Teaching Obesity Treatment Options to Adult Learners (TOTAL): A Multi-site RCT

NCT05346575

April 13, 2023

VA RESEARCH CONSENT FORM

Subject Name:		**Date:**	
Title of Study:	**Teaching Obesity Treatment Options to Adult Learners (TOTAL): A Multisite Randomized-Controlled Trial (RCT)**		
Principal Investigator:	Dr. Luke Funk, MD, MPH	**VAMC:**	Madison, WI and Greater Los Angeles, CA

STUDY SPONSOR:
Veteran Affairs Health Services Research & Development (VA HSR&D)

STUDY NUMBER:
2021-1441

WHY ARE RESEARCHERS DOING THIS STUDY?
The purpose of this study is to examine whether an intervention called "Teaching Obesity Treatment Options to Adult Learners (TOTAL)" is effective at increasing participation in weight management services, including participation in the VA MOVE! program. TOTAL consists of an educational video and three (3) telemedicine motivational sessions to encourage Veterans to begin weight management treatment. Motivational sessions occur one-on-one with study staff and are designed to support and encourage Veteran weight management treatment initiation.

WHAT WILL MY PARTICIPATION INVOLVE?
This study has a usual care group as well as an intervention group. If you are eligible and interested in participating, you will be randomly assigned into one of these groups. Your group will be chosen by chance, like flipping a coin. You will not be able to select which group you are assigned to. You will have equal chance of being assigned to either group.

If you are randomized into the **intervention group**, you will participate in 4 VA Video Connect telemedicine sessions (VVC) with study staff and complete a series of short survey assessments.

- In **Session 1**, you will be asked to complete a short baseline survey and watch an 18-minute educational video. Session 1 will last about 30 minutes and occur approximately 1-2 weeks from agreeing to participate in the study.
- In **Sessions 2, 3, and 4**, you will be asked to complete a one-on-one telemedicine session with a health coach. You will also complete a brief survey assessment. Session 2 will occur 1-2 weeks after Session 1. Session 3 will occur 6 months after Session 1; and Session 4 will occur 12 months after Session 1. Each of these sessions will take 30-60 minutes to complete.
- **Lastly**, you will be asked to complete a brief survey assessment, which will occur 18 months after Session 1 and take less than 5 minutes to complete.

Sessions 2, 3, and 4 will be audio-recorded to monitor quality and consistency of study staff adherence to the motivational scripts and to inform future research practices. Only study team members will have access to the recordings. Additionally, you will be asked to report your weight at each time point. If randomly placed into the intervention group, you may be contacted at the end of the study asking for your participation in a 30-minute interview. This interview will be audio recorded.

At the start of each VVC session, you will be asked for your physical location/address in case of an emergency. Current VA regulations require us to keep study records for a period not to exceed 7 years after the close of the study.

If you are randomized into the **usual care group**, you will complete a short baseline survey **1-2 weeks** after agreeing to participate in the study. You will also be asked to complete a brief survey assessment at **1 week**, **6 months**, **12 months**, and **18 months** after completing the baseline survey. Additionally, you will be asked to report your weight at each time point. At study completion, you will be offered the opportunity to watch the 18-minute educational video. You do not have to watch the video if you do not want to.

Additional details for both groups: At each time point, you will be asked to report your current weight either by emailing a picture of your weight to study staff or uploading a picture of your weight directly into the electronic survey assessment tool. This picture should be taken close enough to the scale for researchers to be able to read the number. Your feet or toes may be included in the picture but no other identifying features are needed. Sending us a picture of your weight is optional but must be sent only to the study staff VA email provided to you. You will also be asked if you have recently participated in any weight management treatment, such as participating in Weight Watchers or starting a weight loss medication. A calibrated scale will be mailed to you so you can consistently and routinely report your weight to study staff. You may keep this scale. Additional study information will also be mailed at this time. Full study participation will occur over the span of about 18 months. Participants will be recruited from the Madison, WI VA and the Greater Los Angeles, CA VA.

