Positive Minds Strong Bodies Implementation (PMSB-E)

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Principal Investigator: Margarita Alegria, PhD
Protocol Title: Positive Minds Strong Bodies Implementation
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Version Date: 7/24/25

Trial Protocol

Note: This online supplement presents the Trial Protocol as it was written just prior to the onset of the recruitment process and hence many sentences are written in the future tense.

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Background and Significance

By 2030, the US population of older adults (65+) is projected to increase to 72.1 million.[1] Nearly one in five will suffer from mental health and/or substance use conditions,[2] with mood disorders being the most significant source of emotional distress,[3] and will be at risk for mental and/or physical disability.[4] Older adults are also becoming more diverse, with more than one-fourth of older adults expected to belong to a racial/ethnic minority group by 2030.[5] Minority older adults are at a greater risk for severity, persistence, and recurrence of psychiatric disorders. Yet, minority older adults have less access to mental health care[6-8] and disability prevention than non-Hispanic Whites. Minority older adults with mental health problems and at risk of disability may not access clinical services due to stigma[9] and self-reliance,[10,11] limited English proficiency,[12] undocumented status, and lack of recognition[13] of their mood symptoms. Furthermore, recognition of mental health problems does not result in increased help-seeking among older adults.[14,15] Despite the great need, 90% of older adults with mental health conditions receive *no* mental health treatment and no disability prevention services. This is in part due to workforce shortages of healthcare professionals,[16] particularly for serving racial/ethnic and linguistic minorities in either clinical or community settings. This represents a missed opportunity, given that mood disorder treatment has been shown to reduce disability days by 40%-45% in those with severe to moderate depression.[17] Furthermore, the prevalence of impairments and frailty in older adults can be significantly reduced after participation in physical activity programs.

Previous pre-clinical or clinical studies leading up to and supporting the proposed research

At the time of original submission of this protocol, our team was completing the Positive Minds Strong Bodies study, testing the effectiveness of the Positive Minds (10 sessions of individual psychoeducation and activities adapted from CBT) and Strong Bodies (24 sessions of exercise provided over 14 weeks) interventions (PMSB). PMSB was administered to minority older adults ages 60+ by a community health worker (Positive Minds) and an exercise trainer (Strong Bodies). The interventions have been delivered in English, Spanish, Mandarin, and Cantonese, yielding a unique program to address the unmet needs of linguistic minority older adults in geographic areas within diverse settings. Preliminary results show much promise. The current project incorporates critical adaptations to yield an enhanced intervention, PMSB-E, that improves upon therapeutic strategies, facilitates the work of CHWs, and incorporates ongoing group sessions in mental health and disability prevention to maintain gains.

To address disparities and prevent disability among minority older adults, we proposed a renewal grant of our NIA/NIMH-funded project, “Building Community Capacity for Disability Prevention for Minority Elders” (R01AG046149), ending in April 2019. The current grant tests the effectiveness of an Enhanced Positive Minds-Strong Bodies intervention (PMSB-E) in preventing disability. More importantly, we hope to transfer what seems to be an effective intervention into a product ready for implementation in low-resource community settings. The renewal grant tests: 1) a streamlined PMSB-E intervention, to increase effectiveness by augmenting adherence and enabling a stronger and lasting effect on outcomes; 2) implementation readiness, evaluating issues such as feasibility, planned adoption, and potential barriers to

sustainability; and 3) a dissemination toolkit to facilitate uptake in new agencies with similar interests in disability prevention.

We have received two research supplements to this grant and a diversity supplement. One expands the sample to 450 enrolled participants, 1/3 non-Latino Black, 1/3 Asian, and 1/3 Latino. The second addresses the COVID-19 pandemic, to assess the impact of the COVID-19 pandemic on stressors and responses to public health interventions (i.e. confinement, social distancing and isolation, mass communications, testing, intention to vaccinate and contact tracing) among ethnic/racial minority older adults in the new trial as well as the original trial. (We note that the supplement will also work with older adults from the original PMSB trial to understand whether the intervention shows a trend of reducing mortality in participants in the original intervention and potentially mitigates effects in reducing mental health symptoms. We will amend that protocol accordingly. For the purposes of publishing this protocol for the study's primary outcomes, we will not include the details of the diversity supplement, which is not included in the main paper.

I. Rationale behind the proposed research, and potential benefits to patients and/or society

This study aims to address service disparities and prevent disability among minority older adults through collaborative research for the provision of evidence-based mental health and disability prevention interventions in community-based organizations.

The combined Positive Minds-Strong Bodies (PMSB) intervention model provides an ideal opportunity to improve physical and mental health outcomes for minority older adults. For this renewal, we made important adaptations to yield an Enhanced PMSB, intended to facilitate easier adoption at the organizational level, mental health symptom reduction beyond 6 months, and greater adherence to exercise components.

Few studies focus on adaptations for feasibility and sustainability of health service innovations,[34,35] resulting in an expansive literature filled with "effective" psycho-social treatments that never get adopted. Sorting out the factors that enhance or challenge feasibility and sustainability in CBOs and clinics can facilitate the adoption of health service innovations.[36] We define *feasibility* as the degree of ease/burden associated with CHWs/Exercise Trainers' use, the resource requirements, and risks seen as acceptable; and *sustainability* as the continuation of an innovation within an organization or clinic.[36,37] We propose to expand our work from the original grant to focus on capacity building for the sustainable delivery of disability prevention services in CBOs and clinics.

Fostering clinical competency among lay personnel within CBOs and community clinics is a promising model for reducing service disparities. The number of mental health and rehabilitative professionals in communities of color is inadequate, and the availability of primary care providers is seriously limited.[39,40] The Affordable Care Act recognizes the importance of CHWs in improving health care access, outcomes, and quality of life.[41] International data demonstrates significant decreases in depression and disability over one year of using CHWs to offer treatment, and U.S. evaluations of CHWs' efficacy in providing mental health and disability prevention interventions remain limited but promising.[42,43,44-46] Our study can help determine whether a CHW/trainer-administered intervention is ready for broad-scale implementation. In Aim 3, we propose identifying aspects to accelerate implementation and scalability if the PMSB-E continues to prove feasible, effective, and sustainable. We will create and test the utility of a multimedia toolkit approach for dissemination, which incorporates guidelines, videos, and materials for fast implementation of the PMSB-E.

Specific Aims

The current protocol only refers to Aims 1 and 2 of our grant application. We will include subsequent Aims of dissemination and implementation of the study if they include human subjects research per IRB request at a future date.

Our specific aims are to:

Aim 1: Evaluate the acceptability, effectiveness, and twelve-month sustainability of the Enhanced Positive Minds-Strong Bodies intervention offered by CHWs and Exercise Trainers in CBOs and community clinics.

Aim 2: Assess implementation readiness of the Enhanced PMSB (PMSB-E) intervention by evaluating factors associated with acceptability, feasibility, adoption, and sustainability.

We divide the description of the Detailed Protocol by Aim:

AIM 1

Subject Selection: To identify the population in need, CHWs will screen 1800 participants over years 1-4, to enroll approximately 495 eligible participants (only 25-30% will be eligible). With attrition, we expect at least 450 participants to participate in the trial (225 intervention participants and 225 enhanced control participants), of which about 1/3 will be Latino, 1/3 non-Latino Blacks, and 1/3 Asian.

Inclusion Criteria: Latino, Asian or Black (African American or Afro-Caribbean) or non-Latino White older adults 60+ years of age with mild, moderate, or severe depressive (PHQ-9$\geq$5 or GDS-15$\geq$5)[83] or anxiety symptoms (GAI $\geq$8),[77,84] and without any specialty mental health care in the past 3 months. We selected a score of PHQ-9 $\geq$5, allowing for a wide range of severity, as this preventive intervention could impact the avoidance of disability. Fulfilling rigorous diagnostic criteria for mood disorders is relatively rare in late life.[85] Participants using antidepressants will be included, and medications will be recorded and used as a covariate. We will also include community-dwelling participants with scores between 3 and 11 on the SPPB[82] who have some mobility limitations but are *not home-bound.*[86] We used the virtual SPPB (vSPPB) in 3.7% of participants who had concerns about in-person activities during the early months of the COVID-19 pandemic. Given the high numbers of vaccinations in older adults and the success of our testing of the in-person SPPB, we returned to using the in-person SPPB for eligibility for the majority of participants (96.3%).

