

**SENSE-Cog: Understanding How to Support People with**

**Dementia and Sensory Impairment:**

**Intervention Field Trial**

**Participant Information Sheet: Study Partner**

We would like to invite you to take part in a research project that involves assisting your relative or friend to receive a Sensory Support package in their own home, to understand how the care needs of people with memory, hearing and vision problems might best be met.

This information sheet explains what taking part would involve. 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 part of a larger research programme, called **SENSE-Cog**, involving several EU countries (France, Cyprus, Greece). This project is supported by the University of Manchester and participating NHS Trusts. It is led by Drs Iracema Leroi and Piers Dawes at the University of Manchester.

**What is the purpose of the study?**

The purpose of the study is to deliver the Sensory Support package and see how well it works. This is a **home based intervention study** which aims to improve:

* Hearing and vision impairment
* Quality of life
* Activities of daily living
* Memory functioning
* Mental functioning

**Why have I been invited?**

You have been invited because you are a relative or friend of a person who has received a diagnosis of dementia and also has hearing and / or vision difficulties. Our understanding of how best to support people with these combined needs is limited and we are seeking to improve this by welcoming your feedback.

**What will I be required to do?**

A researcher will visit you and your relative / friend at their home on between 3-6 occasions, for a maximum of two hours per visit. At the start and the end of the study, you and your relative / friend will be asked to complete a set of paper-based questionnaires.

Your friend / relative will receive a full assessment of their hearing and / or vision by professionals in their own home. They may receive free glasses and a lamp to improve their vision. They will receive a free hearing aid to improve their hearing, if eligible.

Additionally, a Sensory Support Worker may visit your relative / friend in their home once a week over a 12 week for around one hour. You would accompany your relative or friend when these visits take place. The Sensory Support Worker will work with you and your relative / friend to develop a personalised plan which aims to assist your relative / friend achieve their goals. They may be given information, advice and support to increase their social circle, directed to local services and events which may be of interest to them, assisted with tasks around the home, or any other goals they would like to work towards. We may ask you to complete a short diary after each visit by the Sensory Support Worker to document what you thought was good and what you thought could be improved.

The maximum time in the research across these 12 weeks will be 35 hours 20 minutes, although it may be less than this. Some sessions may be audio-recorded. You may request for the recording to stop or be deleted at any time.

At the end of the study, we may invite you to take part in an audio-recorded, semi-structured interview to give us feedback about your experiences with the Sensory Support package.

**Do I need to inform my GP I am involved?**

We will send a letter to your friend or relatives G.P. to let them know they are participating. We will not inform your G.P. you are participating.

**Can I choose whether or not to take part?**

Yes. It is up to you to decide whether or not you want to take part. You are free to withdraw from the study at any time without giving a reason. If you decide not to participate, this will not affect any of the care you receive.

**How will the study benefit me?**

You may receive regular support and information about any assistance you may be entitled to and assistance in accessing these services. You may receive information and support to assist you in helping your relative / friend with their dementia and sensory impairment.

Your contribution will be extremely valuable and will help to shape improved services for people with dementia and sensory impairment in the future.

**Will my participation in the study be kept confidential?**

**Your participation and all the information we collect about you will be kept confidential.** All the information gathered from you will be completely anonymous and cannot be linked to your personal information. Only the study team at the University of Manchester will have access to your personal information. Data from the diaries, assessments and interviews will be held in a separate filing system to your personal information so that you cannot be identified from your responses.

The information gathered from all participants will be analysed at the University of Manchester by members of the SENSE-Cog team. The information gathered in Manchester will be combined with similar information gathered by our other study sites in Nicosia, Cyprus and Bordeaux, France. Participants at these sites will fill in the same questionnaires as you will and send them across to Manchester for analysis.

Once the analysis of the data is complete, your personal data will be held securely for up to 10 years at the University of Manchester and will be carefully destroyed as soon as it is not needed. Documents that may identify you will be stored in a secure separate location from any of the data you provide.

Individuals from the University or regulatory authorities may need to access the data collected to ensure that the study is being carried out properly. This is to protect you by ensuring that we are doing the research in a safe and ethical way. All individuals will be authorised representatives from each organisation and will have a **duty of confidentiality** to all research participants.

It is also possible that the data collected in this study might be useful for other research taking place in the future. If we used your data in future research, it would all be anonymous for both the analysis and reporting of results.

If you have any questions about what will happen to your data during the study please contact the research team whose details are at the end of this document.

**What will happen to the results of the study?**

The results of the study will inform the further development of the sensory intervention which will then be tested in a full scale randomised controlled trial. We will present the findings at conferences and publish them in scientific journals. 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. **All your information will be anonymised** and **you will not be identified personally**.

**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.

If there are any issues regarding this research that you would prefer not to discuss with members of the research team, please contact the Research Governance and Integrity Team by either writing to 'The Research Governance and Integrity Manager, Research Office, Christie Building, The University of Manchester, Oxford Road, Manchester M13 9PL', by emailing: Research.Complaints@manchester.ac.uk, or by telephoning 0161 275 7583 or 275 8093.

In the event that something does go wrong and you are harmed during the research you may have grounds for a legal action for compensation against the University of Manchester or NHS Trust but you may have to pay your legal costs.

You can also contact the Patient Advice & Liaison Service (PALS) if you would like independent advice. Their phone number is: 0161 276 8686 or email: [pals@cmft.nhs.uk](mailto:pals@cmft.nhs.uk)

**Who has reviewed the study?**

This research has been looked at by an independent group of people, called a Research Ethics Committee to protect your safety, rights, well-being and dignity. This study has been reviewed and been given a favourable opinion by the IRAS Committee on 30th September, 2016

**Who can I contact for further information?**

For further information, see our website: [www.sense-cog.eu](http://www.sense-cog.eu).

Or alternatively, please contact:



Dr Zoe Simkin (Research Assistant)

University of Manchester

Division of Neuroscience and Experimental Psychology

Faculty of Biology, Medicine and Health

Jean McFarlane Building, 3rd Floor, Oxford Road,

**Tel: 0161 306 7954**

Email: [zoe.simkin@manchester.ac.uk](mailto:joshua.wood@manchester.ac.uk)

Dr Jemma Regan (Research Associate / Study Co-ordinator)

University of Manchester

Division of Neuroscience and Experimental Psychology

Faculty of Biology, Medicine and Health

Jean McFarlane Building, 3rd Floor, Oxford Road,

**Tel: 0161 306 7957**

Email: [jemma.regan@manchester.ac.uk](mailto:jemma.regan@manchester.ac.uk)

**Thank you for reading this information and**

**for considering whether to take part in the study.**