**Participant information sheet**

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

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

**Department:** Division of Psychiatry

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

 Danielle Proctor E: tact-study@ucl.ac.uk T: 0203 108 6274

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

* You are being invited to take part in a remotely delivered version of the TACT pilot trial, either because you are currently a participant in the trial, or because you recently took part in this trial.
* 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
* 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 works on a smaller scale. We want to find out useful information that will help the main trial be a success. As you are aware, we have already been carrying out a test run (pilot) of the main trial, which you have participated in. We have already learned a lot from the information we have already collected from participants, such as you. We have learnt that people with mild cognitive impairment were willing to take part, engage with the hearing aid and healthy ageing interventions, and be followed for 6 months.

The Coronavirus pandemic (COVID-19) means that face to face contact carries a risk of spreading the virus. We would now like to test in this trial if it is possible to provide support and assistance with hearing aids remotely, so it is safe even with the pandemic going on. Instead of face-to-face visits, we are providing hearing aids and support remotely, such as by phone, email, and by post.

**What is the intervention?**

**The Remote Hearing Intervention:**

This intervention will be carried out by a research assistant and research audiologist. After you have given your consent, we will go through some questionnaires with you about your health, mood, memory and hearing. Our audiologist will use your previous hearing test results to programme your new hearing aids, and you will receive them in the post along with other useful equipment and instructions for use. After you have had a few days to try out your new hearing aids, a researcher from our team will call you to answer any questions you may have and advice will be given on how to use, clean and charge your new hearing aids. You will be supported via telephone calls, text messages and/or email correspondence during the trial period (depending on your personal preferences), and you are encouraged to call the team with any issues you may be experiencing. For a full overview of what the trial involves, please see Section 4 of this information sheet.

1. Why am I being asked to take part?

Due to the current COVID 19 pandemic, we have had to suspend our previous face-to-face TACT pilot trial interventions (hearing and healthy ageing interventions). We will now be focusing on providing hearing aids and support remotely to participants, as this is safer during this pandemic. As you were previously eligible for the TACT trial, we are now inviting you to take part in this remote delivery trial to see if we can successfully provide our hearing aids and support to participants from a distance.

1. Do I have to take part?

No, it is up to you to decide if you want to take part. If you do decide to take part, you will be sent this information sheet, and we will contact you to confirm your consent to take part over the telephone. We will record the conversation where we take your verbal consent. 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 call you to check you are still eligible for the trial and will go through the consent form with you. You will be asked to give your consent over the telephone and this will be recorded by an audio device so there is a record of your agreement.

There will then be four sessions over a month.

* Session 1: This will take place after you have given verbal consent to take part. This will involve completing questionnaires about your health, mood, memory and your hearing.
* The audiologist will then use your previous hearing test results to programme your new hearing aids and these will be sent to you in the post, along with other useful equipment and information.
* Session 2: Once you’ve had a few days to try out your new hearing aids, the audiologist will call you to provide further support and assist with any issues you may be experiencing.
* Session 3: The research assistant/audiologist will call you again one week later (or at a time that suits you) to provide any further support you may require. You will be encouraged to call the team any time you require extra assistance or have any questions throughout the trial period.
* Session 4: The final session will be carried out around 1 month after you joined the trial. You will be asked to repeat the questionnaires on mood, memory, and hearing. We will also check to see how you are getting on with your hearing aids and whether you require any assistance.

All four sessions will take place remotely via telephone calls, text messages and/or email communication (depending on your personal preferences). We will aim to contact you at times that best suit you.

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 their new hearing aids, as well as professional support and guidance being provided to them remotely. This trial will help us further understand ways in which we can support people remotely even if there is a pandemic and lockdown. This will not only provide useful information in times like the current pandemic, but will also give us information on the options we have to support people with mild cognitive impairment and hearing loss even when there is no lockdown.

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

We do not feel there are any risks associated with this trial. There is a very small chance you might experience dizziness, nervousness or headaches or local discomfort when wearing the hearing aids. 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 Danielle Proctor, 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 you 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 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. Audio recordings of the consent process will be transferred to a secure data storage system (the Data safe Haven) at University College London that can only be accessed by authorised members of the research team.

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 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 send a reminder of our team contact details should you be experiencing any issues with your new hearing aids. You will be asked if you are happy to receive text messages 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.

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 Danielle Proctor, Trial Manager for the TACT pilot trial

Division of Psychiatry, UCL

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 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.**