Addressing insufficient positive airway pressure use among older Veterans with obstructive sleep apnea

NCT04868682

May 6, 2024

Participant Name: _____ Date: _____

Title of Study: The Effectiveness of Sleep Education to Improve Sleep Quality in Veterans

Principal Investigator: Cathy Alessi, MD VA Facility: VA Greater Los Angeles Healthcare System

iRIS-GLA-v2020-07

KEY SUMMARY INFORMATION ABOUT THIS STUDY

You are being invited to take part in a research study that is being funded by the VA Health Services Research and Development Service. Before you decide to take part, it is important for you to know why the research is being done and what it will involve. This includes any potential risks to you, as well as any potential benefits you might receive. Taking part in this study is completely voluntary.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

By doing this study, we hope to determine which of two sleep education programs is most effective in helping Veterans get better quality of sleep and which program Veterans like better. Your participation in this research will last about 12 months.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

By participating in this study, you may learn about common sleep conditions, like sleep apnea and insomnia, and you will learn about non-medication strategies to help you sleep better. For a complete description of benefits, refer to the Detailed Information section of this informed consent form.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

You may not want to volunteer for this study, because you might feel uncomfortable answering some of the questions, or it might be inconvenient for you to attend the research sessions. For a complete description of risks, refer to the Detailed Consent and/or Appendix.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of the study is Cathy Alessi, MD at the VA Greater Los Angeles Healthcare System. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study her contact information is:

VAGL

VA GLA IRB
Effective Date: May 6, 2024

Participant Name: _____ Date:_____

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DETAILED INFORMATION ABOUT THE STUDY

WHAT IS THE PURPOSE OF THIS STUDY?

The purpose of this study is:

1. to compare two different sleep education programs that we have developed to help Veterans get better sleep quality
2. to determine the components of the education programs that Veterans like best

HOW LONG WILL I BE IN THE STUDY?

This research study is expected to take approximately 4 years to complete. Your individual participation in the project will take 12 months, with the majority of the activities occurring in the first two months.

A total of 300 Veterans will be enrolled into this study.

WHAT WILL HAPPEN IF I TAKE PART IN THE STUDY?

Due to the COVID-19 pandemic, some or all research visits may occur using VA approved video telehealth platforms, like VA Video Connect. Study staff will help you use this system on your personal computer or smartphone. If the visits are in-person, you will be required to answer COVID-19 screening questions prior to each visit, wear a mask throughout the visit, and maintain social distancing.

If you decide to take part in this study, this is what will happen:

Baseline Visit 1 (30 minutes):

1. You will be asked questions about your health, medications, memory, and personal information, such as your marital status, years of education, and employment.
2. You will be asked to keep a diary about your sleep each night for a week. Filling out the sleep diary will take about 1-2 minutes per day. You will return the sleep diary by mail to the Sleep Research office.
3. You may be screened for sleep apnea. At the end of visit 1, you may be given (or mailed) a portable sleep apnea monitoring device to wear for one night. This device is worn on your wrist and has two sensors: a plastic sensor worn on the index finger and a 2” sensor worn on the chest to detect snoring and body position. These sensors are painless. You will return the device to the Sleep Research office either in-person or by mail.

Baseline Visit 2 (60 minutes):

1. You will be asked another set of questions about your sleep patterns and habits, mood, and quality of life.

<u>Medical Record Review</u>

If you volunteer to participate in this study, you are also agreeing to let the research staff review your VA medical records to obtain information about:

- any tests you have had to diagnose a sleep disorder and any treatments you may have been prescribed
- use of VA services over the past year
- diagnoses and treatments (including diagnoses and treatments related to mental health conditions and drug and alcohol abuse)
- current medications

Final eligibility determination

Information collected from the health and sleep evaluation, the medical record review, and the results of your sleep apnea screening test will be reviewed by the research team to see if you are eligible for continuing in the study. If you suffer from any condition that would make it difficult for you to take part in study activities, you will be excluded from further participation. If this condition is a new finding, we will inform you, and with your permission, your doctor of these findings.

Sleep Education Program

If you are eligible to be in the study, you will receive one of two sleep education programs, Program A or Program B. Which education program you receive will be determined randomly (like flipping a coin).

For both education programs, you will meet with a trained sleep coach for 5 in-person (or video) sessions and 4 telephone visits. The table shows the schedule for the education program.

Week	Session	Location	Amount of time
1	1	In-person or video	30-45 minutes
2	2	In-person or video	30-45 minutes
3	3	In-person or video	30-45 minutes
4	4	In-person or video	30-45 minutes
8	5	In-person or video	30-45 minutes
12	6	Telephone	10 minutes
16	7	Telephone	10 minutes
20	8	Telephone	10 minutes
24	9	Telephone	10 minutes

These sessions will take place at the VA West Los Angeles or Sepulveda campuses, or by computer using a VA approved video telehealth platform.

