Participant Information Sheet – for friend or family informant

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

Study title: Social Cognition and Functioning in Alzheimer's Dementia (SOCIAL) – *Behavioural observation sub-study*

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

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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?

We are asking some of the participants of the Social Cognition and Functioning in Alzheimer's Dementia (SOCIAL) study to take part in a sub-study. We want to understand what affects social functioning so that we know how to help people with Alzheimer's dementia to improve this.

In the SOCIAL study we will be testing the social cognition of people with Alzheimer's dementia and then assessing how this is linked to social functioning which we will assess using questionnaires. However, we would also like to assess social functioning in real-time by observing brief social interactions between people with Alzheimer's dementia and other people and then evaluating verbal and non-verbal communication skills. 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 Alzheimer's dementia.

Who can participate in the study?

We are asking around 50 people with the early stages of Alzheimer's dementia who are taking part in the SOCIAL study to participate in this sub-study, and want a friend or family member who knows them well to also take part alongside them.

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. You can continue in the main SOCIAL study and not participate in this sub-study.

What will happen to me if I take part?

If you agree to participate we will ask you to complete a consent form to indicate that you agree to take part in this part of the study.

First assessment

Following the main assessments during your first SOCIAL study assessment, we will complete the substudy assessment. We will set up two small video cameras in the meeting room. We will then ask you and your friend or family member with dementia who is involved in the study to have a 5 – 10 minute informal conversation about their favourite hobbies. We will audio- and video-record this conversation. We will then ask you to leave the room and the person with Alzheimer's dementia will have a further 5 – 10 minute video/audio-recorded informal conversation with the researcher.

After 1 year

The researcher will meet with you again as part of the SOCIAL study and after the main study assessments, we will again ask you to have video-recorded 5-10 minute conversations with your family or friend with Alzheimer's dementia.

Our research team will then store your recording on the UCL data safe haven, and will use standard scales to assess the verbal and non-verbal communication observed. Once this has been done the recordings will be deleted.

What are the possible disadvantages and risks of taking part?

There are no known personal risks or side-effects associated with taking part. 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.

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 data safe haven. We will label your data with an identification code that will only be accessed by members of the research team. Once the recordings are analysed, we will delete the video-and audio-recordings.

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.

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. You can continue to participate in the main SOCIAL study even if you decide to withdraw from this substudy.

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, and video/audio-recordings, 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 is Dr Andrew Sommerlad. You can find out more about 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: name, contact details, phone use. 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 page 1).

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