Study Protocol: Positive Psychology for Chronic Pain Self-management

NCT04321239

The Positive STEPS program

July 1, 2020

A1. Overall study objective:

To conduct a pilot study of a community health worker (CHW)-delivered, positive-psychology-based chronic pain self-management (CPSM) intervention for older African American adults in an underserved urban community (Detroit, MI).

A2. Background/Significance: Evidence-based cognitive-behavioral self-management strategies can bring about modest improvements in pain intensity and pain-related thoughts, while avoiding medication-associated risks. The 2016 National Pain Strategy called for expanding access to CPSM support, and the Federal Pain Research Strategy designated research on sustainable CPSM delivery models a "Top Priority." These same documents also highlight the urgency of addressing racial and socioeconomic disparities in pain and pain treatment. Yet few programs to support chronic pain self-management have been designed around the needs of low-income, minoritized older adults. A recent trial by Thorn et al. of a CPSM program ("LAMP") adapted for patients with low health literacy is an important step toward broadening access to underserved populations. However, LAMP is a group-based program designed for all ages and led by clinical psychologists. This model is likely not sustainable in resource-challenged urban setting where psychology professionals are scarce; nor sufficiently accessible to older adults who have transportation difficulties and/or low functional status.

We are currently conducting pilot research to address these gaps by modifying a guided internet program for chronic pain management, *Engage,* for use by older African American adults in a low-income, urban setting. In this adapted program, which we are calling STEPS 2 (Seniors using Technology to Engage in Pain Self-management – note that a prior, different study we conducted was also called STEPS – Seniors Tracking Exercise for Pain Self-management), CHWs deliver weekly telephone sessions to supplement participant use of online educational modules. CHWs are non-professionals who are trained in specific health care-related tasks.[6] They are members of the communities they serve, enjoy a high level of client trust, and deliver culturally relevant services. CHWs have been increasingly involved in the delivery of evidence-based psychological treatments. The role of the CHWs in the ongoing STEPS pilot is to: a) help participants apply web module content to their daily lives; b) set behavioral goals and address barriers; and C) refer to community resources, as needed.

We propose to expand on learnings from the ongoing STEPS 2 study by testing the feasibility of an intervention using the same model (web-based, supported by CHWs) but with a different approach to pain self-management. While current STEPS modules address standard cognitive-behavioral content (e.g., sleep, communication), the modules in the new positive-psychology intervention will teach ways to induce positive affect and enhance psychological resilience (e.g., Savoring, Meaning-Making, Music as Medicine). Such resilience-building strategies are an engaging, easily-taught approach that may promote effective CPSM. Rooted in positive psychology, these activities help patients upregulate positive psychosocial factors and may improve pain outcomes via improved mental health, decreased catastrophizing, and increased social support.

B. Specific Aims:

Aim 1: Via a systematic process of needs assessment and usability testing, we will: 1) develop a series of online modules that teach skills for inducing positive affect and building resilience, and are tailored to the needs of the priority population; and b) develop materials and procedures for CHWs to conduct weekly telephone sessions to help participants apply skills taught in online modules.

1a) Convene older adults with chronic pain from the priority population for focus groups (n=20) and iterative usability testing (n=5) to inform the development of positive-psychology focused modules.

1b) Convene 3-5 CHWs with prior experience working with older African American clients, and engage them in an iterative feedback process to refine the protocol and materials for the CHW-delivered component of the Positive STEPS program

Aim 2: Randomize 50 older adults with chronic pain to the Positive STEPS or waitlist-control groups, and assess the acceptability of the intervention and its effect on pain-related outcomes. We will use mixed methods

to evaluate key program processes and outcomes. Finally, we will explore potential psychological and behavioral mechanisms of effect.

C. Methodology

C1. Information about the "Positive STEPS" intervention to be developed in Aim 1**:** The format and style of the new Positive STEPS program will be based on the *Engage* intervention (Murphy, Janevic, Lee, & Williams, 2018) —which is being adapted for the priority population in ongoing pilot work by the PI (HUM00154949). Engage has two primary components, both of which will also be included in Positive STEPS but with different content: 1) web modules with videos and downloadable worksheets designed to teach cognitive-behavioral skills for osteoarthritis self-management (to be modified in the current study to focus on positive psychology activities and skill-building), and 2) a manual for weekly occupational therapist-delivered sessions (interventionists to be changed to community health workers). The intervention will also draw from content in the PRISM program, a resilience-focused program for chronic pain management currently being tested by study Co-Investigator Dr. Afton Hassett.

Participants in Positive STEPS will be taught strategies for increasing engagement in daily activities and other activities they can do to induce positive affect and positively engage with life. The videos will present expert-delivered content on these topics, and will serve as both a teaching tool for patients and an "electronic textbook" for CHWs.

C2. Aim 1a: Identifying adaptations to CHW-facing program components (**NOTE: Aim 1a does not include Human Subjects**)

Participants: We will continue to work with the 3 CHWs from the current STEPS program.

Procedure: During meetings with the CHWs we will elicit ideas about topics planned for *Positive STEPS* in community-relevant and culturally sensitive ways. CHWs will give feedback on drafts of program protocols and materials, with attention to feasibility of program delivery, relevance and perceived usefulness of content, and use of effective communication strategies for the priority client population. In a final CHW meeting, the CHWs will review participant-facing program refinements (based on focus group feedback, see Aim 1b), as an additional verification of fit. During this final meeting, we will also seek CHW input on a CHW training protocol for the program. We anticipate that this training will use an active learning approach, focusing on skill building and core processes of care, including record keeping and managing referrals for acute events (Patel, Chowdhary, Rahman, & Verdeli, 2011). Meetings will be audio-recorded to facilitate using the information to guide changes to program components.

C3. Aims 1b and 2 Recruitment and Procedure: (**NOTE: These Aims DO include Human Subjects**)

Participant eligibility criteria for both Aims 1 and 2 are as follows:

- *Inclusion criteria*:
    - English-proficient
    - Age $\geq$ 60 years
    - Ambulatory with or without assistive device
    - Community-living
    - Have a cell or landline phone
    - Have Internet access (home or elsewhere);
    - Self-reported chronic musculoskeletal pain (pain in muscles or joints for $\geq$ 3 months); $\geq$4 (0-10 scale) average pain level over last week; $\geq$1 day/previous 30 when pain made it difficult to do usual activities.

- *Exclusion criteria*:
    - *S*erious acute illness or hospitalization in last month
    - Planned surgery in next three months
    - Severe cognitive impairment or other severe physical or psychiatric disorder judged by study team to pose significant barrier to deriving program benefit

Aim 1: Focus groups and usability testing for program materials adaptation

Recruitment method 1A: Flyers advertising groups will be displayed or distributed at community locations in Detroit serving older adults.

Flyers will include an email address and phone number of the research hotline, so that interested individuals can contact us directly. We will only contact participants via email if they contact us that way, and if they indicate that email is their preferred mode of contact. No sensitive information will be transmitted over email by us to participants; only a generic study description or logistical information (e.g., scheduling phone calls or orientation sessions etc.).

After describing the study to potential participants, research staff will screen interested individuals over the phone. Participants meeting eligibility criteria will be scheduled in one of two focus groups, according to participant time preference and available space. These groups will take place at The University of Michigan Detroit Center. When scheduling, we will ask for the best way to provide a reminder (email, or call) the day before the focus group is to be held. Participants will be told that they will be offered a $25 gift card as a thank you gift after completing the focus group. Informed consent will take place on-site prior to the focus group.

Recruitment method 1B: (if 1A does not yield the desired sample size within a designated period) We will contact people, via their preferred method, from a list of more than 30 African American older adults with chronic pain who were participants, potential participants, or who otherwise expressed interest in our prior work and who indicated that they wish to be contacted by us for future pain-related research. In the call, research staff will assess the eligibility of interested individuals, answer any questions, and invite to participate, if appropriate. We will also ask anyone with whom we make contact whether or not they want to remain on the "contact" list. We will phone people on this list, selected in a random order. If we are able to speak with the person, we will follow a recruitment script to inform them about the study and to screen for eligibility. If no one answers, we will leave up to two voice mail messages inviting the individual to call our toll-free study number if they would like to learn more about an opportunity to take part in a new study.

