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Both EARS training package (BEARS) to maximise hearing abilities in older children and teenagers with bilateral cochlear implants

Submission date	Recruitment status	[_] Prospectively registered
06/01/2023	Recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
03/04/2023	Ongoing	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
24/07/2025	Ear, Nose and Throat	[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Deafness is the most frequent human sensory deficit. Cochlear implantation is the primary intervention. Currently, over 6000 people have bilateral cochlear implants (CIs) in the UK, and most of these are children. Two implants are supposed to provide better access to sound, but it is challenging to interpret and integrate what is heard from both sides. The 'Living with cochlear implants' Patient and Public Involvement group reported that everyday communication is challenging and tiring, with extra effort required to integrate information from two ears, especially in noise. They reported that current rehabilitation techniques are not engaging, or appropriate to their lifestyles. To address these issues, researchers have developed a set of virtual reality games called BEARS (Both EARS). BEARS trains sound localisation and listening in noise. These are skills required in everyday listening. The aim of this study is to determine whether using the directional listening training delivered through the BEARS training package for 3 months alongside usual care compared to only receiving usual care improves speech-in-noise perception, hearing experiences, vocabulary and quality of life and reduces listening effort in young people between 8-16 years old (inclusive) with two CIs. The study will be carried out in clinical CI departments in NHS or University hospitals.

Who can participate?
Patients aged 8-16 years with severe/profound bilateral hearing loss who use bilateral cochlear implants

What does the study involve?
Participants will be randomly allocated into one of two groups:
1. Receive the BEARS training package to use for 3 months alongside usual care. This group will be given a head-mounted display or iPad with the BEARS training package pre-installed. The participants will be asked to complete the BEARS training package for a minimum of 2 x 30-minute sessions a week during the 3 months and also complete a training diary and answer some questions about the BEARS training package on a weekly basis.
2. Continue with usual care
All participants will complete hearing assessments and questionnaires before completing the 3-

month intervention. They will be followed up for the next 9 months through online and in-person appointments. Participants and clinicians can also consent to interviews.

What are the possible benefits and risks of participating?
Participants who receive the BEARS training package of virtual reality games will be given training separate to usual care, which is hoped will develop and improve their hearing ability. The BEARS training package will be carried out using either an Oculus virtual reality head-mounted display or an iPad with headphones. Both devices are licensed for everyday use. There are risks associated with using the Oculus virtual reality head-mounted display, which are detailed in the device's safety manual on the Oculus website. The main risk associated with this trial and using the Oculus device is falling while playing the games. For this reason, all participants must play the games whilst sitting down on a chair.

BEARS Program Development Grant (PDG)
Some people may find it hard to take part in research, especially if they are from a minority community or feel excluded for other reasons. We want our research results to apply to everyone, so we want to make sure that the people who take part are similar to the population as a whole. We have an additional Program Development Grant from NIHR to look at how diverse the children involved in BEARS are, and how we can improve this.

PDG Work plan
We will look at the children who have agreed to take part in the first 6 months of BEARS and see if they are similar to the UK population of deaf children with implants. We will look at their ethnicity, socioeconomic status, home language, sex, number of siblings, and parent/carer educational level. However, first we will need to look at lots of different information sources to find out about the diversity of deaf children in the UK, as this is not known at the moment. We can then compare with the children recruited to BEARS and see which groups are not being included. We will hold a workshop for the BEARS team and the clinicians at the participating centres to plan how to make recruitment fairer for the rest of the trial. We will then interview children and parents who chose not to take part in BEARS and find out what put them off. We will also talk to clinicians, teachers and other family representatives to ask their opinions on what makes it difficult to be involved in BEARS. We can then plan to make the BEARS NHS roll-out after the trial more inclusive. We hope this may also help other researchers to include a more diverse population of families with deaf children in future.

Where is the study run from?
Guy's and St Thomas' NHS Foundation Trust and UCL's Comprehensive Clinical Trials Unit (CCTU) (UK)

When is the study starting and how long is it expected to run for?
January 2021 to December 2026

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

Who are the main contacts?
1. Debi Vickers, dav1000@medschl.cam.ac.uk
2. Liz Arram, cctu.bears@ucl.ac.uk

Study website
http://www.guysandstthomasbrc.nihr.ac.uk/microsites/bears/

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Additional identifiers

EudraCT/CTIS number
Nil Known

IRAS number
319903

ClinicalTrials.gov number
Nil Known

Secondary identifying numbers
IRAS 319903, CPMS 55521

Study information

Scientific Title
A Phase III, unblinded, multi-centre randomised controlled trial to evaluate whether 3 months of spatial-listening training delivered via the Both EARS training package (BEARS) in addition to Usual Care compared to Usual Care alone improves hearing abilities and quality of life and is cost-effective in older children and teenagers with bilateral cochlear implants

Acronym
BEARS

Study objectives
The overall aim of the BEARS clinical trial is to determine whether using the spatial-listening training delivered via the BEARS training package for 3 months alongside usual care compared to only receiving usual care improves Speech-in-Noise perception, hearing experiences, vocabulary and quality of life in young people with bilateral cochlear implants.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 14/03/2023, Yorkshire & The Humber - South Yorkshire Research Ethics Committee (+44 (0)20 71048282; sheffield.rec@hra.nhs.uk), ref: 23/YH/0046

Study design
Multi-centre unblinded interventional randomized controlled Phase III trial

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 contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Speech-in-Noise outcomes in older children and teenagers with bilateral cochlear implants

Interventions
Participants will be randomized using Sealed Envelope, which is an online software application.

Intervention: Both EARS training package (BEARS) and Usual Care:
BEARS is a compilation of virtual reality games designed specifically for young people with bilateral cochlear implants. The hardware is either: a head-mounted display device or an iPad with headphones. The BEARS training package comprises of three games addressing different hearing functions: speech-in-noise perception, music listening and sound-source localisation. Each game is based on an audio-visual task performed through a virtual-reality interface. Players are guided through on-screen visual prompts to support the gameplay with feedback given on their performance and progress through levels of increasing difficulty. The BEARS training package design allows for the training to be self-administered and played anywhere and at any time. There is no upper limit to the frequency of use of the BEARS training package, it is advised to play the games for a minimum of 1 hour a week over a minimum of 2 x 30-minute sessions, all three games will need to be played.

Usual Care:
This is an annual review appointment with the patient and their clinician. This could be face-to-face, virtual video consultation, questionnaire, or cochlear remote care checks. As a minimum this review will check the following: microphone covers changed, reported or recorded device use, all external and internal equipment working (known through no reported or recorded degradation in hearing ability). During the appointment, the clinician would establish if there were any concerns regarding the cochlear implant functioning and the patient's rehabilitation programme. They will then make any repairs or adjustments to the device and manage additional support and contact as required. Between the annual review appointments patients can attend the implant centre for repair appointments or have spare equipment posted. There is no limit to the level of contact between the patient and the implant centre.

All participants will complete hearing assessments and questionnaires before completing the 3-month intervention. They will be followed up for the next 9 months through online and in-person appointments. Participants and clinicians can also consent to interviews.

Intervention Type
Behavioural

Primary outcome measure
Speech-in-noise perception score (% correct overall task), derived from the spatial speech in noise (SSiN-VA) test and measured at baseline and 3 months

Secondary outcome measures
SSiN-VA test outcomes:
1. Speech-in-noise perception score (% correct of the overall task), derived from the spatial speech in noise (SSiN-VA) test and measured at baseline and 12 months.
2. Relative localisation score (% correct), derived from the spatial speech in noise (SSiN-VA) test and measured at baseline, 3 months and 12 months.
3. Average reaction time (measure of listening effort) for word identification selections, derived from the spatial speech in noise (SSiN-VA) test and measured at baseline, 3 months and 12 months.
4. Average reaction time (measure of listening effort) for location shift selection, derived from the spatial speech in noise (SSiN-VA) test and measured at baseline, 3 months and 12 months.
5. Spatial index for word identification, derived from the spatial speech in noise (SSiN-VA) test and measured at baseline, 3 months and 12 months.
6. Spatial index for relative localisation, derived from the spatial speech in noise (SSiN-VA) test and measured at baseline, 3 months and 12 months.

Spatial ASL test outcomes:
1. Speech reception threshold (for better ear, worse ear, and average of both), derived from the spatial adaptive sentence list (Sp-ASL) test and measured at baseline, 3 months and 12 months.
2. Spatial release from masking score (for better ear, worse ear, and average of both), derived from the spatial adaptive sentence list (Sp-ASL) test and measured at baseline, 3 months and 12 - months.

British Picture Vocabulary Scale (c) test outcome:
1. Vocabulary age, derived from the British Picture Vocabulary Scale and measured at baseline and 12 months

Vanderbilt Fatigue Scale: Child self-report version (VFS-C) questionnaire outcome:
1. Listening-related fatigue score, derived from the Vanderbilt Fatigue Scale: Child self-report version (VFS-C) questionnaire and measured at baseline, 3 months and 12 months

Health economic outcomes:
The economic evaluation will calculate incremental cost per quality-adjusted life-year (QALY) gained by offering BEARS and usual care, compared to usual care, from an NHS, Personal Social Services (PSS) and Local Education Provider perspective over the 12 months of the trial.

Overall study start date
01/01/2021

Completion date
31/12/2026

Eligibility

Key inclusion criteria
1. Participant is a simultaneous or sequential bilateral cochlear implant user*, who either has:
1.1. Congenital severe/profound bilateral sensorineural hearing loss and have received at least

one implant ≤36 months of age
1.2. Progressive or acquired severe/profound bilateral sensorineural hearing loss (no age at implant restrictions for these patients)
2. Participant has stable programmes (defined as no longer using progressive programmes to work through)
3. Participant has had at least two usual care checks/clinical appointments with stable aided levels (+/-10 dB across 500 Hz-4 kHz) and no progressive maps to still work through, if they have had re-implantation of internal implant devices.
4. Participant is aged 8-16 years, inclusive

*(a bilateral CI user is defined as a patient who uses both CI processors for a minimum of 6 hours per day over a month)

Participant type(s)
Patient

Age group
Child

Lower age limit
8 Years

Upper age limit
16 Years

Sex
Both

Target number of participants
272

Key exclusion criteria
Current exclusion criteria as of 02/12/2024:
1. Participant (or parent/legal representative) does not speak/understand English sufficiently to undertake assessments
2. Participant has an intellectual disability at a level that would prevent their ability to understand the trial the intervention or assessment questions
3. Participant has a comorbid condition impacting ability to participate in intervention and/or outcome assessment
4. Participant has an audiological profile impacting ability to participate in intervention and/or outcome assessments
5. Participant is actively participating in other trials that may affect hearing outcomes or impact their ability to participate in the intervention
6. Participant is currently or anticipated to receive treatment and/or intervention that may affect hearing outcomes or adapt implant settings/programming
7. Participant is refusing to consent to trial activities/protocol
8. Participant is awaiting reimplantation following device failure or infection
9. Participant is a non-user of one or both implant processors (i.e., must use both processors for a minimum of 6 hours per day over a month)
10. Participant is a full-time boarder at a boarding school
11. Participant has unresolvable issues found in device checks that render one of the implants

unusable
12. Participant is a female that is pregnant
13. Participant has a diagnosis of epilepsy or history of seizures of any kind

Previous exclusion criteria:
1. Participant (or parent/legal representative) does not speak/understand English sufficiently to undertake assessments
2. Participant has an intellectual disability at a level that would prevent their ability to understand the trial the intervention or assessment questions
3. Participant has a comorbid condition impacting ability to participate in intervention and/or outcome assessment
4. Participant has an audiological profile impacting ability to participate in intervention and/or outcome assessments
5. Participant is actively participating in other trials that may affect hearing outcomes or impact their ability to participate in the intervention
6. Participant is currently or anticipated to receive treatment and/or intervention that may affect hearing outcomes or adapt implant settings/programming
7. Participant is refusing to consent to trial activities/protocol
8. Participant is awaiting reimplantation following device failure or infection
9. Participant has had any changes to the programmes of either CI within the last 4 weeks
10. Participant has had a change of CI processor model or upgrade within the last 4 weeks
11. Participant is a non-user of one or both implant processors (i.e., must use both processors for a minimum of 6 hours per day over a month)
12. Participant is a full-time boarder at a boarding school
13. Participant has unresolvable issues found in device checks that render one of the implants unusable
14. Participant is a female that is pregnant
15. Participant has a diagnosis of epilepsy or history of seizures of any kind

Date of first enrolment
28/02/2023

Date of final enrolment
31/07/2026

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Emmeline Centre for Hearing Implants
Hills Road
Cambridge
United Kingdom
CB2 0QQ

Study participating centre
GSTT, Hearing Implant Centre
Ear, Nose and Throat (ENT) Services
2nd Floor, Lambeth Wing
St Thomas' Hospital
Westminster Bridge Road
London
United Kingdom
SE1 7EH

Study participating centre
University of Southampton Auditory Implant Service
University of Southampton Highfield Campus
Building 19, Highfield
Southampton
United Kingdom
SO17 1BJ

Study participating centre
Great Ormond Street Hospital, Cochlear Implant Programme
GOSH Sight and Sound Centre
40-41 Queen Square
London
United Kingdom
WC1N 3AJ

Study participating centre
UCLH, Auditory Implants Programme
The Royal National ENT and Eastman Dental Hospitals
47-49 Huntley Street
London
United Kingdom
WC1E 6DG

Study participating centre
St George's Hospital, Auditory Implant Service
ENT & Audiology Dept
Ground Floor, Lanesborough Wing
St George’s Hospital
London
United Kingdom
SW17 0QT

Study participating centre
Birmingham Paediatric Cochlear Implant Programme
Optegra Building
Aston University Campus
Birmingham
United Kingdom
B4 7ET

Study participating centre
Nottingham Cochlear Implant Programme
Ropewalk Court
113 The Ropewalk
Nottingham
United Kingdom
NG1 5DU

Study participating centre
Oxford Auditory Implant Programme
ENT, West Wing
John Radcliffe Hospital
Headley Way
Oxford
United Kingdom
OX3 9DU

Study participating centre
The Scottish Cochlear Implant Programme
The Raj Singh Cochlear Implant Centre
University Hospital Crosshouse
Kilmarnock
United Kingdom
KA2 0BE

Study participating centre
North East Regional Cochlear Implant Programme
The James Cook University Hospital
Marton Road
Middlesbrough
United Kingdom
TS4 3BW

Study participating centre
Belfast Auditory Implant Centre
Beech Hall Day Centre
21 Andersonstown Rd
Belfast
United Kingdom
BT11 9AF

Study participating centre
Manchester Royal Infirmary, Cochlear Implant Department
Manchester Royal Infirmary
Peter Mount Building
Oxford Road
Manchester
United Kingdom
M13 9WL

Study participating centre
Yorkshire Auditory Implant Service
Listening for Life Centre
Bradford Royal Infirmary
Duckworth Lane
Bradford
United Kingdom
BD9 6RJ

Sponsor information

Organisation
Guy's and St Thomas' NHS Foundation Trust

Sponsor details
R&D Department
16th Floor, Tower Wing, Great Maze Pond
London
England
United Kingdom
SE1 9RT
+44 (0)20 7188 7188
r&d@gstt.nhs.uk

Sponsor type
Hospital/treatment centre

Website
http://www.guysandstthomas.nhs.uk/Home.aspx

ROR
https://ror.org/00j161312

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care 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
The trial results will be disseminated regardless of the direction of effect. The results publication will comply with the BEARS-specific publication policy (generated through BEARS Work Package 8 on Dissemination) and will include submission to open-access journals.

A lay summary of the results will also be produced and uploaded to the BEARS trial website. All participants will be able to view this document. This has been detailed in the patient information sheets. A summary of results will be included online on the publicly accessible HRA website within 12 months of trial closure.

Intention to publish date
31/12/2027

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study will be published as a supplement to the results publication and the datasets generated during and/or analysed during the current study will be available upon formal request to the study Sponsor, Programme Management Group, Programme Steering Committee and NIHR's approval.
The exact data types that will be available for sharing, the duration and restrictions on use will be further detailed pending the completion of the trial publication policy.

IPD sharing plan summary

Available on request, Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			26/07/2023	No	No