UNIVERSITY OF EXETER

TITLE PAGE

Tallored ManagEment of Sleep (TIMES) for people living with dementia or mild cognitive impairment (MCI) in the community who experience sleep difficulties.

Times
Tallored ManagEment of Sleep

Short study title/acronym: Tallored ManagEment of Sleep (TIMES) for people with dementia/mild cognitive impairment

HRA PROTOCOL AND COMPLIANCE DECLARATION

This protocol has regard for the HRA guidance and order of content (From Final Version 1.1 March 2016 - Qualitative Protocol Tool)

Protocol version number and date: V1.0_03.05.22

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UCL
UNIVERSITY OF HULL
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NHS Norfolk and Waveney Clinical Commissioning Group
UNIVERSITY OF LEICESTER
UEA University of East Anglia
Aston University
UNIVERSITY OF OXFORD

RESEARCH REFERENCE NUMBERS

IRAS number: 313504

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SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirement.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor.

I also confirm that I will make the findings of the study publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

For and on behalf of the Study Sponsor:

Signature:

Date:
03/05/2022

Name (please print): Ms Pam Baxter

Position: Research Governance Manager (Health & Social Care)

Chief Investigator:

Signature:

Date:
03/05/2022

Name: Professor Chris Fox

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PLEASE NOTE: This ethics application refers to one specific work package (WP) of a five-year NIHR programme grant – WP1b. WP1b will be led by Professor Joanne Reeve, Dr Andrea Hilton and Dr Anne Killett. The tables which follow describe the key study contacts for the entire TIMES programme. The Programme Steering Committee, Programme Management Committee and Patient and Public Involvement (PPI) Committee will have oversight of and input into WP1b and so are listed in full below.

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STUDY SUMMARY

Study Title	TaIlored ManagEment of Sleep (TIMES) for people living with dementia or mild cognitive impairment in community care: Describing the conceptual framework for a new complex intervention
Short title	TaIlored ManagEment of Sleep (TIMES) for people with dementia/mild cognitive impairment
Study Design	Developing a realist programme theory to define the core components of a new complex intervention for sleep management in people living with dementia (PLWD) or mild cognitive impairment (MCI) – the TaIlored Management of Sleep (TIMES) approach. Through synthesis of data generated using mixed methods – Focused ethnography, observations, focus groups, national survey, realist review, and stakeholder engagement.
Study Participants	General practice (GP) site staff, PLWD or MCI, carers of PLWD or MCI.
Planned Size of Sample (if applicable)	**Focused ethnography:** observation of 6 GP sites, including up to 30 consultations between health professionals and patients, 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.
Planned Study Period	June 2022 – May 2023
Research Question/Aim(s)/Objectives	**Research questions:** 1. What do clinicians understand as the value, nature, and impact of tailored healthcare, for PLWD and MCI? 2. How does tailored care fit into individual and collective everyday practice (if at all)? 3. What factors/resources enable or prevent the delivery of tailored care to this PLWD/MCI? (Exploring Data, Explanation, and Trust (Figure 1) whilst also remaining open to other concepts). 4. How do clinicians learn from and develop their practice? **Aims:**

	To describe enablers and barriers to tailored management of healthcare needs for PLWD/MCI, including sleep disturbances. **Objectives of WP1b:** 1. To recruit a purposive sample of staff, PLWD/MCI and current carers involved in healthcare decision making for PLWD and MCI. 2. To observe actions and impacts of whole-person (tailored) healthcare for this group, with particular reference to sleep management. 3. To describe PLWD/MCI, carer, and professional perceptions of delivery of tailored care for this group (how achieved; enablers and barriers), with particular reference to sleep management. **4.** To synthesise empirical findings with explanatory findings from a realist review (secondary analysis - WP1a of five-year TIMES programme) of published data to generate a new conceptual framework (programme theory) outlining the tailored management of healthcare for PLWD/MCI with specific reference to sleep management.

FUNDING AND SUPPORT IN KIND

FUNDER(S)	FINANCIAL AND NON-FINANCIAL SUPPORT GIVEN
NIHR Programme Grants for Applied Research	£2,349,999.00
British Geriatrics Society	Letter of support
Royal College of Psychiatrists	Letter of support
NIHR Applied Research Collaboration East of England	Letter of support
Alzheimer's Society	Letter of support
Prescribing Service	Letter of support
Together in dementia every day (TIDE)	Letter of support
Norwich Clinical Trials Unit	Letter of support

ROLE OF STUDY SPONSOR AND FUNDER

The University of Exeter is the study sponsor. Responsibility for all aspects of study design, initiation and management, conduct, data analysis and interpretation, manuscript writing, and dissemination of results will be delegated to the Chief Investigator. The sponsor controls the final decision regarding any of these aspects of the study.

ROLES AND RESPONSIBILITIES OF STUDY MANAGEMENT COMMITEES/GROUPS & INDIVIDUALS

The steering groups described in this protocol provide an overview of the whole five-years TIMES programme. WP1b, the sole focus of this application, will be presented for scrutiny to each of these groups at key stages.

GROUP	ROLES AND RESPONSIBILITIES
Programme Steering Group (PSG)	Provide overall supervision for the TIMES project on behalf of our Sponsor and Funder and to ensure that our research is conducted to the rigorous standards set out in UK Policy Framework for Health and Social Care Research Guidelines for Good Clinical Practice. This will be convened in accordance with NIHR guidelines to oversee and advise the research team from an external perspective. The Committee will include around 12 members, representing stakeholder groups, clinical practitioners (e.g. General Practitioner, Pharmacist, Psychiatrist, Admiral Nurse, Allied Health Professional), 1-2 commissioners (capturing health, social care and integrated services commissioning), social care (e.g. social worker, provider of home care and of care home) two carers, two PLWD/MCI, 2 third-sector organisation representatives (e.g. TIDE (dementia carers organisation), the Alzheimer's Society) and advisors who bring methodological expertise (trialist, health economics, implementation, qualitative methods). It will be chaired by an independent expert (Simon Coulter). The PSG will meet twice per year and will be attended by all members of the core research team (CI, Study Co-Organiser, Co-investigators).
Programme Management Group (PMG)	To assist the day-to-day management of the project. The study will be delivered across four work packages over five years (Feb 2022 – Feb 2027). The University of Exeter have set up collaborative agreements between all partner organisations to detail each partner's specific responsibilities and role. A PMG co-chaired by the CI (Chris Fox) and the Study Co-Ordinator (Leanne Greene) will be responsible for overseeing reports and high-level monitoring delivery against study objectives. Chris Fox will mentor and supervise Leanne Greene in her academic leadership role. The PMG will meet monthly with research team members and PPI advisors identified and independently supported by Rachael Litherland (Innovations in Dementia), George Rook (Dementia Engagement and Empowerment Project [DEEP]), Ruth Eley (TIDE]) Joanne Reeve, Anne Killett, Geoff Wong and Yoon Loke to ensure effective project management across all sites and that key work package milestones are met. Three research co-leads, Joanne Reeve, Andrea Hilton and Anne Killett, who are experienced qualitative methodologists, will oversee WP1b. The study is supported by University of Exeter research delivery policies available at: http://www.exeter.ac.uk/research/services/governance/governance/. Pam Baxter, Research Governance Manager at University of Exeter is

	Sponsor representative, responsible for overall oversight/project management, financial reporting, and adherence to university and national ethical and quality polices. The PMG's activities will be supported by Study Co-Ordinator, Leanne Greene, and the Research Fellows (TBA) who are responsible for day-to-day activity coordination. This group will be responsible for writing and submitting NIHR progress reports, ethics reports and amendment approvals.
Patient and Public Involvement (PPI) group	To ensure our research is being carried out 'with' or 'by' members of the public rather than 'to', 'about' or 'for' them. Roles and responsibilities will include, but are not limited to, offering advice as members of the PSG and/or PMG, commenting on and developing research materials, co-design and dissemination. Some members will have full independence from Sponsor and Investigators, others will not be independent. PPI member recruitment will encompass participant selection aimed at including diversity of members in the group. Equality, Diversity and Inclusion leads include Dr Geoff Wong, Dr Yoon Loke, Ms Di Burbidge (Chinese Wellbeing) and Mr Shahid Mohammed (TIDE).
International Advisory Panel on Sleep in Cognitive Impairment and Dementia	Members will offer expertise and feedback on the data that emerges from our development phase. Some members full independence from Sponsor and Investigators, others are not independent.

PROTOCOL CONTRIBUTORS

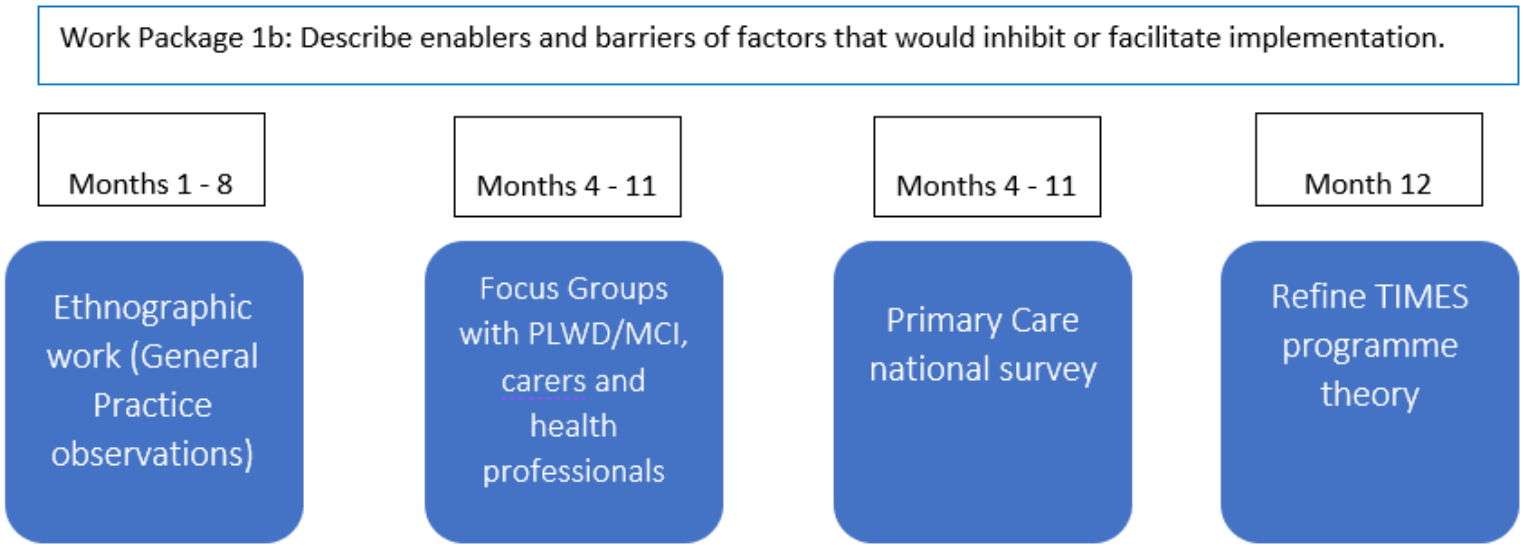
Contributors to the protocol	**Roles and Responsibilities**
Funder Contact	Corresponding contact: Saima Siddiqui, Programme Manager for Research Programmes (PGfAR) at the NIHR Central Commissioning Facility (CCF). TIMES was a researcher led proposal submitted to the NIHR PGfAR funding stream. The bid was submitted to NIHR staff and independent peer review to assess the need for the research; the quality of the design; and the feasibility of delivery (including study team and resource requested). The funder judged TIMES to be an important study worthy of funding. The funder checked the quality and relevance of the research including dissemination. The funder has not defined/dictated study design, conduct, data analysis and interpretation, manuscript writing, and dissemination of results.

Sponsor & Sponsor Representative	The University of Exeter is the Sponsor for the research and responsible for overall oversight/project management, financial reporting, and adherence to university and national ethical and quality polices. The Sponsor will check the quality and relevance of the research including dissemination. The Sponsor will not define/dictate study design, conduct, data analysis and interpretation, manuscript writing, and dissemination of results but will support and oversee the entire research process. Pam Baxter, Research Governance Manager (Health & Social Care) at University of Exeter is Sponsor Representative contact.
PPI protocol design	The TIMES programme bid was designed after conversations with PLWD/MCI and carers. PPI consultation with 12 carers from 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.

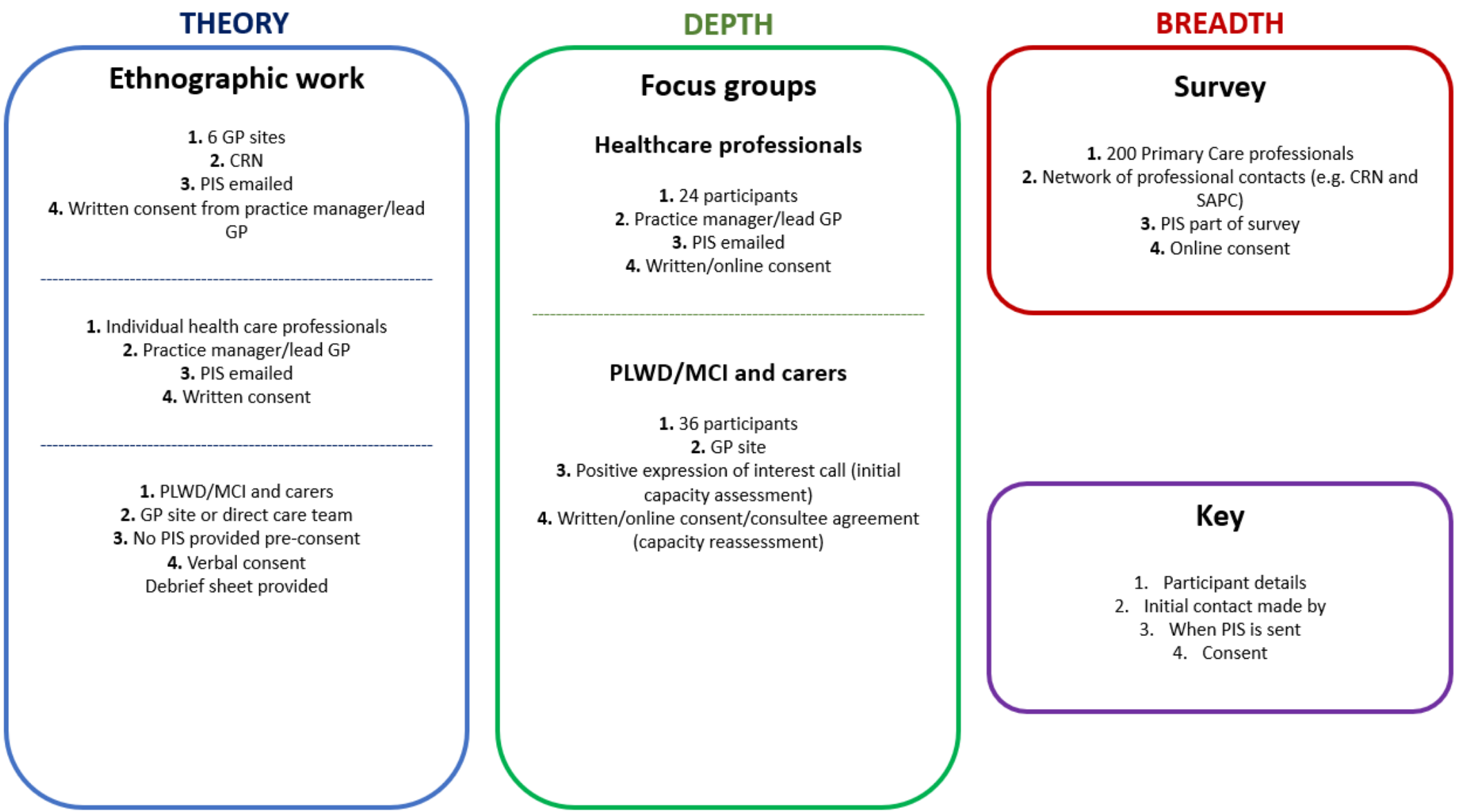
KEY WORDS

Dementia, mild cognitive impairment (MCI), carer, healthcare professional, sleep disturbance/problem/issues, primary/community care, GP.

STUDY FLOW CHARTS



Task	Month 1	Month 2	Month 3	Month 4	Month 5	Month 6	Month 7	Month 8	Month 9	Month 10	Month 11	Month 12
Ethnographic work (General Practice observations)												
Focus Groups with PLWD/MCI, carers and health professionals												
GP national survey												
Refine TIMES Programme Theory												


THEORY
Ethnographic work
1. 6 GP sites
2. CRN
3. PIS emailed
4. Written consent from practice manager/lead GP
1. Individual health care professionals
2. Practice manager/lead GP
3. PIS emailed
4. Written consent
1. PLWD/MCI and carers
2. GP site or direct care team
3. No PIS provided pre-consent
4. Verbal consent
Debrief sheet provided
DEPTH
Focus groups
Healthcare professionals
1. 24 participants
2. Practice manager/lead GP
3. PIS emailed
4. Written/online consent
PLWD/MCI and carers
1. 36 participants
2. GP site
3. Positive expression of interest call (initial capacity assessment)
4. Written/online consent/consultee agreement (capacity reassessment)
BREADTH
Survey
1. 200 Primary Care professionals
2. Network of professional contacts (e.g. CRN and SAPC)
3. PIS part of survey
4. Online consent
Key
1. Participant details
2. Initial contact made by
3. When PIS is sent
4. Consent

STUDY PROTOCOL

Tallored ManagEment of Sleep (TIMES) for people living with dementia or mild cognitive impairment in community care: Describing the conceptual framework for a new complex intervention

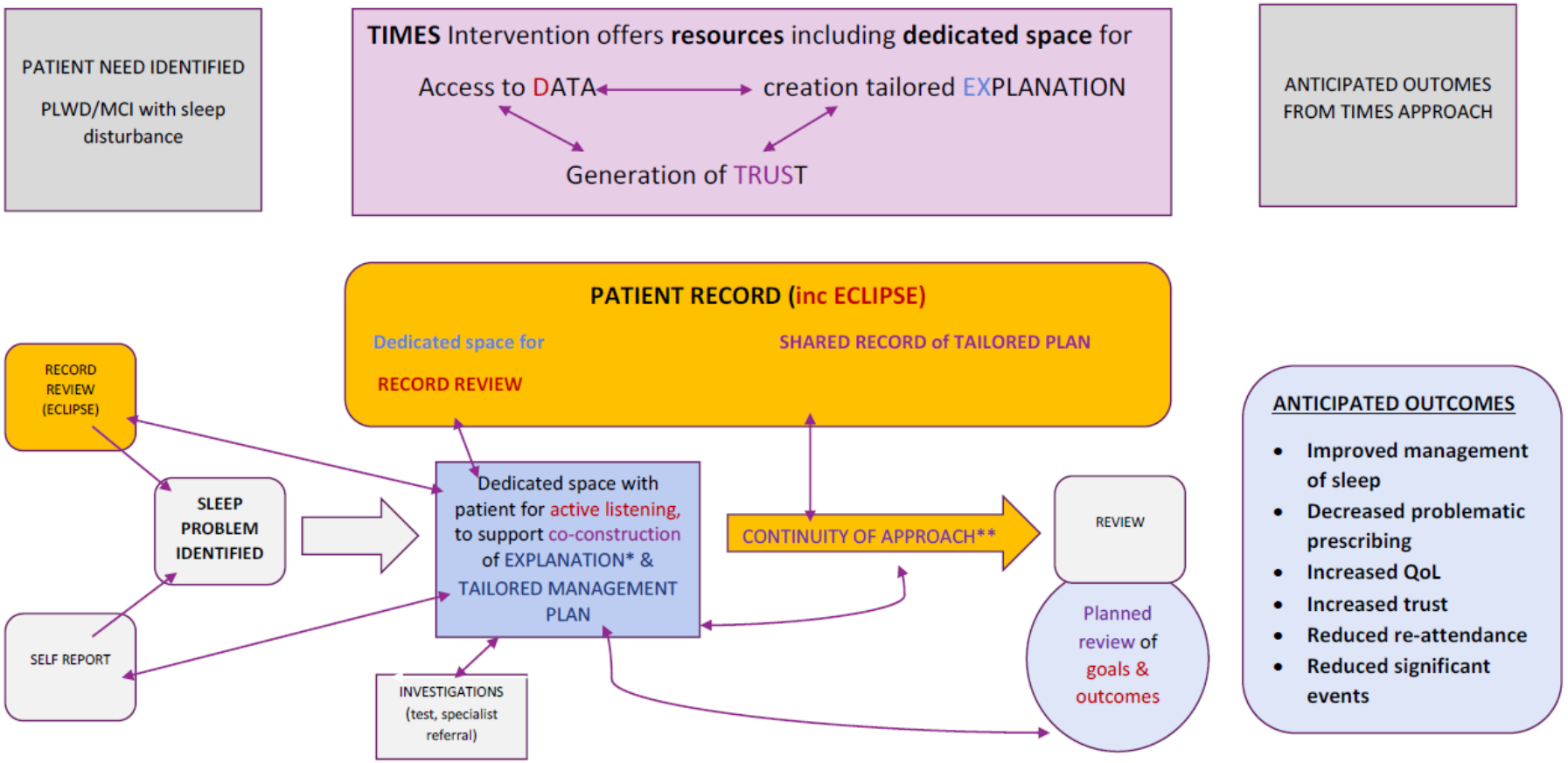
1. BACKGROUND

The Tallored ManagEment of Sleep (TIMES) for PLWD or MCI and sleep disturbance is a five-year NIHR funded research programme. Our previous work using Normalisation Process Theory (survey design) has described four context barriers to tailored medication use in primary care (Figure 1).[1] In follow up work, we described practice-based resources needed to support implementation of complex interventions, including flexibility of approach and expertise for knowledge translation (mixed methods including observation, interview & focus groups, survey).[2] Based on our previous work, a recent review of the literature, and stakeholder input, we have an outline model (draft TIMES programme theory) describing the clinical work involved in the development and delivery of tailored approaches to managing sleep problems in PLWD and MCI (Figure 2). We offer this model as the basis for a new tailoring sleep management tool for clinical practice. The project consists of four WP which will be completed over the five years (start date 01.02.22). The TIMES project is designed to refine through research, piloting and implementation and to overall evaluate the impact of this new model of care. This ethics application is **solely for WP1b** (12 months of work), which will develop an evidence-informed logic model (programme theory) for the new intervention, incorporating data from mixed methods (i.e. focused ethnography, observations, focus groups, national survey, realist review, and stakeholder engagement). We will briefly mention WP1a and WP2 for context purposes.

In WP1a, we will systematically and critically analyse and refine/redraft the TIMES programme theory (Figure 2) based on a realist review (secondary analysis of published data) to describe when, how and for whom tailored care in sleep management might work. WP1a is **NOT** the focus of this ethics application as it will only use secondary data, rather than collecting primary data. Alongside WP1a, WP1b aims to explore the current in-practice enablers/barriers to tailored sleep management in populations living with dementia/MCI. Synthesis of data/findings from the two WPs will describe the conceptual framework for a new complex sleep intervention. This approach is in line with the Medical Research Council's 'Complex Intervention' guidance which highlights the importance of robust theoretical development for successful research outcomes.[3]

Please see Appendix 1 for a brief outline of the TIMES five-year programme.

FIGURE 1. Outlining the TIMES Intervention supporting DExTrus tailored sleep management

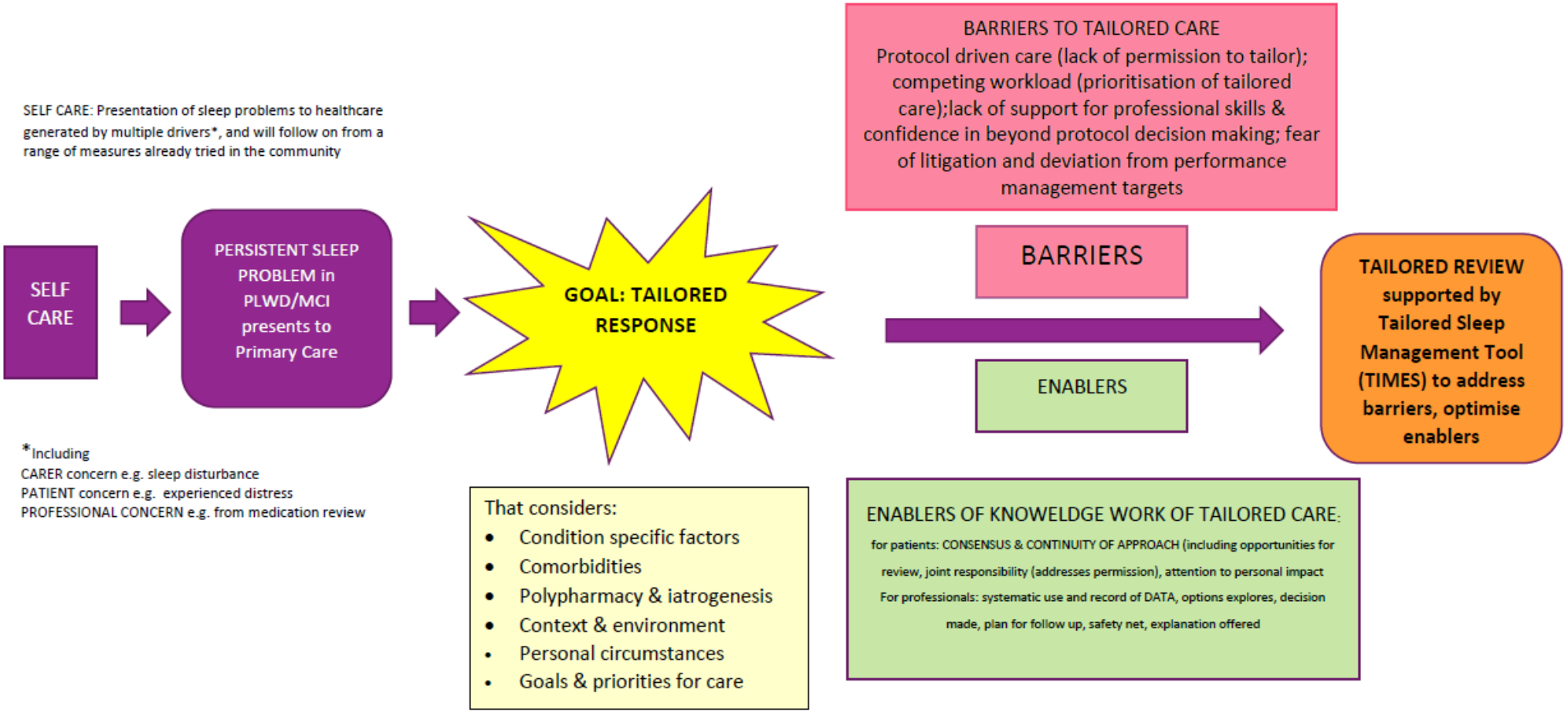


COLOUR CODE: Usual care in grey ; Times RESOURCES in orange ; TIMES DEDICATED SPACES in blue

*Based on consideration of biomedical, biographical, and professional mindline (guidelines in professionals head- Gabbay 2016) data

**Supported through shared record

FIGURE 2: An evidence informed overview of what is needed for sleep disturbance in PLWD/MCI



The theoretical framework for WP1b is Normalization Process Theory (NPT). NPT provides a conceptual framework for understanding and evaluating the introduction implementation and embedding of new complex interventions in health care (implementation) and monitoring how well these new practices are sustained (integration).[4] NPT describes that for clinicians to implement and sustain new ways of working, the new model must make sense to them, they must engage with the new model, have the skills and resources to deliver the work required and get feedback that enables/encourages them to continue the new model. NPT thus supports the systematic identification of professional, practice and system elements needed to implement the principles of tailored care 'on the ground' in GP surgeries. Previously, NPT has been helpful in supporting the design of complex healthcare interventions.[4, 5]

WP1a and WP1b will run in parallel to each other with frequent cross-reference. The concepts described by the emerging programme theory from WP1a will be used to stimulate in depth empirical exploration during WP1b. The empirical work (WP1b) will inform the realist reviews data interpretation. Both WP1a and WP1b will generate a set of data principles and options that define the successful delivery of tailored care for PLWD/MCI experiencing sleep problems. These concepts will be utilised in WP2 (co-design) for consensus building around what the TIMES intervention looks like in practice.

2. RATIONALE

The research questions/aims being addressed are important because sleep problems are common in PLWD (20- 90%) and MCI (18.3–45.5%).[6-10] Both the current literature[11-13] and conversations with our PPI collaborators have highlighted that sleep disturbance for PLWD or MCI is a serious issue. Problems with sleep can involve disturbance to the quantity, quality, and timing of sleep, and can stem from physical or psychological conditions.[14] Poor sleep can also be exacerbated by factors such as age-related changes in the circadian rhythm, medication side effects, and co- morbidities.[15] Sleep disturbance in dementia and MCI populations has been associated with poorer daily functioning and behavioural/psychological disturbances[11, 16] which impacts caregivers.[17]

Sleep management in dementia and MCI populations is complex, requiring a multidisciplinary understanding and tailored approach that considers individualised priorities and actions. Licensed sleep medications are not recommended for individuals with dementia/MCI and may be associated with adverse events[18], although many are prescribed these. From our previous work, PLWD fear 'abandonment' through reducing or stopping sleep medication. Therefore, sleep management is a 'wicked design problem' because the issue is complex, the knowledge required to understand and address it includes multiple disciplines and subject expertise, and because interventions do not 'fix' but rather support best management in context.[19, 20]

We are going to gather data to better understand what sleep disturbance means in dementia and MCI, diagnosis, assessments, and interventions/management used for sleep disturbance in dementia and MCI, their 'active ingredients', how they were implemented, what measures were used, and to what extent they worked; for whom and why. We are interested in data from PLWD and MCI at home, in assisted living, or in a care home and their carers and the primary/community healthcare professionals who assess/manage sleep disturbances. Findings are important for informing and refining theoretical

models describing the intervention components needed to support individually tailored optimisation of care in the context of sleep disturbance in dementia and MCI populations.

We know that current models/guidance are not sufficient to support complex, tailored care within primary care. But we lack strong theoretical models needed to develop new ways of working. Medical Research Council guidance recognises this as a vital first step to developing better tailored interventions.[3] The findings from WP1a and WP1b are needed to refine the intervention components necessary to support individually tailored optimisation of care in the context of sleep disturbance in dementia/MCI populations. Our data will, therefore, need to consider what sleep disturbance means for PLWD/MCI (what they need); its impact on diagnosis, assessments and management of both dementia/MCI and sleep problems. We will examine best practice to identify 'active ingredients', how they were implemented, and to what extent they worked; for whom and why. We are interested in data from PLWD/MCI at home, in assisted living, or in a care home and their carers and the GP site healthcare professionals who assess/manage sleep disturbances.

Therefore, to supplement the conceptual findings identified from secondary analysis of existing data (Wp1a) we will collect new data from professional patients and carers to understand if and how tailored care is delivered, enablers and barriers, and what is needed to enhance care.

3. THEORETICAL FRAMEWORK

The theoretical framework for this study is Normalization Process Theory (NPT) and is described section 1 (background). The new way of working recognised in our study highlights tailored management of care, in this case, sleep problems for PLWD/MIC. Matching explanations and care to the distinct needs of individuals and their personal circumstances can require health professionals to go beyond protocol delivery of care. Tailored care is an example of understanding guidelines as "guidance not tramlines".[21] For an individual, best care may not follow a single pathway of care described within evidence-based pathway guidance/protocols.

Health professionals have previously described that delivering tailored, 'beyond protocol' care is a challenge in modern healthcare settings[22]. In our recently completed Tailor Medication Synthesis (TAILOR) project (NIHR HTA 17/69/02), we identified four potential enablers/barriers to tailored care in reference to medication prescribing; (i) the need for appropriate data, (ii) resource to support generation of explanation, (iii) the use and maintenance of trust, (iv) and supportive infrastructure (see Figure 1). Existing evidence[23] describes the knowledge work done by health professionals to use evidence in daily practice to create practice-based evidence (mindlines) from externally generated scientific evidence.

TIMES will support healthcare professionals and PLWD/MCI, and carers in the generation, implementation, and evaluation of tailored interpretations of illness and healthcare need. TIMES seeks to describe a framework by which healthcare professionals and PLWD/MCI, and carers can be supported to co-develop and implement tailored care. NPT predicts that for a new intervention to become integrated into usual practice, there needs to be continuous investment by all parties in four areas of work. These include:

1. Making Sense of the intervention: everyone must understand how the intervention is distinct from other ways of working and why it matters
2. Engagement: individuals and collectively people must commit to do the work of the new practice
3. Action: people must have the skills and resources to deliver the new way of working
4. Monitoring: people must get feedback which reinforces and encourages this way of working

Previously, NPT has been helpful in supporting the design of complex interventions.[4, 5]

In WP1b, we will use NPT to identify practice-based data on how professionals currently manage the knowledge work of tailored care. Findings will be synthesised/integrated with the WP1a realist review to describe the core components of a new complex intervention supporting tailored care for sleep problems for PLWD/MCI.

4. RESEARCH QUESTION/AIM(S)

1. What do clinicians understand as the value, nature, and impact of tailored healthcare, for PLWD and MCI?
2. How does tailored care fit into individual and collective everyday practice (if at all)?
3. What factors/resources enable or prevent the delivery of tailored care to this patient group? (Exploring Data, Explanation and Trust (Figure 1) whilst also remaining open to other concepts)?
4. How do clinicians learn from and develop their practice?

4.1 Objective

To critically develop and describe what is needed to deliver community-based tailored sleep management safely and effectively with individuals with dementia/MCI and their carers (if they have one).

4.2 Outcome

To describe an integrated care (GPs, pharmacy, community, social, patient and carer) model of tailored sleep management based on empirical work. To generate a set of data principles and options that will combined with findings from WP1a and utilised in WP2 (co-design) for consensus building around what the TIMES intervention looks like in practice.

5. STUDY DESIGN AND METHODS OF DATA COLLECTION AND DATA ANALYIS

5.1 Design and Methods

Data collection: (1) observational and focus group data will be used to explore contextual factors in depth, (2) survey data using the NoMAD tool will provide breadth.[4, 24, 25]

We will examine if and how tailored health care is delivered in general to PLWD/MIC in GP practices, with a focus on sleep management issues. Analysis will identify any difference in the application of principles and practice for sleep management compared with other health issues.

1. Ethnography (observational data)

The aim of the ethnographic work is to observe if and how health professionals do tailored care for long-term conditions/complex illness for the general population but with a particular interest for older people.

To understand individual and organisational processes, enablers, and barriers to tailored care management of sleep problems we will use:

- Focused ethnographic study using standard methods in general practice contexts to understand if and how practitioners and practices currently manage tailored healthcare at the level of the consultation.[26] Ethnography is particularly well suited to research based within primary care as it allows the researcher to capture intricate and naturally occurring social interactions. [27]
- Observation of clinical care, staff meetings, and quality improvement activities to understand practice and policy level influences on practice. We will purposively sample 6 GP sites in England (inclusion variables: urban/rural, single practice/part of a network, population demographics and ethnicity). We anticipate up to two days of observation in each practice. We will contact practices to identify when and how they organise clinical complex patient and care home review consultations/sessions, and also when they run team/MDT meetings. We will aim to visit practices on two separate occasions - to observe focused clinical practice, and to separately observe team meetings and practice management discussions. We will seek to identify if and how necessary components for tailored care (figure 1) are currently delivered in practice.
- We will arrange to shadow key healthcare staff to observe interactions between patients, staff and carers which consider patient-defined healthcare needs. We will not restrict observations to consultations addressing sleep issues or dementia/MCI.
- We anticipate observing up to 30 consultations (5 from each of the 6 practices) will provide us with sufficient data to analyse and draw conclusions from.
- We will also attend non-patient contact events with the staff we are shadowing including staff meetings (e.g. multidisciplinary staff meetings), informal coffee discussions, and practice meetings.
- During observations, the researcher will discreetly make detailed field notes to capture their observations. The field notes will be the data which the team will analyse using inductive analysis.
- This work will be led by a University of Hull Research Fellow and supervised by Professor Joanne Reeve, Dr Andrea Hilton, and Dr Anne Killett who both have experience facilitating ethnography research.

2. Focus group data

To explore in-depth barriers and enablers to tailored care, including sleep management in PLWD/MCI, we will:

- Develop topic guides informed by WP1a and ethnography findings
- Pilot topic guides with GP site healthcare staff (e.g. Pharmacist, General Practitioners, Nurses) and PPI collaborators (up to 6) covering the target focus group population
- Healthcare professionals from collaborating GP sites will participate in one 90-minute focus group.
- PLWD/MCI and carers (patients from collaborating GP sites) will be recruited to take part in one 90-minute focus group.
- Focus groups will explore experiences of delivering/receiving tailored care, including consideration of how components described in our draft programme theory model (Figure 2) or identified in WP1a are, or could be, delivered in practice; identify any missing elements; and seek to explain the observations identified in practice, including any variation across sites.

- This work will be led by a University of Hull Research Fellow and supervised by Professor Joanne Reeve, Dr Andrea Hilton, and Dr Anne Killett who all have experience facilitating focus groups.
- The focus groups will be tape recorded on a digital recorder and transcribed by a University of Hull approved transcription service.

3. Survey data

The research groups previous work using NPT (survey design) has described four context barriers to tailored medication use in primary care.[1] In follow up work we described practice-based resources needed to support implementation of complex interventions, including flexibility of approach, and expertise for knowledge translation (mixed methods including observation, interview & focus groups, survey).[2] This research will extend these findings into the context of tailored sleep management. We will examine the generalisability of observational and focus group findings within the wider UK primary context through the development and use of:

- A study-bespoke version of the NoMAD tool (theoretically derived 23-item instrument for assessing implementation processes of NPT-informed practice).[1, 4, 26, 28] NoMAD is a validated tool for assessing 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. The generic tool has been designed to be adapted and applied to critically examine individual projects. We have undertaken such surveys successfully in previous studies.[1, 2]
- The questionnaire has been adapted from the NOMAD[29]/NPT toolkit[4] tools by the research team and will be piloted with a small sample of GPs and pharmacists to ensure it is useable.
- Data collection will be via an on-line participant completed survey using the piloted NoMAD tool. The invitation, PIS, consent recording and data collection will all be incorporated within the survey tool on JISC.
- Sampling frame will be CRN and Education & Cost-analysis Leading to Improved Prescribing Safety & Efficiency (ECLIPSE)[1] who will circulate invitations and links to the tool. Invitations will also be circulated on Twitter and via newsletters including by the SAPC.
- This work will be led by a University of Hull Research Fellow and supervised by Professor Joanne Reeve, Dr Andrea Hilton and Dr Anne Killett who both have experience facilitating NPT research.

5.2 Analysis

Ethnographic work and focus group data

Inductive analysis will generate themes describing the process of barriers and enablers to tailored sleep management. A constant comparison approach will also be applied with a focus on deviant cases to

- [1] ECLIPSE is a new computer system designed to optimise prescribing by utilising powerful computerised technology interfacing with primary care computer systems. ECLIPSE has over 2000 practices.

explain differences. Themes will be mapped to NPT concepts to describe how, based on observation of current practice, tailored sleep management may be achieved in context. Analysis will remain open to additional concepts not recognised by NPT. The research team will conduct all the analyses for WP1b. NVivo (version 20) will be used to analyse data. All data will be transcribed by an approved University of Hull transcription service and participant data will be fully de-identified before data is sent.

Survey data

We will follow a traffic lights approach which we have successfully used in our previous work[30] and which is based on the framework analysis approach.[31] Using SPSS (version 28.0.1.6), we will report a descriptive analysis of the participants including; who has responded to the survey and the extent to which participants recognise a need for tailored care. We will analyse the data to look for evidence of anticipated and actual facilitators to implementation of new interventions (marked as green), anticipated barriers (amber) or actual barriers (red) in each of the four domains described by NPT[4]. We will analyse the free text responses using a constant comparative approach[30] to identify enablers and barriers to tailored care.

6. STUDY SETTING

The CRN will support us in finding GP sites where the data will be collected. GP sites will facilitate two aspects of WP1b, (i) ethnographic work and (ii) focus group.

Ethnographic work will take place in 6 GP sites. We aim to use focused ethnography for up to 30 consultations within GP sites, 5 from each of the 6 GP sites. Observations of consultations will help us to understand if and how practitioners and practices currently manage tailored healthcare at a consultation level. We will observe interactions between patients, staff and carers. We will also observe clinical care, staff meetings and, quality improvement activities within the GP surgeries.

The CRN will help us to recruit GP sites. We will purposively sample 6 sites in England (inclusion variables: urban/rural, single practice/part of a network, population demographics and ethnicity). We anticipate up to two days of observation in each practice. We will contact practices to identify when and how they organise clinical complex patient and care home review consultations/sessions, and when they run team/MDT meetings. We will aim to visit practices on two separate occasions - to observe focused clinical practice with this patient group, and to separately to observe team meetings and practice management discussions. 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. This could be done through text services, a note on the GP website or receptionists mentioning the research during telephone calls. We hope this approach will allow participants more time to decide if they would mind a researcher sitting in on their consultation. This endeavour will be led by the GP sites and will be based on their capacity, resources, and preferences. The research team will provide the GP site with a script so they can briefly explain what the research is aiming to achieve.

Focus group participants will be recruited via the six GP sites who undertook the ethnographic work. The sessions will be approximately 90 minutes long and will be held with 24 healthcare professionals (4 per the 6 collaborating GP sites) and 36 PLWD/MCI or current carers of PLWD/MCI (6 per the 6 collaborating

GP sites). An email invitation will be sent to all eligible healthcare staff via the Practice Manager/Lead GP. The PIS will also be added as an attachment. Healthcare professionals will be given at least one week to respond, and a follow up email will be sent if there are insufficient numbers. GP sites will identify potential dates which will be suitable to conduct focus groups. PLWD/MCI will be identified by the practice using International Classification of Disease (ICD) 10 SNOMED codes (systematically organized computer-processable collection of medical terms which provide codes (e.g. 26929004), terms (e.g. Alzheimer's disease), synonyms and definitions used in clinical documentation and reporting). The GP site will post research invitations, which will include a copy of the PIS, to eligible participants who will directly contact the research team if they are interested in finding out more information. As there is a possibility that practices may be large and as we are limited to places in the focus group, the practice will randomly split the list of eligible participants and send invitations out in batches of 30 until six individuals (PLWD/MCI or carers) provide a positive expression of interest. For pragmatic reasons, no follow-up will be made for PLWD/MCI/carers who do not respond to the initial letter. Focus groups will be conducted either face-to-face or virtually, depending on the participants preferences. If conducted face-to-face, it is anticipated that the group would be held in a suitable room at the GP practice and government guidelines concerning COVID-19 would be adhered to. Focus groups will explore if and how components described in our draft model (Figure 3) or identified in WP1a (realist review) are, or could be, delivered in practice; identify any missing elements; and seek to explain the observations identified in practice, including any variation across sites.

Surveys

The NoMAD tool will be sent to GP practices across England through CRN contacts and ECLIPSE (which has 2000 practices). We will work with SAPC partners, regional RCGP, pharmacy, First Five and other continuing professional development networks to raise study awareness and invite participation. We will also utilize social media to engage survey recruitment.

7. SAMPLE AND RECRUITMENT

7.1 Eligibility Criteria

Ethnographic work:

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.

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.

We will not conduct observations of consultations with patients under 18 years of age.

Focus Groups

Health professionals: Any health professional working in a participating GP site can take part in the focus groups (e.g. GP, nurse, pharmacist, dietitian physician associate).

PLWD/MCI or carers: Individuals with a diagnosis of dementia or MCI who have been allocated a relevant ICD-10 SNOMED code.

There will be no exclusion for gender, age or ethnicity for healthcare professionals or PLWD/MCI/carers.

Survey

We seek responses from any health professionals (e.g. 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.

7.2 Sampling

7.2.1 Size of sample

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[30]). 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.

7.2.2 Sampling technique

GP Surgeries

Purposive sampling will be used to recruit 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 which 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.

Focus Groups

Healthcare professionals: Purposive sampling will be used to recruit healthcare professionals. The sample will be derived from the collaborating GP surgeries. An email will be sent to all eligible staff in the GP surgery to ask if they would like to participate in a focus group.

PLWD/MCI or carers: The sample will be derived from the collaborating GP surgeries. Purposive sampling will be used to collate a list of individuals who have been diagnosed with dementia/MCI in collaborating GP sites. The lists will then be randomly split into groups of 30 and approached systematically until the

focus group quota is reached. Snowball sampling will be used to recruit carers of the PLWD/MCI participating in the focus group.

Survey
The sample will be derived from GP sites across England. Purposive sampling will be used to invite healthcare professionals via email to complete the survey.

7.3 Recruitment

GP Surgeries
The CRN will facilitate in the identification and recruitment of GP surgeries. The Primary Care Research Recruitment: A Practical Guide will be referred to by researchers during the recruitment of GP surgeries.[32] 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 which 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.

Focus Groups
Healthcare professionals: Will be identified through self-referral via a positive expression of interest to an email sent out via the Practice Manager/Lead GP. Any healthcare professionals within our collaborating GP sites are eligible to take part in the focus groups (e.g. GP, nurse, pharmacist, dietitian, social prescribers). The research team will then provide individuals with the PIS and take written informed consent (if group is face-to-face) or REDCap consent if the participant would like to continue or consent.

PLWD/MCI and carers: Will also be identified through self-referral via a positive expression of interest to a letter sent out via the collaborating GP site. The participant eligibility screening process has been described in section 7.1. The research team will then provide individuals with the PIS and take written informed consent (if group is face-to-face) or REDCap consent if the participant would like to continue or consent.

Survey
We will collaborate with the CRN, SAPC and ECLIPSE partners to distribute the survey. We will also use purposive social media platforms to invite health professionals to take part. Participants will be recruited through self-referral and will complete an online consent form.

7.3.1 Sample identification

GP sites for ethnographic work

The CRN will facilitate in the identification and recruitment of GP surgeries. When the practices are contacted, we will explain that we are interested to observe the care for people with long-term conditions/complex illness and to learn how their practice does this. The research team will liaise with GP

sites on an individual level prior to the research commencing (at least 1 week but we anticipate a longer period) to decide which days will be optimal to conduct the ethnographic work. This individualised approach and initial conversations will ensure that (i) we visit the GP site when health professionals interested in the research are working and (ii) the professionals are undertaking consultations which are likely to include long-term conditions/complex illness, with particular interest of older people (e.g. ward round for care homes, community based outreach appointments). We know that some practices have dedicated times/clinics where they schedule consultations for individuals with complex health needs and that these are usually led by GPs with a special interest in the area, advance nurse practitioners and physician associates. We envision that this early and open communication will prevent us from sitting in on 'protocol driven' consultations such as chronic disease check-up clinics. The research team will remain flexible, and the GP site will advise which days will work best. The Primary Care Research Recruitment: A Practical Guide will be referred to by researchers during the recruitment of GP surgeries.[32]

Focus Groups

Healthcare professionals: The Practice Manager or Lead GP will identify all eligible staff based on their knowledge of their own GP surgery. An email will then be sent to staff by the Practice Manger/Lead GP and participants will be identified through self-referral via a positive expression of interest.

PLWD/MCI carers: The GP site will run a search on their patient database using the ICD-10 dementia/MCI SNOMED codes. Once a list has been generated, the GP site will randomly split the list into batches of 30 and will systematically send letters of invitation out until the quota for the focus group is filled. During screening, identifiable personal information in patient records will only be seen by the potential participants direct clinical care team. The initial approach to potential participants will also be via their direct care team (i.e. a letter from their GP surgery). The potential participant will make a positive expression of interest to the research team via email or phone.

No participants will be recruited through Patient Identification Centres (PICs). The research team will NOT be accessing patient medical records.

Survey

The survey will be advertised via CRN, SAPC and ECLIPSE networks. We will also use purposive social media platforms to invite health professionals to take part. Participants will volunteer to take part on their own accord. No participants will be recruited through PICs.

Finance for sample identification and recruitment

Our funding covers site costs associated with study delivery (set-up meetings, administrative time), and NHS staff time. There is also financial cover for NHS staff time to attend focus groups and GP consent to be observed during consultations. If focus groups are face-to-face then reasonable travel expenses will be paid for healthcare professionals who travel to the GP surgery on their day off and for PLWD/MCI/Carers. Light refreshments provided by the research team will also be available during the focus group.

7.3.2 Consent

Ethnographic Work

GP sites: We will obtain individual health practitioner consent for those who take part in the observational data collection. The GP site decision maker and interested healthcare staff will be provided with PIS to allow them to make a fully informed choice about taking part. There will be time for discussion about the research and anyone interested in taking part will have sufficient time (at least one week if not more) to ask questions.

Patients: Again, consent will have two levels. Upon entering the consultation, PLWD/MCI and carers will be given a brief verbal overview of the research highlighting that we are observing examples of clinical care interactions between healthcare professionals and patients. Patients/carers will be asked if it is OK for the researcher to observe the consultation. If they agree then consent will be gained verbally before the consultation begins, similar to when healthcare professional trainees observe a consultation/procedure for learning purposes. It will be emphasised that the observation is voluntary, and patients will be provided the opportunity to say no. If they say no the researcher will leave the consultation. During the observation, the researcher will make detailed fieldnotes about the consultation, but in order to protect the rights and privacy of observed patients/carers, no personal details will be recorded. When the consultation ends, the patient/carer will be asked again if they are comfortable for their fieldnotes to be included in the analysis. Observations will NOT be video/audio recorded. The researcher will only engage with the patient/carer if they initiate a conversation. A de-brief sheet will be provided to the patient/carer at the end of the consultation explaining again what the objective of the observations are and highlighting important factors of the research. As consultations are typically very brief (approximately ten minutes) and we do not want the research to have a detrimental impact on the care of the patient we will not be formally assessing capacity. If it is evident that the PLWD/MCI does not have the mental capacity to provide informed consent then we will be guided by the consultation lead/carer and any sign of dissent will be respected.

Focus Groups

Face-to-face: If focus groups are running face-to-face then written informed consent will be obtained on the day. Participants will have previously been sent a copy of the PIS to read (either via email or post) but printed copies will also be available on the day. The researcher will provide a paper consent form and make it clear that there is ample time before the focus group begins to discuss the research and ask any questions.

For PLWD/MCI, there is the possibility that they may lack the mental capacity to provide informed consent to take part in the focus group. We echo other researchers who strongly believe in the inclusion of adults who lack capacity to consent to research[33], highlighting the NIHRs INCLUDE initiative[34], and emphasising the argument that it is unethical to exclude adults who lack capacity from research.[35] Prior to the focus group, one of the researchers would have had an expression of interest telephone call with the PLWD/MCI or their carer to discuss the research and determine if they would like further information posted/emailed. During this call, the researcher will assess the individual's level of capacity through informal conversations. Using a conversational and person-centred approach applied in other research[36],

the researcher will sensitively ask the PLWD/MCI questions about the research to determine (i) their understanding of the purpose of the research, (ii) their understanding of what the research involves, benefits, risks and burdens, (iii) their understanding of alternatives to taking part and, (iv) their ability to retain the information in order to make an informed and voluntary decision. If the researcher feels that the PLWD/MCI lacks the capacity to provide informed consent, then they will sensitively raise the topic of a personal/professional consultee. On the day of the focus group, the researcher will again informally and briefly check if the PLWD/MCI is capable of making the decision to take part in the focus group. If they are then written consent will be obtained and if they are not a consultee agreement will be obtained.

Remote:

If focus groups are run remotely (via Microsoft Teams or Zoom based on participants preferences) then consent will be obtained online via REDCap Cloud. Participants will have previously been sent a copy of the PIS to read (either via email or post). Similar to the face-to-face process, an expression of interest phone call will be made to participants beforehand, and capacity of the PLWD/MCI will be assessed.

Although we appreciate that there is a digital divide which affects older adult use of technology, evidence suggests that many older adults utilised online information and technology during COVID-19.[37, 38] The research team will facilitate the online consent and video call via telephone and email support.

Survey

The surveys will include a short introductory paragraph containing sufficient information to enable potential participants to reach an informed decision about whether to complete the survey or not. There will be a link to the study website where further, more detailed information about the study, the research team and updates on findings can be found, as well as the TIMES study email address so the team can be contacted directly at any time. Participants will be asked to complete an online consent form before they begin the survey via the JISC link.

8. ETHICAL AND REGULATORY CONSIDERATIONS

Obtaining valid informed consent

Based on the extensive experience of the research team, specific ethical issues will relate to obtaining valid informed consent from PLWD and their family/friend supporters. There are also ethical issues around consent for ethnographic research. A detailed description of obtaining informed consent/consultee agreement for the current research is in section 7.3.2.

General Data Protection Regulations and Data Protection Act 2018

The research will adhere to the UK GDPR and Data Protection Act 2018 regulations when managing or sharing personal details.

PPI

The research team will involve PPI teams throughout WP1b, for example, reading sections of the protocol, co-designing the PIS and consent forms, analysing the data and in dissemination activities.

8.1 Assessment and management of risk

We anticipate that the likelihood and the consequences of harm for this study will be very minimal. However, we recognise that with every research project there is risk and burden and we have outlined these below.

Length of focus group

We appreciate that 90 minutes is a long time to have a meeting. There will be at least a 10 minutes break during focus groups and more if needed.

Pressures on PLWD and carers

We discussed the physical, emotional and logistical pressures PLWD and carers face when enrolling in research and the best practices for trying to minimise this. PPI representatives informed and contributed to identifying the practicalities of arranging face-to-face meetings more appropriately to different needs. They also advised that offering flexible options (e.g. telephone interviews or online evaluation) could often be less least burdensome to their daily lives. This feedback has contributed to the methods proposed in this study, and collaboration with PPI representatives will continue at each stage of the project.

Distress

Living with dementia/MCI or caring for someone who has dementia/MCI can be hard. There is a chance that individuals may become upset when discussing issues around dementia. If this happens, the participant will be asked if they are happy to continue with the research and supported to stop/leave if they wish. However, previous work has shown PLWD/MCI often enjoy speaking about their experiences, as this can prompt feelings of inclusion and personhood. Similarly, family supporters of PLWD/MCI can derive benefit from talking about their life with their loved one with someone independent from the situation.

Staff Burden

Staff may view the research (e.g. making participants aware about ethnographic research or the staff survey) as an additional burden to their day-to-day work. Every effort will be made to reduce this burden. For example, the survey will be designed to be as brief as possible (whilst still collecting the required information). The survey will be piloted in house within the sponsor/collaborating organisations with ease of completion and potential burden in mind, and adjustments made to the design where necessary.

Expenses incurred by the participants:

If focus groups are running face-to-face, travel expenses will be reimbursed.

Confidentiality

All information collected from participants will be kept confidential. Participants will not be identifiable in any reports, findings, or materials published from the study. The only reason confidentiality may be broken is if a participant says something that raises concerns that they or someone else may be at risk. If this happens, appropriate steps will be taken, and an appropriate professional will be alerted within their

GP site. This will be clearly explained to participants and if confidentiality does have to be broken for this reason, they will be fully informed of what is happening and the reasons for this.

Anonymity

All participants will remain anonymous throughout the course of the study. Data will be anonymised before analysis, with each participant given a unique code to identify them. Any personal data collected will be kept on secure servers, on a spreadsheet in a separate folder to other study data.

Ethical implications of working with PLWD/MCI and fluctuating capacity

PLWD/MCI will be supported wherever possible to participate in the consultations and focus groups. If a person with dementia is not able to attend a focus group session, they will be supported to contribute to the group in another way e.g., via phone call or one-to-one meeting. Support will also be provided for people to access the group if it is held online e.g., by providing technical help sessions. The materials and content used in the groups will be made as clear and understandable as possible. It is important that the groups end on a positive note and that people feel they have made a meaningful contribution. At the end of each session, group members will be thanked, and time will be spent acknowledging their contribution.

Data protection

All research data will be held securely on the University of Hull server conforming to General Data Protection Regulations (GDPR) and Data Protection Act 2018. Identifiable paper information (e.g., information recorded on consent forms) will be kept in locked filing cabinets or in a separate electronic folder in a different location to all other data. Only the research team will have access to the data. At the end of the study, paper copies of any data, such as handwritten notes from group discussions, will be destroyed. Anonymised data will be securely stored at the University of Hull for 10 years. This is also covered in section 8.8.

COVID-19

With the uncertainty around the pandemic, we have employed a hybrid approach to research meaning that both remote and in-person techniques may be utilised, depending on participant preference and government guidelines. Remote research will be held online, using platforms such as Zoom or Microsoft Teams. Support will be provided for people who require it to access these platforms.

Discontinuation/Withdrawal of Participants from study

In line with GDPR guidelines, participants rights to access, change or move their information are limited, as the research team needs to manage information in specific ways in order for the research to be reliable and accurate. If participants withdraw from the study, the research team will keep the information they have already obtained. To safeguard the participants rights, we will use the minimum personally identifiable information possible. This process will be clearly outlined in the participant information sheet and the consent form.

Benefits

There are no direct benefits to participants, however, it is well documented that PLWD/MCI often enjoy speaking about their experiences, as this can prompt feelings of inclusion and personhood. Similarly, family supporters of PLWD/MCI can derive benefit from having conversations about their experiences. Discussions during qualitative research can often benefit individuals' self-acknowledgment, sense of purpose, and empowerment. Benefits for PLWD/MCI and sleep disturbances in the future may be a result of this research.

Conflict of Interest

There are no conflicts of interest for this research programme.

8.2 Research Ethics Committee (REC) and other Regulatory review & reports

Before the start of the study, a favourable opinion will be sought from a UK Research Ethics Committee and NHS Health Research Authority. Substantial amendments that require review by NHS REC will not be implemented until that review is in place and other mechanisms are in place to implement at site. All correspondence with the REC will be retained. The Chief Investigator will produce annual reports as required and will notify the REC of the end of the study. An annual progress report (APR) will be submitted to the REC within 30 days of the anniversary date on which the favourable opinion was given, and annually until the study is declared ended. If the study is ended prematurely, the Chief Investigator will notify the REC, including the reasons for the premature termination. Within one year after the end of the study, the Chief Investigator will submit a final report with the results, including any publications/abstracts, to the REC.

8.3 Regulatory Review & Compliance

Before any site can enrol patients into the study, the Chief Investigator or designee will ensure that appropriate approvals from participating organisations are in place. Specific arrangements on how to gain approval from participating organisations are in place and comply with the relevant guidance. Different arrangements for NHS and non NHS sites are described as relevant.

For any amendment to the study, the Chief Investigator or designee, in agreement with the sponsor will submit information to the appropriate body in order for them to issue approval for the amendment. The Chief Investigator or designee will work with sites (R&D departments at NHS sites as well as the study delivery team) so they can put the necessary arrangements in place to implement the amendment to confirm their support for the study as amended.

8.4 Amendments

The sponsor will submit a valid notice of an amendment to the REC for consideration. The sponsor will decide if an amendment is substantial or non-substantial for the purposes of the submission to the REC. If applicable, other specialist review bodies need to be notified about substantial amendments in case the amendment affects their opinion of the study. If necessary, amendments will also be notified to the national coordinating function of the UK country where the lead NHS R&D office is based and communicated to the participating organisations (R&D office and local research team) departments of participating sites to assess whether the amendment affects the NHS permission for that site.

Amendment history will be tracked as follows. The research team will maintain an ongoing list of potential protocol changes, both administrative and research substantive. To reduce paperwork and to keep processes contained, we will aim to batch protocol changes together in one amendment, when possible. In a clearly labelled folder, separate to the active version, we will maintain a working version of the protocol amendment where the proposed changes have been tracked. We will create a protocol amendment summary document for each amendment which will individually list the changes and the rationale behind them. Version numbers will be amended as so: substantial amendment to V1.0 becomes V2.0; non-substantial amendment to V1.0 becomes V1.1. Version numbers and version dates will be monitored closely. Amendments will be vetted through the research team.

8.5 Peer review

The TIMES programme has been subject to rigorous internal and external NIHR reviews which provide independent, expert, and proportionate peer review. The research has also been designed with PPI representatives to ensure the research is relevant.

8.6 Patient & Public Involvement

The TIMES programme bid was designed after conversations with PLWD/MCI and carers to ensure the research was acceptable and relevant. PPI consultation with 12 carers from TIDE and 10 PLWD/MCI from the 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 PIS, consent forms etc.). Other representatives from our PPI group have also been consulted about the design of the research and the current ethics application and supporting documents. PPI input will be valued throughout WP1b, and we aim to involve people with lived experience in a variety of research tasks including, but not limited to, focus group question development, analysis of data and dissemination.

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.

8.7 Protocol compliance

Accidental protocol deviations will be adequately documented on the relevant forms and reported to the Chief Investigator and Sponsor immediately. All members of the research team will be responsible for reporting protocol deviations. Deviations from the protocol which are found to frequently recur will receive immediate action and discussions with the Chief Investigator and Sponsor will decide if the deviation should be classified as a serious breach.

8.8 Data protection and patient confidentiality

All investigators and study site staff must comply with the requirements of the Data Protection Act 2018 with regards to the collection, storage, processing and disclosure of personal information and will uphold the Act's core principles. All research data will be held securely on the University of Hull server conforming to General Data Protection Regulations (GDPR). Identifiable paper information (e.g., information recorded on consent forms) will be kept in locked filing cabinets or in a separate electronic folder in a different location to all other data. Fieldnotes, focus group audio files and transcriptions, and survey data will be de-identified and the research team will create a depersonalised code where the participant's identifying information is replaced by an unrelated sequence of characters. The direct research team will have access to the data. Potential access may also be required by the Sponsor and regulators for monitoring and audit purposes. We aim to limit access to the minimum number of individuals necessary for quality control, audit, and analysis. At the end of the study, paper copies of any data, such as handwritten notes from group discussions, will be destroyed. Anonymised data will be securely stored at the University of Hull for 10 years under a Data Sharing Agreement arranged by the University of Exeter, as Sponsor. The data custodian is Professor Joanne Reeve, one of the leads for WP1b.

8.9 Indemnity

The University of Exeter will provide insurance and indemnity to meet the potential legal liability of the sponsor(s) for harm to participants arising from the management or design of the research. NHS insurance and/ or indemnity will be in place to meet the potential legal liability of investigators/collaborators arising from harm to participants in the conduct of the research.

8.10 Access to the final study dataset

Only the direct research team, Sponsor and regulators of the research will have access to the full anonymised dataset, limiting access to the minimum number of individuals necessary for quality control, audit, and analysis.

9. DISSEMINIATION POLICY

9.1 Dissemination policy

The University of Exeter will own the data arising from WP1b. On completion of the study, the data will be analysed and combined with findings from WP1a to inform the work for WP2. We also aim to write up the findings for a peer reviewed journal and may present results at relevant conferences. We will involve our PPI representatives during the analysis and dissemination activities. As our funding body, the NIHR will be acknowledged within all publications. Participants including GP sites as a whole) will be given the option during the consent process to be informed of the outcome of the study. We will notify participants of the findings from WP1b through email/post via a plain English summary and send PDFs of any published peer reviewed articles. We will also provide participants with the option of signing up to an annual newsletter which will be published throughout the TIMES programme.

9.2 Authorship eligibility guidelines and any intended use of professional writers

The study will grant authorship on study reports in accordance with The International Committee of Medical Journal Editors criteria:

- Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
- Drafting the work or revising it critically for important intellectual content; AND
- Final approval of the version to be published; AND
- Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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Appendix 1.
TIMES work package overview for five-year research programme

WP1a. Realist Review, months 1 – 18

What are the key factors influencing interpretation of sleep disturbance and so clinical decision making by clinicians, patients and carers in dementia or MCI?

WP1b. Ethnography (GP consultation observations), focus groups (people with dementia, carers, primary care staff, and primary care staff survey, months 1 – 18

What are in-practice enablers/barriers to tailored sleep management?

WP2. Co-design structure and implementation, months 13 – 25

What should be included in the intervention, who should deliver it and how?

WP3. Feasibility cluster randomised control trial, months 19 – 36

Is a randomised controlled trial (RCT) of this intervention feasible?

WP4. Cluster RCT with internal pilot, months 29 – 60
Is a system-embedded tailoring sleep management tool to improve outcomes of people living with dementia/MCI and sleep disturbance clinically and economically effective to implement from a health and personal social service perspective? Which intervention components provide benefit for which groups in dementia and MCI?

Appendix 2.
Amendment History

Amendment No.	Protocol version no.	Date issued	Author(s) of changes	Details of changes made