Lastly, your medical record will be reviewed periodically by study staff throughout the course of your participation as well as at the end of your participation. This will include demographic information (e.g., age, body mass index) and weight management treatment initiation (e.g., participation in MOVE!, weight loss medication use, bariatric surgery referral, etc.).

WHAT ARE SOME REASONS I MIGHT – OR MIGHT NOT – WANT TO BE IN THIS STUDY?

You may want to be in this study if you are:	You may NOT want to be in this study if you:
• comfortable being randomly assigned to either the usual care or the intervention group. • willing to participate for the full course of the study, about 1.5 years. • interested in contributing to the scientific knowledge even though you may not benefit directly from the study.	• may not have time to complete all study activities. • are uncomfortable providing your weight to study staff and/or discussing your weight loss treatment goals and progress.

ARE THERE ANY RISKS?

The main risk to taking part in this study is that your information could become known to someone outside of the research team, which might make you uncomfortable. It is possible that you may feel anxious from talking about personal experiences with weight loss treatments or because your motivational sessions are being audio recorded. You do not have to answer any questions that make you uncomfortable. You do not have to pursue any obesity treatment options if you do not want to. Due to the 'randomly assigned' aspect of this study, you may be assigned to a less effective treatment group.

We will request your email address to send the assessment surveys, share the VVC invite web links (if in the intervention group), and communicate about scheduling as needed (if preferred by the participant). Similarly, text messages may be sent for scheduling purposes (if preferred by the participant). Study staff will not include any identifying information within emails or text messages. Email/text message is generally not a secure way to communicate about your health as there are many ways for unauthorized users to access email. You should avoid sending sensitive, detailed personal information by email/text message. Email/text message should also not be used to convey information of an urgent nature. If you need to talk to someone immediately, please contact your provider for healthcare needs/questions or contact Dr. Luke Funk at (XXX) XXX-XXXX ext. XXXXX for study-related questions.

ARE THERE ANY BENEFITS?

Participating in this study may encourage you to seek weight loss treatment, which could involve healthier lifestyle behaviors, medication use, and/or bariatric surgery. If participants initiate weight management treatment and lose weight, they may experience improvements in health behaviors, health conditions, weight, and quality of life. More broadly, participation in this study will inform future

research efforts as well as VA obesity treatment best practices, locally and nationwide, whether or not you personally benefit from this study.

ARE THERE ANY COSTS?

There are no costs directly associated with participation in the study. If you choose to initiate obesity treatment with behavioral weight management (MOVE!), obesity medications, and/or bariatric surgery, you will be required to pay routine co-payments for medical care and services provided at the VA. Should you receive any data charges due to participation in this study, you may be reimbursed up to $10.00 upon verification of data overages.

Veterans participating in this VA study will not be required to pay for care received as a subject in a VA research project. Some veterans are required to pay co-payments for medical care and services provided at the VA. These co-payment requirements will continue to apply to medical care and services provided by the VA that are not part of this study.

WILL I BE PAID FOR PARTICIPATING IN THE STUDY?

Yes. You will receive $20 after completing the 1-week assessment; $20 for completing the 6-month assessment; $30 for completing the 12-month assessment; and $30 for completing 18-month assessment. Therefore, if you complete all study activities, you will receive a total of $100 in appreciation of your time. If you are selected and participate in the 30-minute interview at the end of the study, you will receive an additional $50 for your time.

To receive payment for your participation in this study, you will be required to provide your bank account information. Reimbursement will be made available by direct deposit through Electronic Funds Transfer (EFT). Payments will be made through [Service] and will generate Internal Revenue Service Form 1099 regardless of reimbursement amount. Your SSN and bank account information will be used for reimbursement purposes only and will not be kept by the study team.

