Improving Access to Sleep Apnea Care: A Pragmatic Study of New Consultation

NCT05419323

ICF Document Date: 02/04/2024

Veteran's Name: Date:

Title of Study: Improving Access to Sleep Apnea Care: A Pragmatic Study of New Consultation Models

Research Staff Member Name and Initials:

Site:

[INTRODUCTION]

The interviewer calls the potential participant, confirms that he/she is speaking to the right person and states:

Good Morning/Afternoon Mr./Ms.____ My name is [Interviewer Name] and I am calling you about a research project sponsored by the Department of Veterans Affairs at [Name of site VA Facility].

You are being asked to participate in this study because you have been scheduled for in-lab sleep apnea testing at VA XXX Medical Center. What I'd like to do is describe the study in detail and go through the consent process so that you can decide if you'd like to participate. Please feel free to interrupt me at any time and ask questions as we go. Before we review the project, I would first like to ask you if you are in at a location where you would feel comfortable speaking about this study. Are you OK to learn about the project now?

If yes, continue
If no, schedule call back if needed.

[*BACKGROUND AND PURPOSE*]

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. As you consider participating, you should keep in mind that taking part in this study is completely voluntary.

The purpose of this study is to compare the accuracy of in-lab sleep testing with sleep apnea testing procedures that are usually conducted in the Veteran's home. By doing this study, we hope to learn if home sleep apnea testing (HSAT) is accurate as in-lab sleep testing. Your participation in this research will last for one night of testing.

This study is sponsored by a Department of Veterans Affairs Health Services Research and Development (HSR&D) grant.

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LSI Approval Date: N/A

LSI Verification Date: N/A

[*STUDY PROCEDURES]*

You will undergo in-lab sleep testing (also known as polysomnography, or PSG) – as scheduled – at a VA Medical Center. This is not part of research – the PSG procedure will occur as part of your usual clinical assessment for sleep apnea. The in-lab PSG will last between 8-10 hours.

As part of the research to collect data for home sleep apnea testing, the following equipment may be added to the usual in-lab PSG set-up:

- A nasal cannula (thin plastic tube that fits under the nose) will monitor airflow as you breathe in and out.
- One additional elastic belt will be attached around your chest, and one additional elastic belt will be attached around your abdomen (belly) to monitor your effort to breathe.
- Oximeter – a device that attaches to the wrist/hand and monitors blood oxygen levels and heart rate
- Additional equipment as needed

If you decline to add the equipment for home sleep apnea testing, you will still be able to have the in-lab test as scheduled.

The in-lab sleep test will then take place as usual. A care provider at the VA Sleep Clinic will oversee the test and monitor your progress throughout the process.

[*POSSIBLE RISKS OR DISCOMFORTS*]

Risks might include discomfort with in-lab or home sleep testing equipment and procedures. Any discomfort associated with sleep testing will be addressed through standard approaches employed by the Sleep Clinic's technicians, and may include re-application of elastic belts, oximeters, and nasal cannulas.

Another potential risk of study participation is loss of confidentiality, privacy and data security. Usual VA procedures will be employed to protect privacy and confidentiality of all patients.

There is always a chance that any procedure can harm you. The procedures in this study are no different. In addition to the risks described above, you may experience a previously unknown risk or side effect.

Risks of the usual care you receive are not risks of this study. Those risks are not included in this research. You should talk with your health care providers if you have any questions about the risks of usual care.

[*POTENTIAL BENEFITS]*

We can't promise that you will get any benefits from taking part in this research study.

You may benefit from participating in this study. You may receive indirect benefit given that you are contributing to medical science or helping to advance future understanding of sleep apnea.

Direct benefits may include information about your apnea obtained from the sleep testing results.

[*ALTERNATIVES TO PARTICIPATING IN THIS RESEARCH]*

You have the alternative not to participate in this research study. Refusal to take part in the study will involve no penalty or loss of benefits to which you are otherwise entitled.

[*CONFIDENTIALITY*]

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 agreeing to participate in this study, 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, date of birth and other data.

In addition, Institutional Review Boards, the Food and Drug Administration (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.

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. Only those individuals who are authorized to review your information will have access to it.

[*COSTS TO PARTICIPANTS AND PAYMENT*]

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.

You will not receive any payment for your participation in this study.

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[MEDICAL TREATMENT AND COMPENSATION FOR INJURY]

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.

[*PARTICIPATION IS VOLUNTARY*]

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 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 care provider or other staff members, and it will not affect the usual care that you receive as a patient.

If you decide to stop participating in the study, call us to let us know by using the phone numbers on the information sheet that we will send to you.

[PERSONS TO CONTACT ABOUT THIS STUDY]

We will send you an information sheet with the names and contact information for people who can answer questions about the study.

My name is [name of Research Staff member] and my phone number is [give phone number] if you would like to write it down now in case you have further questions.

[AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY]

At this time, I want to make sure that you fully understand the purpose of this study, and what is involved if you choose to participate. Remember, your participation is completely voluntary. If you decide to take part in the study, you may withdraw at any time. There may be no direct benefits to you for taking part in this research study. However, the information we obtain from this study might help us to better diagnose and treat Veterans with sleep apnea.

Do you consent to be enrolled in this study?

Yes ☐ No ☐

- *If the potential participant says no, the interviewer will thank the potential participant for their time before ending the call.*

Interviewer's signature below signifies they have covered all information in this script, answered all of participant's questions, and the participant has consented for the study.

Study Staff Member Signature and Date

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