ISRCTN17441953 https://doi.org/10.1186/ISRCTN17441953

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

Submission date
19/03/2021

Recruitment status
No longer recruiting

Registration date
22/03/2021

Overall study status
Completed

Last Edited
07/05/2025

Condition category
Neonatal Diseases

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

Contact information

Type(s)
Scientific

Contact name
Dr Joanne Cleland

ORCID ID
https://orcid.org/0000-0002-0660-1646

Contact details
40 George Street
Glasgow
United Kingdom
G1 1QE
+44 (0)1506200361
joanne.cleland@strath.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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

Study type(s)
Treatment

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 SonospeechTM.

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(s)
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

Key secondary outcome(s))

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

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

Healthy volunteers allowed
No

Age group
Child

Lower age limit
4 years

Upper age limit
16 years

Sex
All

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
United Kingdom

Scotland

Study participating centre
Royal Hospital for Children
1345 Govan Road
Glasgow
United Kingdom
G51 4TF

Sponsor information

Organisation
University of Strathclyde

ROR
https://ror.org/00n3w3b69

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
National government

Location
United Kingdom

Results and Publications

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		06/05/2025	07/05/2025	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	version v1.0	15/02/2021	22/03/2021	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version v2.0	19/03/2021	22/03/2021	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes