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

Cleft@18-23
SHAPING FUTURES TOGETHER

Research Clinics
Participant Information Sheet

What is Cleft@18-23?

Cleft@18-23 is a research programme taking place in the UK.

It involves people who were born with a cleft and NHS staff who work in cleft centres.

We are inviting you to take part.

Who can take part?

Any young adult aged 18-23 years old who:

- has a cleft lip and/or palate
- had their 1st operation for their cleft before the age of 2 years old
- had their 1st operation for their cleft and continued their treatment in the UK
- has been discharged from their cleft centre more than 6 months ago

What will happen if you take part?

We will invite you to come to a Cleft@18-23 Research Clinic. These will be held at one of the 16 Cleft Centres across the UK. You will be at the clinic for about 3 hours.

At the clinic we will ask you to:

- Complete questionnaires
- Have photos taken of your face & mouth
- Record a sample of your speech & have your hearing checked
- Have your teeth checked

You will receive a £50 voucher as a thank you for taking part. We will also reimburse your travel expenses.

For more detailed information about the study and how to take part, please read the rest of this information sheet.

Thank you for reading on!

Please take some time to read the information, think about it, maybe talk to someone else about it and let us know if you would like to take part.

You can **contact us** to ask us any questions you might have – there is no such thing as a silly question.

Taking part is your choice, you do not have to take part, and you are also free to withdraw from the study at any time. Whatever you decide about taking part, any care or treatment you have now or in the future will not be affected.

In this information sheet you will find:

- What Cleft@18-23 is
- Why it is happening
- Who can take part
- What taking part would mean for you
- What to do next
- Who is funding, organising and making sure that it is safe
- What will happen to your data

Contact details

Website: https://www.bristol.ac.uk/cleft18-23

Study team email: cleft-1823@bristol.ac.uk

Study team phone: 0117 3310025

Mobile: 07484515858

University of BRISTOL

NHS University Hospitals Bristol and Weston NHS Foundation Trust

CLAPA Cleft Lip + Palate Association

FUNDED BY NIHR | National Institute for Health and Care Research

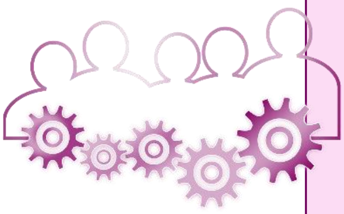
What is Cleft@18-23 and why is it happening?

The aims of the study are to:

- understand what it is like to be a young adult who was born with a cleft and had their treatment in the UK.
- find out about your well-being and also whether your cleft has had an impact on how you look or how your speech sounds and how you feel about that.
- know if there are differences between groups of people - such as men and women or people from different ethnic backgrounds.

We want to hear from you if you are really happy with your life or if you are struggling or anything in between.

Who can take part in Cleft@18-23 clinics?



Any young adult aged 18-23 years old who:

- has a cleft lip and/or palate
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- has been discharged from their cleft centre more than 6 months ago

The project is looking at the care and treatment in the UK. If you have had part or all of your care/treatment outside of the UK you will not be able to take part. If you think this might be you but are not sure, feel free to get in touch with us and we can work it out together.

Email: cleft-1823@bristol.ac.uk Telephone: 0117 3310025 Mobile: 07484 515 858

We are keen that the Cleft@18-23 Research Clinics are accessible to all.

If you would like this information printed out or in an easy read version, then please let us know and we will get that to you as soon as possible.

What would taking part look like?

We think it is important that everyone who is aged 18-23 years old, was born with a cleft and had their treatment in the UK, is able to take part. If there is anything we can do to help you to take part, then please get in touch.

If you decide to take part, then you will be invited to attend one of the 16 cleft centres in the UK to take part in a Cleft@18-23 Research Clinic. This will usually be the centre you had your treatment in but if you have moved, it may be possible to go to one closer to where you live.

In the clinic you will be asked to:

- complete some questionnaires about you, your health and wellbeing
- see a medical photographer to take pictures of your face, mouth/teeth like they did during your treatment
- talk to a speech & language therapist who will take a short video recording of your speech and check your hearing
- see a dental therapist who would measure things like your dental health & take scans (no moulds or impressions will be made)

We anticipate that you will be at the Research Clinic for about 3 hours.

We understand that travelling to a clinic and giving up your time might be difficult and cost you money.

We would like to offer you a £50 voucher as a thank you for your time. We will also pay back your travel costs. If you need help arranging transport, then please get in touch.

There will be refreshments (drinks & snacks) provided at the clinic.

What are the possible advantages of taking part?

There are unlikely to be any direct treatment or care advantages for you. This Research Clinic will be for research only and will not help you to get any care or treatment you might need. Please contact your cleft centre for help with your treatment.

You will be given a £50 voucher as a thank you for your time.

Your data will help us improve our services for future generations of children and young adults born with a cleft.

What are the possible disadvantages and risks of taking part?

There are no risks expected for you taking part. Some people may feel uncomfortable answering some of the questionnaires or having scans/photos taken. We would like to help you to feel more comfortable so please do let us know if there is anything extra we can do. There will also be time to speak to a psychologist or member of the cleft team if you want to at the end of the Research Clinic.

Coming to the Research Clinic might be difficult for you, take time and cost you travel money. We hope that the offer of paying back your travel costs will help.

Next steps if you would like to take part

We think it is important that everyone who is aged 18-23 years old, was born with a cleft and had their treatment in the UK, is able to take part. If there is anything we can do to help you to take part, then please get in touch.

Step 1

If you think you might like to take part, then the first step would be to complete a **form** (paper or electronic forms are available). This form will ask you questions about yourself, your cleft and where you live.

This is so that we can make sure the research includes as many young adults as possible that represent the young adult cleft community – in other words, males & females, different gender identities, different types of cleft, a variety of ethnicities and people from all over the UK.

The link to the electronic form is: [add link]

A paper copy is available from the Cleft@18-23 study team (see contact details at the end of this document)

Step 2

Once we have looked at your initial contact form, we will get in touch with you to discuss attending a clinic. We will then send you a **consent form** (paper or electronic copies available).

Filling in this consent form shows that you understand what taking part in Cleft@18-23 Research Clinics involves.

We will go through the form with you at the start of the clinic to make sure that you are happy with what you are consenting to.

We might run out of space!

We have a limited number of study appointments. If we have run out of space, we may need to add you to a reserve list, and it is possible that you will not be able to take part in the Research Clinics. There will be other opportunities as part of Cleft@18-23 and we will let you know about these via your preferred method of communication when the time comes.

What will happen to the results of this study?

We will use your data to help us find out if there are some groups of people born with a cleft who do better or worse than other groups in terms of how they feel, or how they look or how they sound. With this information – and the results from other studies we are carrying out – we will be able to determine ways to support people who are more likely to have concerns about how they feel, look or sound in the future.

You will be able to keep up with how the projects are going and any results via the Cleft@18-23 newsletter, by checking the website (https://www.bristol.ac.uk/cleft18-23) and by following Cleft@18-23 on social media (see the contact section at the end of this document).

Who is funding, organising & making sure Cleft@18-23 is safe?

Cleft@18-23 is:

- The money for this project is provide by a Programme Grant from the National Institute for Health and Care Research (NIHR)
- sponsored by University Hospitals Bristol & Weston NHS Foundation Trust (UHBW). Sponsors have the responsibility to make sure that the study is set up and run properly.
- led by the University of Bristol with involvement of researchers from other universities as well as cleft specialist clinicians and people who were born with a cleft.

The Cleft@18-23 Research Clinic study has been reviewed and approved by a research ethics committee. All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by ________________Research Ethics Committee.

What if you have any concerns?

Concerns or Complaints

If you have a concern about any aspect of this study, please contact:

- the Cleft@18-23 study team - email: cleft-1823@bristol.ac.uk call: 0117 3310025

Each team member will do their best to answer your questions.

If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. You can contact the hospital's Patient Advice Liaison Service (PALS) or local Clinical Commissioning Group. For more information on the NHS complaints procedure or to find your local contact go to: http://www.nhs.uk/choiceintheNHS/Rightsandpledges/complaints/

Harm

This is an NHS-sponsored research study. If there is negligent harm during the project when the NHS body owes a duty of care to the person harmed, NHS Indemnity covers NHS staff, medical academic staff with honorary contracts, and those conducting the project. NHS Indemnity does not offer no-fault compensation and is unable to agree in advance to pay compensation for non-negligent harm. Ex-gratia payments may be considered in the case of a claim.

How will we use information about you?

We will need to use information from you for this research project. We think that it is important **to keep your information safe**.
This section tells you more about this.

In the Cleft@18-23 Research Clinics, we will collect information from you including responses to self-administered questionnaires about your health and wellbeing, dental and oral health, scans & photos of your mouth and face, a voice recording and a hearing test.

What are your choices about how your information is used?

We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

Accessing your data from other records

With your permission, we would like to access your **medical records** including locally and nationally held records. These records are collected by the NHS (England, Wales & Scotland) and the Health and Social Care Board (Northen Ireland).

A great deal of information is collected and stored about all of us in our official government records. This information gives a detailed picture of many aspects of our life, such as our health, the care and treatments we receive and our education. Cleft@18-23 can use this information alongside the information you give us to improve our understanding of treatments and outcomes for young adults with cleft once they leave routine care.

We will only request the minimum information that we need for our study, and we won't be looking at your whole medical record.

Information can only be released with your consent. To access the information, we will provide the minimum necessary personal details (such as your name, address and date of birth) to the government departments and organisations holding the information. These details will only be used to identify your information. Before the departments and organisations send any information you have authorised back to us, your name and other details will be removed. None of your questionnaire responses or clinic results will be disclosed to these sources for any other purpose. The information from other sources will be kept completely confidential in accordance with the Data Protection Act and General Data Protection Regulation (GDPR).

All you need to do is agree to us accessing your health records on the consent form and we will do the rest.

You can choose not to agree to us accessing your medical records without it affecting your involvement in the rest of the study. You are free to tell us to stop at any time without giving a reason.

We would also like to ask your permission to access the records collected by your cleft team.

We will ask to access your **education records** to see if having a cleft impacts how well you did at school.

School education records are collected by 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). School education records are held by the Office for National Statistics (ONS) in England and Wales. Education records are recorded in databases for all children in state schools in, linking information about them to school learning aims and attainment.

The Cleft@18-23 Study Team would like to collect the routinely collected information about your education from the Department for Education. This is information about:

- your achievements at school (Key Stage Assessments and GCSEs in England, Wales and Northern Ireland and 5-14 levels and Standard Grades in Scotland)
- the characteristics of pupils in your school (ethnicity, special educational needs, absences)

Some of you will have records about your cleft care in the **CRANE database**. It started collecting information in the early 2000's so it is possible some of you might not.

The CRANE database is a record of information collected routinely after the birth of children born with cleft lip and/or palate throughout England, Wales, Scotland and Northen Ireland. This information is stored at The Royal College of Surgeons of England and is funded by the National Health Service. Information held on this database includes:

- details of the type of cleft the child was born with
- patient name, address, and postcode
- whether there is a history of cleft lip or palate in the family

With your consent, we would like to access your information on the CRANE database; this will help us to get as much information as possible about your cleft without having to ask you directly. For more information about CRANE, take a look at their website: https://www.crane-database.org.uk.

All of this information will help us to answer the questions we have about outcomes for young adults with cleft once they leave routine care.

Sharing information with other researchers

With your permission, the Cleft@18-23 Study Team will allow other researchers to access data from this study to promote research, particularly in relation to cleft. All researchers requesting access will need approval from a research ethics committee to make sure your rights are protected. The Cleft@18-23 Study Team will only share anonymous data with other researchers unless the data being shared is photographs and videos. It is not possible to anonymise photographs and videos because your face will be visible in these.

You can choose whether you consent to these being shared.

Other researchers will not have access to your personal information. A unique ID number will be the only way the information can be linked to you. Only the Cleft@18-23 Study Team will be able to link you to the unique ID number; this is important so that we can contact you in the future.
Your confidentiality will be safeguarded during and after the study.

Storing your information

All our procedures for handling, processing, storing and destroying your data meet all relevant regulations including the General Data Protection Regulation (GDPR) and the Data Protection Act. We will keep all information about you safe and securely stored.

Unless you request otherwise, we will store your data indefinitely. It will be held securely in the University of Bristol Research Data Storage Facility (RDSF).

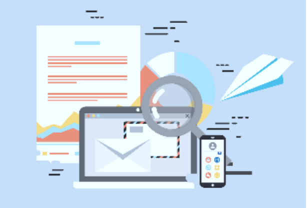
University Hospitals Bristol and Weston NHS Foundation Trust (UHBW) is the joint Data Controller along with the University of Bristol. Which means that both organisations are responsible for the management and oversight of the data.

Where can you find out more about how your information is used?

You can find out more about how we use your information:

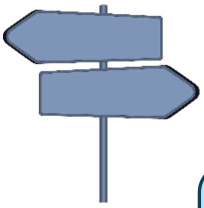
- at www.hra.nhs.uk/information-about-patients/
- the sponsors leaflet available from https://www.uhbristol.nhs.uk/research-innovation/for-patients-and-public/how-we-use-your-information-(gdpr)/
- Email the University of Bristol Data Protection Officer: data-protection@bristol.ac.uk
- by asking one of the Study Team
- by sending an email to cleft-1823@bristol.ac.uk, or
- by ringing us on 0117 3310025 or 07484 515858

Sharing the results



The anonymous findings of this research will be reported in professional publications, meetings and conferences. We will share the findings with those working in the NHS as well as policy makers and others who make decisions about NHS care and treatment.

Results will also be shared with other cleft organisations and charities such as CLAPA and with members of the general public.
You will not be personally identified in any report, presentation or publication. If there are any photographs of you that we would like to use, we will always ask your permission first.



What would happen if you change your mind?

Taking part is **voluntary**, and if you decide to take part but change your mind and want to withdraw, that is fine. This section tells you what to do if you change your mind.

Whatever you decide about taking part, any care or treatment you have now or in the future will not be affected. You can stop being part of the study at any time without giving a reason.

If you would like all or some of the photographs, speech & hearing results, dental assessments and questionnaire responses destroyed, please let us know.

If you choose to stop taking part in the study, we would like to continue collecting information about you from your medical records, education records and from the CRANE database (if you have a record). If you do not want this to happen, tell us and we will stop.

If you would like to stop taking part, please let the Cleft@18-23 research team know.

Email: cleft-1823@bristol.ac.uk Call: 0117 3310025 Mobile: 07484 515858

Cleft@18-23

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Study Team Contact Details

To learn more please check out our website

https://www.bristol.ac.uk/cleft18-23

Or feel free to contact us via our Study Team

email: cleft-1823@bristol.ac.uk

phone: 0117 3310025

Mobile: 07484 515 858

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