

## **The TIMES Study** – Tailored Management of Sleep for people with dementia and mild cognitive impairment

### **Carer Participant Information Sheet**

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

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 sleep and help people feel at their best.**

A good night's sleep can improve the overall health and wellbeing of the person you care for. However, current treatments to help improve sleep for People Living with Dementia (PLWD) and Mild Cognitive Impairment (MCI) are not always available or effective. New assessment and management techniques that adopt a tailored, whole-person, approach to care, may improve our ability to address this gap. The TIMES study involves developing a tailored health plan that is co-created by patients, carers, and their GP, to improve sleep and wellbeing. By participating, you'll help contribute to the development of better care for PLWD/MCI, and their carers.

#### ***Why have you been invited to take part?***

The person you care for, who has dementia or MCI, has been invited to take part in the TIMES study. They have suggested that you might be suitable to take part in this study with them, as you normally support or provide care for them.

#### ***Do you have to take part?***

**No.** It is entirely 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 family member or friend's 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?***

- 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 the person who you care for, including their 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 approximately 30 minutes per person each time.
- If you are assigned to the TIMES intervention group, we will ask you and the person you care for to attend a 30 minute and a 15 minute consultation with their GP.
- During these consultations, we will discuss the general health of the person you care for and develop a plan to improve their sleep.
- We may also ask you and the person you care for to share your experience of the TIMES study through optional interviews and questionnaires.

Everyone who takes part in this study needs to have a family member, friend or carer who can take part with them. **Your main role will be to support the person for whom you provide care and to complete questionnaires about their health and wellbeing.**

A Research Nurse or GP will contact you to talk to you about the study and answer any questions you may have. They will have received your contact information from your friend or family member, or from their GP.

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 the patient notes of your family member/friend, and in the TIMES trial records. Consent is required from both yourself (the carer) **and** the person you care for (the patient), or Consultee declaration if the patient lacks capacity, for the two of you to participate in this study.

### ***What are the risks and benefits of taking part?***

Participating in the TIMES study carries minimal risks. Some people may experience emotional distress when discussing health concerns and changes to the wellbeing of the person you care for. 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 the capacity of potential participants as required by the Mental Capacity Act. They are able to appoint a consultee can be appointed to act on behalf of the patient if needed. Any disclosure of participant information that may lead to safeguarding concerns relating to the safety of participants or others, will be reported to the participant's GP.

While participation may or may not have direct benefits for you, taking part in this research could lead to improvements in our future understanding of care 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 the GP practice of the person who you care for. For more information <insert name and email/phone no. practice Research Nurse/Manager/Administrator>

### ***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**

### **You and your family member or friend who you provide care for**

- The person who you provide care for has identified that you may be eligible to take part in this study.
- You will be contacted by a nurse and asked about your family member or friend's diagnosis of dementia or MCI.
- You will go through a screening process to see if you both meet the specific study criteria.



### **At home or care home**

- If you meet the eligibility criteria, you and the person you provide care for will be approached for informed consent.
- You and the person you provide care for will participate in an initial baseline assessment to gather information about their health and wellbeing, demographics, and contact details. These assessments will be coordinated by a research nurse.
- You and the person you provide care for will be randomly allocated to one of the following two groups. You both will be in the same group.
  - **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 baseline assessment, you and the person you care for will be asked to complete some questionnaires about their sleep, health and wellbeing.
- Assessments will be done by a research nurse or TIMES researcher over the phone, video call, or in-person. These will take approximately 30 minutes per-person to complete each time.

### **Optional interviews and questionnaire**

- 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 complete after 15 weeks.
- **Your family member or friend's 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 be interviewed to provide feedback on their experience of participating in the TIMES study. The interview is an **optional** part of the study. You and the person you care for 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 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 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 again at the 15-week follow-up**. We will send you the survey by email or post. This will be done by authorised members 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 MCI, to test whether the TIMES intervention improves their sleep and wellbeing.

### ***What will this study tell us?***

- Whether the TIMES intervention **effectively improves sleep and wellbeing** for people living with dementia or MCI.
- 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.

Payment will be provided to care homes involved in identifying potential participants, where professional care workers (care home staff) can potentially also be enrolled to support patient participants as a patient-carer pair.

### **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 by contacting the study team using the Contact Information provided at the end of this information sheet. However, if you are willing to share your reason it could help us make improvements in the future. If you decide to stop taking part, we will ask your family member or friend if there is another person who could be invited to take part in your place.

#### ***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.

### ***How will we use information about you?***

For this research project, we will need to use information from you and the person you care for.

This information will include your:

- Initials
- Name
- 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
- The GP practice of the person you care for
- 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 will be anonymised so 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](mailto: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 the person you care for from their GP. 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](http://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](mailto: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 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 of 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 the GP practice of the person you care for. In this study, the principal investigator is likely to be their GP.

**Research nurse** – a nurse who specialises in research. Research nurses are employed by the NHS where the GP practice of the person you provide care for 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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