

# Boosting baby behaviour and bonding for parents with enduring difficulties in managing emotions and relationships

<b>Submission date</b> 20/11/2017	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 21/11/2017	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 20/12/2023	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

For mothers, the early years of their child's life can be a wonderful time but also bring with them lots of challenges and emotional ups and downs, particularly for mothers who are experiencing mental health difficulties. Research suggests that parents who are experiencing enduring difficulties in managing their emotions and relationships with others may find this particularly problematic and complicated. These types of mental health difficulties are sometimes known as complex emotional needs or personality disorder. Parents with these experiences can sometimes feel negative about themselves as parents and their relationship with their child and can struggle to feel confident and competent. Existing research on this topic has been predominantly negative in focus, emphasising the challenges that parents can face in attuning to and responding to their child's communication, and highlighting the increased risk their children may face in developing their own emotional and social skills. However, no high-quality research to date has sought to address the strengths and capacity for positive growth that can be characteristic of this group of parents, nor to evaluate the potential of supportive parent-infant interventions for helping parents and children. Research with other families facing social or emotional challenges has shown a brief six-session video-feedback intervention can help parents tune in and respond positively to their child's communication, and can reduce the risk of children developing emotional or behavioural difficulties in the future. The present research will therefore establish whether parents with enduring difficulties in managing emotions and relationships consent to and complete this video feedback intervention, how they think it could be improved, and whether it is feasible to test it in a larger trial in the future. The researchers will first pilot the intervention in eight parents, then randomly assign 20 parents to receive video feedback in addition to their usual treatment, and 20 to receive usual treatment alone. They will interview the parents about their experiences of the intervention and the research, and use their feedback to decide how to adapt the intervention and whether to test it in a larger trial in the future.

### Who can participate?

Adults aged 16 to 35 who are a primary caregiver of a child aged 6-36 months old who have experienced enduring difficulties in managing emotions and relationships, consistent with personality disorders.

### What does the study involve?

In Phase 1 of the study, all participants receive six Baby Behaviour and Bonding sessions and the researchers give participants some questionnaires before and afterwards, and ask for participant's feedback, in order to improve the way the Baby Behaviour and Bonding sessions and the research is done. In Phase 2 of the study, participants are randomly allocated to one of two groups. Those in the first group receive six Baby Behaviour and Bonding sessions. Those in the second group receive a Baby Behaviour and Bonding Information booklet. The researchers give participants some questionnaires before and afterwards, and ask for participant's feedback, in order to improve the way the Baby Behaviour and Bonding sessions, the Baby Behaviour and Bonding Information booklet.

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

The research is at an early stage and therefore it cannot be said with certainty that taking part will be of benefit. However, the information given to participants and the Baby Behaviour sessions have been used in research studies previously and parents have found it helpful. The disadvantages of taking part are likely to be small. If a participant is allocated to receive the Baby Behaviour sessions they would need to put some time aside for these appointments. Some people can find it embarrassing to watch clips of themselves and can start to feel self-critical or worry that others will judge them. The health 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?

This study is being run by the Centre for Psychiatry, Central and North West London NHS Foundation Trust and takes place in Mental Health Services in the greater London area.

### When is the study starting and how long is it expected to run for?

June 2017 to May 2020

### Who is funding the study?

National Institute for Health Research (UK)

### Who is the main contact?

Dr Kirsten Barnicot

Kirsten.Barnicot@city.ac.uk

## Contact information

### Type(s)

Public

### Contact name

Dr Kirsten Barnicot

### Contact details

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**Type(s)**

Scientific

**Contact name**

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## Additional identifiers

**EudraCT/CTIS number**

Nil known

**IRAS number****ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

CPMS 34179

## Study information

**Scientific Title**

Boosting Baby Behaviour and Bonding: A feasibility trial of video feedback versus treatment as usual to reduce the risk of behaviour problems in the children of parents with enduring difficulties in managing their emotions and relationships, consistent with a personality disorder

**Acronym**

BOOST

**Study objectives**

The aim of this study is to evaluate the feasibility and acceptability of conducting a randomised controlled trial of the Video feedback intervention for Positive Parenting (ViPP) versus treatment as usual in parents experiencing difficulties in managing emotions and relationships consistent with a personality disorder and who are a primary caregiver of a child aged six-36 months.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

London - Camden & Kings Cross Research Ethics Committee, 22/05/2017, ref: 17/LO/0669

### **Study design**

Randomized; Interventional; Design type: Treatment, Prevention, Psychological & Behavioural

### **Primary study design**

Interventional

### **Secondary study design**

Randomised parallel trial

### **Study setting(s)**

Community

### **Study type(s)**

Treatment

### **Participant information sheet**

See study outputs table (Phase 2)

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

Difficulties in managing emotions and relationships, consistent with personality disorder

### **Interventions**

The first phase of the research (Phase 1) uses an uncontrolled pilot trial design in which the Baby Behaviour and Bonding (ViPP) intervention is piloted in eight parents with enduring difficulties in managing their emotions and behaviour, consistent with a personality disorder, and their feedback is used to modify intervention delivery in order to increase the feasibility and acceptability of the intervention.

Once 8 parents have received the intervention and their feedback has been gained and used to modify the protocol for intervention delivery, Phase 2 will commence.

Phase 2 of the research uses a parallel group randomised controlled feasibility trial design in an additional 40 parents with enduring difficulties in managing their emotions and behaviour, consistent with a personality disorder. 20 parents are allocated to receive the intervention (Baby Behaviour and Bonding (ViPP) sessions, Behaviour and Bonding Information and treatment as usual) and 20 are allocated to the control condition (Baby Behaviour and Bonding Information and treatment as usual). This allows establishment of objective indices of feasibility and acceptability for the intervention: the proportions consenting, completing the intervention, and completing the trial, and the acceptability and variance of the proposed outcome measures.

Intervention condition: Six 90 minute Baby Behaviour and Bonding sessions using the Video-feedback Intervention to promote Positive Parenting (ViPP), to be delivered approximately every two weeks over a three to five month period. ViPP is a manualised intervention which provides parenting feedback based on videoed interactions between parent and child. ViPP helps parents to recognise, understand and respond sensitively to their child's behaviour. Positive and non-judgemental feedback is used to focus on parents' strengths and help them feel confident in their parenting. Additional elements are incorporated into the training for clinicians delivering the intervention, to help them focus on building trust and addressing parents' concerns around feeling judged. Sessions are primarily delivered in participants' homes but clinicians and participants may request to hold the sessions in the clinic if this is more feasible. The therapists receive monthly supervision from a certified ViPP supervisor. Participants receiving the intervention also access treatment as usual from perinatal, adult mental health and/or social services during the trial. Some participants may disengage from services during the trial, and in order to meet the ethical requirement to provide support given the potential difficulties faced by themselves and their children, all participants receive the Baby Behaviour and Bonding information booklets developed by the NSPCC (Handle with care: A guide to keeping your baby safe. NSPCC, 2013; All babies count: Support for parents, NSPCC, 2013; Encouraging better behaviour: A practical guide to positive parenting. NSPCC, 2013.) These booklets contain practical advice on holding babies, coping with crying, dealing with difficult behaviour, looking after your own emotional health, and where to go for additional help.

Control condition: Control participants are allocated to receive treatment as usual from perinatal, adult mental health and/or social services including medication management, monitoring and psychological therapy as deemed appropriate by the clinician responsible for their care. For the ethical reasons stated above, all participants also receive the Baby Behaviour and Bonding information booklets developed by the NSPCC (Handle with care: A guide to keeping your baby safe. NSPCC, 2013; All babies count: Support for parents, NSPCC, 2013; Encouraging better behaviour: A practical guide to positive parenting. NSPCC, 2013.) These booklets contain practical advice on holding babies, coping with crying, dealing with difficult behaviour, looking after your own emotional health, and where to go for additional help.

Participants are followed up at five months and eight months after randomisation to assess the feasibility of the study.

## **Intervention Type**

Behavioural

## **Primary outcome measure**

Percentage of participants in the treatment arm receiving and completing the intervention, measured as attending  $\geq 4$  sessions, by the time of the 8 month post-randomisation follow-up.

## **Secondary outcome measures**

1. Percentage of potentially eligible participants consenting to be contacted by researchers, measured as the % of parents with a child aged 6 to 36 months who clinicians deem potentially eligible and give information about the research, who consent to be contacted by the researchers
2. Percentage of eligible participants consenting to participate, measured as the % of parents meeting the study inclusion criteria who consent to take part in the research
3. Percent completing the outcome measures at each follow-up, measured as the % of participants completing all outcome measures at the 5 month follow-up, and the % of participants completing all outcome measures at the 8 month follow-up

4. Pre-post effect sizes and confidence intervals on outcomes relating to child socioemotional health, parenting competencies and parental mental health for participants receiving ViPP versus participants receiving treatment as usual, assessed at the baseline, 5 month and 8 month follow-up using the Child Behaviour Checklist (for children aged  $\geq 12$  months only) , Brief Infant-Toddler Socio-emotional Assessment, Infant-Toddler Symptom Checklist, Parental Sense of Competence Scale, Parental Stress Scale, CORE, Emotional Availability Scale and Complex PTSD Scale

**Overall study start date**

01/06/2017

**Completion date**

31/05/2020

## Eligibility

**Key inclusion criteria**

1. Experience enduring difficulties in managing emotions and relationships, consistent with personality disorder
2. Primary caregiver of a child aged 6-36 months
3. Capable of giving informed consent
4. Aged 16 to 65 years

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

16 Years

**Upper age limit**

65 Years

**Sex**

Both

**Target number of participants**

Planned Sample Size: 48; UK Sample Size: 48

**Total final enrolment**

48

**Key exclusion criteria**

1. A sibling or co-parent is participating in the trial
2. The eligible child has a clinical diagnosis of a learning difficulty, developmental disorder or sensory impairment
3. 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**

01/06/2018

**Date of final enrolment**

31/07/2019

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre****Imperial College London**

Centre for Psychiatry

Central and North West London NHS Foundation Trust

7th Floor Commonwealth Building

Du Cane Road

London

United Kingdom

W12 0NN

**Study participating centre****Hillingdon Perinatal Mental Health Service**

Riverside Centre

Pied Heath Road

Uxbridge

London

United Kingdom

UB8 3NN

**Study participating centre****Northwick Park Hospital Antenatal Clinic**

Brent & Harrow Perinatal Mental Health Service

Watford Road

Harrow

London

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HA1 3UJ

**Study participating centre**

**Coombe Wood Unit**

Brent & Harrow Perinatal Mental Health Service  
Park Royal Mental Health  
Centre Acton Lane  
London  
United Kingdom  
NW10 7LF

**Study participating centre****Kensington, Chelsea & Westminster Perinatal Mental Health Service**

South Wharf Road  
London  
United Kingdom  
W2 1NY

**Study participating centre****Hackney Perinatal Mental Health Service**

Homerton Row  
London  
United Kingdom  
E9 6SR

## **Sponsor information**

**Organisation**

Central and North West London NHS Foundation Trust

**Sponsor details**

1st Floor Bloomsbury Building  
St Pancras Hospital  
4 St Pancras Way  
London  
England  
United Kingdom  
NW1 0PE

**Sponsor type**

Hospital/treatment centre

**ROR**

<https://ror.org/05drfg619>



# Funder(s)

## Funder type

Government

## Funder Name

National Institute for Health Research

## Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

## Funding Body Type

Government organisation

## Funding Body Subtype

National government

## Location

United Kingdom

# Results and Publications

## Publication and dissemination plan

Planned publication in a peer-reviewed journal.

## Intention to publish date

31/05/2021

## Individual participant data (IPD) sharing plan

The anonymised datasets generated during the current study will be available upon request from Kirsten Barnicot (Kirsten.Barnicot@city.ac.uk), providing the requesters outline an analysis and dissemination plan for their use of the data that the research team agree clearly meets NIHR quality criteria, namely:

1. A sound and appropriate research design
2. A strong likelihood that tangible benefits for NHS patients and other users of health and social care services will be realisable in the short to medium term
3. A team with the right mix of skills and experience for the research question
4. Evidence of relevance for a public or patient community

Additionally, the researchers will require individuals requesting the data to sign an agreement specifying exactly which individuals will have access to the data, and agreeing not to share the data with any further individuals. Individuals requesting the data will be asked to declare any conflicts of interest or intention to profit financially from their use of the data; requests involving a conflict of interest or financial profit will be denied.

## IPD sharing plan summary

Available on request

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		26/08/2022	09/09/2022	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Other publications</a>	Qualitative interview study	22/02/2023	20/12/2023	Yes	No