A feasibility study and pilot RCT of a modified video-feedback parenting intervention for children in foster care with reactive attachment disorder: Brief study protocol

Short Title: VIPP-FC protocol

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Keywords: Foster care, reactive attachment disorder, attachment, treatment, randomised controlled trial. **MeSH terms**: problem behavior, pilot projects, feasibility studies, social work

Word count: 3885 (excluding title page, references, figures and tables)

Abstract

Introduction: Looked after children are at significantly greater risk of experiencing attachment difficulties. There is an urgent need to develop and make available effective and cost-effective interventions for this group of highly vulnerable children. Video-Feedback Intervention to Promote Positive Parenting and Sensitive Discipline (VIPP-SD) is an extensively evaluated and effective treatment that is a promising intervention for children in care with attachment difficulties.

Methods and analysis: This is a mixed-methods study. Firstly, with the guidance of experts in the field we will adapt the VIPP–Foster Care intervention for use in the context of children in foster care in the UK with symptoms of reactive attachment disorder. The identification of eligible participants will be supported by a screening mechanism run by the local authorities in collaboration with the university. Through a pilot randomised controlled trial we will test the screening process and the acceptability of the intervention and research assessments. Qualitative interviews will be conducted with key stakeholders and with carers who receive the new intervention.

Ethics and dissemination: The complex consent process was designed based on consultation with experts and local authorities. This feasibility study and pilot trial will determine a range of key feasibility parameters in preparation for a future full-scale trial of the effectiveness and cost-effectiveness of VIPP-FC. Findings of the pilot RCT and interviews will be published in peer-reviewed journals and presented to various audiences.

Trial registration: This study was registered in the ISRCTN registry, with number ISRCTN18374094, on 05-22-2017 and the Central Portfolio Management System, CPMS ID: 34889.

Strengths and limitations of this study

- This study benefits from expert input to develop a treatment manual for children in foster care who need support with their attachment difficulties, particularly in the realm of reactive attachment disorder.
- The intervention is based on an evidence-based parenting programme recommended for children in care with attachment difficulties.
- It includes both quantitative and qualitative methods to assess the acceptability, efficacy cost-efficacy of the new intervention.
- The involvement of a highly experienced team and inclusion of diverse sites, maximises learning in working with a population and setting expected to be challenging.
- Main limitations are the uncertainty in rates of reactive attachment disorder in this population, and the dependency on an effective collaboration with partner local authorities for recruitment.

INTRODUCTION

Looked After Children are a very vulnerable group, who are at greatly increased risk of experiencing mental health problems and poor long-term social, emotional and educational outcomes.[1,2] Despite this, remarkably few interventions exist with proven efficacy for intervening in, or preventing, poor outcomes for these children.[3] There is clearly an urgent need to develop new and effective interventions to improve the outcomes of children in care. Critically, the number of children in care has been rising steadily in the UK over the past 5 years and is now higher than at any point since 1985, up 7% between 2010 and 2014 to 68,840.[4] Seventy-five percent of looked after children are in foster care. Given the size and disproportionately at-risk nature of this group, and the level of responsibility borne by foster carers, there is great need for evidence-based foster-carer led interventions to support them in improving the short- and long-term outcomes of looked after children.

Children who are looked after have typically been exposed to a variety of risk factors, of which abuse, neglect and major disruptions in parent-child bonds are prominent.[5] Although these risk factors almost certainly affect child development in a number of ways, one very well documented and important area is in the development of attachment.[6,7]

Following an extensive review of the literature, a recent NICE guideline identified three clinically important forms of sub-optimal attachment patterns that should be considered important targets for intervention among children in care.[8] These patterns, referred to collectively as 'attachment problems' by the guideline group, are reactive attachment disorder (RAD), disinhibited social engagement disorder (DSED) and disorganized attachment. RAD and DSED are observed almost exclusively among children who have been subjected to extreme neglect and/or repeated changes in caregivers, whereas Disorganized Attachment may arise in the context of abuse, neglect or highly insensitive/atypical parenting.[9] RAD is considered an attachment disorder in DSM-5 (previously referred to as the RAD-inhibited subtype in DSM-IV), and refers to a pervasive absence

of attachment behaviour by young children towards their carers, combined with highly withdrawn and fearful behaviour and emotional volatility. RAD is observed at relatively high rates among children raised in institutions (43% in Zeanah et al., 2004), but there is considerable uncertainty regarding its prevalence among children in UK foster care (Zeanah et al. reported 35% RAD in a US foster care sample).[5]

While we currently lack evidence regarding the most effective treatments for RAD, the most promising approach for young children who are not showing attachment behaviour when distressed is to focus on improving parental awareness and understanding of the child's distress and encouraging comfort seeking by supporting what contemporary attachment theory and research indicates is the central driver of *secure* attachment – parental sensitive responsiveness. Any such intervention would also benefit from incorporating support for carers in managing challenging behaviour.[10] Two independent and wide-ranging reviews, one commissioned by the HTA, the other conducted by NICE, both concluded that interventions promoting sensitivity had the best evidence of effectiveness for reducing attachment problems among children in care. The NICE guidance specifically recommended video-feedback methods due to their good efficacy and cost-effectiveness profiles.[8] Video-Feedback to Promote Positive Parenting and Sensitive Discipline (VIPP-SD) is the most rigorously tested sensitivity-focused video feedback intervention,[11] has repeatedly been shown to improve parental sensitivity to attachment cues (d = .47, k = 12) and has been used in a broad range of contexts and age ranges (up to age 5-6 years), making it an attractive choice for a brief and cost-effective treatment for children in foster care and a compelling choice as a candidate treatment for RAD.

It is critical to note, however, that the HTA review also highlighted the fact that no study has yet tested whether any intervention can effectively treat RAD.[12] Also a key research priority identified by that review was to carry out better randomised controlled trials of interventions to improve attachment outcomes for children in care. The current study would thus represent an

important step towards addressing a serious gap in the capacity of the NHS and social care services to meet the needs of looked after children.

METHODS

ETHICS

This study was reviewed by the London - Harrow Research Ethics Committee (reference number 17/LO/0987) and given a favourable opinion in August 2017.

DESIGN

In this study we will conduct all of the preparatory steps necessary to pave the way for a full-scale randomised trial of VIPP for children in foster care with RAD, using a mixed-methods approach with a three-phase design. Firstly, we will adapt the VIPP-FC manual for the target population; secondly, we will run a series of case studies to test the modified intervention and a scoping study using stakeholders interviews; and thirdly, we will run a pilot RCT of the modified intervention and interviews with their recipients.

PATIENT AND PUBLIC INVOLVEMENT (PPI)

PPI input to the study design, treatment development and evaluation protocol is a vitally important part of the project. Specifically, foster carers will be engaged in reviewing and shaping the modified clinical intervention, providing feedback on study measures and in planning recruitment, participant engagement and study dissemination.

A carer advisory group will contribute to all aspects of study design, as well as provide input to the manual development working group and the Steering Committee. The carer advisory group will be organised and facilitated by an experienced foster carer who has experience convening similar groups for the NSPCC and other organizations. In addition to these mechanisms for PPI for

this study, the study itself is designed to collect detailed qualitative and quantitative information about foster carers' perceptions of the intervention.

PROCEDURE AND ANALYSIS

Phase 1: Refining VIPP-FC for young children in foster care with RAD. The existing VIPP-FC manual, which is a modification of VIPP-SD resulting from pilot clinical work conducted in the Netherlands,[13] will undergo further modification to specifically take account of the clinical features of RAD, as well as incorporate local (UK) health and social care policies and practices. An Expert Advisory Group of the programme developers, UK clinicians (including colleagues in CAMHS, social care and the third sector and foster carers will be set up to review the existing manual and advise a Manual Development Working Group (composed of members of the study team) who will implement the recommended changes. The consultation and revision process will be iterative, consisting of three advisory meetings and up to four rounds of manual revision. This phase will involve no research participants.

Phase 2a: Conducting and evaluating a test case series. We will train a group of practitioners in VIPP-FC to work with 6 children in foster care and their carer, purposively sampled to reflect variations in age and presentation of RAD, in order to road-test the modified VIPP-FC and examine its clinical suitability for children with RAD in real-world clinical practice. The 6 pilot cases will be identified using a screening measure of RAD with the help of the local authorities. Specifically, we will work with up to two local authorities, and will screen approximately 100 children. The 6 cases that are identified to take part (including both foster parent and foster child) will participate in the full screening process, all research assessments and the full intervention.

Participants will receive information sheets detailing their involvement in the case series and consent will be gained from both foster carers and those holding parental responsibility, by the research team. The case series will also establish initial feasibility of the intervention protocol, the

acceptability of the program and outcome assessments to foster carers. Foster carers and clinicians will take part in qualitative interviews, which will be transcribed and subjected to thematic analysis, [14] focused on identifying factors that facilitate or hinder the clinical fit of the programme to the child and foster carers' needs and that affect carers' engagement and willingness to put the techniques and ideas into practice. Treatment progress and process will be closely monitored using single case methodology.[15] The results of the qualitative and single case analysis will be presented to the expert group (from Phase 1), who will consider further appropriate manual modifications. The results of the case series will also inform revision of the protocol in preparation for Phase 3. The Manual Development Group will review any suggested changes arising from the case series and will decide when the manual is sufficiently adapted for use in the pilot trial.

Phase 2b: Conducting a scoping study with key stakeholders to inform pilot trial design. Delivering interventions and testing their efficacy is inevitably a complex process for children in foster care for a number of reasons. Thus, a full-scale trial is likely to encounter a number of significant hurdles that we will document and develop solutions to. Through qualitative interviews with key stakeholders, we will investigate these questions:

A. What are the key barriers and solutions to establishing a collaborative consortium of local authorities and CAMHS to operate a common screening system for identifying foster children with RAD? Can recruitment be effectively supplemented by self- and professional referrals, in addition to screening mail-outs?
B. What treatments are currently offered to foster children with RAD both within CAMHS and elsewhere; what referral criteria are applied? This information will inform the definition of the comparator arm of the pilot trial.

C. What concerns might carers, parents and social workers/local authority have regarding participation in research? What are the clinical and ethical concerns of stakeholders about diagnosis, randomisation and treatment in this population; how can these be overcome?
D. What are the barriers to obtaining appropriate consents for children in foster care with differing legal statuses?

We will use documentary sources and detailed interviews to address these questions. Qualitative interviews will involve local authority children's services managers (N=3), CAMHS managers (N=3), social workers (N=3), foster carers (N=3) and birth parents with children currently in foster care (N=3) across the two geographical locations (N=24 interviews in total). Semi-structured interview schedules will be developed, following established guidelines.[16] Participant sheets will be provided and written consent will be gained to take part in the interviews. Interviews will be audio recorded and transcribed verbatim for qualitative analysis. The results of the analysis will inform the set-up of the screening system for case identification, the definition of the comparator arm of the trial, the handling of diagnostic and clinical data, and procedures for obtaining informed consent.

Phase 3: Running a pilot RCT of modified VIPP-FC

The final phase of the study will consist of a pilot RCT, in which a new group of children with RAD symptoms (i.e., not those involved in the initial non-randomised clinical pilot series) will be randomised to receive VIPP-FC + Usual Care, versus Usual Care only. We will run a large community screening process, aiming for a minimum screening sample of 500 foster carers in total. Children with RAD will be identified initially using this community screening process in 6-10 local authorities to identify, at-source, children experiencing high levels of behavioural signs of RAD that could indicate a potential RAD diagnosis. In-depth research assessments of RAD will determine

whether sufficient RAD symptoms are present for the child to enter the pilot trial. For the screening phase, active consent will be provided by the foster carer only, as it does not involve direct contact with the foster child. A letter will be sent to all parents explaining the study and offering them the opportunity to ask questions and opt-out if they have concerns. Parents will be given a minimum of two weeks to notify the Local Authority or the research team if they wish to opt out from the screening. If a child meets the RAD threshold, full consent from those holding parental responsibility would then be obtained and the child and foster carer (if all parties are happy to proceed) will enter the pilot trial. Prior to randomisation, the child and foster carer will be invited to attend a baseline assessment and then randomised individually to VIPP-FC or CAU in a 1:1 ratio, stratified by age, gender and site. As this is a pilot trial 40 cases would be randomised in total, which is sufficient to test the feasibility questions described below and estimate approximate confidence intervals for key study parameters. Researchers conducting outcome assessments will remain blinded to treatment allocation. Identifiable information will be kept securely and separated from research assessments data.

VIPP-FC will be delivered in-home by trained CAMHS practitioners or other appropriately qualified VIPP-trained interveners, in 6 sessions over approximately 4 months. This modified programme is designed to specifically address the attachment difficulties often shown by children in foster care.[13] VIPP-FC will be compared to usual care, as there is no pre-existing integrated care pathway for children in foster care. Care as usual varies widely from locality to locality and good data is not recorded that would currently allow precise specification of CAU in a planned trial. Systematically documenting CAU is therefore a key objective of this study. We will use the Child and Adolescent Service Use Schedule (CA-SUS) to systematically describe and quantify the services received by children and carers in the comparator arm of the pilot trial.[17]

Baseline and end of treatment outcomes will include validated research diagnostic assessments of RAD and co-occurring conditions, security of attachment (including disorganized

attachment), sensitivity of parenting, child adjustment, carer wellbeing, and the CA-SUS measure of service use. See a SPIRIT chart on Table 1. Process data will be collected during the pilot RCT to document the uptake, numbers completing treatment, rate and stage of dropout, and acceptability of the treatment to participating families. In addition to these outcome measurements, we will also conduct qualitative interviews regarding carers' experiences of the programme and perceptions of VIPP-FC. The pilot RCT will allow us to:

A. Test the feasibility of identifying sufficient numbers of appropriate cases through social care using appropriate screening instruments and diagnostic assessments of cases screening positively for RAD across several local authorities and locales (rural and urban).
B. Test the feasibility of recruiting and consenting foster families with children with RAD to an RCT (numbers contacted, consented).
C. Conduct an initial evaluation of the feasibility of randomising to VIPP-FC or CAU (numbers refusing randomisation).
D. Document study throughput: uptake, numbers of sessions attended and numbers completing treatment, rate and stage of dropout, and acceptability of the treatment.
E. Establish the feasibility and acceptability of baseline and outcome assessments and level of data completeness.
F. Modify and test a version of the CA-SUS to ensure suitability for pre-school/primary school fostered children.
G. Identify the most appropriate primary outcome.
H. Obtain initial estimates of variance of key outcome measures and constrain effect size estimates.
I. Explore appropriateness of exclusion criteria, particularly concerning co-occurring conditions.

J. Establish the optimal and most acceptable screening tools for RAD as recently redefined in DSM-5.

K. Collect qualitative data on carers' experiences of VIPP, the facilitators of change, what carers feel they have learnt that they can take forward in their work, and areas needing improvement. Collect qualitative data on good practice and barriers to delivery from practitioners, social workers and service managers.

At the end of phase 3 we will incorporate further feedback from foster carer's interviews, supervision and ongoing fidelity checks into a final version of the treatment manual.

Feasibility parameters will be based on proportions—proportions of cases identified, consented, randomised, completing treatment and outcome measures. Approximate variance estimates will be obtained for the main outcome measures using the upper 80th percentile of the relevant confidence interval. For qualitative interviews, following full transcription, the qualitative data will be entered into NVivo3 and analysed using thematic analysis in two stages that will involve the introduction of codes across the data followed by further examination of the coded data extracts to identify patterns/themes across the data.

TARGET POPULATION

The target population is children in foster care aged between 11 months old and 6 years old and their foster carer(s). As a pragmatic study we deliberately minimise exclusion criteria in order to reach a participant population that is broad and representative so that we can address the clinical suitability of VIPP for a wide range of children in foster care. We will however collect detailed information about factors that might be relevant to the suitability of the VIPP intervention for children with RAD, such as co-occurring conditions, placement variables and care order.

ELIGIBILITY CRITERIA

Inclusion criteria

Families recruited into the study will be eligible if the following criteria are met:

Parental figure:

(a) foster carer(s) who is primary carer for the child

(b) the foster carer must be aged 18 years and over;

(c) proficient in English;

Child:

(a) living with foster carer(s) in a placement planned to be at least 4 months;

(b) lived with foster carer for at least 4 weeks

(c) presence of DSM-5 defined RAD or

(d) aged between 11 months and 6 years

Note: because of the uncertain prevalence of RAD in UK foster care populations, the RAD eligibility criterion will be reviewed after 15 cases have been assessed. If fewer than 3 (out of 15) cases scoring over the screening threshold (> 66th percentile on screening measure) actually meet diagnostic criteria, we propose to include sub-diagnostic cases with elevated symptoms in the feasibility RCT based on the screening threshold. Further, for the case series, we will include a mix of cases that meet the RAD diagnosis and those falling short of the diagnostic threshold in order to explore the suitability of the intervention for both groups of children and expedite the rapid progress of manual refinement.

Exclusion criteria

Parental figure:

(a) already engaged in a similar parenting intervention.

Child:

(a) severe developmental disability.

END OF TRIAL

The study is planned to run for 30 months. Overall, participant involvement will be no longer than 6 months. The end of trial will be the last patient, last visit of phase 3 (pilot trial).

HEALTH ECONOMICS

The health economic component of this feasibility study will involve two main elements. The first will involve modification and testing of an appropriate version of the child and adolescent service use schedule (CA-SUS), which has been successfully applied in a pre-school population with autism,[18] and is currently being implemented in an evaluation of a mental health screening and early intervention for under 4s, including looked after children.[19] These versions of the CA-SUS will form the basis of a modified version suitable for the current population, with modifications being determined initially by expertise in the research group and subsequently by testing for acceptability and comprehensiveness in the proposed pilot study. Specifically, this initial draft version will then be tested and modified in two main ways.

First, we will assess respondents' understanding of the questions and modify the wording or add explanation if anything is unclear. Secondly, we will assess the measure's comprehensiveness in capturing all relevant services. Testing may identify items which are redundant or important services that have been omitted. The CASUS is used as an interview and in the feasibility stage researchers will probe for any missing items and explore (and record) contact with certain key services, such as CAMHS, local authority services and charities about the nature of the contact.

The second component will involve exploration of recent literature to assess how realistic it might be to include a measure of health-related quality of life capable of generating quality adjusted life years (QALYs) in this young age group. Without such a measure, it is difficult to make clear resource allocation decisions. However, no measure currently exists for children under 7 years old

and although we are aware of research exploring this issue, results are not yet available and are unlikely to be of value for infants and very young children. Review of the most recent evidence may highlight possible solutions, although we do not anticipate there will be a perfect solution for the full age range of 0 to 6. Any subsequent full RCT will therefore be reliant on cost-effectiveness analysis, focusing on the primary clinical measure of outcome.

DISSEMINATION

Our team has a very strong track record of dissemination through publication, policy documents, advisory groups (including NICE and NHS England) and service development and presentations to academic, clinical, policy and public audiences, in the UK and internationally. We will disseminate research outputs to the following key audiences: academic dissemination of the modified manual and study findings, foster carer and general public audiences, local authorities, and clinical and policy audiences.

Declarations:

Consent for publication: this manuscript does not contain any individual person's data in any form.

Data sharing statement: All data requests should be submitted to the corresponding author for consideration.

Competing interests: the authors declare that they have no competing interests.

Funding: this study is funded by the HTA programme of the National Institute for Health Research, reference 15/118/01, which has reviewed this protocol.

Authors' contributions: PF was a major contributor in writing this protocol. PO was responsible for adapting it to this shortened version and format for publication. All co-authors have contributed to writing the protocol.

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Table 1. SPIRIT chart.

	TIME POINT					
	Screening	**Post-Screening interview**	**Baseline**	**Allocation**	**Treatment**	**Post-Treatment**
ENROLMENT:						
Eligibility screen	X	X				
Informed consent	X		X			
Allocation (randomisation)				X		
INTERVENTIONS:						
A) CAU **OR** B) VIPP-FC + CAU					X	
ASSESSMENTS:						
DAWBA	X*		X			X
ASA	X					X
DAI		X				X
SDQ		X				X
SSP			X			X
CBCL			X			X
Parental sensitivity			X			X
PSES			X			X
PSI			X			X
CA-SUS			X			X

Note. CAU: care as usual; VIPP-FC: Video-feedback Intervention for Positive Parenting—Foster Care; DAWBA: Development and Well-Being Assessment;[20] ASA: Attachment Screening Assessment;[21] DAI: Disturbances of Attachment Interview;[22] SSP: Strange Situation Procedure;[23,24] CBCL: Child Behaviour Checklist;[25] PSES: Parenting Self-Efficacy Scale;[26] PSI: Parenting Stress Index;[27] CA-SUS: Child and Adolescent Service Use Schedule;[17] SDQ: Strengths and Difficulties Questionnaire.[28] *Attachment-related items only at this time point.

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