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Tailored management of sleep (TIMES) for people with dementia or mild cognitive impairment

Submission date
24/11/2025

Recruitment status
No longer recruiting

Registration date
16/01/2026

Overall study status
Ongoing

Last Edited
28/01/2026

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
We would like to find ways to improve sleep and help you feel at your best. A good night's sleep can improve your overall health and wellbeing. We want to involve people who have dementia or mild cognitive impairment and their family members, friends or carers. This is because current treatments to improve sleep for these people are not always available or effective. The TIMES study uses a tailored health plan that is created by patients, carers, and their GP, to help improve sleep. By participating, you'll help us understand how to provide better care for people living with dementia or mild cognitive impairment, and their carers.

What does the study involve?
-All participants will be randomly assigned to either the TIMES intervention OR treatment as usual.
-The study runs for 15 weeks. During this time, we will ask you to complete some questionnaires about your sleep, health, and wellbeing. This will happen at the start of the study, and again at 9 weeks and at 15 weeks. It should take no more than 30 minutes each time. Your family member, friend, or carer will help with this.
-If you are assigned to the TIMES intervention group, we will ask you to attend a 30 minute and a 15 minute consultation with your GP. Your family member, friend or carer will also attend these consultations.
-During these consultations, we will discuss your general health and develop a plan to improve your sleep.
-We may also ask you to share your experience of the TIMES intervention through optional interviews and questionnaires.

What are the possible benefits and risks of participating?
Participating in the TIMES study carries minimal risk. Some people may experience emotional distress when discussing any health concerns and changes to their wellbeing. However, the study team will be there to support you if needed.

The consent process to participate in this study will be completed by a qualified Research Nurse who is trained to assess capacity of potential participants and is familiar with the Mental Capacity Act. They are able to appoint a consultee who can act on your behalf if needed. Any disclosure of participant information that may lead to safeguarding concerns, in relation to your safety or others, will be reported to your GP.

While participation may or may not have direct benefits for you, taking part in this research could lead to improvements in our future understanding and care for people living with dementia and mild cognitive impairment.

Where is the study run from?
Select GP practices throughout England

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

Who is funding the study?
National Institute of Health and Care Research (UK)

Who is the main contact?
TIMES@exeter.ac.uk

Contact information

Type(s)
Public, Scientific

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Principal investigator

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Additional identifiers

Integrated Research Application System (IRAS)
355061

Central Portfolio Management System (CPMS)
67068

National Institute for Health and Care Research (NIHR)
202345

Study information

Scientific Title
The clinical, social and cost effectiveness of a decision support tool to optimise community-based tailored management of sleep (TIMES) for people living with dementia or mild cognitive impairment – a cluster randomised controlled definitive trial

Acronym
TIMES

Study objectives
To determine the effectiveness of a tailoring sleep management tool (TIMES) that enables community-based clinicians to optimise the tailored care of PLWD or MCI, and their carers, to improve sleep at 15 weeks, compared to treatment as usual

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 19/11/2025, Wales Research Ethics Committee 3 (Health and Care Research Wales Support Centre, Castlebridge 4, 15-19 Cowbridge Road East, Cardiff, CF11 9AB, United Kingdom; +44 29 2078 5741; Wales.REC3@wales.nhs.uk), ref: 25/WA/0327

Primary study design
Interventional

Study design
Definitive two-arm single-blinded multi-centre cluster-randomized controlled trial complex intervention

Study type(s)
Quality of life, Treatment

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

Interventions
The TIMES intervention is an ongoing, clinical assessment and management support tool, in which a tailored health-plan is co-created by the patient-carer dyad and GP, and subsequently reviewed and (if necessary) revised by the patient-carer dyad and GP one month later. Clinicians in the intervention arm will have attended a pre-recorded refresher/training course (totalling approximately 60 minutes), provided by the research study team in video format.

The intervention is comprised of the following three elements:
I. Assessment in Context: Patient participants will be asked to complete a one-off Sleep Activities of Daily Living (SADL) pre-consultation evaluation. The SADL will explore and capture holistic social-, health-, and healthcare-domains, that are associated with disruption to daily living and that may be improved by optimising sleep in PLWD/MCI. The SADL will be completed after the baseline assessment and before the first intervention consultation with their GP.

Invitations to complete the SADL will be managed by an unblinded site administrator or Research Nurse, through standard practice procedures. This may include text message, email, mailout with return envelope, phone or video call, or similar platforms that link information to the patient's medical records (i.e. https://accurx.nhs.uk/). If possible, input from the care-partner should also be sought, to ensure comprehensive answers to the questionnaire.

