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Document: Study Protocol

Study Title: Chronic Pain Self-management for Older Adults With Cognitive Impairment: A Randomized Pilot Trial

Document Date: 6/30/2025

NCT Number: NCT06182423

Chronic pain self-management for older adults with cognitive impairment: A randomized pilot trial

STEPS-CI Pilot Trial

National Clinical Trial Number (clinicaltrials.gov): NCT06182423

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STATEMENT OF COMPLIANCE

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 Good Clinical Practice (Social and Behavioral) 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:	Chronic pain self-management for older adults with cognitive impairment: A randomized pilot trial
Study Description:	The purpose of this study is to test the acceptability and preliminary effects of a chronic pain self-management intervention, modified to be suitable for people living with mild to moderate cognitive impairment. We hypothesize that participants in the intervention, compared to a randomized control group, will have greater improvements in pain interference, pain intensity, and subjective cognitive functioning at 10 weeks from baseline.
Objectives*:	Primary Objective: To develop a chronic pain self-management intervention for people living with mild to moderate cognitive impairment, and assess its acceptability. Secondary Objective: To assess the effects of the intervention compared to a randomized control condition.
Endpoints*:	Primary Endpoint: Improvement in pain interference at 10 weeks Secondary Endpoints: Improvement in pain intensity, and subjective cognitive functioning at 10 weeks
Study Population:	We will recruit 50 adults, primarily from underserved urban and rural communities, age 50+ years who report chronic musculoskeletal pain of at least 3 months' duration and mild to moderate cognitive impairment that at least sometimes interferes with daily activities.
Phase* or Stage:	NIH Behavioral Intervention Stage I
Description of Sites/Facilities Enrolling Participants:	Participants (N = 50) will be primarily recruited through community locations in Detroit and northern Michigan.
Description of Study Intervention/Experimental Manipulation:	This intervention is a community health worker (CHW)-led chronic pain self-management program designed for older adults with chronic pain and mild to moderate cognitive impairment. It is a 7-week intervention that includes two primary components: a website that includes brief instructional videos on pain management skills as well as testimonials from individuals living with the two target health conditions; and weekly telephone sessions with a CHW to support and motivate participants in setting goals related to pain management. Reminder strategies and content addressing pain management challenges related to cognitive impairment are incorporated throughout. Participants may choose to work with a care partner during intervention activities.
Study Duration*:	1 year
Participant Duration:	10 weeks

1 RATIONALE & BACKGROUND

1.1 Study Rationale

An increasing number of older Americans are living with both chronic pain and cognitive impairment. These two conditions have overlapping and interacting symptoms such that they can result in a "downward spiral" leading to significant disability. Given the heavy burden and risks of medication use in older adults, and especially those with cognitive impairment, it is crucial that safer, non-drug options for managing pain are developed.

1.2 Background

Cognitive-behavioral strategies can reduce pain's negative impact on daily functioning and quality of life, and teaching self-management skills is part of optimal chronic pain care. While a variety of medications are prescribed for pain in older adults, many are associated with serious risks (e.g., falls) and may further impair cognition. Therefore, there is a critical need to manage pain effectively through non-pharmacological strategies, yet the evidence for behavioral interventions to address pain in this population is extremely limited. The few behavioral interventions studied for people with MCI/ADRD have mostly been directed at caregivers or focused on movement therapy or complementary therapies like massage, rather than on self-management skill-building. Given the deficits in attention, learning, perception, and memory seen in MCI/ADRD, learning and applying self-management strategies such as goal setting and symptom tracking may be challenging. Yet there is accumulating evidence that adapted behavioral interventions focused on lifestyle change or disease management can be feasible in this group.

In the STEPS (Seniors using Technology for Pain Self-Management) intervention, which is the subject of the parent R01 for this administrative supplement-funded study, community health workers (CHWs) deliver chronic pain self-management (CPSM) education and support to older adults with chronic pain. STEPS uses cognitive behavioral strategies to help individuals better manage their pain and includes web-based videos to teach cognitive-behavioral pain management to participants.

The original STEPS is designed to address barriers common among older adults in low-income areas such as low health literacy, resource needs, and lack of transportation. In the current study, we will modify STEPS to be suitable for older adults with comorbid chronic pain and MCI/ADRD. The proposed pilot intervention (referred to as STEPS-CI, for "cognitively inclusive" throughout this protocol, but the name is subject to change based on Advisory Council input after study launch) will add to the nascent body of research on behavioral interventions for persons living with both MCI/ADRD and chronic pain by testing an intervention that is delivered by community health workers. In addition to presenting simplified chronic pain education and skill-building, STEPS-CI will also focus on connections to local and national resources related to living with MCI/ADRD and caregiving.

1.3 Specific Aims

Aim 1: Refine and finalize draft curriculum and intervention materials for STEPS-CI. Initial materials will be developed based on already-completed interviews and focus groups, and we will work with a newly convened Advisory Board made up of NADM members to further refine the intervention prior to launch.

Aim 2: Train two community health workers to deliver STEPS-CI to 50 older adults (with or without a caregiver/supporter) age 50+ with chronic musculoskeletal pain of at least 3 months' duration and mild to moderate cognitive impairment and assess the program's acceptability and effects using a randomized control design. We will use mixed methods to evaluate key program processes and outcomes (primary = pain-related interference; secondary = pain intensity, subjective cognitive function). Pain medication reduction is an exploratory outcome. We will also explore potential moderators, including urban vs. rural location and degree of cognitive impairment.

1.4 Risk/Benefit Assessment

1.4.1 Known Potential Risks

A plausible but unlikely risk to participants is psychological distress during the course of the telephone data collection surveys or telephone intervention sessions. If that occurs, study staff will terminate the interaction (if deemed necessary) and/or offer psychological resources to the participant(s).

We will have an updated list of Detroit-area and Northern Michigan resources for psychological support, which will be offered and mailed to participants as needed. Participants will be informed as part of their informed consent process and immediately prior to each telephone survey that they can drop out of the study at any time and that they can refuse to answer any of the questions.

In the event of participants reporting serious depressive symptoms or suicidal ideation, the staff member or CHW communicating with the participant will follow an established protocol, used in our other studies, which will include notifying the PI, providing a suicide hotline number, and referring or calling 988 together if needed.

Another plausible but unlikely risk is a breach of confidentiality. Rigorous data security measures 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 messages will only be used to reply to or contact participants if they choose this mode. A secure UM email (Google) account will be created 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 MPIs and to the University of Michigan Health Sciences and Behavioral Sciences IRB. 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 MPIs, and as appropriate, to the IRB. All research data presented in reports, presentations, or manuscripts will use aggregate statistics only.

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 help ensure that all data quality and IRB policies and procedures are being followed.

1.4.2 Known Potential Benefits

The intervention being tested has minimal risks to participants with potential benefit to physical or mental health, as it incorporates evidence-based psychological principles to support self-management of chronic pain. Our study design means that every participant will have access to key elements of intervention content, since control group members will be offered all intervention materials and a workshop following their follow-up data collection.

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. The original STEPS intervention, from which STEPS-CI will be adapted for the MCI/ADRD population, has been pilot-tested for feasibility and potential efficacy, and incorporates evidence-based strategies that may improve health and functioning. Burdens typical to research studies, such as frequent travel to a study site, have been eliminated and participants have the benefit of access to an intervention they can largely or entirely participate in from their homes. If the program is effective, it has the potential to be an adjunct to clinical care. Overall, given that the potential risks of participation are minimal, the potential benefits outweigh the potential risks.

