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Document: Study Protocol

Study Title: An Efficacy Trial of Community Health Worker-Delivered Chronic Pain Self-Management Support for Vulnerable Older Adults

Document Date: 8/30/2024

NCT Number: NCT05278234

An Efficacy Trial of Community Health Worker-Delivered Chronic Pain Self-Management Support for Vulnerable Older Adults

STEPS RCT

National Clinical Trial Number (clinicaltrials.gov): NCT05278234

Principal Investigator:

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

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Summary of Changes from Previous Version:

Revision	Affected Section(s)	Summary of Revisions Made	Rationale
2	**1.4**	Added breach of confidentiality to risks	Per IRB pre-review request
2.1	**9**	Clarified which PEERRS training	Per IRB pre-review request
2.1	**4.4**	Added description of how verbal consent is documented	Per IRB pre-review request
2.2	**1.4.1, 4.4**	Will send Detroit Resource List to all participants along with copy of consent form.	IRB post-review request

3	**2.1, 4, 4.3, 5.2, 5.2.2, 6.1, 9**	Added language about possible discomfort due to activity tracker (2.1), Added language describing additional resources to address participant barriers to study participation (4); updated informed consent options (4.4); activity tracker changed to Wyze Watch (5.2); added detail to describe intervention completion (5.2.2), Study Activity table updated to reflect changes in study measures and baseline assessment procedures for delayed participation in the intervention (6.1) Updated references for measures; updated internet platforms/electronic security (9) fixed section numbers to match with table (Sections 7 – 14)	These changes will improve the study design, including the recruitment strategies. Details were also added to clarify study activities and procedures.
4	**5.2**	Updated study orientation length (5.2)	Participants typically spend more time with CHWs during the orientation because they're spending more time connecting and sharing about themselves and/or needing a bit more support with the website and activity tracker. We updated this in the protocol to be more accurate.
5	**1.4.1.**	Following an AE (Adv00050649) in which a participant reported a muscle pull from exceeding her walking goal, we are adding muscle strain as a risk to study documents including consent forms.	Per IRB request
6	**10.2.2**	Added language to allow 2-month surveys to be completed prior to last intervention session, if needed.	Some participants may need additional flexibility for scheduling the 2-month survey to ensure it is within the assessment windows.
7	**4.6, 6.2**	Added checks as the default incentive options. Gift cards will remain as an alternative for participants who are not able to use checks.	Participants have had issues with the HSIP gift cards that result in difficulty using the gift cards.

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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:	An Efficacy Trial of Community Health Worker-Delivered Chronic Pain Self-Management Support for Vulnerable Older Adults
Study Description:	The purpose of this study is to test the efficacy of the STEPS (Seniors using Technology to Engage in Pain Self-management) intervention. We hypothesize that participants in the STEPS intervention, compared to a randomized control group, will have greater improvements in pain interference and pain intensity, and a more positive Global Impression of Change immediately following the intervention and at 12 months from baseline.
Objectives*:	Primary Objective: To test the efficacy of the STEPS intervention compared to a waitlist control condition. Secondary Objective: To examine the mechanisms of action of the STEPS intervention and to identify factors affecting engagement and program implementation.
Endpoints*:	Primary Endpoint: Improvement in pain interference at Months 2 (post-program) and 12 Secondary Endpoints: pain intensity, Global Impression of Change at Months 2 and 12
Study Population:	We will recruit 414 adults from the Detroit community, age 50+ years who report chronic musculoskeletal pain of at least 3 months' duration.
Phase* or Stage:	NIH Behavioral Intervention Stage III
Description of Sites/Facilities Enrolling Participants:	Participants (N = 414) will be primarily recruited through the Henry Ford Health System and community locations in Detroit.
Description of Study Intervention/Experimental Manipulation:	STEPS is a community health worker (CHW)-led chronic pain self-management program designed for older adults living in underserved communities. It is a 7-week intervention that includes three primary components: a website that includes brief instructional videos for 6 weekly modules; weekly telephone calls with a CHW to support application of the content in a given module by reinforce key points, help participants practice new skills, discuss adaptations needed for a participant's situation, and set a related goal. CHWs will also screen for social needs that could be addressed with appropriate community referrals; e.g. utility or insurance issues. Participants will set goals each week related to walking (step counts), using step-count data from the physical activity. Participants will also be given a wearable physical activity tracker at the orientation session to use throughout the course of the program track daily step counts by replying to an automated text each evening.
Study Duration*:	5 years
Participant Duration:	One year

1 RATIONALE & BACKGROUND

1.1 Study Rationale

Our overall objective in this efficacy trial is to determine if an intervention developed and pilot-tested by our team (STEPS, or Seniors using Technology to Engage in Pain Self-management),[1] which is delivered by CHWs with support from mobile health tools, can improve outcomes among older adults with musculoskeletal pain. Older adults in disadvantaged urban communities such as Detroit, Michigan, the study's setting, face a barrage of psychosocial and environmental stressors that contribute to high levels of chronic pain-related disability. Older adults of color are especially at risk due to the health-damaging effects of structural racism, and many vulnerable older adults lack opportunities to learn cognitive-behavioral skills that can improve pain and functioning, and that – unlike medications – are virtually risk-free. Most CPSM interventions are group-based and face-to-face, making them hard to access for older adults with transportation or mobility challenges. Moreover, existing interventions do not address the social determinants of health (SDOH; e.g., housing issues) stemming from structural inequities, which strongly affect pain and its management. Thus, current CPSM programs fail to meet the needs of precisely those older adults who could most benefit from them. One novel way to bridge this gap is to enlist community health workers (CHWs) – frontline, lay public health workers with close ties to the communities they serve – to deliver telephone-based CPSM support that also addresses SDOH.

1.2 Background

Chronic pain is a significant, modifiable factor affecting older adults' ability to remain independent in their daily lives. Evidence-based cognitive and behavioral self-management strategies can help patients with chronic pain improve daily functioning and quality of life, while avoiding risks associated with opioids and other pharmacological treatments. Unfortunately, few chronic pain patients are offered structured opportunities to learn and practice self-management skills. The 2016 National Pain Strategy[2] calls for expanding access to chronic pain self-management (CPSM) support, and the Federal Pain Research Strategy designates research on sustainable CPSM delivery models as a "Top Priority"[3]). These federal documents shaping current directions in pain research also highlight the need to address population disparities in pain and pain treatment. Such disparities are amply documented in the literature. For example, African American adults and people of low socioeconomic status (SES) regardless of race have greater chronic pain severity and pain-related disability compared to their White and higher-SES counterparts, while having inferior access to high-quality pain treatment.[4-6] [7,8]

One untested but promising approach to providing CPSM support to underserved populations is through community health workers (CHWs). CHWs are non-professionals who have formal but limited training for specific health care-related tasks.[9] [10] Typically, CHWs are members of the communities they serve. They therefore enjoy a high level of client trust and deliver culturally appropriate, patient-centered services, such as supporting health behavior change, addressing social determinants of health, and providing linkages to formal health care services. This study will assess the efficacy of engaging CHWs to deliver chronic pain self-management support to underserved older adults.

1.3 Specific Aims

Aim 1: Conduct a randomized controlled trial to assess the effects of a CHW-led chronic pain self-management intervention among 414 primarily African American older adults. We will enroll adults aged ≥50 years, given accelerated aging in African American adults due to the health effects of structural racism.

H1: Intervention participants will have lower Pain Interference (primary outcome) compared to a usual-care control group at Months 2 (immediately post-program) and 12. **H2:** Compared to controls, the intervention group will have lower pain intensity and more positive Global Impression of Change (secondary outcomes).

Aim 2: Assess potential mediators and moderators of intervention effects.

H3: Intervention effects will be mediated by psychological changes (e.g., increased self-efficacy for managing pain) and behaviors (e.g., increased physical activity, addressing SDOH). **H4:** Intervention effects will be moderated by age, sex, baseline pain interference, and therapeutic alliance with the CHW.

Aim 3: Collect qualitative data from participants, CHWs, and other stakeholders to uncover subjective mechanisms of action, and factors affecting engagement and program implementation. This will provide context for quantitative findings and inform a toolkit for dissemination, if STEPS is successful. Otherwise, findings will inform a modified approach to providing CPSM support to this population for further testing.

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 telephone data collection (or telephone intervention sessions, for Intervention arm participants). If that occurs, study staff or community health workers will terminate the interaction (if deemed necessary) and/or offer psychological resources to the participant(s). We have an updated list of Detroit-area resources for psychological support, which will be provided to all participants (mailed or emailed along with a copy of their consent form). Participants will be informed as part of their informed consent process and immediately prior to each telephone interview 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 calling 911 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.

A final risk is discomfort or skin irritation from the activity tracker wristbands. If this is reported by a participant, study staff will work with that participant to find a more comfortable option for wearing the tracker.

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. 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 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 may benefit physical and/or mental health and functioning, as it incorporates evidence-based psychological principles to support self-management of chronic pain. The waitlist control group design, in which control group members will have the option of participating in a version of the intervention following the final data collection point and will receive all intervention materials, means that all participants will have access to key elements of intervention content.

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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 intervention 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

