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Improving outcomes by addressing variation at the end of routine care for young adults born with cleft lip and/or palate

Submission date
10/12/2024

Recruitment status
Recruiting

Registration date
07/01/2025

Overall study status
Ongoing

Last Edited
18/11/2025

Condition category
Other

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

Plain English summary of protocol

Background and study aims
Cleft lip and/or palate is a lifelong condition affecting 1 in 700 babies. Individuals born with cleft lip and/or palate in the UK have multiple operations and support from specialist dentists, speech and language therapists, psychologists and nurses until they are discharged from routine care when they are between 15- and 25 years old.
Currently, we don't know what variation there is in outcomes (i.e. how well individuals do in response to different NHS interventions) for this population after they are discharged from routine care. This programme of research will determine whether outcomes vary depending on things like where they live, their biological sex or gender, or their ethnicity. Once we understand how outcomes vary, and the scale and type of variation, we will work with young adults born with cleft lip and/or palate and specialist clinicians to develop ways to ensure that everyone born with a cleft has the same opportunity to do well.

Who can participate?
Individuals aged 18-23 years born with a cleft lip and/or palate in the UK, who have received all of their cleft treatment in the UK and have been discharged at least 6 months ago

What does the study involve?
Participants attend a research clinic at their nearest cleft centre. Participants who consent to take part will be requested to complete questionnaires, have photos of their face and mouth taken, record a speech sample and have their hearing and teeth checked.

What are the possible benefits and risks of participating?
This is a great opportunity for young adults born with a cleft lip and/or palate to have their say and contribute to cleft research in the UK. Participants who attend the research clinic will be given a £50 voucher as a thank-you for their time and participation. Travel costs to and from the clinic will also be reimbursed. The researchers don't anticipate any risks by taking part in the study.

Where is the study run from?
The study will be conducted across all 16 regional cleft centres in the UK.

When is the study starting and how long is it expected to run for?
April 2024 to March 2029

Who is funding the study?
National Institute of Health and Care Research (NIHR) (UK)

Who is the main contact?
1. Prof. Yvonne Wren, yvonne.wren@bristol.ac.uk
2. Kerry Humphries, k.humphries@bristol.ac.uk

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Scientific

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Additional identifiers

Integrated Research Application System (IRAS)
345805

Central Portfolio Management System (CPMS)
65237

National Institute for Health and Care Research (NIHR)
205006

Study information

Scientific Title
Improving outcomes by addressing variation at the end of routine care for young adults born with cleft lip and/or palate

Acronym
CLEFT@18-23

Study objectives
There is variation in outcomes for young adults born with cleft lip and/or palate for people when considered using EDI variables.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 26/11/2024, South West - Frenchay Research Ethics Committee (Ground Floor, Temple Quay House, 2 The Square, Bristol, BS1 6PN, UK; +44 (0)207 1048106, frenchay.rec@hra.nhs.uk), ref: 24/SW/0128

Study design
Both; Design type: Process of Care, Education or Self-Management, Cross-sectional

Primary study design
Observational

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Cleft lip and/or palate

Interventions
STUDY DESIGN AND SETTING:
Cleft@18-23 Research Clinics is a multi-centre cross-sectional cohort study to be conducted across all UK NHS regional cleft centres. The populations served by these centres are large and varied and also differ in terms of ethnicity and levels of deprivation. These clinics will enable us to see a large number of young adults born with cleft lip and/or palate and collect data on a range of outcomes relative to cleft. With these data, we can describe variations in outcomes for different subpopulations of young adults born with cleft lip and/or palate.

STUDY SAMPLE:
The target sample size is 600 (aiming to recruit 640 as a contingency for any missing data) over a 2-year period from January 2025 to March 2027. A sample of 600 has been calculated to be sufficient to have confidence in the results for the primary outcome of well-being in this population. Approximately 1000 babies are born each year with a cleft, meaning that there are approximately 6000 individuals who were born with a cleft and are aged 18 to 23 in any one year. We will recruit over two years, which will add an extra 1000 to the population we can recruit from, making the total 7000 and a recruitment rate of just under 9% of those eligible.

TARGET POPULATION AND RECRUITMENT:
Broad inclusion criteria will be applied so that young adults born with cleft lip and/or palate aged between 18 and 23 with any cleft subtype, with or without an identified syndrome and additional needs, will be eligible. Only those who have not completed routine care or have received any treatment related to their cleft outside of the UK or had their primary cleft repair surgery after age 2 will be excluded.

Potential participants will hear about the study from one of four routes:
- Letter of invitation from NHS Regional Cleft Centre and accompanying flyer with information about the study
- Direct communication from the Cleft Lip and Palate Association (CLAPA – third sector organisation)
- Social media or advertising about the study
- Letter of invitation to families who were participants in another University of Bristol study, Cleft Care UK, and whose children are now eligible for Cleft@18-23

Each of these routes will include brief information about the study and either a QR code or URL link which will take potential participants to the study website where they can read the study Participant Information Sheet and view the Study Consent Form. They can sign up by completing a form on the website to say they are interested in participating in the study. The form will ask them for some information to confirm their eligibility for inclusion and some additional information to help the study team monitor recruitment. Specifically, the form will ask them their age, their cleft subtype, their ethnicity, their biological sex and gender, the name of the centre or centres where they received their cleft care and the first four letters of the postcode for where they were living when they did their GCSEs. This last point is to help us ensure we have participants from a variety of backgrounds in the sample and where they live at age 18-23 might be misleading with regards to that. We will also ask participants for their contact details so that we can liaise with them and ask them about their preferred method for us to communicate with them.

The form will be received by a member of the study team who will make contact with the potential participant. They will discuss the study and what will happen at the research clinic. They will also discuss the consent form and if the potential participant is happy to go ahead, they will be asked for verbal consent to participate in the study. This is the point at which they are recruited to the study. During this call they will also discuss and agree on a date, time and venue for them to attend a research clinic. They will also discuss travel arrangements for reaching the clinic and any needs for the study team to prebook travel for the participant will be identified. They will also be asked if they are likely to need any help in participating in any of the clinics so that arrangements can be made in advance (for example, help with reading and writing or wishing to have someone with them).

DATA COLLECTION:
On the day of the research clinic, the participant will be greeted by a member of the study team or a member of the local clinical team. They will be asked to complete and sign the consent form which was previously discussed with them. They will then attend the following stations at the clinic in sequence:
1. Self-Report Questionnaires Part 1
2. Medical Photography
3. Speech and Hearing Assessment
4. Dental Examination
5. Self-Report Questionnaires Part 2
6. Data Collection from National Databases/data linking to other records
A range of data relevant to young adults born with cleft lip and/or palate will be collected at each station as summarised in the protocol.

Consent will be requested from participants for the study team to access and link to health, education and CRANE (Cleft Registry and Audit Network) data. Health data from NHS England /NHS Wales/NHS Scotland or the Health and Social Care Board (Northern Ireland), will be requested to provide information on surgical interventions received by the participant, this will assist in explaining variation in outcomes.

Education data from the Department for Education (England), the Department for Education and Skills (Wales), the Scottish Government Learning Directorate (Scotland) and the Department of Education and the Education Authority (Northern Ireland) as well as School education records held by the Office for National Statistics (ONS) in England and Wales, will be used to provide information on education outcomes.

CRANE data will provide information on 5-year-old outcomes for some participants in the sample, permitting an analysis of the degree to which outcomes at age 5 years old are predictors for outcomes at the end of routine care.

We will also ask for consent to access specific data from cleft records held at regional cleft centres, specifically the information on the participants' cleft subtype, syndromic status, additional diagnoses, and number and type of surgeries. These data will be important for stratifying the sample and also for use as confounder and covariate variables in statistical analyses.

We will only collect the minimum data necessary for our research.

DATA ANALYSIS:
Statistical analysis will be used to describe the range of outcomes observed across the difference areas that are important for cleft care. Further analysis will determine if the variation is within a reasonable range or whether the scores for some groups are better than others.

These results will be further informed by a series of semi-structured interviews with participants and by the consensus-building work on what constitutes a good outcome. Further details on these aspects of the programme of research and the work to develop a new intervention will be submitted as amendments to this application in the future.

PPI INPUT TO PLANS:
These plans have been developed based on focus groups with 10 young adults aged 18-30 who

were born with cleft lip and/or palate and also our core PPI group who have been set up as part of the study and who will be advising us and be involved in every step of the research programme.

The plans have also been informed by meetings with representatives of the cleft regional specialist teams and the clinical excellence networks for cleft specialist dentistry (restorative and orthodontics), speech and language therapy and psychology.

Intervention Type
Other

Primary outcome(s)
Limitation in usual role activities because of emotional problems, measured using the subscale from the Short Form 36 (SF36) on a self-report questionnaire at baseline

Key secondary outcome(s))
Measured on a self-report questionnaire at baseline:
1. Satisfaction with appearance and function measured using the CLEFT-Q
2. Depression measured using the Patient Health Questionnaire (PHQ-8)
3. Anxiety measured using Generalised Anxiety Disorder (GAD-7)
4. Resilience measured using Connor-Davidson Resilience Scale (CD-RISC-10)
5. Health literacy measured using the Health Literacy Questionnaire (HLS-Q12)
6. Satisfaction with oral health measured using Oral Health Impact Profile (OHIP-14)
7. Productivity loss (measure of health economics) measured using Work Productivity and Activity Impairment (WPAI)
8. Economic impact on health resources measured using Modular Resource Use Measure (ModRUM)
9. Social functioning measured using the Harter Self-Perception Profile
10. Worldview and life orientation measured using the Life Orientation Test (LOT-R)
11. Global health-related quality of life measured using Patient Reported Outcome Measurement Information System (PROMIS)

Measured by clinical assessment at baseline:
1. Nasolabial appearance assessed using the Asher McDade score (from photos)
2. Facial shape assessed using 3D score (from 3D images)
3. Hearing assessed using pure tone audiometry
4. Speech assessed using CAPS-A analysis (of video recordings)
5. Dental arch alignment assessed using the Modified Huddard Bodenham Index (MHBI)(from intra-oral scans)
6. Dental occlusion assessed using Peer Assessment Rating (PAR) scores (from intra-oral scans)
7. Dental caries assessed using Decayed and Filled Teeth (DFT/T)
8. Periodontal health assessed using the Community Periodontal Index of Treatment Need (CPITN) and Modified Plaque Index (MPS)

Completion date
31/03/2029

Eligibility

Key inclusion criteria

Broad inclusion criteria will be applied such that young adults aged 18-23 years with any cleft subtype, with or without an identified syndrome and additional needs, will be eligible.

1. Born with a cleft of the lip or palate or both (including microform cleft lip and submucous cleft palate)
2. Initial cleft repair carried out in the UK prior to age 2 years
3. Cleft care continued in the UK since the primary repair
4. Aged between 18 and 23 years at the time of recruitment
5. Completed routine cleft care more than 6 months ago
6. Ability to give informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
23 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Received any cleft treatment outside of the UK

Date of first enrolment
01/01/2025

Date of final enrolment
31/12/2027

Locations

Countries of recruitment
United Kingdom

England

Northern Ireland

Wales

Study participating centre
University Hospitals Bristol and Weston NHS Foundation Trust
Trust Headquarters
Marlborough Street
Bristol
England
BS1 3NU

Study participating centre
Greater Glasgow and Clyde
Gartnavel Royal Hospital
1055 Great Western Road
Glasgow
Scotland
G12 0XH

Study participating centre
The Newcastle upon Tyne Hospitals NHS Foundation Trust
Freeman Hospital
Freeman Road
High Heaton
Newcastle upon Tyne
England
NE7 7DN

