ISRCTN15349263 https://doi.org/10.1186/ISRCTN15349263

A study to explore the suitability of group online peer support, music, and health education interventions to caregivers of unsettled babies with colic, reflux, and/or cow's milk protein allergy

Submission date	Recruitment status	[_] Prospectively registered
06/08/2021	No longer recruiting	[X] Protocol
Registration date	Overall study status	[X] Statistical analysis plan
12/11/2021	Completed	[_] Results
Last Edited	Condition category	[_] Individual participant data
21/01/2025	Other	[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Infant colic, gastro-oesophageal reflux, and cow's milk protein allergy are common in the first 6 months of life. They lead infants to be irritable and unsettled, as evidenced by excessive crying, retching, pulling up knees, clenching fists and/or loose stools. These symptoms and their difficult management lead to high caregiver anxiety and stress, particularly for those less experienced and supported. The cause of infant colic and reflux is poorly understood, and treatment mainly focuses on supporting and educating caregivers. Music, health education, and peer support interventions have shown utility for instilling caregiver confidence and wellbeing. Caregivers often struggle to help seek for concerns regarding their infant's condition due to fears of being negatively judged. Online intervention delivery thus offers an opportune solution to this problem. This project is a research collaboration between the University of Liverpool and Alder Hey that offers an alternative nonmedical approach to the management of infant colic, reflux and cow's milk protein allergy. The primary research aim is to establish whether the interventions are feasible and acceptable to participants and staff, so that a full-scale trial and economic evaluation may follow. Another research aim is to explore whether music intervention, online parenting support, and health education interventions are beneficial in increasing parenting sense of competence, mother-infant bonding, decreasing depression and anxiety symptoms, and improving perceived satisfaction with healthcare professional support when compared with treatment as usual.

Who can participate?
The present study will recruit caregivers, referred to the Alder Hey infant feeding team due to difficulties with infant unsettledness due to infant colic, reflux, and cow's milk protein allergy. Infants must be younger than 6 months at the time of referral, born at >34 gestational weeks,

without known co-morbidities or evidence of faltering growth as per NICE guidance (2017). Caregivers must not have a current or historic clinical diagnosis of a serious mental health condition i.e., bipolar disorder, schizophrenia, and/or psychosis.

What does the study involve?
Treatment as usual
This will be delivered by the infant feeding specialist nurse at Alder Hey whom the caregiver has been referred to. The clinician will provide guidance, advice, and treatment as the caregiver would usually receive upon referral to Alder Hey.

Health Education Intervention
This six-week intervention will be delivered by infant feeding specialist nurses at Alder Hey who are experienced in group moderation. The overarching aim is to provide health education to improve caregiver mood and improve the management of infant's symptoms. In weeks 1-3, there will be three weekly groups, and remote sessions which will focus on the normalisation of infant behaviour, feeding management advice and soothing techniques. Each session will last 60 minutes, divided into two parts. The first part will focus on educating parents about, e.g., reflux, colic, cow's milk protein allergy, baby development and weaning. The second part will focus on providing tailored advice and guidance in the form of a moderated Q&A session. Participants will put the skills, techniques, and strategies taught into practice independently for the remaining three weeks of the intervention.

Online Peer Support Group Intervention
This six-week intervention component will be delivered by a member of the research team (LJ) and a Maternal Voices Partnership (MVP) representative. The overarching aim is to provide emotional support and social cohesion with an aim to improve social support, caregiver emotional wellbeing, and ability to cope with infant distress. In weeks 1-3, there will be three weekly sessions which will focus on introducing what peer support is and its benefits, hearing success stories from women who have had personal experience with infantile colic, reflux, and cow's milk protein allergy [MVP representative] and sharing personal experiences. Each session will last 60 minutes. An online parenting support group chat, on the WhatsApp online platform, will be set up by a member of the research team and used throughout the intervention period. Prompts will be used by the moderating member of the research team to initiate conversations and promote participation.

Music intervention
This six-week intervention will be delivered by an arts coordinator and arts psychotherapist at Alder Hey who are experienced in group moderation. The overarching aim is to guide parents in identifying and using songs of kin e.g., lullabies, to improve caregiver mood and improve management of infant's symptoms. In weeks 1-3, there will be three weekly group, remote sessions which will focus on the benefits of infant-directed singing, developing and using songs of kin e.g., lullabies to improve caregiver mood and improve management of infant's symptoms. Each session will last 60 minutes. Participants will use infant directed singing independently for the remaining three weeks of the intervention.

At the start of week 7, participants in each intervention arm will take part in a focus group to evaluate what worked well and what could be improved regarding their allocated intervention arm, for use in evaluation while scaling up the current pilot and feasibility study (intervention arms) and for service evaluation (treatment as usual arm). Throughout all 6 intervention weeks, caregivers will complete short validated measures. Study protocols for individual intervention arms may be provided upon reasonable request.

What are the possible benefits and risks of participating?
Taking part in the current study has the potential to improve caregiver self-efficacy, depression and anxiety symptomatology, and improve perceived satisfaction with healthcare professional support for caregivers managing infant colic, reflux and/or cow's milk protein allergy symptoms.

Some people might find questions about negative mood, experiences of infant colic, reflux, and /or cow's milk protein allergy, and evaluating care upsetting. We advise caregivers not to take part if they feel that discussing sensitive topics might be too distressing for them. Sensitive questions on surveys will have a "prefer not to say" response options. Participants will be frequently reminded, verbally and written, that if at any point they should experience any discomfort or disadvantage as part of the research that they are free to withdraw without giving a reason and without it affecting their access to their usual healthcare. In the unfortunate event that a caregiver becomes distressed during the study, signposting procedures have been emplaced by the research team (standard procedures for which can be provided upon reasonable request).
If a caregiver mentions something during the course of the study which makes the researcher think that they or someone else may be at immediate 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 and in the focus group, anything discussed during the study should be treated as confidential and not discussed outside of the study setting. This is to protect the identities of everyone in the focus group. 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 the caregiver thinks that they might find particularly sensitive and/or distressing to share publicly, we urge them to consider whether they would feel comfortable sharing that information or not.

Where is the study run from?
University of Liverpool (UK)

When is the study starting and how long is it expected to run for?
August 2021 to October 2022

Who is funding the study?
The Hugh Greenwood Legacy Fund for Children's Health Research, University of Liverpool (UK)

Who is the main contact?
Dr Leanne Jackson, Leanne.Jackson@liverpool.ac.uk

Study website
https://amlab.liverpool.ac.uk/studies_bit.html

Contact information

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
296579

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 296579

Study information

Scientific Title

Investigating the acceptability and feasibility of online group peer support, health education, and music interventions to caregivers of unsettled infants with colic, GOR(D), and/or CMPA: An empty trial study

Study objectives

Current study hypothesis as of 03/01/2024:
1. To determine the acceptability and feasibility of online group peer support, music, and health education interventions to caregivers of infants with colic, reflux, and/or cow's milk protein allergy, and to delivering members of the research team.
2. To explore benefit of the peer support, music, and health education interventions to caregivers in terms of parental confidence, depression, anxiety, and mother-infant bonding scores, when compared with treatment as usual.
3. To explore differences between respective intervention arms in terms, quantitatively (via psychometric measures mentioned in hypothesis two) and through qualitative exploration (via conversation analysis and thematic analysis).

Previous study hypothesis from 26/06/2023 to 03/01/2024:
1. To establish whether the detailed interventions are feasible and acceptable to participants and staff, so that a full-scale trial and economic evaluation may follow.
2. To explore whether peer support, health education, and music intervention are perceived as beneficial to perceived parenting confidence, depression, anxiety, and mother-infant bonding when compared with treatment as usual.

Original study hypothesis:
1. To establish whether the detailed interventions are feasible and acceptable to participants and staff, so that a full-scale trial and economic evaluation may follow.
2. To explore whether peer support, health education, and music intervention are perceived as beneficial in reducing infant colic and reflux symptoms and improving perceived parenting confidence, mental health (namely depression and anxiety), and caregiver–baby bonding, when compared with treatment as usual.

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. Approved 28/06/2021, University of Liverpool (4th Floor Thompson Yates Building, Faculty of Health and Life Sciences, University of Liverpool, Liverpool, L69 3GB, UK; +44 7717 863747; no email provided), ref: UoL001641
2. Approved 21/10/2021, HRA and Health and Care Research Wales (Health Research Authority, Skipton House, 80 London Road, London, SE1 6LH, UK; +44 (0)20 7972 2545; hra.approval@nhs.net), ref: 21/NW/0258
3. Approved 02/11/2021, Health Research Authority Wales (De Vere Village Hotel, 29 Pendwyallt Road, Coryton, Cardiff, CF14 7EF, United Kingdom; +44 (0)2922 940912; HCRW.approvals@wales.nhs.uk), ref: 21/NW/0258

Study design

Feasibility study

Primary study design

Interventional

Secondary study design
Non randomised study

Study setting(s)
Internet/virtual

Study type(s)
Quality of life

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Improving parenting confidence and mother-infant bonding, reducing anxiety and depression symptomatology through non-clinical, remote group interventions.

Interventions
Current interventions as of 03/01/2024:
The current study will aim to investigate the acceptability and feasibility of three non-clinical remote group interventions to support caregivers of unsettled babies with colic, GastrOesophageal Reflux [Disease] (GOR[D]), hereafter referred to as 'reflux') and/or Cow's Milk Protein Allergy (CMPA), when compared with treatment as usual. Intervention arms include music intervention, health education, and peer support. Parents who have been referred to Alder Hey Children's NHS Foundation Trust (hereafter referred to as 'Alder Hey') with infant feeding difficulties related to either/multiple of the conditions detailed above are eligible to participate.

40 participants with infants under 6 months of age at referral will be sought. Eligible caregivers will be identified and approached by staff employed by Alder Hey. Participant allocation to intervention condition will be determined opportunistically based on staff capacity. After i) 10 participants have been recruited to the given intervention arm, or ii) After 1 month of continuous recruitment efforts, the given intervention arm will run. All caregivers and infants will continue to receive treatment as usual. The decision for this is three-fold. Firstly, evidence shows that infantile colic, reflux, and cow's milk protein allergy symptoms self-resolve (Czinn & Blanchard, 2013; Wolke, Bilgen, & Samara, 2017). To maximise the potential benefit to caregivers, therefore, participants will be allocated to an intervention arm opportunistically so that the given arm can run without unnecessary delay. In this respect, infantile symptoms will be captured at a more acute stage, where the level of need is greater. The time-sensitive nature of colic, reflux, and cow's milk protein allergy symptoms means that progressing to intervention delivery swiftly is of utmost importance for influencing caregiver wellbeing outcomes.

Secondly, randomisation of participants, based on the number of referrals to Alder Hey, would result in participant recruitment taking an estimated four months to complete. Delaying study commencement for the purpose of randomisation in this way may consequently increase rates of dropout due to improved infant symptoms over time. More concerningly, delaying study commencement may increase caregiver emotional distress by means of delays to support acquirement. Pragmatic sampling is thus determined to be a more viable option for the current study, in the best interest of the target population.

Treatment as usual
This will be delivered by the infant feeding specialist team at Alder Hey whom the caregiver has

been referred to. The clinician will provide guidance, advice, and treatment as the caregiver would usually receive upon referral to Alder Hey. The participant will receive no additional intervention from the research team. All participants will receive treatment as usual.

Health Education
This 6-week intervention will be delivered by infant feeding specialists at Alder Hey who are experienced in group moderation. The overarching aim is to provide health education to improve caregiver mood by improving understanding and management of an infant's symptoms. In weeks 1-3, there will be three weekly groups, remote sessions which will focus on the normalisation of infant behaviour, feeding management advice and soothing techniques. Each session will last 60 minutes, divided into two parts. The first part will focus on educating parents about, e.g., reflux, colic, baby development and weaning. The second part will focus on providing tailored advice and guidance in the form of a moderated Q&A session. Participants will put the skills, techniques, and strategies taught into practice independently for the remaining three weeks of the intervention.

Peer Support Group
This 6-week intervention component will be delivered by a member of the research team and a Maternal Voices Partnership (MVP) representative. The overarching aim is to provide emotional support and social cohesion with an aim to improve social support, caregiver emotional well-being, and ability to cope with infant distress. In weeks 1-3, there will be three weekly sessions which will focus on introducing what peer support is and its benefits, hearing success stories from women who have had personal experience with infantile colic and reflux [MVP representative] and sharing personal experiences. Each session will last 60 minutes. An online parenting support group chat, on the WhatsApp online platform, will be set up by a member of the research team and used throughout the intervention period. Prompts will be used by the moderating member of the research team to initiate conversations and promote participation.

Music intervention
This 6-week intervention will be delivered by an arts coordinator and an arts psychotherapist at Alder Hey who are experienced in group moderation. The overarching aim is to guide parents in identifying and using songs of kin e.g., lullabies, to improve caregiver mood and improve management of the infant's symptoms. In weeks 1-3, there will be three weekly groups, remote sessions which will focus on the benefits of infant-directed singing, developing and using songs of kin e.g., lullabies to improve caregiver mood and improve management of the infant's symptoms. Each session will last 60 minutes. Participants will use infant-directed singing independently for the remaining 3 weeks of the intervention.

All intervention arms
Each intervention arm will conclude with an evaluative focus group in week seven. Here the participants will be able to discuss what they thought worked well and what could be improved with the current study.

Primary outcome measures
The primary outcome measure of this study will be perceived parenting self-efficacy, measured using pre and post-intervention administration of the Perceived Maternal Parenting Self-Efficacy (PMPSE) tool (Barnes & Adamson-Macedo, 2007). The PMPSE will be distributed in week 1 and week 6 of each intervention arm to assess change over time. The survey will be distributed to participants via email and will be created through the Qualtrics online survey platform. Full details regarding pre, post, and interim questionnaires administered for all intervention arms may be provided by the research team upon reasonable request.

Secondary outcome measures
The secondary outcomes measures include: perceptions of infant colic (ICS; Ellett et al, 2002) and /or reflux (I-GER-Q; Kleinman et al, 2006) symptoms, infant feeding method (Davie, 2018), depression symptoms (10-item Edinburgh Postnatal Depression Scale, EPDS; Cox, Holden, & Sagovsky, 1987), anxiety symptoms (16-item Postpartum Specific Anxiety Scale, PSAS; Fallon et al, 2021), and patient satisfaction with healthcare professional support (7-item Short Assessment of Patient Satisfaction, SAPS; Hawthorne et al, 2014).
The aforementioned surveys will be distributed in week 1 and week 6 of each intervention arm to assess change over time. The survey will be distributed to participants via email and will be created through the Qualtrics online survey platform. Full details of intervention arm-specific administration of pre, post, and interim questionnaires may be provided by the research team upon reasonable request.

Procedure for assessing primary and secondary outcomes
For the peer support intervention arm, participants will also be reminded about completing questionnaires in the WhatsApp group by the moderating member of the research team. All intervention arms will be reminded to complete pre, post, and interim questionnaires via email on two occasions. Questionnaire responses will be stored on the Qualtrics online platform. This anonymous data will be exported after the completion of the intervention group, for analysis on aggregate, anonymous data only.
Survey links will be completely anonymous so it will not be possible to reidentify participants from their responses. Interim questionnaires will also be distributed to participants between weeks 2-5 to assess the level and quality of engagement with the intervention arm, and to determine the perceived usefulness of content covered in each given week. Survey details can be shared on reasonable request to the PI.

Previous interventions from 26/06/2023 to 03/01/2024:
The current study is a feasibility study to assess the acceptability and feasibility of three non-clinical remote group interventions to support caregivers of unsettled babies with colic, GastrOesophageal Reflux Disease (GORD, hereafter referred to as ‘reflux’) and/or Cow's Milk Protein Allergy (CMPA), when compared with treatment as usual. Intervention arms include music intervention, health education, and peer support. Parents who had been referred to Alder Hey Children’s NHS Foundation Trust (hereafter referred to as ‘Alder Hey’) are eligible to participate.

40 participants with infants under six months of age at referral will be allocated to four conditions (10 participants in each intervention arm): music intervention, health education, peer support, and treatment as usual. All caregivers and infants will continue to receive treatment as usual.

Evidence shows that infantile colic, reflux, and cow’s milk protein allergy symptoms decline over time (Czinn & Blanchard, 2013; Wolke, Bilgen, & Samara, 2017). To maximise the potential benefit of the current study to caregivers and infants in terms of alleviating infantile symptoms and improving caregiver coping and well-being with infantile symptoms, it is imperative to capture when infantile colic and reflux symptoms are most acute and thus when the need for support is likely to be most crucial for determining infant and caregiver wellbeing outcomes. Recruiting caregivers when infantile symptoms are most acute is imperative to accurately assess whether intervention attempts are effective in improving perceived parenting confidence, reducing depression and anxiety symptomatology, and improving mother-infant bonding and satisfaction with healthcare professional support.

Randomisation of participants, based on the number of referrals to Alder Hey, would result in participant recruitment taking an estimated four months to complete. Delaying study commencement for the purpose of randomisation in this way may consequently increase rates of dropout due to improved infant symptoms over time. More concerningly, delaying study commencement may increase caregiver emotional distress in comparison with if the intervention arm were to commence sooner after recruitment, as pragmatic sampling would allow for the earlier intervention of emotional and informational support (peer support), techniques and skills (education, music) for caregivers to use outside of group sessions with their infants. Hence, commencing each intervention arm as early as possible maximises the potential to benefit caregivers and infants. This is the primary aim of the current study.

Other than the potentially confounding effects of time that recruitment delays would have on infantile symptoms for caregivers recruited earlier in the sampling process than those recruited later on as previously detailed, another issue with this strategy would be that the study would not meet the pre-determined funding deadline of April 2022.

Treatment as usual
This will be delivered by the infant feeding specialist team at Alder Hey whom the caregiver has been referred to. The clinician will provide guidance, advice, and treatment as the caregiver would usually receive upon referral to Alder Hey.

Health Education
This six-week intervention will be delivered by infant feeding specialists at Alder Hey who are experienced in group moderation. The overarching aim is to provide health education to improve caregiver mood by improving understanding and management of an infant's symptoms. In weeks 1-3, there will be three weekly groups, remote sessions which will focus on the normalisation of infant behaviour, feeding management advice and soothing techniques. Each session will last 60 minutes, divided into two parts. The first part will focus on educating parents about, e.g., reflux, colic, baby development and weaning. The second part will focus on providing tailored advice and guidance in the form of a moderated Q&A session. Participants will put the skills, techniques, and strategies taught into practice independently for the remaining three weeks of the intervention.

Peer Support Group
This six-week intervention component will be delivered by a member of the research team (LJ) and a Maternal Voices Partnership (MVP) representative. The overarching aim is to provide emotional support and social cohesion with an aim to improve social support, caregiver emotional well-being, and ability to cope with infant distress. In weeks 1-3, there will be three weekly sessions which will focus on introducing what peer support is and its benefits, hearing success stories from women who have had personal experience with infantile colic and reflux [MVP representative] and sharing personal experiences. Each session will last 60 minutes. An online parenting support group chat, on the WhatsApp online platform, will be set up by a member of the research team and used throughout the intervention period. Prompts will be used by the moderating member of the research team to initiate conversations and promote participation.

Music intervention
This six-week intervention will be delivered by an arts coordinator and an arts psychotherapist at Alder Hey who are experienced in group moderation. The overarching aim is to guide parents in identifying and using songs of kin e.g., lullabies, to improve caregiver mood and improve management of the infant's symptoms. In weeks 1-3, there will be three weekly groups, remote sessions which will focus on the benefits of infant-directed singing, developing and using songs

of kin e.g., lullabies to improve caregiver mood and improve management of the infant's symptoms. Each session will last 60 minutes. Participants will use infant-directed singing independently for the remaining three weeks of the intervention.

The primary outcome measure of this study will be perceived parenting self-efficacy, measured using pre and post-intervention administration of the Perceived Maternal Parenting Self-Efficacy (PMPSE) tool (Barnes & Adamson-Macedo, 2007). Full details regarding pre, post, and interim questionnaires administered for all intervention arms may be provided by the research team upon reasonable request. All pre, post, and interim questionnaires will be set up on the Qualtrics online platform and will be administered via anonymous links to the participant's email address. For the peer support intervention arm, participants will also be reminded about completing questionnaires in the WhatsApp group by the moderating member of the research team. All intervention arms will be reminded to complete pre, post, and interim questionnaires via email. Questionnaire responses will be stored on the Qualtrics online platform. This anonymous data will be exported after the completion of the intervention group, for analysis on aggregate, anonymous data only.

The secondary outcomes measures include: perceptions of infant colic (ICS; Ellett et al, 2002) and /or reflux (I-GER-Q; Kleinman et al, 2006) symptoms, infant feeding method (Davie, 2018), depression symptoms (10-item Edinburgh Postnatal Depression Scale, EPDS; Cox, Holden, & Sagovsky, 1987), anxiety symptoms (16-item Postpartum Specific Anxiety Scale, PSAS; Fallon et al, 2021), and patient satisfaction with healthcare professional support (7 item Short Assessment of Patient Satisfaction, SAPS; Hawthorne et al, 2014). Full details of intervention arm-specific administration of pre, post, and interim questionnaires may be provided by the research team upon reasonable request.

After the participant's involvement in the 6-week intervention, all caregivers in each intervention arm will take part in a focus group evaluation of the study where they will be able to discuss what they thought worked well and what could be improved with the current study, for feasibility and acceptability assessment for scaling up the current intervention. During these audio-recorded conversations, the caregivers in each intervention arm will have the opportunity to talk about whether they found the time that they started taking part in the current study i.e., if they felt it was at a time when they felt they would benefit from having extra support (if no, if they would have liked for their involvement to have started sooner/later).

Based on the feedback received, sampling timing and/or method will be evaluated as part of the feasibility and acceptability assessment for the study scale-up.

Original interventions:
The current study is a pilot and feasibility study to assess the feasibility and acceptability of three non-medical remote group interventions to support caregivers of unsettled babies with colic and/or GastrOesophageal Reflux Disease (GORD, hereafter referred to as 'reflux'), who had been referred to Alder Hey Children's NHS Foundation Trust (hereafter referred to as 'Alder Hey'). Intervention arms include music intervention, health education, and peer support. The acceptability and benefits of these arms will be compared to treatment as usual.

40 participants with infants under six months of age at referral will be allocated to four conditions (10 participants in each intervention arm): music intervention, health education, peer support, and treatment as usual. All caregivers and infants will continue to receive treatment as usual.

Evidence shows that infantile colic, reflux, and cow's milk protein allergy symptoms decline over time (Czinn & Blanchard, 2013; Wolke, Bilgen, & Samara, 2017). To maximise the potential benefit of the current study to caregivers and infants in terms of alleviating infantile symptoms and in improving caregiver coping and wellbeing with infantile symptoms, it is imperative to capture when infantile colic and reflux symptoms are most acute and thus when need for support is likely to be most crucial for determining infant and caregiver wellbeing outcomes. Recruiting caregivers when infantile symptoms are most acute is imperative to accurately assess whether intervention attempts are effective in reducing perceived severity of infant colic and reflux symptoms, improving perceived parenting confidence, mental health (namely depression and anxiety), and caregiver–baby bonding, for feasibility and acceptability assessment for study scaling up and larger scale implementation in clinical settings.

Randomisation of participants, based on the number of referrals to Alder Hey, would result in participant recruitment taking an estimated four months to complete. Delaying study commencement for the purpose of randomisation in this way may consequently increase rates of drop out due to improved infant symptoms over time. More concerningly, delaying study commencement may increase caregiver emotional distress in comparison with if the intervention arm were to commence sooner after recruitment, as pragmatic sampling would allow for earlier intervention of emotional and informational support (peer support), techniques and skills (education, music) for caregivers to use outside of group sessions with their infants. Hence, commencing each intervention arm as early as possible maximises the potential to benefit caregivers and infants. This is the primary aim of the current study.

Other than the potentially confounding effects of time that recruitment delays would have on infantile symptoms for caregivers recruited earlier in the sampling process than those recruited later on as previously detailed, another issue with this strategy would be that the study would not meet the pre-determined funding deadline of April 2022.

Treatment as usual
This will be delivered by the infant feeding specialist team at Alder Hey whom the caregiver has been referred to. The clinician will provide guidance, advice, and treatment as the caregiver would usually receive upon referral to Alder Hey.

Health Education
This six-week intervention will be delivered by infant feeding specialists at Alder Hey who are experienced in group moderation. The overarching aim is to provide health education to improve caregiver mood by improving understanding and management of infant's symptoms. In weeks 1-3, there will be three weekly group, remote sessions which will focus on normalisation of infant behaviour, feeding management advice and soothing techniques. Each session will last 60 minutes, divided in two parts. The first part will focus on educating parents about, e.g., reflux, colic, baby development and weaning. The second part will focus on providing tailored advice and guidance in the form of a moderated Q&A session. Participants will put the skills, techniques, and strategies taught into practice independently for the remaining three weeks of the intervention.

Peer Support Group
This six-week intervention component will be delivered by a member of the research team (LJ) and a Maternal Voices Partnership (MVP) representative. The overarching aim is to provide emotional support and social cohesion with an aim to improve social support, caregiver emotional wellbeing, and ability to cope with infant distress. In weeks 1-3, there will be three weekly sessions which will focus on introducing what peer support is and its benefits, hearing success stories from women who have had personal experience with infantile colic and reflux

[MVP representative] and sharing personal experiences. Each session will last 60 minutes. An online parenting support group chat, on the WhatsApp online platform, will be set up by a member of the research team and used throughout the intervention period. Prompts will be used by the moderating member of the research team to initiate conversations and promote participation.

Music intervention
This six-week intervention will be delivered by an arts coordinator and arts psychotherapist at Alder Hey who are experienced in group moderation. The overarching aim is to guide parents in identifying and using songs of kin e.g., lullabies, to improve caregiver mood and improve management of infant's symptoms. In weeks 1-3, there will be three weekly group, remote sessions which will focus on the benefits of infant-directed singing, developing and using songs of kin e.g., lullabies to improve caregiver mood and improve management of infant's symptoms. Each session will last 60 minutes. Participants will use infant directed singing independently for the remaining three weeks of the intervention.

The primary outcome measure of this study will be perceived parenting self-efficacy, measured using pre and post intervention administration of the Perceived Maternal Parenting Self-Efficacy (PMPSE) tool (Barnes & Adamson-Macedo, 2007). Full details regarding pre, post, and interim questionnaires administered for all intervention arms may be provided by the research team upon reasonable request. All pre, post, and interim questionnaires will be set up on the Qualtrics online platform and will be administered via anonymous links to the participant's email address. For the peer support intervention arm, participants will also be reminded about completing questionnaires in the WhatsApp group by the moderating member of the research team. All intervention arms will be reminded to complete pre, post, and interim questionnaires via email. Questionnaire responses will be stored on the Qualtrics online platform. This anonymous data will be exported after the completion of the intervention group, for analysis on aggregate, anonymous data only.

The secondary outcomes measures include: perceptions of infant colic (ICS; Ellett et al, 2002) and /or reflux (I-GER-Q; Kleinman et al, 2006) symptoms, infant feeding method (Davie, 2018), depression symptoms (10-item Edinburgh Postnatal Depression Scale, EPDS; Cox, Holden, & Sagovsky, 1987), anxiety symptoms (16-item Postpartum Specific Anxiety Scale, PSAS; Fallon et al, 2021), and patient satisfaction with healthcare professional support (7 item Short Assessment of Patient Satisfaction, SAPS; Hawthorne et al, 2014). Full details of intervention arm specific administration of pre, post, and interim questionnaires may be provided by the research team upon reasonable request.

After the participant's involvement in the 6-week intervention, all caregivers in each intervention arm will take part in a focus group evaluation of the study where they will be able to discuss what they thought worked well and what could be improved with the current study, for feasibility and acceptability assessment for scaling up the current intervention. During these audio recorded conversations the caregivers in each intervention arm will have the opportunity to talk about whether they found the time that they started taking part in the current study i.e., if they felt it was at a time where they felt they would benefit from having extra support (if no, if they would have liked for their involvement to have started sooner/later).

Based on the feedback received, sampling timing and/or method will be evaluated as part of feasibility and acceptability assessment for study scale-up.

Intervention Type
Behavioural

Primary outcome measure
Perceived parenting self-efficacy, measured using pre and post intervention administration of the Perceived Maternal Parenting Self-Efficacy (PMPSE) tool (Barnes & Adamson-Macedo, 2007). This measure will be administered before, and after the participant's 6 week involvement in the current intervention study.

Secondary outcome measures
Current secondary outcome measures as of 26/06/2023:
Measured before and after the participant's 6-week involvement in the current study:
1. Infant feeding method (Davie, 2018)
2. Depression symptoms (10-item Edinburgh Postnatal Depression Scale, EPDS; Cox, Holden, & Sagovsky, 1987)
3. Anxiety symptoms (16-item Postpartum Specific Anxiety Scale, PSAS; Fallon et al, 2021)
4. Patient satisfaction with healthcare professional support (7-item Short Assessment of Patient Satisfaction, SAPS; Hawthorne et al, 2014). All aforementioned measures will be administered
5. Each intervention arm will also assess adherence and satisfaction with the intervention to which they had been allocated on an interim, weekly basis during the six-week intervention period using bespoke questionnaires

Previous secondary outcome measures:
Measured before and after the participant's 6 week involvement in the current study:
1. Perceptions of infant colic (ICS; Ellett et al, 2002) and/or reflux (I-GER-Q; Kleinman et al, 2006) symptoms
2. Infant feeding method (Davie, 2018)
3. Depression symptoms (10-item Edinburgh Postnatal Depression Scale, EPDS; Cox, Holden, & Sagovsky, 1987)
4. Anxiety symptoms (16-item Postpartum Specific Anxiety Scale, PSAS; Fallon et al, 2021)
5. Patient satisfaction with healthcare professional support (7 item Short Assessment of Patient Satisfaction, SAPS; Hawthorne et al, 2014). All aforementioned measures will be administered
6. Each intervention arm will also assess adherence and satisfaction with the intervention to which they had been allocated on an interim, weekly basis during the six-week intervention period using bespoke questionnaires

Overall study start date
06/08/2021

Completion date
17/10/2022

Eligibility

Key inclusion criteria
Current participant inclusion criteria as of 26/06/2023:
1. Caregivers of babies referred to Alder Hey infant feeding team for infant feeding difficulties due to unsettledness relating to infant colic, reflux, and/or cow’s milk protein allergy.
2. Infant age must be younger than 6 months at time of referral, born at >34 gestational weeks, without known co-morbidities or evidence of faltering growth as per NICE guidance (2017)
3. Caregivers must not have a current or historic clinical diagnosis of a serious mental health condition i.e., bipolar disorder, schizophrenia, and/or psychosis.

Previous participant inclusion criteria:
1. Caregivers of babies referred to Alder Hey for infant colic, reflux, and/or cow's milk protein allergy with infants younger than 6 months at time of referral, born at >34 gestational weeks, without known co-morbidities or evidence of faltering growth as per NICE guidance (2017)
2. Caregivers must not have a current or historic clinical diagnosis of a serious mental health condition i.e., bipolar disorder, schizophrenia, and/or psychosis.

Participant type(s)
Carer, Service user

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
40

Total final enrolment
7

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
30/10/2021

Date of final enrolment
05/10/2022

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Alder Hey Children's Hospital
Alder Hey Children's NHS Foundation Trust
Eaton Road
Liverpool
United Kingdom
L12 2AP

Sponsor information

Organisation
University of Liverpool

Sponsor details
4th Floor Thompson Yates Building
Faculty of Health and Life Sciences
Liverpool
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L69 3GB
+44 (0)151 794 8339
sponsor@liverpool.ac.uk

Sponsor type
University/education

Website
http://www.liv.ac.uk/

ROR
https://ror.org/04xs57h96

Funder(s)

Funder type
University/education

Funder Name
Hugh Greenwood Legacy Fund for Children’s Health Research, The University of Liverpool

Funder Name
University of Liverpool

Alternative Name(s)
The University of Liverpool, , Universidad de Liverpool, UoL

Funding Body Type
Government organisation

Funding Body Subtype

Universities (academic only)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Current publication and dissemination plan as of 27/11/2024:
Study findings have been shared with the clinical team at Alder Hey in the form of a 2-page summary document, which has been fed into a service AUDIT at the hospital. For this, a thematic analysis was conducted on TAU focus group data. LJ will attend Alder Hey to disseminate study findings to the clinical team, also (awaiting correspondence from the principal investigator regarding a suitable date for this).

The current study was submitted to Sage Digital Health (20/08/2024) and was rejected on 12/11/2024. However, the manuscript has been transferred via SAGE Path to an appropriate sister journal (pending allocation from three suitable, selected journals).

No identifiable information will be shared during the dissemination of the current study.

Previous publication and dissemination plan as of 03/01/2024:
The named authors intend to disseminate current study findings in the form of a written report for clinical practice at Alder Hey. For this, a thematic analysis will be conducted on the treatment as usual evaluative focus group to form an AUDIT for Alder Hey service provision. Additionally, the named authors intend to disseminate findings in manuscripts for submission to relevant journal articles and intend to present findings at relevant conferences. No identifiable information will be released in any written reports or publications associated with the current study, as participants will be assigned pseudonyms immediately after providing electronic consent (qualitative), so that no one will be able to tell who the participants are from the information that they share during the focus group.

Previous publication and dissemination plan:
The named authors intend to disseminate current study findings in the form of a written report for clinical practice at Alder Hey. Additionally, the named authors intend to disseminate findings in manuscripts for submission to relevant journal articles and intend to present findings at relevant conferences. No identifiable information will be released in any written reports or publications associated with the current study, as analysis will be performed on aggregate data only (quantitative) and participants will be assigned pseudonyms immediately after providing electronic consent (qualitative).

Intention to publish date
31/05/2025

Individual participant data (IPD) sharing plan
Current IPD sharing statement as of 03/01/2024:
Due to unanticipated, exceptionally low levels of recruitment, anonymised quantitative data will not be made publicly available for re-use. No participants completed any of the pre-, post-, or interim questionnaires. Furthermore, part-completed surveys had exceptionally high levels of

missingness. In light of this knowledge, the potential benefit of anonymised quantitative data is limited. The anonymised WhatsApp group transcript will be made publicly available pen-access publishing and data sharing from the University of Liverpool Repository, through Liverpool Research Data: https://livrepository.liverpool.ac.uk/. This is in accordance with the University of Liverpool Open Access Publication Policy, and in line with the Research Excellence Framework policy. WhatsApp group data spanned all 7 weeks of the peer support intervention and is likely to offer novel insights into the lived experiences of parenting a child with colic, GOR(D), and/or cow's milk protein allergy. The anonymised evaluative focus groups will also be made publicly available by the same means. These data will be made publicly available from the anticipated study endpoint (defined as when study findings have been published in a relevant journal) i.e. 31 /01/2025.

Previous IPD sharing statement from 26/06/2023 to 03/01/2024:
The final anonymised dataset will be stored in a publicly available repository. Anonymised focus group and WhatsApp transcripts will also be made available via open-access publishing and data sharing from the University of Liverpool Repository, through Liverpool Research Data: https://livrepository.liverpool.ac.uk/. This is in accordance with the University of Liverpool Open Access Publication Policy, and in line with the Research Excellence Framework policy. These data will be made available from the anticipated study endpoint (defined as when study findings have been published in a relevant journal) i.e. 15 December 2023.

Previous IPD sharing statement:
The datasets generated during and/or analysed during the current study will be stored in a publicly available repository. The final anonymised dataset and anonymised qualitative transcripts will be made available via open-access publishing and data sharing from the University of Liverpool Repository, through Liverpool Research Data: https://livrepository. liverpool.ac.uk/. This is in accordance with the University of Liverpool Open Access Publication Policy, and in line with the Research Excellence Framework policy. This data will be made available from the anticipated study endpoint i.e. 15 April 2022.

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Health education intervention version 1.2	15/04/2021	25/08 /2021	No	Yes
Participant information sheet	Music intervention version 1.3	15/04/2021	25/08 /2021	No	Yes
Participant information sheet	Peer support group intervention version 1.3	15/04/2021	25/08 /2021	No	Yes
Participant information sheet	Staff evaluation version 1.3	15/04/2021	25/08 /2021	No	Yes
Participant information sheet	Treatment as usual (TAU) version 1.1	15/04/2021	25/08 /2021	No	Yes
Protocol file	version 1	15/04/2021	25/08 /2021	No	No

Statistical Analysis Plan	23/06/2023	No	No
HRA research summary	28/06/2023	No	No