IMPACT Trial Summary

Overview

The **IMPACT Trial (IMplemented by Parents And Carers Therapy)** is a multicentre, randomised controlled trial evaluating the efficacy of a parent-implemented therapy, the "It Takes Two to Talk" (ITTT) programme, in addition to standard care on language development in deaf children with cochlear implants (CIs) aged less than 5 years old.

Intervention: It Takes Two to Talk (ITTT)

- **ITTT** is a structured parent/carer training programme developed by clinicians at the Hanen Centre in Toronto, Canada designed to support parents/carers of children with language and communication delays.
- **Format:** Online tele-practice sessions delivered remotely to groups of parents by trained Speech and Language Therapists (SLTs) independent from trial sites.
- **Structure:**
  - 1 orientation session
  - 8 interactive small-group sessions
  - 3 individual feedback sessions (video-based coaching)
- **Duration:** Approximately 3-4 months to complete the course

Trial Design

- **Population:** 158 children <5 years old newly implanted with bilateral cochlear implants and their families
- **Intervention Group:** Standard NHS care + ITTT delivered remotely to parent/carers
- **Control Group:** Standard NHS care alone
- **Outcome:** Primary outcome: receptive language development at 12 months measured using the Pre-School Language Scale-5 (PLS-5 UK) measured by independent blinded assessors
- **Setting:** UK paediatric CI centres
- **Duration:** 60 months total (recruitment starting June 2025 for 26 months; follow-up period is 12 months post-randomisation)

Trial Assessments

- **Trial assessments completed at site:** Pre-School Language Scale PLS-5 UK (primary outcome), Schedule of Growing Skills questionnaire to measure child development.
- **Parent completed questionnaires at baseline and 12-months:** Strengths and Difficulties Questionnaire (SDQ), Ages and Stages Questionnaire – Social Emotional-2 (ASQ:SE-2), and Language Use Inventory (LUI)).

Eligibility Criteria

Children and their families will be recruited from approximately 10 cochlear implant centres across the UK. Participation in the IMPACT trial will be limited to children and parents who meet the eligibility criteria below:

Inclusion criteria

Children

- Aged less than 5 years old at time of Cochlear Implant (CI) surgery
- Meets UK NICE criteria for bilateral cochlear implantation
- Bilateral cochlear implants with full electrode insertion in both ears
- History, examination and pre-operative imaging suggests a structurally normal and fully patent cochlea with normal cochlear nerves bilaterally

Parents

- Capable of understanding and speaking English*
- Ability to provide informed consent

Exclusion criteria

Children

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

Parents

- English not the dominant spoken language at home (including BSL) *

*Where English is not the dominant language spoken at home, parents may be invited to take part in interviews as part of a nested qualitative research sub-study.

Site Responsibilities

- ✓ **Recruitment:** Identifying and enrolling children who meet the trial criteria, approximately 16 participants per site over 26-month recruitment period starting in Summer 2025.
- ✓ **Assessments align with standard care**: PLS-5 UK and SGS assessments completed in clinic, visits at baseline, 6 and 12-months after randomisation, avoiding duplicate appointments/assessments where possible.
- ✓ **Screening Logs:** Screening data uploaded to REDCap for all children in the CI centre pathway.
- ✓ **Data Collection:** Use of REDCap for electronic data entry for screening logs, demographics, medical history and trial assessments.
- ✓ **Minimal additional workload** as ITTT is delivered remotely by independent Speech and Language Therapists.

Key Site Requirements

- ✓ **Principal Investigator (PI):** Must have Good Clinical Practice (GCP) certification and prior clinical trial experience.
- ✓ **Research Team:** Trained staff to conduct language assessments (PLS-5, SGS).
- ✓ Computer/laptop for data entry.
- ✓ Archiving facilities for trial documentation (minimum 7 years).
- ✓ Potential translation services for those with English as an additional language for the sub-study interviews.

Support

The IMPACT trial is being coordinated by dedicated staff at the NCTU who will help guide all trial sites through the site set-up process and will offer general research and trial-specific training before you start recruiting and throughout the course of the trial. Sites will also have access to the trial website containing information resources for sites and potential participants: www.impact-trial.ac.uk.

Next Steps

- ➢ Interested sites should **complete the Site Selection Questionnaire and return** to: **impactstudy@nottingham.ac.uk**
- ➢ Any queries? Contact the IMPACT team at the email above or by calling 01158 231587

IMPACT TRIAL PATIENT PATHWAY

Child enters Cochlear Implant Centre pathway

Screening Logs
Data entry completed at site

CI Suitability Assessments
Participant identification and eligibility confirmation at site

CI Surgery Confirmed
Informed Consent for trial at site

Baseline Assessments
PLS-5 & Schedule of Growing Skills at site
Parent-completed questionnaires in parents' own time

Cochlear Implant Surgery and Switch-on
as per standard care, timelines not dictated by trial

Randomisation
(within 4 months of switch on)
Eligibility reconfirmed at site
NCTU reconfirm consent and randomise

Child receives standard NHS care only

Child receives standard NHS care + their parent/carer participates in the ITTT programme*

6-months post Randomisation
PLS-5 at site

12-months post Randomisation
PLS-5 & Schedule of Growing Skills at site
Parent-completed questionnaires in parents' own time

End of trial parents receive token of appreciation for taking part

**For ITTT group only, the programme is delivered remotely and centrally by independent SLTs over 3-4 months*