Study participating centre
Alder Hey Children's NHS Foundation Trust
Alder Hey Hospital
Eaton Road
West Derby
Liverpool
England
L12 2AP

Study participating centre
Manchester University NHS Foundation Trust
Cobbett House
Oxford Road
Manchester

England
M13 9WL

Study participating centre
Nottingham University Hospitals NHS Trust
Trust Headquarters
Queens Medical Centre
Derby Road
Nottingham
England
NG7 2UH

Study participating centre
Birmingham Women's and Children's NHS Foundation Trust
Steelhouse Lane
Birmingham
England
B4 6NH

Study participating centre
Cambridge University Hospitals NHS Foundation Trust
Cambridge Biomedical Campus
Hills Road
Cambridge
England
CB2 0QQ

Study participating centre
Guys and St Thomas' NHS Foundation Trust
249 Westminster Bridge Road
London
England
SE1 7EH

Study participating centre
Oxford University Hospitals NHS Foundation Trust
John Radcliffe Hospital
Headley Way
Headington

Oxford
England
OX3 9DU

Study participating centre
Salisbury NHS Foundation Trust
Salisbury District Hospital
Odstock Road
Salisbury
England
SP2 8BJ

Study participating centre
Swansea Bay University Local Health Board
Tonna Hospital
Tonna Uchaf
Tonna
Neath
Wales
SA11 3LX

Study participating centre
Belfast Health and Social Care Trust
Trust Headquarters
A Floor - Belfast City Hospital
Lisburn Road
Belfast
Northern Ireland
BT9 7AB

Study participating centre
Leeds Teaching Hospitals NHS Trust
St. James's University Hospital
Beckett Street
Leeds
England
LS9 7TF

Study participating centre
Great Ormond Street Hospital for Children
Great Ormond Street

London
England
WC1N 3JH

Study participating centre
Mid and South Essex NHS Foundation Trust
Prittlewell Chase
Westcliff-on-sea
England
SS0 0RY

Sponsor information

Organisation
University Hospitals Bristol and Weston NHS Foundation Trust

ROR
https://ror.org/03jzzxg14

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF)

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the Cleft@18-23 study will be stored in two non-publicly available repositories: REDCap (https://sscmredcap.bris.ac.uk/redcap/) for the duration of the study and University of Bristol Research Data Storage Facility (https://www.bristol.ac.uk/acrc/research-data-storage-facility/) after the study has closed. Data will be available upon request from the study's data management team at cleft-research-data@bristol.ac.uk. The shared data may include questionnaire responses, examination results, test scores, and demographic information. Identifiable data, such as scans, images and audio, will only be shared for the specific purpose of analysis and scoring and will not be shared with external researchers beyond the approved study team. Data will remain available for the duration of the study and once it has concluded. It will be shared with qualified researchers subject to review and

approval. Access to the data will be granted to researchers affiliated with recognised institutions, conducting analyses aligned with the study's objectives, such as research on cleft outcomes, healthcare access, or patient-reported outcomes. Applicants must provide a clear research plan detailing the intended analyses, their qualifications, and evidence of ethical oversight. Where appropriate, data will be shared in an anonymised format to protect participant privacy. Consent for data sharing was obtained from participants as part of the study' s informed consent process. Ethical and legal restrictions, including compliance with GDPR and the Data Protection Act (2018), may apply, particularly for data containing sensitive or potentially identifying information. Requests for data access will be assessed on a case-by-case basis to ensure compliance with these restrictions. Data sharing will occur via secure transfer mechanisms, such as encrypted files or University-approved data repositories (e.g., RDSF).

IPD sharing plan summary

Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		04/11/2025	18/11/2025	Yes	No
Other files	version 1.0	17/10/2024	20/12/2024	No	No
Participant information sheet	version 2.0	19/11/2024	20/12/2024	No	Yes
Participant information sheet	version 2.0	19/11/2024	20/12/2024	No	Yes
Protocol file	version 1.0	01/10/2024	20/12/2024	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes