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Tailored sleep management for people living with dementia and mild cognitive impairment

Submission date
15/03/2024

Recruitment status
No longer recruiting

Registration date
20/03/2024

Overall study status
Completed

Last Edited
02/07/2025

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, which can have an impact on their health and wellbeing, and that of the people who care for them. Sleep problems are difficult to manage well as they can be complex and require individually tailored healthcare. The research team have developed an intervention (TIMES) to help clinicians deliver better-tailored care for people with dementia and mild cognitive impairment who have sleep problems. The intervention was developed in the observational Tailored Management of Sleep (TIMES) study (WP1; https://www.isrctn.com/ISRCTN54015716). This follow-on study (WP3) is a small feasibility trial to assess whether running a larger study to test the TIMES intervention would be acceptable.

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

What does the study involve?
The TIMES study is a Randomised Controlled Trial. This means that participants will be randomly assigned to either the TIMES intervention OR treatment as usual. The study runs for 15 weeks. During that 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 approximately one hour each time. A family member, friend, or carer will help with this. If participants are assigned to the TIMES intervention group, they will be asked to attend a 30-minute and a 15-minute consultation with their GP to discuss their sleep disturbance. The family member, friend or carer will also attend these consultations. During these consultations, the participant's sleep difficulties will be discussed, and a plan will be developed to improve their sleep. Participants may also be asked to share their experience of the TIMES intervention through an optional interview and online questionnaire.

What are the possible benefits and risks of participating?
Whilst participation may or may not have direct benefits, taking part in this research could lead to improvements in the future understanding and treatment of sleep disturbance for PLWD/MCI.

Participating in the TIMES study carries minimal risks, such as possible emotional distress when discussing health concerns and changes to your sleep patterns, but the study team will be there to help if needed.

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

Where is the study run from?
The University of Exeter

When is the study starting and how long is it expected to run for?
June 2023 to July 2025

Who is funding the study?
The National Institute for Health and Care Research (reference: NIHR202345)

Who is the main contact?
Dr Jayden van Horik, University of Exeter, TIMES@exeter.ac.uk

Contact information

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Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
330115

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 60833, IRAS 330115

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 and sleep disturbance – a cluster randomised feasibility trial

Acronym
TIMES – Feasibility

Study objectives
The observational Tailored Management of Sleep (TIMES) study (WP1; https://www.isrctn.com/ISRCTN54015716) examined what is needed to deliver community-based tailored sleep management to individuals with dementia or Mild Cognitive Impairment and their carers (if they have one).

The hypothesis of this feasibility study (TIMES – Feasibility) is that it is feasible, acceptable and cost-effective to test an intervention that supports clinicians improve tailored care for sleep disturbance in people with dementia and mild cognitive impairment (TIMES) in primary care.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 15/03/2024, London - Harrow Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; None provided; harrow.rec@hra.nhs.uk), ref: 24/LO/0123

Study design

Randomized controlled feasibility trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Dementias and neurodegeneration

Interventions
Trial design:
- Feasibility study: to see if the intervention is acceptable to participants and GPs, sufficient numbers of participants can be recruited and engaged with the intervention, and sufficient data can be collected to assess improvement in sleep, general health and wellbeing, and economic evaluation.
- Two-Arm: There are two treatment groups, one will receive the intervention and the other will receive treatment as usual (control)
- Single-blinded: research practitioners collecting participant-reported outcome measures will not know which arm participants are allocated to GPs and participants will know which group they are in.
- Multi-centre: recruiting 8 GP practices.
- Cluster-Randomised Controlled Trial: Once all 8 participating GP Practices (sites) have been identified to participate in the study, half of them will be randomly allocated using a block design to deliver the intervention and the other half will deliver treatment as usual. Randomisation is therefore clustered by site, rather than at the participant level. This method allows more effective delivery of the intervention as GPs in the control group will not receive TIMES intervention training or access to the intervention materials.
- Complex Intervention: allows flexibility in how the 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 them, and who have sleep problems. 64 patient-carer pairs will be recruited in total, half will receive the intervention and the other half treatment as usual.
Recruitment:
- Pre-Screening- Patient medical records from their GP practice are used to identify patients with a diagnosis of dementia or mild cognitive impairment. Eligible patients sent expressions of interest emails or text messages with link sign-posting where to find more information about the TIMES study and who to contact. This is done by site administrative staff and ECLIPSE an NHS-approved data processor who has the approval to approach patients. Site administrative staff may also pone participants.
- Patient expresses interest in TIMES or contacts their participating GP practice for more information.
- Screening (non-invasive) - The research nurse or equivalent asks the patient about the carer's availability to participate in TIMES and, if available, assesses the patient and the carer's eligibility criteria.
- If eligible, the research nurse/clinician discusses the study with the patient & carer, provides PIS and ascertains capacity to provide informed consent.
- If eligible, has the capacity and is willing to take part - patient & carer informed consent obtained.

