A feasibility study and pilot trial of a modified video-feedback intervention for children and foster carers to improve mental health outcomes of children with reactive attachment disorder.

Short Title:

VIPP-FC

Protocol

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Sponsor Information: University College London,
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SHORT TITLE

Video feedback support for foster care

GENERAL INFORMATION

Identifiers	
IRAS Number	215947
REC Reference No	
Sponsor Reference No	16/0647
Other research reference number(s) (if applicable)	
Full (Scientific) title	A feasibility study and pilot trial of a modified video-feedback intervention for children and foster carers to improve mental health outcomes of children with reactive attachment problems
Health condition(s) or problem(s) studied	Mental Health
Study Type	Feasibility Study
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Study Duration/length	30 months
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NHS Partners:

CNWL Central and North West London NHS Foundation Trust

LYPFT Leeds and York Partnership Foundation NHS Trust

NELFT North East London Foundation NHS Trust

SLaM South London and Maudsley NHS Foundation Trust

TPFT Tavistock and Portman NHS Foundation Trust

TEWV Tees, Esk & Wear Valley NHS Trust

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Role: Data collection and data management

R&D representative: Hannah Charles Portfolio Officer

ABBREVIATIONS AND DEFINITIONS OF TERMS

Organisations involved in the delivery of the study:

CNWL	Central and North West London NHS Foundation Trust
CTU	Clinical Trial Unit (Imperial)
LYPFT	Leeds and York Partnership Foundation NHS Trust
TEWV	Tees, Esk & Wear Valley NHS Trust
NELFT	North East London Foundation NHS Trust
SLaM	South London and Maudsley NHS Foundation Trust
TPFT	Tavistock and Portman NHS Foundation Trust
UCL	University College London

Personnel involved in the study:

CI	Chief Investigator
RA	Research Assistant
TM	Trial Manager

Further abbreviations and definitions:

CAMHS	Child and Adolescent Mental Health Service
CA-SUS	Child and Adolescent Service Use Schedule
CRN	Clinical Research Network
CTU	Clinical Trials Unit
DAI	Disturbances of Attachment Interview
DAWBA	The Development and Well-Being Assessment
FCO	Full Care Order
HTA	Health Technology Assessment

ICO	Interim Care Order
LA	Local Authority
LAC	Looked After Children
NIHR	National Institute of Health Research
PIS	Participant Information Sheet
PSI	Parenting Stress Index
PPI	Patient and Public Involvement
RAD	Reactive Attachment Disorder
RCT	Randomised Controlled Trial
R&D	Research & Development Department
SDQ	Strengths and Difficulties Questionnaire
SSC	Study Steering Committee
CAU	Care as Usual
VIPP-FC	Video-Feedback to Promote Positive Parenting – Foster Care

Signatures

The Chief Investigator and the JRO have discussed this protocol. The investigator agrees to perform the investigations and to abide by this protocol.

The investigator agrees to conduct the trial in compliance with the approved protocol, the UK Data Protection Act (1998), the Trust Information Governance Policy (or other local equivalent), the current Research Governance Framework, the Sponsor's SOPs, and other regulatory requirements as amended.

Chief investigator

Prof. Pasco Fearon 18/12/18

UCL **Sponsor representative** Date 18/12/18

Suzanne Emerton

Sponsorship Officer

1. INTRODUCTION

1.1 SUMMARY

There were 68,840 looked after children in the UK at 31 March 2014, an increase of 1% compared to 31 March 2013 and an increase of 7% compared to 31 March 2010. Of children looked after at 31 March 2014, 51,340 were cared for in foster placements. Looked after children are at significantly greater risk of experiencing childhood mental, emotional and behavioural problems, including sub-optimal attachment patterns (Ford, Vostanis, Meltzer, & Goodman,2007; Rutter, 2009 Tarren-Sweeney & Hazell, 2006). Despite this, access to children's mental health services and therapeutic interventions is highly variable and children are often denied access to CAMHS (BAAF, 2015). Furthermore, many interventions to treat emotional or behavioural difficulties or to promote positive wellbeing and attachment have not been tested rigorously among looked after children. There is thus an urgent need for effective and cost effective interventions to be developed and made available for this large group of highly vulnerable children. Video-Feedback to Promote Positive Parenting (VIPP) is an extensively evaluated and effective treatment for promoting sensitive parenting and increasing rates of secure attachment. With the guidance of experts in the field we intend to refine and optimise the VIPP–Foster Care (VIPP-FC) intervention for use in the context of children in foster care with Reactive Attachment Disorders (RAD). The identification of children in foster care with RAD will be supported by a screening mechanism run by the local authority in collaboration with the university. The screening process we envisage will be essential to the success of this project and will depend on an effective collaboration with local authorities, who will send out information sheets, initial consent forms and screening measures to all foster carers in the study localities. Through a pilot randomised control trial we 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 for this population of children.

1.2 OVERALL OBJECTIVE OF THE STUDY

The overall objective of this study is to conduct all the preparatory steps necessary for a full-scale randomised trial of VIPP for children in foster care with RAD. This will be achieved via a two-phase research process. Firstly, with extensive input from experts and clinicians in the field, the VIPP-FC manual will be revised to incorporate the complexities of RAD. No research participants are involved in this phase. Secondly, the modified clinical manual will be tested with a small series of children and foster carers (N=6). During this phase, we will also conduct a small scoping study of the organizational, ethical and practical landscape within which a trial of VIPP for RAD will need to operate. The research protocol and clinical manual will be amended as required as a result of learning from this phase. Finally, a new group of children

with RAD and their foster carers will be recruited for a pilot RCT of the proposed intervention, assessing key feasibility parameters, and monitoring usual treatment.

2 BACKGROUND AND RATIONALE

2.1 PRIOR LITERATURE

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 (Ford, Vostanis, Meltzer, & Goodman,2007; Tarren-Sweeney & Hazell, 2006). Despite this, remarkably few interventions exist with proven efficacy for intervening in, or preventing, poor outcomes for these children (Luke, Sinclair, Woolgar, & Sebba, 2014). There is clearly an urgent need to develop new and effective interventions to improve the outcomes of children in care. In particular, looked after children are at five-fold increased risk of all childhood mental, emotional and behavioural problems and six to seven times more likely to have conduct disorders. In adulthood they are between four and five times more likely to self-harm. 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. 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 (Zeanah et al., 2004). 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 (Bowlby, 1969). Attachment is a critical early-appearing developmental phenomenon, observable in the first year of life, in which children maintain proximity to, and selectively seek comfort from their carers when they are worried, anxious or distressed and is thought to be critical for their optimal long-term development. Attachment is believed to be largely instinctive but the way in which a child's attachment behaviour comes to be manifested, or organized, is dependent on the environment and particularly on the quality of care (see Fearon, Groh, Bakermans-Kranenburg, van Ijzendoorn, & Roisman, 2016). A large body of research has demonstrated that sub-optimal and disordered patterns of attachment behaviour can arise when children experience insensitive, frightening, neglectful or abusive care and frequent changes of carers (Fearon et al., 2015; Zeanah, 2015). These early difficulties in attachment leave the child at-risk for poor social and emotional outcomes (Fearon, Bakermans-Kranenburg, van Ijzendoorn, Lapsley, & Roisman, 2010; Rutter, Kreppner, & Sonuga-Barke, 2009). In contrast, a secure attachment, where a child is able to openly communicate their attachment needs and be readily comforted by contact, is consistently associated with better

developmental outcomes across a range of areas (Fearon et al., 2010; Fearon et al., 2016; Groh, Roisman, van IJzendoorn, Bakermans-Kranenburg, & Fearon, 2012).

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 (NICE, 2015). 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 (Rutter et al., 2009). 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. (2004) reported 35% RAD in a US foster care sample). Although DSED has traditionally been defined as an attachment disorder (previously referred to as RAD-disinhibited subtype), it has been re-classified as a disorder of social behaviour in DSM-5. These children show a striking lack of reticence with strangers, are prone to engaging in inappropriately intimate social (especially physical) contact with strangers, and may wander off with strangers or become lost, despite showing attachment behaviour—even sometimes of the secure type—to their primary caregivers in standard separation reunion procedures like the Strange Situation Procedure (Zeanah & Gleason, 2015). The evidence is quite clear that RAD and DSED are different disorders, showing distinct characteristics, aetiologies and course (Rutter et al., 2009). Although the precise relation between DSED and the attachment construct is controversial, it is generally accepted that it reflects a lack of selectivity of approach, which is at least closely related to attachment (Lyons-Ruth, 2015). Disorganized Attachment is observed in around 3-15% of normative populations, and is much more prevalent among children raised in highly deprived circumstances or those exposed to abuse (48% of abused pre-schoolers are Disorganized according to meta-analytic work, see van IJzendoorn, Schuengel, & Bakermans-Kranenburg, 1999). Disorganized attachment is also observed at elevated rates in children in foster care compared to controls (d = .41, see van den Dries, Juffer, van Ijzendoorn, & Bakermans-Kranenburg, 2009). Disorganized Attachment is not a disorder, and is arguably more accurately described as a relational or developmental vulnerability factor that increases the likelihood of adjustment difficulties in the future.

A large number of intervention studies have shown that it is possible to increase the rate of secure attachment and reduce rates of disorganized attachment in a range of normative, at-risk and clinical populations by improving the sensitive responsiveness of parental care (Bakermans-Kranenburg, van, & Juffer, 2003; NICE, 2015; Wright et al., 2015). Such interventions often combine a number of treatment elements, but share the common objective of helping parents to become sensitively attuned to the child's attachment cues, and responding to them consistently and appropriately. Video-feedback techniques are a commonly used effective strategy for helping parents to increase their sensitivity to attachment cues and video-feedback-based interventions reliably increase rates of secure attachment and reduce rates of disorganized attachment (d = .44, k= 5; Wright et al., 2015). Indeed, video-feedback interventions may be particularly helpful for high-risk children who have experienced significant disruptions in care. Three trials have used video-feedback interventions focused on improving caregiver sensitivity as a means of reducing attachment difficulties (specifically disorganized attachment) among children who had been adopted or maltreated (Bernard et al., 2012; Juffer et al., 2008; Moss et al., 2011), and all reported positive, significant and sizeable treatment effects (Bernard *d* = .72;Moss *d* = .90; Juffer *d* = .80). 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 (NICE, 2015). VIPP is the most rigorously tested sensitivity-focused video feedback intervention, 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.

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 (Wright et al., 2015). Given the likely high prevalence of RAD in the foster care population (Zeanah et al., 2014) this is a serious gap. It is also noteworthy that no studies have tested the effectiveness of VIPP for improving attachment security and reducing attachment problems in a UK healthcare setting for any target group, although our group is leading the first UK trial of VIPP for children at risk of behavioural problems, which is currently underway (UKCRN ID: 18423). However, that study does not target children in care and will not include children with RAD.

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 (NICE, 2010). VIPP represents the most thoroughly tested video-feedback intervention for promoting sensitive responsiveness, includes techniques for behaviour management, and is specifically recommended by NICE for treating attachment problems for children in care, and is a compelling choice as a candidate treatment for RAD. Crucially, correctly reading and being consistently sensitive and attuned to a child's attachment cues may be maximally difficult, and therefore needing of enhanced support and training, when a child has attachment problems and a complex and traumatic history.

Regarding DSED, we note that there is evidence of a) its striking persistence over time, even in children who have gone on to receive good permanent alternative caregiving and b) that these children can concurrently have secure attachments to their caregivers (which is the main reason that DSED was re-classified to no longer be considered an attachment disorder in DSM-5). Therefore, while DSED may be found in this sample, we consider it imprudent to expect that a parental sensitivity intervention would be an effective intervention for this domain of problems. Assessing the presence of DSED, and other comorbidities, is nevertheless important as a potential predictor of treatment response.

2.2 Limits of Current Approaches

In planning the proposed study we considered a number of alternative treatments. To begin with, there are a number of approaches that are sometimes used in practice with children in foster care who might be described as having RAD, such as Dyadic Developmental Psychotherapy or Theraplay. However, there is currently no evidence supporting their use in relation to improving the quality of children's attachments and are not NICE recommended treatments for attachment problems for children in foster care. We paid particular attention to two other treatments that are credible treatment options for RAD for children in care: the Treatment Foster Care Oregon (previously called Multidimensional Treatment Foster Care, MTFC; Fisher & Kim, 2007) and Attachment and Biobehavioural Catch-Up (ABC) programmes (Bernard et al., 2012; Dozier et al., 2009). MTFC has only been tested against an attachment outcome on one occasion (Fisher & Kim, 2007), but this was a measure lacking thorough validation, and furthermore the intervention itself was not specifically designed to promote sensitive care and attachment. Furthermore, the UK trial of MTFC showed no reliable treatment effects (Green et al., 2014). We therefore did not view this as a persuasive choice of treatment in this context. The ABC programme has many similarities to VIPP and has been tested in one clinical trial for children in foster care (Dozier et al., 2009) with positive results (although only in relation to a non-standard assessment of attachment).

We believe that both ABC and VIPP are promising treatments for RAD, but we opted for VIPP for the following reasons: 1) VIPP has, in general, been more extensively trialled (12 RCTs). Second, VIPP has been used with a substantially broader age range than ABC (ages 4 months-5 years, and recently extended to 6 years for VIPP, ages 2 months to 2 years for ABC). Third, as the VIPP developers are based in the Netherlands, their substantive contribution to optimising the programme for children in foster care was much more practicable (and a highly valuable feature of this study). Fourth, our group has extensive expertise in using VIPP and training practitioners to deliver it in CAMHS in the UK, which will ensure efficient clinical delivery during the study. Fifth, we estimate that there will be considerable and growing take-up of VIPP across UK CAMHS in the coming years and hence a trial of VIPP for children in foster care would contribute to the establishment of coherent and sustainable services of this kind for a range of problems and contexts. Finally, VIPP is currently being trialled for children in foster care in the Netherlands, and hence there is considerable opportunity for the two projects to mutually inform and strengthen each other. This modified programme (VIPP-Foster Care [VIPP-FC]) pays particular attention to the need to help carers recognise signals that are specific to foster children--that may be quite challenging and difficult to understand--so that they are better equipped to respond sensitively, and to support the child's secure attachment to them as their carer. VIPP-FC is thus designed to specifically address the attachment difficulties often shown by children in foster care. In particular, these children tend to demonstrate attachment signals that are very subtle, highly distorted or absent – e.g. not crying when hurt because they are not used to being comforted; becoming angry or fearful when comforted. By helping foster carers become aware of these subtle, distorted or absent signals and training them to respond appropriately, the child can learn that foster carers can be relied on in times of need and that it is safe to show their distress and seek comfort. For many children in foster care, their experience of physical interactions with carers has been extremely negative in the past, and hence VIPP-FC also specifically addresses how to gently and sensitively support the child's needs for physical contact and comfort (see Schoemakern et al., under review). However, as part of the manual development process, we also propose to undertake a review of the treatment components of all interventions identified by the NICE guideline (including ABC), in order to map their common and distinct elements. Best practice from this process will be considered by an expert group, which will include patient and public involvement, and be incorporated into an integrated video-feedback programme for children in foster care.

2.3 Rationale for Study

A key research priority identified by a recent HTA review (Wright et al., 2015) was to carry out better randomised controlled trials of interventions to improve attachment outcomes for children in care. This

large systematic review found only one study that had examined the clinical effectiveness of treatments for attachment disorders (Chapter 8, priority 3), and that study provided only generic didactic training for foster carers and did not appear to be effective (Minnis, Pelosi, Knapp, & Dunn, 2001). The authors argued that more intensive intervention was likely to be necessary to bring about improvements in RAD symptoms and overall adaptive functioning. 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.

2.4 Patient and Public Involvement (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. A care-leaver advisory group will also be established to support the work of the study team. The carer and care leaver advisory groups will be organised and facilitated by Will Hasrauth, who is an experienced foster carer and 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.

3 Study Objectives

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: 1) modifying an existing clinical manual to meet the requirements of children with RAD and the UK foster care context, 2) testing the acceptability of the intervention from the point of view of practitioners and foster carers, and work with local authorities, foster carers, parents and young people to establish the optimal systems, procedures and ethical considerations required to identify and support children with RAD in UK foster care populations, and 3) investigate the feasibility of a randomised trial of the modified intervention.

3.1 Aims

Phase 1: Aim - Refine VIPP-FC for young children in foster care with RAD

Phase 2a: Aim - Conduct and evaluate a test case series

Phase 2b: Aim - Conduct a scoping study with key stakeholders to inform optimal trial design

Phase 3: Aim - Run a pilot RCT of modified VIPP-FC

4 STUDY DESIGN

4.1 OVERVIEW

A three-phase design will be employed. *Phase 1* will involve the refinement of the VIPP-FC manual through iterative consultation with an expert advisory group (including the developers, expert clinicians and foster carers), leading to the production of an initial treatment manual. *Phase 2* will involve the initial testing of the treatment (no random allocation) with a small series of children with RAD-type difficulties and their foster carers (*N*=6); in parallel with this, Phase 2 will also involve a scoping study of the organizational, ethical and practical landscape within which a trial of VIPP for RAD will need to operate. *Phase 3* will then recruit a new group of children in foster care with RAD, and undertake a pilot RCT of VIPP-FC (with random allocation).

As a treatment development and feasibility study, we propose a mixed-methods approach (broadly defined as a sequential explanatory design in phase 3), in which quantitative and qualitative data will be collected sequentially and integrated at the analysis stage in order to obtain a better understanding of the treatment development process, the organizational and professional context that will constrain the operation of a future trial, and carers', practitioners' and care managers' experiences and views of the programme, as well as evaluating the feasibility of a randomised trial using a small-scale pilot. In doing so, we adopt a pragmatic implementation-focused approach to establishing the initial feasibility of evaluating a complex intervention such as this, in line with the approach advocated in the MRC guidance (Craig et al., 2008). The clinical intervention and assessment framework is grounded in attachment theory and methods (Juffer et al., 2008), which conceives of attachment as a critical biobehavioural process that develops in the context of routine caregiving interactions, serving to support children's needs for comfort when they are anxious or vulnerable. In addition to providing a rich and evidence-based account of the environmental mechanisms that shape the development of attachment (which are the targets of attachment-focused interventions), attachment research provides a well-developed set of systematic and rigorously evaluated tools for

measuring attachment at different ages. In the current study, we use gold-standard instruments for evaluating attachment difficulties (the Disorders of Attachment Interview and the Strange Situation) so that we can show that their use is feasible within a clinical trial in this context, which will ensure confidence in the findings of any future full-scale trial.

4.2 METHODS

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 (Schoemakern et al., under review), 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, these 6 cases (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. 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 (Pope, Ziebland, & Mays, 2000), 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 (Kazdin, 2011). 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. The pilot trial may therefore begin before the case series' follow-up assessments have all been completed.

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. The first is that services for children in care are highly variable across different localities (NICE, 2010) and tend to be delivered by a range of different agencies and professionals, including the local authority, CAMHS and the third sector. There is no comprehensive source of information regarding usual care for children in foster care in the UK in general, and less still about what treatments are offered to children with RAD. This makes it difficult to know what a usual care comparator in a trial would consist of, or how one might select appropriate research sites so that consistency in usual care can be assured. A second important challenge is the legal position of children in foster care, which complicates the process of gaining appropriate consents (Bogolub & Thomas, 2005). Third, as noted by the NICE guideline group (2015), there is a great deal of confusion in clinical practice regarding the diagnosis of RAD, which has tended to lead to poor identification of RAD in young children, and particularly over-reporting of RAD in older children (Woolgar & Scott, 2014). Among other things, this means that we cannot rely on referral systems to identify appropriate cases. Furthermore, in light of the relatively small numbers of young children in foster care (from 2014 DfE data 18% of children in England who were looked after for at least a year were aged 5 and under, averaging 56 cases per local authority) and the uncertainty regarding prevalence of RAD in this population we will work collaboratively with several local authorities to ensure adequate recruitment (both for a full trial but also for a pilot trial). Setting up such a collaborative system of case identification will be crucial for the success of the study. Finally, for a range of reasons, including the sometimes-precarious position of young children in foster care, stakeholders are understandably concerned to ensure that participating in research does not impact on their care and wellbeing. Examples of concerns that carers, parents or social workers may have include whether participation in treatment has implications for the likelihood of reunification, the relationship between the local authority and birth parents, or whether randomisation disadvantages some children in receiving appropriate treatment. Carers and practitioners may also express ethical concerns about the implications for a child of receiving a RAD diagnosis. In our initial discussions with foster carers and practitioners in the local authorities, all of these were raised as important issues for this study to address.

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 (Smith, 1995), to elicit detailed accounts of clinicians', managers', social workers', foster carers' and parents' views regarding the key relevant questions listed above. 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 (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. Children with RAD will be identified initially using a large 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 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. VIPP-FC will be delivered in-home by trained CAMHS practitioners or other appropriately qualified VIPP-trained interveners. Baseline and end of treatment measures will include validated 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. In addition to these outcome measurements, we would also conduct qualitative interviews regarding carers' experiences of the programme and perceptions of VIPP among social workers and VIPP interveners. As a pragmatic study, we would aim to include as representative a group of children as possible and therefore we would aim to apply minimal exclusions based on comorbidity or type of foster care. 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.

