Provider Supported Self-Help Cognitive Behavioral Therapy for Insomnia (Tele-Self CBTI)

NCT03727438

Written informed consent form

Approved 4/15/21

Participant Name:	**Date:**
Study Title: A Telehealth-Supported Self-Management Intervention for Insomnia (Tele-Self-CBTI).	
Principal Investigator: Christi S. Ulmer, Ph.D.	**VAMC**: Durham

Please read this form carefully. It tells you important information about a **voluntary** research study. As the study staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. It is important that you understand the information on this form. If you would like to check that this study is approved by the Durham VAMC's Institutional Review Board, please call the research office at (919) 286-6926 or (888) 878-6890, extension 6926.

WHY IS THIS RESEARCH BEING DONE?

The purpose of this research is to determine if a telehealth-supported self-management program for insomnia is an effective approach to the treatment of insomnia. Many Veterans have insomnia symptoms. Although there are helpful interventions for insomnia, few providers across the VA have been trained in these approaches. We hope that what we learn from this study will help us to increase Veteran access to insomnia treatment.

You are being asked to participate in this research study because you have reported experiencing insomnia symptoms and you have no prior treatment with Cognitive Behavioral Therapy for Insomnia.

We plan to recruit and enroll up to 200 Veterans into this study, and we expect the entire project to last for a period of 3 ½ years.

WHAT IS THE EXPERIMENTAL PART OF THIS RESEARCH STUDY?

The experimental part of this research study is a tele-health supported self-management approach to insomnia treatment.

WHAT PROCEDURES, DRUGS, OR TREATMENTS ARE INVOLVED IN THIS RESEARCH STUDY?

If you agree to participate in this research study you will first be asked to complete a screening interview and complete a short questionnaire to assess your eligibility for the study. This screening session should take no more than 30 minutes. If the information obtained from this interview and the questionnaires show that you have a significant sleep problem, and that it would be safe for you to participate, you will be accepted into the study. If you are scheduled to receive an evaluation or treatment in the Durham VA Behavioral Sleep Medicine clinic, that will be suspended while you are in this study. However, you may receive treatment in this clinic in the future or at any time when you are not enrolled in this study. You would then be asked to complete a number of additional procedures for research purposes.

1. First, you will call into a phone number for 3 two-week periods and respond to questions about your sleep pattern over the past 24 hours by entering numbers on your phone keypad. It should take you no more than a few minutes each morning to complete the phone-based sleep diary. In the event of technical difficulties, paper sleep diaries are provided.
2. Second, you will wear a small device, similar to a wrist watch and called an actigraphic monitor or Actiwatch, during this same two-week period. This device is used to monitor your activity level throughout the day and your sleep during the night. This movement information can be transferred to a computer program that will provide estimates of your sleep and wake time while you are wearing the device.
   At the end of this 2-week Baseline assessment period, you will be contacted by our study staff and asked to complete questionnaires about sleep, fatigue, mood, and quality of life over the phone. This should take no more than 1 hour. You will also be asked to return the actiwatch by using a prepaid UPS envelope.

RANDOMIZATION

Following completion of Steps 1 to 3 above, you will be randomly assigned to one of two groups using a process that is similar to flipping a coin. You will have a 50% chance of being assigned to the Cognitive Behavioral Therapy for Insomnia intervention group and a 50% chance of being assigned to the Health Education group.

COGNITIVE BEHAVIORAL THERAPY FOR INSOMNIA INTERVENTION GROUP:

If you are assigned to the intervention group, you'll receive a workbook in the mail to be used throughout the intervention period. During the six- week intervention period, you will be asked to track your sleep, read assigned topics from the workbook, and participate in weekly 20-minute phone sessions with the nurse interventionist.

At the end of the intervention period and again at 6 months after your enrollment in the study, you will complete the same 2-week assessment process completed previously. Your involvement in the study will conclude following the 6-month assessment period.

Completion of all Intervention condition activities outlined above is estimated as follows: 2 hours and 15 minutes of phone-based assessment; 2 hours of phone sessions with nurses; and 6 hours of home-based sleep diary tracking. This estimate does not include time wearing the actigraphy device.

HEALTH EDUCATION GROUP:

If you are randomized to the Health Education Group, you will engage in the same procedures described above, with the exception you will receive a workbook on various health topics, and the nurse phone calls will provide you with education about specific health topics such as medication safety, cancer screening, and vaccinations. Each of these calls should last no more

than 15 minutes. After completing the study, patients in the control group will be offered treatment at the Durham VA Behavioral Sleep Medicine clinic which may include both face to face and remote treatment options. Completion of all Health Education Control Group activities involves 2 hours less time than the Intervention.

I give permission to Dr. Ulmer and her study staff to leave a detailed message for me regarding the research study and associated sleep diaries.

YES ☐ NO ☐ Initials:_____ Date:_____

All of the procedures described in the above paragraphs will be done for research purposes and are not part of your necessary or routine care. You will be allowed to enroll and continue in this study as long as your medical and mental condition allows you to do so safely and without risk of any harm to you or others. If any of the investigators determine that it would not be safe for you to continue in this study, the Principal Investigator, Dr. Ulmer, may terminate your participation in this research study. Your primary doctor will also be informed of this decision and our reasons for concern. If you decide to withdraw from this research, there will be no penalty to you and you will be allowed to continue in the care for which you are eligible at this VA Medical Center.

CAN I REFUSE TO BE IN THIS RESEARCH STUDY OR WITHDRAW AT A LATER TIME?

Absolutely. You do not have to join this or any other research study. If you do join and later change your mind, you may quit at any time. If you withdraw from the study, no new data about you will be collected for study purposes. If you refuse to join or if you withdraw from the study, there will be no penalty or loss of any benefits to which you are otherwise entitled. This will not affect your relationship with or treatment by the Veterans Health Administration (VHA) or your rights as a VHA patient. You will still receive all the medical care and benefits for which you are otherwise eligible.

WHAT OTHER OPTIONS DO I HAVE?

Taking part in this study is your choice. You have the option not to participate.
If you choose not to take part in this study, your other choices may include:

- Getting no treatment
- Getting treatment without being in a study

HOW LONG WILL I BE IN THIS RESEARCH STUDY?

Your active participation will last for about 6 months.

WHAT ARE THE RISKS AND DISCOMFORTS OF PARTICIPATING IN THIS RESEARCH STUDY?

This research study consists of completing questionnaires, clinical interviews, and sleep monitoring procedures for the time periods stated above. There are few known psychological hazards or risks

associated with the study procedures. However, there are some inconveniences and minor risks to this research and we are unable to predict who might be affected by these risks.

Since you will be asked many questions about yourself during interviews and when completing the research questionnaires, there is the potential risk of loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed. Some people feel uncomfortable answering some of the personal question asked during the interview or on the questionnaires. You will be free to refuse to answer any of these questions that you do not wish to answer. Also, you will experience some monitoring procedures in your home. If you find the study too burdensome or inconvenient, you may withdraw from the study at any time without affecting your ongoing medical care at this VA facility. If you experience discomfort that you think may be related to the research, you can call the study team.

WILL I BENEFIT FROM TAKING PART IN THIS RESEARCH STUDY?

You may not personally be helped by taking part in this study, but your participation may lead to knowledge that will help others. Knowledge learned from this study may benefit other veterans with sleep problems. If you do enroll in this study, you may learn strategies for improving your sleep.

DOES PARTICIPATION IN THIS RESEARCH STUDY COST ANYTHING?

There will be no costs to you for any of the research treatment or research testing done as part of this research study. Some Veterans are required to pay co-payments for medical care and services provided by VA. These co-payment requirements will continue to apply to medical care and services provided by VA that are not part of this study.

WILL I RECEIVE ANY COMPENSATION (MONEY OR OTHER) FOR TAKING PART IN THIS RESEARCH STUDY?

You will be compensated in the amount of $58 for each of 3 assessment periods. You will receive an additional $3 per day (up to $42 for the 2-week period) for completion of sleep diaries. In sum, you may receive up to $100 for each 2-week assessment period, for a total of $300 for completion of all study procedures. Payment occurs in the form of a check to be mailed to you or electronic funds transfer within 6 to 8 weeks of completion of each study period. Participants not completing the entire study will not be compensated for incomplete study periods. Money that you receive for participating in research is considered taxable income per Internal Revenue Service (IRS) regulations. The money may be reported to the IRS and you may receive an IRS Form 1099.

HOW WILL I BE COMPENSATED?

You will receive a check or electronic fund transfer (EFT) for completion of <u>each of the study phases</u> noted above. If you do not complete the study, you will be compensated only for the study activities that you have completed in the amounts outlined above. Partial payment will not be provided when the procedures for an assessment period are only partially completed.

ARE THERE REASONS THAT MY RESEARCH PARTICIPATION MAY END EARLY?

Dr. Christi Ulmer may take you out of the study without your consent for one or more of the following reasons: she decides that continuing your participation could be harmful to you, or failure to follow instructions of the research staff.
In case of research related injury resulting from this study, you should contact the principal investigator at 919-286-0411 ext. 174044 during the day and at 919-475-5052 after hours.

WILL MY CLINICAL OR OTHER RESEARCH TEST RESULTS BE SHARED WITH ME?

We will let you know of any important discoveries made during this study which may affect you, your condition, or your willingness to participate in this study. If you have been randomized to the intervention group you will receive individual feedback from the telehealth interventionist about your progress throughout the intervention.

WILL THE RESULTS OF THIS RESEARCH STUDY BE SHARED WITH ME?

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, along with a summary of the results after study completion.

DO ANY OF THE RESEARCHERS HAVE A FINANCIAL INTEREST RELATED TO THIS RESEARCH STUDY?

No, Dr. Christi Ulmer will not financially benefit from the study.

HOW WILL MY RESEARCH DATA BE PROTECTED AND SECURED?

As part of the study, Dr. Christi Ulmer and her study team will record information about you that contains your name and other personal identifiers. Study records that identify you will be kept confidential as required by law. Federal Privacy Regulations provide safeguards for privacy, security, and authorized access. Except when required by law (HIPAA), you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier in study records disclosed outside of the VA Medical Center. Electronic data will be stored on secure VA servers on a restricted folder. Paper study documents will be kept in locked file cabinets in the Legacy Building research staff's office. Staff use VA approved computers that are encrypted and password protected. Electronic and paper research data can only be accessed by this study's research staff. Your research records will be maintained and destroyed according to VHA records retention

requirements. Some of your calls with our interventionists will be recorded for the purpose of quality control. No one but study staff will have access to these recordings and they will be stored on a secure server behind the VA firewall.

CONSENT TO BE RECORDED

I consent to have some of my calls with the nurse interventionist recorded for the purpose of quality control. If I do not consent to this, it will not affect my eligibility to participate.

YES ☐ NO ☐ Initials:_____ Date:_____

WILL ANYONE ELSE HAVE ACCESS TO MY RESEARCH DATA?

If results of this study are reported to others, you will not be identified by name, by recognizable photograph, or by any other means without your specific consent.
Your research records may be reviewed by Durham VA staff who are responsible for the safe conduct of this research. We may also provide your research records to federal agencies such as the Office for Human Research Protections (OHRP), the VA Office of the Inspector General (OIG), and the Office of Research Oversight (ORO).

ARE THERE ANY LIMITS TO THE PRIVACY AND CONFIDENTIALITY OF MY RESEARCH INFORMATION?

If during the study any information reveals suicidal intent, depression, or other major clinical findings, your primary physician will be notified. In addition, if you reveal current intent to harm yourself or someone else, we may be required to enact our safety plan to ensure your safety or the safety of others, as applicable.

WHERE CAN I FIND OTHER INFORMATION ABOUT THIS RESEARCH STUDY?

Should you need additional information about this research study, you may ask any of the research staff to answer your questions. You may also contact the Principal Investigator as indicated below.

WHO DO I CONTACT IF I HAVE QUESTIONS OR CONCERNS ABOUT THE RESEARCH STUDY?

If you have questions about the research or need to talk to the study team, you can contact Dr. Christi Ulmer at 919-286-0411 ext. 174044 during the day or at 919-475-5052 at night.
If you have questions about the research or your rights as a research participant, would like to obtain information, offer input, or have other concerns or complaints, you may contact the administrative officer of the research service at (919) 286-0411, extension 177632.

PROMISE TO RETURN VA EQUIPMENT

The device we will be mailing you is VA-owned study equipment (Actiwatch) to use for collecting data at home. Please understand that this equipment is on loan and you must return this equipment as indicated in the study procedures. If you have not returned study equipment according to study procedures, study personnel will contact you about return of the equipment and will assist you in returning the equipment, including sending an additional pre-paid envelope for mailing the study equipment back.

AFFIRMATION FROM PARTICIPANT

My rights as a research participant have been explained to me, and I voluntarily consent to participate in this study. I have received an explanation of what the study is about and how and why it is being done. I authorize the use and disclosure of my identifiable information as described in this form. I will receive a signed copy of this consent form.

Participant's Signature	**Date**
Signature of Person Obtaining Consent	**Date**