STUDY PROTOCOL AND

INFORMED CONSENT FORM

Mamas in Harmony: a feasibility study and pilot randomised controlled trial and process evaluation of a music and social support group intervention for postnatal mothers and their infants

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Mamas in Harmony: a feasibility study and pilot randomised controlled trial and process evaluation of a music and social support group intervention for postnatal mothers and their infants

PROTOCOL

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Background

Perinatal mental health problems have the potential to lead to multiple negative outcomes for both mother and child, and mental health in the perinatal period is a current leading public health issue with significant economic burden if untreated (Dennis et al., 2017). The perinatal period lasts for the duration of pregnancy and for 1 year after the birth of the child (NICE, 2022). Symptoms of low mood, anxiety, stress, feeling isolated, and difficulties with mother-infant attachment are frequently experienced by both antenatal and postnatal mothers. Obsessive compulsive disorder (OCD), psychosis and post-traumatic stress disorder (PTSD) are conditions perinatal mothers can also develop (MIND, 2022). Factors such as lack of family or social support, poor housing, relationship breakdown, financial difficulty or previous traumatic life events may further increase the risk of experiencing poor perinatal mental health (MIND, 2020).

It is reported that anxiety is often overlooked in the perinatal period, with limited research carried out in relation to perinatal anxiety compared to depression. With little knowledge around epidemiology or effectiveness of interventions for perinatal mental health conditions other than postnatal depression (PND) (Howard et al., 2014). This is despite the associations found between maternal anxiety and adverse outcomes for the child (Dennis et al., 2017).

A systematic review conducted in 2016 of observational studies, including 221,974 women across 34 countries, showed prevalence of anxiety symptoms as 22.9% across the three trimesters of pregnancy, and 17.8% in the first 4 weeks following childbirth, decreasing only slightly to 15% thereafter (Dennis et al., 2017). Overall findings from the review showed a significantly higher rate of anxiety among the maternal population compared to the adult population in general. No differences in prevalence rates were found between studies published before 2010 compared to those published afterwards (Dennis et al., 2017), indicating that perinatal anxiety is an ongoing concern.

Associations between maternal anxiety and decreased coping strategies (George et al., 2013) and increased rates of suicide have been found (Farias et al., 2013). Studies investigating the effect of poor postnatal mental health have found an adverse impact on mother-infant attachment (McMahon et al., 2006), bonding, self-regulation and empathy (Rossen et al., 2016). Consequently, mothers find it difficult to engage with their infants both emotionally and behaviourally resulting in reducing their physical contact (Holt et al., 2021). Provision by the mother of a less stimulating environment, being less attuned to their infant (Brummelte and Galea, 2016) and reduced competence and low mood in the mother (Beebe et al., 2011) are also reported effects.

Poor child development outcomes in the longer term, involving behavioural and emotional problems in children aged 4 years (O'CONNOR et al., 2002) and attention deficit hyperactivity disorder symptoms at age 8-9, were also shown when mothers experienced high levels of maternal anxiety (Van den Bergh and Marcoen, 2004). Children of mothers with postnatal depression were more likely to be underweight and have poor social, emotional and cognitive development (Yang et al., 2019). Long lasting significant effects on the mother can occur if mental health issues are left untreated (Bauer et al., 2014).

Restrictions were introduced by the UK government in March 2020 to reduce the spread of Coronavirus (Covid 19). The impact of measures at that time such as requiring people to stay at home, social distancing and closure of non-essential businesses and activities (GOV.UK, 2020) had far reaching consequences for perinatal women's psychological state and social interaction (Fallon et al., 2021). Qualitative research conducted with women in Australia found becoming a mother during the pandemic was reported as an isolating experience, having increased desire for social support, and needing to manage the stress and anxiety caused by constant unknowns and the limited access to health and support services (Sweet et al., 2021). Similar findings were noted from a UK study and in addition reported the prevalence rates during the pandemic of clinically relevant maternal depression and anxiety in the UK being much higher than pre-pandemic (Fallon et al., 2021).

Together, this indicates a heightened need for attention and intervention to improve mental health among mothers and the associated outcomes beyond the existing vulnerability they experience during the perinatal period. While government restrictions have now been removed since the start of the pandemic, it is reasonable to maintain an ongoing awareness of the additional impact posed to future perinatal mothers should restrictions return due to Covid 19 or similar crises (PHA, 2022).

Regular screening for perinatal depression and anxiety disorders by health professionals is recommended by National Institute for Health and Care Excellence (NICE) guidelines from the first contact with the mother, throughout pregnancy and the postnatal period using assessment tools. These include Edinburgh Postnatal Depression Scale (EPDS) and Generalised Anxiety Disorder 7 Scale (GAD-7) (NICE, 2020). However postnatal mental health problems often go unidentified, undiagnosed, and untreated for many women or they do not meet the eligibility threshold for specialist mental health services after the birth of their baby (Coates et al., 2015). Women may fear stigma and negative perceptions if they disclose a mental health problem in pregnancy or the postnatal period. It is further acknowledged that there are individuals who are pregnant or who have given birth, that may not identify as women, so the terms 'woman' or 'mother' should be taken to be inclusive of those individuals in accordance with NICE guidelines. In addition, where the term 'parents' is used , this should be taken to include anyone who has main responsibility for caring for a baby (NICE, 2021).

The NHS Long term Plan identified that the consequences of not receiving high quality perinatal mental health care is estimated to cost the NHS and social care £1.2 billion per year (NHS, 2019). Perinatal anxiety is shown to cost approximately £35,000 per case of which £14,000 relates to the impact on the child. While this is just under half of the estimated cost for perinatal depression at £74,000 in total, there is a high degree of overlap and therefore the cost of anxiety is likely to already be accounted for in those costs for depression (Bauer et al., 2014).

Current pharmacological treatment options offered by health professionals involved in the care of mothers often have potential for side effects and low uptake and adherence, especially for breastfeeding mothers (Yang et al., 2019). Psychotherapy has presented challenges of mixed results, and short-lived improvements (Morrell et al., 2009); (Cooper et al., 2003). Consequently there has been an increase in interest in non-pharmacological interventions, such as arts in health programmes (Fancourt, 2017).

A systematic review published in 2015 investigating the effect of interventions for PND that focused on the mother-infant dyad relationship, found promoting maternal responsiveness had the greatest efficacy when reducing symptoms of PND (Tsivos et al., 2015). It has been suggested that interventions focusing solely on maternal depression may not be enough to reduce the risks to

infant development and further research is needed to assess outcomes relevant to both mother and infant (Tsivos et al., 2015). It is acknowledged that women with PND may have difficulty adhering to interventions that are dyadic due to the nature of their symptoms (Nylen et al., 2006). An intervention that has a strong focus on direct physical face to face stimulation and interaction between mother and infant would be well placed to not only protect against the potentially damaging effects of PND but strengthen the mother-infant relationship at the same time. The mother-infant relationship is reliant on reciprocity of the interaction between them and the intimate relationship between mother and infant is nurtured by the mutual satisfaction expressed during these moments (Vlismas et al., 2013). A mothers sensitivity and affection are communicated to her infant through her voice, gestures and rhythmical movement (Vlismas et al., 2013).

Arts in Health

The field of arts in health is rapidly expanding with evidence reporting a plethora of benefits from arts based initiatives in primary and secondary care. Strong evidence supports the arts in improving wellbeing and quality of life among adults (Fancourt et al., 2020). Arts in health activities are wide ranging and, in particular, include performing arts, which comprises of music, dance and theatre and visual arts and crafts such as drawing, woodwork, painting, ceramics and photography. Music, as a user friendly and low cost activity, is further used in the literature to refer to a wide spectrum of activities including singing, playing instruments and listening to music (Dingle et al., 2021a). A number of systematic reviews have shown a variety of benefits of singing among different populations (Reagon et al., 2016; Williams et al., 2018; Irons et al., 2020). Participants with mental health conditions, across the UK and Australia, showed improvements in depression, quality of life, and mental wellbeing following singing interventions lasting at least 8 weeks (Williams et al., 2018). Irons and colleagues reviewed the effect of singing among people with long term health conditions associated with persistent pain, which showed some potential to reduce pain intensity and interference; however, the findings from the review were limited by included studies having variable quality (Irons et al., 2020). When investigating health-related quality of life, in adults with a chronic health condition, singing interventions conducted primarily in the UK or Australia were found to either maintain or improve health-related quality of life and mood (Reagon et al., 2016). Despite this evidence, limitations persist within and between experimental studies with a high level of heterogeneity present, including differences in study participants, differences in frequency, setting and duration of the intervention and outcome measures (Reagon et al., 2016). A high or unclear risk of bias concerning random sequence allocation and treatment allocation concealment was found in experimental studies of singing interventions for individuals with mental health conditions (Williams et al., 2018).

A recent systematic review, developed by the current project team, set out to assess the effect of mother-infant group music classes (any type of music as the primary component) on a range of maternal outcomes, including postnatal depression and maternal anxiety (Colella et al., 2021). The review has since been conducted and identified 2 studies from the UK and Australia, both measuring depression following 10 weekly sessions with a total sample of 123 mothers. Results from a meta-analysis did not show a statistically significant reduction in depression post intervention. However, the point estimate favoured the music intervention (SMD: -1.61; 95%CI: -4.09, 0.87). Further meta-analyses could not be performed. A narrative synthesis reported that secondary outcomes of anxiety and stress showed a statistically significant reduction in both outcomes and also statistically significant improvement in maternal self-efficacy post intervention (Colella et al., 2021). Findings

from this review suggest potential for effect of music-based mother-infant group interventions on maternal anxiety, stress and self-efficacy.

Qualitative synthesis of a process evaluation of a singing intervention, which was included in the review, found postnatal mothers reported that it provided an opportunity for mothers to interact socially after the sessions (Fancourt and Perkins, 2019). Receiving social support was shown to be a welcome service for postnatal mothers (Fancourt and Perkins, 2019). A variety of community organisations recognise this need and provide 1 to 1 or group based social support in the postnatal period. Considering a risk factor for postnatal depression is low, or a lack of, social support (Brugha et al., 1998), a key ingredient of group interventions should include the provision of social support and cohesion (Dingle et al., 2021b).

The gap that remains in current literature is an arts in health based group intervention for mother-infant dyads, supporting the reduction in symptoms of anxiety and stress, promoting social support and targeting an improvement in the mother-infant relationship (Estevao et al., 2021). This study will seek to explore the feasibility and the potential benefit of a new mother-infant group intervention, Mamas in Harmony, that combines group music classes with social support.

A common finding among systematic reviews is the high risk of bias (Williams et al., 2018) and high heterogeneity (Yang et al., 2019) between included studies. More high quality randomised controlled trials are required. Intervention-based research should involve robust methodologies and transparent reporting especially in the underpinning theory of change, a detailed description of the content of the intervention and the intervention facilitator including their training and experience. The MRC framework will be utilised to underpin this study. There is a need for feasibility work before a full phase 3 trial so to pilot the study design, recruitment, intervention and data collection methods and allow any challenges to be identified and amendments to be made.

Study aim

This study aims to explore the feasibility of Mamas in Harmony, a novel 8 week combined music and social support community based group intervention for postnatal mothers and their infants.

Study objectives

- Test the feasibility of conducting a randomised controlled trial (RCT) of Mamas in Harmony in comparison to usual care, in terms of recruitment and retention rates, acceptability of outcome measures, and promise of effect on symptoms of anxiety, depression, perceived stress, perceived social support, postnatal attachment, health related quality of life and cost-effectiveness
- Establish feasibility of the Mamas in Harmony intervention in terms of acceptability, adherence and maternal satisfaction
- Understand the experiences of mothers who received the Mamas in Harmony intervention and intervention facilitators delivering Mamas in Harmony
- To explore quality of implementation, potential mechanisms of change and context

Methods

Study design

The study will consist of two sequential phases. Phase 1 will involve a feasibility study with a pilot randomised controlled trial and economic evaluation. Phase 2 will involve a process evaluation with a survey evaluation and semi-structured interviews. The UK National Institute for Health and Care Research (NIHR) describe feasibility studies as occurring early in the research process and pilot studies then test whether the main components can all work together (Eldridge et al., 2016). The literature appears to have little consensus on the appropriate sample size for feasibility and pilot studies, and suggested sample sizes can range from 12 (Julious, 2005) to 50 (Sim and Lewis, 2012). Therefore for this study a sample size of 40 mother-infant dyads for the intervention group and 20 mother-infant dyads for the control group has been chosen. It is acknowledged this allocation favouring the intervention group may influence mothers participating compared to a 1:1 allocation. However, it ensures only the number of participants required are recruited, it is sufficient for a feasibility study and increases the pool of potential participants for process evaluation interviews. It is anticipated that between 10-12 mother-infant dyads will participate in a Mamas in Harmony group at a time for 8 weeks and then repeated 3-4 times to reach the required sample size receiving the intervention.

Participants

Inclusion criteria:

- Mothers who have a baby aged ≥14 days to ≤4 months at time of consent
- Aged 16 years or over
- Able and willing to provide consent identified by having a satisfactory understanding of English and comprehension of the participant information sheet and consent form

Exclusion criteria:

- Mothers who have given birth in the last 14 days
- Infants >4 months at time of consent
- Identified as not having satisfactory understanding of English and comprehension of the participant information sheet and consent form
- Mothers who have received a diagnosis of, or being treated for, severe mental illness including Bipolar disorder, Psychoses or Schizophrenia within the past 6 months (discovered through self-report at time of eligibility screening). This is due to the existing evidence supporting the use of singing interventions on mild-moderate symptoms of anxiety/depression (Fancourt & Perkins 2018; Williams et al. 2018) and not as a treatment for severe mental health conditions.

For the delivery of the intervention, sessions will be held in a suitable meeting room with the required capacity at a Queens University Sport facility in Belfast, Northern Ireland. This venue is accessible by public and private transport as well as being suitable to access on foot and has free parking, with pram storage and baby changing facilities available. Sessions will be held on Tuesdays at 11am to allow for any older siblings to be dropped off to school or childcare and mothers to have

sufficient time to travel to the venue. This fits into the current scheduled timetable at the venue for the room and parking.

Recruitment and randomisation

The recruitment strategy to identify and approach potential participants will involve the use of social media, websites and email contact lists of relevant parenting support organisations, along with posters/flyers in local community centres.

Recruitment will be pursued via social media using a post on Twitter and Facebook groups for local mothers (Recruitment material 15-01-2023 Vn 1.1). National Childbirth Trust (NCT) groups, HomeStart, the Junior Academy for Music at QUB and the wider University and community choir audience will be asked to distribute the recruitment flyer (Recruitment material15-01-2023 Vn 1.1) via email to relevant contact lists of mothers/other interested individuals, display recruitment posters on communal/public facing noticeboards (Recruitment material 15-01-2023 Vn 1.1) and share social media content created by the researchers (Recruitment material 15-01-2023 Vn 1.1) on their social media platforms. Local Women's and Community Centres, community mother and baby classes, social support organisations, SureStart Children's Centres (Department of Education funded), and newborn photographers will be asked to display posters/flyers (Recruitment material 15-01-2023 Vn 1.1) and share social media content created by the researchers (Recruitment material 15-01-2023 Vn 1.1) on their social media platforms (if used).

Mothers will be invited to make contact for further information about the study via the poster/flyer, email and social media posts, and will contain an email address for contacting the PhD researcher. A QR code will be included in all communication, which, when scanned, directs mothers to a webpage containing an introduction to the study (Webpage content 21-08-2022 Vn 1.0), a link to download the participant information sheet (PIS for pilot study 15-01-2023 Vn 1.2) and online contact form to complete if they are interested in hearing more (Online contact form 21-08-2022 Vn 1.0). If a potential participant contacts the QUB researcher via email, they will be directed to the webpage and online contact form. If the contact form is completed by the mother, telephone details will be received by the QUB researcher (Contact details for mothers 21-08-2022 Vn 1.0), who will make contact. Contact details will be saved and stored securely on QUB OneDrive. The mobile phone used by the researcher to call participants will be password protected however no participant telephone numbers will be saved on the phone and numbers will be deleted from the call list on the phone immediately after the call. During the telephone call, the researcher will describe the study and establish eligibility to participate. If the potential participant is eligible, further information will be provided about the study (Dialogue for eligibility screening 15-01-2023). If interested in participating, mothers will be emailed or posted (depending on preference of the mother) the participant information sheet (PIS) (PIS for pilot study 15-01-2023 Vn1.2) and copy of the consent form (Consent form for study for mother 15-01-2023 Vn 1.1). Additional contact details of postal address or email address will be requested depending on preference of contact (Contact details for mothers 21-08-2022 Vn 1.0). The researcher will provide each mother at least 48 hours to consider participation before making contact again by telephone (Dialogue for obtaining consent for study 21-08-2022 Vn 1.0). This will be an opportunity for the researcher to answer any further questions the mother may have and confirm they are happy to consent. If a mother wishes to participate, they will be asked to sign and return a consent form (Consent form for study for mother 15-01-2023 Vn 1.1) to the researcher who will countersign and return a copy to them. Electronic copies will be generated in MS Forms and stored securely and separately in QUB SharePoint. A stamped addressed

envelope will be supplied to be returned to QUB, if paper copies are preferred. Paper copies will be stored securely on university premises in a locked filing cabinet accessible only by the research team behind a locked door. Screening logs will be used to record the number of mothers who get in contact, how they heard about the study, number who are screened as eligible or not, number who are interested in participating, and any reasons for non-participation, if disclosed on request, consented to first approach, recruited to study, accepted to participate and any reasons for non-acceptance, if disclosed on request (Screening log 21-08-2022 Vn 1.0).

The baseline questionnaire (Baseline questionnaire 13-02-2023 Vn 1.2) will then be provided via an electronic link in an email from the online Qualtrics survey platform and completed questionnaires saved within the Qualtrics platform. A stamped addressed envelope will be supplied to be returned to QUB, if paper copies are preferred. Paper copies will be stored securely on university premises in a locked filing cabinet accessible only by the research team behind a locked door. All data will be stored in accordance with the Data Protection legislation and will be destroyed 5 years following completion of the study.

Following completion of the baseline questionnaire, participants will be randomised, with their babies, on a 2:1 allocation to the intervention (Mamas in Harmony plus usual care) and control group (usual care alone). This allocation ratio was chosen to increase data available on the intervention, owing to it being a feasibility pilot RCT. The focus is not on effect size and so, for the purposes of this study, a power calculation has not been estimated. The recruitment, baseline data collection and randomisation process will be repeated with the aim of recruiting 60 participants in total, 40 allocated to the intervention group and 20 to the control group. The sequence generation for randomisation of study participants will be carried out using a computer-generated random allocation sequence completed by a 3rd party researcher within the School of Nursing & Midwifery, QUB to test feasibility of the process for concealment of allocations from the research team. The 3rd party will inform the participant, via their preferred form of communication (email or telephone) (Dialogue from 3rd party for allocation 21-08-2022 Vn 1.0), of their allocation. They will inform those in the intervention group of the start date for the group sessions, with the aim of there being 1-2 weeks notice before sessions commence. The 3rd party will inform those in the control group that they will be contacted by the QUB researcher in 3 months for follow up data collection. The intervention group will also be provided with information giving directions and accessibility details for the venue (Directions to venue 21-08-2022 Vn 1.0). Intervention delivery will then commence. Four waves of recruitment and delivery of Mamas in Harmony are planned over an 18-month period.

During intervention delivery, the QUB researcher will send mothers a text message as a reminder for attendance the day before each weekly session (Text message reminder 21-08-2022 Vn 1.0).

All mothers in the intervention and control group will have been advised during the recruitment process that they will be contacted by the research team at approximately 3 months and 6 months post randomisation (for further data collection with questionnaires provided in the same way as the baseline assessment). The recruitment, randomisation and data collection process flow diagram is presented below:

13-02-2023 Vn (1.3)

PHASE 1: RECRUITMENT

Mothers see recruitment material and use QR code or email to contact the research team

Research team contact mother to establish eligibility and provide participant information sheet and consent form

Research team establish if mother willing to participate

YES – willing to participate

Consent obtained

NO – not willing to participate

Thank mother for interest

Mother continues with usual care

BASELINE DATA COLLECTION

Mother completes baseline questionnaire and indicates interest in interview

RANDOMISATION

Mother randomised on a 2:1 allocation

INTERVENTION GROUP

Mother receives 8x weekly Mamas in Harmony sessions + usual care.

Mother completes evaluation form in week 8

T2 (3 months) DATA COLLECTION

Mother completes T2 questionnaire

T3 (6 months) DATA COLLECTION

Mother completes T3 questionnaire

CONTROL GROUP

Mother receives usual care

T2 (3 months) DATA COLLECTION

Mother completes T2 questionnaire

T3 (6 months) DATA COLLECTION

Mother completes T3 questionnaire

PHASE 2: Research team review mothers who indicated interest in interview at baseline

MOTHER INDICATED INTEREST

Research team contact mother to provide participant information sheet and consent form

YES – willing to participate

Consent obtained

SEMI STRUCTURED INTERVIEWS WITH MOTHERS

END OF STUDY

SEMI STRUCTURED INTERVIEW WITH INTERVENTION FACILITATOR/S

MOTHER DID NOT INDICATE INTEREST

END OF STUDY

NO – not willing to participate

Thank mother for interest

END OF STUDY

The schedule for enrolment, delivery of intervention and assessment of outcomes for all phases has been created and illustrated in a Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) diagram (Appendix A).

Mamas in Harmony intervention

This novel music and social support intervention is delivered to mother-infant dyads in a group format in a community setting. Sessions will be delivered by a professional individual experienced in delivering music based community groups to a varied population. Mothers will attend with their babies and be invited to sit upon soft cushioned play mats. Small colourful age and developmentally appropriate toys and sensory objects will be available for baby to look at and touch. Mothers will have been requested to bring a blanket for their baby to lie on or this will be supplied, if required. Mothers and babies will be encouraged to create a circle formation. The singing component will last 40 minutes and begin with a welcome song sung by the intervention facilitator, mothers will be encouraged to join in, feel connected to each other through the song and will involve some gentle bouncing/rocking movements with baby. This song will remain the same each week to promote familiarity and confidence building for the mother.

The middle section involves the facilitator introducing a mix of songs that are easy to learn and pleasing to listen to without the need for lyric sheets. Mothers will be encouraged to sing along. Mothers will be encouraged to interact with their baby through various sensory stimuli involving touch, sound and visual, for example; tickling fingers, gentle massage and humming sounds close to baby's ear.

The end of each singing session involves a short period of quiet time, where room lights are dimmed, and calming lighting effects are turned on. Soothing sounds are provided by the intervention facilitator using voice and instruments, and mothers are encouraged to sit or lie with their babies and enjoy a period of bonding time together with minimal distraction.

Mothers are then invited to stay for informal social support with refreshments. This is facilitated by the intervention facilitator and assisted by the QUB researcher. Mothers will be encouraged to interact with other mothers to promote social connection. Acknowledging the potential for successful interaction occurring between mothers, the facilitator and assistant will step back after 20 minutes and allow mothers to continue without their direct involvement for up to an additional 30 minutes. This time will allow social support to be given and received. Mothers will be invited to sit and relax, to feel comfortable in attending to any of their babies needs as they chat and/or listen to others.

In addition to Mamas in Harmony sessions, mothers and infants in the intervention group will also receive usual postnatal care from health and social care services.

Usual care for control group

Mothers in the control group will not receive the music and social support sessions but will receive usual postnatal care offered by Health and Social Care (HSC) services in Northern Ireland provided by their community midwife, GP and health visitor. This usually comprises of mother and infant health and wellbeing checks, infant weighing, infant feeding advice and support, developmental assessments and additional visits based on need and capacity (DHSSPS, 2010).

Phase 1 - Feasibility study with a pilot randomised controlled trial (RCT)

Data collection

Baseline data will be gathered in the baseline questionnaire (Baseline questionnaire 13-02-2023 Vn 1.2) and will include sociodemographic details on age of mother and infant, marital status, number of children living with them, ethnicity, educational attainment, and average household income.

Further questionnaires will be administered at T2 (3 months post randomisation) (T2 questionnaire 15-01-2023 Vn 1.1) and T3 (6 months post randomisation) (T3 questionnaire 15-01-2023 Vn 1.1). All questionnaires will be administered via an electronic link in an email from the online Qualtrics survey platform and completed questionnaires saved within the Qualtrics platform. A stamped addressed envelope will be supplied to be returned to QUB, if paper copies are preferred. Paper copies will be stored securely on university premises in a locked filing cabinet accessible only by the research team behind a locked door. All data will be stored in accordance with the Data Protection legislation and will be destroyed 5 years following completion of the study.

Feasibility outcomes

The feasibility outcomes of the study will be:

1. The recruitment rate of study participants
2. Reasons for non-participation (if disclosed)
3. Adherence and retention of participants, including reasons (if disclosed) for attrition during the intervention.
4. Attrition rate of mothers at the follow up timepoints at 3 months and 6 months post randomisation
5. Acceptability of outcome measures for anxiety, postnatal depression, perceived stress, perceived social support, maternal postnatal attachment, health-related quality of life, and service use.
6. Quality of implementation, potential mechanisms of change and context

Outcome measurement

Recruitment and allocation of participants will be collected and then reported and presented in a CONSORT flow diagram (Schulz et al., 2010). Screening logs will be used by the researcher during recruitment to record numbers of mothers who agreed to participate and those who declined to participate and reason (if given) (Screening log 21-08-2022 Vn 1.0) and may be used to discover influences over recruitment and/or retention of mothers. Mothers will have the option to declare that they prefer not to say. An attendance register (Attendance register 15-01-2023 Vn 1.1) will be used at each session to gather information on mothers attendance at the group music component and social support component and if any further information was provided by mothers such as their late arrival or early departure from sessions. This will be used to establish retention of participants and adherence to the intervention.

Attrition rates from the research study will be recorded and analysed to assess feasibility of follow up immediately post-intervention and longitudinal follow up ≥6 months in duration within a full trial. Acceptability of outcome measures will be assessed from completion rates of outcome measures, missing data and promise of effect on outcome. A standardised service use log will be provided at baseline, one to be collected at 3 months (post randomisation) (3 month service use log 15-01-2023 Vn 1.1) and one to be collected at 6 months (post randomisation) (6 month service use log 15-01-2023 Vn 1.1) to establish completion rates.

Implementation components of dose, reach, context, fidelity and challenges for intervention delivery will be reported on using data from attendance registers (dose), screening logs for discovering how mothers heard about the study (reach), semi-structured interviews during process evaluation (context, fidelity and challenges). Also use of evaluation forms (fidelity). The INNATE framework (Warran et al., 2022) used to support the design and implementation of the intervention will then be utilised following the process evaluation as a guide to attempt to identify potential causal mechanisms that may have led to an effect on outcomes.

Data analysis

Quantitative data will be analysed with descriptive statistics using SPSS version 27. Continuous data will be presented as means and standard deviations and categorical and dichotomous data presented as frequencies and percentages. Baseline comparisons between groups will be made using one-way ANOVAs, Kruskal-Wallis test and Chi-square test for linear, ordinal and categorical data respectively. Differences in (Generalised Anxiety Disorder 7 Scale) GAD-7, Edinburgh Postnatal Depression Scale (EPDS), Perceived Stress Scale (PSS), Social Support Survey (SSS), Maternal Postnatal Attachment Scale (MPAS) and EQ-5D-5L scores between groups at 3 months and 6 months (post randomisation) will be assessed using two way ANOVAs, with baseline scores included as co-variates where collected. Any differences in score between groups on follow up will be of interest as evidence of promise. Mothers who dropped out versus retained at 3 months and mothers dropped out versus retained at 6 months will be reported on in terms of maternal characteristics at baseline across the two groups.

Phase 2 – Process evaluation

The aim of the process evaluation is to understand mothers' experiences and opinions of the Mamas in Harmony intervention using evaluation forms and semi structured interviews completed by mothers from the intervention group. Insight will be sought as to the acceptability of the intervention in terms of being liked or disliked, appropriate, benefits gained, to identify any barriers to attendance and/or engagement that exist and recommendations for improvement. Responses from evaluation forms collected will be analysed and be used as prompts for further enquiry during the interview.

Semi structured interviews will also be conducted with mothers from the control group to provide insight on the acceptability of the research study by gaining a broader understanding of recruitment methods, attrition of mothers during study and completion rates of outcome measures.

Finally semi structured interviews will be conducted with the intervention facilitator/s to allow them to provide their professional opinion on the implementation of the intervention and to advise on challenges/improvements to facilitation to inform future research.

Recruitment

Potential participants will be identified from both intervention and control group mothers who indicate their interest in participating in an interview at the baseline data collection timepoint. A separate participant information sheet (PIS for interview for mothers 15-01-2023 Vn 1.1) and consent form (Consent form for interview for mothers 15-01-2023 Vn 1.1) have been developed for this phase and will be provided either by email or post depending on the mother's preference (as indicated at recruitment for the pilot RCT) after completion of the pilot study when interviews are due to be scheduled. Mothers who indicated an interest in taking part in an interview will have their study ID entered into a MS Excel file where a random number generator will be used to compile a random list of all the study IDs. It is anticipated that 12 (20%) will indicate they will be interested in an interview and that on invite, 8 of these will agree, consent and participate. In the first instance, the mothers of the first eight randomly generated study IDs will be approached by the researcher through the participant's preferred mode of contact, informed of this component of the study and invited to participate (Dialogue for interest in interview 21-08-2022 Vn 1.0). Recruitment will continue, by contacting the mother assigned to sequential Study IDs on the list.

If interested in participating, mothers will be emailed or posted (depending on preference of the mother) the participant information sheet (PIS) (PIS for interview for mothers 15-01-2023 Vn 1.1) and copy of the consent form (Consent form for interview for mothers 15-01-2023 Vn 1.1). The researcher will provide each mother at least 48 hours to consider participation before making contact again by telephone (Dialogue for obtaining consent for interview 21-08-2022 Vn 1.0). This will be an opportunity for the researcher to answer any further questions the mother may have and confirm they are happy to consent. If a mother wishes to participate, they will be asked to sign and return consent forms to the researcher who will countersign and return a copy to them. Electronic copies will be generated in MS Forms and stored securely and separately in QUB SharePoint. A stamped addressed envelope will be supplied to be returned to QUB, if paper copies are preferred. Paper copies will be stored securely on university premises in a locked filing cabinet accessible only by the research team behind a locked door. All data will be stored in accordance with the Data Protection legislation and will be destroyed 5 years following completion of the study. Then mothers will be contacted by telephone (Dialogue for arranging interview 21-08-2022 Vn 1.0) to arrange a suitable date and time for interview and to confirm preference (face to face or Microsoft Teams).

The intervention facilitator/s will be invited to attend an interview and will receive an electronic copy of the participant information sheet (PIS for interview for facilitators15-01-2023 Vn 1.1) and consent form (Consent form for interview for facilitators 15-01-2023 Vn 1.1), or paper copy if preferred, and will be stored as described above.

Data collection

The following processes will be undertaken:

1. Evaluation forms (Evaluation form 21/08/2022 Vn 1.0) will be administered to mothers allocated to the intervention group in person in week 8 at the end of the final session of the intervention. A box will be provided at the side of the room for mothers to place their completed forms. Mothers will be reminded that all thoughts on the intervention will be valued and used to help improve the intervention content and delivery. They will be informed that they do not have to complete the form if they do not wish to, and that the forms are anonymous. The facilitator and researcher will leave the room while mothers complete the forms. The researcher will collect the box with the completed evaluation forms after the session has closed and all mothers have departed. The forms will be used to explore expectations of and satisfaction with the intervention and ideas for improvement.

2. Semi structured interviews will be carried out with a subset of participants from the intervention group and will take place after completion of the pilot study so not to impact upon outcome assessment at 6 month follow up. Semi structured interviews were chosen as the preference over focus groups for participants, and an outline interview schedule has been created (Interview schedule for mothers 21-08-2022 Vn 1.0). The interview schedule will comprise of questions for mothers from both the intervention and control groups and questions specific to each group. The interview schedule was informed by using prompts/questions which are existing benefits/implementation characteristics of similar interventions in similar populations and also developed to advise on enablers/barriers to participation to inform future research. Socio-demographic characteristics of participants will be collected at the start of the interview to establish a profile of the participants taking part in the interviews (Demographics for interview 13-02-2023 Vn 1.1). While interviews are more time consuming for the researcher, they are more convenient to the mother and allow confidentiality for the mother in the discussion and so more likely to have higher participation rates and anticipated to provide rich data in relation to the depth of understanding gained of the mothers' experiences. A previous study conducting a process evaluation with mothers and infants following a singing intervention, found low uptake in their focus groups likely due to the logistic challenges of the mother sitting and talking while having a young infant to attend to (Perkins et al., 2018). While this will still be the case for the mother regardless of method, it is planned that semi-structured interviews will be conducted face to face in person or virtually via Microsoft Teams, at a date and time convenient to the mother to allow as much flexibility as possible. Interviews will be digitally recorded via Microsoft Teams, then saved and stored securely on QUB SharePoint. If completed face to face, recording will take place using two digital voice recorders in the event of technical failure and saved and stored securely on QUB OneDrive. Transcription of audio recordings will take place as soon after data collection as possible. Transcripts will be identified by study ID only. Recordings will be destroyed after transcripts have been checked for accuracy.

3. Semi structured interviews will be carried out with a subset of participants from the control group and will take place after completion of the pilot study so not to impact upon outcome assessment at 6 month follow up. Interviews will be conducted, recorded and data handled and stored as described in (2). The interview schedule (Interview schedule for mothers 21-08-2022 Vn 1.0) was informed by using questions based on feasibility outcomes to gain a broader understanding of recruitment methods, attrition of mothers during study and

completion rates of outcome measures. Socio-demographic characteristics of participants will be collected at the start of the interview to establish a profile of the participants taking part in the interviews (Demographics for interview 13-02-2023 Vn 1.1).

4. A single interview will take place with the intervention facilitator/s following completion of all cycles of sessions. The interview will be conducted, recorded and data handled and stored as described in (2). The interview schedule (Interview schedule for facilitators 21-08-2022 Vn 1.0) was informed by implementation characteristics of similar interventions in similar populations. Also to allow the facilitators to provide their professional opinion on the implementation of the intervention and to advise on challenges/improvements to facilitation to inform future research.

Data analysis

1. Evaluation forms will enable expectations and satisfaction of the intervention to be reported on and ideas for improvement to be made.
2. Semi structured interviews with the intervention group will allow acceptability of the intervention to be reported on.
3. Semi structured interviews with the control group will allow acceptability of the research study to be reported on.
4. Semi structured interviews with the intervention facilitator/s will allow an understanding of the facilitators' experiences of their involvement with the intervention to be gained.

All recordings from the interviews will be transcribed verbatim by the researcher and pseudonymised transcripts will be uploaded to NVivo and analysed using an interpretive qualitative approach based on the principles of thematic analysis (Braun et al., 2014). This type of analysis focuses on identifying themes throughout the data and then be coded by identifying persistent words, phrases, experiences or concepts. Data will then be grouped according to topic, allowing further identification of sub-themes. Following coding, the data will be categorised to reflect the overall picture of the data and relationships between categories. Related categories will be merged into themes (Green and Thorogood, 2018). Reflexivity will be practiced through individual analysis conducted by the research team, then discussion and agreement. This allows any biases or assumptions about the content to be examined and for the researchers to undergo a process of self-examination (Campbell et al., 2021). These themes will be used to gain an understanding of the experiences of mothers participating in the intervention.

Ethical considerations

Ethical approval will be sought from the Faculty of Medicine, Health and Life Sciences Research Ethics Committee at QUB prior to commencing the study.

Confidentiality is paramount and will be maintained during and after the study. All information collected about participants during the course of the research will be kept strictly confidential with the exception that if they disclose information that indicates that they or someone they mention is at risk of harm, the researcher is legally obliged to pass on this information in accordance with professional guidelines. Participants are advised that all information shared within group discussions

will be treated confidentially. Any personally identifiable information entered by participants within questionnaires will be removed, anonymised or pseudonymised as appropriate.

A study advisory group will be formed, comprising of local and national professionals, paraprofessionals and parents to provide ongoing insight and expertise as the study progresses. The group will meet online at key milestones of the study, expected to be on a 6-monthly basis.

Potential risks to the study participants

Physical harm: No significant physical risks are expected to be associated with the participation in this study. A health and safety assessment of the venue for its suitability for mother and infant classes will be conducted prior to commencement of the study and on an ongoing basis during the study in accordance with QUB health and safety policy.

Psychological harm: The risk of psychological harm is expected to be minimal. Previous research using a similar intervention has shown no adverse events to study participants (Fancourt and Perkins, 2018). The intervention facilitator and assistant facilitator will be vigilant during delivery of the intervention, process evaluation interviews and during any other contacts with study participants for any sign of distress observed or verbalised by the mother. If this occurs, the researcher will take appropriate action as set out in the distress protocols for both the Mamas in Harmony sessions and interviews (Distress protocol – study 21-08-2022 Vn 1.0; Distress protocol – interview 21-08-2022 Vn 1.0).

It is acknowledged that outcome data provided at post intervention and follow up timepoints by mothers during the study would not normally be analysed until completion. However, due to completion of outcome measurement tools for anxiety and depression (EPDS and GAD-7) having the potential to identify scores above the recognised clinical threshold for the tool representing significant symptoms and/or risk to the mother and infant, these data will be analysed by the researcher within one week of receipt of the completed questionnaire from the mother. This will enable the researcher to signpost the mother to her GP and other appropriate supports as per the distress protocol (Distress protocol – study 21-08-2022 Vn 1.0). Contact will be made with the mother by the research team immediately in the event that the research team identify the mother's score as being on/above the threshold indicating the potential need for follow up care, as per the measurement tool's guidelines. A letter will be forwarded to the mother by email or post depending on preference to present to her GP providing the context for the contact (GP letter 13-02-2023 Vn 1.0). In addition to these measures, should a mother express to the intervention facilitator and/or assistant facilitator that they, their infant, or someone else may be at risk of harm, consent will be sought from the mother for the researcher to contact her health visitor and/or GP within 24 hours of disclosure to share the information. Health visitor/GP contact details will be requested directly from the mother. Safeguarding advice will be sought by the researcher from the QUB designated safeguarding officer as required.

Mothers may feel they are experiencing a level of inconvenience due to the required number of questionnaires administered. Each questionnaire will take approximately 25 minutes to complete, of which the participant will be made aware of in the participant information sheet and at the beginning of each questionnaire. Data collection at all three timepoints will take place via the Qualtrics survey platform, or by post if preferred, in order to be less intrusive to the mothers home

life and potentially be more convenient. They will be able to complete the questionnaires at a time to suit their needs and that of their infant and can be saved and returned to before submitting.

Covid 19

The researcher will be following Public Health Agency guidance regarding Covid 19 at the time of the individual stages of the intervention and follow up. The researcher will complete health and safety documentation as required to identify and reduce risk.

Benefits

The benefits to the intervention and control groups will be the opportunity to participate in research and contribute knowledge to the evidence base. The intervention group may further benefit by taking part in group based activities with their infant. All participants will receive a £15 Amazon gift card as a thank you and to acknowledge their time in taking part at the end of the study.

Dissemination

Research findings will be disseminated to audiences through academic conferences and stakeholder-related event presentations, as well as peer-reviewed academic journal publications. A study webpage will be created to disseminate progress of the study and findings to study participants and the wider public. Social media will also be used to disseminate findings to reach a wider audience and maximise impact.

The study results will be implemented to decide on progression to a definitive RCT, using data on acceptability of the intervention and recruitment and attrition rates. The process evaluation will assist in exploring the quality of implementation, potential mechanisms of change and context, allowing for the intervention and conduct of the trial to be optimised and refined as required.

Project Timetable

A Gantt chart presents the anticipated schedule of recruitment, delivery of the intervention, data collection, data analysis and dissemination (See attached).

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Appendices

A. SPIRIT diagram (separate document)
B. GANTT chart (separate document)

13-02-2023 Vn (1.3)

Consent form for Mamas in Harmony study

STUDY ID _____

	Please initial
1. I confirm that I have been given and have read and understand the Participant Information Sheet (15-01-2023 Version 1.1). I have had the opportunity to ask and receive answers to any questions I may have had.	☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason and without my legal rights being affected.	☐
3. I understand that the data provided until the point of withdrawal will be retained and used for analysis.	☐
4. I understand that my personal information will be held securely on university premises and should comply with relevant data protection legislation and data collected as part of the research may be looked at by authorised individuals from Queen's University Belfast (QUB) where relevant and I give permission for these individuals to have access to this information.	☐
5. I understand what is discussed during the Mamas in Harmony study will be kept confidential by the research team with the exception that if I disclose information that indicates that I or someone I mention is at risk of harm, the researcher is legally obliged to pass on this information in accordance with professional guidelines.	☐
6. The research team cannot ensure confidentiality of information shared between, and/or by other mothers during or after Mamas in Harmony sessions	☐
7. I understand that I will not be identifiable in any data published in relation to this project.	☐
8. I agree to take part in the above study.	☐

_____	_____	_____
Name of Participant	Date	Signature
_____	_____	_____
Researcher	Date	Signature