- If eligible, but patient lacks capacity - consultee identified, research nurse discusses the study with the patient (to their ability) and consultee and obtains consultee's opinion of patient's wishes.
- The consent form includes the option to choose to participate in an audio-recorded process evaluation interview and online questionnaire.
Baseline assessment:
- Participants are contacted by a nurse via phone or in-person to administer questionnaires. Questionnaires take PLWD/MCI and carer each approximately one hour to complete
- Patient and carer questionnaires: Demographics, residence status (own home or care home), contact details
- Patient (PLWD/MCI) medical records: Diagnosis, comorbidities; current prescribing; laboratory reports; alcohol intake;
- Patient questionnaires: daytime sleepiness; quality of life; health; wellbeing; service use.
- Carer questionnaires (proxy reports on behalf of the PLWD/MCI): Sleep disturbance; activities of daily living; quality of life; health; neuropsychiatric symptoms; service use; cognition
Treatment allocation:
- TIMES intervention: Patient and carer to complete a brief questionnaire about their general well-being and sleep (online via text message, email or phone call); attend 30-minute in-person consultation with their GP to co-develop a tailored care plan; attend a second 15-minute in-person consultation with their GP to review the tailored care plan.
- Treatment as usual: standard NHS care Follow-up assessments:
- Patient and carer to complete the same assessments as at Baseline, 9 weeks and 15 weeks later, either on the phone or in person with a clinical researcher.
Optional participation (from patients, carers, or healthcare professionals, if consent is provided):
- 45-60 min encrypted audio-recorded interview to share thoughts and experiences about using the intervention (Process Evaluation); held with TIMES researcher over the phone or in-person. The audio recording will be securely uploaded to the University of Exeter and then deleted from the audio recorder.
- 20-minute online survey about preferences in using the intervention (Discrete Choice Experiment)

Intervention Type
Behavioural

Primary outcome(s)
This is a Feasibility study that is aimed at determining whether a subsequent full-scale definitive trial should proceed.
Feasibility trial outcome measures are measured using data collected in study records:
1. The proportion of people in a primary care setting who meet the following criteria (per 1000 registered patients):
1.1. PLWD/MCI with problematic sleep disturbance
1.2. PLWD/MCI with problematic sleep disturbance who also have a professional or family carer
1.3. PLWD/MCI with problematic sleep disturbance who also have a professional or family carer and meet other trial eligibility criteria
2. The proportion of eligible people who consent to participate in the study
3. The proportion of consented participants in the intervention arm who start the intervention
4. The proportion of consented participants in the intervention arm, who start the intervention and complete all three stages of the intervention: Assessment in Context (SADL); Co-created Tailored Plan consultation; and Review and Revise consultation
5. The proportion of consented participants who remain in the study until final follow-up at 15 weeks

6. The proportion of consented participants who remain in the study and provide valid outcome data for clinical and health-economic measures, including the putative primary outcome for a definitive trial (see below) at 9- and 15-week follow-ups
7. The acceptability of the intervention as assessed through the process evaluation using an online or in-person interview and an online survey at the end of the study
8. Mean and standard deviation, plus between-group mean difference with 95% confidence interval and Intraclass Correlation Coefficient (ICC) for the proposed primary outcome of the definitive trial (and any proposed outcomes that may be key secondary outcomes for which a power calculation is performed), used to verify or revise the proposed primary outcome and sample size calculation for the definitive RCT

Proposed Clinical Outcome Measures for a Definitive Trial:
Primary Outcome: Sleep disorders measured using the Sleep Disorders Inventory (SDI) at Screening, and the 9- and 15-week follow-ups

Key secondary outcome(s))
The following secondary outcome measures are assessed at baseline, and the 9- and 15-week follow-ups:
1. Day-time sleeping/dozing behaviour measured using the Epworth sleepiness scale (ESS)
2. Daily living measured using the Activities of Daily Living (ADL): Assessed with the Disability Assessment for Dementia (DAD)
3. Quality of life measured using the Dementia Quality of Life Measure (DEMQOL)
4. Wellbeing measured using the EQ-5D 5 level
5. Wellbeing and quality of life measured using the ICEpop Capability measure (ICECAP-O)
6. Neuropsychiatric symptoms measured using the Neuropsychiatric Inventory Questionnaire (NPI-Q)
7. Health and social care service use measured using the Client Service Receipt Inventory (CSRI)
8. Non-visual cognitive assessment completed over the phone using the Telephone Montreal Cognitive Assessment (T-MoCA)

Completion date
31/07/2025

Eligibility

Key inclusion criteria
Patient participants (PLWD/MCI):
1. Aged >18 years old
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 sleep problems of any type that are considered problematic 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 (see section 6.2 carer definition)
7. Able to communicate in English sufficiently well to complete the outcome measures and questionnaires
8. Has the capacity to provide informed consent OR has a personal or professional consultee who is able to provide favourable opinion on behalf of the PLWD/MCI

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

Participant type(s)
Patient, Carer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
23

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 the 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 >3 weeks during intervention and follow-up (i.e approximately the next 4 months)

Date of first enrolment
01/05/2024

Date of final enrolment
31/03/2025

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
NIHR CRN: South West Peninsula
F7, Bowmoor House, Royal Devon and Exeter Hospital (Wonford)
Exeter
United Kingdom
EX2 5DW

Study participating centre
NIHR CRN: East of England
Floor 4, Rouen Road
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NR1 1QQ

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
The datasets generated during and/or analysed during the current study will be stored in a publicly available repository housed by the University of Exeter. The datasets generated and/or analysed during the current study will be published as a supplement to the results publication

IPD sharing plan summary
Stored in publicly available repository, Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 2	08/03/2024	19/03/2024	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes