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An investigation as to which speech samples lead to the most reliable listener judgements when assessing speech in 3-year-old children with cleft palate with or without a cleft lip

Submission date
10/02/2021

Recruitment status
No longer recruiting

Registration date
22/02/2021

Overall study status
Completed

Last Edited
02/11/2023

Condition category
Genetic Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
A cleft is a gap or split in the upper lip and/or roof of the mouth (palate) that is present from birth. This research aims to develop an assessment framework to assess speech in three-year-old children with cleft palate. To develop the assessment framework the researchers need to find out the following information:
1. Which speech samples (the type of speech produced e.g. single words in picture naming, repeating sentences, playing with and talking about toys) are most easily completed by 3-year-olds with a cleft palate?
2. How do different speech samples, and rating scales impact upon speech ratings made by Cleft Speech and Language Therapists?
3. Which speech samples and rating scales do Cleft Speech and Language Therapists find easiest or the most appropriate to use?
The researchers will then use the information they have collected to put forward a new assessment framework.
In the UK one of the key times that Speech and Language Therapists see children with cleft palate with or without a cleft lip for an assessment is when they are 3 years old. This is an important assessment time as they can pick up on any problems with their speech and arrange for them to have any extra help if they need it before they start school. However, at the moment there is no agreed format on how best to assess speech at this age. If an assessment framework was developed this could be used at different cleft centres across the UK. This may allow Speech and Language Therapists to compare how patients are doing and track their progress between ages 3 and 5.

Who can participate?
1. 3-year-old children with cleft palate with or without a cleft lip
2. 3-year-old healthy volunteers
3. Speech and Language Therapists who specialise in the area of cleft palate with or without a cleft lip

What does the study involve?
Children taking part in the study will be seen by a Cleft Speech and Language Therapist working at the designated cleft unit. In children with cleft palate with or without a cleft lip, this will be when they attend their usual Speech and Language Therapy appointment at age 3. Children taking part in the study will complete different assessment activities e.g. naming pictures, repeating short phrases, playing with toys. This is similar to the usual assessment activities at age 3 but children will be asked to complete more than one activity. As part of the study, all the assessments will be video recorded.
The study assessment may take longer than an hour. Usually, a 3-year assessment takes 30-60 minutes. Children taking part in the study can take breaks during the assessment if they need to. After the appointment, a report will be provided from the Cleft Speech and Language Therapist. The recording will be checked to make sure that the sound and video are of high quality. Cleft Speech and Language Therapists will watch the video and analyse the children's speech.

What are the possible benefits and risks of participating?
Children will receive their speech assessment at 3 years of age as usual (this would be the case if they didn't participate in the study). Children and their families may be helping the researchers to improve speech assessments for children affected by cleft palate in the future. Although the assessment should take no longer than an hour (excluding any breaks the child might want to take) the assessment may take slightly longer than the usual 3-year assessment.
There are no anticipated disadvantages to healthy volunteers participating in the study. Children and their parent/guardian will need to travel to Birmingham Children's Hospital and to stay for the assessment session; this will take up some of their time. Children participating in the study will receive a speech assessment which they may not have had otherwise. A short report about the child's assessment will be provided after the appointment. In the unlikely event that the Speech and Language Therapist has any concerns about a child's speech, parents/guardians will be asked to give consent to refer their child to community Speech and Language Therapy services.
Speech and Language Therapists participating in the study will be contributing to the development of cleft speech assessments at age 3 years.
Participating in the study will take some time either work time or personal time.

Where is the study run from?
The West Midlands Cleft Lip and Palate Service, based at Birmingham Children's Hospital (UK)

When is the study starting and how long is it expected to run for?
October 2017 to October 2022

Who is funding the study?
1. Coventry University (UK)
2. Investigator initiated and funded

Who is the main contact?
Elizabeth Fitzpatrick
beth.fitzpatrick@nhs.net

Contact information

Type(s)
Public

Contact name
Miss Beth Fitzpatrick

ORCID ID
http://orcid.org/0000-0003-2072-4156

Contact details
Speech and Language Therapy Department
Birmingham Children's Hospital
Birmingham
United Kingdom
B4 6NH
+44 (0)121 333 9382
beth.fitzpatrick@nhs.net

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
242296

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
3.4, IRAS 242296

Study information

Scientific Title
The early assessment of speech outcomes in 3-year-old children with cleft palate +/- cleft lip

Acronym
EASO

Study objectives
Study aim:
To propose an assessment framework to validly and reliably assess speech outcomes in three-year-old patients with CPL through the examination of different speech samples, rating methods and scales, and the acceptability and usability of the assessment to SLTs.

Study objectives:
1. To undertake a scoping and identification exercise, to inform the parameters of speech that should be assessed in three-year-old children with CPL, and the types of speech samples which are included in the speech assessment.
2. To determine the extent to which 3-year-old participants with CPL can complete different target speech samples, and how this is different to participants without CPL (acting as a control group).

3. To determine the impact of different speech samples on the validity and reliability of listener judgements.
4. To ascertain the impact of different rating methods and scales on the reliability of judgements made by listeners of the speech characteristics associated with velopharyngeal function.
5. To gain further information regarding the specificity of the speech assessment by using the assessment with 3-year-old participants without CPL and any known speech difficulties (acting as a control group) and examining Cleft SLT listener judgements.
6. To measure the acceptability and usability of the speech assessment and rating methods to the Cleft SLTs who act as listeners.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 15/01/2019, East Midlands - Nottingham 1 Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; +44 (0)207 104 8115, +44 (0)207104 8036; Nottingham1@nhs.net), REC ref: 18/EM/0253

Study design
Reliability study (randomized)

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Cleft palate +/- cleft lip

Interventions
3-year-olds with cleft palate +/- cleft lip, and 3-year-old typically developing control group participants will complete two different speech samples in the same assessment session. Participants will be randomized as to the order in which they complete the speech samples. The assessments will be video recorded. Specialist Speech and Language Therapists will rate the participants' speech from the videos. Ratings will be compared to determine if one speech sample leads to more reliable listener ratings across a variety of assessment parameters. Specialist Speech and Language Therapists will also provide feedback regarding the acceptability of the speech samples.

Intervention Type

Other

Primary outcome measure
Listener reliability ratings for both speech samples using both ordinal and visual analogue scales (VAS) following the collection of the speech sample data: listening session 1 (ordinal), listening session 2, minimum 4 weeks later (ordinal), listening session 3, minimum 4 weeks later (ordinal and VAS)

Secondary outcome measures
1. The acceptability of the speech samples as judged by Specialist Speech and Language Therapists following the completion of all of the listening sessions
2. Completion rates of the speech samples by 3-year-old participants calculated in statistical analysis following the completion of all of the listening sessions

Overall study start date
01/10/2017

Completion date
01/10/2022

Eligibility

Key inclusion criteria
1. Children with a diagnosis of cleft palate +/- cleft lip
2. Aged between 36-47 months
3. Treated at a specific Cleft Unit in the UK
4. Children eligible for a speech assessment at age 36-47 months

Healthy volunteers:
1. Children aged 36-47 months at the time of assessment
2. No current or previous involvement with Speech and Language Therapy, nor are waiting for a Speech and Language Therapy initial assessment
3. No medical condition(s) associated with communication impairments
4. Parent(s)/guardian(s) do not have any concerns about their child's communication
5. Research Team do not have any concerns about the child's communication

Speech and Language Therapists (SLTs):
1. The individual is currently working as an SLT
2. The SLT has designated sessions working with paediatric Cleft Patients in an NHS Cleft Centre
3. SLT has completed CAPS-A training and has participated in consensus listening in the audit assessment of children at five years of age

Participant type(s)
Mixed

Age group
Mixed

Sex
Both

Target number of participants
Individuals with cleft palate +/- cleft lip: 20, Control group: 2-5, SLT group: 6

Total final enrolment
32

Key exclusion criteria
Individuals with cleft palate +/- cleft lip:
1. Individuals with Submucous Cleft Palate (SMCP)
2. Individuals with an identified genetic syndrome
3. Individuals from a non-English speaking family
4. Failure/technical problem with the recording of the speech assessment

Control group:
1. Failure/technical problem with the recording of the speech assessment
2. Children from a non-English speaking family

Speech and language therapists:
1. The SLT has carried out the study assessment with either a Cleft or Control Group Participant or has carried out a speech assessment with the Cleft Group Participant in the last year

Date of first enrolment
27/02/2019

Date of final enrolment
15/10/2019

Locations

Countries of recruitment
England

Scotland

United Kingdom

Study participating centre
Birmingham Children's Hospital
Steelhouse Lane
Birmingham
United Kingdom
B4 6NH

Study participating centre
Glasgow Dental Hospital and School
Sauchiehall Street
Glasgow

United Kingdom
G2 3JZ

Study participating centre
Cambridge University Hospitals
Addenbrooks Hospital
Hills Road
Cambridge
United Kingdom
CB2 0QQ

Study participating centre
Salisbury District Hospital
Odstock Road
Salisbury
United Kingdom
SP2 8BJ

Study participating centre
Great North Children's Hospital
Royal Victoria Infirmary
Newcastle
United Kingdom
NE1 4LP

Sponsor information

Organisation
Coventry University

Sponsor details
Associate Pro Vice Chancellor (Research)
Alan Berry Building
1 Priory Street
Coventry
England
United Kingdom
CV1 5FB
+44 (0)2477659732
iras-sponsor@coventry.ac.uk

Sponsor type

University/education

Website
http://www.coventry.ac.uk/

ROR
https://ror.org/01tgmhj36

Funder(s)

Funder type
University/education

Funder Name
Coventry University

Alternative Name(s)
CU

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a high impact peer-reviewed journal

Intention to publish date
01/10/2024

Individual participant data (IPD) sharing plan
Coventry University will retain a fully anonymised dataset at the end of the study. Consent has been gained only to use the data for the purposes of this research study.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No