Dear Parent or Guardian,

**RE: Children with speech disorders sought for research project**

Queen Margaret University are currently engaged in a study funded by the Chief Scientist Office to investigate the effectiveness of ultrasound technology as speech therapy tool for children with speech disorders. I am sending you this letter on behalf of the research team because I think your child might potentially be suitable for the experimental therapy that is being offered as part of the project because he/she is the correct age and has the right type of speech problem.

Please read the enclosed information sheet and return the cut-off slip below or email Zoe Roxburgh (the research Speech and Language Therapist) on zroxburgh@qmu.ac.uk if you are interested in taking part.

If you are interested the research Speech and Language Therapist, Zoe Roxburgh, will contact you to arrange a time for you to bring your child to Queen Margaret University. You can then discuss whether or not you would like to take part before making a decision.

Yours sincerely,

Speech & Language Therapist

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Ultrasound for Speech Therapy in Children

Child’s Name_____________________  Parent’s Name_________________________

Child’s Age____________  Child’s Speech & Language Therapist________________

☐ YES, we are interested in taking part please contact me by phone/ email on__________________

Please return to: Zoe Roxburgh, Speech & Hearing Sciences, Queen Margaret University, Musselburgh, EH21 6UU or Email zroxburgh@qmu.ac.uk with the above information
Information Sheet for Parents/ Carers of Potential Participants

Ultrasound Visual Biofeedback Treatment for Speech Sound Disorders in Children

More information on ultrasound, including pictures and videos, can be found here: http://www.qmu.ac.uk/casl/ultra/default.htm

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.

What is the purpose of the study?
The aim of this research is to evaluate the effectiveness of ultrasound tongue imaging as a biofeedback device in the diagnosis and treatment of children with Speech Sound Disorders. The project will use standard medical ultrasound to record the movements of the tongue during speech. We want to find out if ultrasound can be used to help children with speech disorders improve their speech. The ultrasound technology will allow your child to view the movements of his or her own tongue whilst s/he is speaking and to modify these movements in order to help with any difficulties s/he may be having producing speech sounds.

Why has my child been asked to take part?
Your child has been invited to take part because he or she has been identified by his or her Speech and Language Therapist as potentially suitable for our research project because he/she has previously been diagnosed with a Speech Sound Disorder (for example, phonological delay/disorder, articulation disorder or dyspraxia/apraxia of speech) and is aged between 6 and 15.
**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 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.

**What will happen if I take part?**

- You will be asked to come to Queen Margaret University for a speech assessment for us to check whether or not your child is suitable, if so, we will offer 10 sessions of therapy and up to 5 further assessment sessions.
- During the sessions your child will be asked to sit in front of a computer screen in a sound-treated studio. Your child will use a headset, which will ensure that the ultrasound transducer can be correctly positioned beneath the chin. The end of the transducer will be covered in medical gel. A microphone and video camera will be attached to the helmet, in order to record the voice of your child and a video of your child’s lips when s/he speaks. The Speech & Language Therapist will be with you during each session and will help you if necessary.
- Your child will be asked to copy various sounds, words and sentences and possibly drink a few sips of water. He or she will also be asked to look at the live image of their own tongue and reflect on this. The sessions will be recorded for analysis.
- Each session will take about 1hr, including rest breaks (as requested by your child) and fun games.
- It will be necessary for both you and your child to travel to Queen Margaret University for the assessment and therapy. Cost of travel to and from the clinic will be reimbursed (public transport or petrol money). We can organise a parking permit for you if it is helpful.
- In addition, in order to obtain relevant background information, your child will be given speech and language assessments.
- With your permission we will consult with your child’s Speech & Language Therapist and report results of assessments/therapy back to her.
- With your permission we will inform your child’s GP that he or she is taking part in the research project.

This diagram shows the number of sessions required over roughly a six month time frame

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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 £20 gift voucher 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 at Queen Margaret University 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 30mins. For this reason, we will limit wearing of the headset to a maximum of 30mins and your child may remove the headset for a rest at any time within this. The experiment can be discontinued at any point if you or your child wishes.

One potential disadvantage of taking part is the inconvenience of travelling to Queen Margaret University for up to 15 separate visits as unfortunately it will not be possible for the ultrasound equipment to be moved to your home or your child’s school.

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 ultrasound therapy. With your permission we will share this information with your child’s speech and language therapist. Due to the time limited nature of research funding, it is unlikely that we will be able to offer your child further ultrasound therapy and you should be aware that this type of therapy is not available from the NHS due to its experimental nature.

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 Queen Margaret University 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:
If you and your child consent to this we will wait until your child turns 16 before uploading any data. 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 the data 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. We will endeavour to write to your child when s/he turns 16 to check that it is still ok for us to keep the data and/or share it with other researchers or on the internet (if consent has been given to do so).

**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 information day 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 Queen Margaret University and the University of Strathclyde and is funded by the Chief Scientist Office of Scotland. The grant runs from April 2015 for 18 months.

**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 South East Scotland REC 01 and Queen Margaret University ethics committee. 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 Janet Beck, 0131 474 0000 or jbeck@qmu.ac.uk.

If you have read and understood this information sheet, and you think you might be interested in participating in the study, please now fill in the tear off slip or email zroxburgh@qmu.ac.uk. There will be an opportunity to ask questions and sign the consent form when you come to Queen Margaret University to meet with the research SLT.

Thank you for taking the time to read this information.

**Contact details of the researcher:**
Name of researcher: Prof Jim Scobbie

**Address:**
Centre for Audiology, Speech and Language Research, Queen Margaret University, Edinburgh Queen Margaret University Drive Musselburgh East Lothian EH21 6UU
Email / Telephone: jscobbie@qmu.ac.uk / 0131 474 0000
If you wish to make a complaint about the study please contact NHS Lothian:

NHS Lothian Complaints Team
2nd Floor
Waverley Gate
2-4 Waterloo Place
Edinburgh
EH1 3EG

Tel: 0131 465 5708