

TIMES Participant Information Sheet

If you need help reading or understanding this information, please contact Molly Megson

Email: TIMES@exeter.ac.uk

Phone: 01392 72 4998

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 difficulties 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 of some but not all the pieces an approach would need. Using expertise from people with lived experience, we will fill the gaps with this new research.

Why have I been asked?

You have been invited to take part because you are either living with dementia or MCI and we want to hear your views.

We are also recruiting carers to the study. A carer could be a relative or a friend who helps you daily. If you have a carer who is interested, or if you are a carer reading this, then please feel free to contact the research team via the details at the bottom of this sheet.

Do we both need to take part?

No. You can both choose separately whether you want to take part. It may be the case that only one of you wants to participate and that is fine. It is also OK if both of you want to take part.

What would I need to do?

We would like to invite you to take part in a 90-minute group discussion. During this focus group, we would like to ask everyone questions about things which might help or hinder tailored care plans for sleep difficulties. The group will be held <at your GP surgery/online Via Zoom/Microsoft Teams>. We will discuss when the best days and time might be to run the group. <If the focus group is held at your GP surgery, then any travel expenses incurred will be reimbursed.>

Who else will be in the group?

The group will have no more than six people in it, one of whom will be a researcher who will guide the discussion.

How will people know if I want to speak during the group discussion?

We will be using yellow 'I want to speak please' cards to make sure everyone has an equal chance to talk. The research team will <provide these on the day/post these to your home if you would like one>.



How will the discussions be recorded?

The researcher will audio record the focus group and make notes. This is to ensure they don't miss anything that is said.

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 approach which we hope will improve the health and wellbeing of people.

What are the possible disadvantages of taking part?

- You will need to give up approximately 90 minutes of your time. There will be at least a 10-minute break, or more if needed.
- Talking about dementia or MCI can be hard and some people may find it upsetting. If you do become upset, we will take a break and you will be able to talk to the facilitator in confidence if you wish.

Do I have to take part?

No. Taking part is voluntary. If you decide not to take part this will not affect the care you usually receive.

What happens if someone has difficulty making decisions, but they would still like to take part?

We understand that dementia and MCI can sometimes make it hard for people to understand information and make decisions for themselves. If you are the carer of someone who might find it challenging to provide informed consent for the research, but you know they would like to take part, then you can be a consultee for them. Please see the consultee information sheet for further details. The research team can answer any questions you might have around this.

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

Who are the research team?

TIMES is a collaborative study which means that different universities are helping with the research. Our researchers are from the University of Exeter, the University of Hull and the University of East Anglia.

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. Any personally identifiable information will be stored separately and securely from information obtained from the research. It will only be kept for a limited time and securely destroyed after 12 months. 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.

What if I lose mental capacity during the study?

If you lose capacity during the study, then we will not collect any further information from you. Data already collected with your consent will be retained and used in the study for the purpose of the research. This could include using your data for further research. You can say yes or no to this on the consent form.

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 your GP or 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 by the people providing your care

Otherwise, all of 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 the research team, 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).

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

We also have a patient and public involvement group which helps us make sure the research is relevant and suitable. They have helped us to design this information sheet, the consent form, and the focus group questions.

Does the study have ethical approval?

Yes. The study has been reviewed by the NIHR and <insert REC board>.

What will happen to the results?

We will write the results up in a report for the funders and decision makers.

We will publish the results in healthcare journals for GPs and other healthcare professionals.

We will write a summary of results for people who took part.

We will tell people about the results by presenting at conferences and meetings.

You can sign up to receive updates about the research if you want to.

You will be given this option when you complete the consent form.

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

You can follow us on Twitter if you would like to. Our Twitter handle is @TrialTimes