The content of sessions in Program A and Program B will vary, but will focus on providing education about common sleep disorders, like sleep apnea and insomnia, and will teach you non-medication strategies to improve your sleep. The education sessions you attend will be audio-recorded for the purpose of making sure that study staff follow the protocol for each session. The recording will not be shared with anyone outside project staff.

Sleeping medications will not be prescribed as part of this study. If you are currently using a sleeping medication, you will continue to follow your doctor's recommendations. During the study, you should also continue to use any treatments that you may have been prescribed for sleep apnea, such as a Positive Airway Pressure (PAP) device. If you no longer have a PAP device or it is not working properly, we can assist you in getting a new device. If you use a PAP device anytime during the study, the study team will collect information about your PAP use from your medical record.

During the sleep education program, you will be asked to answer a questionnaire at the beginning of session 1 and at the end of session 5. These questionnaires ask for your opinions about the sleep education program.

Follow-up Evaluations

You will receive a follow-up evaluation at the end of session 5 of the sleep education program (1 visit) and again after 6-months (1 visit) and 12-months (1 visit). At each of these evaluations, you will be asked to repeat the questionnaires about your sleep, mood, and quality of life. You also will be asked to complete a sleep diary for 7 days. Research staff will again review your medical records for any changes in your health or medications.

Follow-up Interview

After the six-month follow-up evaluation, someone from the study team may ask you to share your opinions about the information and recommendations that you received and your suggestions for changing and/or improving the sleep education program. This interview may be conducted in-person, by video, or by telephone. The interview will be audio-recorded, so research staff can code your responses at a later time.

All activities are being undertaken for research purposes only.

Audiorecording

The study team has explained that by signing this Informed Consent Document, you voluntarily and without separate compensation authorize voice recording(s) to be made of you by the research staff during the 5 education sessions and during the interview after the 6-month follow-up evaluation. These recordings will not be disclosed to anyone outside of the VA study team.

In this study, your agreement to be recorded is optional, please sign here if you agree to the recording in this study (as outlined above):

Signature: _____ Date: _____

WHAT IS EXPECTED OF ME IF I TAKE PART IN THIS STUDY?

- Keep your study appointments. If you miss an appointment, please contact research staff to reschedule as soon as you know you will miss the appointment.
- Return the sleep diaries and sleep monitoring equipment.

WHAT POSSIBLE RISKS OR DISCOMFORTS MIGHT I HAVE IF I TAKE PART IN THIS STUDY?

Any procedure has possible risks and discomforts. The procedures in this study may cause all, some or none of the risks or side effects listed. Unexpected risks also may occur.
You may experience the following risks and discomforts as a result of participating in this study:

Questionnaires: You may feel uncomfortable answering questions about your health, mood, or sleep habits. You can choose to skip any questions that make you feel uncomfortable.

Sleep monitoring: The known risks associated with wearing the sleep apnea monitoring device is minimal. The sensors worn for one night may be annoying or uncomfortable for you. Rarely, they may cause skin irritation. To minimize skin irritation, we have limited the sleep apnea monitoring to one night.

Sleep education program: You may find that attending the 5 education sessions is tiring or inconvenient. As you make adjustments to your sleep habits within the program, you may experience more daytime sleepiness at first. It will be important that you follow the instructions given by your sleep coach if this occurs.

It is possible that there are other unforeseeable risks.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

We do not know if you will get any benefits from taking part in this research study. However, possible benefits may include learning more about common sleep disorders and strategies to improve your sleep quality. In addition, the information we get from this study might help others with sleep problems.

HOW WILL MY PRIVATE INFORMATION BE PROTECTED?

Taking part in this study will involve collecting private information about you. This information will be protected in the following ways:

- We will ask you for your social security number to process your payment check and to access your VA medical record. If you do not wish to provide your social security number, you can still participate, but you cannot receive payment for your participation.
- You will be assigned an identification (ID) number and this ID number will be used instead of your name (or other identifiers) on all study records.
- Research records and payment forms will be kept in locked file cabinets in locked offices and stored on password protected computers. Access will be limited to authorized Sleep Research staff.
- The audio-recordings of the education sessions will not contain your name.
- We will not share your records or identify you unless we are legally required. There are times when we might have to show your records to other people. For example, someone from the Office of Human Research Protections, the Government Accountability Office, the Office of the Inspector General, the VA Office of Research Oversight, the VA Greater Los Angeles IRB, our local Research and Development Committee.
- The results of this study may be published in the medical literature or presented at scientific medical or educational meetings, but your name or identity will not be revealed and your records will remain confidential unless disclosure of your identity is required by law. Because of the need to release information to the parties listed above, absolute confidentiality cannot be guaranteed.