If you do not want to provide your banking information, you can instead sign up for a Direct Express card which would take an additional 6-8 weeks to receive payment for your participation. The Direct Express card is similar to a gift card. If you do not want to use either payment option, you can still participate in this study without receiving any payment for your time.

WILL THERE BE COMPENSATION FOR INJURY?

In the event you sustain injury as a result of participation in this investigation, all necessary and appropriate care will be provided. However, the VA may not pay for the costs of treatment for injuries that result from your non-compliance with study procedures.

HOW MANY PEOPLE WILL BE IN THIS STUDY?

We expect about 494 Veterans to participate in this study. Half of which will be recruited from the William S. Middleton VA in Madison, WI, and the other half will be recruited from the Greater Los Angeles VA in Los Angeles, CA.

DO I HAVE TO BE IN THE STUDY?

No, you do not have to be in this study. Your decision to take part in this study is completely voluntary. You may completely withdraw from the study at any time. You may refuse to participate or stop participating without any penalty or loss of medical care or any legal rights to which you are otherwise entitled. You can ask all the questions you want before you decide whether or not to participate.

Instead of being in this research study, you may independently pursue any or all of these weight loss activities within or outside of the VA. You may also choose to not participate in any weight loss activities.

HOW IS RESEARCH DIFFERENT FROM HEALTH CARE?

When you take part in a research study, you are helping to answer a research question. Study tests and procedures are not for your health care.

WILL INFORMATION FROM THIS STUDY GO INTO MY MEDICAL RECORD?

For each VVC session, note will be added to your medical record that you are participating in this research study and will include the emergency contact information required for VVC sessions; however, any research-related information you provide during this study will **not** be entered into your VA medical record.

HOW WILL MY CONFIDENTIALITY BE PROTECTED?

Your information used for this study will be kept confidential as required by law. The results of your participation in this study may be used for publication or for scientific purposes, but the results will not include any information that could identify you. Current VA regulations require us to keep study records per VA Records Control Schedule (RCS) 10-1 regulations for a period not to exceed 7 years after the close of the study. We may share your data with our research collaborators at the Madison

VA, the Greater LA VA, and the Hines VA. Also, with appropriate confidentiality protections, we may use information that we collect during this study for other research, or share it with other researchers without additional consent from you. By signing this consent form, you are giving us permission to collect this data and share your data with these researchers. Your identity will not be disclosed unless you give specific consent or if required by law. There are times when we may have to show your records to other people. For example, representatives from offices and agencies that oversee research may review your records, such as the University of Wisconsin and the Madison or Greater LA VA research oversight offices or other federal agencies that oversee research such as the Office for Human Subjects Protections, the VA Office of Research Oversight, or the VA Office of the Inspector General.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

WHAT WILL HAPPEN TO MY DATA AFTER MY PARTICIPATION ENDS?
We will keep your data up to 7 years after the study closes. We do not plan to use your data for future research projects. Data will not be shared with your healthcare providers.

WHAT IF I HAVE QUESTIONS?
If you have questions, concerns, or complaints about this research, please contact the study team at **(XXX) XXX-XXXX ext. XXXXX.** For information on the rights of research subjects or if you have complaints about the research study or study team, please contact the VA hospital patient relations representative at (XXX) XXX-XXXX. If you want to confirm this is a valid VA study, please call the VA Research Office at (XXX) XXX-XXXX. In case of medical problems or questions, please contact your individual health care provider.

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AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

You do not have to sign this form. If you refuse to sign, however, you cannot take part in this research study. If you sign this form either electronically or on paper, it means that:

- You have read this consent and authorization form.
- You have had a chance to ask questions about the research study, and the researchers have answered your questions.
- You want to be in this study.
- You give authorization for your protected health information to be used and shared as described in this form.

Participant's Printed Name

Last Four Digits of Participant's Social Security Number

Participant's Signature

Date

Study Staff Printed Name

Study Staff Signature

Date