BOOST-2: Boosting Baby Communication and Play

This protocol has regard for the HRA guidance and order of content

RESEARCH REFERENCE NUMBERS
IRAS ID 289896

TRIAL REGISTRY NUMBER AND DATE

PROTOCOL VERSION NUMBER AND DATE. Version 1.1 22-06-2021

OTHER RESEARCH REFERENCE NUMBERS

SPONSOR REFERENCE ETH2021-0347

SPONSOR : City University of London

Boosting Baby Communication and Play: Optimising video feedback for perinatal mental health

SHORT STUDY TITLE / ACRONYM

BOOST-2: Boosting Baby Communication and Play

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IRAS Number: 289896

ISRCTN Number / Clinical trials.gov Number:

SPONSORS Number:	ETH2021-0347
FUNDERS Number:	MGU0585

SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirement.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the clinical investigation without the prior written consent of the Sponsor

I also confirm that I will make the findings of the study publically available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

Chief Investigator:

Signature: 

Date:

22/06/2021

.....

Name: (please print):

.....KIRSTEN BARNICOT.....

KEY STUDY CONTACTS

Insert full details of the key study contacts including the following

Chief Investigator	Dr Kirsten Barnicot School of Health Sciences City University of London Myddleton Street Building 1 Myddleton Street London EC1R 1UW Email Kirsten.Barnicot@city.ac.uk Tel. 07933 995 456
Sponsor	City University of London School of Health Sciences Myddleton Street Building 1 Myddleton Street London EC1R 1UW
Joint-sponsor(s)/co-sponsor(s)	N/A
Funder(s)	The Barts Charity; Central & North West London NHS Foundation Trust
Clinical Trials Unit	Not applicable
Key Protocol Contributors	Dr Kirsten Barnicot School of Health Sciences City University of London Myddleton Street Building 1 Myddleton Street London EC1R 1UW Email Kirsten.Barnicot@city.ac.uk Tel. 07933 995 456

STUDY SUMMARY

It may be useful to include a brief synopsis of the trial for quick reference. Complete information and, if required, add additional rows.

Study Title	Boosting Baby Communication and Play: Optimising Video Feedback for Perinatal Mental Health	
Internal ref. no. (or short title)	BOOST-2: Boosting Baby Communication and Play	
Study Design	Case series	
Participants	The study will include women who: 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	
Planned Sample Size	N = 10	
Treatment duration	3 to 5 months	
Follow up duration	5 months	
Planned Study Period	01/07/2021 to 31/03/2021	
	Objectives	Outcome Measures
Primary	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	1) % of trained clinicians implementing at least 1 VIPP intervention case 2) % of mothers invited to participate who give informed consent to do so 3) % of mothers initiating and completing the VIPP intervention 4) mother and clinician ratings of the therapeutic alliance during VIPP 5) participants' own accounts of their experiences of the feasibility and acceptability of the intervention, assessed using qualitative interviews

Secondary	To establish pre-post effect sizes and confidence intervals on outcomes relating to parenting stress, parental self-efficacy, the parent-child bond, parent-child interaction and emotional dysregulation	1) Parental Stress Scale 2) Parent Expectations Survey 3) Mother Object Relations Scale – Short Form (MORS-SF) 4) Parent-Infant Interaction Observation Screen 5) Difficulties in Emotion Regulation Scale

FUNDING AND SUPPORT IN KIND

FUNDER(S) (Names and contact details of ALL organisations providing funding and/or support in kind for this trial)	**FINANCIAL AND NON FINANCIALSUPPORT GIVEN**
Barts Charity: 12 Cock Lane, London, EC1A 9BU	£42,637.34
Central and North West London NHS Foundation Trust: 350 Euston Road, Regent's Place, London, NW1 3AX	£ 9,998.00

ROLE OF STUDY SPONSOR AND FUNDER

The sponsor is City University of London. The sponsor is responsible for ensuring that the study design meets appropriate standards, that it has the required resources for initiation and management and that all applicable regulatory approvals have been received before the study starts. The sponsor is also responsible for ensuring that arrangements are in place for appropriate conduct and reporting while the study is active and that there is a clear dissemination and data retention plan once the study has closed. Should the study fail to comply with the applicable laws and regulations, or demonstrate that it is failing to achieve reasonable milestones and this is unlikely to be rectified, the sponsor has the right to withdraw sponsorship.

The funders are The Barts Charity and Central and North West London NHS Foundation Trust. They will have no role in conducting or making decisions about study design, conduct, data analysis and interpretation, manuscript writing, or dissemination of results.

Protocol contributors

The protocol was written by the Chief Investigator Dr Kirsten Barnicot. The protocol was reviewed by a representative of the sponsor to ensure that it complied with Health Research Authority guidance.

