Building an Equitable and Accessible System of Eating Disorder Care for VA, DoD, and Underrepresented Americans With Eating Disorders (EASED Study)

NCT Number: NCT05304104

August 23, 2021

INTRODUCTION

You are invited to participate in a research project sponsored by VA Connecticut Healthcare System and funded by Department of Defense (DoD). You have been invited to take part in this study because you were referred by VA's multidisciplinary eating disorders treatment team who thought this study might be of interest to you. Our research is looking for new ways to test whether a common psychological treatment, delivered through home-based video teleconferencing is helpful for improving eating behavior and mood. Your participation may last up to 12 months.

To decide whether or not you wish to be a part of this research study, you should know enough about its risks and benefits to make an informed judgement. This information sheet gives you detailed information about the research study which a member of the research team will discuss with you. This discussion will go over all aspects of this research: its purpose, the procedures that will be performed, any risks of the procedures, and possible benefits. Once you understand the study, you will be asked if you wish to participate.

STUDY PROCEDURES

If you choose to participate, here is what participation will involve:

The purpose of this study is to assess whether cognitive-behavioral therapy (CBT), a common psychological treatment, is effective in reducing binge eating behaviors when delivered through home-based video teleconferencing. The treatment involves learning several different skills to help reduce binge eating and its impact on your life. The idea around this therapy is to focus on thoughts and behaviors around eating to help improve eating behaviors. If you agree to participate, you will be randomly assigned to receive the teleconferencing session with a clinician (TeleCBT) or a self-help version of the CBT (shCBT). The study uses a procedure like flipping a coin, so that you will have a 1 in 2 chance (a 50% chance) of receiving TeleCBT or shCBT.

No matter which group you are assigned to, at the beginning of the study and again at 3- and 6- months after you get started, you will be asked to complete some questionnaires and interviews about your eating, mood, and physical activity. These questionnaires will take place over the telephone and will last anywhere between 90-120 minutes. About 3 months after you start the study, we will also ask you what you thought about the treatment that you received. These interviews and questionnaires will help us to understand how well the program worked for you.

TeleCBT Treatment– If you are assigned to get the TeleCBT, you will receive up to 10 individual sessions of CBT treatment through a videoconferencing app. Each CBT appointment is led by a clinician and is expected to occur once a week during the 3 month treatment duration. Each appointment will last approximately 60 minutes. You will also be mailed a patient manual that you will be expected to read. In each session, the clinician will review new coping skills covered in the manual chapter for that week. These skills are aimed at changing your behavior and thinking about eating. Each week you will set goals with your clinician to practice these skills on your own at home.

shCBT Treatment– You will receive the same patient manual and other resources that are given to participants in the TeleCBT treatment. We will provide you with a self-guided schedule to follow so that you may cover the material and skills in each chapter at a time that is convenient for you. The materials are designed so that you can do this on your own and without the help of a clinician.

We aim to have 144 Veterans participate in this research study.

POSSIBLE DISCOMFORTS OR INCONVENIENCE

Potential inconveniences are questionnaires and interviews which may be viewed as frustrating and time-consuming. Also, some of the questions we ask may make you feel uncomfortable. We will offer short breaks, and you may request one at any point if you find the procedure tiring. In most cases, we don't foresee individuals having prolonged discomfort. However, if you feel uncomfortable about any question, you can decline to answer, and we'll skip to the next question. Or you can let study staff know that you would like to stop your participation.

If, for any reason, you experience significant distress, we'll discuss it with you and help you connect with your current mental health provider or assist with a referral to one.

You may be asked to walk each day. Beginning a daily walking program, especially if you do not regularly exercise, could lead to physical discomforts such as muscle tightness, muscle soreness, or blisters. If you are experiencing any physical symptoms or discomforts while you are in the study, we will arrange for you to see your provider and be cleared to participate in the walking program again.

POSSIBLE RISKS

Confidentiality of Information

Participation in research may involve loss of privacy. In this study you will be asked about psychological symptoms and we may need to view your VA medical record. All information in electronic format will be stored on secure servers at VA Connecticut. Only a code number will identify your research records. The code number will not be based on any information that could be used to identify you (for example, social security number, initials, birth date, etc.) The master list linking names to code numbers will be kept separately from the research data. We will audio record the counseling sessions to make sure that the information is delivered correctly. Only those people who are approved to work on the study will have access to the voice-recordings. The voice-recordings will not obtain any identifying information (except for your voice) and will be identified by a code number. The electronic files that contain the voice-recording will be stored behind the secure VA firewall. No recordings will be disclosed outside of VA.

Your identity will not be revealed in any reports or publications resulting from this study.

Only authorized persons will have access to the information gathered in this study. Authorized persons may include regulatory agencies such as the Food and Drug Administration (FDA), the Government Accountability Office (GAO), or the Office for Human Research Protection (OHRP), Office of Research Oversight (ORO), The Department of Defense (DoD), and staff of the Research Office at the VACHS. The Department of Veterans Affairs (VA) requires some information to be recorded in the VA electronic medical record for all Veteran and non-Veteran research subjects participating in clinical trials. Therefore, if you participate in this study, a VA Connecticut medical record will be created if you do not already have one. Notes from your visits, procedures, and laboratory tests will be included in this record. In addition to the research team, and the VA staff who provide clinical services, other researchers may be granted approval to access this information in the future. Federal laws and regulation that protect privacy of medical records will apply to your VA record. Your

referring clinician will be able to view these notes in your medical chart and communicate with us if coordination of care is needed.

We will do everything we can to ensure your information is kept private, however, there are certain situations in which your information may be given out if required by law. For instance, if it were learned through the research study that you were a danger to yourself or others, we are required to notify the authorities. Or if you express suicidal thoughts, we will contact your VA provider so that he/she is aware and can contact you for assistance. Additionally, we will be in regular communication with your referring clinician and they will be notified that they can view research information in your medical records. Additionally, referring clinicians can contact study staff at any time with questions/concerns. If your referring providers elect to get information about your participation sent to them, it will be made available or transmitted to them.

There are times when we might have to show your records to other people. For example, our local Research and Development Committee, VA officials, other study monitors who may look at or copy portions of records that identify you, and regulatory agencies such as the Food and Drug Administration (FDA), the Government Accountability Office (GAO), or the Office for Human Research Protection (OHRP), Office of Research Oversight (ORO), the Department of Defense (DoD) and staff of the Research Office at the VACHS. The Department of Defense (DoD) is funding or supporting the study. The confidentiality section allows DoD access to research records as a part of its human subjects protection oversight activities.

POTENTIAL BENEFITS
Your participation in this study may benefit you and future Veterans if the TeleCBT or shCBT treatments are found to be effective for binge eating.

ALTERNATIVES TO PARTICIPATING IN THIS RESEARCH
Participation in the study is voluntary and the alternative is to not participate. You are free to withdraw from the study at any time without giving us a reason. If you choose not to participate or withdraw from the study, this will not affect your relationship with staff or providers in the study or VHA, nor will it affect your medical care.

Also, there are other treatment options for managing binge eating at VHA if you decide this study is not right for you. The clinician who referred you to this study would be able to help navigate you to nutrition, mental health, weight management, and/or primary care.

USE OF RESEARCH RESULTS
If results of this study are reported in medical journals or at meetings, you will not be identified by name, by recognizable photograph, or by any other means without your specific consent. Your medical records will be maintained according to VA requirements. If our questions reveal information concerning suicidal intent, depression, or other major clinical findings your primary physician will be notified immediately. In the event that you express any imminent behavioral health emergency risk during any therapy session or interview, local emergency services and your identified emergency contact will be called. You may be hospitalized involuntarily according to current standards of care if you are found to be a danger to yourself or others, or are gravely disabled or unable to care for yourself due to a mental condition. If any new findings are developed during the course of the research which may affect your willingness to continue in the research, this information will be provided to you.

SPECIAL CIRCUMSTANCES

Costs to Participants

There will be no charge for care received as part of your participation in this study. However, some Veterans are required to pay a co-payment for medical and other services provided by the VA Healthcare System that are not part of the study. These co-payments will continue to apply to medical care and services provided by the VA that are not part of this study.

Payment Offered for Participation
You will be paid as follows for participating in the following assessments: You will be paid ($25) for baseline, ($35) for three-month (post-treatment), ($45) for six-month (follow-up) assessments. You could receive up to $105 for your participation in this study.

You will be paid through direct-deposit if you already have that set up with the VA, otherwise it will come in the mail as a check, please allow approximately 4-6 weeks for processing. In some circumstances, if you owe a debt to the federal government the money associated with your participation in this study may be garnished.

FUTURE USE OF DATA

Identifiers will be removed from the identifiable private information that are collected. After that removal, the information could be used for future research studies or distributed to other investigators for future research studies without additional informed consent from you.

RESEARCH SUBJECT'S RIGHTS

A description of this clinical trial is 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.

If you have any general questions about the study or you experience any distress related to the study, you can call Dr. Robin Masheb at VA Connecticut (203-932-5711 x3954).

As a reminder, if you experience a medical or mental health emergency, please call 9-1-1, or your local VA Medical Emergency Room. You can also call or text the Veterans Crisis Line at any time to speak with a trained professional at 1-800-273-8255 and Press 1 or send a text to 838255.

If you are injured as a direct result of your participation in this research study, the VA will provide necessary medical treatment at no cost to you. Except in very limited circumstances, this medical treatment will be provided in a VA Medical facility. There are no plans to provide compensation for disability or other losses occurring over the long-term or if an injury becomes apparent after your participation in this study has ended. However, by agreeing to participate in this research study, you are not waiving or giving up any legal rights to seek compensation. If you have any questions about your rights as a subject, you may contact the Chairman of the Human Studies Subcommittee at 203-932-5711 x3350. If you have any complaints, concerns or pertinent questions regarding the conduct of this study, or if you have any questions about compensation for injury, you may contact the Human Studies Coordinator in the Research Office at 203-937-3830.

Study staff has explained the research study to you. You have been told of the risks or discomforts and possible benefits of the study. You have been given the chance to ask questions and obtain answers. Please confirm that you have read this information sheet, or it has been read to you and that you agree to participate in the research study.

Study staff (signature): _____

Date:_____