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Is it possible to assess sleep interventions aimed at improving sleep quality and daytime function in people with mild dementia?

Submission date
05/05/2026

Recruitment status
Recruiting

Registration date
13/05/2026

Overall study status
Ongoing

Last Edited
13/05/2026

Condition category
Nervous System Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
In this study, we will evaluate the feasibility of two at-home sleep interventions in people with prodromal or mild to moderate Alzheimer's: a daytime nap intervention and a positional therapy device intervention to improve breathing during sleep.
We will explore the impact of daytime napping on daily cognitive function and sleep quality using a range of questionnaires and sleep monitoring devices. Scheduled, short daytime naps may improve how people feel during the day but could also have a negative influence on sleep at night. Currently it is not known whether it is better to take a nap in the morning or in the afternoon.
We will also explore the feasibility of using the positional therapy device to improve breathing during for people with an intermediate-high risk of sleep apnoea, in addition to prodromal or mild to moderate Alzheimer's. The positional therapy device is thought to reduce symptoms of sleep apnoea.

Who can participate?
Adults (aged 50-90 years) with a confirmed diagnosis of prodromal or mild-moderate Alzheimer's disease.

What does the study involve?
Each intervention has three conditions, and each condition will be implemented for 1 week. Participants who are eligible will be able to do one or both of the interventions; involvement, therefore, lasts 3-6 weeks. Partners of participants will also be invited to join the study and provide information about their partner, as well as support them throughout the study. Participants will undergo a screening visit to determine if they are eligible to take part in the study. This will include questionnaires and clinical assessments. Eligible participants will be provided with a range of devices to be used at home for the duration of the intervention/s to monitor their sleep and circadian rhythms. Participants will also be asked to complete daily questionnaires at three points in the day. If participants' partners are enrolled in the study, they will also be provided questionnaires to complete about their partner.

What are the possible benefits and risks of participating?
This research may lead to the development of new approaches to improve sleep and brain function.

Where is the study run from?
Screening visits will take place at Surrey and Borders Partnership in Chertsey (UK). Training to use the devices in the study and the device set-up will take place in participants' homes.

When is the study starting and how long is it expected to run for?
May 2026 to August 2027

Who is funding the study?
The Dementia Research Institute (UK)

Who is the main contact?
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Additional identifiers

Integrated Research Application System (IRAS)
359038

Central Portfolio Management System (CPMS)
69736

Study information

Scientific Title
Feasibility study to investigate the effect of sleep interventions on sleep quality and daytime function in people living with prodromal or mild to moderate Alzheimer’s disease

Study objectives
Primary objective:
Assess the feasibility of the proposed nap and positional therapy interventions.

Secondary objectives:
Impact of scheduled or no naps on daytime mood, symptoms and cognitive function, and nocturnal sleep continuity, duration, and quality in PLWAD.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 01/12/2025, London-Fulham Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 104 8000; fulham.rec@hra.nhs.uk), ref: 25/LO/0780

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control

Dose comparison

Assignment
Crossover

Purpose
Feasibility of sleep interventions

Study type(s)

Health condition(s) or problem(s) studied
Adults (aged 50 - 90 years) with a confirmed diagnosis of prodromal or mild-to-moderate Alzheimer's disease

Interventions
Participants are allocated to intervention types based on interest and eligibility (non-random). Participants may be eligible only for one intervention or for both. For participants undergoing both interventions, the order of interventions is randomised in a 1:1 ratio. Each intervention has three conditions, and the order of the conditions within an intervention is determined using stratified block randomisation. To ensure an even distribution and control for order effects, participants are assigned to predefined sequences of the three conditions within an intervention (e.g., ABC, BCA, CAB). Randomisation is performed in blocks of 3 for each intervention. The randomisation sequences were produced using a computer-generated algorithm in R.

Positional therapy:
1. 7 days with no device - baseline
2. 7 days with active intervention – positional therapy device
3. 7 days with sham intervention – positional therapy device non-functioning
The order of the active and sham intervention will be randomised. The device to be used will be the Nightshift Sleep Positioner device or BUZZPod and these devices will be worn around the chest each night.
Active condition: if the wearer moves onto their back, the device will gently vibrate and gradually increase in intensity until the user changes position.
Sham condition: no vibrations when user changes position

Nap:
1. Morning nap condition: 7 days of a 30-minute nap scheduled between 10:00 AM and 11:00 AM
2. Afternoon nap condition: 7 days of a 30-minute nap scheduled between 3:00 PM and 4:00 PM
3. No napping condition: 7 days where participants avoid napping during the day
Participants will be provided with a white noise machine that they may choose to use during their naps.
The order of the interventions will be randomised.

Intervention Type
Mixed

Primary outcome(s)
1. Recruitment rate measured using the number of eligible patients who consent to participate in the study at 18 months

2. Completion rate measured using the number of patients who complete the study at 18 months

3. Data completeness measured using percentage of required data present in dataset at end of study

4. Acceptability of devices and interventions measured using the Device Acceptability Questionnaire scores at end of study

Key secondary outcome(s)

Completion date
31/08/2027

Eligibility

Key inclusion criteria
People living with Alzheimer's disease (PLWAD):
1. Male or female aged 50 – 90 years at baseline
2. Have a confirmed diagnosis of prodromal or mild to moderate Alzheimer's disease confirmed by the Surrey and Borders Partnership (SABP) team
3. Have a Standardized Mini-Mental State Examination (SMMSE) score of 15 - 25
4. Be willing and able to give written and oral informed consent
5. Be willing and able to complete all required study procedures, on the judgement of the investigator team
6. Be willing to reside in one place (i.e., home) for the intervention period
7. Have sufficient functional English to allow completion of the assessment instruments
8. If taking hypnotics, or any other medication to support sleep, e.g., psychotropic medications, must have been on a stable dose for 3 months prior to being recruited with no anticipation of changing the dose during the study
9. Be registered with a GP
10. Living in the community
11. If on anti-dementia medication (cholinesterase inhibitors and/or memantine), then must have been on a stable dose for three months prior to being recruited with no anticipation of changing the dose during the study

Nap study only:
1. Must be a habitual daytime napper – taking a daytime nap on the majority of days

Positional therapy intervention only:
1. Have a score of intermediate or high risk of sleep apnoea on the STOP-BANG questionnaire

Study partner (optional – if the PLWAD has a study partner living with them, they will be invited to participate):
1. Male and female aged 18 years or over
2. Single nominated study partner (relative/friend/caregiver) who has known and lives with the PLWAD for at least 6 months and is able to support them with their study participation
3. Have no cognitive impairment, confirmed with an sMMSE score of 27 or greater

Healthy volunteers allowed
Yes

Age group
Mixed

Lower age limit
50 Years

Upper age limit
90 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
PLWAD:
1. A medical condition which is disabling, i.e., prevents the participant from being active, going outside, or being able to perform daily activities, in the judgement of the investigator team
2. A medical condition which requires frequent visits from a healthcare professional or visits to a GP surgery or hospital, which may interfere with study conduct in the judgement of the investigator team
3. A medical condition which is unstable and may interfere with study conduct in the judgement of the investigator team
4. A medical condition which requires a treatment which is not compatible with the protocol, e. g., continuous positive airway pressure (CPAP) treatment, in the judgement of the investigator team
5. A medical condition which would make it unsafe to participate in the research, e.g., poorly controlled diabetes, epilepsy, heart disease, or any other condition in the judgement of the investigator team
6. Alcohol intake exceeds 14 units per week
7. Receipt of any investigational drug within 90 days prior to consenting
8. People with unstable mental states, including severe depression, severe psychosis, agitation, and anxiety, whose medication was changed over the last 4 weeks prior to screening as assessed by the principal investigator (PI)
9. People with severe sensory impairment (severe hearing or visual loss that is not correctable with hearing aids or glasses)
10. Currently have active suicidal ideas as assessed by the SABP team at screening
11. People who require regular elective hospital admission for their physical health monitoring
12. People who are receiving treatment for terminal illness

Date of first enrolment
01/05/2026

Date of final enrolment
06/08/2027

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Surrey and Borders Partnership NHS Foundation Trust
Abraham Cowley Unit, St Peter's Hospital, Holloway Hill
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KT16 0AE

Sponsor information

Organisation
University of Surrey

ROR
https://ror.org/00ks66431

Funder(s)

Funder type

Funder Name
UK Dementia Research Institute

Alternative Name(s)
UK DRI Ltd, UK DRI

Funding Body Type
Private sector organisation

Funding Body Subtype
Research institutes and centers

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available