Sleep Disturbance and Emotion Regulation Brain Dysfunction as Mechanisms of Neuropsychiatric Symptoms in Alzheimer's Dementia

Informed Consent Form

NCT04100057

August 5, 2025

Looking to Understand Neuropsychiatric Symptoms in Alzheimer's Disease (L.U.N.A. Study)

Study Partner Consent Form

Summary of Key Points:

- Your consent is being sought for participation in a research study
- Participation in this study is voluntary and you and the participant are free to withdraw at any time. You have the right to refuse to answer any particular question.
- The purpose of this study is to study on how sleep disruption and brain circuits relate to neuropsychiatric symptoms in those with mild cognitive impairment and mild Alzheimer's dementia. The study is being conducted only for the purposes of research.
- If completing the entire study, your total involvement will involve assisting the participant with up to 14 visits over nine months:
    - Screening session: one two-part session (30 minutes each)
    - Baseline session: one questionnaire (5-10 minutes)
    - Therapy: six sessions over eight weeks (if preferred by the participant)
    - End of Therapy Session: two questionnaires (5-10 minutes each)
    - Six-Month follow up Session: two questionnaires (5-10 minutes each)
- You will accompany the participant in-person or be available to complete required measures via phone or Stanford Zoom during the Screening Visit, Baseline Visit, End of Therapy Visit, and Six-Month follow up visit at a minimum and provide information about his/her daily functioning.
- You have the option to complete questionnaires about your sleep, mood, and quality of life in addition to your participation with the participant.
- The participant will be randomized into one of two therapies. Both groups will meet with a therapist for six sessions.
- CBT-I targets behaviors and cognitions that sustain or add to patients' sleep problems.
- DT-I targets anxiety provoking associations that are activated when patients are trying to sleep and interfere with the sleep onset process.
- If you choose to not participate in this study, you and/or the participant have the right to seek insomnia therapy from your physician.
- There is no alternative for participating in this study.
- There are no foreseeable risks or benefits for your involvement in the study.
- You will receive compensation for your involvement in the study.

For Questions about the Study, Contact:

Dr. Goldstein-Piekarski or a member of her staff can be reached at (650) 721-4780.

Description

You are invited to participate in a research study on how sleep and brain circuits relate to neuropsychiatric symptoms including anxiety, depression, agitation, irritability, and apathy. We hope to learn whether improving sleep will also improve brain function and reduce neuropsychiatric symptoms in those with or at high risk for developing Alzheimer's disease. Researchers expect to enroll 150 participants, all of whom have signs of mild cognitive impairment (MCI) or mild Alzheimer's dementia who are experiencing sleep disturbances. MCI means that a person's memory is impaired, but their overall thinking is not as impaired as it is with Alzheimer's disease dementia. You were selected as a possible participant because you know the participant _____ and you have agreed to participate as his/her study partner.

As the participant's study partner, you have important tasks that need to be carried out for the study to be conducted in the safest and best manner possible. These responsibilities include:

- You must be willing and available to accompany the participant or be available to complete required measures via phone or Stanford Zoom during the Screening Visit, Baseline Visit, End of Therapy Visit, and Six-Month follow up visit at a minimum.

- You also agree to answer questions by phone or via Stanford Zoom if you do not accompany the participant to study visits.
    - **Audio/Video Recording**: We will make an audio recording of each assessment session, which will be evaluated by a research psychologist for quality control. All audio/video recordings will be kept on a secure Stanford server or in a locked cabinet for the required period of six years after study closure, then destroyed.

    _____ Yes, I give permission for audio/video recordings to be made, as set forth above.
    _____ No, I do not give permission for audio/video recordings to be made.

- You are an important source of information about the participant. You will be asked questions to find out whether there are any changes in the participant's functioning or health.

In addition to aiding the participant with their study visits, you have the option to participate in questionnaires about your mood, sleep and quality of life. You would have the option to complete two brief questionnaires regarding the COVID-19 Pandemic and related shelter-in-place restrictions. These questionnaires would ask you about your experience, thoughts, and feelings about the Pandemic.

Time Involvement

Each of the Screening, Baseline, and the End of Therapy Visits will take approximately 1 to 2 hours of your time, depending on the clinical interviews and questionnaires scheduled for the visit. Your

active participation at each visit will last around 0.5-1.5 hours; however, you may need to be close by for the in-person sessions if you are commuting with the participant. Also, because of your role as an important source of information about the participant, you will need be in contact with the participant by phone or in person at least twice a week during the weeks in between the Baseline Visit and End of Therapy Visit.

The total duration you would be involved in this study is approximately nine months.

Risks and Benefits

There are no foreseeable risks or benefits to you for participation in this study, other than the possible inconvenience of attending interview sessions**.** By participating in this study and interacting with new physical locations and individuals, there is an increased risk of COVID-19 infection. However, it is possible contract COVID-19 unrelated to in-person visit at Stanford.

Risk of COVID-19
The research staff has implemented precautions to reduce the risk of COVID-19 infection, including:

1. COVID-19 screening call: The night prior and the day of the in-person study visit, a member of the research staff may call you to ask a series of questions or ask you to fill out an online questionnaire regarding COVID-19 symptoms and indicators of risk to determine if you are cleared for an in-person study visit.

2. Vaccination Requirements: The research staff have all been fully vaccinated and received their booster shots. When coming in-person to research visits, you are required to be fully vaccinated—2 doses (1 for Johnson and Johnson), 2 weeks out. You are also required to be willing to provide additional proof of your vaccination (e.g., CDC COVID-19 Vaccination Card, e-Health record, etc.) to the researcher, if asked, prior to study participation.

3. Social Distancing: Research staff and participants will practice social distancing (> six feet of separation) from individuals not in their household when possible.

4. Temperature Screening: All research staff and participants will be screened with a contactless thermometer for fever upon entry to CNI. Any temperature over 100-degrees Fahrenheit is a contraindication for proceeding with the research study.

5. Face Coverings: Research staff and participants will receive procedural masks on entry to CNI and they must be worn at all times.

6. Redundant Disinfection Protocols: All equipment, including the MRI system and scan accessories at CNI receive thorough cleaning twice between each study using cleaning/disinfection supplies approved by the Environmental Protection Agency (EPA) for reducing risk of infection. This is completed once at the end of a scan, and again prior to starting a new scan. Commonly touched surfaces (door handles, faucets, counters, restrooms) also receive frequent cleaning.

7. Hand Sanitation: Research staff and participants are encouraged to practice good hand hygiene – washing their hands with soap and water or using the available hand sanitizer and to not touch their eyes, nose or mouth with unwashed hands.

These precautions are deemed to significantly reduce the risk of infection, but it is important to recognize that by increasing your contact with other individuals and physical locations, your level of risk of COVID-19 infection does increase.

It is important that you disclose to the research staff any indication of having been exposed to COVID-19, or whether you have experienced any signs or symptoms associated with COVID-19 disease.

Please select an option and initial below.

_____ Yes, I understand that by participating in this study and interacting with new physical locations and individuals that I am increasing my risk of COVID-19 infection. I also acknowledge that I could contract COVID-19 unrelated to my in-person visit at Stanford.
_____ No, I would not like to participate in this study due to the possible increased risk of COVID-19 infection.

Payment/Reimbursement

You will receive a total of $50 for your involvement in the study. You will receive $35 after the end of therapy and an additional $15 after the 6-month follow up visit.

This payment is to help cover any expenses you may incur in the course of your participation, such as costs of transportation and telephone calls to our offices, and for your completion of questionnaires.

Payments may only be made to U.S. citizens, legal resident aliens, and those who have a work eligible visa. You may need to provide your social security number to receive payment.

Participant's Rights

If you have read this form and have decided to participate in this project, please understand your

participation is voluntary and you have the right to withdraw your consent or discontinue participation at any time without penalty. You have the right to refuse to answer particular questions. Your individual privacy will be maintained in all published and written data resulting from the study.
You have read all the preceding information which describes both the subject's participation in the study and your involvement as the subject's study partner. The study has been explained to you in detail. All your questions have been answered to your satisfaction. You voluntarily consent to participate in this study.

CONFIDENTIALITY

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed except as authorized by you or as required by law**.** However, there is always some risk that even de-identified information might be re-identified.

Patient information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or specimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or specimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical therapy; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by National Institutes of Health which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of child or elder abuse and neglect, or harm to self or others.

FUTURE USE OF PRIVATE INFORMATION

National Data Archive:

Data from this study will be submitted to the National Institute of Mental Health Data Archive (NDA) at the National Institutes of Health (NIH). NDA is a large database where coded study data from many NIH studies are stored and managed. Sharing your coded study data helps researchers learn new and important things about brain science more quickly than before.

Coded study data means that all personal information about you (such as name, address, birthdate and phone number) is removed and replaced with a code number. The study researchers will have to collect your personal information from you in order to make that code number. The code number cannot be used to identify you. The study researchers will never send your personal information to NDA.

It is possible that you will participate in more than one study that sends data to NDA. NDA can connect your data from different studies by matching the code number from each study. This data matching helps researchers who use NDA data to count you only one time. It also helps researchers who use NDA to better understand your health and behavior without knowing who you are.

During and after the study, the study researchers will share coded study data about your health and behavior to the NDA. Other researchers across the world can then request your coded study data for different research projects. Every researcher (and the institution to which they belong) who requests your coded study data must promise to keep your data safe and promise not to try to learn your identity. Experts at the NIH who know how to keep your data safe will review each request carefully to reduce risks to your privacy. Sharing your study data does have some risks, although these risks are rare. Your study data could be accidentally shared with an unauthorized person who may attempt to learn your identity. The study researchers will make every attempt to protect your identity.

You may not benefit directly from allowing your study data to be shared with NDA. The study data provided to NDA may help researchers around the world learn more about brain science and how to help others who have problems with brain science.
NIMH will also report to Congress and on its website about the different studies using NDA data. You will not be contacted directly about the study data you contributed to NDA.

You may decide now or later that you do not want your study data to be added to NDA. You can still participate in this research study even if you decide that you do not want your data to be added to NDA. If you know now that you do not want your data in

NDA, please tell the study researcher before leaving today. If you decide any time after today that you do not want your data to be added to NDA, call or email the study staff who conducted this study, and they will tell NDA to stop sharing your study data. Once your data is part of NDA, the study researchers cannot take back the study data that was shared before they were notified that you changed your mind. If you would like more information about NDA, it is available on-line at http://nda.nih.gov.

_____ Yes, I give permission for my de-identified data to be shared with the NDA

_____ No, I do not give permission for my de-identified data to be shared with the NDA

Authorization To Use Your Health Information For Research Purposes

Because information about you and your health is personal and private, it generally cannot be used in this research study without your written authorization. If you sign this form, it will provide that authorization. The form is intended to inform you about how your health information will be used or disclosed in the study. Your information will only be used in accordance with this authorization form and the informed consent form and as required or allowed by law. Please read it carefully before signing it.

What is the purpose of this research study and how will my health information be utilized in the study?

This research study of on how sleep and brain circuits relate to neuropsychiatric symptoms including anxiety, depression, agitation, irritability, and apathy. We will compare two therapies for insomnia and we hope to learn how each therapy effects the brain circuits involved in sleep and neuropsychiatric symptoms. Your information will primarily be used to help us contact you in order to obtain information about the research participant to help determine how sleep and brain circuits relate to neuropsychiatric symptoms.

Do I have to sign this authorization form?

You do not have to sign this authorization form. But if you do not, you will not be able to participate in this research study.
Signing the form is not a condition for receiving any medical care outside the study.

If I sign, can I revoke it or withdraw from the research later?

If you decide to participate, you are free to withdraw your authorization regarding the use and disclosure of your health information (and to discontinue any other participation in the study) at any time. After any revocation, your health information will no longer be used or disclosed in the study, except to the extent that the law allows us to continue using your information (e.g., necessary to maintain integrity of research). If you wish to revoke your

authorization for the research use or disclosure of your health information in this study, you must write to: Dr. Goldstein-Piekarski at 401 Quarry Rd, Palo Alto, CA 94305.

What Personal Information Will Be Obtained, Used or Disclosed?

Your health information related to this study, may be used or disclosed in connection with this research study, including, but not limited to: full legal name, date of birth, place of birth, telephone number, mailing and emailing address, age, and Proof of Vaccination status (e.g. CDC COVID-19 Vaccination Card, e-Health record, etc.) if asked; social security number (if required for payment), information about your sleep, mood and behavior; Video/Audio recordings of study assessments; Vehicle identifiers, including license plate numbers, and certificate/license numbers may be obtained for purposes regarding parking and transport around the Stanford, and will be requested in special circumstances, as described in following. Parking is heavily regulated on the Stanford campus. In rare events, parking permits that are assigned to participants have been incidentally misplaced causing the issuance of parking violation tickets. Vehicle identifiers, license plates, and certificate/license numbers are obtained for the purposes of resolving these parking-related issues when these occur.

Who May Use or Disclose the Information?

The following parties are authorized to use and/or disclose your health information in connection with this research study:

- The Protocol Director Dr. Andrea Goldstein-Piekarski
- The Stanford University Administrative Panel on Human Subjects in Medical Research and any other unit of Stanford University as necessary
- Research Staff

Who May Receive or Use the Information?

The parties listed in the preceding paragraph may disclose your health information to the following persons and organizations for their use in connection with this research study:

- The Office for Human Research Protections in the U.S. Department of Health and Human Services
- The National Institute of Health
- The Food and Drug Administration

Your information may be re-disclosed by the recipients described above, if they are not required by law to protect the privacy of the information.

When will my authorization expire?
Your authorization for the use and/or disclosure of your health information will end on December 31, 2045 or when the research project ends, whichever is earlier.

Will access to my medical record be limited during the study?
To maintain the integrity of this research study, you may not have access to any health information developed as part of this study until it is completed. At that point, you would have access to such health information if it was used to make a medical or billing decision about you (e.g., if included in your official medical record).

_____ _____
Signature of Adult Study Partner Date

_____
Print Name of Adult Study Partner

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 therapy, you should ask the Protocol Director, Andrea Goldstein-Piekarski. You may contact her now or later at (650) 721-4780.

Appointment Contact: If you need to change your appointment, please contact the LUNA Study Staff at lunastudy@stanford.edu or at 650-721-6089.

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.

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, please do not contact me about future research opportunities.

Would you like to participate in optional surveys about your sleep, mood, and quality of life?

_____ Yes, I want to complete optional questionnaires.
_____ No, I do not want to complete optional questionnaires.

Signing your name means you agree to be the participant' study partner in this study. You will receive a copy of this signed and dated consent form.

You have read all the preceding information which describes both the subject's participation in the study and your involvement as the subject's study partner. The study has been explained to you in detail. All your questions have been answered to your satisfaction.

Do you voluntarily consent to participate in this study?

_____

Signature of Adult Participant Date

_____

Print Name of Adult Participant

Signature of Person Obtaining Consent

_____

Signature of Person Obtaining Consent Date

_____

Print Name of Person Obtaining Consent