IMPACT

IMplemented by Parents And Carers Therapy (IMPACT Trial)

Parent/Carer and Families Information Sheet

IRAS ID: 344537

You are invited to take part in our research trial

- This information sheet is to help you understand why the research is being carried out and what it will involve for you and your child should you decide to take part.
- Please take time to read this information and ask us if there is anything that is not clear to you or if you would like more information.
- It is entirely your decision whether to take part in this trial. If you agree to take part, you are free to withdraw at any time without giving a reason. If you choose not to take part, your child's care will continue in the normal way.

A summary of the trial

Previous research has shown that the speech and language skills of cochlear implanted (CI) children vary. Parents/carers play an important role in helping children develop their speech and language skills.

The aim of this trial is to determine if teaching parents/carers different communication strategies using a parent/carer training programme called "It Takes Two to Talk" (ITTT) can improve the child's speech and language skills after they receive their CIs.

We are looking for children under the age of 5 years old who have been offered CIs in both ears and their parents/carers to take part in this trial.

After the child receives their CIs, we will split families into two groups:

1. Standard Care Group: The child receives standard NHS care,
2. Standard Care + ITTT Group: The child receives standard NHS care, and the parent/carer participates in the ITTT programme. ITTT will be delivered online.

The trial will last for up to 20 months depending on your child's surgery time, after you have been placed into one of the two groups you will remain in the trial for 12 months, and all families will have to attend three appointments at their CI centre lasting around 2 hours per visit.

You will receive two vouchers totalling £45 as a token of appreciation for your participation.

Contents

1 What is the purpose of the trial?

The IMPACT trial will help us decide whether a training programme for parents/carers called "It Takes Two to Talk" (ITTT) can help parent/carers improve the speech and language understanding of their children once they have received cochlear implants (CIs).

The outcomes from having a CI may vary. Children who get CIs develop speech and language skills differently. Some children may learn to speak and understand language like their hearing peers, while some children may face greater challenges and may not develop clear speech or good language understanding. There are many factors that affect the outcomes of CIs.

One of these factors is parental involvement. CI children need a lot of exposure to language, along with support to learn to make sense of sound and to develop speech and language skills. Parents/carers play a central role in this process, often acting as the child's primary communication partners. Previous research has shown that their active engagement in speech and language activities helps reinforce what the child is learning, enabling the child to develop their speech and language skills.

Currently, after cochlear implantation, children receive speech and language therapy as part of their standard NHS care plan. These sessions include structured listening games and activities that can be added into the child's daily routine. However, the standard rehabilitation plan does not focus on equipping parents/carers with the skills to interact and communicate more effectively with their child. These skills could maximise the child's potential to develop listening and language skills.

Research has shown that the parent/carer training programme ITTT, which helps parents/carers improve how they interact with their child, can lead to better speech and language development in children with language and communication delays. However, we don't yet know if this programme will work the same way for CI children.

In the IMPACT trial, we will test whether adding the ITTT parent/carer training alongside the standard NHS rehabilitation plan helps to improve the speech and language skills of CI children, compared to using the standard NHS care alone.

2 Am I eligible to take part?

You and your child have been invited to take part in this trial because your child will soon be receiving a CI in both ears. About 79 families in each group (158 total) will take part, from 10 CI centres across the UK. You are eligible to participate if you and your child meet all of the following requirements:

- Your child is less than 5 years old
- Your child is eligible to receive CIs in both their ears
- Your child does not have any known developmental disorders (e.g. brain injury)
- You speak predominantly English at home
- You can read and understand English
- You are able and willing to participate in all research activities.

If you have any questions about any of these criteria, please ask a member of the team, who will be able to discuss this with you

3 Do I have to take part?

It is up to you whether you take part in the trial. Even if you agree now, you are free to withdraw at a later date if you wish. We will talk to you about the trial and answer any questions you may have. If you agree to take part, we will ask you to sign a consent form.

4 What would taking part involve?

If you agree for you and your child to participate in the trial, you will be asked to read and sign the informed consent form before your child's CI surgery. You will be given a copy to take away and refer to later. Please remember that you can withdraw from the trial at any point, even after you sign the consent form.

If you agree to participate in the trial, we will do an eligibility check to find out whether there are any reasons why it would not be suitable for you or your child to take part. With your permission, we will tell your child's GP about you taking part in the trial.

Your name and telephone number will be shared with Esendex, our text messaging provider and their sub processors, and will be used to send you text message reminders about the trial and trial questionnaires whilst you are participating in the trial.

Your participation in the study will last for up to 20 months depending on your child's surgery time, after you have been placed into one of the two groups you will remain in the

trial for 12 months. As part of the trial, you will need to attend three visits to your CI centre, complete three questionnaires twice, and potentially take part in the ITTT programme. We will do our best to schedule these visits at convenient times for you and will send reminders about upcoming appointments. Each of the three trial visits should last no longer than 2 hours, which is a total of 6-hours for all three visits. The three questionnaires that you will be sent to complete at home should take no more than 1 hour in total. Trial visits will be face to face appointments, but the research team may need to contact you by post, email, telephone, or video call in between these visits, this can be done using any method of contact you prefer.

The trial is being coordinated by the Nottingham Clinical Trials Unit (NCTU) at University of Nottingham. If you consent to take part, your information including contact details will be shared with the NCTU trial team. This is so they can contact you with trial information including questionnaires. More details on how your information will be shared and kept safe can be found in section 10.

4.1 Trial steps

4.1.1 Baseline visit

A baseline visit will be scheduled before your child's CI surgery. During this visit, which will take approximately 2 hours, your child will complete three assessments with a speech and language therapist to gather information about their development and speech and language skills. Before the visit, we will send you three questionnaires to complete at home and return in the post to the NCTU trial team, these should take no more than an hour.

4.1.2 Randomisation

Approximately one month after your child's CI surgery, the NCTU trial team will contact you to check that you are still happy to take part in the trial, then you will be randomly placed into one of two groups:

1. Standard Care Group: The child receives standard NHS care,
2. Standard Care + ITTT Group: The child receives standard NHS care plus the parent/carer(s) take part in the ITTT programme

As nobody knows which method helps language development the most, families will be placed into a group by chance, through a process called **randomisation**. A computer programme will do the randomisation.

This gives everyone an equal chance of being in either group. This way, we can fairly compare the two methods and figure out which one works better for future families. Neither you, the doctors, nor the research team can choose which group you're in, because

this could affect the fairness of the results.

4.1.2.1 *It Takes Two to Talk*

Parents/ carers placed in the "Standard Care + ITTT Group" will complete the ITTT programme as part of the trial.

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 is used by qualified speech and language therapists around the world to teach parents/carers how to interact better with their children to help them develop their speech and language skills.

In the ITTT programme, parents/carers will learn how to recognise their child's stage and style of communication, working with a speech and language therapist to identify next steps and set goals. They will also learn how to identify what motivates their child to communicate to build confidence and encourage communication. Parents/carers will discover ways to adjust everyday routines to help their child take turns in conversations, and how to talk to their child in ways that support understanding and future use of language.

The ITTT programme lasts for approximately [to be added] months and involves:

- **One initial pre-programme introduction session**: A one-to-one meeting between the parent/carer and the speech and language therapist to discuss the programme and set expectations.
- **Eight parent/carer group sessions:** These sessions are for parents/carers only and are conducted in a group setting with other families participating in the trial.
- **Three individual sessions**: Personalised sessions between the parent/carer and speech and language therapist. During these sessions, you may be asked to record a video of you and your child interacting together. The speech and language therapist will review the video with you.

All sessions will be held online and will last for approximately 1 to 2 hours each. We will provide you with any support you may need to access these sessions. The approximate time commitment for the whole ITTT course is 25-30 hours across the 12 sessions.

4.1.3 Visit 1

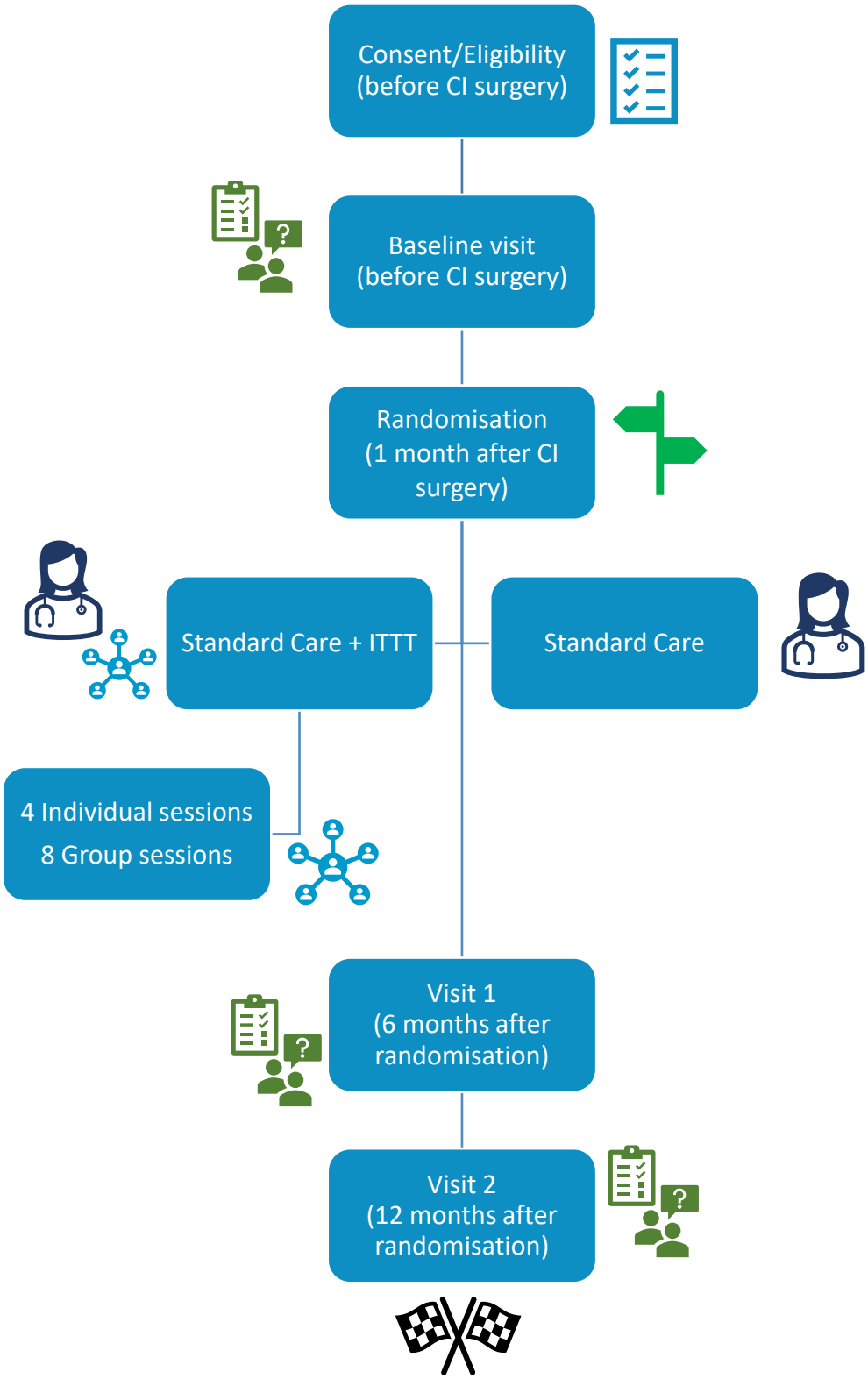
Six months after you have been randomised either to the "Standard Care Group" or the "Standard Care + ITTT Group" you and your child will attend a visit at your CI centre. There, your child will complete **one speech and language assessment** lasting approximately 2 hours.

4.1.4 Visit 2

12 months after you have been randomised either to the "Standard Care Group" or the "Standard Care + ITTT Group" you and your child will attend a visit at your CI centre. There, your child will complete **two speech and language assessments**, lasting approximately 2 hours. Before the visit, we will send you three questionnaires to complete at home and return in the post to the NCTU trial team, these should take no more than an hour.

This visit marks the end of your participation in the trial. After this, you will not need to do anything further, and your child's care will resume as normal at their CI centre.

4.2 Trial Schedule



5 What are the possible benefits of taking part?

Taking part in the trial may not directly benefit you or your child. We expect that one of the benefits of this trial will be for others in the future. We hope the information we get will

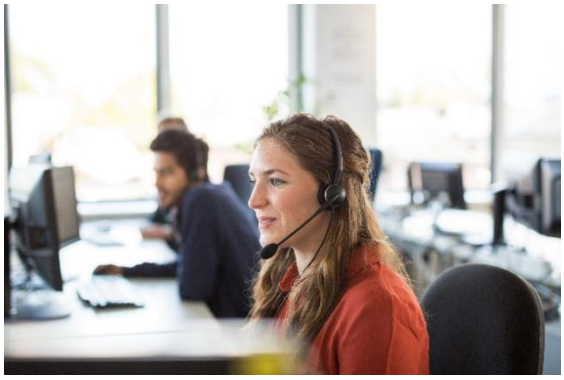
allow us and other researchers and clinicians to design and implement better rehabilitation programmes for CI children.

6 What are the possible disadvantages or risks of taking part?

There are no risks associated with any of the activities you or your child will be undertaking as part of this trial. If you have any questions, please ask a member of the team, who will be able to discuss this with you.

7 What if there is a problem?

If you have concerns or questions about any aspect of this trial, you should ask to speak to the local researchers. Their contact details are at the end of this information sheet.



If any questions remain you can contact the trial coordinating centre:

Tel: <insert trial phone number>,

Email: impactstudy@nottingham.ac.uk.

If you remain unhappy and wish to complain formally, you can do this through the National Health Service (NHS) Complaints Procedure via your local Patient Advisory and Liaison Service (PALS) <insert Local PALS details>.

The University of Nottingham, the Sponsor, has in force the relevant insurance policies which apply to this study. In the event that something does go wrong, and you are harmed during the research, and this is due to someone's negligence then you may have grounds for a legal action for compensation, but you may have to pay your legal costs.

8 What will happen if I don't want to carry on with the trial?

You are free to withdraw at any time, without giving any reason, and without any consequence to your or your child's current or future treatment.

If you would like to withdraw, contact your local researchers / NCTU trial team via email at: impactstudy@nottingham.ac.uk and they can inform you of the next steps.

If you withdraw, we will no longer collect any information about you or from you, but the information collected up until that point will not be erased and this information may still be used in the project analysis.

9 Will I be paid for participating in the trial?

You will not receive payment for taking part in the trial.

You will receive a £20 voucher at the end of your 6-month visit and £25 voucher at the end of your last visit as a token of appreciation for your participation in the trial.

10 How will we use information about you and your child?

We will need to use information from you and your child for this research project.

This information will include your child's NHS number from their medical notes and your and your child's name and contact details. People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

The University of Nottingham is the sponsor of this research and is responsible for looking after your information. "We" (meaning the sponsor) will keep all information about you safe and secure by:

- Following and adhering to the laws relating to General Data Protection Regulation (GDPR)
- Having strict access controls on our electronic systems
- Deleting your personal data (as outlined in this information sheet) when it is no longer required
- Keeping the details we have to contact you separate from the study data

Your data will not be shared outside the UK.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

We may share our research data with researchers in other Universities and organisations, including those in other countries, for research in health and social care. Sharing research data is important to allow peer scrutiny, re-use (and therefore avoiding duplication of research) and to understand the bigger picture in particular areas of research. Data shared in this way will be anonymised.

We will keep your study data for a maximum of 7 years. The study data will then be fully anonymised and securely archived or destroyed.

10.1 What are my choices about how mine and my child's information is used?

- You can stop being part of the trial at any time, without giving a reason, but we will keep information about you and your child that we already have.
- you have the right to ask us to remove, change or delete data we hold about you for the purposes of the study. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this

If you give us your permission, we may keep your contact details so we can get in touch if there is any relevant future research to do with cochlear implantation that you may be interested in taking part in. You will also have the option to take part in future research using your data saved from this trial. If you do not wish for your contact details to be kept for a copy of the trial results to be sent to you or to be contacted about future research, these will also be disposed of securely at the end of the trial.

10.2 Where can I find about more about how my information is used?

You can find out more about how we use your information:

- the leaflet available from www.hra.nhs.uk/patientdataandresearch
- by asking one of the research team
- by sending an email to impactstudy@nottingham.ac.uk
- by ringing the Nottingham Clinical Trials Unit trial team on [phone number]
- by reading the Sponsor's privacy statement at https://www.nottingham.ac.uk/utilities/privacy/privacy-information-for-research-participants.aspx
- by sending an email to the Sponsor's Data protection officer at dpo@nottingham.ac.uk
- at www.nottingham.ac.uk/utilities/privacy/privacy.aspx.

11 Who is organising and funding this trial? How has it been reviewed and approved?

The trial is being organised by the University of Nottingham (the Sponsor) and coordinated by the Nottingham Clinical Trials Unit (NCTU). The funding for the trial is provided by the National Institute for Health and Care Research (NIHR).

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your and your child's interests. This trial has been reviewed and given favourable opinion by the London – Brent Research Ethics Committee. This trial has also been approved by the Health Research Authority (HRA).

12 How have members of the deaf and hearing loss community been involved in this trial?

Parents/carers of children with hearing loss who have previously had CIs or used hearing aids have been essential in shaping our trial. They helped plan and design the study, reviewed all participant materials, and shared their insights on how to best support other parents/carers during the trial. Additionally, parents/carers of children with hearing loss are involved in the teams that oversee the trial, ensuring that the needs of families are always considered.

13 What if relevant new information becomes available?

During the trial, we might get new information about rehabilitation following cochlear implantation. If this happens your research doctor will tell you about this new information and discuss whether you should continue in the trial. If you decide not to carry on, your research doctor will plan for your care to continue as normal. If you decide to continue in the trial, they may ask you to sign a new Informed Consent Form.

14 What happens at the end of the trial?

When the trial ends, your child's healthcare will continue as normal. At the end of the trial the results will be published in scientific medical journals, support group newsletters, professional magazines and presented at conferences. You or your child will not be identified in any publication. We will send you a newsletter with a summary of the trial findings, unless you ask us not to. The results of this trial may be used to inform future research.

15 How to contact us

Contact details of your local care team who will be your main point of contact for the duration of the trial;

- <insert contact details here>

Notes