Mass General Brigham

Official Title: Addressing the Epidemic of Chronic Pain Among Older Adults in Underserved Communities; The GetActive+ Study

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Institutional Review Board
Intervention/Interaction Detailed Protocol

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1. Background and Significance

Chronic musculoskeletal pain among older adults is prevalent and costly.

Chronic musculoskeletal pain (pain >3 months)[1] is common among older adults, with an estimated 60%–75% of older adults reporting at least some persistent pain[2]. The incidence of chronic pain among older adults is expected to increase given the exponential growth in the older adult population over the next three decades and accompanying comorbidities[3]. Estimated US health care costs of chronic pain range from $261-300 billion, far exceeding the cost of diabetes, hypertension, heart disease, cancer, and other common chronic conditions[4]. Among older adults, chronic pain leads to a significant decline in physical and emotional function with substantial disability from reduced mobility, avoidance of activity, falls, depression, anxiety, sleep impairment, and social isolation[5–8]. Sedentarism, lack of engagement in activities of daily living, and impairments in balance and gait[9] are common in older adults with chronic pain and further increase risk for morbidity and mortality.

Older adults from underserved communities are at the highest risks for negative outcomes due to chronic pain.

Older adults from underserved communities have disadvantaged backgrounds, low income, poor education, and tend to be racial and ethnic minorities and immigrants. Chronic pain is often poorly recognized, underestimated, and inadequately managed among these older adults. Disparities in chronic pain management are multidimensional, including gaps in patient/health care provider communication, variability in decision making, and gaps in access to effective treatment[10,11]. Discrimination, systemic racism, stigma, social marginalization, lower education, and Medicaid insurance status are all associated with higher reports of pain intensity, higher psychological distress and disability among older adults with chronic pain.

Management of chronic pain among older adults is inadequate, particularly for older adults from underserved communities.

For older adults, pain medications including opioid analgesics have limited efficacy[12,13], increase risk for adverse events such as falls[14], and can lead to confusion and cognitive decline[15]. Nonpharmacological treatments for chronic pain such as Cognitive Behavioral Therapy (CBT) or Mindfulness Based Interventions (MBIs) are safe for older adults and can improve pain outcomes including physical, and emotional function[16,17]. However, treatment effects are small, decrease over time, and access to timely treatment is scarce[18]. A recent systematic review published in JAMA highlighted the need for novel nonpharmacological treatments for chronic pain in older adults that can produce stronger and sustained effects[18].

Access to nonpharmacologic therapies is limited for many older adults from disadvantaged populations because therapies are not affordable, not recommended by providers, or not available in their community[19-22]. For example, a recent study of specialty pain clinics found that close to half did not accept Medicaid and did not offer psychosocial treatment options[23]. Our qualitative work also suggests that older adults with chronic pain are experiencing significant unrelieved pain and cannot easily access psychosocial interventions in their communities to better manage it[24].

Group Visits (aka Shared Medical Appointments) may be a viable model to overcome many barriers experienced by older, underserved adults to high-quality chronic pain management[25,26].

Group medical visits seek to improve patient health through a blend of medical care, education, and peer support[27]. Previous research on group visits, which has included underserved community health centers[28] and older adults[29], has demonstrated the feasibility, acceptability, and health benefits of group visits for patients with diabetes[30], cancer[31], and headaches[32]. Group visits for older adults with chronic pain have substantial potential to overcome the challenges of patient stigma and insufficient clinician skills by: 1) creating a supportive community of patients who navigate pain together in a supportive clinical setting familiar to them with easy access to their clinical team; 2) providing evidence-based nonpharmacological pain treatment delivered by trained clinic staff; 3) efficiently integrating pain management into the routine flow of primary care; and 4) being financially feasible, scalable, and sustainable within primary care settings, as group medical visits can be reimbursed by Medicare, Medicaid and third party payers [33].

The GetActive program is an evidence-based intervention developed by our team that is feasible and produces sustained moderate to large improvements in pain outcomes.

GetActive[34,35] was developed by our interdisciplinary team using the fear avoidance theoretical model (development and maintenance of pain occurs due to perception of pain as a threat and subsequent avoidance of activity)[36], and guidelines from the International Classification of Functioning, Disability and Health (ICF)[37] and the Initiative on Methods, Measurement and Pain Assessment in Clinical Trials (IMMPACT)[38]. GetActive combines "top down" CBT and MBI skills with walking, a "bottom up", safe and preferred activity for older adults[39]. GetActive directly targets improvement in all aspects of physical function delineated by IMMPACT[38]: 1) self-report; 2) performance based/exercise capacity; and 3) objective (step-count). GetActive teaches: (1) *walking skills* based on behavioral/operant principles (e.g., how to gradually increase step-count by setting SMART (specific, measurable, attainable, realistic, time bound) goals; how to pair increases in walking with engagement in activities of daily living that are meaningful and valued;

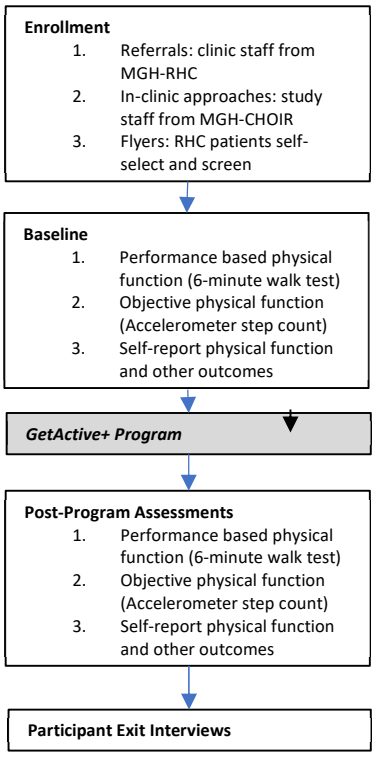
how to apply pacing to safely break the connection between pain and activity; (2) *mind–body skills* to change one's relationship with pain (e.g., reduce reactivity, fear, ruminative self-talk -through relaxation response and mindfulness exercises) and to facilitate walking; (3) *pain, behavior awareness skills* to understand the disability spiral (e.g., how lack of activity perpetuates chronic pain and emotional and physical disfunction); and (4) *positive psychology skills* to engage social support for walking; manage negative reactions from others and cope with stress or walking setbacks (positivity, self-compassion, and gratitude).

The GetActive program can be tailored for the unique needs of disadvantaged, older adults and for routine integration in primary care clinics in underserved communities, as part of Group Medical Visits, with high potential for sustainability and scalability.

While group visits for chronic pain have been initiated[40,41], they have not been developed specifically for older adults, and have not been rigorously tested in older adults or incorporated into routine care for older, disadvantaged adults. Community health centers (CHC) provide primary care for over 24 million patients in the United States, often in medically underserved and lower-income urban and rural communities[42]. Because of the diversity of older patients seen by CHCs, they offer a unique and compelling opportunity to provide high quality psychosocial interventions for chronic pain and improve overall access to chronic pain management.

We partnered with the MGH-Revere HealthCare Center (RHC), which serves a diverse, underserved community, to integrate *GetActive+* into the group visit workflow of their practice to fit the need of their older patients, clinic staff and administration. RHC has a longstanding history of group visits for diabetes and obesity delivered by trained NPs, and will provide an optimal setting, infrastructure, and context for integrating *GetActive+* into a group visit framework. By developing, implementing, and evaluating this integrated model of *GetActive+* at RHC, we will set the stage for our long-term goal to implement and disseminate *GetActive+* in other community health centers in MA and nationally.

Figure 2. Aim 2 Study Schema



*Total number of patient participants (up to N=50)

2. Specific Aims and Objectives

Conduct an open pilot trial (i.e., Aim 2 of P# 2022P001691) of the *GetActive+* program (i.e., a novel mind-body and activity program) followed by optional qualitative exit interviews with RHC patients (up to N=50). We will determine if the feasibility, acceptability, and fidelity of the program meet *a priori* benchmarks. We also hope to establish preliminary efficacy that the program improves physical function and other study outcomes we describe in sections below. We will use qualitative data to optimize the intervention and study procedures for future trials. See Figure 2 for aim 2 study schema.

3. General Description of Study Design

We will conduct an open pilot trial of the *GetActive*+ program followed by individual qualitative exit interviews. We plan to conduct 3-6 groups of approximately 5-10 participants each (up to N=50). At least one of the 3-6 groups will be offered in Spanish and led by a fully trained Spanish speaking social worker and member of study staff. The goal of this phase will be to establish feasibility (primary), acceptability, and fidelity of the *GetActive*+ program and study procedures. We will also explore improvements in study outcomes. We will recruit English and Spanish speaking older adults (55+) with chronic pain currently receiving medical care from RHC. Recruitment will be facilitated through posted IRB approved flyers, in-clinic approaches made by study staff, and referrals from RHC physicians, nurses, psychologists and other relevant staff (see section 4). These recruitment strategies are informed by recommendations from RHC staff and are supported by [redacted] If patients indicate interest in participating, they will be guided through eligibility screening by study staff (see section 4). After screening, interested patients will discuss their availability for a baseline visit and the 10-week *GetActive*+ program. A Research Assistant (RA) will keep track of potential participant preferences with regard to the days and times for intervention delivery and in person versus remote participation. The number of participants per group will vary based on availability, while typically ranging between 3 and 10. At the subsequent in person baseline assessment, patients will provide their informed consent in the presence of study staff and complete all assessments. They will also pick up their ActiGraph watch to wear for 7-10 days (see section 6). They will later return their ActiGraph either in person or in the mail via pre-paid envelop. These same procedures will be followed for Spanish speaking patients. All Spanish speaking patient interactions will be conducted by a native Spanish speaking RA. Additionally, all study materials have either already been translated and validated or will be translated into Spanish by a translation service or a native Spanish-speaking researcher.

The 10-week *GetActive*+ program will be conducted either in-person or via Zoom and led by a fully trained member of study staff. Spanish speaking groups will follow the same structure and will be led by a fully trained native Spanish speaking member of study staff. In the event that group sessions are conducted virtually, we will use an MGB Zoom account. Zoom specifically states that their software is equipped to keep information secure, and the software does not have access to identifiable information. Zoom is HIPPA compliant, MGB approved, and the current video software standard for patient care within our Department of Psychiatry. Participants will be encouraged to attend as many group sessions as possible and complete their home practice assignments between sessions. Participants who can't attend the group sessions will be offered make-up sessions. Throughout these ten weeks, the RA will send participants daily reminders via text message to practice program skills, log home practice, and attend the sessions (contingent on their consent to receive such text messages). These text messages will be sent using Twilio, which will be integrated with our REDCap database. Participants will have the option to attend a 5-10 minute 1-on-1 medical check-in with the nurse practitioner before or after each group session. Within 3 days after the last group session, participants will complete the in person post-program assessments and pick up their ActiGraph to wear for the next 7-10 days (see section 6). They will return the ActiGraph in person or via a pre-paid envelope.

4. Subject Selection

Recruitment for potential open pilot participants (i.e., RHC patients) will be facilitated through 1) IRB approved flyers, 2) RHC provider referrals, and 3) in-clinic approaches made by study staff (see bullet points below).

1. IRB Approved Flyers: Patients who find the flyer will be able to indicate their interest and provide their contact information by accessing the REDCap link provided on the flyer. Study staff will then follow up over the phone with the patients to discuss the study in more detail and schedule an in-person screening visit. Alternatively, patients may have the option to complete screening over the phone with the RA.
2. IRB Approved Rally Post: Patients who find our study via Rally will be able to indicate their interest on the platform. An RA will follow up with all inquiries over the phone. Once contact has been made, the RA will discuss the study with interested participants and either schedule an in-person screening visit or conduct screening virtually over the phone.
3. RHC Provider Referrals: Patients who receive referrals for the study from their provider or medical interpreter will either self-screen via the link provided on the flyer, be guided through screening at RHC by study staff or be contacted directly via phone call by study staff. Only patients who give their medical provider verbal consent to be called by study staff will be contacted. It will be clearly communicated to medical providers at RHC that they should confirm with their patients that they would like to be contacted by study staff prior to giving referrals. In all cases a baseline in person visit will be conducted with those participants who screen in.
4. In-Clinic Approaches by Study Staff: An RA will facilitate patient recruitment via in-clinic approaches. These approaches will ideally be informed through precursory eligibility assessments made by the RA based on the patient's medical record. If time restrictions do not allow for precursory eligibility assessments, the RA will consult RHC staff regarding their patient recommendations. The trained RA will then approach the patient and ask if they can introduce the study and answer any related questions. If patients indicate they are interested in participating, they will be guided through eligibility screening with the RA in person at RHC, or later on over the phone if the participant expresses interest but cannot be screened at that time. A baseline visit will be conducted in person.

At the conclusion of all screenings, the RA will gather patient availability for the in-person baseline assessment and the 10-week *GetActive+* program and email, mail or hand a copy of the informed consent form to participants. This will allow potential participants ample time to review the consent form prior to the baseline visit. All patients will be instructed not to sign it until they undergo formal consent at the in person visit. The recruitment strategies described above are informed by recommendations from RHC staff and are supported by [redacted]. Patients who choose to provide their consent will do so electronically (i.e., eConsent) in the presence of the research assistant to ensure that all questions or concerns associated with participation are answered. Consent will be collected via REDCap, a validated password-protected signature platform approved by MGB. They will receive a signed paper or digital copy of the informed consent form. All participants will be notified that their participation in the following open pilot is voluntary and that they are able to withdraw at any time. All study

participants who are deemed not eligible after screening will be offered a chronic pain resource sheet to provide them with additional pain management resources (email or paper copy). Recruitment procedures for Spanish speaking patients will be identical. All screening for Spanish-speaking patients will be completed with a native Spanish speaking RA. The described methodology has been used successfully by Dr. Vranceanu in other behavioral health studies (P#: 2021P002811; P#: 2020P000095). Per MGB policies on email communication, we will be using secure email to communicate with participants. This will be done using the "SEND SECURE" encryption function. To further protect participants' confidentiality, we will discourage participants from communicating with study staff by non-secure email.

After all group sessions and study assessments have finished, we will create a recruitment video that contains clips of participants speaking briefly to their experience in our groups. Submitting video clips for this recruitment project will be entirely optional, and participants will be informed that the final video will be included in promotional materials for the study. The names or any identifying information for the participants in the video will not be released. All participants will be given the opportunity to contribute a clip to the recruitment video. Participants will be shown their contribution to the video and required to provide written permission by email or paper for the video to be used for recruitment purposes, as described above. We have used this methodology successfully in prior studies (Protocol #2017P000143 and #2022P001766) for creation of a recruitment video, and we found it to work very well with no issue. Participants will also be given the option to submit a group photo for recruitment purposes. All individuals in the photo will also sign the photo release consent form.

Inclusion Criteria:

1. Older Adults (i.e., age >=55, since aging is accelerated by impoverished lifestyles[43])
2. Has diagnosed musculoskeletal chronic pain of any type (e.g., pain duration > 3 months)
3. Pain score >=4 (moderate) on the Numerical Rating Scale
4. Cognitively able to participate as measured by the Short Portable Mental Health questionnaires (e.g., <4 errors)
5. No self-reported current active, untreated psychotic or substance use disorder that would interfere with participation in the research study
6. Self-reported ability to complete the 6-minute walk test
7. Patient at RHC who is cleared for participation by medical staff
8. English or Spanish fluency.

Exclusion Criteria:

1. Current serious medical illness that is expected to worsen in the next 6 months (e.g., cancer)
2. Individuals who are unwilling or unable to wear the ActiGraph device

5. Subject Enrollment

Potential participants will be informed about the study through one of the methods described above (e.g., flyer, provider-including medical interpreters-referral, or via research assistant in the clinic). Participants will complete eligibility screening following any one of the procedures described in section 4. Only after having ample time to review the consent form will the RA

officially guide patients through written informed consent to take part in the research study. Patients who choose to provide their consent will do so electronically (i.e., REDCap eConsent) in the presence of the RA to ensure that all questions or concerns associated with participation are answered. The RA will track participants' preferences with regard to the days and times for intervention delivery and in-person versus Zoom participation. The number of people per group will vary based on participant availability with an expected range between 3 and 10 participants. Once a group is formed and no more than 2 weeks before the first group visit, the RA will schedule an in person visit to conduct informed consent and baseline assessments (see section 6). At this visit patients will receive an ActiGraph watch to wear for 7-10 days, and instructions on how to wear it.

All participants must be capable of understanding the nature of this study as well as the risks and potential benefits. All potential participants will have ample time and opportunity to ask questions or clarify concerns in person (if screened with research assistant) or over email or phone (if screened remotely over REDCap).

All stages of the study will be detailed, including the risks and benefits of the study. No information will be withheld from prospective or active participants regarding the study design. The participant will be reminded that they may decline to participate in this study, and they may discontinue study participation at any time. In this case, a participant will be asked their reason(s) for discontinuation, which may provide valuable feedback for improving future recruitment, retention, or study procedures.

6. STUDY PROCEDURES

Once group times have been set, the RA will meet with participants individually over the phone to schedule a visit to review and sign informed consent, answer any remaining questions, complete the baseline assessments, and distribute program manuals. The RA will supervise the participants as they complete all baseline assessments, providing assistance when needed. Additionally, these participants will receive the program manual and an ActiGraph device to wear for the next 7-10 days with instructions on how to use it. Only participants who have consented and enrolled in the study will complete the baseline assessment. Assessments include sociodemographic surveys (e.g., age, race, ethnicity, etc.), clinical information surveys (pain diagnoses, duration, concurrent medical and psychological treatment, narcotic intake), self-report psychosocial measures (physical function, cognitive function, pain intensity, depression, anxiety, coping, pain catastrophizing, mindfulness, fear of pain, gratitude, compassion), and performance based physical function measurements (e.g., 6-minute walk test) and objective physical function, (activity level over 7-day period via ActiGraph). See Table 2 for a full list of study measures. Following the completion of the baseline questionnaires, participants will be provided with and directed to wear an ActiGraph watch which will measure their activity over the next 7-days. After 7-days of valid wear time, participants will return their ActiGraph in their first group session (for in person visits) or mail it in a pre-paid envelope (for zoom visits). Additionally, prior to their first session, all participants will receive a program manual and access to a web platform to support skill practice.

Table 2. Aim 2 Open Pilot Measures	
Domain	**Measurement Tool and Schedule**
Demographic	**Age/birth date; gender; biological sex; race/ethnicity; education level; employment status; marital status; household income; disability status; language fluency; people and/or children in the household; RUCA code (i.e., zip code); country of birth; country lived in prior to age 12; years lived in the US, parents' countries of origin; ethnic identity; languages spoken at home; assessment of English fluency. Pre**
Clinical	**Type of pain; pain location and number; pain treatments; pain medications; cannabis use for pain; medical comorbidities; mental health conditions and medications. Pre and post, when applicable (chart review and self-report: pain, medication, and medical history questionnaire)** **Tobacco, Alcohol, Prescription medications, and other Substance (TAPS)**[44]; assess substance use behaviors. **Pre, post**
Other	**The Everyday Discrimination Scale – Short (EDS-S)**[45]; assesses experiences of daily discrimination against minority populations. **Pre, post** **PROMIS Sleep Disturbance – Short Form 6a v1.0**; assesses duration and quality of sleep. **Pre, post** **The Pittsburgh Sleep Quality Index (PSQI)**[5446]; assesses sleep quality. Using single item from this scale to assess sleep duration. **Pre, post** **Quota-based pacing questionnaire** – assesses ability to engage in meaningful activities and increase activity level gradually. **Weekly**
Multimodal physical function	**PROMIS Physical Function – Short Form 6b v2.0**; assesses one's ability to carry out activities that require physical actions, ranging from self-care to social and work. **Pre, post** **ActiGraph GT3X-BT**; watch with blank screen that assesses average step count. **Pre, post** **Six-minute walk test (6MWT)** – assesses distance walked in 6 minutes. **Pre, post**
Emotional function	**Generalized Anxiety Disorder – 7 (GAD)**[47]; 7-item measure of anxiety symptoms. **Pre, post** **Patient Health Questionnaire – 8 (PHQ)**[48]; 8-item measure of depressive symptoms. **Pre, post** **Perceived Stress Scale (PSS-4)**[49]; assesses stress perception levels. **Pre, post** **The Post-Traumatic Checklist – 6 (PCL-C)**[50]; assess current Post Traumatic Stress Disorder symptoms. **Pre, post**

	Contrast Avoidance Questionnaire – Shortened (CAQ-S)[51]; a measure of sustaining negative emotionality to protect against sudden shifts in emotion. **Pre, post**
Pain intensity	**Brief Pain Inventory (intensity and interference) – Short Form (BPI)**; measures pain at its "worst," "least," "average," and "now". **Pre, post** **Patient Global Impression of Change (PGIC)**[52, 53]; measures fluctuations in pain. **Post**
Nonadaptive pain reactions	**Pain Catastrophizing Scale (PCS)**[54]; assesses magnification, helplessness, and rumination about pain**. Pre, Post** **The Pain, Enjoyment of Life, and General Activity Scale (PEG)**[55]**;** brief measure of a participant's self-reported pain intensity and pain interference. **Pre, post** **Tampa Kinesiophobia Scale (TSK)**[56]; assesses fear of pain and activities that cause pain. **Pre, Post**
Loneliness	**UCLA-3 Loneliness Scale**; assesses loneliness in relational connectedness, social connectedness and self-perceived isolation dimensions. **Pre, post**
Social support	**Interpersonal Support Evaluation List (ISEL-12)**[57]; assesses perceived availability to potential social resources. **Pre, post**
Adaptive coping	**Self-Compassion Scale – Short Form (SCS-SF)**[58]; assesses participants' capacity for self-compassion. **Pre, post** **Gratitude Questionnaire (GQ-6)**[59] assesses individual differences in the proneness to experience gratitude in daily life. **Pre, post** **Applied Mindfulness Process Scale (AMPS)**[60]; assesses how participants' use mindfulness when facing challenges in daily life. **Pre**, **post** **Cognitive and Affective Mindfulness Scale – Revised (CAMS-R)**[61]; measures mindfulness and the degree to which respondents' experience thoughts and feelings. **Pre, post** **Measure of Current Status (MOCS)**[62]; assesses current self-perceived status on the ability to relax at will, recognize stress-inducing situations, restructure maladaptive thoughts, be assertive about needs, and choose appropriate coping responses as needed. **Pre, post**

The *GetActive+* program will be conducted either virtually or in person (depending on patients' preferences) by trained staff (psychologist or nurse practitioner, or both depending on availability) over the course of 10 weekly sessions. It is important that all eligible patients be able to participate should they choose to enroll. Thus, participants that wish to attend virtually but do not have the appropriate technology will be provided with a smart device, the type of which will be dependent on study funds and device availability. Prior to or directly after each session, participants will have the option to attend a 5-10 minute 1-on-1 medical check-in with the nurse practitioner. The purpose of these check-ins is to ensure that participants feel

physically safe and comfortable with the activity-based component of the program throughout the duration of their participation. Each of the 10 sessions will last approximately 60-minutes. Group sizes will be approximately 3-10 participants, however, this may be subject to change depending on the rate of attrition. Currently, we estimate approximately 20% attrition with the understanding that participant retention for this population might be less than what was observed in prior trials with *GetActive*. The interventionist will be trained by Dr. Vranceanu and Greenberg and supervised weekly.

The *GetActive* + program used in the open pilot, will incorporate mind-body skills, cognitive behavioral and physical restoration skills (e.g., quota-based pacing) to help individuals increase self-reported, performance based and objective (step count) physical function. This program will teach participants four core skills: 1) weekly goal setting for gradual increase in time spent walking paired with activities of daily living that are meaningful and important to participants (i.e. walk instead of drive to the store; walk to the park with kids) 2) quota-based pacing (increasing walking goal gradually non-contingent of pain); 3) mind-body skills (e.g., diaphragmatic breathing to manage intense pain flares and pain anxiety; body scan to increase body awareness and reduce reactivity to pain sensations; mindfulness exercises to understand the transience of pain and change one's relationship with it; self-compassion when falling short of set goals); and 4) understanding the disability spiral (e.g. how reducing activity perpetuates pain and disability), correcting myths about pain or automatic pain-related thoughts that interfere with meeting program goals. Throughout the 10-week program, participants will be encouraged to increase their time spent walking each week. As in prior mind-body and activity studies, the RA will determine a new walking goal weekly based on whether the open pilot participant met their walking goal in the prior week. Each week participants will increase their activity goal by 10%-20% if they met their prior goal, maintain the same goal if they did not meet it, or decrease the goal by 10%-20% if they did not meet their goal for 2 consecutive weeks. Any risks due to walking will be controlled and monitored by the clinician during the first 20 minutes of each session. The clinician will do so by discussing with each participant how walking went in the week prior, troubleshooting any barriers to walking safely, and coming up with an individualized walking plan for the coming week. Participants will have the opportunity to provide informal feedback on the manual and content throughout the study.

Participants will be encouraged to complete their homework (logs for mind-body practice, physical activities) each day. Participants will be given the option to receive homework and session reminders via text messages from study staff. This between-session contact will focus on increasing treatment adherence, maintaining engagement, and session reminders. Specifically, Twilio will be used to send session reminders, reminders to practice program skills, and for links to home practice surveys using a standardized protocol. Twilio is an MGH-approved smartphone app that participants will have the option to consent to using. Text messages will be sent once or twice a week for the duration of the study, for participants who expressed interest in receiving text messages. Participants may opt-out of text message reminders at any point. See Table 3 for details of each program session.

Table 3. Session Content for *GetActive*+

Session	Topic	Skills

Session 1	Live Well with Pain	Deep breathing
Session 2	Outsmarting the Pain	Catching unhelpful thoughts, quota-based pacing
Session 3	Becoming Away	Mindfulness, body scan
Session 4	Staying Engaged with your Life	Mindful walking, meaningful activities
Session 5	Working with Unhelpful Thoughts	Identifying and challenging Negative Automatic Thoughts (NATs)
Session 6	Staying in the Upward Spiral	Skill review
Session 7	Caring for Yourself When in Pain	Self-compassion, mindfulness of pain
Session 8	Feeling Connected with Others	Social connectedness, reducing loneliness
Session 9	Promoting Acceptance	Acceptance
Session 10	Staying on Track and Maintaining Your Progress	Maintenance skills

All participants will wear ActiGraph devices to monitor activity levels for 7-10 days after their baseline assessment and post-intervention assessment. Following the baseline assessment period, participants will return the ActiGraph device either in person at their first group session or mail the device back to study staff if they will be attending group sessions virtually. The post-intervention assessments will be scheduled to take place approximately 3 days after the last group session (e.g., Session 10). Participants will receive their ActiGraph device and wear it for the following 7-10 days. Participants will return their ActiGraphs via pre-paid envelopes provided by study staff. Participants will also be given the option to share contact information with the other group members following the post-program assessments. This is an optional procedure for those interested in staying in touch following group sessions.

Only trained study staff will have access to the data collected at baseline and post-program. Participants' data will be identified by an ID number only, and a link between names and ID numbers will be password-protected and kept separately. The information on the ActiGraph accounts will be password protected and only the study staff and patient will have access to that information. Training sessions will be audio-recorded and reviewed to ensure fidelity. All group sessions will be audio-recorded. Recordings will be used for weekly clinical supervision (e.g., problem solve challenging cases), and to assess study therapist's competency and fidelity to the content of each session. All study staff will have up to date Collaborative Institutional Training Initiative (CITI) certifications. All study procedures will be conducted using our published methodology.

Following the conclusion of the program, patients will have the option to participate in an exit interview. These interviews will be conducted utilizing procedures outlined by Krueger[63, 64] and guided by a semi-structured IRB approved interview guide. The goal of these interviews will be to understand the experiences of participants and garner feedback on the program. This feedback will eventually be used to further optimize the *GetActive+* program for use in future studies. Participants will be able to choose whether they would like to attend the exit interview in person

or remotely (i.e., over Zoom). In the event that exit interviews are conducted virtually, we will use an MGB Zoom account. Zoom specifically states that their software is equipped to keep information secure, and the software does not have access to identifiable information. Zoom is HIPPA compliant, MGB approved, and the current video software standard for patient care within our Department of Psychiatry. We will audio record the focus groups with consent from participants using MGB encrypted devices. We will transcribe recordings after each group and use these transcriptions to conduct qualitative analyses. No PHI will be included in the transcriptions. Outcomes will be used to guide subsequent manual adaptations and protocol, training, and fidelity procedures for the *GetActive+* program.

At the end of study enrollment (e.g., no longer recruiting/enrolling participants or conducting follow-ups with participants), we will conduct open-ended focus group or individual interviews with up to 20 participants who have completed the study. These group or individual interviews will be used to inform the future development of the program and to understand ways to better teach session content to increase understanding and engagement. Participants will be selected based on clinician perception on improvement and benefit and ability to engage in the material in a meaningful way. Interested participants will verbally consent after receiving a study fact sheet. Since we will be pulling from individuals who previously enrolled, we will only be re-consenting individual who choose to participate. We will contact participants via phone to gauge interest in participating, and the focus groups or individual interviews will be conducted in-person for up 60 minutes. We will be compensating participants an additional $40 for their participation.

Our primary outcomes for the open pilot will be the feasibility, acceptability, and fidelity of the *GetActive+* program. Preliminary effectiveness outcomes will also be examined (e.g., multimodal physical function (self-report, 6-minute walk test and activity level measured via ActiGraph) and emotional function (depression and anxiety).

Participants will be compensated $60 for completing the baseline visit and up to $100 for the 7–10-day baseline ActiGraph assessment (e.g., $10 per day up to 7-days; additional $30 for 7 days of complete and valid data). Participants will also receive up to $150 worth of travel compensation (e.g., if sessions are in person, $15 per session for 10 sessions). If participants attend group sessions virtually, they will not be subject to the compensation associated with transportation. To incentivize long-term engagement with the program, participants will receive a $50 bonus for attending at least 8 of the 10 sessions. Participants will also receive $100 for the completion of the post-program assessments and up to $155 for the post-program ActiGraph data collection period (e.g., $15 per day up to 7-days; additional $50 provided for 7 days of complete and valid data). In addition to all the above, participants will be given the opportunity to earn $40 for attending an in-person post-program exit interview ($25 for remote exit interviews). Select participants (based on randomization and interest) can also receive $40 for an additional focus group. Payments will be submitted and sent to participants following each major time point (i.e., baseline, final group session, and post-program exit interview). Overall, participants of the open pilot will earn up to $695.

All study procedures for Spanish speaking groups will be identical to English groups. Participant interactions will be in Spanish through a native Spanish speaking RA and group facilitator (i.e., a native Spanish-speaking social worker). Spanish speaking study staff will be fully trained in the

GetActive+ intervention and study procedures. All study materials are translated and spot check by a Spanish speaking RA.

7. Risks and Discomforts

Potential Risks & Protections Against Risks

We anticipate minimal risk to subjects due to their participation in this study; however, some risks are associated with conducting the study. Potential risks are: (a) loss of confidentiality and (b) potential feelings of distress while completing assessments or participating in the open pilot. Participants may find it inconvenient to participate in the open pilot. Additionally, participants may experience muscle soreness as they increase walking, and this will be discussed, as part of the program, as normal. Following a quota-based pacing regimen will also help minimize this risk because activity will be increased gradually. All participants will be cleared for participation by their medical doctor. There is no risk associated with wearing the ActiGraph other than possible inconvenience. Special attention will be paid to the fact that we are asking older adults to walk. We will ensure that we help identify appropriate spaces to walk, use the Buddy system when applicable (older adults walk with friends or family), and monitor any side effects (e.g., injuries, falls) (See section 6).

Loss of confidentiality

A potential risk is the loss of confidentiality. In order to protect confidentiality, data will be identified only by subject codes, with all identifying information removed. The identity of patients will not be revealed in the presentation or publication of any results from the project. All study personnel will be educated about the importance of strictly respecting patients' rights to confidentiality and will fulfill the required HIPAA training. This study will be conducted in compliance with HIPAA and IRB guidelines on privacy and confidentiality in order to strictly respect and safeguard participants' confidentiality. All identifying data will be stored in locked or password protected files only accessible by study staff. All research data will be identified only by subject codes and identifying information will be removed. The code key connecting IDs to identifying information will be kept in a separate, secure and password protected location. Data in databases will be similarly identified only by coded ID number and will be stored in password protected drives and devices. We have extensive experience in strictly respecting patients' rights and maintaining confidentiality and do not anticipate any breach of confidentiality occurring during the present proposal. Participants will be informed about these risks and told that they may withdraw from the study and have their data removed from the study database at any time.

Experiences of distress while completing assessments

Throughout the course of the open pilot, it is possible that participants experience distress during group visits and/or home practice. In the unlikely event that a participant is determined to be in distress or actively suicidal and at risk for self-harm during any study procedure study staff will intervene. We will use a standardized protocol for assessing and monitoring risk developed by

Dr. Vranceanu that has been successfully used in other trials. Alternatively, in event that suicidality is determined during one of the open pilot group sessions, the study clinicians will contact the PI immediately. We are hoping to avoid this scenario by excluding patients after screening who endorse suicidality or who have untreated severe mental health conditions that would require a higher level of care. We do not expect this unlikely event to occur, as there have been so such occurrences in our previous studies.

It is also important to note that participation this study does not involve treatment or diagnosis. However, it is possible that we may detect previously unknown problems during the open pilot group sessions or from the assessments. If any potential abnormality or medical problem is detected during the course of the study, the participant will be provided with an appropriate referral for medical follow-up. There is some risk of distress associated with the detection of a potential abnormality or medical problem.

Some participants may feel uncomfortable about the exit interviews being taped and transcribed. However, participation in exit interview will be optional. The purpose of the taping will be explained, confidentiality will be maintained, and verbal consent for taping will be obtained.

8. Benefits

Potential Benefits to Participants

During the open pilot (e.g., aim 2), we expect that participants may experience benefits including improvement in physical (self-report, performance, and objective) and emotional (depression and anxiety) function, increases in coping ability, and decrease in catastrophizing and fear of pain. These participants are also expected to benefit from the support of the therapist and group members. The knowledge gained from the research will benefit others by answering questions regarding effective nonpharmacological strategies to provide treatment for chronic pain in this population. Interested participants may also be sent a copy of publications from the open pilot once available. The risks to subjects are reasonable in relation to the anticipated benefits to research participants and others. The risks for participation in both the intervention and assessments are minimal, while the potential benefits are substantial.

Potential Benefits to Society

Our goal is to learn more about the feasibility, acceptability, and fidelity of implementing a group medical visit program in the primary care setting for older adults with chronic pain in underserved communities. We believe that the open pilot will provide insight into what individual, provider, community and environmental/systemic changes are possible and which of these changes may best support treatment for chronic pain in older, ethnically diverse adults. Chronic pain is prevalent and costly, particularly among underserved minority groups. Current standards for psychosocial interventions have several limitations including underwhelming

improvements in pain outcomes, in particular performance based and ambulatory activity (step count). As previously mentioned, the open pilot will enable us to establish the feasibility, acceptability, and fidelity of *GetActive+* program and study procedures. We will use this knowledge to further optimize the program in preparation for the R33 phase of this project as well as future studies and may ultimately help researchers and clinicians better care for patients with chronic pain.

9. Statistical Analysis

Aim 2 open pilot data analysis will be conducted with the primary goal of establishing feasibility as opposed to powering for specific effects for the quantitative outcomes. We propose *a priori* benchmarks for feasibility, acceptability and fidelity based upon our prior research and recommendations in the field (see Table 4). Since this pilot study was powered for establishing feasibility, we will assess preliminary efficacy by testing for signals of improvement in our secondary outcomes. We will first examine the distribution and normality of the data through a combination of histograms and the Shapiro-Willks test, and then conduct pre-post comparisons using paired t-tests or the Wilcoxon signed rank test as the non-parametric equivalent. Cohen's d effect sizes will be interpreted using the following pilot-recommended guidelines: small (Cohen's d = 0.2), medium (Cohen's d = 0.5), and large (Cohen's d = 0.8). For outcomes analyzed with the Wilcoxon signed rank test, we will calculate effect size via the equation $r=Z/\sqrt{N}$. Effect sizes will be interpreted using values commonly published in the literature for non-parametric measures: small (r=0.10 - <0.3), moderate (r=0.30 - <0.5) and large ($r \geq 0.5$). SPSS Version 28 will be used for all quantitative analyses.

Table 4. Measurement of mixed methods implementation outcomes across both phases based upon Aarons' model and Proctor's framework for defining implementation outcomes.

Implementation Outcome	Definition	Recommended Implementation Step in Aarons' Model	Study Aim	Assessment modality (multi-level, mixed methods assessments); Go/No-Go Benchmarks
Feasibility	Suitability and practicality	Early (steps 1-3)	R61 Aim 2; R33 Aim 3)	>= 75% agree to participate in intervention; qualitative feedback (patients; R61 Aim 2; patients and staff and clinicians R33 Aim 3).
Acceptability	Satisfaction with or tolerability of the proposed approach	Early (Steps 1-3)	R61 Aim 2; R33 Aim 3	>=75 enrolled complete >=75 sessions; qualitative feedback (patients; R61 Aim 2 and patients, and staff and clinicians R33 Aim 3).
Fidelity	Delivery of GetActive+ as intended	Early to Mid (Steps 2-3)	R61 Aim 2; R33 Aim 3	>=75% of sessions components delivered by clinicians in the clinic as intended; 20% sessions rated
Adoption	Uptake, intent to implement by organization, clinicians	Early to Mid (Steps 1-4)	R33 Aim 3	Qualitative assessment by staff and clinicians; intention to adopt.

We will utilize rapid data analysis (RDA) to analyze the exit interview data. We will review each transcript in the 24 hours after the interview and then create an RDA matrix to better synthesize responses and inform manual revisions. The matrix format will be synthesized using a deductive approach based on the domains outlined in the guide: Domain 1: The GetActive+ Program, Domain 2: GetActive+ Skills, Domain 3: Clinician and Nurse Practitioner, Domain 4: Assessments, Domain 5: Group Session Modality, Domain 6: Home Practice, Domain 7: Individualized Barriers and Facilitators. Our team has used these methods is prior work in community clinics which gives confidence that these procedures are feasible and effective in detecting nuanced aspects of program and protocol adaptation to inform subsequent implementation of the proposed changes.

10. Monitoring and Quality Assurance

Data Monitoring

The MPIs (Drs. Vranceanu and Ritchie) will have overall responsibility for monitoring the integrity of study data and participant safety

A number of procedures are in place to assure data integrity and protocol adherence. The MPIs will oversee management of the study database. In order to ensure confidentiality, data will be identified only by subject number and date of visit. By recording the study data in this manner, the information can be considered 'de-identified' and therefore compliant with the Standards for Privacy of Individually Identifiable Health Information ("Privacy Rule") of the Health Insurance Portability Act of 1996 (HIPAA). Any data that is transmitted electronically will be fully encrypted and password protected. Subjects' names will not be entered into any database; each will be uniquely identified only by an ID number. Hardcopy data will be kept and filed in locked office cabinets. We will not store identifiable participant data for those who do not enroll.

Safety Monitoring

The MPIs and study staff will be responsible for monitoring patient safety throughout the duration of the study. All participants will be instructed on how to contact study clinicians with any questions regarding their safety in the study.

11. 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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