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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

Submission date
19/07/2022

Recruitment status
No longer recruiting

Registration date
05/08/2022

Overall study status
Ongoing

Last Edited
05/08/2022

Condition category
Mental and Behavioural Disorders

[X] 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
Sleep disturbance often affects people living with dementia (PLWD) or mild cognitive impairment (MCI) and can cause carers stress. Sleep medicines help some people, but these can be harmful or stop working if used long-term. For some people, non-medicine treatments, given either on their own or in combination with tablets, may be better. Help needs to be tailored, meaning that doctors, patients, and carers should work together to find the best solution.

PLWD/MCI and their carers told us that sleep problems matter to them. They helped develop our idea about the importance of tailored care and have told us they want to continue to work with us to complete the research.

We will develop and test a tool to help PLWD, MCI, carers and professionals produce tailored care plans around sleep. We also want to reduce the harm from sleeping medicines. From previous research, we know some but not all of the elements a tool would need. Using expertise from people with lived experience, we will fill the gaps with this new research. We will work together with PLWD, MCI, carers and professionals to design a tool that supports a tailored approach to managing sleep.

We hope to improve health and wellbeing for PLWD or MCI who have sleep problems.

We will produce summaries for different audiences. Dementia and professional organisations will help us prepare and share resources for PLWD, MCI carers and healthcare professionals that help them with tailored sleep care.

Who can participate?
• Health professionals who work within one of the six collaborating GP sites in England and can

provide fully informed consent for consultations to be observed.
• People living with dementia (PLWD) or mild cognitive impairment (MCI) or their carers who have a diagnosis of dementia or MCI and have been allocated a relevant ICD-10 SNOMED code.
• Participants must be able to provide informed consent/consultee assent for observations to be observed.
• We will not conduct observations of consultations with patients under 18 years of age.
• There will be no exclusion for gender, age or ethnicity for healthcare professionals or PLWD /MCI/carers.

What does the study involve?
We will observe consultations from collaborating GP practices. A researcher will observe interactions between patients, staff and carers, as well as observe clinical care, staff meetings and, quality improvement activities within the GP surgeries. This will help us to understand if and how practitioners and practices currently manage tailored healthcare at a consultation level. We will work in collaboration with GP sites to try and ensure that patients who have booked appointments on the day of the ethnography research are aware that they may be asked if it is OK for a researcher to sit in on their consultation.

Participants with PLWD/MCI and their carers, and healthcare professionals from the collaborating GP practices will also be invited to attend a 90-minute focus group, involving discussions about things which might help or hinder tailored care plans for sleep difficulties. Focus groups will be conducted either face-to-face (i.e. GP practice) or virtually (Zoom/Microsoft Teams), depending on the participants preferences. Each group will have no more than six people in it, one of whom will be a researcher who will guide the discussion.

GP practices across England will also be requested to complete surveys about how a proposed intervention to improve tailored sleep management may be achieved in people with PLWD/MCI.

What are the possible benefits and risks of participating?
Benefits: There are no direct benefits to taking part; however, from our previous research we often get feedback from participants saying they enjoyed speaking about their experiences. Your views will also help us develop the TIMES approach which we hope will improve the health and wellbeing of people.

Risks: You will need to give up approximately 90 minutes of your time. There will be at least a 10-minute break, or more if needed. Talking about dementia or MCI can be hard and some people may find it upsetting. If you do become upset, we will take a break and you will be able to talk to the facilitator in confidence if you wish.

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

When is the study starting and how long is it expected to run for?
February 2022 to January 2027

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK).

Who is the main contact?
Dr Jayden van Horik, TIMES@exeter.ac.uk
Professor Chris Fox, christopher.fox@exeter.ac.uk

Contact information

Type(s)
Scientific

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Type(s)
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
313504

Protocol serial number
CPMS 52981, NIHR202345, IRAS 313504

Study information

Scientific Title
Tailored Management of Sleep (TIMES) for people living with dementia or mild cognitive impairment (MCI) in the community who experience sleep difficulties.

