STUDY TITLE:

Effect of Myofunctional Therapy on Functional Status in Patients with Mild-to-Moderate Sleep Apnea

STUDY PI:

Carl J. Stepnowsky, PhD

IRB Approval Date:

8/10/2023

NCT ID:

NCT04608552

Study Title: Effect of Myofunctional Therapy on Functional Status in Patients with Mild-to-Moderate Sleep Apnea

Principal Investigator: Carl J. Stepnowsky, PhD

VA Facility: VA San Diego Healthcare System

Participant Name:	Date:

STUDY SUMMARY

You are being asked to participate in a research study. This section summarizes key information about this study to assist you, or your legally authorized representative, in understanding the reasons why you may or may not want to participate in the research. Your participation is voluntary. You may refuse to participate or withdraw at any time. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer. Carefully review this section and the detailed information that follows before you agree to participate.

WHAT IS THE STUDY ABOUT AND WHY ARE WE DOING IT?

This study is about improving care provided to patients with sleep apnea. It is being funded by Department of Veterans Affairs (VA) Rehabilitation Research & Development Service (RR&D). By doing this study, we hope to learn how well the exercises work for patients with mild-to-moderate sleep apnea.

WHAT DOES THE STUDY INVOLVE AND HOW LONG WILL IT LAST?

The study will involve an educational program that will help you learn more about your sleep apnea and how to manage it. You will be asked to complete questionnaires before you start the study, and then at approximately the 3-month and 6-month time points. You will be given instructions on exercises you can perform to potentially help you manage your sleep apnea. Your participation in this research will last about 6 months.

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

Continuous Positive Airway Pressure (CPAP) therapy is the standard of care for patients with advanced sleep apnea, also referred to as severe sleep apnea. The study will include only patients with mild-to-moderate sleep apnea. The set of exercises that are being tested have already been shown to partially reduce sleep apnea. We are conducting a more rigorous study of how well these exercises work.

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

There is the possible risk of loss of confidentiality through participation in research because of access to your medical record. A complete description of risks is included in the Research Details Study Risks section. A complete description of alternate treatment/procedures is provided in the Research Details Alternatives section.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of the study is Dr. Carl Stepnowsky of the VA San Diego Healthcare System. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his contact information is: (858)642-1240.

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RESEARCH DETAILS

WHO IS CONDUCTING THIS RESEARCH AND WHY?

Carl J. Stepnowsky, PhD is asking for your consent to this research. Dr. Stepnowsky and associates are conducting a research study to find out more about improving care provided to patients with sleep apnea. You have been asked to participate because you have a diagnosis of mild-to-moderate sleep apnea.

Approximately 240 people will take part in this research at this facility.

FOR HOW LONG WILL I BE IN THE STUDY?

Your individual participation will take approximately 30-60 minutes each time you come to the VA hospital, and you will be expected to come to the hospital approximately 5 times over a 6-month period. The entire study will take about 4 years.

WHAT WILL HAPPEN AND WHAT CAN I EXPECT IF I TAKE PART IN THIS STUDY?

If you agree to be in the study, the following will happen to you:

a. You will be randomized to one of two groups that are being studied using a random number generator.
b. Both groups will be asked to follow an online program of exercises and activities that will help you learn more about your sleep apnea and how to manage it. The groups will differ on the types and amounts of exercises and activities.
c. You will be asked to complete questionnaires before you start the study, and then at approximately the 3-month and 6-month time points.
d. You will be set-up with the study website, which will provide you with more detailed instructions on the exercises and activities you can perform to help you manage your sleep apnea.
e. You will be schedule for another Home Sleep Test. Home sleep apnea testing will be utilized for measurement of the apnea-hypopnea index (AHI) at each study timepoint.

WHICH PROCEDURE/S OR TREATMENT/S ARE DONE FOR RESEARCH?

Continuous Positive Airway Pressure (CPAP) therapy is the standard of care for patients with advanced sleep apnea, also referred to as severe sleep apnea. The study will include only patients with mild-to-moderate sleep apnea. The set of exercises that are being tested have already been shown to partially reduce sleep apnea. We are conducting a more rigorous study of how well these exercises work.

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

Participation in this program may involve some risks or discomforts. There is the possible risk of loss of confidentiality through participation in research because of access to your medical record. Safeguards will be

taken to ensure that your confidentiality is not lost. A trained research staff member will access your medical record only to obtain data from your sleep study – the information the research study requires includes summary indices such as your apnea-hypopnea index (the number of breathing disturbances per hour of sleep), oxygen desaturation index (the number of times your oxygen drops ≥3% per hour of sleep), and total sleep time (the total amount of time in minutes that you are asleep). Use of the sleep recording device might results in: (a) minor irritation to the skin caused by the electrode adhesive or (b) disrupted sleep from wearing the sleep equipment, which can result in sleepiness the next day.

Unforeseeable RISKS
Because this is an investigational study there may be some unknown risks that are currently unforeseeable. You will be informed if the researchers learn of any change in the amount of risk to you.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

There may or may not be a direct benefit to you from these procedures. The study, however, may learn more about how best to manage mild-to-moderate sleep apnea. If the study finds out that these daytime exercises help to manage mild-to-moderate sleep apnea, it might mean that some patients may not need to wear a medical device at night while sleeping (like the CPAP medical device or an oral appliance).

WHAT OTHER CHOICES DO I HAVE IF I DO NOT WANT TO JOIN THIS RESEARCH STUDY?

The alternatives to participation in this study are: (a) to not participate; (b) to contact your current physician regarding any sleep apnea-related problems you may be experiencing.

WILL I BE TOLD NEW INFORMATION ABOUT THIS STUDY?

While you are a participant in this study you will be told if any important new information is found that may affect your wanting to continue.

If the results of this research might influence your medical care after you have completed your participation, the investigators will contact you to let you know these results.

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

The VA will provide necessary medical treatment should you be injured as a result of participating in this study and following study procedures. You will be treated for the injury by the VA at no cost to you or your insurance, but no additional compensation is available. Every reasonable safety measure will be taken to protect your well-being.

If you should have a medical concern or get hurt or sick as a result of taking part in this study, call

DURING THE DAY: Yzabel Velazquez at (858)552-4337

AFTER HOURS: Tania Zamora at (858)784-1266

DO I HAVE TO TAKE PART IN THIS STUDY?

Taking part in this research study is your decision. Your participation in this study is voluntary. You do not have to take part in this study, but if you do, you can stop at any time. You have the right to choose not to participate in any study activity or completely withdraw from continued participation at any point in this study without penalty or jeopardy to the medical care you will receive at this institution or loss of benefits to which you are entitled.

RIGHT OF INVESTIGATOR TO TERMINATE MY PARTICIPATION

You may be withdrawn from the study by Dr. Stepnowsky for unanticipated circumstances. Though unlikely, these circumstances may include cancellation of the study, you being unable to participate due to your health concerns or other reasons, or that your continuation may be harmful to you or to others. You may also be withdrawn from the study if you do not follow the instructions given you by the study personnel.

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

There will be no costs to you or your insurance for any procedures or testing done only as part of this research study. If you receive a bill for services that you think could be related to your participation in this study, you should contact Dr. Stepnowsky at (858)642-1240.

Medical care and services provided by the VA that are not part of this study (e.g., normal hospital and prescription expenses which are not part of the research study) may require co-payments if your VA-eligibility category requires co-payment for VA services.

You or your insurance company will be charged for any procedure or test that is medically necessary for the treatment of your illness, including the CPAP treatment, related tests and procedures. You will be responsible for all insurance co-payments and deductibles. The study test and procedures will be provided to you at no cost.

WHAT COMPENSATION WILL I RECEIVE IF I TAKE PART IN THIS STUDY?

You will receive payment for participating in this study. You will receive $25 for completion of the baseline questionnaires, $25 for completion of the 3-month questionnaire and $25 for completion of the final set of questionnaires for a total of $75 for the entire project.

In addition, you can receive an additional $10 per week if you login to the study website on a minimum of 3 separate days within one week and do some of the activities that are on the website. You can earn an additional $120 for the entire study.

This payment will be made directly to your bank account using electronic funds transfer. If you currently have a debt to the Federal Government, your debt may be subtracted from your funds transfer payment for study participation.

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

If you have any questions, complaints, or concerns about the research or other related matters, you may contact Dr. Stepnowsky at (858)642-1240.

If you have any questions or concerns about your rights as a research subject, the validity of a research study, or research personnel you can contact the Research Compliance Officer at 858-642-3817, VA Research Service at 858-642-3657, VA Regional Counsel at 858-642-1540, or the VASDHS Institutional Review Board at 858-642-6362. This is the Board that is responsible for overseeing the safety of human participants in this study.

If you have study related questions or concerns, you can contact the research team at (858)642-3269.

RE-CONTACT

Re-contact. You may be eligible for other research studies in the future. Are you willing to be contacted by this research team to discuss other studies?

☐ **Yes, I may be contacted for future research opportunities as described**. _____ (initial)

☐ **No, I do not wish to be contacted for future research opportunities as described**. _____ (initial)

HOW WILL MY PRIVATE INFORMTION BE PROTECTED?

Participation in this study may involve a loss of privacy, but information about you will be handled as confidentially as possible If study involves treatment, clinical resources, or potential for adverse events a CPRS note is required.

Your research records will be labeled with a code number. The list that matches your name with the code number will be kept in a locked file in the research team's office. Any research records that identify you will be kept only as paper records in a secure VASDHS location, or as files behind the secure VASDHS computer firewall.

Identifiers might be removed from the identifiable private information that are collected. After that removal, the information could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative.

We will include information about your study participation in your medical record.

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We will keep confidential all research and medical records that identify you to the extent allowed by law. However, you should know that there are some circumstances in which we may have to show your information to other people. For example, the Federal Office of Human Research Protections, the General Accounting Office, the VASDHS R&D Committee, the VASDHS Institutional Review Board, and the VA Rehabilitation Research & Development (the sponsor of this study), and federal compliance officers may look at or copy portions of records that identify you.

While this study is being conducted, you will not have access to your research related health records. This will not affect your VA healthcare including your doctor's ability to see your records as part of your normal care and will not affect your right to have access to the research records after the study is completed.

Any presentations or publications from this information will not identify you.

AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

You have been informed 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.

Tania Zamora and/or Yzabel Velazquez has explained the study to me. I have been told of the risks or discomforts and possible benefits of the study. I have been told of other choices of treatment available to me. I have been given the chance to ask questions and obtain answers.

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

I agree to participate in this research study as has been explained in this document.

_____ _____
Participant's Signature Date

_____ _____ _____
Signature of Researcher obtaining consent Name (print) Date

A copy of this document will be provided to the research participant.

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Health Information Portability and Accountability Act (HIPAA)

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 document, you provide your permission called your 'authorization,' for the access, use, and disclosure of information protected by the HIPAA Privacy Rule.

The research team working on the study will collect and use information learned from the procedures described in this consent form. They may also collect other information including your name, address, date of birth, and information from your medical records such as medical history, sleep apnea test results, and progress notes.

The research team may also need to share your health information and the information it collects to other entities as part of the study progress. Other VA entities may include the VA RR&D and the VA Office of Research Oversight (ORO). You also give your permission for the research team to disclose your information to Institutional Review Board, Office of Human Research Protections (OHRP), and the Government Accountability Office (GAO).

Your health information disclosed outside the VA as described in this authorization may no longer be protected by Federal laws or regulations and may be subject to re-disclosure by the recipient.

You can revoke this authorization, in writing, at any time. To revoke your authorization, you may (a) write to the Release of Information Office at this facility; (b) ask a member of the research team to give you a form to revoke the authorization; or (c) send your written request to the Principal Investigator for this study at the following address: 3350 La Jolla Village Drive (111N-1), San Diego, CA 92161.

If you revoke this authorization, Dr. Stepnowsky and his research team can continue to use information about you that was collected before receipt of the revocation. The research team will not collect information about you after you revoke the authorization.

While this study is being conducted you will not have access to your research-related health records.

Treatment, payment, or enrollment/eligibility for benefits cannot be conditioned on you signing this authorization.

Unless you revoke (take back) your permission, your authorization to allow us to use and/or disclose. your information will Expire on December 31, 2027.

AGREEMENT TO AUTHORIZE USE AND RELEASE OF INDIVIDUALLY IDENTIFIABLE HEALTH INFORMATION

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By signing this document below, I give my authorization (permission) for the use and disclosure of my individually identifiable health information as described in this document. This authorization has been explained to me and I have been given the opportunity to ask questions. If I believe that my privacy rights have been compromised, I may contact the VHA facility Privacy Officer to file a verbal or written complaint. I will be given a signed copy of this document for my records.

_____	_____	_____
Participant's Signature	Last 4 of SSN	Date

A copy of this document will be provided to the research participant.

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EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

You have been asked to participate as a subject in medical research.
You have the right to know:

1) The nature and purpose of the study.
2) The procedures in the study and any drug or device to be used.
3) Discomforts and risks reasonably to be expected from the study.
4) Benefits reasonably to be expected from the study.
5) Alternative procedures, drugs, or devices that might be helpful to you and their risks and benefits.
6) Availability of medical treatment should complications occur.
7) You may ask questions about the study or the procedure.
8) You may quit the study at any time without affecting your future care at the VA.
9) You should be given a copy of the signed and dated written consent form for the study.
10) Your consent to participate must be given freely, without being obtained through deceit, force, or coercion.

If you have any questions or concerns about your rights as research subject please contact the VASDHS Research Compliance Officer at (858) 642-3817 or RCO@vapop.ucsd.edu. You may leave an anonymous comment at the VASDHS research compliance hotline at 858-642-6311.

REF: California HSC 24170-24179.5