

Remote Evaluation of Sleep and Circadian Rhythms in Older Adults with Mild Cognitive Impairment and Dementia: Protocol for a Feasibility and Acceptability Study

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Abstract

Background: Sleep disturbances are a potentially modifiable risk factor for neurodegenerative dementia secondary to Alzheimer's disease (AD) and Lewy body disease (LBD). Therefore, we need to identify the best methods to study sleep and circadian rhythms in this population.

Objective: This study will assess the feasibility and acceptability of various wearable devices, smart devices, and remote study tasks in sleep and cognition research for people with AD and LBD.

Methods: We will deliver a feasibility and acceptability study alongside a prospective observational cohort study assessing sleep and cognition longitudinally in the home environment. Adults aged >50 years diagnosed with mild to moderate dementia or mild cognitive impairment (MCI) due to probable AD or LBD and age-matched controls will be eligible. Exclusion criteria include lack of capacity to consent to research, other causes of MCI/dementia, and clinically significant sleep disorders. Participants will complete a cognitive assessment and questionnaires with a researcher and receive training and instructions for at-home study tasks across 8 weeks. At-home study tasks include remote sleep assessments using wearable devices (electroencephalography (EEG) headband, actigraphy watch), app-based sleep diaries, online cognitive assessments, and saliva samples for melatonin- and cortisol-derived circadian markers. Feasibility outcomes will be assessed relating to recruitment and retention, data completeness, data quality, and support required. Feedback on acceptability and usability will be collected throughout the study period and during end-of-study interviews analysed using thematic analysis.

Results: Recruitment started in February 2022. Data collection is ongoing, with final data expected in January 2024 and data analysis and publication of findings scheduled for late 2023 and 2024.

Conclusions: This study will allow us to assess if remote testing utilising smart devices and wearable technology is a viable alternative to traditional sleep measurements, such as polysomnography and questionnaires, in older adults with and without MCI/dementia due to AD/LBD. Understanding participant experience and the barriers and facilitators to technology use for research purposes in this population will assist with development of, recruitment to, and retention within future research projects

using similar technologies to study sleep and cognition outside of the clinic or laboratory.

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Original Manuscript

Remote Evaluation of Sleep and Circadian Rhythms in Older Adults with Mild Cognitive Impairment and Dementia: Protocol for a Feasibility and Acceptability Study

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Abstract

Background: Sleep disturbances are a potentially modifiable risk factor for neurodegenerative dementia secondary to Alzheimer's disease (AD) and Lewy body disease (LBD). Therefore, we need to identify the best methods to study sleep in this population.

Objective: This study will assess the feasibility and acceptability of various wearable devices, smart devices, and remote study tasks in sleep and cognition research for people with AD and LBD.

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Results: Recruitment started in February 2022. Data collection is ongoing, with final data expected in February 2024 and data analysis and publication of findings scheduled for summer 2024.

Conclusions: This study will allow us to assess if remote testing utilising smart devices and wearable technology is a viable alternative to traditional sleep measurements, such as polysomnography and questionnaires, in older adults with and without MCI/dementia due to AD/LBD. Understanding participant experience and the barriers and facilitators to technology use for research purposes and remote research in this population will assist with development of, recruitment to, and retention within future research projects studying sleep and cognition outside of the clinic or laboratory.

Keywords: feasibility, sleep, mild cognitive impairment, dementia, Lewy body disease, Alzheimer's disease, Parkinson's, wearable devices, research

Introduction

Background

Dementia is the leading cause of death in the UK [1]. Whilst the search continues for disease-modifying therapies, key research priorities include preventing, identifying, and reducing dementia risk and improving symptom burden and quality of life for patients with dementia and those who care for them [2]. With increasing evidence to support poor sleep as an important risk factor for dementia [3-5], sleep may offer an untapped opportunity in both reducing dementia incidence and improving quality of life for those with or at-risk of developing dementia.

Sleep and dementia

Sleep is essential for optimal brain function and health [3]. Disrupted sleep and circadian rhythms are considered among the most debilitating symptoms in dementia, and increasing evidence suggests that sleep disturbances are a consequence of and contribute towards neurodegeneration underlying dementia including Alzheimer's disease (AD) and Lewy body disease (LBD) [3, 6].