If needed, the Research Nurse or site administrator will send a reminder to complete the SADL to the patient participant five-seven days after the first message. Participants who do not respond after 7 days of the reminder message will receive a phone call or in-person visit from an unblinded Research Nurse to help them complete their SADL questionnaire.

Information from the SADL will be linked to the patient-participant's routine NHS medical records for review by their GP during their first intervention consultation to co-create their tailored care plan.

II. Co-Create Tailored Plan: A planned/pre-booked extended face-to-face consultation (30 minutes) between an advanced generalist clinician (GP) and the patient-carer dyad will be scheduled by unblinded site staff. It will aim to optimise sleep to improve daily living. This consultation should take place within 3-weeks (window: + 1 week) from the completion of the baseline assessment, at the participant's GP practice, home, or care home, and completion of the SADL. The carer-participant must be present.

The GP will use information from (i) the SADL, (ii) the patient participant's routine NHS clinical record, and (iii) current guidance/best practice on condition management to inform the care planning process (using the intervention training video) alongside the discussion with the patient-carer dyad, to develop a co-created tailored care-plan for the PLWD/MCI that addresses factors with the aim of optimising their sleep. The consultation will draw on best practice in Advanced Generalist Medicine. At the end of the initial consultation, a written explanation of problems, intended actions, and anticipated impact of the tailored care plan will be provided to the patient-carer dyad, which will be reviewed 4 weeks later (window: -1/+2 weeks).

During this initial consultation, the GP and participant dyad will also confirm their availability to meet again 4 weeks later (window: -1/+2 weeks) for a second consultation, to review and revise the co-created tailored plan (as described below).

III. Review and Revise: Four weeks (window: -1/+2 weeks) after the first consultation, in which the Co-created Tailored Plan was developed, the patient-carer dyad will attend a second, pre-booked (by practice), in-person consultation (15 minutes) with their GP, or if appropriate a relevant healthcare professional delegated by their GP, to review and if necessary revise, their Tailored Care Plan.

This review will be based on shared observations of whether the intended benefits/outcomes of the Tailored Care Plan have been met, the impact of goals and outcomes, and whether any changes to the Tailored Care Plan are needed.

This consultation will be at the participant's GP practice, home, or care home. The carer-participant must be present. If the carer-participant is unavailable, then the consultation should be rescheduled to a date that accommodates the participant dyad and GP/healthcare professional.

Subsequent review of goals of the tailored care-plan will fall outside of the trial intervention /assessment evaluation but may be undertaken as part of ongoing usual care.
Patient and carer participants will be advised that they can contact their GP practice at any point in this three-stage process if they have any clinical concerns (safety netting); in such instances participants will receive usual GP care. Usual care beyond the study intervention will include support for any unanticipated changes that occur in between each of the three stages. Unexpected care that is needed during the intervention period will be recorded during follow-up assessments, and reviewed by the TMG to assess if it is related to the intervention, and upward reported to the PSC if necessary.

Intervention training and support
The core study team will deliver intervention training to GPs who will deliver the intervention, and research nurses who will conduct follow-up assessments. Training will be delivered via pre-recorded video link to facilitate accessibility. Additional training, via online meetings, will be provided if deemed necessary by the core study team or if requested by GPs or Research Nurses. Intervention training will take approximately one hour. We will deliver appropriate training to new staff as required.
Training will optimise/emphasise the skills of Advanced Generalist Practice. The one-hour video will be based on the established WISDOM training course (https://www.wisegp.co.uk/wisdom) – offering a tailored/bespoke version created for the TIMES study. Only GPs in intervention sites will be able to access the TIMES specific training materials. Training will introduce GPs to the 3Es framework (Engagement, Enhancement, Extension) to support delivery and recording of Advanced Generalist Practice (AGP) used in the consultation to co-create the tailored care-plan. Training will also address the known barriers to delivery of tailored care, by offering evidence-informed permission for AGP, and enhanced confidence in the skills and practice of AGP.

Randomisation process
Randomisation is at the GP practice (site) level, i.e. cluster randomised. We aim to randomise 66 practices. Further sites will be opened to replace sites that fail to recruit to schedule or fully withdraw from the study. Practices will be randomised in batches of at least two sites at once, in multiples of 2; with their allocation, from a randomised static list, based on the order of site confirmation of capacity and capability (requests for confirmation of capacity and capability will be sent at the same time to each practice in a batch). Thirty-three practices will be allocated to

each study arm (1:1 allocation ratio), using a block design (i.e. 33 practices/clusters allocated to each of intervention or usual care/control). Randomisation will not be stratified. A randomisation list will be generated prior to commencing recruitment of practices by a statistician (or delegate) who is independent to the trial team, following a detailed randomisation specification document written in line with ExeCTU SOPS and signed off by trial statisticians. Allocation concealment is maintained by randomising practices in blocks of multiples of 2. The Trial Manager will inform the site PI and unblinded site staff of sites' treatment allocation at the point of formally opening the site. Randomisation of practices will therefore take place prior to recruitment of participants and their carers.

Intervention Type
Other

Primary outcome(s)
Sleep disorders in PLWD/MCI measured using the Sleep Disorders Inventory (SDI) for PLWD/MCI (Proxy-rated) at baseline, 9 weeks and 15 weeks

Key secondary outcome(s)
1. Daytime sleepiness is measured using the Epworth Sleepiness Scale (ESS) at baseline, 9 weeks and 15 weeks
2. Ability to perform basic and instrumental activities of daily living is measured using the Disability Assessment for Dementia (DAD) at baseline, 9 weeks and 15 weeks
3. Health-related quality of life is measured using the EQ-5D-5L at baseline, 9 weeks and 15 weeks
4. Wellbeing and quality of life in older people is measured using the ICECAP-O at baseline, 9 weeks and 15 weeks
5. Severity of neuropsychiatric symptoms and associated carer distress is measured using the Neuropsychiatric Inventory Questionnaire (NPI-Q) at baseline, 9 weeks and 15 weeks
6. Cognitive impairment is measured using the Telephone Montreal Cognitive Assessment (T-MoCA) Mini Version 2.1 English at baseline, 9 weeks and 15 weeks
7. Health care resource utilisation is measured using an adapted Client Service Receipt Inventory (CSRI) at baseline, 9 weeks and 15 weeks

Completion date
31/01/2027

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. 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
6. Able to communicate in English sufficiently well to complete the outcome measures and questionnaires
7. Has capacity to provide informed consent OR has a personal or professional consultee who is able to provide favourable advice on the views and wishes of the PLWD/MCI lacking capacity in relation to their participation

Carer participants:
1. Aged ≥18 years
2. Resides in England
3. Able to communicate in English sufficiently well to complete the outcome measures and questionnaires
4. Has capacity to provide informed consent
5. Has lived with, or has professional experience of, the person with dementia/MCI who they provide care for
6. Has completed a Sleep Disorders Inventory proxy assessment of the person with dementia /MCI they provide care for, resulting in a score (frequency x severity) ≥4 on at least one item (symptoms 1-7)
7. Is not already enrolled in the study with another patient participant (each carer participant can only take part once)

Participant type(s)
Carer, Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
120 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 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)

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 ≥4 weeks during intervention and follow-up (i.e. approximately next 4 months)

Date of first enrolment
16/02/2026

Date of final enrolment
07/10/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
South West Peninsular RRDN
Royal Devon University Healthcare NHS Foundation Trust, Barrack Road
Exeter
England
EX2 5DW

Sponsor information

Organisation
University of Exeter

ROR
https://ror.org/03yghzc09

Funder(s)

Funder type
Not defined

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
The datasets generated during and/or analysed during the current study will be stored in a publicly available repository held by the University of Exeter. Results of this trial will be disseminated regardless of outcome. We aim to publish findings in peer reviewed scientific and clinical journals, and via presentations at local, national, and international, meetings. We aim to publish results in an open access journal within 24 months of study completion, in line with NIHR guidelines. Outcome papers will adhere to CONSORT guidelines. We will work with PPI groups to provide a lay-accessible summary of the results to all study participants. Participants will be asked to provide their contact method preferences so that they receive the results in a format of their choice (i.e. hardcopy by post or digital copy by email). Participants will not be provided with copies of their individual data, due to the nature of the study the data collected would not be relevant to their continued care. Clinical data recorded in medical records irrespective of their taking part in the research will be available to participants through normal processes for accessing medical records. Results will be posted on the publicly available registry (ISRCTN). A summary of results will be submitted to the HRA within 12 months of the end of the study in line with HRA guidelines. The study protocol will be published in a peer-reviewed journal before the end of the recruitment stage and will be publicly available on the NIHR Journals Library at the end of the study.

IPD sharing plan summary
Stored in publicly available repository