ISRCTN15543219 https://doi.org/10.1186/ISRCTN15543219

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

Submission date
20/01/2017

Recruitment status
No longer recruiting

Registration date
27/01/2017

Overall study status
Completed

Last Edited
30/07/2019

Condition category
Oral Health

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
https://orcid.org/0000-0002-0660-1646

Contact details
University of Strathclyde
School of Psychological Sciences and Health
Room 550, Graham Hills Building
40 George Street
Glasgow
United Kingdom
G1 1QE
+44 141 548 3037
joanne.cleland@strath.ac.uk

Additional identifiers

Protocol serial number
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

Study type(s)
Diagnostic

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 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(s)
Study 1: Gibbon's eight error types in tongue shapes and tongue configuration is measured using the Dorsum Excursion Index and the Procrutes 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.

Key secondary outcome(s))
There are no secondary outcome measures.

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

Healthy volunteers allowed
No

Age group
Child

Lower age limit

3 years

Upper age limit
15 years

Sex
All

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
United Kingdom

Scotland

Study participating centre
Glasgow Dental Hospital and School
Glasgow Dental Hospital
Sauchiehall Street
Glasgow
United Kingdom
G2 3JZ

Sponsor information

Organisation
University of Strathclyde

ROR
https://ror.org/00n3w3b69

Funder(s)

Funder type
Research organisation

Funder Name
Action Medical Research

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 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?
Results article	results	01/07/2020	30/07/2019	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes