

Ultrasound visual biofeedback for speech sound disorders in children

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

Contact information

Type(s)

Public

Contact name

Dr Joanne Cleland

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Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Child

Lower age limit

6 years

Upper age limit

15 years

Sex

All

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

United Kingdom

Scotland

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

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

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?
Basic results		30/04/2018	09/05/2018	No	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes