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

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SYNOPSIS

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
Short title	IMplemented by Parents And Carers Therapy
Chief Investigator	Professor Douglas Hartley
Objectives	Primary: 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: • To compare expressive language development between both groups at 6- and 12-months post-randomisation. • To compare receptive language development between both groups at 6-months post-randomisation. • To compare childhood developmental milestones, child behaviour and social-emotional functioning between both groups at 12-months post-randomisation.
Trial Configuration	A multicentre, parallel group randomised controlled trial design with equal allocation (1:1), an internal pilot phase and blinded primary outcome assessment.
Setting	UK secondary care cochlear implant centres
Sample size estimate	To provide robust evidence of an effect, the trial should be powered to detect a 'medium' effect (between 0.5 and 0.6) To detect an effect size of 0.55 assuming a Standard Deviation (SD) of 17.1, significance level (2-sided) of 5% and 90% power, 71 children with primary outcome data would be required in each arm. Assuming 10% loss of primary outcome data, and no effects due to the clustering of the intervention group a total of 79 children should be randomised to each arm (158 in total).
Number of participants	158 children (approximately 79 in each arm) In the intervention group, it is the parent who is 'participating', the primary and secondary outcomes are measured by assessing the children (participants).

Eligibility criteria[1]	**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).
Description of interventions	Parents engaged in an online ITTT programme alongside child receiving standard NHS care (Intervention arm) The intervention ITTT is a parent/carer training programme developed by clinicians at the Hanen Centre in Toronto, Canada for parents/carers of children with language and communication delays. The ITTT programme will be delivered remotely by trained Speech and Language Therapists (SLTs) to groups of parents. The programme lasts for approximately 3-4 months and involves: • One initial individual pre-programme introduction session where parent/carers meet the SLT • Eight group sessions parent/carer and SLT with other families participating in the trial • Three personalised individual sessions with parent/carer and SLT. During the individual sessions parents may be asked to

[1] 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.

	record a video of themselves and their child interacting together for the SLT to review. Child receiving standard NHS care (Control arm).
Duration of trial	Total trial duration: 60 months Families are expected to be in the trial for a maximum of 20 months total. Time from consent to CI surgery may vary between trial sites, but we expect this would not exceed 4-months, time between CI activation and randomisation will not exceed 4-months and the follow-up period is 12-months post randomisation.
Randomisation and blinding	Treatment allocation will be carried out by staff at the Nottingham Clinical Trials Unit (NCTU) via a bespoke, secure, concealed, dynamic randomisation system developed and maintained by the NCTU and hosted on a secure server, accessed via delegated personnel and run in an access-controlled area. Families will be randomised in a 1:1 ratio allocation using random permuted blocks of varying sizes. Due to the requirement for families to be randomised in groups of at least four, there will be no stratification, but key variables such as site, gender and the child's age will be adjusted for in the analysis. Parents will be aware of their allocation, but their child's treatment team (both usual care and research teams) will be unaware to minimise bias in the treatment and assessment of the children. The NCTU trial statisticians will be unaware of allocation to minimise bias which could be introduced into decisions about data handling and analyses.
Outcome measures	Primary outcome: • Receptive language development 12-months post randomisation measured using the Preschool Language Scale-5 (PLS-5) auditory comprehension subscale Secondary outcomes: • Receptive language development 6-months post randomisation measured using the PLS-5 auditory comprehension subscale • Expressive language development 6- and 12- months post randomisation measured using the PLS-5 expressive communication subscale • Childhood developmental milestones at 12-months post randomisation using the Schedule of Growing Skills questionnaire (SGS) • Child behaviour at 12-months measured using the Strengths and Difficulties Questionnaire (SDQ) • Social-emotional functioning at 12-months measured using the Ages and Stages Questionnaire – Social Emotional-2 (ASQ:SE-2) • Pragmatic language development at 12-months measured using the Language Use Inventory (LUI)

Statistical methods	A detailed statistical analysis plan (SAP) will be approved prior to release of the treatment allocations. All analyses will be carried out in accordance with CONSORT guidelines. Since the trial is explanatory, the primary analyses will be based on a per protocol population which will be detailed in the SAP. The between group difference in the primary outcome - PLS-5 auditory comprehension subscale score 12-months post randomisation - will be analysed using an appropriate regression model including baseline score, site and child's age and gender as co-variates. The adjusted risk difference in scores will be presented alongside the 95% confidence interval. Secondary outcomes will be considered supportive of the primary analysis and will use appropriate regression models (depending on the outcome type) including site, child's age and gender and the baseline value of that outcome if collected.
Qualitative	Where the main trial aims to determine the efficacy of ITTT alongside standard NHS care compared with standard NHS care alone. The exclusion of families where English is not the main language spoken at home is a necessary methodological compromise as the intervention is not currently adapted for delivery in languages other than English. This nested qualitative research aims to explore how non-English speaking families might effectively be included in the ITTT programme Objectives: 1. Estimate the number of non-English speaking families with children under 5 years old on the CI pathway who may potentially benefit from ITTT. 2. To establish the current SLT provision for non-English speaking families on the CI pathway. 3. To assess the views of SLTs in relation to the use of ITTT with non-English speaking families – i.e. its appropriateness and possible adaptations required. 4. To evaluate current practice with non-English speaking families. 5. To provide a roadmap for future adaptation and assessment of ITTT in multiple languages.

PROTOCOL DEVELOPMENT

Amendment number	Protocol version number	Type of amendment	Summary of amendment
NSA01	1.1	Non-Substantial Amendment	Internal Pilot section updated in line with funder requirements, there will be two assessment points, and we have added more detail on how adherence will be measured. Clarity added on the nominated parent and number of additional parents that can attend the intervention sessions. Explanation of collecting information on standard care at each participating site has been added. The participant flow diagram has been updated to display the correct assessments.

ABBREVIATIONS

AE	Adverse Event
ASQ:SE	Ages and Stages Questionnaire: Social-Emotional
BSL	British Sign Language
CF	Informed Consent Form
CIs	Cochlear Implants
(e)CRF	(electronic) Case Report Form
DAP	Data Analysis Plan
DMC	Data Monitoring Committee
DMP	Data Management Plan
EOT	End of Trial
GCP	Good Clinical Practice
HRA	Health Research Authority
ITTT	It Takes Two to Talk
LUI	Language Use Inventory
MPP	Muenster Parental Programme
NCTU	Nottingham Clinical Trials Unit
NHS	National Health Service
NIHR	National Institute for Health and Care Research
PAG	Participant Advisory Group
PCIT	Parent-Child Interaction Therapy
PI	Principal Investigator
PIS	Participant Information Sheet
PLS-5	Pre-School Language Scale – fifth edition
REC	Research Ethics Committee
R&D	Research and Development department
SAP	Statistical Analysis Plan
SD	Standard Deviation
SDQ	Strengths and Difficulties Questionnaire
SGS	Schedule of Growing Skills questionnaire
SLT	Speech and Language Therapist
TMG	Trial Management Group
ToD	Teacher of the Deaf
TSC	Trial Steering Committee

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1 TRIAL BACKGROUND INFORMATION AND RATIONALE

Prevalence and impact of hearing loss in children

Hearing loss affects more than 50,000 children in the UK [1]. Of these children, it is estimated that about 880 are born with moderate-to-profound deafness in the UK every year, and a further 100 children under the age of 5 years old will acquire moderate-to-profound hearing loss each year [2]. Approximately 560 of these children receive cochlear implants (CIs) each year within the UK [3]. Hearing loss affects access to spoken language, which can negatively impact on cognitive development, educational attainment, and social wellbeing [4] that persists into adulthood [5].

Children with hearing loss who fulfil UK NICE criteria for cochlear implantation [6] are offered CIs in both ears on the NHS in England and Wales, with similar criteria in Scotland and Northern Ireland. CIs are neuro-prosthetic devices that enable these children to access spoken language and are a cost-effective intervention. These devices bypass normal acoustic hearing and replace it with electrical signals that directly stimulate the auditory nerve, allowing most deaf children to develop oral communication. In the early stages following cochlear implantation, it is vital for children to experience an environment that facilitates the development of spoken language. To help children make the most of the hearing that they receive from their CIs, the current standard of care in the UK [7] recommends rehabilitation provided by members of the clinical team, including Speech and Language Therapists (SLTs). Whilst most deaf children significantly benefit from their CIs, speech acquisition varies greatly between individuals, even after accounting for the child's age at cochlear implantation and duration of CI use [8]. These vast differences have been attributed to a number of factors, including family factors such as parental involvement [9], parental self-efficacy [10], and parental linguistic input [11]. Parents have a crucial influence on a child's development, and it has been shown that these family factors contribute to the individual differences in communication skills of young children with and without hearing loss [11]. Indeed, the magnitude of these effects are similar to that found for age at cochlear implantation, suggesting that addressing parental behaviours is a critical target for early language learning after cochlear implantation [12].

Need for efficacy studies

Some children who are deaf fail to achieve the anticipated level of success with their CIs, despite standard NHS care [8]. While parents have a crucial influence on a child's development, existing models of NHS service delivery for children with CIs often overlook them as a valuable resource for rehabilitation. Preliminary evidence suggests that parent-implemented therapy can significantly benefit a deaf child’s language development post cochlear implantation [13-16]. However, Level 1b evidence to determine the definitive proof of the clinical efficacy of this therapy in the UK, and its effect size, using standardised language outcomes children with CIs is currently lacking.

Evidence for parent-implemented therapies

Courses designed to improve interactions between parents and children, including “It takes two to talk” (ITTT) [17, 18], Parent-Child Interaction Therapy (PCIT) [19], and the Muenster Parental Programme (MPP) [14], have shown to be effective in improving communication skills in children with normal hearing [19-22], and there is preliminary evidence to support their effect in deaf children with CIs [13-16]. Two of these studies [13, 15] showed that communication had improved following ITTT through analysis of interactions between English-speaking parents and their deaf children with CIs. However, neither of these studies included a control group or any standardised assessments of language abilities. Recently, another two studies have shown that ITTT benefits language development in German- [14] and Italian-speaking [16] children with CIs. Whilst these studies provide preliminary evidence to support benefits of ITTT for

children with CIs, without randomisation the effects they report may be contaminated by selection bias. Assessors were not blinded and most of the outcome measures used were subjective and poorly controlled, thus also risking observational bias. Currently there is no evidence to determine the clinical efficacy of ITTT and its effect size, using standardised language measures in English-speaking children with CIs. Furthermore, we are not aware of any research currently underway investigating the effects of ITTT on children with CIs.

ITTT is a behavioural therapy that was originally developed by the Hanen centre in Toronto, Canada for parents of normally-hearing children with language delay [17, 18]. Unlike PCIT and MPP, ITTT has been successfully adapted for English-speaking families of young (birth to 5 years of age), deaf children with CIs to facilitate their communication skills [13, 15]. ITTT is implemented by parents directly to their child, supported by coaching, training and feedback from ITTT-certified SLTs [17, 18]. ITTT has traditionally been delivered over about 12 months through face-to-face clinician-directed individual sessions (~3), interleaved with group workshops (~8), to coach parents to act as their child's own therapist, using a range of techniques, including problem solving, role playing and analysis of videos. Advancements in technology [23] and the COVID19 pandemic [24] have increased the use of telepractice in speech and language therapy, and a teleservice model of ITTT has been developed by the Hanen centre to deliver the whole course online. Whilst it would be relatively simple to deliver this course to parents alongside standard care, the NHS does not routinely provide ITTT, nor any other parent-implemented models of rehabilitation, to aid CI users. Instead, a clinician-implemented rehabilitation model is the current standard of care following paediatric cochlear implantation in the UK [7].

Clinician-implemented rehabilitation for children with CIs in the UK usually involves about 30-40 outpatient appointments with the SLTs and other professionals over the first three years following cochlear implantation. This rehabilitation, together with visits to the clinic or hospital to adjust their CIs, is estimated to cost £11,137 per person over post-operative years 1-3, with an additional yearly cost of £631 thereafter [25]. Several barriers have been identified to this model of rehabilitation, including rural family location, low parental education, and low socioeconomic status [26]. Arguably, these exclusively professional-centred approaches are also poorly suited to meet the future growing demand for cochlear implantation across the UK and abroad, including in developing countries. Furthermore, these models of care overlook parents as a low-cost resource for rehabilitation. Parent-implemented models of rehabilitation have been estimated to cost approximately £725 per person for the course [27] and, given the constant contact a parent has with their child, their impact is potentially long lasting.

Why is this research needed now?

Around 466 million people worldwide have disabling hearing loss, and it is estimated that this number will grow to over 900 million by 2050 [28]. Hearing loss has a devastating effect on speech and language, communication, education, and employment and poses an annual global cost of US$750 billion [28]. In common with other sensory systems [29], there is considerable evidence to suggest that hearing loss in younger children causes significantly greater and more lasting deficits, compared with older individuals [30, 31]. Since the effects of delayed language development in children are long-lasting and often persist into adulthood, it is imperative that speech and language rehabilitation is optimised for young CI users as early as possible. Whilst the quality of parent interactions plays a formative role in a child's early language and learning, primary caregivers are currently overlooked in standard NHS clinical care models of rehabilitation. Therefore, it seems vitally important to evaluate therapeutic rehabilitation approaches that include parents in the language rehabilitation of their deaf children. Early evidence suggests that one such approach (ITTT) benefits speech and language development in children with CIs. If the IMPACT trial confirms this hypothesis is correct, then ITTT could be used to help ensure deaf children now, and in the future, can reach their full potential.

The positive quality of parent–child interactions are crucial in shaping a child's early language development [32]. For example, conversational patterns between parents and children, including turn taking [33, 34] and direct eye gaze [35], are critical and predictive for later language development. Usually, parents are the primary people engaging and interacting with children on a consistent basis. The first 3 years are the most intensive, as this is when the brain rapidly develops and is able to learn new information. If this critical period passes without adequate interaction and opportunity for language development, it becomes significantly more challenging to accomplish the milestones as the child develops [36, 37].

Currently there is insufficient evidence for healthcare professionals to decide whether to use ITTT for young children with CIs in the UK or not. If, as we hypothesise, the proposed study shows that ITTT is beneficial as an adjunct to standard care in children with CIs, this Level 1b evidence will inform future research to evaluate the effectiveness of ITTT as an adjunct to standard care for the rehabilitation of children with CIs, along with the broader impact and cost-effectiveness of this therapy. Subsequently, this research could provide significant benefits to children with CIs, their parents, CI centres, and healthcare commissioners in the UK, at relatively low cost to the NHS. An intervention that benefits a child's language development is likely to have long-term impact on their quality of life and future needs of support from the NHS. This could lead to significant cost savings for the NHS.

The intervention in the trial is a therapy for parent(s) and/or carer(s) of children who receive cochlear implants. For clarity, parent(s) and/or carer(s) are referred to in the protocol as 'parent(s)'. Although in the intervention group, it is the parent who is 'participating', the primary and secondary outcomes are measured by assessing the children (participants). Hence, we have used the terminology 'parent(s)' and 'child/children' rather than 'participant' to ensure clarity.

2 TRIAL OBJECTIVES AND PURPOSE

2.1 PURPOSE

To evaluate the efficacy of ITTT as an adjunctive therapy to standard care on language development in children with CIs aged less than 5 years old.

2.2 PRIMARY OBJECTIVE

To compare receptive language development at 12-months post-randomisation, measured using the auditory subscale of the PLS-5, between two groups of children with cochlear implants (CIs), one group will continue to receive standard care whilst their parents engage in the ITTT programme as an adjunctive therapy, and a second group who receive standard care alone.

2.3 SECONDARY OBJECTIVES

The secondary objectives are:

- To compare expressive language development between both groups at 6- and 12-months post-randomisation.
- To compare receptive language development between both groups at 6-months post-randomisation.
- To compare childhood developmental milestones, child behaviour, social-emotional functioning and pragmatic language development between both groups at 12-months post-randomisation.

2.4 INTERNAL PILOT

An internal pilot phase has been built into the trial to allow a feasibility assessment which will examine recruitment and primary outcome data collection. The assessment criteria in Table 1 will be used for a preliminary check of trial progress by the funder, 12 months after the first site opens to recruitment. The pilot phase assessment criteria in Table 2 will be used to determine the progression of trial recruitment 15 months after the first site opens to recruitment.

Table 1: Criteria for assessment 12 months after the first site opens

Parameters for assessment	Green	Amber	Red
Number of participants consented	100% N=66	60 to <100% N=40 to 65	<60% N<40
Number of participants randomised	100% N=52	50 to <100% N=26 to 51	<50% N<26

Table 2: Recruitment and progression criteria for internal pilot 15 months after the first site opens

Parameters for assessment	Green	Amber	Red
Number of participants consented	100% N=92	60 to <100% N=55 to 91	<60% N<55
Number of participants randomised	100% N=76	50 to <100% N=38 to 75	<50% N<38
Number of groups randomised	100% N=10	50 to <100% N=5 to 9	<50% N<5
Adherence* i.e. parents attend at least 80% of planned sessions	90% of parents	80 to 89% of parents	Less than 80% of parents
Retention	Up to 10% of families have been withdrawn from the trial	Between 11 and 20% of families have been withdrawn from the trial	More than 20% of families have been withdrawn from the trial
Action	If all criteria met: Continue	If at least one criterion met: Discuss with TSC – improvement plan implemented	If at least one criterion met: Discuss with TSC and funder – consider stopping

*At the time of assessment, parents recently enrolled to the trial will have had few sessions scheduled therefore non-attendance to e.g. one session out of two may have a disproportionate impact on the overall adherence measure percentage. Time enrolled in the ITTT programme will be accounted for when assessing the progression criteria.

Each child will have one nominated parent who should attend all sessions in full. To be considered compliant with the intervention, the nominated parent must attend at least 80% of

planned sessions. While the nominated parent is the primary attendee, another parent may attend the remaining 20% of sessions if needed. Additional parents can also attend alongside the nominated parent, with a maximum of two representatives per child per session. Attendance will be recorded for all attendees at every session.

The above criteria will aid decision making about progression of the trial and have been agreed by the funder. The final agreement on whether the trial should stop, adapt or continue will take place after discussion with NIHR EME (funder).

The Trial Management Group (TMG), Trial Steering Committee (TSC) and Data Monitoring Committee (DMC) will meet to assess trial progress against these criteria as soon as possible after the timepoint of 15-months after randomisation of the first group of families. The TSC will make a recommendation to the funder about trial progression.

3 TRIAL DESIGN

3.1 TRIAL CONFIGURATION

IMPACT is a multicentre, parallel group randomised controlled trial design with equal allocation (1:1) and blinded primary outcome assessment. The trial will compare language development in children with at least one parent who participates in the ITTT programme as an adjunctive therapy to standard NHS care, compared with those who receive standard care alone.

3.2 PRIMARY OUTCOME

The primary outcome is receptive language development, assessed using the Auditory Comprehension subscale of the Preschool Language Scale – Fifth Edition (PLS-5 UK), 12-months post-randomisation. The PLS-5 Auditory Comprehension Subscale [38] is routinely used by healthcare professionals to evaluate a child's comprehension of language from birth to 7 years 11 months with known validity and variability. The test items are used to measure comprehension of basic vocabulary, concepts, morphology, and early syntax. The PLS-5 accounts for earlier development of receptive language skills, compared with expressive language skills, in young children.

The PLS-5 is widely used in clinical practice across the UK to assess language development in paediatric CI recipients. The PLS-5 (and subscales) will be administered and scored in a standardised manner by appropriately trained site staff e.g. Speech and Language Therapists or a Teacher of the Deaf (ToD) who will be blinded to the trial treatment allocation. Those administering the PLS-5 will be independent from the SLT delivering ITTT.

3.3 SECONDARY OUTCOMES

Secondary outcomes were selected based on their ability to capture changes in a child's expressive language, behaviour, social-emotional functioning, and developmental milestones. Secondary outcomes will be measured and scored using standardised processes detailed in the instructions of each test. Secondary outcomes will be administered and scored in a standardised manner by appropriately trained site staff who will be blinded to the trial treatment allocation. Secondary outcomes 4 to 6 will be parent-reported.

Table 3: Primary and secondary objectives and outcome measures

	Outcome	Assessment	Baseline	6 months (T1)	12 months (T2)	Completed by
Primary outcomes						
1	Receptive language development	PLS-5 - Auditory Comprehension Subscale [38]	x		x	Site staff
Secondary outcomes						
1	Receptive language development	PLS-5– Auditory Comprehension Subscale [38]		x		Site staff
2	Expressive language development	PLS-5 - Expressive Communication Subscale [38]	x	x	x	Site staff
3	Childhood developmental milestones	Schedule of Growing Skills Questionnaire (SGS) [39]	x		x	Site staff
4	Child behaviour	Strengths and difficulties Questionnaire (SDQ) [41]	x		x	Parent
5	Social-emotional functioning	Ages and Stages Questionnaires Social Emotional – 2 (ASQ:SE-2) [42]	x		x	Parent
6	Pragmatic language development	Language Use Inventory (LUI) [43]	x		x	Parent

2. Expressive language development

The Expressive Communication Subscale of the PLS-5 UK [38] evaluates the verbal language production skills of children by assessing their ability to describe objects, express quantity, use specific prepositions, and structure sentences.

3. Childhood developmental milestones

The Schedule of Growing Skills Questionnaire (SGS) is a measure of child development through the assessment of nine key areas: Passive Posture, Active Posture, Locomotor, Manipulative, Visual, Hearing and Language, Speech and Language, Interactive Social and Self-Care Social. It is completed by healthcare professionals using focused play [39].

4. Child behaviour

The Strengths and Difficulties Questionnaire (SDQ) is a validated parent-completed brief behavioural screening questionnaire. The SDQ asks about 25 attributes some positive and others negative. These 25 items are divided between emotional symptoms, conduct problems, hyperactivity/inattention, peer relationship problems and prosocial behaviour [41].

5. Social-emotional functioning

The Ages and Stages Questionnaires: Social-Emotional-2 (ASQ:SE-2) is a validated parent-completed questionnaire that assesses communication, problem-solving, and personal adaptive skills of children, providing general findings on children's social-emotional skills and monitoring their developmental status [42].

6. Pragmatic language development

The Language Use Inventory (LUI) is a standardised parent-report measure to assess early social (pragmatic) communication. The LUI will be used to assess pragmatic language development. The LUI covers 14 subscales assessing a child's communication in a wide range of settings and broad variety of functions. The LUI is completed by the parent and scored by the researcher [43].

3.4 SAFETY OUTCOMES

There are no safety outcomes for this trial as there are no safety issues or concerns associated with the trial intervention. The care for all children will not change from NHS standard care.

3.5 STOPPING RULES AND DISCONTINUATION

There is no planned interim analysis or stopping rules. The Sponsor reserves the right to discontinue this trial at any time for failure to meet expected enrolment goals, for safety or any other administrative reasons. The Sponsor shall take advice from the TSC and the funder as appropriate in making this decision.

4 RANDOMISATION AND BLINDING

4.1 RANDOMISATION

Before randomisation can take place, eligibility will be confirmed. Consent is received prior to baseline assessments and reconfirmed prior to randomisation. Availability for specific sessions will be gathered prior to randomisation to ensure all families randomised to the intervention group will be available for ITTT sessions as scheduled. After verbal reconfirmation of consent, randomisation will take place by the trial coordinating centre. Within 4 months of CI switch-on families will be randomised on a 1:1 ratio to receive either standard NHS care or standard NHS care in addition to at least one parent participating in the ITTT programme.

Randomisation will be performed concurrently for families when a minimum of four have confirmed both consent and availability to attend ITTT groups if so randomised.

A minimum of four families will be required for randomisation, but the full randomisation window, 4-months from time of CI switch on, will be used to try to recruit 6-8 families. If this is not possible by the end of the randomisation window and only four families are available, they will be randomised with two in the intervention arm and two in the control arm. The maximum number of families that can be randomised at one time is 16, to be randomised into two groups of eight families.

Clear expectations will be communicated to all parents during the recruitment process and following randomisation regarding their commitment to attend each session, except in cases of illness or other exceptional circumstances, particularly when randomised in a group of two families. SLTs will be instructed to schedule sessions at times that are convenient for both families. In the event of a cancellation, every effort will be made to reschedule the session at a time when both families can attend, wherever possible.

These steps will be followed to ensure the integrity of the Hanen Program, which is fundamentally a group intervention. Additionally, they will help maintain flexibility in scheduling to accommodate the needs of families and the SLT, while ensuring adherence to the trial timelines.

Treatment allocation will be carried out by staff at the NCTU via a bespoke, secure, concealed, dynamic randomisation system developed and maintained by the NCTU and hosted on a

secure server at The University of Nottingham, accessed via delegated personnel and run in an access-controlled area.

Families will be randomised in a 1:1 ratio allocation using random permuted blocks of varying sizes. Due to the requirement for families to be randomised in groups of at least four, there will be no stratification, but key variables such as site, gender and the child's age will be adjusted for in the analysis.

Parents will be informed via email/post of the group to which they are allocated by staff at the NCTU, who will also liaise with the SLTs delivering the intervention to inform them of the parents they should contact for intervention arrangements. This will enable the team at the recruiting sites to remain blinded to the treatment allocation of their families.

4.2 BLINDING

The trial can only practically be conducted using an open design as parents will know whether they are randomised to attend ITTT group sessions or not. The primary outcome will be assessed by an appropriately trained member of staff at the child's trial site who is not aware of the allocation for each child, and the parent accompanying the child to their assessment will be asked not to reveal their allocation. It is not expected that the child will know or be influenced by the allocation.

Table 4: Blinding status per role in trial

Role	Status	Justification
Parent(s) and Children	Not Blinded	Not possible to blind parents. Efforts will be made to minimise expectation bias. It is not expected that children will be affected by knowledge of treatment allocation.
SLTs delivering ITTT	Not Blinded	Delivering intervention. Will not have access to any part of the database with data about the child beyond that required to deliver the intervention; will not have direct access to the assessing SLT.
Clinical/ Research Staff	Blinded	The direct clinical care team, and research staff, delivering and scoring primary and secondary outcomes will be blinded.
Trial Management (TM) Data Management (DM) IT staff at NCTU	Not Blinded	TM, DM and IT staff will be involved in the randomisation process, queries from SLTs delivering ITTT and parents about trial conduct and data cleaning throughout the trial.
Trial Statistician(s)	Blinded	The Trial Statistician will finalise the analysis plan prior to revealing the group allocation codes. Any analyses by treatment group required prior to this will be performed by an independent statistician.
Independent Statistician	Not blinded	The independent statistician will have access to intervention allocations and to data which could directly and indirectly reveal intervention allocations. They will provide data by group for the DMC (normally in the form of a 'closed report') and may provide summary data information to the TMG. All datasets and output used and generated by the independent statistician will be stored in an

		access-controlled area to which the trial statistician will have no access.
Chief Investigator	Blinded	The Chief Investigator will remain blinded to intervention allocation.
Trial Management Group (TMG)	Partially blinded	Except in the specified roles, noted in this table, members of the TMG will not have access to any participant data with the potential to unblind until after database lock. Care must be taken by those who are not blinded, to ensure that TMG reports do not contain data which can either directly or indirectly unblind staff. Where decisions about data are required, the blinding status of those making the decision should be documented. It may be necessary to nominate blinded delegates where decisions must be made to ensure minimisation of bias.
Data Monitoring Committee (DMC)	Not blinded	The independent members of the DMC will be provided with data presented by treatment group to allow them to perform their oversight role. These data will be provided by an independent statistician.
Trial Steering Committee (TSC)	Blinded	Except in the case of a specific recommendation from the DMC, independent members of the TSC will not have access to any participant data with the potential to unblind until after database lock.

4.3 MAINTENANCE OF RANDOMISATION CODES AND PROCEDURES FOR BREAKING CODE

As parents and SLTs delivering the intervention are not blinded to treatment allocation, there is no process required for code breaking. Support for trial related matters will be provided by the NCTU Trial Management team to minimise the potential for unblinding of site clinical and research staff.

At their request, the Data Monitoring Committee (DMC) may review unblinded data. This will be prepared by a statistician from NCTU not involved in the trial (i.e., an independent statistician).

5 TRIAL MANAGEMENT

The project (NIHR154749) is funded by the Efficacy and Mechanism Evaluation (EME) Programme, an MRC and NIHR partnership. The Sponsor is University of Nottingham. The trial will be managed and coordinated by the Nottingham Clinical Trials Unit (NCTU).

The Trial Steering Committee (TSC) will typically meet at least once a year (or as required) and will provide independent oversight of the trial on behalf of the trial sponsor. The Data Monitoring Committee (DMC) will typically meet at least once a year (or as required) to assess effectiveness and safety and will report to the TSC. The Trial Management Group (TMG) will meet more frequently, typically monthly, and will be responsible for the day-to-day management of the trial.

All the oversight groups will have terms of reference/charters agreed in advance of recruitment commencing.

The Chief Investigator has overall responsibility for the study and shall oversee all study management. The data custodian will be the Chief Investigator.

5.1 DURATION OF THE TRIAL AND PARTICIPANT INVOLVEMENT

Trial Duration:
Trial funding is for 60 months total (from start of the funding contract to delivery of the final report).

The recruitment period is expected to be 26 months, including 12-month internal pilot phase, with a 12-month follow-up period for the last group of families randomised. Once follow-up of the last group of families is completed, data cleaning, SAP finalisation, database lock, analysis and dissemination is expected to take a further 8 months.

Participant Duration: Once a child is approved for CI surgery by their clinical care team, the parents are invited to attend a pre-op appointment (and/or a CI surgery consent appointment). Parents of potentially eligible children will be approached and enrolled during those standard clinical appointments. Randomisation will occur within 4-months post-switch on of the CI. Families are expected to be in the trial for a maximum of 20 months total. Time from consent to CI surgery may vary between trial sites, but we expect this would not exceed 4-months, time between CI activation and randomisation will not exceed 4-months and the follow-up period for all families is 12-months from randomisation.

5.2 END OF THE TRIAL

The end of the trial is defined as the date of the final database lock. NCTU will notify the REC that the trial has ended within 90 days of the end of trial. If the trial is terminated early, NCTU will notify the REC within 15 days of the early termination.

6 SELECTION AND WITHDRAWAL OF PARTICIPANTS

6.1 RECRUITMENT

Families will be recruited from approximately 10 secondary care CI centres across the UK, at an average rate of 1-2 per site per month. The initial approach will be from a member of the child's usual care team, which may include members of the research team, during the child's standard clinical appointments. Members of the usual care team will identify potentially eligible families with children under assessments for CI suitability, via medical notes and pre-implantation assessments. The parents of potentially eligible children may be approached by invitation letter, telephone call, or in person at their clinical appointments to explain the details of the trial. Participant Information Sheets (PIS) will be provided, ensuring that parents have sufficient time to consider participating. Summary trial leaflets and posters will be provided to sites for display in waiting areas, offering details on how interested families can obtain more information about the trial.

Parents of potentially eligible children will be encouraged the read the study information in their own time and will be given the opportunity to ask questions before participating in the trial. The study information will contain details on the ITTT programme and parents must confirm that if randomised to the intervention group, they will be available for the online sessions for ITTT delivery. At the end of their standard CI assessment pathway, families will attend a face-to-face meeting with the child's care team in which the child's surgery is confirmed, and consent is obtained for the child to proceed with CI surgery. Either on the same day, or soon after, but prior to surgery, the PI (or delegate) will obtain informed, written consent from those parents/legal guardians of potentially eligible children who are willing and capable of taking part in the trial. This

consent must be obtained prior to the child undergoing any assessment related to the trial. The PI (or delegate) will answer any questions that families have concerning study participation.

It will be explained to the parent that entry into the trial is entirely voluntary and that their child's treatment and care will not be affected by their decision to participate. It will also be explained to parents prior to joining the trial, that they can withdraw at any time, but reasonable attempts may be made to avoid this occurrence. In the event of their withdrawal of consent from all trial activities, it will be explained that theirs and their child's data collected so far cannot be erased and we will use the data in the final analyses where appropriate. This information will be stated in the PIS and reiterated at the point of receiving the withdrawal request.

Once a parent has given their consent to participate, the child's initial baseline assessments will take place, followed by CI surgery. The child's bilateral CIs will be activated (switched on) approximately 1 month following CI surgery, at which time PI (or delegate) at site will confirm that the parent and child still meet the eligibility criteria.
Once eligibility is confirmed, parents will be contacted by the NCTU and asked to verbally re-confirm consent to take part in the trial. Families will then be randomised to receive either standard care of clinician implemented rehabilitation as per local protocol, or standard care with adjunctive ITTT administered online to parents by ITTT trained SLTs following CI switch-on.

If needed, the usual hospital interpreter and translator services will be available to assist with discussion of the trial the participant information sheets, and consent forms. Consent forms and information sheets will not be available printed in other languages.

More detailed information is detailed below in section INFORMED CONSENT6.4 informed consent.

6.2 PARTICIPANT IDENTIFICATION AND SCREENING LOGS

The site team at trial centres will maintain a list of children under the age of 5 who are under assessments for CI suitability, whose parents were approached/not approached to join the trial and those consenting/not consenting, with reasons. Site staff will also request written informed consent from parents of children under the age of 5 years old that enter the CI centre's assessment pathway to obtain demographic information on both parents and children for screening logs, as described below. The purpose of this screening information is to understand barriers to accessing the intervention. All demographic screening data will be entered directly to the secure trial database.

The optional demographic information that will be collected, with parents' consent, includes the following options:

- Site identifier
- Date
- Approach and reasons why not
- If eligible and reasons why not
- If consented to main trial and reasons why not
- Main and additional languages spoken at home
- Ethnicity of parent/carer and child
- DOB of child
- Age of parent(s)/carer(s)
- Postcode (to calculate deprivation index score)

For families not eligible to take part in the trial due to not having English as the primary spoken language at home, contact details will be requested along with consent to be contacted for the purpose of potentially being contacted about participation in the auxiliary qualitative study.

The trial central coordinating team, at the NCTU, may request screening logs from the sites, for monitoring purposes. The sites will redact any personal identifiable information from the logs prior to sending to the NCTU.

Screening log data will be used to guide and inform the recruitment process.

6.3 ELIGIBILITY CRITERIA

The target population for the trial are parents/carers for and children aged less than 5 years old at time of surgery with severe-to-profound hearing loss who meet UK NICE (TAG566) criteria for bilateral cochlear implantation. Their parent(s) will be recruited from UK CI programmes. All children in the intervention and control groups will continue with their standard care in line with NICE guidance. No efforts will be made to intervene or change a child's standard care unless the clinical staff believe that to be necessary. Standard advice about rehabilitation following a cochlear implantation will be given to both groups.

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 re-assessed and children not meeting the criteria will not be randomised into the trial.

6.3.1 Inclusion criteria

Children

- Aged less than 5 years old at time of 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, with English the dominant language spoken at home
- Ability to provide informed consent

6.3.2 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)

6.4 INFORMED CONSENT

All parents will provide written informed consent prior to participation. The Informed Consent Form (ICF) will be signed and dated by the parent before they enter the trial. The PI (or delegate) will

explain the details of the trial and provide a Participant Information Sheet (PIS), ensuring that the parent has sufficient time to consider participating or not. The PI (or delegate) will answer any questions that the parent/carer has concerning study participation.

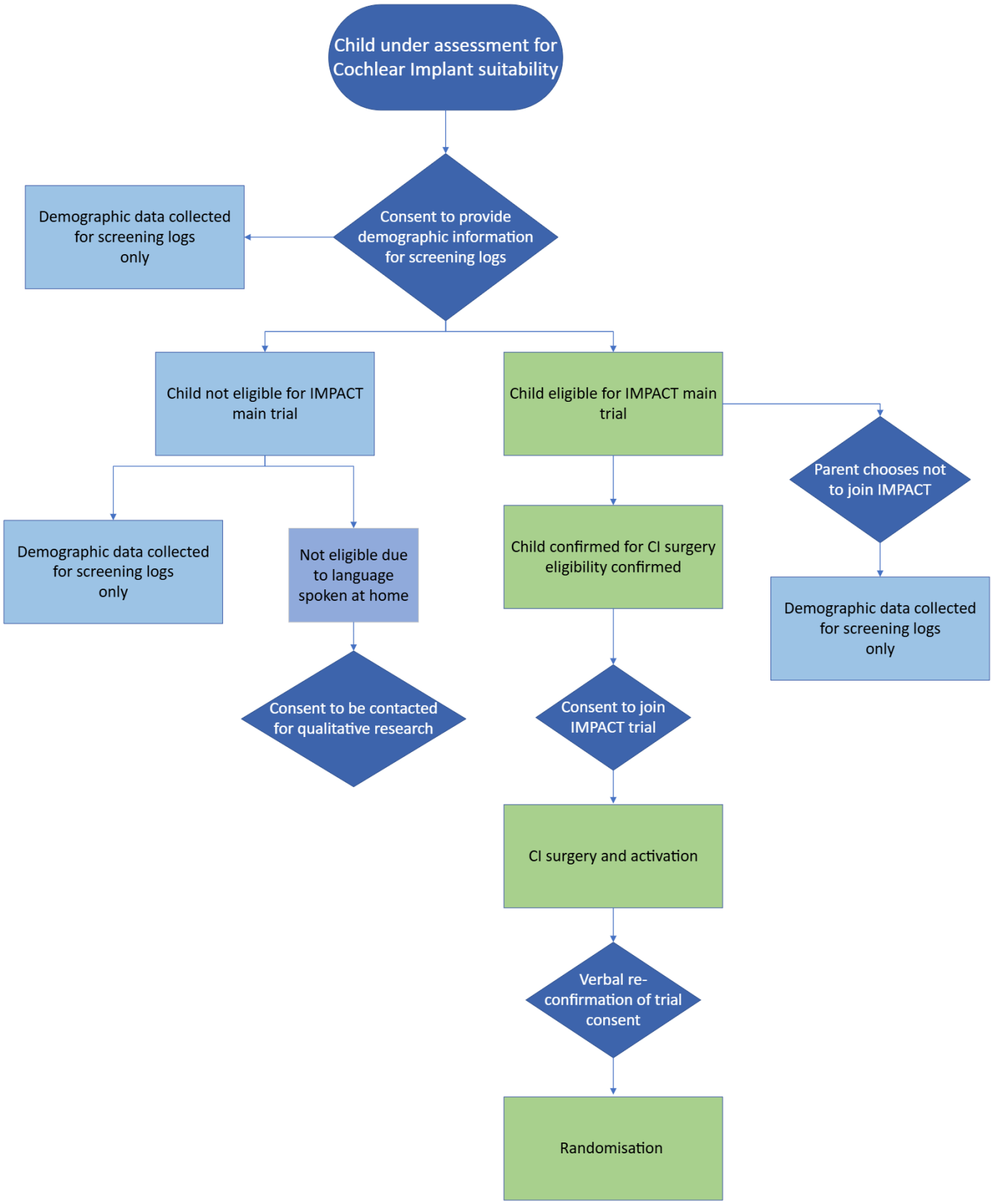
Informed consent will be collected from each parent before they undergo any interventions or assessments (including history taking) related to the study. One copy of the ICF will be given to the parent, one copy will be filed on the child's medical notes, once copy will be uploaded to the trial database for central monitoring by NCTU, and the original will be placed in the Investigator Site File (ISF).

Optional consent

- Parents of children under the age of 5 who are under assessments for CI suitability will have the option to consent to provide demographic information for screening logs. These children may not be eligible to join the main trial, and parents may choose not to join the main trial later (one copy of this ICF will be given to the parent, and the other will be placed in the ISF).
- Parents of children who are not eligible due to not having English as the primary spoken language at home will have the option to consent to provide their contact details and be contacted about participation in the qualitative interviews. This will explain that we want to talk to a small number of parents about their experiences and not everyone who gives consent will be contacted.

Should there be any subsequent amendment to the final protocol, which might affect a parents' participation in the trial, continuing consent will be obtained using an amended Consent form which will be signed by the parent.

Figure 1 Informed consent flowchart



6.5 DISCONTINUATION OF INTERVENTION

Families who completely discontinue the trial intervention for any reason will continue to be followed up in accordance with the trial schedule and continue to provide trial data, including completion of follow-up questionnaires and assessments for use in the analysis, unless they are unwilling to do so. All data collected will be used, and any parent that discontinues the trial intervention will be reminded of the importance of continuing to complete trial questionnaires and assessments. Reasons for trial intervention discontinuation may include parent decision.

6.6 WITHDRAWAL FROM TRIAL

Families may be withdrawn from the trial either at their own request or at the discretion of the PI at site. The parent will be made aware that this will not affect their child's future care. Parents will be made aware (via the information sheet and consent form) that should they withdraw the data collected to date cannot be erased and may still be used in the final analysis.

6.7 WITHDRAWAL PRIOR TO RANDOMISATION

Any parents that request to withdraw their consent prior to randomisation will be withdrawn completely from the trial; they will not be randomised.

Families not randomised within the 4-month time frame from child's CI switch-on, either due to the group randomisation requirement not being met or a change in status regarding intervention participation e.g. family no longer able to attend ITTT sessions, will not be randomised. The coordinating centre will notify parents that they will not continue in the trial. In this instance parents will have provided written informed consent to take part in the trial, and baseline child assessments will have taken place. Children will continue to receive standard care.

Any data collected prior to withdrawal will be retained and used.

6.8 DISCONTINUATION AND WITHDRAWAL POST-RANDOMISATION

Parents may withdraw their consent for follow-up and/or other trial related activities/receiving trial communications. Alternatively, parents may choose to change or reduce their participation in the trial. The NCTU must be informed of all requests by parents to stop or change their involvement in the trial; appropriate action will be taken to ensure that the parent's wishes are followed.

Sites will be trained to determine which activities parents may wish to withdraw from.

Table 5: Use of data according to change in participation status

Type	Procedure	Use of data
Withdraw from full trial	Any parent that requests to have no further involvement in the trial will be marked as withdrawn on the trial database.	Any data collected prior to participant withdrawal will be retained and used in the analysis.
Discontinue from intervention	Any parent that requests to discontinue from the intervention will be asked if they are still willing to complete follow-up questionnaires and for their child to complete clinical assessments.	Any data relating to the intervention collected prior to participant withdrawal will be retained and used. If parents are willing to complete follow-up questionnaires and clinical assessments, then any data

Type	Procedure	Use of data
		collected will be retained and used.
Discontinue from clinical assessments	Any parent that requests to discontinue their child from 6-month and/or 12-month visits where clinician reported outcomes are collected will be asked if they are still willing to complete follow-up questionnaires. Parents will be encouraged to attend the 12-month visit where primary outcome is assessed at a minimum.	Any data collected prior to participant withdrawal will be retained and used. If parents are willing to continue to complete follow-up questionnaires, then any data collected will be retained and used.
Discontinue from follow-up questionnaires	Any parent that requests to discontinue from follow-up questionnaires will be marked as withdrawn from questionnaire collection on the trial database and no further contact will be made with the parent for the purpose of obtaining questionnaire follow-up data. Parents will be asked if they are willing for their child to attend the 6-month and 12-month visits where clinician reported outcomes are collected.	Any data collected prior to participant withdrawal will be retained and used.
Discontinue from other trial communications	Any parent who requests to be withdrawn from other trial communications will be removed from all mailing lists for ongoing trial contact (e.g. newsletters and reminders) but will still receive trial questionnaires and attend trial visits.	N/A communications only
Discontinue from receiving communications about trial findings	Trial results will be sent to all parents, unless a specific request is received to withdraw them from receiving trial results.	N/A trial results only

If site staff are made aware of a family's discontinuation from any trial activities, with the exception of the trial intervention due to blinding requirements, the PI or delegate should record this in the CRF as soon as possible to ensure the correct procedures are followed by NCTU and the site team. Parents will be asked their reason(s) for withdrawal but are not obliged to provide these.

Where a parent wishes to withdraw from the trial, their reason for doing so may be explored by research staff to determine whether there are ways they can remain in the trial - for example by reducing the burden of completing some follow-up questionnaires. If parents choose to change or reduce their participation, they will be encouraged to attend the 12-month visit where the primary outcome is assessed. Sites will receive training on acceptable methods to maximise retention within the trial.

The right of the parent to withdraw from the trial, change or reduce their participation without providing a reason does remain paramount.

Families who withdraw after randomisation will not be replaced and all data collected up to the point of withdrawal will be used in the analysis.

7 TRIAL INTERVENTION AND REGIMEN

7.1 SCREENING

Eligible families will be identified at CI centres by a member of the child's usual care team during CI suitability assessments. Parents of these children will be signposted to the trial via posters and leaflets on display at CI centres.

Once a child is deemed as suitable for CI surgery, parents may be approached about taking part in the IMPACT trial by a suitably delegated member of the child's usual care team. During routine visits, the child will undergo assessments. No trial specific assessments will be made at this stage, and prior to consent being gained. Assessments will be performed as per routine care.

7.2 CONSENT

Eligibility will be assessed by a suitably delegated member of the child's care team. Written informed consent for the trial will be obtained from parents at face-to-face visits, usually the pre-operative appointment where written informed consent is also obtained for the child's CI surgery. Written informed consent will be obtained by the PI or a suitably delegated member of the usual care team. See section 6.4 for further details.

7.3 BASELINE ASSESSMENTS

Following consent, but prior to CI surgery, CI switch on and randomisation, baseline assessments will take place. Baseline questionnaire data (see section **Error! Reference source not found.** and **Error! Reference source not found.** for further information on assessments) will be collected by site staff and parents, electronically e.g. using a tablet or laptop directly into REDCap or written in a paper workbook.

7.4 CI SURGERY AND SWITCH ON

Following baseline assessments, CI surgery will take place, then around 1-month (average) following surgery the child's CIs will be switched on. CI switch on will happen during a face-to-face visit, during this visit parents will be reminded of the trial criteria, and a verbal confirmation of consent will be confirmed, prior to randomisation.

7.5 RANDOMISATION

The NCTU will monitor the number of parents who have consented to take part in the trial and have confirmed availability to participate in specific ITTT sessions. When there are sufficient numbers (between 4 and 16 families) of families able to participate in these sessions, a member of the NCTU team will contact each family to ensure that they are still able to participate in these sessions (if allocated) and that they still consent to being in the trial. These families will

then be randomised concurrently to attend ITTT sessions or not. Randomisation must be within 4 months of CI switch on.

Treatment allocation will be carried out by staff at the NCTU via a bespoke, secure, concealed, dynamic randomisation system developed and maintained by the NCTU and hosted on a secure server, accessed via delegated personnel and run in an access-controlled area.

Families will be randomised in a 1:1 ratio allocation using random permuted blocks of varying sizes. There will be no stratification, but key variables such as site, gender and the child's age will be adjusted for in the analysis.

7.6 INTERVENTION DELIVERY

Randomisation could take place any time between 1 day to 4-months post CI switch on. Following randomisation there would be around 1 month prior to the first ITTT session taking place.

The ITTT telepractice programme will be delivered online by ITTT-certified SLTs to parents in the intervention group over 3-4 months following randomisation as per the ITTT protocol [13, 14]. The programme consists of one orientation session, which includes an assessment of the child and setting communication goals, 8 interactive small group sessions, covering communication and language development and programme strategies and 3 individual virtual feedback sessions, during which parent-child interactions will be recorded during play-based activities. These recordings will subsequently be reviewed by the parent and the SLT to evaluate the effectiveness of the implemented strategies. The sessions will be used to provide individualised feedback to the parent, facilitating the adjustment and refinement of techniques to optimize the child's progress. At least one parent per child will be required to attend each session. Each child will have one nominated parent who should attend all sessions in full. Additional parents can also attend alongside the nominated parent, with a maximum of two representatives per child per session. These children will also continue to receive standard NHS care as per hospital guidelines. Children in the control group will receive standard care alone.

During each session, including group sessions, SLTs will document key aspects of the intervention, including session progress, family member attendance, and parental reports on the implementation of communication strategies. ITTT sessions may be recorded to ensure participant safety and to allow SLTs to review the recordings and accurately complete their notes. Parents will be asked to consent to video and audio recording. Parents will be asked to keep any discussions in intervention sessions confidential.

7.7 CONCOMITANT TREATMENTS

All families participating in the IMPACT trial will continue to receive standard care following cochlear implantation, which is provided by their local CI centre. The standard care for children within this age group varies between centres and is delivered by a range of professionals, including CI specialists, community SLTs, and teachers of the deaf. Standard care is provided independently of the trial.

Typically, the child's keyworker, who may be a speech and language therapist or a teacher of the deaf, will arrange virtual and/or in person sessions with the family at home, or with the child's school or nursery. Participation from parents and educational staff is encouraged but not required. During those visits the keyworker may:

- Provide advice to all carers
- ensure that the sound processor is in good working order
- work individually with each child focusing on the development of listening skills and speech and language skills

- promote the consistent use of spoken language by the child and all their carers
- monitor and assess progress through formal and informal assessment

The timing and frequency of these visits is determined based on the child's progress with input from the parents and other members of the child's healthcare team. Visits may continue as required, over a three-year period. After this, local services will provide continued support through school or home visits.

During the site selection process, potential recruiting sites will be asked to describe their standard care processes for children in this age group. This will include any parent-implemented programmes used or recommended, professionals involved in care, and details of rehabilitation appointments. Over the course of the trial, sites will be asked to inform the trial management team of any changes to standard care and patient pathways. The trial management team will check for updates annually and this information will be retained to allow standard care, across all participating sites in the trial, to be described.

7.8 FOLLOW-UP

Children will be seen at three time points to complete trial assessments: before surgery (baseline), and at 6 (T1) and 12 (T2) months post randomisation (T0). Questionnaire data will be collected by site staff and parents, electronically e.g. using a tablet or laptop either directly into REDCap or a paper workbook. (see sections **Error! Reference source not found.** and **Error! Reference source not found.** for further detail on assessments).

Parent-completed questionnaires will be posted directly to NCTU by the participants and subsequently entered into the eCRF by NCTU staff. We will offer and use all methods of delivery of reminders including postal mail, e-mail, telephone and SMS text for follow-up. Data received from parents will only be received onto password protected devices and accounts. Any SMS texts sent will be done from trial mobile phones held by NCTU, locked with passcodes. At any time during follow-up, parents will be able to contact the trial management team at the NCTU for assistance with the questionnaires as well as their trial site (for technical support or clarification). The trial management team will send reminders (via telephone, text message, letter or email) to participants that questionnaires are ready for completion and will follow up (via telephone, text message, letter or email) outstanding questionnaires to achieve maximum completion.

Follow-up visits and parent-completed questionnaires should be completed within 2 months of the follow-up timepoint as detailed in Table 6.

As a primary outcome, we will assess receptive language development using the Auditory Comprehension subscale of the Preschool Language Scale - Fifth Edition (PLS-5 UK) [38], 12 months post randomisation.

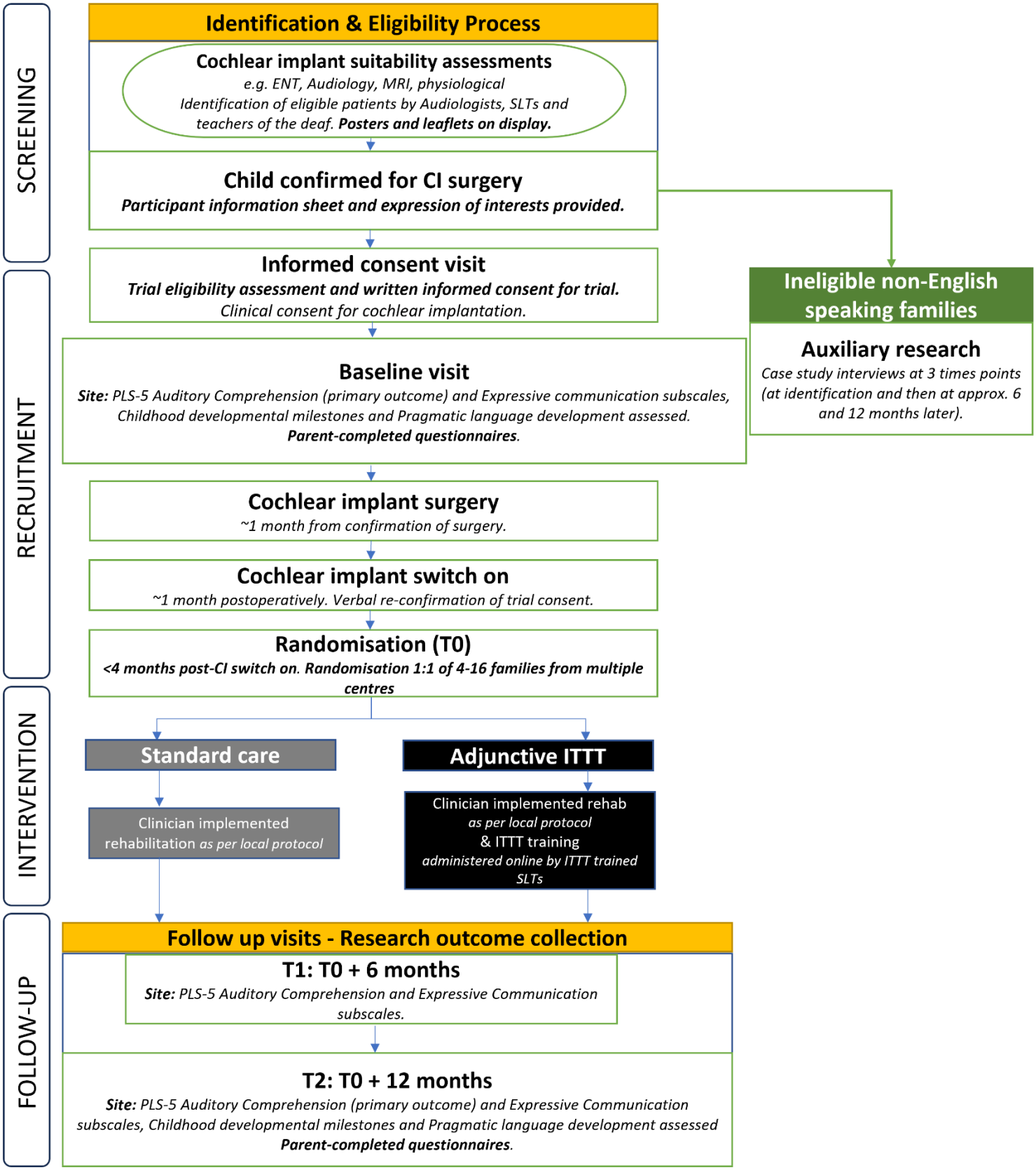
Table 6: Data collection schedule

	Screening	Baseline	CI switch on	Randomisation (T0)	ITTT	Follow-up	
						6 months (T1)	12 months (T2)
Identification and PIS	X						

	Screening	Baseline	CI switch on	Randomisation (T0)	ITTT	Follow-up	
Confirm eligibility		X					
Informed consent		X					
Baseline data collection		X					
PLS-5 – Expressive Communication Subscale		X				X	X
PLS-5 – Auditory Comprehension Subscale		X				X	X
Schedule of Growing Skills Questionnaire		X					X
Strengths and Difficulties Questionnaire		X					X
Ages and Stages Questionnaires		X					X
Language Use Inventory		X					X
Verbal reconsent			X				
Randomisation				X			
ITTT participation					X*		

*Data collected on ITTT participation is only applicable to those randomised to the ITTT group.

Figure 2 Participant flow diagram



7.8.1 Compliance

Adherence to the intervention, ITTT, will be closely monitored by tracking attendance at scheduled individual sessions with the SLT as well as group sessions, as defined in section 2.4. Parents will be considered compliant if they attend group sessions as scheduled, or if, in the event of a missed group session, they arrange a timely one-on-one catch-up session with the SLT. Each child will have one nominated parent who should attend all sessions in full. Additional parents can also attend alongside the nominated parent, with a maximum of two representatives per child per session. Attendance will be recorded for all attendees at every session.

7.8.2 Criteria for terminating trial

On the recommendation of the TSC, the sponsor (in collaboration with the TMG) may stop the trial if emerging evidence of efficacy concerns arise, or if there are significant concerns regarding trial conduct. There should be proof beyond reasonable doubt for overall efficacy futility (internal or external evidence) for the TSC and TMG to recommend the trial is stopped.

Stopping at one site will reflect unacceptable performance in recruitment or poor compliance with the protocol. In the case where a site closure has been decided due to inability to meet its recruitment target or due to poor compliance, the TMG may make this decision without consultation with the TSC.

If, following the pilot phase, the trial is deemed not feasible to continue (using the agreed criteria **Error! Reference source not found.**), and funding is discontinued, the trial will terminate.

8 STATISTICS

8.1 METHODS

The analyses and presentation of results will be carried out in accordance with CONSORT guidelines and will be specified in the Statistical Analysis Plan (SAP) which will be finalised prior to database lock and release of treatment allocation. The statistician(s) producing the SAP will be blinded to trial allocation to minimise any bias made in the decision about final analyses, missing data and other issues which will be included in the SAP.

The primary objective of the trial is to compare receptive language development at 12 months post-randomisation, measured using the auditory subscale of the PLS-5, between two groups of children with cochlear implants (CIs), one group whose parents engage in the ITTT programme as an adjunctive therapy in addition to standard care, and a second group who receive standard care alone. This is an explanatory trial and therefore the primary comparison of the primary outcome will be based on the per protocol (PP) population.

All analyses will place due emphasis on the confidence intervals for between group comparisons. Sensitivity and secondary analyses will be considered supportive to the primary.

Characteristics and baseline data of randomised participants (children and parents) in the two trials arms will be described using appropriate summary statistics. The primary and secondary outcomes will be assessed as described in the following sections.

No formal interim analyses are planned.

All analyses will be performed according to the SAP using Stata Version 17 or above, and where appropriate additional statistical software packages will also be used.

8.2 SAMPLE SIZE AND JUSTIFICATION

In normally-hearing children, the PLS-5 has a standardised mean of 100 (SD 15). The Longitudinal Outcomes of Children with Hearing Impairment study group published 5-year language outcomes assessed using the PLS in 350 prospectively studied, hearing-impaired children with CIs. By 3 years old, the language scores of children with CIs are normally distributed and have a mean of 74.6 (SD 17.1) [44, 45]. We will assume a similar distribution for children in this trial.

There is no published minimum clinically important difference for the score on the PLS-5 auditory comprehension subscale score (the primary outcome). Discussion with clinicians and the trial PAG have concluded that, in order to provide robust evidence of an effect, the trial should be powered to detect a "medium" effect (between 0.5 and 0.6) [46].

In order to detect an effect size of 0.55 assuming a SD of 17.1, significance level (2-sided) of 5% and 90% power, 71 children with primary outcome data would be required in each arm. This equates to detecting a difference in the mean PLS-5 auditory comprehension score of 9.4 between treatment groups.

ITTT will be delivered by one of two SLTs who have received the same training and who will be following the same protocol. We therefore expect little variation with respect to the intervention and have made no adjustments to the sample size to account for potential 'therapist' cluster effects. Parents are aware of the intensive follow up their children need after CI, are counselled on this prior to consenting to surgery and are extremely compliant. Thus, it is not expected that there will be a large proportion of children being withdrawn from the trial. Therefore assuming 10% loss of primary outcome data, and no effects due to the clustering of the intervention group a total of 158 children should be randomised (79 in each arm). The Data Monitoring Committee will be asked to check the assumptions made in the sample size calculation against the accumulating data to determine whether the trial can adequately address the research question with the planned number of participants.

The sample size calculation was performed using PASS 2022 software.

8.3 ASSESSMENT OF EFFICACY

Primary outcome: The between-group difference in the PLS-5 Auditory Comprehension Subscale score 12 months after randomisation will be analysed using an appropriate regression model including the baseline score, site and child's age and gender as covariates.
Given that this is an explanatory trial, the primary analyses will be based on the Per Protocol (PP) population which will be fully defined in the SAP. In short, it will include only participants where acceptable compliance with the protocol has been demonstrated. The analysis will only include data recorded i.e. we will not impute missing values. The adjusted risk difference in scores will be presented alongside the 95% confidence interval.

Sensitivity analyses will be conducted to determine the robustness of the results, by imputing missing primary outcome data, using an intention to treat analysis (including all participants and analysing by allocated treatment group) and potentially including covariates which may be prognostic and appear to be imbalanced at baseline.

Secondary outcomes: Analysis of secondary outcomes will be considered supportive of the primary analysis and will use appropriate (depending on the outcome type) regression models including site, child's age and gender and the baseline value of that outcome variable where collected. Adjusted risk differences or ratios (dependent on the variable) with the associated 95% confidence intervals will be presented. The primary analyses sets for the secondary outcomes will be specified in the SAP.

8.4 ASSESSMENT OF SAFETY

The trial does not include specific safety outcomes as there are no safety issues or concerns associated with the trial intervention.

8.5 PROCEDURES FOR MISSING, UNUSED AND SPURIOUS DATA

Spurious data will be queried using processes documented in the data management plan. Where appropriate, self-evident corrections may be made. All attempts will be made to collect missing data. Where data remains missing, investigations will be made to assess whether these data are likely to be missing completely at random. The primary analyses will not use any imputation techniques. However, the SAP will document where methods to address missing data (for example multiple imputation in a sensitivity analysis) will be used.

8.6 DEFINITION OF POPULATIONS ANALYSED

The per protocol (PP) population is defined as all participants who are deemed to have or be associated with no major protocol deviations that could interfere with the objectives of the study. A full definition of what is considered to be a major protocol violation will be included in the statistical analysis plan. As the trial is an explanatory trial, this will be the primary analysis set for the primary outcome.

The Intention to Treat (ITT) population includes all participants who are randomised. They are analysed according to randomised treatment. A sensitivity analysis of the primary outcome will be performed using the ITT population.

There will be no safety population as there are no safety outcomes being recorded in the trial.

9 QUALITATIVE STUDY

9.1 BACKGROUND AND RATIONALE

The IMPACT trial aims to determine the efficacy of ITTT alongside standard care compared with standard NHS care alone. If efficacy is shown, the next step would be to investigate the effectiveness of the intervention using a more pragmatic design including a broader population who may benefit from the intervention.

At this stage (with a concern for efficacy rather than effectiveness) the exclusion of families where English is not the primary language spoken at home is a necessary methodological compromise. However, looking to the future it is important to build a better understanding of how ITTT might be utilized to benefit families where English is not spoken at home.

9.2 AIMS AND OBJECTIVES

The aim of this nested research is to explore how non-English speaking families might effectively be included in the ITTT programme (presuming that IMPACT will demonstrate the efficacy of ITTT).

This incorporates both a focus upon future pragmatic trials as well as the potential integration of ITTT in NHS services.

Specific objectives are:

1. Estimate the number of non-English speaking families with children under 5 years old on the CI pathway who may potentially benefit from ITTT.
2. To establish the current SLT provision for non-English speaking families on the CI pathway.

3. To assess the views of SLTs in relation to the use of ITTT with non-English speaking families – i.e. its appropriateness and possible adaptations required.
4. To evaluate current practice with non-English speaking families.
5. To provide a roadmap for future adaptation and assessment of ITTT in multiple languages.

9.3 RESEARCH PLAN

This will be a mixed method study which seeks to incorporate an overview of current provision with the views and experiences of key stakeholders (SLTs and families in the CI pathway with specific regard to adoption in multiple languages).

The study will be informed by Normalisation Process Theory (NPT) [47, 48]. NPT focuses upon four core building blocks which will structure this study: (1) is there an agreed need for ITTT in multiple languages, (2) is there a willingness to undertake ITTT with this group, (3) are there adequate resources to provide ITTT, and (4) how will the success of ITTT be judged? A failure to achieve any of these building blocks is a barrier to ITTT being adopted in multiple languages.

NPT has been widely used in applied health and policy research; it has been applied to SLT research [49].

9.3.1 Work package 1 – Current demand/provision

In Work package 1 we will address objectives 1 and 2 by mapping current SLT provision for non-English speaking families.

Data collection

- We will monitor trial screening and recruitment to establish the number of families that are excluded from IMPACT due to the language spoken at home.
- We will survey all NHS paediatric CI SLT services across the UK using Microsoft Forms. In this online survey we will gather data on current SLT support for children with CIs, current provision for non-English speaking families, the languages that have been spoken by families accessing the service, and whether SLTs work in languages other than English (and what those languages are).
- We will use UoN-provided storage for our survey data. UoN licenses Microsoft Teams, allowing for secure and controlled sharing of data among the research team. Microsoft Teams encrypts data both in transit and at rest and is approved against the University's

Data analysis

We will generate simple statistics to describe the local incidence of SLT support offered in multiple languages. Analysis will focus upon NPT concepts: (1) is there a need for multilingual support; and (4) how language outcomes are established.

9.3.2 Work package 2 – SLT views on ITTT for multiple languages

In Work package 2 we will address objective 3 by consulting with SLTs about their views on using ITTT in multiple languages.

Data collection

Using the survey data from WP1 to create a sampling frame we will undertake detailed qualitative interviews with SLTs to capture insight about (i) working with families for whom English is not their primary language, and (ii) prior experience of ITTT with this population.

We will focus upon SLTs from regions where the need for multi-language support is greatest and areas where provision is most varied. We will collect data until saturation has been achieved (i.e. when full and complete understanding of views and experiences are attainted).

This is expected to require 12-20 interviews depending upon how heterogeneous experiences are.

Data analysis
Interview recordings will be transcribed in full and anonymised. Once transcriptions have been checked for accuracy the recordings will be deleted. We will use a framework approach in data analysis [50], preparing a pragmatic framework focused upon the adaption and integration of multi-language ITTT in CI pathways.

All data will be mapped to this framework and synthesised to focus upon NPT concepts: (2) willingness to use ITTT in CI; (3) resources required to deliver ITTT; and (4) how language outcomes are established.

9.3.3 Work package 3 – Evaluating current practice where English is not spoken

In Work package 3 we will address objective 4 in a pragmatic process evaluation of SLT support offered to families who are excluded from IMPACT solely due to the trial's language exclusion criteria.

Data collection
Any family excluded from IMPACT solely due to the trial's language exclusion criteria will be invited to take part in a parallel evaluation of the support that they receive. Families will be invited by their clinician, or they will receive an email from the qualitative researcher, at the University of Nottingham, with the PIS and consent forms for participation. This will take the form of a longitudinal study with data collected at multiple time points whilst they are in receipt of support. Timings may vary according to local provision, but each case study is likely to include three family interviews: at identification and then at approx. 6 and 12 months later. Where required family interviews will be supported by appropriate language translation. Those SLTs involved with the families will also be interviewed at identification about the SLT provision being offered (standard care) and progress made (month 12). We will also record the support that families receive, including that provided by non-NHS providers. All interviews will be audio or video recorded using MS teams or similar as appropriate. The qualitative researcher will undertake the interviews.

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.

Data analysis
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. We will use a framework approach in data analysis [47, 48], utilising the pragmatic framework developed in WP2. All data will be mapped to this framework and synthesised to focus upon NPT concepts: (2) willingness to use ITTT in CI; (3) resources required to deliver ITTT.

9.4 DATA SYNTHESIS AND OUTCOMES

In the final year of the study, we will instigate a core stakeholder group that will meet bi-monthly to review the findings of the 3 Workpackages. The group will include CI professionals, clinical triallists, and non-English speaking families of children with CIs.

The group will review the NPT building blocks to identify those factors which might inhibit the multi-lingual application of ITTT. They will assess and make recommendations about how to normalise ITTT for multiple languages in SLT provision in paediatric CI pathways. They focus upon NHS implementation and/or effectiveness trial design depending upon the progress that IMPACT has achieved.

10 ADVERSE EVENTS

10.1 REPORTING OF ADVERSE EVENTS

The occurrence of an adverse event due to participating in this trial is not expected and no adverse event data will be collected.

The risks of participating in this trial are comparable to that of usual care. The clinical assessments are conceptually similar to those that might have been done as part of usual practice. For example, parents may already be sent questionnaires about their child's condition and history before further clinical investigations take place. There are no known or anticipated safety risks associated with the trial intervention.

10.2 TRIAL INTERVENTION RELATED SAES

There are no known safety risks expected or associated with the trial intervention.

11 ETHICAL AND REGULATORY ASPECTS

11.1 ETHICS COMMITTEE AND REGULATORY APPROVALS

The trial will not be initiated before the protocol, informed consent forms and participant and GP information sheets have received approval / favourable opinion from the Research Ethics Committee (REC), the respective National Health Service (NHS) or other healthcare provider's Research & Development (R&D) department, and the Health Research Authority (HRA) if required. Should a protocol amendment be made that requires REC approval, the changes in the protocol will not be instituted until the amendment and revised informed consent forms and participant and GP information sheets (if appropriate) have been reviewed and received approval / favourable opinion from the REC and R&D departments. A protocol amendment intended to eliminate an apparent immediate hazard to participants may be implemented immediately providing that the REC are notified as soon as possible, and an approval is requested. Minor protocol amendments only for logistical or administrative changes may be implemented immediately; and the REC will be informed.

The trial will be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki, 1996; the principles of Good Clinical Practice, and the UK Department of Health Policy Framework for Health and Social Care, 2017.

11.2 INFORMED CONSENT AND PARTICIPANT INFORMATION

The process for obtaining participant informed consent will be in accordance with the REC guidance, and Good Clinical Practice (GCP) and any other regulatory requirements that might be introduced. The PI (or delegate) and the parent shall both sign and date the Informed Consent Form before the child can participate in the study.

The parent will receive a copy of the signed and dated forms, and the original will be retained in the Investigator Site File (ISF). A copy will be filed in the child's medical notes and a signed and dated note made in the notes that informed consent was obtained for the trial, and another copy will be uploaded to the trial database for central monitoring by NCTU.

The decision regarding participation in the study is entirely voluntary. The PI (or delegate) shall emphasise to them that consent regarding study participation may be withdrawn at any time without penalty or affecting the quality or quantity of the child's future medical care, or loss of benefits to which the parent and child are otherwise entitled. No trial-specific interventions will be done before informed consent has been obtained.

The PI will inform the parent of any relevant information that becomes available during the course of the study, and will discuss with them, whether they wish to continue with the study. If applicable they will be asked to sign revised consent forms.

If the Informed Consent Form is amended during the study, the PI shall follow all applicable regulatory requirements pertaining to approval of the amended Informed Consent Form by the REC and use of the amended form (including for ongoing participants).

11.3 RECORDS

11.3.1 Electronic Case Report Forms (eCRFs)

Each child will be assigned a trial identity code number, allocated at enrolment for use on eCRFs, other trial documents and the electronic database. The documents and database may also use their initials (of first and last names separated by a hyphen or a middle name initial when available) and date of birth (dd/mmm/yyyy). Additional trial identity codes may be allocated to parents in the ITTT group post-randomisation, these will only be accessible to unblinded members of the research team.

Parent contact details will be logged separately to the clinical eCRF data, to ensure participant identifiable data are separate to data used for analysis. The trial team may also use parent contact details to send out trial related questionnaires, correspondence and follow-ups, limited to the duration of the participant's participation in the trial. Participant newsletters will be circulated via email or post on an approximately 3-monthly basis throughout the trial duration, greetings cards may also be sent via email or post to families throughout the trial duration. Parents may also consent to their contact details being retained beyond the duration of their participation in the trial, to be updated about the outcomes of the research or informed of future research.

Quality control checks will be in place to review the completeness and accuracy of the data entered into eCRFs. This will include double data entry in the form of PI sign-off on complete subject records at the end of trial participation, quality control checks of questionnaire discrepancies on data entered at NCTU, and regular auditing/data cleaning of the eCRFs to raise and resolve any data queries. Data collected on parents relating to intervention delivery will be signed off by the SLTs delivering the intervention, due to the site staff blinding requirements.

eCRFs will be treated as confidential documents and held securely in accordance with regulations. eCRFs shall be restricted to those personnel approved by the Chief or local Principal Investigator and recorded on the 'Trial Delegation Log.'

Any paper forms shall be filled in using black ballpoint pen. Errors shall be lined out but not obliterated by using correction fluid. The correction should be inserted, initialled and dated as per GCP guidelines. The Chief or local Principal Investigator shall sign a declaration ensuring accuracy of data recorded in the eCRF.

11.3.2 Source documents

Source documents shall be filed at the PI's site and may include but are not limited to, consent forms, current medical records, laboratory results and records. An eCRF may also completely

serve as its own source data. Only trial staff as listed on the Delegation Log shall have access to trial documentation other than the regulatory requirements listed below.

Any source documents that SLTs delivering the intervention maintain should be held by the SLT securely for the duration of the trial and shared with the coordinating centre at the end of the trial.

11.3.3 Direct access to source data / documents

The eCRF and all source documents, including progress notes and copies of laboratory and medical test results shall made be available at all times for review by the Chief Investigator, Sponsor's designee and inspection by relevant regulatory authorities (e.g. HRA).

11.4 DATA PROTECTION

All trial staff and investigators will endeavour to protect the rights of the trial's participants to privacy and informed consent, and will adhere to the Data Protection Act, 2018. The eCRF will only collect the minimum required information for the purposes of the trial and will be completed electronically. If any paper documents are used to capture personal identifiable data these will be held securely, in a locked room, or locked cupboard or cabinet. Access to the information will be limited to the trial staff and investigators and relevant regulatory authorities (see above). Electronic data including the trial database will be held securely and password protected. All data will be stored on a secure dedicated web server. Access will be restricted by user identifiers and passwords (encrypted using a one-way encryption method). Information about the trial in the child's medical records / hospital notes will be treated confidentially in the same way as all other confidential medical information.

Electronic data will be backed up every 24 hours to both local and remote media in encrypted format.

12 QUALITY ASSURANCE & AUDIT

12.1 INSURANCE AND INDEMNITY

Insurance and indemnity for trial participants and trial staff is covered within the NHS Indemnity Arrangements for clinical negligence claims in the NHS, issued under cover of HSG (96)48. There are no special compensation arrangements, but trial participants may have recourse through the NHS complaints procedures.

The University of Nottingham as research Sponsor indemnifies its staff with both public liability insurance and clinical trials insurance in respect of claims made by research subjects.

12.2 TRIAL CONDUCT

Trial conduct will be subject to a Sponsor systems audit of the Trial Master File for inclusion of essential documents; permissions to conduct the trial; Trial Delegation Log; CVs of trial staff and training received; local document control procedures; consent procedures and recruitment logs; adherence to procedures defined in the protocol (e.g. inclusion / exclusion criteria, correct randomisation, timeliness of visits); adverse event recording and reporting; accountability of trial materials and equipment calibration logs.

The NCTU QA team shall carry out systems and trial audits as part of the NCTU risk adapted annual audit programme. Should this trial be selected for audit, an audit report shall be issued to the Trial Manager and can be disseminated to the appropriate committees should this be appropriate. Where monitoring has identified the need for a site audit, or this is requested of the TMG/TSC, this shall be carried out by a trained member of NCTU staff.

12.3 TRIAL DATA

Monitoring will be carried out as required, following a risk assessment and as documented in the trial monitoring plan. Monitoring of trial data shall include confirmation of informed consent; source data verification (where applicable); data storage and data transfer procedures; local quality control checks and procedures, back-up and disaster recovery of any local databases and validation of data manipulation. The NCTU team, or where required, a nominated designee of the Sponsor, shall carry out monitoring of trial data as an ongoing activity. Site visits may be required based on triggered monitoring as per the trial monitoring plan, in which case entries on eCRFs may be verified by inspection against the source data. In addition, the subsequent capture of the data on the trial database will be checked. Where corrections are required, these will carry a full audit trail and justification.

Trial data and evidence of monitoring and systems audits will be made available for audit/inspection as required.

12.4 RECORD RETENTION AND ARCHIVING

In compliance with the ICH/GCP guidelines, regulations and in accordance with the University of Nottingham Research Code of Conduct and Research Ethics, the Chief or local Principal Investigator will maintain all records and documents regarding the conduct of the study. These will be retained for at least 7 years or for longer if required. If the responsible PI is no longer able to maintain the study records, a second person will be nominated to take over this responsibility.

The Trial Master File and trial documents held by the CI on behalf of the Sponsor shall be finally archived securely in the Microsoft cloud which has multiple redundant systems and backup services. This archive shall include all trial databases and associated meta-data encryption codes. Access to files once archived (e.g. for inspection purposes), will be managed by the NCTU archivist and will only be accepted on approval of the University of Nottingham sponsor.

12.5 DISCONTINUATION OF THE TRIAL BY THE SPONSOR

The Sponsor reserves the right to discontinue this trial at any time for failure to meet expected enrolment goals, for safety or any other administrative reasons. The Sponsor shall take advice from the Trial Steering Committee and Data Monitoring Committee as appropriate in making this decision.

12.6 STATEMENT OF CONFIDENTIALITY

Individual child medical information obtained as a result of this study are considered confidential and disclosure to third parties is prohibited with the exceptions noted above.
Participant confidentiality will be further ensured by utilising identification code numbers to correspond to treatment data in the computer files.

Such medical information may be given to the child's medical team and all appropriate medical personnel responsible for the child and parent's welfare.

If information is disclosed during the study that could pose a risk of harm to the participant or others, the researcher will discuss this with the CI and where appropriate report accordingly.

Data generated as a result of this trial will be available for inspection on request by the participating physicians, the University of Nottingham representatives, the REC, local R&D Departments and the regulatory authorities.

13 PUBLICATION AND DISSEMINATION POLICY

The results of the trial and auxiliary research will be disseminated at scientific conferences, in peer-reviewed journals, meetings and reports to the funder, key stakeholders and NHS decision makers. Findings from both these trials (if a definitive trial is indicated) will be used to inform clinical and service guidelines regarding the use of ITTT within the NHS.

Results will be shared with parents, patient-support groups, healthcare stakeholders and the public through newsletters, social media posts and conferences. Parents who provide consent will be notified of the results in an end of trial newsletter and will be able to view the results on the website.

Workshops will be held with patients/service users, NHS and social care stakeholders and the wider public to determine what engagement would look like to them and what is the best way to inform them about this work. Workshop contributors will be identified via advertisements in the NIHR *People in Research* platform and professional bodies such as the Royal College of Speech and Language Therapists. Members of both the PAGs (trial and auxiliary research PAGs) will be involved in all dissemination activities, e.g. co-producing plain English and language specific summaries.

Any publications and presentations prepared by Investigators must be reviewed by the TMG. Draft manuscripts must be submitted to the TMG in a timely fashion and in advance of being submitted for publication, to allow time for review and resolution of any outstanding issues. Participants will not be identified in any publications or presentations. Publications and presentations (other than the protocol) will typically happen after the end of the trial.

De-identified individual participant data may be shared with researchers external to the trial research team in accordance with the NCTU's data sharing Standard Operating Procedure (SOP 33) wherein the request is considered by a data sharing committee which includes the Chief Investigator and the Sponsor and where a data sharing and use agreement would be required prior to the release of any data.

14 USER AND PUBLIC INVOLVEMENT

Patient and Public Involvement (PPI) will be embedded throughout the project to ensure impact and value to the research.

A Participant Advisory Group (PAG) have been involved in the development of the trial and will continue to be involved in the design of the research at key stages. This group contribute to the trial design and implantation including development of participant information, recruitment strategies, data collection and retention.

There is a PPI co-applicant who is involved in all aspects of trial design, delivery, interpretation and dissemination. Where appropriate, and in line with UK standards for PPIE, information from TMGs will be shared with the wider PAG group. This may include updates on recruitment, strategies, and retention. They will also be contacted on an ad-hoc basis outside these scheduled meetings as-and-when issues with recruitment arise. We will also invite a lay member of the public with experience of children with cochlear implants (parent/carer) to join the TSC.

At the end of the trial, a lay summary of the findings will be written in collaboration with the trial PAG and shared with all parents via a final newsletter, along with links to peer-reviewed publications available at that point. This information will also be disseminated on the study website and social media pages.

15 STUDY FINANCES

15.1 FUNDING SOURCE

This trial (Project Ref: NIHR154749) is funded by the Efficacy and Mechanism Evaluation (EME) Programme, an MRC and NIHR partnership.

15.2 PARTICIPANT STIPENDS AND PAYMENTS

Participants will receive a £20 shopping voucher at completion of the 6-months post-randomisation clinic visit and a £25 shopping voucher at completion of the 12-month post-randomisation clinic visit. In exceptional circumstances, additional costs incurred for travelling to clinic visits in excess of usual care will be reimbursed.

16 SIGNATURE PAGES

Signatories to Protocol:

Chief Investigator: (name) Doug Hartley

Signature: Doug Hartley

Doug Hartley (May 20, 2025 14:31 GMT+1)

Date: 20/05/2025

Trial Statistician: (name) Prema Shanmugasundaram

Signature: S.Prema.

Prema Shanmugasundaram (May 23, 2025 15:12 GMT+1)

Date: 23/05/2025

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