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

Staff evaluation, Information Sheet

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You are being invited to take part in a staff evaluation of the current 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. 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).

2. Why have I been chosen to take part?

You have been invited to take part in the staff evaluation focus group because you are a member of the research team who was involved in administering treatment as usual or an intervention (music intervention, peer support, or health education) associated with the current study, meaning that you will have first-hand experience of what worked well, and what needs improvement with the current study.

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. Only Liverpool researchers and the research lead for Alder Hey Children's NHS Foundation Trust (Dr Francine Verhoeff) will have access to the focus group transcript to make sure that no colleagues outside of those also in this focus group will know your thoughts and opinions about this study.

4. What will happen if I take part?

If you agree to take part, you will take part in a focus group with the other member(s) of staff that you have been working with in the current study to delivery treatment as usual and/or an intervention arm (music, peer support, or health education). During the focus group you will be asked about why you decided to take part in this study, how you have found taking part in this study, how you have found delivering the intervention, and what impact (if any) it has had on you and the families that you have worked with during this study. There are no right or wrong answers, and you will not be judged based on what you say. Everything that you say during the focus group will be kept confidential and will only be used for the purpose of evaluating and improving the current study. The information that you give during the focus group will not be used for any other purpose.

5. How will my data be used?

The focus group discussion will be audio recorded using a Dictaphone and then will be written up in a word document (called transcription) two weeks after the focus group. At this point the audio recording will be destroyed. 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.

To protect the privacy of the other members of the research team in the focus group, it will not be possible to request a copy of the anonymised transcript after the focus group has taken place. The anonymized transcripts will be used to evaluate and improve the quality and accuracy of this intervention study. The information you provide for this study will not be used for any other purpose.

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. The focus group data will only be accessible to University of Liverpool members of the research team, and to the lead researcher from Alder Hey Children's NHS Foundation Trust (Dr Francine Verhoeff). This is to minimize the number of research team members who have access to the thoughts and opinions expressed by Alder Hey staff members, to optimize participant confidentiality. Anonymous data associated with this focus group will be destroyed at the point of study completion (when the findings have been written up as a report and/or used to evaluate study acceptability and feasibility for journal article publication).

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.
How will my data be stored?	Anonymized data will be destroyed at the point of study completion (when the findings have been written up as a report and/or used to evaluate study acceptability and feasibility for journal article publication).

How long will my data be stored for?	No identifiable information will be recorded for staff evaluation focus groups. Anonymous, electronic information will be destroyed at the point of study completion (when the findings have been written up as a report and/or used to evaluate study acceptability and feasibility for journal article publication).
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 University of Liverpool members of the research team, and to the lead researcher from Alder Hey Children's NHS Foundation Trust (Dr Francine Verhoeff). No identifiable information will be recorded for staff evaluation focus groups. During focus group transcription, pseudonyms will replace your name and the names of anyone else mentioned during the focus group. To protect the privacy of the other members of the research team in the focus group, it will not be possible to request a copy of the anonymised transcript after the focus group has taken place. The anonymized transcripts will only be used to evaluate and improve the quality and accuracy of this intervention study. The focus group data will only be accessible to University of Liverpool members of the research team, and to the lead researcher from Alder Hey Children's NHS Foundation Trust (Dr Francine Verhoeff). This is to minimize the number of research team members who have access to the thoughts and opinions expressed by Alder Hey staff members, to optimize participant confidentiality.
Will my data be anonymised?	Due to staff involvement in the administering of the current study, it will not be possible to completely anonymize focus group data. Pseudonyms will be used during transcription to replace the names of the focus group members and anyone else that might be mentioned during the focus group.
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?	University of Liverpool members of the research team, and to the lead researcher from Alder Hey Children's NHS Foundation Trust (Dr Francine Verhoeff), only.
Will my data be archived for use in other research projects in the future?	Anonymous data associated with this focus group will be destroyed at the point of study completion (when the findings have been written up as a report and/or used to evaluate study acceptability and feasibility for journal article publication).
How will my data be destroyed?	Files will be destroyed using software designed to destroy all information from a device.

6. Are there any risks in taking part?

There are no anticipated risks of taking part in the current staff focus group. In the unlikely event that you become distressed during the focus group, arrangements have been put in place to support you, 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, then please contact the 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. The research team cannot provide mental health advice but will signpost you to relevant support services if you feel like you might benefit from receiving additional support.

We recognise that answering questions about treatment as usual and intervention delivery might be potentially sensitive in your professional context. 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. Procedures have also been put in place to limit the number of staff members who will have access to the information you provide during the focus group, to limit the use made of the information you provide, and to limit the storage length for the information you provide during these focus groups. Additionally, pseudonyms will be used to replace yours and the names of others during the transcription process, to protect your identity.

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.

Anything discussed during the focus group 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 members of the research team 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 focus group is completely up to you.

7. Are there any benefits in taking part?

There are no anticipated benefits of taking part in the current study. We hope that taking part in this focus group will improve the quality of the current study for scaling up. Broadly, we hope that taking part in this study will address a key problem faced by Alder Hey Children's NHS Foundation Trust – there has been a year-on-year increase in attendance of unsettled babies with feeding difficulties recorded in both emergency department and secondary care outpatient clinics, and a significant increase in cost of both medication and specialised formula in managing these conditions among clinical commissioning groups, and in primary care. This project will be able to develop cost-effective alternatives to effectively and immediately deal with these problems, which is aligned with the Alder Hey Children's NHS Foundation Trust strategic plan to reduce pressure on the emergency treatment system. Specific to the treatment as usual arm, taking part in the current study has the potential to improve the quality and patient satisfaction with treatment administered at Alder Hey Children's NHS Foundation Trust.

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. The thoughts and opinions expressed during the staff evaluation focus groups will be used by University of Liverpool members of the research team and the lead researcher from Alder Hey Children's NHS Foundation Trust (Dr Francine Verhoeff) to evaluate and improve the quality of the current study, which may be included in study publications and/or reports. Transcripts will be anonymized two weeks after the focus group has taken place (during transcription).

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 due to the group nature of the focus group interview. 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:

Dr Vicky Fallon
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