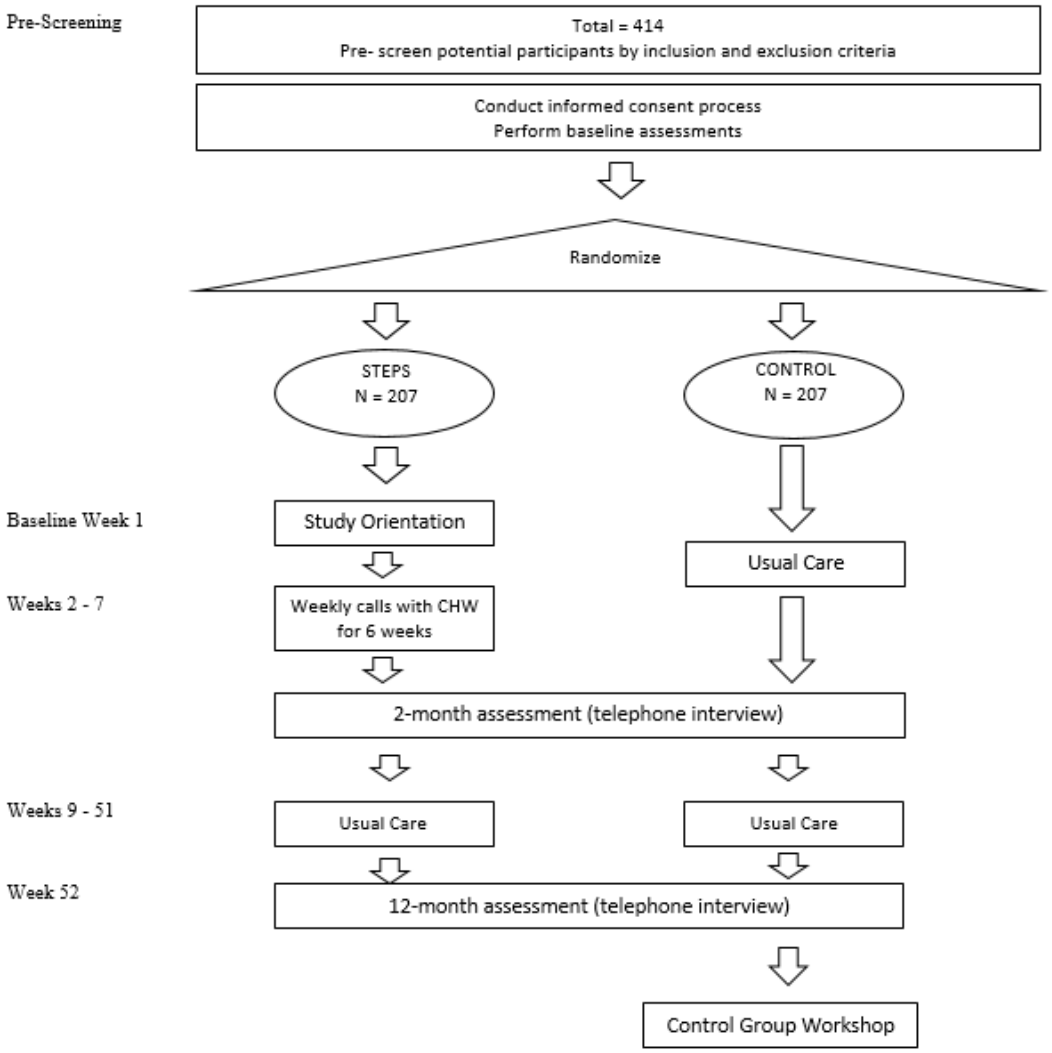
OBJECTIVES	ENDPOINTS	JUSTIFICATION FOR ENDPOINTS
Primary		
To determine if participating in the STEPS intervention leads to decreased pain interference with daily functioning.	PROMIS Pain Interference 6a scale is the primary endpoint (pain interference is assessed at baseline, 2 months (post-program) and 12 months. 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 and perceived change in pain and functioning show greater improvement in intervention vs. control group.	The Pain Numerical Rating Scale (0 to 10) will be given at baseline, 2, and 12 months. Patient Global Perception of Change since baseline will be assessed at 2 and 12 months. Participants will be asked about pain and functioning in separate items.	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. "Global impression of change" variables capture participants' subjective perceptions of intervention benefit.
Tertiary/Exploratory		
To examine whether the intervention is associated with reduced opioid and non-opioid pain medication use.	The Quantitative Analgesic Questionnaire (QAQ) quantifies the pain medication regimen for both prescription and OTC medications, yielding an opioid score, non-opioid score, and total QAQ score.[11]	The STEPS intervention has the potential to decrease reliance on pain medications, if participants are able to derive benefit from non-pharmacological self-management strategies. In pilot work, a substantial number of STEPS participants reported taking less pain medication following the intervention.

3 STUDY DESIGN

3.1 Study Design

- NIH Behavioral Intervention Stage 3 randomized controlled trial to examine the efficacy of the STEPS program in decreasing pain interference among older adults with chronic pain, compared to a waitlist 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 with few exclusions and no upper age limit, in response to recent calls for heterogeneity in clinical trials with older adults and to maximize the relevance of this study to practice. Recruitment yield will be assessed and reasons for refusal will be tracked. Nearly all potential participants in our pilot studies had some form of internet access, but we will not make this a requirement. For the expected small number of participants without access, we will lend them inexpensive tablets pre-loaded with STEPS website content. 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

Participants will be eligible if they:

- Are 50+ years of age
- Community-living
- Have self-reported pain in muscles or joints for $\geq$3 months,
- Report $\geq$4 (0-10 scale) mean pain intensity over last week, $\geq$1 day in past month when pain made it difficult to do usual activities,
- Have a cell or landline phone.
- 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 preclude meaningful participation in study procedures (e.g. severe physical, cognitive, or psychiatric disorder).

4.3 Recruitment

Clinic-based recruitment: In Henry Ford Health System's five Detroit-based Medical Centers, we will recruit via CHW tabling in waiting rooms. The study will also be featured in the CHW Hub quarterly newsletter distributed to HFHS departments and community partners. We will also discuss the study through other departmental meetings such as the monthly CHW Hub meeting, which will allow CHWs from across the system to gain knowledge of the program and refer patients who may be interested.

Community-based recruitment: Flyers will be displayed at community locations in Detroit serving older adults, with or without an accompanying information session by study staff and/or CHWs. Interested participants will be screened on-site or can later call the study hotline.

Healthier Black Elders Center Participant Resource Pool: Individuals meeting broad study criteria (age, diagnosis of musculoskeletal pain condition) will be initially contacted by mail and

given the opportunity to opt out of further contact via the study hotline. Those not opting out will receive a call from study staff.

4.4 Informed Consent & Enrollment

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. Interested individuals will be screened by study staff on site or by telephone to further assess eligibility and invite to participate, if appropriate.

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 at an in-person study orientation session at the participant's home, a HFHS site, or another mutually agreed-on location (or remotely if it is needed due to social distancing). 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 will be delivered over 7 weeks. They will be told that they will be given a wearable physical activity tracker at the orientation session to use throughout the course of the program and keep after the study ends.

After completing the one-year telephone survey, individuals in the control group will be given access to the online program, a wearable physical activity tracker to keep, and will be invited to a one-time in-person (or remote) workshop that includes key intervention content and personalized goal-setting support, and that will be led jointly by study staff and a community health worker.

Participants in both groups will be asked to complete three data collection telephone interviews (at baseline, two months from baseline, and one year from baseline), each of approximately 45 minutes in length. Participants in both groups will also receive a "Welcome to STEPS" kit that includes inexpensive study-themed items to enhance a feeling of belonging to the study.

Informed consent procedures: If the individual expresses interest in participating after hearing the above description, they will be asked to verbally consent over the phone. 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 to them afterward. Consent documents that are mailed or emailed to participants will also include a community/psychological resource list. 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 and securely store the audiofiles. 2) We write their full name, the date, and the interviewer's initials to document that verbal consent was attained and securely store these documents. 3) We will also indicate in REDCap that verbal consent was provided and document the date.

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. For those potential participants who cannot be reached via phone or who say that they did not receive the consent form, a duplicate consent form and reminder letter will be sent.

In some cases, study staff may go through the consent process with a prospective participant in-person (e.g., at an information session). In these cases, they will go through the consent form in detail with the participant and written informed consent will be obtained, and the participant will be given a copy of the consent form for their records.

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

Once patients have completed the baseline interview, and scheduled for their 8-week follow-up interview, randomization will occur to intervention or control groups per a computer-generated block randomization scheme. People who have been randomized to the intervention group will be scheduled into a study orientation session (in person or remote).

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

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, discovery that diagnoses are not consistent with study criteria, etc.) will *not be enrolled*, but instead classified as "screen failures."

4.6 Strategies for Recruitment and Retention

Recruitment: If we are not meeting recruitment goals via the three strategies listed in section 4.3, we will widen community outreach, increase presence in clinics at Henry Ford Health System and consider additional strategies such as social media.

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, 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 two-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. All incentives are provided in the form of gift cards from the Human Subjects Incentive Program at the University of Michigan.

In the STEPS 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. Although not anticipated, if the CHW and participant are not a good match, we will assign a different CHW.

In the control group throughout the one-year period, and in the intervention group following the conclusion of the STEPS intervention, we will encourage retention with such strategies as sending newsletters with study trinkets included (e.g., water bottles), providing incentives for telephone interview completion, and reminding control participants that they will receive a version of the intervention and an activity tracker after the final data collection point.

5 STUDY INTERVENTIONS

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

5.1 STEPS Intervention Overview

This study's overall premise is that community health workers (CHWs) – frontline public health workers with close ties to the communities they serve – can effectively teach cognitive and behavioral pain-management strategies to older adults in a disadvantaged urban setting, with support from mobile health tools. According to the biopsychosocial model of chronic pain, a complex interplay of biological, psychological, and social factors shape the pain experience, including pain-related disability and distress. Chronic pain self-management (CPSM) programs such as STEPS are grounded in this model, and have the overarching goal of reducing pain's interference with daily functioning. Used alone or as an adjunct to medication as part of a multimodal treatment plan, these programs teach cognitive strategies (e.g., distraction) and

behavioral strategies (e.g., relaxation, behavioral activation) derived from cognitive behavioral therapy (CBT) for pain. They also teach progressive physical activity and goal-setting.

STEPS participants will learn evidence-based cognitive-behavioral strategies from short web-based videos featuring University of Michigan experts. Videos can be easily accessed on a mobile device. A literacy-adapted participant workbook will reinforce video content and provide worksheets. Participants will be given an electronic activity tracker to facilitate gradual increase of physical activity. In weekly telephone calls, CHWs will motivate participants and guide them in applying new skills through structured discussions and goal setting. CHWs will draw on their deep knowledge of the Detroit community to connect participants with resources needed to address SDOH and other barriers to pain management (e.g., finding safe places to walk). We will measure pain-related outcomes and hypothesized mediators via self-report assessments at baseline, two months (post-program) and one year from baseline.

5.2 STEPS Intervention Process

Orientation session: Intervention participants will meet with a CHW for a study orientation. The study orientation will be about 1.5 hours for most participants to complete. Depending on participant needs and social distancing guidelines, this can take place at the participant's home, an HFHS site, another community location, 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. If the participant chooses to do the orientation session over the telephone or virtually (via videoconference), program materials will be mailed or delivered prior to the scheduled orientation. Dialpad or UM Zoom/UM Zoom Phone will be used for individual orientation sessions delivered via telephone or videoconference (see page 26 for more details about Dialpad).

At this initial session, participants will learn how to use the online modules, will choose a time for weekly telephone sessions with the CHW, and will be given a wearable activity tracker, also suitable for wheelchair users. Participants can log daily steps by replying to a text each evening or (in the few cases where this will not be feasible) on a worksheet. If the participant must use a worksheet, a CHW or study staff will check in with the participant individually each week, via telephone, to record the daily step counts for that week. They will use the activity tracker throughout the course of the program and keep after the study ends. Via videos and discussion with the CHW, they will receive basic pain psychoeducation; e.g., how symptoms interfere with function, and how feelings and behaviors affect pain. They will be introduced to SMART goal-setting. The HFHS social needs assessment tool will be administered.

Subsequent sessions: Weekly half-hour telephone sessions will be conducted by CHWs. Between sessions, participants will watch brief videos housed on the website, which incorporate familiar and cultural references and feature experts who are diverse in terms of race/ethnicity. (See Table below for details about each session.)

CHW role: CHWs will reinforce important points of that week's topic, help participants practice new skills, discuss adaptations needed for a participant's situation, and set a related goal.

Participants will set incremental (e.g., 10% more than a typical day) step-count goals each week. CHWs will provide basic technical support to participants for problems that arise with the STEPS website or activity trackers; anything they can't resolve will be referred to research staff.

STEPS Intervention Content by Week	
CHW role: All sessions will hav the same structure: 1) Recap key video points; 2) Structured discussion about video topic; 3) Try It Out activity for that week's skill; 4) Goal setting and progress; 5) Review step count goal; 6) Closing and reminders	
Week 1 (Orientation): Understanding Chronic Pain • How body and brain process pain signals • Holistic approach to managing pain signals and maintain quality of life	• Ensure participants have access to videos, activity trackers, program materials • Administer SDOH screener and provide resources • Introduce goal setting and active goals
Week 2: Staying Active • How physical activity helps manage pain and fatigue • Strategies for incorporating physical activity into daily routine • Using step counts to maintain/increase physical activity	• Explore opportunities for physical activity and resources • Problem solve barriers and challenges
Week 3: Relaxing and Reducing Stress • Explore how stress and pain are linked • Learn about the relaxation response and how relaxation help symptoms	• Introduce relaxation techniques (such as deep breathing) • Identify major stressors and review problem-solving steps (if needed)
Week 4: Getting a Good Night's Sleep • How pain impact sleep and vice versa • Learn strategies to get more restful sleep	• Identify any barriers to restful sleep and problem solve • Explore better sleep strategies to try out
Week 5: Partnering with Your Provider • How to get the most out of healthcare visits and planning for visits	• Explore barriers and challenges to getting healthcare and provide resources/referrals • Introduce the appointment preparation worksheet
Week 6: Doing What You Love • Exploring the importance of making time for wellbeing and self-growth	• Identify ways to incorporate pleasant activities into daily life • Explore opportunities available in the Detroit community
Week 7: Moving Forward • Review of sessions and strategies presented • Planning for long term goals	• Celebrate successes and progress • Identify helpful resources moving forward

Cognitive-behavioral content: Core topics are goal-setting, progressive exercise, communication with health care providers, sleep hygiene, pleasant activity scheduling, relaxation, problem solving, and a wrap-up session that focuses on skills maintenance.

Addressing social determinants of health (SDOH): CHWs will assess needs around SDOH via an approved HFHS screening tool. This tool covers domains such as housing, insurance, utilities, food and transportation. In conjunction with HFH, we have developed a list of resources to address the problems elicited by the tool. Additionally, to address other challenges as they come up during sessions, CHWs are trained in an easy-to-use problem-solving process adapted from a

lay-led mental health intervention for low- and middle-income countries.[12] Serving as a "bridge" between communities and formal services is a core CHW competency.[13]

Activity tracker component: The commercially-available Wyze Watch tracker (or near equivalent) activity tracker, can be worn on the wrist. While the device has the capability of being linked to an app compatible with most smartphones, we will not be using this app as part of the intervention. Instead, participants will use the device more like a standard pedometer for the purposes of the intervention, though they are free to use other features including the app, on their own.

Participants will be instructed to wear their tracker during waking hours, except showering, bathing, or swimming, every day throughout the intervention period. At any time if the participant has questions regarding the use of the tracker, a study staff member can be contacted by phone to assist. Participants will track their step counts in one of two ways, depending on preference:

Report by text: Participants will be asked to use the display on their tracker to view and then manually input daily step counts via daily SMS messages they will receive at evening times convenient to them. A second text will be sent one hour later if there is no response to the first.

Record on paper: Alternatively, participants who do not wish to send a text will simply receive a text reminder each evening and will record that day's step count on a form provided to them in the Participant Workbook.

We will have a limited number of trackers to replace those that are lost or damaged. If those replacement trackers run out, participants who lose or damage their device will not be able to get a new one. No participant will receive more than one replacement tracker. All of this will be explained in the consent form.

5.3 Control Study Arm

Participants assigned to the control condition will be administered the baseline, post-program (2 months), and one-year follow-up surveys. After that, they will be given full access to the online program, a wearable physical activity tracker to use and keep, and will be invited to attend a half-day small-group workshop that covers key intervention content and provides individual goal-setting guidance. The session will be led by study staff and a community health worker. In-home or telephone-based sessions will be offered if social distancing is required or there are other significant barriers to in-person attendance.

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 participant reports about working towards their goals during their calls. Adherence to step-count reporting will also be tracked.

5.6 Concomitant Treatment

This study will not restrict participation in other types of treatments. However, participants in the STEPS study will not be able to participate in our other R01 study, Re-Engaging in Self-Care and Enjoying Today (RESET), and vice versa. These two studies are recruiting from the same population and have some overlapping 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. Wisdom) 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 telephone sessions completed by the participants in the STEPS program. The duration of calls will also be recorded.

5.9.2 Community Health Worker Training and Tracking

All CHWs who have not done so already 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. STEPS-specific training will take place over eight training sessions (approximately four-hours each) with additional training as needed. Training content was developed and refined in the pilot, and uses an active learning approach, with an emphasis on 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. A portion of the training will be devoted to assessing SDOH in this context and a review of relevant resources in the Detroit community and at HFHS.

All intervention sessions will be audio recorded, with participants' permission, and fidelity to the CHW manual will be checked via a checklist that was used in the pilot study to determine fidelity to the session protocol in the community health worker STEPS manual. We will test for CHW "drift" from the protocol by listening to a random 10% of recorded calls each quarter of the enrollment and offer refresher training sessions as needed. Each CHW will meet regularly (weekly, biweekly, or monthly) with the supervisor and a research staff member for coaching and feedback.

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 a designated follow-up assessment as possible (2 or 12 months). Participants need to complete the assessment within one month of the first follow-up date and within two months of the second 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 (or both, depending on the point in the study) 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. Participants who sign the informed consent form and are randomized to the intervention but do not begin it may be replaced. 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.

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

Activity	Months												
	0	1	2	3	4	5	6	7	8	9	10	11	12
Eligibility Screening	X												
Consent Process	X												
Demographics	X												
Chronic conditions and overall health	X												
Pain Interference (PROMIS-43 6-item scale)[14]	X		X										X
PROMIS-29 +2[14,15] (except Pain Interference subscale)	X		X										X
Pain Intensity (Numerical Rating Scale)[16]	X		X										X
UCLA Loneliness 3-item and additional items[17,18]	X		X										X
Fear of Movement [19]	X		X										X
Coping and Adaptation Processing Scale [20]	X												X
Religious Coping (RCOPE) Scale [21]	X												
Pain Self-Efficacy Questionnaire[22]	X		X										X
Pain Medication Use (QAQ)[11]	X		X										X
Primary Care Access[23]	X												X
Communication with Provider[24,25]	X												X
Pain Catastrophizing Scale [26,27]	X		X										X
Physical Activity[24]	X		X										X
Health Literacy[28]	X												
Life Space Mobility	X												
Technology Use	X												
Pain Management Strategies[29]	X												X
Falls	X												X
COVID-19 infection and treatment items	X												X
Global impression of change in pain, functioning, quality of life, and use of pain medication[30]			X										X
STEPS Evaluation Questions (intervention group only)			X										
Therapeutic Alliance scale[31] (intervention group only)			X										
STEPS: CHW sessions (intervention group only)		X	X										
Step count tracking (intervention group only)		X	X										X
Qualitative interviews (subsample of intervention group)				X	X								

Notes:

*Shaded rows represent measures on the telephone data collection surveys (at baseline, 2 and 12 months).

**Primary and secondary outcomes are bolded.

***Allowable assessment windows: Participants need to complete the assessment within one month of the first follow-up date and within two months of the second 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, for primary and secondary outcomes only, before starting the intervention and base follow up windows on the second baseline assessment. We will stagger enrollment to allow participants to start the intervention within one month. Delays in starting the intervention may be due to family situations, illnesses, difficult to reach participants, work obligations, etc.

6.2 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.
- *Randomization* – will occur only after all baseline outcome assessments are completed. Once complete, a randomized study schedule with mixed blocks will be used to determine group assignment.
- *STEPS Program (Intervention)* – participants will access the study website, learn how to use their tracker, and prepare for first call with their designated CHW.
- *Qualitative interviews* - A subset of participants in the STEPS intervention study arm will be asked to participate in an approximately 30-minute interview about their experiences with the intervention (n = 30). This will be done to help understand facilitators and barriers to engagement in the program. Participants who are interviewed will be offered an additional $25 incentive (gift card) for their time. We will conduct telephone qualitative interviews with subsamples selected for maximum variation: participants with and without significant improvement, those who were very satisfied, and less satisfied, and those who dropped out (n=5 per subgroup or until data saturation; i.e. no new information emerging). Participant-identified mechanisms of effect will be elicited with questions such as: What do you think helped you the most? Why do you think your pain (and/or function) did (or did not) improve? We will probe the mediating role of addressing SDOH by asking about the experience of getting referrals, whether participants followed up with these or not, and, if they did, what resulted, including impact on ability to manage pain. Other questions will address the relationship with the CHW, use of the online modules, experience with the activity tracker, and what participants liked most/least and why. Additional in-depth interviews will be conducted with CHWs and other stakeholders including representatives of health and social service agencies in Detroit, and HFHS clinical providers. We will pose open-ended questions about challenges, facilitators, and satisfaction with various aspects of STEPS and its implementation.

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 (with the exception of a commercially-available wearable activity tracker) 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.

4. There is an unlikely possibility of potential discomfort with wearing activity tracker due to wrist band. Participants are not required to wear the activity tracker while sleeping and the study team will provide an alternative band, if needed (FREQUENCY: infrequent, SERIOUSNESS: Mild).

Potential Benefits: The intervention for chronic pain self-management will incorporate evidence-supported strategies to promote effective self-management of chronic pain as well as encourage gradual increases in moderate physical activity, and therefore has the potential for beneficial physical and/or psychological effects.

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 in eResearch, Section 32.

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 follow-up interviews at 2 and 12 months 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 in Detroit who are 50+ years of age, predominantly African American, with chronic pain), 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 by the Principal Investigator, Recruitment and Data Collection Coordinator, and Project Manager prior to beginning data collection. Additionally, the Project Manager, in cooperation with the PI and the Recruitment and Data Collection Coordinator, 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 Manager will provide study updates including data and safety issues listed above.

8.3. Auditing

- Auditing Selected Cases for Compliance with IRB Requirements. These annual audits will include a random review of 20% of the cases that have been collected since the previous review.
- Conformance with Informed Consent Requirements. As part of these annual assessments, the project manager and PI will also review all consent forms for participants that have been seen since the previous review.
- 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 for participants who do not report step count data for any reason, or for lost devices.

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 interview.

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 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.

Electronic data security: We will use a commercial platform such as Mosio to send out SMS messages to participants, who choose this option for reporting daily step counts during the intervention period. Information stored about the participants includes first and last name, a telephone number, and a study ID. We understand that SMS is inherently unsecure; to mitigate this, we will only collect step counts, where participants choose to report via SMS instead of syncing with an app, and we will not use identifying language in the SMS questions asking for step count reports.

For the electronic activity trackers, we will not be collecting or storing synced data; rather, participants will manually read their daily step counts and report by SMS or record on paper.

For telephone calls and telephone-based group sessions, we will use DialPad or Zoom Phone to audio record calls and group sessions for quality assurance. Audio recordings will be stored in the secure University of Michigan School of Public Health server or a HIPAA-compliant file storage system (like Dropbox at U-M). Dialpad has strong security measures that take a comprehensive, multi-layered approach, including data encryption and access controls. 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.

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.

Qualitative interview data

All audiofiles and transcripts associated with in-depth participant interviews will be stored on a secure University of Michigan School of Public Health server or a HIPAA compliant could file storage system (like Dropbox at U-M). 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

Sample size for the trial is based on our primary outcome of the PROMIS Pain Interference 6-item subscale. Using the power curves provided by Cella et al. (2019) for this measure[15], which are based on an independent-samples t-test with a 1% two-sided significance test and 80% power, a sample size of 165 in each group will be sufficient to detect a 2.5-point difference in T-score, which is also the minimal clinically important difference for this scale.[32]This amount corresponds to a small effect size, aligning with what is generally observed for pain-related functional outcomes from similar interventions. Assuming a maximum attrition rate of 25% over one year, we will enroll up to 207 patients per arm (total n=414). This sample size will also allow sufficient power for planned moderation and mediation analyses.

10.2 Data Analyses

10.2.1 General Approach

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.

10.2.2 Primary & Secondary Endpoints

We will collect outcome data at three time points: baseline; 2 months from baseline (immediately post-program, for those in the intervention group); and 12 months from baseline. All quantitative process and outcome data will be collected in REDCap. For the primary and secondary endpoints, we will conduct analyses on change in outcomes over the three time points first for completers using one-way analyses of variance and then (to achieve robust findings) in an intent-to-treat model in which linear mixed models will be used to examine all available data. Sensitivity analyses will assess whether different assumptions about missingness and dropouts impact results. We will consider an intervention "completer" to be someone who completed at least 4 telephone sessions (not including orientation) with the CHW.

We will develop a two-level linear mixed-effects model that uses pain interference follow-up scores at 2 and 12 months as the dependent variables; treatment group, time and the treatment-by-time interaction as categorical explanatory variables; and baseline pain interference score as a continuous covariate. If this model shows no significant time-by-group effect, we will drop the interaction term and test for the time-averaged effect of the intervention compared to usual care between 2 and 12 months. An unstructured variance-covariance matrix will be used to model the error variance. Secondary outcomes including pain intensity will be analyzed in a similar manner. We will also conduct a responder analysis by examining the cumulative distribution function of responders (i.e., a continuous plot of the proportion of patients at each scale score by arm who experience change at that level or better), and test whether this proportion differs between treatment groups. We will calculate effect sizes (Cohen's d) for outcomes.

10.2.3 Other Pre-specified Analyses

We will use linear mixed models to examine mediators and moderators with respect to the primary and secondary outcomes. We will conduct descriptive analyses to explore feasibility and satisfaction. We will track and report on intervention process variables, including but not limited to: the frequency and duration of CHW sessions, CHW time spent per participant, participant goals set and level of achievement, and daily step counts.

10.2.4 Qualitative Data Analyses

Qualitative responses captured during interviews will be transcribed from audio recording and thematic codes will be created and verified through rater pairs. Our codebook will include definitions, criteria, and examples. Initial codes will be based on interview questions, then modified as needed to fit the data. We will test the coding scheme on 2-4 transcripts in an iterative process until reaching consensus. The final coding scheme will be applied to enrich our understanding of statistical findings.

11 INTERIM ANALYSIS

Interim analyses will be conducted by the Investigative Team when 50% and 75% of the sample has been accrued. Analyses will examine AEs and SAEs by arm, as well as any eligibility violations. Drop-out by arm and reasons for drop-out will also be assessed. Interim analyses will also include data on recruitment, baseline characteristics by arm, intervention engagement (e.g., sessions completed) for intervention arm, and amount of follow-up data collected.

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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Ame00123028

In Section 4, for the expected small number of participants without access, we will lend them inexpensive tablets pre-loaded with STEPS website content. If telephone minutes are a barrier for some eligible participants, we will provide additional support for this as well, 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.

We will not be using electronic medical records as a recruitment strategy (not approved by

Henry Ford Health; Section 4.1).

In Section 4.4, we removed the option of having participants mail back a signed version of the consent form. To ensure that all participants go through the verbal consent process over the telephone with trained research staff, we will instead ask the participants if they prefer to receive a copy of the consent to review on their own before consenting, then we will schedule a follow up to go through the consent details over the telephone after they've had a chance to receive and review the consent document (1-2 weeks after the consent is mailed or emailed, based on the participant's preferences). If participants are ok with verbally consenting right away or before having a copy of the consent sent to them, trained staff will review the consent details over the phone, obtain verbal consent if the participant is interested in participating, and send the consent document to the participant accordingly (along with a community resource list).

In Section 5.2, we added an orientation session to the intervention and outlined the process for scheduling the intervention session post-baseline survey with the participant. We also included alternative options for participants to send in step counts using a paper step count log if they are unable to text step counts to the team.

The STEPS Intervention Content Table was updated in this section to reflect changes to the sequence of sessions based on feedback from our CHWs and community partners. Information about the Wyze Watch activity tracker was added to this section as well as updated information about the STEPS social determinants of health screener.

In Section 5.6, we outline that participants in the STEPS study will not be able to participate in our other R01 study, Re-Engaging in Self-Care and Enjoying Today (RESET), and vice versa. These two studies are recruiting from the same population and have some overlapping intervention components. We will make this clear in the recruitment process and added a screener question accordingly.

In Section 6, the survey measures and schedule of activities was updated to reflect the updated survey instruments used at baseline, 2-months, and 12-months. We also outline procedures for delays between baseline assessments and intervention start dates. Details related to the qualitative interviews were added to Section 6.

In Section 7.1 (Potential Risks and Benefits), language about the Certificate of Confidentiality was added as well as potential discomforts due to the Wyze Watch.

In Section 9 (Confidentiality and Privacy), information was added about the technology platforms we intend to use for the study, including DialPad and Zoom Phone for weekly sessions. We also included information about UM Dropbox where we will store data securely.

Since survey measures were updated, references were also updated to reflect these changes.

Ame00137679 – 7/7/2023

In Sections 1.4.1 (Known Potential Risks) and 7.1 (Potential Risks and Benefits) we will add the following text: Another possible risk is minor muscle injury, such as muscle strain, from doing physical activity that is encouraged by the STEPS 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 a muscle injury while doing physical activity as part of the STEPS program. To minimize this risk, the STEPS 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 or not a specific activity is appropriate. (FREQUENCY: infrequent, SERIOUSNESS: Mild).

Ame00143442 – 12/13/2023

For participants in the intervention group, we will allow participants to complete the 2-month follow up survey prior to the last intervention session (session 7) if they need additional flexibility based on their schedule and/or if the last intervention session is delayed or missed. The last intervention session is a review and wrap-up session so there will not be new information presented during the session that would impact study outcomes. However, for most intervention participants, research staff will still attempt to conduct the 2-month follow up survey after the last intervention session is completed.

Ame00152596 – 8/30/2024

Instead of offering gift card incentives for telephone survey assessments and qualitative interviews, we will default to using checks instead. Gift cards may still be used if a study participant is not able to cash a check at the bank or has other barriers where a gift card would be preferred. All incentives are provided in the form of checks (or gift cards as a backup option) from the Human Subjects Incentive Program at the University of Michigan. Participants will receive $20 for the baseline assessment, $20 for the 2-month follow up assessment, and $25 for the 12-month follow-up assessment. Participants who complete a qualitative interview will be offered an incentive (a $25 check or gift card) for their time.