Mass General Brigham

Institutional Review Board
Intervention/Interaction Detailed Protocol

Principal Investigator: Tony V Pham, MD, MScGH

Project Title: Mindfulness-based cognitive therapy for the chronic pain-early cognitive decline co-morbidity among older Black individuals in the community; The Feeling of Being Open Pilot

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1. Background and Significance

Chronic Pain (CP) and Early Cognitive Decline (ECD) commonly co-occur, worsen each other over time, and synergistically decrease physical, emotional, and cognitive function increasing risk for ADRD. Older adults with CP are two times more likely to also report ECD. The presence of both CP and ECD has an even greater negative impact on physical and emotional functioning than either of these conditions separately. In addition, pain has an independent, negative effect on cognitive functioning and is a documented modifiable risk factor for Alzheimer's Disease and Related Dementias (ADRDs). Recent research shows that the CP-ECD relationship is bidirectional among older adults. CP accelerates ECD and increases risk for dementia, while ECD alters pain perceptions increasing CP and impairing emotional and physical function. Consequently, older adults with CP and ECD can become caught in a "disability spiral" whereby physical, cognitive, and emotional function progressively worsen over time. By addressing the common CP-ECD comorbidity we can stop the disability spiral, promote healthy aging; improve emotional, physical, and cognitive function; and prevent transition to ADRDs.[1]

Older Black individuals have the highest rates of CP and ECD and are at the highest risk for negative health outcomes due to this comorbidity. Up to 78% of Black older individuals experience CP, a rate substantially higher than that experienced by non-Hispanic White older adults. Although Black older adults are less likely to discuss pain concerns, when they do, they describe higher impairment in physical and emotional function symptoms than their White counterparts. Prevalence of cognitive impairment, including the spectrum from ECD to ADRD, is also higher among Black compared to non-Hispanic White adults. Black adults represent a high-risk group for ECD and have an overall 2-fold higher risk of dementia. This high disease burden, combined with lack of appropriate treatments, also explain the higher rates of mortality among Black

individuals. Developing innovative solutions to bypass barriers to engagement in care and to meaningfully address the CP-ECD comorbidity among older Black individuals are urgently needed.[2]

Older Black individuals with chronic pain and early cognitive decline more frequently fear medications and medication related side-effects (patient factor), providers who may misunderstand and discriminate against them (provider factor), and psychotherapies that do not relate to their lived experience (system factor). Conventional psychotherapies, per reports from older Black individuals, evoke stigma, lack credibility, and misunderstand Black culture.[5] Thus, older Black individuals do not typically seek out, engage, or follow-up with conventional psychotherapies such as Cognitive Behavioral Therapy (CBT), the often recommended, non-pharmacological standard for treating chronic pain and delaying or slowing cognitive decline. On the other hand, mindfulness-based cognitive therapy (MBCT), although not generally considered the gold standard for chronic pain and mild cognitive impairment, has demonstrated benefit in treating chronic pain[6] and delaying or slowing early cognitive decline among older adults[7] while overlapping with health practices well-recognized by older Black individuals (e.g., mindfulness meditation in comparison to contemplative prayer, group-based effects in comparison to community support, strengthening self-awareness in comparison to empowering ethnoracial identity).[8]

Despite MBCT's potential, Black individuals have been grossly underrepresented in the clinical trials backing MBCT,[9] with several negative downstream consequences. Promoters tend to advertise mind-body interventions to White populations,[10] and mind-body interventions have been taught almost exclusively in White, middle-and upper-class settings with minimal utilization among underrepresented groups because of access barriers, high costs, the lack of Black representation among attendees and instructors, and conflicting Buddhist undertones.[11,12] Researchers and providers must then repackage MBCT to broaden its appeal among older Black individuals.[13] Based on focus groups I conducted with older Black individuals with CP-ECD from the Greater Boston Area, a culturally adapted MBCT ("Feeling of Being") could be acceptable and feasible if abbreviated (e.g., 8, 1-hour sessions) and delivered by a lay instructor from the Black community.

2. Specific Aims and Objectives

To continue the development of *Feeling of Being,* a culturally tailored mindfulness-based cognitive therapy (MBCT)-based intervention for older Black adults to be delivered within the community, by training a lay group instructor from the Black community and conducting an open pilot with exit interviews among older Black individuals with chronic pain and early cognitive decline to determine the initial feasibility and acceptability of *Feeling of Being* and the feasibility and fidelity of instructor training.

Hypothesis: Our guiding hypothesis is that MBCT, culturally adapted for the CP-ECD co-morbidity among older Black individuals, will improve physical function (primary outcome), emotional function, pain, and intervention targets (i.e., delaying or slowing cognitive decline). I will formally test this hypothesis in a subsequent R01.

3. General Description of Study Design

Older Black individuals have expressed concern and skepticism when asked to enroll in scientific trials because of prior exploitative studies (e.g., the Tuskegee trials). To address these concerns, I worked with the MGH Community Access, Recruitment and Engagement (CARE) Research Center, the Center for Racial Equity and Justice), community navigator Michael Kincade (MGH) and Union Capital Boston (UCB), a hub where thousands of Black individuals living within under-resourced Boston neighborhoods have engaged in network nights, resource fairs, and other forms of community engagement. We formed a community advisory board (CAB) composed of 20 older Black individuals with CP-ECD. I facilitated four focus groups with our CAB to explore the potential acceptability and feasibility of MBCT (P30AG083196). Thematic analysis of these focus groups suggested that MBCT may be feasible for older Black individuals with the ECD-CP co-morbidity but needs to be (1) centered around values, attitudes, and practices accepted by the older Black adults with CP-ECD, (2) delivered within the community setting, and (3) delivered by lay instructors to mitigate historical issues of lack of trust. Thus, using an abbreviated, evidence-based MBCT protocol (8 60-minute sessions) as a starting point, we then worked with our CAB to develop a preliminary manual for a culturally tailored MBCT ("*Feeling of Being*"). In collaboration with Jin Joo who has deep NIH funded research experience training lay instructors to support people in community settings and Ana-Maria Vranceanu who has experience developing training fidelity protocols (*GetActive* NCCIH R01AT010462) as a starting point,[15] we also developed protocols for lay instructor training and fidelity testing, and study procedures for a feasibility pilot study in Black communities. In this proposal, I will train a Black lay individual to deliver *Feeling of Being* via an open pilot and assess preliminary feasibility and fidelity. All participant activities within this proposal will take place at the Central Boston Elder Services (CBES) conference space, a community-suggested location. CBES is a non-profit access point for aging services that predominantly caters to older people of color. Virtual accommodations will be made available for those who cannot attend in-person.

Open Pilot. I will train a lay group instructor from the Black community and conduct an open pilot with exit interviews (n=8; 1 group) to determine the initial feasibility and acceptability of *Feeling of Being* and the feasibility and fidelity of instructor training. Based on the 2007-2011 American Community Survey of Roxbury, I estimate that the total number of Black individuals over the age of 50 with chronic pain and co-morbid depression to be 1,325. This estimate indicates that the eligible sample size is in excess of the recruitment requirement of *N*=8 participants.

The first two months will involve developing material and conducting trainings with study staff. Recruitment, intervention delivery, and refinement of materials will occur over the subsequent 10 months.

Below, I present proposed milestones for this open pilot.

Table 1. Study Timeline

Major Task 1: Start-up, prepare, and conduct the open pilot for Aim 1.	**Months**
SUBTASK 1: Clinical protocol for NCCIH; prepare IRB. No Data Safety Monitoring Board (DSMB) is required.	
Develop manual, consent forms, protocol, assessments, and tracking forms.	0-2
Coordinate recruitment with CBES and ensure recruitment of racial and ethnic minorities	0-2
Finalize data/time for study weekly meetings as well as check-ins with CBES for recruitment.	0-2
Milestones Achieved: IRB submitted and approved; protocol approved by NCATS; materials developed; meetings set.	
SUBTASK 2: Train study staff in study procedures consistent with protocol.	
Train RA on study procedures, including how to teach participants Zoom for remote delivery.	3
Train lay instructor on *Feeling of Being* manualized protocol	3
Present to CBES staff and train in study procedures.	3
Milestones Achieved: Study team assembled and trained; PI ready to deliver pilot intervention.	
SUBTASK 3: Start recruitment, intervention, and data collection at all assessment periods.	
Recruit 8 participants (8-week intervention)	4-6
Conduct post-intervention assessments and exit interviews with participants.	5-7
Prepare for data analysis.	7-8
Database locked.	8
Milestones Achieved: Recruitment, treatment, and follow-up are completed; database is locked.	
SUBTASK 4: Refine *Feeling of Being* intervention and study procedures (to prepare for Aim 3).	
Analyze data using mixed methods approaches.	8-9
Refine intervention and study procedures based on findings.	9-11
Disseminate initial findings in peer-reviewed journals and/or conferences.	11-12
Milestones Achieved: Intervention and study procedures refined; ready to test for feasibility in Study 3 (Aim 3).	

4. Subject Selection

We will recruit older Black participants with chronic musculoskeletal pain and co-occurring early cognitive decline (**Table 1**).

Table 2. *Inclusion and Exclusion Criteria*

Participant Inclusion Criteria
1. Older adult (age ≥ 50)
2. All individuals who identify with one or more nationalities or ethnic groups originating in any of the Black racial groups of Africa
3. Pain in muscles, joints, bones, or associated soft tissues (NRS>4) lasting longer than 3 months
4. Subjective ECD or MCI
5. Telephone Interview for Cognitive Status-30 score ≥ 17
6. Functional Activities Questionnaire score < 9
7. English fluency/literacy
8. Ability and willingness to participate via in-person and video
9. Willing to provide informed consent and comply with all aspects of the protocol
Participant Exclusion Criteria
1. Current substance abuse/dependence
2. Significant cognitive impairment
3. History of more than 8 sessions of cognitive-behavioral therapy
4. History of previous training in mindfulness or undergoing counseling more than once a month
5. History of or current diagnosis of psychosis
6. Active suicidal ideation or self-harm within the past 90 days

Enrolled participants must be older than 50 years of age, based on community feedback and because chronic diseases are noted in Black Americans at an earlier age.[35–38] Participants must have either preclinical (subjective) or early objective (Mild Cognitive Impairment (MCI)) because they are both comorbid with chronic pain, they are both early precursors of Alzheimer's Disease and Related Dementias (ADRD), and they both require similar adaptations to skill acquisition. Including both also increases generalizability and scalability. Participants must score ≥ 17 on the Telephone Interview for Cognitive Status to ensure that participants do not have prevalent dementia or severe cognitive impairment that would preclude them from meaningfully engaging with the study. Participants must also score < 9 on the Functional Activities Questionnaire to ensure that participants are able to meaningfully engage with the program. Participants must report chronic (≥ 3 months) musculoskeletal pain with a severity of ≥ 4 on the Pain Numeric Rating Scale (NRS).[40] These cut off values are similar to those of other NIH-funded mind-body trials for chronic musculoskeletal pain in community settings.[41]

5. Subject Enrollment

We will recruit from Central Boston Elder Services (CBES) affiliated Catherine Hardaway Residence, a collection of 57 housing units originally developed in 2011 to address the elder housing crisis in the Roxbury community of Boston. The Roxbury community is predominantly Black and has been described by the city as the "heart of Black culture in Boston."[42] I have been working with CBES for the past two years to establish infrastructure to support this project. I will present the study aims to CBES to explain this study and facilitate referrals.

Our CE Studio community navigators (Kincade, Linton) will also assist with referrals but will only be assisting in referring potential participants to the program (i.e., not conducting study procedures). To assist with recruitment, community navigators will present to CBES in-person to distribute IRB approved study fliers. Our community navigators will also e-mail the CBES listserv using an email script. At no point will we cold call any prospective participants. Instead, participants will call our team to indicate interest based on the flyer.

Prospective participants will complete screening and full consent procedures either in-person at CBES via written consent or remotely via eConsent. The primary RA will perform the screening of prospective open pilot participants. She will inform participants that their participation is voluntary, they can refuse to answer any questions, and they can withdraw from the study at any time. The screening form includes a statement about the preference for correspondence over secure vs. unencrypted email, details about the risks using unencrypted email, and a place for the participant to state their preference. Capacity to provide consent will be assessed via the Telephone Interview for Cognitive Status scale. To ensure any cognitive impairment is mild in severity, participants may only provide consent if they score greater than or equal to 17 on the Telephone Interview for Cognitive Status scale.

For in-person screening and full written consent (whenever allowed according to MGH and CDC guidelines), the screening will be conducted face-to-face, and participants will be handed a hard copy of the consent form. If preferred by the participant, the RA will verbally review the study consent form and provide further instructions for signing if the participant expresses confusion. Following completion of consent, the RA who obtained consent will countersign and the participant will receive a hard copy of the completed consent form as well as their first set of surveys.

Remote screening will be through REDCap eConsent. First, each eConsent form will be set up and sent to prospective participants. The participant will then independently review the eConsent form on their own time and have the opportunity to address any study-related questions or concerns with an RA prior to signing. If preferred by the participant, the RA will verbally review the study eConsent form over the phone and provide further instructions for digitally signing eConsent if the participant expresses confusion. Following completion of eConsent, the RA who obtained eConsent will countersign and the participant will receive the completed eConsent in their inbox.

After participants provide either written consent or eConsent, the RA will collect demographic information using REDCap determine which open pilot dates work best for the participant, , email participants a packet with study program materials, and send participants their first set of surveys. The RA will keep track of the number of participants who agree to participate and who participated from those available. I will

review these numbers weekly. The MGH IRB will review and approve all study procedures.

6. STUDY PROCEDURES

Following enrollment, we will train a Black lay individual on how to deliver *Feeling of Being* using our preliminary *Feeling of Being* manualized protocol. Training will follow Dr. Ana-Maria Vranceanu's protocol currently used in an NIH funded multi-site feasibility study (R01AT010462). Training will be completed in-person over the course of 1 week. Trainings will include presentations on (1) the rationale of the program including the fear avoidance model and the CP-ECD co-morbidity (2 1-hour long presentations); (2) *Feeling of Being* goals, potential challenges and strategies to problem solve them, and modeling process factors (e.g., engagement; 2 1- hour sessions) and (3) role-play scenarios that ensure fidelity to intervention.

To assess training fidelity: (a) *Feeling of Being* as delivered by a lay instructor will be video-recorded and rated by me on training fidelity forms; (b) the lay instructor will complete post-training surveys assessing their quantitative knowledge about the program; (c) the lay instructor's adherence and competence in conducting mock intervention sessions will be evaluated on standardized rating scales to establish training fidelity prior to delivery to participants. Additional trainings will be delivered, as needed, until our a priori benchmarks are met. The lay instructor will provide qualitative feedback on any recommended modifications to training procedures that they perceive would improve the training process in preparation for a future pilot RCT and efficacy RCT. Lay instructors will have to meet the following benchmarks for training fidelity: (1) an instructor score ≥8 on training adherence and competency of video-recorded training sessions and mock group sessions (1=poor, 10=outstanding); (2) instructor score ≥80% on post-training knowledge/competency testing.

After the instructor passes all the competencies, the instructor, as part of an open pilot, will lead *Feeling of Being* among 8 older Black individuals with CP and ECD at the CBES conference room. Open pilot sessions will be audio-recorded and reviewed weekly by me for adherence and competence using structured rating scales. Feedback will be provided in weekly supervision. Attendance and home practice will also be tracked. Participants who miss a session will be offered make-up sessions. Instructor fidelity to *Feeling of Being* delivery during the open pilot will again be determined using the aforementioned benchmarks. If drift or deficiencies are noted in the instructor, we will re-train them via "booster sessions" as needed.

At baseline, post-test (i.e., after completing the 8-week program), and 3-month follow-up, participants will complete a reliable and valid battery of questionnaires online via the secure REDCap system. At baseline, we will survey participants for their demographic background (i.e., age, gender, biological sex, religion, race, ethnicity, education, income, marital status) and past/current medical history (i.e., medical diagnoses, treatments, substance use). This demographic data will better characterize the sample and provide valuable information towards a pilot RCT and efficacy trial using the R01 mechanism. At baseline, post-test, and 3-month follow-up, participants will also be surveyed about their

pain (Numerical Rating Scale), physical function (PROMIS Physical Function), cognitive function (Everyday Cognition Scale, Montreal Cognitive Assessment), emotional function (PROMIS Anxiety, PROMIS Depression, PROMIS Emotional Support), adaptive coping, and mindfulness (Measure of Current Status Part A, Cognitive and affective mindfulness scale-revised, Chronic Pain Acceptance Questionnaire, Pain Self-Efficacy Questionnaire, Pain Catastrophizing Scale, Tampa Kinesiophobia Scale). Intervention acceptability will be assessed using individual exit interviews and questionnaires (The Credibility and Expectancy Questionnaire, The Client Satisfaction Questionnaire, Modified Patient Global Impression of Change).

Participants will be compensated $315 for participation in the study. Participants will be made aware of this in the study flyer and during the screening and consent process.

7. Risks and Discomforts

It is unlikely that participants will incur any risk for physical harm from study participation. It is possible that participants will find some topics and questions to be emotionally upsetting, or that they may experience some psychological discomfort while discussing their experiences during the open pilot. I am excluding patients who endorse acute, cancerous, or non-musculoskeletal pain, suicidality, or who have untreated psychosis or substance dependence disorder given that would require a higher level of specialized care.

In the case that any patient or participant endorses active suicidality while screening (or throughout the course of the study), the trained research assistant will immediately contact the Principle Investigator, who will conduct a formal risk assessment. If the participant is assessed to be at acute risk for self-harm or harm to others, the participant will be referred to a higher level of care, including going to the nearest emergency room. A similar procedure will be followed if the participant scores ≥ 30 on the PROMIS Depression scale, if the participant scores <17 on the Telephone Interview for Cognitive Status scale, or if active suicidal ideation is raised during screening, the intervention, or at any other point of contact with the participant. Safety will always be prioritized over study participation. Participants who score ≥ 30 on the PROMIS Depression scale, score <17 on the Telephone Interview for Cognitive Status scale, or endorse active suicidality will not be permitted to remain in the study even while seeking evidence-based treatment for worsening depression/suicidal ideation.

Patients are not obligated to answer any screening or exit interview questions that are uncomfortable
with. Participation in this study will not affect the medical care within the Partners network or any other

healthcare network. Patients can withdraw from the study at any time without consequences. In the
extremely unlikely event that a patient has a severe adverse emotional disturbance while completing
screening or any other study procedure, the trained RA will immediately contact the Principal
Investigator to conduct a thorough risk assessment as soon as possible

Collecting identifiable information carries the risk of loss of confidentiality. However, we will take numerous steps to minimize this risk. Study data will be maintained in a locked filing cabinet and on password protected computers on Partners encrypted Storage Fusion Architectures (SFA). Interviews and questionnaire data will not become part of the patient's medical record and will not contain medical record numbers or names. Hardcopies of study related data and forms will be stored in a lockable file cabinet. Patient information will remain confidential by keeping identifying information (name, medical record number, and subject number) in a separate locked file cabinet. Only the investigators and study staff specified on the consent form will have access to this information. Prior to the audio-recorded interview, participants will be instated not to share identifiable information, and if they do, it will be omitted by study staff in the transcription process.

8. Benefits

There are no direct benefits for participation. However, open pilot participants may benefit from knowing that their participation may help improve care for other older Black community members with chronic pain and co-occurring depression.

9. Statistical Analysis

We will analyze qualitative data derived from exit interviews using a hybrid deductive–inductive approach[91] with the socio-ecological and fear avoidance frameworks informing the structure of the coding framework and the data itself informing the codes. A trained research assistant (RA) and I will meet weekly with Dr. Vranceanu to discuss the thematic framework, categories, and coding plan. We will share the data with our community advisory board and the rest of the mentoring and advisory team to get their input with data interpretation. We will carry out all qualitative analysis using the QualCoder software (Version 2.9). We will analyze quantitative data using "R" (version 4.2.0). We will calculate descriptive statistics comparing pre-, post-, and 3 months post-intervention scores on the standardized outcome instruments. For mixed methods analysis, I will use an Integrative Exploratory Design.[111] This approach is flexible and allows for the integration of qualitative and quantitative data across multiple timepoints, although of note, this open pilot is primarily focused on feasibility and acceptability and not statistical significance or efficacy.[111] Frequency and proportions will be used to assess

feasibility of recruitment and retention procedures. We will not be counting participants who drop out as meeting applicable feasibility criteria. If the proposed benchmarks are not met, revisions will be necessary.

The proposed benchmarks were previously used in NCCIH funded studies by the primary mentor (e.g., #3R34AT009356) and are consistent with guidelines for intervention development.[112] The proposed protocol for fidelity to treatment follows NIH recommendations,[113] co-mentor Joo's training protocol for the *PEERS* Program, and primary mentor Vranceanu's clinical adherence protocol for *GetActive.*[35,37,37,38]

10. Monitoring and Quality Assurance

Sources of material for this study will include participant qualitative interviews and survey questionnaires before and after the open pilot. The PI will monitor the validity of the data and adherence to the IRB approved protocol on a daily basis. A member of study staff will verify that all items on all questionnaires have been addressed. All study staff will complete required Partners human subjects trainings prior to the start of study procedures.

