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Participant identifier Number

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Timing Of Primary Surgery For Cleft Palate (TOPS)- Pilot study to develop methods for speech and language assessment

INFORMATION FOR PARENTS

Research Study Entitled: **Timing Of Primary Surgery For Cleft Palate (TOPS)-Pilot study to develop methods for speech and language assessment**

This study will assess how speech assessments of infants with cleft palate are made, the outcomes of this study will then inform data collection in another project that is exploring the timing of primary surgery in children with cleft palate.

Recruiting Centre Name: <Centre Name>

Recruiting Centre ID number: <Centre ID>

Dear Parent,

We would like to invite your child to take part in a study that is being carried out to help us find out the best way to assess speech in children with cleft palate. Before you decide whether you would like your child to take part we would like to explain to you why the research is being done and what it would involve for you.

Please take time to read the following information carefully. Ask us if there is anything that is not clear or if you would like more information. Talk to others about the study if you wish.

Take time to decide whether or not you wish to take part.

Thank you for reading this information sheet.

1. What is the purpose of this study?

There are a number of ways that a child's speech can be recorded and assessed. The purpose of this study is to develop the method used to record and assess speech in children with a cleft palate. This method will then be used in another project (the TOPS trial) which aims to find out the best age at which to repair a cleft palate in order to give the child the best possible speech.

2. Why has my child been invited to take part?

The TOPS speech therapist at <Centre Name> is inviting all infants and children, aged between 10 and 14 months, 34 and 46 months and 58 and 70 months, to take part in this pilot study. Your child does not need to have a cleft palate for to take part.

3. Does my child have to take part?

No, the research is voluntary. It is up to you to decide whether you take part. We will describe the study and go through this information sheet with you. You will also be given a copy of this information to take home. Should you decide that you would like your child to participate we will ask you to sign a consent form. You are free to withdraw your child from the study at any time, without giving a reason.

If you decide that you do not want your child to participate in this study the care they will receive will not be affected and will be the standard care provided at <Centre Name>.



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4. What will happen if I choose for my child to take part?

If your child is aged 14 months or younger

Your speech therapist will make an audio and video recording of a play situation between you and your child. The purpose of this recording is to analyse the babbling of your child as it is known to be of importance for the language development.

If your child is aged 34 months or older

At the visit the speech therapist will ask your child to say a number of words (between 30 and 36) that have been carefully selected to allow assessment of all aspects of your child's speech. The speech therapist will make an audio and video recording of your child saying these words, and also a recording from spontaneous speech during a play session.

If your child is aged 58 months or older, your child will be asked to repeat sentences and retell a story. We will also ask your child to speak into a special microphone connected to a computer. This will assess how much nasal interference there is with your child's speech. You will also be asked to complete a very short questionnaire about how understandable your child's speech is to different people.

5. What happens to the video recording?

The audio/video recording of your child will be used as part of the training of your speech therapist. It will also be used to develop a training package for all of the speech and language therapists involved in the TOPS trial.

We are doing this so that all of the speech therapists in the TOPS trial follow the same method. We would also like to ask your permission to use this recording to help train speech therapists involved in future studies.

6. What will I have to do if my child takes part?

We would like you to keep the appointment made to see your child's speech therapist, in some cases this will be a usual visit or you may be asked to come for an additional appointment.

Your visit will last around 40-60 minutes.

7. Are there any possible disadvantages and risks or side-effects of taking part?

The speech assessment made by the speech therapist is standard practice with no known risk to your child. The audio and video recording has no known risk to your child.

8. What are the possible benefits of taking part?

Taking part in this study is unlikely to provide any direct benefit to your child. However, your child's recording will help to train speech and language therapists taking part in the TOPS trial which aims to find out if the timing of surgery for cleft palate repair influences a child's speech. The methods we develop for assessing speech may also help improve how we do future research and how speech is assessed in clinical practice.

9. What will happen if something goes wrong?

In the event that something does go wrong due to negligence then you may have grounds for legal action for compensation against <Centre Name> but you may have to pay your legal costs.



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If you have a concern about any aspect of the pilot study you should ask to speak to a member of the cleft team who will do their best to answer your questions (contact number below).

The normal complaints mechanisms in place at <Centre Name> will still be available to you. Details can be obtained from the hospital.

10. What happens if I want to withdraw my child from the study?

You may withdraw your child from the study at any time if you wish. If you withdraw your child from the study your child's ongoing and future care will not be affected by your decision. If you choose to withdraw your child from the study you may also choose for audio/video recordings already made to be destroyed.

11. Will my child taking part in the study be kept confidential?

All information that is collected about you and your child during the course of the study will be kept strictly confidential, and any information that leaves <centre name> will have your child's name and address removed.

We would like to ask your permission to use the audio and video recording for the training of speech and language therapists involved in the TOPS trial and also in future studies about cleft palate. To do this, a copy will be sent to the Data Coordinating Centre in Liverpool who will store the audio and video recording securely and identified by a unique number only. We would also like to ask your permission for a copy of the consent form, which will have your and your child's name on it, to be sent to the Data Coordinating Centre at the University of Liverpool.

All legal requirements applying to research of this kind will be strictly adhered to.

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

The results of the sample speech recordings made in this study will be used to standardise the method of speech sample collection across the TOPS trial. The TOPS trial will assess the effects of the timing of primary surgery for cleft palate on speech development. If you would like a copy of the final TOPS trial report you can indicate so on the consent form.

13. Who is organising and funding the research?

This study and the TOPS trial have been planned by an international collaboration of cleft specialists. The Administrative Centre for the projects is the University of Manchester, UK, and the Data Coordinating Centre for the projects is the University of Liverpool, UK. The study is funded by the National Institute of Dental and Craniofacial Research in the USA.

14. Who has reviewed the study?

All research is looked at by an independent group of people called a research ethics committee to protect you and your child's safety, rights, wellbeing, and dignity. This study has been reviewed and given a favourable opinion by Yorkshire and the Humber – Leeds East Research Ethics Committee.

Contact for further information

If you would like more information about the study please contact:

<Site Coordinator Name>

<Site coordinator Contact Number>



Participant Identifier

Timing Of Primary Surgery For Cleft Palate (TOPS)- Pilot study to develop methods for speech and language assessment

CONSENT FORM FOR PARENTS

Research Study Entitled: **Timing Of Primary Surgery For Cleft Palate (TOPS) Pilot study to develop methods for speech and language assessment.**

Centre Name: **<Centre Name/s>**

Name of Researchers: **<Names of all researches in involved centres>**

To be filled in by the parent/guardian			
Once you have read and understood each statement please tick (✓) and initial			
Agreement to take part in the study			
		Tick box (✓)	Initial
1.	I confirm that I have read and understand the information sheet (version number 3.0, dated, 01-May-2013) for the above study. I have had the opportunity to consider the information and ask questions and have had these answered satisfactorily.	<input type="checkbox"/>	
2.	I understand that the participation of my child is voluntary and that I and my child are free to withdraw at any time, without giving any reason, without our medical care or legal rights being affected.	<input type="checkbox"/>	
3.	I understand that data collected during the study may be looked at by individuals from the research team for training purposes, representatives of the sponsor, from regulatory authorities or from the organization delivering healthcare, where it is relevant to my child participating in this research. I give permission for these individuals to have access to my child's records.	<input type="checkbox"/>	
4.	I agree to copies of my consent form to be sent to the Data Coordinating Centre at the University of Liverpool	<input type="checkbox"/>	
5.	I agree for the recording to be sent to the University of Liverpool	<input type="checkbox"/>	
6.	I agree to audio and video recordings of my child being made and used to train speech and language therapists participating in the TOPS trial.	<input type="checkbox"/>	
7.	I agree to audio and video recording of my child being made and used to train speech and language therapists taking part in other cleft palate research.	<input type="checkbox"/>	
8.	I agree to take part in the above study and I also agree for my child to take part in the above study.	<input type="checkbox"/>	
9.	I would like/ would not like (delete as appropriate) a copy of the final report for the TOPS trial.	<input type="checkbox"/>	

Name of Child

Child's date of birth (dd-mm-yy)

Name of Parent/Guardian

Parent signature

Date signed (dd-mm-yyyy)

Name of Researcher

Signature of Researcher

Date signed (dd-mm-yyyy)

When completed, 2 copies need to be made, 1 for the participant, 1 for the investigator site file and the original must be kept in the medical notes. A copy of the consent form only should be faxed to the Data Coordinating Centre on +44 (0) 151 282 4721