Cover Page for ClinicalTrials.gov

Document: Informed Consent

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

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HEALTH SCIENCES & BEHAVIORAL SCIENCES IRB
UNIVERSITY OF MICHIGAN

STEP-UP 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: STEP-UP (Support, Training, and Education for Pain self-management, Using Podcasts)
Principal Investigator: Mary Janevic, PhD, University of Michigan School of Public Health

The agency sponsoring this study is the National Institute on Aging (NIA).

Post eligibility screening:
We are happy that you are interested in participating in the STEP-UP study! The next step is to complete the consent process. I will go over all aspects of the study to make sure that you understand them and answer any questions you may have about participating.

To make sure we are covering all necessary information about the study to our participants, we would like to record this call. All recordings will be stored securely until the end of the project and then destroyed. Is it okay with you if we record the conversation?

If yes: Great! *Continue to consent*
If no: No problem. We can continue without recording. *Continue to consent*

You are invited to take part in a research study that is a collaboration between researchers at the University of Michigan and the Western Wayne Family Health Center. This verbal consent 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 feel free to stop me and ask questions at any time.

2. PURPOSE OF THIS STUDY

The purpose of this study is to see if an educational program can help adults age 50 and over better 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 pain due to arthritis or other musculoskeletal conditions that interfere with their life or work activities. We plan to recruit 40 eligible study participants.

Do you have any questions about the purpose of the study?

If yes: *Answer all questions before continuing*
If no: *Continue to next section*

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

If you agree to participate in the STEP-UP study, you will be asked to complete two telephone surveys conducted by researchers from the University of Michigan – one at the beginning of the study, and another about two months later. Each survey will take about 45 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. We will ask you about your physical activity and other things you do to manage your health.

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 STEP-UP program group or the Waitlist Control group. You have an equal ("50/50") chance of being in each group.

If you are placed in the STEP-UP program 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 will be completed in person at the Western Wayne Family Health Centers. If needed, it can also be done via Zoom. The orientation session will last about one hour to one-and-a-half hours.

After that, you will begin the STEP-UP program, which will take place over a period of five additional weeks. This program has three main parts:

1. After an initial orientation, you will receive five additional telephone calls from a community health worker, one each week following the orientation session. These calls will vary in length from about 15 to 30 minutes, depending on the week. The community health worker will help you set personal goals that are meaningful to you and that are based on your values and priorities, and that can be shared with your health care provider. The community health worker will also help you learn other skills for managing your pain.

2. Each week, you will listen to a podcast episode, which is like an audiorecording or radio show, on a topic related to managing chronic pain. Podcast episodes are about 15-20 minutes long and will provide information on different skills for managing chronic pain. You can find the recordings on the study website, or call into a phone menu to hear the podcasts.

3. You will also be given a workbook and a pedometer, which you can keep when the study is over.

If you are assigned to the Waitlist Control Group, you will not take part in these activities right away. Instead, we will ask you to complete the two telephone surveys - an initial survey and 2-month survey. After you complete the 2-month survey, you will have the opportunity to participate in the full STEP-UP program as described above. If you

choose not to participate at that time, we will still give you the workbook and pedometer, and access to the podcasts.

4.2 How much of my time will be needed to take part in this study?
To summarize, the two surveys will each take about 45 minutes to complete.

For participants in the STEP-UP program group and for control group members who choose to do the STEP-UP program when they have completed both surveys, the orientation session will take about 1 – 1.5 hours. For the following five weeks, they will listen to a podcast episode (about 15 to 20 minutes each week), have a scheduled call each week with a community health worker (15 to 30 minutes), and practice a chronic pain self-management skill each week. This skill practice would take no more than two hours per week.

Do you have any questions about what you would be doing in the study or how much time you will need to dedicate to the study?
If yes: *Answer all questions before continuing*
If no: *Continue to next section*

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?
The researchers have taken steps to minimize the risks of this study. Even so, you may still experience some risks related to your participation, even though the researchers are careful to avoid them.

Because this study collects information about you, the primary risk of this research is a loss of confidentiality. The study team will take measures to protect your confidentiality and privacy that I will describe in a moment. There is a small chance that the information you provide could be unintentionally disclosed. The researchers will try to minimize this risk by keeping information from this project that identifies you by name confidential. All information will be kept in locked file cabinets or a password-protected database, using state-of-the-art electronic security measures. Only selected persons involved with this study can see this information, including the research sponsors (the National Institutes of Health) and the University of Michigan Institutional Review Board that oversee the safety of the study and study participants. 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. This is because some people may find it uncomfortable or upsetting to answer questions about their health. Please keep in mind that you do not have to answer any questions you don’t want to, and you can end your participation whenever you like. You don’t have to tell us why.

Participants in the STEP-UP 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 STEP-UP program. To minimize this risk, your 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.

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. However, the researchers cannot guarantee benefits.

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.

Do you have any questions about the potential risks or benefits of participating in this study?
If yes: *Answer all questions before continuing*
If no: *Continue to next section*

6. ENDING THE STUDY

6.1 If I want to stop participating in the study, what should I do?
You are free to leave the study at any time with no penalty. If you leave the study before it is finished, please tell one of the study staff. 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.

The research team may end a subject's participation in the study if they become too ill to participate or cannot safely take part in the intervention, or if they are unable to work collaboratively with the Community Health Worker or study team. In these cases, participants will be contacted to see if they can complete the study surveys.

Do you have any questions about how to discontinue participation in the study?
If yes: *Answer all questions before continuing*
If no: *Continue to next section*

7. FINANCIAL INFORMATION

7.1 Will I be paid or given anything for taking part in this study?

You will receive a $20 gift card in the mail after you finish the initial telephone survey and $30 for the 2-month telephone survey, for a total of $50.

All participants can keep the activity tracker after the study ends. If you lose or damage the activity tracker you will not have to pay for it, but we may not be able to get you a new one.

Do you have any questions about the gift cards you will receive for your participation?
If yes: *Answer all questions before continuing*
If no: *Continue to next section*

8. PROTECTING AND SHARING RESEARCH INFORMATION

8.1 How will the researchers protect my information?

As I mentioned before, to keep your information safe, the researchers will keep all information in locked file cabinets or a password-protected, secure database. Only selected persons involved with this study can see this information, including the research sponsors and special boards that oversee the safety of the study.

Do you have any questions about how your information will be protected?
If yes: *Answer all questions before continuing*
If no: *Continue to next section*

8.1.1 Special Protections

This research holds a Certificate of Confidentiality.

This means no one can make us give your information to anyone else, even in a court or with police, unless we have your permission. The Certificate does not stop researchers from reporting suspected abuse, neglect, or risk of substantial harm to self or others.

We want you to know that you are welcome to talk about your involvement in this research with anyone if you wish.

If we share any information with other researchers or in reports, it will not allow someone to identify you.

Do you have any questions about this confidentiality protection? If you would like, I can read you the NIH website address where you can learn more. This website will also be written on the copy of the consent form that we send to you.

https://grants.nih.gov/policy/humansubjects/coc/what-is.htm

If yes: *Answer all questions before continuing and/or read the web address*
If no: *Continue to next section*

8.2 Who will have access to my research records?
There are reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- University, government officials, study sponsors or funders, auditors, and/or the Institutional Review Board (IRB) may need the information to make sure that the study is done in a safe and proper manner.
- Federal or State law may require the study team to give information to government agencies. For example, to prevent harm to you or others, or for public health reasons.

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 collect from you. After seven years, all identifiable data, such as names and contact information, will be deleted, and only de-identified data, like survey responses, 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 may use or share your research information for future research studies. If we share your information with other researchers, it will be de-identified, which means that it will not contain your name or other information that can directly identify you. This research may be similar to 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. A repository is a big database that contains information about many people. Your information will be de-identified. Processes used to protect participant confidentiality include rigorous review to assess risk, modifying data if necessary to protect the confidentiality, and limiting access to datasets. Data will be managed in a secure non-networked environment using virtual desktop technology.

Do you have any questions about how your data will be accessed and stored?
If yes: *Answer all questions before continuing*
If no: *Continue to next section*

9. CONTACT INFORMATION

Who can I contact about this study?

If you have questions about this research, including questions about scheduling or your compensation for participating, you may contact the Principal Investigator or the Project Manager directly.

Please contact the researchers or study team 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

The contact information for the researchers will be listed on the copy of the consent form that we send to you for your records. However, if you would like to write it down now, I can read it off to you.

If yes, they would like to write it down: Do you have a pen and paper to write down their phone numbers?

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

Project Manager: Rebecca Lindsay
Email: reblin@umich.edu
Phone: 734-763-6369

Study team hotline number: 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), you can contact the University of Michigan Institutional Review Board.

Again, this information will be included on the copy of the consent form that we send to you for your records. If you'd like to write it down now, I can give it to you over the phone.

If yes, they would like to write it down:

University of Michigan IRB
Telephone: 734-936-0933 or toll free (866) 936-0933
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 the study. After we complete the consent, you will be mailed (or emailed if you prefer) a copy of this document for your records and one copy will be kept with the study records. Be sure that questions you have about the study have been answered and that you understand what you are being asked to do. You may contact the researcher if you think of a question later.

Do you have any questions about the study? I want to be sure you understand what is being asked of you.
If yes: *Answer their questions.*
If no: *Okay, well if you have any questions later, please don't hesitate to contact us.*

Do you agree to participate in the study?
If yes: *Complete verbal signature below, and date.*
If no: *Thank them for their time and interest in the STEP-UP study.*

_____ _____
Verbal Signature (Print participant's name) Date

_____
Initials of Person Administering Consent

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. Do you consent to being audio recorded? [Check the appropriate box below based on the participant's response]

_____ Yes, I agree to be audio recorded.

_____ No, I do not agree to be audio recorded.

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. If you do not agree to be contacted about future research opportunities, you can still take part in the study. Do you consent to be contacted for participation in future research? [Check the appropriate box below based on the participant's response]

_____ Yes, I agree for the researchers to contact me for future research projects.

_____ No, I do not agree for the researchers to contact me for future research projects.

The next step is to schedule your first survey. Is there a time in the next couple of weeks that would work for you? (Remember to give enough time for consent form/baseline scales to be mailed/received)

Baseline survey scheduled for:

Date: _____ Time: _____

[Mark date and time below, in Google Calendar, and in REDCap Call Backs and Tracking].

When we send your copy of the consent form (via mail or email based on participant preference), you will also receive the "STEP-UP Baseline Survey Scales" in that packet. These will make it easier to follow along during the first telephone survey. Please have the "STEP-UP Baseline Survey Scales" out in front of you when we call for the survey as they will help you answer the survey questions more easily.

Would you prefer a text, phone call, or email reminder for the survey? We will remind you 1-2 days before the scheduled survey call.

[note preference in REDCap]

Thanks again for participating in STEP-UP and we look forward to talking to you soon! We really appreciate your time and participation!