# Does Treatment Of Sleep-Disordered Breathing Improve Functional Outcomes In SCI?

APPROVED CONSENT

NCT02830074

**Approved Date April 2, 2020**

| Department of Veterans Affairs | **VA Research Consent Form** | |
|---|---|---|
| **Title of Study** | Does Treatment of Sleep-Disordered Breathing Improve Functional Outcomes in SCI? | |
| **Participant's Name** | | |
| **Participant ID Number** | | **Date:** |
| **Principal Investigator** | *M. Safwan Badr, M.D., M.B.A.* | **VAMC:** John D. Dingell VA Medical Center |

You are being asked to volunteer to take part in a research study at the John D Dingell VA Medical Center. Participation in this research study is voluntary. This consent form gives you information about the study. It is important that you read and understand the information on this form.

About 250 people will take part in this study at the John D. Dingell VA Medical Center.

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 website at any time.

**Please read this form and ask any questions you may have before agreeing to be in the study.**

**PURPOSE OF RESEARCH STUDY:**
The purpose of the study is to look at how your body controls the way you breathe when you are sleeping. You qualify to participate because you have a chronic spinal cord injury/disorder, your medical conditions are stable, and it has been at least 3 months past the time of your injury/diagnosis.

In this research study, we will be looking at how many people who participate in the study have sleep apnea (where a person stops breathing for short periods of time during the night). The people who have sleep apnea will be asked to continue in the study, and will receive treatment with a device called positive airway pressure (PAP) treatment.

PAP treatment uses a mask that will cover the nose/mouth and will be attached by a flexible tube to a small machine the size of a shoebox that will sit on the table or floor next to the bed. It will blow air into the throat at different pressures to help keep someone with sleep apnea breathing regularly at night. This device is approved by the FDA (the Food and Drug Administration, a government department that oversees drugs and medical devices). This means that if you have sleep apnea or other sleep-disordered breathing, your doctor could give you a prescription for this device whether or not you participate in this study. People with spinal cord

injuries/disorders may have problems breathing during sleep that are different from the general population who have sleep apnea, and in this study, we are comparing two programs of PAP therapy follow-up.

The device and education program that are part of this study will be provided at no cost to you.

**STUDY PROCEDURES:**
If you agree to take part in this research study, you will be asked to complete the following visits:

Enrollment Visit: First we will review this consent form, answer all your questions, and have you sign this form. Next we will review your medical history and complete questionnaires about your health, sleep, mood, and quality of life. We will also ask you to breathe into a machine that tests how well your lungs work and send you home with a sleep diary to fill out for the next 8 days. This visit will take approximately 2 hours and you will be compensated $50 for you time. At the end of the visit we will schedule an evening for you to come and sleep at the lab. We will show you the bedroom, equipment, and setup for the night study. The purpose of the night study is to determine whether or not you have sleep disordered breathing.

Baseline Sleep Study: We will schedule a time that is convenient for you to come and sleep at the lab or we will send you home with equipment for an at-home sleep test to make the diagnosis of sleep apnea, unless you have a study done in the past and the results are found to be effective. If necessary, you will spend the entire night in the lab. You will breathe through a nasal cannula, which will be secured in place using medical tape. During the study your mouth must be closed and/or taped to prevent air leaks. You may be asked to use Afrin nasal spray (oxymetazoline HCl) before starting the study to get rid of any nasal congestion. Monitoring devices will be used during the study, which include bands placed around the chest and abdomen to measure motion, wires taped to the skin to measure brain waves, eye movements, and movement, and an instrument placed on your ear, finger or forehead to measure oxygen levels in your blood. Another instrument will be placed on your finger to measure your heart rate and blood pressure through the night. This visit will take approximately 7-10 hours and you will be compensated $50 for your time.

We will analyze the data from the night study and you will be informed of the results. If we find that you have sleep-disordered breathing, you will be asked to continue in the study. If you are eligible to continue with the study, you will receive one of two sleep education programs. Both programs provide education on sleep, but the content and format of each program will vary. Which education program you will receive will be determined randomly (like flipping a coin). Both groups will receive PAP treatment, a sleep education program, and PAP compliance monitoring and follow-up. You will not know what group you have been assigned to.

PAP Titration Visit: Individuals with sleep disordered breathing will be asked to return to the lab for a PAP titration study (CPAP or BPAP if needed) unless you have a study done in the past and the results were found to be effective. The purpose of this study is to figure out the correct settings for the breathing machine we are going to ask you to use by adjusting the pressure inside the mask. This study follows the standard clinical guidelines. You will receive $50 for this visit.

Randomization Visit: Approximately one week after the PAP titration Visit, participants will be asked to return to the lab to receive a CPAP or BiPAP machine, and general information about sleep during this visit or if you have a machine from the Detroit VA you may use that machine. If you would like to involve someone who helps you with personal care activities (e.g., a family member or caregiver), they may participate in this visit. We will give you a PAP machine to use at home at no cost to you. You will be compensated $50 for your time. One week after the Randomization Visit, we will contact you by phone to assist with any technical difficulties and answer any questions you have.

Follow-Up Phone Contact: You will be contacted by phone 5 more times, approximately once a week. The purpose of these phone calls is to provide you with information about sleep apnea, sleep hygiene, and age-related changes in sleep. If you would like to involve someone who helps you with personal care activities (e.g., a family member or caregiver), they may participate within you in this part of the study and can assist with your PAP equipment.

PAP Compliance Monitoring: The study team will monitor whether or not you are using your PAP machine using a remote tele-monitoring system called EncoreAnywhere. The PAP machine you will be given will be compatible

with this monitoring program. Nightly usage data will be available to the study team. The study team will make sure that the PAP machine has been set up and is transmitting data. The study team will call periodically over the next 3 months to provide follow-up and general information consistent with the standard of care or the targeted PAP adherence program.

One Month & Three Month Follow-Up Visit: One month after beginning the PAP treatment, you will be asked to return to the lab for a mid-treatment visit and then again after three months for a follow-up visit. You will complete questionnaires about your health, sleep, mood, and quality of life similar to the ones you completed at the enrollment visit. We will also ask you to breathe into a machine that tests how well your lungs work and send you home with a sleep diary to fill out for the next 8 days. These visits will take approximately 1 hour and you will receive $50 per visit for your time.

6 Month Follow-Up: Six Months after receiving your PAP machine, you will be asked for your SD card from your CPAP or BiPAP machine so our lab can download the data. The SD card will then be returned to you. For your convenience, we can meet you at your next VA appointment, or we can send you a self-addressed envelope that you can send back to us with your SD card in it. The SD card will be returned to you. Once we successfully receive your SD card download you will be compensated $25.

**RISKS:**
By taking part in this study, you may experience the following risks:

Physical: You may experience discomfort with the PAP mask. Occasionally, the mask may leave a rash or redness on the face. Participants may experience some dry mouth when using the PAP machine or feel air blowing from around the mask towards their eyes if the mask is not properly fitted or moves during sleep. The research team will work with you to resolve these problems.
Participants may report poor sleep or difficulty falling asleep while using the mask and PAP machine during the first week of therapy. This usually improves with education and encouragement and requires that the subject get used to sleeping with mask and PAP.

In rare cases the tape or paste used to affix the EEG/EMG electrodes to the head and chin for the purposes of the sleep study may cause redness or irritation. This normally goes away within several hours of removal of contact with the electrodes.

Emotional: Answering some of the questions about your injury, sleep habits, mood, health, or quality of life may make you feel sad or uncomfortable. You are free to not answer any question that makes you feel uncomfortable. You may find responding to the questionnaires emotionally tiring.

Privacy: It is possible that there may be a breach of privacy regarding your study participation.

There may be unknown risks to women who are or may become pregnant, to unborn babies, and to nursing infants. Therefore, to take part in this study, a medically acceptable form of birth control is required—for female participants. Medically acceptable birth control may include the following methods: barrier protection—such as condoms, intrauterine devices (IUD), abstinence (not having sex), etc. Oral contraceptives may be used but should not be the only means of protection. No birth control method completely eliminates the risk of pregnancy. You should inform the study doctor (PI) immediately if you or your partner intends to get pregnant or if you or your partner should become pregnant while participating in this research study, so that your choices and options can be explored and discussed.

There may also be risks involved from taking part in this study that are not known to researchers at this time.

**BENEFITS:**
The possible benefits to you for taking part in this research study are the diagnosis and treatment of sleep disordered breathing, and information about healthy sleep habits for adults, which could lead to improvement in sleep quality. Additionally, information from this study may benefit other people with similar health issues now or in the future.

**STUDY COSTS:**
Medical care, devices, and education that are part of this research project will be provided at no cost to you.

**ALTERNATE COURSES OF ACTION:**
The alternative to participating in this study is not participating in this study. You are still free to see your healthcare provider for any sleep issues that you have and you will be treated.

**STATEMENT OF RESEARCH RESULTS:**
When the results of this research are published or discussed in conferences, no information will be included that would reveal your identity.

**COMPENSATION:**
For taking part in this research study, you will be compensated for your time and inconvenience. You will receive $50 for the enrollment visit, and $50 for the baseline sleep study. If you qualify for the second part of the study, you will receive $50 for the PAP titration visit and for the Randomization visit. You will also receive $50 at the 1-month and 3-month visit. You will also receive $25 for successful download of your SD card. Parking for all of your visits will be provided free of charge.

**CONFIDENTIALITY:**
As part of standard care, a polysomnogram which is a test conducted to study your sleep patterns record both your sleep study along with audio and video recording. This is to ensure your safety during your sleep study. Video and Audio recording help to confirm your body position along with monitor you for respiratory events during your study. Audio and Video recordings will only be used for clinical purposes to assist in evaluating your sleep. Any recordings obtained during the course of your sleep study will remain confidential and will only be accessed by the physician and designated personnel.
All information collected about you during the course of this study will be kept confidential to the extent permitted by law. You will be identified in the research records by a code name or number. Information that identifies you personally will not be released without your written permission. Federal agencies including, but not limited to, the FDA, OHRP, ORO, and the VA Office of the Inspector General (OIG) may have access to the records. Research records will be kept in a locked cabinet in the locked research lab. Research records will be kept in accordance with the VA record retention policy. Until that time your research records will be kept in a secure location.

**RESEARCH PARTICIPANT'S RIGHTS:**
You have read each page of this consent form or each page has been read to you. A member of the research team has explained the study to you and answered all of your questions. 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 told that 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.

If you have any questions, concerns or complaints about this study now or in the future, you may contact Dr. Badr or one of his research team members at the following phone numbers 313-576-3548 or 313-745-2361. If you have questions or concerns about your rights as a research participant or the validity of this study, the Chair of the Investigational Review Board can be contacted at 313-577-1628. If you are unable to contact the research staff, or if you want to talk to someone other than the research team, you may call the Research Compliance Officer at 313-576-4467 to ask questions or voice concerns or complaints or you may call the Patient Advocate at 313-576-1000. The results of this study may be published, but your records will not be revealed unless required by law. In case there are medical problems or questions, you have been told you can call Dr. Badr at 313-745-2038 during the day.

The VA will provide necessary medical treatment should you be injured by participation in this study. You will be treated for the injury at no cost to you, but no provisions have been made for additional compensation. No reimbursement, compensation or free medical care is offered by Wayne State University. You may be among the veterans 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. Your signature on this form indicates that you have had this research explained to you and your questions about it answered, and you voluntarily consent to participate in this study. You will receive a signed copy of this consent form.

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| x_____ | x_____ | x_____ |
|---|---|---|
| Research Participant's Signature | Date | Time |

| x_____ | x_____ | x_____ |
|---|---|---|
| Signature of person obtaining consent (Study personnel must be approved by IRB.) | (Print Name) | Date |