Building Infrastructure for Community Capacity in Accelerating Integrated Care: The Strong Minds-Strong Communities Randomized Clinical Trial

Study Protocol

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I. Introduction to Protocol:

In this protocol, we have included elements of the funded study that pertain to the Strong Minds-Strong Communities clinical trial, described in the submitted publication. We have not included details of other study activities that go beyond the scope of the clinical trial, and we have synthesized language to be clear for publication. Terminology and roles reflect the primary IRB site, with some adjustments in practice at the cede review site.

II. Background and Significance

For racial/ethnic and linguistic minorities, disparities emerge along the continuum of mental health care. Members of these groups are heavily represented in Medicaid. Nonetheless, they face many barriers to care, including a shortage of trained providers who can provide culturally congruent service in their preferred language and an absence of easy identification of mental health needs. Members of racial/ethnic and linguistic minority groups are less likely to initiate and remain engaged in mental health treatment. When accessing care, they frequently receive less appropriate or poorer quality services. As a result, Latino, Asian, and Black individuals experience greater unmet need compared to non-Latino Whites (~80% vs. 63%).

Although the Affordable Care Act (ACA) expanded Medicaid eligibility, Medicaid expansions do not appear to have decreased the gap in mental health treatment between Whites and racial/ethnic minorities. State Medicaid-based accountable care organizations (ACOs) are increasing in number, with the goal of providing care coordination via team-based approaches, reducing disparities, and linking with community-based services employing a population health approach within capitated financing. However, many ACOs have not yet incorporated mental health services into their provider networks, representing a missed opportunity to close a

treatment gap. To reduce mental health disparities for racial/ethnic and linguistic minorities, this study examines how to successfully build staff capacity and training opportunities to help ACOs implement evidence-based mental health interventions.

The purpose of this research project is to reduce mental health disparities for racial/ethnic and linguistic minorities by establishing community-ACO-academic partnerships to collaborate in building capacity for mental health care; training Community Health Workers (CHWs) to provide an integrated, evidence-based intervention in community settings linked to ACOs; and addressing participants' activation and social needs through a care manager that connects participants to needed services. We propose a model that includes CHWs as mental health providers, who offer an evidence-based mental health intervention called Strong Minds-Strong Communities to address the shortage of trained providers who can offer culturally congruent mental health service in non-English languages in Medicaid-based ACOs, thereby expanding ACO infrastructure and increasing access to and quality of mental healthcare for racial/ethnic and linguistic minorities in North Carolina (NC) and Massachusetts (MA).

The following protocol focuses on Aim 2, the clinical trial portion of the study.

III. Study Design Summary

A. Inclusion/Exclusion Criteria

Inclusion Criteria: Latino, Asian, Black (African American or Afro-Caribbean), or non-Latino White adults 18+ years of age with moderate to severe symptoms of depression and anxiety. This includes participants who score 50+ on the CAT-MH depression administered in English/42+ for the CAT-MH depression administered in Spanish or Chinese and/or 51+ for the

CAT-MH anxiety administered in English /41+ for the CAT-MH administered in Spanish or Chinese; and/or a positive score on the CAT-MH Major Depressive Disorder, and without any mental health care (therapy sessions with psychiatrist, psychologist or social worker) in the past 3 months or upcoming in the next month. Participants must speak English, Spanish, Mandarin, or Cantonese.

Exclusion Criteria: Participants will be excluded if there is evidence of: (1) history of psychosis, mania, or psychotic symptoms; (2) specialty mental health treatment within past 3 months; (3) upcoming behavioral health appointment (pharmacological not excluded); (4) evidence that the participant lacks capacity to consent (measured by a validated screener); (5) evidence of current suicidal risk or harm to others (affirmative responses on Paykel suicide questionnaire); and (6) severe alcohol or substance dependence (CAT score 70+, showing a high level of risk in substance use).

Recruitment goals: We estimate needing to screen 3,525 participants per site (MA and NC, total of 7,050) to end up at roughly 600 eligible and willing to participate in the intervention trial in each site with attrition (1200 across MA and NC).

IV. Source of Subjects and Recruitment Methods

Recruitment in Massachusetts and North Carolina will occur in ACOs with large populations of ethnic minorities, as well as Community Clinics and Community Based Organizations (CBOs) that serve large numbers of racial/ethnic and linguistic minority clients in the ACO catchment areas. We will accept referrals of potential participants to screen from clinicians or staff at the organizations. We will also consider individuals who are not necessarily patients or clients of the participating clinics or community-based organizations. We will also recruit potential participants

via electronic medical records or other patient or client databases, by first sending a letter and then following up by phone to invite potential patients to participate.

Within collaborating ACOs/CBOs, Community Health Workers (either hired by the research sites or ACO/CBO sites) or Clinical Research Coordinators will recruit and screen participants. They will take part in regular supervision and will have access to study staff they can contact while in the field to provide advice and guidance as needed, related to recruitment, consent, screening, and initiation of emergency protocols if needed. Research staff will recruit and screen participants, while potential participants are at the ACOs/CBOs for regular programming. CHWs or CRCs will work closely with the providers to identify potential participants who may be approached for screening. Depending on clinic preferences, CHWs/CRCs may also approach any individual waiting in the clinic. After introducing themselves and explaining that they would like to discuss a new study being implemented at the ACO/CBO, the CHW or CRC and potential participants will move to a private room for consent.

Since the onset of the coronavirus, we will provide the option of continuing our recruitment by phone. We adjusted our protocol to allow audiotaped, phone-based informed consent. This will be particularly useful for participating sites, given that we will contact potential participants by phone identified through health records. We would contact potential participants as described above, via a letter from the PI and clinic director from that site (previously approved by the IRB) and then by phone to assess interest in participating. Staff at community sites can also indicate to their clients on outreach calls that someone from our study will contact them, and then our staff will reach out by phone. Community sites will share the names of clients that we can contact.

V. Subject Enrollment

A. Methods of enrollment, including procedures for obtaining consent

Community Health Workers or Clinical Research Coordinators will administer the informed consent at each ACO/CBO site. The CHW or CRC will go through the Informed Consent Form and ask the potential participant if he/she is interested and willing to be screened. We will ask the potential participant to sign the Informed Consent Form prior to administering the screening. If the potential participant is eligible and willing to take part in the program, the CHW or CRC will administer a capacity to consent form (based on Zayas et al, 2015). Subjects are not limited in the time taken to decide whether or not to participate in the study. However, if they inform us 2 months or longer after their initial screen that they would like to participate, CHWs or CRCs will re-administer the screener to ensure they continue to be eligible.

Following the onset of the COVID-19 pandemic, rather than scheduling an appointment to conduct the consent and screening in person in the clinic or community site with an interested patient, we will allow research staff to administer the full informed consent by phone to potential participants from the participating clinical and community-based organizational sites. If the potential participant expresses interest, then the CHWs will proceed to review the full informed consent and text messaging consent with the participants by phone verbally. We note here that if potential participants share their email addresses with the CHWs and express that they would like to review a copy of the informed consent, we will email them. We will not record the full consent administration, however we will audio-record the participant's screener ID and ask them to confirm verbally that they reviewed the informed consent form and text messaging consent form with the research staff by phone and that they consent to participate and to receive text messages from the study. We will ask them to verbally respond as well on audiotape to the

subsequent questions such as sharing info with the PCP and related to referrals. CHWs will proceed to administer the screener to participants who provide verbal consent to participate in the study. CHWs will administer the Capacity to Consent to eligible participants. We will mail the $15 gift cards to participants who complete the screener.

Participants who are eligible as determined from the screener, pass the Capacity to Consent, and are interested and available to take part in the study will then be passed to baseline. A Clinical Research Coordinator (CRC) will administer the baseline interview. Once the baseline interview is complete, the CRC will contact the Project Director, who will then randomize the participant. The project director will assign participants randomized to the intervention group to a CHW at the participant's ACO/CBO, and the CHW will call the participant to schedule an initial session. The project director will contact participants randomized to the usual care group to inform them that they have been randomized to this group, and that they will be contacted by phone for further assessments.

Participants will receive a $15 gift card for participation in the screening. Those who are enrolled will receive $40 gift cards for completing the baseline, and 3- month assessment, a $75 gift card for completing the 6-month and a $100 gift card for completing the 12- month follow-up assessment. For a small proportion of participants who are not screen-eligible, we will administer the baseline interview and provide them with the $25 incentive. This is to ensure that our screener is accurately identifying positive cases.

VI. Research Procedures - Intervention

The proposed study is an evidence-based intervention (see CERED intervention) which demonstrated effectiveness. Strong Minds-Strong Communities is culturally adapted from

cognitive behavioral therapy and includes mindfulness exercises, promotion of behavioral activation through pleasant activities and developing supportive relationships. The intervention is led by CHWs and organized into 10 sessions, tailored to the participant using a collaborative approach, to improve mood symptoms, augment self-reported functioning, and increase self-reported quality of care among participants with moderate to severe symptoms of depression and/or anxiety. The Strong Minds-Strong Communities intervention seeks to increase engagement, decrease depression and anxiety symptoms, improve functioning, and increase perceived quality of care among low-income racial/ethnic and linguistic minorities. The 10-session intervention is culturally adapted for use among a wide group of minority populations (Latino, Asian, African-American and Afro Caribbean), has few exclusionary criteria to improve generalizability, and is administered by CHWs from within the partner ACOs as opposed to Masters or PhD-level clinicians. The CHW will conduct a welcome visit with eligible participants, introduce them to the program, and provide the workbook and educational materials. The CHW will give feedback on symptoms to the treating primary care provider (PCP) if participants allow it and will use motivational interviewing techniques to increase engagement. The first 5 sessions will occur weekly. Every other week, the CHW will evaluate the participant with either the PROMIS for depression or for anxiety (short form), the 9th question from the PHQ-9 regarding suicidality, and if necessary, the 5-item suicide questionnaire, both for participant safety and to ensure the participant's mental health is not deteriorating to the point where immediate intervention or referral is necessary. This symptom assessment will be done for both intervention and enhanced usual care groups). Sessions will continue until at least 8-10 are completed or 6 months have passed.

The Strong Minds-Strong Communities intervention is complemented by a care manager that links participants to services for needs related to social determinants of health (i.e. education,

housing). The Strong Minds-Strong Communities intervention will be compared with an enhanced usual care group.

Participants can complete the intervention by telephone and/or during off hours (evenings, weekends) to facilitate participation. If we find participants are too severely impaired to benefit (see exclusion criteria), we will link them to mental health or substance abuse services and resources via the care manager.

We will offer a 'flexible approach' option. If someone is eligible after the screener but reports not being interested in participating in the study, we will ask permission to contact them 3 more times within a 6 month period (2 months after the first screening interview, 4 months and 6 months after). If they agree, we would contact them every 2 months to rescreen them and try to enroll them into the trial. 6 months after the first screening interview (after 3 calls), if the person still reports not being interested in participating, we will assume the case to be a decline to enroll, and not contact him/her again. If, after the first screening interview the person who is not interested in being enrolled asks the RA not to continue to contact them, we will also mark the case as declining to enroll.

Participants in the enhanced usual care group will receive an NIH booklet about anxiety and depression in Spanish, English, or Mandarin/Cantonese. The Care Manager will call the participant 4 times over the course of 6 months to administer the PROMIS, the 5-item suicide questionnaire, and a question about medication side effects to mimic the administration schedule in the intervention group, with data entered in Dimagi CommCare. With the participant's permission, the care manager will inform the PCP about screening and other assessments and determine if participants should be referred to mental health or substance services and removed from control group given severity (PHQ-9 >=20, GAD-7>=15 and Paykel

=4 or 5 or active substance use). This will be considered a positive outcome for participant safety.

All enrolled participants (intervention and usual care) will be contacted for assessments over the course of 12 months: baseline, and 3-month, 6-month, and 12-month follow-ups.

Clinical Research Coordinators (also referred to as Research Assistants in some departments) will hold the initial responsibility for conducting baseline and follow-up interviews. Procedures for contacting participants will be as follows: 1) Study staff will notify the CRC of the target interview date, including acceptable window for interview administration; 2) the CRC will attempt to contact participant by phone or in person at the ACO/CBO; 3) If after 2 weeks the CRC has been unable to contact the participant, staff will attempt to contact the participant by phone; 4) If after 1 week staff is unable to contact the participant, we will send a letter informing the participant that we have been attempting to contact them in order to administer an interview, and if we do not hear back, we may visit them at home; 5) If the participant does not respond to the letter, MGH staff will visit the person at home and attempt to administer the interview at that time.

A protocol has been established for the home visit to ensure staff safety, including regular contact to in-office staff by phone or text message. Home visit protocol stipulates that staff will be paid their regular hourly rate for travel to and from participants' homes. Staff have been notified in advance that they may need to visit participants' homes. Safety is monitored by the following procedures: 1) Staff will provide the supervisor with the name and address of the participant they will be visiting prior to traveling to the participant's home; 2) Staff will text/call their supervisor when they have arrived at the participant's home, and will apprise their supervisor of the status of the home visit (e.g., participant not home, interview will proceed as

scheduled, etc.); 3) Staff will text/call their supervisor mid-way through the interview to apprise of status; 4) Staff will text/call their supervisor when they are leaving the participant's home, and when they arrive at their destination (e.g., home or office). In addition, staff are provided a safety code to text or call if a dangerous situation arises during the interview and are required to leave the participant's home immediately if they ever feel unsafe in a participant's home, or if guns or illegal substances are present.

A. Data Collection

Data will be collected at several points. All potential participants will complete a 20-30-minute screener to determine eligibility. Eligible participants will then complete a baseline assessment, as well as follow-up assessments at 3, 6 and 12 months post-baseline. In addition, all participants will complete a biweekly symptom assessment, using the PHQ-9 and GAD-7, and the Paykel Suicide Screener, if necessary.

VII. Biostatistical Analysis

A. Specific data variables being collected for the study (e.g. data collection sheets).

Screener, Baseline Assessment, Follow-up Assessment, Symptom Assessment (PHQ-9 and GAD-7)

The proposed study has four goals:

1) To test the effectiveness of an evidence-based, CHW-led mental health intervention, The Strong Minds-Strong Communities Randomized Clinical Trial (RCT), focused on (1)

decreasing depression and anxiety symptoms, (2) improving functioning, and (3) increasing perceived quality of care among low-income racial, ethnic, and linguistic minorities.

2) To test whether there is a differential effect of Strong Minds-Strong Communities based on participants' race and ethnicity, thereby identifying whether the intervention can be particularly effective for certain racial and ethnic groups.
3) To test whether there is a differential effect of Strong Minds-Strong Communities based on participants' language, thereby identifying whether the intervention can be particularly effective for certain linguistic groups.
4) To test whether there is a differential effect of Strong Minds-Strong Communities in North Carolina compared to Massachusetts, thereby identifying whether the effectiveness of the intervention is associated with a specific geographic location.

Dependent variables. Across all goals, the following post-baseline outcome measures will be used as the main dependent variables. (1) Depression and anxiety symptoms will be evaluated with the Hopkins Symptom Checklist-25 (HSCL-25), a 25-item self-report of anxiety (first 10 items) and depression symptoms (last 15 items) in the past two weeks rated on a 4-point scale from 1 'not at all' to 4 'extremely'. Total scores are calculated as the average of all items (range: 1-4) and higher scores represent worse depression and anxiety symptoms. (2) Level of functioning will be measured using the 12-item World Health Organization Disability Assessment Schedule 2·0 (WHODAS 2·0), a self-report assessing six domains of functioning: cognition, mobility, self-care, getting along, life activities, and participation. Participants are asked to rate difficulties performing activities in each domain in the past 30 days using a 5-point scale from 1 'none' to 5 'extremely or cannot do'. Total scores are calculated as the sum of all items (range: 12−60), and higher scores indicate lower levels of functioning. (3) Perceived quality of care was evaluated using the Global Evaluation of Care domain of the Perceptions of

Care Outpatient Survey (PoC-OP), a clinical-care oriented, self-report satisfaction rating scale assessing patients' perception of the quality of interpersonal care. The Global Evaluation of Care domain includes three items rated on a 4-point scale from 1 'never' to 4 'always', which are transformed into a score from 0 'lowest quality' to 100 'highest quality.'

Independent variable. The main independent variable will be an effect-coded variable for the intervention condition (control = -0·5, intervention = 0·5). In this coding system, the mean of the dependent variable for participants in the control condition is compared to the mean of the dependent variable for participants in the intervention condition.

Covariates. Baseline outcome measures will be used as a covariate.

Moderators. In Goal 2, race and ethnicity will be used as a moderator of the main independent variable (intervention condition). Using self-reported information, participants will be classified into four mutually exclusive categories: Latinx, non-Latinx Black, Asian, and non-Latinx White. In Goal 3, language will be used as a moderator of the main independent variable (intervention condition). Using self-reported information, participants will be classified into four mutually exclusive categories: English, Spanish, Mandarin, and Cantonese. In Goal 4, the site of recruitment will be used as a moderator of the intervention condition. Participants will be classified into two mutually exclusive categories of place of residence: North Carolina or Massachusetts.

Endpoints. The primary endpoints will be change from baseline in depression and anxiety symptoms, level of functioning, and perceived quality of care at month 6 (end of intervention) and at month 12 (6-months post-intervention). The key secondary effectiveness endpoints will

be the change from baseline in the score on the CAT-MH depression (range 0 to 100 with higher scores indicating worse depression symptoms) and the CAT-MH anxiety (range 0 to 100 with higher scores indicating worse anxiety symptoms) at month 6 and 12. The primary and key secondary effectiveness endpoints will be also evaluated in prespecified subgroup analyses based on participant's race and ethnicity, language, and site. Other exploratory endpoints will include changes from baseline in HSCL-25, WHODAS 2·
0, PoC-OP, CAT-MH depression, and CAT-MH anxiety scores at month 3, about midway through the intervention. Finally, the primary and key secondary effectiveness endpoints will be evaluated in exploratory subgroup analyses based on the participant's baseline severity of depression and anxiety.

Statistical Analyses. A two-sided P value of 0·05 will be used to calibrate the significance and false discovery rate. For the primary and key secondary endpoints, we will employ a Benjamini-Hochberg step-down procedure to adjust for the multiple comparisons across 5 outcome scores (HSCL-25, WHODAS 2·0, PoC-OP, CAT-MH depression, and CAT-MH anxiety) at 2 follow-up points (months 6 and 12). If the lowest of the ten P values was less than 0·005 (0·05 ÷ 10), it will be considered to be significant; the second lowest P value will be considered to be significant if less than 0·0056 (0·05 ÷ 9); the third lowest P value will be significant if less than 0·006 (0·05 ÷ 8); and so on. Primary and key secondary efficacy endpoints will be separately analyzed using a general linear model to estimate the treatment effect. Except for PoC-OP, baseline outcome scores will be included as covariates in all analyses. Site (Massachusetts versus North Carolina) will also be included as covariate in all analyses. This general linear model has the following form:

$$y_{i,post-baseline} = \alpha_0 + \alpha_1 Intervention_i + \alpha_2 y_{i,baseline} + \alpha_3 site_i + \varepsilon_i$$

where $y_{i,post-baseline}$ represents an outcome measure for participant i at either 6- or 12-months post-baseline. $Intervention_i$ will be an effect-coded variable equal to -0·5 if participant i was randomized to the control group and equal to 0·5 if participant i was randomized to the intervention group. $y_{i,baseline}$ is the baseline measure of the outcome (except for PoC-OP), $site_i$ is a binary indicator equal to one if participant i was recruited in Massachusetts and equal to 0 if recruited in North Carolina, and ε_i is an error term. Because participants will be recruited in multiple CBOs/clinics across the two sites, in sensitivity analyses we will use generalized linear mixed models with a random intercept accounting for clustering within CBOs/clinics for each primary and key secondary effectiveness endpoint.

Prespecified subgroup analyses of the primary and key secondary endpoints will be performed for participant's self-identified race and ethnicity (non-Hispanic White, non-Hispanic Black, Asian, and Hispanic or Latino), language (English, Spanish, Mandarin, and Cantonese), and site (Massachusetts and North Carolina). Subgroup differences will be tested in three omnibus interaction tests. These three interactions will be examined for 5 outcome scores (HSCL-25, WHODAS 2·0, PoC-OP, CAT-MH anxiety, and CAT-MH depression) at month 6 and month 12, which will result in 30 statistical tests (3 × 5 × 2). No adjustment for the multiple comparisons will be made, and about two statistically significant interaction tests ($P < 0·05$) are expected on the basis of chance alone.

Change from baseline in HSCL-25, WHODAS 2·0, PoC-OP, CAT-MH depression, and CAT-MH anxiety scores at the exploratory endpoint at month 3, and exploratory subgroup analyses based on participant's baseline severity of depression and anxiety will similarly be analyzed using a general linear model which included baseline scores (except for PoC-OP) and site as covariates.

B. Missing data

We will conduct analysis of missing data at either endpoint (primary or exploratory) to test whether that, conditional on the observed baseline variables (including baseline outcome scores), the missing at random assumption is plausible. Missing data for all statistical models (primary and key secondary endpoints, exploratory endpoint, prespecified subgroup analyses and exploratory subgroups analyses) will be handled using model-based imputation. For example, missing values to analyze change from baseline in HSCL-25 scores at the 6-month endpoint will be imputed using a general linear model where HSCL-25 scores at month 6 will be the dependent variable. An effect coded variable for intervention condition, HSCL-25 scores at baseline, and a binary indicator for site (Massachusetts versus North Carolina) will be included as predictors. The model further will also include the auxiliary baseline variables associated with missingness (e.g., participant's age or gender). The same model-based imputation will be employed for all primary and key secondary endpoints, and the exploratory endpoint. Imputation models for subgroup analyses (prespecified and exploratory) will add the moderator and its interaction with intervention condition as predictors. For each model, 20 imputed datasets will be generated. Analyses of imputed data will use Rubin's rules to obtain pooled estimates and their standard errors.

C. Power Analysis (e.g., sample size, evaluable subjects, etc.)

The proposed study aimed to recruit 1,200 participants equally distributed across sites (North Carolina and Massachusetts) and intervention conditions (Intervention and Control). That is N = 600 intervention participants (300 in North Carolina and 300 in Massachusetts) and N = 600 enhanced usual care participants (300 in North Carolina and 300 in Massachusetts).

The target sample size was designed to achieve adequate power for our research questions. Using data from prior studies on the effectiveness of similar interventions, the estimated effect size for the outcomes ranged from 0·24 to 0·68. The nonparticipation rate of enrolled participants was assumed to be 13%. Our sample size of 1,200 (600 treatment and 600 control) from North Carolina and Massachusetts is thus effectively 1044. This sample yielded 87% power to detect an intervention effect size of 0·20, with a two-sided significance level of 0·05. Testing whether there is a differential effect of Strong Minds-Strong Communities based on participants' race and ethnicity means trying to determine whether race and ethnicity moderated the impact of the intervention. The racial and ethnic composition of our sample was roughly 63% Latinx, 14% non-Latinx Black, 13% Asian, 9% White, and 1% other races or ethnicities. Assuming a large effect size of the intervention for White participants (> 0·5), a small effect size for Black participants (< 0·3), and a medium effect size for Asian and Latinx participants (> 0·3 and < 0·5), we will have 80% power to detect a significant intervention effect in each racial and ethnic group with a sample size of 1044. Similarly, testing whether there is a differential effect of Strong Minds-Strong Communities in North Carolina compared to Massachusetts means testing whether site moderated the impact of the intervention.

VIII. Risks and Discomforts

A. Psychosocial (non-medical) risks:

The safety of intervention participants will be closely monitored during the Strong Minds-Strong Communities intervention. Participants will be administered the PHQ-9 depression screener and the GAD-7 anxiety screener during research interviews and biweekly during intervention sessions, and in biweekly check-ins for usual care participants. If participants endorse the Item

9 suicidality question of the PHQ-9, they will be administered the Paykel Suicidality Screener. Those who endorse questions 4 and 5 of the Paykel, suggesting active suicidality, will be provided emergency care following emergency protocol developed by the research team.

During the survey and assessment of community capacity, a possible risk is that some participants may feel uncomfortable answering certain questions. Discomfort when discussing mental health problems may also be a risk. In both cases, participants will be told they have the option of terminating the interview at any time or not answering specific questions as part of the interviews or focus groups.

Additionally, as in all research involving the collection of private health information, there is always a slight risk of loss of confidentiality. However, every precaution will be taken to maintain all rights and privacy protections. All identifying locator data will be stored in locked file cabinets and data used for analysis will be de-identified and assigned an identification number for privacy. All research personnel will have access to the de-identified subject information as part of their assistance with the evaluation component. Only study staff will have access to identifying information for the initial data cleaning period. A data release agreement will be signed by all investigators who work with the data in any way. This agreement outlines the criteria for data access, conditions for research use, incorporates privacy and confidentiality standards to ensure data security, and prohibits manipulation of data.

Participants in the Strong Minds-Strong Communities intervention may feel some discomfort sharing personal information. Participants are reminded during the consent process that they are not required to share information that they do not wish to share, and that any information they share with the CHW or CRC will be confidential, with the exception of mandatory reportable content. They are also reminded that they may terminate an interview or session at any time.

Furthermore, research team members will refer to participants by their study identification numbers, rather than their names, unless necessary for referrals or emergency intervention.

CHWs will receive weekly supervision from MD or PhD level clinicians throughout the intervention. Supervisors will inquire about potential safety issues and will closely monitor participants at risk. Supervisors will report any risk issues to the research team and discuss these issues with the research team and site leaders in biweekly conference calls.

In the event that a participant endorses Items 4 and 5 of the Paykel Suicidality Screener (see above), the CHW or CRC administering the assessment will follow the Emergency Protocol. The protocol calls for an assessment by the local emergency services. The research team member will follow up with the participant within 24 hours. If the person is admitted to emergency psychiatric services, the research team member will follow up with the participant after 30 days. If the participant no longer reports suicidality, he/she will be allowed to continue to the study. In no case will a participant with elevated symptoms be removed from the study without ensuring an appropriate referral. If a participant scores in the severe range on the PHQ-9 or the GAD-7 (corresponding to scores of greater or equal to 20 on the PHQ-9 or greater or equal to 15 on the GAD-7) for two or more assessments, that participant will be monitored closely and the CHW's supervisor will determine whether that individual should be referred to specialty treatment. Depending on the nature of the treatment, the participant may be allowed to continue with the study. The following criteria will be used to remove a subject from the study. The participant's primary care provider will be notified if his/her symptom assessment scores remain in the severe range.

IX. Potential Benefits

A. Potential benefits to participating individuals

In terms of efficacy, it is hoped that this intervention will contribute to reduced depression and/or anxiety among a significant proportion of study participants. Depressive and anxiety symptoms from baseline will be measured by the Hopkins Symptom Checklist-25, the PHQ-9, and the GAD-7, and disability days as measured by the WHO-DAS 2.

B. Potential benefits to society (e.g. increased understanding of disease process, etc.)

We anticipate that the information to be gained from the intervention will illustrate an important model for building community capacity in mental health service delivery and provide a way to engage and treat low-income, non-English speaking and racial/ethnic minority adults with moderate to severe rates of depressive or anxiety symptoms in ACOs. There is a tremendous need for sustainable and affordable solutions that use task shifting for mental health problems. We envision that the proposed model of building community capacity could be delivered and sustained at relatively low costs by participants outside of clinics, making it a unique and much needed intervention model with a high potential for feasibility and sustainability after the project ends. From a public health perspective, this type of model for problem solving and resource building in the community is beneficial.

X. Monitoring and Quality Assurance

A. Independent monitoring of data source

Several regular communications mechanisms have been established to monitor data and safety. The principal investigators, co-investigator, and the research team hold biweekly conference calls to monitor study progress and any risk issues or adverse events. This group also meets biweekly with the site leaders at each ACO/CBO to monitor events within the ACOs/CBOs and to update ACOs/CBOs about study changes. In addition to weekly supervision CHWs hold with licensed clinicians, CHWs hold biweekly support calls with the MGH project coordinator, and RAs have biweekly support calls with the MGH research assistant. These calls update ACO/CBO staff on any changes or important reminders, monitor staff activities, and provide support.

Collection protocols have been established to ensure accuracy and quality of the data obtained from all participant interviews with Clinical Research Coordinators and treatment sessions with CHWs. Interviewers will have biweekly conference calls with Site Leaders at the ACOs/CBOs, and in collaboration with the team where data quality and data analyses will be discussed. These calls will provide a forum for interviewers to discuss issues and concerns pertaining to data collection protocol as well as a time to provide feedback on completed assessments.

For the intervention, quality of the CHWs' work will be monitored by the Site Leaders and supervising clinicians. We will conduct random (15%) adherence checks using a fidelity checklist that mirrors the intervention manual. This checklist documents activities covered in the training session, difficulties encountered, and clinicians' observations regarding the participants' level of understanding and participation in the intervention. In addition, supervisors will lead weekly meetings/conference calls to review the CHWs' caseloads as well as assist them in following the manualized protocol. The investigators from all sites will participate in weekly group supervision and review treatment fidelity checklists required of all CHWs to ensure standard delivery of treatment within and across sites.

B. Safety monitoring

All research team members will follow the procedures of confidentiality adhered to by collaborating institutions. Further, all research staff working on this project will be required to complete training in data confidentiality and security issues and sign a confidentiality agreement prior to working with patients or handling identifying information. The Community Advisory Board (CAB) of this study and all the Site PIs will work with the MGH research team to ensure that the study is monitored from a scientific and ethical standpoint, and we will hold yearly meetings to assess data collection and management.

The study staff will work closely with the Site Leaders, CHWs and RAs at the participating ACOs/CBOs in the set up and ongoing implementation of the study. We will provide required research materials, documents and technology, such as audio recorders, to facilitate this work. The CHWs and RAs will be granted remote access to the server as well to encrypted online data storage provided through Dropbox.com using their Partners secure login, to be able to upload recordings, tracking materials and other information. This information will be monitored through quality control checks by the MGH team. Study staff will provide regular supervision and oversight to CHWs and RAs.

All consent forms will be clearly labeled (with version control information), and the Project Director will work closely with the CHWs at each site in order to ensure that proper consent forms are used at all times to consent the providers and patients participating in the study.

All documents that include identifying information (i.e. names, addresses and telephone numbers) will immediately be separated from the patient assessments, training materials, and

recordings. These items will be stored by research staff authorized by the PI in a locked file and an identifying case number will be generated. The PI and authorized research staff will be the only persons with access to the locked filing cabinet and/or any information or files that link the case number with any patient identifying information. No reports will be made public using any names or identifying information. Raw data and accompanying research protocols will be kept for at least 7 years post publication of findings. Strict measures to assure confidentiality of the data will be taken. Computerized data will be identified by participant number only. All computerized data is stored on a secured central server in the MGH Data Center and backed up daily. The MGH research team, as part of a hospital network is HIPAA compliant and adheres to strict data safety guidelines, implementing network firewalls, antivirus systems, internet screening and auditing systems and network intrusion detection systems. All research staff PCs are password-protected and have standardized, full featured, software and hardware configurations. Only research staff authorized by the PI will have access to the data. The lead analyst working with the data is the only person on-site with network level administrative password privileges. Offsite, only authorized MGH IT department technicians can access the server holding this data. The original data and the encrypted data will not be transported or used at any other location and the data will not be copied onto other computers, discs, CDs etc. We will maintain all print-outs, electronic files, personal computers with restricted data on the hard drives, or other physical products containing data in locked cabinets, file drawers or other secure locations when not in use. Printed material that includes analyses based on restricted data will be promptly destroyed. At the end of the project, all files that include restricted data will be destroyed, including copies and subsets on the MGH server or any project computers. We plan to share and analyze data between the Disparities Research Unit site in Boston and the University of North Carolina site in Greensboro. PIs, Project Managers, and community site partners will work closely to ensure data is protected across sites.

Given that the CAT-MH screening tool and our Strong Minds-Strong Communities Intervention (delivered by CHWs) are relatively new, we will make extensive efforts to ensure the safety of study participants, and to systematically track risks, issues, and outcomes across the MA and NC sites. We will create a monitoring registry where we can tabulate and track any human subjects and systematic issues that arise with implementation across sites, and between intervention and control conditions. We will identify a core set of participant issues that will be flagged if they occur: 1) cases with no improvement or an increase in symptom scores on key outcome variables; 2) no-show for scheduled appointments; 3) staff concerns about participant's well-being; or 4) site operational issues (such as space limitations for sessions, transportation challenges, resistance by site staff to any aspect of the study, such as the procedures for the emergency protocol etc.). These four areas will be programmed into the registry, with an area for notes and additional details. The registry will be maintained by the Project Manager in conjunction with the Care Manager at each site, who will set up the registry to track participants by case ID, clinical site, and date of occurrence. We will create logons for CHWs and Research Assistant interviewers at each site, who can enter information pertaining to their cases. We will set up specialized permissions at the user level to ensure that Research Assistants remain blinded to any information about participant condition. The Project Manager and Care Manager will review the data in preparation for weekly team and supervisor meetings and will download the registry data to review with study staff and supervisors. At the onset of the project, we will work with the study data analysts to program an algorithm to easily query the system to display cases with elevated issues in each of the 4 categories. This process will allow us to flag and highlight individual cases but also generate reports on the frequency of any given issue within and across the sites. Solutions will be discussed and determined by the research team including the PIs at each site, and these will be reintegrated into the protocol by the Project Managers. We will thus systemize our monitoring of outcomes and challenges to view patterns and