Exclusion Criteria: Participants will be excluded if there is evidence of: 1) current or last 3 months use of specialty mental health treatment, 2) evidence that patient cannot consent or is cognitively impaired;[87] and 3) current suicidal risk ('yes' to items 4 or 5 on the Paykel suicide scale),[88] whereby participants will be connected to an emergency services provider or specialty provider based on CBO/clinic preferences, and following a study emergency protocol. Exclusion from Strong Bodies will also happen if a participant is physically unstable, has an acute or an exacerbation of a chronic disease, or a neuromusculoskeletal impairment, or cannot commit to 2 sessions weekly.

During the COVID pandemic, we assessed this by: a total sum score ≥5 on the SARC-F; or an indication that the doctor told them not to exercise because of a medical condition or recent hospitalization. Suppose a participant is only ineligible because of the SARC-F and has a score on the borderline of eligibility (5 or 6). In that case, we will request to check with their primary care provider (PCP) whether they could provide medical clearance for participation. We would also do this for participants scoring 2 on the vSPPB. This would involve asking the participant whether we can check with their PCP and sending the PCP a communication via Epic (if MGB) or phone or fax for non-MGH. We used a medical clearance

form with the info explained to the PCP as requested. Participants who are only administered the SPPB in person would be excluded with a score of 1, 2, or 12.

As of 4/2022 given the status of in-person activities during the pandemic, we are updating our exclusion criteria for the study. We are making efforts to conduct an in-person SPPB physical health screening for all potential participants. Accordingly, we would like to remove the requirement of the SARC-F as part of eligibility for the trial, including removing the related medical clearance. We incorporated the SARC-F when we could not do the in-person SPPB physical health assessment with potentially eligible participants. However, we will continue to administer the SARC-F. If a participant refuses to participate in the in-person SPPB, we will administer the SPPB via Zoom and consult with our exercise intervention expert on whether the case can be considered for eligibility.

Study Design

To test the Enhanced Positive Minds-Strong Bodies intervention with minority older adults with elevated mood symptoms and risk for disability, eligible participants will be randomized after baseline to either the enhanced intervention or an enhanced usual care group. Randomization will be stratified by site using a computer-generated block randomization scheme with a block size of 2 (NQuery software). Primary outcomes are: acceptability (>70% of participants attending >50% of their intervention sessions, reporting satisfaction with treatment) and effectiveness (whether the intervention [1] significantly decreases depressive and anxiety symptoms from baseline as measured by the Hopkins Symptom Checklist [HSCL-25], a widely used measure of depression and anxiety in clinical monitoring and outcome assessment; [2] increases physical functioning objectively measured using the Short Physical Performance Battery [SPPB]; and [3] increases self-reported physical functioning using the function component of the Late Life Function and Disability Instrument [Late-Life FDI]). We will also test the moderating effects of sociocultural (e.g., SES, race/ethnicity, language, time in residency among immigrants) and clinical factors (e.g., baseline PHQ-9, functional impairment, and antidepressant use). To address concerns about in-person activities due to COVID-19, we temporarily used a virtual version of the SPPB (Marsh et al., 2015), set up locally for our team. This will be used for screening and follow-up assessment evaluation.

Recruitment Strategy

We will conduct the PMSB-E intervention in collaboration with CBOs and clinics serving Latino, Black, and Asian older adults. Partner selection was based on 3 criteria: 1) community agencies and clinics that serve large numbers of racial/ethnic and linguistic minority older adults; 2) availability of older adults service programs; and 3) interest in introducing evidence-based practices in their service delivery. As the trial progressed we included both cede review sites and multiple sites not engaged in human subjects research. For confidentiality, we do not include these in the published protocol.

We will include as participants in the project individuals who are not only patients or clients of the participating clinics or community-based organizations (CBOs), but who have been made aware of the project in the community or by other participants. Specifically, our collaborating clinics/CBOs have staff who do outreach in the community and might identify interested participants. In other cases, a participant might mention the study to a friend or acquaintance interested in being screened. We want to allow these participants to similarly be part of the trial. We took a very similar approach in our previously approved protocols. Similarly, we have also spoken with networks of sites that work on behalf of older adults, some of whom are happy to email the flyer to their networks of individuals and organizations. We do not consider these outreach efforts as new 'sites' but will screen potential participants who call or contact us as interested. We will include the distribution of flyers to older adults taking part in activities such as food distribution in the park.

During the pandemic, the study was only conducted virtually, by phone, or via Zoom. As such, it could expand access to individuals who may not be directly connected to a clinic or CBO. We want individuals to contact study staff and self-refer if they hear about the program outside of a specific clinical or organizational visit. For instance, if a research team member discusses the study at a media or public event, and an individual hears about it and contacts the research staff, that participant could be screened. A participant could refer a friend, family member, or other individual to participate. We will also accept other potential participants who are not affiliated with a participating site or referred by a current participant, but who might be known to our CHWs or staff from their connections or communities. We would conduct screening in the same fashion as typically done.

Drawing on discussions with MGH clinic medical directors and staff, we would provide access for our project coordinator to Epic to communicate with providers through Epic in-basket messaging. This secure form of communication would be helpful to providers when sending patient referrals to our team.

As we have done in previous studies, at MGH clinics, we would also like to use the RPDR registry to identify potential participants (with identifying information) to contact and screen. We would request that participants who fulfill specific criteria (i.e.,≥60 years) be determined. Once we receive eligible participant information, we will collaborate with the Medical Director and clinicians at the site to have a letter co-signed by the study PI and the participant's provider, inviting the participant to learn more about the study and to be screened. As we did in our previous study, we will contact participants by phone after sending a letter from the clinic director inviting them to participate. We would also allow community or clinical sites to contact their clients directly by telephone or let them know that our study team will contact them to introduce the study. This would be an alternative to sending the letter. This would allow staff to provide us with a list of participants from their site that our study staff can contact to describe the study, consent, and screen for participation.

The COVID-19 crisis has affected the ability of trials like this one to operate in person. We are including our regular in-person consent and screening plans and a virtual alternative that we have successfully utilized in another clinical trial.

We want to offer the interviews and intervention in person, in some instances where the participant and staff feel comfortable. We will also maintain our remote recruitment and sessions but will allow this as an option. Certain participants indicated that they would only feel comfortable participating in person, given their lack of comfort with using Zoom or other options that rely on technology. We will allow this on a case-by-case basis. Staff and participants should wear masks and maintain social distancing as much as possible. This will also provide the opportunity to offer the SPPB assessment in person as a test against the virtual option. Based on the test of this option, the SPPB in person is a better option in the future. It is done either in participants' homes or in one of the study sites.

Consent and Screening

In person

Clinical Research Coordinators (CRCs), Research Assistants (RAs), and/or Community Health Workers (CHWs) will work closely with clinical providers or community organization staff to identify potential participants who may be approached for a screening. Depending on clinic preferences, CRCs, RAs, and CHWs may approach any individual waiting in the community site or clinic. Recruitment will occur while the participants are at the CBO for regular programming. The research staff (i.e., CRCs, RAs, CHWs) will introduce themselves and explain that they would like to discuss a new study being implemented. After introducing themselves and briefly describing the program to the participant, the CRC/RA/CHW and potential participant will move to a private room for verbal consent administration. These research staff,

hired either by MGH or the collaborating CBOs and familiar with the CBO and the clients who attend the CBO, will administer the informed consent form in the participant's preferred language (English, Spanish, Mandarin, or Cantonese). Participants' rights and precautions for data safety and protection of confidential information will be clearly explained. Consent forms will be tailored to low-literacy participants. The CRC/RA/CHW will read the form aloud if a participant is not literate. During the consent process, the CRC/RA/CHW will obtain participant consent to contact emergency or primary care providers if the participant endorses harmful thoughts or behaviors or reports medical side effects of their medication that require care by the primary care physician (PCP) or emergency health services. Participants who are actively suicidal at the time of screening will not be included in the intervention but will be re-contacted 30 days after the initial screening to reassess if the participant remains ineligible for enrollment in the study. Suppose the potential participant is eligible as determined by the screener and willing to participate in the intervention/usual care. In that case, the CRC/RA/CHW will administer a capacity to consent form (based on Zayas et al, 2005). Participants who are eligible as determined from the screener, pass the Capacity to Consent, and are interested and available to participate in the study will then be enrolled. The CRC/RA/CHW will administer the baseline interview. For a small proportion of participants who are not eligible, we will administer the baseline interview and provide them with the incentive. This is to ensure that our screener accurately identifies positive cases.

In some sites, we will collaborate with community-based organization staff or the Medical Director and clinicians to identify potential participants who might be interested in being screened. We will send a letter cosigned by the PI and community-based staff or clinical staff to invite them to participate in the study and to let them know we will be calling to assess interest. The study flyer will be attached to the letter. The CRC/RA/CHW will meet the participants in person to administer informed consent, ask them to review the Informed Consent Form, provide verbal consent if they are interested and available to participate in the study, and conduct the screening. We will not record the full consent administration; however, we will audio-record the participant's study 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 in and receive text messages from the study. The CRC/RA/CHW will administer the Capacity to Consent form if eligible. If the potential participant passes the Capacity to Consent, the participant will be enrolled in the study, and the CRC/RA/CHW will then schedule the baseline assessment.

We are including a decline form for participants who do not wish to be screened. If they allow us, we will ask these questions to participants in the waiting room or elsewhere who do not wish to participate. If they do not want to answer the demographic questions, we will only ask the reason for not participating. This will help us to understand how best to target the program.

In-person events

For older adults at Community-Based Organizations, Housing Facilities, Senior Centers, and other locations, in-person group events are an opportunity to present the program and engage individuals in a trusted group setting. Study staff will work with site leaders or collaborators at the individual study sites to set up group meetings, using study flyers as promotional tools. On the day of the event, research staff would meet with the group attending to give an overview of information related to mental health and disability prevention pertinent to the study. The research staff would then review with the group the information found in the Informed Consent (PI, Benefits, risks, Study Structure, PCP, risk, text messages, etc). They would pause regularly to ask questions from group members and clarify these continuously. After reviewing the informed consent in the group and responding to questions, they will go around to individuals attending to assess interest. If someone is interested, then staff will talk with them individually, to ask if there are any questions and review any specific areas of the informed consent they request to clarify or have questions about. As this study is approved for verbal consent, research staff will

audio record the participant's response to individual questions to provide consent. As time permits, staff will conduct the in-person SPPB segment of the screener and follow up by telephone for the additional screening pieces for participants who consent. If an individual is eligible, before enrollment and randomization, each participant will also be administered the capacity to consent question that we use to ensure they understand the consent materials.

Virtual

Given the current public health concern surrounding the coronavirus, we will provide the option of continuing our recruitment by phone. In particular, we will adjust our protocol to allow audiotaped, phone-based informed consent. We will work with community/clinical staff to identify potential participants willing to be screened. The organizational/clinic staff will talk to the participant to let them know that a research staff member will contact them. If a call is impossible, we will send the letter described above.

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 next steps virtually. If the potential participant expresses interest, then the CRC/RA/CHW will proceed to review the full informed consent and text messaging consent with the participants by phone. We note here that if potential participants share their email addresses with the CRC/RA/CHW and want 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 study 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 in and receive text messages from the study. A CRC/RA/CHW will proceed to administer the screener to participants who provide verbal consent to participate in the study. A CRC/RA/CHW will administer the Capacity to Consent to eligible participants, as the screener determines. We will mail gift cards to participants who complete the screener. If the potential participant passes the Capacity to Consent, the participant will be enrolled in the study.

We will maintain in shared folders an Excel tracking form with information about the verbal consent process for such participants, the date the consent was obtained verbally, and the response of the participant to the subsequent informed consent form questions regarding sharing info with the PCP and related to referrals.

For participants who consent to receive text messages for the Positive Minds Strong Bodies study, we will invite them to receive the assessment scales via text message during the screener, baseline, and follow-up assessments to streamline the administration of the questionnaire sets. For participants who consent to receive text messages but are not interested in receiving the screener scales, the interview will proceed with the interviewer reading the scale for each question.

For those participants who consent to receive text messages for the Positive Minds Strong Bodies Implementation study, we will allow them to text program staff to discuss availability and to schedule appointments. This will facilitate communication with participants and ensure they can communicate confidentially. We will inform participants during the consent process that we will only respond to text messages during business hours about scheduling appointments and that they should use 9-1-1 for emergencies.

CRCs/RAs/CHWs will administer the baseline interview. Once the baseline interview is complete, the CRC/RA/CHW 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 CBO, and the CHW will call the participant to schedule an initial session. The project director will also inform

the exercise trainer, who will contact the participant to schedule the first exercise session. CHWs will conduct a welcome session to introduce participants to the program and provide a manual with educational and exercise materials. Although we can perform many parts of the project via HIPAA-compliant Zoom or telephone, we will set up safety accommodations for in-person activities. We will encourage intervention participants to have their first session in person, to create a relationship, and to set up Zoom for psychosocial and exercise components. We will also consider the need to meet in person if screening and assessment of the exercise component are challenging for participants to conduct remotely. Staff who visit participants in their homes will be equipped with PPE to make this session as safe as possible, given concerns of COVID-19 transmission.

The CHW will use sessions adapted from CBT and motivational enhancement to engage the participant. Every other week, the CHW will evaluate the participant with the PROMIS and the 5-item suicide questionnaire for participant safety and to ensure that mental health is not deteriorating to the point where immediate intervention or referral is necessary (for intervention and usual care). Sessions will continue until 10 sessions or 6 months have passed. Participants will also be offered 24 Strong Bodies exercise sessions, each lasting 45-60 minutes, with 2-8 older adults per group. 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 by research staff 4 times over 6 months to assess any severe symptomology with PROMIS and the 5-item suicide questionnaire and to provide empathic support.

CRCs/RAs blinded to group assignment will administer the measures at baseline, 3 months, 6 months, and 12 months after baseline. Our original selection of measures was based on brevity of measures, established usage in our previous trial to allow for comparisons, presence of domains with face validity for minority populations, and valid psychometric properties. These measures have been translated, piloted, and/or adapted for use among Spanish-speaking and Chinese-speaking populations by our team 91 and tested in the original project, and by other investigators using state-of-the-art methods for cross-cultural adaptation and translation.[92,93]

The flow of the intervention enrollment and activities would thus be as follows:

- Screening
    - If eligible, a $10 gift card for completing the screening
    - If not eligible - $10 gift card for completing the screening
    - If ineligible only due to the endorsement of active suicidality on the Paykel Suicide Risk Questionnaire (Item 4 and/or 5)
        - Potential participants will be contacted 30 days after the initial screening to be reassessed for eligibility
- Baseline interview scheduled for consented participants, compensated with a $60 gift card
    - If active suicidality is not endorsed on the Paykel Suicide Risk Questionnaire (Item 4 and/or 5)
        - A potential participant can proceed to be enrolled in the study
    - If active suicidality is endorsed on the Paykel Suicide Risk Questionnaire (Item 4 and/or 5)
        - Potential participants will be contacted 30 days after the initial baseline interview to be reassessed with the Paykel Suicide Risk Questionnaire
- Randomization by the project director
- Intervention and Control participants contacted by CRC/RA to conduct interviews at 3 months, 6 months, and 12 months

At the patient level, we assess the acceptability of the intervention based on the percentage of participants attending ≥50% of their intervention sessions. We obtained information from participants during the 6 and 12-month intervention assessment to see if they reported benefiting from the intervention (patient's satisfaction). At the provider or staff level, we examine CHW implementation of the intervention, including fidelity (defined as 70% fidelity to the intervention based on review of a random 15% of CHW audio recordings, CHW fidelity checklist, and review of CHW logs).

We anticipate enrolling all trial cases by the end of Year 4 and completing all assessment interviews by the first 6 months of Year 5.

We want to send appointment reminders by text message to participants enrolled in the clinical trial. We would use an encrypted cellphone and ask participants to complete a text message consent.

We use Zoom for video calls with participants in the intervention sessions or for assessments. This was a more personal alternative to phone calls. We selected Zoom because it has already been vetted and is a technology approved for patient use. Additionally, we request that we use Zoom to record a random sample of exercise sessions, given that we will need to video record sessions to evaluate fidelity to the Strong Bodies intervention.

We will share Zoom video recordings with the exercise supervisor at UPR, who will evaluate fidelity for these cases. We will share videos through a HIPAA-compliant Dropbox or secure MGH server. We may also facilitate video sharing using these methods for other participating sites in the project. We will receive Zoom video recordings from other collaborating sites in the project, who will share videos by HIPAA-compliant Dropbox or through the secure MGH server. We discontinued video fidelity early in the study due to challenges with doing this remotely.

We have created a video for study participants about how to use Zoom for study-related meetings. The video describes how to download the Zoom app and how to join Zoom meetings. We will share the YouTube link for this video with participants to help them set up Zoom.

This is a protocol where the MGH IRB will cover other sites via cede review. Staff from different sites may offer screening, intervention/usual care calls, and interviews with participants recruited from other sites, and we will note this in the consent form.

We let participants know that if there is any concern about physical symptoms during the remote exercise sessions, we may have to put them in touch, remotely or in person, with someone who can assess that they are ok, including their PCP.

Other recruitment options

Project coordinators and research assistants doing recruitment will have access to providers' schedules on EPIC for clinics where this is possible (ie, at MGH). We will use these schedules only to know when to go to the clinics to recruit in person and when there is a good flow of older patients. We will not call patients to recruit from EPIC; we know Partners do not authorize this. Our CRCs/RAs only need access to the schedules and age/language data to identify potential patients. We will enroll research staff for the required EPIC training.

We want to take advantage of the opportunity to recruit patients identified through EPIC as potential candidates for our study. We would work with the Epic Helpdesk to identify patients who fulfill certain criteria. Once we receive eligible patient information, we would collaborate with the Medical Director, clinicians, and the patient's provider, inviting the patient to learn more about the study and be screened.

We will discuss with the clinicians the possibility of contacting the patients by phone to ask them to participate.

The study team may also conduct outreach about the study to outside agencies, including local churches, outpatient geriatric providers, senior housing complexes, or other facilities utilized by older adults. Providers at these facilities may refer older adults to the study. CRCs/RAs will schedule screenings with interested older adults in that case. To screen participants from outside agencies, agency directors will be asked to sign a "Performance Site Not Engaged in Research Form", which will be submitted to the IRB for approval.

Intervention Description

The PMSB-E intervention provides an integrated program to address the dual challenges of mental health and disability among minority older adults. It seeks to improve mood symptoms and augment clinically significant changes in observed and self-reported physical functioning compared to enhanced usual care in participants with elevated depressive (PHQ-9 >5) or anxiety (GAI>8) symptoms and moderate to minimal disability.[76-78]

The Enhanced Positive Minds Intervention for Months 1-6: Positive Minds identifies and corrects negative distortions or cognitions, promotes behavioral activation through engaging the participant in pleasant activities, and encourages developing supportive relationships. All sessions are tailored to the participant's needs using a collaborative approach. We have made several important adaptations to the Enhanced intervention to be more sensitive to cultural beliefs and presentation of therapeutic strategies. The enhanced version expands interpersonal components with effective communication skills, practice activities, additional breathing scripts and exercises, improved psychoeducation, and dedicated attention to nutrition and sleep problems. These additional areas were deemed central in minority older adults' lives and were collaboratively arrived at. We first asked CHWs and supervisors to complete a questionnaire with feedback by session on the manual and participants' workbook. Using this feedback, study staff engaged in two open meetings with CHWs to develop adaptations and with the Executive Research Committee to generate feedback. The research team then integrated changes for review and testing. In this final year of the PMSB project, we have selected 9 participants across sites to pilot test the PMSB-E intervention and determine its acceptability. CHWs have noticed positive responses from participants, including revisions to the psychoeducational material, which helped facilitate patients' problem recognition and engagement for future sessions. CHWs noted that participants expressed deeper understanding of their symptomology, which translates into insight, motivation, and a readiness for change. Including more scenarios and role-play allowed participants who value privacy to practice listener-speaker techniques in fictitious situations instead of divulging personal examples. CHWs also noted improvements in the thought-feeling-behavior triangle integration and new breathing exercises.

Enhanced Positive Minds group component for Months 6-12: We have designed a group session component to strengthen the Positive Minds intervention effects. After participants finish the 10 sessions of Positive Minds, CHWs will offer 2 weekly group sessions as a drop-in program for older adults who want more support and practice after completing PMSB-E. Groups will be structured using a manual that PMSB-E intervention supervisors developed, reinforcing the core components of the intervention and allowing for more group practice. It will also enable participants to meet and support each other. After 6 months of participating in the PMSB-E trial, some participants may be offered a Maintenance intervention that aims to keep the benefits of the PMSB-E intervention and prevent mood and anxiety problems. This is also a combined intervention that involves physical exercise and psychoeducation sessions. The sessions are in a group and provided by CHWs and ETs using Zoom. Sessions occur 3 times a week (2 with the ET and 1 with the CHW), and participants can attend as many sessions as they want for 6 months. All participants enrolled in the intervention arm of the PMSB-E trial will be randomized to

receive the PMSB-E Maintenance intervention or usual care. Both groups will receive two safety assessments to monitor symptom severity and assess the need for referral to behavioral health services. That means that only half of the participants in the intervention arm will be offered the PMSB-E Maintenance intervention.

Strong Bodies: Strong Bodies consists of a series of exercises that are conducted while wearing a weighted vest. Resistance progresses in 2% body weight increments and will be distributed evenly within the vests. Exercise intensity is monitored using the Borg Scale of received exertion (RPE) with a goal of between 11 and 16 (moderate intensity) and stopped or resistance reduced if RPE exceeds 16 or a heart rate above 85% of age-predicted maximum. Resistance is increased when RPE values fall below the targeted range. Progression and technique are modified, and exercises are stopped if the participant experiences persistent physical complaints. The Exercise Trainer supervises the maintenance of safe positioning, posture, and form, and keeps track of participant attendance and compliance with exercise prescriptions. An MD provides close supervision, including bi-weekly calls with the Exercise Trainers to review any concerns or adjustments needed to individual exercise programs. As part of the Enhanced Strong Bodies program, we added scripts to make the sessions more fun, light music (not included after the COVID pandemic), and motivational interviewing training for the Exercise Trainers. Study participants assigned to receive the Strong Bodies intervention may also receive an instructional video of the exercises for at-home use and training for using it safely at home. The video is intended to supplement the in-person classes and allow participants to exercise individually once a week. Participants report video use to their Exercise Trainer for tracking. We provide the opportunity for participants who have finished their 6 months to continue to attend regular scheduled Strong Bodies sessions, to help with maintaining gains. In this renewal, we will additionally incorporate an ongoing group component, after the 6 months of the intervention have passed, in tandem with PM group sessions. The Strong Bodies intervention calls for participants to use several devices: 1) a weighted vest whose weights are adjusted according to participant weight and perceived exertion; 2) an aerobic step to build lower extremity strength, and whose height may be adjusted from 4 – 8 inches; 3) a balance beam (2” tall) to improve balance.

Description of Enhanced Usual Care: Participants in this arm will receive an NIH booklet about anxiety and depression and taking care of one’s mental and physical health in Spanish, English, or Mandarin/Cantonese, based on a NIMH standard resource available. The research assistant will call the participant 4 times over 6 months to assess any severe symptomology with the PROMIS and the 5-item suicide questionnaire to mimic the administration in the intervention group. Based on the work of Gallagher-Thompson and colleagues, they will also provide empathic support if the participant expresses concerns.[9] Such support will consist of a 15-minute call every 2 weeks, with participants receiving 4 calls over eight weeks.

Fidelity Checks: We will standardize the Positive Minds component by strict training and certification (i.e., intervention administration with at least 75% fidelity in 2 pilot cases). CHWs must complete checklists of intervention components delivered during a session and document the time needed to monitor the “dose” delivered. MGH-affiliated graduate students will review a random 10% sample of recordings and treatment fidelity checklists. For the Strong Bodies intervention, we assess fidelity in 3 ways: 1) a training log of elements covered per session and obstacles to completion; 2) random project coordinator spot checks of sessions, documenting areas for improvement; and 3) videotapes of a random sample of sessions, collected by Project Coordinators and reviewed by Dr. Frontera to address concerns or adjustments. We will hold bi-weekly coordination meetings to facilitate communication between CHWs and ETs.

Supervision: We will conduct weekly supervision for CHWs and bi-weekly supervision for ETs. Cases that show no improvement or deterioration will receive more intensive monitoring from the supervising clinicians and, if necessary, will be referred to primary care for medication consult. The supervising

clinicians will meet with the CHWs in weekly 1.5- 2.0-hour phone sessions to discuss participants with worsening depressive or anxiety symptoms or suicidal ideation over the study period. Cases overdue for monitoring calls, non-participation, and other cases, as requested by the CHWs, will be discussed. In an emergency, CHWs will have direct access (through cell phones) to the Site Leader and supervising clinicians at the Boston, New York, and Puerto Rico sites. Participants in intervention and enhanced usual care conditions who respond positively to questions #4 or #5 on the Paykel Suicide questionnaire will be referred for an urgent evaluation. Licensed supervising clinicians will help determine whether immediate referral and removal from the study are necessary.

Aim 2: Assess implementation readiness of the Enhanced PMSB intervention by evaluating factors associated with acceptability, feasibility, adoption, and sustainability.

In Aim 2, we will draw on the lessons learned from organizations and collaborators in our PMSB-E study to identify factors likely to facilitate the success of implementation and sustainability. Informed by the CFIR framework, we will assess facilitators, barriers, and process/potential moderators concerning:

(a) intervention characteristics; (b) inner setting; (c) outer setting; (d) characteristics of individuals; and (e) implementation process.

Study Design

(A) Concerning characteristics of the PMSB-E intervention, we will assess satisfaction and acceptability of PMSB-E at the participant-level (older adults), provider-level (CHWs and primary care team members), and organizational-level (clinic/CBO directors) using a mixed methods approach including quantitative Likert measures of satisfaction and acceptability in conjunction with qualitative semi-structured interviews at the 6 and/or 12-month intervals. (B) Concerning the inner setting, we will evaluate organizational (CBO/clinic) characteristics and implementation readiness. In our first year, we incorporated qualitative (interviews) and quantitative (organizational characteristics survey) measures to assess implementation readiness. We will interview site leaders and staff to reassess potential barriers and facilitators they anticipate when starting the PMSB-E. We will collect an organizational characteristics survey to ascertain baseline data on participating sites and interview site leaders and executive teams about barriers or facilitators to success. Organizational characteristics will be assessed using an organizational characteristics survey including information on organization size (# employees/clients, # sites, total operating budget), and type (clinics, physician led-practices, or stand-alone CBOs); scope of services (primary, urgent, specialty, or integrated care); population covered per 1,000; and level of CHW integration into the clinical/CBO team as a moderator (using SAMHSA's measure of provider integration[117]). Organizational implementation readiness will be assessed using the Organizational Readiness for Implementing Change (ORIC) measure, consisting of 12 items rated on a 5-point ordinal scale. It is a brief, practical, and reliable measure of key domains reflecting an organization's readiness to adopt and implement an evidence-based practice. The survey will also collect demographics of clients served annually, average caseload (age, sex, race/ethnicity, socioeconomic status), and payer mix (Medicare, Medicaid, private payer). As part of our original grant, we prepared site profiles including much of this information, so a portion of the work in year 1 will be updating these materials and seeing changes in the organizations from the onset. This will help us to develop the profile of organizations that can successfully carry out this work.

As part of Aim 2, we will also create a learning community of CBOs, clinical sites, and academic partners to share elements that have contributed to initial success and are essential to strengthening the collaboration. At the onset, we will review the roles and responsibilities of our partnership and create a new memorandum of understanding for our joint work. The learning community will share information through regular calls every 2 weeks to review project progress and in one-on-one discussions between

research staff, site leaders, CHWs/ETs, and other players, such as primary care, to assess barriers and facilitators to success.

In Aim 2, we will work with sites to identify opportunities in the 'outer setting' to facilitate financial sustainability and put into place systems to collect data and monitor information needed to successfully solicit local, state, and federal funding. We will collect data at the start of the project and yearly with the partners to see the utility of a resource packet and training materials to support the development of a toolkit used for dissemination and implementation in Aim 3.

The research team will conduct interviews with Site Leaders, CHWs, ETs, and institutional and clinic directors to address acceptability, barriers, and facilitators of the program, as well as an understanding about how implementation readiness is seen across the CIFR framework. They will also help collect initial information for the Organizational Characteristics Survey. We plan to program the survey into an easy-to-use online questionnaire using REDCap that CRCs/RAs can run through with the participant or that can be self-administered.

We will evaluate factors associated with acceptability, feasibility, adoption, and sustainability of the intervention at collaborating sites and with staff. We will conduct qualitative interviews and focus groups with Site Leaders, CHWs, ETs, and institutional, clinic, and CBO directors and staff to address acceptability, barriers, facilitators, and implementation readiness. We will provide a $50 gift card for participation in the in-depth interview or focus group (unless participants cannot accept it due to organizational affiliation or set up). We include a Cede review from Columbia University for MGB so our collaborator can conduct this work.

Biostatistical Analysis

AIM 1

Statistical methods: We began with descriptive analysis of all data by site, using means, standard deviations, skewness, quartiles, and graphical assessments of the distribution. We compared distributions of baseline characteristics between intervention and enhanced usual care groups in each site to assess the balance of the observed covariates between the randomized groups.
We used intent-to-treat principles and included all randomized participants. We compared changes in outcome scores using repeated measures linear mixed-effects models with a participant-level random intercept for the primary (12-month), key secondary (6-month), and exploratory endpoints (3-month). Expressly, we entered treatment condition (EUC or PMSB-E), time (3-, 6, or 12-months), and treatment-time interactions into repeated measures linear mixed-effects regression models to assess the impact of the treatment over time. All three post-randomization assessments were included in the linear mixed-effects models, which are defined with the following hierarchical structure:

$$y_{it} = \beta_{0i} + \beta_1 Treatment_i + \beta_2 Time_t + \beta_3 (Treatment_i \times Time_t) + \beta_4 PostTime_t + \beta_5 (Treatment_i \times PostTime_t) + y_{i0} + \mathrm{B}' X_i + u_{it} \qquad Eq.[1]$$

where y_{it} is the outcome variable of interest (HSCL-25, Late-Life FDI, SPPB, or WHODAS 2.0 scores) for individual i at post-randomization time t (3-, 6-, and 12-months). This mixed-effects model included two different time terms, $Time_t$, to account for the slope of the outcome trajectory, and $PostTime_t$, which measures time since month 6 to account for a possible change in slope between months 6 and 12 (or to account for a possible change in slope during the group maintenance phase of the intervention). Together, the terms $Time_t$ and $PostTime_t$ specify a linear spline model, with two linear segments joined at month 6 representing, respectively, the trajectory during the one-on-one phase of the intervention (baseline to month 6) and the trajectory during the group maintenance phase (after month 6). To evaluate

the impact of the intervention, we included an effect-coded variable for treatment ($Treatment_i$), and two treatment-time interactions ($Treatment_i \times Time_t$ and $Treatment_i \times PostTime_t$) to allow control-intervention differences to change over time. y_{i0} is the outcome score at baseline. X_i is a vector of covariates to adjust for unintended imbalance between intervention and control conditions. u_{it} denotes the residual error for participant i at time t. The intercept, β_{0i}, was estimated as a random effect that varies across participants. The main coefficients of interest were the treatment effects (i.e., contrasts between the randomized groups) at the primary (12-month), key secondary (6-month), and exploratory endpoints (3-month), which were obtained by centering the time terms at the 12-, 6-, and 3-month endpoints, respectively. Expressly:

1. The intervention effect at the primary 12-month endpoint was obtained by coding $Time_t$ as (-9, -6, and 0) at 3, 6-, and 12-months, respectively. The $PostTime_t$ term was coded as (-6, -6, and 0) at 3, 6-, and 12-months, respectively. Under this coding scheme, the coefficient β_1 from $Eq.[1]$ directly represented the intervention effect at month 12.
2. The intervention effect at the secondary 6-month endpoint was obtained by coding $Time_t$ as (-3, 0, and 6) at 3, 6-, and 12-months, respectively. The $PostTime_t$ term was coded as (0, 0, and 6) at 3, 6-, and 12-months, respectively. Under this coding scheme, here too the coefficient β_1 from $Eq.[1]$ directly represented the intervention effect, but this time at month 6.
3. Finally, the intervention effect at the exploratory 3-month endpoint was obtained by coding $Time_t$ as (0, 3, and 9) at 3, 6-, and 12-months, respectively. The $PostTime_t$ term was coded as (0, 0, and 6) at 3, 6-, and 12-months, respectively. Under this coding scheme, here too the coefficient β_1 from $Eq.[1]$ directly represented the intervention effect, but this time at month 3.

Because of the importance of the different racial/ethnic makeup of the sample, prespecified subgroup analyses were conducted by adding interaction terms between intervention and race/ethnicity and time × intervention × race/ethnicity interactions. The model is flexible enough to incorporate the association of race and ethnicity on the treatment effect. In exploratory analyses, we considered inserting two-way interaction terms to provide preliminary evidence of the heterogeneity of treatment effects by socio-cultural, clinical, and medication factors.

Power Analyses: Participation of a minimum of 400 participants across all sites (assuming a conservative 20% attrition at 12-month follow-up, a total of 320 completions) allows for adequate power to detect the effect of the intervention on primary outcomes. We estimated the power to detect the intervention effect based on $Eq.[1]$, assuming a two-sided type I error rate of 0.05, correlation of 0.5 among repeated measures, and similar standard deviations as in the previous study of the PMSB intervention. For the effect sizes assessed at the 12-month follow-up, we assumed that the enhanced treatment would achieve an effect size that was derived from the prior PMSB study results as follows:

Target Effect Size = ITT Effect Size + 1/3 * (FC Effect Size – ITT Effect Size),

where ITT Effect Size denotes the effect size for the intent to treat analysis, and FC Effect Size denotes the effect size for as-treated analysis assuming full compliance with the protocol. Given the design to enhance compliance in the current study, the effect size should be close to the full compliance effect size. However, we assumed conservatively that the enhancement only improved upon the ITT Effect Size by one-third of the gap between the FC Effect Size and the ITT Effect Size (Table 1). Under those assumptions, we estimated that the PMSB-E would have 78.5%, 86.8%, and 92.3% power to detect a difference in HSCL-25 (Cohen *d* =0.26), SPPB (*d* =0.29), and the function component of the Late-Life FDI (*d* =0.32) between treatment and usual care groups at the 12-month assessment, respectively.

Table 1: Estimated Effect Sizes at 12-month Assessment from Prior PMSB Study

	Intent-to-treat Effect Sizes	Full Compliance Effect Sizes	Target Effect Sizes
Short Physical Performance Battery	0.26	0.35	0.29
Function component of the Late Life Functioning and Disability Instrument	0.28	0.41	0.32
Hopkins Symptom Checklist-25	0.23	0.32	0.26

In prespecified subgroup analyses, with 320 participants, we also estimated 89.3% and 74.3% power to detect a significant interaction between race/ethnicity and treatment for SPPB and Late-Life FDI, respectively. We were nonetheless underpowered to detect a significant interaction for HSCL-25, unless (1) we included only three racial/ethnic groups (Latinos, Asians, and Blacks), or (2) we oversampled Blacks and Whites to have a more even distribution across race/ethnicity. We conducted additional power calculations to determine the needed effective sample size to have adequate power to detect a significant interaction between race/ethnicity and treatment for HSCL-25 under these two scenarios. If we were to limit the study to sample only three racial/ethnic groups (33.3% Latinos, 33.3% Asians and 33.3% Blacks) in equal proportions, an effective sample size of 450 participants, instead of 320, would provide adequate power (73.3%) to detect a significant interaction between race/ethnicity and treatment for HSCL-25. If the racial/ethnic composition comprises 25% Latinos, 25% Asians, 25% non-Latino Blacks, and 25% non-Latino Whites, an effective sample size of 600 participants (150 in each group) would provide 70% power to detect a significant interaction. Given budget and recruitment constraints, our final planned effective sample size was 450 participants in equal proportions across Latino, Asian, and Black racial/ethnic groups.

To ensure that the significance of our findings is not an artifact of assessing multiple outcomes, we will conduct sensitivity analyses that estimate a single multilevel mixed model on an aggregate variable capturing all outcomes[112]. This approach accounts for the correlation between outcomes and is less conservative than a Bonferroni correction. Given the levels of power calculated for the overall intervention effect, we are confident that we will have adequate power to test treatment differences even after this correction for multiplicity is made. Prior experience suggests that treatment outcomes may differ by site, socio-cultural factors, CHW fidelity, and therapeutic alliance. We will conduct exploratory assessments of these treatment differences, recognizing that the sample size is unlikely to provide sufficient power to detect these differences.

Aim 2

Data collection and analysis: The research will conduct interviews with Site Leaders, CHWs, ETs, and institutional and clinic directors to address acceptability, barriers, and facilitators of the program, as well as how implementation readiness is seen across the CFIR framework. They will also help collect initial information for the Organizational Characteristics Survey. We plan to program the survey into an easy-to-use online questionnaire using REDCap that RAs can administer to the participant or that can be self-administered. Given our experience in previous work, we will corroborate information about the organizations or clinics with external data sources or hospital-wide data (in the case of MGH). We will also have data from research interviews with older participants on experiences with care, as well as satisfaction with the PMSB-E program. For qualitative data, RAs and Project Managers will conduct a first round of coding to analyze data using two simultaneous approaches: 1) coding about barriers and facilitators identified a priori; and 2) open coding to identify new concepts. Codes will be compared using the constant comparative method[116,117]. To ensure inter-rater reliability, coders will meet regularly to discuss consistency and resolve discrepancies[118]. Coders will use an axial coding scheme and analyze how themes compare across staff and participants and within/across organizations. Our statistician will analyze the Organizational Characteristics survey to compare key areas of similarity and difference between sites.

We will consider how site-level factors influence outcomes. Student interns will take part in transcription and coding. Results will be discussed with the Executive Committee and used to optimize processes for implementation readiness.

Expected outcomes from the qualitative and quantitative integration include: 1) acceptability of the PMSB-E intervention by both participants and CHWs/Exercise trainers; 2) characterization of site and participant-level factors; 3) identification of opportunities and plans for workforce training and ongoing financial sustainability of the program; and 4) an assessment of implementation readiness, that can be applied to toolkit development.

Risks and Discomforts

AIM 1

We do not anticipate significant risks associated with the proposed study. Minimal risks include the possibility of discomfort when discussing mental health problems and receiving treatment with the CHWs or Exercise trainers (for the intervention arm) or during research assessments or control calls (for both intervention and control). Participants in the treatment condition may become upset in discussing their frustrations dealing with depression and anxiety, or in previously trying to obtain mental health care. Intervention and control participants may experience mild emotional discomfort in responding to sensitive questions in the interview. These inherent risks are typically assessed to be low compared to the long-term potential benefits from this type of research.

Should participants endorse suicidality in any research assessments, CRCs/RAs will follow an emergency protocol tailored to each site (see end of human subjects document for an example) that involves clinics designated to receive emergency cases (see adequacy of protection against risks below). CHWs will discuss potential clinical concerns for their patients in weekly supervision meetings with licensed mental health professionals or on the same day with clinical supervisors. See the adequacy of protection against risks for more details. Participation in the Strong Bodies Exercise component is deemed safe, with exercise trainers attentive to any physical restrictions of participants so that they can adjust activities accordingly.

Enrolled participants will be administered four research assessments as part of the intervention and control groups. Those who answer positively to questions 4 or 5 on the Paykel, suggesting acute suicidality, will be provided emergency care following the emergency protocol developed by the Disparities Research Unit. The emergency protocol involves immediate referral to emergency services for assessment and treatment. The participant's PCP will also be notified, and participants will have consented to this as part of the study consent form.

Participant Privacy: Every effort will be made to uphold participant privacy throughout this study. The research staff will protect information pertinent to an individual's involvement in the study. Participants will be assigned participant identification (ID) numbers, which will be used on study documents (including the tracking logs for the gift card incentives) and communications without any identifying information. Links to these ID numbers will be kept in password-protected documents. All telephone sessions will use phone adapters with landlines that allow interviews to be recorded privately per study protocol. If a landline is unavailable, the speakerphone setting on cellular phones also yields adequate recording quality; this method would be used in private settings. Audio recordings will be saved in secure computer directories to assure confidentiality, then deleted from the audio recorder, once supervision, data cleaning, and data analyses have been completed.

Adequate provisions will be made to protect the privacy of potential and current participants throughout all phases of the research. Staff will schedule assessment interviews in private settings. They will not discuss participant project information with anyone other than research staff, nor leave sensitive messages on voicemails. Staff will ensure that conditions under which information will be collected (e.g., telephone contact, mail, or email) are afforded protections against participants being overheard or inadvertently intercepted. Part of the training for CHWs and Exercise Trainers will include ensuring that the CHWs and Exercise Trainers check whether the participant is receiving the call from a confidential or secluded place to ensure confidentiality of the information. CHWs and Exercise Trainers will undergo a comprehensive training on the confidentiality of participant information. We will also inform participants how their information is secured, particularly emphasizing that their information will not be disclosed to anyone outside the research team. We will clarify how all information is presented in aggregate form so that no one can be identified.

Suppose participants are very hard to reach or have challenges preventing them from participating in certain sessions/interviews at the clinic or by phone. In that case, we will offer the possibility of home visits. This includes conducting the CHW/Exercise Trainer sessions or research assessments in the home. This has been a helpful strategy in previous studies with hard-to-reach patient populations and has been important for reaching participants we are concerned about with serious mental health concerns. We would include information in our consent form to ensure this option is clear to participants. Staff conducting home visits will be trained in safety procedures. Before research staff conduct a home visit, they will alert study staff in the office, and are asked to be in contact before and after leaving the site to ensure that everything is fine. Staff are not mandatory reporters, but if they see anything serious happening in the home, like child or elder abuse, suicidality, or a risk of death, they will implement the emergency protocol and contact supervisors when in doubt to provide advice and jointly determine next steps.

Suppose an older adult suffers from a physical ailment during the PMSB-E sessions that needs care. In that case, we will coordinate a visit through their primary care clinician, or in the event of an emergency, will contact the emergency room of the nearest medical center to the clinic or community-based organization. If hospitalization is deemed necessary for intervention participants, CHWs and Exercise Trainers will proceed with sessions following the participants' discharge and coordinate with emergency clinicians to ensure that participants are referred for additional health services.

AIM 2

Risks to the Subjects

Some participants may feel uncomfortable answering certain questions during in-depth interviews or focus groups. Before interviews commence, participants will be told that they can refuse to answer specific questions or terminate the interviews.

Adequacy of Protection Against Risks

Every precaution will be taken to maintain participants' rights and privacy protections in in-depth interviews and focus groups. All identifying locator data for individuals interviewed or organizations profiled will be stored in locked file cabinets, and data used for analysis will be de-identified and assigned an identification (ID) number for privacy. All research personnel will have access to the de-identified subject information. Only research staff will have access to identifying information for the initial data cleaning period. All investigators who work with the data in any capacity will sign a data release agreement. This agreement outlines the data access criteria, includes research use conditions, incorporates privacy and confidentiality standards to ensure data security, and prohibits data manipulation.

II. Potential Benefits

AIM 1

Potential Benefits of the Proposed Research to the Subjects and Others

Participants in the intervention may achieve decreased depressive and anxiety symptoms, better muscle resistance and mobility, and a reduction in disability days. Participants in the intervention arm, as compared to the enhanced usual care condition, may be better able to recognize and self-manage their mood problems, as well as increase their ability to deal effectively with structural barriers (e.g., stigma) that may impede them from entering and staying in mental health treatment. They may experience physical strengthening and improved mobility due to the exercise component of the intervention. The results of the study may provide evidence of how best to work with minority older adults with depressive, anxiety, and/or disability symptoms in community settings to prevent or decelerate disability. The study may also prove effective for diminishing mental health symptoms, thereby reducing disparities in care and disparities in disability outcomes among minority older adults. Participants randomized into the enhanced usual care group may benefit from support by research staff, such as coordination of appointments in primary care or mental health services, if they request them. Study participants will receive a $60 gift card incentive for each completed assessment interview: baseline, 3-month, 6-month, and 12-month follow-up, for $240 ($250 with the $10 screener gift card). The gift card will be tracked by the participant's assigned ID number and logged in the gift card log book by the research staff. Participants receive no compensation for taking part in the PMSB-E sessions.

To ensure sufficient time for data cleaning, analysis, and paper writing in a no-cost extension period, we plan to finalize clinical trial data collection at the end of October 2024. With this change, a segment of participants will have their final interview 6 months after baseline, rather than 12 months. For these cases, we will move the final qualitative questions to the 6-month rather than the 12-month interview. To ensure we provide the promised incentive, we will provide a $120 gift card at participants' final 6-month assessment (comprising the 6-month and 12-month incentive amount). We will inform participants about this change when we call them to schedule their 6-month interview. Clinical trial recruitment has been finalized, so no changes to the consent form are required.

Importance of the Knowledge to be Gained

We anticipate the information gained from the intervention will illustrate an important model for building community capacity for disability prevention and mental health service delivery. It is also a means of engaging and treating minority older adults with depressive or anxiety symptoms and at risk for disability in CBOs by Community Health Workers and Exercise Trainers. There is a tremendous need for sustainable and affordable solutions that use task shifting for mental health problems and disability prevention for ethnic/racial and linguistic minority older adults. We envision that the proposed model of building community capacity will be able to 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, acceptability, and sustainability after the project ends. From a public health perspective, this type of model for problem solving and building resources in the community is beneficial because it could diminish disability associated with mood and mobility problems among a population that already suffers disproportionately in these areas. In testing this strategy using a randomized clinical trial and collecting data throughout the project, we will be able to determine its benefits.

AIM 2

Potential Benefits of the Proposed Research to the Subjects and Others

The Site Leaders, CHWs, Exercise Trainers, CRCs/RAs, and other staff who consent to participate will be told that their participation in the study may be of no direct benefit to them. Some respondents in the study may find it beneficial to discuss issues of importance in their organization and community related to depression/anxiety among older adults and the context of their community-based organization (CBO) or community clinic, but these benefits will be indirect. Indirect benefits include the knowledge gained about organizational capacity and factors likely to facilitate the success of implementation and sustainability in each site.

Importance of the Knowledge to be Gained

This aspect of the study will contribute significantly to our understanding of implementation readiness and what is required to integrate the intervention at various sites successfully. Expected outcomes include: 1) understanding of acceptability of the PMSB-E intervention by both participants and CHWs/Exercise trainers; 2) characterization of site and participant-level factors; 3) identification of opportunities and plans for workforce training and ongoing financial sustainability of the program; and 4) an understanding of implementation readiness; that can be applied to toolkit development in Aim 3. It will also provide insight on how the intervention fits into each community clinic and organization and what accommodations may need to be made in each context to inform the development of resources and competence for delivering mental health services in ACO sites.

III. Monitoring and Quality Assurance

We will make extensive efforts to ensure study participants' safety and systematically track risks, issues, and outcomes across CBO sites. We will create a monitoring registry using a HIPAA-compliant, web-based program accessible by research teams and supervisors, where we can tabulate and track any human subjects and systematic issues that arise with implementation across sites, as well as between intervention and control conditions. We will identify a core set of patient issues that will be flagged if they occur: 1) cases with no improvement, an increase in symptom scores, or physical pain linked to outcome; 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 Project Manager will maintain the registry and set it up to track patients by case ID, clinical site, and date of occurrence. We will create logons for CHWs/Exercise Trainers and CRC/RA interviewers at each site, who can enter information about their cases. We will use specialized permissions at the user level to ensure that CRCs/RAs remain blinded to any information about participant condition. The Project Manager will review data in preparation for weekly team and clinical supervisor meetings and will download the registry data to review with study staff and supervisors. At the project's onset, we will work with the study data analyst 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 and generate reports on the frequency of any given issue within and across the CBO 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 Manager. We will thus systematize our monitoring of outcomes and challenges to view patterns and optimally address them. The registry will also inform us of our overall understanding of implementation challenges.

Responsibility for data and safety monitoring

We will put in place a Data Safety and Monitoring Board. Data safety is ultimately the responsibility of the Principal Investigator. She will consult with the Human Subjects Office to assess any research risks and work with the IRB as potential issues arise.

Frequency of Data Safety Monitoring (DSM) reviews. We will plan to assemble a Data Safety and Monitoring Board (DSMB) to monitor the study every year. We plan to hold two annual DSMB meetings via teleconference software such as Zoom. The DSMB will review study progress, data quality, and participant safety, per the guidelines in the DSMB charter. If a serious adverse event occurs, we will conduct a special DSM review to ensure that protocols are assessed as needed and revisions are made. The event was addressed and resolved in a manner satisfactory to those involved.

Content of the DSM report

As part of our progress report, we will incorporate a DSM update that summarizes recruitment progress and retention of participants in the intervention, any safety or quality care issues that may have arisen, and a summary of any Adverse events that have occurred. We will also track any changes to the protocol that have been required because of these events.

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.

The MGH research team staff will also work closely with the CBO Site Leader to help put together IRB amendments, yearly IRB continuing reviews, reporting materials as required by the funder, and budget and invoice materials as part of the site subcontracts.

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 CommCare HQ application will be installed on tablets and these tablets will be made available to CRCs/RAs serving as interviewers on the PMSB Implementation study. Our CRCs/RAs 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 data transfers to and from the Dimagi server will be conducted over industry standard transmission encryption (HTTPS). All access to the cloud infrastructure is protected behind a firewall

and require unique VPN access permissions. All data is transferred through channels that are monitored by intrusion monitoring system.
Data on the Dimagi server can be accessed by Partners staff through secure connections. All interactions with the server are saved and catalogued to report user, date, time, and location to better serve with regulations and auditing purposes. Monitoring system admin access: administrative access will be restricted solely to Dimagi and associated sub-vendors. All system level access will be fully logged for auditing purposes. Different Partners users can have different levels of access to the system and require secure authentication to access the data. The server also allows for data integrity, it does not allow for raw data to be altered once it's been entered. All changes are recorded with time and data, creating records for quality control.

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.

Outcomes monitoring:

Quality Control: Collection protocols have been established to ensure accuracy and quality of the data obtained from all participant interviews with CRCs/RAs and treatment sessions with CHWs and ETs. Interviewers will have biweekly conference calls with Site Leaders at the community clinics and/or community-based organizations 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. CHWs and ETs will meet by conference call on a weekly or biweekly basis with supervisory clinicians/MD to discuss any concerns that arise regarding the weekly risk assessments with their participants. Supervisors and CRCs/RAs will hold a conference call every Friday to coordinate the research tasks, problem solve logistical or budgetary issues, and review the progress towards achieving milestones.

For the intervention, the quality of the CHW and ET work will be monitored by the PI, Site Leaders, supervising clinicians, and the MD. 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 CHWs' 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 and assist them in following the manualized protocol. The investigators from all sites will participate in biweekly group supervision and review treatment fidelity checklists required of all CHWs to ensure standard treatment delivery within and across sites. For exercise trainers, fidelity will be assessed through a training log, in which the trainer records their ability to cover all elements of each session and notes any obstacles to keeping up with the prescribed activities each time they meet with a group. Additionally, project coordinators, the MD, and coordinators will work with Site Leaders to conduct random spot checks of the exercise sessions. They will keep notes of areas that might need improvement. Finally, a random sample of videotapes of random exercise group sessions will be collected by the Project Coordinators and reviewed by the exercise supervisor to evaluate fidelity to the Strong Bodies intervention.

Plans for Interim Analysis of Effectiveness Data

We will clean the data periodically as the protocol progresses. This will enable us to undertake interim assessments of the effectiveness of the intervention. We will report on any effectiveness data to date in

the yearly progress report. We determined with the DSMB not to do an interim analysis and removed details of this section from the protocol.

Adverse event reporting guidelines:

Reporting mechanisms of AEs/SAEs

As explained here, we will follow the policies and procedures for adverse event reporting.

Definitions are as follows:

Adverse Event (AE): Any untoward or unfavorable medical occurrence in a clinical research study participant, including any abnormal sign (e.g., abnormal physical exam or laboratory finding), symptom, or disease temporally associated with the participant's involvement in the research, whether or not considered related to participation in the study.

Serious Adverse Events: Any adverse event that: results in death; is life-threatening, or places the participant at immediate risk of death from the event as it occurred; requires or prolongs hospitalization; causes persistent or significant disability/incapacity; results in a congenital anomaly/congenital disability; or is another condition which investigators judge to represent substantial hazards. Given that we are working with an older population, we anticipate that there will be some possibility of serious illness, hospitalization, or death, due to factors not associated with the study or due to natural causes. A summary of these expected SAEs will be reported quarterly to the NIA PO and the DSMB.

Reporting mechanisms of IRB actions

We will report regular changes to the protocol to NIH at the annual progress report. If a serious adverse event requires immediate notification, we will report to NIH and the IRB according to the rules above.

Report of changes or amendments to the protocol

We will report changes to the protocol and amendments at the time of the annual progress report.

Trial stopping rules

Per the rules for management of an SAE, if the IRB deems that a serious adverse event suggests that the risks of the trial outweigh the benefits, we would temporarily stop further data collection until an alternate plan can be developed to ensure the safety of the trial participants.

Management of SAEs or other study risks
In collaboration with the IRB, we will assess the necessity of the following steps.
• changes to the protocol to minimize risks to subjects;
• changes to the consent form to accurately reflect the nature, frequency, or severity of the event;
• Ask subjects to re-consent to participate in the study if necessary.
• placing the study on temporary hold to new enrollment and/or discontinuing procedures if, based on the information available, the risk-benefit ratio appears unfavorable to the subjects.

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