**Communication Partner information sheet**

**YOU WILL BE GIVEN A COPY OF THIS INFORMATION SHEET**

**Title of trial:** Treating Auditory impairment and CogniTion (TACT) pilot trial

**Department:** Division of Psychiatry

**Name and contact details of the Trial Manager:**

 Miss Kingsley Powell E: tact-study@ucl.ac.uk T: 0203 108 6274

We would like to invite you to take part in a research project

* Before you decide whether to take part, it is important for you to understand why the research is being done and what it will involve for you.
* Please take the time to read the following information carefully. Discuss it with friends and relatives if you wish. Take time to decide whether or not you wish to take part.
* Ask us if there is anything that is not clear or if you would like more information.
* Thank you for reading this information sheet.
1. Why are we doing this trial?

It is a new finding that hearing loss increases the risk of developing dementia. Hearing loss is common in people over 65 but is often left untreated. We want to find out if treating hearing loss can delay or prevent the onset of dementia in people already at greater risk of dementia, those with mild cognitive impairment.

To do this, we need to run a large trial involving hundreds of people comparing a hearing aid support intervention versus a ‘control’ group, a group that does not receive the hearing aid support intervention. The control group will instead receive a healthy ageing intervention that will address other risk factors for dementia (e.g. blood pressure).

Before we can run this large trial, we need to see if it is possible. We want to find out useful information that will help the main trial be a success. So, this trial is a test run (pilot) of the main trial that will not in itself answer the question about whether a hearing aid support intervention or healthy ageing intervention can reduce the risk of dementia. This pilot will help us to find out if people with mild cognitive impairment are willing to take part, if the hearing aid and health ageing interventions are acceptable, and if people are willing to stay in the trial for 6 months.

**What are the interventions?**

**The hearing intervention:**

This intervention will be carried out by a research assistant and research audiologist. In this intervention the participant will be fitted with hearing aids, taught how to use them, and they will be given practical advice and support.

**The healthy ageing intervention:**

This intervention will be carried out by a research assistant. In this intervention the participant will be given information about healthy ageing factors that may reduce the risk of developing dementia. Specifically they will receive information about lowering systolic blood pressure, regulating blood glucose, physical activity and maintaining healthy bones, joints and muscles.

**How is it decided which intervention the participant will receive?**

Each participant who takes part will receive either the hearing aid support intervention or the healthy ageing intervention for the length of the trial. Neither the researcher nor the participant gets to decide which intervention they will receive. It is decided by a process called ‘randomisation’ which is carried out by a computer. It means they have an equal chance of receiving either intervention, which makes sure it is a fair test. Either intervention could be equally as effective, we do not know.

1. Why am I being asked to take part?

We have invited you to take part in this trial because you are a communication partner of someone with a diagnosis of mild cognitive impairment who is over the age of 55 and has also agreed to take part in this trial.

1. Do I have to take part?

No, it is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. You can withdraw at any time without giving a reason. If you decide to withdraw, any identifiable information we have collected about you will be destroyed, but data which is not identifiable may be kept. Your withdrawal will not affect the participant’s continuation in the trial.

If you do not want to formally want to take part, you do not have to, but you are still welcome to support the participant with the intervention.

1. What will happen to me if I take part?

First, a research assistant and research audiologist will meet with the participant to check if they are eligible for the trial, which will include a hearing test. If they have hearing loss and meet the other eligibility criteria, we will ask you, the communication partner, if you would also like to take part in the trial. If you decide to take part in the trial after reading this information sheet and have had the opportunity to ask any questions, we will ask you to sign a consent form. You will be asked to answer some questionnaires at a visit from a research assistant after the participant has been allocated to one of the interventions. These questionnaires will include questions about the quality of the communication between yourself and the participant, your mood, and your quality of life, and also questions about the participant including their mood, social function, and activities of daily living. You will then be asked the same questions about six months later at the final trial visit. These questionnaires will last approximately 60-70 minutes.

You will also be invited to attend the four intervention visits in between the assessment visits, to support the participant with the intervention. All visits will either take place at the participant’s home or at the Division of Psychiatry, UCL, depending on the participant’s preference. If you do not formally want to take part, you do not have to, but you are still welcome to attend the trial visits and support the participant with the intervention.

At the end of the trial, if you agree to be contacted, we may ask you if you would be willing to participate in an interview to discuss your experience of the trial. This is optional and you will be asked to complete a separate consent form if you decide to take part.

1. What are the possible benefits of taking part?

We believe participants could potentially benefit from a hearing test and appropriate treatment. Also, the information we get might lead to a larger trial which might help to improve things for people with mild cognitive impairment in the future.

1. What are the possible disadvantages and risks of taking part?

We do not feel there are any risks associated with this trial for communication partners. If at any time you are upset or wish to move on during the assessments, you can inform the researcher. If you feel upset or distressed by the assessments you can speak to the researcher afterwards.

1. .What if something goes wrong?

If you have a concern about any aspect of this trial you should ask to speak to the researcher or Miss Kingsley Powell, Trial Manager, in the first instance (see the contact details at the end of the information sheet). Alternatively you can contact the Chief Investigator, Dr Sergi Costafreda (email tact-study@ucl.ac.uk or telephone +44(0) 207 679 9059).

If you feel your complaint has not been handled satisfactorily, please contact the Patient and Liaison Service (PALS) at your NHS Trust. PALS can provide information on Trust policies and put you in touch with the relevant people to help your resolve your concerns. PALS can also assist people in making formal complaints if necessary. You can find your nearest PALS office on the NHS choices website, or ask your GP surgery or hospital for the details (or phone NHS on 111).

**Insurance**

The management of the research will be covered by UCL insurance for negligent harm.

1. Will my taking part in this project be kept confidential?

All the information that we collect about you during the course of the research will be stored at University College London and kept strictly confidential and only accessed by authorised members of the research team. All data collected about you will be anonymised by using participant ID numbers which will uniquely identify each individual and be stored in a locked filing cabinet. Data will also be stored electronically on password protected computers. Identifiable information is only kept electronically where it is necessary for the conduct of the trial. You will not be able to be identified in any ensuing reports or publications. The research team will occasionally need to allow monitors from Regulatory Authorities to inspect the study paperwork, in order to meet legal, ethical and safety requirements. All individuals who have access to data will be bound by strict data protection and confidentiality rules.

If you take part in an interview at the end of the trial, it will be audio-recorded to ensure we have an accurate record of what is discussed. The recording will be transcribed (written up with the exact words used by you and the interviewer) by a third party who will be bound by the same strict data protection regulations as the research team. During transcription any identifiable information (e.g. names and places) will be removed so that you cannot be identified. These recordings will be destroyed once the information has been transcribed and analysed.

**Limits to confidentiality:**

If during the interview or assessments you tell the researcher something that makes them concerned for your safety, or the safety of others, they will have to share this information as appropriate with the safeguarding team.

1. What will happen to the results of this trial?

We intend to publish the results of this study in scientific journals. All results will have your personal data (identifiable information, for example your name and address) removed so you cannot be identified in any published articles. We will also provide you with a short summary of the findings.

1. Data Protection Privacy Notice

University College London (UCL) is the sponsor for this trial based in the United Kingdom. We will be using information from you in order to undertake this trial and will act as the data controller for this trial. This means that we are responsible for looking after your information and using it properly.

Please see UCLs Privacy Notice for participants in healthcare research available at: <https://www.ucl.ac.uk/legal-services/privacy/participants-health-and-care-research-privacy-notice> for further details.

In addition to the processing outlined in the notice above, please be aware that we will further process your personal data in the following way:

UCL will use your name and contact details to contact you about the research trial. Individuals from UCL and regulatory organisations may look at your research records to check the accuracy of the research trial. The only people in UCL who will have access to information that identifies you will be people who need to contact you to carry out the trial visits or audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name or contact details.

UCL will keep identifiable information about you for 6-12 months after the trial has finished.

**Your rights**

Under certain circumstances, you may have the following rights under data protection legislation in relation to your personal data:

* Right to request access to your personal data;
* Right to request correction of your personal data;
* Right to request erasure of your personal data;
* Right to object to processing of your personal data;
* Right to request restriction of the processing your personal data;
* Right to request the transfer of your personal data; and
* Right to withdraw consent.

If you wish to exercise any of these rights, please contact the Data Protection Officer.

**Contacting us**

You can contact UCL by telephoning +44 (0)20 7679 2000 or by writing to: University College London, Gower Street, London WC1E 6BT.

Please note that UCL has appointed a Data Protection Officer. If you have any questions about this Privacy Notice, including any requests to exercise your legal rights, please contact our Data Protection Officer using the details set out below:

Data Protection & Freedom of Information Officer

data-protection@ucl.ac.uk

**Complaints**

If you wish to complain about our use of personal data, please send an email with the details of your complaint to the Data Protection Officer so that we can look into the issue and respond to you.

You also have the right to lodge a complaint with the Information Commissioner's Office (**ICO**) (the UK data protection regulator). For further information on your rights and how to complain to the ICO, please refer to the [ICO website](https://ico.org.uk/).

1. Who is organising and funding the trial?

This trial is organised by University College London (UCL). The funder is Alzheimer’s Research UK.

1. Who has reviewed the trial?

This trial has been reviewed by an independent group of people, called the Research Ethics Committee, to protect your safety, rights, well-being and dignity. The trial has been given a favourable opinion by London - Surrey Research Ethics Committee.

1. Contact for further information

Miss Kingsley Powell, Trial Manager for the TACT trial

Division of Psychiatry, UCL

6th Floor, Wing A, Maple House

 149 Tottenham Court Road

London

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Telephone: 0203 108 6274

Email: tact-study@ucl.ac.uk

**Thank you for reading this information sheet and for considering to take part in this research trial.**