Bright Light Therapy for Residual Daytime Symptoms Associated With Obstructive Sleep Apnea

NCT04299009

May 27, 2021

Subject Name: _____ Last 4 SSN: _____ Date: _____

Title of Study: Bright Light Therapy for Residual Daytime Symptoms Associated with Obstructive Sleep Apnea (Bright DayS)

Principal Investigator: Isabella Soreca, MD VAMC: Pittsburgh (646)

LAY TITLE: Bright light therapy for continued daytime sleepiness

KEY ELEMENTS:
This is a research study to determine if bright light therapy glasses are effective in reducing daytime sleepiness in individuals using a Continuous Positive Airway Pressure (CPAP) device. Each participant will receive bright light therapy glasses to wear for two 4-week sessions. Each of the 4-week periods will give you Bright Light Therapy utilizing different types of light (different colors and spectrums) with one week in between for a washout period. You will also be asked to wear an actigraphy watch that tracks movement during the day.
Each of the study visits will take approximately 45 minutes. Your participation in this study is voluntary.

There are risks to this study that are described in this document. Risk from wearing bright light therapy glasses could include: discomfort, headache or eye-strain. Risk from wearing actigraphy watch could include discomfort or irritation. You may directly benefit from participating in this study. Direct benefits may include reducing daytime sleepiness and being seen more frequently. You may also, receive indirect benefit given that you are contributing to medical science or helping to advance future understanding of daytime sleepiness in veterans with Obstructive Sleep Apnea (OSA).

Some research requires that the full purpose of the study not be explained before you participate. We will give you a full explanation as soon as you complete the study.

If you do not participate in this study, alternate treatments for daytime sleepiness include: treatment with medication or possibly other studies you may qualify for.

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

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, or if you experience any illness, injury or other medical problem that you feel may be related to this study, please call the principal investigator, Dr. Isabella Soreca at 412-360-6315.

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In the case of a medical emergency contact your local emergency medical service or go to your local emergency room.

PRINCIPAL INVESTIGATOR:
Isabella Soreca, MD
VA Pittsburgh Healthcare System
University Drive C
Pittsburgh, PA 15240
412-360-6315

STUDY SPONSOR:
Rehabilitation Research and Development (Prog 822)
Additional information regarding the study sponsor can be provided upon request.

PURPOSE OF THE RESEARCH STUDY: The purpose of this research study is to see if receiving Bright Light Therapy (BLT) via therapy glasses will reduce residual daytime sleepiness in patients with obstructive sleep apnea (OSA) who are using a CPAP device.

You are being asked to participate in this research study because you currently have a diagnosis of OSA and are using a CPAP machine but still experiencing residual daytime sleepiness.

This is a local pilot study where 25 veterans will be tested and given the Re-Timer therapy glasses to wear for two sessions of four weeks each with a one-week break in between. The Re-Timer glasses are commercially available and used by the general population. A pilot study is a small study that looks to see if a certain design works before using the design on a larger scale. All visits will occur at VA Pittsburgh Healthcare System.

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DESCRIPTION OF THE RESEARCH STUDY:

STUDY ENTRY/ VISIT 1 (Informed Consent and Screening):
If you choose to participate you will be asked to sign this form and follow the study procedures listed below. You will come to the Sleep Clinic. A study team member will go over this document with you and answer any questions you may have about the study.
After signing the informed consent, you will fill out three questionnaires about sleeping habits, daytime sleepiness and depression. You will receive an actigraphy, which is worn like a watch, to take home for 1 week along with a sleep diary to fill out. The actigraphy can be worn in the shower, while you sleep, and throughout the day. It should be worn as much as possible until your next visit. The questionnaires take about 20 minutes to complete. You will be scheduled for a visit one week after your Study Entry visit.

BASELINE/ VISIT 2:
At Visit 2 you will return the actigraphy and sleep diary. After returning these, you will be randomized (like the flip of a coin) to one of two treatments for the first four weeks of the study. You will receive the other treatment at visit 4.

During this visit you will come to the Sleep Clinic, fill out four questionnaires about sleeping habits, daytime sleepiness, depression, and quality of life. You will receive a new actigraphy to take home and will receive Re-Timer glasses with instructions. Optionally, you will be given a study provided timer or you may choose to use your own alarm clock, phone timer, etc.

You will be asked to wear an actigraphy for the full duration of the study (nine weeks). The actigraphy can be worn in the shower, while you sleep, and throughout the day. You should wear the actigraphy as much as possible during the study. The Re-Timer glasses will be worn for 60 minutes in the morning at the recommended alarm time. This time is based on when your sleep diary and actigraphy show you usually get up. You can wear the glasses for all normal morning activities except for showering or going outside.

You will be scheduled for your next visit, Visit 3, which is about four weeks after this visit.

PHONE CALL 1:
You will receive a phone call one week after the Re-Timer glasses have been dispensed. During this phone call, we will ask about how often you have been using your glasses and help with any troubleshooting issues and answer any questions you may have. We will also confirm your next appointment for your Visit 3. This phone call should take approximately 15 minutes.

VISIT 3:
At Visit 3 you will return the Re-Timer glasses but you will continue to wear an actigraphy.

During this visit you will come to the Sleep Clinic, fill out four questionnaires about sleeping habits, daytime sleepiness, depression, and quality of life. We will ask if you have experienced any issues with the device. You will then be scheduled for your Visit 4 in one week. Between Visit 3 and 4 you will not receive treatment but will continue to wear the actigraphy. A newly charged actigraphy will be dispensed at this visit.

VISIT 4:
During Visit 4, you will come to the Sleep Clinic, fill out four questionnaires about sleeping habits, daytime sleepiness, depression, and quality of life. You will receive a different set of Re-Timer glasses with instructions. Optionally, you will be given a study provided timer or you may choose to use your own alarm clock, phone timer, etc.

A newly charged actigraphy will be dispensed at this visit and you will be asked to continue to wear the actigraphy for the full four weeks. The actigraphy can be worn in the shower, while you sleep, and throughout the day. The Re-Timer glasses will be worn for 60 minutes starting at the recommended alarm time. You can wear the glasses for all normal morning activities except for showering or going outside.

You will be scheduled for your next visit, Visit 5, which is about four weeks after this visit.

PHONE CALL 2:
You will receive a phone call one week after the Re-Timer glasses have been dispensed. During this phone call, we will ask about how often you have been using your glasses and help with any

troubleshooting issues and answer any questions you may have. We will also confirm your next appointment for your Visit 5. This phone call should take approximately 15 minutes.

VISIT 5:
At Visit 5 you will return the Re-Timer glasses and the actigraphy.

During this visit you will come to the Sleep Clinic, fill out four questionnaires about sleeping habits, daytime sleepiness, depression, and quality of life. We will ask if you have experienced any issues with the device. You will then be scheduled for your Visit 6 in four weeks.

VISIT 6:
Visit 6 is the last study visit.

During this visit you will come to the Sleep Clinic, fill out four questionnaires about sleeping habits, daytime sleepiness, depression, and quality of life. You will be asked open ended questions about your experience using the device. After this visit your participation in the study will be over.

RISKS AND BENEFITS:
In terms of risks involved with this study, it is primarily that of discomfort, headache or eye-strain when using the bright light therapy glasses.

You could feel discomfort or irritation when wearing the actigraphy watch.

You may feel uncomfortable answering some of the questionnaires. If so, you are able to skip any of those that make you feel uncomfortable.

You may be inconvenienced by the additional visits for the study, however we will attempt to have the appointment coincide with other clinic appointments.

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Please note that it is important to disclose your participation in other research studies. Because there may be other risks associated with participating in multiple research studies, you must tell the research staff about any other studies you are currently participating in, both within and outside of the VA.
You may benefit from participating in this study. Direct benefits may include: reduction of daytime sleepiness.
You may not directly benefit from participating in ~~the banking portion of~~ this study. You may however, receive indirect benefit given that you are contributing to medical science or helping to advance future understanding of daytime sleepiness.
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.

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.

If you decide that you no longer wish to continue to participate after you have signed the consent, you should contact Dr. Soreca at 412-360-6315. Any information obtained from you up to that point will, however, continue to be used by the research team.

Your doctor is also involved as an investigator in this research study. As both your doctor and a research investigator, she 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

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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.

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.

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 receive $25.00 for each of four completed visits, at Baseline(Visit 2), Visits 3, 5 and 6 for a total of $100.00. Payments will be submitted at the end of each completed visit. 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. If you are a Veteran eligible for Beneficiary Travel, please speak with the research team to understand how research visits may impact your ability to receive Beneficiary Travel.

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.

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, and medications, date of birth and questionnaire responses

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. If your answers to the questionnaires indicate that you are at risk for suicidality, we

will need to disclose this information so you can receive proper treatment. We will ask you to inform your existing behavioral health provider or we will refer you to behavioral health for evaluation and treatment.

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. Your social security number will be used to process payment to you.

FUTURE USE AND RECONTACT

Identifiers may be removed from the identifiable private information collected for this study and data may be used to design future research studies but will not be distributed to other investigators for future research studies without additional informed consent from you.

Future use is part of this study. By signing this form you are authorizing and permitting uses and/or disclosures of your data for future research purposes (e.g., future studies) as described in this document. All data will be stored on a VA-approved on-line database accessible only by the study team or in a locked office in the Research Office Building.

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.

Isabella Soreca, MD

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VA Pittsburgh Healthcare System (VAPHS)
University Drive C
Pittsburgh, PA 15240

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.

In addition to consenting to the study you have the option to consent to be contacted about future bright light therapy studies. If you say yes, we will record this in a log along with your phone number and/or your address to contact you when a future study arises that you may be eligible for. We already collect this information as part of the study and will not be collecting any additional information from you other than your permission to be contacted. The contact log can only be accessed by study personal and is stored as a password protected file.

RESEARCH SUBJECTS' RIGHTS: You have read or have had read to you all of the above. Dr. Isabella Soreca 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.

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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 (412) 360-2394.

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.

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

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

OPTIONAL CONSENT TO BE CONTACTED ABOUT FUTURE STUDIES

Do you consent to be contact about future bright light therapy research studies that you may be eligible for? Your answer will not impact your ability to participate in this study.

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

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