# Escalating Proportion of Weight-Loss Maintainers Via Modules Prior to Weight Loss

Informed Consent Form

NCT03014414

November 30, 2018

# STANFORD HEALTHY HEART STUDY ♥

## QUESTIONS ABOUT THE STUDY

Please contact Protocol Director, Michaela Kiernan PhD at (650) 721-6684 or Department of Medicine, Stanford Prevention Research Center, 1070 Arastradero Road, Suite 300 Palo Alto, CA 94304 or mkiernan@stanford.edu.

## STUDY DESCRIPTION

People with elevated blood pressure are at higher risk of having a heart attack or stroke than people with lower blood pressure. Losing a modest amount of weight—such as 15 or 20 pounds—can reduce the risk of having a heart attack or stroke. However, it can often be a struggle to **maintain** weight loss over time.

You are invited to participate in a research study examining if two weight-management programs help people maintain weight loss over time. In this study, 346 adults will be randomly assigned (like flipping a coin) to one of the programs and followed for 36 months (i.e., 3 years) to see how their weight and blood pressure may change.

If you decide to participate, you need to be willing to:

(1) **Be randomly assigned and attend one of two 12-month weight-management programs**

**FUN FIRST**: If randomly assigned to this program, you will attend 90-minute weekly group sessions for the first 6 months at the Stanford Prevention Research Center at 1070 Arastradero Road, Palo Alto, CA and then receive monthly phone calls from our health coaches for the second 6 months.

The FUN FIRST sessions may be audio recorded to be sure they are delivered as intended. You will be informed before anything is audio recorded and you can refuse to be recorded. The audio recordings will be destroyed ten years after the research study ends. Do you agree to the possibility of being audio recorded and that the recordings may be used for quality assurance purposes? ____Yes ____No

**WEIGHT WATCHERS**: If randomly assigned to this program, you will have study-paid access to weekly Weight Watchers meetings at a Bay Area location of your choice and their online tools for up to 12 months.

(2) **Fill out a brief online survey** at 2 months about your experience in your weight-management program to date.

(3) **Weigh yourself at home on a study-provided scale** at least once every 3 months over the 36-month study. The scale transmits values via nearby cell towers to our central online account rather than connecting to participants' home wireless. There is no personal information connected to this scale (e.g., your name), only a study ID number.

(4) **Attend 5 clinic visits at our research center** at the start of the study and 6, 12, 24, and 36 months later (i.e., during and after the weight-management programs are over). Your height, body weight, and blood pressure will be measured by our trained research staff. The first visit takes 1 hour and the remaining visits take 30 minutes. Before each visit, you will fill out an online survey about your attitudes and lifestyle habits which will take 90 minutes.

## WHAT HAPPENS NEXT?

If you decide to participate in the research study, you need to be willing to be randomly assigned to either the Fun First program or Weight Watchers. If randomized to Fun First, you will attend one of two session times: Wednesdays (6:30-8:00 pm) or Saturdays (8:30-10:00 am). You will be able to select the session time depending upon availability. Once you select the session time, you will not be able to switch. If you are randomly assigned to Weight Watchers, you can attend any meetings at a Bay Area location, day, and time of your choice depending upon availability. Because the start of any weight management program is so important, all participants need to be able to attend all of the first 10 sessions. If you have a scheduling conflict for the first 10 sessions that you cannot change (such as vacation), we will be unable to enroll you in the study.

If you decide to participate in the study, you will be invited to attend a baseline clinic visit and asked to sign this consent form. After your height, body weight, and blood pressure are measured, you will be randomly assigned to one of the two weight-management programs. You have a ~50% chance of being assigned to either program.

## RISKS AND BENEFITS

There are risks, discomforts, and inconveniences associated with any research study. The risks associated with this study are minimal. Given you will be physically active, you may experience temporary muscle soreness, sprains, strains, or inflammation (e.g., plantar fasciitis); increased injuries to joints, tendons, or ligaments (e.g., from tripping or falling when walking or playing sports); and some shortness of breath or dizziness. Medical risks of the assessments (e.g., weight, blood pressure, online surveys) are minimal. There is a small chance you may become overly preoccupied with your weight, or find commuting to our research center for classes or clinic visits inconvenient at times due to traffic. It is possible that, based on information gained during this study, the investigators may be required to report information (e.g., relating to suicide, physical or sexual abuse) to the appropriate authorities. The benefits that could be reasonably expected from participating in this study include gaining knowledge about nutrition, activity, and weight management. You may lose a modest amount of weight and improve your lifestyle habits. However, we cannot and do not guarantee or promise that you will receive any benefits from this study. Your decision whether or not to participate in this study will not affect your medical care. After the entire study is over (~5 years), the Protocol Director will send all participants a summary of the study results.

## TIME INVOLVEMENT

Your participation in this study will take approximately 36 months (3 years).

## PAYMENTS

You will not be paid to participate in this research study. This study and all costs are paid for by a National Institutes of Health grant. There will be no costs to you for participation other than transportation to our research center.

If randomized to Fun First, you will be asked to download the Lose It! Premium phone application ('app') for tracking your food intake and steps for up to 12 months. The study will provide you with a $40 pre-loaded gift card to cover the cost of the premium app. If you have an Android phone, you will be asked to download the free Google Fit app for tracking your steps. There may be minor data plan charges when using the two apps while not on Wi-Fi.

If randomly assigned to Weight Watchers, the study will pay for your access to weekly Weight Watchers meetings and online e-Tools for up to 12 months with sets of 13 pre-paid vouchers. To receive a new set of vouchers, you will need to send your Weight Watchers Success Story booklet that tracks meeting attendance to us in a study-provided envelope.

You will be provided with a study-provided scale to use at home that is purchased with study funding. The scale must be returned at the last clinic visit.

## YOUR RIGHTS AS A PARTICIPANT

If you have read this form and have decided to participate in this study, please understand 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. The results of this research study may be presented at scientific or professional meetings or published in scientific journals. However, your identity will not be disclosed.

## 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 examine what strategies successfully help people maintain weight loss over time. The term 'your health information' used below refers to the information collected in this study such as during the clinic visits and online surveys. Some summary information will be submitted to the National Institutes of Health. The results of this research study may be presented at scientific meetings or published in scientific journals. However, your identity will not be disclosed.

### 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, including receiving any research-related treatment. 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 must write to the Protocol Director, Michaela Kiernan PhD at Department of Medicine, Stanford Prevention Research Center, 1070 Arastradero Road, Suite 300 Palo Alto, CA 94304.

### 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 your height, weight, and blood pressure as measured at the clinic visits as well as the information on the online surveys.

## 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, Michaela Kiernan PhD and the study staff
- The Stanford University Administrative Panel on Human Subjects in Medical Research and any other unit of Stanford University as necessary.

## Who May Receive / 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
- National Institutes of Health

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 end on March 2027 or when the research project ends, whichever is earlier.

## Will access to my medical record be limited during the study?

To maintain the integrity of this research study, you may not have access to any health information developed as part of this study until it is completed. At that point, you would have access to such health information if it was used to make medical or billing decision about you (e.g., if included in your official medical record).

_____ _____

Signature of Adult Participant Date

_____

Print Name of Adult Participant

## 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, documents, or biospecimens 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, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local 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 The National Institutes of Health which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of child or adult abuse or neglect, or threats or evidence of harm to self or others.

## WITHDRAWAL FROM STUDY

The Protocol Director may withdraw you from the study without your consent because of failure to follow instructions of the research staff, behavior disruptive to the conduct of the classes, unwillingness to follow approved study protocols, or other administrative reasons.

## CONTACT INFORMATION

If you have any questions, concerns, or complaints about this research study, its procedures, or risks and benefits, you should ask the Protocol Director, Michaela Kiernan PhD at (650) 721-6684. You should also contact her at any time if you feel you have been hurt by being a part of this study.

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.

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

_____ _____
Signature of Participant Date

_____
Print Name of Participant

_____ _____
Signature of Person Obtaining Consent Date

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Print Name of Person Obtaining Consent