Cover Page for ClinicalTrials.gov

Document: Informed Consent

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

Document Date: 9/5/2024

NCT Number: NCT05278234

HEALTH SCIENCES & BEHAVIORAL SCIENCES IRB
UNIVERSITY OF MICHIGAN

STEPS Informed Consent Form

UNIVERSITY OF MICHIGAN CONSENT TO BE PART OF A RESEARCH STUDY

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title: STEPS (Seniors using Technology to Engage in Pain Self-Management)
Principal Investigator: Mary Janevic, PhD, University of Michigan School of Public Health
Co-Investigator(s): Sheria Robinson-Lane, PhD, University of Michigan School of Nursing; John Piette, PhD, University of Michigan School of Public Health and Medicine; Susan Murphy, PhD, University of Michigan School of Medicine; Robin Brewer, PhD, University of Michigan School of Information; Kimberlydawn Wisdom, MD, Henry Ford Health

Agency sponsoring the study: National Institute on Aging (NIA) (1R01AG071511-01)

You are invited to take part in a research study that is a collaboration between the University of Michigan and Henry Ford Health. This form contains information that will help you decide whether to join the study.

Taking part in this research project is voluntary. You do not have to participate, and you can stop at any time. Please take time to read this entire form and ask questions before deciding whether to take part in this research project.

2. PURPOSE OF THIS STUDY

The purpose of this study is to see if an educational program can help older adults more effectively manage their chronic pain.

3. WHO CAN PARTICIPATE IN THE STUDY

3.1 Who can take part in this study?

This study is for adults, ages 50 and over, who have chronic pain. We plan to recruit 414 study participants.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

If you agree to participate in the STEPS study, you will complete three telephone surveys with staff from the University of Michigan: an initial survey, a 2-month survey, and a final 12-month survey. Each survey will take about 60 minutes and will ask questions about your health and well-being. For example, we will ask you about the types of health problems you have and how they affect your daily life.

After you complete the first telephone survey, we will place you randomly into one of two groups by chance, like flipping a coin. These are the STEPS intervention group or the Control group. You have an equal (“50/50”) chance of being in each group.

If you are placed in the STEPS intervention group, you will be asked to attend an

orientation session, where you will learn more about the program and meet your community health worker, this orientation session may be done at a Detroit-based location, over the phone or via video link, or at your home. The orientation session takes most participants about 1.5 to 2 hours to complete.

After that, you will begin the STEPS program, which will take place over a period of six weeks. This program has three main parts:

1. First, you will be given an activity tracker to wear every day for seven weeks. You will report your daily step count to the STEPS study team by text message.

2. Second, you will visit the study website at least once each week, to watch educational videos about different ways to manage chronic pain. Each week will have a different topic. You will also be given a workbook that has more information and suggested activities that will help you practice the skills that you learn in the videos.

3. Third, you will receive one telephone call each week from a Community Health Worker: six telephone calls total. These calls will be about 30 minutes each. The community health worker will discuss that week's video with you and help you set personal goals related to walking and other skills for managing your pain.

If you are in the Control Group, you will not take part in these activities. However, we will ask you to complete the three telephone surveys (initial survey, 2-month survey, and 12-month survey). After you complete the final 12-month survey, you will be invited to participate in a workshop about chronic pain management with a community health worker. Workshops will be in-person or virtual (like Zoom). You will also have access to STEPS program videos, and we will provide you with an activity tracker and STEPS workbook.

4.2 How much of my time will be needed to take part in this study?

In summary, the three telephone surveys take about 60 minutes each to complete.

In addition, Intervention group participants will complete the 7-week STEPS program including the 1.5 – 2-hour orientation, 30-minute weekly telephone calls with a Community Health Worker, watching weekly videos (5-10 minutes each), reporting daily step counts, and practicing skills learned in the program. Participants can decide how much time they want to spend on personal goals and skills practice.

5. INFORMATION ABOUT STUDY RISKS AND BENEFITS

5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?

This study has very few risks, but there are always possible risks to participants in any research study. The researchers have taken steps to avoid risks as much as possible.

Although the study team takes many steps to protect your information, there is a small chance someone could accidentally see your information outside of the study team, resulting in loss of confidentiality. The study team takes your confidentiality very seriously and will keep all information in locked file cabinets or secure password-protected databases. We will assign you a study identification number, without your name, to track your responses to help protect your confidentiality. At the end of the study, the links between your name and the information we collect will be destroyed.

Although unlikely, you may experience some psychological distress while answering some survey questions. Some people may find it uncomfortable or upsetting to answer questions about their health. You do not have to answer any questions you don't want to, and you can end your participation at any time.

Participants in the STEPS program 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 you 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 you in increasing activity levels slowly and will encourage you to check with your doctor if you do not know whether or not a specific activity is appropriate for you.

Some people may find the activity tracker wristbands uncomfortable. If that happens, we will work with you to find a more comfortable option.

5.2 How could I benefit if I take part in this study? How could others benefit?
You may not receive any personal benefit from being in this study. It is possible that you will learn things that you find helpful in managing chronic pain. It is also possible that you will make positive changes in your lifestyle, such as increased walking. The researchers cannot guarantee benefits, however.

Although you may not directly benefit from being in this study, other people in the future may benefit because we may learn more about how to help people manage chronic pain.

6. ENDING THE STUDY

6.1 If I want to stop participating in the study, what should I do?
Taking part in this research project is completely voluntary. You do not have to participate, and you can stop at any time. You will be compensated for the surveys that you have completed during your time in the study. Please tell one of the study staff if you would like to leave the study so the research team knows not to continue trying to contact you.

If you choose to tell the researchers why you are leaving the study, your reasons may be kept as part of the study record. The researchers will keep the information collected about you for the research unless you ask us to delete it from our records. If the researchers have already used your information in a research analysis it will not be possible to remove your information.

7. FINANCIAL INFORMATION

7.1 Will I be paid or given anything for taking part in this study?
You will receive a $20 check in the mail after you complete the first telephone survey, another $20 check after completing the 2-month telephone survey, and a $25 check for completing the final, 12-month telephone survey: for a total of $65 for participating in the study.

All participants will be invited to keep the electronic activity tracker after the study ends. You will not need to pay for it if you lose or damage your activity tracker during the study, but we may not be able to replace it.

8. PROTECTING AND SHARING RESEARCH INFORMATION

8.1 How will the researchers protect my information?
As mentioned in section 5.1, the researchers will take many steps to protect your information including keeping all information in locked file cabinets or a secure password-protected database.

8.1.1 Special Protections
This research holds a Certificate of Confidentiality from the National Institutes of Health.

This means no one can make us give your information to anyone else unless we have your permission. However, you are welcome to talk about your participation in this research if you wish.

The Certificate does not stop researchers from reporting if you or others are at risk of substantial harm.
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More information about Certificates of Confidentiality and the protections they provide is available at

https://grants.nih.gov/policy/humansubjects/coc/information-protected-coc.htm

8.2 Who will have access to my research records?
Only selected persons involved with this study can see this information, including the research sponsor (the National Institutes of Health) and the University of Michigan Institutional Review Board that oversee the safety of study participants.

8.3 What will happen to the information collected in this study?
We will keep the information we collect about you during the research for future research projects and for study recordkeeping. Your name and other information that can directly identify you will be stored securely and separately from the research information we collected from you. After seven years, all names and contact information will be deleted, and only survey response data will be kept.

The results of this study could be published in an article or presentation but will not include any information that would let others know who you are.

8.4 Will my information be used for future research or shared with others?
Researchers at the University of Michigan or Henry Ford Health may use or share your research information for future research studies. If we share your information with other researchers, it will not contain your name or other information that can directly identify you. This research may be like this study or completely different. We will not ask for your additional informed consent for these studies.

8.4.1 Special Requirements
A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by the National Institutes of Health (NIH). This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

We will put the information we collect from you into a repository. The repository contains information about many people. Again, this will just be survey response data, your name and other identifying information will not be included. The repository has many ways to protect the data and confidentiality, including safety reviews and limiting who can access the data. Data is also kept in a secure virtual environment, in other words, data is stored electronically in a secure way.

9. CONTACT INFORMATION

Who can I contact about this study?
Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator: Mary Janevic
Email: mjanevic@umich.edu
Phone: 734-647-3194

Study Coordinator: Rebecca Lindsay
Email: reblin@umich.edu
Phone: 734-763-6369

Study Hotline: 1-844-456-4668

If you have questions about your rights as a research participant, or wish to obtain information, ask questions or discuss any concerns about this study with someone other than the researcher(s), please contact the following:

University of Michigan
Health Sciences and Behavioral Sciences Institutional Review Board (IRB-HSBS)
2800 Plymouth Road
Building 520, Room 2144 Ann Arbor, MI 48109-2800
Telephone: 734-936-0933 or toll free (866) 936-0933
Fax: 734-936-1852
E-mail: irbhsbs@umich.edu

You can also contact the University of Michigan Compliance Hotline at 1-866-990-0111.

10. YOUR CONSENT

Consent to Participate in the Research Study
By verbally consenting you are agreeing to be in this study. Make sure you understand what the study is about before agreeing to participate.

11. OPTIONAL CONSENT

Consent to use audio recordings for purposes of this research.
This study involves audio recordings for quality control purposes. If you do not agree to be audio recorded, you can still take part in the study. Recordings will only be accessed by study staff, and we will always ask you before we begin audio recording.

Consent to be Contacted for Participation in Future Research
Researchers may wish to keep your contact information to invite you to be in future research projects that may be similar to or completely different from this research project. Would you like to be contacted for future research projects?

We have recorded your responses to the consent during the verbal consent process over the telephone. This copy of the consent document is for your records only. You do not need to mail it back to us. If you have any questions about the study and/or the consent, you can contact the study team using the information in Section 9 at any time.

Thank you so much for your time and participation!