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Investigating the acceptability and feasibility of three online interventions, for caregivers of infants with feeding difficulties.

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Abstract:	Introduction: Colic, Gastro-Oesophageal Reflux (Disorder; GOR[D]) and Cow's Milk Protein Allergy (CMPA) are common infantile afflictions in the first six months of life. These conditions are associated with high levels of infant irritability, prescription costs, and poor caregiver wellbeing. For other perinatal mental health concerns e.g., postpartum depression, peer support, music, and health education have been identified as effective interventions for nurturing caregiver wellbeing. However, these interventions have yet to be piloted in an online delivery format, among caregivers of infants diagnosed with colic, GOR(D), and CMPA. The current study aimed to determine the acceptability and feasibility of a non-clinical peer support, health education, and music intervention to caregivers of infants with colic, GOR(D), and CMPA, when compared with treatment as usual. Methods: Eligible caregivers were recruited during routine appointments with the infant feeding team at Alder Hey Children's NHS Foundation Trust. Consenting caregivers were assigned to one of the four intervention arms. For peer support only, a WhatsApp group accompanied group sessions. Intervention weeks 1-3 involved a one-hour online group session, where skills were developed with an aim to improve management of infantile symptoms, and to nurture self-care practices. In weeks 4-6, participants were encouraged to use skills obtained from weeks 1-3, independently. In week 7, evaluative focus groups were conducted. WhatsApp group data underwent conversational analysis and evaluative focus group data underwent thematic analysis. Results: Feasibility was not achieved due to recruitment difficulties. However, the peer support intervention was deemed acceptable by mothers and staff. Peer support participants valued the flexibility access to support via WhatsApp with other mothers with shared life experience. Conclusion: Evaluative focus groups identified study strengths and limitations which will provide insight to digital health researchers seeking to develop interventional research for caregivers of infants afflicted with colic, GOR(D), and/or CMPA.

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Methods

Eligible caregivers were recruited during routine appointments with the infant feeding team at Alder Hey Children's NHS Foundation Trust. Consenting caregivers were assigned to one of the four intervention arms. For peer support only, a WhatsApp group accompanied group sessions. Intervention weeks 1-3 involved a one-hour online group session, where skills were developed with an aim to improve management of infantile symptoms, and to nurture self-care practices. In weeks 4-6, participants were encouraged to use skills obtained from weeks 1-3, independently. In week 7, evaluative focus groups were conducted. WhatsApp group data underwent conversational analysis and evaluative focus group data underwent thematic analysis.

Results

Feasibility was not achieved due to recruitment difficulties. However, the peer support intervention was deemed acceptable by mothers and staff. Peer support participants valued the flexibility access to support via WhatsApp with other mothers with shared life experience.

Conclusion

Evaluative focus groups identified study strengths and limitations which will provide insight to digital health researchers seeking to develop interventional research for caregivers of infants afflicted with colic, GOR(D), and/or CMPA.

Keywords: Colic, Milk hypersensitivity, Gastroesophageal Reflux, Pilot Projects, Self-care, Caregivers, Maternal Health.

1. Introduction

Infant colic (hereafter referred to as 'colic') is defined as full force crying for at least three hours per day, on at least three days per week, for three continuous weeks or more[1]. Cow's Milk Protein Allergy (CMPA) is a common food allergy in infancy which is described as a reproducible, adverse reaction to one or more cow's milk protein(s)[2]. Reaction severity differs and may manifest with skin, respiratory, and/or gastrointestinal symptoms e.g., eczema, rhinitis, vomiting, or loose stools[3]. Gastro-oesophageal reflux (GOR) is when stomach acid flows back up the oesophagus: it is a normal physiological process which can occur after eating and affects healthy individuals of all ages[4]. When GOR causes troublesome symptoms or complications, e.g., regurgitation of milk, it is referred to as GOR(D)[5].

Colic, GOR(D), and CMPA are common in the first six months of life[6-8] and are associated with high levels of infant irritability and, in the cases of colic and CMPA, unsettledness[9]. Infants with these conditions have high rates of hospital attendances and prescription costs of medication(s) and of special formula milk(s). Furthermore, colic, GOR(D), and CMPA symptoms are often overlapping or comorbid, rendering accurate diagnosis arduous and time-consuming[10]. Lengthy treatment pathways contribute to experiences of high parental anxiety and stress; frustration, poor self-efficacy; and poor sleep quality commonly observed among caregivers of infants who are affected by these conditions[11-13]. Caregiver wellbeing may also suffer due to the conflicting messages and inconsistent information provided by healthcare professionals regarding treatment options e.g., one healthcare practitioner may recommend a particular brand of specialis milk to aid in managing infantile symptoms, which may be then discouraged in a later appointment by a different healthcare practitioner[14]. Since Colic, CMPA, and GOR(D) symptoms usually self-resolve, interventions have traditionally focused on promoting parental coping and infantile symptom management.

Infant irritability in public e.g., full-force crying, is perceived negatively by the general public[15]. Additionally, new parents also frequently report concerns that one's inability to settle their infant when they are distressed may depict them as an inadequate mother[14]. Such concerns are especially pronounced among babies who have colic, reflux, and CMPA[1]. This stigmatisation can result in help-seeking avoidance among caregivers for their baby's condition, due to fears of receiving negative judgement from others[16]. This manifests in an overreliance on emergency services, once infantile symptoms have become especially acute[17]. Delivering caregiver support online offers an opportune solution[18-19]. Specifically, peer support[20], health education[21], and music interventions[22] have been significantly associated with improved maternal wellbeing and perceived infant settledness. Likewise, WhatsApp groups have proven fruitful when used in postnatal interventions[23]. To the authors' knowledge, however, there have been no attempts to investigate the respective feasibility and acceptability of peer support, health education, and music interventions in a single study. Additionally, no previous research has investigated the potential benefit of these respective interventions to a population of caregivers with unsettled infants due to colic, GOR(D), and/or CMPA, when delivered in an online group format.

An empty trial refers to a study which contains exceptionally high dropout rates, which has hindered ability to evaluate intervention arms[24]. Reporting unfeasible and unsuccessful research holds as much academic merit as successful trials[25]. Certainly, transparent reporting is the cornerstone of quality scientific reporting[26]. This argument, too, has been corroborated by the Strengthening The Reporting of Observational studies in Epidemiology (STROBE) guidelines for experimental trials[26]. For example, reporting on reasons for drop-out at each stage of study conduct allows important comparisons to be made between non-participants and participants, which can benefit future research endeavours[27].

Manuscripts yielding significant findings are more likely to be accepted for publication, are published more quickly, and in higher impact journals when compared with research reporting unconventional or null findings[28]. Issues pertaining to publication bias in this manner have diminished confidence in conclusions drawn from interventional research, due to overstated and inflated positive reporting[29]. Empty trials can offer important insights when designing interventions, by reflecting on and avoiding unsuccessful practices. To illustrate this point, common barriers to participant retention in feasibility research include cumbersome time commitments (e.g., having many follow-up sessions) and recruiting from sensitive populations (e.g., caregivers of infants experiencing colic)[30]. The current study is considered an empty trial due to the low final sample size of seven participants, of a desired final sample of forty participants.

1.4 The current study

The current study aimed to determine the acceptability and feasibility of an online, group: peer support, health education, and music intervention to caregivers of unsettled infants with colic, GOR(D), and/or CMPA, when compared with treatment as usual. A mixed-methods approach was adopted to address this overarching aim. Firstly, psychometric measures distributed pre- and post- intervention were compared across respective intervention arms. It was hypothesised that, when compared with treatment as usual, caregivers assigned to one of the three intervention arms would score higher in parental confidence, satisfaction with healthcare professional support, and would score lower on measures of postnatal depression and anxiety. A significant difference between respective intervention arms on distributed measures was expected. Post-intervention focus groups were also conducted with participants and with staff, separately, to evaluate perceived benefit of the respective intervention arms in greater depth. Finally, a conversation analysis was conducted on WhatsApp group data, which spanned the peer support intervention arm, only.

2. Methods

The current study was reported in line with CONSORT pilot and feasibility trial guidelines[31].

2.1 Ethical statement

Research Ethics Committee (REC) and Health Research Authority (HRA) ethics approvals were attained on 21 Oct 2021 (ID: 21/NW/0258). Sponsor approval from The University of Liverpool was obtained on 25 November 2021 (Sponsor Ref: UoL001641).

2.2 Study design

The present study was pre-registered through the International Standard Randomised Controlled Trial Number (ISRCTN) registry on 06 Aug 2021 (ID: ISRCTN15349263). The full study protocol can be found through this pre-registration. The current pilot study aimed to investigate the feasibility and acceptability of an online group peer support, health education, and music intervention for caregivers of infants affected by colic, reflux, and GOR(D).

In the current study, the largest risk of harm was psychological distress. The distress protocol can be made available on reasonable request to the corresponding author. Measures were taken throughout the design and implementation of the study to protect caregiver wellbeing. For example, a distress protocol was developed for the unfortunate event that a participant became upset during the study. All group sessions and the focus group were attended by two members of the research team if the distress protocol needed to be carried out. Consent was taken electronically and verbally during the intervention and focus group, respectively, to respect consent as a continuous process. Participants were reminded in the information sheet and at the start of each session of their ability to withdraw from the study at any point and without needing to give a reason.

The peer support group carried additional risks of harm when compared with the music and health education arm. Specifically, setting up the WhatsApp group meant sharing the participant's mobile number and profile picture with other peer support intervention participants. Caregivers were made aware of this feature of the study before deciding to take part in the intervention arm and were given instructions on how to mute notifications, block contacts, and remove their profile picture icon if they felt uncomfortable at any point. Participants were reminded that they could interact with the other members as much or as little as they liked throughout the peer support intervention. The first group session of the peer support intervention laid ground rules for appropriate behaviour in the WhatsApp group e.g., not creating splinter groups, not discussing medical advice in the group, keeping anything discussed in the WhatsApp group completely confidential etc. Powerpoint slides for this session can be made available on reasonable request to the corresponding author.

The WhatsApp group was monitored by a member of the research team to ensure that participants were being treated considerately throughout the intervention [SD]. Research participants were made aware of this before deciding whether to take part in the current study or not. Participants were also informed that the WhatsApp group chat would be analysed and written up into a report. Participants were informed in the information sheet and first group session that if they preferred for any message(s) not to be included in final analysis, that they should either i) put a padlock emoji on the

message, or, ii) include a note asking please to exclude from analysis. Please see pre-registration for the full study protocol, which provides extensive information on measures emplaced to protect participants from harm throughout study design and conduct.

2.3 Participants

Recruitment was opportunistic. Mothers who had been referred to Alder Hey Children's NHS Foundation Trust (Hereafter referred to as 'Alder Hey') with their unsettled infant, due to infant feeding difficulties relating to Colic, GOR(D), and/or CMPA, were identified by clinicians employed at Alder Hey. All caregivers who met the following eligibility criteria were approached by their clinician during routine appointments: over the age of 18, and no previous or current clinical diagnosis of a serious mental health condition i.e., bipolar disorder, schizophrenia, and/or psychosis (confirmed via self-report on initial contact [LJ], described below). Infants needed to be younger than six months old at time of referral, born full-term (i.e., >34 weeks' gestation), without known comorbidities or evidence of faltering growth[34] for their caregiver to be eligible to participate.

If interest was expressed on clinician approach, the parent was given an information pack containing a study advertisement, information sheet, and expression of interest form. Eligible caregivers completed and returned the expression of interest form. Contact details were securely transferred to LJ and an initial call was made after approximately 48 hours. During the initial call LJ confirmed caregiver eligibility, provided information on the intervention arm to which they had been assigned, and answered any questions about the study. An email was then sent to the participant, containing: an electronic consent form, an active Qualtrics survey link to complete an initial baseline survey (approx. 5-10 min completion time), and details of the first group Zoom intervention session.

2.4 Group allocation and intervention details

A pragmatic sample of 40 participants was sought[32]. Treatment as usual ran first due to lack of prior preparation required to set up the intervention arm. Clinician capacity meant that six weeks' notice was required to block out sufficient time to run the health education intervention arm alongside their usual caseloads. Therefore, the health education intervention arm ran third, and the peer support intervention arm ran second due to lack of pre-preparations needed to run this intervention arm. Music intervention ran last due to capacity of the employed harpist, who facilitated scheduled group intervention sessions.

Each intervention arm ran either i) once 10 participants had been recruited to the arm, or, failing this target being met, ii) After one month of continuous recruitment efforts. Inability to recruit 10 participants to an intervention arm within one month of continuous efforts was deemed as the arm being unfeasible for scaling up to a full intervention. Principally, this decision was made to recognise the self-resolving nature of infantile symptoms for these conditions i.e., to maximise intervention benefit to parents who had been screened into the study earlier in the recruitment bracket.

Treatment as usual ran in February 2021, after one month of continuous recruitment efforts in January 2021. Two women participated in treatment as usual, of 14 contacted (14% uptake). One father took part in the treatment as usual focus group, only, on participant request. Peer support ran in March 2021, after one month of continued recruitment efforts in February 2021. Three women were recruited to peer support, of 10 contacted (30% uptake). One participant was recruited to music, of 20 contacted (.05% uptake). The music intervention ran in March 2021 after one month of continuous recruitment efforts in February 2021. However, the singular participant chose to withdraw after the first online session. This participant withdrew due to discomfort taking part in the intervention arm alone, due to its advertisement as a group intervention.

No participants were recruited to health education after one month of continuous recruitment efforts in April 2021: eight women had been contacted (0% uptake). Non-participating individuals either i) did not respond to three attempts at contact, spaced 24 hours apart, or ii) hung up on two consecutive contact attempts, spaced 24 hours apart. See Table 1 for participant demographic information.

[Insert Table 1]

At the rate of recruitment recorded in the current study i.e., one – three participants screened to an intervention arm per month, each intervention arm would run after approximately four – ten months of continuous recruitment efforts. This is problematic because a parent recruited in month one would likely have very different support needs than a parent recruited in month ten, making intervention delivery and analysis cumbersome. More problematic than this, parents recruited earlier in the recruitment bracket may have infants whose symptoms have since self-resolved. This may have caused undue distress by being recruited into a study which they were unable to then benefit from, due to reasons outside of their own control.

Where it has been feasible to do so, intervention arm design has been standardised. All intervention arms spanned seven weeks. For weeks 1-3, each participant was invited to attend a one-hour online session. Each session was split into two sections: in the first 40 minutes the delivering member of staff taught mothers techniques and/or skills to use with their unsettled infant (the content of which was adapted for the intervention arm). The remaining 20 minutes of each online session was used as an opportunity for any questions and/or informal socialising among the attendees. In intervention weeks 4-6, parents were told to use the skills and/or techniques acquired during the group sessions as much or as little as they would like, in their own time.

To further standardise our approach, each online group session took place on a Monday morning. On the Friday morning of the same intervention week participants were sent an interim questionnaire to assess how useful they found the intervention content for that week, and how much they had engaged with it. Questions were tailored for each intervention arm e.g., 'Did you find [using songs of kin e.g., lullabies/using the WhatsApp group] helpful this week, when your baby was

unsettled?'. All participants were also sent the same psychometric measures at baseline and post-intervention.

All participants took part in an evaluative focus group for the pilot study, which took place in week 7, in the Monday morning slot whereby the group online sessions had been taking place. In week 6, participants were sent the baseline survey from week 0 to complete again so that the research team could determine change over time. After completing this post-survey, participants were redirected to a downloadable debrief sheet on Qualtrics and then were asked if they would be interested in taking part in an audio recorded focus group to share their experiences of taking part in the study. If the participant selected 'yes', they were re-directed to a separate Qualtrics survey where they were presented with an information sheet for the focus group, and a consent form to sign. Participants who signed the focus group online consent form were then sent details of the scheduled focus group. Please see Appendices A – D for a more detailed breakdown of each intervention arm's design. PowerPoint slides for each group session can be made available on reasonable request, and details of intervention arm delivery are summarised below. *2.4.1 Treatment as usual*

All participants continued to receive their usual care at Alder Hey. Participants in all intervention arms received treatment as usual.

2.4.2 Health Education

Infant feeding specialists employed by Alder Hey, led organised group sessions [CJ, HM]. Sessions aimed to normalise infantile symptoms through education and the provision of tailored advice and guidance on symptom management. Group sessions covered the following topics: understanding colic, GOR(D), and CMPA; symptom management; and both infant development and weaning behaviour. Group sessions were 40-minutes in length followed by 20-minutes of Q&A's.

2.4.3 Music

An arts coordinator and arts psychotherapist employed by Alder Hey [SR, MT], and an academic researcher employed by The University of Liverpool, who specialises in the psychological study of music [EC], led organised group sessions. This intervention aimed to educate caregivers on the use of songs of kin e.g., lullabies, to manage infantile symptoms and to improve caregiver mood and confidence. Group sessions covered the following topics: the benefits of Infant-Directed Singing (IDS[36]) developing parental confidence using IDS and addressing barriers and/or anxieties for its use. Group sessions were 40-minutes in length followed by 20-minutes of Q&A's.

2.4.4 Peer Support

Academic researchers employed by The University of Liverpool, who specialise in perinatal mental health and infant development research [LJ, SD, VF] and a Maternal Voices Partnership (MVP) representative [HS] led organised group sessions. The aim of this intervention arm was to improve caregiver mood and confidence via social cohesion and normalising infantile symptoms by sharing lived experiences. Topics covered in group sessions included: what peer support is and why it is beneficial; ground rules for using the WhatsApp group; success stories from parents with previous experience of caring for an infant with colic, GOR(D), and CMPA; managing challenges; and use of self-care strategies.

2.5 pre-and post-assessment questionnaires

The following were administered at baseline and in week 6 of each intervention arm, including treatment as usual, to assess change over time:

- Infant feeding method was assessed using a validated 11-point Likert Scale with percentage response options varying from 100% formula fed to 100% breastfed over the past 48-hour period[33]

- *Perceived Maternal Parenting Self-Efficacy (PMPSE) tool*[34]: a 20-item self-report questionnaire to assess perceived parenting self-efficacy with four subscales reflecting: infant caretaking, evoking behaviour(s), reading behaviour(s) or signalling, and situational beliefs. Response options included: *'strongly disagree', 'disagree', 'agree',* and *'strongly agree'*. Higher scores reflected higher parenting self-efficacy.

- *Edinburgh Postnatal Depression Scale* (EPDS[35]): a 10-item self-report questionnaire to assess postpartum depressive symptoms. Higher scores reflected higher levels of depression.
- *Postpartum Specific Anxiety Scale* (PSAS[36]): a 16-item self-report questionnaire to assess postpartum-specific anxiety symptoms. The questionnaire contained four sub-scales: psychosocial adjustment to motherhood anxieties, practical infant care anxieties, maternal competence and attachment anxieties, and infant safety and welfare anxieties. The PSAS is measured on a 4-point Likert scale with response options ranging from '0 Not at all' to '3 Almost Always'. Higher scores on the PSAS reflected higher levels of anxiety.
- *Short Assessment of Patient Satisfaction* (SAPS[37]): a 7-item self-report questionnaire to assess perceived satisfaction with healthcare professional support. Response options included, *'very satisfied', 'satisfied', 'Neither satisfied nor dissatisfied', 'Dissatisfied',* and, *'Very dissatisfied'*. Higher scores on this scale reflected higher perceived satisfaction with healthcare professional support.

2.6 Procedure

After providing consent, the following demographic information was recorded in the baseline survey: maternal age, infant age, infant feeding method, occupational status, highest level of education, marital status, and parity. Each intervention arm ran for seven weeks. For peer support, music, and health education, weeks one through three consisted of attending a weekly, one-hour online group session. For which, session information was distributed via email [LJ]. In weeks four through six, participants were asked to implement the skills and techniques acquired in the group sessions, independently. Interim questionnaires were administered each Friday in intervention weeks two through five, to assess frequency and quality of engagement, and perceived helpfulness of the intervention arm (See Appendices A – D for treatment as usual, peer support, music intervention, and health intervention protocols, respectively).

Evaluative focus groups took place in week seven for all intervention arms, and for delivering members of staff to explore acceptability and feasibility in greater depth (See Appendix E and F for intervention and staff focus group topic guides, respectively). A WhatsApp group accompanied the peer support arm, only, with participant consent. Participants were informed that they could interact with one another as much or as little as they liked outside scheduled intervention sessions, including face-to-face meetups. The WhatsApp group was monitored, and conversational prompts were periodically posted to facilitate conversation [SD]. Participants were informed that they could request that a message(s) be removed from analysis by using a padlock emoji or by specifying that their post is private.

2.7 Analysis

2.7.1 pre-, post- and interim assessment measures

No participants completed pre- or post-intervention measures. Neither did any participants complete interim assessment measures. Coupled with exceptionally poor levels of recruitment, quantitative examination of pre-, post-, and interim assessment measures was not possible.

2.7.2 Conversation analysis

All consented exchanges from the peer support WhatsApp group were exported to NVivo 12, and a conversational analysis was conducted[38] [GPA, LJ]. Here, talk-in interactions were assessed e.g., turn-taking[39]. The structural organising rules of talk can be detected by analysing sequences of naturally occurring conversation, where a bidirectional relationship exists between social interaction and context[40]. Analysis was inductive and consultative[41].

2.7.3 Reflexive thematic analysis of focus groups

Topic guides were reviewed by all members of the research team, who collectively possessed expertise in clinical care, perinatal and qualitative research methods, and lived experiences of parenting an infant with colic, GOR(D), and/or CMPA. The intervention topic guide covered: motivations for participation, appropriateness and experience of recruitment, satisfaction with the intervention arm (mode, frequency and type of delivery, benefit; Appendix E). The Treatment as usual topic guide fed into a service AUDIT

for Alder Hey, and is thus, not presented in the current paper. The staff topic guide covered: motivation for working on the current project; satisfaction with involvement in the study; views and experiences of study design, recruitment, and session delivery (Appendix F).

Peer support and staff focus groups ran in March and June 2021, respectively. Interviews lasted between 60-91 minutes (Mean = 73 minutes). The peer support focus group was conducted via video conference calling software and the staff focus group was conducted face-to-face at The University of Liverpool. All participants were debriefed within 24 hours of the focus group concluding. The peer support focus group was led by LJ and facilitated by SD, while the staff focus group was led by an independent researcher who was otherwise unaffiliated with the current study, and blind to its aims. Focus groups were audio recorded using a Dictaphone and transcribed verbatim. Transcription and analysis were supported by NVivo 12 [RD, LJ]. Researchers used reflexive thematic analysis[42], involving familiarisation with the transcripts, generation of initial codes, identification, review, and defining themes, and report writing [RD, LJ]. All authors reviewed and refined identified themes, following an inductive and consultative approach[41], to derive the final thematic structure. See supplementary documentation for author reflexivity statement.

3. Integrated results and discussion

The current study aimed to investigate the feasibility and acceptability of online group peer support, health education, and music interventions to caregivers of infant's referred to Alder Hey, due to infant feeding difficulties relating to colic, GOR(D), and/or CMPA.

3.1 Peer support: conversation analysis

Conversation analysis identified two major themes, '*Trial-and-error symptom management*' and, *''Us' against 'them''*. Five sub-themes were identified: '*Infant care anxieties'*, *'Halved problems, shared solutions'* (trial-and-error symptom management), *'My baby is more than just unsettled'*, *'Frustrated and judged'*, and *'Feeling like a bad mother'* (*'Us'* against *'Them'*). Figure 1 provides a diagrammatic overview of the final thematic structure.

[Insert Figure 1]

'Trial-and-error symptom management' was characterised by the sharing, validation, and normalisation of one another's difficulties with unsettledness management. The second major theme, *''Us'* against *'them'*, captured the use of humour, rapport, and group membership to alleviate otherwise distressing and shame-inducing experiences. Rapport built between WhatsApp group members countered the negative effects of perceived negative judgement from others regarding their infant's condition (See Appendix G for supporting quotes). Elevated anxiety was attributed to upward

comparisons made with caregivers of infants unafflicted by Colic, GOR(D) and/or CMPA. For the multiparous participant, upward comparisons were also made with their older, unaffected child. This may be explained by self-discrepancy theory: when one believes themselves to be failing self-imposed expectations, feelings of inadequacy, guilt, and shame ensue[43]. Ideal-actual comparisons can lead to the onset and maintenance of other psychiatric symptoms, such as postpartum anxiety and depression[44]. This is especially pronounced among mothers who have infants with colic, GOR(D), and/or CMPA[11-13].

Symptom management anxieties were intensified by healthcare professional support when perceived to be unhelpful, dismissive, and inconsistent. In other domains of maternity care, such as infant feeding, receiving care which was not mother-centered resulted in poorer health outcomes and dissatisfaction with care, while satisfaction protected maternal emotional wellbeing and optimised infant health outcomes[45]. Current findings reaffirm the need for holistic, mother-centered care which considers maternal emotional wellbeing and autonomy as key intermediaries of maternal and infant wellbeing outcomes[46]. Healthcare practitioners are in an influential position to protect the *'good mother'* by closing the ideal-actual discrepancy. To do this, proactive normalisation of infantile symptoms, dispelling myths, and tailoring advice to maternal needs is necessary[45].

Parenting guilt is unfortunately common[45]. Under intensive motherhood theory, infant unsettledness deviates from the *'good infant'* prototype and predisposes new parents to feelings of inadequacy[47]. In the current study, participants avoided parenting groups due to fears of being judged by other mothers: this is characteristic of shame[48]. Attending parenting groups with other caregivers who had shared life experiences renewed one's ability to enjoy quality time with their unsettled infant, in public. Heightened anxiety was also common, for which the WhatsApp group acted as a platform to celebrate infant development milestones beyond their afflictions[49]. In this regard, the WhatsApp group acted as a safe haven for participants, which nurtured the *'good mother'* identity[47]. This was achieved by neutralising negative judgement received from outsiders with validating and empowering assurances[48,49].

For the peer support intervention arm, online group sessions in week two and three focused on normalising infantile symptoms, sharing lived experiences; and discussing self-care techniques, respectively (See appendix B for more details). These sessions were particularly well received by mothers in this intervention arm, and facilitated self-acceptance, self-compassion, confidence, and perseverance as self-reported in the evaluative focus group (See Appendix G and H for supporting illustrative quotations). Self-efficacy is conceptualised as one's belief in their ability to carry out an intention, successfully[50]. In health research, self-efficacy predicts health status and disease prevention[51]. The current study finds peer support to offer cost-efficient benefit to mothers of infants with colic, GOR(D), and/or CMPA, extending previous work conducted with childbearing populations[52]. Signposting to local peer support services and to specialized helplines e.g., Cry-sis[53], during routine appointments, is thus recommended. Signposting to population-specific self-help resources and support groups during routine healthcare appointments may also serve to alleviate pressure on primary healthcare services[54,55]

3.2 Evaluative focus groups, staff, and peer support

See Table 2 for a thematic summary of study strengths and weaknesses. For supporting illustrative quotes and interpretations for identified themes, see Appendix H.

[Insert Table 2]

While peer support was an acceptable intervention, its feasibility was not established due to poor participant uptake. Thematic analysis identified two overarching themes: effective study design and delivery, and issues with recruitment and delivery. In the current study, any parent who visited the infant feeding team at Alder Hey Children's Hospital due to symptoms of colic, reflux, and/or CMPA and who met eligibility criteria, were invited to take part in the current study by their clinician. However, uptake to the current study was exceptionally poor (treatment as usual uptake: 14%, peer support uptake: 30%, music uptake: .05%, health education uptake: 0%). This resulted in overall study uptake of 10% from those who were contacted for participation. Non-participating individuals either i) did not respond

to three attempts at contact, spaced 24 hours apart, or ii) hung up on two consecutive contact attempts, spaced 24 hours apart. During the treatment as usual and peer support evaluative focus groups, participants spontaneously mentioned that on approaching Alder Hey Children's Hospital for their child's unsettledness, they had already exhausted all community-based sources of support e.g., General Practitioner, Health Visitor.

Participants went on to express that by the time they were contacted about the current study, their infant's symptoms had either started to subside, or they had been in a mentally exhausted position after many signposting attempts to gain support for their infant's condition. For those interviewed, this was a pressing barrier for taking part in the current study. Delivering members of the research team agreed with the participant's reflections. Establishing community-based recruitment e.g., through health visiting services and parenting support groups, would allow eligible caregivers to be identified at a point where level of need is greater[54], and might subsequently reduce overreliance on emergency services[55].

Regarding study strengths, personalised recruitment calls with direct contact from the delivering research team facilitated intervention uptake. This echoes previous research which also demonstrated the benefits of personalised recruitment[56]. Online intervention delivery further improved intervention accessibility: strengthening evidence for the use of videoconferencing software in peer support interventions[57]

However, in the peer support evaluative focus group, suggestions were made to deliver the intervention arms in a hybrid format, opposed to current delivery which was entirely online. For the peer support arm, mothers reported having liked to have had the opportunity to meet face-to-face for an icebreaker activity e.g., coffee and biscuit morning, to acquaint themselves with one another. This was perceived as being particularly important given the deeply personal intervention topic. After this icebreaker activity, mothers reported having been happy with all remaining sessions being held online, as they were able to meet up as much or as little as they liked outside of these sessions.

Patient perspectives on post-COVID-19 maternity service reconfiguration echoes these findings, with perinatal women consistently expressing a desire for elements of in-person interactions[58]. Hybrid intervention delivery with an in-person icebreaker component is a previously undocumented, novel finding. Based on these findings, the research team propose that researchers developing perinatal group interventions in future incorporate an informal icebreaking session before commencing with intervention delivery, to give participants the opportunity to start building rapport. Condensing intervention sessions from 60 minutes to 45-minutes was also suggested to better accommodate childcare commitments in intervention delivery. Finally, developing online, self-help resources for parents to use outside of scheduled group sessions was recommended to improve support accessibility, which would extend parental benefit beyond the lifespan of the intervention. Online resources have demonstrated acceptability and efficacy for parents of unsettled infants[60], further supporting this cost-effective recommendation.

The peer support intervention was acceptable both to staff and to parents. Peer support reduced feelings of self-blame and reinstated maternal confidence. For example, two of the three peer support participants noted in the evaluative interview that taking part in the intervention allowed them to attend parenting support groups with the other intervention participants, as having the presence of others with shared life experiences gave them comfort and empowered them to enjoy time with their baby despite their unsettledness (see Appendix G for supporting illustrative quotations). Regarding maternal confidence, the presence of the other peer support participants held mothers accountable to protect time for self-care activities e.g., putting on make-up in the morning because they wanted to.

Also, sharing one's life experiences normalised their infant's symptoms and protected their good mother identity, by allowing their infant's symptoms to exist without judgement. Sharing personal experiences also facilitated belongingness and offered a platform for mothers to explore non-medical solutions for managing their infant's symptoms e.g., use of blackout curtains, white noise etc., in a safe and understanding space. These findings are consistent with previous literature[48]. Trialling a moderated online support forum specifically for parents of unsettled infants afflicted with colic, GOR(D), and/or CMPA, was proposed for future acceptability research. This recommendation was made via study insight highlighting the importance of creating a safe, non-judgemental environment for disclosure of concerns.

3.3 Overall study strengths and limitations

Co-design was a highlighted strength of the current study: harmonising the needs of parents, clinician capacity, and research pragmatism optimised project acceptability[590]. This highlights the value of co-design in all stages of health intervention design, conduct, and write-up[60,61]. The multidisciplinary team co-designed intervention arms which harmonised the following priorities known to determine research impact: maternal need, clinician capacity, and research pragmatism[62]. This underscores the value of co-design at all stages of the research process and supports the integration of patient and public involvement in the development of subsequent interventions[63].

Longitudinal, naturalistic data collection through the WhatsApp group permitted rich, in-depth understandings of caregiver experiences to be illuminated. Although the current study suffered from exceptionally poor recruitment, critical analysis of study strengths and weaknesses offer important insights for improving intervention acceptability and feasibility for research conducted with caregivers of infants with colic, GOR(D), and/or CMPA, and for engagement with healthcare services.

Secondly, the multiparous mother found study engagement more difficult alongside conflicting responsibilities, compared with primiparous mothers. This confounding factor should therefore be considered in future research endeavours. Specifically, recruitment should be stratified by parity to discern acceptability and feasibility. Finally, participant-facing documentation detracted from the informal nature of the intervention. Producing ethically sound, lay information on a research project is notoriously challenging[64]. Including a summary leaflet in recruitment information packs would facilitate caregiver understanding of study expectations.

4. Conclusion

The current study aimed to establish acceptability and feasibility of an online group peer support, health education, and music intervention to caregivers of infants with colic, GOR(D), and/or CMPA, when compared with treatment as usual. The peer support intervention was acceptable to participants and to staff. Validating one another's experiences and normalising infantile symptoms empowered mothers and protected the good mother identity. Signposting caregivers to colic, GOR(D), and/or CMPA-specific parenting groups is recommended to enhance caregiver coping, self-efficacy, and emotional wellbeing. Evaluative focus groups identified key study strengths and limitations which can be used to inform future interventional work. Specifically, recommendations are made for an earlier point of recruitment, a study summary leaflet included in initial information packs, and for hybrid study delivery to optimise potential benefit.

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Author contributions

Conceptualisation (VF, FV), Data curation (LJ), Formal Analysis (LJ, RD, GPA), Funding Acquisition (VF, FV), Investigation (LJ, EC, LDP, VC, SMD, CJ, HM, SR, HS, MT, VF), Methodology (LJ, EC, LDP, SMD, VF, HS, FV, VC, CJ, HM, SR, MT), Project Administration (LJ, VF, FV), Resources (LJ, EC, LDP, VC, SMD, CJ, HM, SR, HS, MT, FV, VF), Software (EC), Supervision (VF, FV), Validation (LJ), Visualization (LJ, GPA, RD), Writing -Original Draft Preparation (LJ, RD, GPA), Writing – Review & Editing (EC, LDP, VC, SMD, CJ, HM, SR, HS, MT, FV, VF).

Statements and declarations

Ethical considerations

Research Ethics Committee (REC) and Health Research Authority (HRA) ethics approvals were attained on 21 Oct 2021 (ID: 21/NW/0258). Sponsor approval from The University of Liverpool was obtained on 25 November 2021 (Sponsor Ref: UoL001641).

Consent to participate

All participants provided electronic consent before being allocated to an intervention arm. All participants gave separate, electronic consent to take part in the evaluative focus groups. Verbal consent was taken at the start of each focus group session.

Consent for publication

Findings are reported on aggregated participant data, only, which has been consented to by all participants. No identifiable information is reported in the current manuscript.

Declaration of conflicting interest

The authors declared no potential conflicts of interest with respect to the research, authorship, or publication of this article.

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Data availability

Pseudoanonymised interview transcripts will be made available on the data sharing repository, Dryad, on manuscript publication. Pseudoanonymised qualitative data is also available upon reasonable request to the corresponding author. Due to poor completion of quantitative surveys and associated risk of re-identification, survey data will not be made available for re-use.

Guarantor

The corresponding author, Dr Leanne Jackson (Leanne.Jackson@liverpool.ac.uk) acts as the guarantor for the current manuscript.

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Appendix A: Protocol, treatment as usual

Appendix B: Protocol, peer support

Appendix C: Protocol, music intervention

Appendix D: Protocol, health education

Appendix E: Topic guide, intervention arms

Appendix F: Topic guide, staff evaluation

Appendix G: Supporting evidence with illustrative quotes, conversation analysis on WhatsApp group data.

Appendix H: Thematic analysis supporting illustrative quotes

Appendix I: Reflexivity statement

Table 1: Participant characteristics and pseudonym assignment

Intervention arm	Parent pseudonym	Infant pseudonym	Number of children (including youngest)	Parental age	Occupation	Highest level of education	Marital status	Youngest infant age/months	Infant feeding method
Treatment as usual	Hannah	Willow	2	**NR***	**NR***	**NR***	**NR***	20	Formula feeding
Treatment as usual	Freida+	Kimberly	1	32	Associate professional occupation	College	Living with partner	2	Combination feeding
Treatment as usual^^	Terry+	As Frieda	As Frieda	28	Managers, directors, and senior officials	Undergraduate Degree	Living with partner	As Frieda	As Freida
Peer support	Barbara	William	1	34	Professional occupations	Master's Degree	Married	4	Combination feeding
Peer support	Silvia	George	1	28	Managers, directors, and senior officials	Master's Degree	Living with partner	2	Formula feeding
Peer support	Madison	Billie	2	29	Professional occupations	Undergraduate Degree	Single	5	Formula feeding
Music	Alanta	**NR***	**NR***	**NR***	**NR***	**NR***	**NR***	**NR***	**NR***

NR*: Field received no response. Please note that occupation categories and education categories were taken from the UK Government (2020) and (2021), respectively. +Terry and Frieda are cohabiting partners. ^^This participant only took part in the focus group, on Frieda's request.

Figure 1: Conversation analysis thematic structure

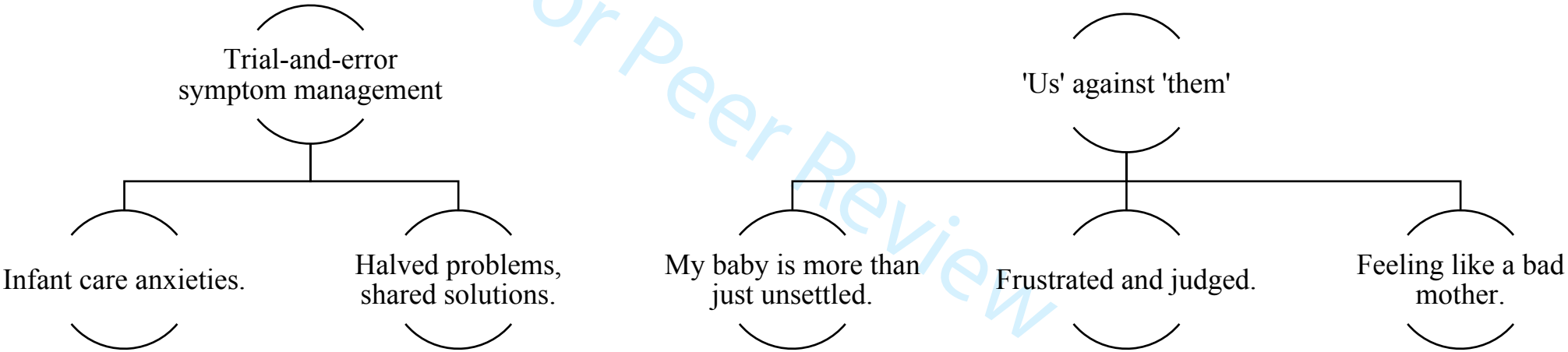

Table 2: Thematic summary of study strengths and weaknesses.

	Major theme	**Sub-theme**
Study strengths	Effective study design and delivery	1. A personal touch 2. Accessibility and instilled confidence
Study weaknesses	Issues with recruitment and delivery	1. Delayed point of entry 2. A mismatch of the formal and informal 3. Hybrid delivery and condensed sessions

Appendix A:
Protocol (Treatment As Usual; TAU)

IRAS ID: 296579

Version 1.1, 15th April 2021

Intervention

Duration: 6 weeks

Procedure:

- Referral into infant feeding clinic after review by Health visitor, GP, emerging department Clinician or General paediatrician.

Treatment as usual-specific measures (before, during and after the intervention)

Pre- and post-assessment questionnaires

Firstly, participants will answer a few demographic questions about their home composition, age, infant date of birth, the first three characters of their postcode (to determine socioeconomic status), and their infant feeding method. Infant feeding method will be assessed using a validated 11-point Likert Scale with percentage response options varying from 100% formula fed to 100% breastfed over the past 48-hour period (Davie, 2018).

Perceived Maternal Parenting Self-Efficacy (PMPSE) tool (Barnes & Adamson-Macedo, 2007).

20-item self-report questionnaire to assess perceived parenting self-efficacy with four sub-scales reflecting different parenting domains: care taking procedures, evoking behaviour(s), reading behaviour(s) or signalling, and situational beliefs. Response options include, 'strongly disagree', 'disagree', 'agree' and 'strongly agree'. Higher scores on this questionnaire reflect higher perceived parenting self-efficacy.

Edinburgh Postnatal Depression Scale (EPDS; Cox et al., 1987)

10-item self-report questionnaire administered to screen for depressive symptoms in the postnatal period. It is the most widely used screening scale for postnatal depression. Higher scores indicate higher levels of depression. A clinical cut-off score of ≥13 identifies scores consistent with major depressive disorder, although the self-report measure does not replace a clinical diagnosis.

Postpartum Specific Anxiety Scale (PSAS; Fallon et al, 2021)

16-item self-report questionnaire to assess perceived parenting anxiety in the postpartum period. Questionnaire items cover four domains of parenting: psychosocial adjustment to motherhood anxieties, practical infant care anxieties, maternal competence and attachment anxieties, and infant safety and welfare anxieties. Higher scores indicate higher levels of anxiety. Measured using 4 point Likert scale response options from '0 Not at all' to '3 Almost Always'.

Short Assessment of Patient Satisfaction (SAPS; Hawthorne et al, 2014)

7-item self-report questionnaire to assess perceived satisfaction with healthcare professional support. Response options include, 'very satisfied', 'satisfied', 'Neither satisfied nor dissatisfied', 'Dissatisfied', and, 'Very dissatisfied'. Higher scores on this scale correspond with greater perceived satisfaction with healthcare professional support.

Researcher-developed items, tailored for TAU:

1. Did your midwife discuss different forms of feeding for your baby with you? Yes/No
2. Did you find this information useful? Yes/No
3. Other than the Hospital infant feeding team, who have you sought infant feeding advice from for your unsettled/distressed baby? Midwife/Health visitor/GP/Walk-in Centre/Hospital Emergency Department/Paediatrician/Other

AFTER the intervention, it would be also relevant to measure the perceived effectiveness of treatment as usual

Same measures that were administered before the intervention (1) are to be administered again to assess change over time and effectiveness of treatment as usual.

First appointment

Duration: 30 mins

Timing: Start of Week 1

Aims:

- First appointment generally face-to-face. Assessment made, advice given, and family directed to Hospital web site for the relevant patient information leaflets (Hospital, N/Aa; Hospital, N/Ab).
- Follow-up appointment, if required, often video or telephone consultation.

Follow-up appointment(s) then organised as required.

Discharge back to universal services and primary care when input from specialist services no longer required.

Focus group

Duration: 1 hour

Timing: After the intervention (start of Week 7)

- Discuss relevant issues related to treatment as usual for feeding back into clinic service evaluation e.g. accessibility of service, effectiveness of communication with healthcare practitioner(s), evaluation of virtual care compared with face-to-face care.

References

[Reference removed due to identifiable content for Hospital site]

[Reference removed due to identifiable content for Hospital site]

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Appendix B:
Protocol (peer support)

IRAS ID: 296579

Version 1.3, 15th April 2021

Intervention

Duration: 6 weeks

Procedure:

- Participate in 3 weekly groups sessions (see below for content) in Weeks 1-3
- Ask carers to use WhatsApp group for emotional support and social interaction only, and to contact their health professional for medical guidance. Remind participants that their posts in the chat will be anonymised and analysed, unless the participant indicates through an emoji that they would like their post to be excluded from analysis.

Peer support-specific measures (before, during and after the intervention)

Pre-intervention only

1. Firstly, participants will answer a few demographic questions about their home composition, age, infant date of birth, the first three characters of their postcode (to determine socioeconomic status), and their infant feeding method. Given that the engagement with the WhatsApp support group may be related to past social media experiences and value attributed to peer support it would be important, therefore, for carers to be administered a social media usage history questionnaire **BEFORE** the intervention starts, only.

- Do you use online parenting support groups to support you when your baby is unsettled? Yes/No.
- How often did you use online parenting support groups in the last 48 hours? Not at all/1-2 times a day/3-5 times a day/>5 times a day
- Have you found using parenting support groups helpful in soothing your baby's symptoms when they are unsettled? Most of the time/Often/Sometimes/Never
- Did you experience positive feelings whilst using online parenting support groups to help support you with your unsettled baby? Most of the time/Often/Sometimes/Never
- Please complete this statement: My baby is conent… Most of the time/Often/Sometimes/Never

The next question will be assessed using 5 point Likert-scale response options:

Please complete this statement: When my baby is unsettled I feel…

1 Useless 2 3 4 5 Able to cope

1 Anxious 2 3 4 5 Calm

1 Guilty 2 3 4 5 Not Guilty

1 Lonely 2 3 4 5 Supported

1 Frustrated 2 3 4 5 Patient

Pre- and post-assessment questionnaires

To examine the effectiveness of the intervention condition, the following questionnaires will be administered before and after the 6-week intervention involvement in this study:

Infant feeding method will be assessed using a validated 11-point Likert Scale with percentage response options varying from 100% formula fed to 100% breastfed over the past 48-hour period (Davie, 2018).

Perceived Maternal Parenting Self-Efficacy (PMPSE) tool (Barnes & Adamson-Macedo, 2007).

20-item self-report questionnaire to assess perceived parenting self-efficacy with four sub-scales reflecting different parenting domains: care taking procedures, evoking behaviour(s), reading behaviour(s) or signalling, and situational beliefs. Response options include, 'strongly disagree', 'disagree', 'agree' and 'strongly agree'. Higher scores on this questionnaire reflect higher perceived parenting self-efficacy.

Edinburgh Postnatal Depression Scale (EPDS; Cox et al., 1987)

10-item self-report questionnaire administered to screen for depressive symptoms in the postnatal period. It is the most widely used screening scale for postnatal depression. Higher scores indicate higher levels of depression. A clinical cut-off score of ≥13 identifies scores consistent with major depressive disorder, although the self-report measure does not replace a clinical diagnosis.

Postpartum Specific Anxiety Scale (PSAS; Fallon et al, 2021)

16-item self-report questionnaire to assess perceived parenting anxiety in the postpartum period. Questionnaire items cover four domains of parenting: psychosocial adjustment to motherhood anxieties, practical infant care anxieties, maternal competence and attachment anxieties, and infant safety and welfare anxieties. Higher scores indicate higher levels of anxiety. Measured using 4 point Likert scale response options from '0 Not at all' to '3 Almost Always'.

Short Assessment of Patient Satisfaction (SAPS; Hawthorne et al, 2014)

7-item self-report questionnaire to assess perceived satisfaction with healthcare professional support. Response options include, 'very satisfied', 'satisfied', 'Neither satisfied nor dissatisfied', 'Dissatisfied', and, 'Very dissatisfied'. Higher scores on this scale correspond with greater perceived satisfaction with healthcare professional support.

Please rate how much to you agree with each of the following statements using a scale ranging from 0 (completely disagree) to 10 (completely agree)

- I use online parenting support groups about my baby's distress
- I think it is very important to use online parenting support groups about my baby's distress
- I experience positive feelings when using online parenting support groups
- Accessing online parenting support groups helps me to manage by baby better
- Accessing online parenting support groups helps me to manage my baby when he/she is distressed

During all intervention weeks (1-6):

2. **DURING** the intervention, to quantify engagement with the virtual support group and the state of the infant and the carer it would be very important to monitor the following variables on a weekly basis:
    - *How often did you use the online parenting support group over the past week?*
        - *Every day, most days, about half of the week, rarely, never*

Perception of infant's symptoms that week (e.g., amount of crying, general distress, hours of sleep, etc.

- Did you feel that using the online parenting support group has given you support to soothe your baby when he/she was distressed? Always, Usually, About half the times, Rarely, Never
- Did you feel that using the WhatsApp support group helped you to cope and feel better, generally? Always, Usually, About half the times, Rarely, Never
- Did you feel that using the WhatsApp group has helped you to cope and feel better, when your baby was distressed? Always, Usually, About half the times, Rarely, Never

Post-intervention involvement (week 6):

3. **AFTER** the intervention, it would be also relevant to measure the perceived importance of peer support. Same measures that were administered before the intervention (1) are to be administered again to assess change over time and effectiveness of the intervention.

First group session

Duration: 1 hour

Timing: Start of Week 1

Aims:

- 35-minute introduction
  To inform carer about what peer support is
  To inform carer about the benefits of peer support (use success stories from other projects)
  To provide an overview of the WhatsApp group
  The carer will be briefed on ground rules for using the peer support WhatsApp group i.e., what can and cannot be posted on the group, how breaches of these rules will be handled, group confidentiality and online safety (e.g., use of pseudonyms if desired), and how one can choose to exclude posts from analysis.
  Caregivers will be encouraged to engage in conversation in response to pro-active posts by the research team and will be encouraged to use the group as and when needed between these check-ins. Particular focus will be placed on the importance of shared experiences and emotional support/connection in improving caregiver wellbeing and coping.
  5 minutes for any questions about introductory information.

  Moderating member of the research team will set up a WhatsApp parenting group, using mobile numbers provided in the consent forms for this intervention arm. As a 'homework task, caregivers will be asked to introduce themselves to the WhatsApp group:
    - This can include encouraging mothers to talk about what they would like to gain from the group (Trickey et al, 2017) and introducing their infant to the group before the next session e.g., one cute fact. It will be emphasised that engagement is voluntary, throughout all intervention sessions.
    - What techniques they currently use to soothe their baby when he/she is distressed.

Second group session

Duration: 1 hour

Timing: Start of Week 2

Aims:

- 20 minutes [PPIE blinded for review] representative to talk about personal success stories relevant to infant colic and reflux (Regan & Brown, 2019).
- 15 minutes time for informal discussion between attendees e.g., how they're getting on with baby's symptoms, emotionally, how engaging with support group (field notes to be taken by research assistant).
- 5 minute 'WhatsApp engager' (ask mothers to share a new hobby/activity they have picked up during lockdown in the parenting group to boost engagement in the WhatsApp group).

Third group session

Duration: 1 hour

Timing: Start of Week 3

Aims:

- To follow-up on the first two sessions, identify potential problems/difficulties, increase confidence, etc. Is there anything that we could have done to improve your experience?
- Set groups off with 'engager' activity to share experiences.

Focus group

Duration: 1 hour

Timing: After the intervention (start of Week 7)

- Discuss relevant issues related to interventions (e.g., experience, perceived benefits, barriers, etc.)

WhatsApp group (throughout intervention)

Aims: To encourage a sense of group belongingness and increase feelings of emotional support between group sessions. To improve caregiver self-confidence and general wellbeing through group cohesion and shared experiences. Prompts are to be posted by the moderating member of the research team on a weekly basis, adopting a pro-active approach to peer support exchanges (Martinez-Brockman et al, 2019).

The group will be moderated by one member of the research team to ensure that group rules are being adhered to (Regan & Brown, 2019). This moderating member of the research team will be briefed on the disclosure of health 'red flags' which would need professional referral prior to setting up the group chat (Merewood & Philipp, 2003). After reiterating the ground rules for using the WhatsApp group, the following prompt schedule will be implemented by the moderating member of the research team:

Week 1 "Welcome to the group. Let's get to know each other! Post your favourite mum and baby meme and share a little bit about your experience with your baby's colic/reflux.'

Week 2 "What were your thoughts on the speaker in this week's group session? Was there anything that came up in the session, that you haven't tried before, or that you think might help? Do you identify with what was talked about?"

Week 3 "What are your favourite self-care activities? Share something that you plan on doing to take some time out for yourself this next week!"

Week 4 "Using only a gif, share how your week has been!"

Week 5 "It's Friday! Does anyone have any nice plans for the weekend?"

Week 6 "Tell me something positive that you are going to take away from being part of this support group!"

The WhatsApp group will also be used to send a reminder about completing weekly interim surveys and post-intervention surveys at the end of week 6.

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Appendix C:
Protocol (music intervention)

IRAS ID: 296579

Version 1.4, 15th April 2021

Intervention

Duration: 6 weeks

Procedure:

- Participate in 3 groups sessions during Week 1, 2 and 3.
- Careers will engage with Infant Directed Singing (IDS) in moments of infant distress throughout the whole intervention period (Weeks 1-6)

Measures (before, during and after the intervention)

1. Pre-intervention only

Firstly, participants will answer a few demographic questions about their home composition, age, infant date of birth, the first three characters of their postcode (to determine socioeconomic status), and their infant feeding method. Given that the engagement with music may be related with past musical experiences and value attributed to IDS, it is important that each carer is administered a musical history questionnaire about their singing habits with the infant **BEFORE** the intervention starts.

The questions pertaining to the pregnancy period are the following (adapted from Persico, 2017):

- Do you sing to your baby when they are unsettled? Yes/No.
- How often did you sing to your baby in the last 48 hours? Not at all/1-2 times a day/3-5 times a day/>5 times a day
- Have you found singing to your unsettled baby helpful in soothing their symptoms? Most of the time/Often/Sometimes/Never
- Did you experience positive feelings whilst singing to your unsettled baby? Most of the time/Often/Sometimes/Never
- Please complete this statement: My baby is content… Most of the time/Often/Sometimes/Never

The next question will be assessed using 5-point Likert-scale response options:

Please complete this statement: When my baby is unsettled, I feel…

1 Useless 2 3 4 5 Able to cope

1 Anxious 2 3 4 5 Calm

1 Guilty 2 3 4 5 Not Guilty

1 Lonely 2 3 4 5 Supported

1 Frustrated 2 3 4 5 Patient

The questions pertaining to the period after birth will also be used to evaluate potential changes in singing behaviours and perceived value of singing from pre- to post-intervention periods (see next section).

2. Pre and post-assessment questionnaires

To examine the effectiveness of the music intervention, the following questionnaires will be administered before and after the 6-week intervention involvement in this study:

Infant feeding method will be assessed using a validated 11-point Likert Scale with percentage response options varying from 100% formula fed to 100% breastfed over the past 48-hour period (Davie, 2018).

Perceived Maternal Parenting Self-Efficacy (PMPSE) tool (Barnes & Adamson-Macedo, 2007).

20-item self-report questionnaire to assess perceived parenting self-efficacy with four sub-scales reflecting different parenting domains: care taking procedures, evoking behaviour(s), reading behaviour(s) or signalling, and situational beliefs. Response options include, 'strongly disagree', 'disagree', 'agree' and 'strongly agree'. Higher scores on this questionnaire reflect higher perceived parenting self-efficacy.

Edinburgh Postnatal Depression Scale (EPDS; Cox et al., 1987)

10-item self-report questionnaire administered to screen for depressive symptoms in the postnatal period. It is the most widely used screening scale for postnatal depression. Higher scores indicate higher levels of depression. A clinical cut-off score of ≥13 identifies scores consistent with major depressive disorder, although the self-report measure does not replace a clinical diagnosis.

Postpartum Specific Anxiety Scale (PSAS; Fallon et al, 2021)

16-item self-report questionnaire to assess perceived parenting anxiety in the postpartum period. Questionnaire items cover four domains of parenting: psychosocial adjustment to motherhood anxieties, practical infant care anxieties, maternal competence and attachment anxieties, and infant safety and welfare anxieties. Higher scores indicate higher levels of anxiety. Measured using 4 point Likert scale response options from '0 Not at all' to '3 Almost Always'.

Short Assessment of Patient Satisfaction (SAPS; Hawthorne et al, 2014)

7-item self-report questionnaire to assess perceived satisfaction with healthcare professional support. Response options include, 'very satisfied', 'satisfied', 'Neither satisfied nor dissatisfied', 'Dissatisfied', and, 'Very dissatisfied'. Higher scores on this scale correspond with greater perceived satisfaction with healthcare professional support.

To evaluate potential changes in singing behaviours and perceived value of singing, the Value of Music Scale (adapted from Cevasco, 2008) will also be used:

> *Please rate how much to you agree with each of the following statements using a scale ranging from 0 (completely disagree) to 10 (completely agree)*

- I sing to my baby when she/he is distressed
- I think it is very important to sing to my baby when she/he is distressed
- Singing helps my baby feeling better
- I experience positive feelings whilst singing to my baby

3. Weekly measures (Weeks 1-6):

DURING the intervention, in order to quantify engagement with different coping strategies and the state of the infant and the carer we will monitor the following variables on a weekly basis:

- Frequency of engagement with different IDS
  - *How often did you sing to your baby over the past week?*
    - *Every day, most days, about half of the week, rarely, never*
  - *How often did you sing to your baby when she/he was distressed over the past week?*
    - *Always, Usually, About half the times, Rarely, Never*
- Perceived impact on the infant (e.g., amount of crying, general distress, hours of sleep, etc.)
  - *Did you feel that singing to your baby when she/he was distressed helped them feel better.*
    - *Always, Usually, About half the times, Rarely, Never*
- Perceived impact on the carer (e.g., mood, well-being, etc.)
  - *Did you feel that singing to your baby when she/he was distressed helped you cope and feel better? Always, Usually, About half the times, Rarely, Never*

First group session

Duration: 1h

Timing: Start of Week 1

Aims:

- To informs carer about the main benefits of Infant Directed Singing (IDS) for the baby and the carer with a particular focus on live singing with songs of kin.
  - IDS can favour self-regulation (including pain), the general promotion of well-being of infant and carers, and the quality of carer-infant interactions (e.g., Haslbeck, 2014; Loewy, 2015). Particularly important for this study is the fact that maternal singing can favour the relaxation and stabilization of the baby, decrease the mother's anxiety and sense of helplessness, and enable her to participate in the infant's care and well-being (e.g., Arnon et al., 2014; Filippa et al., 2013).

- To provide carers with information about singing and giving them the confidence to sing to the infants.

  - Modelling of simple musical ideas based on carer/infant vocalisation.
  - Vocalising with physiological cues from infant.
  - Making suggestions and examples of pre-composed songs that may be used with infants, from nursery rhymes to pop songs, tailored to infant development.
  - To ask carers to think about songs of kin (e.g., lullabies) that they would like to use during the intervention. Songs should be soothing (as opposed to exciting or playful). If not possible, suggest possibilities.

Second group session

Duration: 1h

Timing: Start of Week 2

Aim:

- To support the carer to sing the song of kin and increase their confidence to do so.
  - Further modelling of how to tailor parent chosen song to infant.
  - Sharing information about what makes a song soothing and why.

- Allow space for discussion between participants and facilitators, to explore any issues and/or anxieties.

Third group session

Duration: 1h

Timing: Start of Week 3

Aims:

- To identify potential problems/difficulties and increase carers' confidence in singing to their babies.
  - Allow for organic discussion of any issues and/or anxieties.
  - Facilitators to ask more direct questions about obstacles and challenges to infant directed singing.
  - Further modelling and examples given if needed.
  - Allow a space for reflection on aspects participants feel have gone well and share experience and support with each other.

Focus group.

Duration: 1 hour

Timing: After the intervention (start of Week 7)

- Discuss relevant issues related to interventions (e.g., experience, perceived benefits, barriers, etc.)

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Davie, P (2018). Measuring milk: A call for change in quantifying breastfeeding behaviour. *Midwifery, 63,* 6-7

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Appendix D:

Protocol (Health education)

IRAS ID: 296579

Version 1.2, 15th April 2021

Intervention

Duration: 6 weeks

Procedure:

- Participate in 3 groups sessions (see below) Weeks 1-3
- Ask carers to use skills learnt during group sessions in moment of infant distress weeks 1-6

Health education-specific measures (before, during and after the intervention)

Pre-intervention only

1. Firstly, participants will answer a few demographic questions about their home composition, age, infant date of birth, the first three characters of their postcode (to determine socioeconomic status), and their infant feeding method. Given that the engagement with health seeking behaviour may be related with past experiences of seeking health information to learn about one's baby and perceived importance of health information seeking, it would be important that each carer is administered some a short historic questionnaire, eventually focused on their health information seeking habits with the infant **BEFORE** the intervention starts.

- Do you seek health information about your baby's condition when he/she is unsettled? Yes/No.

- How often did you seek health information about your baby in the last 48 hours? Not at all/1-2 times a day/3-5 times a day/>5 times a day

- Have you found seeking health information about your baby's condition helpful in soothing your baby's symptoms when he/she is unsettled? Most of the time/Often/Sometimes/Never

- Did you experience positive feelings whilst seeking health information about your unsettled baby's condition? Most of the time/Often/Sometimes/Never

- Please complete this statement: My baby is content… Most of the time/Often/Sometimes/Never

The next question will be assessed using 5-point Likert-scale response options:

Please complete this statement: When my baby is unsettled, I feel…

1 Useless 2 3 4 5 Able to cope

1 Anxious 2 3 4 5 Calm

1 Guilty 2 3 4 5 Not Guilty

1 Lonely 2 3 4 5 Supported

1 Frustrated 2 3 4 5 Patient

Pre- and post-assessment questionnaires

To examine the effectiveness of the intervention condition, the following questionnaires will be administered before and after the 6-week intervention involvement in this study:

Infant feeding method will be assessed using a validated 11-point Likert Scale with percentage response options varying from 100% formula fed to 100% breastfed over the past 48-hour period (Davie, 2018).

Perceived Maternal Parenting Self-Efficacy (PMPSE) tool (Barnes & Adamson-Macedo, 2007).

20-item self-report questionnaire to assess perceived parenting self-efficacy with four sub-scales reflecting different parenting domains: care taking procedures, evoking behaviour(s), reading behaviour(s) or signalling, and situational beliefs. Response options include, 'strongly disagree', 'disagree', 'agree' and 'strongly agree'. Higher scores on this questionnaire reflect higher perceived parenting self-efficacy.

Edinburgh Postnatal Depression Scale (EPDS; Cox et al., 1987)

10-item self-report questionnaire administered to screen for depressive symptoms in the postnatal period. It is the most widely used screening scale for postnatal depression. Higher scores indicate higher levels of depression. A clinical cut-off score of ≥13 identifies scores consistent with major depressive disorder, although the self-report measure does not replace a clinical diagnosis.

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16-item self-report questionnaire to assess perceived parenting anxiety in the postpartum period. Questionnaire items cover four domains of parenting: psychosocial adjustment to motherhood anxieties, practical infant care anxieties, maternal competence and attachment anxieties, and infant safety and welfare anxieties. Higher scores indicate higher levels of anxiety. Measured using 4 point Likert scale response options from '0 Not at all' to '3 Almost Always'.

Short Assessment of Patient Satisfaction (SAPS; Hawthorne et al, 2014)

7-item self-report questionnaire to assess perceived satisfaction with healthcare professional support. Response options include, 'very satisfied', 'satisfied', 'Neither satisfied nor dissatisfied', 'Dissatisfied', and, 'Very dissatisfied'. Higher scores on this scale correspond with greater perceived satisfaction with healthcare professional support.

Please rate how much to you agree with each of the following statements using a scale ranging from 0 (completely disagree) to 10 (completely agree)

- I seek out health information about my baby's condition
- I think it's very important to learn about my baby's condition
- Learning about my baby's condition helps me to manage them better
- Learning about my baby's condition helps me to feel positive

During all intervention weeks (1-6):

1. **DURING** the intervention, in order to quantify engagement with the intervention and the state of the infant and the carer it would be very important to monitor the following variables on a weekly basis:

- *How often did you use the techniques learned and advice given over the last week?*
  - *Every day, most days, about half of the week, rarely, never*

Perception of infant's symptoms that week (e.g., amount of crying, general distress, hours of sleep, etc.

- *How often did you use the techniques learned and advice given over the last week when he/she was distressed?*
  - *Every day, most days, about half of the week, rarely, never*
- *Did you feel that using the techniques learned and advice given over the last week with your baby when she/he was distressed helped them to feel better?*
  - *Every day, most days, about half of the week, rarely, never*
- *Did you feel that using the techniques learned and advice given over the last week with your baby when she/he was distressed helped you to feel better?*
  - *Every day, most days, about half of the week, rarely, never*

2. **AFTER** the intervention, it would be also relevant to measure the perceived effectiveness of treatment as usual. Same measures that were administered before the intervention (1) are to be administered again to assess change over time and effectiveness of the intervention.

Session 1

Duration: 1 hour (40-minute information provision and 20-minute moderated discussion)

Timing: Start of Week 1

Aims:

40-minute informational provision portion of the group discussion will focus on reflux, and will cover the following topics:

- What is reflux (what does it mean) and what is normal?
- Physiology (why are babies more prone to reflux)
- What is cow's milk protein allergy and symptoms?
- General timeline of symptoms (when start, when at its peak, when getting better)

Management

- Feeding: volumes, frequency, common problems and solutions
- Medication (pros and cons and how they work)
- When to worry about vomiting, including monitoring output and growth
- Supporting parents, through moderated group discussion (20 minutes) of questions and discussing shared and unique parental experiences and coping strategies.

Second session

Duration: 1 hour (40-minute information provision and 20-minute moderated discussion)

Timing: Start of Week 2

Aims:

40-minute informational provision portion of the group discussion, will focus on colic and will cover the following topics:

- What is colic (definition)

- Why does it happen?
- Timeline of symptoms, baby crying graphs – what is normal.
- Coping strategies (ICON, N/A)
- When to worry about crying
- Supporting parents, through moderated group discussion (20 minutes) of questions and discussing shared and unique parental experiences and coping strategies.

Third session

Duration: 1 hour (40-minute information provision and 20-minute moderated discussion)

Timing: Start of Week 3

Aims:

40-minute informational provision portion of the group discussion will focus on baby development and weaning, and will cover the following topics:

- Normal development and what to do if you are worried about development
- How to encourage development (tummy time etc)
- Normal sleep patterns including tiredness cues and night time feeding
- Signs of readiness for weaning
- Early weaning pros and cons
- Gagging/ choking (difference between)
- Finger foods v purees
- Should you avoid certain foods in refluxy babies?

Focus group.

Duration: 1 hour

Timing: After the intervention (start of Week 7)

- Discuss relevant issues related to interventions (e.g., experience, perceived benefits, barriers, etc.)

References

[Reference removed due to re-identifiable information about the hospital site]

[Reference removed due to re-identifiable information about the hospital site]

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Appendix E: Intervention topic guide questions

IRAS ID: 296579

Version 1.2, 15 April 2021

We would like to hear about how you found the intervention. We would like to know why you decided to take part, what it was like for you, and what impact (if any) it has had on you and your baby. We would also like to hear about how things have been since the intervention, if things have improved, and whether you're satisfied with what's happened.

Accessing the intervention

What was it that made you decide to sign up to the study?

Were you given enough information to make an informed choice?

Did you have any initial reservations about taking part?

Experiences of receiving the intervention

I. Format and content

1. **Thinking about when you started taking part in this study, did this happen at a point where you felt that extra support would be helpful for you?**
    - Would you have liked to have started taking part earlier? Later?
    - Why (not)?
2. **How did you find the sessions overall?**
    - Were there any specific sessions you found particularly helpful/unhelpful?
    - Was there anything missing that you would have liked?
    - How did you find the activities set in between sessions?
3. **How did you find the group nature of the sessions?**
    - Anything you particularly liked/disliked about the group environment?
4. **How did you find the online nature of the intervention?**
    - Anything you particularly liked/disliked about the online environment?
    - How would you feel about participating in the same intervention face to face?
    - [For peer support probe both group sessions and WhatsApp]

II. Delivery

1. In terms of who led the sessions, what did you think of their approach?
    - Anything you found particularly helpful/unhelpful?
2. Was the information they provided helpful?
    - Was there anything less helpful?

III. Time

1. How did you find the length of each session?
2. Were the sessions frequent enough/not frequent enough?
3. Were you happy with the number of sessions overall?

Views on outcomes

1. How did you find putting the information and skills you learned during the intervention into practice?
2. How do you think that taking part in the intervention has had an effect on you personally (positive/negative)?
    a. Has it helped you?
    b. In what ways?

3. How do you think that taking part in the intervention has had an effect on the way you manage your baby?
    a. Has it helped you?
    b. In what ways?

4. How do you think that taking part in the intervention has had an effect on your baby's symptoms?
    a. Has it helped them?
    b. In what ways?

5. Did you enjoy the sessions?
6. Are you satisfied with what you were offered?
7. Would you recommend it to other people?
8. Was there anything you didn't like or would change?

Staff Focus Group Babies in Tune

IRAS ID: 296579

Version 1.3, 15 April 2021

I'd like to find out your views about the intervention, why you decided to take part in it, what it was like, and what impact (if any) it has had on you. . I'd also like to find out what's happened since the intervention and whether it has changed the way you work in any way.

Involvement in the intervention

What was it that made you decide to work on the study?

Were you provided with sufficient information about the study?

Were you sufficiently involved in the development of the study? Did you have any initial reservations about your role on the project?

Preparing the sessions

1. **How did you find preparing the sessions overall?**
    - Were you sufficiently supported?
    - Were there any specific sessions you enjoyed/didn't enjoy preparing?

Experiences of delivering the intervention

I. Format and content

1. Thinking about when participants were recruited for this study, did this happen at a point where you felt that the caregivers and infants would find extra support beneficial?
    - Should participants be recruited earlier? Later?
    - Why (not)?

2. How did you find delivering the sessions overall?
    - Did you find delivering the sessions enjoyable overall?
    - Were there any aspects which were stressful?
    - Were there any specific sessions you enjoyed/didn't enjoy delivering?
    - Was there anything missing that you would have liked?
    - How did you find the activities set in between sessions?

3. How did you find the group nature of the sessions?
    - Anything you particularly liked/disliked about the group environment?

4. How did you find the online nature of the intervention?
    - Anything you particularly liked/disliked about the online environment?
    - How would you feel about participating in the same intervention face to face?
    - [For peer support probe both group sessions and WhatsApp]

III. Time

1. How much time did it take you to prepare the sessions?
2. How did you find the length of each session?
3. Were the sessions frequent enough/not frequent enough?
4. Were you happy with the number of sessions overall?

5. How did being involved in this study impact on your day to day workload?

Views on outcomes

1. How do you think that delivering the intervention has had an effect on you personally (positive/negative)?
    a. Has it helped you?
    b. In what ways?
2. How do you think that taking part in the intervention has had an effect on the way families manage their babies?
    a. Has it helped them?
    b. In what ways?
3. How do you think that taking part in the intervention has had an effect on baby's symptoms?
    a. Has it helped them?
    b. In what ways?
4. Did you enjoy the sessions?
5. Are you satisfied with what you offered?
6. Would you recommend it to other practitioners?
7. Was there anything you didn't like or would change?

Appendix G: Supporting evidence with illustrative quotes, conversation analysis on WhatsApp group data.

Major Theme	Sub-theme	Description of theme	Example exert
Trial-and-error symptom management		Comparisons made with infants unafflicted by CMPA, Colic, and GOR[D] intensified one's distress. Negative interactions with other parents and dismissive clinicians also had adverse effects on maternal mental health. The WhatsApp group was frequently used for sharing infant care practices and non-clinical symptom management techniques for their infants, which aided in normalising the infant's condition.	
	Halved problems, shared solutions	Characterised by difficulties managing infant unsettledness, exacerbated uncertainties about infant development, turn-taking working towards acceptance of infant's condition, irony, and humour used to prompt candid exchanges.	*Barbara: William went down around half 8.... Woke at half 10, 1am, 3.30am, 5am, 7am and then half 8…Lately he's been waking randomly throughout the night...'* *Silvia: Awww no is it the 4-month sleep regression? This is all I hear about 😂😂! I put George down at 7 and then dream fed him at 11 and he woke at 4 for a bottle then 6 with little pains he was so windy bless him and then he went back to sleep until 8 for his next bottle! [...]* *Barbara: Most likely it is... I was reading about that and found a guide as to how to improve sleep at this stage... I use my sleepless nights to read about babies and sleep... Oh the irony* 🤦

	Also characterised by frustrations held towards healthcare practitioners e.g., receiving contradictory advice. Sharing one's unsatisfactory experiences prompted information exchange between group members, as well as recognition and validation of one another through farcifying one's own experiences and encouraging one another to do what works best for them.	*Silvia: Barbara if you ever want to try neocate I have loads of tins here I can give you […] Although it threw me the other day, the consultant told me not to rule out an allergy […]* *Barbara: Crazy how little they know about allergies in babies that they would suggest swapping like for like! Thanks Silvia 👍 If there's no improvement in his eczema etc after 2 or 3 weeks on this formula, I'll try the neocate 👍 […] early on, our allocated HV was off sick, [and the replacement] said that if he [baby] didn't have issues with his bowels it couldn't be an allergy... When we eventually got seen at [Hospital]the paediatrician said with his eczema and reflux, it absolutely could be an allergy... […]* *Silvia: […] I hope you've called the doctor to have that prescription and you're not paying for it. It's a ridiculous amount of special formulas !! … It sounds like we have had a similar experience of one saying no it's not an allergy and one saying no it could be! Where does that ever leave us then in knowing for sure […]*
Infant care anxieties	Expressing vulnerability in the peer support group was met with instilled confidence by other group members	*Barbara: The paediatrician actually suggested early weaning for William... I'm afraid to start though because he chokes sometimes when his milk comes up... I'm terrified what would happen if it were food he was bringing up and choking on □ xx* *Silvia: I was going to say I'm considering early weaning! […] It's scary isn't it to try but go*

		with your instincts on what you think he can handle and when! It's hard to make sure we're not causing any other issues isn't it xx
	WhatsApp group was used to seek reassurance, other mothers responded drawing on their previous experience to reassure the mother of normal infant behaviour at this developmental stage. Multiparous mother placed by other group members as the 'knowledgeable, experiences' advisor.	*Silvia: Does anyone else stress over how much sleep their little one gets in the day 😕🤦‍♀️I find myself really stressing over him getting enough daytime sleep because I'm scared it'll affect the night-time sleep and I just wish I was more chilled out about it […]* *Madison: […] My little one doesn't sleep much a day I don't think but neither did my 7-year-old […] I do feel like some days she sleeps even less if she's having a bad reflux day x* *Silvia: Ahh thanks that makes me feel better I just feel like I'm always trying to force him [to sleep] because I see so much about it affecting night sleep and then getting overtired it's overwhelming when it's your first and you don't have anything to compare to 😂x*
'Us' against 'Them'	The WhatsApp group was often used to promote coping through humour, validation, and normalisation of one another's experiences. All mothers had received negative judgement and/or insensitive comments from family, healthcare practitioners, and/or other parents, which elicited feelings of shame. The WhatsApp group offered a safe platform for the mothers to keep in perspective	

	that their infant's condition will improve with time. Finally, the WhatsApp group enabled mothers to share details of infant development that extended past their condition, and to cherish their infant's progression with their condition.	
Frustrated and judged	Expressing empathy for one another's feelings bridged into sharing one's own, likened experience of parenting an infant with GOR, reflux and/or CMPA. Comparisons made between their unsettled infant and unafflicted babies resulted in feelings of disappointment. Having space to reflect and share in a candid manner allowed for a more optimistic reflection of one's circumstances to be maintained	*Madison: […] my poor Dad doesn't really get to hold her [Billie] much and he's such a lovely grandad loves just holding them but when they unsettled and crying I know he doesn't like it so passes her on! […]* *Silvia: Aww I know the feeling I feel like every time I take George to my mum and ads he cries 🙈I have 3 nephews and 1 niece all from ages 16 to 11 months and none of them have been like George it's so sad because I just want him to be happy and content especially when my nephew so close in age is so smiley and happy! […] At least we know we're not alone! X*
	Barbara opened a conversation about her negative experience of attending a parenting group, whereby her infant's unsettledness was met with intolerance. Again, another group member responded by sharing their personal reservations about attending group sessions, normalising infant behaviour, and reassuring Barbara that she had done the *'right thing'*.	*Barbara: (…) I went to a baby group this morning and William brought up milk all over the lovely carpet and screamed any time I tried to put him on his back to join in... When we were leaving I'm sure we were the only ones the group leader did not say "Hope to see you next week" to 🙈😊xx* *Silvia: 😂😂oh nooo! Do you know that I've not taken him to a group yet because I'm so scared of him crying the whole time 🙈but I*

	Silvia's reassuring response prompted Barbara to focus on more positive experiences of attending parenting groups, although worries were still persistent regarding how one appears to other mothers.	*just need to do it because babies cry it is what it is! Why should they miss out on anything! Xx* *Barbara: Absolutely! I take William to a different group every day... We never get through a session without crying but if he enjoys even a small part of it it's worth it 👍 Even though it really is beyond embarrassing when he screams and I can't settle him…Some of the things people say to you are mad though... One mum suggested that I feed him □ Another reassured me that you don't have to stay for the full session □ Would be great if she took her own advice, I thought 😂xx*
Feeling like a bad mother	Expressions of emotional vulnerability and insecurity were common conversation triggers. Here, Barbara indicates how her infant's unsettledness had enveloped her in feelings of shame (blinded for review). As consistently shown during these group interactions, a second mother then intervenes, leading with reassurance and empathy and rationalising maternal difficulties as normal and transient. Rationalising and normalising Barbara's feelings and experiences served to remove the intensity of their negative valance	*Barbara: I feel like they must just think I'm a rubbish mum! Wish they knew more about it because it's hard to explain xx* *Silvia: Aww they will not think you're a rubbish mum at all, as you said they've seen it all so they must know how much discomfort he's in and how difficult it can be to settle him. We will all get there with them being more settled and happy they just need to pass through this unfortunately and for us it will feel like a lifetime but we will look back on it and think how quickly it went I'm sure □□☺□ xx* *Barbara: That's really lovely Silvia 😊 Someday we'll look back at all of this and laugh... Well maybe that's too far... Look back and not cry □ xx*
	Avoidance behaviour (a common manifestation of shame; blinded for review) was consequential to	*Silvia: Oh my god I can't believe some people honestly, how you can expect not to hear baby's cry in groups is beyond me 😂I'm like*

	receiving insensitive, judgemental comments from other parents. This was met with understanding and validation by the other group members	*you though I feel embarrassed if I can't settle him but I need to just do it! In my head I keep saying I'll wait until he's 3 months so is more alert to enjoy it but honestly I think it's just an excuse in my head xx* *Barbara: You're absolutely right to wait 3 months. I only did one group for 3 months... [parenting group and baby sensory group] and he used to just scream through it or sleep through it* 🙈
	Reassurances from other group members protected the *'good mother'* (blinded for review) identity from feelings of shame	*Madison: Sorry tough night getting little miss down, her reflux seems to have peaked again! She does still try to spit it out* 🙈 *I hold her across my legs, so her head is tilted back slightly. It's awful traumatic I think actually for them, but you know what you're doing is to help them isn't it!! X* *Barbara: Absolutely! You know you are only doing right by them xx*
My baby is more than just unsettled	Mothers were keen to attend sessions together, further substantiating their emotional intimacy through face-to-face support. Re-phrasing infant's unsettledness using humour unified maternal confidence to attend sessions, despite insecurities	*Barbara: ... If you're local, you should come along.... We could compete for fussiest baby* 🏆 *[List of days, times, and locations of various baby groups in local area]* *(...)* *Silvia: Ahh yeah I am local I'm [area in city] so id definitely come it would be so good to go with someone who doesn't mind the crying* 😂 *(...)*

After attending a face-to-face parenting group together, Silvia initiated a conversation by expressing pride in William and George having attended a group session without an unsettled episode. Both mothers acknowledged the non-linear nature of the infant's symptoms. Silvia then goes on to identify feelings of grief regarding the infant's development, which was perceived to be tainted by their condition, which was reaffirmed by Barbara's views. Both mothers were exhausted with inadequate available support for their managing their infant's condition-related challenges:

Silvia: Aww Barbara I'm so proud William and George where the only babies who didn't cry during the massage 😊who are these babies □ […]

Barbara: The only babies who didn't cry □ Can you believe it? 😊So proud of both of them □ […]

Silvia: Ahh Barbara bless him [George] □😓 it's so hard isn't it, the impact it has on enjoying all these moments with them is really sad, and everyone says oh they grow out of it by the time they're 1! Well my mat leave will be over then and I'll feel like I've not really enjoyed any of it as I could have done if he hadn't had this □ hope he has a better day today □□□□ xx

Barbara: You couldn't have put it better Silvia... I feel exactly the same □ I don't want to wish the first year of my baby's life away just to see the back of something that there should be help for! Xx

Appendix H: Thematic analysis supporting illustrative quotes

Major theme	Sub-theme	Example quote	Interpretation
Effective design and delivery	A personal touch	*"...getting a personal phone call to say this study might suit you and your baby was quite nice. And actually, I signed up probably for that reason and I might not have had [it] been generic in the hospital." (Barbara, peer support).*	The personalised nature of recruitment was commended: having direct interactions with delivering members of the research team played a pivotal role in motivating participants to commit time to the intervention.
		"I think the delivery was really good…having the kind of balance of there being information on the slides…while also having the balance of being able to interact with each other, and kind of know our thoughts and, and what would be useful for us and things like that." (Silvia, peer support).	
		"I'm not sure if there were ten parents, I'm not sure you'd have the kind of closeness in the group that you have, because on a message, when you're only one of three and a message comes up, there's sort of an onus on you to respond, and you're, you are very visible in the group." (Barbara, peer support).	The peer support arm was intended for ten participants, which was not achieved due to exceptional recruitment difficulties. However, value was placed on the small-group nature of the WhatsApp group. This was attributed to increased feelings of personal responsibility and social cohesion when in a smaller group.
		"It was a good blend I thought of clinical practice, art practice and research practice. I think that's definitely one of the strengths and probably one of the most slightly innovative aspects of the project and to bring all those together." (XX, staff).	For the research team, multidisciplinary collaboration and co-design was critical for impactful research. Contributing diverse expertise and life experiences enhanced study benefit.

Accessibility and instilled confidence	*"If it were face-to-face every week, that would be far too much ... I think you would find it difficult to for people to sign up to that, because it's a lot and it's a lot to work everyone's schedule and things like that, and even just getting your baby out of the house at that time can be hard." (Babara, peer support).*	Online delivery was thought to improve intervention accessibility, especially for parents who were struggling to manage a busy schedule.
	"If it [WhatsApp group] had gone quiet for a couple of days, you [XX] kind of just put something into a general message to ask how everyone was doing. And I think that was enough to then get the conversation going again…it was just the right amount of inputs really… I've got the most value out of the WhatsApp group." (Silvia, peer support).	The WhatsApp group widely benefited participants in terms of normalising infantile symptoms. Facilitative prompts used were perceived to be appropriate.
	"...because I know other babies that are like this now... that's had a huge impact emotionally, definitely, yeah. There's less self-blame, less negative emotions around it, the emotions around it now are much more positive." (Barbara, peer support).	Engaging with other parents with shared life experiences ascribed benefits to maternal wellbeing and confidence.
	"Even knowing that there's other babies in that situation makes you attribute less of it to yourself, and actually, conversationally, because you're talking to other moms, I've tried this, I've tried this, you're not in the conversation. So I suppose you're not the problem". (Barbara, peer support).	
	"I think the most I got out of it for me as well is realizing that I needed to take a little bit of time for myself. I think going through that kind of session where there was kinds of things that we need to do for ourselves as well to be able to have a little break, like mentally. And I think that I have definitely started putting things in place after that just to know that I needed a break from [baby]..." (Silvia, peer support).	Session three of the peer support arm, which focused on self-care and compassion, was particularly valued by participants for fostering emotional resilience.
	"I get up before [baby], I now do that, after we talked about that [in the group session], I now do that religiously… and actually take that time to myself in the morning to get ready and have a coffee and have all that before I get him, before he wakes." (Barbara, peer support).	

Study weaknesses	Delayed point of entry	*"By the time you come to [Hospital], there's a couple of things that have to happen…you'll have maybe spoken with a health visitor, you might have gone to [emergency department] ...[Hospital] is sort of a last resort, really." (Barbara, peer support).*	Participants noted that study retention may have been improved by recruiting at an earlier point in their infant's illness trajectory. Staff accounts were congruent with maternal concerns.
		"...we were too late in the intervention, by the time they [parents] have gone to visit their health visitors, GPs, end of the line was [Hospital] ...they would have wanted [the intervention] when [their infant was] two months old not when they were four months old." (XX, Staff)	
		"... [it would be good if] in that initial meeting with the health visitor or your midwife, for you to be invited to the study then, because actually with things like this they tend to be at their worst at the very beginning and then they get easier as time goes on." (Barbara, peer support).	By recruiting earlier, for example through universal health visiting services, eligible caregivers could be approached when level of need was more appropriate.
		"...speak to health visitors and give them the information, because I think there's a lot of people who kind of just accept that the baby might have colic,and might not necessarily take the baby to kind of follow up anything" (Silvia, peer support).	Some participants were concerned that recruitment delays might have inadvertently resulted in some parents going without much needed support.
	A mis-match of the formal and informal	*"...what [the intervention] boils down to is Zoom and a WhatsApp group and it's nothing more complicated than that. So just to have that summarized in a sheet I think will be really helpful." (Barbara, peer support).*	Participant-facing documentation was described as being overly convoluted. Recommendations were made to include a leaflet which clearly summarised participant responsibilities prior to study screen-in.
		"I think the information sheet was terrible. I don't think I've ever managed to read through it all." (XX, Staff).	
		"I don't think the information sheet really outlined exactly what was like expected of us really, or what we were like, what was going to happen. And then she [recruiting consultant] didn't	Some recruiting members of staff at [Hospital] lacked study

	really know much about it herself to kind of tell me about it really either." (Silvia, peer support).	insight, which further added to caregiver confusion when deciding whether to take part in the intervention:
	"I think how you're called to the study doesn't reflect actually the running of the study. The running of the study is very informal, very relaxed, very in fact, it's to promote openness and engagement and it works around you and your baby…how you're actually called to the study just doesn't marry up with actually that's how the study runs." (Barbara, peer support).	The clinical environment, from which parents were recruited, contrasted with the informal nature of the intervention. This resulted in ill-reflective study expectations on screening into the study.
	"[Hospital is a], very professional, clinical, formal environment. So, you feel like, what's being asked of you is also professional clinical formal ...you tend to have quite a close, friendship, informal sort of relationship with your health visitor. So, your health visitor relaying that study to you, I think you're more likely to take it up." (Barbara, peer support).	Recruiting in the community was perceived to be a more appropriate fit for the nature of the current study.
	"...Some [participants] might not want music, they might have wanted peer support, or health education. But the nature of the design and the amount of referrals you were getting at [hospital] we couldn't have randomised or given them any kind of choice in the matter." (XX, Staff).	Staff believed allowing participants to select their intervention arm would further encourage participant retention.
Hybrid delivery and condensed sessions	*"…put an extra session in where you do meet face to face just for an informal chat, really…it could help break the ice a little bit." (Silvia, peer support).* *"By the time it actually came about to start running [the intervention] everyone was sick to death of Zoom." (XX, Staff)*	Although online session delivery was preferred among participants, introducing an *'initial f*ace-to-face session was suggested, to facilitate initial rapport-building. Offering a hybrid delivery would also combat screen fatigue.

"if your baby is napping, then 45 minutes to an hour is, your baby will start to wake up after that …if [the Zoom session] could be condensed to 45 minutes, that would be great". (Barbara, peer support).	Condensing sessions to 45-minutes was noted as being more suitable for fitting around childcare commitments.
"[What if] people needed something immediate, no? Is the format actually a page where they can get all the information, have the information, videos, demonstrate you know that they can immediately go home and engage with that and have all the support in a webpage." (XX, Staff).	Recommendations were made to develop online resources for use outside of scheduled sessions. This would further extend intervention benefit beyond the lifespan of the project.
"For peer support you could have forums online with moderators, maybe even channels dedicated to first time mothers, second time mothers. Places where people can congregate [between intervention sessions]." (XX, Staff).	

Author reflexivity statement

XX is a Master's student in clinical Psychology at University La Sapienza, Rome. English was XX's second language, which he found challenging when translating audio files and interpreting colloquialisms during analysis. All transcribed audio files were checked for accuracy by an independent researcher who was otherwise unaffiliated with the current study, and blind to its aims [XX]. Any inconsistencies and/or inaccuracies were mended at this point. Additionally, a perinatal researcher with extensive experience in qualitative research methods co-analysed the WhatsApp data [XX], to ensure that final thematic structures were appropriately embedded in participant accounts[48-49]. In one respect, XX considered that being male may have limited their ability to empathise with maternal accounts as deeply as a female analyst. However, having a sibling who had been afflicted with GORD enabled a deeper level of understanding to be held towards participants affected by the conditions under investigation.

Thematic analysis was conducted by XX, a Psychology Conversion MSc student at the [University]. XX is a nulliparous cis-female who does not have any clinical training or personal experience related to colic, GOR(D), and/or CMPA. This lack of direct experience was viewed as an advantage as it allowed XX to analyse with greater objectivity and minimal personal biases. Conversation and thematic analyses were co-analysed by XX, who is an early career researcher in perinatal mental health with extensive experience in qualitative research methods. XX does not have clinical training, which allows for an objective stance to be taken during conversations about infant symptomatology and treatment. Final thematic structures were revised and agreed upon by all members of the research team, including perinatal and music academics [XX, XX, XX, XX], clinical staff with neonatal, infant feeding, and maternity expertise [XX, XX, XX, XX, XX, XX], and a parent with relevant lived experience [XX].

Supplementary materials: CONSORT statement

Section/topic	Item number	Checklist item	Where detailed in manuscript
Title and abstract	1a	Identification as a randomised trial in the title	Study was not a randomised trial, but title identifies it as a feasibility study, "Investigating the acceptability and feasibility of three online interventions, for caregivers of infants with feeding difficulties"
	1b	Structured summary of trial design, methods, results, and conclusions	See abstract, "**Methods:** Eligible caregivers were recruited during routine appointments with the infant feeding team at Alder Hey Children's NHS Foundation Trust. Consenting caregivers were assigned to one of the four intervention arms. For peer support only, a WhatsApp group accompanied group sessions. Intervention weeks 1-3 involved a one-hour online group session, where skills were developed with an aim to improve management of infantile symptoms, and to nurture self-care practices. In weeks 4-6, participants were encouraged to use skills obtained from weeks 1-3, independently. In week 7, evaluative focus groups were conducted. WhatsApp group data underwent conversational analysis and evaluative focus group data underwent thematic analysis. **Results:** Feasibility was not achieved due to recruitment difficulties. However, the peer support intervention was deemed acceptable by mothers and staff. Peer support participants valued the flexibility access to support via WhatsApp with other mothers with shared life experience. **Conclusion:** Evaluative focus groups identified study strengths and limitations which will provide insight to digital health researchers seeking to develop interventional research for caregivers of infants afflicted with colic, GOR(D), and/or CMPA."
Introduction			
Background and objectives	2a	Scientific background and explanation of the rationale	See Section 1, 'Introduction'.
	2b	Specific objectives or hypotheses	For operationalised objectives and hypotheses, see section 1.4 of the introduction, 'Current study'
Methods			
Trial design			Details on intervention design can be found in section 2.4 of the methods. Appendices A-D also provide more detailed information on set up of the respective intervention arms and highlights where standardising efforts have been made. See section 2.4 for information on pragmatic sampling and group allocation. See section 2.2. Study design, "The current pilot study aimed to investigate the feasibility and acceptability of an online group peer support, health education, and music intervention for caregivers of infants affected by colic, reflux, and GOR(D).
	3a	Description of trial design (such as parallel, factorial) including allocation ratio	Study is identified as a pilot study to investigate the acceptability and feasibility of three group online interventions throughout the introduction and methods sections of the manuscript.
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	Not applicable. No changes were made to the methods after trial commencement.
Participants	4a	Eligibility criteria for participants	This information can be found in section 2.3 'Participants' sub-section of the methods, "Mothers who had been referred to Alder Hey Children's NHS Foundation Trust (Hereafter referred to as 'Alder Hey') with their unsettled infant, due to infant feeding difficulties relating to Colic, GOR(D), and/or CMPA, were identified by clinicians employed at Alder Hey. All caregivers who met the following eligibility criteria were approached by their clinician during routine appointments: over the age of 18, and no previous or current clinical diagnosis of a

			serious mental health condition i.e., bipolar disorder, schizophrenia, and/or psychosis (confirmed via self-report on initial contact [LJ], described below). Infants needed to be younger than six months old at time of referral, born full-term (i.e., >34 weeks' gestation), without known comorbidities or evidence of faltering growth[34] for their caregiver to be eligible to participate.
		4b	Settings and locations where the data were collected	Not applicable – participants were recruited from one site, only. Information on eligibility criteria and recruitment process can be found in section 2.3 'Participants' of the methods in the current manuscript. All participants were recruited by their healthcare practitioners, Employed by Alder Hey. Full details on the recruitment process and data collection can be found in sections 2.3, 2.4, and 2.6 of The methods in the current manuscript.
	Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	Full information on set up of the intervention arms, including where design has been standardised can be found in section 2.4 of the manuscript's methods. See appendices for more detailed break down of the respective intervention arms. PowerPoint slides from each intervention arm can also be made available on reasonable request.
	Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	Psychometric measures administered at baseline and in week 6 to assess change over time in wellbeing measures, which are detailed in section 2.5' pre-and post-assessment questionnaires' section of the methods. Evaluative focus groups were also conducted in week 7 to investigate lived experiences of taking part in the pilot study, to inform design in scale up of the interventions.
		6b	Any changes to trial outcomes after the trial commenced, with reasons	Not applicable. No changes were made to the trial outcomes after trial commencement.
	Sample size	7a	How sample size was determined?	A pragmatic sample of 40 participants was sought, as is common in feasibility research. This information can be found in section 2.4 'Group allocation and intervention details' sub-section of the methods.
		7b	When applicable, explanation of any interim analyses and stopping guidelines	Interim questionnaires were administered on the Friday of each intervention week to assess usefulness of each intervention week. However, due to poor completion rates, these measures were not analysed in final write up of the study. This information can be found in section, '2.7.*1 pre-, post- and interim assessment measures'* of the methods.
	Randomization			
	Sequence generation	8a	The method used to generate the random allocation sequence	Not applicable. See section 2.4 'Group allocation and intervention details' sub-section of the methods for details on sampling method.
		8b	Type of randomization; details of any restriction (such as blocking and block size)	Not applicable. See section 2.4 'Group allocation and intervention details' sub-section of the methods for details on sampling method.
	Allocation concealment mechanism	9	The mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	Not applicable. See section 2.4, "Treatment as usual ran first due to lack of prior preparation required to set up the intervention arm. Clinician capacity meant that six weeks' notice was required to block out sufficient time to run the health education intervention arm alongside their usual caseloads. Therefore, the health education intervention arm ran third, and the peer support intervention arm ran second due to lack of pre-preparations needed to run this intervention arm. Music intervention ran last due to capacity of the employed harpist, who facilitated scheduled group intervention sessions."

Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	Not applicable. See section 2.4 'Group allocation and intervention details' sub-section of the methods for details on sampling method.
Blinding	11a	If done, who was blinded after assignment to interventions (e.g., participants, care providers, those assessing outcomes) and how	Details of intervention arm design can be found in the following section of the methods, "*2.4 Group allocation and intervention details"* including information on how the intervention arms were standardised where it has been possible to do so. More detailed information on the respective intervention arms can also be found in Appendices A-D. PowerPoint slides for the respective intervention arms can also be made available on reasonable request. See section 2.4 for more information on participant allocation to intervention arms, "Treatment as usual ran first due to lack of prior preparation required to set up the intervention arm. Clinician capacity meant that six weeks' notice was required to block out sufficient time to run the health education intervention arm alongside their usual caseloads. Therefore, the health education intervention arm ran third, and the peer support intervention arm ran second due to lack of pre-preparations needed to run this intervention arm. Music intervention ran last due to capacity of the employed harpist, who facilitated scheduled group intervention sessions."
	11b	If relevant, description of the similarity of interventions	Details of intervention arm design can be found in the following section of the methods, "*2.4 Group allocation and intervention details"* including information on how the intervention arms were standardised where it has been possible to do so. More detailed information on the respective intervention arms can also be found in Appendices A-D. PowerPoint slides for the respective intervention arms can also be made available on reasonable request.
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	Inferential statistics were not performed on administered psychometric measures (pre-post comparison or interim assessments) due to exceptionally poor completion rates. See section 3 'Integrated results and discussion section' for discussion of findings from the conversation analysis and reflexive thematic analysis, from collected qualitative data.
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	Not applicable – see above.
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned received intended treatment and were analyzed for the primary outcome	Not applicable – see above. See section 2.4 for information on the number of participants included in the final sample for each intervention arm.
	13b	For each group, losses and exclusions after randomization, together with reasons	Information on participant attrition and final sample size per intervention group can be found in section 2.4 'Group allocation and intervention details' in the methods of the manuscript.
Recruitment	14a	Dates defining the periods of recruitment and follow-up	Information on periods of recruitment can be found in section 2.4 'Group allocation and intervention details' in the methods of the manuscript.
	14b	Why the trial ended or was stopped	Information on participant recruitment period, attrition, final sample size per intervention group, and why the recruitment period was not extended can be found in section 2.4 'Group allocation and intervention details' in the methods of the

			manuscript.
Baseline data	15	A table showing the baseline demographic and clinical characteristics for each group	See Table 1.
Numbers analyzed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	Not applicable – inferential statistics were not performed on administered psychometric measures (pre-post comparison or interim assessments) due to exceptionally poor completion rates. Information on this can be found in section 2.7 'Analysis' sub-section of the methods. A conversation analysis (see section 2.7.2 of the methods) was conducted on the WhatsApp group data collected for the peer support intervention arm and a reflexive thematic analysis was conducted on evaluative focus group data (see section 2.7.3 for details in the methods of the manuscript for more information).
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	Inferential statistics were not performed on administered psychometric measures (pre post comparison or interim assessments) due to exceptionally poor completion rates. See section 3 'Integrated results and discussion section' for discussion of findings from the conversation analysis and reflexive thematic analysis, from collected qualitative data.
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	Inferential statistics were not performed on administered psychometric measures (pre post comparison or interim assessments) due to exceptionally poor completion rates. See section 3 'Integrated results and discussion section' for discussion of findings from the conversation analysis and reflexive thematic analysis, from collected qualitative data.
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	See section 3 'Integrated results and discussion section' for discussion of findings from the conversation analysis and reflexive thematic analysis, from collected qualitative data. Also see Figure 1, Table 2, and appendices G and H for illustrative quotations and supporting evidence for qualitative findings and discussion.
Harms	19	All-important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	See section 2.1 'Ethical statement' for consideration of participant harm in study set up.
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, the multiplicity of analyses	See section 3 'Integrated results and discussion section' for extensive discussion of study limitations and suggestions for improvements.
Generalizability	21	Generalizability (external validity, applicability) of the trial findings	See section 3 'Integrated results and discussion section' for extensive discussion of these points.
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	See section 3 'Integrated results and discussion section' for interpretation of findings in relation to relevant literature, consideration of benefits and harms and providing insights for future research.
Other information			
Registration	23	Registration number and name of trial registry	See section 2.2 Study design and title page, "The present study was pre-registered through the International Standard Randomised Controlled Trial Number (ISRCTN) registry on 06 Aug 2021 (ID: ISRCTN15349263).
Protocol	24	Where the full trial protocol can be accessed, if available	See section 2.2 Study design and title page, "The present study was pre-registered through the International Standard Randomised Controlled Trial Number (ISRCTN) registry on 06 Aug 2021 (ID: ISRCTN15349263)." The full study protocol can be found here.

Funding	25	Sources of funding and other support (such as the supply of drugs), the role of funders	Funding statement can be found on the title page of the manuscript and at the end of the manuscript, "This study was funded by the Hugh Greenwood Legacy for Children's Health Research (Ref: C14). Please note that the funder was not involved in the set-up, conduct, or write up of the current project as submitted for publication."