The TIMES Study – Tailored management of sleep for people with dementia or mild cognitive impairment

Patient Participant Information Sheet

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

This information sheet explains why the study 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 sleep and help you feel at your best

A good night's sleep can improve your overall health and wellbeing. The TIMES study uses a tailored health plan that is created by patients, carers, and their GP, to help improve sleep. By participating, you'll help us understand how to provide better care for people living with dementia or mild cognitive impairment, and their carers.

Why have you been invited to take part?

We want to involve people who have dementia or mild cognitive impairment and their family members, friends or carers. This is because current treatments to improve sleep for these people are not always available or effective.

Do you have to take part?

No. It is up to you to decide whether 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. 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?

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

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 family member, friend, or carer for you both to participate in this study.

What are the risks and benefits of taking part?

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

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

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

Where 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 thinks that you may be eligible to take part in this study.
- You will be contacted by a nurse from your GP Practice and asked about your diagnosis of dementia or mild cognitive impairment.
- 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 to give your informed consent. If you lack mental capacity, a family member, friend or healthcare professional may be approached to provide advice on your views and wishes in relation to participating in this study.

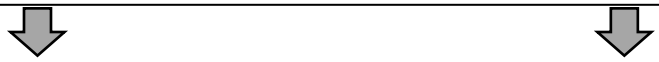
- You and your family member, friend, or carer will participate in a **initial baseline assessment** to gather information about your health and wellbeing, demographics, and contact details. These assessments will be co-ordinated by a nurse.

- You and your family member, friend, or carer will be randomly allocated to both take part together in one of 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.

  OR

    - **Receive Treatment as Usual:** Participation in this group is crucial for this study and offers several benefits. You will have access to established care within a monitored research setting. A research nurse will contact you to complete some assessments, which may ultimately benefit future patients with the same condition. Your participation in these assessments may also lead to closer attention to your healthcare and potentially earlier detection or management of any changes or complications.



Follow -up at home or care home

- At **9** and **15 weeks** after your initial 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, by phone, video call, or in-person if you are living in a care home. They will take approximately 30 minutes per person to complete each time.
- We will include regular breaks, and you can choose to stop the assessments at any time.

Optional interviews and questionnaires

- If you are interested, a researcher will contact you by phone, email, video call, or in person, to ask about your experience of participating in the study. This **interview** will take no more than **15 minutes.**
- If you are interested, we will also send you a **questionnaire** by post or email, to ask about your preferences in using the TIMES intervention. This questionnaire will be sent once at the start of the study and again at the end of the study, and should take approximately **15 minutes** to complete.

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.**
- Please contact your GP if you participated in the TIMES intervention and would like to discuss continuing your tailored care plan as part of your ongoing usual care

Further information about the study

Optional Interviews

We are inviting people to provide feedback on their experience participating in the TIMES intervention. The interview is an **optional** part of the study. 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). Interviews will take no more than **15 minutes** to complete. Quotes from interviews may be used in research publications but we will remove your personal details so that no one will be able to identify you from them. This will all be done by a member of the study team from the University of Hull or University of East Anglia.

Optional Survey

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

If you decide to participate, the survey will take an additional **15 minutes to complete at the initial baseline assessment and at the 15-week follow-up**. We will send you the survey by post or email. This will be done by a member of the University of Exeter study team.

What type of study is TIMES?

You are being invited to take part in a 'Definitive Trial'. This means it involves a large number of people with dementia and mild cognitive impairment, to test whether the TIMES intervention improves their sleep and wellbeing.

What will this study tell us?

- Whether the TIMES intervention **improves sleep and wellbeing** for people living with dementia or mild cognitive impairment.
- If any parts of the intervention should be **improved.**

Will you receive any payment?

While we appreciate you giving up your time to support the study and value hearing your views and experiences, we do not provide payment for patients and carers for participating in this 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. We will discuss options of what data we would like to continue collecting about you. If you do not want this to happen, we will stop all data collection. **Your care will not be affected in any way, should you choose to stop taking part in this study at any time. You can leave the study by contacting the study team using the Contact Information provided at the end of this information sheet.**

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 be if your safety or well-being is

compromised. In such cases, we will inform you promptly, ensuring a smooth transition out of the study.

If your family member, friend, or carer withdraws from the study at any stage, and you wish to continue with the study, we will seek another eligible family member, friend, or 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 should lose your ability to make decisions for yourself,** 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?

We will need to use information from you, from your medical records, from the family member, friend, or carer who is also participating in this study with you, and from your GP. Your GP will share the following information with us:

- Initials
- Name
- NHS number
- Current prescriptions (medication) and health conditions
- Date of birth
- Preferred contact details

People will use this information to do the research or to check your records to make sure that the research is being done properly. 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 code number instead.

The University of Exeter is the Sponsor for this research. The University of Exeter is responsible for looking after you and your information and using it

properly. We will share your information related to this research project with the following organisations:

- University of Exeter
- University of East Anglia
- University of Hull
- Your GP practice
- NHS approved third-party data processors, who have explicit instruction to access your medical records specifically related to the study, as approved by your GP
- Regulatory authorities where it is relevant to the research

We will keep all information about you safe and secure by using and storing your data in compliance with the:

- EU General Data Protection Regulation 2018 (GDPR). Since the UK left the EU, key principles of EU GDPR have been adopted in a UK-only version (UK GDPR)
- Data Protection Act 2018 (DPA 2018)

The University of Exeter's lawful basis to process personal data for research is for 'public interest', and your data will not be shared outside the UK.

We (the sponsor) 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. 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 the trial database, with restricted access.

If you agree to take part in the optional **interviews**, all information we collect 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 or University of East Anglia. Quotes from interviews may be used in research publications but we will remove all your personal information so that no one will be able to identify you from them.

If you decide to participate in the optional survey, data that we gather from you will be securely stored on the access restricted study database 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.

If you have any queries about the University of Exeter's processing of 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 email the **University of Exeter's Sponsor Representative** using the **contact details provided below**.

International transfers

Your data will not be shared outside the UK

How will we use information about you after the study ends?

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

In line with University of Exeter policy, at the end of the trial, we will keep your study data for a maximum of 10 years. The study data will then be fully anonymised and securely archived or destroyed.

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 may need to keep information about you that we already have.** To safeguard your rights, we will use the least personally-identifiable information possible.

- If you choose to stop taking part in the study, we would like to continue collecting information about your health from your GP and carer. We will

ask you about this at the time and if you do not want this to happen, tell us and we will stop.

- You have the right to ask us to access, remove, change or delete data we hold about you for the purposes of the study. You can also object to our processing of your data. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this.
- If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

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/patientdataandresearch
- By asking one of the research team (see contact details page below)
  - By sending an email to informationgovernance@exeter.ac.uk

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 contact details page below).
- 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 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 a group of people called a Research Ethics Committee. They are independent from the research team so as to protect your interests. This study has been reviewed by the Wales REC 3 Board and has received a favourable opinion.

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 below.

In the unlikely event that 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 also 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 below. Alternatively, you can use the NHS complaints procedure. In the first instance it may be helpful to contact 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 is trained 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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