INFORMATION SHEET FOR RESEARCH PARTICIPANTS

YOU WILL BE GIVEN A COPY OF THIS INFORMATION SHEET

Title of study: SHAPER-PND: Community singing interventions for postnatal depression: a hybrid type II effectiveness-implementation trial

Invitation Paragraph

We are a group of researchers from King's College London (KCL) and University College London. We are researching community singing sessions, delivered by a non-for-profit organisation called Breathe Arts Health Research. The programme, Melodies for Mums (M4M) is aimed at mothers experiencing symptoms such as low mood and anxiety, which can be symptoms of postnatal depression. We would like to invite you to take part in this research project. Before you decide whether you want to take part, it is important for you to understand why the research is being done and what your participation will involve. Please take time to read the following information carefully and discuss it with others if you wish. You can ask the research team if there is anything that is not clear or if you would like more information.

What is the purpose of the study?

The purpose of the study is to understand whether singing sessions for mothers experiencing low mood and anxiety can help improve the symptoms faster than other community-based sessions. We also aim to assess whether this 10-week programme can be delivered on a larger-scale, providing the same benefits for mothers.

Postnatal depression (PND) affects somewhere between 13% and 30% of new mothers. Many mothers engage in community group activities with their babies, such as attending mother-infant play groups. Such activities have been identified as ways of relaxing mothers, providing good sources of social interaction, decreasing the monotony of each day and also providing a sense of personal fulfilment for mothers. Previous research has shown that daily singing to babies is associated with fewer symptoms of PND and higher levels of wellbeing, self-esteem and perceived mother-infant bond.

This study will provide information on the effectiveness of singing in improving PND symptoms and how to scale this intervention so that it can be delivered to more mothers. This study could help many families in the future and provide a support programme for mothers.

Why am I invited to take part?

You are being invited to participate in this study because you (like many mothers) have symptoms that could indicate you have been experiencing postnatal depression. In addition to this, you are eligible if you are 18 years-old or older and have a baby between 0 and 9 months old and score above a certain number in a questionnaire that assesses your mood. You may be unable to take part if your child is older than 9 months, are unable to commit to the 10-week program or are unable to give informed consent.

Your attendance to the 10-week singing program (one session per week) is vital for our research and we would like to ask you to consider your availability before consenting to the trial.

Please note that if you do not wish to participate to the study, there will be an option for you to consent to participate in a short interview (on the phone or in person, as you prefer) to understand why you prefer not to be involved, so that we can learn how to improve things for the future. However, it is important to know that this is completely voluntary, and you are under no obligation to provide feedback on why you have declined to participate in our study.

What will happen if I take part?

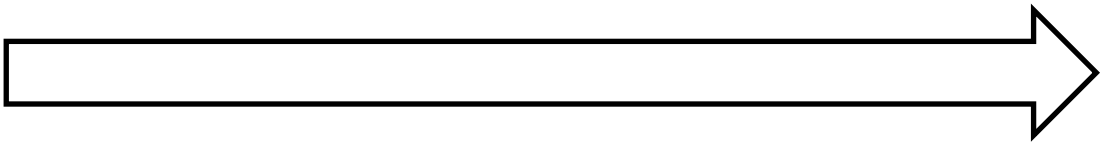
If you choose to take part, you will be asked to attend a 10-week singing program (one session per week) at a children's/community venue (or online if deemed necessary, see next paragraph), for women in the boroughs of Lewisham, Southwark or Lambeth. To ensure your safety, your baby's safety or anyone from Breathe involved in the programme, we might have to deliver some of these sessions online. We will have this option for the case of someone needing to self-isolate due to potential or confirmed exposure to COVID-19.

To fully assess whether the singing program is more beneficial than standard mother-and-baby classes available in your community, if you consent to take part to the study you may be asked to either start immediately the 10-weeks singing program or to first attend 10 weeks of other mother-and-baby classes, and then attend the singing program. The decision of the group you will be placed in will be made by a computer by chance alone.

In addition to participate to the activities as described above, you will be asked to complete a set of questionnaires and interviews that will collect information about you, your circumstances and your mental health. The questionnaires and interviews will vary but we will collect information before the start of the 10-week block of sessions and then at certain points during your participation on the trial (weeks 6, 10, 20 and 36). Some of the questionnaires will be completed with the researchers during the assessment visits, others will be completed online by you in your own time.

Regardless of the group you are placed in, you will also be asked to participate to the following activities, which are an integral part of the study:

- Providing your saliva samples to measure hormones related to stress, before the start of the 10-week block of sessions and at week 10. This is painless and non-invasive, and you can do this at home using little tubes. Your researcher will tell you whether you should mail the samples back to us, bring them to a singing session or that they will be collected from your home address. In addition, you will be asked to provide saliva samples before and after the first and the last session.
- Providing saliva samples from your baby for exactly the same reasons and at the same time as yours.
- Providing your hair sample, at the end of the study (week 10), again to measure hormones related to stress. This will be painless and non-invasive. Hair samples will be collected by a researcher at either the final session, at your home, or at the Institute of Psychiatry, Psychology and Neuroscience/King's College Hospital.



Baseline

- Pre- and post-session saliva samples from mother and baby
- Saliva samples at home from mother and baby

After session 10

- Pre- and post-session saliva samples from mother and baby
- Saliva samples at home from mother and baby
- Hair sample from mother

- Participating in a video-recording of you and your baby playing together, before and at the end of the 10-week block of session and as a follow-up after approximately 6 months; these videos will be used to examine how the intervention improves the way you and your baby interact.
- Participating in optional focus groups and interviews to give feedback on your experiences, at the end of the 10-week block of sessions. Your views will be recorded and transcribed using a professional transcription service.

The singing sessions will be led by a trained artist from Breathe Arts Health Research: an arts organisation that specialises in delivering community programmes for mothers and their babies. The sessions will be one hour long, and groups will have up to 13 women and their babies. Babies are welcome to attend the sessions, but mothers can attend on their own if they wish to. No prior knowledge of music or singing is expected, and the songs will be adapted to the group with the possibility of mothers creating their own songs.

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.

We will cover reasonable travel costs if requested, please discuss with a member of the research team.

We will offer a £20 gift card (from Love2Shop) for every research visit that you complete with us to compensate you for your time.

Do I have to take part?

Participation is completely voluntary. You should only consent if you want to and choosing not to be involved will not disadvantage you in any way. Once you have read the information sheet, please contact us if you have any questions that will help you decide. If you decide to consent to taking part, we will ask you to sign a consent form and you will be given a copy of this form to keep.

Your General Practitioner's (GP) details will be collected and they will be informed of your participation in the study. If there are any concerns regarding your or your baby's wellbeing during the trial and if strictly found necessary by the clinical team on the research project, we will speak to you about either us or you contacting your GP to discuss the best way to support you.

What are the possible risks and benefits of taking part?

No significant risks are expected to be associated with the participation in the trial. Theoretically it might be upsetting to discuss personal issues with the researchers, but you can stop at any time and we will support you in the process. We will be assessing your wellbeing during the study and find ways of helping you if your mood gets worse.

How will we use information about you?

We process your personal information in order to learn about the effect of the singing sessions on your wellbeing. We will use some of the information you provide for this research study.
The information we collect includes personal data, such as your personal details, your health, your baby's health and some of your medical history. Researchers will use this information to do the research or to make sure that the research is being done properly.
People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead that will ensure your identity stays protected.
We will keep all information about you safe and secure. All non-identifiable data we collect from you will be stored on REDCap, a secure server for anonymised data. Any identifiable information we

collect from you, including your contact details, audio-recordings, and video-recordings, will either be securely stored on KCL's Microsoft SharePoint, a secure server for KCL data, or on UCL's Data Safe Haven, a secure server for UCL data. Only members of the research team will have access to these files and they will all be password-protected.
Once we have finished the study, we will keep some of the data so we can check the results and this information will be securely kept for 10 years, either locked in a cabinet or on a secure server, after which point everything will be destroyed. Furthermore, anonymised data we collect and use for publication will be securely archived with KCL's Research Data Management System, so that it can be accessed by researchers again in the future. Any data that is archived will contain no personal identifiable information, and thus we will not archive any of your personal details, your video recordings, or your audio recordings. We will write our reports in a way that no-one can work out that you took part in the study.

Anonymised data may be shared with collaborating research projects that have been scientifically and ethically approved, within and outside the EU. Consent will be sought for this purpose.

What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
We need to manage your records in specific ways for the research to be reliable. This means that we will not be able to let you see or change the data we hold about you.
If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study. The data will only be used for approved future research.

KCL is the lead Sponsor for this study and will process and store your data according to GDPR. The data controllers for this study are KCL and the South London and Maudsley NHS Trust (SLAM). UCL and Breathe Arts Health Research are data processors.

Data handling and confidentiality

The legal basis for processing your personal data under GDPR on this occasion is Article 6(1) (e) (research purposes in the public interest).

- We will ensure anonymity by giving you an ID number if you take part. We will put that ID number and your date of birth in the questionnaires and any saliva or hair samples we collect.
- Your identifiable data (e.g. name, telephone number, address) will only be shared within the research team at KCL, UCL and Breathe Arts Health Research and unless you give permission on the consent form for it to be held for us to contact you in the future, it will be destroyed following the end of the study.
- Your anonymous data will only be used for medical and scientific research. The researchers analysing the data will not be able to identify you.
- We will retain the anonymous data for 10 years after publication.
- The saliva and hair samples will be held at the Maurice Wohl Clinical Neuroscience Institute, part of King's College London. Only the research team will have access to the data. The samples will only be used for medical and scientific research and may be used for future ethically approved studies. The researchers analysing the data will not be able to identify you from the samples you provide.
- All data will be held and processed in compliance with UK data protection standards (GDPR).

Where can you find out more about how your information is used?

You can find out more about how we use your information:

- at www.hra.nhs.uk/information-about-patients/
- or www.hra.nhs.uk/patientdataandresearch

- to find out more about how the university deals with your personal information, including your rights and who to contact if you have a concern, please see the university's core privacy notice at https://www.kcl.ac.uk/terms/privacy.aspx.
- by asking one of the research team members
- by sending an email to shaperpnd@kcl.ac.uk or by ringing us on xxxxxxx.

How is the project being funded?

This study is being funded by the Wellcome Trust, a UK-based research charity.

What will happen to the results of the study?

The results of the study will be summarised in papers to be published in scientific journals and presented at conferences or in newsletters. You will never be identified in such publications.

Who should I contact for further information?

If you have any questions or require more information about this study, please contact us using the following contact details:

SHAPER-PND (Carolina Estevao – Trial Manager)
Stress, Psychiatry and Immunology Lab, Institute of Psychiatry, Psychology and Neuroscience, King's College London
The Maurice Wohl Clinical Neuroscience Institute, Cutcombe Road, London, SE5 9RX
E-mail: shaperpnd@kcl.ac.uk
Direct line: 020 xxxx xxxx

This research study meets regulatory and governance requirements and has obtained all the legal approvals.

What if something goes wrong?

If you believe this study has harmed you in any way or if you wish to make a complaint about the conduct of the study you can get in touch with the research team. You can also contact Dr Gill Dale, the Director of Research Quality at the Joint SLaM NHS FT/IoPPN Research & Development Office, via e-mail: gill.dale@kcl.ac.uk.

Statement about insurance cover

In the event that something does go wrong and you are harmed during the research you may have grounds for legal action for compensation against King's College London and/or SLaM NHS Foundation Trust, but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate). King's College London has obtained insurance which provides no-fault compensation i.e. for non-negligent harm, you may be entitled to make a claim for this.

Thank you for reading this information sheet and for considering taking part in this research.