Changes to sleep such as shorter total sleep time, more nocturnal awakenings, less time spent in deep slow-wave and rapid eye movement (REM) sleep, and a slight shift to earlier circadian rhythms are

commonly observed as we age [7, 8]. Most of these changes appear to stabilise around the seventh decade of life in healthy older adults [9]. In AD, sleep and circadian disturbances are more robust and severe than the changes seen in normal aging [10, 11]. Some people with AD also experience a phenomenon known as ‘sundowning’ (worsening of neuropsychiatric symptoms in the late afternoon or evening), which is thought to be in part caused by disturbances in circadian rhythms [12, 13]. LBD is more typically associated with worse subjective sleep quality, REM sleep behaviour disorder (RBD), sleep-related movement disorders such as restless legs syndrome, and higher levels of daytime sleepiness [5] compared to other dementias.

Sleep as a modifiable risk factor for dementia

Individuals with sleep disorders (such as insomnia), sleep-disordered breathing, sleep-related movement disorders, circadian rhythm disorders, and poor quality or insufficient sleep problems are more likely to develop dementia later in life [14].

Mechanistically, chronic sleep deprivation and fragmentation is associated with various neurodegenerative processes including neuroinflammation [15], amyloid deposition [16, 17], autophagy [15], tau phosphorylation [18], and hippocampal atrophy [19, 20]. Sleep and circadian disturbances can precede cognitive and functional impairment, appearing in cognitively unimpaired older adults with AD biomarkers such as decreased cerebrospinal fluid amyloid-beta 42 and in mild cognitive impairment (MCI), and correlate with severity of cognitive impairment in AD [21-23]. Sleep disturbances also appear early in the disease course for LBD, particularly RBD [24, 25]. Profiling sleep may offer non-invasive biomarkers for earlier diagnosis and staging, as well as targets for intervention to improve prognosis.

Improving quality of life and symptom burden for people with dementia

Sleep disturbances impact daily functioning, socialisation, emotional wellbeing, and cognitive function in patients [26] and have a profound impact on caregivers [27]. Identifying targets for sleep interventions, whether tailored to an individual’s sleep profile or general advice given alongside dementia diagnosis or care, could help to improve quality of life for both persons with dementia and their caregivers. A single night of sleep deprivation disrupts cognitive performance [28], increases AD-related pathology such as amyloid burden [29] and reduces waste clearance in the brain [30], and improving sleep through treating sleep-disordered breathing has been associated with improvements in both neuropsychological assessments and blood biomarkers relating to AD in people with MCI [31]. Therefore, improving sleep could also benefit those with already established dementia and MCI, in addition to reducing incidence.

Further research is warranted to identify the most important sleep metrics and different sleep profiles in older adults with and without cognitive impairment to help identify targets for intervention [32].

Measuring sleep in individuals with, or at-risk of, dementia

Technological advancements in ‘wearables’ (such as smartwatches and electroencephalography (EEG) headsets), ‘nearables’ (such as mattress or room sensors), and smartphones offer unprecedented ability for tracking sleep at home for both consumers and researchers—to varying degrees of accuracy and accessibility [33, 34]. The use of wearable technology is not new to sleep medicine or research; the current gold standard for sleep medicine is polysomnography (PSG) conducted under laboratory conditions and wrist-worn actigraphy has been used for decades alongside paper-based sleep diaries to monitor rest and activity patterns typically over days or a couple of weeks [35]. However, most studies to date assessing sleep in individuals with MCI and early dementia have used questionnaires, with fewer studies adopting objective sleep technologies that could complement them such as actigraphy and EEG [32, 36].

Alongside technological advancements, improved digital literacy and accessibility in older adults in recent years offers great promise for sleep research. A 2020 survey identified that 94.6% of 55-64

year olds, 85.5% of 65-74 year olds, and 54% of those aged 75+ had used the internet in the last three months [37]. Leveraging technology and remote assessments offers several potential benefits above PSG under laboratory conditions. PSG is often used across one or two nights which potentially leaves results vulnerable to the well-established ‘first-night effect’ which describes how sleep is quantitatively and qualitatively different during the first compared to subsequent night recordings. This has been observed to affect REM and non-REM sleep, awakenings, total sleep time, and subjective sleep quality [38]. PSG also limits mobility during the night. Conducting research in the home setting is more likely to capture naturalistic sleep as participants can largely continue their usual sleep-wake routines. Remote assessments enable longitudinal assessment which may uncover natural night-to-night sleep variations. Newer sleep technologies enable the collection of both objective (via wearables, nearables) and subjective (via smartphone apps) sleep data which is considered best practice to accurately capture sleep quality in older adults [39]. Subjective and objective sleep data may produce complementary or conflicting results [22] and allows multiple aspects of sleep (architecture vs. experience) to be captured, enabling comprehensive profiling of sleep. Circadian and infradian rhythms may also be more accurately captured over a longer assessment period than is practical in a laboratory or outpatient setting, using actigraphy and repeated saliva samples that participants complete themselves. Finally, since participants do not need to attend sleep clinics, remote and technology-supported research may improve accessibility to research studies for those with less access to transport, reduce participant and study partner burden, and be more affordable, allowing for larger sample sizes.

However, before large-scale clinical trials and observational studies invest in and adopt technology- and home-based sleep measurements for dementia research, it is important to determine whether research conducted in this way is feasible and acceptable to older adults with and without cognitive impairment or dementia. People living with MCI and dementia experience changes in their communication or thinking which may influence their experience of remote research, or they may have difficulty remembering to complete or understanding tasks without in-person support from a researcher, however remote research may offer significant benefits including overcoming logistical issues typically faced in research and thus increase participation whilst reducing study burden [40]. The few studies which have addressed feasibility of home-based sleep research and wearable technologies have often collected basic short-term feasibility data across only a few nights [41, 42] and have typically required participants to be supported by a caregiver or care home staff [43, 44]. Research is needed to see if community-dwelling participants with MCI and early dementia tolerate remote sleep and memory testing across an extended period of weeks or months (as would be expected in a clinical trial setting) and if they themselves can complete the study tasks. Caregivers or partners can provide important contributions in sleep and dementia research [45, 46] but themselves often report poor quality sleep and high burden [47, 48], and requiring a study partner may be a barrier to enrolment in research [49]. Independent (or minimally supported) involvement in research in milder stages of cognitive impairment may also positively acknowledge someone’s cognitive ability to engage in autonomous decision-making regarding their health [50].

Improving how we measure sleep and cognition in this population can deepen our understanding of the link between sleep and brain health, better inform the care we give to patients, and improve monitoring in future interventional studies.

Objectives

We will test the feasibility and acceptability of remote, in-home sleep and cognitive testing in a cohort of older adults with MCI or mild to moderate dementia due to AD or LBD and older adults without cognitive impairment. We hypothesise that using technology (wearable devices, smart devices) and remote study tasks will be well-tolerated by all study participants. Specifically, we will:

- Apply mixed methods to evaluate the feasibility and acceptability of remote study tasks based on recruitment and retention of study participants, participant adherence in remote study

tasks, data quality and completeness, and qualitative feedback on study tasks from participants;

- Explore whether sociodemographic or clinical variables explain any of the variability in feasibility and acceptability outcomes (whether someone is supported with tasks at home, cognitive impairment at baseline, and psychological variables at baseline such as apathy and anxiety);
- Compare agreement on core sleep outcome measures (such as total sleep time, sleep efficiency, nocturnal awakenings, sleep quality) across different measures;
- Explore key themes in feedback from participants to identify strengths, limitations, and guidance for future sleep and remote-based research.

It is envisaged that these outcomes will be used to inform future research methodologies for both observational and interventional sleep research in older adults with and without dementia.

Methods

Study design

This is a mixed-method study assessing the feasibility and acceptability of a novel combination of remote technology-supported sleep and cognitive assessments in older adults with and without cognitive impairment and dementia. The feasibility study is embedded within a prospective, longitudinal, observational cohort study called the Remote Evaluation of Sleep To enhance understanding of Early Dementia (RESTED) study. Participants will complete baseline assessments and undergo remote sleep and cognitive assessments for a main study period of 8 weeks and a follow-up cognitive assessment at 6 months. Feasibility and acceptability will be assessed through analysis of quantitative and qualitative data collected throughout the study and during end-of-study interviews. Qualitative data will help to contextualise and enhance quantitative outcomes to deliver a more comprehensive analysis of feasibility and acceptability [51].

Setting

The study will be conducted at the Bristol Brain Centre, Southmead Hospital within North Bristol NHS Trust and is sponsored by the University of Bristol. Baseline and follow-up assessments will be conducted at Southmead Hospital, remotely via phone or video call, or at the participant's home. Participants will be asked to complete study activities from home, with visits from a researcher where needed to deliver or collect study materials or provide support with study activities. Participants will be asked to complete a follow-up cognitive assessment at 6 months.

