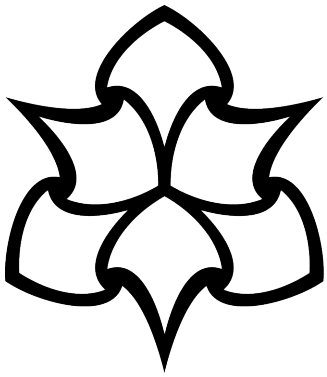

Manchester Metropolitan University

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What Works for Children's Social Care

Trial Evaluation Protocol

Evaluation of the Empowering Parents and Professionals Using Video Interaction Guidance (VIG) programme (Babies1st)

Evaluators: IFF Research and Manchester Metropolitan University (Policy Evaluation and Research Unit)
Principal investigator(s): Lorna Adams and Stephen Morris

Evaluation of the Empowering Parents and Professionals Using Video Interaction Guidance (VIG) programme (Babies1st)

Intervention Developer	Babies 1st
Delivery Organisations(s)	Achieving for Children, Stockport Borough Council, Bath and North East Somerset Council, London Borough of Hounslow
Evaluator	IFF Research and Manchester Metropolitan University
Principal Investigators	Lorna Adams and Stephen Morris
Protocol Author(s)	Lorna Adams, Stephen Morris, Siv Svanaes, Kelsey Beninger, Andrew Smith, Sandor Gellen, Hollie Jones
Type of Trial	Effectiveness
Age or Status of Participants	A family with a child aged 12 months or less, subject to a Child in Need Plan or a Child Protection Plan
Number of Participating Sites	Four
Number of Children and Families	N~=252 family dyads
Primary Outcome(s)	1. Representation – 'warmth' 2. Representation – 'invasion'
Secondary Outcome(s)	1. Parental self-efficacy 2. Parental stress 3. Step-up child protection outcome
Contextual Factors	To be identified through implementation and process evaluation

Summary

The Video Interaction Guidance (VIG) programme is being implemented between March 2021 (with intake from July 2021) and June 2022 in four English Local Authorities (LAs). VIG is a relationship based parenting intervention in which a VIG practitioner films a parent and child interacting in short, one-to-one sessions. By providing feedback on these sessions based on edited clips of better than usual moments, VIG aims to promote parental sensitivity, child attachment and longer term social and emotional development.

The intervention developer, Babies 1st, will train and supervise 21 VIG Practitioners across the four LAs. Practitioners will undertake the role in addition to their substantive role (e.g. social or family worker) and will each work with a minimum of six families (typically a focal parent and infant dyad) over eight sessions or more.

The programme is being evaluated by IFF Research and the Policy Evaluation and Research Unit (PERU) at Manchester Metropolitan University (Man Met). The evaluation comprises impact, implementation (process) and cost components. The impact study design is a pragmatic, multi-site, effectiveness trial, with individual family dyads allocated to intervention and control within sites, at random, on a 1:1 intervention to control basis. Families allocated to the intervention group will receive VIG in addition to their usual care; those in the control group will receive usual care only. All families will be asked to complete a baseline questionnaire containing psychometric measures prior to randomisation and also at four months post-randomisation. In addition, LAs will supply child protection outcomes from administrative data six months post-randomisation.

Intake will begin in August 2021 and will continue until the end of March 2022. Randomisation will begin in July 2021, and the intervention for all families will end by June 2022. An evaluation report will be published by the end of August 2022.

The evaluation includes a review point (September 2021) to allow for changes to the protocol and evaluation activity on account of factors which are currently unknown (e.g., the amount of dropout and proportion of parents requiring translation services or additional support to complete the survey). For further details see p.12.

Table of Contents

Background and Problem Statement **6**

Intervention and Theory of Change **6**

- Logic Model 9
- Interventions 10
- Mechanisms 10
- Outcomes 10

Impact Evaluation **11**

- Research Questions 11
- Design 12
- Randomisation 14
- Participants 15
- Sample Size / Minimum Detectable Effect Size Calculations 16
- Outcome Measures 18
- Analysis Plan 20
- Primary Analysis 21
- Secondary Analysis 24
- Exploratory Analysis 25
- Contextual Factors Analysis 25

Implementation and Process Evaluation **26**

- Aims 26
- Research Questions 26
- Design 26
- Methods 27
- Analysis 30

Cost Evaluation **31**

Risks **33**

Ethics & Participation **34**

Registration **34**

Data Protection **34**

Personnel **36**

Timeline **40**

Appendix A: Scales used in baseline and follow-up questionnaires **41**

Background and Problem Statement

Problem Statement

There were 399,500 children in need on 31st March 2019 in England (ONS, March 2019), and 19,489 of them were under one year old.

Parents who have themselves been neglected and abused will frequently struggle to tolerate their babies' cries and interpret them in a realistic and benign manner. Babies' vulnerabilities may evoke in parents their own unconscious experiences of being looked after. If parents have experienced harsh parenting, parents may be prone to replicate this pattern of behaviour.

The first twelve months of a child's life provide a 'window of opportunity' to increase parental sensitivity, reduce risk and support changes in parenting styles, leading to changes in the trajectory of parent-infant relationships, infant speech development, school readiness, and other life outcomes.

The aim of the VIG programme is to improve the practice of social workers and family workers to make a difference to the lives of vulnerable families and give parents and their babies a genuine chance for a better start in life.

Intervention and Theory of Change

Brief name: Empowering Parents and Professionals Using Video Interaction Guidance (VIG) programme (Babies1st)

Why: Parents who have themselves been neglected and abused will frequently struggle to tolerate their babies' cries and interpret them in a realistic and benign manner. Babies' vulnerabilities may evoke in parents their own unconscious experiences of being looked after. If parents have experienced harsh parenting, parents may be prone to replicate this pattern of behaviour. The aim of the programme is to support families with a child under 12 months who is the subject of a Child in Need (CiN) or Child Protection (CP) Plan through the use of Video Interaction Guidance (VIG) in order to improve parental self-esteem and confidence, to enhance parental reflective functioning, capacity to mentalise, and lower parental stress.

What: VIG is a relationship-based parenting intervention in which a VIG practitioner films the parent and child interacting in short, one-to-one sessions[1]. From these recordings, the practitioner selects micro-moments of interaction that demonstrate 'good' interaction, namely attuned responses of the parent to signals from the child. These moments are jointly reviewed by the parent and practitioner. Parents are helped to see themselves with a benign lens, supported by the practitioner to delight in these positive moments, and helped to reflect on themselves as parents, their role, and their responsibilities. Parents are encouraged to think about their babies' needs, identify what they are already doing well when they see themselves responding sensitively to their babies and how they can apply this learning to more stressful situations.

[1] See the following video link for an overview and demonstration of VIG by Monika Celebi, founder of Babies1st: https://www.youtube.com/watch?v=bEi0ggNDVNI

A sizable body of evidence supports the impact that VIG has in promoting these outcomes, particularly across populations where parental sensitivity may be compromised (such as cases of domestic violence, social isolation, or maternal depression). Much of this evidence is summarised in the recent 2019 *Cochrane Review on the efficacy of Video feedback for parent sensitivity and attachment security*.[2] Reviewing 22 randomised controlled trials (RCT) conducted in Europe and North America, the review found that among a range of parent and child outcomes, Video feedback most strongly improved parental sensitivity as measured by various validated psychometric questionnaires. Other evidence specifically discusses the effectiveness of VIG for neglected children in the United Kingdom[3].

Who provides: The intervention will be delivered by social and family workers in four local authorities. The social and family workers will be trained in VIG by Babies1st, a group of nationally accredited VIG trainers with additional expertise in the early years. The training will consist of an introductory training and follow-up workshop as well as fortnightly individual and monthly group supervision sessions, plus a Midpoint Review Day and Accreditation Day with external AVIGuk accredited trainers.

How: The intervention will be delivered face-to-face. Social and family workers will meet with the focal parent and child. Some sessions may also include other family members (e.g. another parent) if suitable, although we expect the majority of intervention recipients to be parent-infant dyads, with the parent being the infant's mother in most cases. The intervention will also be delivered face-to-face wherever possible during any further Covid-19 lockdown periods. The Shared Reviews will either be face to face or online.

For the purposes of the evaluation, the 'focal parent' is defined as the infant's primary caregiver who will be the main recipient of the VIG intervention, and who will also complete the baseline and follow-up questionnaires.

Where: The intervention will focus on four areas:

- London Borough of Hounslow
- Stockport Borough Council
- Bath & North East Somerset Council
- 'Achieving for Children', which covers Kingston Council, Richmond Council and Windsor & Maidenhead Council

When and how much: 252 parent-infant dyads will be included in the trial, with the understanding that half will be randomly allocated to the intervention group, and the other half allocated to receiving 'support as usual' from their LA. Random assignment will be stratified at the LA level. Focal parents are most likely to be mothers but fathers will also be included where they are the only/primary care giver to the child. Parents will be recruited on an ongoing basis starting mid-July 2021, with delivery starting in August.

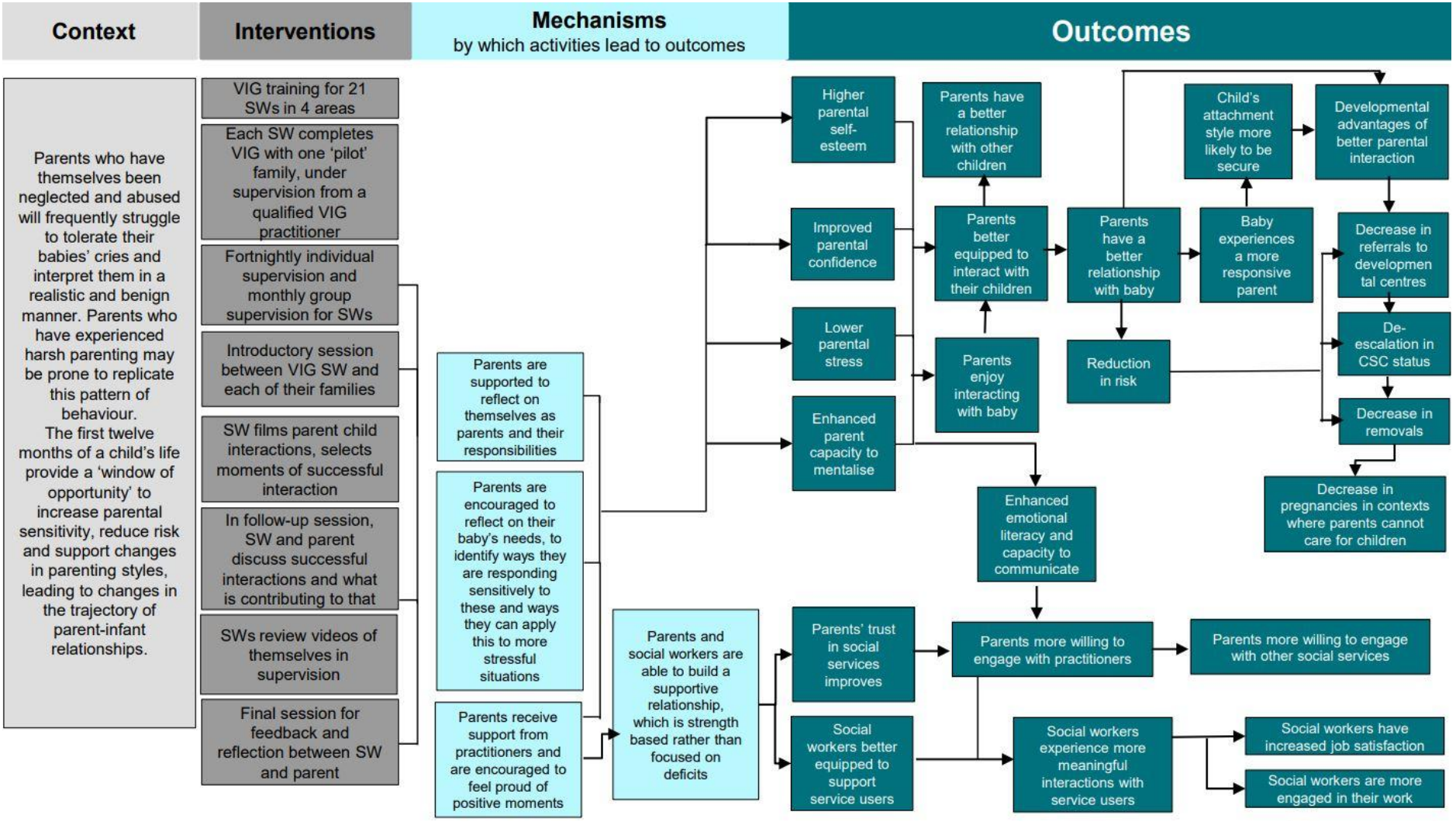
The 21 practitioners will see a minimum of six families each, for a minimum of eight sessions or more if needed, over the course of 12 months. The eight sessions consist of an initial

[2] O'Hara L, Smith ER, Barlow J, Livingstone N, Herath NINS, Wei Y, Spreckelsen TF, Macdonald G. *Video feedback for parental sensitivity and attachment security in children under five years*. Cochrane Database of Systematic Reviews 2019, Issue 11. Art. No.: CD012348. DOI: 10.1002/14651858.CD012348.pub2.
https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD012348.pub2/full

[3] Kennedy, H., Macdonald & Whalley, P., (2016), 'Video Interaction Guidance, Providing an effective response for neglected children'. *in* Barlow, J et al., (2016) *Tackling child neglect: Research, policy and evidence-based practice*. Jessica Kingsley Publishers.

meeting, followed by three cycles of VIG and a final evaluation and feedback session. Each cycle consists of one session where the social worker films interactions between the parent and child and a Shared Review where the social worker highlights examples of positive interactions and encourages the parent to reflect on what they did well, what they can learn and how to replicate positive behaviour. Each session lasts around 45 minutes.

Logic Model[4]



[4] Version 2

Interventions

The intervention will be delivered by 21 social and family workers in four local authorities. The social and family workers will be trained in VIG by Babies1st and the training will consist of an introductory training and follow-up workshop as well as fortnightly individual and monthly group supervision sessions, plus a Midpoint Review Day and Accreditation Day with external AVIGuk accredited trainers.

As part of their training, social and family workers have been supported to complete the VIG intervention with at least one 'pilot' family, under close supervision of a qualified VIG practitioner from Babiest1st.

The intervention includes a minimum of eight sessions between the social and family worker and parent dyad, over the course of 3-4 months. The eight sessions consist of an initial introductory meeting, followed by three cycles of VIG and a final evaluation and feedback session. Each cycle consists of one session where the social and family worker films interactions between the parent and child and a Shared Review where the social and family worker highlights examples of successful interactions and encourages the parent to reflect on what they did well, what they can learn and how to replicate positive behaviour. Each session lasts around 45 minutes.

Mechanisms

During the Shared Reviews, the parent will be encouraged to reflect on themselves as a parent and the responsibilities that comes with this. They are also supported to be more aware of and reflect on their baby's needs. They will be encouraged to identify ways in which they are already responding sensitively to these needs, as well as opportunities to apply this positive behaviour to more stressful parenting situations.

The family and social worker supports the parent to celebrate and understand examples of sensitive parenting, encouraging the parent to feel proud of these moments.

Outcomes

It is hypothesised that the intervention will lead to the following short term outcomes:

- Higher parental self-esteem
- Improved parental confidence
- Lower parental stress
- Enhanced parental reflective functioning and capacity to mentalise
- Increased parental trust in social services
- Increase in social workers' ability to support service users

These immediate outcomes are expected to lead to:

- Improved relationship between parent and other children in the family
- Improvement in parents' ability to interact with their children
- Increase in parents' enjoyment of interacting with their baby
- Enhanced emotional literacy and capacity to communicate among parents
- Parents more willing to engage with practitioners
- Social workers experience more meaningful interactions with service users
- Parents have a better relationship with baby
- Reduction in risk
- Parents more willing to engage with practitioners
- Parents more willing to engage with other community and social services

- Social workers experience more meaningful interactions with service users
- Social workers have increased job satisfaction
- Social workers are more engaged in their work

The long terms outcomes are hypothesised to be:

- Child's attachment style becomes more secure
- Baby experiences a more responsive parent
- Developmental advantages of better parental interaction
- Decrease in referrals to developmental centres
- De-escalation in CSC status
- Decrease in removals
- Decrease in pregnancies in contexts where parents cannot care for children

Impact Evaluation

Research Questions

The primary research questions to be addressed in the impact evaluation are:

1. What is the difference in the average perceived 'warmth' of the relationship (*outcome*) with their baby, for focal parents with a child 12 months or less in age and with a social worker (*population*), randomised to receive Video Interaction Guidance (*intervention*), compared to focal parents in dyads randomised to control (business as usual; *control*) conditions?

2. What is the difference in the average perceived 'invasion' (*outcome*) reported by focal parents, with a child 12 months or less in age and with a social worker (*population*), and that are randomised to receive Video Interaction Guidance (*intervention*), compared to focal parents in dyads randomised to control (business as usual; control) conditions?

Secondary research questions are:

3. What is the difference in the average level of parental self-efficacy among focal parents with a child 12 months or less in age and with a social worker, in dyads randomised to receive Video Interaction Guidance, compared to focal parents in dyads randomised to control (business as usual) conditions?

4. What is the difference in the average level of parental stress among focal parents with a child 12 months or less in age and with a social worker, in dyads randomised to receive Video Interaction Guidance, compared to focal parents in dyads randomised to control (business as usual) conditions?

5. What is the probability that a focal child aged 12 months or less and with a social worker in dyads randomised to receive Video Interaction Guidance, 'steps down' from being a child-in-need (CiN) or on a child protection plan (CPP) over a three month period subsequent to the intervention, to being on a CPP if they were not already, or becoming a CLA (child who is looked after), or pre-proceedings are initiated,

compared to focal children in dyads randomised to control (business as usual) conditions over the same period?

Design

Trial type and number of arms		**Pragmatic multi-site trial with two arms**
Unit of randomisation		Parent-infant dyad
Stratification variables **(if applicable)**		Site
Primary outcome(s)	Variable	- Representation – 'warmth' - Representation – 'invasion'
	Measure (instrument, scale)	- Mothers Object Relations Short Form (MORS-SF) – warmth - Mothers Object Relations Short Form (MORS-SF) – invasion
Secondary outcome(s)	Variable(s)	- Parental self-efficacy - Parental stress - CSC Step-up
	Measure(s) (instrument, scale)	- Karitane Parenting Confidence Scale - Parental Stress Scale - Whether a focal child status changes from CiN to CPP, CPP to CLA, or pre-proceedings were initiated (indicators combined to form a binary outcome with constituent measures obtained from social care records)

The impact study design is a pragmatic, multi-site, effectiveness trial, with parent-infant dyads allocated to intervention and control within sites, at random, on a 1:1 basis. As a result, dyads are randomised within sites, which are local authorities, and the resulting data are clustered by site. Outcomes are recorded for the focal parent and focal child within dyads. There are four sites in total, with family dyads identified within each site by local intervention coordinators and then randomised to treatment and control using a randomised permuted block approach described more fully below.

Trained social workers are responsible, after training and discussions with Babies 1st, for identifying all eligible dyads that meet the inclusion criteria (with the exception of those for whom exclusion criteria apply), completing a referral form for each dyad and administering consent procedures. The referral form contains the following information:

- Focal parent's contact details
- Focal parent's age
- Focal child's age
- Focal child's gender
- Focal child subject to formal multi-disciplinary planning process (i.e. CP, CiN, Early Help Plan)?
- Other children in the household subject to formal multi-disciplinary plan?
- Ethnicity
- Focal parent's care history
- Focal parent has other children taken into care?
- Does the focal parent smoke?

- Current accommodation
- Age focal parent finished full-time education
- Focal parent currently suffers from anxiety
- Focal parent currently suffers from depression
- Focal parent's alcohol consumption

Once referral and consent procedures are complete, details of each dyad are passed to IFF Research, who check the completeness of the referral form data and confirm eligibility (that the dyad meets the study inclusion criteria). Subsequently, IFF administer a baseline questionnaire to the focal parent. The baseline questionnaire contains the following measures, details of which can be found in Appendix A: MORS-SF, Karitane Parenting Confidence Scale, Parental Stress Scale. For the sample randomised between July and November 2021, child protection outcomes (CiN, CPP, CLA and initiation of pre-proceedings) are collected from administrative case data held by the local authorities and further details provided later in this section. Full details of the measures included within the baseline questionnaire, along with the justification for their choice, and the reliance on self-completion questions rather than observations, is provided in the section entitled 'Outcome measures' below.

The respondent (focal parent) is expected to be the focal child's mother but may be the father where he is the only, or primary, care giver. Dyads are given two weeks to complete the questionnaire. It is important to note, that the study's funders have decided that all dyads that meet the study inclusion criteria and who provide their consent should be randomised, regardless of whether a complete baseline questionnaire is received. This means that some missing data, either item or unit (dyad) missing, can be expected at baseline. The evaluators in partnership with Babies 1st and the study sites will take a number of steps to limit non-response or missingness at baseline, such as telephone reminders to non-respondents, telephone support for focal parents to complete the questionnaire, and support for social workers and VIG Practitioners to support and encourage parents to participate.

Once the period of time given to dyads to complete the baseline questionnaire has elapsed, IFF Research link the questionnaire return to the dyad's referral form data, pseudonymise the data and pass the data record to Manchester Metropolitan University (Man Met). A researcher based in Man Met's Policy Evaluation and Research Unit (PERU), who is blind to the identities of the dyads concerned will then randomise that dyad. Full details of the randomisation procedures are set out below. Once the dyad has been randomised, the outcome of randomisation is communicated by Man Met to IFF Research who in turn inform the Local Authority (LA) of the outcome. Following randomisation, LAs are free to commence work with dyads allocated to the intervention. It is expected that LAs will commence work with dyads very soon after randomisation so that the time between the end of the intervention and collection of post-intervention data is consistent across dyads. LAs should therefore only refer dyads for whom intervention delivery could commence immediately.

IFF Research will administer a follow-up questionnaire to all dyads (including those that did not supply a baseline questionnaire) five months following randomisation. Dyads will be given two weeks to complete the follow-up questionnaire. In large part, the follow-up questionnaire will contain the same or similar questions as the baseline questionnaire, and a similar set of procedures will be followed in order to limit attrition and missingness. IFF Research will seek a complete follow-up questionnaire from all randomised dyads, regardless of whether a dyad completed a baseline questionnaire.

At the end of the 'follow-up' fieldwork period, IFF Research will pseudonymise the follow-up questionnaire data and pass them to Manchester Met for analysis. Full details of the analysis are discussed below.

In addition to the data collected using questionnaires, IFF Research will also receive child protection outcomes from local authorities. These data will record whether a new CPP, CLA has commenced or pre-proceedings have been initiated for the focal child in the sample dyads. Initially, the outcomes will be derived and analysed for those cases randomised between July and November 2021 only, though with the option to extend the analysis to the full sample should the timetable for the research be extended. This is so outcomes can be examined for a period of 6 months subsequent to randomisation and so that analysis can take place within the current timetable for this project. Measures will be appended to the dyad's pseudonymised record for analysis by Man Met. A combined measure that will capture whether there has been an escalation in care will be derived as a binary response variable. We refer to this measure as a CSC 'step-up' outcome.

Randomisation

Randomisation will be stratified by site in order to ensure balance in allocation to intervention and control groups within each LA. Man Met will use permuted block Randomisation to balance the allocation of dyads to the intervention and control groups within sites, and to allow dyads to be randomised as they enter the evaluation. Creating randomisation sequences upfront will allow for dyads to be randomised as they are identified as eligible for the study and after they have completed baseline questionnaires. Effectively this will create a mechanism whereby dyads can flow into the study and be randomised, avoiding the need for them to wait and be randomised in batches.

Blocks will be generated using the R package randomizeR[5]. Each site will therefore have a separate allocation sequence (the length of which will be the number of dyads expected for the site) which contains multiple blocks of two, four or six allocations. Within each block the allocations to treatment and control will be on a 1:1 ratio. Furthermore, the generation of blocks themselves will be randomised by randomizeR by block length (random block constellation). This reduces the likelihood that subsequent allocations (e.g., treatment, control) within a sequence might be discerned by those wishing to manipulate assignment; a situation made more likely if the block length is known and constant throughout the sequence. Table 1 below illustrates this for each Local Authority and the R code to achieve this is detailed in the section immediately following. Man Met will use another script to merge IFF's trial database with the sequence allocations, thereby avoiding manual allocation of treatment and control assignments to pseudonymised dyads.

[5] https://www.jstatsoft.org/article/view/v085i08

Table 1. Illustrative example of permuted blocked randomisation schema

	Achieving for Children	BANES	London Borough of Hounslow	Stockport
Block 1	4	2	6	4
Block 2	6	2	6	6
Block 3	2	4	2	4
Block 4	6	6	4	6
Block 5	2	2	4	2
	etc. until a total of 120 is reached	etc. until a total of 24 is reached	etc. until a total of 24 is reached	etc. until a total of 84 is reached

R code for Randomised Permuted Block Randomisation

```
library(randomizeR)

#define block lengths
rb <- c(2, 4, 6)

#Generate sequences for Achieving for Children
paramsAFC <- rpbrPar(120, rb)
(RAFC <- genSeq(paramsAFC))
getRandList(RAFC)
saveRand(RAFC, file="myRandListAFC.csv")
plotSeq(RAFC, plotAllSeq = T)

#Generate sequences for BANES
paramsBANES <- rpbrPar(24, rb)
(RBANES <- genSeq(paramsBANES))
getRandList(RBANES)
saveRand(RBANES, file="myRandListBANES.csv")
plotSeq(RBANES, plotAllSeq = T)

#Generate sequences for Hounslow
paramsHouns <- rpbrPar(24, rb)
(RHouns <- genSeq(paramsHouns))
getRandList(RHouns)
saveRand(RHouns, file="myRandListHouns.csv")
plotSeq(RHouns, plotAllSeq = T)

#Generate sequences for Stockport
paramsStock <- rpbrPar(84, rb)
(RStock <- genSeq(paramsStock))
getRandList(RStock)
saveRand(RStock, file="myRandListStock.csv")
plotSeq(RStock, plotAllSeq = T)
```

Participants

The participants in this study are families (expected to be represented mostly mother-baby dyads) within four English local authorities (LAs), recruited using convenience sampling. Formal expressions of interest were originally received from five LAs, and partnerships with four LAs meeting all eligibility criteria were finalised by mid-March 2021. Babies1st then trained social and family workers in each LA to become VIG Practitioners, assuming that each practitioner would work with around six dyads.

Table 2: Dyad recruitment and VIG practitioner numbers by site

Local Authority	Dyads recruited	VIG Practitioners
Achieving for Children (AfC)	120	10
Bath and North-East Somerset (BANES)	24	2
London Borough of Hounslow	24	2
Stockport	84	7

Criteria for including families in the study have been determined by local authorities in conjunction with Babies 1st, and are as follows:

- The family has a focal child aged 12 months or less; and
- The focal child is subject to either a Child in Need plan (CiN) or a Child Protection plan (CPP)

Families meeting these criteria will be eligible for inclusion unless they meet one or more of the following exclusion criteria:

- The focal parent does not speak or read English and does not have access to an interpreter (though this will be reviewed in September 2021 and the criteria may change);
- The referring social worker believes there to be a reason why the parent(s) cannot manage a psychological intervention at time of referral, due to:
    - serious mental health concerns;
    - serious physical health concerns;
    - being actively engaged in substance misuse.

Translation of the questionnaire instruments and provision of an interpreter for respondents who do not speak or read English were not planned due to budgetary constraints because VIG is primarily delivered in English. Furthermore the instruments the evaluation is using to measure the primary and secondary outcomes are not validated for the full range first languages spoken by parents. However, in September 2021 this will be reviewed following initial programme intake and through discussions with LAs. If there is a need for translations they will be undertaken.

Sample Size / Minimum Detectable Effect Size Calculations

In line with WWCSC analytical guidance[6], we will estimate the average effect of intention-to-treat (AITT) at the dyad (family) level using a two-sided test for statistical significance. We will obtain sample estimates of AITT via regression adjustment including an outcome measure derived from the baseline questionnaire as a covariate along with site fixed effects. The sample estimate of AITT will be converted from a regression coefficient into an effect size consistent with Glass's Delta for continuous outcomes. For binary outcomes, incident rates will be reported.

The table below presents the Minimum Detectable Effect Size (MDES) that the sample described is capable of detecting at the 95 per cent level of statistical significance and 80 per power. These calculations are considered to be provisional. They are made subject to an assessment of the degree of compliance with the intervention among the intervention group dyads. This assessment will be made at the Evaluation Review Point, which is discussed in more detail below. Should the assessment suggest that the assumptions made in these calculations are inaccurate, a revised protocol with updated calculations will be issued, with

[6] What Works for Children's Social Care (2021).'What Works for Children's Social Care Randomised Controlled Trial Statistical Analysis Guidance.' https://whatworks-csc.org.uk/wp-content/uploads/WWCSC-RCT-Statistical-Analysis-Guidance-V1.1-1.pdf

further corrective actions take where necessary and possible within the general constraints faced by the trial.

MDES calculations account for the variation in sample sizes across local authorities by incorporating an estimate of cluster size based on the harmonic mean[7] for the completed cases sample. Calculations were based on the assumed proportion of the variance in the outcome accounted for by the covariates in the fixed effects estimator (R^2). To establish the correlation coefficient, we identified the test-retest reliability for the MORS-SF warmth scale (0.70)[8]. This was then used to calculate the R^2 as the basis for the MDES.

MDES (Proportion of a Standard Deviation)		0.44
Proportion of Variance in Outcome Explained by Covariates[9] (R^2)	Child	n/a
	Family (focal parent)	0.50
	Social Worker	n/a
Intracluster Correlations Coefficient (ICCs)	Family	n/a
	Social Worker	n/a
	Team	n/a
Alpha		0.05
Power		0.8
One-Sided or Two-Sided?[10]		Two-sided
Level of Intervention Clustering		Site
Average Site Size (harmonic mean)		21
Sample Size	Intervention	71
	Control	70
	Total	141

The sample size in the table above considers assumed missingness in the data, due to participants not completing a baseline questionnaire, a follow-up questionnaire, or both). We have assumed close to full compliance with the intervention; though as discussed previously this assumptions is subject to review. The calculations are illustrated in the following table:

[7] Dong, N., & Maynard, R. A. (2013). 'PowerUp!: A tool for calculating minimum detectable effect sizes and minimum required sample sizes for experimental and quasi-experimental design studies.' Journal of Research on Educational Effectiveness, 6(1), 24-67.
doi: 10.1080/19345747.2012.673143.
[8] Oates, J. and Gervai, J. (2019) 'Mothers' perceptions of their infants', Journal of Prenatal and Perinatal Psychology and Health, vol. 33, pp. 282-300.
[9] This includes, and will most likely be most influenced by, a baseline measure of the outcome.
[10] By default, we would recommend two-sided tests.

Table 3: Anticipated sample sizes at baseline and follow-up

	Recruited eligible dyads	As randomised sample	Baseline questionnaires obtained	Follow-up questionnaire (those not supplying a baseline response)	Follow-up questionnaire (those supplying a baseline response)
Achieving for Children	120	120	96	12	67
Stockport	84	84	67	8	47
BANES	24	24	19	2	13
London Borough of Hounslow	24	24	19	2	13
Total	**252**	**252**	**202**	**25**	**141**
Assumed response patterns					
Non-responder at both waves	25				
Responder at baseline missing at follow-up	60				
Missing at baseline responder at follow-up	25				
Responder at both waves	**141**				

Outcome Measures

The impact evaluation has two co-primary and three co-secondary outcomes, selected by the evaluation team, intervention developers and funder to correspond to those thought to be important. Prioritisation of outcome measures was determined through the development of a theory of change/logic model (see Logic Model diagram). Outcome data will be obtained in the main from self-completion questionnaires (with telephone support where required) rather than direct observation, and from local authority administrative sources. Although there are limitations with self-report measures (e.g. their subjective nature, response biases such as social desirability), using them allows the evaluation to proceed to agreed timescales and adopt relatively light-touch data collection. The measures selected are all well-validated and have been used extensively for research purposes by academics and practitioners in diverse contexts. All self-report measures can be found in Appendix A.

Table 4: Evaluation outcomes and related measures

Logic Model Outcome	Evaluation Outcome	Measure	Source
	Co-primary outcomes		
Parents have a better relationship with the baby	1. Representation – warmth	MORS-SF (warmth)	Baseline and follow-up questionnaires
	2. Representation – invasion	MORS-SF (invasion)	Baseline and follow-up questionnaires
	Co-secondary outcomes		
Improved parental confidence	1. Perceived Parental Self-Efficacy	Karitane Parenting Confidence Scale	Baseline and follow-up questionnaires

Lower parental stress	2. Parental Stress	Parental Stress Scale	Baseline and follow-up questionnaires
Escalation in CSC status	3. CPP, CLA or pre-proceeding initiated	Step-up binary indicator	Data supplied by LAs

MORS-SF[11]

MORS-SF is a 14 item instrument which measures a parent's 'representations' of their infant's thoughts, feelings and intentions towards them. The instrument comprises two scales: 'warmth' and 'invasion', which are calculated and reported separately, and therefore form two separate co-primary outcomes in this evaluation. 'Warmth' measures the parent's model of their infant's emotional warmth towards them. It is obtained from statements such as 'my baby smiles at me' and 'my baby likes doing things with me. 'Invasion' measures the parent's model of their infant's emotional invasion or control over them (or in other words, it measures the level by which the parent experiences their infant as disruptive and invasive), and is obtained from statements such as 'my baby annoys me' and 'my baby wants too much attention' (see Appendix A for all 14 statements). As such both scales provide a measure of the parent's relationship with the baby.

Both scales have a total possible score of 35. A score of 11 or less on the warmth scale should indicate concern. Concern on the invasion scale is indicated by a score of over 17.

Karitane Parenting Confidence Scale (KPCS)[12]

The Karitane Parenting Confidence Scale is a 15 item instrument which measures perceived parental-self efficacy (PPSE) - perceptions of confidence with regard to the parenting role. This scale will be used to provide an estimate of impact for the first co-secondary outcome consistent with the outcome 'improved parental confidence' identified as important in the development of the theory of change/logic model.

The KPCS is scored by summing across all responses with the possible range of scores being 0-45. The cut-off score is 39, such that parents scoring 39 or less may be experiencing low levels of parenting confidence.

Parental Stress Scale (PSS)[13]

The Parental Stress Scale is an 18 item instrument measuring parental stress - a parent's perceived stress relating to the parenting role. This scale will provide a measure of the 'lower parental stress' outcome identified through the logic model/theory of change process. A number of items are reverse scored, and scores are summed to give an overall score in the range 18-90. Higher scores indicate higher levels of perceived parental stress.

CSC 'step-up'

Data on the third co-secondary outcome will be obtained from social services administrative case data obtained from LAs by IFF Research and linked to the trial data set in pseudonymised form. The outcome will be a binary response coded to '1' if the focal child in a dyad is observed to have had a 'step up' outcome. By step-up outcome we mean that there is a new CPP in place (where none-existed previously, i.e. the focal child was CiN), or a CLA, or pre-proceeding have been initiated in relation to the focal child. For a dyad to be coded to '1' a new CPP must have materialised in the six months since randomisation, or the onset of a CLA occurred over this period, or pre-proceeding initiated. If none of these events occur the outcome is coded to '0'. Only data for the dyads randomised between July and

[11] Oates, J., Gervai, J., Danis, I., Lakatos, K. and Davies, J. (2018) 'Validation of the Mothers' Object Relations Scales Short-Form (MORS-SF)', Journal of Prenatal and Perinatal Psychology and Health, vol. 33, pp. 38–50.

[12] Črnčec, R., Barnett, B., & Matthey, S. (2008). Karitane Parenting Confidence Scale: Manual. Sydney South West Area Health Service. Sydney: Australia.

[13] Berry, J. O., & Jones, W. H. (1995). 'The Parental Stress Scale: Initial psychometric evidence. Journal of Social and Personal Relationships', 12, 463-472.

November 2021 will be included in analyses of this indicator, such that a period of six months since randomisation could elapse within the time scales for this trial. If the timescales for the trial are extended, then more of the study sample will be included in this analysis.

Correcting for multiple comparisons

In line with WWCSC's statistical analysis guidance[14] (p.11) no correction for multiple comparisons will be made (this is a two arm trial and there are less than four outcomes in each category – primary and secondary).

Analysis Plan

The primary analysis will be conducted according to the principle of intention to treat (AITT), recognising the possibility that some dyads allocated to the intervention will remain unexposed to the intervention. There is also a possibility that some dyads allocated to control, through error or subversion, are exposed to VIG. Essentially the trial data are analysed consistent with the allocation dyads received at randomisation regardless of whether they then went on to be exposed to VIG. This situation is slightly complicated by the challenges of missing data both at baseline and/or follow-up. These features of the data effectively create the following distinctions in the trial data:

- ***The referred sample as randomised*** – this sample contains complete records from the referral forms for all dyads referred and randomised.

- ***The baseline sample as randomised*** – this sample is all those dyads referred and randomised and who supplied the required data at baseline.

- ***The follow-up sample at analysis*** – this sample is all those dyads referred and randomised and who supplied complete data at follow-up. *Note*, we assume for child protection outcomes, obtained from administrative case files, there are no missing data at follow-up.

- ***The completed cases sample at analysis*** – this sample is all those dyads referred, randomised and who supply the necessary responses to the baseline and follow-up, such that the primary analysis described below can be conducted; that is prior to imputation

- ***The imputed sample at analysis*** – imputation at analysis will take different forms depending on which of the co-primary outcomes is considered (a full discussion of missing data and imputation strategy is provided below). For the primary outcomes derived from the MORS-SF scale the imputed sample at analysis contains all dyads referred and randomised, with either their observed values derived from the relevant items in the baseline and follow-up questionnaires, or where missing, their values on the relevant items required for the primary analysis filled-in using multiple imputation, should this prove a possible/viable strategy.

- ***Imputed sample at analysis (bounds)*** – We propose to obtain estimates using extreme bounds for the two co-primary outcomes. With this approach sample missing values are imputed using two different approaches. In these data, missing values at the baseline for both approaches are imputed using mean imputation with a missing value indicator derived for each sample case for which baseline imputation is

[14] What Works for Children's Social Care (2021).'What Works for Children's Social Care Randomised Controlled Trial Statistical Analysis Guidance.' https://whatworks-csc.org.uk/wp-content/uploads/WWCSC-RCT-Statistical-Analysis-Guidance-V1.1-1.pdf

conducted. Two samples are then created. In the first sample, missing follow-up values for the intervention sample are set at the maximum value for the observed distribution at follow-up for the outcome. Conversely, for the control group, missing values are set to the minimum value of the observed distribution. A second data set is then created where missing values in the intervention group are set to the minimum value and in the control group to the maximum value. The primary analysis is then conducted on both data sets. The results give a feel for the possible range of plausible treatment effect estimates, from a maximum plausible estimate to a minimum estimate. The wider this range the greater the degree of caution that should be exercised in the interpretation of sample estimates in the presence of appreciable levels of missing data.

Primary Analysis

The purpose of the primary analysis is to provide estimates of the average effect of intention to treat (AITT) – that is the average effect of the offer of VIG to members of the study intervention sample on the co-primary outcomes at follow-up. The estimator from which sample estimates of AITT are obtained is chosen on the basis that the trial is multi-site by design and that sites are a convenience sample. For all analyses, sites are treated as fixed effects, consistent with the requirements set out in the funder's Statistical Analysis Guidance[15].

The primary analysis involves obtaining a sample average treatment effect estimate. The analysis will be performed first on the *completed cases sample*, and then repeated on the *imputed sample at analysis* and *imputed sample at analysis – bounds,* in order to assess the likely consequences for the sample estimates of missing data. The average effect of intention to treat will be obtained on the basis of the following estimator[16] for the warmth outcome (first co-primary outcome) derived from MORS-SF:

$$Y_{ij} = \sum_{j=k}^{J} \alpha_k S_{k,ij} + \beta_1 T_{ij} + \beta_2 X_{ij} + \varepsilon_{ij} \ldots.[1]$$

Where Y_{ij} is an observed value on the warmth scale derived from the MORS-SF instrument for dyad i at site $j = k$. This is a raw unstandardised value obtained from sample responses to the MORS-SF statements by focal parents, included in the follow-up questionnaire. The raw response values are preferred in order to maintain transparency and interpretability, and are derived by summing item scores across the seven items corresponding to the warmth scale. The assumption is that the respondent is the focal parent. The variable $S_{k,ij}$ is a binary indicator set equal to '1' for dyad i at site $j = k$, zero otherwise. The variable T_{ij} is also a binary indicator variable, set equal to '1' where dyad i at site $j = k$ is randomised to the intervention, zero otherwise. The constant term is suppressed, which means that sample estimates of α_k are the mean outcomes of Y in the control group at each site. The variable X_{ij} is a raw, unstandardised value for the baseline measure of Y for dyad i at site $j = k$. The

[15] What Works for Children's Social Care (2021).'What Works for Children's Social Care Randomised Controlled Trial Statistical Analysis Guidance.' https://whatworks-csc.org.uk/wp-content/uploads/WWCSC-RCT-Statistical-Analysis-Guidance-V1.1-1.pdf

[16] The preferred estimator is what Miratrix et al (2021) refer to as the precision weighted estimator. Where the assignment ratio differs by site in the completed cases sample file and site specific effects differ or are correlated with site size, this estimator can be biased. In such circumstances a full treatment site interaction term should be included in the model. In order to determine the extent of such problems, sensitivity tests are specified that include a model with full treatment site interaction terms, with sample estimates of ITOT and standard errors derived using site weighted averages.

coefficient β_1 is the sample estimate of the average effect of intention to treat ($\beta_1 = \hat{\beta}_{ITOT}$). Inference will be performed through constructing frequentist 95 percent confidence intervals.

The study's funder requires that sample estimates of AITT are presented as effect sizes consistent with that defined by Glass, known as Glass's Delta for a continuous outcome. In the case of this study, Glass's Delta for the first co-primary outcome derived from the MORS-SF scale will be obtained by dividing $\hat{\beta}_{ITOT}$ by the unconditional control group standard deviation. A 95 per cent confidence interval for Glass's Delta will be derived using bootstrap procedures based on 500 replications.

The second co-primary outcome (invasion) derived from the MORS-SF instrument will be analysed in the same manner as the first (warmth) described above. Essentially this means that equation [1] is altered such that Y_{ij} is now an observed value on the 'invasion' scale derived from the MORS-SF instrument for dyad i at site $j = k$, and the variable X_{ij} is a raw, unstandardised value for the baseline measure of Y for dyad i at site $j = k$.

These analyses will be performed in STATA v17 statistical software. All code will be provided in an annex to the project reports with values for random number seeds.

Sensitivity analysis – primary outcomes

For the primary outcomes derived from the MORS-SF instrument – 'warmth' and 'invasion' – two further analyses will be performed. These analyses aim to sensitivity test key assumptions underpinning the chosen primary analysis described above. They will be conducted on the completed cases sample file. First, an equation of the following form will be estimated using linear regression:

$$Y_{ij} = \sum_{j=k}^{J} \alpha_k S_{k,ij} + \sum_{k=1}^{J} \beta_k S_{k,ij} * T_{ij} + \beta_2 X_{ij} + \varepsilon_{ij}$$

Here we allow for the effects of the intervention to vary across sites through the inclusion of a treatment by site interaction term. This specification permits us to test whether imbalances between intervention and control groups by site resulting from attrition, should they emerge, affect our sample estimates. We propose to obtain a sample average estimate by taking a weighted average of the site specific effects obtained from this model as follows:

$$\hat{\beta}_{ITOT} = \sum_{J=1}^{J} \frac{N_J}{N} \hat{\beta}_k$$

Where $\frac{N_J}{N}$ is the proportion of the total sample at site J. The standard distributional assumptions regarding ε_{ij} are made. A weighted average of the standard error will also be formed in a similar manner. Site specific standard errors will be obtained using bootstrap procedures based on 500 replications. Inference on $\hat{\beta}_{ITOT}$ will be performed through constructing frequentist 95 percent confidence intervals.

The second form of sensitivity analysis for the two primary outcomes involves an extension to model [1] above. It is proposed to include a full range of covariates in an extended regression analysis. Alongside a baseline measure of the dependent variable and site specific dummy variables we propose to obtain a sample estimate of AITT from a regression equation including additional covariates capturing:

- focal parent's age,

- baby's age in months; and
- presence of a partner

This analysis will test the sensitivity of the results to the specification of the regression equation and choices made over the inclusion of various covariates.

Missing data and imputation

As previously mentioned, one major challenge for this study will be missing data at both baseline and follow-up for the first two of the three co-primary outcomes derived from survey questionnaires (as well as secondary outcomes). In other words, obtaining unbiased estimates of AITT from the estimator represented by equation [1] above will likely be compromised by both unit and item non-response where estimates are obtained from fitting the statistical model to the completed cases sample file.

In principle, because baseline data are collected prior to randomisation, missingness will not lead to bias in estimates of AITT (Sullivan et al., 2018)[17]. Completed cases analysis where baseline observations are missing is unlikely to cause bias but would lead to a diminished sample size. The same is not likely to be the case where observations are missing at follow-up. It seems highly probable that follow-up missing data processes will differ in the trial arms; for example, it seems possible that follow-up interviews will more likely be obtained from those assigned to the intervention. Given that we anticipate missing data at both baseline and follow-up for the primary outcomes derived from the MORS-SF instrument, we are faced with two potentially different missing data processes acting to generate the achieved sample simultaneously. In the case of follow-up data, missing data processes are most likely to be experimentally MAR or MNAR. For the baseline, missingness is uncorrelated with randomisation in expectations due to the fact that baseline measures are collected prior to randomisation.

Our approach is to conduct the primary analyses for each of the co-primary outcomes identified, following the approach set out in the previous sections, on the completed cases sample at analysis. Then for the co-primary outcomes derived from the MORS-SF instrument, to sensitivity test the results from these analyses by assessing the likely consequences for sample estimates of missing data being MAR. Whilst MAR could in theory be addressed through adding the necessary covariates to the model implied by equation [1], the proposed strategy we adopt, that of Multiple Imputation, preserves sample size. We propose to fit an imputation model, using the data augmentation approach (based on cycles of imputation using the MCMA algorithm) and multivariate normal assumption in STATA v17 (using the mi impute suite of commands) where values for the primary outcome Y and covariate X are imputed on the basis of a model containing further covariates from the referral forms and possibly values of the other outcomes available at follow-up and baseline depending on patterns of missingness in these variables[18]. The burn-in phase for the imputation will consist of 500 imputation cycles with the number of imputed data sets set equal to the highest FMI (fraction of missing information) for either Y or X determined from an initial run, and with 100 cycles between the creation of each imputed data set. Imputation will be conducted in intervention and control groups separately. The stability of the imputation will be assessed through inspecting variance information and standard plots for Y and X. If these appear satisfactory, equation [1] will be estimated on the final merged

[17] In the case where baseline covariate values only are missing, null or mean imputation methods are likely to work well in preserving power and unbiased AITT because the values of the coefficients on the Xs are not in and of themselves of interest and they are uncorrelated with T in expectations (Puma et al., 2009)

[18] There are arguments against the use of multiple imputation in randomised trials. Sullivan et al. (2018) show some loss of efficiency when compared to completed cases analysis with full regression adjustment but this result is obtained where data are missing on the outcome at follow-up only. We believe in the case of this study, multiple imputation if achievable, represents the most practical strategy open to us.

imputed datasets for each primary outcome as appropriate and results compared to the completed cases analysis.

If multiple imputation does not appear to perform satisfactorily, then we propose to first estimate a drop out model where the probability of missingness at follow-up is modelled on the basis of a full set of variables derived from the referral form and captured at baseline, in a logistic regression. Variables that appear to be associated with missingness at follow-up will be added to the regression model [1] as additional covariates, and the model re-estimated on the completed cases at analysis sample file.

Given that there are no wholly satisfactory approaches to addressing the situation where missing data are suspected to be MNAR experimentally, our assessment of the potential consequences of missing data for our analysis of the co-primary outcomes (MORS-SF) will conclude with estimation of extreme bounds on the sample estimates of AITT (Gerber, Alan & Green, Donald, 2012; Puma et al., 2009). Under this approach we make no assumption about the missing data process. First we propose to conduct mean imputation for missing baseline observations with dummy variables indicators for dyads with a missing value on X at the baseline. Then an upper bound on AITT will be calculated through imputing missing outcomes at follow-up for the control group at the minimum value for the outcomes concerned at their site, whilst for the intervention group imputing missing values set to the maximum value for the relevant outcome at their site. A lower bound AITT can be obtained by imputing missing values for the control group on the relevant outcome at follow-up equal to the maximum observed value at their site, whilst for the intervention group the minimum observed value. If the range between the upper and lower bound is quite large this tells us to exercise a high degree of caution in relation to results from the completed cases analysis.

Secondary Analysis

Secondary analysis will consist of two sets of distinct analysis: first the derivation of sample estimates of the average effect of intention to treat on (1) parental self-efficacy (Karitane Parenting Confidence Scale); (2) Parental stress (Parental Stress Scale); and (3) the step-up/CSC escalation binary indicator. Second, for the primary analyses discussed above, for both co-primary outcomes, sample estimates of complier average causal effects (CACEs) will be obtained if it has proved possible to collect accurate take-up measures for individual dyads

Sample estimates of AITT for self-efficacy and parents stress will be obtained from fitting regression models to the relevant data consistent with the Equation [1] above, and using the same statistical procedures, where the dependent variables 'Y' and covariate 'X' are derived from the relevant scales and questionnaire data at baseline and follow-up. All model estimates will be derived from the completed cases sample files for the relevant data items.

A sample estimate of AITT for the step-up binary outcome will also be obtained as part of the secondary analysis. Sample estimates will be obtained from a linear probability model containing the following covariates, where the binary response is the dependent variable:

- Focal parent's age at randomisation (from the referral form)
- Focal baby's age in months at randomisation (from the referral form)
- Whether the father is present in the family home at randomisation (from the referral form)

The analysis will be performed on sample cases for those dyads randomised between July and November 2021. We anticipate that this sample will comprise some 150 cases. This analysis should not be affected by missingness. For binary outcomes, effect sizes will reported as differences in adjusted incident rates.

If possible we will seek to obtain records on programme exposure for each dyad, whether allocated to intervention or control. If such indicators are of sufficient reliability and quality we propose to obtain complier average causal effects on the co-primary outcomes (Glennerster & Takavarasha, 2013).

Exploratory Analysis

We will undertake exploratory analysis to explore VIG Practitioner outcomes. As defined by the Logic Model these pertain to engagement and job satisfaction. This analysis is exploratory due to the absence of a counterfactual group (the evaluation commissioning process did not allow for random allocation of social and family workers to VIG Practitioner training), and the small sample size (n = 21).

These outcomes will be explored using the psychological construct of work engagement. This is understood by occupational psychologists to be the opposite of burnout; engaged employees are connected with and energised by their work, and they are able to deal effectively with the demands of their job. The Shortened Utrecht Work Engagement Scale (UWES-9)[19] is a self-report questionnaire comprising 9 items measuring three dimensions which constitute work engagement. Examples of scale items are:

> "When I get up in the morning, I feel like going to work." (*vigor*)
> "I am proud of the work that I do." (*dedication*)
> "Time flies when I am working." (*absorption*)

Vigor, associated with high levels of energy and mental resilience while working, the willingness to invest effort in one's work, and persistence even in the face of difficulties. *Dedication* refers to being strongly involved in one's work and experiencing a sense of significance, enthusiasm, inspiration, pride, and challenge. *Absorption*, characterised by being fully concentrated and happily engrossed in one's work, whereby time passes quickly and one has difficulties with detaching oneself from work.

Items are rated on a 6–point Likert scale (1 = almost never , 6 = always). Dimension scores are obtained by calculating the mean of the items in the subscale. The overall work engagement scale score is obtained by calculating the mean of all 9 items.

The instrument will be administered to VIG Practitioners either as part of face-to-face interviews or by email before delivery commences (in early July 2021) and again in February 2022.

VIG Practitioner overall mean and dimension mean scores will be compared pre- and post-intervention and will also be compared with a reference norm group.

Contextual Factors Analysis

Contextual factors will be explored within the context of the implementation and process evaluation and will not be quantified for analysis of impacts.

Evaluation Review Point

[19] Schaufeli, W. B., & Bakker, A. B. (2004). 'Bevlogenheid: Een begrip gemeten.' Gedrag en organisatie, *17*, 89-112.

The scoping stage and the process of developing the trial protocol flagged questions that may influence the trial design and the quality and accuracy of results. These are discussed above and summarised below:

- Possibility of greater programme drop-out than expected
- Possibility of more parents requiring translation services than expected

To strike a balance between trial robustness and pragmatic delivery, the evaluation team and WWCSC agreed to review the evaluation design and delivery after two months of referrals (27th Sept 2021) to formally review programme referrals, their implications to trial delivery and agree any refinements to trial delivery. This will include updating power calculations based on programme participants at that time.

Implementation and Process Evaluation

Aims

The implementation and process evaluation will assess how the intervention has been implemented and whether the elements of the theory of change underpinning the programme worked as intended. It will also explore outcomes among social workers and families, such as **improved parental self-esteem and confidence, reduced parental stress, VIG Practitioner work engagement.**

Research Questions

- Has set-up taken place as intended? What adjustments have been made?
- Is the training perceived by VIG practitioners as adequately equipping them to deliver VIG?
- How have VIG Practitioners experienced delivery of VIG?
- What difference is VIG perceived to make to parents, and why?
- What difference is VIG perceived to make to VIG Practitioners, and why?
- When / for who is VIG perceived to be most effective?

Design

The IPE consists of two phases. The first phase focuses on setup and implementation of the intervention and will take place once social workers have completed their training and referral routes have been implemented in all four LAs. The second phase will focus on

experiences of delivery and will take place after the first batch of parents have completed the baseline survey.

IPE Design Table	
Indicators	**Method and Time Point**
1. Has set-up taken place as intended? What adjustments have been made?	
- Extent to which VIG intervention was delivered as planned within each LA - Adjustments made and justification for these - Challenges faced and mitigation strategies	In-depth interviews with delivery leads, trainers and VIG Practitioners at the end of setup/implementation and at the end of delivery
2. Is the training perceived by VIG practitioners as adequately equipping them to deliver VIG?	
- How prepared/ confident do VIG Practitioners feel to deliver VIG? - What support needs do VIG Practitioners have throughout the intervention?	In-depth interviews with delivery leads, trainers and VIG Practitioners at the end of setup/implementation and at the end of delivery
3. How have social workers experienced delivery of VIG?	
- How do VIG Practitioners describe the experience of delivering VIG? - What went well and what went less well? - Can VIG Practitioners identify any areas of improvement?	In-depth interviews VIG Practitioners at the end of setup/ implementation and at the end of delivery
4. What difference is VIG perceived to make to parents and why?	
- How have parents experienced VIG? - What elements of VIG did parents find most/least useful? - What difference is VIG perceived to make to parents, and why? (e.g. parents' relationship to the focal child and to other children in the family; experience of parenting; relationship to social services) - When/for who is VIG perceived to be most effective?	In-depth interviews with parents at the end of delivery
5. What difference is VIG perceived to make to VIG Practitioners and why?	
- What difference is VIG perceived to make for VIG practitioners, and why? (e.g. ability to support families; engage with families; engagement with their work; job satisfaction) - What social worker characteristics/factors are perceived to influence VIG delivery?	In-depth interviews VIG Practitioners the end of delivery
6. When / for who is VIG perceived to be most effective?	
- What parent characteristics/factors are perceived to be related to effective VIG? - What social worker characteristics/factors are perceived to influence VIG effectiveness?	In-depth interviews with delivery leads, trainers, VIG Practitioners at the end of setup/implementation and delivery leads, trainers, VIG

Methods

Sample and Recruitment

Sample

All families in the four areas with a baby under 1 year (at the start of the intervention) who is the subject of a CiN or CP plan (i.e. with an allocated social worker) will be eligible for the trial. The main recipient of VIG ('focal parent') will be the focal child's primary care giver, which is expected to be the mother but in some circumstances might be the father where they are the only, or primary, care giver.

Parents with active substance misuse or serious mental ill health issues will be excluded.

Parents who are unable to read and speak English fluently will also be excluded. However, this will be reviewed in September 2021.

Recruitment

The local authority will be responsible for promoting the service and for identifying and recruiting families. They will have all the relevant information about potential participants to decide whether VIG should be offered and will pass referrals to IFF. IFF will check to determine eligibility.

Babies 1st will not be actively involved in recruitment of families. Their role is to train and supervise the workers to deliver the VIG ensuring a high standard of VIG is provided.

The Local Authority will essentially set up a VIG service for their area. They will be responsible for promoting the service to staff and setting up a referral process. The families are going to be asked to participate in the project to help shape the policies of social services for them and future families who need support. (Babies1st will liaise and support LAs with relevant information). By agreeing to be part of the project, the families will be told that they will be helping to find out what LA services are doing that helps families like them. They will be told that the service they receive will be evaluated and they will be asked to share their opinion on what they think worked well and what could be done better.

Consent procedures

Parents will be asked to consent to take part in the study on behalf of themselves and their baby.

It is possible that some parents will be aged under 16. Parents/infants likely to be eligible for the study may face multiple areas of disadvantage and challenge. Information will therefore be presented in a range of formats to ensure that it is easy to access and understandable by all. Throughout the recruitment process, LAs will make sure that young persons and participants from vulnerable groups will have sufficient understanding of the proposed project. Information will be presented in a way comprehensible to potential participants in the form of short accessible information sheets that Local Authorities can use to ensure that potential participants are fully informed.

After randomisation, participants who are allocated to receive treatment will be further informed about VIG: there is a client information sheet used by Babies1st that the practitioner talks through with a parent before starting VIG. Moreover, a bespoke animation for Babies1st will be used to introduce VIG to parents of babies.

All parents will also be issued with a withdrawal form and can withdraw from the study at any time by sending this to IFF. By doing so their data will be removed from the trial database and will not be further processed.

Information will be presented in a way comprehensible to potential participants. WWCSC will create animations and short accessible information sheets that Local Authorities can use to ensure that potential participants are fully informed.

Parents may feel that their treatment by social services is conditional on their participation in the trial. All communications will overtly state that there is no obligation to take part, and that their decision will not affect their ongoing and future care.

Qualitative data collection - stage 1

The first phase of fieldwork, focusing on setup and implementation fieldwork will include:

- **4-5 in-depth interviews with delivery leads** from each of the participating areas, and Babies1st overall lead. These interviews will focus on experiences of elements such as recruitment of VIG Practitioners and parent dyads, training of VIG Practitioners, as well as any perceived risks to the programme and associated mitigation strategies. We expect these to last around 60 minutes.

- **Focus group with 4-8 trainers and supervisors** from Babiest1st, to gain a deeper understanding of the training and guidance VIG Practitioners are provided with and what their support needs are seen to be.

- **Focus groups with VIG Practitioners** in each area. In areas with more than 6 VIG Practitioners taking part, focus groups will be split into two groups, totalling six groups. The discussion will focus on their expectations of the programme, views on the training and guidance they have received and what ongoing support they feel they need.

Qualitative data collection will take place in August 2021, shortly after intake.

Qualitative data collection - stage 2

The second phase of fieldwork will include:

- **Visits to each of the participating areas** to carry out interviews with delivery leads and all 21 participating VIG Practitioners. For this phase, we will conduct interviews with VIG Practitioners on a one-to-one basis, to give sufficient time to be able to discuss detailed experiences with specific parent dyads without fear of disclosure to others. Any VIG Practitioners unable to participate on the day of the visit will be interviewed by video call at their convenience. In addition to exploring issues around process, VIG Practitioners will be asked a few more quantitative questions about impact e.g., self-reported 'work engagement' etc. As this group is small and not being randomised this is a proportionate approach to obtaining impact measures. We will however make exploratory comparisons between VIG practitioners' outcomes and those of established norm groups reported by test developers.

- **A focus group with supervisors over video call and observations of four group supervision sessions**, to better understand any challenges or support needs among VIG Practitioners and how these are met.

- **In-depth interviews with 24 families**. In order to capture the experiences of parents and their views on the outcomes achieved, we will carry out interviews with 24 parents, spread across VIG Practitioners participating in the programme, upon completion of the 3-month intervention. Parents will receive all VIG sessions in person, and the Shared Reviews will be either in person or online. This will allow for maximum parental participation in the evaluation. Interviews will last approximately 60 minutes and as a thank you for their time, parents will be offered £30, in the form of a voucher (e.g., Amazon, Paypal, Love2Shop). This will not have an impact on state benefits that parents might be receiving. To reduce barriers to participation, we will be flexible with parent fieldwork. For example, interviews may be split over two, shorter sessions. We will not request permission to access the VIG session recordings because we will not include this in the evaluation analysis.

It is unlikely we will hit saturation because the Social Workers and families are expected to be different, with different experiences, especially since the 21 practitioners come from 4 different LAs with different CSC structures and practice standards. However, we will have ongoing discussions about what we are learning and if we feel we are starting to hear the same things with nothing new emerging then we would raise this with WWCSC and discuss whether to end interviews, and how best to reallocate that evaluation budget elsewhere in the evaluation.

Method	Sample size	Time point
In-depth interviews with delivery leads	4-5 respondents	Early August 2021
Focus group with trainers and supervisors	4-8 trainers and supervisors	Early August 2021
Focus groups with VIG Practitioners in each area	Total of six groups (4-6 respondents in each group)	Early August 2021
Interviews with delivery leads and all participating VIG Practitioners in local areas	20-25	November/December 2021
A focus group with supervisors over video call	4-6 respondents	November/December 2021
Observations of four group supervision sessions	5-15 participants	August – December 2021
In-depth interviews with families	24 families	May/June 2021

Analysis

Our analytical approach for the qualitative research will be iterative and inductive – building upwards from the views of participants – incorporating elements of 'grounded theory' analysis e.g. the thematic review and continual analysis of hypothesis from participants dialogue and researchers' impressions of the discussion (e.g. pauses, tone). Analysis will begin informally during fieldwork itself; as our research team work closely together throughout the fieldwork period, feeding back headline findings to each other as discussions are conducted, and continually updating our approach and thinking as we amass data. All interviews are written up in detail, including verbatim quotes, in an analytical framework in Excel. The framework will be structured around the logic model and research questions, and include key sample data, to allow for comparison of findings by different characteristics. The data will then be analysed to search for themes and trends, both present and absent. Once qualitative analysis is complete we will then compare those findings with other evidence to

challenge and address gaps. Director-led analysis sessions will bring this thinking together, encourage challenge of assumptions and identify areas for further, targeted analysis.

Cost Evaluation

The overriding aim of the cost evaluation will be to ascertain the cost of the resources needed to deliver the intervention during the trial. From this we derive the following research questions:

1. What are the estimated delivery costs of the VIG trial;
    a. in total?
    b. per LA?
    c. per dyad?
2. What would be the estimated cost of implementing VIG in the four LAs over three years?

As such the cost-evaluation will take the form of a Cost Feasibility analysis, representing a guide to the affordability of VIG, rather than a comparison between VIG and an alternative intervention (which would also make a judgement about effectiveness by incorporating outcome data from both[20]).

Scope
This analysis will primarily take a fiscal perspective, i.e. pertaining to the Local Authority in order to derive findings which are relevant to organisational stakeholders – the LA as the essential decision maker. This perspective will also assume that no outside funding is being provided, and will therefore clearly articulate the likely costs of VIG if the intervention were to be continued in the trial LAs beyond the trial, or were to be implemented in other LAs. In addition a secondary analysis will consider costs no matter by whom they are incurred.

Resource implications will be considered for the intervention as delivered, and will note any likely potential changes to costs in the future (for example doing more of the work face-to-face rather than by video as the pandemic abates). Therefore data collection will seek to estimate both the current costs and future costs.

Method
The essential method behind this is the 'ingredients method' which comprises the following steps:

1. Identifying and specifying ingredients. This will include all the resources required to achieve the program's intended impact.
2. Valuing and pricing ingredients.
3. Calculating costs to address research questions (1 and 2 above).

Identifying, specifying and valuing ingredients
The ingredients method essentially uses triangulation to combine data from various sources to arrive at a precise cost estimate. The ingredients and their values will be derived from the following:

- A review of programme documentation (logic model), other information supplied by Babies 1st such as training details, documentation about previous VIG evaluations and systematic reviews, financial records.
- Questions embedded within the existing process evaluation undertaken by IFF.
- Cost capture interviews carried out by Man Met. With professionals:
    - Training staff

[20] Levin, H.M., McEwan, P.J., Belfield, C., Bowden, A.B. and Shand, R., 2017. *Economic evaluation in education: Cost-effectiveness and benefit-cost analysis*. SAGE publications.

- VIG Practitioners
- Managers of VIG Practitioners
- Potentially accountants in local authorities

We provisionally expect the ingredients to be categorised as follows:

a. Personnel. Who (qualifications etc.). VIG Practitioner time to deliver the intervention.
b. Training. Costs of training delivery, VIG Practitioner time to attend training.
c. Facilities. Costs of room hire for delivery of the intervention.
d. Equipment and materials. Any equipment which is purchased for the delivery of the intervention.
e. Other program inputs.

Calculating costs

The cost calculation in essence focuses on additionality, estimating the difference between the treated and the care-as-usual groups. This is expected to be straightforward, simply being an estimation of the costs of delivering VIG, rather than comparing VIG with an alternative intervention. Nevertheless it will be important to monitor the care-as-usual condition in each LA, something which is to be achieved by the process evaluation.

Cost estimates will be categorised as follows:

1. Pre-requisites (required for the implementation of the intervention, but that LAs already have).
2. Start-up costs (resources necessary to implement the intervention for the duration of the trial).
3. Ongoing costs for the programme as if implemented at operational scale over three years. In effect these will be derived from annual recurring costs.

Estimates will be subject to sensitivity analyses[21] to consider:

1. Heterogeneity, i.e. how costs and resources vary between LAs. This may involve specifying different costing models (e.g. London-based LAs and those outside London).
2. Parameter uncertainty, where we need to make assumptions or judgements about the value of the resource – this would involve discussing how overall costs may vary due to the judgements made.
3. Adjustments for inflation.
4. The value of money over time.

[21] Education Endowment Foundation (2019). *Cost evaluation guidance for EEF Evaluations.*

Risks

Some of the key challenges that this research presents (and our strategies to handle them) are that:

Risk	Mitigation
Specific risks (although minor) may arise due to the nature of the survey and interview questions. The surveys will contain multiple measures of a psychological and development nature (e.g., stress, confidence, parenting ability). Responding to statements included in these measures may potentially alert parents to their behaviours and beliefs, and as a result may cause them some concerns.	At the end of the surveys parents will be instructed to speak to their case working social worker or VIG practitioner in the first instance if they have any concerns about the questions to which they responded, either in the surveys or in the interviews. Dyads assigned to the intervention or control groups will both receive the usual LA-specific support provided to infants who are on a Child Protection or Child in Need plan, and their parents. Given that all these families will be open to children's social care, they will all have a social worker and be receiving this support. The VIG practitioners involved are awarded a national recognized accreditation, proving they have reached the desired skills level. The training and supervision they receive is delivered by highly experienced VIG trainers. They have delivered similar training in many and various projects over the last 10 years, including in mother baby units, the NSPCC, CAMHS, Children's Services, Family Drug and Alcohol Courts, and Family Assessment units. Hence, practitioners will have the expertise to mitigate psychological risk or discomfort that may arise during the intervention.
Parents struggle to complete the online survey due to literacy issues, issues with understanding the survey measurements, or lack of access to internet	Telephone reminders will be carried out to non-responders and as part of this call interviewers will offer support in order for parents to complete the survey. Social workers and VIG practitioners will also be provided with a copy of the survey and information about how to support and encourage parents to participate.
Parents struggle to complete the online survey due to lack of English comprehension	Social workers are asked to confirm that the focal parent is sufficiently fluent in English to take part in the surveys.
Low response to the online surveys	Telephone reminders will be carried out to all non-responders. Social workers and VIG practitioners will be provided with information about the survey and asked to encourage parents to participate. All parents in the trial will be invited to complete the follow-up survey, including those who do not respond to the baseline survey. Parents in both the intervention and control groups will be offered a financial incentive of £5 to complete both the baseline and follow up surveys.
Low response to qualitative interviews	Social workers, delivery leads and trainers will be recruited with support from nominated leads for the intervention in each LA, as well as Babiest1st. Staff will be provided with accessible information about the IPE and why their participation is needed. Staff who are unable to participate during group sessions or site visits will be offered a one-to-one interview by telephone or video call at a time convenient to them.

	Interviews with parents will similarly be offered at a time which suits them and parents will be given a financial incentive of £30 as a thank you for their time.
Recruitment will be managed by each participating local authority and there is therefore a risk that areas do not take a consistent approach to recruitment and engage slightly different cohorts of parents.	Areas have been asked to appoint a recruitment lead to confirm eligibility before submitting recruited parents to IFF for randomisation and each lead will be provided with guidance materials on eligibility. Any notable differences between cohorts will be analysed upon completion of the baseline survey.
There remains considerable uncertainty about how the Covid-19 pandemic will play out over the delivery period.	This means we will need to be understanding and flexible in our dealings with Babies 1st and with participating local authorities (LAs). This may mean needing to adapt our fieldwork approach and timings for process evaluation and we are happy to do this

Ethics & Participation

WWCSC's Research Ethics Committee have given ethical approval

Mat Met also submitted a separate ethics application (no. 33599) to the University's Arts and Humanities ethics committee in respect of their role as data processors. This was approved on 21/05/2021.

All staff participating in the IPE (including LA staff and Babiest1st staff) will be provided with information upon recruitment explaining the research and how their data will be used. These documents will stress the voluntary nature of their participation. Verbal consent to participation and to recording of the interview will be collected before the interview begins.

Parents in the trial will be contacted by IFF's in-house recruitment team in order to encourage completion of the online survey and to be invited to take part in qualitative interviews. Recruiters will use an accessible information sheet to explain the purpose of the surveys and qualitative interviews to parents and the value of their participation. Recruiters will stress that participation is entirely voluntary and will not affect their dealings with their social worker or the social care system more broadly in anyway. Verbal consent to participation and to recording of the interview will be collected before the interview begins and parents will be informed that they can choose to withdraw their consent at any time.

Registration

This protocol will be published on WWCSC's website and also the Open Science Framework (OSF) website

Data Protection

IFF, as data controller, is registered with the Information Commissioner's Office for Data Protection under registration number Z5571698. IFF is accredited with ISO27001, the international standard for information security. We are fully compliant with GDPR and GDPR training is given to all staff members. All our storage, handling and processing or personal and sensitive data is conducted within the UK; and in line with ISO27001 (the international data security standard, with which IFF Research is accredited). All personal data is stored on our secure drive, which only the project team has access to. Data will be shared with Man Met using a password protected Excel document, transferred via IFF's secure file sharing

site. Man Met (as data processor) will keep all data secure from any unauthorised or accidental use, access, disclosure, damage, loss or destruction by using the University's Research Data Storage system.

We explain to research participants, at the point of interviewing them, their rights to see the personally identifiable data we hold on them, to change this data, or to have it deleted, whilst their personal data is held. Under GDPR, participants can have their personal data deleted at any point in time, whilst it is held. At this point we also signpost them to an FAQ's page on our website giving research participants information about the legal basis for taking part, what we do with their data, and the rights that they have. https://www.iffresearch.com/gdpr/

All personal data will be securely deleted no later than one year after the end of the project.

Furthermore, it is our intention to share participant identifiers with WWCSC who will securely store those to enable a longer term follow-up with CSC admin based measures.

Personnel

Lorna Adams, Director (IFF)

Project role

- Principal Investigator (overall project lead)
- Responsible for quality delivery to timetable
- Lead research design
- Conduct some interviews
- Lead analysis session
- Report author, deliver presentation

Lorna has 25 years' research experience and has been a Director at IFF for 20 years. She has worked extensively across the fields of children and families, education, employment, welfare and wellbeing. She is particularly experienced in the delivery of complex quantitative surveys and in the delivery of process and impact evaluations. She has worked extensively for the DWP, DfE, EHRC and BEIS.

Education

- BA (Geography) St Catharine's College Cambridge (2:1)

Professor Stephen Morris (Man Met)

Project role

- Principal Investigator (PERU team lead)

Stephen is Professor of Evaluation at Manchester Metropolitan University (MMU) and Deputy Head of the Research Centre for Applied Social Science at MMU (since February 2016). With a career spanning over 25 years, Stephen has held senior positions at NatCen Social Research, the Policy Studies Institute and UK Civil Service, where he has worked on a wide range of applied quantitative and mixed method social science research projects, specialising in programme evaluations and intervention studies. Stephen's interests lie in the understanding and application of methods of causal inference particularly as they relate to the evaluation of social programmes and interventions in education, social security, labour markets and crime and justice. Stephen was one of the pioneers of the use of randomised trials in social policy in the UK. Stephen authored the government's influential Magenta Book and designed a number of high-profile national evaluation studies, contributing to the development of evaluation as a discipline. Stephen is a member of the UK Government Trial Advice Panel, A member of the editorial board for the journal Sociological Research Online, an Associate of the Centre for Ageing Better, a member of the Evaluation Advisory Group of the What Works Centre for Children's Social Care, Honorary Fellow of the Institute for Employment Studies and a member of the Education Endowment Foundation's peer review group.

Education: MA Development Economics, (Sussex) (1992)
BA Economics, 2(i), (Econ) (1991)

Siv Svanaes, Associate Director (IFF)

Project role

- Overall project manager
- Day-to-day point of contact
- Conduct interviews
- Participate in analysis and reporting

Siv has 10 years of experience in social research and specialises in qualitative research and evaluation work. Before joining IFF in 2016, Siv worked for the specialist agency FK&S, focusing on research with families, children and schools. Siv brings expertise conducting research with children and young people, as well as research on sensitive subjects, such as debt, poverty and physical and mental health. She also brings experience managing multistrand projects and synthesizing data from different stands into powerful and actionable insights for our clients.

Education

- 2010-2011 - MSc Culture and Society (London School of Economics)
- 2006-2009 - BA Humanities (Oslo University, Norway)

Hollie Jones, Research Manager (IFF)

Project role

- Project management deputy
- Day-to-day point of contact
- Conduct interviews
- Participate in analysis and reporting

Hollie has 7 years of experience in social research and specialises in survey research. She also has a wealth of experience in a range of quantitative and qualitative methods, statistical analysis, delivering training and presentations. She is also skilled at facilitating focus groups and staff workshops, and tailoring research to meet client needs.

Before joining IFF Research, Hollie has previously worked on a number of national and international projects, including the English Housing Survey and the Health Survey for England. She has conducted research for clients such as the Ministry of Housing, Communities & Local Government; the Foreign, Commonwealth & Development Office; Shelter UK; UNICEF; and the World Health Organization.

Education

- 2013 - 2015. MA Social Research (University of Leeds)
- 2010-2013. BSc Social Psychology & Sociology (University of Essex)

Andrew Smith, Senior Research Associate (Man Met)

Project role

- Main operational contact in the PERU team.

Andrew is a Senior Research Associate at Manchester Metropolitan University (since 2017), specialising in experimental and quasi-experimental impact evaluation and is currently working on two national school based RCTs funded by the Education Endowment Foundation. As well as his full-time role, Andrew is working on a PhD investigating the external validity of RCTs in education. Before joining PERU Andrew trained and worked as a psychologist, and has extensive experience in developing and using psychometric tools.

Education

- PhD (expected 2024). 'The generalisability of the findings of Randomised Controlled Trials in education: assessing the state of the art and signposting future directions.'. Manchester Metropolitan University.
- Master of Science Occupational Psychology (Distinction). 2012- 2013. The University of Sheffield, Management School
- Bachelor of Science Psychology (1st Class Honours). 2005-2008. The Open University.

Sandor Gellen, Research Associate (Man Met)

Project role

- Quantitative data analysis and project support

Sandor has joined PERU as a Research Associate in March 2021. He specialises in quantitative research methods and is currently working on a variety of projects evaluating the implementation of programmes focusing on housing, homelessness and DA. Before joining PERU, Sandor - in his previous role - carried out advanced statistical analysis in HE settings and co-led educational research projects in Man Met.

Education

- MSc Applied Quantitative Methods (Distinction). 2017-2018. Manchester Metropolitan University
- BSc Psychology (1st Class Honours). 2014-2017. Manchester Metropolitan University
- MA Honours Literature & Linguistics (Merit). 2006-2010. University of Szeged

Dani Cervantes, Senior Research Executive (IFF)

Project role

- Day-to-day project support
- Manage local authority communications
- Lead on fieldwork logistics and updates
- Support with interviews and framework entry
- Input into reporting outputs

Dani joined the research team at IFF in January 2021, having built experience of qualitative and quantitative research methods at two market research agencies, following a career

change from marketing in the education and charity sectors. Dani has experience working on children and family focused projects for central and local government. For example, aiming to improve the home learning environment for infants from lower socio-economic backgrounds, multiple healthy eating & lifestyle landscape & communications insight projects and product testing a perinatal wellbeing digital tool.

Education

- 2016 - 2017. MSc Psychology (University of Westminster)
- 2002 - 2006. BA Media & Cultural Studies (University of Sussex)

Amy Hillel, Research Executive (IFF)

Project role

- Day-to-day project support
- Manage local authority communications
- Lead on fieldwork logistics and updates
- Support with interviews and framework entry
- Input into reporting outputs

Amy joined IFF research in September 2020 as a Trainee Research Executive and has since then worked on a range of projects, using both qualitative and quantitative methods.

Education

- 2015-2018. BSC Hons Equine Science, University of West England

Kelsey Beninger, Associate Director (IFF)

Project role

- Consultative role
- Conduct interviews
- Participate in analysis and reporting

Kelsey is an evaluation and qualitative methods specialist with 10 years' experience in designing and managing complex, mixed method evaluations for government departments and VCS organisations, typically drawing on theories of change or leading collaborative development of logic models. Kelsey joined IFF in 2019, after 5 years at Kantar. She is a UK Evaluation Society, Market Research Society, Social Research Association member, and an advisor on the What Works for Children's Social Care Evaluation Advisory Group.

Education

- 2010 - 2011. MSc Social Psychology (London School of Economics)
- 2005 - 2010. BA Psychology (University of British Columbia)

Timeline

Please see the timeline outlined below:

		2021												2022						
	Responsibility	Mar	April	May	June	July	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	June	July	Aug	
Set-up meeting	All																			
Trial protocol and ethics application	PERU																			
Parent recruitment	Babies 1st																			
Parent baseline and randomisation	PERU																			
VIG delivery	LAs																			
Process evaluation fieldwork – W1	IFF																			
Parent follow-up survey	IFF																			
Process evaluation fieldwork – W2 (practitioners)	IFF																			
Process evaluation fieldwork – W2 (parents)	IFF																			
Analysis	PERU/IFF																			
Report delivery	PERU/IFF																			

Appendix A: Scales used in baseline and follow-up questionnaires

MORS-SF

1. My baby smiles at me
2. My baby annoys me
3. My baby likes doing things with me
4. My baby 'talks' to me
5. My baby irritates me
6. My baby likes me
7. My baby wants too much attention
8. My baby laughs
9. My baby gets moody
10. My baby dominates me
11. My baby likes to please me
12. My baby cries for no obvious reason
13. My baby is affectionate towards me
14. My baby winds me up

Warmth items: 1, 3, 4, 6, 8, 11, 13
Invasion items: 2, 5, 7, 9, 10, 12, 14

Scoring: 5 = Always; 4 = Very often; 3 = Quite often; 2 = Sometimes; 1 = Rarely; 0 = Never. No reverse scoring. Item scores are summed.

Karitane Parenting Confidence Scale

1. I am confident about feeding my baby
2. I can settle my baby
3. I am confident about helping my baby to establish a good sleep routine.
4. I know what to do when my baby cries
5. I understand what my baby is trying to tell me
6. I can soothe my baby when he/she is distressed
7. I am confident about playing my baby
8. If my baby has a common cold or slight fever, I am confident about handling this.
9. I feel sure that my partner will be there for me when I need support.
10. I am confident that my baby is doing well
11. I can make decisions about the care of the baby.
12. Being a mother/father is very stressful for me.
13. I feel I am doing a good job as a mother/father
14. Other people think I am doing a good job as mother/father
15. I feel sure that people will be there for me when I need support

Scoring: 3 = Yes, most of the time; 2 = Yes, some of the time; 1 = No, not very often; 0= No, hardly ever. No reverse scoring. Item scores are summed.

Parental Stress Scale

1. I am happy in my role as a parent.
2. There is little or nothing I wouldn't do for my child(ren) if it was necessary.
3. Caring for my child(ren) sometimes takes more time and energy than I have to give.

4. I sometimes worry whether I am doing enough for my child(ren).
5. I feel close to my child(ren).
6. I enjoy spending time with my child(ren).
7. My child(ren) is an important source of affection for me.
8. Having child(ren) gives me a more certain and optimistic view for the future.
9. The major source of stress in my life is my child(ren).
10. Having child(ren) leaves little time and flexibility in my life.
11. Having child(ren) has been a financial burden.
12. It is difficult to balance different responsibilities because of my child(ren).
13. The behaviour of my child(ren) is often embarrassing or stressful to me.
14. If I had it to do over again, I might decide not to have child(ren).
15. I feel overwhelmed by the responsibility of being a parent.
16. Having child(ren) has meant having too few choices and too little control over my life
17. I am satisfied as a parent.
18. I find my child(ren) enjoyable.

Scoring: 5 = Strongly agree; 4 = Agree; 3 = Undecided; 2 = Disagree; 1 = Strongly disagree. Items 1, 2, 5, 6, 7, 8, 17, and 18 are reverse scored. The item scores are then summed.