KEY WORDS:

Perinatal mental health

Infant mental health

Parent-infant intervention

LIST of CONTENTS

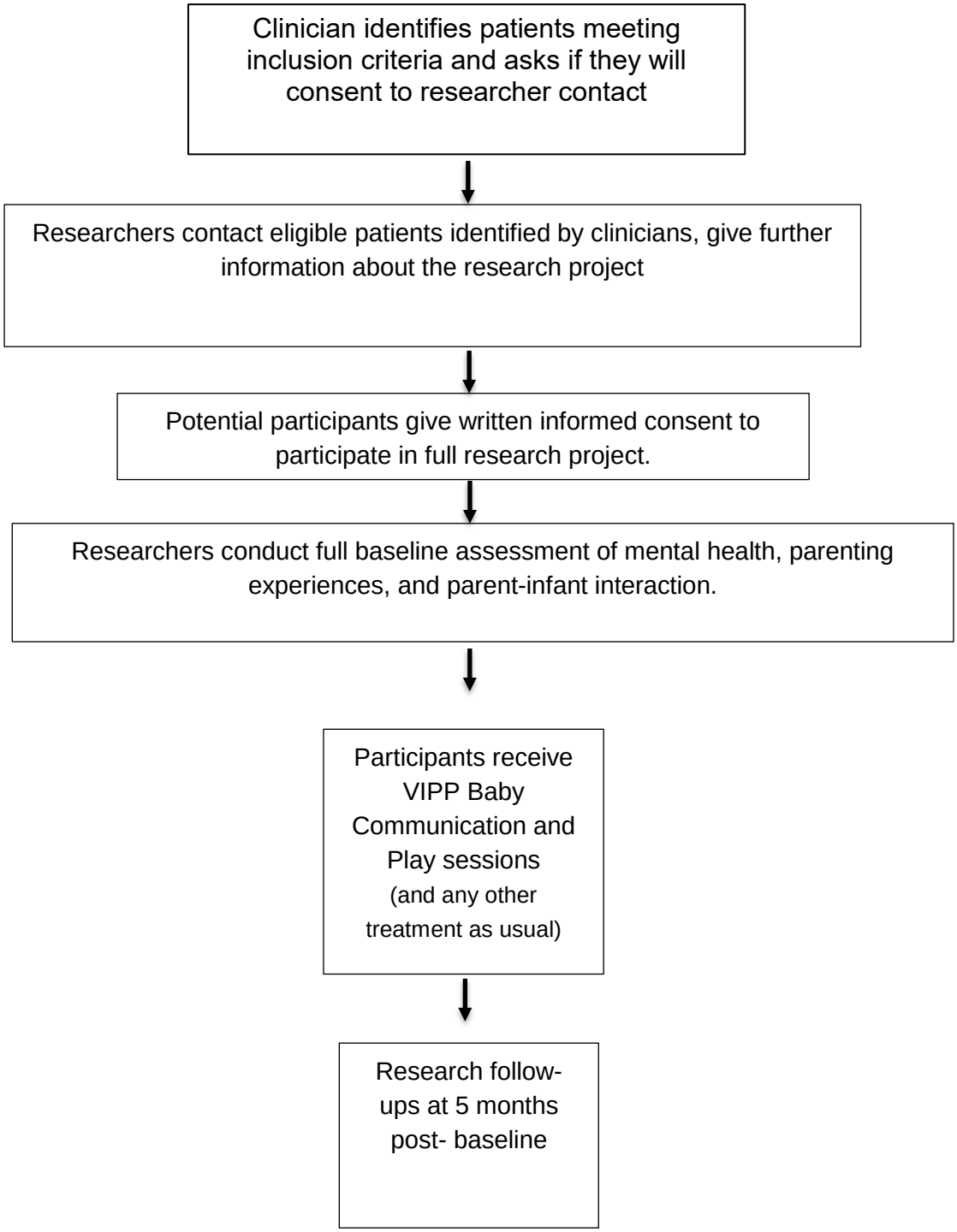
LIST OF ABBREVIATIONS

Define all unusual or 'technical' terms related to the trial. Add or delete as appropriate to your trial. Maintain alphabetical order for ease of reference.

AE	Adverse Event
AR	Adverse Reaction
CA	Competent Authority
CI	Chief Investigator
CRF	Case Report Form
CRO	Contract Research Organisation
CTA	Clinical Trial Authorisation
DMC	Data Monitoring Committee
DSUR	Development Safety Update Report
EC	European Commission
EU	European Union
EUCTD	European Clinical Trials Directive
GCP	Good Clinical Practice
IB	Investigator Brochure
ICF	Informed Consent Form
ICH	International Conference on Harmonisation of technical requirements for registration of pharmaceuticals for human use.
IDMC	Independent Data Monitoring Committee
ISF	Investigator Site File
ISRCTN	International Standard Randomised Controlled Trials Number
S	Member State
NHS R&D	National Health Service Research & Development
NIMP	Non-Investigational Medicinal Product
PI	Principal Investigator
PIC	Participant Identification Centre
PIS	Participant Information Sheet
QP	Qualified Person
RCT	Randomised Control Trial
REC	Research Ethics Committee
SAE	Serious Adverse Event
SAR	Serious Adverse Reaction
SDV	Source Data Verification

SOP	Standard Operating Procedure
SSI	Site Specific Information
TMG	Trial Management Group
TAG	Trial Advisory Group
TMF	Trial Master File

STUDY FLOW CHART



STUDY PROTOCOL

The BOOST-2 study: Boosting Baby Communication and Play: Optimising Video Feedback for Perinatal Mental Health

1 BACKGROUND

Between 10 and 20% of women develop a mental illness during pregnancy or within the first year after having a baby. Perinatal mental illness carries a total long-term cost to UK society of £8.1 billion for each one-year birth cohort (Bauer et al. 2014). Nearly three-quarters of this cost relates to adverse long-term impacts on the child rather than the mother, including mental health and behaviour problems. Negative impacts on child development are in part likely to stem from early difficulties in parent-infant interactions and relationships, that have been linked to maternal perinatal mental illness. In particular, mothers experiencing perinatal illness have been shown to find it harder to understand and respond sensitively to their infant's communication. Such difficulties have been linked in meta-analytic studies to early parent-child relationship problems and subsequent problems in children's socioemotional development (DeWolff & van Ijzendoorn 1997, Ranson & Urichichuk 2008). Birth to age three is a unique period of neuroplasticity, with neurogenesis in brain regions responsible for cognitive and emotional development beginning to rise rapidly at 6 months and peaking at 36 months, driven by early life experiences (Shonkoff & Phillips 2000, Siegel 2015). Intervening at this stage offers a critical opportunity to prevent the lifelong damaging effects of early problematic socioemotional experiences (Shonkoff & Phillips 2000). In line with this, the NHS Long-Term plan has identified increasing access to evidencebased care for women with moderate to severe perinatal mental health difficulties, including parent-infant interventions, and increasing support for children's mental health from birth onwards, as a priority (NHS 2019). Perinatal mental health services, which treat women with moderate to severe difficulties, are ideally placed to offer such interventions. However, the evidence base for implementing parent-infant interventions in NHS services is minimal. There are currently to our knowledge no published trials of such interventions in perinatal mental health services.

Video feedback parent-infant interventions specifically target the types of problems with parentchild interaction that are believed to partially explain the link between perinatal mental illness and poor child outcomes i.e. mothers' ability to understand and respond sensitively to their infants' communication. Meta-analysis has shown that the most effective interventions for improving parental sensitivity incorporate direct feedback to the parent based on recording and playing back videos of parent-infant interaction (Bakermans-Kranenburg et al. 2003). Our team of applicants has recently successfully tested one such intervention – the video feedback for positive parenting intervention (VIPP)- in three perinatal mental health services in London (The BOOST trial, ISRCTN 10052006). Trials in other at-risk groups - mothers with bulimia nervosa, insecure attachment or low sensitivity, and infants with behavioural problems – have shown that VIPP is more effective than control treatments in improving parental sensitivity, reducing child behaviour problems, and improving child socio-emotional development (Kalinauskiene et al. 2009, Klein Velderman et al. 2006, Stein et al. 2006, Van Zeijl et al. 2006). Our team has recently completed the NIHR-funded BOOST trial: the first randomised controlled trial of this intervention in perinatal mental health services. This was a small feasibility trial in 34 women using perinatal mental health services. Uptake of the intervention was high, with 95% of women randomised to VIPP initiating the intervention and 75% completing all 6 sessions. Feedback from mothers receiving the intervention and from perinatal mental health clinicians showed that VIPP was received very positively. Mothers consistently told us that VIPP helped to give them a different perspective on their relationship with their child,

boosting their confidence in their parenting abilities, and giving them new insights into how to understand and respond positively to their children's communication. This effect was reflected in the quantitative data on changes in parental sensitivity in the intervention and control groups, as shown in Figure 1 in the attachment. Ratings of parental sensitivity were conducted based on analysis of video data by a psychologist who was blind to intervention allocation, with clear positive intervention effects. In the group who received VIPP, just 35% were rated as sensitive in their interactions with their children at baseline; this rose to 50% at the 5-month follow-up (postintervention) and 64% at the 8-month follow-up. By contrast, in the control condition mothers who did not receive VIPP, average levels of sensitivity dropped over time. Whilst 50% of control mothers were rated as sensitive in their interactions with their children at baseline, this dropped to 44.5% at the 5-month follow-up and 33.25% at the 8-month follow-up.

2 RATIONALE

Despite these promising findings, the BOOST trial also highlighted two challenges for VIPP intervention delivery with mothers using perinatal mental health services. The aim of the proposed research is to test a modified protocol for intervention delivery, in order to address these two challenges. This is an essential pre-requisite before the intervention can be tested in a future largescale randomised controlled trial.

Challenge One. Minimum child age for intervention delivery. VIPP was originally developed for children aged 6 months and above. However, women most commonly come into contact with perinatal mental health services during pregnancy or soon after giving birth. During the BOOST trial, we found that by the time their child was aged 6 months, women had often been discharged from the service, either due to improving sufficiently in their mental health so as to no longer require support from the service, or due to having disengaged from contact with the service. This meant that some women and their children who could have benefited from the intervention were not able to receive it. The standard intervention protocol contains elements that may not be suitable for very young babies, such as filming parents building towers of blocks with their babies. Therefore, to increase the feasibility of VIPP delivery in perinatal mental health services, and to optimise recruitment to a future randomised controlled trial, we have adapted the intervention protocol to include activities that are appropriate for younger babies. These adaptations were based on a survey of 50 mothers with young babies.

Challenge Two. Evidence from interviews with clinicians and mothers experiencing mental health difficulties (Dunn et al. 2020) suggest a need to modify the intervention to target maternal emotional dysregulation during parent-infant interaction, as this is a major contributor to parent-infant relationship problems in this population (Bartsch et al. 2015, Murphy 2016,Yelland et al. 2015), and is not currently addressed by VIPP. Parental emotional dysregulation predicts parent-infant relationship problems, poor parental sensitivity, child behaviour problems and adolescent emotional dysregulation, mediated by parents' difficulty in acknowledging and regulating their child's emotions (Brake et al. 2020, Buckholdt et al. 2014, Carreras et al. 2019, Dittrich et al. 2019, Han & Shaffer 2013, Stepp et al. 2012, Yelland et al. 2015). Relatedly, parents in our feasibility trial told us that VIPP was most helpful when they received feedback on challenging and mutually emotionally dysregulating parent-infant interaction. Therefore, to optimise the potential for the intervention to improve emotional dysregulation during parent-infant interaction, we have modified it to include brief psychoeducation materials on helpful emotion regulation strategies. These were drawn from grey literature on parenting and evidence-based approaches including dialectical behaviour therapy and mentalization based therapy and evaluated for potential helpfulness and feasibility in a survey of 50 mothers with young babies.

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. Using a case series of 10 women, we will evaluate 1) feasibility of intervention delivery by perinatal mental health staff; 2) acceptability of the intervention for mothers using perinatal mental health services; 3) pre-post changes in parental sensitivity, parenting stress, parental self-efficacy, the parent-child bond and emotional dysregulation. Our findings will inform a future planned largescale randomised controlled trial of the intervention in this population.

2.1 Assessment and management of risk

1) Risk of participant distress. Participants may feel criticised or judged by being asked to take part in parent-focussed research, or whilst receiving feedback during the video feedback sessions. We will manage this by training both researchers and clinicians to emphasise throughout that this is a positively-focussed, non-judgemental intervention aiming to boost parents' confidence and highlight their strengths. We will train the therapists delivering to debrief at the end of each session to help parents process their feelings around watching and discussing the videos, and to incorporate ideas from dialectical behaviour therapy (an evidence-based treatment for personality disorder (Stoffers et al. 2012) to help parents manage their self-judgements during the intervention. Participants will be interviewed by researchers in a sensitive, empathic and non-judgemental style. Researchers will emphasise to the participants that they do not have to answer any questions if they do not want to. These techniques were reported to be very helpful, in feedback interviews with mothers taking part in our previous BOOST research project.
2) Risk of criminal or other disclosure. Participant responses and data will be kept confidential within the research team and stored pseudo-anonymously. However, participants will be informed that if they disclose information which indicates an immediate and serious risk of severe self-harm or harm to others, or if there are concerns for the neglect or abuse of children, their confidentiality will be broken and their clinical team informed.
3) Risk to participant or researcher.
   a. Coronavirus pandemic. As a default, all participant research assessments, and delivery of the VIPP intervention, will take place virtually over video conferencing software. If preferred by the participant and/or necessary for technical reasons, home visits may take place if allowed by the participant's NHS Trust, agreed to by the participant and researcher, and City University of London individualised coronavirus risk assessments are satisfactory (e.g. neither researcher nor participant have recent coronavirus symptoms nor a condition requiring shielding). Any home visits occurring will following social distancing recommendations (e.g. 2m distance between participants and researcher), all parties aged above 10 years old will wear masks and the researcher will use anti-viral hand gel on entering and leaving the premises.
   b. Lone working. Once allowed by the participating NHS Trusts, if agreed to by the participant and if City University of London risk assessment thresholds for the researcher and participant are not exceeded, researchers may visit participants in their homes to conduct assessments. To minimise risk to researchers, City University of London policy on lone working will be adhered to, whereby prior to the first visit with an unknown participant, the researcher will complete a risk assessment, and during the visit itself and any subsequent visits will continue to remain aware that risk within a home visit situation can escalate and will therefore continue

to dynamically assess risk throughout the visit. Additionally, a buddy system will be implemented whereby before each visit, the researcher will notify a colleague of the address that they are visiting and the expected end-time of the visit. The researcher will then contact the buddy colleague once they have left the premises of the participant's home. If more than 30 minutes elapse after the expected end time of the visit, with no contact from the researcher, the buddy will call the researcher. A code word will be established to enable the researcher to notify the buddy if they are in trouble. The buddy will then notify the local or national police and ask them to undertake a welfare visit to the participant's home address. If the buddy cannot reach the researcher on the phone after 3 attempts, the buddy will then notify the local or national police and ask them to undertake a welfare visit to the participant's home address.

3 STUDY DESIGN

Case series of N = 10 mothers using perinatal mental health services and offered our adapted version of VIPP. Case series are useful for establishing the feasibility of a novel or adapted intervention (Kooistra et al. 2009, Stewart et al. 2019). They are often used for piloting and gaining feedback on adapted versions of intervention protocols before moving to conducting a full randomised controlled trial. For instance in our previous study we piloted an adapted version of VIPP for parents experiencing personality-related mental health difficulties in 9 mothers, before moving to test it in a trial; and the ACORN study piloted an adapted version of the Towards Parenthood intervention in a small case series of pregnant women before moving to test it in a trial (ISRCTN10052006; Wilkinson et al. 2016). We will follow guidance on designing high quality case series by using a prospective design; clearly defining our population, intervention, outcomes, and follow-up; and not making causal inferences about the treatment effect (Kooistra et al. 2009). Our planned sample size of 10 follows established good practice in carrying out case series in previous related research (ISRCTN10052006; Wilkinson et al. 2016) and in the wider literature, where case series usually have 10 or fewer participants with the average being 8 (Abu-Zidan et al. 2012). Additional mothers will be recruited should initial recruits discontinue the intervention prematurely or be lost to follow-up.

3.1 Intervention

Six 90 minute Baby Communication and Play sessions using the Video-feedback Intervention to promote Positive Parenting (VIPP), to be delivered every two weeks. 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. As in our previous BOOST research study, based on feedback from our expert-by-experience co-investigator Parker, and our PPI group of parents with a diagnosis of a personality disorder, we have incorporated additional elements into the training for clinicians delivering the intervention, to help them focus on building trust and addressing parents' concerns around feeling judged. For this new project, as detailed above, we have adapted the intervention protocol to include activities that are appropriate for younger babies, and to include brief psychoeducation materials on helpful emotion regulation strategies. We have gained management support for perinatal mental-health clinicians to train in and deliver the intervention. Sessions will primarily be delivered using Zoom video conferencing software with participants situated in their homes and clinicians situated in their clinic. The therapists will receive supervision on every session by certified VIPP supervisors.

Participants receiving the intervention will also access treatment as usual from perinatal, adult mental health and/or social services during the trial.

4 STUDY SETTING

This is a multi-centre study. The study will be run in perinatal mental health services, in Central and North West London NHS Foundation Trust, Oxleas NHS Foundation Trust and East London NHS Foundation Trust. All participants will be recruited from and treated in perinatal mental health services. Each site will be both a recruitment site and an intervention site.

Requirements for a site:

1) Community perinatal mental health service
2) Management agreement for clinicians to train in and deliver the video feedback for positive parenting intervention

Requirement for individuals delivering the intervention:

1) A registered or trainee mental health professional working in a perinatal mental health service
2) Attendance of intervention training provided by the research team
3) Commitment to deliver the intervention to at least 2 participants over the duration of the research

5 ELIGIBILITY CRITERIA

5.1 Inclusion criteria for service-user participants

The study will include women (people assigned female at birth and/or currently identifying as female) who:

- Are using community perinatal mental health services
- Are a primary caregiver of a child aged 2-3 months at intervention initiation
- Are capable of giving informed consent
- Are aged 16 to 65

5.2 Exclusion criteria for service-user participants

The study will exclude:

- Families where a sibling or co-parent is participating in the trial
- Families in which the eligible child has a clinical diagnosis of a learning difficulty, developmental disorder or sensory impairment.
- 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.

5.3 Inclusion criteria for clinician participants

The study will include clinicians who:

- Were trained in the video feedback for positive parenting intervention as part of this study OR
- Have management responsibility for a clinician who was trained in the video feedback for positive parenting intervention as part of this study

5.4 Exclusion criteria for clinician participants

The study will exclude clinicians who:

- N/A

6 STUDY PROCEDURES

Intervention or Procedure	Total number of interventions or procedures received by each participant as part of research protocol	How many times would each participants receive each intervention or procedure as part of routine care	Average time taken per intervention or procedure	Who will conduct the intervention or procedure	Where will it take place
Clinician discusses research with potential participant	1	0	15 minutes	A clinician responsible for the participant's care in a perinatal mental health service	Video conferencing software or phone
Participant gives verbal consent for researcher contact	1	0	5 minutes	A clinician responsible for the participant's care in a perinatal mental health service	Video conferencing software or phone
Researcher contacts potentially eligible participants to invite to take part in research assessment	1	0	10 minutes	Researcher	By phone, video, email or post
Written informed consent for	1	0	15 minutes	Researcher	Video conferencing software,

participation in full study					email or post (patient preference)
Self-report questionnaires	2	0	20 minutes	Researcher or self-administered	Video conferencing software, online, email or post
Video assessment of parent-child interaction	2	0	10 minutes	Researcher	Video conferencing software
Receive VIPP Baby Communication and Play Sessions	6	0	90 minutes	A registered or trainee mental health professional who has been trained by the research team to deliver Baby Communication and Play Sessions	Video conferencing software
Qualitative interview	1	0	30 minutes	Researcher	Video conferencing software or phone

6.1 Recruitment

Service-user participants will be recruited from perinatal mental health services. Clinicians will identify patients meeting inclusion criteria and ask if they will consent to researcher contact. Following this verbal consent to contact, researchers will contact eligible patients identified by clinicians, to give further information about the research project. Following this, if the patient is willing to participate, they will sign a consent form.

Clinician participants will be recruited from perinatal mental health services. Clinicians who were trained in the video feedback for positive parenting intervention as part of this study, or have management responsibility for a clinician who was trained in the video feedback for positive parenting

intervention as part of this study, will be asked to take part in a qualitative feedback interview at the end of the study.

6.1.1 Participant identification

Service-user participants will be identified by a clinician responsible for their care in a perinatal community mental health service, who will refer them to the research based either on the clinician's clinical judgment that they meet eligibility criteria. The clinician will make a judgement on the inclusion and exclusion criteria. Clinicians will obtain verbal permission from mothers to pass their details to the research team and these will be emailed to the researchers over NHS-mail to NHS-mail encrypted server. This verbal consent will be recorded in the potential participant's medical records. The researchers will then confirm that the participant meets eligibility criteria.

Only a member of the patient's existing clinical care team will have access to patient records in order to identify eligible participants.

Clinician participants will be approached directly by the research team.

6.2 Consent

The Principal Investigator (PI) will retain overall responsibility for the informed consent of participants at their site and will ensure that any person delegated responsibility to participate in the informed consent process is duly authorised, trained and competent to participate according to the ethically approved protocol, principles of Good Clinical Practice (GCP) and Declaration of Helsinki.

Informed consent will be obtained prior to any participant undergoing procedures that are specifically for the purposes of the trial and are out-with standard routine care at the participating site, including the collection of identifiable participant data.

The right of a participant to refuse participation without giving reasons will be respected.

The participant will remain free to withdraw at any time from the trial without giving reasons and without prejudicing his/her further treatment and will be provided with a contact point where he/she may obtain further information about the trial.

The PI takes responsibility for ensuring that all vulnerable subjects are protected and participate voluntarily in an environment free from coercion or undue influence

- During the informed consent process, the potential participant and a member of the research team will discuss the nature and objectives of the trial and possible risks associated with their participation
- The potential participant will be presented with a written information sheet and will be asked to give written informed consent using documents approved by the REC and in compliance with GCP, local regulatory requirements and legal requirements.
- Potential participants will have the opportunity to ask questions
- The researchers taking consent will be trained in assessing the capacity of the person to consent to taking part, i.e. if the potential participant is able to:
    - understand the purpose and nature of the research
    - understand what the research involves, its benefits (or lack of benefits), risks and burdens
    - understand the alternatives to taking part
    - retain the information long enough to make an informed decision.

- make a free choice
- make this particular decision at the time it needs to be made
- understand how their interests will be protected

Potential participants will be assumed to have the mental capacity to make a decision unless it is shown to be absent. Those deemed to lack capacity to consent will be ineligible for study participation.

6.4 Baseline data

1) Sociodemographics and treatment history interview. Brief interview to record participants' age, gender, ethnicity, employment status and type, educational level, relationship status, number and age of children, years in contact with mental health services, risk history, lifetime history of psychiatric inpatient admissions, lifetime history of A&E admissions for mental health reasons, perinatal mental health and childrens' social services referrals. This information, in addition to current primary psychiatric diagnosis, will also be recorded from patients' clinical records where available.

2) Parental emotion dysregulation. This will be assessed using the Difficulties in Emotion Regulation Scale (DERS-16) (Gratz and Roemer, 2004, Bjureberg et al., 2016), a 16-item self-report measure. The measure demonstrates high internal consistency, good test–retest reliability, and adequate construct and predictive validity (Gratz and Roemer, 2004, Bjureberg et al., 2016).

3) Parental borderline personality traits. This will be assessed as an indicator of complex emotional needs linked to emotional dysregulation, using the McLean Screening Instrument for Borderline Personality Disorder. A cut-off of 7 identifies the presence of borderline personality traits with a sensitivity of .90 and specificity of .93 (Zanarini et al. 2003).

4) Parenting Stress. This will be measured using the Parental Stress Scale. This is an 18 item self-report scale assessing positive and negative experiences of parenthood. The measure has demonstrated good internal consistency and test-retest reliability, as well as convergent validity with measures of emotional distress and parenting satisfaction (Berry & Jones 1995).

5) Parental self-efficacy. This will be measured using the Karitane Parenting Confidence Scale. This is a 15- item self-report scale assessing mothers' perceived self-efficacy in caring for their child. The measure has demonstrated good internal consistency and test-retest reliability, as well as convergent validity with measures of generalised stress and confidence in parenting (Crncec et al. 2008).

6) Parent-child bond. This will be assessed using the Mother Object Relations Scale – Short Form (MORS-SF). This is a 14-item self-report scale assessing the quality of the parent-child relationship. MORS-SF is recommended by the Royal College of Psychiatrists as a routine outcome measure in perinatal psychiatry. The measure has demonstrated good internal consistency and convergent validity with measures of infant temperament and parental mental state (Oates et al. 2019).

7) Child socioemotional development. This will be assessed using the 19-item parent-completed Ages and Stages – Social Emotional Questionnaire (version 2) for ages 1 to 3 months (Squires et al. 2015).

8) Parental sensitivity. This will be rated by a trained researcher based on video data of parent-child interaction, using the Parent-Infant Interaction Observation Screen. This is an observational coding

tool that provides a measure of parental sensitivity based on 3 to 4 minutes of video footage. It has demonstrated good internal consistency and inter-rater reliability, and convergent validity with other measures of parent-child interaction *(Svanberg et al. 2013).*

6.5 Study assessments

6.5.1 Post-intervention assessment

This will occur at 5 months after baseline, at which point participants should have completed the intervention. The following measures will be used:

1) Parental emotion dysregulation. This will be assessed using the Difficulties in Emotion Regulation Scale (DERS-16) (Gratz and Roemer, 2004, Bjureberg et al., 2016), a 16-item self-report measure. The measure
demonstrates high internal consistency, good test–retest reliability, and adequate construct and predictive validity (Gratz and Roemer, 2004, Bjureberg et al., 2016).

2) Parenting Stress. This will be measured using the Parental Stress Scale. This is an 18 item self-report scale assessing positive and negative experiences of parenthood. The measure has demonstrated good internal consistency and test-retest reliability, as well as convergent validity with measures of emotional distress and parenting satisfaction (Berry & Jones 1995).

3) Parental self-efficacy. This will be measured using the Karitane Parenting Confidence Scale. This is a 15- item self-report scale assessing mothers' perceived self-efficacy in caring for their child. The measure has demonstrated good internal consistency and test-retest reliability, as well as convergent validity with measures of generalised stress and confidence in parenting (Crncec et al. 2008).

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5) Child socioemotional development. This will be assessed using the 22-item parent-completed Ages and Stages – Social Emotional Questionnaire (version 2) for ages 3 to 8 months (Squires et al. 2015).

6) Parental sensitivity. This will be rated by a trained researcher based on video data of parent-child interaction, using the Parent-Infant Interaction Observation Screen. This is an observational coding tool that provides a measure of parental sensitivity based on 3 to 4 minutes of video footage. It has demonstrated good internal consistency and inter-rater reliability, and convergent validity with other measures of parent-child interaction (Svanberg et al. 2013).

7) Therapeutic alliance. This will be assessed using the Helping Alliance Questionnaire-II (HAQ-II). This is a 17-item self-report scale, with a service-user completed version and a clinician-completed version, assessing the quality of the therapeutic alliance between the service-user and the clinician. The measure has demonstrated good internal consistency and convergent validity with other measures of the alliance (Luborsky et al. 1996).

6.5.2 Qualitative interview

Additionally, participants will be asked to take part in a qualitative interview about their experiences of the intervention and of the study. This will occur at 5 months after baseline, at which point participants should have completed the intervention. Interviews will be guided by a semi-structured topic guide, which will include some predetermined questions but will also be open-ended and flexible in order to allow for the emergence of new themes during the interviews. We will investigate the acceptability of the modified VIPP intervention through addressing themes such as parents' expectations and experiences of the intervention, its appropriateness for their child's stage of development, what they found helpful or less helpful, and potential changes that could be made to improve their overall experience of the intervention. We will explore their opinions on the acceptability and feasibility of virtual intervention delivery. The interview will be designed to last approximately 30-60 minutes and will be audio tape recorded for subsequent transcription.

Clinicians delivering the intervention will also be interviewed after intervention delivery, to explore their experiences of benefits, challenges, feasibility, acceptability and suitability for babies aged 2 to 6 months.

6.7 Withdrawal criteria

Participants will be withdrawn from the study if:

1) They ask to be withdrawn

2) The Chief Investigator or the participant's mental health care clinician believe that participating in the study is causing the participant harm

3) The participant lost capacity to decide whether or not to participate in the study

Reason for withdrawal would be documented. No further data on that participant would be collected. Data collected on the participant up to the point of withdrawal would be retained and used.

6.8 Storage and analysis of samples

Biological samples will not be taken as part of this research.

STATISTICS AND DATA ANALYSIS

7.1 Sample size

The case series size of N = 10 mothers follows established good practice in carrying out case series in previous related research (ISRCTN10052006; Wilkinson et al. 2016) and in the wider literature, where case series usually have 10 or fewer participants with the average being 8 (Abu-Zidan et al. 2012). Additional mothers will be recruited should initial recruits discontinue the intervention prematurely or be lost to follow-up.

7.2 Planned recruitment rate

We plan to recruit from perinatal mental health in:

1) Central and North West London NHS Foundation Trust
2) East London NHS Foundation Trust
3) Oxleas NHS Foundation Trust

Predicted consent rate: In our previous BOOST study in a related sample, 52% of mothers approached by their clinician about the study met eligibility criteria and gave informed consent to participate.

Predicted recruitment rate: We plan to recruit 10 mothers between July 2021 and October 2021 i.e. 2 to 3 women a month.

7.3 Analysis plan

Qualitative analysis. The interview transcripts will be analysed using thematic analysis (Braun & Clarke 2006), by a research assistant and by Jennie Parker, a service-user researcher who has previously co-analysed the qualitative feedback interviews generated during BOOST. Analysis will be supported by NVivo coding software. We will use the findings to make judgements about intervention acceptability and feasibility for mothers and clinicians, any facilitators and barriers to this, and any further minor modifications to the protocol that may be helpful.

Quantitative analysis. We will establish objective indices of feasibility and acceptability by determining:
1) % of trained clinicians implementing at least 1 VIPP intervention case
2) % of mothers invited to participate who give informed consent to do so
3) % of mothers initiating and completing the VIPP intervention
4) mother and clinician ratings of the therapeutic alliance during VIPP

We will calculate effect sizes and standard deviations for improvement in maternal sensitivity, parenting stress, parental self-efficacy and the parent-child bond from pre- to post-intervention. We will then combine these parameters with data on older infants (6 months plus) from BOOST in order to calculate the sample size required in a definitive randomised controlled trial. Additionally, we will compare the obtained effect sizes to those obtained when using the standard VIPP protocol in this population during BOOST, to check whether there is any evidence that the changes to the intervention protocol have led to dilution of intervention effects. For instance, in the BOOST trial, the percentage of mothers receiving VIPP who were rated as sensitive increased by 15% from pre-post intervention; by contrast the percentage rated as sensitive in the control group who did not receive VIPP deteriorated by 17%. Thus if the percentage of mothers rated as sensitive does not increase, or deteriorates, from pre-post intervention using the adapted protocol, we will consider this as potential evidence that the adapted intervention effect has been diluted relative to the standard protocol.

7.4 Subject population

Data from any participant recruited into the study will be analysed, regardless of whether they received any sessions of the allocated treatment (intention-to-treat analysis).

8 MONITORING, AUDIT & INSPECTION

The study will be subject to monitoring, auditing and inspection by the sponsor or the sponsor's delegated representatives and the relevant authorities responsible for each of the sites where the research will take place. The purpose of the monitoring is to ensure that the study is conducted in accordance with the authorised study protocol, the principles of GCP and all applicable regulations.

The sponsor and regulators will require access to the study site for these inspections which will be supervised by the site investigator(s). The inspection activities apply to the following, and associated, areas in order to:

- review the study master/site file (hard and soft copies);
- review the study participant consent forms;
- review research documents as approved by applicable regulatory body and those referenced in protocol;
- review participant facing, current and superseded versions;
- review study measures and assessments as completed by participants;
- view the storage facilities/spaces for research documentation (paper and electronic);
- review site delegation of duties log;
- review trial amendment log.

9 ETHICAL AND REGULATORY CONSIDERATIONS

9.1 Research Ethics Committee (REC) review& reports

Before the start of the trial, approval will be sought from a REC and from the relevant NHS R&D departments for the trial protocol, informed consent forms and other relevant documents e.g. advertisements and GP information letters

Substantial amendments that require review by REC will not be implemented until the REC and the relevant NHS R&D departments grant a favourable opinion for the study.

All correspondence with the REC will be retained in the Trial Master File/Investigator Site File

An annual progress report (APR) will be produced by the Chief Investigator and will be submitted to the REC within 30 days of the anniversary date on which the favourable opinion was given, and annually until the trial is declared ended. The Chief Investigator will notify the REC of the end of the study. If the study is ended prematurely, the Chief Investigator will notify the REC, including the reasons for the premature termination. Within one year after the end of the study, the Chief Investigator will submit a final report with the results, including any publications/abstracts, to the REC

9.2 Public and Patient Involvement

Patients and members of the public have been, and will be, involved in the Design, Management, Undertaking and Analysis of the research.

The PPI lead for the project will be Jennie Parker. Jennie will draw on her lived experience of using mental health services in addition to her previous experience analysing the feedback given by mothers who took part in BOOST, to share insights with the clinicians being

trained on how mothers experience the intervention and how mothers' anxieties around video feedback can best be addressed. During the study, Jennie will draw on her experience of using qualitative interviewing and analysis to lead on interviewing participating mothers, to understand how they experienced the intervention and any challenges faced.

Additionally, we have recruited 3 mothers who have experience of using perinatal mental health services – 1 of whom received the VIPP intervention during the previous BOOST study - who will form the PPI panel for the study. We have shared the plans for the study with them and they have provided feedback as well as reviewing the draft participant information sheets. We have incorporated their feedback to improve our ability to engage mothers and ensure they are well-informed and reassured about what the study involves. For instance, the Mum who had received VIPP emphasised how anxious potential participants may be feeling about who will see the videos and whether they will be judged. Following this feedback, we have added additional information about who will see the videos, data protection and confidentiality, and have added quotes from mothers who took part in BOOST explaining how positive and non-judgemental they found the intervention.

The panel will meet again in the middle of the study to help us analyse early feedback data from participating mothers, and once at the end to help us interpret the study findings and decide how to take them forward.

9.3 Data protection and patient confidentiality

All investigators and trial site staff will comply with the requirements of the Data Protection Act 1998 and the General Data Protection Act (2018) with regards to the collection, storage, processing and disclosure of personal information and will uphold the Act's core principles.

All electronic data files will be pseudonymised (i.e. identified only by a participant code and containing no other identifiable data). These will be stored only on City University of London's Egress system and accessible only to the research team. The pseudonymised information and identification key will be stored separately so that participants cannot be easily identified.

Any paper-based data will be stored in a locked filing cabinet at City University of London.

Video data will be stored securely in a private and secure encrypted zone on City University of London's Egress system and will only be accessible by the research and clinical team involved in this project. Please see here for more information about Egress: https://www.egress.com/secure-file-sharing/collaboration

All personal data will be kept only for 12 months after the end of the study in order to allow dissemination of a summary of study findings to participants. Additionally, participants will be able to opt-in to allow their contact details to be stored for 10 years after the research so that the researchers can let them know if they are doing any more research related to parents and children that may be of interest to them. All pseudonymised and video research data will be stored for 10 years and then destroyed, in accordance with the International Committee of Medical Journal Editors' recommendation (ICMJE 2016) that primary research data should be retained for a minimum of ten years so that it can be used to address any questions from patients, clinicians, academics or the public that arise from the publication of the study findings.

9.4 Indemnity

The study will provide indemnity through the City University of London insurance scheme should liability arise as a result of the study management, design or conduct.

9.5 Amendments

The Chief Investigator Dr Kirsten Barnicot will be responsible for the decision to amend the protocol and will liaise with the sponsor to decide whether an amendment is substantial or non-substantial.

The Health Research Authority will be notified of all amendments. Only those amendments labelled as substantial will be sent to the REC for review and favourable opinion.

Substantial amendments will be made using the Notice of Substantial Amendment form within IRAS and Non-substantial amendments will be made by completing an NHS REC Notification of Amendment form.

All amendments will detail the rationale for and nature of the amendment, and will be supported by the revised versions of the protocol and participant documents, as apllicable, with new version numbers and dates.

Both the Notice of Substantial Amendment form and NHS REC Notification of Amendment form and the amended protocol and participant documents will be sent to the sponsor for approval and then submitted to the Health Research Authority, if applicable, to the NHS REC who provided the original approval for the study, and to the R&D departments of the participating NHS Trusts.

Amendments will not be implemented until approval has been obtained from all of these bodies.

All amendments will be recorded on an amendment log within the trial master file and all investigator site files which outlines with the amendment number and date and reason of the amendment and documents that have been modified for the amendment

9.6 Post study care

The NHS Trusts from which participants were recruited will be responsible for provision of care as appropriate, including access to mental health services and psychological treatments, once the study is complete.

Participating clinicians will determine whether to continue to offer the study intervention (video feedback for positive parenting) to patients once the study is complete – however, there are no special funding arrangements in place to enable this, and we do not yet know whether the intervention is feasible to deliver or effective.

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