

# Sing to Your Bump

|  |   |  |
|--|---|--|
| <b>Submission date</b><br>09/06/2016   | <b>Recruitment status</b><br>Stopped                          | <input checked="" type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol            |
| <b>Registration date</b><br>15/06/2016 | <b>Overall study status</b><br>Stopped                        | <input type="checkbox"/> Statistical analysis plan<br><input type="checkbox"/> Results                       |
| <b>Last Edited</b><br>01/09/2017       | <b>Condition category</b><br>Mental and Behavioural Disorders | <input type="checkbox"/> Individual participant data<br><input type="checkbox"/> Record updated in last year |

## Plain English summary of protocol

### Background and study aims

Many women can experience feelings of depression (low mood) and anxiety during pregnancy. Many studies have shown that music can help improve the mental state of people suffering from anxiety and depression. It is widely available, inexpensive and doesn't carry the same stigma (negative associations) as other types of therapy. This study will be investigating how listening to specially composed songs, or taking part in a guided singing group might help reduce anxiety and depression in pregnant women, as well as have a beneficial effects on the behaviour and cognitive development of their babies. The aim of this study is to find out whether this musical engagement is effective at relieving anxiety and depression in pregnancy and to find out whether active (singing) engagement is more effective than passive (listening) engagement.

### Who can participate?

Pregnant women aged 18-45 who are suffering from mild to moderate depression and anxiety.

### What does the study involve?

Participants are randomly allocated to one of three groups. Those in the listening group listen to songs for 20 minutes a day while sitting down at home starting. This intervention starts at 20 weeks into pregnancy to six weeks after giving birth. Those in the singing group take part in a weekly 90-minute guided singing group starting at 20 weeks pregnant to six weeks after giving birth. At the singing group, the women will sing the same songs as those used in the listening group. Those in the standard care group receive standard care. These participants are able to take part in the singing group after the end of the study. At the start of the study (when they are 20 weeks pregnant) and then 1, 3 and 6 months after they have had their baby, women in all groups complete a number of questionnaires about their depression, anxiety and stress levels. The bonding between mother and child is also assessed at these times as well as the child's development when they are six months old.

### What are the possible benefits and risks of participating?

Participants may benefit from reduced anxiety and depression and feelings greater social support. There is also the benefit of being involved in research that could have an impact on antenatal mental health care in the future. It is possible that some of the participants may become distressed when answering some personal questions or completing the self-report

questionnaires. It is also possible that listening and singing the songs may evoke strong emotions and it is possible, but unlikely, that these strong emotions could cause them some psychological distress.

Where is the study run from?  
Highgate Mental Health Centre (UK)

When is the study starting and how long is it expected to run for?  
January 2016 to November 2019

Who is funding the study?  
Goldsmiths, University of London (UK)

Who is the main contact?  
Ms Katie Rose Sanfilippo  
ksanf001@gold.ac.uk

**Study website**  
[www.singtoyourbump.com](http://www.singtoyourbump.com)

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Ms Katie Rose Sanfilippo

**Contact details**  
Goldsmiths, University of London  
New Cross  
London  
United Kingdom  
SE14 6NW  
+44 7570 553177  
ksanf001@gold.ac.uk

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
STYB

## Study information

**Scientific Title**

Sing to Your Bump: Music for well-being in pregnancy

**Study objectives**

1. Musical engagement during pregnancy will decrease anxiety and depression in pregnant women suffering from these conditions antenatally as compared to standard care
2. Active engagement in music (singing group) will have a stronger positive effect on mental well-being than passive musical engagement (listening)

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Not provided at time of registration

**Study design**

Single-centre three-arm randomised controlled trial

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Community

**Study type(s)**

Quality of life

**Participant information sheet**

Not available in web format, please use the contact details below to request a patient information sheet.

**Health condition(s) or problem(s) studied**

Mild to moderate anxiety and depression during pregnancy.

**Interventions**

Interventions as of 25/07/2016:

Participants will be randomly assigned following simple randomization procedures to 1 of 3 treatment groups. Randomization sequence will be created using R-studio with a 1:1:1 allocation.

Listening group: Mothers will listen to songs at home. The songs are specifically composed for the purpose of being used for pregnant women. They will be asked to listen to the songs 20 minutes a day while sitting down. This intervention will start between 16-20 weeks gestation and end 6 months after birth.

Singing group: Mothers will be asked to attend a 90 minute guided singing group once a week. In the singing group the women will sing together the same songs that are used in the listening group. The intervention will start between 16-20 weeks gestation and continue after birth for 6 months.

Control group: Mothers will be treated with standard care, without any intervention. However, this group will be invited to participate in the singing group 6 months after birth.

Participants in all groups are followed up 1, 3 and 6 months post-natal.

Original interventions:

Participants will be randomly assigned following simple randomization procedures to 1 of 3 treatment groups. Randomization sequence will be created using R-studio with a 1:1:1 allocation.

Listening group: Mothers will only listen to the lullabies at home, rather than participate in the singing group. The lullabies are specifically composed by Jennie Muskett for the purpose of being used for pregnant women. They will be asked to listen to the lullabies for 90 minutes a week. This intervention will start at 30 weeks gestation and end 6 months after birth.

Singing group: Mothers will be asked to attend a 90 minute singing group once a week. In the singing group, run by Jennie Muskett in her home in Highgate, the women will sing together the same lullabies that are used in the listening condition as well as work on composing their own lullabies under the direction of Jennie Muskett. The intervention will start at 30 weeks gestation and continue after birth for 6 months.

Control group: Mothers will be treated with standard care, without any intervention. However, this group will be invited to participate in the singing group 6 months after birth.

Participants in all groups are followed up 1, 3 and 6 months post-natal.

## **Intervention Type**

Behavioural

## **Primary outcome measure**

Primary outcome as of 25/07/2016:

Depression is measured using the The Edinburgh Postnatal Depression Scale (EPDS) at baseline (16-24 weeks gestation), 26 weeks gestation, 32 weeks gestation, and 1, 3 and 6 months postnatal.

Original primary outcomes:

1. Depression is measured using the The Edinburgh Postnatal Depression Scale (EPDS) 30 weeks antenatal and 1,3 and 6 months postnatal
2. Anxiety is measured using the Peer Relations Assessment Questionnaires-Revised (PRAQ-R) and The State-Trait Anxiety Inventory (STAI) 30 weeks antenatal and 1,3 and 6 months postnatal
3. Stress is measured using Parenting Stress Index (PSI-4-SF) 30 weeks antenatal and 1,3 and 6 months postnatal
4. Mother Infant bonding is measured using Maternal Antenatal Attachment Scale at 30 weeks antenatal and The Mother-Infant Bonding Scale (MIBS) 1, 3 and 6 months post-natal

## **Secondary outcome measures**

Secondary outcomes as of 25/07/2016:

1. Anxiety is measured using the Pregnancy Related Anxiety Questionnaire -Revised (PRAQ-R2) and The State-Trait Anxiety Inventory (STAI) at baseline (16-24 weeks gestation), 26 weeks gestation, 32 weeks gestation and STAI only 1, 3 and 6 months postnatal
2. Stress is measured using Perceived Stress Scale (PSS) at baseline (16-24 weeks gestation), 26 weeks gestation, 32 weeks gestation, and 1, 3 and 6 months postnatal

3. Mother Infant bonding is measured using Maternal Antenatal Attachment Scale at baseline (16-24 weeks gestation), 26 weeks gestation, 32 weeks gestation and Maternal Postnatal Attachment scale (MPAS) and The Mother-Infant Bonding Scale (MIBS) 1, 3 and 6 months postnatal
4. Social support is measured using the Multidimensional Scale of Perceived Social Support (MSPSS) at baseline (16-24 weeks gestation), 26 weeks gestation, 32 weeks gestation and STAI only 1, 3 and 6 months postnatal
4. Infant cognitive and behavioral development is measured using the Infant Behaviour Questionnaire revised (IBQ-R), Bayley Scales of Infant and Toddler Development and the Still Face Procedure at 6 months postnatal
5. Mother's Cortisol and Cytokine levels are measured using saliva samples measured at baseline (16-24 weeks gestation), 32 weeks gestation, and 1 and 6 months postnatal

Original secondary outcomes:

1. Infant cognitive and behavioral development is measured using the Bayley Scales and Still Face procedure measured at 6 months after birth
2. Mother's Cortisol and Cytokine levels are measured using a saliva samples measured monthly starting at 30 weeks antenatal, then months 1,3 and 6 postnatal

**Overall study start date**

11/01/2016

**Completion date**

06/11/2019

**Reason abandoned (if study stopped)**

Objectives no longer viable

## Eligibility

**Key inclusion criteria**

1. Fluent in English
2. 18-45 years old
3. Singleton pregnancy
4. Mild to moderate depression and anxiety

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Upper age limit**

45 Years

**Sex**

Female

**Target number of participants**

210

**Key exclusion criteria**

1. Serious medical disorder, psychosis, bipolar disorder or drug abuse
2. Severe depression or anxiety

**Date of first enrolment**

01/10/2016

**Date of final enrolment**

01/03/2017

**Locations****Countries of recruitment**

England

United Kingdom

**Study participating centre****Highgate Mental Health Centre**

Dartmouth Park Hill

London

United Kingdom

N19 5NX

**Sponsor information****Organisation**

Goldsmiths, University of London

**Sponsor details**

New Cross

London

England

United Kingdom

SE14 6NW

**Sponsor type**

University/education

**ROR**

<https://ror.org/01khx4a30>

# **Funder(s)**

## **Funder type**

University/education

## **Funder Name**

Goldsmiths, University of London

# **Results and Publications**

## **Publication and dissemination plan**

Planned publication in a peer review journal as well as presentations at academic conferences.

## **Intention to publish date**

31/10/2019

## **Individual participant data (IPD) sharing plan**

## **IPD sharing plan summary**

Available on request