



Dear Parent or Guardian,

RE: Children with Cleft Palate Sought for Research Project

We are writing to you because your child attends the speech therapy clinic at the children's hospital. The specialist cleft lip and palate Speech and Language Therapist (SLT) you normally see at the hospital thinks you might be interested in your child taking part in a research project which aims to compare traditional speech therapy to real time visual biofeedback of tongue movements. In the project children will be randomly allocated to either six weeks of traditional speech therapy or six weeks of biofeedback speech therapy. The biofeedback involves showing your child their own tongue moving while they speak with an ultrasound scanner (placed under the chin) and using this information to teach children correct tongue movements. Both types of therapy will be provided at the children's hospital by the SLTs who work there. Your child would also need to attend three additional assessment sessions: one before and two after the therapy, either online or at the University of Strathclyde. **If you think you might be interested please read the following more detailed information sheets and consent form and email the research Speech and Language Therapist on xxxxx@strath.ac.uk to let them know you might be interested in taking part.** You will then have an opportunity to discuss the project before you decide whether or not to take part. Information sheets for your child to read are also included.

Yours Sincerely,

Lisa Crampin, Glasgow Dental Hospital and School
Linsay Campbell, Glasgow Dental Hospital and School
Joanne Cleland, University of Strathclyde

Information Sheet for Parents/ Carers of Potential Participants

SonoSpeech Cleft Pilot: A pilot randomised control trial of ultrasound visual biofeedback versus standard intervention for children with cleft lip and palate.

Invitation and Summary.

Your child is being invited to take part in a research study. Before you decide whether or not to 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. Talk to others about the study if you wish. Contact us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish for your child to take part.

The aim of this research is to compare ultrasound tongue imaging as a biofeedback tool for the treatment of children with speech disorders associated with cleft palate to traditional treatment. This project is a pilot/feasibility study. This means it is a small study where we are focussing on finding out how feasible and acceptable the treatment is to families to plan for a larger study. If you agree for your child to take part they will be randomly allocated to either the ultrasound biofeedback treatment or traditional articulation therapy. You cannot choose which group your child is in, but your child will be able to have either type of speech therapy after the project is finished if your Speech and Language Therapist (SLT) agrees it is appropriate.

Group 1: Ultrasound Biofeedback

Children randomly allocated to this group will use standard medical ultrasound to record the movements of the tongue during speech. The ultrasound technology will allow your child to view the movements of his or her own tongue while they are speaking and to modify these movements in order to help with any difficulties they may be having producing speech sounds.



A picture of the ultrasound setup showing a child viewing ultrasound images of their tongue on a computer screen

Group 2: Traditional Speech Therapy

Children randomly allocated to this group will work with the SLT to modify their speech using instructions, pictures, feedback, and practice.

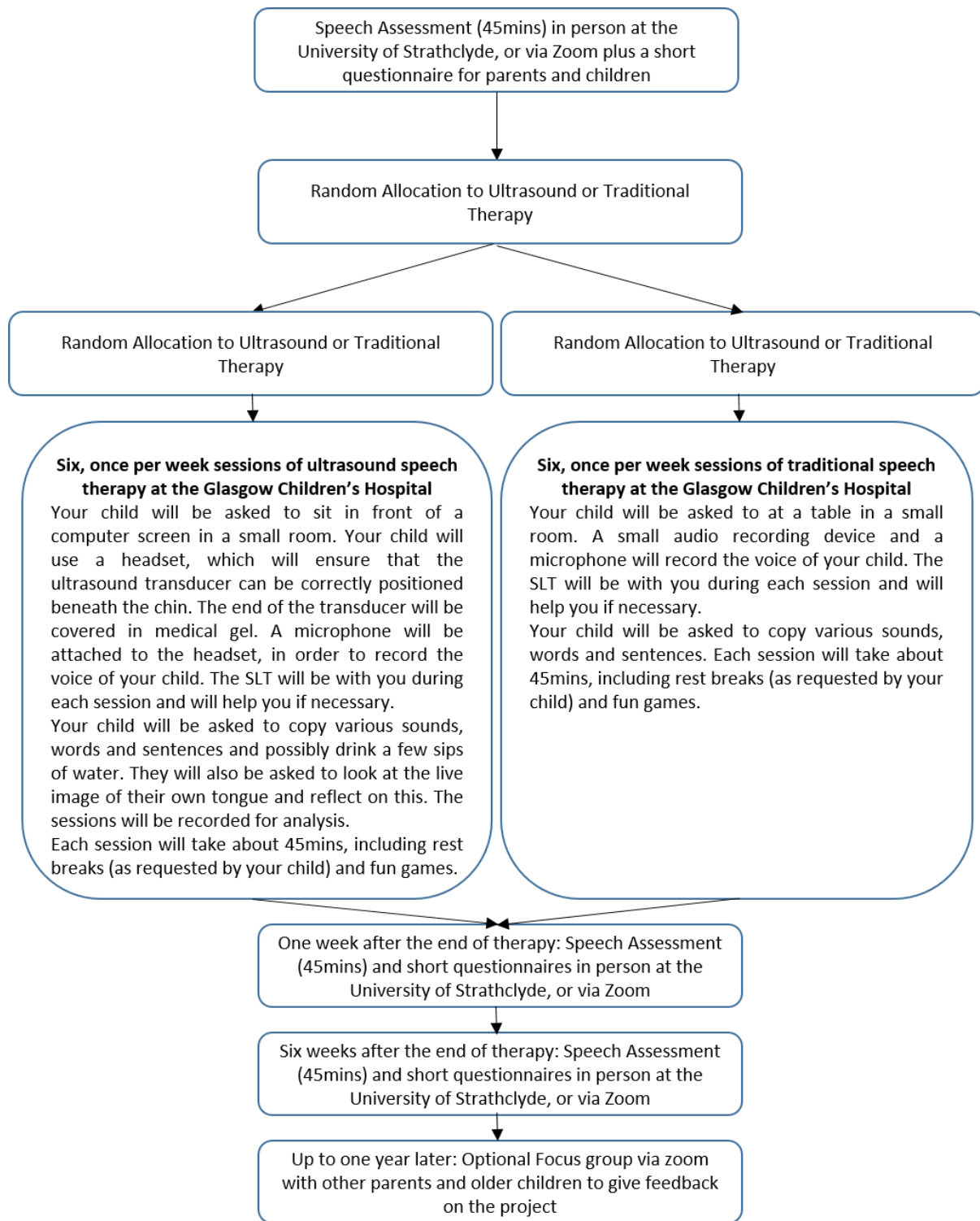
What will happen if we take part?

- You and your child will be invited to an assessment session with the research SLT at the University of Strathclyde (George Street, near Glasgow Queen Street Station) to find out if your child is suitable for the project and to measure your child's speech. We would like to do this in

person so we can use the ultrasound machine to measure your child's tongue movements. However, we can do this over zoom/TEAMS (or another video-call technology) if there are restrictions in place or if you prefer. If we do the assessment over video call then you will need a laptop/PC or tablet and you will need to stay in the room with your child.

- After the assessment we will let you know if your child is suitable for the project and if so which group your child has been randomly assigned to. You will not be able to choose the group, but your child will be able to have either therapy after the project if they need it. We will arrange six once per week therapy sessions for your child at the Glasgow Children's hospital. We will then do two follow-up assessments to see if your child's speech has improved. During these we will ask you to fill in some short questionnaires, these ask questions such as "do you understand your child- always, usually, sometimes, rarely or never" (see here https://cdn.csu.edu.au/_data/assets/pdf_file/0010/399970/ICS-English.pdf)
- Towards the end of the research project (up to one year later) we will invite you and your child, if they are over 12) to take part in an online focus group to discuss your experiences of the research project. This is entirely optional and we will provide you with further information nearer the time so you can decide if you want to take part.

This flowchart summarises what will happen during the research project



- Cost of travel to and from the hospital or the university will be reimbursed (public transport or petrol money up to £10 per visit).
- In addition, in order to obtain relevant background information, your child will be given speech and language assessments.
- With your permission we will inform your child's GP that he or she is taking part in the research project.

All data will be anonymised. Your child will not be mentioned by name in any report or presentation. However, if some of the data were played at a verbal presentation, there is the possibility that the voice of your child may be recognisable.

What are the possible benefits of taking part?

If you take part in the project you will have the benefit of an in-depth speech and language assessment and a course of speech therapy which may or may not help your child with his or her speech disorder. All reasonable travel costs will be reimbursed and your child will receive a certificate as a thank you for their participation.

What are the possible disadvantages and risks of taking part?

It is not thought that there are many disadvantages and Ultrasound is subject to rigorous safety assessments. At all levels of intensity used for diagnostic imaging, there are no known risks associated with ultrasound and there are no specific dangers or safety requirements. The ultrasound equipment and headset has been used before by the researchers with both children and adults.

Your child may experience some mild discomfort from wearing the headset as it can start to feel heavy after around 45mins. For this reason, we will limit wearing of the headset to a maximum of 45mins and your child may remove the headset for a rest at any time within this. The research can be discontinued at any point if you or your child wishes.

Do I have to take part?

No, it is up to you and your child to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason but we will keep any data you have previously provided. Deciding not to take part or withdrawing from the study will not affect the healthcare or speech and language therapy your child receives.



The Ultrasound Headset

What happens when the study is finished?

We will write to you within two months with a report detailing your child's individual speech skills and their individual progress with the therapy. The specialist cleft palate speech therapist at the Dental Hospital will advise on whether or not further therapy is required, with or without the ultrasound.

Will taking part in the study be kept confidential?

All the information we collect during the course of the research will be kept confidential and there are strict laws which safeguard your privacy at every stage. Your child's name will be removed from the data so that s/he cannot be recognised from it. Data will be kept at the Hospital and the University of Strathclyde. With your consent we will inform your child's Speech and Language Therapist that you are taking part.

Who will my child's data be shared with?

In order to participate in the study the ultrasound and voice recordings will be shared with members of the research team for analysis. Results of the analysis will be published anonymously. This is all you need to consent to in order to take part.

Optional Data Sharing

We ask you to consider **additionally and optionally** consenting to sharing this data with students (for teaching purposes) and researchers in other universities across the World. Further, we will ask you to think about whether we can share short ultrasound and voice recordings of your child on the internet in a publically-viewable website, similar to the site found here: <https://www.seeingspeech.ac.uk/>. This is entirely optional and your child can still be included in the project if you do not wish to share the recordings in this way.

How long will you keep the data for?

We will keep your name and contact details for the duration of the project so that we can contact you about the project results and to invite you to the focus group. After that this data will be destroyed. We will keep the anonymised data (audio and ultrasound recordings without your or your child's name on them) indefinitely for future analysis. However, you (before your child is 16) or your child (at any age) may withdraw consent by writing to or emailing us. We can then destroy the raw data but will not be able to retract any published articles.

What will happen to the results of the study?

The results of the study will be shared with the public, Speech and Language Therapists and academics via our website, conference presentations and publication in academic journals. We will invite you to attend an online presentation to tell you about the results of the study towards the end of the project and will post a plain English summary of our findings on our website

Who is organising the research and why?

This study has been organised by NHS Greater Glasgow and Clyde and the University of Strathclyde and is funded by the Chief Scientist Office of Scotland. The grant runs from June 2021 for two years.

Who has reviewed the study?

The study proposal has been reviewed by independent reviewers for the funders. A favourable ethical opinion has been obtained from REC xx. NHS management approval has also been obtained.

It is entirely up to you to decide whether or not to take part in the project. If you do decide to participate, you will be given this information sheet to keep and be asked to sign a consent form. You and your child are free to withdraw from the study at any stage without giving a reason.

If you would like to consult an independent person, who knows about this project but is not involved in it, you are welcome to contact Dr Wendy Cohen, wendy.cohen@strath.ac.uk

If you have read and understood this information sheet, and you think you might be interested in participating in the study, please contact the research SLT via phone XXXXX or email XXX@strath.ac.uk. There will be an opportunity to ask questions over the phone, via email or when

Version 1.0 15/02/21

you attend the first appointment. You can sign the consent form during the first appointment or post it to the address below.

Thank you for taking the time to read this information.

Contact details of the researcher:

Name of researchers: Dr Joanne Cleland, Lisa Crampin, and Lindsay Campell

School of Psychological Sciences and Health
University of Strathclyde
Room 550, Graham Hills Building
40 George Street
Glasgow
G1 1QE
0141 548 3037
Joanne.cleland@strath.ac.uk

If you wish to make a complaint about the study please contact NHS Greater Glasgow and Clyde:

Email: complaints@ggc.scot.nhs.uk

Tel: 0141 201 4500

SonoSpeech

Once you have consented to take part in the project please complete the following details.

Parent/Guardian Name: _____ Child's Name _____

DOB of Child _____ Gender of Child: _____

Cleft lip and/or palate type: _____

Does your child have any additional relevant medical diagnoses? If so please detail:

Which Language/s does your child speak at home? _____

List any other languages your child speaks: _____

How long has your child lived in Scotland? _____

What accents do the adults living at home speak with? (for example, Dad has a Northern Irish Accent, Mum has a Scottish accent etc):

Home address:

Post Code: _____

Phone number:

Email Address:

Name of Child's Speech and Language Therapist: _____

Contact details (if known):

Name and address of GP:

Please return to the cleft palate speech and language therapist or the research speech and language therapist. Personal details will be kept strictly confidential and not shared with anyone outside of the research team at any time.



Information Sheet for Children Aged 12 and Over

Visualising Speech: Ultrasound Visual Biofeedback Therapy for Cleft Palate

You are being invited to take part in a research study because you attend one of the Cleft Lip and Palate clinics at the Glasgow Dental Hospital. It is up to you to decide whether or not you want to take part so please read this information sheet and discuss it with the adult who looks after you. Talk to others about the study if you wish. Contact us if there is anything that is not clear or if you would like more information.

Why are we doing this study?

The aim of this research is to compare two different types of speech therapy for children who have had a cleft palate. The two types of speech therapy are called “articulation therapy” and “ultrasound therapy”. Articulation therapy means working with a speech and language therapist to help you to speak more clearly. It usually involves listening to the speech therapist and trying to make different speech sounds. Ultrasound therapy is similar, except you also see moving pictures of your tongue while you are speaking. Ultrasound is a machine used by doctors to see pictures of inside the body. For this project we will place an ultrasound probe under your chin to look at the movements of your tongue when you speak.



A picture of the ultrasound setup

Can I choose which type of therapy I have?

No, you won't be able to choose. The type of therapy you have will be chosen randomly, this is like picking it out of a hat. Research studies do this so they can compare different types of therapies or treatment. However, after the project your speech and language therapist will let you know if you need more speech therapy and if so you will decide together with your speech therapist if that should be ultrasound or articulation therapy.

Do I have to take part?

No, it is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a form to say we are allowed to record you. If you decide to take part you can still change your mind at any time without giving a reason but we will keep any informationⁱ you have already provided. Deciding not to take part or

withdrawing from the study will not affect the speech and language therapy you receive from your regular Speech and Language Therapist.

What will happen if I take part?

- We will ask you to come to the University for an appointment to record you speaking with the ultrasound machine. If we are in lockdown or you are worried about coming to the university then we can do this over face-time (Zoom for example). We won't be able to use the ultrasound machine over facetime so if you choose this option we will just record your voice.
- You will then come to the hospital to see the speech and language therapist for 6 therapy sessions, once a week: either ultrasound or articulation therapy.
- If you are in the articulation group you will sit at a table and use pictures and games to copy sounds, words and sentences to
- If you are in the ultrasound group you will sit in front of a computer screen in small room. We use a headset (see picture) to hold the ultrasound in place. The end of the ultrasound probe will be covered in a type of jelly which helps us to get a clear picture of your tongue. A microphone will be attached to the headset, to record your voice. Sometimes we might ask if it is ok (you may say no) to make videos of your whole face. A Speech & Language Therapist will be with you during the recording.
- After the six session of therapy we will ask you to come to the University for two more appointments to record you speaking with the ultrasound machine. Again, if we are in lockdown or you are worried about coming to the university then we can do this over face-time (Zoom for example).
- We might contact you after this to ask if you want to join other young people with cleft lip and palate in an online chat to talk about whether or not you enjoyed taking part in the project. This is optional and we will give you more information about it later.

We will not use your name or any other personal information when we report our findings. However, if some of the sound recordings were played at a presentation (for example to people training to become Speech and Language Therapists), then someone might be able to recognise your voice. If you give us permission to take videos then your face would be in view and would be easily recognisable.

What are the benefits of taking part?

If you take part in the project you will get an in-depth speech assessment and speech therapy that may help you to speak more clearly. You will receive a certificate as a thank you for taking part.

What are the disadvantages of taking part?

We have used ultrasound many times with children as young as three years old. However, the ultrasound headset can start to feel little uncomfortable after around 30mins. For this reason, you won't need to wear it for longer than 30mins and you can ask us to take it off at any point for a rest.



The Ultrasound Headset

What happens when the study is finished?

We will write to the person who looks after you within two months with a report detailing your individual speech skills.

Will taking part in the study be kept confidential?

Yes. All information will be kept confidential. Your name will be removed from the information so that you cannot be recognised from it. Information will be kept at the University of Strathclyde.

Who else will see my information?

In order to take part the ultrasound and voice recordings will be shared with members of the research team for analysis. Results of the analysis will be written up to share with other scientists and members of the public, but this will be in words only, not sound or video recordings. This is all you need to consent to in order to take part.

Optional Information Sharing

We ask you to think about whether we can share your information with students (for teaching purposes) and researchers in other universities across the World. Also, we will ask you to think about whether we can share short ultrasound and voice recordings of you on the internet in a website similar to this one: <http://www.seeingspeech.ac.uk> . This is entirely optional and you can still be included in the project if you don't want this to happen.

How long will you keep my information for?

We will keep the information forever. However, you can write to us or email us at any time in the future if you no longer wish us to analyse your information. We can then destroy it but will not be able to change any articles which have already been published.

What will happen to the results of the study?

The results of the study will be shared with the public, Speech and Language Therapists and scientists via our website, presentations and publications. We will invite you to attend an online presentation to tell you about the results of the study towards the end of the project and will post a summary of our findings on our website

Who is organising the research and why?

This study has been organised by the University of Strathclyde and the NHS. It is funded by the Chief Scientist Office of Scotland. The grant runs from June 2021 for two years.

It is entirely up to you to decide whether or not to take part in the project. If you do decide to participate, you will be given this information sheet to keep and be asked to sign a consent form. You are free to withdraw from the study at any stage without giving a reason.

If you have read and understood this information sheet, and you think you might be interested in taking part in the study, please talk to the person who looks after you about it.

Thank you for taking the time to read this information.

Contact details of the researcher:

Name of researcher: Dr Joanne Cleland

School of Psychological Sciences and Health
University of Strathclyde
Room 550, Graham Hills Building
40 George Street
Glasgow
G1 1QE
0141 548 3037
Joanne.cleland@strath.ac.uk

If you wish to make a complaint about the study please contact NHS Greater Glasgow and Clyde:

Email: complaints@ggc.scot.nhs.uk

Tel: 0141 201 4500

Visualising Speech: Ultrasound Visual Biofeedback for Cleft Palate

Please
Initial Box

1. I have read the information sheet for the research project. I have been able to ask questions and these have been answered. ☐
2. I know that I don't have to take part in this project if I don't want to and that if I want to change my mind later on I can. ☐
3. I understand that videos, recordings of my voice and photographs of me can be kept and studied by the researchers. My name will not be on anything the researchers keep. ☐
4. I understand that the results of the research project can be shared with other people, but my name won't be on anything. ☐
5. **I agree to take part in this study** ☐

Please also let us know if it is ok to do any of the following:

6. Videos and recordings of my voice can be used in university teaching for people learning how to be Speech Therapists. ☐
7. Videos and recordings of my voice can be uploaded to the internet or played at special events that anyone can go to. ☐
8. Videos and recordings of my voice can be copied and given to other researchers outside of the University of Strathclyde to study. ☐
9. The people working on the research project can look at my Speech & Language Therapy notes. ☐
10. The people working on the research project can to speak to my usual Speech & Language therapist about my speaking skills. ☐
11. The people working on the research project can write to my Doctor to tell him or her that I am taking part in this project. ☐

Name: _____ Age: _____

Your name in your own writing: _____

Signature of researcher: _____

Date: _____

Name of researcher: _____

Email _____@strath.ac.uk

ⁱ For this project information is: Audio (sound) recordings of your voice; Ultrasound (video) recordings of your tongue movements; video of your lips moving.



SonoSpeech: Speech Therapy Research Project

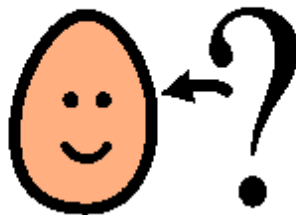
Information Sheet for Children: To be read to children by parent/carer

Would you like to take part in an experiment about speaking?



- Please read the information below carefully and ask about anything you don't understand.
- This will help you to make up your mind about whether you would like to take part in the experiment or not.
- If you have any questions or worries, please ask the adult who looks after you, or feel free to contact **Joanne Cleland on 0141 548 3037**

Ask me questions



- This experiment will compare regular speech therapy to speech therapy using a computer. We will pick your name out of a hat to decide which speech therapy you get.

WHAT DO I HAVE TO DO IF I TAKE PART?

- We will come with your Mum, Dad or person who looks after you to the Hospital or the University for the recordings of your speech and speech therapy.
- We will ask you to come for 9 times on 9 different days.
- For some of the recordings you will have a special headset/helmet to wear so we can record how your tongue moves when you say different things.
- You might want to do some of the recordings over face time at home. That is ok, but we won't use the special headset for these.



A picture of the ultrasound headset and an ultrasound therapy session.

- We will use a special microphone and computer to record you speaking out loud when you are wearing the headset.
- You will be asked to say some words and to have a chat with the speech and language therapist. We will ask you to look at some pictures and talk about them with the speech and language therapist.

- Some children will have speech therapy where they mainly use the special computer and some children will have speech therapy where they mainly listen to the speech therapist and play games. We will tell you which one you are having.

WHAT HAPPENS AFTER I TAKE PART?

- We will give you a certificate for taking part.
- We will keep the recordings we made on the computer and the recording we made with the audio recorder.
- We will write to your mum, dad or person who looks after you to tell you what we found out in our research project.

DO I HAVE TO TAKE PART?

- No, you do not have to take part.
- If you change your mind about taking part just tell us and you can stop the recordings.