Study to explore how acceptable and practical online support groups are in supporting caregivers of unsettled babies with colic and/or reflux.

Peer Support Group Information Sheet

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You are being invited to take part in a research study. Before you decide whether to take part, it is important that you understand why the research is being done and what it will involve. Please take the time to read the following information carefully and feel free to ask us if you would like more information or if there is anything that you do not understand. Please also feel free to discuss this with your friends, relatives and healthcare providers if you would like. We would like to stress that you do not have to accept this invitation and should only agree to take part if you want to.

Thank you for reading this.

1. What is the purpose of the study?

This study is run by the University of Liverpool and Alder Hey Children's NHS Foundation Trust, funded by the Hugh Greenwood Legacy Fund for Children's Health Research. The study aims to explore how acceptable and practical non-medical online support groups are in supporting caregivers of unsettled babies with colic, reflux, and/or cow's milk protein allergy. These groups include a health education delivered by infant feeding specialists; music intervention delivered by music therapists; a peer support group delivered by researchers and other caregivers; and no intervention (called treatment as usual). You have been put into the peer support group.

2. Why have I been chosen to take part?

You have been chosen to take part because your unsettled baby is under six months old and has been referred to the Infant Feeding Team at Alder Hey Children's NHS Foundation Trust due to colic, reflux, and/or cow's milk protein allergy. You have also been chosen to take part because you are over 18 years of age and you are living in the UK. Finally, you can understand the English language to a degree where you can understand the written information provided. Due to the sensitive nature of topics that might be covered during the course of this study, to be eligible to take part you must not have a current or historic clinical diagnosis of a serious mental health condition i.e., bipolar disorder, psychosis, and/or schizophrenia.

3. Do I have to take part?

No - taking part is entirely your choice. You do not have to take part and can stop taking part at any time without giving any reason, and without it affecting your access to or quality of your normal care at Alder Hey Children's Hospital.

4. What will happen if I take part?

If you agree to take part, you will be involved in this study for a total of seven weeks. This is what the seven weeks will look like if you decide to take part:

Week	What to expect
Study start	Complete online surveys about: your baby's symptoms, parenting confidence, depression, and anxiety.
Week 1	Online group session with nine other caregivers. Online group session will last about one hour. This session will be an introductory session and what peer support is and its benefits At the end of this week, you will be sent a short online questionnaire by email. This questionnaire will ask you about: your mood, how often you are using the techniques learnt in group sessions with your baby, and how useful you are finding the techniques and sessions.
Week 2	Online group session with nine other caregivers. Online group session will last about one hour. This group session will be an informal discussion about personal success stories, baby's symptoms, and how attendees are engaging with the support group. At the end of this week, you will be sent a short online questionnaire by email. This questionnaire will ask you about: your mood, how often you are using the techniques learnt in group sessions with your baby, and how useful you are finding the techniques and sessions.
Week 3	Online group session with nine other caregivers. Online group session will last about one hour. This session will session will look at any problems, difficulties, and how to improve experiences of peer support. At the end of this week, you will be sent a short online questionnaire by email. This questionnaire will ask you about: your mood, how often you are using the techniques learnt in group sessions with your baby, and how useful you are finding the techniques and sessions.
Week 4	Using the skills learned from weeks 1-3 with your baby. At the end of this week, you will be sent a short online questionnaire by email. This questionnaire will ask you about: your mood, how often you are using the techniques learnt in group sessions with your baby, and how useful you are finding the techniques and sessions.
Week 5	Using the skills learned from weeks 1-3 with your baby. At the end of this week, you will be sent a short online questionnaire by email. This questionnaire will ask you about: your mood, how often you are using the techniques learnt in group sessions with your baby, and how useful you are finding the techniques and sessions.
Week 6	Using the skills learned from weeks 1-3 with your baby. At the end of this week, you will be sent a short online questionnaire by email. This questionnaire will ask you about: your mood, how often you are using the techniques

	learnt in group sessions with your baby, and how useful you are finding the techniques and sessions.
Week 7	Focus group with the other caregivers in the peer support group. The focus group will be held over Zoom, with a member of the research team, and will last about one hour. You will be asked about why you decided to take part in this study, your experiences of the peer support group, and your opinions on how useful you found the group you were put in.

5. How will my data be used?

The information you give in the online surveys will be completely anonymous. Your anonymous contribution to this study will only be known by the research team and will be kept safe and secure. Once we have finished the study, we will analyse the results and write up reports about what we find. These reports may be published in academic journals and talked about at conferences. No one will be able to tell who you are from the information you have given us. Anonymous, electronic information will be made available through open access publishing and data sharing and may be used by other researchers via a data repository e.g., Dryad.

Focus groups will be audio recorded and transcribed (this means that we will write up a paper version of your audio recording). The anonymous transcript will then be analysed and prepared to be published in peer-reviewed journals and conferences. On request, you can also ask for a copy of your anonymous focus group transcript if you would like. When we transcribe focus groups, you and anyone else you may mention in the focus group will be given a fake name so that no one will be able to tell who you are from the information you have given us. This is called anonymization.

All information related to this study will be stored on a University of Liverpool secured computer servers, which can only be accessed via a secure password from the research team. Your identifiable data, that is your consent form and contact details will be stored securely and separately from all other study information and will not be made available for re-use. This information will also be stored safely and securely and will only be available to the named research team. Identifiable data will be destroyed at the point of study completion (when the findings have been written up as a report and/or journal articles).

Under UK data protection legislation, the University of Liverpool is responsible for personal data collected as part of the University's research. The Principal Investigator, Dr Vicky Fallon, acts as the Data Processor for this study. Any questions about how your data is being handled can be sent to her at: vfallon@liverpool.ac.uk.

Further information on how your data will be used can be found in the table below.

How will my data be collected?	Focus groups will be held over Zoom and will be audio recorded. Surveys will be completed online and sent via email links.
How will my data be stored?	Anonymized data will be made available through open access publishing and data sharing and may be used by other researchers via a data repository e.g., Dryad.
How long will my data be stored for?	Identifiable information will be destroyed at the point of study completion i.e., when results have been written as a report and/or journal article manuscript.

	Anonymous, electronic information will be made available through open access publishing and data sharing and may be used by other researchers via a data repository e.g., Dryad.
What measures are in place to protect the security and confidentiality of my data?	All study information will be stored on secure University of Liverpool computer servers and will be kept in password protected folders, only available to the research team. You are given a fake name when you agree to take part in this study, so no one will be able to tell who you are from the information you give us in this study. Identifiable information i.e., consent forms and contact details, will be stored securely and separately from all other study documents and will be destroyed when the study is complete.
Will my data be anonymised?	Your data will be fully anonymous when you agree to take part in this study.
How will my data be used?	Anonymised data may be used in peer reviewed publications and conference presentations.
Who will have access to my data?	Members of the research team, only.
Will my data be archived for use in other research projects in the future?	Anonymous contributions to this study will be made available to other researchers through open access publishing and data sharing and may be used by other researchers via a data repository e.g., Dryad.
How will my data be destroyed?	Files will be destroyed at the end of the 10-year storage, using software designed to destroy all information from a device.

6. Are there any risks in taking part?

Some people might find questions about negative mood, experiences of infant colic, reflux, and/or cow's milk protein allergy, and evaluating care upsetting. If you feel that answering questions about these topics would be too distressing, we advise you not to take part. Sensitive questions will have a "prefer not to say" option which you can tick if you wish. Other sections of the survey which have sensitive items can be skipped if you would like. You are also reminded that if at any point you should experience any discomfort or disadvantage as part of the research that you are free to withdraw without giving a reason and without it affecting your access to or quality of usual healthcare. During the study you may stop taking part by closing the survey. Responses to questions you have completed up until this point will be included in analysis. This is because you being given a fake name will mean that no one will be able to tell who you are from the information you have given us. If you are unhappy with any aspect of the study, please feel free to contact the research team and we will try to help. The research team are not clinically trained and cannot provide therapeutic help or support if you experience distress. There are contact details for UK support agencies in the participant debrief which we advise you to access if you feel like you may need additional support. If you think that you may become distressed, then we urge you to consider whether you wish to take part. You can choose not to answer any question that you feel uncomfortable with.

We recognise that answering questions in the focus group about your baby's symptoms and your mental health can be sensitive and may cause distress. If you feel that answering questions about these topics would be too distressing, we advise you not to take part. You can choose not to answer any question that you feel uncomfortable with. The research team cannot provide mental health advice but will signpost you to relevant support services if you feel like you need additional support. We have arrangements in place to support you in the unfortunate event that you become distressed during the group sessions or focus group, with a moderating member of the research present so that if you become upset, you can be put into a Zoom breakout room with a member of the research team.

If you become distressed at any point during the course of the study, then please contact the principal investigator or research team. We will then decide together whether you would like to continue with the study or not. If you would like, a courtesy call will then be made in a days' time to check in to see how you are feeling.

If you mention something during the course of the study which makes the researcher think that you or someone else may be at risk of harm, then the researcher may need to break confidentiality and to inform relevant members of authority so an appropriate course of action can be taken. There is only a duty to disclose confidential information if there is a risk of harm.

Due to the sensitive nature of topics covered in group sessions, focus groups, and in the parenting WhatsApp group, anything discussed during the study should be treated as confidential and not discussed outside of the study setting. This is to protect your identity, and the identities of the other caregivers in this study. Although the greatest efforts have been made to encourage everyone to maintain confidentiality, this cannot be completely guaranteed. Because of this, if there is anything that you think you might find particularly sensitive and/or distressing to share publicly, we urge you to consider whether you would feel comfortable sharing that information or not. How much or how little you contribute to this study is completely up to you and will not affect your access to or quality of your usual healthcare.

Part of this study will mean you being added to a WhatsApp group with the other caregivers who have been put into the peer support group intervention. To take part in this study, you need to agree not to break the WhatsApp group ground rules: be respectful and sensitive to one another's experiences and choices, avoid passing judgement about feeding, sleep, and parenting practices, no hate/bullying/discrimination in any form, no multi-level marketing or direct sales posts, and no posting to provide medical advice (any medical concerns and/or questions should be directed to your usual healthcare provider). These ground rules are in place to make sure everyone feels safe and happy in the WhatsApp group. You will be reminded of these ground rules in the first group session. If you break a ground rule, you will be warned by the moderating member of the research team via telephone call, and repeated instances of breaking ground rules may lead to your involvement in the current study ending early.

7. Are there any benefits in taking part?

We hope that you will feel more confident in managing your baby's colic, reflux, and/or cow's milk protein allergy as a result of taking part in this study.

8. What will happen to the results of the study?

We aim to publish the results of this study in peer-reviewed academic journals and conferences. At the end of the seven weeks that you have taken part in this study, you can indicate if you would like to receive a summary of the study findings and/or a copy of the final written report(s) for this study.

9. What will happen if I want to stop taking part?

You can stop taking part at any time if you want, without explanation. We will include the information that you have given us up until the point that you withdraw, in analysis. This is because you will be given a fake name after you have given consent, so it will not be possible to tell which information is yours. If you would like to withdraw your participation then please contact the principal investigator, Dr Vicky Fallon at vfallon@liverpool.ac.uk.

10. Disclosure of criminal activity

In the event that disclosure of criminal activity is revealed during the study then confidentiality may need to be broken to inform relevant members of authority.

11. What if I am unhappy or there is a problem?

If you are unhappy, or if there is a problem, please feel free to let us know by contacting Dr Vicky Fallon at vfallon@liverpool.ac.uk. If you remain unhappy or have a complaint which you feel you cannot come to us with then you should contact the Research Governance Officer on 0151 794 8290 (ethics@liv.ac.uk). When contacting the Research Governance Officer, please provide details of the name or description of the study (so that it can be identified), the researcher(s) involved, and the details of the complaint you wish to make. Participants taking part in a University of Liverpool ethically approved study will have cover.

The University strives to maintain the highest standards of rigour in the processing of your data. However, if you have any concerns about the way in which the University processes your personal data, it is important that you are aware of your right to lodge a complaint with the Information Commissioner's Office by calling 0303 123 1113.

If you have any concerns or questions about Alder Hey Children's NHS Foundation Trust, you can also contact the Patient Advice and Liaison Service (PALS) via telephone: 151 252 5374 or 0151 282 4907, online: https://www.alderhey.nhs.uk/parents-and-patients/feedback/pals, or by post: PALS, Alder Hey Children's NHS Foundation Trust, Eaton Road, Liverpool L12 2AP.

12. Who can I contact if I have further questions?

Please contact the research team with any questions you may have:

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