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

Submission date
20/11/2017

Recruitment status
No longer recruiting

Registration date
21/11/2017

Overall study status
Completed

Last Edited
20/12/2023

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
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Contact information

Type(s)
Public

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Scientific

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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 ≥ 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 >= 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
United Kingdom
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
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St Pancras Hospital
4 St Pancras Way
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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?
Results article		26/08/2022	09/09/2022	Yes	No
HRA research summary			28/06/2023	No	No
Other publications	Qualitative interview study	22/02/2023	20/12/2023	Yes	No