Participant Confidentiality. The PI will obtain all materials strictly for research purposes. Data from individuals deemed ineligible will be immediately shredded, and only study staff will have access to the data. Participants' data will be identified by an ID number only, and a link between names and ID numbers will be kept separately under lock and key. Interviews will not become part of the patient's medical record and will not contain medical record numbers or names.

Data Validity and Security. Recordings will be immediately deleted from the recording device and stored under password protection. All study forms will be stored in locked storage spaces, to which only study staff will have access and electronic forms stored on an encrypted Partners SFA. All interventionists and assessors will have advanced training in clinical interviewing and assessment. Participants will be informed that they may refuse to answer questions that make them feel uncomfortable or they do not wish to answer.

Study data will be maintained in a locked filing cabinet and on password protected computers. Hardcopies of study related data and forms will be stored in a lockable file cabinet. Patient information will remain confidential by keeping identifying information (name, medical record number, and subject number) in a separate locked file cabinet. Only the investigators and study staff specified on the consent form will have access to this information. Data from this study will be stored for three years after the publication of all study results, at which time all paper screening and consent forms will be shredded, and computer files will be deleted.

To maximize accuracy and security, all survey data will be collected and stored on REDCap. Research staff will ensure that proper consent has been obtained before sending the REDCap survey to each participant. REDCap (Research Electronic Data Capture) is a free, secure, HIPAA compliant web-based application hosted by the Partners HealthCare Research Computing Enterprise Research Infrastructure & Services (ERIS) group. Vanderbilt University, with collaboration from a consortium of academic and non-profit institutional partners, has developed this software toolset and workflow methodology for electronic collection and management of research and clinical study data. Data collection projects rely on a study-specific data dictionary defined by members of the research team with planning assistance from Harvard Catalyst, The Harvard Clinical and Translational Science Center EDC Support Staff. This iterative development and testing process results in a well-planned data collection strategy for individual studies. Using REDCap, the research team can also design web-based surveys and engage potential respondents using a variety of notification methods. REDCap provides flexible features that can be used for a variety of research projects and provides an intuitive interface to enter data with real time validation (automated data type and range checks). The system offers easy data manipulation with audit trails, reports for monitoring and querying participant records, and an automated export mechanism to common statistical packages (SPSS, SAS, Stata, R/S-Plus).

Safety Monitoring. Risks to participants are minimal. the PI will discuss with Drs. Vranceanu and Jackson strategies to ensure the safety the participants. Additionally, all participants will provide contact information (phone number and email) for at least 1 friend or family member that we can contact in case of emergency. In the unlikely event that a participant will be at risk for self-harm or actively suicidal, the PI, under the supervision of the Dr. Vranceanu, will contact the participant and/or the friend or family member depicted as a safety contact to conduct a safety assessment (assessment, referral, emergency room visit, as needed). Safety will always be prioritized over study participation.

All study staff have been trained in responsible research conduct through a Collaborative Institutional Training Initiative (CITI) course. In addition, the study RA will be trained during onboarding procedures on the importance of maintaining confidentiality through the assignment of ID numbers. All data will be kept confidential, under lock-and-key, accessible only to trained study staff. Participants' data will be identified by ID number only, and a link between names and ID numbers will be kept separately. Interview recordings will be immediately downloaded from the recording device to the secure computer and subsequently deleted from the recording device. Recordings will be labeled with the participants' ID and will be password protected.

Throughout the study subjects will be monitored for the occurrence of events defined as any undesirable experience or unanticipated risk. Lack of effect of treatment is not considered an event. If the PI or a member of his research team identifies an adverse event (e.g., via study participants, research team members), they will follow the steps below:

Serious Adverse Events. Any event that meets the Food and Drug Administration (FDA) definition of a serious adverse event or that is deemed by the PI or team to impose significant hazard, contraindication, side effect, precaution, will be reported to IRB within 24 hours; and to NCCIH (including responses of the IRB) within 7 days. Under this categorization, (1) spontaneous expression of suicidal ideation and (2) answers of 1, 2, or 3 on Question 9 of the PHQ-9 will result in will result in emergent evaluation by a licensed clinician member of study staff (Dr. Pham, licensed psychiatrist) for appropriate assessment and triage.

Non-Serious Adverse Events. At the end of the year, the IRB and NCCIH will receive a summary of adverse events, including number and types of events, severity, time point, and determination of whether the events were study related.

Other Safety-Related Reports. At the end of the year, the IRB and NICCH will receive an un-blinded report of study retention and reasons for nonparticipation.

Study Stopping Rules. No stopping rules exist for phase 1 activities, which involve a single interview per dyad and the completion of survey assessments.

All adverse events will be reported on an adverse event form. The Principle Investigator has the responsibility of reporting serious adverse events (death, life threatening illness or injury, serious injury, or permanent disability) to PHRC within 24-72 hours of notification.

11. Data and Research Material Sharing

Screening results, consent forms, survey responses, exit interview data, and analyses will be sent among investigators and study staff only. To maintain confidentiality, patients will be identified using a specific ID. Only the RA and study clinicians will have access to the file connecting patients' names and study Ids. All data and materials will not be linked back to individual participants such that the investigators could re-identify participants. The recipient of the data and materials will not be able to use a link to re-identify participants. Data and materials will only be sent using encrypted email and stored on password protected computers on Partners encrypted Storage Fusion Architectures (SFA). Data and materials will not be stored at collaborating sites outside Mass General Brigham for future use. All participants have the right to withdraw their

data/materials by contacting the study team. This will be explained during the consent process.

A) Receiving Data/Materials from Research Collaborators outside Mass General Brigham

Data and materials will not be received by research collaborators outside Mass General Brigham.

B) Sending Data/Materials to Research Collaborators outside Mass General Brigham

Data and materials will not be sent to research collaborators outside Mass General Brigham.

12. Privacy and Confidentiality

- ☒ Study procedures will be conducted in a private setting.
- ☒ Only data and/or specimens necessary for the conduct of the study will be collected.
- ☒ Data collected (paper and/or electronic) will be maintained in a secure location with appropriate protections such as password protection, encryption, physical security measures (locked files/areas)
- ☐ Specimens collected will be maintained in a secure location with appropriate protections (e.g. locked storage spaces, laboratory areas)
- ☒ Data and specimens will only be shared with individuals who are members of the IRB-approved research team or approved for sharing as described in this IRB protocol.
- ☒ Data and/or specimens requiring transportation from one location or electronic space to another will be transported only in a secure manner (e.g. encrypted files, password protection, using chain-of-custody procedures, etc.)
- ☒ All electronic communication with participants will comply with Mass General Brigham secure communication policies.
- ☒ Identifiers will be coded or removed as soon as feasible and access to files linking identifiers with coded data or specimens will be limited to the minimal necessary members of the research team required to conduct the research.
- ☒ All staff are trained on and will follow the Mass General Brigham policies and procedures for maintaining appropriate confidentiality of research data and specimens.
- ☒ The PI will ensure that all staff implement and follow any Research Information Service Office (RISO) requirements for this research.
- ☒ Additional privacy and/or confidentiality protections

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APPENDIX A

Data Monitoring Committee / Data and Safety Monitoring Board Appendix

- *To be completed for studies monitored by Data Monitoring Committee (DMC) or Data and Safety Monitoring Board (DSMB) if a full DMC/DSMB charter is not available at the time of initial IRB review.*

- *DMC/DSMB Charter and/or Roster can be submitted to the IRB later via Amendment, though these are not required* if this Appendix has been completed and approved by the IRB.

A Data Monitoring Committee (DMC) or Data and Safety Monitoring Board (DSMB) will be convened for safety monitoring of this research study. The following characteristics describe the DMC/DSMB convened for this study (Check all that apply):

☐ The DMC/DSMB is independent from the study team and study sponsor.

☐ A process has been implemented to ensure absence of conflicts of interest by DMC/DSMB members.

☐ The DMC/DSMB has the authority to intervene on study progress in the event of safety concerns, e.g., to suspend or terminate a study if new safety concerns have been identified or need to be investigated.

☐ Describe number and types of (i.e., qualifications of) members:
Click or tap here to enter text.

☐ Describe planned frequency of meetings:
Click or tap here to enter text.

☐ DMC/DSMB reports with no findings (i.e., "continue without modifications") will be submitted to the IRB at the time of Continuing Review.

☐ DMC/DSMB reports with findings/modifications required will be submitted promptly (within 5 business days/7 calendar days of becoming aware) to the IRB as an Other Event.