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Use of contactless sleep technology for measuring sleep in people living with dementia and mild cognitive impairment

Submission date
12/09/2025

Recruitment status
Recruiting

Registration date
08/10/2025

Overall study status
Ongoing

Last Edited
20/01/2026

Condition category
Mental and Behavioural Disorders

[X] 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
Sleep problems are common in people living with dementia and mild cognitive impairment (MCI); this can affect their health and wellbeing, and that of the people who care for them. Sleep problems can be difficult to manage in general practice, and GPs often rely on carers to notice and report issues with a person's sleep.
However, sometimes carers may not notice any sleep problems, especially if they are busy or do not live with the person with dementia or MCI. This could make personalised care plans to help improve sleep less effective because they rely on carers identifying and reporting sleep problems.
To help with this, we want to study the use of a bedside sleep tracker device to measure sleep in people living with dementia and MCI. Our aim is to see if this is a practical way to understand sleep in dementia and MCI. We also want to find out the thoughts of carers on using this device, and understand what GPs think of the sleep information collected using this technology.

Who can participate?
People aged 18 years old and over living with dementia or mild cognitive impairment who have a paid or unpaid carer.

What does the study involve?
The SleepXacT study is a single-arm feasibility trial. This means that all participants will have their sleep measured at their home or care home using the bedside sleep tracker device, and they (and their carer) will meet with their GP to set up a personalised care-plan to help improve their sleep. To learn more about the sleep care-plan or intervention, please visit https://www.isrctn.com/ISRCTN54015716.
The study runs for 15 weeks. During this time, participants will be asked to complete some questionnaires about their sleep, health, and well-being. This will happen at the start of the study, and again at 9 weeks and 15 weeks, and should take about twenty-five minutes each time. A family member, friend, or carer will help with this.
Participants will also have their sleep measured using the bedside sleep tracker device for 3 to 7 days. This will happen at the start of the study, and again at 9 weeks and 15 weeks. A family

member, friend, or carer will help with this.
The family member, friend or carer will be asked to share their thoughts of helping to set up and use the sleep tracker during a short interview (lasting 30 to 60 minutes, over the phone or in person).
Participants, along with their family member, friend or carer, will also be invited to meet with their GP twice to talk about their sleep (1st appointment, 30 minutes; 2nd appointment, 15 minutes). During these consultations, the participant's sleep problems will be discussed, and a care-plan will be set up to help improve their sleep.

What are the possible benefits and risks of participating?
Taking part in the study may or may not have direct benefits for the participants, but their involvement could help improve how poor sleep in dementia and MCI are understood and treated in the future.
Taking part in the study carries minimal risks, such as possible emotional distress when discussing health concerns and changes to sleep, but the study team will be there to help if needed.
A trained professional will support the consent process for this study. They will assess whether each potential participant can give informed consent about taking part. If someone isn't able to make that decision for themselves, the professional will ask a consultee (someone who knows the potential participant well) to share what they think the potential participant would want. If any information shared during the study raises concerns about the safety of the participant or others, this will be passed on to their GP.

Where is the study run from?
The study is run from the University of East Anglia, with the University of Exeter as the Sponsor (UK)

When is the study starting and how long is it expected to run for?
November 2024 to September 2026

Who is funding the study?
The National Institute for Health and Care Research (reference: NIHR206949)

Who is the main contact?
Dr Bindiya Shenoy, University of East Anglia, sleepxact@uea.ac.uk

Contact information

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Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
333820

ClinicalTrials.gov (NCT)
Nil known

Central Portfolio Management System (CPMS)
58351

National Institute for Health and Care Research (NIHR)
206949

Study information

Scientific Title
Feasibility and practicability of low-cost contactless sleep tracking devices to measure objective sleep quality and the effectiveness of sleep interventions in PLWD/MCI (SleepXacT)

Acronym
SleepXact

Study objectives

1. Assess the feasibility of collecting and analysing objective sleep measures using a contactless sleep tracker in patients living with dementia or mild cognitive impairment.
2. Assess the acceptability of the contactless sleep tracker using qualitative semi-structured interviews with carers.
3. Determine the usefulness of objective sleep data for GPs in the identification and management of sleep problems in patients living with dementia or mild cognitive impairment.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 30/06/2025, London - Camberwell St Giles Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 2071048276; camberwellstgiles.rec@hra.nhs.uk), ref: 25/LO/0306

Study design
Interventional multi-center single-arm non-randomized feasibility study

Primary study design
Interventional

Study type(s)
Treatment, Other

Health condition(s) or problem(s) studied
Dementia or mild cognitive impairment

Interventions
- Feasibility study: To see if the use of a contactless sleep tracker is feasible and acceptable to patient participants, carer participants, and GPs; if sufficient numbers of participants can be recruited and will engage with the objective sleep measurements (alongside the other outcome assessments and the tailored intervention); if sufficient data can be collected to objectively assess sleep (and general health and wellbeing) across the 15-week study period.
- Single-Arm: All participants will complete all outcome assessments and be offered the Tailored Management of Sleep (TIMES study, https://www.isrctn.com/ISRCTN54015716) intervention.
- Multi-centre: Recruiting 7 GP practices in England.
- Complex Intervention: Allows flexibility in how the TIMES intervention is delivered as it needs to be tailored to individual participants, based on their specific needs.
- Participants: People living with dementia or mild cognitive impairment (PLWD/MCI), in primary care, who have a paid or unpaid carer to support their study participation, and experience poor sleep or wish to improve their sleep. 40 patient-carer pairs will be recruited in total.

Intervention Type
Behavioural

Primary outcome(s)
Feasibility outcomes:
1. The proportion of people in a primary care setting who meet the following criteria (per 1000 registered patients):
1.1. PLWD/MCI with poor sleep or wish to improve their sleep, and who also have a professional

or family carer measured using screening logs at screening.
1.2. PLWD/MCI with poor sleep or wish to improve their sleep, who also have a professional or family carer, and meet the other eligibility criteria measured using eligibility assessment records at recruitment.
2. The proportion of eligible people who consent to participate in SleepXact measured using screening logs, eligibility assessment records, and consent forms at recruitment.
3. The proportion of consented participants who complete at least one objective sleep monitoring session measured using the contactless sleep tracker at the baseline, 9-week, and 15-week follow-up assessments.
4. Total number of nights with use of the contactless sleep tracker measured using the contactless sleep tracker at the baseline, 9-week, and 15-week follow-up assessments.
5. Number of nights with available recorded data (i.e., no significant data loss) from the contactless sleep tracker measured using the contactless sleep tracker at the baseline, 9-week, and 15-week follow-up assessments.
6. Median hours of device recording per night measured using the contactless sleep tracker at the baseline, 9-week, and 15-week follow-up assessments.
7. Median sleep recording quality with the contactless sleep tracker, measured using the contactless sleep tracker at the baseline, 9-week, and 15-week follow-up assessments.
8. Objective sleep and wake summary measures, assessed using the contactless sleep tracker at baseline, 9-week, and 15-week follow-up, including (but not limited to):
8.1. Total time spent in bed
8.2. Sleep onset latency (i.e., the time taken to fall asleep)
8.3. Total sleep time
8.4. Wake after sleep onset (i.e., time spent awake after sleep onset)
8.5. Sleep efficiency (total sleep time / time spent in bed * 100)
8.6. Number of awakenings
8.7. The time spent in light sleep, deep sleep, and rapid-eye movement (REM) sleep

Key secondary outcome(s))
1. The proportion of consented participants who remain in the study until final follow-up at 15 weeks measured using study records at the end of the study.
2. The proportion of consented participants who remain in the study until final follow-up and provide valid outcome data, including the objective sleep measure, at baseline and both follow-up assessments measured using contactless sleep tracker data and study records at baseline, 9 weeks, and 15 weeks.
3. Acceptability and practicality of the contactless sleep tracker to the participants is measured using semi-structured interviews with the carer participant during the 15-week follow-up period.
4. Usefulness of the contactless sleep tracker for identification and management of sleep problems in PLWD/MCI is measured using an online GP survey and qualitative elicitation focus groups with GPs during the study.

Completion date
30/09/2026

Eligibility

Key inclusion criteria
PATIENT PARTICIPANTS (PLWD/MCI)
1. Aged >18 years
2. Clinical diagnosis of dementia/MCI of any subtype and stage
3. In primary care and registered with a participating general practice

4. Residing at home or in a community care home in England
5. Has poor sleep of any type or has expressed an interest in improving their sleep,as indicated by the PLWD/MCI,their family or carer
6. Have a family or professional carer who provides support at least one hour per week and is willing to solely assist with completion of outcomes
7. Able to understand and communicate in spoken and written English well enough to complete the outcome measures and questionnaires
8. Has capacity to provide informed consent OR has a personal or nominated consultee who is able to provide the opinion that the PLWD/MCI would have no objection to taking part in the study

CARER PARTICIPANTS
1. Aged >18 years
2. Resides in England
3. Able to understand and communicate in spoken and written English well enough to complete the outcome measures and questionnaires
4. Has capacity to provide informed consent
5. Has lived- or professional-experience of poor sleep in the PLWD/MCI who they provide care for,or has noted an interest from the PLWD/MCI in improving their sleep
6. Is not already enrolled in the study with another patient participant (each carer participant can only take part once)
7. Patient participant residence (at home or in a community care home) offers physical space at the bedside for the positioning of the contactless sleep tracker

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
100 years

Sex
All

Total final enrolment
0

Key exclusion criteria
PATIENT PARTICIPANTS (PLWD/MCI)
1. Deemed overburdened or has severe unstable (mental or physical) health problems
2. Unable to communicate (in English) even with augmentative and alternative communication support
3. Does not have a family or professional carer

4. Undergoing end of life care
5. Planned unavailability for >3 weeks during intervention and follow-up (i.e.,approximately next 4 months)
6. Carer is unable and/or unwilling to handle (e.g.,switch on and off) the contactless sleep tracker

CARER PARTICIPANTS
1. Deemed overburdened or has severe unstable (mental or physical) health problems
2. Diagnosis or health condition that may impair their ability to complete outcome assessments, as determined by the carer
3. Planned unavailability for >3 weeks during intervention and follow-up (i.e.,approximately next 4 months)
4. Unavailability or unwillingness to participate in a semi-structured interview relating to the lived experience of using the contactless sleep tracker

Date of first enrolment
27/10/2025

Date of final enrolment
11/05/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
-
-
-
England
-

Sponsor information

Organisation
University of Exeter

ROR
https://ror.org/03yghzc09

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
Anonymised copies of the datasets generated during this study will be stored in open access repositories at the University of East Anglia and at the University of Exeter after the study concludes. Participants will provide informed consent for this anonymised data sharing as part of the consent process.

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 2	27/05/2025	08/10/2025	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes