The TIMES Study – TaIlored ManagEment of Sleep for people with dementia/mild cognitive impairment

PLWD/MCI Participant Information Sheet

We would like to invite you to take part in a research study about sleep

This information sheet explains why the research is being done and what taking part would involve. Please take time to read the following information carefully. Talk to family and friends about the study if you wish. You can also ask us if there is anything that is not clear or if you would like more information.

Why is this research being done?

We would like to find ways to improve your sleep and make your life better

People living with dementia (PLWD) or mild cognitive impairment (MCI) often experience sleep problems. This can affect their well-being and the well-being of those who care for them. The TIMES study aims to improve our understanding and management of sleep disturbances in PLWD or MCI. TIMES involves a tailored health-plan, which is co-created by patients, carers, and their GP. By participating in this research, you will help advance our knowledge of sleep problems, and contribute to improving quality of life for PLWD or MCI.

Why have you been invited to take part?

We want to involve people who have been diagnosed with dementia or MCI and experience problematic sleep disturbance.

Do you have to take part?

No. It is entirely up to you to decide whether or not to take part. You do not have to give a reason if you do not want to be involved and your usual care will not be affected in any way. If you decide to take part and then change your mind later, that is fine too.

What would taking part in the TIMES 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 this time, we will ask you to complete some questionnaires about your sleep, health, and wellbeing. This will happen at the start of the study, and again at 9 weeks and at 15 weeks, and should take approximately one hour each time. Your family member, friend, or carer will help with this.
- If you are assigned to the TIMES intervention group, we will ask you to attend a 30 minute and a 15 minute consultation with your GP to discuss your sleep disturbance. Your family member, friend or carer will also attend these consultations.
- During these consultations, we will discuss your sleep difficulties, and develop a plan to improve your sleep.
- We may also ask you to share your experience of the TIMES intervention through an optional interview and online questionnaire.

If you are interested in taking part in this study, the nurse or GP will ask for the **contact details of a close family member, friend, or carer.** This is because everyone who takes part in this study also needs to have someone to help and support them. Your family member, friend or carer will also need to complete some questionnaires for the study. Some of the questionnaires they complete will be about you.

If you are happy to take part in this study, you will be asked **to sign a consent form**, and will be given a copy of this to take away. Copies of the consent form will be filed in your patient notes and trial records. Consent is required from both yourself **and** your carer in order to you (the patient/carer pair) participate in this study.

What are the risks and benefits of taking part?

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 you if needed.

The consent process to participate in this study will be completed by a qualified Research Nurse who is trained to assess capacity of potential participants and is familiar with the mental capacity act 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 participants GP.

Whilst participation may or may not have direct benefits for you, taking part in this research could lead to improvements in our future understanding and treatment of sleep disturbance for PLWD/MCI.

Where to find more information

If you are interested in learning more about the TIMES study, please continue to read the participant information leaflet below. You can also speak with a member of the study team from your GP practice for more information <insert name and email/phone no.>

What will happen next?

A nurse or GP will discuss this study with you and see if you have any questions. You will then be asked whether you would like to take part.

Your study pathway

<u>You and your family member, friend, or carer</u>

- Your GP practice has identified that you may be eligible to take part in this study.
- You will be contacted by a nurse from your GP Practice and asked to about your diagnosis of dementia or MCI and whether you experience sleep problems.
- You will go through a screening process to see if you meet the specific study criteria.

At home or care home

- If you meet the eligibility criteria, you will be contacted for informed consent. If you lack mental capacity, a family member, friend or healthcare professional may approached on your behalf to provide a favorable opinion that you would like to participate.
- You and your family member, friend, or carer, will participate in a baseline assessment to gather information about your health and wellbeing, demographics, and contact details. These assessments will be coordinated by a nurse.
- You and your family member, friend, or carer, will be randomly allocated to both take part together in one of the following two groups.
    - **Take part in the TIMES intervention:** you and your family member, friend, or carer will participate in two consultations with your GP to co-develop a tailored care-plan to improve your sleep disturbance.

OR

- **Receive Treatment as Usual**

Follow up at home or care home

- At **9** and **15 weeks** after your baseline assessment, you and your family member, friend, or carer, will be asked to complete some questionnaires about your sleep, health and wellbeing.
- Assessments will be done by a nurse, over the phone, video call, or in-person if you are living in a care home, and will take approximately 60 minutes to complete each time.
- We will include regular breaks, and you can choose to stop the assessments at any time.

Optional interview and online questionnaire

- If you are interested, a researcher will contact you by phone, video call, or in person, to ask about your experience of participating in the study
- The interview will take no more than **1 hour**
- If you are interested, we will send you an email or text, with a link to a brief survey about your preferences in using the TIMES intervention.

At the end of the study

- The study ends when the questionnaires are completed after 15 weeks.
- **Your care will continue as normal and your involvement in the study will be complete**

Further information about the study

Optional Interviews

We are inviting people to provide feedback on their experience of participating in the TIMES intervention. The interview is an **optional** part of the study. **All interviews will be audio-recorded**. You and your family member, friend or carer can still take part in the study without participating in an interview. Interviews will be carried out by telephone, video call, or in-person (depending on your preference). An anonymised version of the audio recording will be typed up and analysed. Quotes from interviews may be used in research publications, but will be anonymised so no one will be able to identify you from them. This will all be done by a trained and authorised member of the study team from the University of Hull or University of East Anglia.

Optional Online Survey

We are inviting participants to fill out an online survey to gather information about **their preferences** of the TIMES intervention. This will help us better understand how you would prefer the TIMES intervention to be delivered. Participating in the online survey is **optional** and you can still take part in the TIMES study without responding to the online survey.

If you decide to participate, the survey will take between **10 to 20 minutes to complete at baseline and at the 15-week follow-up**. We will send you a secure weblink to the survey by text or email. This will be done by ECLIPSE, a nationally accredited provider for the NHS that is authorised to securely manage NHS clinical records on behalf of GPs at your GP Practice.

What type of study is TIMES?

This is a feasibility study. This means it involves a small number of people that will help us determine whether people with dementia or MCI with sleep problems feel that the TIMES intervention is helpful. Findings from this study will help us to improve procedures for a much larger study in the future.

What will this study tell us?

- If it is **possible to carry out a much larger study** in the future called a 'clinical trial' to find out if the TIMES intervention effectively improves sleep disturbance for people living with dementia or MCI.
- If it is possible to provide the intervention to **patients in primary care**
- If any parts of the intervention should be **changed or improved**

Will you receive any payment?

You will not be paid for taking part in the study.

Stopping participation in the study

What if you change your mind about taking part?

Your participation in the study is **voluntary**. You can leave the study at any time without giving a reason. However, if you are willing to share your reason it could help us make improvements in the future. You can also choose to stop some parts of the study and continue with others. For example, you may wish to stop participating in the intervention but continue with the questionnaires.

If you choose to stop taking part in the study, **we would like to continue collecting information** about your health from central NHS records, your friend, family member or carer, and your GP. This will help improve the quality of the study. If you do not want this to happen, please tell us and we will stop. **Your care will not be affected in any way, should you choose to stop taking part in this study at any time.**

A family member, friend or carer will take part in the study with you. If they decide to stop taking part, we will ask you if there is another person who could be invited to take part in their place.

If you decide to stop taking part in the study but your family member or friend decides to continue, we will ask you if it is ok for them to continue completing the questionnaires about you. You can say no to this.

We may withdraw you from this study

There are certain situations where we may need to withdraw you from participating in this study. This will primarily be if your safety, well-being, or adherence to the study protocol is compromised, or if you experience prolonged adverse events. In such cases, we will prioritise your safety and inform you promptly, ensuring a smooth transition out of the study.

If your family member, friend, or person who provides care for you withdraws from the study at any stage, and you wish to continue with the study, we will seek another eligible carer to participate in the study. If no replacement carer participant is identified, then you will also be withdrawn from the study. This is because a carer participant is required to support your participation in the study and is needed to help complete the assessments.

During the study, **if you lose your ability to make decisions for yourself** (this is officially known as lacking mental capacity), we will approach your family member/friend, carer or GP to seek their opinion on whether you would wish to continue in the study. They, or your medical care team, may advise that you be withdrawn from the study if they think it is in your best interest.

How will we use information about you?

The University of Exeter is the Sponsor for this trial. We are responsible for looking after you and your information and using it properly. Your data will be stored and used in compliance with data protection legislation. In 2018 changes in the way that data is processed came into force, with the EU General Data Protection Regulation 2018 (GDPR) and the Data Protection Act 2018 (DPA 2018). Since the UK left the EU, key principles of EU GDPR have been adopted in a UK-only version (UK GDPR) and the DPA 2018 still applies. The University of Exeter's lawful basis to process personal data for research is for 'public interest'.

We will need to use information from you, your medical records, and your GP for this research project. This information will include your name, date of birth, NHS number and contact details. We will also collect information from the NHS records your doctor keeps about health conditions and medicines. The information we collect will help us to understand your sleep problems and what kind of care might help you. People will use this information to do the research or to check your records to make sure that the research is being done properly. This may include people from your participating GP practice, authorised data processors from ECLIPSE, regulatory authorities where it is relevant to the research, and authorised collaborators in the TIMES study team from the University of Exeter, University of Hull, and University of East Anglia.

Your GP may need to refer you to a different NHS service provider for some parts of the study. If this is the case, your information will be securely transferred so they are able to contact you and deliver the service.

If you receive the TIMES intervention, we will ask you and your carer about your sleep problems. This will help your GP develop a care-plan for you. This information will be collected by a data processing company used by your GP practice called ECLIPSE, and will be linked to your patient records. ECLIPSE, is a nationally accredited provider for the NHS, which is authorised to securely manage health data and provide healthcare

and safety programmes. ECLIPSE will remove any information that could be used to identify you and will then share the dataset with researchers at the University of Exeter.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a unique code number instead. We will keep all information about you safe and secure. Information collected about you for the trial ('trial data') will be entered onto a trial database hosted by the University of Exeter. This information will not contain identifiable information and you will be identified by a code number. The University of Exeter will also store electronic or scanned copies of your consent form, which will include your name. This will be kept on a separate secure database from the trial data, with restricted access.

If you agree to take part in the **interview**, we will **audio-record it**. All information collected during the interview will be kept strictly **confidential** and stored either on an encrypted password protected computer, or in a locked cabinet in a secure office at the University of Hull. Audio recordings will be transcribed by authorised members of the study team from the University of Hull, where they will also be anonymised. Quotes from interviews may be used in research publications, but will be anonymised so no one will be able to identify you from them. The Researcher will upload encrypted audio-recordings of interviews at their earliest opportunity via secure file transfer to the University of Exeter where they will be stored in a secure SharePoint folder with restricted access. Once receipt has been confirmed by the research team member and the file checked, the Researcher will be instructed to delete the original audio-recording from their computer and the audio-recorder.

If you decide to participate in the online survey, data that we gather from you will be **anonymised** and **securely** transferred from the ECLIPSE database to an access protected SharePoint folder at the University of Exeter. Your data will only be available to the TIMES project researchers at the University of Exeter and will be analysed to help improve the design of the TIMES intervention.

Once we have finished the trial, we will analyse the data and write our reports in a way that no-one can work out that you took part in the trial. If you agree, information collected about you will be used to support other research in the future and shared anonymously with other researchers. In line with University of Exeter policy, at the end of the trial, your data will be securely archived for a minimum of 5 years. Arrangements for confidential destruction will then be made.

If you have any queries about the University of Exeter's processing of your personal data that cannot be resolved by the research team, further information may be obtained from the Data Protection Officer by emailing ***dataprotection@exeter.ac.uk or phoning 01392 726842.***

If you have any concerns about how the data is controlled and managed for this study then you can also contact the University of Exeter Sponsor Representative using the contact details on page 11.

What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but **we will keep information about you that we already have.** To safeguard your rights, we will use the minimum personally-identifiable information possible.

We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

Where can you find out more about how your information is used?

You can find out more about how we use your information in the following ways:

- at www.hra.nhs.uk/information-about-patients/
- by asking one of the research team (see page 11 for contact details)

What will happen to the results of this study?

- We will send you a newsletter with the results if you choose to receive them.
- The results will be presented at medical conferences and in scientific journals.
- We will also share the results on our website (see page 11 for details).
- This could be around 2 years after you join the study.

You will not be identified in any report or publication. We may use your words in reports and publications. However, we will not use your name or other identifying details so that you cannot be recognised.

Who is organising and funding this study?

The University of Exeter is the Sponsor for the trial and has overall responsibility for the trial. The trial is being organised and run on their behalf by Exeter Clinical Trials Unit, University of Exeter. Professor Chris Fox from the University or Exeter is the Chief Investigator and is overseeing the trial, alongside collaborators from the University of Hull and the University of East Anglia. This trial is funded by the National Institute for Health and Care Research (NIHR 202345).

Who has reviewed this study?

Any research conducted in the NHS is reviewed by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed by <insert REC name> and has received a favourable opinion. The ethics committee who reviewed the study are independent from the research team.

What if there is a problem?

Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. If you have any concerns about any aspect of this study, you should speak to your study team or doctor who will do their best to answer your questions, their contact details are listed in page 11 of this information sheet.

If in the unlikely event something does go wrong and you are harmed during this research study as a result of the managing organisation (the University of Exeter), compensation may be available but you may have to pay your legal costs. The NHS GP Practice where you receive your treatment has a duty of care to you, and the University of Exeter accepts no liability for negligence or misconduct on the part of the GP Practice's employees. If you are harmed and this is due to someone's negligence, then you may have grounds for a legal action for compensation against the GP Practice, but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

If you wish to complain or have any concerns about any aspect of the way you have been approached or treated during this study, you can do this through the Sponsor of the trial, the University of Exeter, details on page 11. Alternatively, you can use the NHS complaints procedure. In the first instance it may be helpful to contact the Patient Advice and Liaison Service (PALS) at your GP Practice on < GP Practice to insert number>, or make a formal complaint by writing to <GP Practice to insert address>. This will not affect your care or treatment in any way.

Contact Information

Principal Investigator:
<Insert PI Name**>,**
<Insert PI email**>,**
<insert PI phone number**>**

Research Nurse/Administrator:
<Insert name>,
<Insert email>,
<Insert phone number>

Sponsor Representative:
University of Exeter
Email: res-sponsor@exeter.ac.uk

Visit our **website** for more information: https://carecoachtimes.org/times/

Thank you for taking the time to read this information sheet and to consider this study.

Additional information

Different team members involved in this study:

Research studies can involve lots of different people and organisations working together. Here are some of the types of people involved:

Principal investigator – an individual who is responsible for the study at your GP practice. In this study, the principal investigator is likely to be your GP.

Research nurse – a nurse who specialises in research. Research nurses are employed by the NHS where your GP practice is based and bound by the same duty of confidentiality as all other NHS employees. In this study, research nurses will contact you to complete the screening questions, consent to participate in the study and the questionnaires.

Trial manager – a trial manager looks after all aspects of a research study to make sure everything runs well and answers questions about the study. In this study, the trial manager works at the University of Exeter.

Researcher – a person who interviews people for research studies to find out what they think about the study or their health condition. In this study, the qualitative researchers work at the University of Hull or The University of East Anglia. You will meet them if you consent to an interview.

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