

# Visualising speech: ultrasound assessment and speech therapy for children with cleft lip and palate

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<b>Registration date</b> 27/01/2017	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 30/07/2019	<b>Condition category</b> Oral Health	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

When a baby is born with an opening in the roof of their mouth this is known as a cleft palate. The reason babies are born this way is unknown. Surgery can fix a cleft palate, however it can cause future problems for children learning how to speak, requiring the help of speech and language therapy. The normal therapy is for Speech and Language Therapists (SLTs) to listen to a child speak and help children say the correct sounds based on what they hear, assuming the child does not know the difference between different sounds. However, there are now tools (such as ultrasounds that use sound waves to make a picture) allow a view of the tongue while speaking and this shows that children are making unnoticeable errors, changing how a SLT should help their patients with their speech. This study has two parts and aims to develop a way to evaluate speech for children with cleft palates using an ultrasound to allow a child to see their tongue move in real time and correct their speech using visual aids.

### Who can participate?

Children aged 3-15 with cleft palates who speak English

### What does the study involve?

Participants in the first part of the study (study 1) spend an extra 10 to 20 minutes of their usual therapy appointment having an ultrasound recording made while they are speaking. This involves sitting in a small room with a speech and language therapist and having their tongue scanned with an ultrasound machine (placed under the chin) while they name some pictures and read some sentences.

Participants in the treatment study (study 2) take part in the treatment during their regular speech therapy appointments. Instead of standard speech therapy, they use the ultrasound machine to view their own tongue moving when they speak to help them to learn speech sounds more quickly. After three initial treatments, this therapy continues for ten weeks with follow up on week 14 and week 2 to see if their speech has improved.

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

Participants 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 participants 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?

Glasgow Dental Hospital and School (UK)

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

May 2016 to July 2018

Who is funding the study?

Action Medical Research (UK)

Who is the main contact?

Dr Joanne Cleland

joanne.cleland@strath.ac.uk

## Contact information

### Type(s)

Scientific

### Contact name

Dr Joanne Cleland

### ORCID ID

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

2.0

# Study information

## Scientific Title

Visualising speech: using ultrasound visual biofeedback to diagnose and treat speech disorders in children with cleft lip and palate

## Study objectives

Study 1: The aim of this study is to develop an ultrasound-based diagnostic assessment for identify imperceptible speech errors in children with a cleft palate to be a tool for clinical practice and circumvent practical problems associated with electropalatography (EPG).

Study 2: The aim of this study is to evaluate the effectiveness of Ultrasound Visual Biofeed Therapy (U-VBF) in r-mediating speech disorders in children with a cleft palate.

Hypothesis (Study 1 and 2): After therapy, both treated words and untreated words have increased in accuracy relative to the baseline recording.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

NHS West of Scotland, 15/03/2017, ref: REC 1: 17/WS/0045

## Study design

Study 1: Cross-sectional study

Study 2: Multiple baseline non randomised study

## Primary study design

Interventional

## Secondary study design

Non randomised study

## Study setting(s)

Hospital

## Study type(s)

Diagnostic

## 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

Cleft lip and palate

## Interventions

Study 1: Diagnostic Study

Participants take part in the research on the same day as attending one of their regular appointments at the Dental Hospital. They spend an extra 10 to 20 minutes of their

appointment providing an ultrasound recording of their speech. This involves sitting in a small room with a speech and language therapist and having their tongue scanned with an ultrasound machine (placed under the chin) while they name some pictures and read some sentences.

#### **Study 2: Intervention Study**

Participants undergo the 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.

The Ultrasound Visual Biofeedback Therapy uses 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, participants sit next to an ultrasound scanner in a room. They need a stabilizing headset, which ensures that the ultrasound probe does not move too much once it is correctly positioned. The children are 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, as this gives 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 designs individual therapy plans for children using ultrasound. This study includes multiple baselines (x3), midtherapy, posttherapy and maintenance phases. Participants will receive 10 weekly sessions of ultrasound. Each session will last approximately one hour. The schedule is as follows:

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**

Study 1: Gibbon's eight error types in tongue shapes and tongue configuration is measured using the Dorsum Excursion Index and the Procrustes Index at the time of the study.

Study 2: 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.

#### **Secondary outcome measures**

There are no secondary outcome measures.

#### **Overall study start date**

01/05/2016

#### **Completion date**

31/07/2018

# Eligibility

## Key inclusion criteria

1. Aged 3 to 15
2. Diagnosis of Cleft palate (and cleft lip)
3. Spoken English, at home or at school

## Participant type(s)

Patient

## Age group

Child

## Lower age limit

3 Years

## Upper age limit

15 Years

## Sex

Both

## Target number of participants

48

## Total final enrolment

39

## Key exclusion criteria

1. No spoken English (at home or at school)
2. Evidence of severe/profound current hearing loss
3. Evidence of severe/profound learning disability

## Date of first enrolment

01/05/2017

## Date of final enrolment

31/05/2018

# Locations

## Countries of recruitment

Scotland

United Kingdom

## Study participating centre

**Glasgow Dental Hospital and School**  
Glasgow Dental Hospital  
Sauchiehall Street  
Glasgow  
United Kingdom  
G2 3JZ

## **Sponsor information**

### **Organisation**

University of Strathclyde

### **Sponsor details**

16 Richmond Street  
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Scotland  
United Kingdom  
G1 1QE

### **Sponsor type**

University/education

### **ROR**

<https://ror.org/00n3w3b69>

## **Funder(s)**

### **Funder type**

Research organisation

### **Funder Name**

Action Medical Research

## **Results and Publications**

### **Publication and dissemination plan**

Planned publication in a high-impact peer reviewed journal.

### **Intention to publish date**

30/04/2019

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

The datasets generated during and/or analysed during the current study are/will be available upon request from Joanne Cleland.  
joanne.cleland@strath.ac.uk

## IPD sharing plan summary

Available on request

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/07/2020	30/07/2019	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No