

Participant Information Sheet

Caring for unsettled babies – a health visitors' and community health nurses' perspective (CUBs study)

Researcher: Dr Sam Hornsey, Dr Ingrid Muller, Lucy Smith
ERGO number: 82667

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 provide verbal consent at the start of the interview.

What is the study about?

Some babies cry or vomit or seem more unsettled than others, with common symptoms/behaviours 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.

We are a research team running this study at the University of Southampton Primary Care Research Centre. This is an interview study to better understand health visitors' and community health nurses' experiences of supporting families who have unsettled babies, in relation to their beliefs around assessment and management of behaviours. Additionally, we want to understand how health visitors and community health nurses perceive the training they receive on how best to support unsettled babies. This study will help with knowing when and how to provide support in dealing with these symptoms.

We want to chat to health visitors and community health nurses who have supported families with unsettled babies in the past 12 months.

This study is funded by the NIHR School of Primary Care Research. This study is sponsored by the University of Southampton and it has been reviewed by the University of Southampton Faculty of Medicine Research Ethics Committee (ERGO reference 82667).

Why have I been invited?

You have been asked to take part in this study as you may be a member of the health visiting team or a community health nurse

Do I have to take part?

No, it is entirely up to you to decide whether or not to take part. If you would like to take part, you will be asked to complete an expressions of interest form. We will contact you to confirm whether you would still like to take part. Once an interview date is arranged, we will send you an electronic copy (PDF or word document) of the consent form for you to read over, but you don't need to send this back to us at this stage. We will then obtain verbal consent at the start of the interview, for you to show that 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 provide verbal consent at the start of the interview. The researcher will contact you to arrange a time that suits to have a chat about your experiences of supporting families with an unsettled baby. This may be by phone or videoconference (via Microsoft Teams) depending on what suits you best. The consent process will take around 10 minutes. We will then begin the interview which will take around 30 – 50 minutes. With your permission, this conversation will be recorded and transcribed to written text. All personal details will be removed and fully anonymised. There will be no requirement for any further involvement after this study.

Are there any benefits in my taking part?

You will be given a **£25 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 experiences of working with families with unsettled babies, and of working alongside other agencies such as GPs to support families. Data such as your gender, age, years of

practice and ethnicity will also be collected. This will help us understand more about the how diversity of health visitors and community health nurses may shape experiences of caring for unsettled babies We will also ask you for demographic information about the typical families you support. This will help us to understand more about the types of families that are being supported with their unsettled babies, and to identify the need for tailored support according to family demographic.

What happens to the data being collected?

After the interview, the recording will be put on a university password-protected computer/server 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 health visitors tell us. This will help us understand health visitor's experiences of supporting families with 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. This information will be encrypted and secured with a password, that will only be known to the researchers working directly on this study. 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 would like to withdraw, you can contact Lucy Smith, a member of the research team on . 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, unless it has already been used anonymously in the analysis or results of the study (for the purposes of achieving the objectives of the study only).

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:

Lucy Smith
Primary Care Research Centre
Faculty of Medicine
University of Southampton
Aldermoor Close
Southampton
SO16 5ST

Email: L.Smith@soton.ac.uk or cubs@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 (lsmith@soton.ac.uk or cubs@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).