

Cleft Care UK

2010-2012

Information Leaflet for Parents/Guardians

Summary

You have been given this leaflet because your child has been cared for by the regional cleft team and we want to invite you and your child to take part in this study.

Clefts of the lip and palate affects one child in every 600 to 700 born in the United Kingdom (UK). Ten years ago a research study assessed the quality and availability of services for children with Cleft lip & palate and led to the creation of larger specialist cleft centres. Our aim is to see how these changes have affected current cleft care and outcome.

This study will be undertaken across all the Cleft centres within the UK. Altogether we are aiming to collect information from around 250 five year old children with complete unilateral cleft lip and palate. This information will be anonymous and stored on an encrypted data storage device.

Who is organising the project?

This project has been funded by the UK National Institute of Health Research. Researchers from Bristol University are working with your local Cleft team to carry out this research.

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What is the purpose of this study?

The aim of our research is to evaluate care and outcome for cleft lip and palate in the UK.

Why has my child been chosen?

Your child is born between the dates 1st April 2005 to 31st March 2007 with a complete unilateral cleft lip and palate, which meets the inclusion criteria for this study. Children born with clefts of the lip & palate require comprehensive care. So the outcome in children with cleft lip and palate allows us to assess the quality of care.

Does my child have to take part?

You do not have to agree to your child taking part in the study.

Are there any disadvantages in taking part?

No, there are no disadvantages in taking part in this project. It will not affect any care you receive from your local Cleft team.

What will be required from my child if we take part?

On the day you attend for your routine follow up appointment at your Regional Cleft centre, you will be asked if you would like to participate in the study. If you agree you will sign a consent form, which allows us to collect information about your child. This study may be repeated in the future after ethical approval and the information collected may be compared with other findings. We will also ask you to consent to the research team collecting additional information via linkage to your child's medical record and educational records. The linkage to educational records will establish if having a cleft influences educational attainment negatively and allow us to explore possible reasons for this. The data collected will be anonymous and remain confidential. The NHS Information Centre and the Medical Research Information Service (MRIS) will assist us with this data processing.

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On the day, we will invite your child to have:

- **Photographs** of their face [part of regular assessment]
- **Moulds** (impressions) and/or **photographs** of their teeth if they have not had these taken recently [part of regular assessment]
- Evaluation of **primary surgery** [part of regular assessment]
- A **hearing assessment** [part of regular assessment]
- Recordings of their **speech** undertaken by your Speech & Language therapist [part of regular assessment]
- An assessment of their **dental health** (dental check-up) to look for any decay and the cleanliness of your child's teeth [part of regular assessment]
- Measurements for **weight, height** and their **head circumference** [part of regular assessment]
- You will be asked to complete the following:
 - a **psychosocial questionnaire** [part of regular assessment]
 - a **satisfaction with service questionnaire** [part of regular assessment]
- You will also be asked if you would like to complete a **research questionnaire** in your home, it will take about 40 minutes to complete and mail it back to us in a prepaid envelope provided to you.

What will happen to the results of the research study?

At the end of the project, the data will be analysed and published in medical/dental journals and a report will be sent to the Department of Health. The results will be presented at National/International Conferences related to Cleft care. If you want, we will send you a summary of the findings.

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Who has reviewed the study?

A National Health Service Research Ethics Committee has approved the study. This means that the Committee is satisfied that your rights are being respected and you have been given adequate information on which to make an informed decision to participate or not.

Contact information

If you have any questions about this study please feel free to contact the research team co-ordinator who will be able to answer your queries or direct your questions to other members of the research team who will return your call as soon as they can.

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