

TIMES Participant Information Sheet

Study title

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

What is the research about?

We have spoken to:

- People living with dementia
- People living with MCI
- Current or former carers of someone living with dementia or MCI

And they have told us that sleep problems are common and need to be researched more.

TIMES is a five-year research study aiming to develop approaches to help healthcare professionals, patients, and carers to work together to develop tailored care plans for sleep. From previous research, we know some but not all the elements a tool would need. Using expertise from people with lived experience, we will fill the gaps with this new research.

What would you need to do?

There are two parts to this study.

Focused ethnography work: We would like to observe if and how healthcare professionals do tailored care for long-term conditions/complex illness for the general population, with a particular interest for older people. We would like to visit the practice for two days to observe five or more consultations between healthcare professionals and patients, and to sit in on staff meetings and quality improvement activities to understand practice and policy level influences on tailored care. If you are interested in this part of the research, then we will work closely with you to find days and times which are suitable for you.

Focus groups: We would like four or more healthcare professionals to take part in a 90-minute focus group to talk about things which might help or hinder tailored care plans for sleep problems. The focus group will take part at the GP surgery on a date and time suitable for the participants. The discussion will be audio recorded.

You do not need to take part in both parts of the study. You can volunteer for one part without being obliged to do the other.

What are the possible benefits of taking part?

There are no direct benefits to taking part; however, from our previous research we often get feedback from participants saying they enjoyed speaking about their experiences. Your views will also help us develop the TIMES tool which we hope will be useful to healthcare professionals as well as improving the health and wellbeing of patients.

What are the possible disadvantages of taking part?

You will need to give up approximately 90 minutes of your time

Do I have to take part?

No. Taking part is voluntary. If you decide not to take part this will not affect you in anyway.

What if I want to take part or I want more information?

The research team are happy to answer any questions and to tell you more about the research. You can contact the research team on:

Email: TIMES@exeter.ac.uk

Telephone: 01392 72 4998

TIMES Supporting Information

How will we use information about you?

We will need to use information from you for this research project.

This information will include your

- Initials
- Name
- 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.

We will keep all information about you safe and secure.

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.

How will my data be used and kept safe?

The University of Exeter is the legal sponsor for this study and will act as the data controller. The sponsor is responsible for looking after your information and using it properly.

We will limit the number of people who can see your data. As well as the direct research team, potential access may be required by the Sponsor and regulators for monitoring and audit purposes.

All information collected in this study 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. You will be allocated a unique participant number, to ensure your information will be protected and cannot be identified outside of the research team. At the end of the study, we will save some of the data in case we need to check it. We might also use the data for future research, and we will ask you if this is OK or not. We will make sure no-one can work out who you are from the reports we write. Any personally identifiable information will be stored securely from information obtained from the research and will be destroyed after 12 months of the study ending. Non-identifiable research data will be kept for 10 years and will then be 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 will keep information about you that we already have. 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. 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:

- At <https://www.exeter.ac.uk/about/oursite/privacy/research/>
- By asking one of the research team
- By sending an email to times@exeter.ac.uk or
- By contacting the University of Exeter Sponsor Representative Ms Pam Baxter - Research Governance Manager (Health & Social Care)

Address: University of Exeter, Research Ethics and Governance Office,
Lafrowda House, St Germans Road, Exeter, EX4 6TL

Tel: 01392 723588

Email: p.r.baxter2@exeter.ac.uk

Are there any circumstances in which confidentiality would be broken?

The researcher has a duty to inform Adult Safeguarding if they become aware of:

- Information that either indicates a risk or harm to yourself or others
- Information indicating evidence of abuse or malpractice

Otherwise, all the information you provide during the research will be confidential.

What if there is a problem?

If you have a concern about any aspect of this study, you should speak to the researchers who will do their best to answer your questions. You can contact the team via email on times@exeter.ac.uk or on <insert number>.

If you would like to speak to the Principal Investigator of the study then you can contact Professor Chris Fox, Email: christopher.fox@exeter.ac.uk, Tel: 01392 722 043.

If you would like to speak to someone outside of the research team, then you can contact your local Patient Advice and Liaison Services (PALS) via <insert local PALS contact details>

Who is funding the study?

The funding of this study comes from the National Institute for Health Research (NIHR).

Who are the research team?

TIMES is a collaborative study between the University of Exeter, the University of Hull and the University of East Anglia.

Have you asked people with lived experience about the research?

Yes. We designed the research after conversations with:

- People living with dementia
- People living with MCI
- Current or former carers of someone living with dementia or MCI

Does the study have ethical approval?

Yes. The study has been reviewed by the NIHR and has HRA and HCRW Approval.

What will happen to the results?

We will write the results up in a report for the funders and decision makers. We will also publish the results in journals and present the findings at conferences. You can sign up to receive updates about the research if you want to on the consent form.

You can visit our website for updates www.carecaochtimes.org

You can follow us on Twitter @TrialTimes