4.3 Target Population

Children in foster care aged between 11 months old and 6 years old and their foster carer(s).

4.4 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*
(d) aged between 11 months and 6 years

Note: as outlined below, 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 trial based on the screening threshold (defined below).

For the pilot 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.

*If during the RCT phase number of participants deemed eligible is inadequate to allow delivery of the final study aim (i.e. run the modified VIPP programme for foster care) we will expand the eligibility criteria to include carers with children who do not necessarily meet the RAD criterion.

Exclusion criteria

Parental figure:

(a) already engaged in a similar parenting intervention.

Child:

(a) severe developmental disability.

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. It is a pragmatic requirement of this form of intervention that the foster carer has some proficiency in English language because of the reliance of this program on dialogue between the carer and practitioner as part of the video feedback procedure. Thus far, VIPP has not been tested using interpreters and we consider that this project is not the appropriate context in which to do such testing. Furthermore, on the basis of consultation with colleagues in the local authorities we have determined that very few foster carers would not have adequate command of English language to participate in the program. The RA in contact with the foster carer will make a judgement on the suitability of their English language, making sure they meet the minimal requirements necessary to take part in the study. While the program is suitable for children with a range of levels of cognitive ability and would be appropriate for children with physical and mild to moderate disabilities it has not been used before among children with very severe global delay; such global delay would also substantially complicate, if not preclude, a reliable RAD diagnosis and hence children with global developmental delay would need to be excluded from the study. This exclusion criterion will be assessed by asking carers if the child has any medical diagnoses relating to severe developmental delays. Due to the risk of participant over-burden and contamination/confounding of treatment effects, it would be problematic for families to be engaged in similar parenting interventions simultaneously and hence this is also an exclusion criterion. We do not consider it to be problematic that families are involved in other forms of social or medical treatment and

hence no such exclusion criteria are applied. Furthermore, we will explicitly assess the presence or absence of comorbid psychiatric conditions in the child because these may be important factors influencing both clinical management and outcome and are also likely to be quite prevalent. Exclusion on that basis would therefore be inappropriate. However, where other diagnoses are identified that warrant intervention (e.g., ADHD) we will notify the child's social worker and foster carer and recommend a referral.

Extensive consideration was given to the range of care arrangements that should be eligible for this pilot project. Children in foster care can be subject to a range of different care orders and placement arrangements (e.g., interim care order, full care order, Section 20 Voluntary placement). Children placed in family and friends care may be placed under a Special Guardianship Order, a Residence Order or a Care order and rarely as an informal placement. These issues are primarily relevant to the feasibility of intervention delivery rather than child mental health need (as children in all these circumstances are likely to present with raised rates of attachment problems and RAD). In consultation with colleagues in the local authorities, we have taken the view that this is a vital feasibility question, and exclusion on the basis of placement setting or type of order would unhelpfully limit the learning that this feasibility study could produce. Regarding family and friends care in particular, there was a clear view from our consultation, which was highly consistent with recommendations made by NICE (2015) that family and friends care, which is increasingly common, should be within the scope of this study. Children placed under a Section 20 (a voluntary placement, where the parents retain full parental responsibility), or on an interim care order, may present the most difficulties from a practical point of view because the duration of the placement will be uncertain. Nevertheless, it is not uncommon for such placements to last at least 6 months (i.e., long enough for an intervention to be put in place), and duration cannot be predicted in advance. Therefore, our view, which is supported by our discussions with local authorities, is that an inclusive strategy be taken. One critical point to emerge from these discussions is that there may be great value in considering adaptations to the intervention that allow for the programme to *follow the child* when there is a transition in the placement arrangements (e.g., to adoption, to a more permanent foster care placement, or back to the child's parents). A lack of continuity in care is a problem highlighted by many in the field and by children in care themselves (NICE, 2010, 2015). This process would be discussed carefully with the study advisory groups, and we will test, in a small number of cases as they arise, the workability of the plan they recommend. In such cases we anticipate that the work would not begin again, but would focus on transferring what has been learnt during treatment to the subsequent placement, and supporting a smooth transition.

5 INTERVENTION (PHASE 2A AND 3)

VIPP-FC will be delivered in two parts of this study – in the first phase VIPP-FC will be provided as part of a non-randomised pilot series to a small group of children with RAD symptoms (Phase 2A); subsequently, in the second phase, VIPP-FC will be provided as part of a pilot trial (Phase 3).

5.1 INTERVENTION DESCRIPTION

Video-Feedback to Promote Positive Parenting (VIPP): VIPP is a brief home-based attachment and parenting intervention: it is highly acceptable to families, has a clear and empirically supported model of change and has strong evidence of efficacy with families of young children in many settings (Juffer, Bakermans-Kranenburg & van IJzendoorn, 2008). Staff that have received training in the intervention will visit families at home for six 90-min sessions over 4 months. Sessions 1 to 4 take place biweekly and focus on improving carer sensitivity to the child. Session 6 is a booster session, and can take place approximately a month after the 5th session and focuses on consolidating the information provided in sessions 1 to 4 and teaching carers sensitive discipline skills. Sessions involve both carer and child and start by video-recording carer-child interactions, which provides the basis for themed discussion in the next session. Themes include recognising the child's attachment signals and expressions, providing prompt and adequate responses to them, promoting empathy for the child, praising positive behaviour, and appropriate ignoring of negative behaviour. Carers are also given exercises and tips. Session content is consistent across families, although its presentation and the video feedback are tailored to the specific needs of each family. VIPP has recently been modified specifically for the foster care context by the developers of VIPP in the Netherlands. This modified programme (VIPP-Foster Care [VIPP-FC]) pays particular attention to the need to help carers recognise signals that are specific to foster children--that may be quite challenging and difficult to understand--so that they are better equipped to respond sensitively, and to support the child's secure attachment to them as their carer. VIPP-FC is thus designed to specifically address the attachment difficulties often shown by children in foster care. In particular, these children tend to demonstrate attachment signals that are very subtle, highly distorted or absent – e.g. not crying when hurt because they are not used to being comforted; becoming angry or fearful when comforted. By helping foster carers become aware of these subtle, distorted or absent signals and training them to respond appropriately, the child can learn that foster carers can be relied on in times of need and that it is safe to show their distress and seek comfort. For many children in foster care, their experience of physical interactions with carers has been extremely negative in the past, and hence VIPP-FC also specifically addresses how to gently and sensitively support the child's needs for physical contact and comfort (see Schoemakern et al., under review).

5.2 CARE AS USUAL (CAU)

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. Initial consultations with CAMHS teams in our study sites, identified several likely treatments that may be offered within CAU: 1) Theraplay, 2) 1-3 sessions of foster carer consultation 3) network consultation, 4) Incredible Years, 5) foster carer support, 6) 6-12 sessions of psychotherapy, 7) behaviour support, 8) foster parent groups. As assessments of attachment disorders are rarely undertaken it is not possible to determine the extent to which the type and intensity of services offered to this particular group is different to other young children in foster care referred to CAMHS. 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, as well as detailed qualitative information from the scoping study (Phase 2b). The CA-SUS will ask participants to confirm whether they have attended any health services, mental health services, support services or childcare services and if so how many times they have attended these services in the last 6 months.

5.3 TRAINING

We will train a group of individuals from each NHS Child and Adolescent Mental Health Service (CAMHS) team involved in this study, as well as other appropriately qualified practitioners from other providers, in delivery of the VIPP-FC intervention. Each intervener will be trained by an accredited trainer, and will undertake supervised practice before becoming a study therapist. Accredited supervision will be provided to all practitioners during the pilot case series and feasibility trial.

5.4 TREATMENT FIDELITY

All therapeutic sessions will be audio recorded to enable assessment of fidelity by independent raters in 20% of sessions (tested using intra-class correlations, target ICC > .70). For every home-visit the practitioners will use a record form in which the goals and activities of the home-visit are described.

5.5 SETTING

This project is a multi-site collaboration between 3 universities, 5 NHS Trusts and linked local authorities and takes place across two large and distinctive regions in England, Greater London and the Yorkshire and Humber region. As noted already, a substantial number of local authorities is necessary to ensure adequate recruitment and to capture important variability in organisational contexts that will be important to understand when preparing a future larger-scale clinical trial. The identification of children in foster care with RAD will be supported by a screening mechanism run by the local authority in collaboration with the

university. If necessary additional support will be offered to the Local Authorities to do follow-up phone calls to foster carers by a member of the local CRN or the research team with appropriate honorary contracts. Also, during routine appointments, social workers will seek verbal consent from foster carers to pass on their contact details to the research team so that they can contact them directly to follow-up completion and return of questionnaires. Once potential participants have been identified by the screening process and indicated their interest in taking part by returning the initial questionnaires and consent form or completing the online consent form and online questionnaires, the assessment of eligibility will be undertaken by the research team through an in-depth assessment conducted in the participants' homes. After randomisation the clinical intervention will be delivered by practitioners from one of the participating intervention teams. Below we provide further contextual information regarding each of the sites:

North East London Foundation NHS Trust (NELFT): NELFT provides care to a population of around 1.75 million people. The CAMHS services provide support for looked after children in the local authorities of Barking, Havering, Waltham Forest and Dagenham, and will shortly extend to Essex (providing scope for additional recruitment sites for this study if necessary). The research is strongly supported by the Interim Medical Director and its Research Director is a co-investigator (Peter Fonagy). There are approximately 120 children in foster care under 7 (excluding Essex, which has a similar number).

Central and North West London NHS Foundation Trust (CNWL): CNWL provides care across a broad span of North West London, and beyond London. It employs approximately 7,000 staff to provide more than 300 different health services across 150 sites and in many other community settings. It provides CAMHS services across five London boroughs and to Milton Keynes. There are well-established links between CAMHS and social care in each of these settings, including specialist Looked After Children services. The local authorities covered by CNWL have approximately 250 children in foster care aged under 7.

South London and Maudsley NHS Foundation Trust (SLaM): SLaM provides a full range of mental health services to the people of Croydon, Lambeth, Southwark, and Lewisham as well as national specialist services. It has a budget of £290 million. The service is made up of five clinical units: National & Specialist, with a national & international reach and the local South East London boroughs of Lambeth, Southwark, Lewisham and Croydon. South London and Maudsley NHS Foundation Trust has the largest child and adolescent mental health service in the country. The local authorities have approx. 250 children in foster care aged under 7.

Tavistock and Portman NHS Foundation Trust (TPFT). TPFT provides CAMHS services for Camden and Haringey Local Authorities in north London. The Haringey First Step service uniquely provides psychological screening for *all* looked after children in Haringey. The Tavistock has an active collaboration with the developers of VIPP at the University of Leiden and is the leading UK centre for VIPP training. Currently there are approximately 450 LAC in Haringey and around 100-150 are under 7 years.

Leeds and York Partnership Foundation NHS Trust (LYPFT) provides services for City of York local Authority (population 200,000) and North Yorkshire Local Authority (population 600,000). LYPFT runs in-patient and specialist CAMHS, while community CAMHS is run by Tees Esk and Wear Valley (TEWV) Trust. LYPFT has excellent links with TEWV and if needed TEWV could also be engaged in the study. These two authorities have around 120 children in foster care under 7 year.

6 SAMPLING AND RECRUITMENT

6.1 STUDY SAMPLES

Pilot Intervention Series

For *Phase 2a,* the pilot case series (non-randomised), we aim to recruit 6 cases for piloting the clinical intervention in a systematic case-series. Recruitment for this pilot case-series will also provide an opportunity to pilot the screening process that would operate on a larger scale in phase 3. Specifically, we will work with up to two of the Trusts for this initial pilot screening and case-series. As noted above, cases would be screened using screening instruments, and we propose to include a mixture of cases meeting RAD diagnostic criteria and some falling just short of this threshold in order to explore whether the intervention requires adjustment for both of these groups of children, and to maintain the pace of manual development in the event that prevalence is lower than expected.

Qualitative Scoping Study

For *Phase 2b* (the feasibility scoping study) we will conduct qualitative interviews and scrutinise documentary data sources in collaboration with participating local authorities and CAMHS services. 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 parents (N=3) across the two geographical locations (N=24 interviews in total). These stakeholders will be purposively chosen to reflect the range of different service contexts so that findings will be as generalisable as possible, and it is anticipated that this sample size will capture a diverse range of views without necessarily reaching data saturation.

Pilot RCT

For *Phase 3* (the pilot RCT) we will again undertake a screening process to identify children in foster care with RAD. We will then randomise 40 children (and their carers) to receive either VIPP (plus care as usual) or care as usual only. Based on data obtained from the Department of Education from 2014 (which we have corroborated against a selection of figures obtained in 2016 from our participating local authorities) we expect the full population of children in foster care in our target age groups across sites to be in the region of 700. Previous research experience with this population and on the basis of our small pilot screening, we would expect more than 80% of foster carers to take part in the initial screening and return the questionnaires. This estimate seems reasonable, since in the study of Green et al. (2014) of 523 foster families who were approached, only 56 refused (a further 57 were ineligible). Conservatively therefore we will aim for a sample size for the screening stage of 500. In order to identify cases likely to be diagnosed as RAD we will choose cases above the highest 66th percentile for symptoms of RAD (initially based on normative data), leading to a sample size of 150 who would be invited to take part in a more in-depth assessment. We expect a minimum of two thirds of those to agree to take part and complete the assessment. In the randomised controlled trial of the Fostering Changes programme, (Briskman et al., 2012) 77/125 took part in the intervention (following a higher rate of initial interest and questionnaire return), so two-thirds agreeing to an initial assessment is a conservative estimate. From this pool of 100 children we would therefore have scope to identify at least 40 cases that would be eligible for treatment as long as the prevalence of RAD in the high-scoring screened group was 50% (allowing for a further 10% dropout at this stage). Note that we would seek to obtain consent to treatment at the in-depth intake assessment stage, which is why we estimate the throughput of cases to be lowest at this point. As noted already, we lack reliable information concerning the prevalence of RAD in UK foster care and so the 50% prevalence within the population of children exceeding the symptom threshold is subject to uncertainty. Consequently, we propose an interim analysis after 15 cases have been assessed to establish whether the proportion of RAD cases is below this expected proportion. The lower bound of the 95% confidence interval around a proportion of .50 is .22 with a sample size of 15. Thus, identification of fewer than 3 cases out of 15 would suggest that the prevalence is lower than .50. In this event, we propose to widen the eligibility criteria to include children scoring over the screening threshold, but not meeting full RAD diagnostic criteria.

The sample size targets above are reasonable based on considerations of the level of precision with which we can identify key feasibility parameters, in particular the proportion of participants successfully consented (of those identified/approached) and the proportion of participants successfully completing the post-treatment outcome assessments (of those randomised), which we view to be key feasibility questions. A sample size of 40 provides a reasonable balance between precision and cost. Assuming the proportion of

participants successfully completing the key outcome assessment is 75% (30/40; note that in the Fostering Changes trial this figure was 80%), then this yields a 95% CI of 59% to 87%. The consent/up-take rates will be estimated at two stages – for consent to take part in the eligibility assessment, and following eligibility, the proportion entering treatment/being randomised. The former will be estimated with higher precision as they are based on larger samples. Assuming 67% (100/150) take part in the eligibility assessment, this yields a 95% confidence interval of 59% to 74%. Similarly, assuming that 80% of cases identified with RAD (40/50) go on to be randomised, we would obtain confidence intervals around that proportion of 66% to 90%.

6.2 Recruitment and Consent

Phase 1 Manual Development: No research participants are involved in Phase 1, and so recruitment and consent considerations do not apply.

Phase 2b Scoping Study:

For the qualitative interviews that contribute to the phase 2b scoping study our colleagues in the collaborating local authorities and CAMHS teams will contact local authority children's service managers, social workers and CAMHS practitioners by email, providing an information sheet and study contact details for interested parties. VIPP interveners delivering VIPP-FC with other appropriate providers may also be invited to take part in this stage of the study. Foster carers will be contacted through community foster carer groups, to whom information sheets will be distributed. Finally, parents will be approached by the local authorities through their parent liaison groups and provided with an information and study contact details for those interested in taking part.

Information sheets will be provided detailing the qualitative study process and confidentiality arrangements, and written, informed consent will be obtained from all parties prior to interviewing.

Phase 2a and Phase 3 (Intervention)

As the recruitment and consent process for the non-randomised pilot case series (Phase 2A) and the pilot RCT (Phase 3) are essentially the same, we describe them together in this section.

Screening and identification stage

As noted above, the screening process we envisage will be essential to the success of this project and will depend on an effective collaboration with local authorities, who will send out information sheets, initial consent forms and screening measures to all foster carers in the study localities. In addition, local

authorities will send out a letter to all parents explaining the study and the opting-out process, including contact details of the research team. In Phase 2A we will work with up to two local authorities, and will screen approximately 100 children. In phase 3 we will aim for a minimum screening sample of 500 foster carers from 6-10 local authorities. In both cases, all foster carers or special guardians registered with the local authority caring for children under 7 will be sent an information sheet, screening measures, a consent form and contact details of the research team so that they may ask questions if they wish. Screening measures and completed consent forms will be returned using a pre-paid envelope by foster carers to the University or completed online via study database, Redcap. Letters will also be sent to foster care agencies with information and contact details of the research team that may be given to potential participants registered with these organisations. Where self-referrals are received, foster carers will be asked for the child's social worker's details in order for the local authority to initiate the screening process, including contacting the birth parents. As with the families that are contacted through the local authorities, self-referrals will have the contact details of the research team if they wish to discuss the study in more detail. A minimum two-week period will be given between sending out the letter to parents and initiating the child's participation in the study.

Once initial consent forms (paper and online) and screening measures have been received by the research team, they will contact participants, thanking them for their response and re-iterating the research process. Invitations and follow-up phone calls will be made to all foster carers reporting RAD symptoms over the screening cut-off to take part in a face-to-face interview assessment to confirm eligibility (establishing diagnostic status). This interview would take place at the foster carer's home.

As the screening/identification stage (which consists of a postal and/or an online survey and carer interview) involves no direct contact with the child and involves minimal burden or risk, we will only obtain active consent from the foster carer. However, a letter will be sent to all parents with an explanation of the study and the process of opting-out (except in circumstances where the local authority deems this inappropriate). If after the two-week period for opting-out the Local Authority or the research team has not been contacted by the parent to opt-out, the screening process will be initiated. Foster carers will receive an information sheet explaining the study fully, and a contact telephone number of a member of the research team if they have any questions. The information sheet will explain that completing the screening measures does not entail any obligation to participate in the other stages of the study (the pilot intervention). Written consent will be provided on the consent form (completed by the carer but not a member of the research team at this stage) and posted to the research team along with the screening questionnaires. The study team will receive email notifications from the study database when a participant

gives consent and completes the questionnaires online. Both paper and online consent forms will require the carer to provide their contact details (including the child's initials) in order for the research team to contact them if they meet the screening cut-off. Carers will be given a £10 voucher to thank them for completing the screening questionnaires.

Post-Screening Stage

If eligibility is confirmed, a baseline assessment will take place as quickly as possible (the target will be within 4 weeks). The baseline assessment will take place either in our partner CAMHS services, the local authorities premises, or within the University (UCL) depending on the preference of the foster carer. The research team will liaise with carers about the outcome of the randomisation. Carers will be paid £30 at both the baseline and post-intervention outcome assessment to thank them for their time. Carers will also be reimbursed any travel expenses.

The determination of who must provide consent for a child in foster care to take part in a research study, and how this should be done, is recognised in the literature as a complex problem (Bogolub & Thomas, 2005). An important aim of the current study is to investigate the range of views on how this should be achieved, from local authorities in different regions, and from parents and carers. However, our starting point for the purposes of this study is to follow a procedure used in another NIHR pilot trial being conducted by our group for older children in foster care (6-16 years; NHS REC reference 15/EE/0032). The consent protocol for that study was developed from a review of the literature, and consultation with a local authority Director of Social Care and their legal department. The general principle informing the protocol is that written, informed consent to take part in the study must be received from all parents and from the local authority when holding parental responsibility and that every effort should be made to secure the consent of parents where they do not have sole legal parental responsibility. For children on full care orders, an opt-out letter (with a 14-day period for opting-out) will be used. Children on a full care order may enter the trial without parental consent if the local authority (who may act as Corporate Parent) deems it not in the child's best interests to seek it, or where every attempt has been made to inform parents of the study and to secure consent, but this has failed. For all other children, full written consent will be obtained from the child's parent. Active refusal of consent by a parent would always be respected regardless of the care order. Furthermore, a parent's decision to withdraw their child's involvement once the child has started in the study will again be respected regardless of the care order. Full informed consent would be obtained from all participating foster carers. As the children will all be aged 6 or under they will not provide written consent, but the researchers will be trained to obtain verbal assent in an age appropriate fashion for children old enough to do so (age 4 years and older). For children aged 5-6 years,

information sheets will be provided, with the expectation that the researcher or foster carer will help children read the information. Such forms will be provided prior to the research visits (initially supplied by post to the carer to read to the child, then reiterated by the researcher at the start of the visit), and prior to the first intervention visit for those children assigned to VIPP-FC. The child's social worker will initially make contact with the parent(s), and will provide parents with the information sheets, and obtain verbal consent for their contact details to be passed to the research team. Full written consent will then be sought by a study researcher, which will also provide opportunity for parents to ask more in-depth questions.

Note that for the completion of the screening measures and Disturbances of Attachment Interview (for details, see below; these measures will be conducted in the carers' home) we will only obtain active consent from the foster carer, as it does not directly involve the child, and will initiate the more comprehensive consent process (consent to in-depth assessment and treatment), as described above, after the screening/identification stage. The forms of care order and their respective documentation are listed in Table 1.

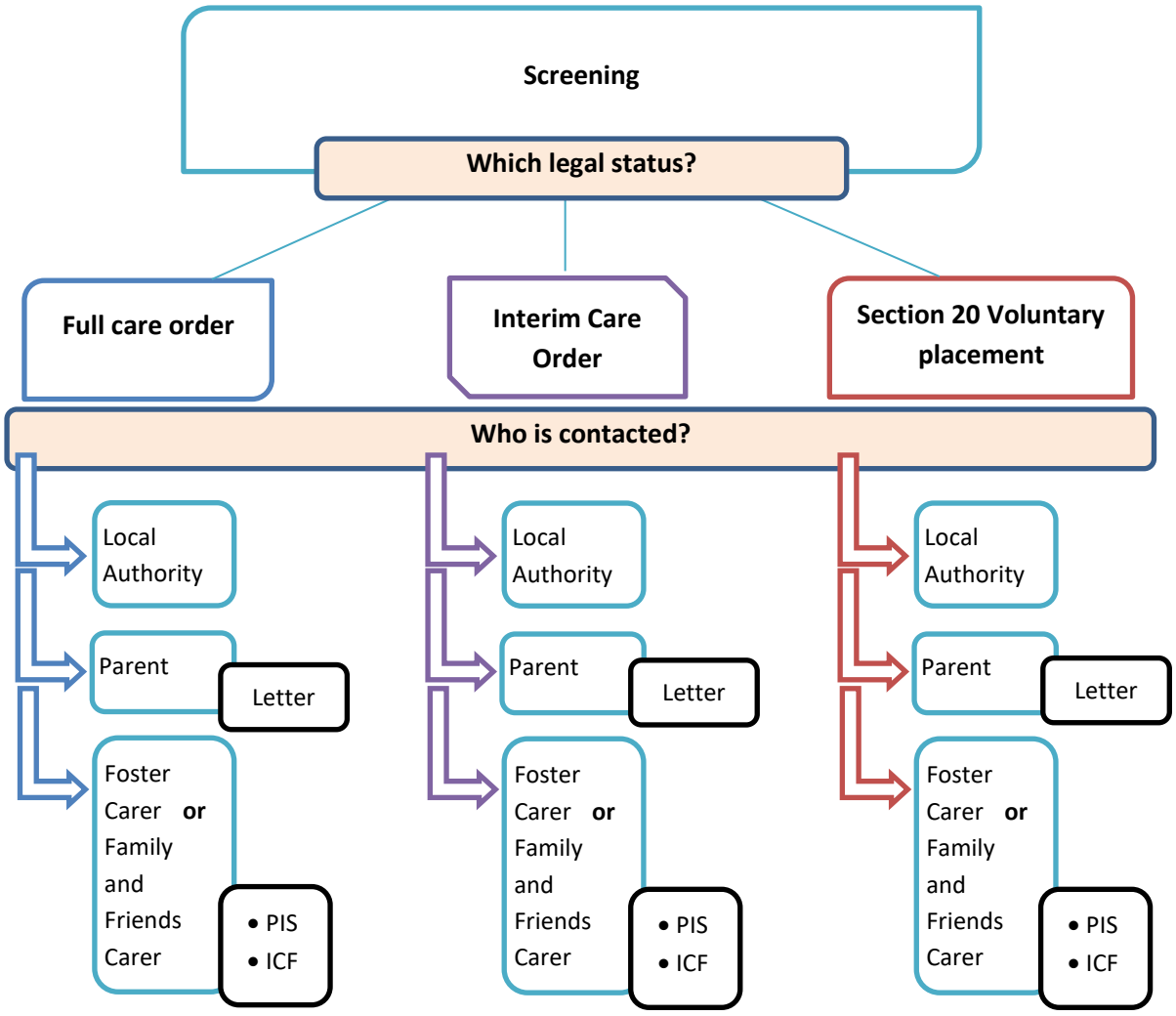
Additional/Optional consent

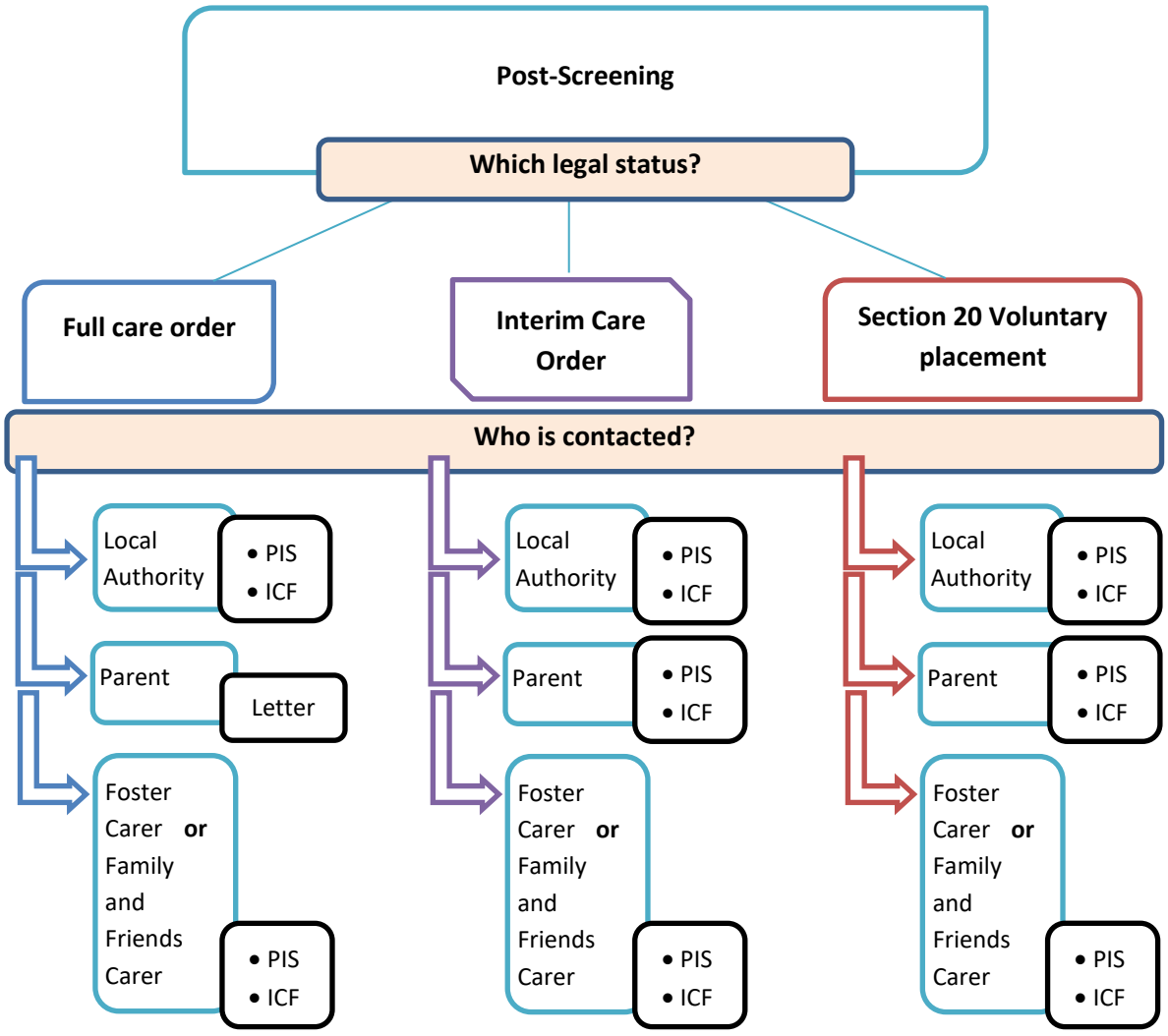
The video recordings obtained during the study provide an opportunity to share learning about the processes and outcomes of this study and, particularly, the modified VIPP-FC manual, among practitioners and other relevant professional audiences.

Participants who have consented to taking part in the study and have been randomised to receive CAU+VIPP will be approached to ask if they are willing to give permission for the video recordings to be used for such purposes. We will use Optional Consent to Use Recordings Form to document this, which will be given to participants at the follow-up/post-intervention research visit.

Dissemination of video material will be strictly limited to professional contexts such as intervenor training and professional conferences. We will use software to disguise participants' faces when using recording material in professional conferences.