optimally address them. The registry will also inform our understanding of implementation challenges overall.

To improve the security of data collection, we will be working with the Dimagi Corporation, using their secure server to collect data via the CommCare HQ technology. This is installed in a series of secure tablets through which research assessments will be collected. Dimagi is a HIPAA compliant, secure, encrypted server that allows for host intrusion and intrusion monitoring system. All technology can only be accessed through secure and password servers. The CommCareHQ application will be installed on tablets and these tablets will be made available to research assistants serving as interviewers on the PCORI study. Our research assistants have already undergone training by Dimagi.

The Dimagi CommCare HQ system is a healthcare data collection application installed on tablets designated solely for study use. Dimagi is bound by a confidentiality agreement and has various data safeguards in place including: a secure, multi-tenant system hosted in Dimagi's Secure Private Cloud, based in Chicago, IL; Network Intrusion Detection System (NIDS): Web Application Firewall (WAF); Host Intrusion Detection System (HIDS); Server Event and Information Management (SEIM); encrypted hard drives; data destruction policy; and being Health Insurance Portability and Accountability Act (HIPAA) compliant.

All audio-recorded interviews will also be uploaded immediately to the same secure, password protected server maintained at MGH. No reports will be made public using any names or identifying information. Our coded dataset will be stored on a secure central server. Only authorized research staff approved by the site Institutional Review Boards will have access to the data. PHI will be destroyed according to standard protocols, 7 years after the completion of the study.

C. Outcomes monitoring

NA

XI. Adverse event reporting guidelines:

A. Sample Self-Harm/Risk Emergency Protocol

The following protocol is an example of the mental health self-harm/risk reported to study staff for patient participants in the intervention. We would adapt this protocol to study sites per local requirements and for physical health issues that might be experienced.

The emergency procedure is prompted if a patient endorses a 4 or 5 on the Paykel suicidality screener over the last 30 days. The questions include: “Has there been a time in the last 30 days/since the last assessment when you reached the point where you seriously considered taking your own life, or perhaps made plans how you should go about doing it?” = yes or “Has there been a time in the past 30 days/since the last interview when you made an attempt on your own life?” = yes.

1) At the end of the session or interview, study staff should inform the participant: “*I am not a clinician; however, when anyone tells us they’ve been feeling this way recently, we connect them with a clinician who can ask some questions about how you’ve been feeling. We will also contact your primary care doctor to let them know about this conversation and make sure you are safe. We want to ensure your safety, so let me connect you right now. Could you please tell me where you are located right now?*”

2) **Study staff should immediately connect the patient to the correct Emergency Services provider** for assessment.

- Place the patient on hold (or have them wait a moment when in person).
- When speaking to emergency services team, refer to the study: I have a patient on the line as part of the research study who scored high on a suicide screening tool. I am not a clinician, and am hoping the patient can be assessed for risk by phone -- he/she has given consent to this as part of the study.
- Take the name of the person who you are talking to.
- The emergency services provider will need the following information from you:
    - patient's name
    - phone number
    - present location
    - what was said by patient re: suicidality
- If a Spanish, Mandarin, or Cantonese speaking clinician is not readily available, study staff are allowed to translate only in the capacity of informing the patient of what the emergency services provider says are the 'next steps' (i.e., someone is going to call you back in 5 minutes, etc.)

If for some reason, the participant is not able to be or refuses to be connected right away you should:

1) Provide the patient with the emergency services contact number, depending on where they are located.

2) Contact the emergency services provider based on where the patient is located and share the pertinent information as described above. Immediately inform the study PI and your supervisor.

Emergency Protocol Documentation Form

Patient ID #: _____

Date: _____

Items endorsed:

____ 4 on the past 30 days Paykel

____ 5 on the past 30 days Paykel

Description of event: _____

_____

_____

Primary Care Provider's name: _____

Information to collect for Emergency Services

Name _____

Contact phone number right now _____

Where the patient is right now _____

What the patient said about suicidality _____

_____

_____

Patient Date of Birth (if available) _____

Patient Insurance (if available) _____

Name of person who you talked to _____

Post-call checklist

Send Message to PCP _____

Email to Site Leader and PI _____

Inform PCP of outcome _____