Improving Sleep and Functioning in Veterans with Posttraumatic Stress Disorder

NCT04007796

July 21, 2020

Department of Veterans Affairs	INFORMED CONSENT FORM
Subject Name:	**Date:**
Title of Study: Improving Sleep and Functioning in Veterans with Posttraumatic Stress Disorder	
Principal Investigator: [redacted]	**San Francisco VAHCS**

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

This is a research study about treatments for sleep problems in Veterans who have posttraumatic stress disorder (PTSD). The study researcher, [redacted] or the study Research Coordinator will explain this study to you.

STUDY SUMMARY

Introduction: We are asking you to consider taking part in a research study being done by [redacted], at the San Francisco VA Healthcare System.

The first part of this consent form gives you a summary of this study. We will give you more details about the study later in this form. The study team will also explain the study to you and answer any questions you have.

Purpose of the study: The purpose of this study is to see whether one treatment for sleep problems is better than another treatment among Veterans who have PTSD. You are being asked to participate because you were diagnosed with sleep apnea and reported symptoms that we often see in people who have PTSD.

Study Procedures: If you choose to be in this study, you will work with a therapist for 6 sessions to learn how to improve your sleep at night. You will be "randomized" into one of the study treatments described later in this form. One treatment is called “Apnea and Insomnia Relief” (or “AIR”) and one is called Sleep Education (or “SE”). Randomization means that you are put into a treatment by chance. A computer program will place you in one of the treatments. Neither you nor your doctor can choose the group you will be in. You will have an equal chance of being placed in either group. You will also attend extra research-related appointments during which you will complete written and interview-based surveys. All appointments will be from home using video-based technology or telephone. You will be in this study for approximately five months, with most appointments taking place in the first two months. Your sleep treatment appointments will take place over video. Three months after you finish treatment, we will ask you to update us about how you are doing by completing surveys, which you can do from home.

Possible Risks: There are risks to taking part in a research study. Some of the most likely risks of participation in this study include:

- Feeling uncomfortable talking about your sleep or mental health
- Feeling tired while adjusting to treatment recommendations

- Losing confidentiality

We will tell you more about these risks and other risks of taking part in the study later in this consent form. There may also be risks that we do not know about.

Possible Benefits: You may benefit from participating in the study, but this cannot be guaranteed.

Your Other Options: You do not have to participate in this study. Your other choices may include:

- Getting treatment or care for your condition without being in a study
- Taking part in another study
- Getting no treatment

Please talk to your doctor about your choices before agreeing to participate in this study.

Following is a more complete description of this study. Please read this description carefully. You can ask any questions you want to help you decide whether to join the study. If you join this study, we will give you a signed copy of this form to keep for future reference.

DETAILED STUDY INFORMATION

This part of the consent form gives you more detailed information about what the study involves.

Research studies include only people who choose to take part. Please take your time to make your decision about participating, and discuss your decision with your family or friends if you wish. If you have any questions, you may ask the researchers.

You are being asked to take part in this study because you have been diagnosed with sleep apnea and have reported symptoms we often see when people have insomnia and PTSD.

Why is this study being done?

The purpose of this study is to see whether one treatment for sleep problems is better than another treatment among Veterans who have PTSD.

This study is sponsored by the VA Rehabilitation Research and Development Service.

How many people will take part in this study?

About 80 people will take part in this study.

What will happen if I take part in this research study?

If you agree, the following procedures will occur:

First, you will need to have the following "screening" tests or procedures to find out if you can participate in the main part of the study:

- You will talk with a trained clinical interviewer. He or she will interview you for about 3 hours over phone or video The researcher will ask you to describe your current and past mental health symptoms, sleep symptoms, and medication use. You may be asked basic information about traumatic or stressful events you have experienced, but you will not have to go into detail about what happened. You can choose to not answer anything that makes you uncomfortable. The clinical interviewer will make a sound recording of your conversation.

If the screening exam shows that you can be in the main part of the study and you choose to continue, this is what will happen next:

- You will complete several surveys online.
- A member of the research staff will show you how to complete a Sleep Diary. This will take approximately 10 minutes and can be done over phone or video.
- You will log your sleep every morning on the Sleep Diary starting one week before your first treatment appointment and ending one week after your last treatment appointment This will take 1-2 minutes each day.
- You may wear a special watch that will track when you are asleep starting one week prior to your first treatment appointment and ending one week after your last treatment appointment. Not all participants will be asked to do this.
- You will be "randomized" into one of the study treatments described below. Randomization means that you are put into a treatment by chance. A computer program will place you in one of the treatments. Neither you nor your doctor can choose the group you will be in. You will have an equal chance of being placed in any treatment.
    - If you are assigned Apnea and Insomnia Relief, you will receive 6 weeks of Apnea and Insomnia Relief. All six appointments will be conducted via VA Video Connect (video to home.) Your therapist will help you learn to adjust to CPAP. Your therapist will recommend a specific bedtime and wake time and help your mind and body learn to sleep more soundly in bed. These are all strategies that are often provided as part of routine care for sleep problems.
    - If you are assigned Sleep Education, you will receive 6 weeks of Sleep Education. All six appointments will be conducted via VA Video Connect (video to home.) Your therapist will help you learn about the purpose of sleep and stages of sleep. Your therapist will describe strategies to help you cope with stress. You will also learn about creating a healthy sleep environment. These are all strategies that are often provided as part of routine care for sleep problems.
- You will meet with your sleep therapist for your first sleep therapy appointment over VA Video Connect (video-to-home). You will complete surveys just before your appointment. A researcher may look up your CPAP use data and share this with your therapist to be discussed during your appointment. This visit will take approximately 1 hour, 10 minutes. Your therapist will make a sound recording of your appointment.
- About a week later you will have your second sleep therapy appointment over VA Video Connect (video-to-home). You will complete surveys just before your appointment. A researcher may look up your CPAP use data and share this with your therapist to be discussed during your appointment. This visit will take approximately 1 hour, 5 minutes. Your therapist will make a sound recording of your appointment.

- About a week later, you will have your third sleep therapy appointment over VA Video Connect (video-to-home). You will complete surveys just before your appointment. A researcher may look up your CPAP use data and share this with your therapist to be discussed during your appointment. This visit will take approximately 1 hour, 10 minutes. Your therapist will make a sound recording of your appointment.
- About a week later, you will have your fourth sleep therapy appointment over VA Video Connect (video-to-home). You will complete surveys just before your appointment. A researcher may look up your CPAP use data and share this with your therapist to be discussed during your appointment. This visit will take approximately 1 hour, 5 minutes. Your therapist will make a sound recording of your appointment.
- About a week later, you will have your fifth sleep therapy appointment over VA Video Connect (video-to-home). You will complete surveys just before your appointment. A researcher may look up your CPAP use data and share this with your therapist to be discussed during your appointment. This visit will take approximately 1 hour, 10 minutes. Your therapist will make a sound recording of your appointment.
- About a week later, you will have your sixth sleep therapy appointment over VA Video Connect (video-to-home). You will complete surveys just before your appointment. A researcher may look up your CPAP use data and share this with your therapist to be discussed during your appointment. This visit will take approximately 1 hour, 5 minutes. Your therapist will make a sound recording of your appointment.
- About a week later, you will have your post-treatment assessment appointment over phone or video. You will complete surveys and a clinical interview about your mental health and sleep symptoms, and a short interview about your opinions about your experience in sleep therapy (for example, what you liked and what you didn't like). You will also complete a survey about your experience in sleep therapy. The clinical and feedback interviews will take place over the phone or video. A sound recording will be made of your clinical and feedback interviews. A researcher will look up your CPAP use data. This appointment will take about 3 hours, 20 minutes.
- 3 months after you finish sleep therapy, we will ask you to complete surveys. This will take approximately 30 minutes. A researcher will look up your CPAP use data. You will complete these at home. We will also ask you to track your sleep using a sleep diary for one week. This will take 1-2 minutes each day.

