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Sing to Your Bump

Submission date	Recruitment status	[X] Prospectively registered
09/06/2016	Stopped	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
15/06/2016	Stopped	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
01/09/2017	Mental and Behavioural Disorders	[ ] 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

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