2 OBJECTIVES & ENDPOINTS

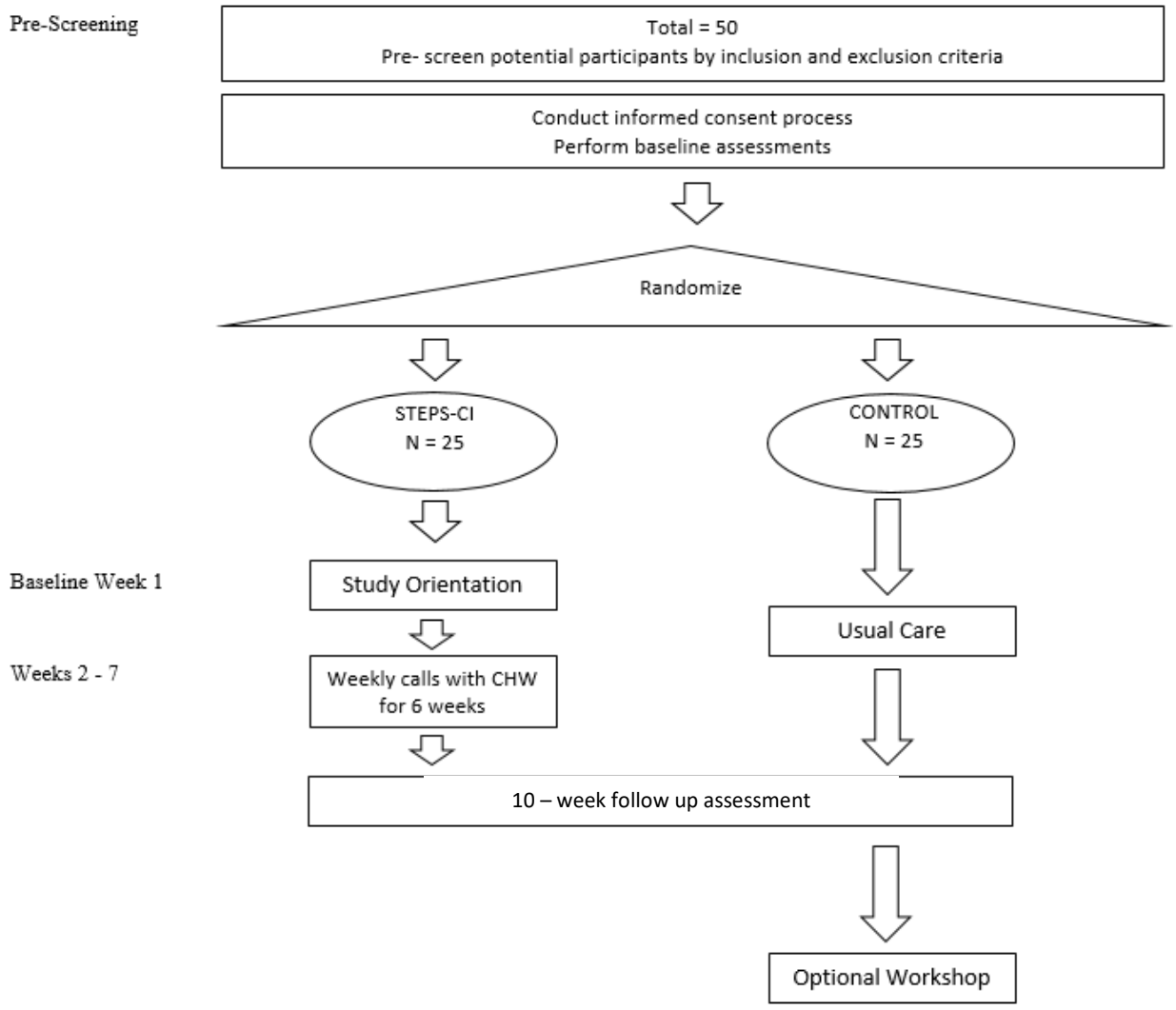
OBJECTIVES	ENDPOINTS	JUSTIFICATION FOR ENDPOINTS
Primary		
To determine if participating in the STEPS-CI intervention leads to decreased pain interference with daily functioning.	PROMIS Pain Interference 6a scale is the primary endpoint (assessed at baseline and 10 weeks from baseline). A 2.5 point difference 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 to gradually increase engagement in daily activities such as goal setting. It targets psychological mediators such as self-efficacy and fear of movement and behavioral mediators such as physical activity.
Secondary		
To determine if pain intensity shows greater improvement in intervention vs. control group.	The Pain Numerical Rating Scale (0 to 10) will be assessed at baseline and 10 weeks from baseline.	Although the intervention focuses on enhancing functioning rather than reducing pain per se, pain intensity may decrease as well, as seen in our pilot work.
To examine whether the intervention is associated with improvement in perceived cognitive functioning.	The 4-item PROMIS Cognitive Function-Abilities Short Form 4a V. 2.0 will be assessed at baseline and 10 weeks from baseline.	The STEPS-CI intervention encourages behaviors, including physical activity and relaxation, which may have a positive short-term impact on thinking and memory. Therefore, it has the potential to improve participants' perceptions of their cognitive functioning.

3 STUDY DESIGN

3.1 Study Design

- NIH Behavioral Intervention Stage 1 randomized pilot trial to examine the acceptability and preliminary effects of the STEPS-CI program on pain interference among older adults with chronic pain and mild to moderate cognitive impairment, 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 SELECTION AND ENROLLMENT OF PARTICIPANTS

Eligibility criteria are broad and self-reported, with few exclusions and no upper age limit, to maximize the relevance of this study to practice. Recruitment yield will be assessed and reasons for refusal, where participants are willing to provide this data, will be tracked. If telephone minutes are a barrier for some eligible participants, we will provide additional support on an individual basis, such as a prepaid phone or additional telephone minutes. We will also support participants in getting a government issued telephone (such as an Obama Phone) if they are eligible.

4.1 Inclusion Criteria

- Age ≥ 50 years;
- Have a cell or landline phone and internet access;
- Self-reported chronic musculoskeletal pain (pain in muscles or joints for > 3 months);
    - >1 day/previous 30 when pain made it difficult to do usual activities.
- Self-reported mild cognitive impairment (MCI)/ memory difficulties that at least sometimes interfere with usual daily activities
- Willingness to meet by phone or video with a community health worker to learn potentially new ways to manage pain and commit to the duration of the program
- Able to converse comfortably in English.

4.2 Exclusion Criteria

- Serious acute illness or hospitalization in last month; planned major surgery in next three months that would interfere with program participation (e.g., knee replacement)
- Other issues that are judged by study team to preclude meaningful participation in study procedures (e.g. severe physical, cognitive, or psychiatric disorder).
- Current or prior participation in the parent STEPS study or the RESET (Re-Engaging in Self-Care and Enjoying Today) Study.

4.3 Recruitment

We have two priority populations for this supplement study – older adults from underserved urban and rural communities – and a variety of planned strategies for recruitment, as detailed below:

Older adults in an underserved urban community: We will work with our parent study partners, Henry Ford Health, as well as the network of senior centers and senior housing facilities with which we have developed relationships over a number of years. We will use flyers, information sessions, and word of mouth. At information sessions we will collect names and contact information for any interested individuals; flyers will include contact information for the study team, including an email address and toll-free telephone number. We will also apply to use the Healthier Black Elders Center registry, housed at the Institute of Gerontology at Wayne State University, and send potential participants a letter introducing the study, followed by a phone call.

We have a list of potential participants who were screened but opted out of participating in the parent STEPS study because they felt that their memory problems would get in the way, and who agreed to be contacted for future research. We will call any of these participants who agreed to be contacted for future research and let them know that we have developed a new program that is tailored for individuals who have both chronic pain and cognitive impairment, and invite them to be screened.

We will also identify potential participants via the registry of more than 1300 older adults interested in research participation, maintained by the Healthier Black Elders Center at the Wayne State University Institute of Gerontology, which we have used successfully in multiple pilot studies. Individuals meeting the broad study criteria (age, pain-related condition such as osteoarthritis as well as "memory problems" or "Alzheimer's or other dementia") will be contacted by letter describing the study. This initial contact will be followed by a phone call to further assess eligibility, answer any questions, and to invite to participate, if appropriate.

Older adults residing in an underserved rural community: Consultant Joan Ilardo of Michigan State University will facilitate recruitment conducted in partnership with the Northeast Michigan Community Service Agency, which is in the Charlevoix and Alpena area and houses the Region 9 Area Agency on Aging. Recruitment will be done via flyers, mailings, and word of mouth, and will focus outreach initially on clients who are accessing resources and programs for caregivers. The role of this the Region 9 AAA will be to hand out our flyers, put a blurb in their newsletter, and share via their social media accounts (Facebook). They will be referring all interested people to the University of Michigan team for any questions and/or for screening.

Other potential recruitment methods: There are a number of additional recruitment mechanisms that we can use as needed. These include reaching out to members of the National Council of Dementia Minds, prioritizing those who reside in one of our geographic areas of focus (Detroit or Northern Michigan);

Recruiting participants via their family members/care partners: At community events or other locations where we might encounter people who are family members or care partners (i.e., caregivers) of individuals living with cognitive impairment and chronic pain, we will provide them with a piece of paper (not a sign-up sheet whether other names are visible, in order to ensure privacy) on which they can write the name and contact information of their potentially eligible family member. We will explain to the *referring person* that we will let the *person being referred* know how we got their name and from whom. A member of the study team will follow standard screening procedures to contact the prospective participant, which include explaining, in cases where a referral took place, who we got their name from.

For participants who contact the study for more information (includes those who send an email to us, provide their contact information using the Qualtrics survey that is linked to the QR code on the flyer, and those who phone into our study hotline and leave a message:

Study staff will call the potential participant and follow procedures for screening, consenting, and enrollment.

If they email and do not provide a phone number, we will send them the following email: Thank you for contacting the STEPS-CI team at the University of Michigan! We would love to contact you about the study and give you more information. Would you please share your telephone number and a good time to reach you? Or you can call us at our hotline number: 844-862-2737. Thank you again for your time and interest!

4.4 Informed Consent & Enrollment

All prospective participants will be assigned a study ID (unique participant identifier) for internal use. During recruitment contacts, whether they take place in person or via telephone, each patient will hear a brief description of the study before being asked if they wish to be screened for eligibility (see inclusion/exclusion criteria at the beginning of this section). 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. If the individual agrees to participate after hearing the program and study description, we will begin the informed consent process, as explained below.

Screening will take place over the phone, which will help protect privacy. It is possible, though unlikely, that we will screen someone on site at an information session rather than over the telephone. If this is the case, the screening will be done in a private area, away from others.

The intervention and control conditions will be described as follows. Individuals in the intervention group will meet with a community health worker for a remote study orientation session. At this session, they will be introduced to the program, learn how to use the online modules and choose a day and time for future weekly telephone sessions. The program is designed to be delivered over 7 weeks, but will allow for flexibility.

After completing the 10-week follow-up telephone survey, individuals in the control condition will be given access to all intervention materials and all other study materials and will be invited to attend a one-time remote session that summarizes intervention content and that will be led jointly by study staff and a community health worker.

Participants in both groups will be asked to complete two data collection telephone surveys (at baseline, and 10 weeks from baseline). The baseline survey is estimated to take 45-60 minutes, can be done over two phone calls if participants wish, and includes an online portion that participants will complete on their own (paper version available for those who can't do the online version); while the follow up survey is estimated to take about 30 minutes.

Family caregivers/care partners will be welcome to be present at each stage of consent and enrollment.

<u>Informed consent procedures:</u>
Given that all our participants will be living with some degree of cognitive impairment, our approach is to make the consent process interactive in a way that provides opportunities for the

individual with MCI/ADRD to demonstrate capacity to understand the study while not overwhelming them with information or adding undue burden to the consent process.

After completing the recruitment and screening procedures, eligible individuals who wish to participate will have the option to receive a mailed and/or emailed Consent Information Sheet (a simplified version modeled after the form for assent for minors) before the baseline survey appointment, typically scheduled for 1-2 weeks later.

The verbal consent process will take place prior to the baseline survey (both of these are by telephone). Study staff will review the main points of the Consent Information Sheet with a comprehensive oral script and schedule the baseline survey at the end of the consent call.

To assess understanding of details of the research, the study team will ask guiding questions during the consent process to ensure the participant understands what it means to give consent. While we will not use a formal tool to assess for decisional capacity, we will develop the guiding questions to be asked by study staff based on the University of California, San Diego Brief Assessment of Capacity to Consent (UBACC), and in consultation with the STEPS-CI Advisory Council. These questions will assess participants' understanding of the study, that participation is voluntary, possible risks and benefits, and participants' ability to withdraw at any time for any reason. "Teach-back" techniques such as these (e.g., "please tell me what your understanding is about what happens if you want to drop out of the study?") have been shown to enhance the informed consent process for people with cognitive deficits.

As this is a pilot trial in preparation for a potential larger clinical trial, we will also use our guiding questions to identify aspects of the protocol and expectations for participation that the prospective participant found unclear. Study staff will complete a form in REDCap following each consent process indicating any areas of potential confusion or other challenges, as well as facilitators to understanding.

Study staff conducting recruitment calls will be trained in good communication techniques when working with individuals with cognitive impairment.

If a participant does not seem to have capacity (i.e., they do not appropriately answer all the UBACC-derived items [e.g., he/she answers "*Do you have to be in this study if you do not want to participate?*" with "Yes"]), the study staff member will first try to correct the mistake and explain the section again. After another understanding check, if the participant still is unable to answer correctly, we will temporarily pause the intake process and ask the potential participant to continue at a later date and time. If, on a second occasion, problems with understanding are still observed, the staff member will consult with the MPIs and will call the potential participant back, if needed, to let the participant know that the study is not an appropriate fit for them.

In the beginning of the consent process, participants are asked if it is okay if we record the call (if no, we will continue without recording). If they are okay with the call being recorded, we will record only the verbal consent process, to ensure that the interviewer covers each section of the consent in detail and allows for questions, and to continue to refine best practices for obtaining consent from this population. All recordings will be done through UM Zoom/UM Zoom Phone. The recording files will be saved in access restricted folders and destroyed at the end of the study. All recruitment and consent data will be tracked in REDCap.

Throughout recruitment and consent processes, each patient will be encouraged to ask questions and will be reminded that even if they consent to be in the study, they are free to withdraw from it at any time.

Next steps after informed consent: Once patients have consented, they will be mailed a packet, which includes a brief welcome letter, a copy of the consent form for the participant to keep for their records, and the baseline survey scales to help them follow along during the telephone survey, as well as a paper copy of the QDRS as an option to doing the online version (they can complete it on paper on their own and share the responses with the staff person who conducts the baseline survey). Next, they will complete the telephone baseline survey. Next, they will be randomized to the intervention or control group per a computer-generated block randomization scheme. People who have been randomized to the intervention group will be scheduled into a study orientation session.

4.5 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) will *not be enrolled*, but instead classified as "screen failures."

4.6 Strategies for Recruitment and Retention

Recruitment: Recruitment strategies are described in 4.3 above.

Retention: We will followed 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 or email address, mail and/or email 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 originally scheduled date has passed.

- We will reschedule attendance at the orientation session (intervention participants only) a maximum of 4 times.

- All contact attempts will be documented in REDCap.

We will offer incentives for each data collection point ($40 each for baseline and follow-up surveys). All incentives are provided in the form of checks from the Human Subjects Incentive Program at the University of Michigan.

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

5 STUDY INTERVENTIONS

Participants will be randomized to one of two study arms in a 1:1 ratio: Arm 1 will receive the STEPS-CI intervention and Arm 2 will be the control group and will be waitlisted to receive a one-time STEPS-CI workshop and all intervention materials.

5.1 STEPS-CI Intervention Overview

The overall goal of this research is to develop a scalable intervention for enhancing chronic pain self-management skills among older adults with MCI/ADRD, delivered by community health workers and with educational content available via web-based videos. This intervention will be designed to be suitable for underrepresented (urban and rural) older adults, as the need for self-management support in these groups is greatest.

The CHW(s) who are delivering STEPS-CI will be employed and supervised by the University of Michigan.

5.2 STEPS-CI Intervention Process

Orientation session: Intervention participants will meet with a CHW for a 45-minute study orientation. Depending on participant needs, this can take place by telephone or virtually. This orientation session will be scheduled after the participant completes the baseline survey and is randomized into the intervention group. A CHW or research assistant will contact the participant to schedule the orientation session, based on their availability. Program materials will be mailed or delivered prior to the scheduled orientation. UM Zoom/UM Zoom Phone will be used for individual orientation sessions delivered via telephone or videoconference.

At this initial session, participants will learn how to use the online modules, and will choose a time for weekly telephone or video sessions with the CHW. A social needs assessment tool will be administered, which will include items about resources related to dementia and caregiving.

Subsequent sessions: Weekly half-hour telephone sessions will be conducted by CHWs. Between sessions, participants will watch brief videos, which will be tailored to the needs of people living with cognitive impairment and housed on the STEPS-CI website.

	Topic	Session Content and Activities

		NOTE: Most sessions will include a Wellness Goal, Try it Out (weekly skill), and Reminder Plan
0	Orientation Session	Welcome participants; goals of STEPS-CI and how the program will work Establish a comfortable/safe space, normalizing cognitive difficulties, promote self-compassion. Screening for resource needs-MCI/ADRD and caregiving
1	Rethinking Pain	Thoughts and activities can turn the pain dial up or down Pain and memory/thinking can also affect each other Set first Wellness Goal and establish a tailored reminder strategy
2	Move More, Live Better	Understand why moderate physical activity is helpful for both pain management and cognition. Benefits of walking and how setting goals can help gradually increase activity level. Balance and strength options in the Workout to Go booklet and other resources for increasing activity
3	Finding Your Calm	Understand the impact of stress on pain Mindfulness and relaxation techniques may also increase cognitive reserve Know a variety of relaxation techniques
4	Embracing Enjoyment	Chronic pain and cognitive impairment can prevent people doing things they enjoy. Why doing things that are enjoyable or meaningful helps with chronic pain and cognition. Benefits of music for pain and cognition. Identify an activity that is enjoyable or rewarding and that they would like to do more of
5	Rest and Refresh	Recognize that sleep difficulties are common among people with CI and pain Understand how a good night's sleep can help both conditions Know how to get better sleep through good sleep techniques
6	Moving Forward	Reflect on the program experience Think about which skills they would like to continue to use going forward. Set final goal and encourage to continue to set goals after program ends

5.3 Control Study Arm

After completing the 10-week follow-up telephone survey, individuals in the control condition will be given access to the online program and all other study materials and will be invited to attend a one-time remote session that summarizes intervention content and that will be led jointly by study staff and a community health worker.

5.4 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.

5.5 Study Intervention Adherence

Attendance of community health worker sessions will be the main mechanism of tracking adherence. Community health workers will also log information from participants about working towards their goals during their calls.

5.6 Concomitant Treatment

This study will not restrict participation in other types of treatments. However, participants in the STEPS-CI study will not be able to participate in our other R01 studies, including the parent STEPS study and the RESET (Re-Engaging in Self-Care and Enjoying Today) study- and vice-versa. These studies all have some overlapping eligibility criteria and intervention components. We will make this clear in the recruitment process.

5.7 Lifestyle Considerations

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

5.8 Intervention Discontinuation

A participant may be temporarily suspended from the study if they are too acutely ill to participate or have a drastic change in disease severity in which the physician on the study team (Dr. Maust) feels that they should not take part in the intervention. These instances will be recorded as protocol deviations and all participants will be contacted to determine if they can complete outcome assessments if possible.

5.9 Treatment Fidelity

5.9.1 Overall compliance

Compliance will be recorded as the number of sessions completed by the participants in the STEPS-CI program. The duration of calls will also be recorded.

5.9.2 Community Health Worker Training and Tracking

CHWs hired to deliver STEPS-CI will have completed the Michigan Community Health Worker Alliance (MiCHWA) CHW Certification Training (a 126 hour training that covers topics such as motivational interviewing, navigating community resources, and healthy lifestyles). STEPS-CI training will take place over 4-5 days and will be led by the study team. Training content will be adapted from the parent study training curriculum. We use an active learning approach, with an emphasis on roleplay with feedback. We will focus on how to interact with older adults with MCI/ADRD, as well as knowing when to consult with a supervisor and the study team. CHWs will also complete prerecorded educational offerings from the Alzheimer's Association Michigan Chapter, including Understanding Alzheimer's and Dementia; Living with Alzheimer's, Early Stage and Middle Stage versions; and Effective Communication Strategies, with debrief discussions afterwards.

We will use quality control strategies used in the parent study. CHWs will record each telephone session using a HIPPAA-compliant system and use REDCap during the sessions to check off each element as they complete it, and to record information such as weekly goals. This process helps ensure that all core topics are covered. Study staff will evaluate recordings, using structured fidelity rating forms, on the following schedule: all program sessions for the first two intervention series per CHW; and thereafter a random 20% subsample of sessions. CHWs will meet regularly with the MPIs and study staff to reinforce training principles, discuss specific cases, and obtain feedback to reduce drift from protocols.

5.10 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 10 week follow-up assessment as possible. Participants need to complete the assessment within one month of their scheduled 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 next scheduled assessment window(s).
- 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.

5.11 Lost to Follow-up

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

6 STUDY PROCEDURES

6.1 Schedule of Activities (for individual study participants)

Activity	Weeks										
	0	1	2	3	4	5	6	7	8	9	10
Eligibility Screening	X										
Consent Process	X										
Chronic conditions and overall health	X										
Quick Dementia Rating System (QDRS)	X										
Pain Catastrophizing Scale	X										X
Pain Medication Use	X										
PROMIS-29+2 PROMIS Applied Cognition 4a Short Form	X										X
Demographics	X										
Global impression of change in pain, functioning, quality of life, use of pain medication											X
STEPS-CI Evaluation Questions (intervention group)											X
CHW sessions (intervention group only)		X	X	X	X	X	X	X	X	X	
Qualitative interviews (with care partners)											X

Notes:

- Shaded rows represent measures on the telephone data collection surveys (at baseline and 10 weeks).
- We will ask participants to complete the QDRS in advance of the baseline survey. They will be given the option to complete it via REDCap electronic survey or on paper. If they choose paper, during the telephone interview, the interviewer will ask them what their response is for each item, after confirming that they have already completed the paper survey. Participants will be encouraged to complete the QDRS survey with a care partner, if available.
- Participants will be asked if they would like to complete the baseline over two phone calls, to make it less tiring/burdensome.
- Allowable assessment windows: Participants need to complete the assessment within one month of the follow-up date in order to be counted as non-missing.
- If participant does not start intervention within one month of baseline assessment, then we will re-baseline them (if time allows in the study period; otherwise participant may be withdrawn from study), for primary and secondary outcomes only, before starting the intervention and base follow up windows on the second baseline assessment. Delays in starting the intervention may be due to family situations, illnesses, difficult to reach participants, work obligations, etc.
- While the intervention is expected to take place over 7 weekly sessions, by offering a 10-week window in which to complete sessions, we have built in flexibility to reschedule missed sessions.
- PROMIS Pain Interference (6-item scale) and Cognitive Function & Abilities are each asked twice in the baseline survey in order to estimate test-retest reliability.

6.2 Description of Activities

- *Data collection surveys* – participants will complete the validated measures tested as outcomes listed above as well as other measures to help characterize health and functional status, cognition, quality of life, and satisfaction with the intervention. These will primarily take place by telephone but the baseline survey has one scale, the Quick Dementia Rating System (QDRS), which we will ask participants to complete online, if possible; and if not, to complete on paper prior to the survey and answers will be read out loud to the interviewer. Participants will be encouraged to fill out the QDRS with a caregiver.
- *Randomization* – will occur only after a participant's baseline outcome assessment is completed. Once complete, a randomized study schedule with mixed blocks will be used to determine group assignment.
- *STEPS-CI Program (Intervention)* – described in 5.2 above.
- *Qualitative interviews with caregivers/supporters* We will invite any family caregiver/supporter who has been present with the participant during at least some intervention activities to give us their feedback on the program in the form of a 30-minute in-depth interview, conducted by a staff member over the phone. **NOTE: We will seek approval for this particular study activity in a separate, linked IRB application or amendment to this one.**

7 SAFETY

7.1 Potential Risks & Benefits

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

Below we list the potential 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 surveys or telephone sessions.
2. Breach of confidentiality during study activities (FREQUENCY: rare, SERIOUSNESS: Mild).

3. Risk of forced disclosure by entities outside of the research team (FREQUENCY: Rare, SERIOUSNESS: Mild). The study has a Certificate of Confidentiality (CoC), formal confidentiality protection, authorized by the Public Health Service Act (PHSA) section 301(d) (42 U.S.C § 241(d)) to protect the privacy of human research participants enrolled in the study by withholding identifying characteristics from those not connected to the research. As a result, the study team may not be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to identify participants.

Note: We do not anticipate elevated risk of injury or other adverse health events due to the moderate weekly increases in low-to medium intensity physical activity that participants will be encouraged to do.

Potential Benefits: The intervention incorporates evidence-based strategies for encouraging positive health behaviors that may improve functioning and quality of life.

7.2 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 below.

7.3 Definitions for Events

This study will use standard definitions of AEs/SAEs/ORIOs 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 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.
- **ORIO** – Other reportable incidents or occurrences describe a myriad of events that can have a direct effect on a participant safety and/or data integrity. Typical ORIOs include protocol deviations (see more information in 8.4), participant complaints, and incidents involving participants, their data or research facilities (e.g. breach of confidentiality, administering an incorrect version of a survey or consent, etc.)

7.4 Classification of Adverse Events

7.4.1 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

7.4.2 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

7.4.3 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 behavioral intervention study, 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 the follow-up survey at 10 weeks from baseline; community health workers may also 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.

7.4.5 Process for reporting AEs and SAEs

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. After reporting to the UM IRB-HSBS, the PI in conjunction with other investigative team members will determine necessity for further reporting and next steps, which will include the following:

- No further reporting of a "definitely not related" AE (but not SAE) will occur.
- All deaths will be reported to the UM IRB-HSBS within 24 hours of learning about this event.
- All adverse events that are both serious (SAE) and unexpected (i.e., have not been previously reported for the study's intervention) will be reported to the UM IRB-HSBS within 48 hours of the study's knowledge of the SAE. (All deaths within 24 hours, as per above.)
- The summary of all SAEs will be reported to NIH Program Officer quarterly.

N**o 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, which is chronic musculoskeletal pain). At the same time, it is certainly possible, based on the high morbidity and multimorbidity of this population (i.e., adults who are 50+ years of age, with chronic pain and MCI/ADRD, and most of whom will be from underserved and/or marginalized populations), that there will be one or more hospitalizations and/or other moderate to severe illness-related events during the study period that are 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

8 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 prior to beginning data collection. Additionally, we will develop a detailed manual of procedures, case report forms and other related study materials. The manual of procedures 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

- Weekly or biweekly team meetings with all core study staff present, at which we will review enrollment and retention, participant safety, protocol adherence, completeness and integrity of data collection, and any problems encountered.

- The investigative team will meet on a regular basis and the PI and project staff will provide study updates including data and safety issues listed above.

8.3 Auditing

- Quality Control for Telephone Surveys: We will check a random 10% of all data from telephone surveys input into REDCap by listening to audio recordings of the surveys 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 survey items or entire surveys. Participants can decline to answer any survey question for any reason.
- 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.

Reportable protocol deviations will be reviewed at the project staff and investigator meetings, and summarized in the DSMB or ISM report that will be submitted to the U-M IRB--HSBS and NIH at annual review (coinciding with the scheduled continuing review) and in other DSMB or ISM reports (if applicable).

9 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 survey.

Email 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 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 for Social and Behavioral Research. 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.

For all interactions taking place over phone or video link, we will use UM Zoom or Zoom Phone to audio record calls and sessions for quality assurance. Audio recordings will be stored in UMDropbox. Zoom and Zoom Phone are HIPAA-compliant and supported by the University of Michigan.

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.

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

Qualitative interview data

All audio files and transcripts associated with the qualitative interviews with caregivers will be stored in UM Dropbox, a HIPAA compliant cloud file storage system). No names or other identifying information will be included in transcripts, and thus no information will be included in any published or unpublished reports using interview data that could be used to identify any participant.

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.

10 STATISTICAL CONSIDERATIONS

10.1 Sample Size

This is a NIH Behavioral Intervention Stage 1 pilot trial. As such, our objective for statistical analysis is to look for a pattern of results suggesting the promise of the adapted "STEPS-CI" intervention. This study, with an n of 50, is not powered to determine the statistical significance of effects.

10.2 Data Analyses

10.2.1 General Approach

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. Descriptive statistics will be used to summarize background variables for the overall sample and by treatment group. 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 evaluate normality using normal quantile plots and standard tests of normality incorporated in basic statistical packages, including SPSS and SAS.

10.2.2 Primary & Secondary Endpoints

We will collect outcome data at two time points: baseline and 10 weeks from baseline (post-program, for those in the intervention group). We will convert the PROMIS outcomes (6-item Pain Interference and 4-item Cognitive Abilities) 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 on primary and secondary outcomes, 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 10-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 of $\geq$ 3 T-score points in PROMIS pain interference.

We will also assess the moderating effect of selected variables such as sex, age, level of cognitive impairment, program engagement and rural vs. urban location. Moderation analyses will use standard approaches to evaluate interactions between these covariates and treatment group.

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

10.2.3 Qualitative Data Analyses

Interviews with family care partners and other open-ended data from study processes (e.g., CHW case notes about success and challenges in each session) will be transcribed, or detailed notes compiled, as appropriate, and reviewed and coded for salient themes by two independent analysts. Following NIH/OBSSR guidelines for mixed method research, the themes identified in this analysis will inform program modifications prior to a subsequent NIH Behavioral Stage 3 trial of the program. Qualitative findings will also shed light on quantitative results from this pilot study, including program engagement/acceptability and outcomes.

11 INTERIM ANALYSIS

No interim analysis is planned, due to the fact that this is a small pilot study of a behavioral intervention with minimal risk; and because this is a feasibility and not an efficacy trial.

12 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.

13 PROTOCOL AMENDMENT HISTORY

See cover page.

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Community partners will also use email messages to inform their clients of the STEPS-CI study. Interested individuals will be given the study team hotline number so they can contact the study team about next steps for participation (see Section 4.3 Recruitment).

We will conduct a one-on-one telephone check-in with STEPS-CI advisory council members to assess their experience on the advisory council and for feedback on how to improve the experience of council members. The telephone check-in will be 15-20 minutes, and advisory council members will receive a $20 check in the mail as an incentive. A study team member will email the advisory council members to see if they are interested in participating; council members can opt out if they prefer not to do the check-in. For those that would like to do the check-in, study team members will schedule a day/time with each council member. Prior to the check-in, there will be a short verbal consent process. We will audio record the check-in (using UM Zoom Phone), if the council member agrees to be audio recorded. The study team member will also take written notes during and after the check-in to document their ideas and feedback.

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Per the STEPS-CI ORCR audit, we are removing the ICH GCP language as we were told that it does not apply to our study.