Citizen Science to Promote Sustained Physical Activity in Low-Income Communities

NCT03041415

8/31/2019

Abby C King, Principal Investigator
Stanford University
Stanford, California 94305

Informed Consent Form

CONSENT TO PARTICIPATE IN A RESEARCH STUDY
STANFORD UNIVERSITY
Steps for Change Study

What is this research study about?

The purpose of this research study is to test programs that promote physical activity and healthy lifestyles.

What will I be asked to do?

If you decide to participate in this study, you will attend a class that aims to help you be more physically active. The class will be located in the participating affordable housing sites or at community locations nearby.

- You will receive an initial group session (approximately 60 minutes) to review the expectations and content of the program.
- You will attend group sessions, every other week for the first 6 months, to promote healthy living lifestyles. After the first 6 months, the group will continue to meet on a regular basis for ongoing support and motivation for healthy living for at least the following 6 months.
- You may be asked to use an e-tablet to take photos and record audio narratives about features in your neighborhood that make it easier or harder for you to be physically active or to practice healthy living styles.
- You will be asked to wear a pedometer (small device that counts your steps).
- You may be asked to keep a record of your physical activity
- You will be asked to complete physical activity and technology-related questionnaires at the beginning, 6, 12, 18 and 24 months of the study.
- You will be asked to perform physical function and strength tests at the beginning, 6,12,18 and 24 months of the study. These tests involve: grip strength, balancing, walking at a normal pace, standing up from a chair and a 2 minute step test.
- You will be asked to wear a small accelerometer (worn at your waist and about the size of a pager) that measures the speed of your movement, at the beginning, 6,12,18 and 24 months of the study. . The accelerometer is worn

during waking hours only for 7 days at each time point.

- You may be asked to carry an easily-worn monitor that is small and lightweight for a short period of time to measure air quality and noise in your environment.

- Some of the study participants may be asked if they want to assist group leaders and study staff with recruitment activities at their housing site and may be offer the opportunity to provide additional help and feedback to study staff around study activities, these types of activities may occur on group meetings or by telephone. Some of study participants may also be asked to help facilitate study activities in or around the housing site and attend additional meetings.

- All activities will take place at participating housing facilities or at community centers nearby

Audio-taping or Videotaping: During the class sessions you may be asked to be audio-taped, or on occasion, videotaped. The purpose of these recordings is to make sure that the advisor (i.e., class instructor) gives the information as expected. The audiotapes and videotapes will be destroyed 5 years after the end of the research study. You may refuse to be audio- or videotaped.

Do you agree to be audio-taped? (circle one): Yes No
Do you agree to be videotaped? (circle one): Yes No

If you circled "yes" above, we also need for you to tell us how we can use the videotape and audiotape. We will only use the audio/videotape in ways that are agreeable to you. In any use of the recording, you would not be identified. If you do not initial the space below, the audio/videotape will be destroyed.

The audio/videotape can be studied by the research team for use in the research project. Please initial: _____

Risks and Benefits

There are risks, discomforts, and inconveniences associated with any research study. In general, there will be low potential risk involved as a participant in this study. The Protocol Director and study staff have conducted similar studies over the past 20 years with no participant experiencing a major medical problem or injury related to the physical activity program. However, given that you will be asked to make changes in your lifestyle habits such as increase your physical activity by walking, you may experience discomforts such as temporary muscle and joint soreness. Unless there is damage due to a previous injury, serious orthopedic complications are uncommon as a result of the physical activity being recommended. There is a remote risk that persons completing questionnaires or interviews focused on psychological issues may become distressed. You do not have to answer any questions. Benefits that could reasonably

be expected include learning more about physical activity and healthy lifestyle habits. Some participants may improve their lifestyle habits. However, we cannot and do not guarantee or promise that you will receive any benefits from this study.

Costs and Payment

There is no cost to you to participate in this study. All costs for the study will be supported by an award from the National Institutes of Health (NIH)

You will receive a gift equivalent to approximately $10 for completing the questionnaires and evaluations at the beginning, 6,12,18 and 24 months of the study.

Your Rights as a Participant

If you have read this form and have decided to participate in this research study, please understand that your participation is voluntary and you have the right to withdraw your consent or discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled. You have the right to refuse to answer particular questions. Your individual privacy will be maintained in all published and written data resulting from this study.

CERTIFICATE OF CONFIDENTIALITY This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, or documents that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information and documents protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is any law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by National Cancer Institute, which is funding this project. .

The Certificate of Confidentiality will not be used to prevent disclosure as required by

federal, state, or local law of neglect, or harm to self or others.

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document.A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Authorization to Use Your Health Information for Research Purposes

Because information about you and your health is personal and private, it generally cannot be used in this research study without your written authorization. If you sign this form, it will provide that authorization. The form is intended to inform you about how your health information will be used or disclosed in the study. Your information will only be used in accordance with this authorization form and the informed consent form and as required or allowed by law. Please read it carefully before signing it.

What is the purpose of this research study and how will my health information be utilized in the study?

The purpose of this study is to test programs that give physical activity advice and support. Any health information collected will be used in publications or reports to describe the general characteristics of the study participants.

Do I have to sign this authorization form?

You do not have to sign this authorization form. But if you do not, you will not be able to participate in this research study. Signing the form is not a condition for receiving any medical care outside the study.

If I sign, can I revoke it or withdraw from the research later?

If you decide to participate, you are free to withdraw your authorization regarding the use and disclosure of your health information (and to discontinue any other participation in the study) at any time.

After any revocation, your health information will no longer be used or disclosed in the study, except to the extent that the law allows us to continue using your information (e.g., necessary to maintain integrity of research). If you wish to revoke your authorization for the research use or disclosure of your health information in this study, you may write to: Dr. Abby King at 1070 Arastradero Road, Suite 100, Palo Alto, CA 94304-1334.

What Personal Information Will Be Used or Disclosed?

Your health information related to this study, may be used or disclosed in connection with this research study, including, but not limited to:

- Name, ethnicity, date of birth, street address, zip code, email address, and telephone number.
- Medical history
- Height and weight
- Health-related questionnaire data
- Physical function data
- Cognitive testing data

Who May Use or Disclose the Information?

The following parties are authorized to use and/or disclose your health information in connection with this research study:

- The Protocol Director (Dr. Abby King)
- The Stanford University Administrative Panel on Human Subjects in Medical Research and any other unit of Stanford University as necessary
- Research Staff (Study Coordinator, research assistants, data analyst)

Who May Receive or Use the Information?

The parties listed in the preceding paragraph may disclose your health information to the following persons and organizations for their use in connection with this research study:

- The Office for Human Research Protections in the U.S. Department of Health and Human Services
- The National Institutes of Health
- Research collaborators at Stanford University
- Research collaborators and data analyst from other institutions
- Project Advisory Committee, partially comprised of non-Stanford scientists

Your information may be re-disclosed by the recipients described above, if they are not required by law to protect the privacy of the information. **When will my authorization expire?**
Your authorization for the use and/or disclosure of your health information will expire on December 31, 2037.

_____ _____
Signature of Participant Date

_____
Print Name of the Participant

Contact Information

Questions, Concerns, Complaints, or Injuries: If you have any questions, concerns or complaints about this research study, its procedures, risks and benefits, or alternative courses of treatment, you should ask the Lab Manager Ines Campero at 650-736-7274. You should also contact her at any time if you feel you have been hurt by being a part of this study.

Alternate Contact: If you cannot reach the Lab Manager, please call the Protocol Director, Dr Abby King, at 650-723-2880.

Independent Contact: If you are not satisfied with how this study is being conducted, or if you have any concerns, complaints, or general questions about the research or your rights as a participant, please contact the Stanford Institutional Review Board (IRB) to speak to someone independent of the research team at (650)-723-5244 or toll free at 1-866-680-2906. You can also write to the Stanford IRB, Stanford University, 3000 El Camino Real, Five Palo Alto Square, 4th Floor, Palo Alto, CA 94306.

We may share your survey responses with approved collaborators and data analysts within Stanford University and from other institutions. If you do NOT wish to share your survey responses, please check this box. ☐

The extra copy of this consent form is for you to keep.

_____ _____
Signature of the participant Date

_____
Print Name of the Participant

_____ _____
Signature of individual obtaining consent Date

_____
Print Name of the individual obtaining consent