A New Model to Reach Vulnerable Older Adults With Pain Self-management Support

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Consent to Participate in a Clinical Research Study
STEPS STUDY

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Invitation to participate in a research study

We invite you to participate in a study called "STEPS PLUS." This study is being conducted by the University of Michigan Schools of Public Health and Nursing. It is funded by the American Pain Society and 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 10 people will enroll in this study.

Description of subject involvement

If you agree to participate in the STEPS PLUS 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, 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.

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

First, you will be given a FitBit Zip to wear during waking hours every day for 6 weeks. Each evening, you will report that day's step count to your STEPS PLUS health coach, either by text message OR by automatically syncing with your phone, tablet, or computer.

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. 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.

Third, you will receive up to six telephone calls from a health coach, one each week during the program. These calls will last up to 30 minutes each. The health coach 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.

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 a $10 gift card in the mail after you finish the first telephone interview. Then, you will receive a $20 gift card for the second telephone interview, after the program ends, for a maximum total of $30. All participants will be invited to keep the FitBit Zip after the study ends. You will not be held financially responsible if you lose or damage your Fitbit 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.

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.

Special Requirements

This trial will be registered and may report results on www.clinicaltrials.gov. This site 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.

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