SENSE-Cog Lewy: Investigating sensory function and its relationships with symptoms, support needs and quality of life in older adults with cognitive impairment

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Study Partner Information Leaflet

We would like to invite you to take part in a research study aimed at shedding light on the frequency of age-related hearing, vision and smell loss in individuals with difficulties in memory and other cognitive functions (e.g. concentration, attention) and on how sensory loss relates to cognitive difficulties, the way the person thinks, feels and acts, and on how such loss pertains to difficulties in activities of everyday life, quality of life and needs of care and support. As we age, the likelihood of developing problems with hearing, vision, smell increases. These problems affect the quality of life of older adults, impair communication with family members and friends and may worsen the impact of cognitive difficulties on activities of daily living. We are interested in studying sensory loss in older adults with cognitive impairment and its relationships with their cognitive difficulties, the way they think, feel and act, as well as with their support- and care needs and quality of life. Before deciding on whether or not you wish to take part, you should understand the risks and benefits of the study. This is called 'informed consent'. If you choose not to take part, this will have no effect on your medical care or treatment.

This information sheet explains what taking part involves. Please read it carefully, discuss it with others if you wish, and ask us if anything is unclear or if you would like more details.

This study is led by Drs I. Leroi (St. James's Hospital/Trinity College Dublin), S. O'Dowd (Tallaght University Hospital), S. Kennelly (Tallaght University Hospital and Trinity College Dublin) and J. Kane, Queen's University Belfast. Three clinics for cognitive impairment in Dublin and Belfast are involved in it.

PART 1 – THE STUDY

What is the purpose of the study?

The purpose of the study is to assess hearing, vision and smell problems in older adults with cognitive difficulties, as well as to investigate whether and how sensory loss relates to their cognitive difficulties (e.g. difficulties with memory, concentration), the way they think, feel and act (e.g. presence of anxiety symptoms or sleep difficulties),their social functioning, their difficulties with activities of everyday life (e.g. cooking, shopping), their quality of life and the support they need from their care partners. We are hoping that by collecting data on the co-existence of sensory loss and the difficulties which people with cognitive impairment due to different diseases (e.g., Alzheimer's disease, Lewy bodies, Parkinson's disease) and their care partners face the importance of sensory loss assessment and treatment in people with cognitive difficulties will become evident.

Why have I been invited?

You have been invited to participate because you are a care partner of a person with cognitive difficulties and therefore form part of the population of people that could benefit from sensory loss assessment and treatment. In addition, the person who supports and helps you with everyday activities is also invited to participate in the study.

We need 60 adults over 60 with cognitive difficulties and their study partners aged 18 or older to take part in our Ireland sample.

What will I be required to do?

You will undergo a series of questionnaires for demographic data, care related data, your relationship with your study partner as well as for his/her quality of life at Clinics for cognitive impairment at St. James's Hospital or Tallaght University Hospital in Dublin.

As the assessments require face-to-face contact all necessary measures of protection regarding the COVID-19 pandemic crisis will be taken, namely, compliance with the rules of social distancing and the use of personal

protective equipment. Measures to reduce the face-to-face contact time as much as possible have been put in place.

Can I choose whether or not to take part?

Yes, you can decide whether or not you want to take part. You or your study partner are free to withdraw at any time without giving a reason; this will not affect any of the care you receive. Your withdrawal will be recorded, and no more information will be collected and recorded about you. If you give us permission, we will use the data that we have collected up until that point. Otherwise, your data will be removed from the study.

How will the study benefit me?

Taking part in this study may reveal sensory difficulties in the person with cognitive impairment you care for which may be corrected (e.g., use of glasses, or hearing aids) leading to an improvement in your communication with him/her.

Are there any risks to me taking part?

There are no anticipated risks associated with the assessments.

Data Privacy: Your personal data will be accessed by the study team at the hospital at which you will be assessed. Please refer to Section 2 (Data Protection) for information on how we protect your identity.

What will happen to the results of the study?

