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Maternal moments

Submission date	Recruitment status	[X] Prospectively registered
16/05/2017	Stopped	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
25/05/2017	Stopped	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
15/04/2019	Mental and Behavioural Disorders	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims:
It has been found that antenatal (during pregnancy) anxiety and depression affects 10% of mothers and has potential long-term consequences for their future child. This means that there is a real to find methods that are widely available, inexpensive and non-stigmatizing (labeling) that can be used easily by women to help cope with anxiety and depression during pregnancy. Music is an activity which uses different senses and has been shown to help with anxiety and depression in many different groups of people. A previous small study found that listening to the same specifically composed songs, for just 20 minutes a day, reduced anxiety and depression in a community-recruited sample. The current study builds upon this study through the recruitment of women diagnosed with depression and or anxiety as a way to investigate on a larger scale this as a possible treatment option. By recruiting women from Whittington Hospital who are suffering from anxiety and depression, this study aims to investigate, using questionnaires and biological samples, the effect music listening, compared to the treatment the women receive as usual, has on maternal wellbeing during pregnancy and after giving birth.

Who can participate?
Pregnant women aged 18-45 who have a computer or smart phone

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group continue to receive standard care for the duration of the study. Those in the second group listen to especially composed songs for pregnancy in their own home while sitting down for 20 minutes a day, from when they are 16-24 weeks pregnant until after they have had their baby. All participants fill in online questionnaires three times during pregnancy and three times after they have had their baby to assess anxiety and depression levels. Samples of saliva are also collected to look for chemical indicators of stress and when the babies are six months old, mothers are observed interacting with their baby to assess the bond between them.

What are the possible benefits and risks of participating?
The study has a few direct benefits. After the study is over (6 months after birth) all participates will receive a copy of the music. If they chose to participate in the mother-infant follow up at 6 months they will receive a 10-pound voucher for their time and reimbursement for travel cost via public transportation, Uber or taxi to and from the hospital. There are no disadvantages or risks in taking part in this study, either to the mother or her baby.

Where is the study run from?
Whittington Hospital (UK)

When is study starting and how long is it expected to run for?
November 2016 to June 2020

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

Who is the main contact?
Ms Katie Rose Sanfilippo
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
V0.2

Study information

Scientific Title
Maternal Moments: Investigating music listening for well-being in pregnancy

Study objectives
Participants in the music group will exhibit a greater reduction in antenatal depression, anxiety, and stress compared with treatment as usual.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NHS Health Research Authority: London- Camden and Kings Cross, 21/03/2017ref: 17/LO/0118

Study design
Longitudinal two-arm randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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
Antenatal anxiety and depression

Interventions
Participants will be randomly assigned following simple randomization procedures to 1 of 2 conditions. The randomization sequence will be created using R-studio with a 1:1 allocation.

Control condition: Mothers will be treated with standard care, without any additional intervention. This includes the care that is provided to the women by Dr Lucinda Donaldson and Dr Amelie Bobsien.

Treatment condition (music group): Mothers will listen to specially composed songs for pregnancy in their own home. They will be asked to listen to the songs while sitting down for 20 minutes a day. This intervention will start at 16-24 weeks gestation and end after birth.

All participants will fill in online questionnaires in their own home. They will fill in 3 during pregnancy (one around 20 weeks, one around 26 weeks, and one around 32 weeks) and 3 after they have given birth (one at 1-month post birth, one 3 months post birth and one 6 months post birth). Each questionnaire will take no more than 30 minutes in total and will be completed online at home.

Saliva samples will also be collected. They will be collected at 3 different times (one around 20 weeks, one around 30 weeks, and finally one 6 months post birth). This should take about 5 minutes to do in total.

When the women's baby is approximately 6 months of age they will be invited back to complete two tasks with their baby. For the first task, the still face procedure, a saliva sample from the baby, which is a completely non-invasive procedure, will be taken before and after the procedure. This first task takes about 30 minutes in total. For the second task, Bayley's III, the mother and her baby will be observed while interacting normally as well complete a few tasks. This task will take around two hours.

Intervention Type
Behavioural

Primary outcome measure
1. Depression is assessed using the Edinburgh Postnatal Depression Scale (EPDS) at 20 , 26 and 32 weeks, and 1, 3 and 6 months postnatal
2. Anxiety is assessed using the Spielberger State and Trait Anxiety (STAI) at 20 , 26 and 32 weeks, and 1, 3 and 6 months postnatal and the Pregnancy-Related Anxiety Questionnaire Revised (PRAQ-R2) at 20, 26 and 32 weeks
3. Stress is assessed using the Perceived Stress Scale (PSS) at 20 , 26 and 32 weeks, and 1, 3 and 6 months postnatal

Secondary outcome measures
1. Mother-infant attachment is assessed using the Mother Infant Bonding Scale (MIBS) at 1 and 3 months postnatal, the Maternal Antenatal Attachment Scale (MAAS) at 20, 26 and 32 weeks and the Maternal Postnatal Attachment Scale (MPAS) at 1, 3 and 6 months postnatal
2. Infant cognitive and behavioural development is assessed using the Infant Behaviour Questionnaire revised (IBQ-R) and the Bayley Scales of Infant and Toddler Development (Bayley III) at when the child is 6 months old
3. Biological changes in cortisol and various cytokines are measured using saliva samples at 0 weeks, 32 weeks and 6 months postnatal

Overall study start date
20/11/2016

Completion date
12/06/2020

Reason abandoned (if study stopped)
Participant recruitment issue

Eligibility

Key inclusion criteria
Mother inclusion criteria:
1. Have a computer or a smart phone at home
2. Referred by the clinical team
3. Fluent in English
4. Aged 18-45 years old
5. Singleton birth

Infant inclusion criteria:
1. Born after 37 weeks

2. Age 6 months
3. No major disability or medical disorder

Participant type(s)
Patient

Age group
Mixed

Lower age limit
18 Years

Upper age limit
45 Years

Sex
Female

Target number of participants
150

Key exclusion criteria
Mother exclusion criteria:
1. Not enough time to dedicate to the study
2. Serious medical disorder, psychosis, bipolar disorder or drug abuse
3. If the baby is born before 37 weeks, is still born, or the mother has a miscarriage the mother will not be included in the study will be discontinued

Infant exclusion criteria:
1. Any medical disorder or major disability
2. Born before 37 weeks

Date of first enrolment
12/06/2017

Date of final enrolment
01/01/2020

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Whittington Hospital
Magdala Avenue
London

United Kingdom
N19 5NF

Study participating centre
Queen Charlotte's and Chelsea Hospital
Du Cane Road
London
United Kingdom
W12 0HS

Sponsor information

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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
Plan to publish the results in academic/practioner-based journals and to present the findings at conferences and meetings so that other's can learn from the research. This will be done within one year of the end of the trial.

Intention to publish date
12/06/2021

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Katie Rose Sanfilippo (ksanf001@gold.ac.uk)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No