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

Submission date
18/03/2015

Recruitment status
No longer recruiting

Registration date
19/03/2015

Overall study status
Completed

Last Edited
20/09/2021

Condition category
Mental and Behavioural Disorders

✓ Prospectively registered
✓ Protocol added
? SAP not yet added
✓ Results added
? Raw data not yet added
✓ Study completed

Plain English Summary
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
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Protocol/serial number

18423

Study information

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

Study hypothesis
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

Secondary study design
Randomised controlled trial

Study setting(s)
Home

Study type(s)
Treatment

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

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

Secondary outcome measures
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): Pre-treatment 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): Pre-treatment 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

Overall study start date
01/10/2014

Overall study end date
31/12/2021

Eligibility

Participant 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

Age group

Mixed

Sex
Both

Target number of participants
Planned Sample Size: 300; UK Sample Size: 300; Description: 1. 150 receiving the intervention 2. 150 receiving standard care/treatment as usual

Total final enrolment
300

Participant 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

Recruitment start date
15/04/2015

Recruitment end date
31/07/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Central and North West London NHS Trust
London
United Kingdom
NW1 2PL

Study participating centre
Whittington Health NHS Trust
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

Sponsor details
Joint Research Compliance Office
Charing Cross Hospital
Fulham Palace Road
London
England
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W6 8RF

Sponsor type
University/education

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

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
31/12/2022

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	15/11/2017		Yes	No
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
HRA research summary			28/06/2023	No	No