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A study to evaluate if an online parent training programme can help to improve language development in young deaf children with cochlear implants

Submission date
24/04/2025

Recruitment status
Recruiting

Registration date
29/04/2025

Overall study status
Ongoing

Last Edited
02/07/2025

Condition category
Ear, Nose and Throat

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol
Background and study aims
The IMPACT trial is investigating whether a parent-implemented therapy (ITTT - "It Takes Two to Talk") can improve language development for young children with cochlear implants. Families are randomly allocated to receive either standard care or standard care plus the parent engaging with the ITTT programme. The trial aims to find out if offering ITTT in addition to standard care leads to better communication and developmental outcomes for children.

Who can participate?
Children under the age of 5 who meet NICE criteria for bilateral cochlear implantation and their parents. Children and parents must speak predominantly English at home and read and understand English. Children should not have any known developmental disorders known to impact on cochlear implantation outcomes e.g. brain injury.

What does the study involve?
Participants will be randomly allocated to one of two groups after their child receives a cochlear implant (CI):

Standard Care Group: children will receive standard care.

Standard Care + ITTT Group: children will receive standard care, and their parent(s)/carer(s) will take part in the It Takes Two to Talk (ITTT) online programme.

All participants will remain in the trial for approximately 12 months following randomisation. Trial participation involves attending three face-to-face visits at their cochlear implant centre, completing three questionnaires on two occasions, and for those in the ITTT group attending additional online sessions as part of the intervention.

The trial includes the following steps:
- Baseline visit (pre-surgery): the child attends two speech and language assessments (totalling approximately 2 hours) at the cochlear implant centre, then the parent completes 3 questionnaires at home.
- Randomisation (within 4 months of cochlear implant activation): participants are randomly allocated to either the Standard Care group or the Standard Care + ITTT group using a computer-generated system to ensure unbiased allocation.
- Intervention (ITTT group only): the ITTT programme is a parent training course developed by the Hanen Centre, delivered by trained speech and language therapists. It consists of:
• One introductory one-to-one session,
• Eight group parent/carer sessions,
• Three individual coaching sessions using video feedback.
Sessions are delivered online and last approximately 1–2 hours each.
- Follow-up Visit 1 (6 months post-randomisation): the child attends a 1-hour language assessment at the cochlear implant centre.
- Follow-up Visit 2 (12 months post-randomisation): the child attends two speech and language assessments (totalling approximately 2 hours) at the cochlear implant centre, and the parent /carer completes a second set of 3 questionnaires at home.
After the final visit, no further trial activities are required, and standard care continues.

What are the possible benefits and risks of participating?
Taking part in the IMPACT trial may not directly benefit parents or children. We expect that trial findings could benefit others in the future. Information obtained will allow researchers and clinicians to design and implement better rehabilitation programmes for children with cochlear implants.
There are no risks associated with the intervention It Takes Two to Talk.
Risk of inconvenience or discomfort: Families will be asked to attend 3 trial visits at the cochlear implant centre, lasting no more than 2 hours each time. Parents will also be asked to complete 3 questionnaires at 2 separate timepoints, these can be completed at home in the parents' own time. Parents randomised to the ITTT group will be enrolled into the programme for 3-4 months, this consists of 1 initial pre-programme introduction session, 8 group sessions and 3 individual sessions with the Speech and Language Therapist. All sessions are delivered online and will last approximately 1-2 hours each.
Additionally, families will receive a total of £45 in vouchers as a small token of appreciation for their time to complete baseline and follow-up measures.
Risk of breach of confidentiality: All members of the research team will have undergone GCP training. No personal information will be sent to the research team prior to receiving a 'consent to contact' form from the parent/carer. The trial database (REDCap) is designed so only relevant members of the research team can see the outcome measures of their participants. It is a validated secure web-based platform which allows for data tracking via date-stamped audit logs. Participant data will be identified only by their unique trial ID number to protect from bias and ensure confidentiality.

Where is the study run from?
The IMPACT trial is organised and sponsored by the University of Nottingham and coordinated by the Nottingham Clinical Trials Unit (NCTU) (UK)

When is the study starting and how long is it expected to run for?
Recruitment is due to begin 01 June 2025 and expected to run until 31 July 2027.

Who is funding the study?
The funding is provided by the Efficacy and Mechanism Evaluation (EME) programme, a Medical

Research Council (MRC) and National Institute for Health and Care Research's (NIHR) partnership (UK).

Who is the main contact?
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
344537

Protocol serial number

CPMS 64358, NIHR154749

Study information

Scientific Title
IMPACT (IMplemented by Parents And Carers Therapy) trial: A multicentre randomised controlled trial to evaluate the efficacy of a parent-implemented therapy on language development in deaf children with cochlear implants

Acronym
IMPACT Trial

Study objectives
Primary objectives: To compare receptive language development at 12 months post-randomisation between two groups of children with cochlear implants (CIs), one group will continue to receive standard care whilst their parents engage in the It Takes Two to Talk (ITTT) programme as an adjunctive therapy, and a second group who receive standard care alone.

Secondary objectives:
1. To compare expressive language development between both groups at 6- and 12-months post-randomisation.
2. To compare receptive language development between both groups at 6-months post-randomisation.
3. To compare childhood developmental milestones, child behaviour and social-emotional functioning between both groups at 12-months post-randomisation.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 17/04/2025, London - Brent Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 2071048131; brent.rec@hra.nhs.uk), ref: 25/LO/0236

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Parent-implemented therapy on language development in deaf children with cochlear implants

Interventions
This trial aims to find out whether a parent-led programme called "It Takes Two to Talk" (ITTT) can help young children with cochlear implants (CIs) develop better language skills than they would with standard care alone. The children in this study are under five years old and have recently had their cochlear implants activated. Parents play an important role in language

development, and ITTT trains them to use specific strategies during everyday interactions to support their child's communication.

In the trial, some families will take part in the ITTT programme in addition to receiving standard NHS care. Other families will receive only the standard care currently offered to children with CIs. We will compare the children's ability to understand spoken language (receptive language) after 12 months to see if ITTT provides additional benefits.

Intervention: Parents in the ITTT group will complete a 3–4-month online programme, including group sessions and individual coaching from a trained speech and language therapist, to learn how to help their child develop language skills.

Comparator: Families in the control group will continue with the standard care provided for children with CIs, such as appointments with audiologists and speech therapists.

Children will be assessed before the trial starts, at 6 months, and at 12 months after randomisation. The assessments will include assessments completed by the clinical team at the CI centres and questionnaires that are completed by the families. The primary outcome will be measured at 12 months, by the clinical sites, because research suggests that this is when the benefits of ITTT are likely to be most noticeable. We will also look at other factors, such as children's expressive language, child behaviour, emotional and social development, and developmental milestones.

This design will help us understand whether ITTT is an effective and practical way to improve language development in children with cochlear implants. If successful, it could become a valuable tool for families and healthcare providers.

The qualitative nested study involves three steps. Firstly, a survey of speech and language therapists (SLTs) from CI centres across the UK to understand the support they provide for non-English speaking families and identify if any common languages are spoken by these families. Secondly, we will conduct 12-20 interviews with SLTs to understand their experiences and views on adapting ITTT for families for whom English is an additional language. Finally, we will invite up to 10 families excluded from the IMPACT trial, due to the language spoken at home, to share their experiences of SLT support through interviews conducted three times over a year. We will aim to recruit up to 10 families and might expect an average of 5 interviews (3 with the family and 2 with the SLTs involved) to be completed in each case study. Should it be not possible to recruit 10 families, we will interview (once) families who have previously experienced SLT support in languages other than English. We will map the support offered and how this aligns with the ITTT programme – identifying those aspects of ITTT that are currently used and how they have been adapted. Interview recordings will be transcribed in full and anonymised.

Intervention Type
Behavioural

Primary outcome(s)
Receptive language development is assessed using the Auditory Comprehension subscale of the Preschool Language Scale – Fifth Edition PLS-5 UK at baseline and 12-months post-randomisation

Key secondary outcome(s))
1. Receptive language development - measured by the PLS-5 Auditory comprehension subscale at 6 months post randomisation

2. Expressive language development - measured by the PLS-5 Expressive communication subscale at baseline, 6-months and 12-months post randomisation
3. Childhood developmental milestones - measured by the Schedule of Growing Skills questionnaire (SGS) at baseline and 12-months post-randomisation
4. Child Behaviour measured by the Strengths and Difficulties Questionnaire (SDQ) at baseline and 12-months post-randomisation
5. Social emotional functioning measured by the Ages and Stages Questionnaire: Social Emotional – 2 (ASQ:SE-2) at baseline and 12-months post-randomisation
6. Pragmatic language development measured using the Language Use Inventory (LUI) at baseline and 12-months post-randomisation

Completion date
31/07/2027

Eligibility

Key inclusion criteria
Children:
1. Aged less than 5 years old at time of CI surgery
2. Meets UK NICE criteria for bilateral cochlear implantation
3. Bilateral cochlear implants with full electrode insertion in both ears
4. History, examination and pre-operative imaging suggests a structurally normal and fully patent cochlea with normal cochlear nerves bilaterally

Parents:
1. Capable of understanding and speaking English
2. Ability to provide informed consent

NB: Parents will be recruited and consented once the child's CI implantation surgery has been confirmed. Prior to randomisation, eligibility criteria in relation to CI surgery will be assessed and children not meeting the criteria will not be randomised into the trial.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Upper age limit
5 years

Sex
All

Key exclusion criteria
Children:
1. Incomplete electrode insertion in one or both ears

2. Developmental disorders known to impact on CI outcome including but not limited to brain injury, brain tumour, Down syndrome, and fragile X syndrome
3. English not the dominant spoken language at home (including British Sign Language (BSL))
4. Structural brain malformation, severely malformed cochlea, Auditory Neuropathy Spectrum Disorder, cochlear nerve deficiency and/or post-meningitis deafness
5. Any known factor that may restrict full insertion of the electrode array
6. Participation in any other CI intervention clinical trial

Parents
1. English not the dominant spoken language at home (including BSL)

Date of first enrolment
01/07/2025

Date of final enrolment
31/07/2027

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
-
United Kingdom
-

Sponsor information

Organisation
University of Nottingham

ROR
https://ror.org/01ee9ar58

Funder(s)

Funder type
Government

Funder Name
NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC)

Results and Publications

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1.1	02/04/2025	29/04/2025	No	Yes
Protocol file	version 1.1	15/05/2025	11/06/2025	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes