Participant Information Sheet

NHS Research Ethics Committee Approval ID Number: (22/LO/0145)

Study title: Social connection in long-term care home residents (SONNET) – Aim 3

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 take time to read the following information carefully and discuss it with others if you wish. Please ask us 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?

Social connection is a way to describe the relationships we have with others and the roles these relationships have in our lives. Social connections are important for everyone, including those in long-term care homes. Good social connections are linked to improved quality of life and better physical and mental health.

We need to be able to measure social connection in care homes accurately as it will allow researchers and other professionals to show what works to improve social connection. Our group evaluated the approaches currently available and sought feedback from long-term care residents, caregivers, care staff and researchers to help us improve the tools. We created a new measurement tool that we would like you to complete. We would also like to ask a caregiver or care staff to complete a few questionnaires about you to help us evaluate the utility and validity of tool.

Who can participate in the study?

We are inviting long-term care residents and their care staff to participate in this study. All residents must be adults over the age of 65 years old with adequate English language proficiency. Caregivers and care staff must be aged over 18 years, have adequate English language proficiency and visit or care for the resident at least once weekly (not including when visitor restrictions are in place).

Do I have to take part?

No. It is up to you to decide whether you would like to take part. If you do decide to participate you will be given this information sheet 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?
We will review this consent form with you and answer any questions you may have. If you wish to proceed once we have answered all your questions about the study, we will ask you to sign a hard copy of this consent form.

Long-term care residents: Once you have signed the consent form, we will collect some basic information about you (e.g., age, gender, race/ethnicity, education) and ask you to complete a questionnaire to assess your social functioning. The session will last about 15 minutes. With your permission, we will also ask one of your caregivers or care staff to complete a few questionnaires about your cognitive abilities, social function, activities of daily living and quality of life. For some residents, we will ask permission to return 2-4 weeks later to repeat the questionnaire about social functioning, lasting around 10 minutes. You can say no to this, and only meet with us on a single occasion if you prefer.

Caregiver or care staff: Once the long-term care resident or their substitute decision maker and you have signed the consent form, we will collect some basic information about you (e.g., age, sex, gender, race/ethnicity) and ask you to complete a series of questionnaires about the long-term care resident regarding their cognitive abilities, social function, activities of daily living, quality of life and social cognition. Completing the various questionnaires will take up to 30-60 minutes. For some residents, we will ask permission to return 2-4 weeks later to repeat the questionnaire about social functioning, lasting around 10 minutes. You can say no to this, and only meet with us on a single occasion if you prefer.

What are the possible disadvantages and risks of taking part?
There is a possibility that you may become distressed by the topics contained in the questionnaires. However, you may choose not to answer any question that makes you uncomfortable and you can also choose to discontinue the session at any time or to resume at a later time or date. There may also be inconvenience from making time to complete the questionnaires.

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 long-term care residents in the future. Each participant (resident and care staff) will receive a £20 gift certificate as a token of our thanks for your time.

Will my taking part be kept confidential?
We respect confidentiality but cannot keep it a secret if anyone is being seriously harmed or is at high risk of serious harm. So if any person in the study tells us that that a resident or carer is being harmed, we will ask their permission to disclose the information to their supervisor or care provider.

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 in a password-protected files on the secure 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 archived securely for 10 years. Our team are working with a similar study taking place at the same time at University Health Network, Toronto, Canada, so the information we collect will be shared with the research team there (without names)so that our findings can be applied across different countries. The research team in Canada may have different levels of data protection regulations to those in the UK.

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. 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.

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 make a formal complaint, please write to the Research Governance Sponsor of this study, University College London. Please contact the UCLH/UCL Joint Research Office, R&D Directorate, Roseheim Wing, Ground Floor, 25 Grafton Way, London WC1E 5DB. 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 for this research project. This information will include your contact details, name, age, sex, gender, race/ethnicity, occupation. People will use this information 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.

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.

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?
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 dop.sonnet@ucl.ac.uk or Sponsor Data Protection Officer 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, gender identity, ethnicity, marital status, role, 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 Alzheimer's Association and Brain Canada.

Who is organising the research?
University College London is taking part in this multi-site study along with the University Health Network located in Ontario, Canada.

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 NHS Research Ethics Committee (22/LO/0145).

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. You may also contact the study investigator Dr. Andrew Sommerlad (a.sommerlad@ucl.ac.uk).

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