

# Ultrasound visual biofeedback for speech sound disorders in children

<b>Submission date</b> 21/10/2016	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 26/10/2016	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 09/05/2018	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Speech, Language and Communication difficulties (SLCD) are common in childhood. They pose a major challenge to society, affecting educational attainment and the social and emotional health of over one million children and young adults in the UK. The most common type of SLCD is a speech sound disorder (SSD), in which children's speech is difficult to understand. Traditionally, treatment programs for SSDs relied heavily on listening skills, in that patients listen to themselves speaking and change the way that they speak using what they hear. This is difficult for children for with weak listening skills and teaching children to speak clearly is problematic because the target pronunciations are difficult to see or describe. This project will use ultrasound to create images of the tongue in realtime, providing children and their Speech and Language Therapists with visual feedback that can be used to help in the treatment of previously intractable speech sound disorders. The aim of this study is to find out whether using ultrasound can be an effective way of improving treatment outcomes in children with SSD.

### Who can participate?

Children aged 6 to 15 who have SSD.

### What does the study involve?

Each child who takes part in the project visits the university centre for a course of ultrasound-based speech therapy designed specifically to improve their speech. Children are invited to attend three assessment sessions before they begin the therapy to check that they are suitable for the project. During these assessments, children are asked to say some words and read some sentences whilst their tongue movements are recorded using ultrasound via a special headset. Each child then receives 10 speech therapy sessions where they use the real-time images of their own tongue moving to help them learn how to improve their speech. The treatment varies from child to child as the Speech and Language Therapist designs individual therapy programs tailored to their specific needs. After the therapy and again three months later, each child's speech is recorded again with the ultrasound to check whether or not their speech has improved.

### What are the possible benefits and risks of participating?

Children who take part will benefit from having an in-depth speech and language assessment and a course of speech therapy which may help them with their speech disorder. There are no

notable risks involved with participating, although some children may experience some mild discomfort from wearing the ultrasound headset as it can start to feel heavy after around 30 minutes.

Where is the study run from?

Clinical Audiology Speech & Language Research Centre, Queen Margaret University (UK)

When is the study starting and how long is it expected to run for?

May 2015 to March 2017

Who is funding the study?

Chief Scientist Office (UK)

Who is the main contact?

Dr Joanne Cleland

### **Study website**

<http://www.qmu.ac.uk/casl/ultraphonix/default.htm>

## **Contact information**

### **Type(s)**

Public

### **Contact name**

Dr Joanne Cleland

### **ORCID ID**

<http://orcid.org/0000-0002-0660-1646>

### **Contact details**

Psychological Sciences and Health

University of Strathclyde

Glasgow

United Kingdom

G1 1QE

## **Additional identifiers**

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

2.0

## **Study information**

**Scientific Title**

Ultrasound visual biofeedback treatment for speech sound disorders in children

**Study objectives**

Research questions:

1. Does a course of ultrasound visual biofeedback treatment improve accuracy of the targeted speech sounds(s) in:
  - 1.1. Words and phrases trained during the therapy (treated word lists)?
  - 1.2. Words and phrases not trained during the therapy (untreated wordlists)
2. Does a course of Ultrasound Visual Biofeedback (UVBF) treatment improve intelligibility outside of the clinic environment?

Hypotheses:

1. Posttherapy, both treated words and untreated words have increased in accuracy relative to baseline recording
2. Posttherapy scores on the Intelligibility in Context Scale will have improved

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

South East Scotland REC 01 (NHS Ethics), 30/03/2015, ref: 15/SS/0037

**Study design**

Single-centre non-randomised study

**Primary study design**

Interventional

**Secondary study design**

Non randomised study

**Study setting(s)**

Other

**Study type(s)**

Treatment

**Participant information sheet**

Not available in web format, please use the contact details below to request a patient information sheet

**Health condition(s) or problem(s) studied**

Developmental speech sound disorders in children

**Interventions**

Ultrasound Visual Biofeedback Therapy to treat speech sound disorders. This treatment uses standard medical ultrasound to image the tongue and uses this as a biofeedback tool for motor-based speech therapy.

20 Children will be recruited to the project and each child will undergo assessment and therapy with ultrasound.

The study will use a standard medical ultrasound machine in tandem with a computer to record acoustics (speech) and articulation (tongue movement and lip moment from a camera) simultaneously. The ultrasound technique used is not physically invasive. For this particular study, children will sit next to an ultrasound scanner in a soundproofed studio. They will need to a stabilising headset, which will ensure that the ultrasound probe does not move too much once it is correctly positioned. The children will be asked to read words, name pictures or imitate spoken words from a computer. They may be asked to drink a few sips of water during the recording, this will gives us a fuller image of the inside of the mouth. They may also be recorded during unscripted spontaneous conversation.

In order to evaluate the effectiveness of ultrasound as a speech therapy tool, a qualified Speech & Language Therapist will design individual therapy plans for children using ultrasound. A single subjects design with multiple baselines (x3), midtherapy, posttherapy and maintenance phases will be used. Children will receive 10 weekly sessions of ultrasound at the speech clinic at Queen Margaret University. Each session will last approximately one hour.

Week 1: Baseline

Week 2: Baseline

Week 3: Baseline

Weeks 4 to 13: 10 sessions of therapy

Week 14: Maintenance Recording

Week 26: Follow up Maintenance Recording

### **Intervention Type**

Behavioural

### **Primary outcome measure**

Intelligibility is measured using the Intelligibility in Context Scale at each of the three baselines, immediately post-intervention and at 3 months post-intervention.

### **Secondary outcome measures**

Accuracy of speech production is measured using probe word lists and the Diagnostic Evaluation of Articulation and Phonology at each of the three baselines, immediately post-intervention and at 3 months post-intervention.

### **Overall study start date**

14/05/2015

### **Completion date**

31/03/2017

## **Eligibility**

### **Key inclusion criteria**

1. Aged 6 to 15 years
2. Diagnosed with a Speech Sound Disorder involving difficulty with lingual articulations

### **Participant type(s)**

Patient

**Age group**

Child

**Lower age limit**

6 Years

**Upper age limit**

15 Years

**Sex**

Both

**Target number of participants**

20

**Key exclusion criteria**

1. No spoken English (at home OR at school)
2. Evidence of severe/profound current hearing loss
3. Major physical disability or structural abnormality of the vocal tract

**Date of first enrolment**

01/06/2015

**Date of final enrolment**

01/11/2016

## **Locations**

**Countries of recruitment**

Scotland

United Kingdom

**Study participating centre**

**Queen Margaret University**

Clinical Audiology Speech & Language Research Centre

Queen Margaret University Drive

Musselburgh

United Kingdom

EH21 6UU

## **Sponsor information**

**Organisation**

Queen Margaret University

**Sponsor details**

Queen Margaret University Drive  
Musselburgh  
Scotland  
United Kingdom  
EH21 6UU

**Sponsor type**

University/education

**ROR**

<https://ror.org/002g3cb31>

**Funder(s)****Funder type**

Government

**Funder Name**

Chief Scientist Office

**Alternative Name(s)**

CSO

**Funding Body Type**

Government organisation

**Funding Body Subtype**

Local government

**Location**

United Kingdom

**Results and Publications****Publication and dissemination plan**

Planned publication is a high-impact peer-reviewed journal.

**Intention to publish date**

01/08/2018

**Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study are/will be available upon request from Professor James Scobbie (jscobbie@qmu.ac.uk). Raw data (ultrasound images of tongue movements before and after intervention) and metadata is available for non-commercial purposes to researchers from academic institutions in relevant fields at <http://www.cstr.ed.ac.uk/downloads/> for secondary analysis. Consent was obtained from participants for anonymous data sharing with researchers in other institutions. The data will be available from 01/09/2018, indefinitely.

## IPD sharing plan summary

Available on request

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Basic results</a>		30/04/2018	09/05/2018	No	No
<a href="#">HRA research summary</a>			28/06/2023	No	No