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Treating auditory impairment and cognition pilot trial

Submission date
17/02/2020

Recruitment status
No longer recruiting

Registration date
20/02/2020

Overall study status
Completed

Last Edited
11/03/2026

Condition category
Nervous System Diseases

[_] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
It is a new finding that hearing loss is major risk factor for subsequent dementia. Hearing loss increases dementia risk more than lacking education, being diabetic or depressed or having a poor diet. Therefore, untreated hearing loss may be a missed opportunity to delay and prevent dementia in a substantial number of people. The researchers want to find out if a hearing aid intervention can prevent or delay the onset of dementia in older adults who are at greater risk of developing dementia (i.e. those with mild cognitive impairment). Before the researchers can do a full trial to answer this question, the researchers need to run a pilot trial to see if the researchers can recruit participants and assess the acceptability of the proposed interventions.

The researchers plan to compare two interventions in this pilot trial. The hearing intervention will involve hearing aid provision and support over four sessions, while the healthy ageing intervention will involve standard audiological care (i.e. the participant will be informed of their hearing loss and advised to see their GP) and four one-to-one sessions with a researcher on behavioural changes that can promote healthy ageing and may reduce risk of progression from mild cognitive impairment to dementia.

Due to the COVID-19 pandemic the initial face-to-face hearing aid and support intervention would not be suitable as it could put participants at increased risk of contracting the virus. The study team have redeveloped the TACT Remote Hearing Intervention Sub-study to test the feasibility and acceptability of a Remote Hearing Intervention during the COVID-19 pandemic.

Who can participate?
Persons living in the community, 55 years of age or older with mild cognitive impairment and hearing loss.

What does the study involve?
Participants will be randomly allocated to receive either a hearing aid plus support or home based sessions on behavioural changes. Each eligible participant will receive seven visits over six months, including the four intervention sessions. At two of the visits (baseline and follow up) they will be asked to complete some cognitive and mood assessments.

For the TACT Remote Hearing Intervention Sub-study (during COVID-19) participants will be provided with programmed hearing aids through the post. They will receive four sessions over one month, with support provided by a Research Assistant and a Research Audiologist. All four sessions will take place remotely via telephone calls, text messages and/or email communication. At sessions one and four (baseline and follow-up) they will be asked to complete a cognitive and mood assessment.

What are the possible benefits and risks of participating?
Benefits: Participants could potentially benefit from a hearing test and appropriate treatment. Also, the information the researchers get might lead to a larger trial which might help to improve things for people with mild cognitive impairment in the future.
Risks: The researchers do not feel there are any risks associated with this trial. There is a small chance that participants who are asked to wear a hearing aid might experience dizziness, nervousness or headaches or local discomfort. The researchers ask participants about any problems they are experiencing with the hearing aid and the research audiologist will try to correct these. Some of the questionnaires ask sensitive questions. If participants become upset or distressed by any of these questions, they do not have to answer them and ask to move on.

Where is the study run from?
University College London (UK)

When is the study starting and how long is it expected to run for?
October 2018 to February 2021

Who is funding the study?
Alzheimer's Research UK

Who is the main contact?
Dr Sergi Costafreda Gonzalez (scientific)
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Contact information

Type(s)
Scientific

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Public

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Additional identifiers

Integrated Research Application System (IRAS)
246188

Protocol serial number
18/0079

Study information

Scientific Title
Treating Auditory impairment and CogniTion: a randomised, parallel, pilot trial in older adults with mild cognitive impairment and hearing loss of an intervention to provide and support hearing aid use vs a health education intervention for dementia risk.

Acronym
TACT

Study objectives
Current study hypothesis as of 01/03/2021:
The aim of the study is to establish feasibility of recruitment, randomisation, retention, acceptability of the study interventions (Hearing Intervention and Healthy Ageing Intervention).

TACT Remote Hearing Intervention Sub-study:
During the COVID-19 pandemic, the trial will instead pilot a remotely delivered version of the active intervention of the TACT trial. The aim of this sub-study is to test recruitment, feasibility and acceptability of a remotely delivered intervention in this population.

Previous study hypothesis:
The aim of the study is to establish feasibility of recruitment, randomisation, retention, acceptability of the study interventions (Hearing Intervention and Healthy Ageing Intervention).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Current ethics approval as of 01/03/2021:
1. Approved 24/08/2018, London - Surrey Research Ethics Committee (Health Research Authority, Skipton House, 80 London Road, London, SE1 6LH, UK; +44 (0)207 104 8222; NRESCommittee.SECoast-Surrey@nhs.net), ref: 18/LO/1196
2. TACT Remote Hearing Intervention Sub-study substantial amendment approved 25/09/2020, London - Surrey Research Ethics Committee (Health Research Authority, Skipton House, 80 London Road, London, SE1 6LH, UK; +44 (0)207 104 8222; NRESCommittee.SECoast-Surrey@nhs.net), ref: 18/LO/1196

Previous ethics approval:
Approved 24/08/2018, London - Surrey Research Ethics Committee (Health Research Authority, Skipton House, 80 London Road, London, SE1 6LH, UK; +44 (0)207 104 8222; NRESCommittee.SECoast-Surrey@nhs.net), ref: 18/LO/1196

Primary study design
Interventional

Study design
Single-centre randomized unblinded parallel pilot trial with a single-arm non-randomised remote intervention sub-study

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Mild cognitive impairment and hearing loss

Interventions
Current interventions as of 01/03/2021:
Hearing intervention:
Home-based hearing aid fitting and one-to-one adherence support over 12 weeks.

Healthy Ageing Intervention:
Home-based, one-to-one sessions with a researcher (matching the intensity of social contact of the Hearing Intervention) on behavioural changes that can promote healthy ageing and may reduce risk of progression from MCI to dementia (blood pressure, diet, physical activity, healthy bones, joints and muscles).

Participants will be randomised to either the Hearing Intervention or Healthy Ageing Intervention by computer programme on a 1:1 ratio.

TACT Remote Hearing Intervention Sub-study (during COVID-19):
Remotely delivered version of the active intervention of the TACT pilot trial. Hearing aids will be sent through the post and support will be provided remotely over 4 weeks.

Previous interventions:
Hearing intervention: Home based hearing aid fitting and one-to-one adherence support over 12 weeks.

Healthy Ageing Intervention: Home-based, one-to-one sessions with a researcher (matching the intensity of social contact of the Hearing Intervention) on behavioural changes that can promote healthy ageing and may reduce risk of progression from MCI to dementia (blood pressure, diet, physical activity, healthy bones, joints and muscles).

Participants will be randomised to either the Hearing Intervention or Healthy Ageing Intervention by computer programme on a 1:1 ratio.

Intervention Type
Behavioural

Primary outcome(s)
Current primary outcome measure as of 01/03/2021:
This pilot trial aims at establishing the feasibility of a full-size trial of the hearing aid intervention versus healthy ageing intervention in people with MCI. The pilot's primary objective is therefore to establish feasibility of recruitment, randomisation, retention, and the acceptability of the trial interventions as follows:
1. Recruitment and randomisation: Proportion of eligible participants who are randomised into the trial
2. Retention: proportion of participants who are followed for the 6 months of trial duration, and endpoint measures are obtained
3. Acceptability of the Hearing Intervention: proportion of participants allocated to the Hearing Intervention completing ≥2 intervention sessions

TACT Remote Hearing Intervention Sub-study (during COVID-19):
The Primary outcome of the Remote Hearing Intervention sub-study in keeping with the overall TACT primary objective, will be the feasibility of the Remote Hearing Intervention, in terms of:
1. Recruitment: achieving n=12 participants
2. Acceptability of the Remote Hearing Intervention proportion of participants allocated to the Hearing Intervention completing ≥2/3 intervention sessions– expected value ≥80%.
3. Retention: proportion of participants completing outcome collection– expected value ≥80%.

Previous primary outcome measure:
This pilot trial aims at establishing the feasibility of a full-size trial of the hearing aid intervention versus healthy ageing intervention in people with MCI. The pilot's primary objective is therefore to establish feasibility of recruitment, randomisation, retention, and the acceptability of the trial interventions as follows:
1. Recruitment and randomisation: Proportion of eligible participants who are randomised into the trial
2. Retention: proportion of participants who are followed for the 6 months of trial duration, and endpoint measures are obtained
3. Acceptability of the Hearing Intervention: proportion of participants allocated to the Hearing Intervention completing ≥2 intervention sessions

Key secondary outcome(s)

Current secondary outcome measures as of 01/03/2021:
1. Proportion of participants maintaining hearing aid use, defined as a minimum of 4h a day on average since last trial assessment (when at home and in usual health) as established by data-logging at 6 months (end of trial), based on the hearing aid with the highest average use (as each participant has two hearing aids). Self-reported hearing aid use may also be employed if needed, for instance, if no data-logging is available for a participant
2. Participants rating of the interventions based on Likert scale scores.
3. Cognitive scales and the following other trial outcomes:
3.1. Delayed word recall test (DWRT): encoding and recall
3.2. Addenbrooke Cognitive Examination (ACE-III)
3.3. Trail Making Test (TMT) Part A and B
3.4. Self-reported hearing disability - Hearing Handicap Inventory for the Elderly – Screening version (HHIE-S)
3.5. Geriatric depression scale (GDS)
3.6. Quality of life questionnaires: Short Form 36 and EQ-5D
3.7. Items of the Lawton – Brody Instrumental Activities Of Daily Living Scale (I.A.D.L.): A. Telephone, F. Transport, G. Medication, H. Finances
3.8. Social function scale SF-DEM – patient rated version
3.9. UCLA Version 3 Loneliness Scale
3.10. Grip strength
3.11. Accelerometer
4. Communication Partner (when available):
4.1.The Hearing Impairment Impact–Significant Other Profile
4.2. Health-related quality of life of communication partner with SF36 and EQ-5D
4.3. Hospital anxiety and depression HADS
4.4. Carer-rated version of the SF-DEM
4.5. Brody Instrumental Activities Of Daily Living Scale
5. Number of potential participants referred to the study researchers, screening visits scheduled and completed
6. Feasibility of the schedule of assessments, which will include proportion of completed interviews and completion rates of instruments and questionnaires, as well as relevant biometric data
7. Completion rates of the interventions by recording the proportion of participants who completed the intervention, any refused or discontinued visits for the Hearing Intervention and Healthy Ageing Intervention, and any refused or discontinued tests and instruments from the schedule of assessments
8. For the Hearing Intervention, we will record the number of participants with hearing aid fitted within 3 months and reported side effects
9. Average hearing aid daily use measured as number of hours of use on average over 7 days (when at home and in usual health) as established by data-logging at 6 months (end of trial) for the Hearing Intervention and Healthy Ageing Arms. Self-reported hearing aid use may also be employed if needed, for instance if no data-logging is available for a participant, as further specified in the Statistical Analysis Plan
10. Number of unscheduled contact with participants, including type of contact (face to face or other) and whether this was with RA or research audiologist
11. Number of hearing aids lost by participants in the intervention and control arm
12. ROC analysis of HearCheck and Shoebox audiometry relative to gold standard full audiometric testing conducted by the trial audiologist, on the detection of hearing loss as defined for this trial (four-frequency pure tone average (0.5, 1, 2, 4 kHz) in the better-hearing ear of >= 25 decibels Hearing Level (dB HL) and <70 dB HL or a pure tone audiometric threshold at 4

KHz in the better ear of >= 30 decibels dB HL)
13. Reported side effects

TACT Remote Hearing Intervention Sub-study (during COVID-19):
The Secondary Outcomes of the Remote Hearing Intervention sub-study, in keeping with the overall TACT objective, will include:
1. Evaluation of the deliverability and acceptability of the Remote Hearing intervention
1.1. Completion rates of the Remote Hearing Intervention measured by recording the proportion of participants who completed each contact visit of the intervention, any refused or discontinued visits, and any refused or discontinued tests and instruments from the remote schedule of assessments.
1.2. Qualitative assessment of the remote intervention measured using interviews with up to 12 participants about the Remote Hearing Intervention (involvement, practicality, acceptability) and about their opinion of the assessment.

Previous secondary outcome measures:
1. Proportion of participants maintaining hearing aid use, defined as a minimum of 4h a day on average since last trial assessment (when at home and in usual health) as established by data-logging at 6 months (end of trial), based on the hearing aid with the highest average use (as each participant has two hearing aids). Self-reported hearing aid use may also be employed if needed, for instance, if no data-logging is available for a participant
2. Participants rating of the interventions based on Likert scale scores.
3. Cognitive scales and the following other trial outcomes:
3.1. Delayed word recall test (DWRT): encoding and recall
3.2. Addenbrooke Cognitive Examination (ACE-III)
3.3. Trail Making Test (TMT) Part A and B
3.4. Self-reported hearing disability - Hearing Handicap Inventory for the Elderly – Screening version (HHIE-S)
3.5. Geriatric depression scale (GDS)
3.6. Quality of life questionnaires: Short Form 36 and EQ-5D
3.7. Items of the Lawton – Brody Instrumental Activities Of Daily Living Scale (I.A.D.L.): A. Telephone, F. Transport, G. Medication, H. Finances
3.8. Social function scale SF-DEM – patient rated version
3.9. UCLA Version 3 Loneliness Scale
3.10. Grip strength
3.11. Accelerometer
4. Communication Partner (when available):
4.1.The Hearing Impairment Impact–Significant Other Profile
4.2. Health-related quality of life of communication partner with SF36 and EQ-5D
4.3. Hospital anxiety and depression HADS
4.4. Carer-rated version of the SF-DEM
4.5. Brody Instrumental Activities Of Daily Living Scale
5. Number of potential participants referred to the study researchers, screening visits scheduled and completed
6. Feasibility of the schedule of assessments, which will include proportion of completed interviews and completion rates of instruments and questionnaires, as well as relevant biometric data
7. Completion rates of the interventions by recording the proportion of participants who completed the intervention, any refused or discontinued visits for the Hearing Intervention and Healthy Ageing Intervention, and any refused or discontinued tests and instruments from the schedule of assessments
8. For the Hearing Intervention, we will record the number of participants with hearing aid fitted

within 3 months and reported side effects
9. Average hearing aid daily use measured as number of hours of use on average over 7 days (when at home and in usual health) as established by data-logging at 6 months (end of trial) for the Hearing Intervention and Healthy Ageing Arms. Self-reported hearing aid use may also be employed if needed, for instance if no data-logging is available for a participant, as further specified in the Statistical Analysis Plan
10. Number of unscheduled contact with participants, including type of contact (face to face or other) and whether this was with RA or research audiologist
11. Number of hearing aids lost by participants in the intervention and control arm
12. ROC analysis of HearCheck and Shoebox audiometry relative to gold standard full audiometric testing conducted by the trial audiologist, on the detection of hearing loss as defined for this trial (four-frequency pure tone average (0.5, 1, 2, 4 kHz) in the better-hearing ear of >= 25 decibels Hearing Level (dB HL) and <70 dB HL or a pure tone audiometric threshold at 4 KHz in the better ear of >= 30 decibels dB HL)
13. Reported side effects

Completion date
28/02/2021

Eligibility

Key inclusion criteria
Current participant inclusion criteria as of 01/03/2021:
1. Clinical diagnosis of MCI following internationally recognised clinical criteria (ICD 10), as diagnosed (or confirmed) by an NHS memory Service and not superseded by a diagnosis of dementia
2. 55 years of age or older (as MCI under 55 is rarely linked to neurodegeneration and future dementia)
3. Living in the community (not in hospital or residential care)
4. Mental capacity to provide informed consent to trial procedures
5. Audiometric hearing impairment. Participants must have adult-onset hearing impairment with a four-frequency pure tone average (0.5, 1, 2, 4 kHz) in the better-hearing ear of ≥25 decibels Hearing Level (dB HL) and <70 dB HL or a pure tone audiometric threshold at 4 KHz in the better ear of ≥30 decibels dB HL
6. Phoneme Recognition in Quiet score ≥60% in better ear. A phoneme recognition in quiet score <60% suggests hearing impairment that may be too severe to benefit from conventional amplification devices such as hearing aids
7. No previous prescription of hearing aids, or, if the potential participant has been prescribed hearing aid in the past, they report no hearing aid use at all in the past month (see temporary exclusion criteria number 8a under temporary exclusion criteria), or low use because of lack of perceived efficacy. Low use is defined as less than 2 hours per day on average over the past 7 days (when at home and in usual health).
8. Willingness to participate, be randomized and adhere to the protocol. Participants must be willing and able, in the opinion of the researchers, to consent to participate in the trial, to be randomized, and to adhere to the trial protocol, including willingness to wear hearing aids on a daily or near daily basis if allocated to the intervention arm, and to be followed for the duration of the trial (30 weeks)

TACT Remote Hearing Intervention Sub-study (during COVID-19):
1. Consented for the randomised trial prior to the onset of COVID-19, therefore meeting the inclusion and exclusion criteria at the time they consented to participate in TACT, and who fulfill

one of the following:
1.1. Completed the healthy ageing intervention and are not using hearing aids
1.2. Included in the trial but not could not complete their allocated intervention due to the onset of COVID-19.

Previous participant inclusion criteria:
1. Clinical diagnosis of MCI following internationally recognised clinical criteria (ICD 10), as diagnosed (or confirmed) by an NHS memory Service and not superseded by a diagnosis of dementia
2. 55 years of age or older (as MCI under 55 is rarely linked to neurodegeneration and future dementia)
3. Living in the community (not in hospital or residential care)
4. Mental capacity to provide informed consent to trial procedures
5. Audiometric hearing impairment. Participants must have adult-onset hearing impairment with a four-frequency pure tone average (0.5, 1, 2, 4 kHz) in the better-hearing ear of >= 25 decibels Hearing Level (dB HL) and <70 dB HL or a pure tone audiometric threshold at 4 KHz in the better ear of >= 30 decibels dB HL
6. Phoneme Recognition in Quiet score ≥60% in better ear. A phoneme recognition in quiet score <60% suggests hearing impairment that may be too severe to benefit from conventional amplification devices such as hearing aids
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8. Willingness to participate, be randomized and adhere to the protocol. Participants must be willing and able, in the opinion of the researchers, to consent to participate in the trial, to be randomized, and to adhere to the trial protocol, including willingness to wear hearing aids on a daily or near daily basis if allocated to the intervention arm, and to be followed for the duration of the trial (30 weeks)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

Total final enrolment
0

Key exclusion criteria
Current participant exclusion criteria as of 01/03/2021:
1. Spoken or written English is not sufficient for trial procedures, including reading of the trial materials, in the opinion of the research team
2. Diagnosis of hearing loss with onset in childhood (<18 years of age) as reported by the patient

during the initial clinical interview
3. Participant meets ICD-10 criteria for current substance use disorder (abuse or dependence) or alcohol-related brain damage
4. If the audiological assessment shows that the participant meets criteria for onward medical referral (according to British Academy of Audiology criteria), and the issue has not already been investigated or addressed, we will request their permission to write to their GP with the results of our assessment and recommendation for referral. Where clinically appropriate the participant will continue in the trial, or the participant may be temporarily or permanently excluded based on the audiologist's clinical judgement as to whether the issue identified is a contraindication for hearing aid treatment.'
5. Presence of conductive hearing impairment as determined by standard audiological assessment using the difference between air audiometry and bone audiometry ("air-bone gap") greater than 20 dB over at least 4 frequencies of 0.5,1,2,3,4 KHz on both ears, as well as tympanometry and tuning fork test (British Academy of Audiology, 2017). Because the impact of a conductive (versus a sensorineural) hearing loss on cognitive functioning may potentially differ and programming for hearing aids differs for conductive hearing loss, participants with permanent conductive hearing loss are excluded from the trial
6. Unwillingness or inability, in the opinion of the researchers, to complete trial procedures and /or wear hearing aids on a daily or near daily basis.
7. Concurrent participation in other interventional research: participants will be excluded if they are already participating in another trial
8. Temporary Exclusion Criteria:
8.1. Potential participants will be excluded if hearing aids were prescribed in the past three months, irrespective of their use; however, we will contact these potential participants again after 3 months following prescription of their hearing aids and they will be eligible if they report no or low use of hearing aids. Low use is defined as less than 2 hours per day on average over the past 7 days (when at home and in usual health)
8.2. Participants determined to have occluding cerumen as per otoscopy. These participants may be enrolled after cerumen removal. We will advise participants with occluding cerumen to access accredited cerumen removal services, following recent NICE guidelines (https://cks.nice.org.uk /earwax, and "Hearing loss in adults: assessment and management"; NICE Guideline, June 2018 [NG98]). Participants who are identified as needing cerumen removal will be advised to consult their GP to arrange cerumen removal. They will also be offered reimbursement if they choose to have privately arranged cerumen removal by an accredited provider instead. If practicable, and at the discretion of the trial audiologist, participants may also be offered cerumen removal by the trial audiologist, who has undergone necessary training for cerumen removal procedures

TACT Remote Hearing Intervention Sub-study (during COVID-19):
1. In the opinion of the research team, would be unable to complete remote procedures
2. Report any new ear pain or discharge or any audiological symptoms that would require face-to-face audiological assessment prior to inclusion

Previous participant exclusion criteria:
1. Spoken or written English is not sufficient for trial procedures, including reading of the trial materials, in the opinion of the research team
2. Diagnosis of hearing loss with onset in childhood (<18 years of age) as reported by the patient during the initial clinical interview
3. Participant meets ICD-10 criteria for current substance use disorder (abuse or dependence) or alcohol-related brain damage
4. If the audiological assessment shows that the participant meets criteria for onward medical referral (according to British Academy of Audiology criteria), and the issue has not already been investigated or addressed, we will request their permission to write to their GP with the results

of our assessment and recommendation for referral. Where clinically appropriate the participant will continue in the trial, or the participant may be temporarily or permanently excluded based on the audiologist's clinical judgement as to whether the issue identified is a contraindication for hearing aid treatment.'
5. Presence of conductive hearing impairment as determined by standard audiological assessment using the difference between air audiometry and bone audiometry ("air-bone gap") greater than 20 dB over at least 4 frequencies of 0.5,1,2,3,4 KHz on both ears, as well as tympanometry and tuning fork test (British Academy of Audiology, 2017). Because the impact of a conductive (versus a sensorineural) hearing loss on cognitive functioning may potentially differ and programming for hearing aids differs for conductive hearing loss, participants with permanent conductive hearing loss are excluded from the trial
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7. Concurrent participation in other interventional research: participants will be excluded if they are already participating in another trial
8. Temporary Exclusion Criteria:
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Date of first enrolment
22/10/2018

Date of final enrolment
15/01/2021

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University College London
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Wing A, 6th Floor
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Sponsor information

Organisation
University College London

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Charity

Funder Name
Alzheimer’s Research UK

Alternative Name(s)
Alzheimer's Research Trust, AlzResearchUK, AlzheimersResearch UK, ARUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/01/2025	11/03/2026	Yes	No
HRA research summary			26/07/2023	No	No
Protocol file	version 1.6	27/07/2020	20/09/2024	No	No
Statistical Analysis Plan	version 4.0	22/04/2021	22/11/2024	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes