

Participant Information Sheet

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

Study title: Social Cognition and Functioning in Alzheimer's Dementia (SOCIAL) – *Remote Monitoring 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 in the Social Cognition and Functioning in Alzheimer's Dementia (SOCIAL) study to take part in a sub-study. This sub-study is to test how accurately a mobile phone application (app) called RADAR-Base can measure the social lives of people who have Alzheimer's dementia.

We usually assess social functioning for research studies by asking people questions from a questionnaire or scale about how their social lives have been over the past few weeks, but this can be imprecise as it relies on people accurately remembering what they have done socially. We want to test whether the RADAR-Base app, which continuously checks some mobile phone information such as the number of phone calls or text messages someone has made, can be a more reliable and accurate measure of social life.

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. They will need to have an ANDROID smartphone (not an Apple iPhone).

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 the study. Then the researcher will support you to download the app to your mobile phone. There is nothing further required from you – we would like you to continue using your phone as you normally would – and the app will run continuously on your phone to collect data for the study.

The RADAR-Base app collects the following information from your phone:

- Number of phone-calls to and from your phone, the duration of the call and identity of the other phone: each telephone number will be anonymised using a code, rather than using the telephone number, which will allow the research team to count how many different telephone numbers contact or are contacted by the study participant
- Number of text messages to and from your phone, and anonymised identity
- Number of contacts in phone contact list
- Number of nearby Bluetooth devices and number connected to your phone
- Location of phone, which is anonymised using a code
- Status of the app, and battery level of phone, used to clarify any reason for problems with the data collection.

The data will be briefly stored within the RADAR-Base server which is compliant with General Data Protection Regulations (GDPR) and then transferred to secure storage at UCL.

What are the possible disadvantages and risks of taking part?

There are no known personal risks or side-effects associated with taking part. The app requires some battery usage and also sends information to our computer servers either using wifi networks or your mobile phone contract's data, but we have minimised battery use and data use by limiting the data we collect, and this is further limited if your phone is running low on battery.

We will prioritise that data is sent from your phone to our servers by a wifi network, which will be free of charge, but if your phone does not connect to a wifi network, then your mobile phone's contract data would be used. This is estimated to cost up to £15 over the course of a year, so we will give you a £30 shopping voucher to compensate you and to thank you for your contribution to our research.

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 a UCL online server and then transferred to 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. The anonymised data will be kept securely for 10y.

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.

If you ask to stop taking part in this study, then we will stop the app from collecting any more data from your phone via our central computer system. You or a friend or relative can then delete the app from your phone – we will advise you how to do this – or we can visit you to do this for you.

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. continue providing data using the mobile phone app) 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 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 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.