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Version 1, 15th April 2021

Pilot of remote group interventions for caregivers of unsettled babies with colic and/or Gastroesophageal Reflux Disorder (GORD)

Pilot and feasibility study of remote group interventions for caregivers of unsettled babies with colic and/or Gastroesophageal Reflux Disorder (GORD)

Version 1, 15th April 2021

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STUDY SUMMARY

This protocol describes the '*Pilot and feasibility study of remote group interventions for caregivers of unsettled babies with colic and/or Gastroesophageal Reflux Disorder (GORD)'* study and provides information about procedures for entering participants. Every care was taken in its drafting, but corrections or amendments may be necessary. These will be circulated to investigators in the Study. Problems relating to this Study should be referred, in the first instance, to the Chief Investigator.

This study will adhere to the principles outlined in the UK Policy Framework for Health and Social Care Research (v3.2 10th October 2017). It will be conducted in compliance with the protocol, the Data Protection Act 2018, and other regulatory requirements as appropriate.

GLOSSARY OF ABBREVIATIONS

HRA	Health Research Authority
REC	Research Ethics Committee

KEYWORDS

Colic, Gastroesophageal Reflux, Cow's Milk Protein Allergy, Internet-Based Intervention, Self Efficacy, Pilot Projects, Feasibility Studies.

TITLE

Pilot and feasibility study of remote group interventions for caregivers of unsettled babies with colic and/or GastrOesophageal Reflux Disease (GORD).

DESIGN

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

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

Caregivers who have been referred to Alder Hey with unsettled infants due to colic, reflux, and/or cow's milk protein allergy will be approached by Alder Hey healthcare practitioners, as part of treatment as usual. Here they will be provided with a study advertisement and information sheet for the current pilot and feasibility study. At this point, the Alder Hey clinician will provide the caregiver with some brief information about the current study. Caregivers who indicate that they would be interested in taking part in the current study, with consent, will then have their contact details i.e., name, email address, and telephone number, securely transferred to research assistants LJ/SD. The caregiver will be contacted by LJ or SD after a 48 hour 'cool off period' to digest the provided information from their clinician. LJ/SD will call the potential participant to screen participants, to ensure that caregivers meet necessary eligibility criteria to take part in the current study, to ask if they have any questions and/or concerns, to talk through the information sheet, and to check participant's email address so that LJ/SD can send them an electronic information sheet and consent form to sign (sent via secure Qualtrics

survey link). After providing electronic consent, the participant will then be redirected to a separate Qualtrics survey to complete initial pre-intervention validated measures. At the point of providing electronic consent, the participant is assigned a pseudonym to protect their identity.

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

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

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

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

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

Treatment as usual

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

Health Education

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

Peer Support Group

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

Music intervention

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

AIMS

The current study aims to address a key problem currently faced by Alder Hey: there has been a year-on-year increase in attendance of unsettled babies with feeding difficulties recorded in both emergency department and secondary care outpatient clinics, and a significant increase in cost of both medication and specialised infant formula in managing these conditions. With the intention of leading towards a future larger trial, this study aims to investigate feasibility, acceptability, and benefit of an online music intervention, health educational, and peer support, when compared to treatment as usual, for

caregivers of unsettled babies with colic, reflux, and/or cow's milk protein allergy who had been referred to Alder Hey. This project is aligned with the Alder Hey strategic plan to reduce pressure on the emergency treatment system. Specifically, research aims are:

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

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

The secondary outcomes measures include: perceptions of infant colic and/or reflux symptoms (I-GER-Q scale, Kleinman et al, 2006), infant feeding method (Davie, 2018), depression symptoms (10-item Edinburgh Postnatal Depression Scale, EPDS; Cox, Holden, & Sagovsky, 1987) and anxiety symptoms (16-item Postpartum Specific Anxiety Scale, PSAS; Fallon et al, 2021). Each intervention arm will also assess adherence and satisfaction with the intervention to which they had been allocated on an interim, weekly basis during the six-week intervention period (See appendices A-D for intervention arm-specific information).

POPULATION ELIGIBILITY

The present study will recruit caregivers, referred to Alder Hey for infant colic, reflux, and/or cow's milk protein allergy with infants younger than 6 months at time of referral, born at >34 gestational weeks, without known co-morbidities or evidence of faltering growth as per NICE guidance (2017). Presence or absence of infantile reflux will be determined using I-GERQ (Kleinman et al, 2006) and presence or absence of infantile colic will be determined using the ICS (Ellett et al, 2002). The I-GERQ and ICS were piloted by Alder Hey healthcare practitioners as part of treatment as usual to determine acceptability and feasibility for use in the current study. Caregivers must also not have a current or historic clinical diagnosis of a serious mental health condition i.e., bipolar disorder, schizophrenia, and/or psychosis. This will be detailed in the study advertisement, information sheet, and consent form. Also, the screening member of the research team (LJ/SD) will go through eligibility criteria with the potential participant as a part of the initial screening process for participation, before providing electronic consent (see below for full details regarding participant recruitment).

Caregivers who have been referred to Alder Hey with unsettled infants due to colic, reflux, and/or cow's milk protein allergy will be approached by Alder Hey healthcare practitioners, as part of treatment as usual. Here they will be provided with a study advertisement and information sheet for the current pilot and feasibility study. At this point, the Alder Hey clinician will provide the caregiver with some brief information about the current study. Caregivers who indicate that they would be interested in taking part in the current study, with consent, will then have their contact details i.e., name, email address, and telephone number, securely transferred to research assistants LJ/SD. The caregiver will be contacted by LJ or SD after a 48 hour 'cool off period' to digest the provided information from their clinician. LJ/SD will call the potential participant to screen participants, to ensure that caregivers meet necessary eligibility criteria to take part in the current study, to ask if they have any questions and/or concerns, to talk through the information sheet, and to check participant's email address so that LJ/SD can send them an electronic information sheet and consent form to sign (sent via secure Qualtrics survey link). After providing electronic consent, the participant will then be redirected to a separate Qualtrics survey to complete initial pre-intervention validated measures. At the point of providing electronic consent, the participant is assigned a pseudonym to protect their identity.

DURATION

Participants will be involved in the intervention arms of the current study for a total of seven weeks. Involvement will include attending three weekly, hour long group sessions, held over Zoom. Content of sessions will differ depending on group allocation (See appendices A-D for more information). During their involvement, participants will be required to complete a series of validated measures before and after the six-week period, to assess change in: infant colic and reflux symptoms, depression, anxiety, parenting sense of competence, and satisfaction with healthcare professional support. Caregivers assigned to the treatment as usual group will also complete aforementioned validated measures. This is to compare treatment as usual with the effectiveness and acceptability of intervention arms. Additionally, participants will be prompted to complete intervention-tailored interim weekly questions to access engagement and satisfaction with the individual intervention arm (see appendices A-D for intervention-specific information). All pre, post, and interim questionnaires will be set up on the Qualtrics online platform and will be administered via anonymous links to the participant's email address. For the peer support intervention arm, participants will also be reminded about completing questionnaires in the WhatsApp group by the moderating member of the research team. Questionnaire responses will be stored on the Qualtrics online platform. This anonymous data will be exported after the completion of the intervention group, for analysis on aggregate, anonymous data only.

The current study is estimated to commence April 15 2021 and terminates April 15 2022. Participants will additionally take part in a focus group at the beginning of week 7 to evaluate what worked well and what could be improved regarding their allocated intervention or treatment as usual, for review and study scaling up (intervention arms) or to contribute towards a service evaluation (treatment as usual). See supplementary documentation for focus group topic guide, consent forms, information sheets and debrief forms. All study documentation was reviewed by MVP representatives to assess acceptability and feasibility before submission to ethics.

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1. INTRODUCTION

1.1 BACKGROUND

Infant colic, gastro-oesophageal reflux, and cow's milk protein allergy are common in the first 6 months of life. They lead infants to being irritable and unsettled, as evidenced by excessive crying, retching, pulling up knees, clenching fists and/or loose stools. These symptoms and their difficult management lead to high caregiver anxiety and stress, particularly for those less experienced and supported (Cox & Roos, 2008). Infant colic, reflux and cow's milk protein allergy often lead to increased hospital activity, prescribing costs and formula milk use (Steutl et al. 2014). Excessive infant crying, often seen in infant colic, reflux, and cow's milk protein allergy is associated with more frequent emotional/behavioural difficulties in later life, due to increased infant care burden for caregivers, the deterioration of caregiver-child bonding (Smarius et al., 2017) and poor caregiver psychosocial outcomes (Christl et al., 2013).

The cause of infant colic and reflux is poorly understood, and treatment mainly focuses on supporting and educating caregivers (Zeevenhooven et al., 2017) with little evidence for the benefits of medicine (Rosen et al, 2018). This focus is hindered by the reluctance of caregivers of unsettled babies due to colic, reflux, and cow's milk protein allergy to access community support groups, due to how unsettled their infants can become. The current COVID-19 pandemic, and the personal-social limitations it has brought, have additionally burdened families of infants with infant colic, reflux, and cow's milk protein allergy through restricted support of family, particularly grandparents, access to services, and increased stress and anxiety. This has led to discussions between Alder Hey staff and University of Liverpool academics about novel ways of support offered remotely for these families during these crises.

Music interventions represent a promising form of such support, with growing evidence about its efficacy in reducing stress, anxiety, and perceived symptoms in several clinical settings (Sand-Jecklin & Emerson, 2010; Kühlmann, 2018). In perinatal populations, music interventions are increasingly recognized as beneficial in reducing stress and anxiety (Corbijn van Willenswaard et al., 2017; Wulff, Hepp, Fehm, & Schaal, 2017), and parental reports of calmed infants (Mascheroni & Ionio, 2019). Crucially, given the current COVID-19 pandemic, online music interventions have demonstrated

efficacy (Baker & Krout, 2009). The music intervention will have an immediate impact on caregivers and infants by helping families to manage infant colic, reflux, and cow's milk protein allergy symptoms through Infant Directed Singing, enhancing caregiver confidence, developing coping skills, improving the caregiver-infant relationship, and improving emotional wellbeing. Given the efficacy of music interventions in alleviating caregiver distress, group sessions will focus on using songs of kin which are meaningful to the caregiver as strategies to improve caregiver confidence and wellbeing, and to alleviate infantile symptoms of colic, reflux, and/or cow's milk protein allergy.

As such, this project is a research collaboration between the University of Liverpool and Alder Hey that offers an alternative nonmedical approach to management of infant colic, reflux and cow's milk protein allergy. In the context of infant feeding, optimal caregiver and infant outcomes are better supported by health educational interventions, integrated with emotion-focused forms of support (Skouteris et al., 2014). The health education intervention will have an immediate impact on caregivers and infants by helping families to manage infant colic, reflux, and cow's milk protein allergy symptoms better, enhance caregiver confidence, develop coping skills, and mental health. Given that excessive crying can lead to premature cessation of breastfeeding, overfeeding, or early weaning, the health education intervention will focus on normalising infant behaviour, feeding management advice, and soothing techniques, which are recognized as important in reducing symptoms of infant colic, reflux, and cow's milk protein allergy, and improving child health and development.

Evidence from previous parenting peer support group interventions demonstrates that the proactive sharing of personal experiences and receiving instrumental, social, practical, and emotional peer support has beneficial outcomes for caregiver coping and breastfeeding outcomes (Chepkirui et al, 2020; Regan & Brown, 2019; Thomson & Crossland, 2019; Trickey et al, 2017), identifying promising avenues for intervention development. The peer support intervention will have an immediate impact on caregivers and infants by helping families to gain confidence and cope better when managing infant colic, reflux and cow's milk protein allergy symptoms, increasing feelings of social cohesion and perceived support, improving the caregiver-infant relationship, and improving emotional wellbeing outcomes. Given the importance of proactive rather than reactive sharing of personal experiences, and the importance of broadly encompassing domains of social support in enhancing infant feeding and

emotional wellbeing outcomes, the peer support intervention will focus on sharing and normalising experiences of having an infant with colic, reflux, and cow's milk protein allergy, and facilitating feelings of group belongingness and perceived social support. This is with an aim to improve caregiver confidence in managing infant symptoms and improving emotional wellbeing and caregiver coping strategies.

Online delivery of the interventions has the potential to mitigate the difficulty experienced by caregivers in reaching support groups, in the worry that their experience would be hindered by their unsettled baby. Additionally, online delivery of interventions during the COVID-19 pandemic allows for social distancing measures to be easily adhered with (gov.uk, 2020). Additionally, caregivers often find it difficult to cope with symptoms of infant colic, reflux, and cow's milk protein allergy which negatively affects caregiver confidence and caregiver mental health. Music interventions are increasingly recognized as a beneficial approach to reducing psychological distress in the perinatal period, increasing caregiver reports of calmed infants. With the intention of leading towards a future larger trial, this study aims to investigate feasibility, acceptability and benefit of a remote music intervention, peer support, and health education intervention are, when compared to treatment as usual, in caregivers of unsettled babies due to colic, reflux, and cow's milk protein allergy who had been referred to Alder Hey.

1.2 RATIONALE FOR CURRENT STUDY

This project is a research collaboration between the University of Liverpool and Alder Hey that offers an alternative nonmedical approach to management of infant colic, reflux, and cow's milk protein allergy. It will have an immediate impact on caregivers and infants by helping families to manage infant colic, reflux and cow's milk protein allergy symptoms, enhance caregiver confidence, develop coping skills, and mental health. From the perspective of the University of Liverpool Research Strategy 2026, we are developing a meaningful partnership for public benefit with a clear pathway for large-scale impact that will develop the reputation of University of Liverpool and the city of Liverpool in areas related to healthcare research. Furthermore, this project is aligned with the University of Liverpool, "Personalised Health" and "Starting Well, Living Well, Aging Well" research themes.

From the perspective of Alder Hey, this project directly addresses its strategic objective to develop interventions focuses on exploiting digital excellence. Also, it links to the priorities of the Alder Hey Innovation Centre which are focused on sourcing innovative alternative healthcare solutions to mitigate the impact of COVID-19. More generally, we will be addressing a key problem faced by Alder Hey – there has been a year-on-year increase in attendance of unsettled babies with feeding difficulties recorded in both emergency department and secondary care outpatient clinics, and a significant increase in cost of both medication and specialised formula in managing these conditions among clinical commissioning groups, and in primary care. This project will be able to develop cost-effective alternatives to effectively and immediately deal with these problems, which is aligned with the Alder Hey strategic plan to reduce pressure on the emergency treatment system.

2. STUDY OBJECTIVES

With the intention of leading towards a future larger trial, this study aims to investigate feasibility, acceptability and benefit of an online music intervention, online peer support, and health education intervention, when compared to treatment as usual, in caregivers of unsettled babies due to colic, reflux and cow's milk protein allergy who had been referred to Alder Hey. The primary research aim is to establish whether the interventions are feasible and acceptable to participants and staff, so that a full-scale trial and economic evaluation may follow. Another research aim is to explore whether the music intervention, online parenting support, and health education intervention are beneficial in increasing parenting sense of competence, satisfaction with healthcare professional support, and decreasing depression and anxiety symptoms, when compared with treatment as usual.

3. STUDY DESIGN

The current study is a feasibility and pilot study to assess the feasibility, acceptability, and benefit of an online music intervention, health education, and online peer support intervention among caregivers of unsettled babies with colic, reflux, and cow's milk protein allergy who had been referred to Alder Hey, when compared with treatment as usual.

Caregivers who have been referred to Alder Hey with unsettled infants due to colic, reflux, and/or cow's milk protein allergy will be approached by Alder Hey healthcare practitioners, as part of treatment as usual. Here they will be provided with a study advertisement and information sheet for the current pilot and feasibility study. At this point, the Alder Hey clinician will provide the caregiver with some brief information about the current study. Caregivers who indicate that they would be interested in taking part in the current study, with consent, will then have their contact details i.e., name, email address, and telephone number, securely transferred to research assistants LJ/SD. The caregiver will be contacted by LJ or SD after a 48 hour 'cool off period' to digest the provided information from their clinician. LJ/SD will call the potential participant to screen participants, to ensure that caregivers meet necessary eligibility criteria to take part in the current study, to ask if they have any questions and/or concerns, to talk through the information sheet, and to check participant's email address so that LJ/SD can send them an electronic information sheet and consent form to sign (sent via secure Qualtrics survey link). After providing electronic consent, the participant will then be redirected to a separate Qualtrics survey to complete initial pre-intervention validated measures. At the point of providing electronic consent, the participant is assigned a pseudonym to protect their identity.

Participants will be allocated to groups via quota sampling, with a total of 40 participants with infants under six months of age at referral being allocated to four conditions (10 participants in each intervention arm): music intervention, health education, peer support, and treatment as usual.

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

professional support, and mental health (namely depression and anxiety), for feasibility and acceptability assessment for study scaling up and larger scale implementation in clinical settings.

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

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

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

Therefore, participants will be pragmatically allocated, by means of opportunity sampling, to one of four conditions: music intervention (n=10), health education (n=10), online peer support (n=10), and

treatment as usual (n=10). Total number of participants to be recruited will be 40 (N=40). Irrespective of group allocation, all caregivers and infants will continue to receive support and treatment as usual:

Treatment as usual

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

Health Education Intervention

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

Online Peer Support Group Intervention

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

team to initiate conversations and promote participation See Appendix C for online peer support group intervention protocol.

Music intervention

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

3.1 STUDY OUTCOME MEASURES

The primary outcome measure is perceived self-efficacy, measured using the Perceived Maternal Parenting Self-Efficacy tool (Barnes & Adamson-Macedo, 2007). This 20-item measure will be administered pre and post each intervention arm and pre and post 6 weeks of treatment as usual to assess the effectiveness of each intervention in improving self-efficacy and to enable comparison of self-efficacy across conditions.

The secondary outcome measures also measured pre and post intervention and treatment as usual will be perceptions of infant colic, reflux, and cow's milk protein allergy symptoms (measured using the I-GERQ and ICS scales), infant feeding method (Davie, 2018), depression symptoms (EPDS; Cox, Holden, & Sagovsky, 1987) and anxiety symptoms (PSAS; Fallon et al, 2021). Demographic questions will also be asked for the purpose of descriptive statistics, including: household composition (i.e., how many people do you live with, who do you live with), maternal age, infant date of birth, and the first half of their postcode (for assessment of socioeconomic status). Two questions will also be asked regarding clinical diagnoses of anxiety and depression for descriptive purposes alongside validated measurements of caregiver mood, 'Do you have a current, clinical diagnosis of [anxiety/depression]?' with response options, 'Yes, treated with medication and/or therapy', 'Yes, untreated', 'No', and

'Prefer not to say'. Demographic questions will be administered in the pre- intervention questionnaire only. Interim weekly assessments, tailored to each intervention condition and treatment as usual, will be administered to assess engagement and perceived satisfaction with each condition throughout the 6 weeks of participant involvement in the intervention or treatment as usual group. See appendices for full details of measurement administration and frequency per intervention arm.

At the start of week 7, participants in each intervention arm will take part in a focus group to evaluate what worked well and what could be improved regarding their allocated intervention arm, for use in evaluation while scaling up the current pilot and feasibility study (intervention arms) and for service evaluation (treatment as usual arm). See supplementary documentation for focus group topic guides, consent forms, information sheets, and debrief forms.

4. PARTICIPANT ENTRY

4.1 PRE-REGISTRATION EVALUATIONS

Eligibility criteria for the current study include: Caregivers referred to Alder Hey with their unsettled infant due to colic, reflux, and/or cow's milk protein allergy. The infant must be younger than 6 months at time of referral, born at >34 gestational weeks, without known co-morbidities and evidence of faltering growth as per NICE guidance (2017).

Caregivers who have been referred to Alder Hey with unsettled infants due to colic, reflux, and/or cow's milk protein allergy will be approached by Alder Hey healthcare practitioners, as part of treatment as usual. Here they will be provided with a study advertisement and information sheet for the current pilot and feasibility study. At this point, the Alder Hey clinician will provide the caregiver with some brief information about the current study. Caregivers who indicate that they would be interested in taking part in the current study, with consent, will then have their contact details i.e., name, email address, and telephone number, securely transferred to research assistants LJ/SD. The caregiver will be contacted by LJ or SD after a 48 hour 'cool off period' to digest the provided information from their clinician. LJ/SD will call the potential participant to screen participants, to ensure that caregivers meet necessary eligibility criteria to take part in the current study, to ask if they have any questions and/or

concerns, to talk through the information sheet, and to check participant's email address so that LJ/SD can send them an electronic information sheet and consent form to sign (sent via secure Qualtrics survey link). After providing electronic consent, the participant will then be redirected to a separate Qualtrics survey to complete initial pre-intervention validated measures. At the point of providing electronic consent, the participant is assigned a pseudonym to protect their identity.

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

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

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

sessions with their infants. Hence, commencing each intervention arm as early as possible maximises the potential to benefit caregivers and infants. This is the primary aim of the current study.

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

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

4.2 INCLUSION CRITERIA

The present study will recruit caregivers, referred to Alder Hey for infant colic, reflux, and cow's milk protein allergy with infants younger than 6 months at time of referral, born at >34 gestational weeks, without known co-morbidities or evidence of faltering growth as per NICE guidance (2017). Caregivers must not have a current or historic clinical diagnosis of a serious mental health condition i.e., bipolar disorder, schizophrenia, and/or psychosis. This will be detailed in the study advertisement, information sheet, and consent form. Also, the screening member of the research team (LJ/SD) will go through eligibility criteria with the potential participant as a part of the initial screening process for participation, before providing electronic consent (see below details for participant recruitment).

Caregivers who have been referred to Alder Hey with unsettled infants due to colic, reflux, and/or cow's milk protein allergy will be approached by Alder Hey healthcare practitioners, as part of treatment as usual. Here they will be provided with a study advertisement and information sheet for the

current pilot and feasibility study. At this point, the Alder Hey clinician will provide the caregiver with some brief information about the current study. Caregivers who indicate that they would be interested in taking part in the current study, with consent, will then have their contact details i.e., name, email address, and telephone number, securely transferred to research assistants LJ/SD. The caregiver will be contacted by LJ or SD after a 48 hour 'cool off period' to digest the provided information from their clinician. LJ/SD will call the potential participant to screen participants, to ensure that caregivers meet necessary eligibility criteria to take part in the current study, to ask if they have any questions and/or concerns, to talk through the information sheet, and to check participant's email address so that LJ/SD can send them an electronic information sheet and consent form to sign (sent via secure Qualtrics survey link). After providing electronic consent, the participant will then be redirected to a separate Qualtrics survey to complete initial pre-intervention validated measures. At the point of providing electronic consent, the participant is assigned a pseudonym to protect their identity.

4.3 EXCLUSION CRITERIA

Infants who have not been referred to Alder Hey due to their unsettled infant's colic/reflux/cow's milk protein allergy symptoms, infants older than 6 months at time of referral, born at <34 gestational weeks, and/or with co-morbidities or evidence of faltering growth (NICE, 2017) would be ineligible to take part in the current study.

Caregivers who have a current or historic clinical diagnosis of a serious mental health condition i.e., bipolar disorder, schizophrenia, and/or psychosis will be unable to take part in the current study. This will be detailed in the study advertisement, information sheet, and consent form. Also, the screening member of the research team (LJ/SD) will go through eligibility criteria with the potential participant as a part of the initial screening process for participation, before providing electronic consent.

4.4 WITHDRAWAL CRITERIA

Participants will be reminded in information sheets of their right to withdraw at any point, without explanation, and without it affecting the caregiver's access to or quality of treatment as usual. Once the caregiver has provided electronic consent, they will be assigned a pseudonym. At this point (called anonymisation) it will no longer be possible to identify the participant's data, and therefore any

information provided up until the point of withdrawal will be included in analysis. Any identifiable information that the participant had provided for the purpose of being contacted by the research team for involvement in the current study i.e., name, telephone number, and email address, will be destroyed using software designed to destroy all data from a device, at point of withdrawal and will not be used for any other purpose.

5. ADVERSE EVENTS

5.1 Serious Adverse Events

If the participant discloses risk of immediate harm to self or to others, the participant will be informed privately that the member of the research team will need to break confidentiality, to inform the relevant person(s) necessary to ensure appropriate safeguarding is in place. For this, standardised procedures have been developed for the administering member of the research team to follow in the unfortunate event that confidentiality may need to be broken (a general procedure for general and WhatsApp group use; a domestic violence, and suicide-risk specific procedure have been developed).

Group sessions

A particular issue to consider with group sessions is that the handling of sensitive material and ensuring confidentiality is potentially problematic because more than one participant will be present at every group session. Emphasis will be placed on confidentiality and anonymity, in recognition of the potentially sensitive nature of discussions. From the outset the researchers will clarify in group discussions that each participant's contribution will be shared with others in the group as well as the researchers present. In the participant information sheet, participants will be informed that although the greatest efforts have been made to encourage other group members to maintain confidentiality regarding discussions and/or activities held in group sessions, that this cannot be completely guaranteed. As such, the participant will also be informed at this point that if there is anything that they would find particularly sensitive and/or distressing to share publicly, that they should consider whether they would feel comfortable sharing this information or not. This will also be reiterated in the participant consent form.

Peer support, WhatsApp group

A particular issue to consider with the WhatsApp group is that handling sensitive material and ensuring confidentiality is potentially problematic because it is impossible to monitor the online activity of other members of the group e.g., copying/forwarding messages. Emphasis will be placed on confidentiality and anonymity, in recognition of the potentially sensitive nature of discussions. From the outset the moderating member of the research team will state in their initial post in the WhatsApp group that each participant's contribution will be shared with others in the group as well as the researchers present. At this point the moderating member of the research team will explicitly state that it is prohibited to copy, forward or otherwise share the contributions and/or personal information of other members of the group with anyone outside of the parenting WhatsApp group. In the participant information sheet, participants will be informed that although the greatest efforts have been made to encourage other group members to maintain confidentiality regarding the participant's personal information (i.e., their mobile phone number, profile icon, and name) and contributions to the WhatsApp group, that this cannot be completely guaranteed. As such, the participant will also be informed at this point that if there is anything that they would find particularly sensitive and/or distressing to share publicly, that they should consider whether they would feel comfortable sharing this information or not. This will also be reiterated in the participant consent form. In the participant information sheet and consent form, it will be urged that the caregiver consider whether they would like to take part in the current study given the sensitive nature of discussions and/or potential issues with maintaining confidentiality from other members of the group.

Focus groups

A particular issue to consider with focus groups is that the handling of sensitive material and ensuring confidentiality is potentially problematic because more than one participant will be present at each focus group. Emphasis will be placed on confidentiality and anonymity, in recognition of the potentially sensitive nature of discussions. From the outset the researchers will clarify before starting the focus group that each participant's contribution will be shared with others in the group as well as the researchers present. In the participant information sheet, participants will be informed that although the greatest efforts have been made to encourage other group members to maintain confidentiality regarding discussions held in the focus group, that this cannot be completely guaranteed. As such, the participant will also be informed at this point that if there is anything that they would find particularly

sensitive and/or distressing to share publicly, that they should consider whether they would feel comfortable sharing this information or not. This will also be reiterated in the participant consent form.

There are expected to be no other potential Serious Adverse Events as a consequence of taking part in the current study. The current feasibility study is low risk: contact with the participant will be limited to online Zoom calls and online platform communication i.e., WhatsApp (peer support only) and email. Caregivers who had been referred to the infant feeding team in Alder Hey for issues regarding infant colic, reflux, and cow's milk protein allergy will be approached about the current study by Alder Hey healthcare practitioners and will be reminded that their decision to take part in the current study is entirely voluntary and will not affect their access to or quality of treatment as usual. All caregivers, irrespective of condition, will continue to receive treatment as usual.

Mothers assigned to one of the three intervention arms will attend hour long sessions, once per week (for a total of three weeks) with an aim to reduce symptoms of infant colic, reflux, and cow's milk protein allergy and to improve: caregiver wellbeing, parenting confidence, and coping. See appendices for further information regarding intervention arm-specific activities and measurements. Taking part in the intervention arms is predicted to increase caregiver understanding of their infant's condition and allow the caregiver to learn practical ways to manage symptoms that can be sustained in long term. Participating in the intervention arms will equip caregivers with alternative skills (e.g., interactive music making, group cohesion, health information acquirement) to soothe their infant and self-care techniques, which may enhance caregiver confidence and reduce psychological distress when managing infant symptoms. This may, in turn, contribute towards improved caregiver emotional wellbeing, parenting confidence, and coping. Caregivers of unsettled babies due to colic, reflux, and cow's milk protein allergy are often reluctant to attend baby groups due to prolonged episodes of crying/distress which limits the availability of informal social support. Formal social support has also been limited through restricted physical access to services during COVID-19. The online group interventions proposed overcome both barriers and offer alternative methods of enhancing social support in this population. This intervention is therefore expected to have numerous benefits for infant, caregiver, and mother-infant relationship.

5.2 REPORTING PROCEDURES

If the participant discloses risk of immediate harm to self or to others, the participant will be informed privately that the member of the research team will need to break confidentiality, to inform the relevant person(s) necessary to ensure appropriate safeguarding is in place. Additionally, the chief investigator will be informed so that the named research team may collaboratively agree on an appropriate course of action in the best interest of caregiver and infant wellbeing. In the event that a participant becomes distressed during the intervention so that the distress protocol (detailed below) requires implementation, the chief investigator will also be informed so that the named research team may collaboratively discuss the appropriate course of action regarding the conduct of the current study so to ensure the safety and wellbeing of caregiver and infant.

Due to the potentially sensitive nature of topics covered during group sessions, focus group and in the WhatsApp group (peer support arm only), caregivers who have a current or historic clinical diagnosis of a serious mental health condition i.e., bipolar disorder, psychosis, and/or schizophrenia, will unfortunately be ineligible to take part in the current study. This is to prevent any unnecessary triggering of past traumas and/or distress for caregivers experiencing elevated levels of emotional distress.

If a participant becomes distressed at any point during the course of the study, then they are advised to contact the principal investigator or research team. The research team will then decide together with the participant if they feel comfortable and able to continue with the study or not. If they would like, a courtesy call will then be made in a days' time to check in to see how the participant is feeling. Please see non-serious adverse effects section for further details on implemented study procedures.

5.2.1 Non serious AEs

Group allocation

If between interim assessments, group sessions, and/or the focus group, the participant decides that they would like to stop taking part in the current study, they will be able to do so without having to give a reason and without incurring any disadvantage. To withdraw from the current study the participant may contact a member of the research team. Contact details of the chief investigator, Alder Hey research lead, LJ and SD are provided on participant study advertisements, information sheets, consent forms,

debrief forms, and at the end of very interim questionnaire. At the point of withdrawal from the current study, the participant will be reminded that the information that they have given up until the point of withdrawal will still be included in data analysis. This is because the participant was given a pseudonym upon providing electronic consent and so it will not be possible to tell which information is the participants for destruction. The participant will also be reminded that no one will be able to tell who they are from the information that they have given us, and that their choice to withdraw their participation will not affect their access to or quality of treatment as usual.

In the unfortunate event that the participant experiences distress and/or disadvantage due to their involvement in the current study, they may use the contact details for the research team [VF, FV, LJ, SD, SR, HM] to request a courtesy call. The participant will be reminded of this in the participant information sheet, debrief form, and at the end of all interim questionnaires. During this call, the member of the research team and the participant will collaboratively decide whether the individual would like to stop taking part in the current study or if they would like to continue taking part in the current study.

The research team are not clinically trained and cannot provide therapeutic help or support if the participant experiences distress or disadvantage due to taking part in the current study. If the participant indicates that they would like to withdraw their involvement at this point, the participant will be redirected to support groups outlined on the debrief sheet and, if necessary, will be encouraged to contact their healthcare practitioner, GP, or mental health provider. The participant will also be asked if they would like the moderating member of the research team to contact a family member or friend. A courtesy call will also be made approximately 24-hour hours after the initial conversation (if the participant consents) to check participant wellbeing.

If the participant expresses a wish to continue participation, they will be reminded that their decision to take part in the current study is completely voluntary and will not affect their access to or quality of treatment as usual. At this point they will also be reminded that for interactive components of the intervention, that they are able to participate as much or as little as they would like, and that for interim questionnaires they do not have answer any question(s) that they do not feel comfortable with. With the participant's consent, the member of the research team who they have had their initial conversation

with will then give the participant a courtesy call approximately 24 hours after their initial conversation to check participant wellbeing and happiness with taking part in the current study. If the participant is still happy to continue their participation, they will be reminded that they are able to reach out if they have any other issues, and that they are able to withdraw their participation at any point and without it affecting their quality of or access to their usual healthcare at Alder Hey if they would like, in the event that they change their mind at a later point.

If the participant is unhappy with any aspect of the study, they are given the contact details of the named research team, University of Liverpool Research Governance officer, the Information Commissioner's office research team, and the Patient Advice and Liaison Service (PALS) at Alder Hey, and we will try to help. This information can be found on the participant information sheet, debrief form, and at the end of every interim questionnaire.

Pre, post, and interim questionnaire completion

Some individuals may find questions relating to negative mood, experiences of infant colic, reflux, cow's milk protein allergy, and evaluating care upsetting. It is detailed in the information sheet that if the participant expects that answering questions about these topics would be too distressing for them, that they would be advised not to take part in the current study. Furthermore, due to the potentially sensitive nature of topics covered during group sessions, focus group and in the WhatsApp group (peer support arm only), caregivers who have a current or historic clinical diagnosis of a serious mental health condition i.e., bipolar disorder, psychosis, and/or schizophrenia, will unfortunately be ineligible to take part in the current study. This is to prevent any unnecessary triggering of past traumas and/or distress for caregivers experiencing elevated levels of emotional distress.

The participant will be given the contact details of the chief investigator and research team for any questions or concerns which they might have during the study in the participant information sheet, debrief form, and at the end of all interim questionnaires. The research team are not clinically trained and cannot provide therapeutic help or support if the participant experiences distress or disadvantage due to taking part in the current study. However, there are contact details for UK support agencies in the participant debrief which may be accessed if the participant feels that they would benefit from receiving additional support.

Sensitive questions in all administered questionnaires will have a "prefer not to say" option which the participant will be able to select if they wish. Other sections of the survey which contain sensitive items can be skipped if the participant does not feel comfortable answering a particular question(s). The participant is reminded of this in the information sheet, consent form, and at the start of every administered questionnaire. During the study, the participant may withdraw by closing the survey. Responses to questions completed up until the point of withdrawal will be included in analysis. This is because the participant is assigned a pseudonym upon providing electronic consent, so it will not be possible to tell which information is the participants.

In the information sheet and at the start of every questionnaire, the participant will be reminded that if at any point they experience any discomfort or disadvantage as part of the research that they are free to withdraw without giving a reason and without it affecting their access to or quality of usual healthcare. If the participant is unhappy with any aspect of the study, they are given the contact details of the named research team, University of Liverpool Research Governance officer, the Information Commissioner's office research team, and the Patient Advice and Liaison Service (PALS) at Alder Hey, and we will try to help. This information can be found on the participant information sheet, debrief form, and at the end of every interim questionnaire.

All pre, post, and interim questionnaires will be set up on the Qualtrics online platform and will be administered via anonymous links to the participant's email address. For the peer support intervention arm, participants will also be reminded about completing questionnaires in the WhatsApp group by the moderating member of the research team. Questionnaire responses will be stored on the Qualtrics online platform. This anonymous data will be exported after the completion of the intervention group, for analysis on aggregate, anonymous data only.

In the unfortunate event that a participant becomes distressed due to completing the pre, post, and/or interim questionnaires, they may request a courtesy call by contacting the research team, using contact details provided on the participant information sheet, debrief form, and in all interim questionnaires. The participant will be reminded of this in the participant information sheet, debrief form, and in all interim questionnaires. During this call, the moderating member of the research team and the participant will collaboratively decide whether the individual would like to stop taking part in the

current study or if they would like to continue taking part in the current study.

If the participant indicates that they would like to withdraw their involvement at this point, the participant will be redirected to support groups outlined on the debrief sheet and, if necessary, will be encouraged to contact their healthcare practitioner, GP, or mental health provider. The participant will also be asked if they would like the moderating member of the research team to contact a family member or friend. A courtesy call would also be made approximately 24-hour hours after the initial conversation (if the participant consents) to check participant wellbeing.

If the participant expresses a wish to continue participation, they will be reminded that they do not need to answer any question(s) that they do not feel comfortable with, that their responses to questionnaires are completely anonymous and that they will not be judged based on what they say. With the participant's consent, the moderating member of the research team will then give the participant a courtesy call 24 hours after their initial conversation to check participant wellbeing and happiness with taking part in the current study. If the participant is still happy to continue their participation, they will be reminded by the moderating member of the research team that they are able to reach out if they have any other issues, and that they are able to withdraw their participation at any point and without it affecting their quality of or access to their usual healthcare at Alder Hey if they would like, in the event that they change their mind at a later point.

Group sessions

Some individuals may find activities and topics covered in group sessions e.g., negative mood, experiences of having an infant with colic, reflux, cow's milk protein allergy, and evaluating care, distressing. Before providing electronic consent, participants are reminded that their decision to take part in the current study is completely voluntary and that if they feel like they may find taking part in group sessions with potentially sensitive topics distressing, then the research team urge the participant to consider whether they wish to take part. The participant will be reminded that if at any point they should experience any discomfort or disadvantage as part of the research that they are free to withdraw without giving a reason and without it affecting their access to or quality of usual healthcare. If they are unhappy with any aspect of the study, they will be reminded that they are able to contact the research team as detailed on the participant information sheet, debrief form, and at the end of all interim

questionnaires. The research team are not clinically trained and cannot provide therapeutic help or support if the participant experiences distress. There are contact details for UK support agencies in the participant debrief which we advise the participant access if they feel like they may need additional support.

Participants are also reminded in the information sheet and at the start of every group session that they do not need to take part in anything that they do not feel comfortable with. They are reminded that how much or how little they contribute is completely up to them and will not affect their access to or quality of treatment received as usual. The participant can choose not to answer any question that they feel uncomfortable with. As such, if a participant does not want to take part in any group activity or conversation, that they will be able to mute themselves, turn their camera off, and just listen in to the group session if they wish. The participant will be reminded of these previously mentioned details in the participant information sheet. At the start of every group session, the participants will be reminded that to protect the confidentiality of all caregivers in the focus group session, that anything discussed during the group session will be kept confidential and not discussed outside of the group session. Additionally, participants will be reminded that the group sessions is designed to be a safe space whereby everyone is able to express their experiences and opinions without judgement or disadvantage.

A distress protocol has been developed in the unfortunate event that a participant becomes distressed during the intervention. In the unlikely event that the participant becomes distressed, a member of the research team will speak privately with the distressed caregiver in an independent 'break out room' (meaning that two members of the research team will be present for each session). In this private break out room, the facilitating member of the research team will decide collaboratively with the caregiver on whether they would like to continue their involvement in the intervention, or whether they would like to leave the session and/or withdraw their participation. If the participant indicates that they would like to withdraw their involvement, the participant will be redirected to support groups outlined on the debrief sheet and, if necessary, will be encouraged to contact their healthcare practitioner, GP, or mental health provider. The participant will also be asked if they would like the facilitating member of the research team to contact a family member or friend. A courtesy call would also be made approximately 24-hour hours after the initial conversation (if the participant consents) to check participant wellbeing. If the participant expresses a wish to continue participation, they will be allowed

as much time as they need before re-joining the group session. The researcher will liaise with the participant after group session completion to assure wellbeing and to offer the same support mechanisms defined above if required.

Peer support, WhatsApp group

Participants will be informed in the information sheet and consent form that if they decide to take part in the peer support intervention arm, that this will involve a member of the research team setting up a WhatsApp group with other caregivers who had also been allocated to this intervention arm, and that therefore this will involve the other members of the intervention arm knowing the participants names, mobile numbers, and profile icons. The information sheet and consent form will detail that the participant may remove their profile icon and/or use their pseudonym for their profile name instead of their real name, if they wish. The participant will be informed in the information sheet that they can contact the moderating member of the WhatsApp group for instructions on how to do this if they would like. Participants will be informed that how much or how little they share on the parenting peer support group chat will be completely up to them.

To avoid an unfortunate event whereby misinformation is spread in the WhatsApp group, there will be a moderating member of the research team present in the parenting group, to prompt conversations and to monitor group conversations to ensure that medical advice is not shared on the group. Participants will be informed of this in the first week online group session, participant information sheet, consent form, and will be reminded of this in the first WhatsApp post put in the group by the moderating member of the research team. The participant will also be reminded that because of this, if the participant breaks this rule, the moderating member of the research team may remove this message from the group chat and that repeated offences may result in the early termination of their involvement in the current study.

Although pro-active and light-hearted prompts are to be utilised by the moderating member of the research team to encourage interaction on the group chat (and to promote a sense of group belongingness), some individuals may find some of the potential topics discussed on the WhatsApp group e.g., negative mood, experiences of having an infant with colic, reflux, cow's milk protein allergy, and evaluating care, upsetting. Before providing electronic consent, participants are reminded

that their decision to take part in the current study is completely voluntary and that if they feel like they may find taking part in WhatsApp group discussions which may cover potentially sensitive topics distressing, that they should consider not taking part in the current study. The participant will be given the contact details of the chief investigator and research team for any questions or concerns which they might have during the study. This information can be found in the participant information sheet, debrief form, at the end of all interim questionnaires, and upon request in the WhatsApp group.

In the unfortunate event that a participant becomes distressed due to taking part in the WhatsApp group, they may request a courtesy call by contacting the research team, using contact details provided on the participant information sheet, debrief form, and in all interim questionnaires. The participant will be reminded of this in the participant information sheet, debrief form, in all interim questionnaires, and in the initial post in the WhatsApp group by the moderating member of the research team. During this call, the moderating member of the research team and the participant will collaboratively decide whether the individual would like to stop taking part in the current study or if they would like to continue taking part in the current study.

If the participant indicates that they would like to withdraw their involvement at this point, the participant will be redirected to support groups outlined on the debrief sheet and, if necessary, will be encouraged to contact their healthcare practitioner, GP, or mental health provider. The participant will also be asked if they would like the moderating member of the research team to contact a family member or friend. A courtesy call would also be made approximately 24-hour hours after the initial conversation (if the participant consents) to check participant wellbeing.

If the participant expresses a wish to continue participation, they will be reminded that they can take part in group discussions as much or as little as they would like, and that they do not have to share any information that they are not comfortable with. At this point, the member of the research team will recommend that the participant mute the WhatsApp group for 24 hours to take a break. With the participant's consent, the moderating member of the research team will then give the participant a courtesy call 24 hours after their initial conversation to check participant wellbeing and happiness with taking part in the current study. If the participant is still happy to continue their participation, they will be reminded by the moderating member of the research team that they are able to reach out if they have

any other issues, and that they are able to withdraw their participation at any point and without it affecting their quality of or access to their usual healthcare at Alder Hey if they would like, in the event that they change their mind at a later point.

Participants will be informed in the information sheet that what they post in the WhatsApp group will be analysed by the research team but that pseudonyms will be used in analysis and in report writing up to maintain participant confidentiality. If the participant would prefer for a particular message or messages not to be included in analysis, they will be able to use a padlock emoji or write 'private post' in their message, so that the research team know not to use this post when analysing the data. Participants will be reminded of this in the first online group session on Zoom, in the participant information sheet and consent form, and by the moderating member of the research team upon setting up the peer support WhatsApp group, in the first initial post put in the parenting group.

At the end of the six weeks involvement in the intervention, the moderating member of the research team will leave the WhatsApp group. At this point the University of Liverpool and Alder Hey will no longer be responsible for this group chat, and it is the choice of the participant whether they would like to keep using the group for support, without monitoring, or if I would like to leave. The participant is informed of these policies in the information sheet, consent form, and in an initial 'ground rules' message posted by the moderating member of the research team at the start of setting up the parenting support group. Additionally, participants will be given a 24-hour warning for when the moderating member of the research team does leave the peer support WhatsApp group.

If a participant breaks the ground rules during any part of the study, then they will be warned privately by the moderating member of the research team, via telephone call. During this call the participant will be told how they have broken the ground rules and given suggestions as to how to avoid this happening again. For the WhatsApp group, the problematic message(s) will be removed by the moderating member of the research team. Repeat instances of breaking group guidelines may result in the caregiver's involvement in the current study being ended early.

Focus groups

Answering questions in the focus group about infant symptoms and mental health can be sensitive and

may cause distress. Before providing electronic consent, participants are reminded that their decision to take part in the current study is completely voluntary and that if they feel like they may find taking part in the focus group which will cover potentially sensitive topics distressing, that they should consider not taking part in the current study. This information is detailed in the participant information sheet. The participant will also be reminded in the information sheet and before the focus group commences that they can choose not to answer any question(s) that they do not feel comfortable with, and that how much or how little they contribute to the focus group discussion will be entirely up to them and will not affect their access to or quality of treatment received as usual.

At the start of the focus group, the participants will be reminded that to protect the confidentiality of all caregivers in the focus group session, that anything discussed during the group session should be kept confidential and not discussed outside of the group session. Additionally, participants will be reminded that the group sessions is designed to be a safe space whereby everyone is able to express their experiences and opinions without judgement or disadvantage.

In the unfortunate event that a participant becomes distressed during the focus group, the distress protocol detailed for the group sessions will be followed i.e. a member of the research team will speak privately with the distressed caregiver in an independent 'break out room' (meaning that two members of the research team will be present for every focus group conducted). In this private break out room, the facilitating member of the research team will decide collaboratively with the caregiver on whether they would like to continue their involvement in the intervention, or whether they would like to leave the focus group and/or withdraw their participation. If the participant indicates that they would like to withdraw their involvement during this conversation, the participant will be redirected to support groups outlined on the debrief sheet and, if necessary, will be encouraged to contact their healthcare practitioner, GP, or mental health provider. The participant will also be asked if they would like the facilitating member of the research team to contact a family member or friend. A courtesy call would also be made approximately 24-hour hours after the initial conversation (if the participant consents) to check participant wellbeing. If the participant withdraws their participation, information provided in the group discussion up until the point of withdrawal will be included in analysis because the participant will have been assigned a pseudonym at the point of giving consent, so it will not be possible to tell which information is the caregivers. The participant will be reminded of this in the event that they

withdraw from the current study.

If the participant expresses a wish to continue participation, they will be allowed as much time as they need before re-joining the focus group. The researcher will liaise with the participant after the focus group is finished to check caregiver wellbeing and to offer the same support mechanisms defined above if required. The research team cannot provide mental health advice but will signpost the participant to relevant support services if they feel like they need additional support. The debrief sheet contains contact details for relevant mental health charities, the research team, and University of Liverpool Ethics, if the participant feels that they would benefit from receiving additional support. If the participant is unhappy with any aspect of the study, they are given the contact details of the named research team, University of Liverpool Research Governance officer, the Information Commissioner's office research team, and the Patient Advice and Liaison Service (PALS) at Alder Hey, and we will try to help.

6. ASSESSMENT AND FOLLOW-UP

Once the caregiver has been allocated in to one of the four intervention arms by means of opportunity sampling, they will be given a series of short, validated measures to assess: infant colic symptoms, infant reflux symptoms, depression, anxiety, parenting sense of competence, and caregiver-infant bonding. See Appendices A-D for full details on measurement administration and frequency. After taking part in the six-week intervention, the caregiver will then be administered the same scales as were completed prior to starting the six-week intervention so to assess change over time, and more broadly to assess effectiveness, acceptability, and feasibility of intervention conditions.

Participant satisfaction, and rates of recruitment, participation, compliance, and drop-out will also be recorded to investigate study feasibility and acceptability with intention to scale up to a full trial with economic assessment. Participants will additionally take part in a focus group at the beginning of week 7 to evaluate what worked well and what could be improved regarding their allocated intervention arm, for review and study scaling up (intervention arms) and to contribute towards a service evaluation (treatment as usual). See Appendices A-D for full details on measurement administration and frequency.

Before intervention only

To evaluate the participant's prior knowledge and understanding with the intervention condition to which they had been allocated, prior to taking part in the study they will complete an intervention arm-specific, very brief questionnaire. This questionnaire will be set up on the Qualtrics online platform and will be administered via anonymous links to the participant's email address. For the peer support intervention arm, participants will also be reminded about completing questionnaires in the WhatsApp group by the moderating member of the research team. Questionnaire responses will be stored on the Qualtrics online platform. This anonymous data will be exported after the completion of the intervention group, for analysis on aggregate, anonymous data only.

All intervention arms will be administered the same demographic questions, which will be recorded for the purpose of reporting descriptive statistics. Demographic questions will include: household composition (i.e., how many people do you live with, who do you live with), maternal age, infant date of birth, and the first half of their postcode (for assessment of socioeconomic status). Two questions will also be asked regarding clinical diagnoses of anxiety and depression for descriptive purposes alongside validated measurements of caregiver mood, 'Do you have a current, clinical diagnosis of [anxiety/depression]?' with response options, 'Yes, treated with medication and/or therapy', 'Yes, untreated', 'No', and 'Prefer not to say'.

Peer support

Since giving birth, have you used online parenting support groups on a social media platform? YES/NO

How many? What platform(s)?

How frequently do you access this/these groups?

How helpful do you find this/these groups for support?

Music intervention

Music during pregnancy (adapted from Persico, 2017):

- Since giving birth, have you sung to your unsettled baby? Yes/No.
- Has singing to your unsettled baby helped to support you and your wellbeing? Yes/No
- Have you found singing to your unsettled baby, helpful in soothing their symptoms? Yes/No
- Did you experience positive feelings whilst singing to your unsettled baby? Yes/No

Health education

- Since giving birth have you sought out health information about your unsettled baby? Yes/No.
- Has learning about your unsettled baby helped you to feel better prepared to look after your baby? Yes/No.
- Have you found the health information you received about your unsettled baby, helpful? Yes/No.
- Have you experienced positive feelings whilst learning about your unsettled baby? Yes/No.

Before and after intervention

Perceptions of infant colic, reflux, and cow's milk protein allergy symptoms will be measured using the I-GERQ (Kleinman et al, 2006) and the ICS (Ellett et al, 2002). 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). These questionnaires will be set up on the Qualtrics online platform and will be administered via anonymous links to the participant's email address. For the peer support intervention arm, participants will also be reminded about completing questionnaires in the WhatsApp group by the moderating member of the research team. Questionnaire responses will be stored on the Qualtrics online platform. This anonymous data will be exported after the completion of the intervention group, for analysis on aggregate, anonymous data only.

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.

Interim assessments

Once time per week, for the six weeks that the participant is involved in the intervention, participants will be required to complete interim assessments, in the form of a Qualtrics survey. The aim of these questionnaires is to evaluate how effective the interventions are, and to see change over time in caregiver mood and infant symptoms. Interim questionnaires will be set up on the Qualtrics online

platform and will be administered via anonymous links to the participant's email address. For the peer support intervention arm, participants will also be reminded about completing questionnaires in the WhatsApp group by the moderating member of the research team. Questionnaire responses will be stored on the Qualtrics online platform. This anonymous data will be exported after the completion of the intervention group, for analysis on aggregate, anonymous data only.

Peer support

o 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

Health Education

o 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.

o 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

o 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

o 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

Music intervention

state of the infant and the carer we will monitor the following variables on a weekly basis:

- Frequency of engagement with different IDS

o How often did you sing to your baby over the past week?

 Every day, most days, about half of the week, rarely, never

o 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.)

o 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.)

O 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

7. STATISTICS AND DATA ANALYSIS

The sample size for the current study was determined pragmatically based on number of referrals at Alder Hey, clinician capacity, and agreed funding timeline by the Hugh Greenwood Legacy Fund for

Children's Health Research. Feasibility studies allow for a smaller sample of participants to be recruited: 10 participants have been recruited per intervention arm in recent maternity literature for preterm infants, for texting interventions with an aim to support women experiencing emotional distress, and for a support group intervention for children with congenital Zika syndrome (Belotti, Altarfim, & Linhares, 2019; Fletcher et al, 2019; Smythe et al, 2020).

For quantitative data collected from validated scales, means and standard deviations will be reported for all measures assessed pre intervention and post intervention to descriptively quantify change over time. Paired samples t-tests will be run on pre and post intervention measures to assess predicted improvements over time. Between subjects t-tests will also be conducted on post intervention measures across intervention arms to assess the respective effectiveness of the different treatment arms. A repeated measures ANOVA will be conducted with treatment condition as the independent variable (treatment as usual, music intervention, peer support, and health education), with frequency of engagement, perceived impact on infant symptoms, depression, and anxiety as dependent variables. Quantitative data will be analysed in SPSS version 24. For focus group data, thematic analysis (Braun & Clarke, 2006) will be conducted on transcripts from each intervention arm, which will then be compared across groups. The 'treatment as usual' focus group analysis will feed into a service evaluation at Alder Hey. Qualitative data will be transcribed and analysed in NVivo 12.

8. REGULATORY ISSUES

8.1. ETHICS APPROVAL

The Chief Investigator has obtained approval from Hugh Greenwood Legacy Fund for Children's Health Research and will seek relevant HRA/REC ethical approval upon gaining University of Liverpool Sponsor approval. The study will also be sent to representatives from Alder Hey for Confirmation of Capacity and Capability. The study will be conducted in accordance with the recommendations for physicians involved in research on human subjects adopted by the 18th World Medical Assembly, Helsinki 1964 and later revisions.

8.2 CONSENT

Caregivers who have been referred to Alder Hey with their unsettled infant due to colic, reflux, and/or cow's milk protein allergy will be approached by Alder Hey healthcare practitioners, as part of treatment as usual. Here they will be provided with a study advertisement and information sheet for the current pilot and feasibility study. At this point, the Alder Hey clinician will provide the caregiver with some brief information about the current study. Caregivers who indicate that they would be interested in taking part in the current study, with consent, will then have their contact details i.e., name, email address, and telephone number, securely transferred to research assistants LJ/SD. The caregiver will be contacted by LJ or SD after a 48 hour 'cool off period' to digest the provided information from their clinician. LJ/SD will call the potential participant to screen participants, to ensure that caregivers meet necessary eligibility criteria to take part in the current study, to ask if they have any questions and/or concerns, to talk through the information sheet, and to check participant's email address so that LJ/SD can send them an electronic information sheet and consent form to sign (sent via secure Qualtrics survey link). After providing electronic consent, the participant will then be redirected to a separate Qualtrics survey to complete initial pre-intervention validated measures. At the point of providing electronic consent, the participant is assigned a pseudonym to protect their identity.

8.3 CONFIDENTIALITY

The Chief Investigator will preserve the confidentiality of participants taking part in the study and will abide by the Data Protection Act 2018. Confidentiality will be maintained in accordance with the NHS code of confidentiality and the University of Liverpool information security policy. Research assistants and the chief investigator have received appropriate Good Clinical Practice training in preparation for the current study. Confidentiality and anonymity will be maintained throughout the study and it will not be possible to identify the participant in any publications as analysis will be performed on anonymised aggregate data only (quantitative) and participants will be assigned pseudonyms immediately after providing electronic consent to take part in the current study (qualitative). If the participant discloses an immediate risk of harm to self or to others, they will be informed of the need for the named research team member to break confidentiality to inform the relevant person(s) to ensure appropriate safeguarding. For this, standardised procedures have been

developed for the administering member of the research team to follow in the unfortunate event that confidentiality may need to be broken (a general procedure for general and WhatsApp group use; a domestic violence, and suicide-risk specific procedure have been developed).

At the start of the focus group the participants will be reminded that to protect the confidentiality of all caregivers in the focus group, that anything discussed during the focus group will be kept confidential and not discussed outside of the focus group. This information will also be detailed in the participant consent form and information sheet.

After the participant provides electronic consent to take part in the current study, they will be assigned a pseudonym to protect participant confidentiality. Identifiable participant information i.e., name, email address, and telephone number will be stored on a password protected excel sheet, separate from all other study documentation, so that participant confidentiality can be maintained. All stored information relating to the current study is electronic and will be stored in accordance with the University of Liverpool electronic data storage policy. Any data transfers will be encrypted using Bitlocker (Windows 7), via university M: drives, accessible via remote access working i.e., AppsAnywhere. Upon completion of the study, all electronic study documentation will be stored for 10 years, in accordance with the University of Liverpool data storage policy. All electronic study documents will then be destroyed using software designed to remove all data from a device.

Data included in the current study will be made available via open access publishing and data sharing from the University of Liverpool Repository, through Liverpool Research Data. This is in accordance with the University of Liverpool Open Access Publication Policy, in line with the Research Excellence Framework. This enables the enhancement of knowledge by helping research to reach a wider audience within the University of Liverpool, and thus broadens potential impact of findings. No identifiable participant information will be published or made available for re-use.

8.4 INDEMNITY

The University of Liverpool holds Indemnity and insurance cover with Newline Insurance Company, which apply to this study.

8.5 SPONSOR

The University of Liverpool will act as Sponsor for this study. It is recognised that as an employee of the University the Chief Investigator has been delegated specific duties, as detailed in the Sponsorship Approval letter.

8.6 FUNDING

The University of Liverpool are funding this study. The Hugh Greenwood Legacy Fund for Children's Health Research has granted the named research team £16,299 to conduct the current feasibility trial. The justification of costs are as follows:

-Research Assistant (Leanne Jackson, University of Liverpool) 20% FTE for 12 months - £5,835 - ethics, data collection, management, analysis, and write up
-Research Assistant (Sian Davies; Honorary Research Assistant UoL) - 40 hours @ £15.99 = £639.60 - support for PDRA
-Professional Musician – (1 pilot + 6 intervention – 1-hour delivery + 30 mins prep) - 7 x 1.5 hour @ £150 per hour: £1575
-Music Therapist (Band 7) - (1 pilot + 6 intervention – 1-hour delivery + 30 mins prep) - 7 x 1.5 hour @ £20.91 per hour: £219.55
-Arts Coordinator (Band 6): 8 hrs/per week x 6 weeks: £1,469 - consulting music therapist
-Infant feeding specialists– 4 days (Band 6) x 2 = £1239.68 - preparation of health education intervention
-Dietician – 1 day (Band 7) = consultancy to inform health education intervention - £182.08
Patient and Public Involvement (PPI) – 20 hours @ £60 p/h = £1200
Headsets x 3 @ £20 = £60
Musical instruments: £100

Infant feeding specialists:
Delivery of 12 x health education interventions in kind £19.37 x 12 x 2 = £464.88
In kind clinician consultancy and supervision:
Dr Mark Wigglesworth - 1 day = £600

In kind academic consultancy and supervision:

Dr Vicky Fallon – 12 months @ 5%FTE = £3072.33

Dr Francine Verhoeff - 5 days @ £860 per day = £4300

Dr Leonardo de Pascalis - 12 months @ 5%FTE = £3072.33

Dr Eduardo Coutinho - 12 months @ 5%FTE = £3793.94

8.7 AUDITS

The study may be subject to inspection and audit by the University of Liverpool under their remit as sponsor and other regulatory bodies to ensure adherence to GCP and the UK Policy Framework for Health and Social Care Research (v3.2 10th October 2017).

9. STUDY MANAGEMENT

The day-to-day management of the study will be coordinated through Dr Victoria Fallon (Chief Investigator, University of Liverpool) and Dr Francine Verhoeff (Alder Hey research lead). The chief investigator is a faculty chair on the University of Liverpool research ethics committee.

The named research team will meet on a bi-weekly basis to discuss study progression, and to discuss and resolve any non-urgent issues with the intervention arm(s) and treatment as usual. A member of the named research team [HS] is a PPI representative (MVP) who has been involved in evaluating the acceptability and feasibility of study set up, alongside MVP volunteers. HS will also be present at bi-weekly meetings as a PPI representative for study progression and/or the discussion and resolution of any emergent non-urgent issues. Sessions in individual intervention arms and treatment as usual will be managed by specialist clinician members of the named research team who have experience and expertise in providing support and advice to caregivers of unsettled babies with colic, reflux, and cow's milk protein allergy. Pre, post, and interim Qualtrics questionnaires and focus group data will be managed by University of Liverpool members of the research team [LJ, SD, EC, LDP, VF] and by the Alder Hey research lead [FV].

10. END OF STUDY

The end of the current study is defined as once the final dataset has been analysed and disseminated in

a written report and/or journal manuscript.

11. ARCHIVING

Once the study is complete (when research findings have been disseminated in a written report and/or publication manuscript) all personally identifiable information related to the current study i.e., name, email address, and telephone number, will be destroyed using software designed to destroy all information from a device. Generated data from the current study will be stored in password protected folders on secure University of Liverpool M: drives for 10 years after study completion, to meet the University of Liverpool's data storage policy. After this period of storage, all data will be destroyed using software designed to destroy all information from a device. Electronic information will only be accessible to the named research team. Information about data storage will be available in participant information sheets and participants will be reminded of this policy before providing electronic consent.

Anonymised data included in the current study will be made available via open access publishing and data sharing from the University of Liverpool Repository, through Liverpool Research Data. This is in accordance with the University of Liverpool Open Access Publication Policy, in line with the Research Excellence Framework policy. This enables the enhancement of knowledge by helping research to reach a wider audience within the University of Liverpool, and thus broadens potential impact of findings.

No identifiable participant information will be published because participants will be assigned pseudonyms immediately after providing electronic consent. Additionally, analysis will be conducted on anonymised, aggregate data, meaning that no identifiable information will be made available. Additionally, pseudonyms will be used alongside illustrative quotes in qualitative analysis and report write up. Any personally identifiable participant information will be destroyed at the point of study completion using software designed to destroy all information from a device. All non-identifiable electronic documentation associated with the current study will be stored for 10 years after study completion, to meet the University of Liverpool's data storage policy. After this period of storage, all data will be destroyed using software designed to destroy all information from a device. Paper documentation is not involved in the current study.

12. PUBLICATION POLICY

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

After taking part in the intervention, participants will be emailed a link to a short online Qualtrics survey, where they will be asked if they would like to receive a summary of the research findings in the form of a newsletter. In this survey, the participant will also be asked if they would like to receive a copy of the final written report. If the participant responds 'yes' to either of these questions they will be asked to provide their email address so that the research assistants may distribute this information. Provided contact details will be kept in a password protected excel sheet, separate to all other study documentation, to maintain participant anonymity. All electronic information for the current study will be stored in password protected files on secure University of Liverpool M: drives and will only be accessible to the named research team.

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14. APPENDICES

Appendix A *Treatment as usual protocol*

Appendix B *Health education protocol*

Appendix C *Online peer support group protocol*

Appendix D *Music intervention protocol*

Appendix A Treatment as usual protocol

Draft protocol (Treatment As Usual; TAU)

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

Perception of infant symptoms of colic, reflux, and cow's milk protein allergy will be measured using the I-GERQ (Kleinman et al, 2006) and ICS (Ellett et al, 2002) scales. 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.

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 Alder Hey 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 Alder Hey web site for the relevant patient information leaflets (Alder Hey, N/Aa; Alder Hey, 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 in to 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.

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Draft protocol (Health education)

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. 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.

- Since giving birth have you sought out health information about your unsettled baby? Yes/No.

- Has learning about your unsettled baby helped you to feel better prepared to look after your baby? Yes/No.

- Have you found the health information you received about your unsettled baby, helpful? Yes/No.

- Have you experienced positive feelings whilst learning about your unsettled baby? Yes/No.

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:

Perception of infant symptoms of colic, reflux, and cow's milk protein allergy will be measured using the I-GERQ (Kleinman et al, 2006) and ICS (Ellett et al, 2002) scales. 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 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)
- 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 incl 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

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Appendix C *Online peer support group protocol*

Draft protocol (peer support)

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

3. 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.

Since giving birth, have you used online parenting support groups on a social media platform?
YES/NO

- How many? What platform(s)?
- How frequently do you access this/these groups?

- How helpful do you find this/these groups for support?

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:

Perception of infant symptoms of colic, reflux, and cow's milk protein allergy will be measured using the I-GERQ (Kleinman et al, 2006) and ICS (Ellett et al, 2002) scales. 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):

4. **DURING** the intervention, in order 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):

5. **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.
6.

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 MVP representative to talk about personal success stories relevant to infant colic, reflux, and cow's milk protein allergy (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 your favourite technique for soothing your baby :)"

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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Draft protocol (music intervention)

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

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):

- Since giving birth, have you sung to your unsettled baby? Yes/No.
- Has singing to your unsettled baby helped to support you and your wellbeing? Yes/No
- Have you found singing to your unsettled baby, helpful in soothing their symptoms? Yes/No
- Did you experience positive feelings whilst singing to your unsettled baby? Yes/No

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:

Perception of infant symptoms of colic, reflux, and cow's milk protein allergy will be measured using the I-GERQ (Kleinman et al, 2006) and ICS (Ellett et al, 2002) scales. 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 favours 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.)

References

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