Informed Consent Document

Tracking Physical Activity for Chronic Pain Management Among Older Adults in Detroit

NCT03285958

Principal Investigator: Mary Janevic, University of Michigan

Protocol date: June 19, 2018

Consent to Participate in a Clinical Research Study
STEPS STUDY

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

Co-Investigators: John Piette, PhD, University of Michigan School of Public Health and Susan Murphy, PhD, Physical Medicine and Rehabilitation, University of Michigan Medical School

Invitation to participate in a research study

We invite you to participate in a study called "STEPS" (Seniors Tracking Exercise for Pain Self-management). This study is being conducted by the University of Michigan School of Public Health. It is funded by the Claude D. Pepper Older Americans Independence Center at the University of Michigan.

You were recently screened over the phone and are eligible to enroll in this study. This study is about the use of wearable physical activity monitors ("FitBit Zip") to count the number of steps you take each day. It is for adults age 60+ who have chronic pain due to arthritis or other musculoskeletal conditions. Moderate physical activity, like walking, helps many people manage their pain.

This study is being done to test different ways that people can report their daily step counts to health professionals. Researchers estimate 50 people will enroll in this study.

Description of subject involvement

If you agree to participate in the STEPS study, you will be asked to complete two telephone interviews – one at the beginning of the study and another about six weeks later. Each interview will take about 30 to 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. We will also ask how you use technology like cell phones and the internet.

After you complete the first telephone survey, you will be assigned to one of two groups by chance, the STEPS group or a Control group. Because there will be 30 people in the STEPS group and 20 in the Control group, you will have a slightly higher chance of getting placed in the STEPS group.

If you are placed in the STEPS group, you will be asked to attend a one-hour orientation session in downtown Detroit. After that, you will wear a FitBit Zip during waking hours every day for 6 weeks. Each evening, you will report that day's step count to STEPS project staff. The way in which you report your steps will change every 2 weeks over the 6-week period:

Half of the people in the STEPS group will be assigned by chance to receive automated phone calls for the first two weeks of the study and then text messages for the next two weeks. For the remaining people, the order will be reversed.

For the automated telephone calls, you will be asked to use your phone's keypad to enter your step count for that day.

For the text messages, you will be asked to report your step count for that day by replying to the text.

Finally, a research assistant will help you set up your FitBit to automatically send your daily step count to STEPS project staff during the last two weeks of the study. This can be done through a smartphone, tablet, or computer.

If you are assigned to the Control Group, you will not wear a FitBit Zip and you will not report your steps. However, we will ask you to complete the two telephone interviews, about six weeks apart, as described above.

Benefits

You may not receive any personal benefit from being in this study. If you are in the STEPS Group, tracking your daily steps may help you become more aware of your physical activity patterns.

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 activity monitors can be used 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 each time you finish a telephone interview, for a maximum total of $20. All participants will be invited to keep the FitBit Zip after the study ends. Control group participants who would like to have a FitBit Zip will be mailed one after the study ends.

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 sponsor, National Institute on Aging (NIA).

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. Paper containing data will be stored in a locked file-cabinet in a locked study office.

The researchers will retain 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 and shredding paper 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.

Contact information

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

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 researcher if you think of a question later.

I agree to participate in the study.

Signature Date