

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

<b>Submission date</b> 06/01/2023	<b>Recruitment status</b> Recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 03/04/2023	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 09/03/2026	<b>Condition category</b> Ear, Nose and Throat	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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

## Contact information

**Type(s)**

Principal investigator

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**Type(s)**

Public

**Contact name**

Ms Liz Arram

**Contact details**

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cctu.bears@ucl.ac.uk

## **Additional identifiers**

### **Clinical Trials Information System (CTIS)**

Nil Known

### **Integrated Research Application System (IRAS)**

319903

### **Protocol serial number**

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@hpa.nhs.uk), ref: 23/YH/0046

### **Study design**

Multi-centre unblinded interventional randomized controlled Phase III trial

### **Primary study design**

Interventional

### **Study type(s)**

Treatment

### **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(s)**

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

## **Key secondary outcome(s)**

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.

#### 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  $\leq 36$  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 ( $\pm 10$  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

#### Healthy volunteers allowed

No

**Age group**

Child

**Lower age limit**

8 years

**Upper age limit**

16 years

**Sex**

All

**Total final enrolment**

0

**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**

United Kingdom

England

**Study participating centre**

**Emmeline Centre for Hearing Implants**

Hills Road  
Cambridge  
England  
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  
England  
SE1 7EH

**Study participating centre**

**University of Southampton Auditory Implant Service**

University of Southampton Highfield Campus  
Building 19, Highfield  
Southampton  
England  
SO17 1BJ

**Study participating centre**

**Great Ormond Street Hospital, Cochlear Implant Programme**

GOSH Sight and Sound Centre  
40-41 Queen Square  
London  
England  
WC1N 3AJ

**Study participating centre**

**UCLH, Auditory Implants Programme**

The Royal National ENT and Eastman Dental Hospitals  
47-49 Huntley Street  
London  
England  
WC1E 6DG

**Study participating centre**

**St George's Hospital, Auditory Implant Service**

ENT & Audiology Dept  
Ground Floor, Lanesborough Wing  
St George's Hospital  
London  
England  
SW17 0QT

**Study participating centre**

**Birmingham Paediatric Cochlear Implant Programme**

Optegra Building  
Aston University Campus  
Birmingham  
England  
B4 7ET

**Study participating centre**

**Nottingham Cochlear Implant Programme**

Ropewalk Court  
113 The Ropewalk  
Nottingham  
England  
NG1 5DU

**Study participating centre**

**Oxford Auditory Implant Programme**

ENT, West Wing  
John Radcliffe Hospital  
Headley Way  
Oxford  
England  
OX3 9DU

**Study participating centre**

**The Scottish Cochlear Implant Programme**

The Raj Singh Cochlear Implant Centre  
University Hospital Crosshouse  
Kilmarnock  
Scotland  
KA2 0BE

**Study participating centre**

**North East Regional Cochlear Implant Programme**

The James Cook University Hospital  
Marton Road  
Middlesbrough  
England  
TS4 3BW

**Study participating centre**

**Belfast Auditory Implant Centre**

Beech Hall Day Centre  
21 Andersonstown Rd  
Belfast  
Northern Ireland  
BT11 9AF

**Study participating centre**

## **Manchester Royal Infirmary, Cochlear Implant Department**

Manchester Royal Infirmary  
Peter Mount Building  
Oxford Road  
Manchester  
England  
M13 9WL

## **Study participating centre**

### **Yorkshire Auditory Implant Service**

Listening for Life Centre  
Bradford Royal Infirmary  
Duckworth Lane  
Bradford  
England  
BD9 6RJ

## **Study participating centre**

### **West of England Hearing Implant Programme**

Children's Hearing Centre, Level D  
St Michael's Hospital  
Bristol  
England  
BS2 8EG

## **Sponsor information**

### **Organisation**

Guy's and St Thomas' NHS Foundation Trust

### **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

**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?
<a href="#">HRA research summary</a>			26/07/2023	No	No
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes