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Study Title: The development of a re-usable learning object for parents of infants with Pierre Robin Sequence

PARTICIPANT INFORMATION SHEET

Research Ethics Reference: 294-1902
Version 2.0 Date: 30/04/19

We would like to invite you to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. One of our team will go through the information sheet with you and answer any questions you have. Please take time to read this carefully and discuss it with others if you wish. Ask us anything that is not clear.

What is the purpose of the research?
My name is Dr Karine Latter and by conducting this research project, I hope to develop a resource that parents of infants born with Robin Sequence can access after the birth of their baby to gain accurate and up to date information about the condition.

Why have I been invited to take part?
You have been invited to take part in this research because you are a parent or carer of an infant with Pierre Robin Sequence over the age of 18 years.
We will be recruiting up to fifteen participants in this study.

Do I have to take part?
No. It is up to you to decide if you want to take part in this research. We will describe the study and go through this information sheet with you to answer any questions you may have. If you agree to participate, we will ask you to sign a consent form and will give you a copy to keep. However, you would still be free to withdraw from the study at any time, without giving a reason and without any negative consequences, by advising the researchers of this decision. This would not affect your legal rights

1. What will happen to me if I take part?

A researcher will contact you to go over the information sheet, explain the procedures. If you agree to take part in the study, you will be asked to attend a single focus group at the University of Nottingham for a half day.

Upon arrival we will talk you through the study procedures and give you chance to ask any questions.

The study will involve talking about what information should be included in the resource for parents of infants with Robin Sequence alongside other parents. This should take approximately 3.5 hours

If you are still happy to take part, then you will then be asked to sign a consent form.

2. What is a focus group?

Focus groups are used to gain information from a group of people about a subject.

3. Are there any risks in taking part?

There are no perceived disadvantages of taking part in the project apart from the cost to your time.

4. Are there any benefits in taking part?

There will be no direct benefit to you from taking part in this research but your contribution may help us to improve the experiences of parents whose infants are diagnosed with Pierre Robin Sequence.

5. Will my time/travel costs be reimbursed?

Participants will receive travel expenses to travel to Nottingham to participate in the study.

6. What happens to the data provided?

The **research data** will be stored confidentially. To help ensure your privacy, you will be assigned a volunteer study identification number (for example P01 for participant number 1), and it will be used instead of your name. We will save all research data using that volunteer study identification number so that none of the data will have your real name or other individual identifiers associated with them. Your name and any information about you will not be disclosed outside the study centre.

Personal / sensitive data will be stored confidentially in a secure and locked office, and on a password protected database. Any information about will have your name and address removed (anonymised) and a unique code will be used so that you cannot be recognised from it. The researcher will have access to personal and research data

All research data and records will be stored for a minimum of 7 years after publication or public release of the work of the research.

We would like your permission to use anonymised data in future studies, and to share our research data (e.g. in online databases) with other researchers in other Universities and organisations both inside and outside the European Union. This would be used for research in health and social care. Sharing research data is important to allow peer scrutiny, re-use (and therefore avoiding duplication of research) and to understand the bigger picture in particular areas of research. All personal information

that could identify you will be removed or changed before information is shared with other researchers or results are made public. Data sharing in this way is usually anonymised (so that you could not be identified)

7. What will happen if I don't want to carry on with the study?

Even after you have signed the consent form, you are free to withdraw from the study at any time without giving any reason and without your legal rights being affected. Any personal data will be destroyed.

If you withdraw we will no longer collect any information about you or from you but we will keep the anonymous research data that has already been collected and stored as we are not allowed to tamper with study records. This information may have already been used in some analyses and may still be used in the final study analyses. To safeguard your rights, we will use the minimum personally-identifiable information possible.

8. Who will know that I am taking part in this research?

All information collected about you during this research would be kept strictly confidential. All such data are kept on password-protected databases sitting on a restricted access computer system and any paper information (such as your consent form, contact details and any research questionnaires) would be stored safely in lockable cabinets in a swipe-card secured building and would only be accessed by the research team.

Under UK Data Protection laws the University is the Data Controller (legally responsible for the data security) and the Chief Investigator of this study (named above) is the Data Custodian (manages access to the data). This means we are responsible for looking after your information and using it properly. Your rights to access, change or move your information are limited as we need to manage your information in specific ways to comply with certain laws and for the research to be reliable and accurate. To safeguard your rights we will use the minimum personally – identifiable information possible.

You can find out more about how we use your information and to read our privacy notice at:

https://www.nottingham.ac.uk/utilities/privacy.aspx/

Designated individuals of the University of Nottingham may be given access to data for monitoring and/or audit of the study to ensure we are complying with guidelines.

With your consent, we will keep your personal information on a secure database in order to contact you for future studies.

Anything you say during a focus group will be kept confidential, unless you reveal something of concern that may put yourself or anyone else at risk. It will then be necessary to report to the appropriate persons.

9. What will happen to the results of the research?

The research will be published in Cleft Palate Journal.

10. Who has reviewed this study?

All research involving people 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 the Faculty of Medicine and Health Sciences Research Ethics Committee (Reference number: FMHS xx-xxxx).

11. Who is organising and funding the research?

The study is being organised by Dr Karine Latter and is funded by Nottingham University Hospitals Charity.

12. What if something goes wrong?

If you have a concern about any aspect of this project, please speak to the Principal Investigator Dr Karine Latter who will do her best to answer your query. The researcher should acknowledge your concern within 10 working days and give you an indication of how she intends to deal with it.

If you remain unhappy and wish to complain formally, you should then contact the FMHS Research Ethics Committee Administrator, Faculty Hub, Medicine and Health Sciences, E41, E Floor, Medical School, Queen's Medical Centre Campus, Nottingham University Hospitals, Nottingham, NG7 2UH or via E-mail: FMHS-ResearchEthics@nottingham.ac.uk

13. Contact Details

If you would like to discuss the research with someone beforehand (or if you have questions afterwards), please contact:

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