Once the study is complete, we will present the findings at conferences and publish them in scientific journals. You will not be identified personally in any publications. We will also write to you (if you choose) and let you personally know the outcome of the study. If you would like this information or would like more information about future studies, please leave us your name and address (which we will keep confidentially). Also, you can look at our website: www.sense-cog.eu.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions (contact details at the end of this leaflet).

Who has reviewed the study?

This research has been looked at by an independent group of people, called the St James's Hospital/Tallaght University Hospital Joint Research Ethics Committee to protect your safety, rights, well-being and dignity. This study has been reviewed and been given a favourable opinion by (insert date).

PART 2 – DATA PROTECTION

The study team will make every effort to protect your privacy on this study and will do so in accordance with European and Irish laws. The following sections will explain how your data is being used.

According to Art. 6(1)(e) and Art. 9(2)(j) of GDPR,yYour data is being used in this study for the purpose of scientific research in the public interest, while the right to data protection will be respected and your rights and interests will be safeguarded through the necessary measures being described in the following lines.

St James's Hospital, Tallaght University Hospital, Trinity College Dublin and Queen's University Belfast are independent data controllers for the study data. St James's Hospital and Tallaght University Hospital are the data controllers for your personal data. Data controllers determine what information to collect, how it is used and how long to keep it. The data for this project will be kept up to a maximum of seven years after data analysis is complete.

What will happen to my personal data?

All of your study information will be labelled with a unique study ID number instead of your name. This is called 'coded' data.

The study teams either at St James's Hospital or at the Tallaght University Hospital, depending on the hospital at which you will be assessed, will have access to your identifiable personal information and the link between your name and the study ID number. Regulatory authorities may need access to your identifiable data to ensure that the study is being carried out properly.

Data collected will include information on your demographic data, care related data, your relationship with your study partner as well as on his/her quality of life.

'Coded' data from assessments will be held separately to your personal information so that you cannot be identified from your responses.

Your 'coded' study data will be sent electronically to the Mercer's Institute for Research on Ageing (MIRA) at St. James's Hospital and to Trinity College Dublin to be analysed. 'Coded' electronic data will be stored on a secure database in St. James Hospital or in Tallaght University Hospital until it is transferred to MIRA and Trinity College Dublin to be analysed.

How will my privacy be protected?
We will only collect the minimum information required for this study. Anyone accessing your personal information will be trained in data privacy and will be required to protect your privacy.

What are my rights to data?
Under GDPR, you have the following rights (unless the request would make it impossible or very difficult to conduct the research):

a. To access and receive a copy of your data
b. To restrict or object to the use of your data
c. To object to any further processing of the information we hold about you (except where it is de-identified)
d. To have inaccurate information about you corrected or deleted
e. To receive your data in a portable format and to have it transferred to another data controller
f. To request deletion of your data

If you wish to request any of the above or have any questions about your data on this study, you can do so by contacting the research assistant (contact details at the end of this leaflet) or the hospital data protection officer (*dataprotection@stjames.ie or DPO@tuh.ie*).

If you are not satisfied with the response, you can also lodge a complaint with the Irish Data Protection Commissioner (www.dataprotection.ie) or by post to: Data Protection Commission, 21 Fitzwilliam Square South, Dublin 2.

Future research (Optional)
It is possible that the 'coded' data collected in this study might be useful for other research related to sensory loss and cognitive impairment which will take place in the future and which will have been approved by a Research and Ethics Committee. We would like to ask you to consent to future use of your coded data by researchers collaborating with the principal investigator and/or consultant co-investigators' of the present study. Any researchers accessing this data will make sure that your data is protected to the same standard as this study. You may decide if you wish to have your data used in future research or not.

PART 3 – CONTACT DETAILS

Who can I contact for further information on this study?

Ms Rachel Fitzpatrick, Study Coordinator, Trinity College Dublin at fitzpar9@tcd.ie or 01 4103863

OR

Dr Adam Roche, Study Coordinator, Lecturer Registrar, Global Brain Health Institute, Trinity College Dublin at adam.roche@gbhi.org or 01 4103863

Thank you for reading this information and for considering whether to take part in the study.