Study title: We-PAP: A Couples-based Intervention for Sleep Apnea

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Consent and Authorization Document

Research Study Title: We-PAP: A Couples-based Intervention for Obstructive Sleep Apnea

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STUDY SUMMARY

We have summarized the key information about this research study at the beginning of this consent document. More complete details are included following this summary.

We invite you to take part in a research study because you or your partner has mild or moderate sleep apnea. Sleep apnea is a common sleep disorder that includes pauses in breathing or shallow breaths while you sleep and affects the sleep of both the patient and his/her partner. The most common treatment for sleep apnea is continuous positive airway pressure (CPAP). It is your choice whether to be in the study.

The purpose of the study is to design a new intervention to improve the treatment of sleep apnea and learn if a couples-based intervention helps patients and their partners as they start to use CPAP treatment. The study will last for 3 months. Everyone in the study will answer questionnaires, complete cognitive testing, and wear a wrist-watch sleep monitor during the study. You will either be assigned to an couples-based intervention group (only you and your partner) that receives 3 online video visits of approximately 75 minutes, 60 minutes, and 60 minutes of total time each, respectively, or assigned to another group that receives educational information about sleep apnea. What group you will be in is decided by chance, like flipping a coin. The study procedures will be described in more detail later in this document.

There are minimal risks to participating in this study. For example, it may be uncomfortable to answer some of the questions about your emotions. There is a risk of loss of confidentiality. All the risks will be described in more detail later in this document. You may benefit from being in the study, but there is no guarantee of benefits. You might help others in the future by being in this research study.

You can receive standard care for sleep apnea even if you decide not to be in this study.

You may discuss with your family members or doctor before deciding to take part in this research study. You will be notified about any new findings that may influence your willingness to participate in the study.

Please take your time and read this information carefully. You should ask the research staff if you have any questions about this study or if there is anything you do not understand. If you decide to take part in the study, you will be asked to sign this form.

BACKGROUND AND PURPOSE

Sleep apnea is a common sleep disorder that includes pauses in breathing or shallow breaths while you sleep. Continuous Positive Airway Pressure (CPAP) is a treatment that uses mild air pressure to keep the airways open during sleep. It consists of a mask that fits over the nose and mouth. The mask is attached to a machine that delivers air at positive pressure. This acts like a "splint" to prevent you from having breathing pauses or decreased breathing while sleeping. Having sleep apnea and starting CPAP affects both the patient and his/her partner.

The purpose of this study is to understand whether a new treatment for couples can help patients and their partners adjust to using CPAP and improve their sleep.

STUDY PROCEDURES

This study involves a total of 3 video-based assessments (via Zoom) that will be approximately 60-75 minutes in duration. These assessments will occur at pre-intervention, as well as at 1 month and at 3 months after starting CPAP. Both the patient and partner will complete the study visits. The visits will be completed remotely (no travel to the clinic required).

Before you are assigned to the intervention group, you will complete a pre-intervention assessment. The pre-intervention assessment will include questionnaires about your demographics (e.g., marital status, age, medical history), mood, expectations for CPAP, and relationship quality and health, as well as cognitive testing (such as memory tests), wearing a wristwatch sized sleep monitor for 7 days, and completing a sleep diary. You will complete the pre-intervention assessment before you start using CPAP at home. This may mean that you need to delay starting the use of your CPAP right away.

After completion of the pre-intervention assessment, you will be assigned to either a couples-based intervention group or to a group that receives educational materials about sleep apnea. The intervention you receive will be chosen by chance, like flipping a coin. Neither you nor the study doctor will choose what intervention you get. You will have an equal chance of being given each intervention.

- <u>If you are randomized to the educational information group</u>: You will be provided with written information to help you learn more about sleep apnea and CPAP treatment. Researchers will call you to make sure that you received it and answer any questions that you have.

- <u>If you are randomized to couples-based treatment group:</u> You will receive the educational materials. In addition, you and your partner will participate in 3 visits of approximately 75 minutes, 60 minutes, and 60 minutes of total time each via video (Zoom). In these visits, you will watch educational videos and discuss strategies with a study interventionist for using your CPAP and improving the sleep of both the patient and partner. Between visits there may be some forms to complete, such as a daily record of your sleep.

Regardless of what group you are in, you will complete the intervention assessment questionnaires again at 1 month and at 3 months after starting CPAP. At the 3-month timepoint,

you also will complete the cognitive testing and wear the wristwatch sized sleep monitor for 7 days.

RISKS
There are minimal risks to participating in this study. Participants may experience irritation from wearing the actigraph (wrist monitor) or emotional discomfort in completing questionnaires. You do not have to answer any questions that you do not want to answer. You may stop answering questions at any time without affecting your medical care. All of your answers will remain confidential.

There is a minimal risk of breach of confidentiality regarding collection of medical record information. All research information about you will be handled in a confidential (private) manner consistent with other hospital medical records.

At the conclusion of the study, participants can request results of their sleep data collected via actigraphy.

You and your insurance company will be charged for the health care services that you would ordinarily be responsible to pay, such as the CPAP. You should check with your insurance to see what services will be covered by your insurance and what you will be responsible to pay.

BENEFITS
We cannot promise any benefits to you or others as a result of this study. Participants may benefit from the intervention. They may experience improvements in their sleep as a result of participation. If the study is successful, we may learn about new strategies for helping improve sleep for patients with sleep apnea and their partners.

ALTERNATIVE PROCEDURES
You have the option not be part of this study. If you do not take part, you will continue to receive the standard care for sleep apnea.

RETURN OF RESEARCH EQUIPMENT
As part of this study, you will be mailed a wristwatch sized sleep monitor. We will ask you to provide the contact information for someone who can help reach you in case we have difficulty reaching you to retrieve the device. We recognize that damage may occur to the device through normal wear and tear, and if this happens, you will not be liable. If the device is lost or damaged due to negligence (e.g. failure to return it), then you may be liable for the costs in replacing it ($800). Because we have a limited number of devices, we ask that you return the device in a timely manner. By participating in this study, you agree to return the sleep monitor within 3 business days either by arranging with us to pick it up or returning it in a postage-paid envelope provided to you.

PERSON TO CONTACT
If you have questions, complaints or concerns about this study, if you wish to revoke your permission to use your data or if you think you may have been injured from being in this study,

please contact Kelly Baron, PhD (801) 585-7588. She is available from 9 am to 5 pm, Monday-Friday.

Institutional Review Board: Contact the Institutional Review Board (IRB) if you have questions regarding your rights as a research participant. Also, contact the IRB if you have questions, complaints or concerns which you do not feel you can discuss with the investigator. The University of Utah IRB may be reached by phone at (801) 581-3655 or by e-mail at irb@hsc.utah.edu.

Research Participant Advocate: You may also contact the Research Participant Advocate (RPA) by phone at (801) 581-3803 or by email at participant.advocate@hsc.utah.edu.

VOLUNTARY PARTICIPATION

Participation in this research study is voluntary. You have the option to not be part of this study. If you do not take part, you will receive the routine treatment usually provided to patients with sleep apnea. Your decision to participate or not participate will not affect any other part of your care. Refusal to take part or stopping participation will not result in any penalty or loss of benefits to which you are entitled. Your decision to take part or not take part will not affect your legal rights, available remedies or the quality of health care that you will receive.

COSTS AND COMPENSATION TO PARTICIPANTS

There will be no cost to you to take part in the research study. The costs of your standard medical care will be billed to you or your insurance company in the usual manner.

- You will receive up to $180 for participation in the study ($70 for the pre-intervention assessment, $40 at 1 month, $70 at 3 months)
- Each person will be paid for what they complete (up to $360 per couple).
- If you complete portions of the study, the payment will be prorated as the following: $10 for completion of study questionnaires, $30 for 7 days of actigraphy, and $30 for cognitive testing.

You can request payment in either an online Amazon gift card or a check delivered in the mail. If you would like to be paid by check, you will need to provide us with your social security number on a W-9 Form that will be filed with our accounts payable department. The amount you get for being in this study may be turned in to the Internal Revenue Service (IRS) as taxable income. You can still be in the study and not give us your social security number. However, we will not be able to pay you as outlined in this consent form. You will be mailed payment in the form of a check to the address you provide in approximately 2 to 4 weeks after the completion of the study.

NUMBER OF PARTICIPANTS

We expect to enroll approximately 40 couples at the University of Utah.

AUTHORIZATION FOR USE OF YOUR PROTECTED HEALTH INFORMATION

Signing this document means you allow us, the researchers in this study, and others working with us to use some information about your health for this research study.

This is the information we will use and disclose in our research records:

- Demographic and identifying information like name, address, telephone number, email address
- Related medical information about you like medical record number, height, weight, sleep study results and CPAP usage
- Relationship status and quality
- Current sleep habits, sleep duration, daytime sleepiness, daily activities, work schedule, and exercise

How we will protect and share your information:

We will do everything we can to keep your information private but we cannot guarantee this. We will be recording video and audio during the zoom assessment and intervention sessions. Study information will be kept in a secure manner (password protected online university server) and recordings will be destroyed by deleting them at the end of the study. We may also need to disclose information if required by law.

- In order to conduct this study and make sure it is conducted as described in this form, the research records may be used and reviewed by others who are working with us on this research:
    - Members of the research team and University of Utah Health
    - The University of Utah Institutional Review Board (IRB), which reviews research involving people to make sure the study protects your rights
    - The National Institute on Aging, which sponsors this study

- If we share your identifying information with groups outside of University of Utah Health, they may not be required to follow the same federal privacy laws that we follow. They may also share your information again with others not described in this form.

- The results of this research study will be provided to the sponsor, National Institute on Aging (and/or its representatives). In addition, data from this study will be put in a public data set that will be available to other research investigators. This public data set will not contain any identifying patient data.

- If you do not want us to use information about your health, you should not be part of this research. If you choose not to participate, you can still receive health care services at University of Utah Health.

What if I decide to Not Participate after I sign the Consent and Authorization Form?

- You can inform us verbally or in writing at any time that you do not want to be in this study and do not want us to use your health information. If you change your mind, we

will not be able to collect new information about you, and you will be withdrawn from the research study. However, we can continue to use information we have already started to use in our research, as needed to maintain the integrity of the research.

This authorization does not have an expiration date.

Please **INITIAL** the appropriate statement to indicate whether or not you give permission for future contact.

YES_____ I give permission to be contacted in the future for research purposes. (Please initial)

NO _____ I do not give permission to be contacted in the future for research purposes. (Please initial)

CONSENT

I confirm that I have read this consent and authorization document and have had the opportunity to ask questions. I will be given a signed copy of the consent and authorization form to keep. **I agree to take part in this research study and authorize you to use and disclose health information about me for this study, as you have explained in this document.**

_____
Participant's Name

_____ _____
Participant's Signature Date

_____
Name of Person Obtaining Authorization and Consent

_____ _____
Signature of Person Obtaining Authorization and Consent Date