

Participant Information Sheet

Exploring parents' experiences of common baby symptoms

Researchers: Ms Sam Hornsey, Dr Ingrid Muller

You are invited to take part in a research study. To help you decide whether you would like to take part or not, it is important that you understand why the research is being done and what it will involve. Please read the information below carefully and ask questions if anything is not clear or you would like more information. You may like to discuss it with others, but it is up to you to decide whether or not to take part. If you are happy to take part you will be asked to sign a consent form.

What is the study about?

Some babies cry or vomit or seem more unsettled than others, with common symptoms such as:

- excessive crying (not stopping crying for hours without being settled),
- fussing unless being held
- vomiting
- rash
- changes in their nappies
- excessive gas/wind or congestion.

This study is to better understand parents and carers' experiences of these baby symptoms, when and where they seek help, support or information, and how having an unsettled baby might affect feeding decisions. This study will help with knowing when and how to provide support in dealing with these symptoms.

We want to chat to parents of babies who have had any or multiple common symptoms (such as the symptoms listed above) when they were less than 4 months old, even if they have never consulted a GP or a nurse about this. We would also like to speak to parents who have considered **Cow's Milk Allergy, Reflux or Colic** (whether or not they have received a diagnosis of this).

This study is funded by the NIHR School of Primary Care Research and is being run (and sponsored) by the University of Southampton.

Why have I been invited?

You have been asked to take part in this study as you may have a baby (less than 1 year old).

Do I have to take part?

No, it is entirely up to you to decide whether or not to take part. If you decide you want to take part, you will sign a consent form to show you have agreed to take part.

What will happen to me if I take part?

If you decide to take part, you will be asked to sign a consent form. The researcher will contact you to arrange a time that suits to have a chat about your experiences of having an unsettled baby. This may be by phone or videoconference (e.g. TEAMS or Zoom) depending on what suits you best. The interview will take 30 mins to an hour. With your permission, this conversation will be recorded and transcribed (to written text). All personal details will be removed and fully anonymised.

Are there any benefits in my taking part?

You will be given a **£15 gift voucher** for taking part in the study. The findings of this study will help researchers understand how to better support parents with unsettled babies.

Are there any risks involved?

There are minimal risks to taking part in this study. You may find it upsetting to talk about your experiences. If this happens, we will stop the interview and give you details where you can get advice and support.

What data will be collected?

The interviewer will ask questions about your baby's symptoms and how you made sense of the symptoms. They will also ask about what support and advice you have received from friends/family, online, or from health professionals such as health visitors or GPs, as well as possible causes you may have considered and how this affected your baby and your family. Data such as gender and ethnicity will also be collected, optionally.

What happens to the data being collected?

After the interview, the recording will be put on a university password-protected computer and deleted from the recording device. The recording will be typed up by a professional transcriber or a member of the research team. They will keep everything they hear private and will type code names instead of your name and any other names or places, so no-one can find out who you are. We will delete all audio recordings on completion of the study. Only anonymised information will be analysed.

We will review what you have told us and put that together with what other parents tell us. This will help us understand parents' views and experiences of an unsettled baby. Your personal details and code name will be stored separately from the typed-up interviews and audio-recordings; all of this information will be stored securely on computers at the University of Southampton and will only be accessible by the research team. We will delete the personal details that match your code name at the end of the study.

Will my participation be confidential?

Your participation and the information we collect about you will be kept strictly confidential. We will not share your interview with anyone who is not a member of the research team. We follow strict regulations about how health research is carried out. At times, individuals from regulatory authorities may require access to the information we collect about you to check that we are carrying out the research correctly. Only individuals from regulatory authorities will be able to see your information. These people have a duty to keep your information strictly confidential.

What happens if I change my mind?

You have the right to change your mind and withdraw at any time without giving a reason. If you decide to withdraw, any data you have provided will be kept up to the point of withdrawal but will be deleted if you request this.

What will happen to the results of the research?

Your personal details will remain strictly confidential. The results of the study will be written up as a report for NIHR School of Primary Care Research and will be published in scientific journals and presented at research conferences. We may use quotes from the interview but none of your personal details that could identify you will be used (like your name).

Where can I get more information?

If you have any questions about this study, please contact:

Sam Hornsey
Primary Care Research Centre
Faculty of Medicine
University of Southampton
Aldermoor Close
Southampton
SO16 5ST

Email: babyfuss@soton.ac.uk

What happens if there is a problem?

If you have a concern about any aspect of this study, you should speak to the researcher (babyfuss@soton.ac.uk) who will do their best to answer your questions. If you remain unhappy or have a complaint about any aspect of this study, please contact the University of Southampton Research Integrity and Governance Manager (023 8059 5058, rgoinfo@soton.ac.uk).

Thank you

Thank you for taking the time to read the information sheet and considering taking part in the study.

Data Protection Privacy Notice

The University of Southampton conducts research to the highest standards of research integrity. As a publicly-funded organisation, the University has to ensure that it is in the public interest when we use personally-identifiable information about people who have agreed to take part in research. This means that when you agree to take part in a research study, we will use information about you in the ways needed, and for the purposes specified, to conduct and complete the research project. Under data protection law, 'Personal data' means any information that relates to and is capable of identifying a living individual. The University's data protection policy governing the use of personal data by the University can be found on its website (<https://www.southampton.ac.uk/legalservices/what-we-do/data-protection-and-foi.page>).

This Participant Information Sheet tells you what data will be collected for this project and whether this includes any personal data. Please ask the research team if you have any questions or are unclear what data is being collected about you.

Our privacy notice for research participants provides more information on how the University of Southampton collects and uses your personal data when you take part in one of our research projects and can be found at <http://www.southampton.ac.uk/assets/sharepoint/intranet/Is/Public/Research%20and%20Integrity%20Privacy%20Notice/Privacy%20Notice%20for%20Research%20Participants.pdf>

Any personal data we collect in this study will be used only for the purposes of carrying out our research and will be handled according to the University's policies in line with data protection law. If any personal data is used from which you can be identified directly, it will not be disclosed to anyone else without your consent unless the University of Southampton is required by law to disclose it.

Data protection law requires us to have a valid legal reason ('lawful basis') to process and use your Personal data. The lawful basis for processing personal information in this research study is for the performance of a task carried out in the public interest. Personal data collected for research will not be used for any other purpose.

For the purposes of data protection law, the University of Southampton is the 'Data Controller' for this study, which means that we are responsible for looking after your information and using it properly. The University of Southampton will keep identifiable information about you for 10 years after the study has finished after which time any link between you and your information will be removed.

To safeguard your rights, we will use the minimum personal data necessary to achieve our research study objectives. Your data protection rights – such as to access, change, or transfer such information - may be limited, however, in order for the research output to be reliable and accurate. The University will not do anything with your personal data that you would not reasonably expect.

If you have any questions about how your personal data is used, or wish to exercise any of your rights, please consult the University's data protection webpage (<https://www.southampton.ac.uk/legalservices/what-we-do/data-protection-and-foi.page>) where you can make a request using our online form. If you need further assistance, please contact the University's Data Protection Officer (data.protection@soton.ac.uk).