Participants and sample size

Participants will be eligible if they are aged ≥ 50 years at consent, have full capacity to consent and are willing to adhere to study procedures, have Wi-Fi at home, and meet criteria to fall into one of the three study arms:

- AD group: clinical diagnosis of MCI due to probable Alzheimer's disease (AD) or mild AD dementia obtained from medical records. This may include participants with mixed dementia where AD is considered a significant component to clinical presentation.
- LBD group: clinical diagnosis of established or prodromal Parkinson's disease dementia, dementia with Lewy bodies, MCI due to Parkinson's disease, or MCI due to Lewy body disease obtained from medical records. This may include participants with mixed dementia where LBD is considered a significant component to clinical presentation.
- Matched controls: no known cognitive impairment or neurodegenerative condition. Efforts will be made to match the AD and LBD cohorts on age and sex.

Participants with a clinically significant untreated sleep disorder pre-dating or unrelated to a dementia diagnosis (such as narcolepsy or untreated sleep apnoea), a severe medical or psychiatric comorbidity which may substantially impact sleep (such as refractory epilepsy), or a diagnosis of dementia other than AD or LBD will be excluded from the study.

Study participants will be recruited from cognitive and movement disorders clinics at the North Bristol NHS Trust, volunteer databases, and Join Dementia Research (JDR). The study is expected to be open to recruitment between February 2022 and June 2023 with a recruitment target of 75 participants (n=25 in each group). Prospective participants will be introduced to the study via a telephone call from the research team or during a meeting with their clinical team and provided with a digital or paper copy of the participant information sheet. Those who are interested in taking part will be invited to a screening visit for further discussion and, if agreeable, to provide consent. Participants will be asked if they would like to attend with a friend or relative, but we will not recruit formal study partners.

Following consent, participants will undergo a Montreal Cognitive Assessment (MoCA). Those scoring $< 11/30$ will be withdrawn from the study as this would indicate more advanced cognitive impairment, unless in the opinion of the principal investigator there is a mitigating factor impacting performance on the MoCA (such as prominent speech disorder), in which case they will be eligible to continue in the study.

Outcome measures

Brief overview of the RESTED study

Participants in the RESTED study will be asked to undergo the following:

1. Screening and baseline assessments: MoCA; medical and clinical observations; questionnaires on sleep (Pittsburgh Sleep Quality Index [52], including responses from a cohabitant if available at the assessment), Epworth Sleepiness Scale [53], STOP-Bang Questionnaire [54], REM Sleep Behavior Disorder Single-Question Screen [55], Ultra-Short Version of the Munich ChronoType Questionnaire [56]), anxiety (Generalised Anxiety Disorder – 7-item scale [57]), depression (Patient Health Questionnaire depression scale – 8 [58]), and apathy (Apathy Evaluation Scale [59]);
2. Blood biomarker testing for potential biomarkers of AD (amyloid beta 40 and 42, phosphorylated tau 181), neuroinflammation (glial fibrillary acidic protein) and neurodegeneration (neurofilament light chain);
3. Overnight pulse oximetry using the Nonin 3150 WristOx₂ ® to screen for OSA (except where a diagnosis of OSA has already been given or assessment has been completed within 6 months of recruitment to the study);
4. 8 weeks of remote study tasks: sleep diaries (Consensus Sleep Diary – Main [60] with a bespoke additional question on comparison of the previous night to typical sleep), wrist-based actigraphy (Axivity AX3), and regular online cognitive tests (choice reaction time, digit span, and self-ordered search via Cognitron). Throughout the main study period, participants are supported by researchers via MyDignio, a patient-facing mobile platform designed specifically for delivering remote healthcare, using task reminders and checklists;
5. During 1 of the 8 weeks, participants will undergo an ‘intensive week’ consisting of: daily online cognitive testing; wearing a Dreem 2 EEG headband during sleep; saliva samples for dim light melatonin onset (evening) and cortisol awakening response analyses (morning); verbal memory recall and recognition tasks via a video link with a researcher;
6. Participants will also be asked to provide feedback on their experiences throughout the study. A subsample of participants will be invited to take part in an end-of-study interview;
7. 6-month follow-up MoCA.

Table 1. Summary of data collection methods and frequency of remote home-based study tasks for the Remote Evaluation of Sleep To

enhance understanding of Early Dementia (RESTED) study.

Remote study task	Method of data collection	Frequency of data collection	Duration of data collection
Sleep diary	App-based, MyDignio	via Daily	8 weeks
Actigraphy	Wrist-based actigraphy	Continuous	8 weeks
Remote online cognitive tasks	Online on participants' own device, via Cognitron	Twice per week, then daily during intensive week	8 weeks
Recall and recognition tasks with a researcher	Online, via video conferencing software	Four brief tasks to complete across four separate days (< 5 minutes each)	1 week (intensive week only)
Overnight electroencephalography (EEG)	Dreem EEG headband	Every night	1 week
Saliva samples for cortisol awakening response	Saliva swabs	Three swabs (0, 30, 60 minutes after awakening)	1 morning
Saliva samples for dim light melatonin assay	Passive drool samples	Seven samples hourly starting from five hours before usual bedtime	1 evening
Overnight oximetry for pulse sleep apnoea screening	Pulse oximeter	Overnight	2 nights

Feasibility outcomes

The feasibility and acceptability outcomes will be predominantly based on data relating to recruitment and retention, the remote study tasks (Table 1), and participant feedback. The core outcomes of the study are outlined in Figure 1. Conceptual map of feasibility and acceptability outcomes for the Remote Evaluation of Sleep To enhance understanding of Early Dementia (RESTED) study. The core outcomes will be recruitment and retention, data quality, resources required, and participant experience.



Figure 1. Conceptual map of feasibility and acceptability outcomes for the Remote Evaluation of Sleep To enhance understanding of Early Dementia (RESTED) study. The core outcomes will be recruitment and retention, data quality, resources required, and participant experience.

Recruitment and retention rates

Recruitment and retention to the study will be described and presented in a STROBE flowchart (Figure 2). Key recruitment and retention outcomes will include the proportion of eligible patients who consent to take part in the study and the proportion of patients who withdraw from the study after consent. Reasons for ineligibility and non-participation at each stage (pre-screening, screening, main study period, follow-up) as well as barriers and facilitators to recruitment will be summarised. Sample characteristics will be presented tabularly.

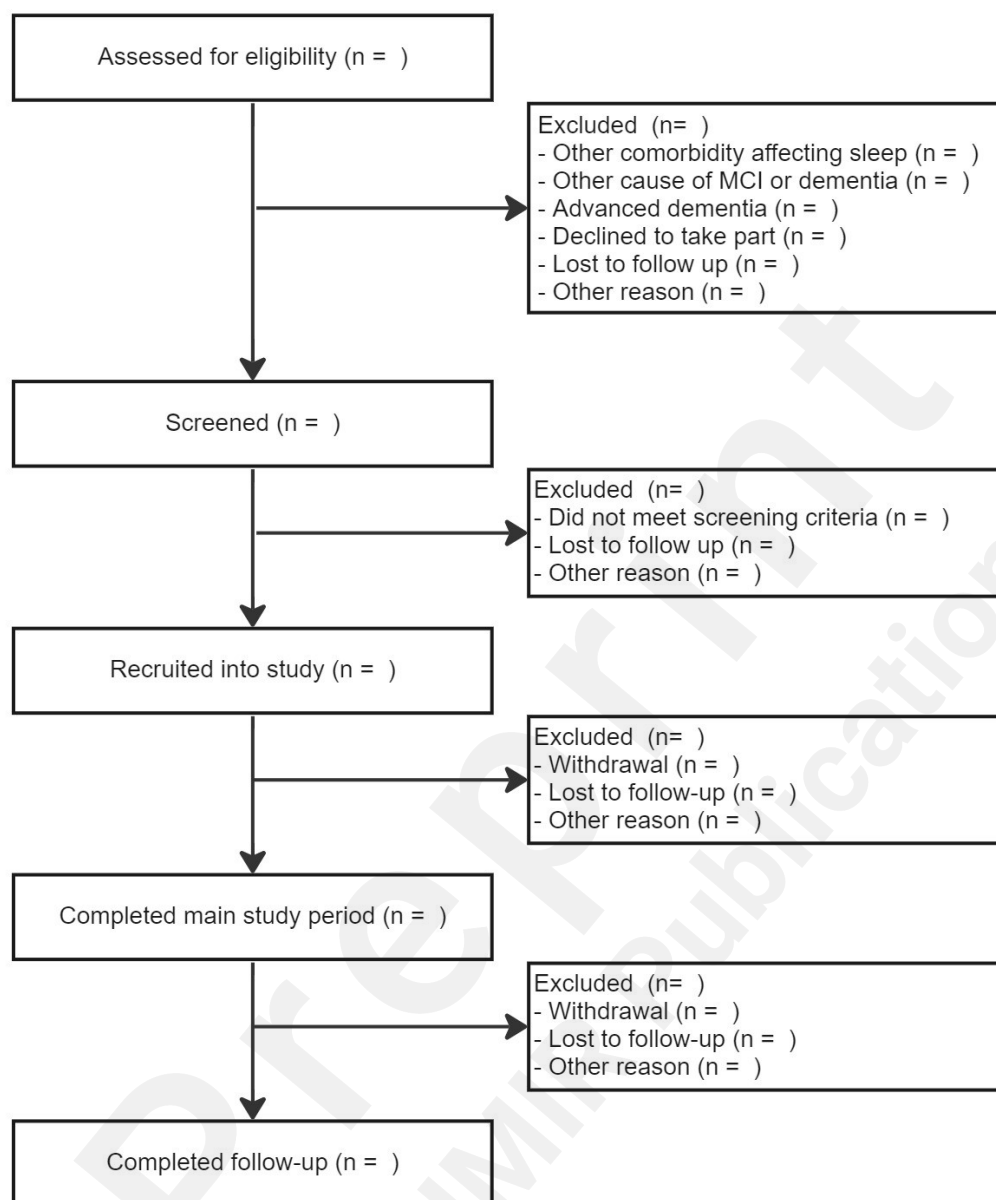


Figure 2. A template flowchart of participant flow through the RESTED study, based on Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) and CONSORT guidelines. This flowchart will document participant recruitment and retention at each stage of the study.

Data quality, participant adherence, and data completeness

Participants will be provided with written and verbal guidance and reminders on how and when to complete each of the study tasks. Descriptive statistics on adherence and data completeness for each remote study task will be summarised (e.g., number of nights EEG headband worn, number of completed sleep diaries). Reasons for incompleteness (e.g., participant non-adherence, technical problems) and methods used to encourage or improve data completion (e.g., reminders to complete tasks) will be described.

We will also assess the extent to which data appears to be valid and of sufficient quality for analysis of core sleep metrics (e.g., for EEG data, this will include individual EEG channel and overall record quality metrics).

Where multiple sleep metrics are measured on a single night (e.g., total sleep time via actigraphy, sleep diary, and EEG), agreement between different measurement tools will be calculated (e.g., Bland-Altman plot comparing sleep diary-adjusted actigraphy to EEG).

Resources

We will assess the amount of support and resources (e.g., in-person visits, email, app-based and telephone support) required from the research team to complete remote study tasks. Though the study will not require a study partner, we will also record whether participants perceive that they access to support from outside of the study team (e.g., family member, carer, friend), whether this support is utilised, and what support is provided (e.g., technical support, reminders).

Barriers, facilitators, and participant feedback

We will review participant feedback expressed before, during, and at the end-of-study interviews to identify barriers and facilitators in:

- participating in remote sleep and cognitive research in general
- study-specific remote tasks

End-of-study interviews were designed and guided by the COM-B system model of behaviour, which suggests that capability, opportunity, and motivation interact with behaviour in a system [61]. The interviews will probe capacity to engage in the study activities (capability), habits and decision making around study involvement (motivation), external factors that influenced behaviour and completion of study tasks (opportunity). Interview transcripts will be coded and organised into themes using QSR NVivo version 20 (or newer) software. We will use an inductive approach to thematic analysis and aim to identify semantic and latent themes [62, 63].

Where appropriate and scientifically sound, we will incorporate feedback on acceptability and feasibility to improve the study design. Changes to study design due to feasibility or acceptability or based on feedback from prospective or enrolled participants will be documented.

Sub-group analyses

We will compare acceptability and feasibility outcomes between study arms (AD/LBD/controls) and conduct exploratory analyses to determine whether subjective sleep quality support from a relative or friend, or baseline apathy and anxiety predict overall adherence to study tasks.

Ethical considerations

This study has been approved by the Health Research Authority (Yorkshire & the Humber - Bradford Leeds Research Ethics Committee, reference 21/YH/0177) and carries minimal risk to participants. The study will be conducted in accordance with Good Clinical Practice and the Helsinki Declaration to protect the rights and welfare of all participants. All data will be kept securely and handled in accordance with the General Data Protection Regulation (EU 2016/679). Capacity to consent to the research study will be assessed and participants will be required to provide full written informed consent prior to participation in any study activities. Participants will be reminded of their right to withdraw at any point, without providing a reason, and without this affecting their healthcare. Participants will be offered cash reimbursement for travel or postage expenses incurred during the study. Participants will be assigned a study ID at consent to allow pseudonymisation of participant data, with personal information stored separately and securely from de-identified data. The final manuscript and any data shared will contain no information that allows for identification of individual participants.

Results will be presented at scientific meetings and conferences and published in peer-reviewed journals. Summaries will be provided to participants where they have indicated consent to be contacted about results from the study.

Results

The study opened to recruitment in February 2022. Participant recruitment is scheduled to be completed in 2023. Data collection is anticipated to continue until January 2024, with analysis beginning in 2023 and continuing into 2024.

Results will be reported in line with guidance from the STROBE checklist [64] and the CONSORT 2010 extension [65] for pilot and feasibility trials [66].

Discussion

Sleep is a fundamental component of health, and sleep disturbances are commonly observed in people living with MCI and dementia. Insufficient or poor sleep may represent both a risk factor and a symptom of these conditions, but more work is needed to confirm the relationship between sleep and MCI/dementia. Improvements to the way we measure sleep, such as measuring sleep in someone's natural home environment and using technologies to supplement data collected from sleep questionnaires, may help us to better understand the sleep profile in these conditions compared to normal aging, identify targets for intervention, and monitor disease progression [32, 67]. However, we first need to understand whether it is possible to collect good quality sleep and cognitive data from people living with MCI and dementia in their own homes. Accordingly, this paper proposes a study to investigate the feasibility and acceptability of remote sleep and memory data collection using study tasks designed to be completed at home by people living with MCI or dementia. The study aims to assess whether people with MCI or dementia are willing to engage in sleep studies using technology and home-based study tasks, describe participant experience, and evaluate the study tasks based on retrieving complete and analysable data. The findings from this study will guide future research design in sleep and memory.

Limitations

The eligibility criteria for the study require participants to have an internet connection and be willing to use technology for the duration of the study. Understanding the feasibility and acceptability of technology-supported remote research is the purpose of the study however this inherently may introduce bias into the study. For example, it is possible this may mean those who are unfamiliar or uncomfortable with technology may not take part, or those who are particularly interested in technology may find the study more acceptable or feasible. If recruitment, retention rates, or feedback from patients who would otherwise be eligible but were unable or unwilling to take part because of limited access to or ability to use the internet or a smart device, we may offer an adapted version of the study and will record whether this influences recruitment rate and other relevant outcomes.

Subjective measures used in the study may be prone to recall bias and may be difficult for individuals with cognitive impairment to answer accurately. Whilst participants themselves will need to provide answers to questions during the study, they can be supported by a family member, friend, or carer where needed and requested by the participant. Subjective measures will also be complemented by objective measures which are not prone to recall bias.

The longitudinal and remote nature of the study may result in a greater proportion of missing data compared to sleep research studies conducted in a laboratory setting. As a study enrolling persons with MCI and dementia, it is also expected that participants may have difficulty remembering to complete study tasks. Reasonable efforts will be taken to encourage adherence and data completion throughout the study period, particularly in the intensive week (e.g., schedules, digital reminders via SMS or email). Automated scheduled reminders and task lists will be supplemented with ad-hoc contacts from the research team directly (e.g., contacting to ascertain reasons behind consecutive days of missing data).

Conclusion

Technological advancements and improved digital literacy offer the opportunity to research sleep longitudinally and in the home environment. However, further research is needed to understand whether these developments may benefit MCI and dementia study design. This protocol outlines a mixed-methods study which examines the feasibility and acceptability of remote sleep and cognitive testing in a cohort of older adults and specifically those with MCI or dementia due to probable AD or LBD. Outputs from the study will inform the approach to study sleep in people with MCI or dementia in this population, contributing towards global efforts to identify and better understand potentially modifiable risk factors in these conditions.

Conflict of interest

The authors declare that they have no conflict of interest.

Authors' contributions

VG: Manuscript authorship, protocol authorship, study management, study design, participant recruitment, participant consent, data collection.

JB & HM: Protocol authorship, study design, sub principal investigators, participant recruitment, participant consent, data collection, manuscript review.

EC: Project conception, study design, principal investigator, manuscript review.

BB: Study design, data collection, manuscript review.

HL: Participant recruitment, participant consent, data collection

NT: Data analysis methodology

AJ, WT & AH: Cognitive task formulation

AW, GR & RG: Study design

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Data Availability

Datasets generated during this study are available from the corresponding author upon reasonable request.

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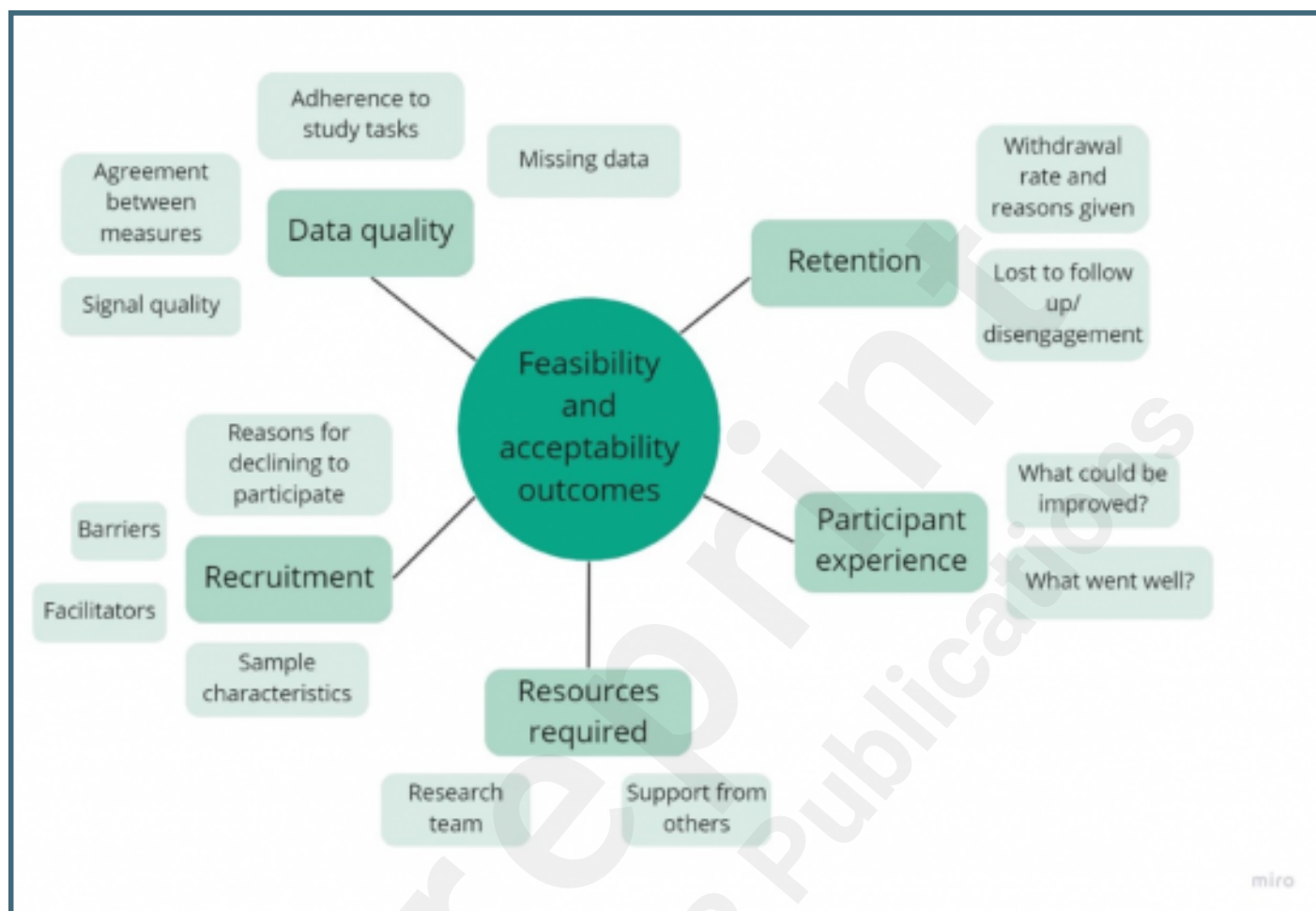
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Supplementary Files

Figures

Conceptual map of feasibility and acceptability outcomes for the Remote Evaluation of Sleep To enhance understanding of Early Dementia (RESTED) study. The core outcomes will be recruitment and retention, data quality, resources required, and participant experience.



A template flowchart of participant flow through the RESTED study, based on Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) and CONSORT guidelines. This flowchart will document participant recruitment and retention at each stage of the study.

