Enhancing pulmonary rehabilitation in veterans with chronic obstructive pulmonary disease through internet-based cognitive-behavioral treatment for insomnia

NCT04700098

August 13, 2024

Subject Name: _____Last 4 SSN:_____ Date: _____

Title of Study: Enhancing daily function using Internet-based cognitive-behavioral treatment for insomnia

Principal Investigator: VAMC: Pittsburgh (646) _____

LAY TITLE: Improving sleep in Veterans with COPD

KEY ELEMENTS:

Insomnia is a common sleep disorder. People who have insomnia have problems falling asleep or staying asleep. People with insomnia often have daytime problems, such as tiredness, concentration problems, and irritability. Individuals with chronic obstructive pulmonary disease (COPD) often report having problems falling asleep or staying asleep. Insomnia can worsen quality of life and make daily activity difficult. This is a research study to find out if treating insomnia can help sleep problems and daily function in veterans with COPD. Your participation in this study is voluntary.

Our research study will use questionnaires, an activity monitor for evaluating sleep and daily activity, a home sleep apnea test, lung function testing, a walking test, and two non-medication approaches to manage your insomnia. There will be 3 study visits at VA Pittsburgh Healthcare System. Each study visit will last approximately 2 hours.

There are risks to this study that are described in this document. Some risks include: feeling uncomfortable while answering questionnaires, shortness of breath from walking test and lung function testing, and short-term sleepiness associated with the insomnia intervention. There is no guarantee that you will benefit from taking part in this research study. Although it is possible that you may experience some relief of symptoms from insomnia.

If you do not participate in this study, alternate treatments for insomnia include: medications and face-to-face cognitive-behavioral intervention for insomnia.

If you are interested in learning more about this study, please continue reading below.

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STUDY CONTACT INFORMATION:
If you have a general question about this research study, or if you have any concerns or complaints related to this research study, you may call any of the investigators listed below.

If you experience any illness, injury or other medical problem that you feel may be related to this study, please call , PhD, Principal Investigator at . In the case of a medical emergency contact your local emergency medical service or go to your local emergency room.

Principal Investigator:

Co-Investigator:

Co-Investigator:

Co-Investigator:

Co-Investigator:

Co-Investigator:

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STUDY SPONSOR:
VA RR&D Merit Review
Additional information regarding the study sponsor can be provided upon request.

PURPOSE OF THE RESEARCH STUDY: The purpose of this multi-site research study is to find out if treating insomnia can help sleep problems and daily function in veterans with COPD.

We plan to enroll a total of 96 veterans with COPD and insomnia from the VA Pittsburgh Healthcare System and the VA Detroit Healthcare System. You are being asked to participate in this research study because you are a veteran with COPD. To be eligible to participate in our study, you must be 40 years of age or older, have COPD and insomnia, and have an email address and reliable internet access.
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 Website will include a summary of the results. You can search this Web site at any time.

DESCRIPTION OF THE RESEARCH STUDY:

As part of this study, you will undergo 1) 3 study visits that last approximately 2 hours each; 2) in-home monitoring of activity for 1 week; 3) home sleep apnea test; and 4) insomnia intervention. You will be asked to not take some of your COPD medications before each study visit.

1. Study Visit 1. You will come to the University Drive Division of the VA Pittsburgh Healthcare System for the study visit. This visit will take approximately 2 hours. At this visit, the following baseline data collection procedures will be performed:

Questionnaires. You will complete questionnaires about your sleep, respiratory symptoms, and daily activity. The questionnaires will take approximately 20-30 minutes to complete.

Six-minute walk test. This test is performed by having you walk for six minutes. During the test you will be allowed to stop and rest as often as desired, but you may be encouraged to continue walking. After six minutes, the total distance walked is measured and recorded.

Spirometry (lung function testing) and maximum bronchodilation. Spirometry is a simple breathing test that measures the amount of air you have in your lungs and how well you can move that air by forcefully blowing into a mouthpiece that is attached to a computer. You will then inhale a bronchodilator (an inhaler that opens up your airways - albuterol) to see if your lung function gets better. 2 puffs of albuterol will be given for this test. This test will take approximately 30-45 minutes to complete.

In-home activity monitoring. At the time of your study visit, you will be given an activity monitor (Actiwatch) to wear for one week. You will be provided a pre-paid mailer to return the Actiwatch, once you are done. During the one-week time period that you are wearing the Actiwatch, you will also keep a sleep diary.

> **Activity monitor.** During the same time that you keep your sleep diary, you will wear an activity monitor called Actiwatch. The Actiwatch is about the size of a wrist watch and is worn on the non-dominant wrist. The Actiwatch measures how active you are by recording how much you move. You will be asked to wear the Actiwatch 24/7 for the one week time period since it is water resistant.
>
> A **sleep diary** is a short questionnaire you complete daily, after you wake up in the morning. You will be asked about your sleep on the previous night and about your daytime activities from the previous day. It takes less than 5 minutes to complete the sleep diary each day. You will fill out the paper sleep diary for 7 days.

Home sleep apnea test. Finally, you will complete a one-night home sleep apnea test to see if you have sleep apnea. If you are currently being treated for sleep apnea or have had a sleep apnea screening within the past year, you may be able to skip this step. At the time of your study visit, you will be given a home sleep apnea test device called a WatchPat. When you wear the WatchPat you should go to sleep as you normally would and let the WatchPat record your breathing during

the night. You will be provided a pre-paid mailer to return the WatchPat, once you are done.

If the WatchPat screening shows severe sleep apnea (periods of shallow breathing and/or pauses in breathing), you will be referred to the VA Pittsburgh Healthcare System Sleep Medicine team for further evaluation and treatment for your sleep apnea, and you will not participate in remainder of the study. If the screening reveals a lesser degree of apnea, you will be referred to the VA Pittsburgh Healthcare System Sleep Medicine team for follow-up evaluation but can still participate in our study. If the screening does not indicate the presence of significant sleep apnea, you will continue on through the study, as indicated below.

2. Intervention: After you have completed the in-home activity monitoring, you will be randomly (like a flip of a coin) assigned by a computer program to receive one of two types of intervention. The study group you are assigned to might not be the group you would prefer to be in. It might also prove to be less effective than the other study group for your condition.

Internet Cognitive-Behavioral Treatment for Insomnia (CBTI) Intervention. CBTI is a non-medication research intervention for insomnia. Traditionally, it involves meeting with a psychologist or other therapist. In this study you would, if you are assigned to this intervention, receive the intervention by way of the internet, using a self-guided, interactive, and web-based program that is tailored to your specific sleep problems. The information is divided into six sections or Cores. You will be able to begin a new Core 7 days after completing the previous one. Each Core will begin by identifying what will be learned that week and why it is important. You will receive information about managing your sleep problem using a variety of behavioral changes and other exercises. Each Core will also include: review of previous week's homework and sleep diary information; new material; and assignment of homework (intervention strategies for the coming week). Throughout the 9 week intervention phase, we will also ask you to complete a brief online sleep wake diary every day at home that will be used to tailor the intervention. You will have continued access to the Internet program for 8 weeks after you have completed it.

Online insomnia patient education. If you are assigned to this intervention, you will be given access to a website which contains information about insomnia and ways to improve your sleep.

3. Study Visit 2 and Visit 3 (post-intervention and 3 months post-intervention): We will ask you to return to the University Drive Division of the VA Pittsburgh Healthcare System for evaluation immediately after the 9 week intervention phase and 3 months after the intervention phase. Each of these visits will take approximately 2 hours. At each of these visits, the following procedures will be performed:

- **Questionnaires.** Questionnaires completed at Visit 1 will be completed again at Visit 2 and Visit 3.
- **Six-minute walk test.** Procedures done at Visit 1 will be done again at Visit 2 and Visit 3.
- **Spirometry and maximum bronchodilation.** Procedures done at Visit 1 will be done again at Visit 2 and Visit 3.
- **In-home activity monitoring.** Actiwatch will be worn and sleep diary filled out for 1 week following Visit 2 and Visit 3.

RISKS AND BENEFITS:
There are no known risks associated with the **Home sleep apnea testing**.

Completing questionnaires and sleep diaries. You may feel uncomfortable while answering questions. If you feel uncomfortable, you may refuse to answer a question or questions.

Actiwatch. There is a small risk that your skin may be irritated by the Actiwatch. This is very rare, but should it occur we will not expect you to continue wearing the watch.

Six-minute walk test. There is a low risk that you may experience slight soreness in muscles and/or breathlessness due to the effort involved during this test. You can request to stop walking during the test.

Withdrawing COPD medications prior to spirometry. You will be asked to not use certain COPD medications prior to each research visit for the purpose of lung function testing (spirometry). As a result, you may experience an increase in your COPD symptoms. If your COPD symptoms worsen or you are unable to hold your medications, you should take your medication as needed and call the study staff.

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Spirometry and maximum bronchodilation. You might have coughing, lightheadedness, or shortness of breath with spirometry. If this occurs and does not go away on its own, you may be given 2 puffs of an albuterol inhaler.

Internet Cognitive-Behavioral Intervention for Insomnia (CBTI). You may experience short-term sleepiness, concentration and attention deficits, irritability, and other mood changes potentially associated with CBTI. We ask that you exercise caution when driving and operating machinery during the first few weeks of CBTI, when you may be adjusting to changes in your sleep/wake schedule. Please contact study staff with any concerns. This intervention does not provide human support, meaning that you will not talk with a person about the intervention. As a result you may encounter technical difficulties and experience frustration. You may request technical support if needed, but not additional help with the insomnia intervention itself. Because internet-delivered programs do not have the ability to be as flexible or tailored as a clinician might be, it is possible that you may not follow the intervention as accurately and thoroughly as if you were working with a clinician.

There is no guarantee that you will benefit from taking part in this research study. Although it is possible that you may experience some relief of symptoms from insomnia.

ALTERNATIVES TO PARTICIPATION:
There may be other studies that you qualify for. Talk to your provider about such options.
You have the alternative not to participate in this research study.

NEW FINDINGS:
You will be informed of any significant new findings during the course of the study, which may affect your willingness to continue to participate. No clinically relevant results will be returned to you.

INVESTIGATOR INITIATED WITHDRAWAL: The investigator(s) may stop your participation in this study without your consent for reasons such as: it will be in your best interest; you do not follow the study plan; or you experience a study-related injury.

VOLUNTARY PARTICIPATION/RIGHT TO WITHDRAW: Your participation in this study is voluntary. You do not have to take part in this study, and your refusal to participate will involve no

penalty or loss of rights to which you are entitled. You may withdraw from this study at any time without penalty or loss of VA or other benefits to which you are entitled.

Any identifiable research information recorded for, or resulting from, your participation in this research study prior to the date that you formally withdrew your consent may continue to be used and disclosed by the investigators. To formally withdraw your consent for participation in this research study, you should contact the Principal Investigator.

Your doctor may also be involved as an investigator in this research study. As both your doctor and a research investigator, s/he is interested both in your medical care and the conduct of this research study. You are under no obligation to participate in this or any other research study offered by your doctor. Before you agree to participate in this research study, or at any time during your participation in this study, you may discuss your care with another doctor who is not associated with this research study.

If you withdraw your consent and authorization for such use, you may not be able to continue to participate in the research study.

MEDICAL TREATMENT:
In the event that you sustain injury or illness as a result of your participation in this VA approved research study, conducted under the supervision of one or more VA employees, all medical treatment (emergent as well as medical treatment beyond necessary emergent care) will be provided by the VA. Except in limited circumstances, the necessary medical care must be provided in VA medical facilities.

However, if such injury or illness occurred as a result of your failure to follow the instructions for this study, you may not be eligible for free care unless you have independent eligibility for such care under Federal Law.

FINANCIAL COMPENSATION:
If you sustain an injury or illness as a result of participating in this research study, you may be eligible to receive monetary compensation for your damages pursuant to applicable Federal law. If you believe that you are injured as a result of participation in this study, please contact the Principal Investigator. If compensation is available the Principal Investigator will provide you with an explanation as to what that compensation consists of, or where you can obtain further information regarding it.

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COST AND PAYMENTS:
You or your insurance will not be charged for any costs related to the research. However, if you are receiving medical care and services from the VA that are not part of this study, and you are a veteran described in Federal regulations as a "category 7" veteran, you may be required to make co-payments for the care and services that are not required as part of this research study.

You will be paid for your participation. The amount you receive depends on which parts of the study you complete. If you qualify for the study after screening and complete the study visits outlined in this consent form, you will be paid up to $225.

PAYMENT SCHEDULE	
	Amount of payment
Visit 1– Upon return of Actiwatch	$60.00
Visit 2– Upon return of Actiwatch	$75.00
Visit 3– Upon return of Actiwatch	$90.00

Except in limited circumstances, payments issued through VA are generated by Electronic Funds Transfer (EFT). Therefore, in order to receive payment associated with your participation in this study, you must be willing to receive EFT and to provide banking information to VA, if that information has not already been provided. If you are not able to receive payment through EFT, the Direct Express Debit MasterCard may be issued. The Direct Express Debit MasterCard is a prepaid debit card. Please refer to the flyer that study personnel has provided for more information about which services may require a fee if using your Direct Express Debit MasterCard. In addition, due to limitations in the Financial Management System, payments made to you will generate Internal Revenue Service (IRS) Form 1099 regardless of amount. Payments will be reported to the IRS as income and your social security number will be used for this purpose.

RECORD RETENTION: Your research records will be retained in accordance with the Veterans Health Administration (VHA) Records Control Schedule, or longer, if required by other Federal regulations.

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CONFIDENTIALITY AND USE AND DISCLOSURE OF DATA: There are rules to protect your private health information. Federal and State laws and the Federal medical law, known as the HIPAA Privacy Rule, also protect your privacy. By signing this form, you provide your permission called your 'authorization', for the use and disclosure of information protected by the HIPAA Privacy Rule.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. They may also collect other information including:

Information from your Health Records such as diagnoses, progress notes, medications, or findings

Demographic Information such as name, age, race, date of birth

Questionnaire, Survey, and/or Subject Diary

The research team may also need to disclose your health information and the information it collects to others as part of the study progress. Others may include the:

Study Sponsor and Authorized Agents/Funding Source (e.g. a VA or non-VA person or entity who takes responsibility for; initiates, or funds this study): VA RR&D Merit Review

A progress note stating you are participating in this study will be placed within your medical record.

In addition, Institutional Review Board, Food and Drug Administration, Office (FDA), Office of Human Research Protections (OHRP), the VA Office of Research Oversight (ORO), and the Government Accountability (GAO) may have access to your research records. Your health information disclosed pursuant to this authorization may no longer be protected by Federal laws or regulations and may be subject to re-disclosure by the recipient. Additionally, any medical information may be shared with your healthcare provider(s) with your consent, and possibly without your consent if permissible under Federal laws and regulations.

Finally, you consent to the publication of the study results or release of the data when published, so long as the information about you is anonymous and/or disguised so that your identity will not be disclosed.

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Confidentiality risks and precautions to decrease risk:
Every effort will be made to make sure that the information about you obtained from this study will be kept strictly confidential. As private information is collected about you as part of this study, there is a risk to your privacy and confidentiality. The research staff will take every precaution to protect your identity and the confidentiality of the information collected about you.

Any electronic or hard/paper copies of the information collected about you will be stored in a secured location, either in a locked file cabinet or secured VA computer. Only those individuals who are authorized to review your information will have access to it.

Study staff will create your registration account for the Internet CBTI intervention using anonymous information (name, home address, telephone number). We will use your personal email address to create your account. Your email address and any personally identifiable information you may submit to the website during the intervention will be stored on the University of Virginia's secured computer networks and will only be used if necessary for the operation and maintenance of the website, to comply with legal requirements, or protect an individual's personal safety in an emergency situation.

Future Use:
Your research data may be shared with other investigators conducting research; this information will be shared without identifiable information.

Revocation:
You can revoke this authorization, in writing, at any time. To revoke your authorization, you must write to the Principal Investigator at the address below. Your request will be valid when the Release of Information Office receives it. If you revoke this authorization, you will not be able to continue to participate in the study. This will not affect your rights as a VHA patient to treatment or benefit outside of the study.

VA Pittsburgh Healthcare System
University Drive C
Research Office Building (30)

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Treatment, payment or enrollment/eligibility for benefits cannot be conditioned on you signing this authorization. This authorization will expire at the end of the research study unless revoked prior to that time.

RESEARCH SUBJECTS' RIGHTS: You have read or have had read to you all of the above. Dr. or her authorized representative has explained the study to you and answered all of your questions. The risks, discomforts, and possible benefits of this research study, as well as alternative treatment choices, have been explained to you.

A description of the study has been provided to you, including an explanation of what this study is about, why it is being done, and the procedures involved. You have the right to ask questions related to this study or your participation in this study at any time. You should be giving your consent only under conditions in which you (or the person representing you) have sufficient opportunity to carefully consider whether or not to participate in this study. Your consent should not be given under conditions that pressure you or try to influence your decision in any way.

Your rights as a research subject have been explained to you, and you voluntarily consent to participate in this research study. You will receive a copy of this signed consent form.

If you have any questions about your rights as a participant in this study, or wish to speak more about the study with someone not associated with the research study, you can call the Associate Chief of Staff for Research and Development at .

As long as the study is renewed as required by the IRB, your signature on this document is valid for the duration of the entire research study. Should any changes occur during the course of the study that may affect your willingness to participate, you will be notified.

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By signing this form, you agree to participate in this research study.

_____	_____	_____
Subject's Signature	Subject (Print)	Date
_____	_____	_____
Investigator/Person Obtaining Consent*	Researcher (Print)	Date

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