

FIDELITY: Feasibility of Internet DELivery of Intensive TherapY for children with motor speech disorders and cerebral palsy

PARENT INFORMATION SHEET

We would like to invite your child to take part in this research study. Before you decide, we would like you to understand why the research is being done and what it would involve. One of the research team will go through this booklet with you and answer any questions you have.

If you would like to, please discuss the study with others (including your local speech and language therapist and family) to help you decide whether to take part. Please ask the research team about anything that is unclear.

Why is the research being done?

We have developed a therapy to make the speech of children with cerebral palsy easier to understand. Thirty children have tried the therapy so far. On average, people understood around 12-15% more of their speech after the therapy. The children told us that the therapy was acceptable. We would like to test the therapy in a full trial involving lots of children, but need to be sure that the study is acceptable to families. The study your child is being asked to join will be a dummy run for the full trial.

Sometimes it is difficult for children to get to speech therapy appointments. This study will also test if we can give the therapy over the internet, using Skype.

Why has my child been chosen?

We have asked speech and language therapists and teachers in the North East of England if they are working children who have cerebral palsy and are 5 to 17 years old. Your child's speech and language therapist / teacher has said that your child has cerebral palsy and speech difficulties and that you may be interested in your child taking part in the study.

Does my child have to take part?

No, you and your child do not have to join this study. We will describe the study to you; if you want your child to take part we will ask you to sign a consent form. You can withdraw your child from the study at any point, even after you have agreed to join.

If you do not want to take part or if you choose to withdraw your child from the study, this will not affect the treatment your child would normally receive in any way. If you do not want to take part your child will continue their usual therapy.



What is involved in joining the study?

If you decide that your child can take part in the study they will be allocated at random to receive either the new therapy to be given over the internet, via Skype, or to continue with their usual therapy. If your child is allocated to continue their usual therapy he/she will be offered the new therapy at the end of the study.

New therapy via Skype

Children allocated to the new therapy via Skype will receive the new speech therapy three times per week for six weeks from a research speech therapist who is working at Newcastle University.

Sessions will take place at a time that is convenient for the families. Children will receive therapy over their home computer. Each therapy session will last for 30-40 minutes each.

The speech therapy sessions will concentrate on controlling breathing, to “chunk” speech into phrases so that breath can last the whole phrase, rather than the children running out of air, rushing their words and the sounds becoming quieter and harder to hear. The children will be encouraged to speak louder across phrases. Exercises in the therapy will start by helping children to coordinate their breathing and speech in simple vowel sounds (e.g. “ah”), starting speaking as soon as they start to breathe out. Therapy will then move on to increasing the length of time children can say the vowel sounds and changing the pitch of the sounds (e.g. starting at a low pitch and gradually increasing to speak at a high pitch). Exercises will then practice maintaining the breath control to speak loudly across phrases, and to change pitch in sentences and in conversation. Exercises will involve the children repeating words and phrases spoken by the therapist, who will give feedback on the children’s production. It is hoped that by controlling their breathing and speaking more loudly the children will produce speech sounds that are more controlled, easier to hear and understand.

Once before, once during and once after the therapy has finished a member of the research team will talk to you and your child about the therapy and how easy it was to use Skype for therapy. This will help us to decide if the therapy should be given via Skype in the full trial.

Usual therapy

Children allocated to continue their usual therapy will carry on with their usual speech and language therapy from their local therapist during the study, apart from a six week period in which all speech and language therapy will stop. This break in therapy will allow us to test the effects of therapy in the full study. At the end of the study we will talk to you and your child about what it was like to take part. At the end of the study we will offer your child the new therapy via Skype. The new therapy will be given three times per week for six weeks.

Speech recordings

To test out our plan for the full trial we will record children's speech using a digital tape recorder before and after their therapy (no video recordings will be taken). Recordings will be made twice (on two separate days) at five different points after they have joined the study (ten recordings in total).

Each recording will take about 15 minutes. For the recordings the children will say words by rote (numbers up to ten and days of the week), repeat 50 single words and describe cartoon pictures.

Companies in the North East help us with our research. Their employees listen to recordings of children's speech and write down the words they hear. The listeners do not know anything about the children or whether the recordings are taken from before therapy or after therapy. We will calculate the average number of words listeners hear correctly, to see if children's speech is more intelligible after the therapy.

Questionnaires

In the middle of the study and at the end we will ask you and one of your child's teachers to complete a questionnaire about your child's communication. The questionnaire takes about 10 minutes to complete.

At the end of the study we will write up the results for other speech and language therapists. All results will be anonymous. None of the people who took part will be identifiable from the reports. We will also write a report for the people who took part in the study and their families.

What about alternative treatments?

Alternative treatments to the therapy being tested in the study are available from your child's speech and language therapist. Your child's therapist can tell you what other treatments are available. At the moment, the exact benefits of each different type of therapy are not known and we do not know which type of therapy is most effective in helping children's speech intelligibility. This research study will help us to begin to answer this question.

What are the possible side effects of the therapy?

The new therapy aims to teach children to increase their control of their breathing and to speak louder across single words and sentences. To learn new movements takes practice and therapy involves repeating speech exercises. The movements in the exercises are those that the children can already do, but which they may not use in their usual speech. Practicing the speech exercises may be tiring for some children. In the sessions the exercises are varied, so that children do not become bored.

Possible benefits and disadvantages from joining the study

The new therapy may help your child's speech become clearer.

The therapy provided in this study will mean that your child may miss some of their usual activities. The therapy sessions will be scheduled by your child's speech and language therapist and you so that they cause minimal disruption to your family life.

If your child is allocated to the new therapy he/she will not receive other speech and language therapy for 18 weeks during the study. This is to help us determine the effects of the therapy given in the study, rather than it adding to the effects of the therapy they may usually receive.

If your child is allocated to continue therapy as usual they will have a period of 6 weeks without therapy. They will be offered the new therapy at the end of the study.

When will the study stop?

Children will be involved in the study for 26 weeks. After this we will contact you with a report about the results.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak with your child's usual speech and language therapist, the research speech therapists, Naomi Parker or Helen Kelly (0191 282 1382) or Dr Lindsay Pennington (0191 282 1360), who will do their best to answer your questions. If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained from your speech and language therapy department.

In the event that something does go wrong and you are harmed during the research study there are no special compensation arrangements. If you are harmed and this is due to someone's negligence then you may have grounds for a legal action for compensation against Newcastle Upon Tyne Hospitals NHS Trust, but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

Will details about my child be confidential?

Yes. All the information about your child's participation in this study will be kept confidential.

Information collected about your child will be kept in locked offices. Some information will be entered onto a computer database that will be password protected and only available to study research staff.

During the study, some parts of your child's medical records and the information collected for the study will be looked at by trial staff. Medical records may also be looked at by people from the

regulatory authorities and the team in charge of the study – this is to check that the study is being carried out as planned.

Information will be stored for at least 10 years and then disposed of securely. We will not pass information about your child or family to anyone other than your local paediatrician or speech and language therapist. The records we will make for the study are:

- Tape recordings of the children's speech
- Written descriptions of your child's speech production and movements for speech
- Written records of therapy
- Paper score sheets used by listeners when listening to children's tape-recorded speech
- Computer files containing copies of children's speech (as back-ups to the originals) and number of words heard correctly by listeners.

All of the records will identify children by their research number only. Computer files will be held on Newcastle University computer. Files will be protected by passwords and accessible only to the research team. All information collected for the research will be handled according to the Data Protection Act 1998.

What if new information becomes available?

If new information becomes available about the therapy the research speech and language therapist will discuss this with you. You can withdraw your child from the study at any stage. Your local speech and language therapist will be able to discuss alternative treatments with you.

If the study is stopped for any other reason, you will be told why and your child's continuing speech and language therapy will be arranged.

What will happen to the results of the study?

The findings of the study will be written-up for publication in journals read by speech and language therapists and other health workers, and in newsletters for families such as Disability Now, Communication Matters. All results will be anonymous. None of the children who participated in the study will be identifiable in the reports. Copies of a summary report will be provided to you. Full details of the study will be available from Dr Lindsay Pennington.

If you give permission, we may use information gathered from this study (e.g. questionnaire totals; recordings of speech; definitely no identifiable information about you or your child) in future research. The research will have been approved by an ethics committee.

Who is organising and funding the research?

This study is organised and conducted by Dr Lindsay Pennington (Senior Lecturer and Speech and Language Therapist) at the Institute of Health & Society, Newcastle University. The sponsor of the study is Newcastle upon Tyne Hospitals NHS Foundation Trust.

Funding for the trial comes from the National Institute for Health Research, Research for Patient Benefit Programme.

Who has reviewed the study?

The following Authorities and Committees who look at the way health research is done have reviewed the study and said they are happy with study plans:

- The local NHS Research Ethics Committee
- The Research and Development Department of your NHS trust

Contact for Further Information

If you would like further information or need to contact someone during the study please call:

Naomi Parker or Helen Kelly (Research speech and language therapists)

Tel: 0191 282 1382

Email – naomi.parker@ncl.ac.uk

helen.kelly@ncl.ac.uk

Thank you very much for taking the time to read this information. If you agree to your child taking part in the study please sign both copies of the attached consent form and return one copy in the envelope provided. The second copy of the consent form and this letter are for you to keep. There are two copies of the assent form for your child to sign if they would like to, one for you to keep and one for us.