The EMBER Trial for Weight Management Engagement

NCT05424081

November 30, 2023

IRB Use Only
Approval Date: November 30, 2023
Expiration Date: November 30, 2024

Title of Study: The EMBER Trial for Weight Management Engagement	
Title of Consent (if different from Study Title):	
Principal Investigator: [redacted]	VAMC: VA Palo Alto HCS

What is this research about?

You are invited to participate in a research study about EMBER, a self-help tool to increase weight loss treatment engagement among Veterans.

What is expected of me? (Procedures)

If you participate, you will be randomly assigned to receive either: 1) information about VA weight management programs or 2) EMBER, an interactive tool to help you think about weight and whether you might want to start a VA weight management program. You have a 1 in 2 chance of being assigned to the tool. You will receive the information or the tool on paper or in a digital format via email, depending on your preference. This is **not** a weight loss treatment study. It is a study on **engaging** Veterans in weight management treatments.

In addition, we will call you ~10 days after we send the materials to discuss whether and how you used them. If you agree, we will record this call (this is not required) so we have a record of your responses. You can ask us to pause or stop recording at any time. We may also transcribe audio-recordings and/or use written quotes in future presentations/papers, but your identity will not be made known. Recordings will be stored on a secure VA server to which only study staff have access.

We will also ask you to answer questions about your health and health behaviors, such as your weight, your height, your eating and exercise habits, and your use of weight management programs. We will ask these questions at the beginning of the study, 2-months after the beginning of the study, and 6-months after the beginning of the study. You may receive calls from Houston VA research staff (the other study site). A professional assessment company, Davis Research, will conduct the 2-month and 6-month assessments. All assessments will be done over the phone.

Finally, we ask your permission to obtain information about your diagnoses, height, weight, vital status, and medical care from your VA medical record.

Your participation will take a total of 3 hours spread over 6 months (four study contacts).

What are the possible risks or discomforts?

The risks associated with this study are minimal and limited to breach of confidentiality.

Will I benefit from the study?

The benefits which may reasonably be expected to result from this study are increased information about weight loss treatments. We cannot and do not guarantee or promise that you will receive any benefits from this study.

What are my alternatives to being in this study?

Your alternative is to not participate.

Will I get paid?

You will be paid $20 for each of the study contacts when you answer questionnaire questions, up to $60.

To receive payment you will need to provide your social security number and, if you do not already use direct deposit with VA, you will need to provide your bank information.

Will I have to pay anything?

You will not have to pay anything to be in this study.

Do I have to be in this study?

No and your decision whether or not to participate in this study will not result in any penalty or loss of benefits the participant may be entitled.

Can I change my mind later and stop being in this study?

You can withdraw from the study at any time without penalty or loss of benefits you may be entitled.

Will my information be protected from the public?

We will keep your name and all the information you tell us in this study as confidential as possible. We may publish the results of this study for others to read about, but you will not be identified in any articles about the study by name, social security number, address, telephone number, or any other direct personal identifier. Also, other federal agencies as required, such as the VA Office of Research Oversight and the VA Office of the Inspector General may have access to your information.

It is possible that, based on information gained from this study, the researchers may have serious concerns (relating to matters such as severe depression, eating disorder, etc.) about your health and/or safety; in such a case, the researchers may contact you and provide a referral for your care. If information is revealed about child abuse or neglect, elder or dependent abuse or neglect, or potentially dangerous future behavior to others or yourself, the law requires that this information be reported to the proper authorities.

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.

What happens if I think I've been hurt by being in this study?

If you are injured as a direct result of being in this study, medical treatment will be available. If you are eligible for veteran's benefits, the cost of such treatment will be covered by the VA. If not, the cost of such treatments may still be covered by the VA depending on a number of factors. In most circumstances, the treatment must be provided in a VA medical facility. No other form of compensation for injuries is available. However, by signing this form you have not released the VA from liability for negligence.

Who can I talk to if I have questions about the research, problems related to the study or if I think I've been hurt by being a part of the study?

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 principal investigator, [redacted] at [redacted]. You should also contact her at any time if you feel you have been hurt by being a part of this study.

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, and would like to speak to someone independent of the research team please contact the Stanford Institutional Review Board (IRB) at [redacted] or toll free at [redacted]. You can also write to the Stanford IRB, Stanford University, [redacted].

VA Health Services Research & Development is providing financial support and/or material for this study.

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

If you agree to participate in this research, please indicate this to the researcher by saying, yes I agree to participate.

If it is not ok to audio record the 10-day call, please indicate this to the researcher by saying, I do not agree to audio recording or, if it is ok, say, I agree to audio recording.

If it is ok to send you reminders about study-related appointments, please indicate your preferred method (phone, email, and/or text message) and give permission by saying, yes you may contact me about appointment reminders.

If it is ok to contact you about future research, please indicate this to the researcher by saying, yes you may contact me about future research.

If you would like to receive information about the study results, please indicate your preferred method (mail or email) and give your permission by saying, yes I would like to receive study results information.