Boosting baby communication and play

Submission date	Recruitment status No longer recruiting	[X] Prospectively registered		
10/09/2021		[X] Protocol		
Registration date	Overall study status	Statistical analysis plan		
13/09/2021	Completed	[X] Results		
Last Edited	Condition category	Individual participant data		
07/03/2024	Mental and Behavioural Disorders			

Plain English summary of protocol

Background and study aims

When a new mother experiences mental illness, this can have negative effects not just on herself, but also on her relationship with her child and on her child's future development and mental health. The NHS Long-Term plan states that increasing access to interventions to improve parent-infant relationships should be a priority. However, we have very little evidence on what parent-infant interventions actually work when implemented in real-world NHS services. Our team has recently evaluated the video feedback for positive parenting intervention (VIPP) in perinatal mental health services for women experiencing mental illness in the first year of their child's life. Mothers are videoed interacting with their babies, and given positive and non-judgemental feedback. We found potential benefits for mothers and children receiving VIPP, in how confident mothers felt and how they interacted with their children.

However, VIPP is currently designed for infants aged above 6 months. To help more women using perinatal mental health services, we have now adapted VIPP for younger babies and have also added tips on what strategies parents can use to feel calmer if they are feeling stressed while interacting with their child.

We now need to pilot the modified intervention with Mums using perinatal mental health services, to check it is feasible for clinicians to deliver, and to gain Mums' and clinicians' feedback. We will train clinicians in perinatal mental health services to deliver the modified intervention. We will evaluate how well perinatal mental health staff are able to deliver the intervention; mothers' attendance and feedback; changes in mothers' responses to their babies' communication, parenting-related stress, parental self-confidence and bond with their baby. We will assess these using questionnaires and videos of the mothers playing with their babies, as well as by carrying out feedback interviews with mothers and clinicians.

Who can participate?

Mothers currently under the care of a perinatal mental health service who have a child aged 2 months 0 days to 3 months 31 days old.

What does the study involve?

Step 1. We will ask mothers about their current and past mental health, their feelings about being a Mum, and their baby's development. We will film short clips of Mum and baby playing together.

Step 2. Mothers will then be offered six sessions of the video feedback intervention for positive parenting. The clinician will make film clips of Mum and baby playing together and then you will

watch them back with the clinician so that you can talk together about what your baby's behaviour means, their bond with you and what he/she is communicating.

Step 3. We will check in with the mothers again, to find out how they are doing in terms of their mental health, their feelings about being a Mum, and their baby's development. We will again film short clips of Mum and baby playing together. We will also ask mothers to give us feedback about their experiences of the intervention.

What are the possible benefits and risks of participating?

We are in the early stages of this research and therefore we cannot say with certainty that taking part will be of benefit. However, the Baby Communication and Play sessions have been used in research studies previously and parents have found them helpful. Afterwards, mothers will be able to download their own copy of the clips of baby and themselves playing together. The disadvantages of taking part are likely to be small. Mothers will need to put some time aside for the video feedback visits. Some people can find it embarrassing to watch clips of themselves and can start to feel self-conscious, judge themselves or worry that others will judge them. The professionals conducting the visits are specially trained to be aware of this and to help participants deal with these feelings.

Where is the study run from? City University of London (UK).

When is the study starting and how long it is expected to run for? April 2021 to May 2022.

Who is funding the study?

The study is funded by City University of London and Central & North West London NHS Foundation Trust (UK).

Who is the main contact?

The main contact is Kirsten Barnicot at City University of London.

Contact information

Type(s)

Scientific

Contact name

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Type(s)

Public

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

289896

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

IRAS 289896

Study information

Scientific Title

Video feedback for positive parenting in perinatal mental health services: Developing and piloting an optimised protocol

Acronym

BOOST-2

Study objectives

To evaluate the feasibility and acceptability of the adapted Video feedback intervention for Positive Parenting (VIPP), for mothers using perinatal mental health services and their 2 to 6 month old infants.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 29/06/2021, East of England - Cambridge South Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; no telephone number provided; cambridgesouth.rec@hra.nhs.uk), ref: 21/EE/0139

Study design

Multi-centre interventional feasibility case series

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Community

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Mothers experiencing moderate to severe perinatal mental health difficulties

Interventions

Video feedback intervention for positive parenting. A 7 session intervention in which mothers and their child are filmed playing together and given positive feedback on the interaction from the child's perspective, with the aim of enhancing maternal sensitivity and parent-child relationships. The intervention sessions are scheduled every 2 weeks and the intervention thus lasts on average 3 months. Research follow-up will be at 5 months post-baseline.

This is an uncontrolled case series; there is no control/ comparator intervention.

Intervention Type

Behavioural

Primary outcome measure

Percentage of mothers initiating and completing the VIPP intervention measured using patient records at the end of the study

Secondary outcome measures

- 1. Percentage of mothers invited to participate who give informed consent to do so measured using patient records at the end of the study
- 2. Mother and clinician ratings of the therapeutic alliance measured using the Helping Alliance Scale during VIPP at month 5 post-baseline
- 3. Participants' own accounts of their experiences of the feasibility and acceptability of the intervention, assessed using qualitative interviews at month 5 post-baseline
- 4. Parental Stress Scale at month 5 post-baseline
- 5. Parent Expectations Survey at month 5 post-baseline
- 6. Mother Object Relations Scale Short Form (MORS-SF) at month 5 post-baseline

- 7. Parental sensitivity measured using the Parent Infant Interaction Observation Scale at month 5 post-baseline
- 8. Difficulties in Emotion Regulation Scale at month 5 post-baseline

Overall study start date

01/04/2021

Completion date

30/05/2022

Eligibility

Key inclusion criteria

- 1. Are using community perinatal mental health services
- 2. Are a primary caregiver of a child aged 2 to 3 months
- 3. Are capable of giving informed consent
- 4. Are aged 16 to 65 years

Participant type(s)

Patient

Age group

Adult

Sex

Female

Target number of participants

10

Key exclusion criteria

- 1. Families where a sibling or co-parent is participating in the trial
- 2. Families in which the eligible child has a clinical diagnosis of a learning difficulty, developmental disorder or sensory impairment.
- 3. Families in which the eligible parent has English language or learning difficulties that are sufficiently severe to prevent them completing study measures even with assistance.

Date of first enrolment

13/09/2021

Date of final enrolment

30/11/2021

Locations

Countries of recruitment

England

United Kingdom

Study participating centre Central and North West London NHS Foundation Trust

350 Euston Road Regent's Place London United Kingdom NW1 3AX

Study participating centre East London NHS Foundation Trust

9 Allie Street London United Kingdom E1 8DE

Study participating centre Oxleas NHS Foundation Trust

Pinewood House Pinewood Place Dartford United Kingdom DA2 7WG

Sponsor information

Organisation

City, University of London

Sponsor details

Northampton Square London England United Kingdom EC1V 0HB +44 (0)20 7040 5060 Anna.Ramberg.1@city.ac.uk

Sponsor type

University/education

Website

http://www.city.ac.uk

ROR

https://ror.org/04489at23

Funder(s)

Funder type

Charity

Funder Name

Barts Charity

Alternative Name(s)

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

United Kingdom

Funder Name

Central and North West London NHS Foundation Trust

Results and Publications

Publication and dissemination plan

We will publish the study in a peer-reviewed journal and disseminate the findings at conferences.

Intention to publish date

31/05/2022

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request. k.barnicot@imperial.ac.uk

IPD sharing plan summary

Available on request

Study outputs

Output type Details Date created Date added Peer reviewed? Patient-facing?

Protocol file	22/06/2021	13/09/2021	No	No
HRA research summary		28/06/2023	No	No
Results article	05/03/2024	07/03/2024	Yes	No