Eligible individuals who agree to take part in focus groups will be sent a reminder letter that confirms the location, purpose, date, and time of the group.

We will enroll 10 people in each of two planned focus groups, with the expectation that 8 will show up. Focus group participants will be offered a $25 gift card.

AIM 1b: Usability testing recruitment: We will follow essentially the same recruitment procedure as for the focus groups, using the same modes of recruitment to recruit a total of 5 people to take part in one-hour usability testing session at the UM Detroit Center assessing the user experience with the prototype program website and associated hard-copy materials. Usability testers will be offered a $15 gift card as a thank you gift after completing the session. Informed consent will take place on-site prior to the session.

Aim 2: Pilot randomized trial of Positive STEPS intervention

The following recruitment strategies will be used in parallel until the target sample size (n=50) is reached. Recruitment and program implementation will happen on a rolling basis. Note that participating in focus groups or usability testing does not preclude eligibility for the Aim 2 pilot trial.

Recruitment method 2A: Flyers will be displayed or distributed at community locations in Detroit serving older adults. Potential trial participants will call the toll-free number. Research staff will further assess eligibility, answer any questions, and invite to participate, if appropriate.

Recruitment method 2B: We will first send letters about the study, following up with a call to people from the updated contact list described in 1B above. In the call, research staff will assess the eligibility of interested individuals, answer any questions, and invite to participate, if appropriate.

Recruitment method 2C: We will recruit from the registry available to University of Michigan (UM) researchers via the UM Geriatrics Center collaboration with Wayne State University Institute of Gerontology. This registry includes information about older African American adults living in or near Detroit who have expressed interest in participating in research. As of January 2017, the database included 1400 individuals with an arthritis diagnosis; many of these people will meet pain-related study criteria. Individuals meeting the broad study criteria (age, gender, diagnoses) will be contacted by letter describing the study (or an email, if they have indicated that they prefer to be contacted this way). This initial contact will be followed by a phone call to further assess eligibility, answer any questions, and to invite to participate, if appropriate.

Procedure for recruitment/screening calls, regardless of recruitment method:

During the recruitment telephone contact, 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. Individuals in the intervention group will meet with a community health worker at an in-person study orientation session at the UM Detroit Center.

COVID-19 MODIFICATION: To accommodate any social distancing guidelines that may be in place, this orientation session may be provided over the phone.

At this session, they will be introduced to the program, learn how to use the online modules and any associated materials, and choose a day and time for future weekly telephone sessions. The program will be delivered over approximately 6 weeks. Participants will also be given a wearable physical activity tracker at the orientation session to use throughout the course of the program. They will elect to report daily step counts either by automatically syncing to an app or by manual reporting via SMS text message. Participants will be invited to keep the tracker after the study ends.

After completing the follow-up 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 2.5-hour in-person workshop that includes key intervention content and that will be led jointly by study staff and a community health worker.

COVID-19 MODIFICATION: To accommodate any social distancing guidelines that may be in place, this workshop may instead take the form of a 1-hour, one-on-one phone call with a community health worker.

Participants in both groups will be asked to complete two data collection telephone interviews (at baseline and eight-week follow-up) of approximately 40 minutes in length each.

If the individual agrees to participate after hearing the above description, they will be asked whether they prefer to verbally consent over the phone or be mailed a packet and send back a signed consent form. For a detailed description of informed consent procedures please see the “Informed Consent Process” section of this protocol.

Upon completing verbal consent or returning 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.

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.

Provisions to protect or maintain subject privacy during recruitment:

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. 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. 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 study staff, including community health workers, and research assistants will complete PEERRS (Program for Education and Evaluation in Responsible Research and Scholarship). Proof of their certification and completion of the training program will be kept on file. 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 and IRB policies and procedures are being followed.

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 HIPPAA 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 open-ended questions, we will produce coding manuals with detailed instructions for issues such as how to adjudicate coding decisions when survey response options are unclear. A coding-decisions log will be maintained to ensure that coding is consistent.

Retention Plan

Because Aim 1 consists of one-time focus groups or usability testing only, retention activities are not applicable. For Aim 2, 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 Unable to Contact or Lost to Follow-up.
- 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 Unable to Contact.
- We will reschedule a participant's baseline survey 5 times. Reschedule the follow-up as many times as it takes to get the participant to complete it.
- We will reschedule attendance at the orientation session (intervention participants only) 2 times.

For Aim 2, we will offer incentives for each data collection point ($10 for each completed survey, including, for intervention group participants, $15 for a qualitative post-program survey). Participants will be paid through the UM's Human Subjects Incentive Program payment system which is an automatic, electronic payment system and bills directly to the project, thereby making more efficient use of staff time and eliminating the possibility of abuse of gift cards.

***AME00101151: We are now offering up to $20 for the baseline survey ($10 for original survey and an additional $10 for responding to a COVID-19 module. We have increased the follow-up survey incentive to $15.

Informed Consent Process

AIM 1: Informed consent for focus groups and usability tests

Moderator will read through consent forms out loud before beginning discussion (focus groups) or session (usability tests). Participants will be given a chance to ask any questions. Participants will be asked to sign, and will be given a copy of the form for their records. See Focus Group and Usability Testing consent forms uploaded in Section 10-1.

AIM 2: Informed consent for Positive STEPS intervention pilot test

After completing the recruitment and screening procedures described in Section 8-1.3, eligible individuals who wish to participate will be asked whether they prefer to verbally consent over the phone or be mailed a packet and send back a signed consent form.

We are offering the verbal option in order to minimize participant burden and make our recruitment processes more efficient. Those that complete a verbal consent will receive the same information as those that receive the written consent in the mail. If the participant chooses verbal consent, the interviewer will read aloud the informed consent document, stopping after each section to confirm whether the participant understands the

content or has further questions. Understanding of all content will be confirmed before requesting a verbal signature of consent.

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. All recordings will be stored securely and then destroyed at the end of the study. Participants choosing this option will be mailed a copy of the consent document for their records.

If participants prefer to have a consent packet mailed to them, two copies of the consent form (one for signing and returning to the research team, and one for the patient's records) will be mailed to their verified address along with a pre-addressed and stamped envelope. Research staff will call potential participants approximately one week after mailing the consent form to review consent information 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.

Upon completing verbal consent or returning a signed written consent form, the participants will be enrolled in the study and will be scheduled for a baseline interview, to be completed prior to scheduling in an in-person orientation session at the UM Detroit Center.

Qualitative "participant experience" interviews will take place over the phone. All Aim 2 participants will be invited to be scheduled for an interview. Because these will take place over the phone, the informed consent document will be reviewed over the phone with the interviewer. Participants will be asked to provide verbal consent to the interview and its audio recording.

NOTE: As directed by the IRB-HSBS, because this is a NIH funded study it is covered by a Certificate of Confidentiality and we have included language to this effect in all consent forms.

***AME00101151: We are no longer going to be conducting separate qualitative “participant experience” interviews. Instead, we are adding a module with open and close ended questions about program satisfaction to the standard follow-up interview (and because it is now longer, increasing the incentive offered).

Aim 1: Focus groups and usability testing

Plan for Assignment of Participants: Aim 1 participants will not be assigned to groups.

Focus groups: We will convene two focus groups of up to 10 participants each at the University of Michigan Detroit Center in midtown (central) Detroit. Focus group participants will be presented with selected existing and new *Engage* content and asked how to enhance its appeal and usability.

Usability testing: Five people from the priority population will try out online modules and materials in an iterative process. We will observe and ask questions about their experience. Changes will be made before additional rounds of testing.

Procedure: We will develop Positive STEPS content according to data collected from a user-centered design process, as follows:

Step 1 - Input on existing materials: We will seek feedback from two focus groups of individuals from the target population (n=8-12 each). Participants will be presented with selections from the existing Engage program and asked about the appeal and usability of the material. Additional topics will include: (1) desired characteristics of CHWs to serve as program facilitators; (2) participants’ “surface” (e.g., terminology) and “deep” (e.g., etiology) understanding of chronic pain (Resnicow, Baranowski, Ahluwalia, & Braithwaite, 1999), and how well the program materials reflect these. A copy of the focus group questions is included in the IRB application.