Acronym
TIMES

Study objectives
To examine what is needed to deliver community-based tailored sleep management with individuals with
dementia or Mild Cognitive Impairment and their carers (if they have one).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 29/06/2022, Wales REC 6 (Floor 4, Institute of Life Science 2, Swansea University, Swansea, SA2 8PP, UK; +44 2920 230457; Wales.REC6@wales.nhs.uk), ref: 22/WA/0148

Study design
Observational qualitative

Primary study design
Observational

Study type(s)
Other

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

Interventions
Our research design uses 3 data collection methods to enable us to explore the depth and breadth of the topic:
1. Intial ethnographic work allows us to study (observe) in depth the presence or absence of tailored management of healthcare in older people living with chronic illness. We will observe if and how staff work with patients with complex needs to tailor care
2. The focus groups allows us to focus our understanding of tailored management for people living with dementia, and especially sleep problems. Focus groups with staff will allow us to critically explore and understand what we have observed, and then focus our work on examining if and how the observations can be applied to the specific management of PLD and sleep management. We will conduct separate groups with staff and patients
3. Our final survey design enables us to gather a breadth of data from across the service to understand if the depth findings from our observation apply in wider health service settings. The survey will be sent only to staff

The aim of the ethnographic work is to observe if and how health professionals do tailored care for long-term conditions/complex illnesses for the general population but with a particular interest for older people (given that dementia predominantly affected older people). Ethnography is particularly well suited to research based within primary care as it allows the researcher to capture intricate and naturally occurring social interactions.

Healthcare professionals will consent for the researcher to sit in on relevant consultations. The number of consultations observed for each healthcare professional is flexible and will be determined by the professionals themselves. It is anticipated that the researcher will spend two days in each GP site (6 GP sites will be recruited in total) carrying out the ethnographic work. GP sites will choose the days the researcher attends.

Patients of the GP surgery will be asked whether it is OK for the researcher to observe their consultation. Once the consultation has finished, there will be no further contact with the patient.

Focus groups will allow us to explore in-depth barriers and enablers to tailored care, including sleep management in PLWD/MCI. Both healthcare professionals and PLWD/MCI/carers will be asked to take part in one 90 minute focus group. There will be at least a 10 minutes break during focus groups and more if needed.

The survey element of the research will then allow us to examine the generalisability of observational and focus group findings within the wider UK primary context. Primary care professionals will be asked to complete the survey once.

Preparation for the research will begin in April 2022 with an ethics submission. From June to August 2022, we will carry out the preparation of setting up collaborating GP sites. From September 2022 to March 2023, we will conduct the ethnographic work. Running in parallel to the ethnographic work, the focus groups and survey will be undertaken between November 2022 to June 2023. The TIMES programme theory will be refined in July 2023 and findings will inform work package 2.

In the majority of qualitative research, there is a risk of researcher bias. The research team are experienced with both ethnographic and focus group work and measures to mitigate researcher bias will be implemented at both the design (e.g. assigning trained researchers to undertake observations) and analysis (e.g. practicing ongoing self-reflection regarding objectivity) stages.

Focused ethnography: observation of 6 GP sites, including up to 30 consultations between health professionals and PLWD/MCI, 5 from each site.
Focus groups: 24 primary care professionals, 36 PLWD/MCI or current carers of PLWD/MCI.
Survey: We aim to collect responses from 200 healthcare professionals who work within GP sites.

Our aim is for maximum variation sampling rather than a statistically representative sample. For observations and focus groups, we believe the proposed numbers will provide us with sufficient data to answer our research questions. In reference to the survey, we are aiming for around 200 responses (which was the response rate we achieved in a previous similar study). A low uptake will not have statistical consequences relating to the progress of the research programme but may impact on the generalisability of our understanding of sleep disturbances in those living with dementia/MCI.

The TIMES programme bid was designed after conversations with PLWD/MCI and carers. PPI consultation with 12 carers from Together In Dementia Everyday (TIDE) and 10 PLWD/MCI from

the Dementia Engagement and Empowerment project (DEEP), told us that sleep disturbance in dementia is a major priority. The PPI representatives wanted better help for sleep problems and feared ‘abandonment’ through reducing or stopping sleep medication. We continue to value PPI input during the design/set-up of the research. One of our co-applicants, Mr George Rook, is living with dementia and is part of DEEP and the Lived Experience Advisory Panel for Dementia UK (LEAP). George is a core member of our research team and has helped to develop this protocol and the associated supporting documents (e.g. the participant information sheets (PIS), consent forms etc.). TIMES is also proactively promoting
equality and diversity throughout the research programme. We are collaborating with DEEP and TIDE who have a significant reach into ethnic minority groups, particularly the Chinese community through Chinese Wellbeing and the Chinese Welfare Trust. We have used these networks to recruit PPI from different ethnic groups and the protocol/supporting documents have been co-designed with them.

