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Is it possible to assess novel technology for monitoring sleep and daily rhythms in people living with mild dementia?

Submission date
12/01/2023

Recruitment status
No longer recruiting

Registration date
08/02/2023

Overall study status
Completed

Last Edited
23/08/2024

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Dementia is a syndrome (a group of related symptoms) associated with an ongoing decline of brain functioning. Alzheimer's disease is a type of dementia.
Sleep problems in dementia profoundly affect the wellbeing of those living with mild cognitive impairment or dementia and their caregivers. Disturbed sleep may be an indicator of disease progression or may in fact drive the development of the disease. As such, sleep is among the most promising targets for treatment in several different types of dementia. In order to effectively carry out long-term sleep monitoring at home, it requires technology that is acceptable, accurately measures sleep in those living with dementia, and is cost-effective.

In this study, we will evaluate the feasibility of assessing sleep in people living with mild cognitive impairment or mild Alzheimer's disease. In addition, we will assess these parameters in the study partners of the people living with dementia (PLWD) as there is limited data available on the impact of caring for PLWD on the sleep and circadian rhythms of the partner/family member/friend/support. We will also assess age-matched controls without dementia.

Who can participate?
Persons aged 50 - 85 years old with or without mild cognitive impairment or Alzheimer’s disease

What does the study involve?
Roughly 50 participants will be recruited to the study in total. The research will last approximately 2 years, with individual participant involvement being around 15 days.

We will assess the acceptability and performance of a variety of sleep/circadian monitoring devices and the information obtained will also provide us with preliminary information about the relationship between disease status/clinical symptoms and sleep/circadian rhythms. We will be collecting blood and urine samples for analysis of indicators of brain rhythms and function, including expression of genes known to vary with time of day and dementia risk.

What are the possible benefits and risks of participating?
Participation in this study will not benefit you directly, but the information we get from this study may help improve the treatment of people living with dementia. We may also detect something relevant to your health e.g., sleep apnoea.
Before participating you should consider if this will affect any insurance you have and seek advice if necessary.
Some insurance companies treat participation in studies of this nature as a material fact that should be mentioned when making any proposal for health-related insurance. Accordingly, your participation in this study should be disclosed to any insurer if you are in the process of seeking or renewing any such insurance, and you should check that participation does not affect any existing policies you may hold. Further information and advice can be obtained from the study doctor.

Where is the study run from?
University of Surrey (UK)

When is the study starting and how long is it expected to run for?
June 2022 to April 2024

Who is funding the study?
UK Dementia Research Institute

Who is the main contact?
Prof Derk-Jan Dijk, d.j.dijk@surrey.ac.uk

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
311763

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
SRCDRI006 / NIHR-403, IRAS 311763, CPMS 54163

Study information

Scientific Title
Feasibility study to monitor sleep and circadian rhythms in people living with (mild) cognitive impairment or (mild) Alzheimer's disease and healthy volunteers

Study objectives
The purpose of the study is to evaluate the feasibility of assessing sleep and circadian rhythms both at home and in the laboratory in people living with mild cognitive impairment (MCI) and mild Alzheimer's Disease (AD) (people living with dementia, PLWD).
In addition, we will assess these parameters in the study partners of the PLWD as there is limited data available on the impact of caring for PLWD on the sleep and circadian rhythms on the partner/family member/friend/support.
We will also assess healthy volunteers without dementia aged 50 – 85 years (we already have comparative data in heterogenous older participants (65 – 80 years) collected in a similar protocol).
We will assess the acceptability and performance of a variety of sleep/circadian monitoring devices and the information obtained will also provide us with preliminary information about the relationship between disease status/clinical symptoms and sleep/circadian rhythms.
The validation of novel sleep/circadian devices in PLWD will allow us to identify devices for long-term monitoring of sleep/circadian rhythms for tracking disease progression and allow for delivery/monitoring of targeted interventions.
Assessment of blood-based biomarkers of sleep/circadian/dementia will provide us with further methodology for assessing disease progression.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 02/11/2022, London - City and East REC (Whitefriars, Level 3, Block B, Lewins Mead, Bristol, BS1 2NT, UK; +44 207 1048134; cityandeast.rec@hra.nhs.uk), ref: 22/LO/0694

Study design
Observational study

Primary study design
Observational

Study type(s)
Other

Health condition(s) or problem(s) studied
Mild cognitive impairment or mild Alzheimer’s disease

Interventions
In this study, we will evaluate the feasibility of assessing sleep in people living with mild cognitive impairment or mild Alzheimer's disease. In addition, we will assess these parameters in the study partners of the people living with dementia (PLWD) as there is limited data available on the impact of caring for PLWD on the sleep and circadian rhythms of the partner/family member/friend/support. We will also assess age-matched controls without dementia. Roughly 50 participants will be recruited to the study in total.

The research will last approximately 2 years, with individual participant involvement being around 15 days. We will assess the acceptability and performance of a variety of sleep/circadian monitoring devices and the information obtained will also provide us with preliminary information about the relationship between disease status/clinical symptoms and sleep /circadian rhythms. We will be collecting blood and urine samples for analysis of indicators of brain rhythms and function, including expression of genes known to vary with time of day and dementia risk. This research may lead to the improvement of existing and the development of new technologies and approaches to monitor sleep and brain function. This involvement will help us gain initial data and a further understanding that will help guide future studies in dementia.

Participants will undergo a screening visit to determine if they are eligible to take part in the study. This will include completion of questionnaires and clinical assessments. Eligible participants will be provided with a range of devices and tools to use for 14 days at home to monitor their sleep and circadian rhythms. At the end of this period they will be invited to attend the laboratory for an overnight residential session which will include sleep monitoring and collection of blood samples for measurement of biomarkers.

Intervention Type
Other

Primary outcome(s)
1. Successful recruitment of people living with dementia (PLWD): Recruitment rate recorded as the number of eligible participant who consent to participate in the study by 18 months
2. Number of participants completing the protocol: Completion rate recorded as the number of eligible participant who complete Session 3 by 18 months
3. Completeness of data: Completeness will be assessed as the number of day/night recordings per device per participants expressed as a percentage
4. Acceptability of devices: Acceptability assessed by scores given for comfort and ease of use by each participant per device.

Key secondary outcome(s))
Performance of devices compared to gold-standard measures of sleep and circadian rhythms at home and in the laboratory. For each device that we are using (AX3, Withings Scanwatch, Dreem headband, Somnomedics Home Sleep Test, Withings Sleep Aanalyser, Somnofy) we will compare the 30 second epochs for the 10 hour recording against PSG to determine:
1. Sensitivity (ability to correctly classify sleep epochs)
2. Specificity (ability to correctly classify wake epochs)
3. Accuracy (proportion of all epochs correctly detected)

Completion date
23/04/2024

Eligibility

Key inclusion criteria
1. All participants
1.1. Be willing and able to give written and oral informed consent
1.2. Be willing and able to complete all required study procedures, on the judgement of the investigator team
1.3. Be willing to reside in one place (i.e. home) for the 14 day at-home monitoring period
1.4. Have sufficient functional English to allow completion of the assessment instruments
1.5. If taking hypnotics, must have been on a stable dose for 3 months prior to being recruited with no anticipation of changing the dose during the study
1.6. Be registered with a GP

2. Participants living with mild cognitive impairment or Alzheimer's disease only
2.1. Male or female aged 50 – 85 years at baseline
2.2. Have a confirmed diagnosis of prodromal or mild Alzheimer's disease confirmed by the SABP team
2.3. Have an sMMSE score of 23 or greater
2.4. Living in the community and have another individual who will support them in their participation by acting as their study partner
2.5. 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

3. Healthy volunteers (will only be recruited if required to age match PLWD aged 50 – 64 years)
3.1. Men and women aged 50 – 85 years at baseline
3.2. Have no cognitive impairment, confirmed with an sMMSE score of 27 or greater
3.3. Any co-morbidities must have been stable for at least the past three months prior to screening, with no change to their current medications and no hospitalisation due to this specific co-morbidity

4. Study Partner
4.1. Men and women aged 18 or over
4.2. Single nominated study partner (relative/friend/caregiver) who has known the person with dementia for at least 6 months and is able to support the person with MCI or AD with their study participation
4.3. Have no cognitive impairment, confirmed with an sMMSE score of 27 or greater

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit

18 years

Sex
All

Total final enrolment
39

Key exclusion criteria
1. All participants
1.1. A medical condition which is disabling, i.e., prevents the participant to be active, go outside, or being able to perform daily activities
1.2. 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
1.3. A medical condition which is unstable and may interfere with study conduct in the judgement of the investigator team
1.4. A medical condition which requires a treatment which is not compatible with the protocol, e. g., CPAP treatment, in the judgement of the investigator team
1.5. 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
1.6. Current smoker. Ex-smokers are eligible provided that they have stopped smoking and not used any cigarettes, nicotine substitutes or vaping for a minimum of 6 months before screening
1.7. Alcohol intake exceeds 14 units per week
1.8. Receipt of any investigational drug within 90 days prior to consenting

2. Participants living with mild cognitive impairment or Alzheimer's disease
2.1. People with unstable mental state including severe depression, severe psychosis, agitation, and anxiety whom their medication was changed over the last 4 weeks prior to screening as assessed by the PI
2.2. People with severe sensory impairment (severe hearing or visual loss that is not correctable with hearing aids or glasses)
2.3. Currently have active suicidal ideas as assessed by the SABP team at screening
2.4. People who require regular elective hospital admission for their physical health monitoring
2.5. People who are receiving treatment for terminal illness

3. Healthy volunteers (will only be recruited if required to age match PLWD aged 50 – 64 years)
3.1. Participant has travelled across more than one different time zone within two weeks prior to the first screening visit, or plans to travel across more than one time zone during the study.
3.2. Participant has been a night-shift worker (works between 22:00 and 06:30) in the six months prior to screening visits, or plans to be a night-shift worker during the study.

Date of first enrolment
25/01/2023

Date of final enrolment
09/04/2024

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Surrey and Borders Partnership NHS Foundation Trust
18 Mole Business Park
Randalls Road
Leatherhead
United Kingdom
KT22 7AD

Study participating centre
Surrey Sleep Research Centre / Surrey Clinical Research Facility (University of Surrey)
Egerton Road
Guildford
United Kingdom
GU2 7XP

Sponsor information

Organisation
University of Surrey

ROR
https://ror.org/00ks66431

Funder(s)

Funder type
Research organisation

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
All data generated or analysed during this study will be included in the subsequent results publication.

IPD sharing plan summary
Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		29/02/2024	23/08/2024	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes