Study Title: A Partnership to Translate an Evidence-based Intervention (Take Heart) for Vulnerable Older Adults with Heart Disease

NCT02950818

12/20/2016

Consent to Participate in a Clinical Research Study
TAKE HEART STUDY

Principal Investigator: Cathleen Connell, PhD, Center for Managing Chronic Disease, University of Michigan School of Public Health (UM SPH)
Co-investigators: Daniel Eisenberg, PhD, UM SPH; Mary Janevic, PhD, Center for Managing Chronic Disease, UM SPH; and Roderick Little, PhD, UM SPH
Project Director: Jessica Ramsay, MPH, Center for Managing Chronic Disease, UM SPH

Invitation to participate in a research study

The Take Heart Study is being conducted by the University of Michigan School of Public Health in partnership with the Detroit Area Agency on Aging. You were recently screened over the phone and are eligible to enroll in this study. The partnering organizations invite you to participate in a research study about helping adults age 50+ better manage their heart disease, or health conditions that could lead to heart disease.

This study is being done to test the effectiveness of the *Take Heart* program in community-based settings. Researchers estimate 400 people will enroll in this study. The study is funded by the National Institute of Aging (NIA).

Description of subject involvement

If you agree to participate in the Take Heart study, you will be asked to complete two telephone interviews – one at the beginning of the study and another approximately 1 year later. Each interview will take about 30 to 60 minutes and contains questions about your health and well-being, as well as your use of health care services. For example, we will ask you about the types of health problems you have and how they affect your daily life. We will be asking you about your thoughts and feelings about your health. We will also ask you about the number of times you have seen your doctor or stayed in the hospital.

Next, you will have a 50-50 chance to be assigned to one of two study groups. After you complete the first telephone survey, we will use a process (like flipping a coin) to randomly assign you to be in one of two groups: The Take Heart Program Group or Usual Care/Program Waitlist. Regardless of your group assignment, you will continue to receive the usual care from your medical care provider.

If you are assigned to the Take Heart Program Group, you will be asked to talk to a health educator/heart disease counselor two times over the phone, and five times in person as part of a group. These sessions will happen over a 7-week period. Transportation will be provided if you need it. Each group session will last 120-160 minutes and telephone sessions will be 30-50 minutes each.

During the Take Heart education sessions, you will learn ways to improve how you manage your health conditions related to your heart. You will learn information about the benefits of physical activity, healthy eating, and reducing stress, and how to improve communication with your doctor. You will also learn a goal-setting and problem-solving process so that you can work on achieving your own personal goals related to your health. You will be provided a binder of materials as part of this program. At the end of the 7 weeks of sessions, you will be asked to complete a questionnaire that asks what you did and did not like about the program. During the 8 months after the sessions and before you complete your final 12-month follow up survey, the health educator will keep in touch with you by mailing newsletters and calling you once. The purpose of the follow-ups is to continue to provide you with information and check in on your progress towards your goals.

If you are assigned to the Usual Care/Waitlist group, you may, if time and funding allows, have an opportunity to participate in the Take Heart program as described above after you complete the 12-month follow-up interview.

Benefits

You may not receive any personal benefit from being in this study. Since you have heart disease, or health conditions related to heart disease, it is hoped that you will benefit from the health information you will receive as a participant in the study.

Although you may not directly benefit from being in this study, other people in the future may be helped because of what is learned about this educational heart disease self-management program.

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. 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 $20 gift card in the mail each time you finish a data collection telephone interview.

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. Cathleen Connell, Professor and Chair
Health Behavior Health Education
1415 Washington Heights
SPH I, Rm 3790
Ann Arbor MI 48109-2029
Phone: 734-647-3189

Study Coordinator
Jessica Ramsay, Project Director
University of Michigan, School of Public Health
1415 Washington Heights
SPH I, Rm 3811
Ann Arbor, MI 48109-2029
Phone: 734-764-5420
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