ISRCTN14707506 https://doi.org/10.1186/ISRCTN14707506

# Community singing interventions for postnatal depression

| Submission date | Recruitment status | [_] Prospectively registered |
|---|---|---|
| 04/11/2022 | No longer recruiting | [X] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 14/11/2022 | Completed | [_] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 10/03/2026 | Mental and Behavioural Disorders | [X] Record updated in last year |

**Plain English summary of protocol**

Background and study aims
Postnatal depression (PND) affects over 13% of new mothers but there is still not an ideal treatment for all cases. Pharmaceutical and psychotherapy have offered solutions but there are challenges in treatment uptake and adherence and long waiting lists for psychotherapy. Many mothers attend group activities with their babies, some including music and singing. Community group singing has shown improvement in mental health and singing to babies has shown improvement in mother-infant interaction and reduced infant distress. The aim of this study is to find out whether 10 weeks of community singing reduces symptoms of postnatal depression.

Who can participate?
Mothers (aged 18 years and over) and their babies (aged 0-9 months), residing in London, with an Edinburgh Postnatal Depression Scale (EPDS) score of 10 or above

What does the study involve?
Melodies for Mums (M4M) is a programme based in Lambeth and Southwark providing 10-week singing and music sessions for mothers with postnatal depression (PND) and their babies in community Children's Centres or online, according to government social distancing guidelines. Participants will be randomly allocated to singing or a waitlist (singing after 10 weeks).

What are the possible benefits and risks of participating?
Studies have demonstrated its effectiveness in reducing symptoms of PND faster than usual care or social groups, and preliminary process evaluations have suggested its suitability. It has also been identified as a strong way of engaging mothers from minority backgrounds who are less likely to seek professional support for their mental health.

Where is the study run from?
King's College London (UK)

When is the study starting and how long is it expected to run for?
February 2021 to December 2024

Who is funding the study?
Wellcome Trust (UK)

Who is the main contact?
Prof. Carmine Pariante, carmine.pariante@kcl.ac.uk
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# Contact information


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Scientific

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# Additional identifiers

**ClinicalTrials.gov (NCT)**
NCT04834622

**Clinical Trials Information System (CTIS)**
2020-001555-41

**Integrated Research Application System (IRAS)**
278445

**Central Portfolio Management System (CPMS)**
52272

# Study information

**Scientific Title**
Scaling-up Health-Arts Programmes: Implementation and Effectiveness Research (SHAPER)

**Acronym**
SHAPER-PND

**Study objectives**

10 weeks of community singing reduces symptoms of postnatal depression.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Approved 01/02/2021, London - West London & GTAC Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; +44 (0)207 1048 007; westlondon.rec@hra.nhs.uk), ref: 20/PR/0813

## Study design
Randomized; Interventional; Design type: Treatment, Psychological & Behavioural, Other

## Primary study design
Interventional

## Study type(s)
Treatment

## Health condition(s) or problem(s) studied
Postnatal depression

## Interventions
Melodies for Mums will be a randomised clinical trial in which postnatally depressed women and their infants will randomly be assigned to 10 weeks of singing sessions or 10 weeks of usual community-based activities. Mother-infant dyads will partake in the trial for a total of 36 weeks, the first 10 of which will be the intervention period, and the remainder of which will be a follow-up period. More specifically, dyads will be assessed for demographic, psychological, social, and biological information either by KCL researchers or asked to complete online questionnaires at baseline (before the start of the intervention period), at week 6, at week 10, at week 20, and at week 36. Furthermore, qualitative data will be collected after week 10 (end of the intervention period) from focus groups and small-group interviews with a small subset of participants. Finally, Implementation Science data regarding the implementation and cost-effectiveness of the singing intervention will be collected from mothers and stakeholders using questionnaires, surveys, interviews and other data collection methods. The end of the trial for a participant will be after the 36-week follow-up or withdrawal from the study.
Control groups are non-musical free community mother and baby activities that will be available in the same geographical area as the venues where the singing sessions will take place or provided online by the same venues/organisations as they would if they were being delivered in person.
The overarching aim of the study is to evaluate both the clinical and implementation effectiveness of community singing for women (and their infants) on their symptoms of postnatal depression. More specifically, the aim of the clinical effectiveness component of this trial is to explore the clinical effectiveness of the intervention in a larger sample size than previous studies for scalability (to ascertain whether the initial findings can be replicated at a larger scale). In order to understand whether singing is an efficacious treatment for postnatal depression, we will collect various psychological, biological, social, and qualitative measures from women and their infants before, during, and after the intervention period. Furthermore, the aim of the implementation effectiveness component of this trial is to explore the implementation effectiveness of the intervention, including its uptake, suitability, acceptability, appropriateness and feasibility (to identify not just ‘if’ but also ‘why’ the intervention works and

support our understanding). It will also explore the cost-effectiveness of the intervention, including the cost of delivering the interventions and the balance of benefit for the health sector, in order to be able to develop a strong business plan for the intervention.

Participants and recruitment process:
This study aims to recruit a total of 400 women and 400 babies (800 participants in total) experiencing postnatal depression and their babies. The process of recruitment will be as follows: potential women and their infants will be identified through a) weigh clinics or other community and clinical centres for postnatal mothers and their babies (through Breathe Arts staff); b) healthcare signposting, including general practitioners, clinical psychologists, and psychiatrists; c) signposting via other health and social care professionals, including midwives, health visitors, community mental health teams and community publicity; d) social media (Facebook, Instagram, Twitter) and online forums; e) self-referral. Once a potential participant has been identified through any of the above-mentioned routes, women will be contacted by the Breathe Arts staff about the study or will directly complete a webform on Breathe's website.
If a participant is interested in partaking, they will be asked to complete a webform containing basic information (name, date of birth, baby's date of birth, address, phone number) and give consent to sharing this data with researchers, after which they will be emailed the Edinburgh Postnatal Depression Scale (EPDS) to complete electronically, to evaluate for postnatal depressive symptoms. Once the webform is completed, consent is given and if their EPDS score is above 10, the KCL research team will receive this information, and they will arrange a baseline assessment. If they score below 10 they will be signposted to other support services within the community. Mothers will not be aware of the screening threshold for the EPDS and will not know their EPDS score.
At the baseline assessment (in-person or online), women will be explained the trial, and given the participant information sheet and informed consent form. All women will then be administered the Structured Clinical Interview for DSM-IV Axis Disorders (SCID) to assess for a current depressive episode. If clinical criteria for current depression are met, women will then be consented and randomised (2:1) to either the intervention group (10 weeks of singing sessions, in community centres or online) or to the control group (10 weeks of community-based activities either in person or online, according to availability of sessions and participant's preference). All women who meet the criteria on the SCID for a current episode of depression will thus take part in all of the subsequent research assessments for both clinical effectiveness and implementation effectiveness (discussed in measures and procedure below), regardless of randomisation allocation. If the criteria for a current episode of depression is not met on the SCID, women will be signposted to other support services within the community.
In addition to the participants, around 30-50 wider stakeholders involved in the intervention will be recruited by research staff for the implementation effectiveness part of the trial. This group includes artists, psychiatrists, GPs, health visitors, commissioners and others involved in the delivery of the intervention. The wider stakeholders and mothers involved in implementation science research will be provided with a stakeholder-specific ICF and a PIS.

Measures collected and procedure:
Measures will be collected from all women in the intervention and control groups at each time point throughout the study. Following the baseline assessment, women will begin their 10-week intervention period (either community singing or control group activity). All women will complete various demographic, psychological, social, and biological measures for the KCL research team at weeks 1, 6 and 10 during the intervention period, and then at weeks 20 and 36 following the intervention period to gather follow-up data. Measures for weeks 6, 20, and 36 will all be completed online due to the self-reporting nature of the measures to be captured. If a mother cannot access a computer, these will be printed and posted to them or provided in print at the session. Measures for week 10 will be collected at participants' homes or online (via a

video-chat platform) due to the interview style of the assessments. There will be a window of two weeks on either side of the session date for these measures to be completed. Additionally, biological measures will be taken from all women and their infants at weeks 1 and 10 if consented.
For online measures, participants will be encouraged to complete these 3 days on either side of the first, 6th and 10th sessions, respectively. However, in order to allow flexibility in the schedule, it will be accepted a +/-1-week variation in the date of collection of the measures below (apart from week 10, when the window will be after the 10th session, weeks 10-12). These measures will be collected from the control and the intervention groups simultaneously. An optional focus group will take place after session 10 of the intervention for women who were allocated to the intervention group, and subsequent interviews will be conducted with a sub-group of women who have particular risk factors for PND. These interviews will take place after the 20-week follow-up either by video call or at the woman's home. These measures will be collected from the control and the intervention groups simultaneously.

The following measures will be collected:
Baseline (screening): baseline demographics, repeated demographics, Brief Life Events Scale, Child Experience of Care and Abuse (CECA-Q), Composite Abuse Scale (CAS) - Pregnancy Version, Intrusive Life Events Scale; Structured Clinical Interview for DSM-IV (SCID), Edinburgh Postnatal Depression Scale (EPDS), Hamilton Depression Rating Scale (HDRS), Beck Depression Inventory (BDI), Office for National Statistics Wellbeing Scale (ONS), State-Trait Anxiety Inventory (STAI), Perceived Stress Scale (PSS); CCI (CARE-index), Maternal Postpartum Attachment Scale (MPAS), Parent Reflective Functioning Questionnaire (PRFQ), UCLA Loneliness Scale, Short General Self-Efficacy Scale (G, SE-6), Multidimensional Scale of Perceived Social Support (MSPSS); Diurnal saliva samples in mothers and babies.
Baseline to Week 1: Pre-intervention saliva samples in mothers and babies.
Week 6: Repeated demographics, EPDS, BDI, ONS, STAI, PSS, MPAS, UCLA Loneliness Scale, GSE-6, MSPSS.
Week 10: Repeated demographics, EPDS, HRDS, BDI, ONS, STAI, PSS, CCI (CARE-Index), MPAS, PRFQ, UCLA
Loneliness Scale, GSE-6, MSPSS, Diurnal saliva samples in mothers and babies, hair cortisol sample, postintervention saliva sample.
Week 20: Repeated demographics, EPDS, BDI, ONS, STAI, PSS, MPAS, UCLA Loneliness Scale, GSE-6, MSPSS.
Week 36: Repeated demographics, EPDS, BDI, ONS, STAI, PSS, CCI (CARE-Index), MPAS, PRFQ, UCLA Loneliness Scale, GSE-6, MSPSS.
Additionally, at week 10, mothers who completed the intervention may participate in focus groups and interviews for qualitative clinical outcomes.
All participants will also be invited to take part in implementation science data collection alongside the wider stakeholder group. The measures to be used for the implementation science portion of the study are: the AIM and semi-structured interviews for intervention acceptability, the IAM and semi-structured interviews for appropriateness of intervention, the FIM and semi-structured interviews for the feasibility of the intervention, EQ5D-5L and AD-SUS for cost-effectiveness, the NOMAD and semi-structured interviews for sustainability and scalability, and information on attrition, retention will also be collected.

Collection, transportation and storage of samples:
Pre-post intervention saliva samples collected from mothers and babies will be retrieved using absorbent swabs (mothers) or SalivaBio Children's Swabs (babies) and will be posted or collected at the NIHR-Wellcome King's Clinical Research Facility (CRF) by one of the researchers in the team and used for cortisol, oxytocin, cytokines and other stress hormones analysis. The samples will be kept on ice and brought to the Maurice Wohl Clinical Neuroscience Institute (King's

College London, Denmark Hill) to be stored at -80 ºC until analysis.
Six saliva samples from mothers (and two samples from their baby, providing consent) will be collected by mothers at home at awakening, +15, +30+ and +60 min after awakening, at 12 noon and 8 pm, and used for diurnal cortisol and other stress hormones. Once taken, samples will be posted or transported to the Maurice Wohl Clinical Neuroscience Institute (King's College London, Denmark Hill), to be stored at -20 ºC until analysis.
Hair samples will be kept at room temperature for short-term storage but will be transferred to -20 ºC for longer-term storage until analysis (cortisol and other stress hormones) is conducted.
Samples will be processed and analysed and the remaining material will be kept for 10 years after the completion of the study.
Results will be identified according to anonymised codes and stored securely.

Storage and access to questionnaires:
There will be a combination of carbon and electronic CRFs, depending on the method of data collection. For home visits and specific group sessions (weeks 0, 6 and 10), researchers will be present and carbon copies of the CRFs will be completed by participants. When researchers do not need to be present or the assessments are to be completed online, electronic versions of CRFs, or paper copies if requested, will be completed by the study participants.
Carbon copies for the PIS, ICF, questionnaires and sample collection CRFs will be transported to KCL (Maurice Wohl) for storage and data input into the trial's database as soon as possible. All self-reporting questionnaires at weeks 6 and 10 to 36 will be completed online using REDCap and they will be accessible to the research teams only. If participants have not completed the online CRFs for the respective week before the session, researchers will bring blank copies of the CRFs to be completed after the sessions take place. If participants cannot access a computer /laptop and/or if they are in the control group, questionnaires will be posted to them.
PIS and ICFs will be kept and stored separately from other carbon CRFS. They will be stored in lockable cabinets so that source data with identifiable participant information (PIS and ICF) will be kept separately from CRFs.
All data will be kept in line with the GDPR preserving the confidentiality of all participants taking part in the study (M4M participants and professional stakeholders). All data, including the surveys and interviews, will be de-identified (i.e., all personally identifiable information will be removed), kept safe and secure on encrypted and password-protected folders and storage media, and separate from the research data.
Participants will be reassured that the data collected will remain strictly confidential and that it will be de-identified so that they will not be identifiable unless via code-breaking. Participants will also be assured that their comments and survey responses will not be attributable to them by the trial team and/or intervention delivery team. Any published data will be devoid of personally identifiable information.
Confidentiality will be strictly adhered to at all times, and personal information will be discussed only with those individuals who have a need or right to know, or/and in those situations where it is deemed necessary in order to ensure the safety of the participant and their family/carers.

Follow-up:
Follow-up with all participants will be done at weeks 20 and 36, using the questionnaires above mentioned. Participants' wellbeing will be monitored through the questionnaires and any issues will be flagged by the UCL team which will do onward reporting if needed. No samples will be collected at follow-up.

Wider stakeholders:
A series of questionnaires/interviews/focus groups will be performed to collect implementation science data only.

## Intervention Type
Behavioural

## Primary outcome(s)
1. The effectiveness of group singing interventions on symptoms of postnatal depression measured using the Edinburgh Postnatal Depression Scale (EPDS) at baseline and Week 10 (end of treatment)
2. The acceptability of the intervention measured using the Acceptability of Intervention Measure (AIM) at week 10 (end of treatment)

## Key secondary outcome(s))
1. Depression measured using the Hamilton Depression Rating Scale (HDRS) at baseline and weeks 6, 10, 20 and 36
2. Depression measured using the Beck Depression Inventory (BDI) at baseline and weeks 6, 10, 20 and 36
3. Stress measured using the Perceived Stress Scale (PSS) at baseline and weeks 6, 10, 20 and 36
4. Wellbeing measured using the Office for National Statistics Wellbeing Scale (ONS) at baseline and weeks 6, 10, 20 and 36
5. Anxiety measured using the State-Trait Anxiety Scale (STAI) at baseline and weeks 6, 10, 20 and 36
6. Observed mother-infant interaction assessed using the Crittenden CARE-Index (CCI) at baseline and weeks 10 and 36
7. Perceived mother-infant relationship assessed using the Maternal Postpartum Attachment Scale (MPAS) at baseline and weeks 6, 10, 20 and 36
8. Perceived mother-infant relationship assessed using the Parent Reflective Functioning Questionnaire (PRFQ) at baseline and weeks 6, 10, 20 and 36
9. Social support and reduces loneliness assessed using the UCLA Loneliness Scale at baseline and weeks 6, 10, 20 and 36
10. Social support and reduces loneliness assessed using the Multidimensional Scale of Perceived Social Support (MSPSS) at baseline and weeks 6, 10, 20 and 36
11. Stress hormones, including hair cortisol, diurnal cortisol and salivary cytokines, analysed using an array of techniques including enzyme-linked immunosorbent assay (ELISA) at week 1 and weeks 6 and 10
12. Levels of salivary oxytocin analysed using an array of techniques including enzyme-linked immunosorbent assay (ELISA) at week 1 and weeks 6 and 10
13. Lived experience of mothers with PND assessed using focus groups immediately following session 10 (if logistically possible) for all mothers focusing on their lived experience of the intervention and their reported mechanisms of effect
14. The phenomenology of PND and how singing intersects with PND among women with particular risk factors for PND (traumatic birth, adverse childhood experiences, and social isolation/loneliness) assessed using semi-structured interviews with three sub-groups of women self-reporting particular risk factors for PND: traumatic birth, adverse childhood experiences, and social isolation/loneliness, at week 10 (end of intervention)
15. The acceptability of the intervention assessed using the Intervention Measure (AIM) at week 10 (end of intervention)
16. Reasons for perceived acceptability of the intervention assessed using semi-structured interviews at week 10 (end of intervention)
17. Uptake/reach of the intervention assessed using recruitment rate records (number of eligible women who sign up to the intervention) at week 10 (end of intervention)
18. The appropriateness of the intervention assessed using Intervention Appropriateness Measure (IAM) at week 10 (end of intervention)

19. The appropriateness of the intervention assessed using semi-structured interviews at week 10 (end of intervention)
20. The feasibility of the intervention assessed using the Feasibility of Intervention Measure (FIM) at week 10 (end of intervention)
21. The feasibility of the intervention assessed using semi-structured interviews at week 10 (end of intervention)
22. Intervention adherence and attrition rates assessed using attendance data (rates and dropout reasons) at week 10 (end of intervention)
23. The adoption of the intervention assessed using participants and stakeholder enrollment rates at week 10 (end of intervention)
24. The cost-effectiveness of the intervention assessed using the 5-level EQ-5D version (EQ5D-5L) at week 10 (end of intervention)
25. The cost-effectiveness of the intervention assessed using the Adult Service Use Schedule (AD-SUS) at week 10 (end of intervention)
26. The cost-effectiveness of the intervention assessed using implementation activity logs (to estimate implementation costs) at week 10 (end of intervention)
27. Factors affecting the sustainability and scalability of the intervention assessed using the NOMAD Scale at week 10 (end of intervention)
28. Factors affecting the sustainability and scalability of the intervention assessed using semi-structured interviews at week 10 (end of intervention)

### Completion date
31/12/2024

## Eligibility

### Key inclusion criteria
1. Women aged 18 years or older
2. Satisfactory understanding of English
3. Women who have a child between 0 and up to 9 months old
4. Women with postnatal depression diagnosed using symptoms of PND at a minimum score of 10 on the Edinburgh Postnatal Depression Scale (EPDS)
5. Access to an internet-connected device (mobile phone, tablet, computer or laptop) to allow completion of assessments and participation in the singing sessions

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 years

### Upper age limit
52 years

### Sex

Female

### Total final enrolment
200

### Key exclusion criteria
1. Child outside of the age range specified
2. Unable to give informed consent

### Date of first enrolment
01/09/2021

### Date of final enrolment
28/09/2023

## Locations

### Countries of recruitment
United Kingdom

England

### Study participating centre
**King's College London**
Psychological Medicine
5 Cutcombe Road
London
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SE5 9RT

### Study participating centre
**Maudsley Hospital**
Denmark Hill
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### Study participating centre
**University College London**
UCL Department of Behavioural Sciences and Health
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# Sponsor information

**Organisation**
King's College London

**ROR**
https://ror.org/0220mzb33

# Funder(s)

**Funder type**
Research organisation

**Funder Name**
Wellcome Trust; Grant Codes: 219425/Z/19/Z

**Alternative Name(s)**
Wellcome, WT

**Funding Body Type**
Private sector organisation

**Funding Body Subtype**
Trusts, charities, foundations (both public and private)

**Location**
United Kingdom

# Results and Publications

**Individual participant data (IPD) sharing plan**
The datasets generated during and/or analysed during the current study will be stored in a non-publicly available repository: After the completion of the study, the anonymised study data will be kept for a period of 10 years. The study data that supports published results will be deposited in a secure data repository (KCL's Research Data Management System data repository, an interdisciplinary open data repository service maintained by KCL, where the data is stored).

**IPD sharing plan summary**
Stored in non-publicly available repository

**Study outputs**

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|

| | | | | |
|---|---|---|---|---|
| Protocol article | 17/11/2021 | 04/11/2022 | Yes | No |
| HRA research summary | | 28/06/2023 | No | No |