Intervention Type
Other

Primary outcome(s)
1. Clinicians' understanding of the value, nature and impact of tailored healthcare, for PLWD and MCI, measured using qualitative interviews
2. How tailored care fits into individual and collective everyday practice (if at all), measured using qualitative interviews
3. Factors/resources that enable or prevent the delivery of tailored care to PLWD and MCI (exploring Data, Explanation and Trust whilst also remaining open to other concepts), measured using qualitative interviews
4. Whether clinicians learn from and develop their practice, measured using qualitative interviews

Analysis: We will examine the generalisability of observational and focus group findings through a study-bespoke version of the NoMAD tool (theoretically derived 23-item instrument for assessing implementation processes of NPT-informed practice). NoMAD assesses anticipated and actual barriers to implementation by describing participants’ views about how an intervention impacts on work, and expectations about whether it could become a routine part of daily activity. We will use inductive analysis to generate themes representing barriers and enablers to tailored sleep management. Themes will be mapped to NPT concepts to describe how, based on observation of current practice, tailored sleep management may be achieved in context.

Key secondary outcome(s))
There are no secondary outcome measures

Completion date
31/01/2027

Eligibility

Key inclusion criteria
Ethnographic work:
1. GP Surgeries: We are aiming to recruit 6 sites in England with a purposeful target to work with one urban and one rural surgery, a single practice and a practice that is part of a network. When selecting GP surgeries, we will be mindful of population demographics and ethnicity to ensure

we have an inclusive sample representation. The CRN will facilitate us in screening, approaching and recruiting GP sites.
2. Participants: Inclusion criteria for health professionals taking part in the ethnographic work is that they work within one of the collaborating GP sites and can provide fully informed consent for consultations to be observed. The inclusion criteria for patients is that they can provide informed consent/consultee assent for observations to be observed.

Focus Groups
3. Healthcare professionals: Any healthcare professional working in a participating GP site can take part in the focus groups (e.g. GP, nurse, pharmacist, dietitian physician associate).
4. PLWD/MCI: Individuals with a diagnosis of dementia or MCI who have been allocated a relevant ICD-10 SNOMED code.
5. Carers: Recruited through snowballing via PLWD/MCI participants.
There will be no exclusion for gender, age or ethnicity for healthcare professionals or PLWD/MCI /carers.

Survey
6. We seek responses from any healthcare professionals (doctors, nurses, pharmacists, nurse associates, physician associates) who would deliver tailored primary care within the UK. We will use our existing network of professional contacts, including the Society Academic Primary Care partners, to distribute our invitation and the link to our survey widely.

There will be no exclusion for gender, age or ethnicity.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Ethnographic work: Observations with patients under 18 years of age.
2. Focus groups: Non-English speakers and formal carers in receipt of payment for their work.
3. Survey: Healthcare professionals outside the UK

Date of first enrolment
01/09/2022

Date of final enrolment
30/06/2023

Locations

Countries of recruitment
United Kingdom

Study participating centre
University of Exeter
College of Medicine and Health
College House
St. Luke's Campus
Exeter
United Kingdom
EX1 2LT

Study participating centre
University of Hull
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Study participating centre
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Sponsor information

Organisation
University of Exeter

ROR
https://ror.org/03yghzc09

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF)

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 current data sharing plans for this study are unknown and will be available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Participant information sheet	Consultee information sheet version 1.0	03/05/2022	28/07/2022	No	Yes
Participant information sheet	For healthcare professionals version 2.0	28/06/2022	28/07/2022	No	Yes
Participant information sheet	For lived experience focus groups version 2.0	28/06/2022	28/07/2022	No	Yes
Protocol file	version 1.1	20/05/2022	28/07/2022	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes