Cover Page for ClinicalTrials.gov

Document: Study Protocol

Study Title: A Feasibility Study of a Chronic Pain Self-management Intervention for Older Adults Incorporating Podcasts and Patient Priorities

Document Date: 1/11/2023

NCT Number: NCT06185101

A feasibility study of a chronic pain self-management intervention for older adults incorporating podcasts and patient priorities

STEP-UP Pilot Trial

National Clinical Trial Number (clinicaltrials.gov): NCT06185101

Principal Investigator (Subproject of P30AG022845)

Mary R. Janevic
Research Associate Professor
School of Public Health
Department of Health Behavior and Health Education
University of Michigan

Supported by:

National Institute on Aging
Grant P30AG022845

Title of Grant: Cornell Edward R. Roybal Center
Translational Research Institute on Pain in Later Life (TRIPLL-III)
MPIs of Grant: M. Carrington Reid, MD/PhD, Karl Pillemer, PhD, & Elaine Wethington, PhD

Version Number v. 1.2
Date: January 11, 2023

STATEMENT OF COMPLIANCE

The trial will be carried out in accordance with International Conference on Harmonisation Good Clinical Practice (ICH GCP) and the following:

- United States (US) Code of Federal Regulations (CFR) applicable to clinical studies (45 CFR Part 46, 21 CFR Part 50, 21 CFR Part 56, 21 CFR Part 312, and/or 21 CFR Part 812)

National Institutes of Health (NIH)-funded investigators and clinical trial site staff who are responsible for the conduct, management, or oversight of NIH-funded clinical trials have

completed Human Subjects Protection and ICH GCP Training.

The protocol, informed consent form(s), recruitment materials, and all participant materials will be submitted to the Institutional Review Board (IRB) for review and approval. Approval of both the protocol and the consent form must be obtained before any participant is enrolled. Any amendment to the protocol will require review and approval by the IRB before the changes are implemented to the study. In addition, all changes to the consent form will be IRB-approved; a determination will be made regarding whether a new consent needs to be obtained from participants who provided consent, using a previously approved consent form.

PROTOCOL SUMMARY[CT.GOV]

Title:	A pilot and feasibility study of a chronic pain self-management intervention for older adults incorporating podcasts and patient priorities.
Study Description:	This randomized pilot trial tests the feasibility of a community health worker (CHW)-delivered chronic pain self-management intervention for older adults ("STEP-UP"; Support, Training, and Education for Pain Self-Management – Using Podcasts) in a primary care setting.
Objectives*:	We will conduct a randomized (waitlist) pilot trial (n=40) in a Federally Qualified Health Center.
Endpoints*:	Primary Endpoint: Improvement in pain interference at 8 weeks (post-program) Secondary Endpoints: physical functioning and global impression of change, and participant engagement and satisfaction (secondary outcomes) at 8 weeks
Study Population:	We will recruit 40 adults from a FQHC who are age 50+ with high-impact chronic pain.
Phase* or Stage:	Stage 1 (Behavioral Stage Model) Pilot Trial
Description of Sites/Facilities Enrolling Participants:	Participants (N = 40) will be primarily recruited through Western Wayne Family Health Center's clinic in Inkster, Michigan.
Description of Study Intervention/Experimental Manipulation:	The STEP-UP chronic pain self-management intervention (Support, Training, and Education for Pain Self-Management – Using Podcasts) will feature an educational podcast series teaching core pain self-management skills. Podcasts will be supplemented by sessions with a Community Health Worker taking place at designated times over a 7-week period. The Community Health Worker will guide participants in a modified Patient Priorities of Care (PPC) approach to help them identify their values and priorities and develop goals that reflect these..
Study Duration*:	One year
Participant Duration:	Eight weeks

1 RATIONALE & BACKGROUND

1.1 Study Rationale

Our overall objective in this pilot trial is to develop and test the feasibility and preliminary efficacy of a pain self-management intervention (STEP-UP, or Support, Training, and Education for Pain Self-Management – Using Podcasts) that combines educational podcasts with community health worker-led sessions eliciting participants' values and related functional goals, and test its feasibility among primarily African American older adults at a Federally Qualified Health Center in a low-income community. STEP-UP is derived from the STEPS intervention, currently being tested in a large RCT (R01AG071511) but uses different educational tools (e.g., podcasts vs. videos in the original STEPS), includes a newly-developed component based on the Patient Priorities Care approach developed by Tinetti and colleagues, and is designed for delivery in a clinic-based (vs. community) setting.

1.2 Background

African American older adults disproportionately face barriers to managing persistent pain, including multimorbidity, chronic psychosocial stressors, and suboptimal pain care--all of which are rooted in structural racism. Yet opportunities to learn chronic pain self-management (CPSM) skills that can improve functioning and quality of life are scarce in underserved communities. Moreover, typical CPSM interventions provide little guidance for how older adults can work with their providers to help ensure that their pain treatment plans reflect their values, priorities, and health goals. We propose to address these gaps by developing the novel STEP-UP intervention (Support, Training, and Education for Pain Self-Management – Using Podcasts). STEP-UP will feature a podcast series teaching core pain self-management skills in a culturally-congruent manner. Podcasts will be accompanied by telephone sessions with a community health worker, who will guide participants in a modified Patient Priorities of Care (PPC) approach (originally developed for older adults with multiple chronic conditions) to identify their most important values and health outcome goals, and healthcare preferences. This information will inform self-management goals and will be shared with providers to promote patient-centered pain care.

1.3 Specific Aims

1. Develop and beta-test the STEP-UP chronic pain self-management intervention.
    a) Create podcast episodes based on content from our existing STEPS and Positive STEPS CPSM interventions and lessons learned from podcast production in our ongoing RESET study.
    b) Design community health worker session protocols and adapt the PPC process for the pain care context with expert and provider input.
    c) Conduct a "beta" test of STEP-UP (n=5 participants) to refine content and processes.

2. Conduct a pilot RCT of STEP-UP.

a) Using a waitlist randomized control design, deliver the STEP-UP intervention to 40 adults, age 50+ with high-impact chronic musculoskeletal pain, in a Federally-Qualified Health Center.
b) Assess baseline to post-program changes in pain interference (primary outcome) and global impression of change in pain and functioning and participant engagement (secondary outcomes). Use mixed methods to evaluate key processes and explore mechanisms of effect.

Conduct qualitative interviews with clinic providers and administrators to: 1) identify factors affecting implementation, and 2) assess needs regarding a future provider-facing STEP-UP component. **JAN 11, 2023, NOTE: This will follow the pilot trial and the sampling plan will be informed by our experience during the trial; therefore, we will seek IRB approval for this element at a later date. ***

1.4 Risk/Benefit Assessment

1.4.1 Known Potential Risks

The risks of study participation are minimal, as we are testing an adaptation of a cognitive-behavioral intervention for chronic pain self-management, which does not involve drugs or devices and is non-invasive.

Below we list the potential risks, and in Section 1.3.b. we discuss how we will protect against/minimize each of these risks.

1. Psychological distress (FREQUENCY: Infrequent. SERIOUSNESS: Mild). A plausible but unlikely risk to participants is psychological distress during the course of the baseline or follow-up assessments or telephone sessions.

In the event of a participant expressing elevated distress as the result of an interaction, study staff will terminate the interaction (if deemed necessary) and/or offer psychological resources. We will have an updated list of Detroit-area resources for psychological support, which will be offered and mailed to participants as needed. Almost all of the survey questions (and all of the questions that are related to sensitive issues such as depressive symptoms) have been used in multiple prior studies, without noted problems. Participants will be informed as part of their informed consent process and immediately prior to each telephone interview that they can refuse to answer any of the questions or drop out of the study at any time. They will be asked if they would like to complete the interview over shorter sessions, if needed.

2. Breach of confidentiality during study activities (FREQUENCY: Rare, SERIOUSNESS: Mild).

Rigorous data security measures and staff training procedures will be put in place to minimize the risk of breach of confidentiality.

As part of their consent process, participants will be informed about the small risk of a breach of confidentiality. Email and text messages will only be used to reply to or contact participants if they choose this mode. For example, a participant may request a reminder text or email for a

scheduled survey or study visit, or they may indicate during enrollment that text or email is the best way to reach them to schedule telephone surveys or study visits. In this case, the study team may reach out to the participant via UM email or via text message. Survey responses or sensitive information will not be shared via email or text message. A secure UM email (Google) account will be created for the study and will be monitored by study staff.

All participant study information will be kept in a secure, HIPAA-compliant REDCap database within the University of Michigan. Additional study files will be secured in a HIPAA-compliant University of Michigan team Dropbox account.

Throughout the study, IRB guidelines and best practices in human subjects research will be followed to ensure the privacy and integrity of the information we collect. Any breach of confidentiality will be immediately reported to the PI and to the University of Michigan Health Sciences and Behavioral Sciences IRB. In addition, any complaints or concerns expressed to the study staff by participants, providers, or anyone else affected by this study will be immediately reported to the PI, and as appropriate, to the IRB.

All study staff, including community health workers, and research assistants will complete the online Social and Behavioral Research Best Practices course (https://research-compliance.umich.edu/hrpp-education-resources) which fulfills the NIH Good Clinical Practice requirement and the web-based University of Michigan's Responsible Conduct of Research Training Program, known as PEERRS (Program for Education and Evaluation in Responsible Research and Scholarship). Proof of their certification and completion of the training program will be kept on file. Training of staff will include information about the importance of privacy and confidentiality and specific techniques to maintain confidentiality of all information in the context of this study. Regular study team meetings will be used to ensure that all data quality and IRB policies and procedures are being followed.

All research data presented in reports, presentations, or manuscripts will be in aggregate and/or de-identified form only.

3. Physical Injury (FREQUENCY: infrequent, SERIOUSNESS: Mild)

Another possible risk is minor physical injury from doing physical activity that is encouraged by the STEP-UP program. Participants are encouraged to engage in physical activity of their choice, at a level that is comfortable for them. As with any physical activity, it is possible that participants could experience an injury while doing physical activity, like muscle strain. To minimize this risk, the STEP-UP Community Health Worker will guide participants in increasing activity levels slowly and will encourage them to check with their doctor if they do not know whether a specific activity is appropriate.

1.4.2 Known Potential Benefits

This intervention for chronic pain self-management will incorporate evidence-supported strategies to promote improved pain coping, and therefore has the potential for beneficial physical and/or psychological effects.

1.4.3 Assessment of Potential Risks and Benefits

This study is considered low risk to participants. It is non-invasive and offers a variety of resources for chronic pain management that are not commonly part of standard pain care. It incorporates evidence-based strategies that may improve health and functioning. If the program is effective, it has the potential to be a useful adjunct to clinical care. Overall, given that the potential risks of participation are minimal, the potential benefits outweigh the potential risks.

2 OBJECTIVES & ENDPOINTS

OBJECTIVES	ENDPOINTS	JUSTIFICATION FOR ENDPOINTS
Primary		
To determine if participating in the STEP-UP intervention leads to decreased pain interference with daily functioning.	PROMIS Pain Interference 6a scale is the primary endpoint (pain interference is assessed at baseline, and 8 weeks from baseline). A 2.5 point difference in T-score is considered clinically significant.	Pain interference is a patient-centered outcome that indicates pain's impact on valued and necessary activities. This intervention teaches skills such as goal setting to gradually increase engagement in daily activities.
Secondary		
To determine if participating in the STEP-UP intervention leads to greater improvement in Global Impression of Change in Pain and Functioning.	Patient Global Perception of Change since baseline will be assessed at 8 weeks. Participants will be asked about pain and functioning in separate items.	"Global impression of change" variables capture participants' subjective perceptions of intervention benefit.

To assess participant engagement in the intervention.	Number of sessions (out of 7) completed at 8 weeks from baseline.	Given the novel nature of this intervention and the barriers that many participants may experience to engagement, it is important to assess whether the intervention as designed yields acceptable engagement levels.
To assess participant satisfaction with the intervention.	Items ask about overall satisfaction with the program, e.g., whether participation increased understanding of pain management (1= Strongly Disagree to 5= Strongly Agree). A higher score indicates higher patient satisfaction.	These items will facilitate understanding of the intervention's acceptability in the priority population as well as highlight potential areas for improvement prior to a larger trial or another future iteration of the intervention.

3 STUDY DESIGN

3.1 Study Design

- NIH Behavioral Intervention Stage 1 randomized pilot trial to examine the acceptability and preliminary effects of the STEP-UP program on pain interference among older adults with chronic pain compared to a control group.
- Participants will be allocated into the two study arms in a 1:1 ratio by block randomization with mixed block sizes.

3.2 Study flow

4

5 SELECTION AND ENROLLMENT OF PARTICIPANTS

5.1 Inclusion Criteria

Participants will be eligible if they:

- Are 50+ years of age
- Report high-impact chronic musculoskeletal pain (defined as pain in muscles or joints for >= 3 months "most days" or "every day" on a scale of never, some days, most days, or every day) AND their pain limited life or work activities over the past 3 months "most days" or "every day"
- Have a cell or landline phone
- Able to converse comfortably in English
- Have not participated in another chronic pain self-management intervention in the last 5 years.
- Participants must be willing to meet by telephone with a Community Health Worker and listen to audio recordings (podcasts) to learn ways to manage pain and commit to the duration of the program. However, the study is voluntary, and participants may leave the study at any time.

5.2 Exclusion Criteria

- Hospitalization in the last month
- Planned major surgery in the next three months that would interfere with program participation (e.g., knee or hip replacement)
- Current or previous participation in either the STEPS or RESET interventions
- Severe cognitive impairment or other severe physical or psychiatric disorder judged by the study team to pose a significant barrier to participation

5.3 Recruitment

Recruitment for this study will take place through the Western Wayne Family Health Center (WWFHC). Several options for recruitment may be used: 1) By identifying potential participants age 50+ with specific diagnostic codes in the electronic medical record (EMR) system and sending them a letter and/or text message/portal message (sent out directly by WWFHC to patients; this process will be done in waves by zip code so that screening and enrollment can be done on a steady, "rolling" basis); 2) by making flyers available in clinic areas (either tables staffed by the UM study team or leaving flyers out for patients to pick up on their own - in the case of UM staffed tables, we will ensure that any screening that happens would take place by trained and IRB-approved UM study staff in a private location off the main clinic); and 3) direct referrals by WWFHC providers. In the case of direct referrals by WWFHC providers, the providers would give the patient a study flyer and/or the UM study team's contact information so the patient can reach out to the UM study team for more information and next steps. The UM study team **will not** receive any patient information directly from WWFHC. Potentially eligible patients will be informed about the study team by WWFHC and directed to contact the UM study team if they are interested in learning more.

Three versions of the study flyers will be available; a simple version with the UM study hotline number and UM study email (used for tabling and recruitment events located at WWFHC and in the community; some WWHFC patients/providers may prefer the simpler version), a version with tabs so interested individuals can take the UM study team's contact information to contact later (for posting at WWFHC and in the community), and a QR code version where interested individuals can use their smartphone camera to scan the code and complete a brief interest form via UM Qualtrics (used for tabling and recruitment events located at WWFHC and in the community). The UM study team will receive automated emails when individuals leave voicemails on the study hotline number and when someone completes the UM Qualtrics interest form. The UM study team will add interested individuals to the REDCap database and reach out to them within one week of receiving their interest form and/or voicemail to follow up accordingly.

5.4 Informed Consent & Enrollment

During recruitment contacts each patient will hear a brief description of the study before being asked if they wish to be screened for eligibility. In addition to meeting eligibility criteria, participants must be willing to meet by phone with a community health worker and listen to audio recordings (podcasts) to learn ways to manage pain and commit to the duration of the program. Interested individuals will be screened by trained and IRB-approved UM study staff on site or by telephone to further assess eligibility and invite to participate, if appropriate.

If a patient expresses interest in participating in the study by contacting the UM study team or at a tabling event, UM study staff will follow up with the patient by telephone (UM Zoom Phone) to see if the participant is interested and, if so, go through the eligibility screener with the patient using the study's UM REDCap database. After this they will complete the verbal consent process over the telephone. This can be completed directly after the screening process, or the patient can schedule it for another time.

In some cases, if there is time and private space available at the WWFHC clinic when UM study staff tabling and handing out flyers, UM study staff may go through the eligibility screener questions with the participant in-person at the clinic then schedule a telephone follow up to complete verbal consent process and next steps. If in-person, UM study staff would record the patient's responses to the eligibility questions on a paper version and enter the responses into REDCap directly after the recruitment event. Paper versions of the eligibility questions will be kept securely in the UM study team's locked office at the University of Michigan School of Public Health. If the participant is eligible, the UM study staff will confirm a day and time to follow up with the participant and complete the verbal consent process over the telephone.

For both, telephone and in-person screening, participant responses to the eligibility questions will be kept securely in the REDCap database.

Participants who are eligible will be offered more details about the study. They will be told that those agreeing to participate in the research will be randomly assigned to one of two groups (with an equal chance of being in either), after completing informed consent and a baseline telephone survey.

The intervention and control conditions will be described as follows. Individuals in the intervention group will meet with a community health worker for a 1-1.5 hour orientation session (typically in person but may be virtual in special cases described in Section 6.2) to get oriented to the program, receive a hard-copy workbook, and engage in a values-clarification and goal-setting exercise. Participants will then be asked to listen to one podcast episode per week for five weeks, each presenting a new pain self-management skill. Podcasts will be made available by both website and an IVR system. Each week, participants will receive a reminder text, voicemail, and/or brief telephone call from the CHW encouraging them to listen to that week's podcast episode, complete corresponding tasks as described in the workbook, and continue to work on their goal. After completing the follow-up telephone survey at 2 months from baseline (see below), individuals in the control group will be invited to take part in the intervention.

Participants in both groups will be asked to complete two data collection telephone interviews (at baseline and 8 weeks from baseline), each of approximately 45 minutes in length.

Informed consent procedures: If an eligible individual expresses interest in participating, they will be asked to verbally consent over the phone, either right away or on a subsequent call, according to participant preference and whether the participant completes the eligibility screener in-person or over the phone as mentioned earlier in Section 5.4. Participants will have the option to have a copy of the consent document mailed or emailed to them to review beforehand, or they can choose to complete the verbal consent first and have a copy of the consent document mailed or emailed to them afterward. The consent document will be mailed in a packet that also contains survey scale options for the initial, baseline survey. These are the response options for each of the survey items so the participant can more easily follow along on the telephone.

During the verbal consent process, the interviewer will read the informed consent document aloud, stopping to ask questions after each section. The verbal consent is documented in three ways. 1) With the participant's permission, we will audiorecord the verbal consent interaction (using UM Zoom or UM Zoom Phone) and securely store the audiofiles in access-restricted UM Dropbox folders. 2) We write their full name, the date, and the interviewer's initials to document that verbal consent was obtained in REDCap. 3) We will also indicate in REDCap that verbal consent was provided and document the date.

For participants who choose to have the consent document mailed to them first, research staff will call potential participants approximately one week after mailing the consent document to go through the verbal consent process over the phone and answer any questions. If the participant preferred an emailed copy of the consent document, research staff may call sooner based on the participants preferences.

Upon completing verbal consent, the participants will be enrolled in the study and will be scheduled for a baseline interview.

5.5 Screen Failures

Individuals who sign the consent document and who subsequently are deemed ineligible or inappropriate for participation (e.g., unable to participate meaningfully in study activities, discovery that diagnoses are not consistent with study criteria, etc.) will *not be enrolled*, but instead classified as "screen failures."

5.6 Strategies for Recruitment and Retention

Recruitment: We expect that the strategies outlined in Section 5.3 will yield enough participants for this pilot study, and we expect that most participants will be WWFHC patients. However, if needed, we will recruit from outside of the clinic, by working with the network of senior centers and senior housing facilities in the Detroit area with which we have developed relationships over several years, using flyers, information sessions, and word of mouth to advertise this study.

Information sessions will be done by trained UM study staff. These would be done at WWFHC clinics or at a senior center/senior housing center. During the information sessions, UM staff provide an overview of the study and answer questions about study participation. Individuals who attend the information session will be invited to provide their contact information to the study team for follow up, if they are interested in participating. In some cases, if time and space allows, the study team may complete the study eligibility screener in-person with the participant and schedule them for a verbal consent over the telephone, as described in Section 5.4.

Retention: We will follow detailed protocols that we have successfully used in past studies with older adults from vulnerable populations to try to retain participants once enrolled, including making a specific number of contact attempts at different times, with the goal of maximizing retention without being bothersome to participants or coercive. Specifically, these are the guidelines we will follow:

- We will call each participant 10 times without answer or response before marking them as Lost to Follow-up (Unable to Contact).

- If we call someone and the number is disconnected, we will arrange for a call-back one week later. If we call then and it is still disconnected we will arrange for a call-back two weeks later, and, if we have their address, mail them an “Unable to Contact” letter. If we call then and it is still disconnected, we will arrange for a call-back one month later. If it still disconnected at that point, we will mark the participant as Lost to Follow-up (Unable to Contact).

- We will reschedule a participant's baseline survey 5 times. We will reschedule the follow-up as many times as it takes to get the participant to complete it, until a one-month window from when the ideal follow-up date has passed (the ideal follow-up date is two months from baseline).

- We will attempt to contact a person for their follow-up survey 5 times; then send an Unable to Contact letter. If we do not hear from them, we will contact them a total of 5 more times.

- We will reschedule attendance at the orientation session (intervention participants only) a maximum of 3 times.

- All contact attempts will be documented in REDCap.

We will offer incentives for each data collection point. All incentives are provided in the form of gift cards from the Human Subjects Incentive Program at the University of Michigan. Participants will receive a $20 gift card incentive for the first data collection point and a $30 gift

card incentive for the second data collection point. Participants will also be given an inexpensive pedometer to count their steps during the program, if they choose to, and as an additional incentive. The study team will not ask participants to report their step counts as part of the study data.

In the STEP-UP intervention group, we will track session adherence. The CHW will be provided with guidelines for contact frequency. If participants do not respond back to the CHW, the study team will reach out to see if there are any issues that can be solved to increase engagement.

6 STUDY INTERVENTIONS

Participants will be randomized to one of two study arms in a 1:1 ratio: Arm 1 will receive the STEP-UP intervention and Arm 2 will be in the control group and will be waitlisted to be invited to receive the intervention.

6.1 STEP-UP Intervention Overview

STEP-UP will feature a podcast series teaching core pain self-management skills. Podcasts will be accompanied by regularly scheduled telephone sessions with a community health worker, who will guide participants in a modified Patient Priorities of Care (PPC) approach (originally developed for older adults with multiple chronic conditions) to identify their most important values and health outcome goals, and healthcare preferences. This information will inform self-management goals and will be shared with providers to promote patient-centered pain care.

6.2 STEP-UP Intervention Process

Orientation session: Intervention participants will meet in person with a CHW for a one-time study orientation (about 1-1.5 hours for most participants) to get oriented to the program, receive a hard-copy workbook, and respond to a brief social needs screener (PRAPARE), allowing the CHW to make referrals to any needed resources. The orientation session will typically be in person, but it may be completed virtually, via UM Zoom link, in special cases such as transportation barriers, scheduling challenges, patient mobility issues, and/or for public health reasons like COVID-19. The UM team will also try to provide transportation for participants to get from their home to the WWFHC clinic if that is a barrier to attending the orientation in-person (like Green Cab or Uber/Lyft). The orientation will be completed in private location where the CHW and participant can speak comfortably. For the social needs screener, the CHW will read the PRAPARE questions out loud and record the participant's answers to the questions in UM REDCap database. The participant can choose to decline answering any of the PRAPARE questions they prefer not to answer. Based on the participant's responses, the CHW will provide community-based resource referrals (such as organizations serving seniors, senior centers, food-related resources, local health department information, etc.). Contact information for referrals will be given to the participant at the orientation so they can follow up if they choose to.

Participants will also engage in a values-clarification exercise ("What Matters Most", in the domains of Connecting, Enjoying Life, Managing Health, Functioning) and goal-setting process, adapted from the Patient Priorities Care model. Participants will set meaningful activity goals that reflect their values. This process will include completing a "My Pain Priorities" summary sheet that can be shared with their provider, which includes information about care that they perceive as helpful or burdensome. The CHW will also complete a fillable form for each participant that states that they are taking part in the STEP-UP study and will include the information from the My Pain Priorities summary sheet. The CHW or study staff will fax this form to the WWFHC secure fax line for patient information and it will be uploaded by WWFHC into the patient's Electronic Health Record (EHR). This is a way for the CHW to put information into the EHR without having to have their own access to the EHR system. By adding the participant's My Pain Priorities summary sheet to their EHR, the participant's healthcare providers can see what the participant's goals and values are for a patient-centered approach to pain management. This may better facilitate conversations between the patient and the provider related to values and priorities. At this orientation, participants will also learn how to access the audio recordings (podcasts) and they will choose a time for weekly telephone sessions with the CHW.

Subsequent sessions: Participants will be asked to listen to one podcast episode per week, each presenting a new self-management skill along with motivational elements to try out the new skill. Podcast audiofiles will be made available on a website or "dial in." Each week, participants will receive a reminder text, voicemail, or phone call from the CHW (based on their preferences) encouraging them to listen to that week's podcast episode, complete tasks as described in the workbook, and continue to work on their values-informed behavioral goal.

During the final week, participants will have a 30-minute wrap-up session with the CHW. This final session can be done in-person or by telephone, depending on the participant's preferences. At this final session, they will reflect on progress made, establish a goal to work on going forward, and receive encouragement to discuss their "My Pain Priorities" summary sheet with their provider if they haven't already. See the table below for more details about the six weekly sessions.

STEP-UP Intervention Content

Week	Format/ CHW contact	Main topics
Week 1 **Orientation**	1-1.5 hr, in person with CHW (Zoom as back up option)	- How STEP-UP program will work - Provide workbook, pedometer, and other materials (e.g., PPC) - Podcasts: explain and practice accessing - Chronic Pain 101: How body and brain process pain signals, holistic approach to managing pain and maintain quality of life - Introduce Patient Priorities of Care approach (via video with discussion): Values identification and SMART goal - Administer SDOH screener (PRAPARE) and provide resources
Week 2 **Staying Active**	CHW 30 min phone session	- How physical activity helps with pain and fatigue - Strategies for incorporating physical activity into daily routine - Explore opportunities for physical activity and resources - Problem-solve barriers and challenges - Goal check-in
Week 3: Relaxing and Reducing Stress	CHW 15 min phone session	- Explore how stress and pain are linked - Introduce relaxation techniques (deep breathing, guided imagery, PMR) - Goal check-in
Week 4: Partnering with Your Provider	CHW 30 min phone session	- Review Patient Priorities Care approach; sharing worksheet with provider - How to get the most out of healthcare visits and planning for visits
Week 5: Doing What You Love	CHW 15 min phone session	- Importance of making time for well-being, self-growth, and fun - Identify ways to incorporate pleasant activities into daily life
Week 6: Moving Forward	30-min CHW phone or in-person session	- Review of sessions and strategies presented - Celebrate successes and progress - Establishing long-term goals and plan for "relapse" - Identify helpful resources moving forward

6.3 Control Study Arm

Participants assigned to the control condition will be administered the baseline and 8-week follow-up surveys. After that, they will be invited to take part in the STEP-UP intervention but will not receive any additional incentive for participating in the intervention, and they will not have additional outcome data collected (meaning the participants will not complete any additional study surveys when participating in the STEP-UP program after their 8-week follow up survey). Process intervention data will be tracked for all control group members who opt to do STEP-UP, such as completion of CHW orientation and subsequent telephone sessions.

6.4 Measures to Minimize Bias: Randomization and Blinding

Participants will be randomized to intervention or control groups using a block randomization scheme with randomly selected block sizes. The study team member who randomizes participants will be blinded to participant responses on the baseline assessment and will only be informed if the assessments were completed. Participants will be informed by the study team of their study arm assignment and will be informed of next steps for their study arm.

6.5 Study Intervention Adherence

Attendance of community health worker sessions (or responding to phone calls/texts during weeks where there is no session) will be the main mechanism of tracking adherence. Community health workers will also log information from participant reports about working towards their goals during their calls. We will assess self-report of listening to podcast episodes (0 to 5).

6.6 Concomitant Treatment

This study will not restrict participation in other types of treatments. However, participants in the STEP-UP study will not be able to participate in our other ongoing R01 studies, Re-Engaging in Self-Care and Enjoying Today (RESET), and the original STEPS intervention trial. These two studies are recruiting from a similar population and have some overlapping intervention components. We will make this clear in the recruitment process.

6.7 Lifestyle Considerations

This study does not have any restrictions regarding lifestyle and/or diet.

6.8 Intervention Discontinuation

We will end a subject's participation upon their request. The research team may end a subject's participation from the study if they are too acutely ill to participate or have a change in disease severity in which the study team (in consultation with Dr. Reid of Weill Cornell Medicine) feels that they should not take part in the intervention. These instances will be recorded as adverse events, and all participants will be contacted to determine if they can complete outcome assessments if possible. We may also end a subject's participation if the research team deems that the participant is not a good fit for the program (e.g., belligerent with staff, too difficult to contact, or confused by study procedures).

6.9 Treatment Fidelity

6.9.1 Overall compliance

See **6.5 Study Intervention Adherence** above.

6.9.2 Community Health Worker Training and Tracking

The study CHW will complete the MiCHWA CHW Certification Training Program, a 126-hour course covering topics such as: communication skills and motivational interviewing, documentation and reporting, navigating community resources, and healthy lifestyles.

STEP-UP-specific training will take place over a series of initial training sessions (the equivalent of approximately 4 full days) with ongoing training/feedback by the PI or other members of the study team or research staff throughout the study period. Our CHW training approach has been refined over a series of studies, and emphasizes role play and practice sessions with feedback. We focus on older adults' needs, including multimorbidity and cognitive issues, as well as record-keeping, teaching goal-setting, managing common issues such as temporary increases in pain after activity, and knowing when to consult with a supervisor and the study team.

All intervention sessions with participants will be audio recorded, with participants' permission, and a checklist will be used to determine fidelity to the session protocol in the community health worker STEP-UP manual. We will test for CHW "drift" from the protocol by listening to all sessions for the first 3 participants, and a random 20% of recorded calls thereafter, and offer feedback and additional training as needed. Recording of session information in REDCap (e.g., information from phone sessions such as goals, also reminder calls/texts and whether response was received from participant) will also be audited, on the same schedule. The CHW will meet regularly (weekly or biweekly) with a research staff member for coaching and feedback. The duration of calls will also be recorded.

6.10 Withdrawal from the Study

If participants withdraw or decline to finish the intervention, every effort should be made to gather primary outcome data (pain interference) as well as a query about adverse events.

- The goal is to collect the information as close to the designated follow-up assessment as possible (8 weeks). Participants need to complete the assessment within one month of the follow-up date in order to be counted as non-missing.
- For intervention group participants wishing to discontinue participation in the intervention, the study team member will ask to call them during the scheduled follow-up window.
- Participants who state that they wish to withdraw completely from the study will not be contacted further.

The reason for participant discontinuation or withdrawal from the study will be recorded in REDCap. Participants who sign the informed consent form and are randomized to the intervention but do not begin it will not be replaced, due to the short overall study period. Participants who sign the informed consent form, and are randomized and receive the study intervention, and subsequently withdraw, or are discontinued from the study, will not be replaced.

6.11 Lost to Follow-up

A participant will be considered lost to follow-up per the protocol presented in 4.6.

7 STUDY PROCEDURES

7.1 Schedule of Activities

Activity	Weeks									
	Pre	0	1	2	3	4	5	6	7	8
Eligibility Screening	X									
Consent Process	X									
Randomization	X									
Demographics		X								
Chronic conditions and overall health		X								
Pain Interference (PROMIS-43 6-item scale)		X								X
PROMIS-29 +2[14,15] (except Pain Interference subscale)		X								X
Pain Intensity (Numerical Rating Scale)		X								X
Pain Self-Efficacy Questionnaire		X								X
Pain Medication Use		X								X
Communication with Provider		X								X
Chronic Pain Acceptance		X								X
Physical Activity		X								X
Fear of Movement		X								X
Patient Activation Measure		X								X
Survey of Pain Attitudes (SOPA) - Control subscale		X								X
Pain Catastrophizing Scale		X								X
Life Control Scale		X								X
PROMIS Meaning and Purpose (4-item)		X								X
Global impression of change in pain, functioning, quality of life, and use of pain medication										X
STEP-UP Program Evaluation Questions (intervention group only; both close- and open-ended)										X

STEP-UP: CHW sessions (intervention group only)			X	X	X	X	X	X		

Notes:

*Shaded rows represent measures on the telephone data collection surveys (at baseline and/or 8 weeks).

**Primary and secondary outcomes are bolded.

***Allowable assessment windows: Participants need to complete the assessment within one month of the follow-up due date to be counted as non-missing.

****If participant does not start intervention within one month of baseline assessment, they will be withdrawn from the study by the study team. If a participant drops out of the intervention, they will be invited to complete the surveys if they want to (intent to treat) or they can withdraw from the study.

7.2 Description of Activities

- *Telephone data collection surveys* – participants will complete the validated measures tested as outcomes or mediators listed above as well as other measures to help characterize health and functional status, quality of life, and satisfaction with the intervention, at baseline and/or 8 weeks from baseline. Participants will be sent response options for each of the survey scales prior to their scheduled telephone survey appointment so they can see the response options and follow along. If participants do not have the survey scales, they can either reschedule or continue with the survey if they prefer (staff will read responses for each question/item on the survey).
- *Randomization* – occurs after a participant completes their baseline telephone survey.
- *STEP-UP Program (Intervention)* – See Table in Section 6.2 for details of intervention activities and flow..

8 SAFETY

8.1 Potential Risks & Benefits - See Section 1.4

8.2 Event Reporting Schedule

This study will use a study-specific reporting schedule for adverse events, protocol deviations, ORIOs and unanticipated problems. The reporting schedule can be found in eResearch, Section 32.

8.3 Definitions for Events

We will use standard definitions of **AEs/SAEs** as follows:

Adverse Event (AE): Any untoward or unfavorable medical occurrence in a human study participant, including any abnormal sign (e.g., abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the participants' involvement in the research, whether or not considered related to participation in the research. The most likely example for the present pilot study is elevated psychological distress.

Serious Adverse Event (SAE): 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 or incapacity; Results in congenital anomalies or birth defects; Is another condition which investigators judge to represent significant hazards. An example in the present study is a hospitalization.

Unanticipated Problem (UP):
Defined by DHHS 45 CFR part 46 as any incident, experience, or outcome that **meets all the following criteria:**

- unexpected, in terms of nature, severity, or frequency, given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the study population;
- related or possibly related to participation in the research (in this guidance document, possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research);
- suggests that the research places participants or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

8.4 Classification of Adverse Events

8.4.1 Severity of Event

We will use the standard grading scale in use by the University of Michigan Institutional Review Board - Health Sciences and Behavioral Sciences (UM IRB-HSBS) as follows:

Grading scale:

1. No adverse event
2. Mild AE – No treatment needed
3. Moderate AE – Resolved with treatment
4. Severe AE – Inability to carry on normal activities, required professional medical attention
5. Life-threatening or disabling AE
6. Fatal AE

8.4.2 Relationship to Participation

We will use the standard relatedness scale in use by the University of Michigan Institutional Review Board - Health Sciences and Behavioral Sciences (UM IRB-HSBS) as follows:

Relatedness scale:

- Definitely related
- Probably related
- Possibly related
- Unlikely to be related
- Definitely not related

Expectedness

- Unexpected
- Expected

8.4.3 Expectedness

For an event to be classified as "expected" it should have been addressed in at least one of the following sources: this document, the research application, literature, proposal document, informed consent, or associated with the characteristics of the study population.

7.4.4. Process for identifying AEs and SAEs

Given the low likelihood of adverse events in this study, and the short length of the active study period (8 weeks for an individual participant), passive monitoring for adverse events will be done by the PI, other research staff, and community health workers on an ongoing basis and will be reported to the IRB and other entities as described in the "AE/SAE Reporting" section below.

It is possible that we will learn of adverse health-related events when conducting follow-up interviews; it is also possible that community health workers will learn of such events when speaking with participants or attempting to make contact. It is also possible that the study coordinator/research assistants providing technical or other support to participants will learn of such events. These staff will all be trained to recognize and immediately report anything that could potentially be an adverse event.

AE/SAE Reporting:
All AEs and SAEs will be collected on an Adverse Event form in the study's REDCap database and will be reported immediately to the PI by the person learning of the event (generally, study staff, or community health workers).

The PI or designated staff member will complete the UM IRB-HSBS Adverse Event Reporting form. Next steps will include the following:

- For all expedited AE/SAE/UP reports, the Cornell Roybal Directors, and/or NIA PO may determine if full DSMB review is required.
- All **adverse events that are both serious** (SAE) and **unexpected** (have not been defined as expected in the DSMP), should be reported to IRB, NIA PO and to Cornell Roybal Directors Reid and Wethington.
- The summary of all other SAEs (i.e., expected or not related SAEs) will be reported to NIA Program Officer and to the Cornell Roybal Directors **quarterly**, or as requested by the Cornell Roybal Directors.
- All **unexpected** deaths will be reported within 24 hours to the NIA PO, Cornell Roybal Directors, and IRB.
- Unanticipated Problems (UP) will be reported to IRB, NIA PO and to the Cornell Roybal Directors **within 48 hours** of the study's knowledge of UP. The Unanticipated Problems report must include a corrective plan and measures to prevent reoccurrence. Reports of Unanticipated Problems, as defined above, should be forwarded to OHRP using ohrp@osophs.dhhs.gov, typically within two weeks of the event.
- AEs will be reported per IRB policies. They should also be reported to the NIA Program Officer and to the Roybal Directors at minimum annually, or at a frequency requested by NIA and/or by the Cornell Roybal.

No related AEs or SAEs are expected for this minimal-risk study of a behavioral intervention (i.e., events known to be associated with the intervention or condition under study, i.e., a cognitive-behavioral

intervention for chronic musculoskeletal pain). Although participants will be encouraged to become more physically active, this will take the form of incremental increases in existing low to moderate intensity physical activities (e.g., walking) and trying the exercises in the NIA *Workout To Go* booklet that has been selected specifically to be done safely by older adults.

However, we do expect unrelated AEs and SAEs, based on the high morbidity and multimorbidity of this population (i.e., adults who are 50+ years of age, most or all of whom will be from underserved and/or marginalized populations). These **unrelated but expected** AEs and SAEs could include hospitalizations, deaths, and/or other moderate to severe illness-related events during the study period that are related to age and pre-existing health conditions and unrelated to study participation. Nonetheless, if these occur, they will be reported as AEs or SAEs and the appropriate steps as outlined above will be taken.

Below are the specific events that will trigger reporting to the parties described above:

Acute Alerts/Serious Adverse Events

- Hospitalization of Study Participant
- Institutionalization of Participant
- Emergency Room Visit of Participant
- Death of Participant

Safety Alerts/Adverse Events

- Severe Medical Problem of Participant
- Participant threatens to harm him or herself or others

9 QUALITY CONTROL AND DATA MONITORING PROCEDURES

We will review study progress, and data and safety issues on a regular basis in the following ways:

8.1. Training

All study staff will complete PEERRS Human Subjects Research Protection course and Good Clinical Practice for Social and Behavioral Research training. They will also be trained on the project protocol, project data collection systems and other study-related topics by the Principal Investigator and/or Project Manager and Project Coordinator prior to beginning data collection. Additionally, the Project Coordinator will develop a detailed manual of procedures, which will provide step-by-step instructions on the conduct of the trial. The manual of procedures and other study documents will be reviewed in detail with the staff and student research assistants involved in data collection. Additionally, any staff who join the team after the project starts will be required to complete the standardized training prior to enrolling participants. Training will be documented in an electronic regulatory binder.

8.2. Meetings

- *Study staff meetings:* Drs. Janevic, the Project Manager, and the Project Coordinator will meet weekly throughout the course of the project to ensure that all data quality and IRB policies and procedures are being followed. This will include reviewing recruitment challenges, and monitoring data collection and quality.

- *Quarterly meetings with Cornell Roybal Executive Committee*: Dr. Janevic will meet quarterly with the Directors and Executive Committee of the Cornell Roybal Center to report on study progress. These meetings will be either in Executive Committee sessions or in the Work-in-Progress seminar. She will also

meet as needed with Cornell's Roybal Center Director Dr. Cary Reid and Co-Director Dr. Elaine Wethington to provide updates and discuss any problems with implementation of this pilot study.

- *Meetings with Western Wayne Family Health Centers*: Dr. Janevic and Ms. Lindsay and/or other staff members will meet at least monthly with Lisa Rutledge, Special Projects Manager at Western Wayne Family Health Centers, and/or other adminstrators as well as the Commmunity Health Worker, when hired. During the active intervention period, the Project Manager, Ms. Lindsay, or other designated staff member, will meet with the Community Health Worker weekly, to provide feedback to ensure optimal fidelity to protocols and to problem-solve as needed. Ms. Rutledge or another WWFHC representative will be invited to attend these meetings as well.

8.3. Auditing

- Conformance with Informed Consent Requirements. At approximately the study's midpoint and end, the project manager and/or PI will also review all consent forms for participants.
- Quality Control for Telephone Interviews: We will check a random 10% of all data from telephone interviews input into REDCap by listening to audiorecordings of the interviews and verifying that data was input correctly. Any deviations will be discussed at regular study staff meetings.

To document adherence to this plan we will maintain a monitoring log and create accompanying monitoring reports for each review. The monitoring log will be kept in the electronic regulatory binder.

8.4 Protocol Deviations

This protocol uses the University of Michigan definition of a protocol deviation (https://az.research.umich.edu/medschool/glossary/deviation) which defines a protocol deviation as "an incident involving non-compliance with the protocol, but one that does not have a significant effect on the subject's rights, safety or welfare, and/or on the integrity of the data. Deviations may result from the action of the participant, researcher or staff."

Reportable protocol deviations will be reported and tracked in the REDCap database and will be discussed at investigator and project staff meetings.

The following events will not be reported as protocol deviations:

- A protocol deviation will not be reported for participants who skip/do not complete telephone interview items or entire interviews. Participants can decline to answer any survey question for any reason. We expect in an intensive, long duration protocol like this that participants may miss some assessments.
- A protocol deviation will not be reported for out-of-window assessments. Use of this data will be assessed by the study investigators for each study analysis; some analyses may need tighter compliance to the assessment window while others will not.
- A protocol deviation will not be reported if an intervention group participant completes their 8-week survey before they have completed the final intervention session.
- A protocol deviation will not be reported if a participant misses an intervention session.

Reportable protocol deviations will be reviewed at the project staff and investigator meetings and submitted to the U-M IRB--HSBS and in other DSMB or NIH reports (if applicable).

10 CONFIDENTIALITY AND PRIVACY

Overview

A number of steps will be taken to ensure participant confidentiality and to protect against the potential risks related to stress from loss of confidentiality, or potential coercion. Participants will be encouraged to ask questions throughout recruitment/screening calls and informed that their participation is voluntary and that they can refuse to participate at any time without penalty. Participants also will be reminded that they can skip questions in surveys that they may not wish to answer. As part of their consent process, participants will be informed about the small risk of a breach of confidentiality. All data collection will take place over the telephone, such that participants can choose a location with the level of privacy they desire. There will be a line in both the recruitment/screening script and the telephone survey script, "Are you in a comfortable place that has the privacy that you desire?" If the answer is no, we can reschedule the interview.

Email and text messages will only be used to reply to or contact participants if they choose this mode. A secure UM email (Google) account will be used for the study and will be monitored by study staff. Throughout the study, IRB guidelines will be followed to ensure the privacy and integrity of the information we collect. Any breach of confidentiality will be immediately reported to the PI and to the University of Michigan Health Sciences and Behavioral Sciences IRB, as an ORIO. In addition, any complaints or concerns expressed to the study staff by participant participants, providers, or anyone else affected by this study will be immediately reported to the PI, and to the IRB as an ORIO. All research data will be presented in reports, presentations, or manuscripts in aggregate statistics only.

Training and Monitoring

As noted above, all study staff, including community health workers, and research assistants will complete the web-based University of Michigan's PEERRS (Program for Education and Evaluation in Responsible Research and Scholarship) course in Human Subjects Research Protection and NIH-approved Good Clinical Practice Training (NCATS Social and Behavioral Best Practices). Proof of their certification and completion of the training programs will be kept on file. Staff will have signed a pledge of confidentiality, and we will ensure that all staff understand that a breach of confidentiality is grounds for dismissal. Training of staff will include information about the importance of privacy and confidentiality and specific techniques to maintain confidentiality of all information in the context of this study. Regular study team meetings will be used to ensure that all data quality protocols and IRB policies and procedures are being followed.

Managing and Protecting Data

All study participant information will be collected, stored and managed by trained study staff and research assistants in REDCap. REDCap is a secure, web-based application designed to support data capture for research studies, providing 1) an intuitive interface for validated data entry; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for importing data from external sources. It is HIPAA compliant and supported by the University of Michigan. This secure web application promotes high quality data collection; forced responses ensure that interviewers are not able to proceed with the survey if required data are missing; and each survey is designed so that only valid responses are entered.

UM Qualtrics will be used to collect contact information for individuals interested in the study if they use the QR code available on the study flyer. UM Qualtrics is HIPAA compliant and secure. Qualtrics is a secure U-M

contracted-for cloud service that can be used to maintain or share the university's sensitive unregulated data, as well as some kinds of sensitive regulated data. Only UM study team members will be able to access this data and manually transfer it to the study's REDCap database for future contacts with potential participants. No other data will be collected or stored using UM Qualtrics.

For telephone calls and telephone-based intervention sessions, we will use Zoom Phone to audio record calls and CHW sessions for quality assurance. Zoom and Zoom Phone are HIPAA-compliant and supported by the University of Michigan. Audio recordings will be stored in the secure University of Michigan School of Public Health server or Dropbox at U-M, a HIPAA-compliant file storage system.

On-site Access and Control: Users are instructed to lock their workstation and to never leave it unattended with an active desktop. This enables access control by allowing only the credentials of the validated user to unlock the workstation. This is especially true when a user is accessing study data.

Remote Access: All connections from remote locations must use the University-configured Cisco VPN client, which encrypts all traffic to and from the servers.

All databases will be maintained in access-restricted files throughout the study. Study personnel who leave the research team will have their access to study files revoked.

The only paper records with identifiers will be the informed consent documents, and these will be kept in a locked office, in locked file cabinets in the University of Michigan School of Public Health. Access to the file cabinets will be restricted.

We will report AEs/SAEs to the IRB, DSMB or ISM, and/or other parties in a blinded manner, using only the unique subject identifier to protect the participant's identity.

Certificate of Confidentiality

To further protect the privacy of study participants, a Certificate of Confidentiality will be issued by the National Institutes of Health (NIH). This certificate protects identifiable research information from forced disclosure. It allows the investigator and others who have access to research records to refuse to disclose identifying information on research participation in any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level. By protecting researchers and institutions from being compelled to disclose information that would identify research participants, Certificates of Confidentiality help achieve the research objectives and promote participation in studies by helping assure confidentiality and privacy to participants.

11 STATISTICAL CONSIDERATIONS

11.1 Sample Size

This pilot study is not powered to determine the statistical significance of effects.

11.2 Data Analyses

11.2.1 General Approach

We will collect outcome data at two time points: baseline and 8 weeks from baseline (post-program, for those in the intervention group). All quantitative process and outcome data will be collected in REDCap. Descriptive statistics will be used to summarize background variables for the overall sample and by treatment group. Prior

to conducting primary analyses, descriptive analyses will be conducted to examine data distribution, outliers and potentially important covariates for inclusion in multivariate model diagnostics. We will evaluate normality using normal quantile plots and standard tests of normality incorporated in basic statistical packages, including SPSS and SAS.

11.2.2 Primary & Secondary Endpoints

We will calculate baseline descriptive statistics and compare groups using independent-sample t-tests for continuous variables and chi-squared tests for categorical variables. We will assess psychometrics of scales used (e.g., internal consistency reliability and concurrent validity). We will convert the PROMIS 6-item Pain Interference subscale score to T-scores (a standardized score with a mean of 50 and SD of 10) by summing the scales and using the conversion tables provided at HealthMeasures.net.

To assess the effect of being in the intervention group, we will use a univariate analysis of variance model for continuous primary and secondary outcomes. The dependent variable in each model will be the value of the outcome at 8-week follow-up; the independent factor will be treatment group (intervention vs. control), with the baseline value of the outcome as a covariate.

Effect size will be indicated by partial eta squared for the treatment group variable. In order to assess the potential clinical relevance of the intervention, we will use chi-squared tests to compare the percentage of participants in each treatment condition who achieved the Minimally Important Difference (MID) of ≥ 3 T-score points in PROMIS pain interference.

We will repeat this analysis with the secondary outcomes: Global Impression of Change in Pain and Functioning. Transformations for non-normality of outcomes will be performed as indicated.

We will also assess the moderating effect of selected variables such as sex, age, baseline pain intensity, and degree of program engagement. Moderation analyses will use standard approaches to evaluate interactions between these covariates and treatment group.

For patient engagement, the secondary outcome indicating feasibility that is composed of: 1) number of sessions completed out of 7; and 2) participant satisfaction on a 5-point Likert scale, we will calculate descriptive statistics. We will also explore differences by age group (under 65/65+) as well as gender. As an exploratory analysis, we will investigate whether satisfaction differs according to whether or not participants achieved the MID on the primary outcome of pain interference.

11.2.3 Other Pre-specified Analyses

To explore potential mechanisms, we will examine the association between: 1) participation in the intervention and the hypothesized composite meditator, Perceived Control Over Pain, as well as each of the 4 component scales (Survey of Pain Attitudes Control subscale, Pain Catastrophizing Scale, Life Control scale, and PROMIS Meaning and Purpose); and 2) between mediators and outcomes. Positive correlations in both cases will provide evidence for a potential mediating effect.

Following intent-to-treat principles, we will include all participants randomized to the intervention group, with sensitivity analyses assessing whether different levels of participant engagement (i.e., session completion) impact results.

12 INTERIM ANALYSIS

This pilot study will not include interim analysis.

13 PUBLICATIONS

This study will be conducted in accordance with the National Institutes of Health (NIH) Public Access Policy, which ensures that the public has access to the published results of NIH funded research. It requires scientists to submit final peer-reviewed journal manuscripts that arise from NIH funds to the digital archive PubMed Central upon acceptance for publication.

14 PROTOCOL AMENDMENT HISTORY