern to their goals; and summarizing what was discussed to clarify an action plan. The final component of SBIRT involves actual referrals to treatment. This begins with determination of the individual's health insurance status. Persons without insurance will be enrolled with the assistance of CHWs (who are certified New York State Insurance Navigators) into New York State health plans (insurance exchange or Medicaid). Based on our preliminary studies, we expect 12 to 15% of subjects to be uninsured. Individuals ineligible for health insurance will be referred to our network of free clinics providing mental health services. Uninsured individuals will also be referred to the NYC Dept. of Health Action Centers, to insurance information, and other social services (see Letters of Support). Referral involves the CHW calling (using study-issued prepaid calling cards) or offering to call the provider's office on behalf of the subject to make an appointment, plus a follow up appointment call reminder the day before the appointment.

Usual Care arm: [Referral as Usual (RAU), n=15 churches]. Distributing depression educational materials and contact information for treatment providers is the most common form of referral. This practice will represent "usual care" for our study. We will utilize depression educational brochures describing the nine hallmark symptoms of depression symptoms and the importance of seeking treatment: one from the National Institute of Mental Health (NIMH), or one from the American Psychiatric Association (APA), or one from National Alliance of Mental Illness (NAMI). CHWs assigned to usual care churches will distribute the list of referral sites and pamphlets to study participants at designated screening events. No specific referrals will be made in this arm. CHWs will meet with participants in this arm at most, 2 sessions. If additional services are needed after the 2 sessions, participants will be referred to Neal Sutton and Cynthia Swagin to provide ongoing support.

Assessments. Within two weeks of completing the PHQ-9, GAD-7 and study enrollment, project Coordinators or a member of the assessment team will contact participants to schedule and conduct telephone baseline assessments with participants who signed informed consent. Participants will have the option to self-administer the 3-month or 6-month assessment via a secure link sent directly to REDCap. If a subject responds positively to any of the suicidality questions during the Baseline, 3-month or 6-month assessment, the CHW will immediately be notified to initiate a safety assessment protocol. The CHW will assess and quantify safety risk with the Columbia-Suicide Severity Rating Scale (C-SSRS). After administering the CSSRS, the CHW will immediately call the on-call study clinician (Drs. Hankerson or Williams or another licensed clinician). The on-call clinician will then conduct a brief, standardized clinical interview that reviews the score on the CSSRS and quantifies the specific suicidal plans and access to lethal means (e.g., firearms). Table 3 shows the name and construct for each clinical measure collected at baseline, 3-months, and 6-months post screening.

Scheduling Assessments and Intervention Arm Sessions: TRIUMPH staff will use CUIMC's Microsoft Bookings, an online and mobile app for teams that offer appointment-based services and can only be used by people with a current, individual CUIMC email or Office 365 account.

Text based reminders: TRIUMPH staff will use CUIMC recommended encrypted text-based communication. REDCap is our HIPAA compliant-platform for data collection and participant text communications for engagement messages and appointment reminders. Mosio is REDCap's integrated HIPAA compliant text messaging solution. CUIMC recommends the use of Doximity Dialer, Google Voice, FaceTime and WhatsApp for communication with research participants if required as part of an ongoing research study.

Virtual study procedures: Considering COVID-19 and the New York State on Pause law, we will also conduct study procedures virtually. Study Project Coordinators will facilitate Columbia-HIPAA compliant Zoom screening events with church members from approved church study sites. The same study procedures outlined above will be followed, however, the interaction will be conducted via Zoom.

Suicidality de-escalation plan: When a comment or DM of concern is received from a non-participant, one of the Study's IRB-approved research personnel will respond to the individual via Direct Message with the following: "Hello, thank you for reaching out to the TRIUMPH Research

Study team. We saw your comment/DM and are concerned for your safety and well-being. If you or someone you know is struggling or in crisis and need immediate support, please reach out to the National Suicide Prevention Lifeline by calling or texting '988'. You can also reach out to the NYC WELL Hotline by sending the text "WELL" to 65173 or call 1-888-NYC-WELL for support with problems like stress, depression, anxiety, or drug and alcohol use. Both services are available 24/7."

STATISTICAL PROCEDURES

The design is a cluster randomized trial with randomization at the level of churches. There will be 30 churches, 15 randomized to the intervention (SBIRT) and 15 to the usual care arm (Referral As Usual). We will screen an average of 100 adults per church, yielding a pool of 3,000 respondents. Based on our pilot study we posit that 20% of church attendees will screen positive for depression, defined as PHQ-910. The primary outcome is treatment engagement for depression (clinical encounters). Secondary outcomes include the QIDS-SR, (mean=16.3, SD=4.0 estimated from a previous study in an ethnically diverse sample), the PROMIS Depression scale (mean=50, SD=10), PROMIS and the SF-12 measure of quality of life (QoL) (mean=50 and SD=10). Clinically meaningful change on the QIDS-SR has been estimated as about 5 points. For the PROMIS short-form measure, a minimally important difference has been reported as an effect size of 0.3 to 0.5 (about one third to one half standard deviation units). There will be three waves of data: baseline, 3- and 6-months. Power calculations are presented for the primary outcome.

Power is > 0.80 for detection of clinically meaningful effects of approximately 10% to 11% group differences in treatment engagement (Primary Outcome).

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