# Healthy Start, Happy Start: helping parents with children's behaviour

Submission date	Recruitment status  No longer recruiting	[X] Prospectively registered			
18/03/2015		[X] Protocol			
Registration date	Overall study status Completed	Statistical analysis plan			
19/03/2015		[X] Results			
<b>Last Edited</b> 17/06/2025	Condition category Mental and Behavioural Disorders	[] Individual participant data			

#### Plain English summary of protocol

Background and study aims

Behavioural problems affect 5-10% of children, and children with established behavioural problems are at risk of significantly worse outcomes throughout their life. Parenting has been identified as a key mechanism of risk in the development of behavioural problems. Interventions (or treatments) that work with caregivers to improve parenting have been found to reduce behavioural problems, and have the potential to improve parental wellbeing. These interventions predominantly target mothers, despite accumulating evidence that interventions targeting two caregivers can be more effective than those involving just one. The proposed intervention, Video-Feedback Intervention to Promote Positive Parenting and Sensitive Discipline (ViPP-SD) is a brief video-feedback intervention derived from attachment and social learning theories. This is the first large-scale study to test ViPP-SD in the UK. A key innovation is the extension of VIPP-SD to include both parents. The aim of the study is to assess the effectiveness and cost-effectiveness of ViPP-SD in preventing enduring (long lasting) behavioural problems in young children aged 12-36 months.

Who can participate?

Parents of young children aged 12-36 months at risk of behavioural difficulties

#### What does the study involve?

Participating families are randomly allocated into two groups. Those assigned to the intervention receive ViPP-SD and those assigned to the control group receive treatment as usual. In this study ViPP-SD is offered to two parents/caregivers, or one parent, depending on the family's preferences. The programme is carried out in the participant's home by trained professionals and involves six visits, lasting 90 minutes, at roughly fortnightly intervals. Each visit involves a video recording session, after which the recording from the previous visit is viewed and discussed with an emphasis on identifying and reinforcing positive interactions. Parents are supported in observing their child's behaviour, empathising with their child, praising their child when they behave in a positive manner, and adopting optimal discipline strategies. Parents in both the intervention and control group are asked to meet with a member of the research team to complete assessments on three occasions: before they are assigned to a group, and four and twenty-four months after assignment. These assessments include questions about the child's behaviour, parental wellbeing, and observations of parent-child interactions.

What are the possible benefits and risks of participating?

It is not known for certain that those families assigned to the intervention will benefit from the programme. However, parents in previous research have found it helpful and it has been shown to have a positive impact on parent-child interaction. There are no known risks to participation in the study. Participation does involve parents' time for both the assessment and programme visits (both of which last about 90 minutes with some variation depending on whether one or two parents take part). The researchers and intervenors are trained to respond sensitively should parents feel uncomfortable or distressed for any reason. Participation is entirely voluntary and families can take a break or end their participation at any time.

Where is the study run from?
Central and North West London and Whittington Health NHS Trusts (UK)

When is the study starting and how long is it expected to run for? April 2015 to December 2021 (updated 25/01/2021, previously: December 2019)

Who is funding the study? National Institute for Health Research (UK)

Who is the main contact? Dr Christine O'Farrelly

### **Contact information**

#### Type(s)

Scientific

#### Contact name

Dr Christine O'Farrelly

#### Contact details

Imperial College London Centre for Mental Health, Hamersmith Campus Du Cane Road London United Kingdom W12 ONN

## Additional identifiers

Protocol serial number 18423

# Study information

#### Scientific Title

Preventing enduring behavioural problems in young children through early psychological intervention: Healthy Start, Happy Start

#### **Study objectives**

Among children with high levels of behavioural problems aged 12-36 months, adding a brief video-feedback parenting intervention (ViPP-SD) to treatment as usual will reduce enduring behavioural problems measured at four months post-randomisation, using the Preschool Parent Account of Childhood Symptoms.

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

NRES Riverside, 12/12/2014, ref: 14/LO/2071

#### Study design

Randomised; Interventional; Design type: Treatment

#### Primary study design

Interventional

#### Study type(s)

Treatment

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

Topic: Children, Mental Health; Subtopic: All Diagnoses, Psychosis; Disease: Mental health issues personality and behavioural changes, All Diseases

#### **Interventions**

Video-Feedback Intervention to Promote Positive Parenting and Sensitive Discipline (ViPP-SD) aims to increase parental sensitivity and improve discipline practices in order to promote optimal parent-child interactions and prevent behavioural problems in young children. It has an established evidence base with positive treatment effects observed on parental sensitivity, discipline strategies, and child behaviour. The intervention is delivered in the home over six sessions at approximately fortnightly intervals. Each session involves filming parent-child interactions and giving parents feedback based on these video clips. There are four core sessions, which aim to enhance the caregiver's capacity to identify the child's exploratory behaviour and attachment cues and to respond to them appropriately. Two further booster sessions repeat the key messages using continuing video interaction material at each session. A key aspect of the intervention is its positive emphasis, and the intervention has been shown to have high levels of parental acceptability. The intervention will be delivered by trained, supervised health professionals, predominantly health visitors. Participants randomised to the intervention will be offered ViPP-SD for one or two caregivers.

Follow Up Length: 24 month(s); Study Entry: Single Randomisation only

#### **Intervention Type**

Behavioural

#### Primary outcome(s)

Child behaviour measured using the Preschool Parent Account of Childhood Symptoms; Timepoint(s): Pre-treatment and four and twenty-four months post-treatment

#### Key secondary outcome(s))

1. Child behaviour measured using the Child Behaviour Checklist; Timepoint(s): Pre-treatment and four and twenty-four months post-treatment

- 2. Child behaviour measured using the Strengths and Difficulties Questionnaire; Timepoint(s): Pre-treatment and four and twenty-four months post-treatment
- 3. Parental anxiety measured using the Generalized Anxiety Disorder 7; Timepoint(s): Pretreatment and four and twenty-four months post-treatment
- 4. Parental couple functioning measured using the Revised Dyadic Adjustment Scale; Timepoint (s): Pre-treatment and four and twenty-four months post-treatment
- 5. Parental mood measured using the Patient Health Questionnaire 9; Timepoint(s): Pretreatment and four and twenty-four months post-treatment
- 6. Parenting practices measured using the Parenting Scale; Timepoint(s): Pre-treatment and four and twenty-four months post-treatment
- 7. Resource use measured using a modified version of the Child and Adolescent Service Use Schedule; Timepoint(s): Pre-treatment and four and twenty-four months post-treatment

#### Completion date

31/12/2021

# **Eligibility**

#### Key inclusion criteria

- 1. Child aged between 12-36 months
- 2. Child scores in the top 20% for behavioural problems on the Strengths and Difficulties Questionnaire (SDQ), based on population norms
- 3. Written informed parental consent

#### Participant type(s)

Patient

#### Healthy volunteers allowed

No

#### Age group

Mixed

#### Sex

All

#### Total final enrolment

300

#### Key exclusion criteria

- 1. Child has severe sensory impairment or learning disability
- 2. Carer has insufficient English language to complete questionnaire assessments
- 3. Siblings participating in the trial
- 4. Families participating in active court proceedings

#### Date of first enrolment

15/04/2015

#### Date of final enrolment

31/07/2017

## Locations

#### Countries of recruitment

**United Kingdom** 

England

#### Study participating centre Central and North West London NHS Trust London

United Kingdom NW1 2PL

# Study participating centre Whittington Health NHS Trust United Kingdom

United Kingdom N19 5NF

# Study participating centre Oxford Health NHS Foundation Trust

Warneford Hospital Warneford Lane Headington Oxford United Kingdom OX3 7JX

# Study participating centre North East London NHS Foundation Trust

Rainham United Kingdom RM13 8GQ

# Study participating centre

Cambridgeshire and Peterborough NHS Foundation Trust

Elizabeth House Fulbourn Hospital Cambridgeshire United Kingdom CB21 5EF Study participating centre
Hertfordshire Community NHS Trust
United Kingdom
AL7 1BW

# Sponsor information

#### Organisation

Imperial College London

#### **ROR**

https://ror.org/041kmwe10

# 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**

### 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

# **IPD sharing plan summary** Available on request

# Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient- facing?
Results article	SWAT results	15/10 /2020	22/10 /2020	Yes	No
Results article	results	15/03 /2021	16/03 /2021	Yes	No
Results article		01/05 /2021	24/05 /2021	Yes	No
<u>Protocol</u> <u>article</u>	protocol	15/11 /2017		Yes	No
HRA research summary			28/06 /2023	No	No
Other publications	Associations of DNA methylation with behaviour, and sex differences	26/04 /2023	17/06 /2025	Yes	No
Other publications	Used data from the screening phase to investigate the psychometric properties of the preschool strengths and difficulties questionnaire (SDQ)	10/10 /2024	17/06 /2025	Yes	No
Participant information sheet	Participant information sheet	11/11 /2025	11/11 /2025	No	Yes