Informed Consent Form: Positive Psychology for Chronic Pain Self-management

NCT04321239

The Positive STEPS program

July 1, 2020

Consent to Participate in a Clinical Research Study
POSITIVE STEPS STUDY

Principal Investigator: Mary Janevic, PhD, University of Michigan School of Public Health

Co-Investigators: Sheria Robinson-Lane, PhD, University of Michigan School of Nursing; Afton Hassett, PhD, University of Michigan Medical School

Invitation to participate in a research study

We invite you to participate in a study called "Positive STEPS." This study is being conducted by the University of Michigan Schools of Public Health and Nursing. It is funded by the National Institute on Aging.

You were recently screened over the phone and are eligible to enroll in this study. This study will test an educational program to help people better manage chronic pain. It is for adults age 60 and over who have pain due to arthritis or other musculoskeletal conditions.

The researchers estimate that 50 people will enroll in this study.

Description of subject involvement

If you agree to participate in the Positive STEPS study, you will be asked to complete two telephone interviews – one at the beginning of the study and another about two months later. Each interview will take about 45 minutes and will have 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 in to one of two groups by chance, the Positive 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 Positive STEPS intervention group, you will be asked to attend a one-hour orientation session in midtown Detroit, where you will learn more about the program and meet your health coach.

In the case that we must maintain social distancing due to the coronavirus pandemic, we will instead hold the first session over the phone with your

community health worker and/or a University of Michigan research assistant. It will last approximately one hour.

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

First, we will provide you with an electronic activity tracker to wear during waking hours every day for 7 weeks. Each evening, you will report that day's step count to the study team by text message. If your first session is over the phone, we will mail you the activity tracker.

Second, we will ask you to visit the study website at least once each week, to watch educational videos about different ways to manage chronic pain, with a focus on positive and enjoyable activities. Each week will have a different topic and a different video. You will also be given a workbook that has more information along with suggested activities that will help you practice the skills that you learn in the videos. If your first session is over the phone, we will mail you the participant workbook.

Third, you will receive up to seven telephone calls from a community health worker, one each week during the program. These calls will last up to 30 minutes each. The community health worker will discuss that week's video with you, as well as help you set personal goals related to walking and other skills for managing your pain. These calls will be audio-recorded for quality assurance.

If you are assigned to the Control Group, you will not take part in these activities. However, we will ask you to complete the two telephone interviews, about two months apart, as described above. After you complete the final telephone interview, you will have the opportunity to participate in either an in-person or over-the-phone workshop about chronic pain management. We will also mail you the activity tracker and workbook after you complete the study.

Benefits

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.

Risks and discomforts

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 when the researchers are careful to avoid them.

There is a small chance that the information you provide could be unintentionally disclosed. To reduce this risk, information from this project that identifies you by name will be kept 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 and special boards that oversee the safety of the study. At the end of the study, any information connected to your name will be destroyed.

Please tell the researchers about any concerns or problems you have during the study. You should also tell your regular health care provider. The study will pay for research-related items or services that are provided only because you are in the study. By signing this form, you do not give up your right to seek payment if you are harmed as a result of being in this study.

Compensation

You will receive up to a $20 gift card in the mail after you finish the first telephone interview and $15 for the second interview, for a maximum study total of $35. All participants will be invited to keep the electronic activity tracker after the study ends. Control group participants who would like to have a tracker will be mailed one after the study ends. You will not be held financially responsible if you lose or damage your tracker during the course of the study, but we may not be able to replace it.

Confidentiality

The results of this study may be published in an article or presented at a scientific meeting, but would not include any information that would let others know who you are.

There are some reasons why people other than the researchers may need to see information you provided as part of the study. This includes organizations

responsible for making sure the research is done safely and properly, including the University of Michigan, government offices or the study sponsors.

To keep your information safe, the researchers will keep all information in locked file cabinets or a password-protected 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. At the end of the study, any information connected to your name will be destroyed.

If you tell us something that makes us believe that you or others have been or may be physically harmed, we may report that information to the appropriate agencies.

Special Protections

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

This means that we cannot be forced to disclose any research information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. In general, we will use the Certificate to resist any demands for information that would identify you, except as described below.

We will disclose your information for any purpose to which you have consented, as described in this informed consent document. This includes sharing your de-identified data with other researchers. We may also disclose your information to the appropriate authorities if we suspect or learn about cases of child or elder abuse or neglect.

Please note that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then we will not use the Certificate to withhold that information.

More detailed information about Certificates may be found at the NIH CoC webpage: https://humansubjects.nih.gov/coc/index

Storage and future use of data

The data you provide will be stored in a secure, designated server at the University of Michigan School of Public Health. The researchers will keep the data for 7 years. After 7 years have passed, researchers will dispose of any data with identifying information by permanently deleting electronic data files.

Data that does not have identifying information will be kept and may be made available to other researchers for other studies following the completion of this research study. For example, if researchers decide to conduct a similar study in the future, the data may be made available to them. It will not contain information that could identify you.

Voluntary nature of the study

Participating in this study is completely voluntary. Even if you decide to participate now, you may change your mind and stop at any time.

If you decide to withdraw early, the researchers will not continue to use or disclose information about you, but will keep it secure until it is destroyed. Sometimes, it may be necessary for information about you to continue to be used or disclosed, even after you have canceled permission or the study is over. Examples of reasons for this include:

- To avoid losing study results that have already included your information
- To provide limited information for research, education, or other activities (This information would not include your name, social security number, or anything else that could let others know who you are.)
- To help University and government officials make sure that the study was conducted properly

You may also want to discuss your participation with your health care provider.

If significant new knowledge is obtained through the course of the research which may relate to your willingness to continue participation, you will be informed.

If, during the course of the study, the researchers determine that you are unable to follow essential study protocols, we may discontinue your participation.

Contact information

If you have questions about this research, including questions about scheduling or your compensation for participating, you may contact:

Study Toll Free Number
1-844-456-4668

Principal Investigator
Dr. Mary Janevic
Health Behavior Health Education
1415 Washington Heights
SPH I, Rm 2815
Ann Arbor MI 48109-2029
Phone: 734-647-3194

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:

University of Michigan Health Sciences and Behavioral Sciences Institutional Review Board 2800 Plymouth Rd., Bldg. 520, Room 1169
Ann Arbor, MI 48109-2800
Phone: (734) 936-0933,
Toll free: (866) 936-0933, irbhsbs@umich.edu

Consent

By signing this document, you are agreeing to be in the study. Please keep one copy of this document for your records and mail one back to 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 researchers if you think of a question later.

I agree to participate in the study.

_____
Print Name

_____ _____
Signature Date

I agree to be audio recorded as part of the study.

_____
Print Name

_____ _____