



Participant Information Sheet for mothers

Mamas in Harmony Research Pilot Study

Summary

We would like to invite you and your baby to take part in our research study. This study is being carried out as part of a PhD by a team of researchers at the School of Nursing and Midwifery, Queen's University Belfast. Before you decide if you would like to take part, it is important that you understand why the research is being done and what it would involve for you and your baby.

Please take time to read this information and discuss it with others if you wish. If there is anything that is not clear, or if you would like more information, please ask us.

What is the purpose of this study?

We want to try out a new group music class called Mamas in Harmony with new mums and babies. We want to find out if the classes might help mums and babies bond, give support to mums and help with their wellbeing. We're looking for mums who have a baby that is 4 months of age or under.

This study is referred to as a feasibility study, which means we want to explore how we can best plan and carry out a pilot randomised controlled trial (RCT) which means all mothers who give their consent to taking part, will be randomly allocated either to a group that attends Mamas in Harmony sessions or a group that continues as normal and does not receive sessions as a comparison group. This means you have equal chance of either being invited to attend Mamas in Harmony or not attending. However, all participants regardless of allocation are providing a valuable contribution to the study and will be involved in the research.

If allocated to attending the Mamas in Harmony sessions, mums are invited to attend weekly group sessions with their baby to enjoy music followed by informal social support while enjoying tea/coffee and biscuits over a period of 8 weeks. This would be for 1 hour each week and is held at Queen's University Sport clubhouse at Malone Playing Fields in Belfast.



If you are allocated to the comparison group that does not receive the music classes, we will offer you the opportunity to attend one session with your baby and experience the music class at the end of the study. This is to say thank you for participating in the study.

All mothers regardless of receiving the group sessions or not will be invited to complete questionnaires including those about their mood, stress levels and confidence when parenting. All mothers contributions will be important to the research because we want to find out whether the Mamas in Harmony sessions are helpful.

Why have I been invited to take part?

You have been invited to take part in the study as you are a mother of a baby 4 months old or under and we believe you can make a useful contribution to our research. We are looking for a total of 60 mothers and their babies to take part.

What should I consider?

We are looking for mums who are 16 years of age or over. If you are under 16, we can't invite you to take part in the study. This is because the law states people under the age of 16 are required to have the consent from a parent or guardian to take part.

We are looking for mums who have not given birth in the last 14 days.

We are looking for mums who have a satisfactory understanding and comprehension of English to be able to read this participant information sheet and our consent form.

We are looking for mums who have not had an episode of severe mental illness or been treated for one in the past 6 months, for example, Bipolar disorder, Psychoses or Schizophrenia. This is because Mamas in Harmony has not been designed for people with recent severe mental illness and so we don't know whether or not it might do them harm.

Do I have to take part?

No, you do not have to take part. Taking part is entirely voluntary. If you decide to take part, you can withdraw at any point without giving a reason. The data provided until the point of withdrawal will be kept and used for analysis.

What will happen if I decide to take part?

If you decide to take part, you will be asked to sign a consent form and if you are allocated to attend Mamas in Harmony sessions, this will involve attending a 1 hour Mamas in Harmony session on a Tuesday morning for 8 weeks. The sessions will be led by a local professional choir leader and the PhD student, Corinna, from Queen's University Belfast (QUB). Sessions would take place at Queen's Sport Upper Malone, 2D Upper Malone Road, Belfast, BT9 5NA which can be easily accessed via local transport (route 8b bus), on



foot/bike or by car. There is convenient parking, pram storage and baby changing facilities for you and your baby.

Regardless of whether or not you are allocated to receive Mamas in Harmony sessions, you will be asked to complete questionnaires on 3 occasions over a 6 month period, these will be provided online or in paper format, whichever you prefer. These will take approximately 25 minutes to complete. Questions you will be asked include: over the last 2 weeks, how often have you been bothered by feeling nervous, anxious or on edge? In the last month how often have you felt confident about your ability to handle your personal problems?

What are the possible disadvantages of taking part in the study?

If you are allocated to the group who attends the Mamas in Harmony sessions, you may feel a disadvantage is using your time to attend and the time it takes to complete the questionnaires. If you are in the comparison group who do not attend the Mamas in Harmony sessions, you may feel a disadvantage is using your time to complete the questionnaires and you don't get to attend the sessions.

There are no direct benefits of taking part in the study. However, if you are allocated to the group who attends the Mamas in Harmony sessions, you may find it enjoyable to attend the sessions with your baby and have the opportunity to meet other mothers and their babies.

We do not think there are any risks for anyone who chooses to take part in this study. However, if you feel any distress at any time during the study and you choose to disclose this information with the research team, we will contact you to provide information on where you can get support. We may also ask for your consent to contact your health visitor and/or GP to share these concerns.

Will I be reimbursed for taking part?

All mothers will receive a £15 Amazon gift card at the end of the study to thank them for their time spent in the study.

Will my taking part in this study be kept confidential?

Only the research team will have access to the information mothers provide us with, however if you attend Mamas in Harmony sessions, all information shared within group discussions will be treated confidentially.

Confidentiality on behalf of the researcher will only be broken if there is a disclosure that indicates that you or someone you mention is at risk of causing harm or being harmed. The researcher is legally obliged to pass on this information in accordance with professional guidelines.



All data will be treated in accordance with General Data Protection Regulation and should comply with data protection legislation.

How will we use information about you?

We will need to use information from you for this research project.

This information will include your name, contact details, marital/civil partnership status, who lives in your household, your ethnic group, your educational attainment and household income. People will use this information to do the research or to check your records 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.

We will keep all information about you safe and secure.

We will write our reports in a way that no-one can work out that you took part in the study.

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 won't be able to let you see or change the data we hold about you.

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

You can find out more about how we use your information

- at <https://www.qub.ac.uk/privacynotice/>
- by asking one of the research team
- by sending an email to info.compliance@qub.ac.uk, or
- by ringing us on 028 9097 2505

Who is responsible for carrying out the study?

The research team consists of researchers at the School of Nursing and Midwifery, QUB and a local professional choir leader.

Who has reviewed this study?

All research in Queen's University Belfast is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed by the Medicine, Health and Life Sciences Faculty Ethics Committee at QUB.



What if I want more information or have concerns about the study?

Given the nature of the study, we think there is very little chance of harm occurring by taking part in this research and we will make every effort to ensure that you are supported and respected as a participant. In the unlikely event that you suffer any harm as a direct consequence of your participation. If you have a concern about any aspect of this study, you can contact the Chief Investigator, Dr Fiona Lynn at: f.lynn@qub.ac.uk or School of Nursing and Midwifery, Queen's University Belfast, 97 Lisburn Road, Belfast, BT9 7BL.

If you remain unhappy and wish to make a formal complaint, you may do so by contacting the Research Governance Team at QUB on 028 9097 2529; email: researchgovernance@qub.ac.uk, who are independent from the research team.

What do I have to do if I want to take part in the study?

If you are interested in taking part, please visit <https://go.qub.ac.uk/mamasinharmony> where there is an online contact form and once completed, a member of the research team will contact you to answer any questions you might have about the study and ask if you would like to take part.

Project Team

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If you would like to request more information, please contact:

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