- In accordance with California law, confidentiality cannot be guaranteed if the investigator becomes aware that you may be a danger to yourself or to others, or becomes aware that child abuse or elder abuse is occurring.
- Identifiers might be removed and the coded information will be used for future research without seeking additional informed consent from you. Your coded information may be distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative.
- Once you sign this informed consent, the study investigator and/or study staff will create a research record. If this is a study with a medical intervention, information about your enrollment in this study will be entered into the VA medical record .

A description of this clinical trial and the currently approved informed consent 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.

WHAT ARE THE COSTS TO ME IF I TAKE PART IN THIS STUDY?

You will not be charged for any treatments or procedures that are part of this study. If you usually pay co-payments for VA care and medications, you will still pay these co-payments for VA care and medications that are not part of this study.

WILL I RECEIVE COMPENSATION FOR PARTICIPATING?

You will be compensated for participating in this study. You will receive a $50 gift card after you complete the initial evaluation and a $50 gift card after each of the three additional follow-up evaluations, for a possible total of $200 in gift cards. If you are invited to participate in an interview after the 6-month follow-up evaluation, you will receive an additional $50 gift card.

You will receive a gift card even if you do not complete the full evaluation. You **will not** receive a gift card if you do not complete **any** part of an evaluation, if you do not return the sleep apnea monitoring device, or if you withdraw from the study before an evaluation is due.

If gift cards are not available, you will be paid via electronic fund transfer (EFT) to your existing Direct Express Card or a new Direct Express Card. Note that your social security number is required to process EFT payments.

WHAT WILL HAPPEN IF I AM INJURED BECAUSE OF MY BEING IN THE STUDY?

If you are injured as a result of taking part in this study, the VA will provide necessary medical treatment at no cost to you unless the injury is due to non-compliance by a study participant with study procedures or if the research is conducted for VA under contract with an individual or non-VA institution.

You do not give up any legal rights or release the VA from any liability by signing this form.

Participant Name: _____ Date:_____

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Principal Investigator: Cathy Alessi, MD VA Facility: VA Greater Los Angeles Healthcare System

DO I HAVE TO TAKE PART IN THE STUDY?

It is up to you to decide whether or not to take part in this study. If you decide to take part you may still withdraw at any time. If you do not wish to be in this study or leave the study early, you will not lose any benefits to which you are otherwise entitled. If you don't take part, you can still receive all usual care that is available to you. Your decision not to take part will not affect the relationship you have with your doctor or other staff and it will not affect the usual care that you receive as a patient.

RIGHT OF INVESTIGATOR TO TERMINATE MY PARTICIPATION

Dr. Alessi has the right to end your participation in this study for the following reasons:

- you do not meet all of the criteria for being in the study after we review your medical record and the responses to the questionnaires;
- we discover that you have a severe medical or psychiatric problem that prevents you from participating or requires referral for specialized treatment;
- you do not follow the study procedures.

WHO DO I CONTACT ABOUT THIS STUDY IF I HAVE QUESTIONS?

If you have questions about your rights as a study participant, or you want to make sure this is a valid VA study, you may contact the Institutional Review Board (IRB). This is the Board that is responsible for overseeing the safety of human participants in this study.

You may call the Research Office and speak to the Office of the Associate Chief of Staff if you have questions, complaints or concerns about the study or if you would like to obtain information or offer input.

FUTURE USE OF DATA AND RE-CONTACT

With your permission, Dr. Alessi and her research team may contact you after this study is completed to invite you to participate in future studies.

Yes, I give my permission to be re-contacted for future research by Dr. Alessi or a member of her research team.

_____ (subject's initials)

Participant Name: _____ Date:_____

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AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

Dr./Mr./Ms_____ _____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 told of other choices of treatment available to you. You have been given the chance to ask questions and obtain answers.

By signing this document below, you voluntarily consent to participate in this study You also confirm that you have read this consent, or it has been read to you. You will receive a copy of this consent after you sign it.

I agree to participate in this research study as has been explained in this form.		
_____ Participant's Name	_____ Participant's Signature	_____ Date

Participant Name: _____ Date:_____

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CALIFORNIA BILL OF RIGHTS
RIGHTS OF HUMAN SUBJECTS IN MEDICAL EXPERIMENTS

Any person who is requested to consent to participate as a subject in a research study involving a medical experiment or who is requested to consent on behalf of another has the right to:

1. Be informed of the nature and purpose of the experiment.

2. Be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized.

3. Be given a description of any attendant discomforts and risks reasonably to be expected from the experiment.

4. Be given an explanation of any benefits to the subject reasonably to be expected from the experiment, if applicable.

5. Be given a disclosure of any appropriate alternative procedures, drugs or devices that might be advantageous to the subject, and their relative risks and benefits.

6. Be informed of the avenues of medical treatment, if any, available to the subject after the experiment if complications should arise.

7. Be given an opportunity to ask any questions concerning the experiment or the procedure involved.

8. Be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation in the medical experiment without prejudice.

9. Be given a copy of any signed and dated written consent form used in relation to the experiment.

10. Be given an opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on the subject's decision.