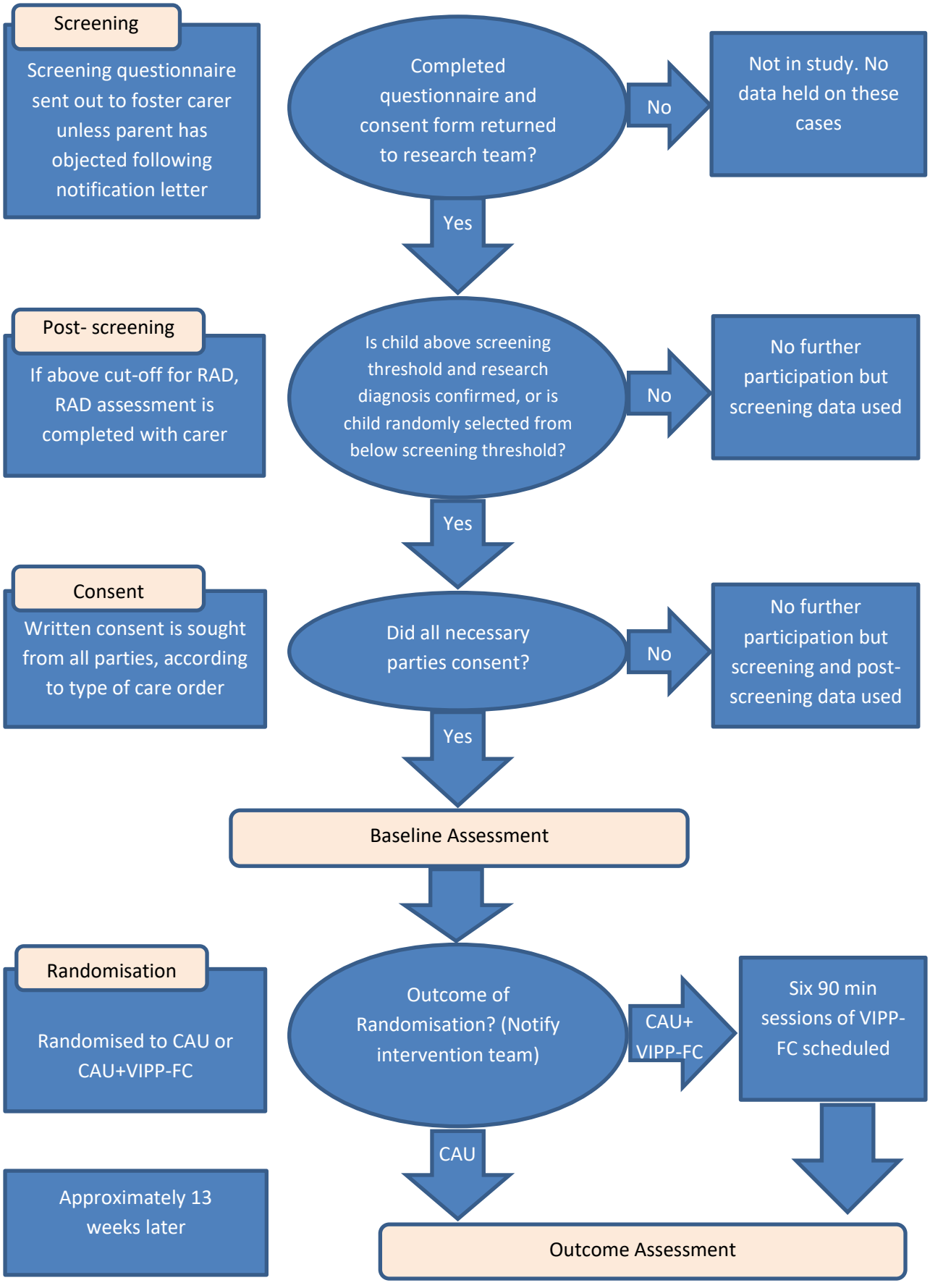
Figures 1 and 2: Consent and study documentation in relation to child's legal status (ICF: Informed Consent Form; PIS: Participant Information Sheet)





Note: These same procedures will be used in a limited roll-out for phase 2a (without randomisation).

Figure 3: Process of recruitment, screening, and randomisation for the pilot trial (phase 3)



Phase 2b (Scoping Study): Qualitative Interviews

6.3 Randomisation (Phase 3)

Participants will be individually randomised in a 1:1 ratio to one of the two treatment arms, CAU + VIPP-FC or CAU-only. Randomisation with minimization will be employed, with minimization factors age (<=4 versus >4), gender and site. Minimization will include a random factor, as implemented in the minimisation program Simin (Wade, Pan, Eaton, Pierro & Ong, 2006). Randomisation will be requested by a member of the research team following completion of all necessary screening and consent procedures, and will be performed by an unblinded member of the trial coordination team. The allocation list will be held in the Trial Master File. We will write to the child's social worker, and VIPP intervener – the latter for those allocated to VIPP-FC. The foster carer, and the individual(s) giving consent on behalf of the child (the parent and/or local authority social worker with parental responsibility as appropriate, see consent section) will be notified of the outcome by letter by the unblinded member of the trial coordination team. The foster carer will also be contacted by telephone (target within 24 hours) to ensure a timely initiation of intervention.

7 Data Collection and Data Management

The data collection instruments are described in relation to each of the data collection phases (Phases 2 and 3).

7.1 Phase 2b Scoping Study

In the scoping study, single qualitative interviews will be undertaken with key stakeholders in their place of work (social work managers, directors of children's services, CAMHS practitioners or other VIPP interveners, and managers) or at home (foster carers, parents) using semi-structured interview schedules developed iteratively via consultation with the study team and advisory groups.

7.2 Measures for Test Case Series (Phase 2a) and Pilot RCT (Phase 3)

Screening Measures

The process of screening of symptoms of RAD is not straightforward, and no fully validated instruments for this purpose exist. This in itself is a significant gap in health technology in this field, as early detection may be critical for improving outcomes for children in care. We propose to use two different instruments that each have their individual limitations, but should make it possible to robustly screen for symptoms of RAD when used together. *The Attachment Screening Assessment* is a new instrument designed specifically to

capture behaviours reflective of the DSM-5 symptoms of RAD and DSED, as well as attachment classifications. The RAD items in particular therefore have greater face validity than the other widely used instrument, the Relationship Problems Questionnaire (RPQ), and have also been found to discriminate well between children in care and those from the community, as well as children with greater overall psychopathology on the SDQ. However, the ASA has thus far not been validated against formal diagnostic assessments, which limits the extent to which it could be used alone as a screening measure. *The Development and Well-Being Assessment (DAWBA)* includes a recently revised set of diagnostic items for DSM-5 RAD. We propose to use these two instruments so that we can test the optimal configuration of items for case identification. This will be achieved through expert consensus and will be combined with adaptive prediction methods as data comes in (specifically, adjusting item weights based on accumulating data from full diagnostic assessments). Since this is a feasibility trial we believe this to be the best way of approaching the uncertainty about the optimal screening tools in this area.

Primary Outcome: Attachment Measure

The Disturbances of Attachment Interview (DAI; Smyke & Zeanah, 1999) is a semi-structured interview to evaluate the presence of signs of disordered attachment (and is recommended by the NICE Guideline on attachment problems in children in care). For each of 12 sections, the interviewer asks multiple questions and follow-up probes sufficient to yield a rating reflecting degree of evidence of disturbed or disordered attachment: 0 = none/never, 1 = somewhat/sometimes, and 2 = considerable/frequently. The first five sections of the interview address signs of emotionally withdrawn/inhibited attachment disturbance (i.e. RAD), yielding total scores ranging from 0 to 10. The next three items address signs of indiscriminate behaviour, and the last four items address other signs of disturbances in attachment behaviour (known as 'secure base distortions'). There is sound evidence for the validity of this measurement system. First, it distinguishes between institutionalised and non-institutionalised children (Smyke, Dumitrescu, & Zeanah, 2002; Zeanah, Smyke, & Dumitrescu, 2002), reliably identifies signs of attachment disturbance in maltreated children (Zeanah et al., 2004) and validly distinguishes RAD from DSED (e.g., Oosterman & Schuengel, 2007). Second, it has shown very good interrater reliability (Oliveira, Fearon, Belsky, Fachada, & Soares, 2015) and high levels of internal consistency (Smyke et al., 2002; Zeanah et al., 2002). Third, criterion validity has been demonstrated through the convergence of attachment disorder diagnosis by different measurements. Construct validity has also been demonstrated by the association of DAI ratings with quality of care (e.g., Oliveira et al., 2005).

Secondary Outcome Measures

Attachment insecurity and disorganization

Strange Situation Procedure: Participants will be observed with their foster parent in a laboratory room for the Strange Situation Procedure. The SSP is a standardised procedure, lasting a maximum of 21-minutes. It is divided into a series of episodes involving brief separations and reunions with the parent/caregiver, exposure to an unfamiliar but friendly adult female, and a period of time alone. These episodes are videotaped for subsequent rating by trained coders, resulting in a classification of the infant–parent dyad into one of the four attachment categories: secure, insecure-avoidant, or insecure-resistant and insecure disorganized. For children older than 24 months, an adaptation of the administration of the SSP (mainly concerning timing of each episode) and the respective coding system for the pre-school years will be implemented (Cassidy & Marvin, 1992). Even though the pre-school rating system was originally created for children up to the age of 54 months, we do not anticipate problems in extending it to the 6 year-old participants. Indeed, the pre-school system was created based on the assumption that the "strategies" associated with each one of the three major attachment categories remain the same throughout development. Beyond the classification of attachment categories or patterns, there are additional aspects of behaviour captured by the SSP that can be very informative for understanding the child's socio-emotional functioning. Namely, an observation of the child's behaviour toward the stranger and the parent, during the episodes of the SSP, has been used to objectively rate their levels of indiscriminate attachment/social behaviour. The Rating of Infant and Stranger Engagement has been used from 12 months to the pre-school years (Lyons-Ruth, Bureau, Riley, & Atlas-Corbett, 2009). Regarding behaviours indicative of RAD, an observational system based on the SSP episodes is being developed by our collaborators, and will be available for use in this study (known as the Rating of Inhibited Attachment Behaviour (RInAB; Corval, Fachada, & Soares, unpublished manual). This coding system rates the child's attachment, exploratory, and socio-emotional behaviour that is relevant for the conceptualisation of RAD. A continuous score as well as a classification of whether or not the child is considered to present RAD are obtained.

Co-occurring disorder/difficulties

• *The Development and Well-Being Assessment* (*DAWBA)* will be used to assess the presence of psychiatric diagnoses co-occurring with RAD, via foster carer interview. The DAWBA is a well-validated diagnostic interview schedule that has been recently extended to children as young as 2 years of age, and has been updated for DSM-5. The DAWBA has been used extensively in clinical trials and epidemiological studies. The system has high-levels of inter-rater reliability and provides automated algorithms for scoring and assigning diagnoses. Note: due to some limitations in its validity for assessing RAD, we rely on the DAI for this diagnosis.

• *Child Behaviour Checklist* (foster carer report): This a very widely used carer-reported questionnaire for assessing children's emotional and behavioural problems and yields well-validated continuous measures of

internalizing problems, externalizing problems, total problems and specific 'syndrome' scales for narrow band symptom areas (such as attention problems, aggression, social problems). It is valid for children from the age of 1.5 years and has age appropriate forms for children aged 1.5-5 years, and 5 years and above.

Broader impact measures

• *Observed carer sensitivity*: We will use standardized observational procedures for assessing carer sensitivity during free play, and routine caregiving interactions (e.g., a snack, completing a challenging task). The interactions will be video-recorded, and scored blind to treatment condition and status (pre- versus post) by trained researchers. The scoring system used will be the Emotional Availability Scales, which have been extensively validated as indicators of interactions relating to attachment (Biringen, 2000). The interactions will be scored by a reliable coder (certified by the coding system developers). As in all our studies, interrater reliability will be tested on a proportion of cases (minimum 25%).

• *The Parent Stress Index* – Short Form (Abidin, 1990) will be used to assess carer wellbeing, strain and the carer-child relationship.

• *The Parenting Efficacy Scale* (Woolgar et al., 2012), a measure of beliefs and confidence about parenting skills.

• *Child and Adolescent Service Use Schedule* (CA-SUS; Barrett, Byford, Chitsabesan, & Kenning, 2006); assessing resource use for health economic evaluation.

• Practitioner feedback forms, to provide qualitative feedback about the experience of using VIPP in practice.

This battery of outcome assessments is similar to those we have used in other trials and cohort studies, and our previous experience is that it is not excessively burdensome. However, we will engage in extensive consultation with foster carers (through the carer advisory group) regarding acceptability and burden, and any changes recommend by that group will be implemented. Establishing the optimal balance between participant time /burden and the robustness of the outcome assessments is an important aim of this project as preparation for a full-scale trial.

	Time Point

Measures	Screening	Post-Screening interview	Baseline	Post-Treatment
DAWBA	X (attachment related items only)		X (excluding SDQ)	X
ASA	X			X
DAI		X (plus SDQ)		X
SSP			X	X
CBCL			X	X
EAS			X	X
PSES			X	X
PSI			X	X
CA-SUS			X	X

Acronyms: DAWBA - The Development and Well-Being Assessment; ASA - Attachment Screening Assessment; DAI - The Disturbances of Attachment Interview; SSP - Strange Situation Procedure; CBCL - Child Behaviour Checklist; EAS - Emotional Availability Scales; PSES - Parenting Self-Efficacy Scale; PSI - Parenting Stress Index; CA-SUS - Child and Adolescent Service Use Schedule; SDQ – Strengths and Difficulties Questionnaire

The research team will attempt to follow-up all families involved in the study, this includes children who have moved to a different placement or who have been given a different care order during the time of the research. Any additional relevant consent that may be required due to placement changes will be obtained (e.g., from the new carer).

Process Data and Qualitative Outcomes

Process data will 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. Records will be kept of the number of families approached and who refuse to take part in the study; data will also be obtained on the range of care pathways observed (e.g., distribution of care orders and placement types, e.g., family and friends care, long-term foster care), numbers moving placements before or after treatment has commenced, and destinations and timing of any movements out of placement). Records will also be kept

of essential information on the child's previous history, such as alleged existence of neglect or abuse and reasons for being taken into care. This data will be obtained from the child's social worker, supplemented with foster carer input and routine social work records. Reasons for refusing to take part in the study, and for dropping out of the intervention will also be examined (see below).

The acceptability data will involve the conduct of qualitative in-depth interviews with all families who received the intervention as part of the pilot RCT (N=20); and brief telephone interviews will be conducted with as many families as possible who refused to take part or who dropped out. The interviews will be conducted at a time of convenience to the participant either in their own home or a setting of their choosing, following the conclusion of the intervention and collection/analysis of post-intervention data. The interviews will be used to examine the factors that facilitated change in those families for whom the quantitative symptom and diagnostic assessments show an improvement in outcome, and the factors that hindered change in those families for whom the quantitative data shows no or some change. Brief telephone interviews will also be conducted with families who did not wish to take part and those families who dropped out, but who are willing to provide consent to take part in these brief telephone interviews. These interviews aim to examine the factors that contributed to their discontinuation with the intervention. The interviews will also be used to explore with families the acceptability of the outcome measures that were utilised.

7.3 Data Management

The data in this study will be collected and processed in accordance with the Data Protection Act (1998). Management of the data will be overseen by the Chief Investigator Pasco Fearon with support from the Trial Coordinating Team. The case-series and pilot data will be collected by an experienced research assistant who has been trained to work with high-risk populations. The RA will be blind to treatment allocation, with all data issues related to unblinding being handled by the Trial Coordinating Team. Regular supervision with the Chief Investigator, Trial Coordinating Team and core study team (RAs) will ensure the reliability of data collection. Where necessary the RAs will be fully trained and certified in administering all research measures. For data that requires coding using standardized measures we will employ trained reliable coders, ensuring sufficient Inter-Rater Reliability (IRR) amongst coders.

7.4 Data Storage

Although a number of NHS Trusts and higher education institutions are involved in this study, all data will be collected, collated and stored at UCL. Information that the family will be taking part in the trial and the

treatment arm to which they are allocated (either CAU and VIPP-FC or CAU only) in the pilot trial (phase 3) will be communicated to the local authority and intervention provider. Any other data shared will be in an anonymised format (e.g. for analysis at Imperial College).

Paper documents

Data collected at all stages will be recorded as a hard copy on paper. The paper forms, along with other paper documents such as consent forms and letters, will be stored in a locked cabinet at UCL, accessible only to members of the research team. These will contain identifiable data as carers will need to provide contact details when returning the screening forms. In the event of participant withdrawal we will seek approval to retain the data previously collected on the participant. If the participant would like to withdraw and to have all data collected removed from the study then we will respect their decision. However, in the event where participants are lost to follow-up and we are unable to contact them, we would proceed to use their collected data consistent with their most recently signed consent.

Database

Data for phase 3 (pilot trial) will then be transcribed onto the trial specific database by the RA. The database will be built using REDCap, a secure web application for building and managing online surveys and databases. Data entered onto the database will be anonymised, with participants identified by a randomisation code and no information that could be used for identification included (e.g. date of birth). A master log of participants that are randomised will be kept as a paper document in the Trial Master File, detailing names and randomisation code. The Trial Master File will also be stored in a locked cabinet at UCL, separate from the participant files and accessible only to members of the trial coordination team and Chief Investigator.

Identifiable data (video and audio recordings)

As part of the study procedures, audio recordings will be made of participants during VIPP-FC session and as part of phase 2b. Video recordings are also made during the VIPP-FC sessions and research assessments. These recordings will be stored within the UCL data safe haven or Citrix, two secure and accredited technical solutions for storing, handling and analysing identifiable data that conform to the NHS Information Governance Toolkit. A standard operating procedure will describe the process of transferring the file from the recording device, ensuring that it is stored correctly and then deleted from the recording device.

8 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).

9 ARCHIVING

Good clinical practice compliant archiving will be completed for the trial master file and all other essential documents, including all those relating to the participants. This will be done following submission of the end of trial report to the REC, and according to UCL archiving procedures. The files will be archived for 10 years.

10 ANALYSIS

Feasibility parameters 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 (see Brown, 1995). Specifically, we will test the following feasibility parameters:

A. Test the feasibility of identifying sufficient numbers of appropriate cases using screening instruments.

1. Target N for screening tests returned N = 500. Test a.1 = proportion and 95% CI of those returning screening instruments from total sent out.

2. Target N of diagnostic assessments N = 100. Test a.2 = proportion and 95% CI of positively screened cases (above upper 66th percentile) agreeing to full assessment.

3. Target N for positive diagnosis from upper 66th percentile of screened cases N = 50. Test a.3 = proportion and 95% CI of cases where diagnosis is confirmed.

4. Test a.4: initial test of false negative rate = proportion (of 25 cases) and 95% CI of detected diagnoses in random sample of cases not meeting screening threshold.

5. Initial non-parametric ROC curve analysis (total N = 125), based on assumption that DAI diagnosis is gold standard.

B. Test the feasibility of recruiting/consenting foster families with children with RAD to an RCT.

1. Target N of consented cases N = 40. Test b.1 = proportion and 95% CI of cases consenting to enter pilot trial from those meeting entry criteria.

C. Investigate feasibility of randomising to VIPP-FC or CAU.

1. Test c.1: proportion and 95% CI of cases accepting randomisation.

D. Document study throughput.

1. Test d.1: proportion and 95% CI of cases randomised completing treatment (definition of completing= 80% of offered sessions).
2. Test d.2: proportion of cases attending each session (6 proportions and 95% CIs).
4. Acceptability of treatment: means and ranges of client satisfaction survey. See also qualitative methods for client experience of treatment interviews.

E. Establish the feasibility and acceptability of baseline and outcome assessments.

1. Test e.1: proportion and 95% CI of cases with complete data. See also qualitative methods for client feedback regarding measures.

F. Identify the most appropriate primary outcome. Key assessment is participant feedback from qualitative interviews. However preliminary tests from H.2 below may also be informative.

G. Obtain initial estimates of variance of key outcome measures and constrain effect size estimates for future power analyses.

1. Test h.1: S.D. of RAD symptom counts and 95% CI.
2. Test h.2: Mean post-treatment group difference and 95% CI (though please see point 8 above).

H. Establish the optimal and most acceptable screening tools for RAD as recently redefined in DSM-5. Tested with qualitative interviews and tests a.4 and a.5 above.

Qualitative Data Analysis:

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. The final report will describe the key themes using quotations to demonstrate the findings.

10.1 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 (Byford et al., 2015) and is currently being implemented in an evaluation of a mental health screening and early intervention

for under 4s, including looked after children (Murphy, 2016). 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.

11 PROJECT MANAGEMENT

The project will be led by Pasco Fearon as Chief Investigator, who will retain overall responsibility for the management of the study, including governance, financial oversight and progress reporting. Pasco Fearon will take responsibility for day-to-day supervision of the research assistant and trial management team, with input from Paul Ramchandani. Each collaborating trust will have a Core study team member allocated to it, who will manage relationships, recruitment set-up, monitoring and communications with their trust and its associated local authorities, with input from the CI where appropriate. Paul Ramchandani will cover CNWL, Matt Woolgar SLAM, Pasco Fearon NELFT, Barry Wright LYPFT and TEWV, and the Tavistock and Portman will be jointly overseen by Rob Senior and Eilis Kennedy. This Core Study Team will meet regularly to ensure coordination and monitoring of the practical implementation of systems for recruitment, and the establishment and monitoring of the clinical service delivery of VIPP in each locality. The trial management team will take responsibility for liaison with the sponsor and ethics committees, setting up secure data capture systems for multi-site data collection, and preparing data quality and progress reports for the Steering Committee and HTA. Peter Fonagy will chair the expert and carer group advising on clinical manual development, and advise on trial design and implementation. Stephen Scott will work closely with the CI in preparing the pilot trial from the point of view of implementation within a foster care setting, as well as

contribute to the work of the treatment manual development group. Danya Glaser will provide expert input to the treatment development group, and will oversee the measurement aspects of the RAD screening system. Jane Barlow will manage the qualitative/mixed methods evaluation. Will Hausrath will lead the carer and care-leaver advisory groups, contribute to the expert and carer advisory group and provide regular input to the core study team regarding foster carers' perspectives on study measures, information sheets and clinical process. There will be quarterly full team meetings at which all investigators would be present.

11.1 GOVERNANCE:

A Steering Committee will be established which will include senior researchers and practitioners with experience in treatment development studies and trials and PPI representatives. The steering committee will meet up to five times and will be used to monitor the progress of the project and advise the research team on matters arising during subsequent phases of the study. The committee will be chaired by an independent senior researcher with extensive experience in the field. The steering committee will receive reports on serious adverse events and data quality from the trial coordinating team.

12 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

1) Academic dissemination: This will include publication of the manual and its development process, a paper on the multiple test case series, a policy/implementation paper on practical barriers and solutions to running attachment-focused trials in the foster care setting, the pilot trial protocol, and the results of the pilot trial. We plan for members of the team to attend two international academic conferences.

2) Foster carer and general public audiences: We will disseminate findings through our institutional websites, a designated project website and through our partner organization the NSPCC. Members of our PPI group will attend, with members of the study team, two national foster care and/or social work conferences such as the British Association of Adoption and Fostering (BAAF). Our findings will be fed back through local meetings with foster care and adoption organizations and agencies (e.g., By The Bridge Fostering, TACT Fostering, Coram), and local authority foster care groups.

3) Clinical and policy audiences: Within local services we will hold regular seminars updating on the progress of the study and later reporting the outcomes of the study. The clinical manual will be made available to participating CAMHS and local authority teams during the study to facilitate dissemination and learning. On a national and international level, we will liaise closely with the NIHR, national organisations (especially the NSPCC) to ensure that national clinical and policy audiences are aware of the project. In addition to academic publications we will also aim to produce a summary publication in a peer-review article for community practitioners, such as Adoption and Fostering. We will also create a short accessible summary of the findings for services, particularly social care services, GPs and CAMHS.

13 TIMETABLE

The study is planned to run for 30 months. Phase 1 (4 months) will adapt and produce intervention manuals. In Phase 2 (6 months) we will train therapists, undertake initial feasibility testing and further examine key implementation parameters. Phase 3 (20 months) will be a pilot RCT, with 12-months for recruitment, 4 months for treatment and outcome assessment and 4 months for final analysis and dissemination. A GANTT chart is presented in Appendix 1. A summary of the key stages of the project is provided below:

Preparation Phase
0-2 months: study set-up (March 2017 – May 2017)

Phase 1

2-4 months: convene Manual Development Group, revise manual in light of recommendations (May 2017 – July 2017)

Phase 2a

4-6 months: train therapists (July 2017 – Sep 2017)

6-8 months: screen cases for test series in one or two sites only (Sep 2017 – Nov 2017)

6-10 months: run test series (Sep 2017 – Jan 2018)

Phase 2b

6-12 months: run scoping study (Sep 2017 – March 2018)

10-12 months: revise manual and protocol, complete ethics revisions (Jan 2018 - March 2018)

Phase 3

11 months – 23 months recruitment for pilot trial (Feb 2018 – Feb 2019)

27 months: Complete final outcome assessment (June 2019)

27-30 months: Finalise analysis and submit final report (Sep 2019)

13.1 Deliverables and indicators of success

For phase 1 of the study the key deliverable will be development of a new treatment (VIPP-FC) and the completion of a comprehensive treatment manual outlining clinical procedures for practitioners at each stage of treatment. This will have a potentially large impact on practice, as no evidence-based treatments currently exist for RAD, and treatment development in this area has been identified as a key health service priority (NICE, 2015; Wright et al., 2015). The initial success of this manual will be indicated by a) the feedback from practitioners and carers obtained in phases 2a and 3 regarding treatment delivery, b) feedback from practitioners during training, and b) feedback from the field through our dissemination activities. Phase 2a will yield a draft trial protocol based on experience of the feasibility case series, as well as refinements to the clinical manual. The findings of the case series will be published in a peer-reviewed journal. Phase 2b will end with the completion of a detailed report and research recommendations for trials of attachment interventions for children in foster care, to be published in a peer reviewed journal, as well as a final trial protocol for guiding the pilot trial in Phase 3 (which will also be published). The results of the pilot trial in phase 3 will produce vital data on the feasibility of a clinical trial of VIPP- RAD that will be used to plan a full-scale efficacy and health economic evaluation. The results of the pilot RCT will be published in a peer reviewed journal and disseminated to clinical and scientific conferences. This phase will yield definitive information about the feasibility of a future trial. Specifically, the following outcomes, were they to be identified by the project, would suggest that a full-scale trial should not proceed as currently configured: 1) inability to identify sufficient numbers of cases meeting diagnostic criteria for RAD, 2) inability to recruitment sufficient numbers of cases to enter treatment (e.g. due to problems with consent), 3) excessive placement instability and drop-out from the programme, 4) serious concerns about the acceptability of the treatment, randomisation or the outcome assessment battery raised by stakeholders. On completion of the study we will convene a group of stakeholders, including representatives of HTA, to consider whether a full trial should proceed, weighing up questions of scale (e.g., number of sites), design, cost and generalizability. Although thresholds for decisions about progression cannot all be determined in advance we consider that retention in treatment of < 70% would make a future trial non-viable. Similarly, an outcome assessment completion rate of < 70% would indicate non-progression. Although recruitment is less clear-cut, as sites can be added, an identification rate of RAD of < 10% would also lead to non-progression.

14 Ethical Considerations:

14.1 Risks and Benefits for Participants

Benefits:

From our experience of running similar trials with carers and their children, participation is often considered a positive experience. Firstly, carers have the opportunity to talk through their current situation with a trained researcher who is sensitive and responsive to their concerns. Filling in questionnaires or answering interview questions allows them a time to reflect on their current situation and mental well-being. Secondly, we have often found that participants benefit from knowing they have contributed to a study which has the potential to help others in similar situations to theirs. For some participants, the study may also increase the identification of difficulties among young children in foster care which may expedite receiving appropriate support.

Burdens & Risks:

The burden of the research assessments at baseline and post-treatment is expected to be about 1 to 1.5 hours at each time point. Families will be fully informed of the time required to participate in the research before they choose to do so.

Although there are no direct risks involved in taking part in the research, carers may find some of the questionnaires and interviews sensitive as they relate to their foster child's current situation and difficulties. The researcher responsible for administering these measures will be trained to handle such situations in a sensitive and appropriate manner. In the event that any concerns arise the CI will be informed and the necessary supervision and additional support to foster carers provided.

Stakeholders have expressed concerns about participation in the study in some way affecting the likelihood of reunification with birth parents, the relationship between the local authority and birth parents and whether randomisation disadvantages some children in receiving appropriate treatment. Phase 2b of this study aims to address these concerns, before the pilot trial begins, by administering qualitative interviews with key stakeholders. Further, the study information should not have a bearing on the legal processes associated with the child's placement, which will be made clear in the study information sheets. Care has been taken in designing this protocol to ensure that participation in the study does not adversely affect the work of social workers and their relationships with parents. Although concerns may be raised about the fairness of randomisation, there is currently no evidence that VIPP is more effective than usual care for supporting children with attachment difficulties such as RAD, and so randomisation does not provide a known effective treatment to one group but not another.

14.2 Risks to Researchers

The risks for the researcher travelling to research assessments will be assessed and monitored at all stages of the study. A record of times and places of all interviews will be kept by a named person at the research sites. The researcher will also have access to a clinical psychologist should they need to discuss any difficulties experienced while doing the assessments. Visits to family homes will always be preceded by a phone call to the main research site, and a call will also be placed at the end of the visit so that the research team is aware of each research visit and its safe conclusion.

Researchers will be trained in the Lone Worker policy and how to manage research visits with their safety in mind, and will be instructed to postpone a visit if they are unsure of their safety, or call the police should an emergency arise once a visit is underway.

14.3 SIGNIFICANT EVENTS:

The term *significant event* applies to an event that may occur during participation in the trial that is deemed relevant enough to impact on the study outcomes. As such, a significant event for this study is defined as one of the following:

- A change of placement
- A significant change within placement
- A change of school
- Identification of learning difficulties or diagnosis of a developmental disorder
- A change of social worker
- A change of contact arrangements
- Return to care of birth family
- Other change in care order
- Allegation e.g. maltreatment/abuse
- Other key transition/experience of loss

Significant event reviews will be undertaken by both the RA and therapists throughout the pilot trial. In the case of a significant event occurring, interpretation of the event will be discussed in collaboration with the social worker and carer. The significant events listed above will be recorded in the CRF following consent but will not be reported to the sponsor due to the high frequency at which these events may occur with this sample. However, in the case of death, hospitalisation or maltreatment the sponsor will be informed by the CI, within 5 working days of becoming aware of the event.

14.4 ETHICAL CONSIDERATIONS

Research Ethics Committee (REC) review and reports

- Before the start of the trial, approval will be sought from a REC for the trial protocol, information sheets, informed consent forms and other relevant documents.
- Substantial amendments that require review by REC will not be implemented until the REC grants a favourable opinion for the study. The HRA will also be notified and communication sent to sites regarding the HRA categorisation and amendment.
- All correspondence with the REC will be retained in the Trial Master File.
- The Chief Investigator will submit an annual progress report (APR) 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.

Data protection and patient confidentiality

The data custodian is Pasco Fearon, the Chief Investigator. The Chief Investigator and all other individuals involved in the research will comply with the requirements of the Data Protection Act 1998 with regards to the collection, storage, processing and disclosure of personal information and will uphold the Act's core principles.

Limits to confidentiality

If the research team or the intervener become concerned about a participant's safety (e.g. if there is an allegation of maltreatment) the child's social worker will be contacted and, if appropriate, the relevant processes will be initiated with the child's Local Authority. Where appropriate and in consultation with the Local Authority, the parent will also receive a letter informing them of the concerns and what course of action the study team will take.

Peer Review

This project is a multi-site collaboration between 3 universities, 5 NHS Trusts and their linked local authorities. As such, the study has benefited from the contributions of research, clinical and statistical

experts in the field in designing the fine details of the research. Furthermore, as part of the funding application additional reviews of the research protocol were undertaken, including a review by 7 members of the PPI group.

Indemnity

NHS bodies are liable for clinical negligence and other negligent harm to individuals covered by their duty of care. UCL provides cover for negligent harm arising from the design of the research.

Protocol Compliance

Non-compliance to the protocol will be documented using study specific documents and any deviations that are systematic, or may be considered a risk to the data integrity or participant safety will be referred to the sponsor.

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Appendix 1: GANTT chart of study time-line