**Participant 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.
* This trial is about reducing risk of dementia by treating hearing loss. **Please note we do not presume that you have hearing loss, but we will offer you a hearing test to see whether you could benefit from taking part.** If a hearing impairment is detected you may be eligible to receive one of our interventions, which are explained in this information sheet.
* 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, where we compare 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, and will not in itself answer the question about whether a hearing aid support intervention or healthy ageing intervention can reduce 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 healthy 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. If you receive this intervention, you will be fitted with hearing aids, taught how to use them, and you will be given practical advice and support.

**The healthy ageing intervention:**

This intervention will be carried out by a research assistant. If you receive this intervention you will be given information about healthy ageing factors that may reduce the risk of developing dementia. Specifically, you 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 you will receive?**

Each person 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 you 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 have a diagnosis of mild cognitive impairment and are aged 55 or over. 76 participants will be recruited in total.

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 and without it affecting any benefits that you are entitled to. If you do withdraw, any identifiable information we have collected about you will be destroyed, but information that is not identifiable may be kept.

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

If you decide you would like to take part in the trial after reading this information sheet, and you have had the opportunity to ask any questions, a researcher will arrange a mutually convenient time to meet with you to carry out a ‘screening’ visit. This initial visit will assess whether you are eligible to take part and will be carried out by a research assistant and a research audiologist. You will be asked to sign a consent form and undergo a hearing assessment. If the research audiologist finds that there is wax in your ear and we need to remove it to find out if you have hearing loss, the research audiologist might be able to remove it or we will give you advice on how the earwax could be removed either through your GP or privately (in which case we may refund the cost, up to a maximum of £200).

If the hearing test shows that you have some hearing loss and you meet the other eligibility criteria, you will be allocated to either the hearing intervention or the healthy ageing intervention. We will also write to your GP with the results of the hearing test. If you have a communication partner (someone you see on a near daily basis), they will also be invited to take part if you are happy for them to do so. If they do not formally want to take part, they do not have to, but they are still welcome to support you with the intervention.

After this, there will be six more visits over approximately six months. You will have a visit after you have been allocated to one of the interventions, to complete questionnaires about mood, memory, quality of life, and activities of daily living. Then you will have four visits to receive the intervention, each lasting about 1 hour. A final visit will be carried out around six months after you joined the trial, to repeat the questionnaires on mood, memory, quality of life, and activities of daily living. The visits will take place either at your home or at the Division of Psychiatry, University College London (UCL), depending on your preference.

If you receive the hearing intervention, we will provide you with a pair of hearing aids. At the end of the trial, you will be able to keep the hearing aids, which will be covered by the standard guarantees of the manufacturer (this may require sharing of your personal contact details, with your agreement, with an approved local hearing care provider at the end of the trial). If, after the trial, you require further audiological advice or care, you will need to seek a referral via your GP to NHS audiological services.

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 from this trial is likely to help us conduct a larger trial, which could in turn improve outcomes 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. If you are asked to wear a hearing aid in this trial, there is a very small chance you might experience dizziness, nervousness or headaches or local discomfort. We will ask you about any problems you are experiencing with the hearing aid, and the research audiologist will try to resolve these.

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. You can also withdraw from the trial at any point, without giving a reason.

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 contact details are 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?

A copy of this information sheet and your signed consent form will be placed in your medical notes so that any health care professionals involved in your care are aware of your participation in the trial.

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 (that is, 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, NHS number and contact details to contact you about the research trial, and make sure that relevant information about the trial is recorded for your care, and to oversee the quality of the trial. Individuals from UCL and regulatory organisations may look at your medical and research records to check the accuracy of the research trial. Your NHS Trust will pass on your name, NHS number and contact details to UCL if you have agreed for them to do so. 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, NHS number or contact details.

We will transfer your contact information (mobile number only) to a 3rd party text messaging service, GreenText – Their privacy policy - <https://www.gntext.com/privacy-data-processing-policy.aspx>. We will transfer your data to GreenText for the purposes of the trial, for example, to remind you to wear your hearing aids if you are in the hearing aid intervention group. You will be asked if you are happy to receive these text reminders during the trial, and at this point, you can opt out of text messages if you do not wish to be contacted in this way.

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 pilot trial

Division of Psychiatry, UCL

6th Floor, Wing A, Maple House

 149 Tottenham Court Road

London

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Email: tact-study@ucl.ac.uk

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