

Ultrasound visual biofeedback versus standard treatment for children with cleft lip and palate

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|----------------------------------------|---------------------------------------------------|--------------------------------------------------------------------------------------------------------------|
| Submission date 19/03/2021 | Recruitment status No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol |
| Registration date 22/03/2021 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 07/05/2025 | Condition category Neonatal Diseases | <input type="checkbox"/> Individual participant data |

Plain English summary of protocol

Background and study aims

Children with cleft lip and palate can continue to have problems producing clear speech after surgery. This can lead to social, emotional, and educational challenges. Treatment involves teaching children the correct tongue movements to produce speech sounds. This is known as articulation intervention. However, this intervention is challenging because the tongue is hidden from view and movements are difficult to see and describe. This project will try a new treatment, ultrasound visual biofeedback (U-VBF), where an ultrasound scanner will be used so that tongue movement can be seen visually. U-VBF has already been used successfully with children with other types of speech disorders and with children with Cleft Lip and Palate to measure the severity of the speech disorder.

The aim of this project is to determine how feasible and acceptable the treatment is to families and to plan for a larger study.

Who can participate?

Children aged 4 to 16 years who have previously had a repair of cleft lip and palate

What does the study involve?

In this treatment, an ultrasound scanner similar to that used to image babies in the womb will be placed under the chin allowing children to see their tongue movements in real-time. The Speech and Language Therapist will help the child to use this real-time dynamic information to change their tongue movements. In this study children with Cleft Lip and Palate will be allocated receive to one of either U-VBF or articulation intervention, with an equal chance of being in either group (like tossing a coin). Participant's speech will be assessed before, during, and after treatment.

What are the possible benefits and risks of participating?

Participants who take part in the project will have the benefit of an in-depth speech and language assessment and a course of speech therapy which may or may not help with their speech disorder. All reasonable travel costs will be reimbursed and participants will receive a certificate as a thank you for their participation.

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 have been used before by the researchers with both children and adults. Participants may experience some mild discomfort from wearing the headset as it can start to feel heavy after around 45 min. For this reason, we will limit the wearing of the headset to a maximum of 45 min and it may be removed for a rest at any time within this. The research can be discontinued at any point.

Where is the study run from?
University of Strathclyde (UK)

When is the study starting and how long is it expected to run for?
From July 2019 to January 2024

Who is funding the study?
Chief Scientist Office, Scottish Government Health and Social Care Directorate (UK)

Who is the main contact?
Dr Joanne Cleland, joanne.cleland@strath.ac.uk

Study website
<https://www.strath.ac.uk/staff/clelandjoannedr/>

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

2.0

Study information

Scientific Title

SonoSpeech Cleft Pilot: A pilot randomised control trial of ultrasound visual biofeedback versus standard intervention for children with cleft lip and palate

Acronym

SonoSpeech

Study objectives

1. To assess the feasibility and inform the design of a full-scale RCT of U-VBF for children with cleft speech characteristics.
2. To enable learning of new articulatory gestures (new speech sounds), improve intelligibility, and improve health-related quality of life.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 04/05/2021, West Midlands - South Birmingham Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; +44 (0)207 104 8345, +44 (0)207 104 8107, +44 (0)207 104 8388; southbirmingham.rec@hra.nhs.uk), REC ref: 21/WM/0104

Study design

Single-centre pilot/feasibility randomized control trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

See study outputs table

Health condition(s) or problem(s) studied

Speech disorders associated with cleft lip and palate

Interventions

Children will be randomised in a 1:1 ratio stratified for age by the Glasgow Clinical Trial Unit. The research has five main time points, each described in more detail below:

1. Assessment
2. Six sessions of intervention, one per week
3. Post-intervention assessment (immediately after intervention)
4. Follow-up assessment
5. Optional focus groups

1. Eligibility/Baseline Assessments, two to three weeks before the intervention.

We will screen potential participants from case-notes and invite them to attend an initial appointment and assessment. This assessment will be either in person at the University of Strathclyde or via video conferencing, with in-person preferred (Covid permitting). This, and all other assessments, will be carried out by a research speech and language therapist who is not aware of which group the patient is in. Screening assessments will comprise the British Picture Vocabulary Test 3 (in this test children choose from 4 pictures to match spoken words of increasing difficulty) and a speech assessment to determine whether patients have at least one error that would be amenable to both U-VBF or AI. The speech assessment involves looking at pictures and saying some words and takes around 20 min. This assessment will be both audio-recorded and recorded with ultrasound tongue imaging, allowing us to view tongue movements directly. Families who opt for the assessment over video-conferencing will complete the same assessments, but with audio recording only. The parent/carer will also be asked to fill out a short 7 item questionnaire that asks how easily their child's speech is to understand.

Following initial assessments the children will be randomised by the Glasgow Clinical Trials Unit in equal numbers to either U-VBF or AI in three age groups, (4.0-6.0, 6.1-8.0, and >8.0 years). Children randomised to AI, the standard intervention, will be offered U-VBF at the end of the trial (after time point 4) if they still present with speech errors.

2. Interventions

Both interventions will be delivered by the cleft palate specialist Speech and Language Therapists (SLTs) in the Glasgow Dental Hospital or Children's Hospital. Therapy will be once per week for six sessions with each session lasting 45 min. It is likely that some children in both groups may require further speech intervention in the future (after the follow-up measures are taken) and this will be provided in line with standard practice, which includes further U-VBF. Both interventions will focus on learning new speech sounds. Patients will be required to repeat the new speech sound at least 100 times in a therapy session, but games and verbal rewards (e. g. "well done, that was great") will be used to keep children motivated. We will record whether children say the new speech sound at least 100 times.

Articulation Intervention (AI): This intervention involves working on a single speech sound at a time. The SLT uses modelling, demonstration, verbal description, and feedback to teach the child the new sound

Ultrasound Visual Biofeedback (U-VBF): The patient sees a real-time image of their tongue moving and guided by the SLT uses this biofeedback to learn a new articulation. The intervention is set out in an open-access manual <https://strathprints.strath.ac.uk/63372/> and involves using the software Sonospeech™.

3. Post-intervention assessments

The same assessments that were carried out at time 1 will be repeated. Children and parents will additionally be asked to fill in three very short questionnaires: one asking about the patient's

experiences of using ultrasound/having articulation therapy; one asking about quality of life; and one asking about the experiences of the research.

4. Follow-up assessments. The assessments that were carried out at time point 3 will be repeated around 3 months after randomisation.

Intervention Type

Behavioural

Primary outcome measure

Percentage targeted consonants correct measured using speech assessment as the percentage of treated speech sounds produced correctly in words at baseline, 6 weeks, and 3 months

Secondary outcome measures

1. Patient- and carer-reported speech function and intelligibility for children aged ≥ 8 years measured using the Intelligibility in Context Scale and the CLEFT-Q speech function scale at baseline, 6 weeks, and 3 months
2. Patient- and carer-reported quality of life for children aged ≥ 8 years measured using the CLEFT-Q quality of life scale at baseline, 6 weeks, and 3 months
3. Patient and carer satisfaction with both interventions measured using the Experience of Service Questionnaire at baseline, 6 weeks, and 3 months

Overall study start date

01/07/2019

Completion date

31/01/2024

Eligibility

Key inclusion criteria

1. Aged 4 to 16 years
2. Diagnosis of cleft lip and palate (repaired)

Participant type(s)

Patient

Age group

Child

Lower age limit

4 Years

Upper age limit

16 Years

Sex

Both

Target number of participants

40

Total final enrolment

19

Key exclusion criteria

1. No spoken English
2. Severe hearing loss
3. Severe learning disability

Date of first enrolment

01/08/2021

Date of final enrolment

31/03/2023

Locations

Countries of recruitment

Scotland

United Kingdom

Study participating centre

Royal Hospital for Children

1345 Govan Road

Glasgow

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G51 4TF

Sponsor information

Organisation

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Sponsor type

University/education

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Funder(s)

Funder type

Government

Funder Name

Chief Scientist Office, Scottish Government Health and Social Care Directorate

Alternative Name(s)

Chief Scientist Office, Scottish Government Health Directorate CSO, Chief Scientist Office, Scottish Government Health Directorates, Chief Scientist Office of the Scottish Government Health Directorates, Scottish Government Health and Social Care Directorate of the Chief Scientist Office, Scottish Government Health Directorate Chief Scientist Office, The Chief Scientist Office, CSO

Funding Body Type

Government organisation

Funding Body Subtype

Local government

Location

United Kingdom

Results and Publications

Publication and dissemination plan

Planned publication in high impact journal

Intention to publish date

01/06/2024

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a publically available repository, the University of Strathclyde's data sharing depository, PURE <https://pureportal.strath.ac.uk/> . With explicit permission from patients and their carers we will share anonymised raw ultrasound and audio data indefinitely. Data will contain some natural

speech/voice samples and it is possible that participant's voices could be recognised, therefore consent to share will be optional. Data will be deposited within 1 year of the end of the project.

IPD sharing plan summary

Stored in repository

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|-----------------------------------------------|--------------|--------------|------------|----------------|-----------------|
| Participant information sheet | version v1.0 | 15/02/2021 | 22/03/2021 | No | Yes |
| Protocol file | version v2.0 | 19/03/2021 | 22/03/2021 | No | No |
| HRA research summary | | | 28/06/2023 | No | No |
| Results article | | 06/05/2025 | 07/05/2025 | Yes | No |