Pre-Treatment			Treatment						Post-treatment	
1 (Today)	2	3	1	2	3	4	5	6	1-Week Follow-Up	3-Month Follow-Up
Consent discussion	Interview	Surveys, learning how to complete sleep diary (and wear actigraphy watch, if applicable). Computer randomly chooses your treatment (AIR or SE).	Surveys, sleep therapy session	Surveys, sleep therapy session	Surveys, sleep therapy session	Surveys, sleep therapy session	Surveys, sleep therapy session	Surveys, sleep therapy session	Interviews, surveys	Surveys
0:30	3:00	0:40	1:10	1:05	1:10	1:05	1:10	1:05	3:20	0:30
		Sleep monitoring (sleep diary, actigraphy watch if applicable) Estimated 5 mins/day								Sleep monitoring (1 week – sleep diary)

- Study researchers will also review your medical record to get information about your health history, treatment, and attendance at appointments. They will also look up your CPAP use data.
- In the event of an emergency during a video-to-home appointment, the emergency contacts you identify on the Video to Home Emergency Contact Information form may be contacted.

- **Study location:** All appointments will take place at home, or another secure location of your choosing. An ideal location for home appointments has reliable Internet access, is quiet and private enough to discuss your sleep and mental health, and is not a moving vehicle.

- **Research vs. routine clinical care:** Receiving a CPAP and attending a CPAP setup appointment is part of routine clinical care. Sleep therapy appointments (whether Apnea and Insomnia Relief or Sleep Education) are part of routine clinical care. This includes both in-person and video appointments. Completing sleep diaries is part of routine clinical care. Looking up your CPAP use data is part of routine clinical care. The clinical interviews before and after treatment, treatment feedback interview after treatment, wearing the actigraphy watch, and completing surveys are part of research. The audio recordings of the therapy appointments and interviews will be used for research purposes. Please note that all recordings will be sound-only and not include video.

How long will I be in the study?

Participation in the study will take a total of 8 weeks, with the first 7 weeks including 6 active treatment sessions, and the last week of participation being a 3-month follow-up.

Can I stop being in the study?

Yes. You can decide to stop at any time. Just tell the study researcher or staff person right away if you wish to stop being in the study.

If significant new results develop during the course of the study that may affect your willingness to continue participating, you will be provided this information as soon as possible.

Also, the study researcher may stop you from taking part in this study at any time if he or she believes it is in your best interest, if you do not follow the study rules, or if the study is stopped.

What side effects or risks can I expect from being in the study?

- Some of the interview on questions may make you uncomfortable or upset, but you are free to decline to answer any questions you do not wish to answer or end the interview at any time.
- You may experience discomfort or fatigue from completing study interviews or surveys. You can stop these at any time or ask to take a break.
- You might find the sleep monitoring watch to be uncomfortable. You may remove it at any time.
- You might feel tired or sleepy while changing your sleep habits.
- You might feel uncomfortable while adjusting to your CPAP.
- You might lose some privacy and confidentiality by participating in the study. The study team will be careful to prevent this where it is possible. There is more information about privacy below.
  - **Randomization risks:** You will be assigned to a treatment program (Apnea and Insomnia Relief or Sleep Education) by chance, and the treatment you receive may prove to be less effective or to have more side effects than the other study treatment(s) or other available treatments.
- For more information about risks and side effects, ask one of the researchers.

Are there benefits to taking part in the study?

- You might experience improved sleep.
- You might experience improved health and functioning.
- If you are randomized to one treatment (either Apnea and Insomnia Relief or Sleep Education) and it treats your condition more effectively/with fewer side effects than the other treatment, you may benefit from participating in the study, but this cannot be guaranteed.
- There may be no direct benefit to you from participating in this study. However, the information that you provide may help health professionals better learn how to treat sleep problems in Veterans with PTSD.

What other choices do I have if I do not take part in this study?

Your other choices may include getting standard treatment for your condition without being in a study, or taking part in another study. If you decide not to take part in this study, there will be no penalty to you. You will not lose any of your regular benefits, and you can still get your care from our institution the way you usually do.

How will my information be used?

Researchers will use your information to conduct this study. Once the study is done using your specimens and information, we may share them with other researchers so they can use them for other studies in the future. We will not share your name or any other personal information that would let the researchers know who you are. We will not ask you for additional permission to share this de-identified information.

Sound recordings will be made for research purposes during this study. We will audio record the clinical interviews about your mental health and sleep symptoms before and after treatment for quality control and researcher decision-making. We will audio record your post-treatment feedback interview so we can make notes about what you liked and did not like about your sleep therapy experience and make improvements to care. These feedback interviews may be transcribed into writing. We will audio record your sleep therapy appointments for therapist quality control and to help us better understand how treatment works. These recordings will only record sound, not video. Your sound recordings files will be recorded on an audio recorder and then saved onto a VA computer server. Then your sound recordings will be deleted from the recorder. Only VA staff associated with this study will listen to the sound recordings.

Will information about me be kept private?

We will do our best to make sure that the personal information gathered for this study is kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

Authorized representatives from the following organizations may review your research data for the purpose of monitoring or managing the conduct of this study:

- Representatives of the Sponsor (Department of Veterans Affairs)
- Representatives of the University of California

Participation in research may involve a loss of privacy, but information about you will be handled as confidentially as possible. Your VA medical record will be updated to indicate you are participating in this study. Your consent form and some of your research test results will be included in this record. Therefore, your other health care providers may see your test results and become aware of your participation. Hospital regulations require that all health care providers treat information in medical records confidentially.

If you appear to be in danger of harming yourself or someone else, we may be required to contact local police to confirm your safety or the safety of the other person.

Are there any costs to me for taking part in this study?

No. The sponsor has agreed to pay for all sleep therapy sessions associated with this research study; you or your insurer will not be billed.

Your CPAP setup appointment and any additional CPAP follow-up appointments with the Sleep Clinic team outside of the 6 sleep therapy appointments are considered standard clinical care. You may be billed for those appointments, depending on your medical coverage status. You can ask for more information about your copay status from the researcher or Member Services.

Will I be paid for taking part in this study?

In return for your time, effort and travel expenses, you will be paid up to $230 for taking part in this study. See the table below for information about the amount of money you will receive for participating in the study procedures. You will be paid for the study procedures you complete. You will receive one payment after your post-treatment assessment, and one payment after your 3-month follow up assessment. If you discontinue participation in the study, you will receive payment after you notify us you are no longer participating. You will be paid via direct deposit to your checking or savings account. If you do not have a checking or savings account, you can be paid via cash, which will require a visit to the Agent Cashier at the VA. If Austin Financial Services Center is disbursing the payment and you generate more than $600 in total research payments in one calendar year, an IRS 1099 form will be generated.

Study Procedure	Payment
Pre-treatment interview	$50
Pre-treatment surveys	$30
Post-treatment interviews and surveys	$50
Sleep monitoring (sleep diaries and actigraphy watch)	$70
3-Month Follow-Up surveys	$30

What happens if I am injured because I took part in this study?

It is important that you tell your study doctor, [redacted], if you feel that you have been injured because of taking part in this study. You can tell the doctor in person or call her at [redacted].

Treatment and Compensation for Injury: If you are experiencing a medical emergency, please call 9-1-1. If you incur an injury or illness as a result of being in this study, the Department of Veterans Affairs (VA) will ensure that treatment is made available at a VA medical facility or non-VA facility, as appropriate. If you were following study instructions, the costs of such treatment will be covered by the VA or the study sponsor (if applicable). If you were NOT following study instructions, the costs of such treatment may be covered by the VA or the study sponsor (if applicable), or may be billed to you or your insurer just like any other medical costs, depending on a number of factors. The VA and a study sponsor do not normally provide any other form of compensation for injury or illness. For further information about this, call the study team at the number(s) provided.

What are my rights if I take part in this study?

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you in any way. You will not lose any of your regular benefits, and you can still get your care from our institution the way you usually do.

Who can answer my questions about the study?

You can talk to the researcher(s) about any questions, concerns, or complaints you have about this study. Contact the researcher, [redacted].

If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers or if you wish to voice any problems or concerns you may have about the study, please call the Institutional Review Board at 415-476-1814.

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.

CONSENT

You have been given a copy of this consent form to keep.

You will be asked to sign a separate form authorizing access, use, creation, or disclosure of health information about you.

PARTICIPATION IN RESEARCH IS VOLUNTARY. You have the right to decline to be in this study, or to withdraw from it at any point without penalty or loss of benefits to which you are otherwise entitled.

If you wish to participate in this study, you should sign below.

_____ _____

Date Participant's Signature for Consent