Step 2 - Development of revised materials: We will create revised participant worksheets for each module as well as record up to four new videos (approximately 5-10 minutes in duration) to enhance the existing Engage

content. In order to represent our priority population, we expect that at least two of these videos will be presented by UM clinician researchers who are African American. We will also have two videos recorded by CHWs, one explaining the program process and the other explaining goal-setting. (Final video plan and details of content will be determined by Aim 1a and 1b findings.) We will employ a private YouTube channel or other mobile-friendly streaming platform during this testing phase and will also develop alternatives for when participants cannot access online videos, e.g. putting them on an inexpensive Kindle Fire that can be loaned to participants.

Step 3 - User experience testing: Three-five people from the priority population will try out the online modules and materials. We will observe them using the online modules and also ask questions about their experience. Changes will be made before a second and then a third round of testing.

Recordings and notes from focus groups and usability testing will be reviewed for actionable information for program modification. The iterative process described above will yield refined, patient-centered materials that are ready for pilot-testing.

***AME00101151: Because of social distancing guidelines, we are no longer going to do face-to-face usability testing. Instead, we will get feedback from community health workers on the website over the phone.

Aim 2: Pilot randomized trial

Recruitment and program implementation for Aim 2 will be conducted on a rolling basis.

Plan for Assignment of Participants: Upon completion of informed consent and a baseline telephone interview, 50 participants will be randomized to either the control group (n=25) or the intervention group (n=25), using a block randomization scheme (sealedenvelope.com). Staff not involved in interviewing the participant will place the randomization assignment in an Enrollment Spreadsheet for the interviewer to see upon completion of the baseline telephone interview. At the end of the interview, the interviewer will open the spreadsheet and inform the participant of their randomization status. This procedure, which we have used successfully in past studies, prevents bias by keeping the interviewer blind to the participant's randomization status until the interview is completed.

Intervention Condition

Participants assigned to the intervention group will meet with a community health worker (CHW) for a one-hour in-person study orientation session at the UM Detroit Center or location of the participant's choosing. At this session, they will be introduced to the program and choose a day and time for future weekly telephone sessions with the CHW. The CHW will instruct each participant in how to use the web-based modules and worksheets between telephone sessions. Note that the website is only used as a place where participants can access content (videos, text and worksheets); they will NOT be uploading or otherwise inputting any information into the site. The site will be publicly-available; that is, no login will be required. Participants will also be given a wearable physical activity tracker at the orientation session to use throughout the course of the program. The program will be delivered over 6 weeks.

***AME00101151: If social distancing guidelines are in place, the orientation will take place over the phone and all program materials will be mailed.

Each week participants will complete a web-based module with associated handouts, and have one telephone session, of approximately 30 minutes in duration. These sessions will be designed to support the content in a given weekly module (see Table 1). CHWs will elicit problem areas related to the weekly topic, reinforce key points, help participants practice new skills, discuss adaptations needed for a participant's situation, and set a related goal. Participants will also set goals each week related to walking (step counts), a process which will be facilitated by the availability of step-count data from the physical activity tracker. The CHW manual will explain how to interpret and use step-count data in sessions. CHWs will also be trained to provide basic technical support to participants for problems that arise with the website or physical activity trackers.

Table 1. Program modules and role of CHW in supporting module content

Web Module	Content	Type of CHW contact	Role of CHW

Program overview	Chronic pain overview, how symptoms interfere with function, goal setting	No phone call (covered in initial orientation session)	Guide participant in setting long- and short- term behavioral goals, show how to use web modules and workbook.
Being Active	The role of physical activity, how realistic goals can help maintain exercise over time.	CHW Call 1	Discuss physical activity options and resources in Detroit.
Pleasant Activity Scheduling	Rationale and skills for allocating time to self-growth and well-being.	CHW Call 2	Discuss pleasant activities selected by participant and barriers; set goal.
Reminiscence and Meaning-Making	Looking back on one's life and reflect on positive moments.	CHW Call 3	Discuss how to select positive life moments and plan for recording (optional): written, video, etc.
Participant choice: Acts of Kindness, Positive Piggy Bank, or Savoring	Participant will be introduced to several positive affect-inducing activities and will choose one to try.	CHW Call 4	Discuss which resilience-based activities (legacy/life story, gratitude, etc.) is most appealing; set goal. (e.g., savoring – guide participant in choosing two everyday experiences to savor each day)
Music as Medicine	Rationale and activities for using music for pain management.	CHW Call 5	Develop plan to incorporate listening to music (of participant's choice) for an hour on at least five days with minimal distraction.
Wrap-up	Review of key skills and relapse prevention strategies.	CHW Call 6	Guide participant in developing plans to continue goal completion.

More details about intervention content:

Note that we are not requiring that participants secure their doctor's approval for physical activity prior to program participation, given that the CHWs will not ask participants to engage in anything more than moderate walking activity. The suggested amount of walking will start out at or close to a participant's usual amount of walking (as measured by daily step counts) and CHWs will encourage participants to increase their daily steps only very gradually (e.g., by 10% per week).

In the event of patients reporting serious depressive symptoms or suicidal ideation, the CHW 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. *Quality assurance* for CHW-delivered sessions will include: (1) observation by the PI or Co-I of several telephone sessions; (2) review by the PI or Co-I of CHW clinical records; and (3) weekly meetings with CHWs consisting of reinforcement of training and case reviews.

More details about activity tracker and how it will be used in the intervention:

The commercially-available LETSCOM activity tracker, provided to all Positive STEPS participants, can be worn on the wrist. (https://www.amazon.com/LETSCOM-Fitness-Activity-Waterproof-Pedometer/dp/B07GCM9N72) While the device has the capability of bring 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.

Participants will be instructed to wear their tracker during waking hours, except showering, bathing, or swimming, every day throughout their enrollment in the study. 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.

More details about protecting subject privacy during implementation of intervention:

A number of steps will be taken to ensure participant confidentiality. As noted above, 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, to transmit non-sensitive information. 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 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 will be presented in reports, presentations, or manuscripts in aggregate statistics only.

All study staff, including community health workers, and research assistants will complete the web-based University of Michigan's Responsible Conduct of Research Training Program, known as PEERRS (Program for Education and Evaluation in Responsible Research and Scholarship). Proof of their certification and completion of the training program will be kept on file. 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.

Control Condition

AME00102985: After completing the baseline interview, we will send a letter to control participants that thanks them for their participation in the study and reiterates that we will be contacting them for a follow-up interview in two months. Along with this letter, we will send the Detroit resource lists (including mental health providers and other community resources) that are found on pp 83-86 of the participant manual. The reason for this is that these materials are not directly related to the intervention but participants may find them helpful, especially given that this study is taking place during the pandemic period. Between the baseline and follow-up surveys, participants in the control condition will not take part in any study activities. After completing the follow-up telephone survey, control group members 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 one-time 2.5-hour in-person workshop that summarizes intervention content and that will be led jointly by study staff and a community health worker.

***AME00101151: To accommodate social distancing guidelines, this in-person group workshop may be replaced with a one-hour 1:1 telephone session with a community health worker.

Managing and Protecting Data

Aim 1 Focus Groups and Usability Testing: Potential and confirmed participants' names and contact information (for mailing reminder letters and Human Subjects Incentive Payment cards) will be stored in REDCap and/or a password-protected Excel spreadsheet on a secure University of Michigan School of Public Health server, accessible only to pre-approved study staff and research assistants.

All audio files and transcripts associated with focus groups and usability testing sessions will be stored on a secure University of Michigan School of Public Health server. No names or other identifying information will be included in the transcribed focus group discussions, and thus no information will be included in any published or unpublished reports using interview data that could be used to identify any participant.

Participants' names will not be included on the short supplemental written survey given before the focus groups; these will be anonymous.

Aim 2: Randomized pilot trial: 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 HIPPAA 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 open-ended questions, we will produce coding manuals with detailed instructions for issues such as how to adjudicate coding decisions when survey response options are unclear. A coding-decisions log will be maintained to ensure that coding is consistent.

Electronic data security: Secure servers (virtual machines) at Michigan Medicine will host the SMS platform, store the participants' contact data and responses, and send out SMS messages to participants, who choose this option for reporting daily step counts during the Aim 2 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, and we will not use identifying language in the SMS questions asking for step count reports.

Pertaining to Both Aims 1 and 2

Remote Access: Staff is discouraged from accessing electronic files from offsite locations. However, when it is necessary, all connections from remote locations must use the University-configured Cisco VPN client, which encrypts all traffic to and from the servers.

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.

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.

Measures.

Telephone surveys will be administered at baseline and 8 weeks from baseline by research assistants not involved in intervention delivery. We will assess all primary and secondary outcomes at both time points. Covariates that are not expected to change over time will only be asked at baseline.

Primary outcomes: Pain interference and physical functioning, which are subscales on the NIH PROMIS-29 Adult Profile Instrument.

Secondary outcomes and/or *potential mechanisms of effect* will include: physical activity (Physical Activity Scale for the Elderly),Connor-Davidson Resilience Scale, Pain Self-Efficacy Scale, depression, anxiety, social participation (PROMIS) and support (PROMIS), pain catastrophizing, positive/negative affect balance (I-PANAS-SF) , life satisfaction, Patient Global Perception of Change.

Covariates/moderators: We will collect data on biological variables that may moderate outcomes, including age, sex, self-reported weight, and comorbidities. Other measures that will be included in one or both surveys include: educational attainment, health literacy, cognitive functioning, pain treatments including use of opioids and other medications, and pain centralization.

Process measures. Program engagement will be indicated by the number of completed CHW sessions, use of web modules, and participant satisfaction. We will use a structured form to evaluate 20% of recorded CHW sessions for fidelity to the intervention protocol.

Post-program qualitative interviews: We will invite participants to take part in an in-depth, semi-structured interview to deepen our understanding of their program experience. These interviews, lasting about 20 minutes each, will be conducted by phone by study staff not involved in intervention delivery, and will consist of open-ended questions about challenges, facilitators, and satisfaction with various aspects of the program and its implementation.

***AME00101151: We are no longer going to be conducting separate qualitative “participant experience” interviews. Instead, we are adding a module with open and close ended questions about program satisfaction to the standard follow-up interviews.

Sample size:

Sample size: Aim 2 represents a Stage 1 pilot trial. As such, our objective for is to look for a pattern of results suggesting the promise of the adapted intervention. This study is not powered to determine the statistical significance of effects.

Statistical analysis plan:

Data analysis: Pre-post (baseline to 8 weeks) differences in outcomes will be assessed for intervention and control groups. Linear regression models modeling each outcome will control for the baseline value of the outcome. We will use multivariate models to identify possible mediators (mechanisms) and whether there are differential effects (moderators) across patient subgroups.

Initial models will include only treatment group as the predictor and the baseline value of the outcome as a covariate. Subsequent nested models will introduce potential mediators (e.g. physical activity or resilience). We will evaluate changes in the relationship between intervention group and outcomes before and after covariates are introduced. We will also assess the moderating effect of selected biological variables (e.g., sex) and process variables such as program engagement and CHW fidelity to protocols. Moderation analyses will use standard approaches to evaluate interactions between these covariates and treatment group.[1]

Per current recommendations for chronic pain intervention research, we will conduct a responder analysis[2] by examining the cumulative distribution function of responders; i.e., a continuous plot of the proportion of patients at each scale score in each arm who experience change at that level or better, and test whether this proportion differs between treatment conditions. We will calculate effect sizes (Cohen’s d) for outcomes by dividing the baseline standard deviation for the complete sample by the difference between the intervention and control groups. [332] This information will be used in sample size calculations for a subsequent larger trial.

Following intent-to-treat principles, we will include all participants randomized to treatment, with sensitivity analyses assessing whether different assumptions about missingness and dropouts impact results.

Qualitative data analysis

Qualitative data from Aim 1 and post-program interviews in Aim 2 will be transcribed, or detailed notes compiled, as appropriate, and reviewed and coded for salient themes by two independent analysts.[4] Following NIH/OBSSR guidelines for mixed method research, the themes identified in this analysis will inform program modifications prior to a subsequent larger trial of the program. Qualitative findings will also shed light on quantitative results from this pilot study, including program engagement/acceptability and outcomes.[5]

Works Cited

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5. JW C, AC K, VL PC, KC S. Best practices for mixed methods research in the health sciences. Office of Behavioral and Social Sciences Research, National Institutes of Health;2011.