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Feasibility of a trial of the ACE programme for NHS patients with hearing impairment

Submission date
13/02/2017

Recruitment status
No longer recruiting

Registration date
02/03/2017

Overall study status
Completed

Last Edited
22/10/2021

Condition category
Ear, Nose and Throat

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

Plain English summary of protocol

Background and study aims
Hearing-impairment affects 10 million people in the UK, 70% over the age of 70. It can lead to loneliness, isolation, social withdrawal and reduced quality-of-life. The usual treatment is to fit hearing-aids. But approximately 1 in 3 people fitted with hearing-aids find them ineffective and struggle, needing further help to gain the potential improvements reported from hearing-aid use. Although reasons for unsuccessful hearing-aid use are well documented, one solution, extra communication help, is rarely provided by NHS hearing services. Communication difficulties experienced by hearing-impaired people often lead to unsuccessful hearing-aid use if they perceive the device to be of little benefit. In two small studies the Active Communication Education programme (ACE) has been shown to improve hearing-impaired adults' communication. The programme teaches patients and family members solutions to everyday situations where communication is difficult, such as conversing in background noise. The aim of this study is to find out whether a large study looking at the effectiveness of ACE plus a hearing aid, versus a hearing aid alone would be possible, by looking at whether people are willing and able to take part.

Who can participate?
Adults with hearing impairment who use their hearing aid for less than three hours per day.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive treatment as usual, which involves attending routine hearing-aid follow-up appointments at audiology departments. Those in the second group continue with usual treatment as well as taking part in the ACE programme with a family member. This involves attending five, two hour, weekly group sessions delivered in each department by a study audiologist. The programme teaches participants solutions to everyday situations where communication is difficult, such as conversing in background noise; communication with difficult speakers. All participants, including family members (significant others) who participate, are asked to complete a questionnaire, once at the beginning of the study and then again six months after being issued with their hearing aid(s). Those who attend the ACE are also asked to complete an additional

questionnaire asking about their experience in completing the ACE programme. A smaller number of participants from both groups are interviewed to find out about their experience of taking part in the study.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
1. BTHFT Audiology Department, Bradford Royal Infirmary (UK)
2. YTHFT Audiology Department, York Hospital (UK)

When is the study starting and how long is it expected to run for?
February 2017 to January 2019

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Dr Nicholas Thyer
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
32595

Study information

Scientific Title
Feasibility of a randomised controlled trial of the Active Communication Education (ACE) programme plus hearing-aid provision versus hearing-aid provision alone

Study objectives
The aim of this study is to determine the feasibility of a future large randomised controlled trial investigating the effectiveness of the Active Communication Education (ACE) programme plus a hearing aid, versus a hearing aid alone in increasing hearing aid use.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South East Coast - Surrey Research Ethics Committee, 16/01/2017, ref: 16/LO/2012

Study design
Randomised; Both; Design type: Treatment, Rehabilitation, Validation of investigation /therapeutic procedures

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Specialty: Ear, nose and throat, Primary sub-specialty: Ear, nose and throat; UKCRC code/ Disease: Ear/ Other disorders of ear

Interventions
A remote, centralised randomisation service provided by the York Trials Unit (YTU) will allocate participants to one of two groups. Eligible, consenting patients from the same study site who have completed their baseline assessments (at the usual three months post hearing aid fitting follow up appointment), will be randomised in batches of 10-14 (intervention: control ratio of 1: 1) using block randomisation in a single large block per batch. Following randomisation, a letter

outlining the next steps will be sent to participants and their Significant Others (SO) where relevant).

Control group: Participants continue to receive treatment as usual (TAU). This involves three audiology department appointments:
1. Information provision and impression taken for an ear-mould
2. Hearing-aid prescription and fitting
3. Follow up

Intervention group: Participants receive the Active Communication Education (ACE) programme, which is delivered by a trained audiologist (trained using standardized ACE training manual and DVD). Over five modules, patients and their significant-others are taught and develop solutions to everyday situations where communication is difficult. These include: establishing their communication needs; listening in background noise; conversation in the home and with difficult speakers; listening to environmental sounds and; building communication confidence. Using WHO's ICF as an underpinning framework, the programme adopts a problem solving interactive approach aimed at reducing everyday communication difficulties experienced by people with hearing-impairment and their significant-others, thereby improving quality-of-life and psychosocial well-being. The programme runs for two hours each week for five weeks, with five to seven patients (plus significant-others) per group. Participants also receive treatment as usual.

Follow-up data (self reported outcome measures) will be collected at three months and at six months post hearing-aid fitting. Follow up data regarding study feasibility and, processes will be collected during delivery of the intervention delivery and throughout the project.

Intervention Type
Behavioural

Primary outcome measure
Feasibility outcomes:
ACE Delivery outcomes:
1. Attendance and attrition: Attendance rates of participants and significant others at ACE sessions will be measured and who attends ACE session with the participant will be recorded
2. Fit of ACE with existing service delivery models: Attendance and attrition rates for ACE delivered at different study sites and their satellite clinics and the effect of using single and block-booking for follow-up appointments will be recorded
3. Whether ACE be delivered as intended in the ACE protocol will be assessed by recording time taken to train audiologists successfully; the number of ACE goals achieved by participants; and audiologist's adherence to the ACE protocol (fidelity)
4. Acceptability is measured using a bespoke acceptability questionnaire/interview regarding study processes administered to participants, significant others and audiologists at final ACE session and at a comparable time for the questions for the control arm

RCT Delivery Outcomes:
1. Recruitment (during 12 month recruitment following 3 month post-hearing-aid fitting follow up appointment): Number of direct referrals; number of direct referrals struggling with their hearing-aid; number of and reasons for exclusions; number of patients who decline to participate and reason for declining; number who miss ACE intervention window (i.e. unable to attend an ACE group within 1-3 weeks after randomisation); number given an appointment for an ACE group session; and number of consented patients who fail to attend ACE
2. Allocation: Time ACE started after randomisation (ACE intervention window); time taken to

recruit and logistics of recruiting an optimally sized and located ACE group
3. Outcome Measure Data: Completion and return rates of outcome measures at each time-point will be recorded as well as extent of missing data within each outcome measure (all self-reported by participants). The feasibility of collecting postal questionnaire data from these outcome measures, at each time point will be evaluated. Similarly the feasibility of collecting postal data from acceptability and resource use questionnaires at each time point will be evaluated for bespoke acceptability questionnaire regarding study processes and bespoke health care resource use questionnaire.

Secondary outcome measures
1. Hearing aid benefit is measured in control and intervention arms at 3 and 6 months post hearing aid fitting using the International Outcomes Inventory for Hearing Aids (IOI-HA)
2. ACE benefit is measured in the intervention arm only, at the end of the ACE intervention and 6 months post hearing aid fitting using the International Outcomes Inventory for Alternative Interventions (IOI-AI)
3. Communication benefit is measured in control and intervention arms at 3 and 6 months post hearing aid fitting using Self-Assessment of Communication (SAC)
4. Quality of Life is measured in control and intervention arms using the EQ-5D-5 and Short-Form 36 (SF-36) at 3 and 6 months post hearing aid fitting
5. Significant Others' benefit from the ACE intervention is measured in the intervention arm only, using the International Outcome Inventory for Alternative Interventions: version for Significant Others (IOI-AI-SO) at the end of the ACE intervention and 6 months post hearing aid fitting
6. Hearing disability associated with significant others is measured in control and intervention arms at 3 and 6 months post hearing aid fitting using the Significant Other Scale for Hearing Disability (SOS-HEAR)

Overall study start date
01/02/2017

Completion date
31/01/2019

Eligibility

Key inclusion criteria
Current inclusion criteria as of 12/03/2018:
1. Adult Direct Access GP referral
2. Moderate or less than moderate self-reported hearing aid benefit, defined by IOI-HA question 2
3. Aged 18 years or over, receiving treatment-as-usual delivered in one of the two participating centres.
4. Hearing impairment: pure-tone average better ear thresholds at 500, 1000, 2000, and 4000 Hz of more than 25 dB HTL.
5. No significant self-reported history of neurological impairment
6. Willing and able to provide written informed consent
7. Able to take part in the intervention by understanding and using spoken English
8. Able to self-complete the English language outcome measure tools

The following inclusion criteria for SOs will be assessed:
Should be a spouse or other family member who lives with or is a carer for a patient recruited to the study.

Previous inclusion criteria:
1. Adult Direct Access GP referral
2. Self-reported hearing-aid use less than three hours a day (supported by amount of use recorded by the hearing aid log if available; less than moderate benefit, defined by IOI-HA49 questions 1 and 2)
3. Aged 18 years or over, receiving treatment-as-usual delivered in one of the two participating centres.
4. Hearing impairment: pure-tone average better ear thresholds at 500, 1000, 2000, and 4000 Hz of more than 25 dB HTL.
5. No significant self-reported history of neurological impairment
6. Willing and able to provide written informed consent
7. Able to take part in the intervention by understanding and using spoken English
8. Able to self-complete the English language outcome measure tools

The following inclusion criteria for SOs will be assessed:
Should be a spouse or other family member who lives with or is a carer for a patient recruited to the study.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 112; UK Sample Size: 112

Total final enrolment
18

Key exclusion criteria
1. Severe or profound bilateral hearing impairment. Pure-tone better ear average thresholds measured at 500, 1000, 2000, and 4000 Hz of more than 85 dB HTL
2. Significant on-going ear related health or mental health issues that, in the audiologist's or associate audiologist's professional opinion would preclude hearing-aid fitting or attendance at ACE sessions
3. Unable or unwilling to give written informed consent

Date of first enrolment
01/04/2017

Date of final enrolment
30/04/2018

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
BTHFT Audiology Department, Bradford Royal Infirmary
Duckworth Lane
Bradford
United Kingdom
BD9 6RJ

Study participating centre
YTHFT Audiology Department, York Hospital
Wigginton Road
York
United Kingdom
YO31 8HE

Sponsor information

Organisation
Bradford Teaching Hospitals NHS Foundation Trust

Sponsor details
The Research Management & Support Office
Bradford Institute for Health Research
Bradford Royal Infirmary
Duckworth Lane
Bradford
England
United Kingdom
BD9 6RJ

Sponsor type
Hospital/treatment centre

ROR

https://ror.org/05gekvn04

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal with an intent to publish date of December 2019.

Intention to publish date
30/04/2021

Individual participant data (IPD) sharing plan
Current IPD sharing statement as of 16/02/2021:
The datasets generated during and/or analysed during the current study are available from Jude Watson (jude.watson@york.ac.uk) on reasonable request

Previous IPD sharing statement:
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	01/08/2018	18/10/2019	Yes	No
Results article		07/04/2021	09/04/2021	Yes	No
HRA research summary			28/06/2023	No	No