

**Communication development of children with motor disorders
Parent Information Sheet**

PART 1

Your child is being invited to take part in a research study. Before you decide if your child will take part it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and to discuss it with others if you wish. Part 1 of this letter tells you the purpose of the study and what will happen if your child takes part. Part 2 gives you more detailed information about the conduct of the study. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you would like your child to take part. Where the word “parent” is used, please read parent/guardian i.e. those who have parental responsibility, which may include a legal representative e.g. grandparent.

Thank you for reading this.

1. Why is the research being done?

Some children with motor disorders find it difficult to communicate by speech or gesture. At present there is no research to tell us which children will have communication difficulties and how severe the difficulties will be. We are conducting research that will show which children are most likely to have speech and communication problems, and how severe these problems will be.

2. Why has my child been chosen?

In the study we are including all children in the North East of England who were born between 1.11.2006 and 31.10.2008 who have motor disorders and a possible difficulty with their speech. Your child has been chosen because their physiotherapist or speech and language therapist has said that your child was born in the above time period, has motor difficulties and may have problems with their speech development.

3. Does my child have to take part?

It is up to you to decide whether or not your child will take part in the study. Participation in the research is entirely voluntary. If you decide your child will take part you will be given this information sheet to keep and be asked to sign a consent form. You will be given a copy

of the signed information sheet and consent forms to keep for your records. If your child takes part he/she is free to withdraw at any time, without giving a reason. A decision to withdraw, or a decision not to take part, will not affect the standard of care your child receives.

4. What is involved in joining the study?

If you decide that your child can take part in the study we will visit you and your child either at home or at a local health centre to assess your child's speech and language development. We will visit once when your child is two years old, once when they are three and once when they are five.

In the visits we will use speech therapy assessments to show if your child has a difficulty with their speech and what type of difficulty this may be. For example, some children may have motor difficulties that affect the muscles used for speech, other children may have speech that is delayed in development, but their muscles for speech may not be affected by their motor disorder. We will also ask you to fill in two questionnaires about how your child currently communicates and how much of their speech is understandable to you and to strangers. If your child becomes tired during the visit we will stop and they can have a break. If you think it would be better to stop the assessments we can arrange a second visit. Most children will need only one visit. The visits will last 90 minutes maximum.

If you agree, we will ask your child's physiotherapist and paediatrician for information on their motor disorder: how your child uses their hands, arms and legs; what type of motor disorder they have (e.g. spasticity).

We would also like to read your child's medical notes to collect information related to type and severity of motor disorder. The only information we will collect is:

- Weight at birth,

- Gestational age at birth,

- Where damage occurred in children's brain if your child has had an MRI scan,

- Results of vision assessments and hearing assessments.

This information will help us predict which children may have speech problems.

Your child's involvement in this study will stop once the information has been collected in the visits.

5. Are there risks associated with the assessments?

The assessments we use in the research are used by many speech and language therapists with young children. They are often completed through play. They show how the children are communicating and how quickly the children's communication is developing. The only possible side effect of the assessments is that children may become bored. If this happens we will have a break and then return to a different assessment. We can visit your child again if they would prefer two shorter visits.

6. Possible benefits and disadvantages from joining the study

This study may benefit families of children with motor disorders in the future, indicating which children may have problems with their speech and how severe these problems will be. You will have the opportunity to discuss your child's communication with a speech and language therapist who has many years experience in working with children who have motor difficulties. However, there may be no direct advantages of joining the study for your child.

If you have any concerns about your child's speech and language therapy these will be discussed with your NHS therapist and together we will find ways to answer your queries. Joining this study will not affect your child's current services and is not thought to have any disadvantages other than the time taken to collect the information from families.

Should you have any worries or concerns about the therapy to be provided or other issues about the study please contact Dr Lindsay Pennington at Child Health, Newcastle University on 0191 282 1360.

7. When will the study stop?

Your child's involvement in this study will stop once the information has been collected during the home visit when they are five years of age. After this point you and your child will be contacted once all the results of the study have been collected and a report has been written. The study will start in 2008 and finish in 2013. At that the end of the study we will write to you to give you a summary of the results. We will also send you a newsletter once a year to tell you how research is progressing, how many children have joined the study, and give you summaries of any results we have from the whole group of children who have joined.

8. Are there any other studies related to this one?

As there is currently no information to tell us how communication develops in the longer term for children with motor disorders we would like to be able to see children at 7, 11, 14 and 18 years of age. Seeing children as they grow up will help us to understand what factors help communication development and how communication skills can influence children's education. As part of this study we will ask you if we can contact you again, when your child is older. You do not have to agree to us contacting you. Saying no to this further contact will not prevent your child from joining this research or your child's therapy provision.

9. What if there is a problem?

Any complaint about the way you or your child have been dealt with during the study or any possible harm you might suffer will be addressed. The detailed information on this is given in Part 2. If you have any complaints please contact Dr Lindsay Pennington 0191 282 1360.

10. Will details about my child be confidential?

Yes. All the information about your child's participation in this study will be kept confidential. The details are included in Part 2.

If you would like to discuss the study further, or have any concerns, please contact:

Dr Lindsay Pennington
Child Health
Newcastle University
Sir James Spence Institute
Royal Victoria Infirmary
Newcastle upon Tyne, NE1 4LP

Tel 0191 282 1360

This completes Part 1 of the Information Sheet.

If the information in Part 1 has interested you and you are considering participation, please continue to read the additional information in Part 2 before making any decision.

PART 2 Further information

11. What if new information becomes available?

Sometimes during the course of a research project, new information becomes available about the question that is being studied. If information about the speech development of children with motor disorders becomes available we will telephone you to tell you about it. You can decide if you want your child to continue in the study. If you decide not to carry on we will tell your child's local therapist. If you decide your child should continue in the study you will be asked to sign an updated consent form.

Also, on receiving new information your speech and language therapist might consider it to be in your child's best interests to withdraw from the study.

If the study is stopped for any other reason, you will be told why.

Participation in the study does not affect your child's current services and any decision to stop the study will not affect your child's therapy.

12. What will happen if I do not want my child to continue with the research?

If you do not wish your child to carry on with the research you can withdraw him/her at any time, without giving reason. Your decision will not affect the therapy your child receives from local services. If you decide to withdraw the information we hold on your child for the research will be destroyed.

13. 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 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 your child is harmed during the research study there are no special compensation arrangements. If your child is 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.

14. Will my child's participation in the study be kept confidential?

All information collected about your child during the course of the research will be kept strictly confidential. No information will have your child's name, date of birth, address or place where they receive therapy (e.g. the name of your local NHS services). When you sign the consent form for the research your child will be given a research number. All records of your child's participation in the study will be identified by the research number only. Research information will be held in a locked cupboard in Child Health, Sir James Spence Institute, Newcastle University open only to Dr Lindsay Pennington.

The records we will make for the study are:

Written descriptions of your child's speech production and movements for speech

Written records of assessment results

Written descriptions of your child's type of motor disorder, weight at birth, gestational age at birth, hand, arm and leg function, vision and hearing, and summarised findings from MRI scans (if available).

All of the above records will identify children by their research number only.

Computer files will be held on Newcastle University computers, which are protected by passwords and are accessible only to the research team (Dr Pennington, Dr Mark Pearce, Professor Helen McConachie and Professor Allan Colver, working at Newcastle University).

All information collected for the research will be handled according to the Data Protection Act 1998.

Information from the study may be looked at by people from regulatory bodies, such as the NHS and Newcastle University, to check that the research is being carried out correctly. Your child's name, however, will not be disclosed outside your child's speech and language therapy department.

The records from the research will be kept for 20 years, in accordance with the Medical Research Council, NHS and University guidelines. After this period all score sheets and computer files will be disposed of securely.

As General Practitioners (GPs) and paediatricians provide continuing care and can take a coordinating role in healthcare we usually inform each child's GP and paediatrician about their participation in the research study. This is not compulsory. The consent form asks if we may do this for your child.

As we are seeking to learn more about children's responses to therapy, and why some children may respond differently to others, we would like to look at children's medical records to see if there is information about how their motor disorder affects their speech and other movements. This is not compulsory. The consent form asks if we may do this for your child.

15. What will happen to the results of the study?

The findings of the study will be written up for publication in medical and speech and language therapy journals and will be presented at conferences for health researchers. We will also write reports for charities that support people with disabilities and their families, such as Scope and Cerebra. 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.

16. Who has funding and reviewed the study?

The study is funded by the Department of Health National Institute of Health Research. Your child's speech and language therapy department will not receive any money in return for your participation in this research project.

This study was given a favourable ethical opinion for conduct in the NHS by Cambridgeshire 4 Research Ethics Committee.

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.