Official title: Napping, Sleep, Cognitive Decline and Risk of Alzheimer's Disease

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UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Study Title: Napping, Sleep, Cognitive Decline and Risk of Alzheimer's Disease

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Study Coordinator:	Bernard Landavazo, MA. e-mail: bernard.landavazo@ucsf.edu.

This is a research study about sleep improvement for older adults with insomnia and mild memory loss. My name is _____, and I am a member of the research team. I will explain the study to you and answer your questions

STUDY SUMMARY

Introduction: We are asking you to consider taking part in a research study being done by Dr. Yue Leng at UCSF.

Purpose of the Study: The purpose of the study is to find out whether it is feasible to use an app-based therapeutic program with a smartphone or tablet to help improve sleep in participants with mild memory loss and sleep problems.

You are being asked to take part in this study because you are at least 65 years of age and expressed interest in the Sleep TIGHT (Sleep Therapeutics Intervention to improve coGnitive HealTh) Study.

Study Procedures: If you choose to be in this study, you will:

- Be assigned at random to one of two groups.
- One group will participate in the app-based sleep therapeutic (Somryst) program for 1-2 hours a week, for 6-9 weeks while the other group participants in app-based information sessions about sleep health.
- Both groups will answer questions about their physical and emotional well-being at the beginning, middle, and end of the study.

Prior to training group participation, you will need to connect via telehealth or visit the research site for a screening visit to ensure you are eligible to participate.

Possible Risks

There are risks to taking part in a research study. Some of the most likely risks of participation in this study include:

- Risk of fatigue; daytime sleepiness as a result of the psychotherapy
- Risk of distress; some of the materials in the questionnaires may be upsetting or make you uncomfortable
- Unknown risks

Possible Benefits: You may benefit from participating in this research study, but this cannot be guaranteed.

Your Other Options: You do not have to participate in this research study. Your other options may include:

- Getting treatment or care for your condition without being in a study
- Taking part in another study.
- Getting no treatment.

Following is a more complete description of this study. Please read this description carefully. You can ask any questions you want to help you decide whether to join the study. If you join this study, we will give you a signed copy of this form to keep for future reference.

DETAILED STUDY INFORMATION

This part of the consent form gives you more detailed information about what the study involves.

Why is this study being done?

The purpose of this study is to learn about the use of a simple psychological sleep therapy, called cognitive behavioral therapy for insomnia (CBT-I), in older adults with mild memory loss and sleep problems, and to explore the benefits of this therapy on sleep and cognition in this population. This study is funded by the National Institute of Health.

Research studies include only people who choose to take part. Please take your time to make your decision about participating, and discuss your decision with your family or friends if you wish. If you have any questions, you may ask the researchers.

How many people will take part in this study?

About *40* people will take part in this study.

Study Procedures

If you agree, the following procedures will occur:

First, you will need to have the following "screening" tests or procedures to find out if you can participate in the main part of the study:

- You will be given a few questionnaires over a teleconference via zoom to report your personal and medical information as well as your sleep problems and any current cognitive difficulties you may be experiencing. It should take about 45-60 minutes to complete these questionnaires.

If the screening exam shows that you can be in the main part of the study and you choose to continue, this is what will happen next:

- You will be given a watch-like device via mail, called actiwatch, to wear on your wrist for 3 consecutive 24-h periods for determining your sleep-wake patterns. The device should be easy to use and won't interfere with your daily routine activities.
- The researcher will explain fully to you how to use the device and will be available to answer any questions you might have. You will be provided with stamped packages to mail back the devices after completion of the measurement.
- You will fill out questionnaires by video-conference to assess your sleep habits and quality of life. We will also conduct a short test of memory and thinking on you via video-conference. It should take about 45-60 minutes to complete this video-conference session of initial tests.
- You will be "randomized" into one of the study groups described below. Randomization means that you are put into a group by chance. A computer program will place you in one of the groups. Neither you nor your doctor can choose the group you will be in. You will have an equal chance of being placed in any group.

- **If you are in group 1:** You will be asked to participate in weekly online, app-based therapeutic sessions with a smartphone or tablet to help improve your sleep. Somryst delivers digital therapeutic content, and can be used on a mobile device, such as a smartphone or tablet.
- During each session, you will engage with the Somryst app (for about 30 minutes) and make daily entries into a sleep diary. The therapeutic content of the app is structured to help change your unhelpful thoughts and teach you skills to improve sleep. In total, you will spend about 1-2 hours each week to complete the session and sleep diary entry.You will have access to the program for 9 weeks.
- **If you are in group 2:** You will be asked to participate in online, app- based interactive sessions to help improve your sleep. The conversation will still provide engaging sleep education but will be unstructured and will only include inactive components of the therapeutic treatment (placebo). You will be referred for standard of care as usual after the study ends.

- Right after the last app-based session, you will be asked to report your satisfaction and acceptability of the treatment. You will also be asked to complete the same questionnaires and tests that you have done as part of your initial video-conference with UCSF research contacts. Furthermore, you will be given the same actiwatch that you are given at the beginning of the study to take home, complete and mail back.
- After 6 months without treatment following the last therapy session, you will be invited back to interview via Zoom teleconference with the researcher and to complete again the questionnaires and tests (about 45-60 minutes) and actiwatch to complete at home and mail back.

Study location: All of these procedures will be done remotely from your place of residence; instructions for using the Somryst therapeutic application and actiwatch will be given over teleconference with research contacts. No in-person contact will occur as part of the study.

How long will I be in the study?

You will be asked to take part in an online therapeutic session every week for nine weeks, followed by a 6-month follow-up without treatment, irrespective of the group you are put into.

Can I stop being in the study?

Yes. You can decide to stop at any time. Just tell the study researcher or staff person right away if you wish to stop being in the study.

Also, the study researcher may stop you from taking part in this study at any time if he or she believes it is in your best interest, if you do not follow the study rules, or if the study is stopped.

What side effects or risks can I expect from being in the study?

- You might experience transient daytime sleepiness as a result of the psychotherapy, but you will be given guidelines on naps to help minimize the problem of sleepiness.
- Some of the materials in the questionnaires may make you uncomfortable or upset, but you are free to decline to answer any questions you do not wish to answer.
- For more information about risks and side effects, please ask one of the researchers.

Are there benefits to taking part in the study?

- You will receive comprehensive assessment of 24-h patterns of sleep and cognition at no cost.
- If you fail screening due to confounding sleep disorders, you will be provided the summary of the results and referral to a sleep disorders center for further investigation or treatment.
- At the end of the treatment phase, you will receive feedback regarding your sleep, cognition, change in clinical status, and suggestions for further intervention if necessary.
- You may increase your knowledge about sleep and ways to improve sleep for people living with memory loss.
- You may feel that you are helping others by contributing to knowledge about memory loss and sleep.
- In addition, the information that you provide may help health professionals better understand/learn more about sleep and cognition.
- We cannot guarantee that you will experience any benefits.

What other choices do I have if I do not take part in this study?

- Your other choices may include taking psychotherapy for sleep that are not part of a research study, taking part in a different research study, or not taking any sleep treatment.

- If you decide not to take part in this study, there will be no penalty to you. You will not lose any of your regular benefits.

How will my information be used?

Researchers will use your information to conduct this study. Once the study is done using your information, we may share them with other researchers so they can use them for other studies in the future. We will not share your name or any other personal information that would let the researchers know who you are. We will not ask you for additional permission to share this de-identified information.

Research results: There may be times when researchers using your information may learn new information. The researchers may or may not share these results with you, depending on a number of factors.

Will information about me be kept private?

We will do our best to make sure that the personal information gathered for this study is kept private. However, we cannot guarantee total privacy.

Your personal information may be given out if required by law. We are legally and ethically required to report certain events to appropriate authorities such as thoughts of suicide or homicide, or suspicions of abuse.

If information from this study is published or presented at scientific meetings, your name and other personal information will not be used without your permission.

Authorized representatives from the following organizations may review your research data for the purpose of monitoring or managing the conduct of this study:

- Representatives of the National Institutes of Health
- Representatives of the University of California

Certificate of Confidentiality

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that:

- Researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection

includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

- There are some important things that you need to know: The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.
- Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

Are there any costs to me for taking part in this study?

You will not be charged for any of the study treatments or procedures.

Will I be paid for taking part in this study?

You will not be paid for the study; however, you will receive FDA-approved therapy or comprehensive sleep information at no cost depending on your random group assignment.

What happens if I am injured because I took part in this study?

It is important that you tell the UCSF Principal Investigator, Dr. Yue Leng, if you feel that you have been injured because of taking part in this study. You can tell the doctor in person or call her at 4152214810 X 26565.

Treatment and Compensation for Injury: If you are injured as a result of being in this study, the University of California will provide necessary medical treatment. The costs of the treatment may be billed to you or your insurer just like any other medical costs, or covered by the University of California, depending on a number of factors. The University and the study sponsor do not normally provide any other form of compensation for injury. For further information about this, you may call the office of the Institutional Review Board at 415- 476-1814.

What are my rights if I take part in this study?

- Taking part in this study is your choice.
- You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time.
- No matter what decision you make, there will be no penalty to you in any way.
- You will not lose any of your regular benefits, and you can still get your care from our institution the way you usually do.

Who can answer my questions about the study?

You can talk to the researcher(s) about any questions, concerns, or complaints you have about this study. Mr. Landavazo and Dr. Leng may be contacted at 4152214810X 26565.

If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers or if you wish to voice any problems or concerns you may have about the study, please call the Institutional Review Board at 415-476-1814.

CONSENT

- You have been given copies of this consent form and the Experimental Subject's Bill of Rights to keep.
- You will be asked to sign a separate form authorizing access, use, creation, or disclosure of health information about you.

PARTICIPATION IN RESEARCH IS VOLUNTARY. You have the right to decline to be in this study, or to withdraw from it at any point without penalty or loss of benefits to which you are otherwise entitled.

If you wish to participate in this study, you should sign or type your name below.

_____	_____
Date	Participant's Signature for Consent
_____	_____
Date	Person Obtaining Consent