Participant Information Sheet
Information for Consultee

NHS Research Ethics Committee Approval ID Number: 23/WA/0157

Study title: Social Cognition and Functioning in Alzheimer's Dementia (SOCIAL) study

Department: Division of Psychiatry, University College London (UCL)

Name and Contact Details of Principal Researcher: Dr. Andrew Sommerlad, UCL Division of Psychiatry, +44 (0) 20 7679 9248, a.sommerlad@ucl.ac.uk

Introduction

We feel your relative/friend is unable to decide for himself/herself whether to continue to participate in this research study. They previously agreed to take part, but are no longer able to make that decision so, to help decide if he/she should remain in the study, we'd like to ask your opinion whether or not they would want to continue to be involved. We'd ask you to consider what you know of their wishes and feelings, and to consider their interests. Please let us know of any advance decisions they may have made about participating in research. These should take precedence.

If you decide your relative/friend would have no objection to continuing to taking part we will ask you to read and sign a consultee declaration form. We'll then give you a copy to keep. We will keep you fully informed during the study so you can let us know if you have any concerns or you think your relative/friend should be withdrawn.

If you decide that your friend/relative would not wish to continue participating, it will not affect the standard of care they receive in any way.

If you are unsure about taking the role of consultee you may seek independent advice.

We will understand if you do not want to take on this responsibility.

The following information is the same as was previously provided to your relative/friend.

Invitation

You are being invited to take part in a research study. Before you decide, it is important for you to understand why the research is being carried out and what it will involve. Please read the following information carefully and discuss it with others if you wish. Please ask if there is anything that is unclear or if you would like more information. Thank you for taking the time to read this information sheet.

What is the purpose of the research?

People with Alzheimer's dementia often have changes in their social functioning, meaning relationships with friends and family and their activities and hobbies. Social functioning is important for quality of life and physical and mental health. We want to understand what affects social functioning so that we know how to help people with Alzheimer's dementia to improve social functioning.

One possible cause of social functioning problems is that Alzheimer's dementia affects social cognition, such as making it difficult to consider what others are thinking. We therefore want to test the social cognition of a large group of people with Alzheimer's disease and then see whether this affects their social functioning. This will help us to understand the symptoms of Alzheimer's dementia, and clarify what sort of treatments, for example training in social cognition, might help people with the condition.

Who can participate in the study?

We are asking around 200 people with the early stages of Alzheimer's dementia to participate in this study, and want a friend or family member who knows them well to also take part so they can give us additional information.

Do I have to take part?

No. It is up to you to decide if you would like to take part. If you do decide to participate you will keep this leaflet for reference. You are free to withdraw at any time and do not have to give a reason.

What will happen to me if I take part?

The study will require a face-to-face appointment at the start of the study for screening and completing questionnaires and tests of social cognition, and a follow-up appointment after one year. We will ask a family member or friend of yours to complete questionnaires at each of the start of the study, after 4 months, 8 months and 1 year. The assessments at 4 and 8 months can be completed via an internet form or by phone.

Around 50 of the participants will be asked to take part in sub-studies involving remote monitoring of social functioning, and behavioural observation and these sub-studies are described in separate information sheets.

1) **First assessment**

If you agree to participate, you will be contacted by a researcher to arrange an initial interview. This can take place at your home, University College London or a local clinical service if more convenient. We will ask you to complete a consent form to indicate that you agree to take part in the study.

Once you have signed the consent form, you will take part in an interview which will last approximately 60-75 minutes. You can take breaks during this or split this interview up over different days if required. First we will collect some basic information about you (e.g., age, sex, ethnicity, previous education and employment), your physical health and Alzheimer's dementia diagnosis. You will also be asked to complete tasks of 'social cognition' on a computer, including by watching videos of scripted social situations and answering questions about these. You will be asked to answer questionnaires about social functioning and your quality of life and to complete a standard test of memory and cognitive function. These are simple questionnaires asking you about your experiences and there are no right or wrong answers.

Your friend or family member will be asked to give some basic information about themselves, complete questionnaires about your social functioning, mental health and activities of daily living, lasting around 35-45 minutes.

2) **After 4 and 8 months**

Your friend or family member will be contacted by phone or email and asked to complete the questionnaire about your social functioning, by phone or computer, taking around 5-10 minutes.

3) **After 1 year**

The researcher will meet with you again for around 1 hour and ask you to again complete tasks of 'social cognition' on a computer, including by watching videos of scripted social situations and answering questions about these. You will be asked to answer questionnaires about social functioning and your quality of life and to complete a standard test of memory and cognitive function. Your friend and family member will also be asked to complete some questionnaires.

What are the possible disadvantages and risks of taking part?

There are no known risks or side-effects associated with carrying out the questionnaires or computerized tasks. You may feel anxious before or tired after taking part in the tasks, but we will do everything we can to minimise or prevent this. You will be asked about your well-being at all times, and you will be given the opportunity to have either a short break or for the testing to be stopped if necessary.

Are there any benefits to taking part?

You may not receive direct benefit from being in this study but information learned from this study may help us to improve care for people with Alzheimer's dementia in the future. Each person with Alzheimer's dementia will receive a £20 gift certificate as a token of our thanks for your time.

Will my taking part be kept confidential?

All information that is collected from you during the research will be kept strictly confidential, anonymised (taken out your name or anything that will mean people know who you are), and will be stored in accordance with the General Data Protection Regulation 2018.

All information collected as part of the study will be stored securely in the UCL network. We will label your data with an identification code that will only be accessed by members of the research team. The anonymised data will be kept securely for 10 years.

The research you are taking part in may be published, and as part of this process the anonymised results of the research may be presented in scientific journals. You will never be identified, and these data are always presented anonymously. The researcher may also share such anonymised data and results with other accredited researchers through a secure data sharing service called Dementias Platform UK or Wellcome Open Research so that the data from the study is as useful as possible. Again, you or the information you provide will never be identified as we will anonymise all of the data.

What will happen if I decide to withdraw my agreement?

You are free to withdraw at any time and do not have to give a reason. If you decide to withdraw your agreement to continue to take part in the study, you will be immediately withdrawn from the study. If

you withdraw from the study, the information that was collected before you left the study will still be used in order to help answer the research question. No new information will be collected without your permission and the remaining research procedures will not be carried out. A decision to withdraw at any time, or a decision not to take part, will not affect you in any way.

Sometimes, people lose ability to make decisions about their participation in a study because of illness. If this were to happen, you can tell us in advance that you would want to complete the study (i.e. repeat the same tests after 1 year as you completed at the first assessment) as long as you do not object, or that you would like to withdraw from the study, or that you would like us to speak to a friend or family to decide on your behalf if you complete the study.

What will happen to the results of the research study?

Anonymous results may be published in academic journals and presented in posters and talks at academic conferences. You will not be identified personally in any publication.

If you would like to receive information about the results of the study, then you can indicate this in the consent form and we will keep your contact details to send you a summary of the results after the study is finished.

What if I have a complaint or something goes wrong?

If you have any comments or concerns about any aspect of the study (e.g. the way you have been approached or treated during the course of the study), you should in the first instance contact Dr. Andrew Sommerlad (a.sommerlad@ucl.ac.uk).

If you remain unhappy and wish to complain formally, you can do this from the NHS Complaints Procedure. Details can be obtained from the (NHS site), Patient advice and liaison service (PALS). PALS can be contacted online (https://www.uclh.nhs.uk/contact/patient-advice-and-liaison-service-pals) or by telephone (020 3447 3042) or email: uclh.pals@nhs.net. All correspondence will be addressed in strict confidence. The study is covered by UCL liability insurance.

How will we use information about you?

We will need to use information from you, including your contact details, name, age, sex, ethnicity, for this research project. This information will be used to do the research or to check your records to make sure that the research is being done properly. We will keep all information about you safe and secure.

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.

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

The data custodian will be Dr Andrew Sommerlad. You can find out how we use your information

- at www.hra.nhs.uk/information-about-patients/ or www.ucl.ac.uk/legal-services/privacy
- by asking one of the research team
- by ringing us on 020 7679 9248

- by sending an email to a.sommerlad@ucl.ac.uk or data-protection@ucl.ac.uk

Data Protection Privacy Notice

The data controller for this project will be University College London (UCL). The UCL Data Protection Office provides oversight of UCL activities involving the processing of personal data and can be contacted at data-protection@ucl.ac.uk (Data Protection Officer's name: Alexandra Potts).

This 'local' privacy notice sets out the information that applies to this particular study. Further information on how UCL uses participant information can be found in our 'general' privacy notice:

https://www.ucl.ac.uk/legal-services/sites/legal-services/files/ucl_general_research_participant_privacy_notice_v1.pdf

The information that is required to be provided to participants under data protection legislation (GDPR and DPA 2018) is provided across both the 'local' and 'general' privacy notices.

The categories of personal data used will be as follows: age, sex, gender identity, ethnicity, marital status, education and employment information. The lawful basis that will be used to process your personal data are: 'Public task' for personal data and' Research purposes' for special category data.

Your rights under the General Data Protection Regulations include right of access, right to rectification and erasure, right to object, and automated individual decision-making.

If you are concerned about how your personal data is being processed, or if you would like to contact us about your rights, please contact UCL in the first instance at data-protection@ucl.ac.uk.

Your personal data will be processed so long as it is required for the research project. We will anonymise the personal data that you provide and will do our best to minimise the processing of personal data wherever possible.

Who funds this research?

This work is being funded by the Wellcome Trust.

Who has reviewed this research?

A Research Ethics Committee reviews all proposals for research using human participants before they can proceed. This project has been approved by the Wales Research Ethics Committee 6 (23/WA/0157).

Contacts for further information

If you have any questions after reading this information sheet, please ask the researcher you have been dealing with for their contact details or contact Dr Andrew Sommerlad (contact details on pg 1).

Thank you for taking the time to consider participating in our research.