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Department of Veterans Affairs

RESEARCH CONSENT FORM

Title of Study: Cognitive-Behavioral Therapy to Increase CPAP Adherence in Veterans with PTSD eProtocol#35623	
Principal Investigator: **Lisa Kinoshita, PhD**	VAMC: VA Palo Alto HCS

Cognitive-Behavioral Therapy to Increase CPAP Adherence in Veterans with PTSD

Informed Consent

Are you participating in any other research studies? _____ yes _____no

PURPOSE OF RESEARCH

You are invited to participate in a research study of non-drug treatments for obstructive sleep apnea (OSA).

We hope to learn if either cognitive-behavioral therapy or an educational-based approach works best for adults with obstructive sleep apnea. You were selected as a possible participant in this study because you may have posttraumatic stress disorder (PTSD), sleep apnea and you chose to start using a continuous positive airway pressure (CPAP) machine. You will either be randomly assigned to a cognitive-behavioral treatment led by a clinical psychologist or to an education-based treatment led by a sleep specialist.

This study is being done together by researchers at VA Palo Alto Health Care System (VAPAHCS) and Stanford University.

The VA Palo Alto expects to enroll up to 300 research participants with obstructive sleep apnea to participate in this study. The study will be conducted at VA Palo Alto Health Care System.

VOLUNTARY PARTICIPATION

Your participation in this study is entirely voluntary. Your decision not to participate will not have any negative effect on you or your medical care. You can decide to participate now, but withdraw your consent later and stop being in the study without any loss of benefits or medical care you are entitled to.

DURATION OF STUDY INVOLVEMENT

The entire research study is expected to take approximately four years. Your participation in the study will last approximately one year. Participation in this study will require a screening visit, a baseline visit, and eight treatment visits (once per week for four weeks, then once every three months). The initial screening process will take approximately –4 - 6 hours, will include breaks and meals, and could be split into three different visits to accommodate schedules, the consent, screening and the baseline visit.

PROCEDURES

If you decide to participate in the study, you will complete a series of screening steps to determine the nature of your sleep problem, mental health status, and memory and thinking. The order of these steps may vary. If at any point during the evaluation portion of this study, we determine that our treatments are not appropriate for your sleep problem, we will end your participation in this study and suggest possible referral resources. Research visits may be conducted either in-person or via telehealth

(e.g., via video or telephone). Telehealth sessions are subject to approval by the research team. Videoconferencing in particular, requires certain features such as hardware, internet accessibility, and telephone capability.

	Consent	Screen	BL *	Pre-Intervention Phase		Early Intervention Phase			Booster Session Phase			Final Booster Session
Treatment Session				1	Start CPAP	2	3	4	5	6	7	8
Procedure Day		-28 to -14		0		7	14	21	90	180	270	365
Consent	X	X*										
Med Hx review		X	X*									X
Blood Sample				X								
Self-reports		X	X*					X	X	X	X	X
Semi-structured Clinical Interview		X	X*									X
Cognitive Battery		X	X*									X
Self-Efficacy Measure for Sleep Apnea				X				X	X	X	X	X
Working Alliance Inventory				X		X	X	X	X	X	X	X
In-clinic treatment sessions				X		X	X	X	X	X	X	X
CPAP Usage (Measurement Periods)					X →	→	→	→	→	→	→	

*If Baseline (BL) visit is needed, it will include the activities that were not completed during the screening visit

Procedures: Screening Evaluation.

In-clinic/Telehealth Treatment Sessions. The in-clinic/telehealth screening process will last 4 – 6 hours, will include breaks, including a meal break, and could be split into two different visits (screening and baseline) to accommodate participants' schedule. For in-clinic screenings, meal vouchers will be provided during the meal break. We will ask you to provide blood samples and a number of psychological questionnaires and interviews about your sleep and mental health prior to your first treatment session. For those participants with telehealth sessions, blood samples can be collected at an

alternate time. You will have a chance to bring up issues you believe are relevant to your sleep problem(s). We will also do tests to examine your memory and thinking. Portions of the in-clinic/telehealth sessions will be recorded on audiotape and retained with other study records.

_____ Yes, I give permission for my responses to be audiotaped, as set forth above.

_____ No, I do not give permission for my responses to be audiotaped.

Blood Samples: We will take a blood sample (10 cc or 2 tablespoons) to analyze for genetic and inflammatory biomarkers at the screening visit or other scheduled time (if you will be doing telehealth). The sample will be stored for future analyses. This will take about 15 - 30 minutes.

Schedule. Before treatment begins you will be provided with a schedule for all future appointments. If rescheduling is needed, please contact study staff as soon as possible.

Procedures: Treatment.

After you have completed the screening session described above, we will determine if our study is appropriate for you. If it is, you will be randomly assigned to either the Cognitive-Behavioral Treatment or the Education-Based Treatment. Cognitive-Behavioral Therapy is designed to identify incorrect ideas, challenge their validity, and replace them with correct information. This therapy tries to reduce worry, anxiety, and fear that one won't sleep by providing accurate information about sleep and CPAP usage. In the Education-Based Treatment, you will be provided with education about sleep problems, PTSD, cardiovascular disease, and skills to improve your sleep and general well-being.

The treatment part of the study lasts one year. During the treatment, you will meet with a clinician either in-person or via telehealth for a total of eight sessions. Sessions 1 - 4 will occur in the first four weeks of treatment. Sessions 5 - 8 will occur every three months following the start of treatment. The first session will last approximately 80-90 minutes with each of the following sessions lasting approximately 50-60 minutes. For Sessions 5-7, you will be asked to stay for an extra hour to complete self-report questionnaires. At the final session, you will also be asked to repeat psychological questionnaires, interviews about your sleep and mental health, and tests to examine your memory and thinking. Portions of all sessions will be recorded on audiotape and retained until the conclusion of the study.

Sleep Diary. During the first in-clinic/telehealth treatment session, we will show you how to complete daily sleep diaries. A sleep diary is designed to gather information about your daily sleep pattern. You will be asked to keep a daily sleep diary for the first month of treatment, one week before each booster session, and for one month before the last session.

Procedures: Follow-up.

We expect the benefits of your treatment to continue and improve with time, and we encourage you to continue practicing the treatment instructions to maintain your progress.

Please note that the data collected is for research purposes only. The data is not meant to affect your clinical care at the VA Palo Alto or other medical facilities. Access to research data will not be available to you; however, all documentation (lab results, visit notes) in your electronic VA medical record can be obtained through the Release of Information Office.

___ I understand that the research data collected as part of this study will NOT be available to me.

Tissue Banking for Future Research

As part of this research we would like to save any leftover blood samples for future research. Your blood samples will be stored at the Palo Alto VA and will be used for future research on problems concerning sleep, mental health and aging. Your samples will continue to be stored and used for research until the sample is used up. Your sample and information about you will be labeled with a code that does not contain your name, initials, SSN, date of birth, or other ways that identify who you are. The research we conduct with your blood is being done for research purposes only, and we will not tell you or your doctor about the results of the research.

You may withdraw your permission for us to use your blood for future research at any time. Contact Dr. Kinoshita at 650-493-5000 extension 60482 to withdraw your permission. If you take back your permission, the research team can continue to use information about you collected before you decided to take back your permission, but they will not collect any information about you going forward and any remaining samples will be destroyed.

The research we conduct using your blood may result in inventions or discoveries that could be used to make new products or diagnostic or therapeutic agents. These inventions and discoveries may become financially valuable. You will not receive any money or other benefits from any commercial or other products that are made using your specimens. Any tissues you have donated which are used in research may result in new products, tests or discoveries. In some instances, these may have potential commercial value and may be developed and owned by the researchers, and/or others. However, donors of tissues do not retain any property rights to the materials. Therefore, you would not share in any financial benefits from these products, tests or discoveries.

_____ Yes, I give permission for my samples to be saved for future research, as set forth above.

_____ No, I do not give permission for my samples to be saved for future research.

Tissue Sampling for Genetic Testing

As part of the analysis on your samples, the investigators will do genetic testing. Genetic research is research that studies genes, including gene characteristics and gene versions that are transmitted by parents to children. Genetic research may include looking at information, such as personal appearance

and biochemistry, gene sequences, genetic landmarks, individual and family medical histories, reactions to medications and responses to treatment. Genetic research raises certain questions about informing you of any results. Possible risks of knowing results include: anxiety; other psychological distress; and the possibility of insurance and job discrimination. A possible risk of not knowing includes being unaware of the need for treatment. These risks can change depending on the results of the research and whether there is a treatment or cure for a particular disease.

The genetic tests we plan to do will allow us to study the impact of different genes on sleep disruption, its treatment, and its relationship to aging and to various disorders.

Sometimes patients have been required to furnish information from genetic testing for health insurance, life insurance, and/or a job. A Federal law, the Genetic Information Nondiscrimination Act of 2008 (GINA), generally makes it illegal for health insurance companies, group health plans, and employers with 15 or more employees to discriminate against you based on your genetic information.

We will protect the confidentiality of your samples and information about you. Your samples will be stored in a locked area and all information about you will be stored in a locked file cabinet or on a password protected secure computer.

PARTICIPANT RESPONSIBILITIES

As a study participant, your responsibilities include:

- Follow the instructions of the investigators and study staff.
- Keep your study appointments. If it is necessary to miss an appointment, please contact the investigators or research study staff to reschedule as soon as you know you will miss the appointment.
- Tell the investigators or research study staff about any side effects, doctor visits, or hospitalizations that you may have.
- Keep your sleep diaries as instructed.
- Complete your questionnaires as instructed.
- Ask questions as you think of them.
- Tell the investigators or research staff if you change your mind about staying in the study.

WITHDRAWAL FROM STUDY

If you first agree to participate and then you change your mind, you are **free to withdraw** your consent and stop your participation at any time. If you decide to withdraw from the study, you will not lose any benefits to which you would otherwise be entitled and your decision will not affect your ability to receive medical care for any condition.

If you want to stop being in the study you should tell the investigators or study staff. You can do this by phone by calling Dr. Lisa Kinoshita at 650-493-5000 extension 60482.

If you withdraw from the study for any reason, you must return any study-related equipment still in your possession.

The investigators may also withdraw you from the study without your consent for one or more of the following reasons:

- Failure to follow the instructions of the investigators and/or study staff.
- The investigators decide that continuing your participation could be harmful to you.
- You need treatment not allowed in the study.
- The study is cancelled.
- Other administrative reasons.
- Unanticipated circumstances.

POSSIBLE RISKS, DISCOMFORTS, AND INCONVENIENCES

There are risks, discomforts, and inconveniences associated with any research study. These deserve careful thought. You should talk with the Protocol Director if you have any questions. This study involves the following risks, discomforts, and possible inconveniences:

Evaluation and testing. There are virtually no risks involved in the cognitive testing and psychological measurements other than the anxiety that can be associated with any test. It is possible that you might become tired or frustrated by some of our testing. You may find answering the questionnaires annoying, boring, or repetitive. If this happens, please tell us and we will take a break or skip a particularly difficult test. Evaluations of mood and mental status may be slightly frustrating or produce fatigue and boredom.

CPAP Use Delay. Your CPAP use may be slightly delayed as you complete the screening process. The risks of waiting a few more days to allow for completion of the study screening process could possibly lead to a change in OSA severity. The difference is likely very minimal and you may not even notice a difference.

Sleep Log and Questionnaires. There are no harmful effects to filling out the sleep log and questionnaires, but you may find answering the questionnaires annoying or boring.

Cognitive-Behavioral Therapy may lead you to reorganize your schedule and plan a more organized or regimented sleep schedule. Some people may find this frustrating or uncomfortable.

Blood sampling. The risks of drawing blood include temporary discomfort from the needle stick, bruising, and rarely, infection.

Confidentiality. If, in an interview, you disclose that (a) you intend to harm yourself or someone else, (b) that a child had been abused or neglected, or (c) that an elder or dependent had been abused, we are required by California law to notify the appropriate authorities.

Should you be considered to be at imminent risk of harming yourself or others during an in-person session, the supervising clinician will be contacted for support in contacting appropriate authorities.

In the event that you are at imminent risk of harming yourself or others during a telehealth session, the supervising clinician will be alerted as well as appropriate authorities in your geographic area.

Telehealth. We will follow all research guidelines to maintain the confidentiality of your data. Use of communication technologies such as videoconferencing and telephone have the potential for disruption as well as vulnerability to computer viruses, hackers, and accessibility to unsecured electronic files.

POTENTIAL BENEFITS

There may be no direct benefits to you for participation in this study. Your sleep may improve. Your participation may help us to learn more about the causes of insomnia.

WE CANNOT AND DO NOT GUARANTEE OR PROMISE THAT YOU WILL RECEIVE ANY DIRECT BENEFITS FROM THIS STUDY.

ALTERNATIVES

You do not have to participate in this research study in order to receive treatment for any medical condition. There are other behavioral treatments for sleep problems, as well as various drug treatments for sleep problems, that are not included in this study. Your study doctor can discuss any alternatives with you before you agree to participate in this study.

PARTICIPANT'S RIGHTS

Your participation is voluntary. You should not feel obligated to agree to participate. Your questions should be answered clearly and to your satisfaction.

You have a right to refuse to answer any particular questions.

You will be told of any important new information that is learned during the course of this research study, which might affect your condition or your willingness to continue participation in this study.

ClinicalTrials.gov

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 Web site will include a summary of the results. You can search this Web site at any time.

CONFIDENTIALITY

We will keep your name and all the information you tell us in this study as confidential as possible. We may publish the results of this study for others to read about, but you will not be identified in any articles about the study by name, social security number, address, telephone number, or any other direct personal identifier. Also, other federal agencies as required, such as the VA Office of Research Oversight and the VA Office of the Inspector General may have access to your information.

If you decide to participate in other studies at the VA, data about you from this study may be combined with data about you collected for other studies.

Telehealth: Efforts to maintain confidentiality during telehealth sessions (e.g., videoconferencing, telephone) will be made similar to in-person visits; however, it should be noted that there are some threats to confidentiality while using any telecommunication technologies such as computer viruses, hackers, and potential access to unsecured electronic files.

Confidentiality during telehealth sessions may be improved at your location by ensuring you are in a private setting.

FINANCIAL CONSIDERATIONS

Payments

Participants will receive $10 for the consent visit, $20 for the screening visit and $20 for the baseline visit (if the baseline visit is needed). On the day of the screening visit and final visit, participants will receive up to $10 reimbursement for meals. If you are eligible for the study, you will receive stipends of $25 for all 8 in-clinic visits: 1) Session 1 (Day 0), 2) Session 2 (Day 7), 3) Session 3 (Day 14), 4) Session 4 (Day 21), 5) Session 5 (Day 90), 6) Session 6 (Day 180), 7) Session 7 (Day 270), Session 8 (Day 365) (8 x $25 = $200). Participants who complete all research visits will receive a $100 completion bonus. Thus, subjects who complete all the study visits will receive a total of $350.You may need to provide your social security number to receive payment. This payment is to help cover any expenses you may incur in the course of your participation, such as costs of transportation, internet connectivity, and telephone calls to our offices. Payment will be made by check. You should receive your check 4 to 8 weeks after the completion of the study.

Costs

There will be no costs to you for any of the treatment or testing done as part of this research study. However, 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.

Sponsor

The Department of Veterans Affairs is providing financial support for this study.

COMPENSATION for Research Related Injury

If you are injured as a direct result of being in this study, medical treatment will be available. If you are eligible for veteran's benefits, the cost of such treatment will be covered by the VA. If not, the cost of such treatments may still be covered by the VA depending on a number of factors. In most circumstances, the treatment must be provided in a VA medical facility. No other form of compensation for injuries is available. However, by signing this form you have not released the VA from liability for negligence. For further information, you may call the Human Protections Administrator at (650) 493-5000, ext. 67593 or the V.A. Regional Counsel at (415) 750-2288.

CONTACT INFORMATION

Questions, Concerns, or Complaints: If you have any questions, concerns or complaints about this research study, its procedures, risks and benefits, or alternative courses of treatment, you should ask Dr. Lisa Kinoshita at 650-493-5000 extension 60482. You should also contact Dr. Kinoshita or any member of the research staff at any time if you feel you have been hurt by being a part of this study.

Appointment Contact: If you need to change your appointment, please contact the study staff at 650-493-5000 extension 60482.

Independent Contact: If you are not satisfied with how this study is being conducted, or if you have any concerns, complaints, or general questions about the research or your rights as a participant, please contact the Stanford Institutional Review Board (IRB) to speak to someone independent of the research team at (650)-723-5244 or toll free at 1-866-680-2906. You can also write to the Stanford IRB, Stanford University, 1705 El Camino Real, Palo Alto, CA 94306.

EXPERIMENTAL PARTICIPANT'S BILL OF RIGHTS

As a research participant you have the following rights. These rights include but are not limited to the participant's right to:

- be informed of the nature and purpose of the experiment;
- be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized;
- be given a description of any attendant discomforts and risks reasonably to be expected;
- be given an explanation of any benefits to the subject reasonably to be expected, if applicable;
- be given a disclosure of any appropriate alternatives, drugs or devices that might be advantageous to the subject, their relative risks and benefits;
- be informed of the avenues of medical treatment, if any available to the subject after the experiment if complications should arise;

- be given an opportunity to ask questions concerning the experiment or the procedures involved;
- be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation without prejudice;
- be given a copy of the signed and dated consent form; and
- be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion or undue influence on the subject's decision.

May we contact you (by phone or letter) about related studies that may be of interest to you?

_____ Yes. I would like to be contacted for future research opportunities.

_____ No. Do not contact me about future research opportunities.

Signing your name means you agree to be in this study and that you were given a copy of this consent form.

Signature of Participant Date

Print Name of Participant Date

Person Obtaining Consent:

Signature of Person Obtaining Consent Date

Print Name of Person Obtaining Consent

☐ Confirm the participant signed the VA HIPAA Authorization (VA 10-0493)