Trial Evaluation Protocol
ParentChild+

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PROJECT TITLE	Efficacy Trial of the ParentChild+ programme
DEVELOPER (INSTITUTION)	Family Lives
EVALUATOR (INSTITUTION)	University of York, Durham University & Leeds Beckett University
PRINCIPAL INVESTIGATOR(S)	Louise Tracey & Carole Torgerson
PROTOCOL AUTHOR(S)	Louise Tracey, Carole Torgerson, Charlie Welch, Caroline Fairhurst, Nicole Gridley, Erin Dysart & Xiaofei Qi
TRIAL DESIGN	Two-arm within-local authority RCT with randomisation at the family level
CHILD AGE RANGE	2-3 years of age
NUMBER OF LOCAL AUTHORITIES	4
NUMBER OF CHILDREN	320
PRIMARY OUTCOME	British Picture Vocabulary Scale (BPVS-III; Dunn, Dunn and NfER, 2009) (Receptive Vocabulary)
SECONDARY OUTCOMES	• Communication, personal-social skills and fine motor skills sub-sections of the Ages & Stages Questionnaire (ASQ-3; Squires and Bricker, 2009) • Home Learning Environment (HLE) Index (Melhuish, 2010) • School attainment as recorded in the National Pupil Database (NPD) eg. Reception Baseline Assessment (RBA), EYFS Profile

Protocol version history

VERSION	DATE	REASON FOR REVISION
1.1	04/12/2019	Trial protocol updated during recruitment: • The criteria for family eligibility was extended to include families not eligible for free childcare provision but living in

		Super Lower Output areas as fewer families than anticipated were fulfilling the original eligibility criteria. • The recruitment period was extended to the end of January 2020 to fulfil recruitment targets. • The protocol was updated to recognise that some children are cared for, on a regular basis, by close family members. Thus, the intervention could be delivered to children while in the care of a close family member. • The protocol was updated to make the eligibility criteria regarding language requirements clearer.
1.0 [*original*]	11/09/2019	

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Intervention

An intensive home visiting programme developed in the US in the 1960s, ParentChild+ (previously the Parent-Child Home Programme) aims to increase parent-child interaction, promote positive behaviours and encourage language and other emerging literacy skills to enhance the home learning environment, promote school readiness and foster academic success. It is a targeted-selective programme primarily aimed at low income families with children aged 2-3 years of age. It is delivered in the home by specially trained home visitors over a 15 month period. It models positive parent-child interaction using age appropriate books and toys which are then gifted to programme participants.

Table 1: TIDieR

Aspect of TIDieR	Exemplification relating to the evaluation
Brief name	ParentChild+
Why: Rationale, theory and/or goal of essential elements of the intervention	Intensive home visiting programme with strong evidence of promise as evidenced by a number of evaluations in the US. This will be the first impact evaluation of the programme in the UK.
Who: Recipients of the intervention	Parents/carers of children aged 2-3 eligible for, but not taking up, the free child care places, and their 2-3 year old children. Recipients also include those who are not entitled to free child care places but do live within Lower Super Output Areas (LSOA).
What: Physical or informational materials used in the intervention	Manualised programme. Educational books and toys provided weekly and used for modelling good practice.
What: Procedures, activities and/or processes used in the intervention	Home visitors modelling home learning environment (HLE) activities in the home.
Who: Intervention providers/implementers	Family Lives / home visitors.
How: Mode of delivery	One-to-dyad (home visitor to parent/carer-child).
Where: Location of the intervention	In the home.
When and how much: Duration and dosage of the intervention	Twice weekly visits (30 minutes) - 92 visits over a 15 month period.
Tailoring: Adaptation of the intervention	• Adaptations according to home language. • If safeguarding issues two home visitors attend. • If twins intervention delivered for one hour as opposed to 30 minutes. • Delivery can become community-based if safeguarding issues. • If child carer changes (eg. due to foster care) the programme follows the child and accepts a change in primary carer. • If parent missing for one week programme can be delivered to another adult present in the household.
How well (planned): Strategies to maximise effective implementation	Monitoring by Family Lives of attendance and mid-point checks by Team Leader. Weekly staff meeting to promote continued professional development and peer learning.

Study rationale and background

The programme has strong evidence of effectiveness in the US (cf. Astuto, 2014). It is currently being piloted in the UK but has not been subject to evaluation using a rigorous randomised controlled trial (RCT). The aim of this efficacy trial is to assess the effectiveness

of ParentChild+ on child language skills, child behaviour, school readiness and parent-child interaction among 2-3-year-old children in disadvantaged families.

Social disadvantage is a primary risk factor for later academic attainment (Asmussen et al., 2016). The gap in educational attainment starts early, prior to school entry, and tends to increase (Asmussen et al., 2016; Sylva et al., 2012). Preschool skills differences between advantaged and disadvantaged children have been found to be predominantly in language and communication skills (Phillips & Lonigan, 2009; Hart & Risley, 1995; Marmot, 2010). Lee (2011) also found that vocabulary size at age 2 significantly predicted subsequent language and literacy development up to the fifth grade (aged 9-10 years). It has been well established that the Home Learning Environment (HLE), in comparison to other environments, is particularly important for child development including cognitive ability in general, and language and literacy development in particular (cf. Sylva et al., 2004; Niklas & Schneider, 2013; Tarelli & Stubbe, 2010).

The introduction of government-funded childcare to disadvantaged two-year-olds in 2013 aimed to reduce the attainment gap and improve school readiness, based on research indicating that attending early years childcare can have significant positive impacts on a range of outcomes (Melhuish et al., 2015). Disadvantaged children in particular have been seen to benefit significantly from good quality pre-school experiences (Sylva et al., 2003). Since the introduction of this policy there is some evidence to indicate that it has reduced the gap between disadvantaged children and their peers by the end of Reception as measured by the Early Years Foundation Stage Profile (EYFS) (Teager & McBride, 2018). Yet overall national take-up of this free provision was approximately 72% in 2018 and this varies considerably by region. Research suggests that there may be cultural and linguistic factors at play in terms of overall take-up of provision (Teager & McBride, 2018). For the Local Authorities of interest in this study the corresponding figures for take up of the free 2 year old nursery places for eligible families in 2018 were: Rotherham, 79%; Barnsley, 73%; Doncaster, 72%; and Sheffield, 62% (DfE, 2018). This means that this study will be able to explore take-up in one Local Authority above the national average, two at the national average and one considerably below. These Local Authorities were selected for participation in the study as a result of collaboration between the programme Delivery Team (DT: Family Lives) and South Yorkshire Futures aiming to reduce social inequality in the region.

Studies conducted in the US show positive effects on cognitive outcomes for pre-school children from disadvantaged backgrounds. Astuto et al. (2014) conducted two RCTs indicating that the programme (formerly known as the Parent Child Home Programme) improved children's receptive vocabulary compared to the control group (ES=0.318), and resulted in higher language scores (ES=0.372). It also improved some aspects of self-regulation, and children were less likely to display problem behaviours. Other, quasi-experimental studies have indicated that the programme improved children's school readiness (Manz et al., 2015; Mann et al., 2009).

While ParentChild+ does not yet have impact data in the UK other, less-intensive programmes aimed at working with parents to improve the HLE have some (limited) evidence of effectiveness. For example, Wood et al. (2015) found that a six-week, 1.5 hours a week intervention with parents and children (Early Words Together) improved children's spoken language (measured by the Pearson pre-school Language Scale), with particular improvements noted in girls. The intensity of visits and provision of resources involved in the programme suggests, therefore, that, in theory, ParentChild+ has the potential to demonstrate effectiveness in improving the Home Learning Environment and consequently children's early

language and literacy development. However, programmes such as this face barriers in engaging disadvantaged families and approaches to such parents must be carefully considered (Tracey et al., 2014). The use of paid, trained home visitors, drawn from the communities being served, with cultural and linguistic matching is one way in which such barriers could be overcome. By improving child cognitive development, particularly language and literacy skills prior to formal school entry, the potential for long term gains in overall academic achievement (and beyond) is great (Marmot & Bell, 2012). In addition, due to the high resource-intensive nature of ParentChild+ a rigorous evaluation, using a RCT design, is particularly important in terms of stakeholder decision-making regarding implementation and potentially wider rollout.

Impact Evaluation

Research questions

The primary research question is:

- What is the impact of the ParentChild+ programme on children's language development as evidenced by their receptive vocabulary and measured via the British Picture Vocabulary Scale (BPVS)?

The secondary research questions are:

- What is the impact of the ParentChild+ programme on verbal and non-verbal interaction, developing positive behaviours and early literacy skills, as measured by the Ages & Stages Questionnaire (ASQ)?
- What is the impact of the ParentChild+ programme on the Home Learning Environment as measured by the Home Learning Environment Index?
- What are the longer term impacts of the ParentChild+ programme as measured by the statutory school-based assessments (i.e. the Reception Baseline Assessment (RBA) and the Early Years Foundation Stage (EYFS) profile)?

Design

This is a two-arm efficacy RCT with allocation at family level to evaluate this intervention against usual care, with an embedded implementation and process evaluation. As ParentChild+ is currently being piloted in the UK it seems reasonable to move to the next stage of evaluation using an efficacy trial design.

Trial type and number of arms		Two-armed, efficacy trial, randomised within local authority.
Unit of randomisation		Family-level
Stratification variables		Local Authority
Primary outcome	Variable	Receptive vocabulary
	measure (instrument, scale)	BPVS-III

Secondary outcome(s)	variable(s)	Communication skills
	measure(s) (instrument, scale)	Communication subscale of the Ages & Stages Questionnaire (ASQ)
	variable(s)	Personal-social skills
	measure(s) (instrument, scale)	Personal-social skills subscale of the ASQ
	variable(s)	Fine motor skills
	measure(s) (instrument, scale)	Fine motor skills subscale of the ASQ
	variable(s)	Home Learning Environment (HLE)
	measure(s) (instrument, scale)	Home Learning Environment (HLE) Index
	variable(s)	Educational attainment
	measure(s) (instrument, scale)	National Pupil Database (Reception Baseline Assessment (RBA), Early Years Foundation Stage profile (EYFS))

Randomisation

Once parents have consented to participate and all baseline testing has been completed, the household will be randomly allocated 1:1 to receive either the intervention or business as usual. Stratified block randomisation will be used with variable block sizes, by Local Authority (Barnsley, Doncaster, Sheffield and Rotherham). An independent trial statistician at the York Trials Unit will be responsible for generating the allocation schedule. As rolling recruitment is to be conducted, the unique participant/household ID numbers will be sent to the statistician in possession of the allocation schedule in batches on a regular basis. These ID numbers will then be placed in a random order (within each stratum) and matched against the next available allocations. The allocations will then be communicated to the participants and the delivery team will be sent a list of those participants allocated to the intervention. Local Authorities will also be informed of study and programme participants after randomisation under an arrangement whereby programme participation will be accepted by the Department for Education in lieu of take-up of free 2 year old nursery places. This does, however, mean that local authorities will not be blind to condition.

Participants

Recruitment will be conducted by the Delivery Team (DT). Given that recruitment is to an RCT as opposed to the programme *per se*, the Evaluation Team (ET) will work closely with the DT to ensure that participants are clear about involvement in the study (to reduce the potential for later attrition). Recruitment will be of disadvantaged families with children aged 2-3 years who are eligible for, but not taking up, the 2-year free nursery place offer. Recruitment of disadvantaged families will also include families who are not entitled to free child care places but do live in Lower Super Output Areas (LSOA) i.e. families who fall within the lowest 20% of the population based on deprivation of; income, employment, education skills and training, health and disability, crime, barriers to housing and services and living environment. Parents/carers will be identified through collaboration with local authorities.

The DT Coordinators will work with local authority Heads of Service for Early Years, Early Years Inclusion Officers and Family Centre/ Children's Centre Outreach Teams to recruit families and work with key staff such as Health Visiting Teams, Family Support and other locality team staff to promote and generate referrals to the study.

A minimum threshold for spoken English language fluency will be applied as an inclusion criterion as this would potentially impact on ability to complete the measures used in the trial and to participate fully in the programme (where resources, materials and a suitable home visitor fluent in the primary language used in the home may not be available).

There will be two stages for checking English language thresholds are met. First, participating parents should be able to complete consent forms when help is provided (i.e. by home visitor or family member). Second, at pre-test families will be considered eligible if they are able to complete the forms with data collector assistance. For practical reasons it is not possible to use an external interpreter.

Children experiencing language delay will be included providing that they meet the other eligibility criteria (eligible, but not taking up, the 2-year old offer or living in a LSOA). Similarly, children will not be excluded due to special needs if it was felt that the family could benefit from inclusion, providing the other criteria were met.

Whilst we are interested in those children with a Child in Need status this will be monitored retrospectively. However, where Local Authorities chose to use referral routes into the programme they will be requested to prioritise this group. Families who are recruited from Lower Super Output Areas will also be monitored retrospectively.

Where potential participants are new to the UK, and their eligibility to a free 2-year old nursery place for their child is not yet confirmed they will be placed on a waiting list to receive the programme, providing notification is received prior to the end of the recruitment period, unless informal notification of eligibility is received from the Local Authority, in which case they will be considered immediately eligible.

Eligible families will be classed as recruited when they have:

- signed a consent form;
- agreed to participate in the programme, if offered;
- completed the pre-test measures; and
- met the minimum English threshold.

We would ensure that one parent/carer or a close family member who regularly cares for the programme child is identified to complete the programme and the measures at pre-and post-test. This should be the person completing the consent form if they are the main parent/carer. However, we will monitor (through the DT) the extent to which both parents and/or close family members are involved in the programme and, if delivery is extended to both parents or other close family members, the ET will collect process evaluation data from both parents or close family members where applicable. In instances where a close family member is to complete the programme, consent should be gained by the main parent/carer.

Incentives for participating parents

We anticipate offering a £10 high street voucher in exchange for participation in each round of data collection to all participating parents or close family members in the study The voucher will be given to those parents/carers or close family members who are directly

involved in the programme. We feel that this is justified by the additional burden of the parent self-complete measures. In addition, we will offer a £10 voucher to the subsample of parents taking part in the Home Observation measure and a DVD of the videos recorded with their child (see Implementation and Process Evaluation below). A mid-point incentive (three toys carefully selected by the DT) will be provided to the control group at the mid-point of trial participation, this will be coordinated by the ET. Change of address incentives (£5 voucher) will also be provided by the ET to enable families to be tracked.

Sample size calculations

Sample size calculations were conducted using Stata v15.0. Although the unit of randomisation will be households, in the vast majority of these there will be only one eligible child. Therefore, the sample size has been conducted as for an individually randomised trial. Multiple eligible children within a household will be allowed to take part, and in these cases we will use the mean of the available scores obtained within the household for statistical analyses. The DT have estimated that they would have capacity to support 160 families in the intervention (40 in each of 4 geographical regions including those from Lower Super Output Areas). Using equal randomisation, we aim to recruit 320 families. Assuming scores obtained at baseline and follow up are approximately bivariate normal with a correlation of 0.7 and 20% attrition at follow up (n=64), this sample size (n=256) gives a minimum detectable effect size (MDES) of 0.25 in a two-sided test of the difference between groups adjusted for baseline with nominal type 1 and 2 error rates of 5% (i.e. alpha of 0.05) and 20% (i.e. power of 80%), respectively. This would mean that this study would be able to detect lower effect sizes than those in the US studies discussed above.

Outcome measures

The primary child outcome will be the **British Picture Vocabulary Scale** (BPVS-III; Dunn, Dunn and NfER, 2009) administered one-to-one by independent assessors blind to condition, trained and organised by the University of York. The BPVS-III is a standardised measure of receptive vocabulary based upon the Peabody Picture Vocabulary Test (PPVT: Dunn and Dunn, 1981) which has been used in a number of US evaluations of ParentChild+. The basic testing activity involves showing the child a series of images, four to a page, one of which will match a pre-specified word the assessors says to the child. The child is required to point to the picture they believe most closely resembles the word given. It takes between 5 and 8 minutes to administer. As no reading or verbal response is required it is considered suitable for young children and those for whom English is an Additional Language. It is also easy to administer and takes a relatively short time to complete enabling children to remain focused during the assessment period. The BPVT-III has proven to be highly correlated with later literacy acquisition (Dunn, Dunn and NfER, 2009). It is standardised for children aged 3 to 16 years, but can also be administered to two year olds. The previous version of the BPVS (BPVS-II) was standardised for two and a half year old children. Consequently we expect it to be suitable to be administered to two-year-olds but we will pilot the BPVS-III prior to its use to confirm its suitability for this study. The pilot will take place with 10-15 children aged between 18 months and three years of age recruited from nurseries and local parent- and play-groups in order to confirm that there is no floor effect. We will aim to have a mixture of children for whom English is an Additional Language and who are eligible for the two-year old free nursery places. The measure will be regarded as suitable providing there is variation in response and no floor effects are detected. Assuming its suitability, the BPVS-III will form the primary pre-test and be administered by data collectors from the University of York prior to randomisation.

The secondary outcomes are:

- **Ages & Stages Questionnaire®, Third edition (ASQ®-3)** (Squires & Bricker, 2009)**.** This 30-item parent/carer-completed measure is standardised for children aged one month to 5½ years, so is suitable for this age group (with different questionnaires depending on child developmental stage). It measures communication, gross motor skills, fine motor skills, problem solving, and personal-social skills. This measure will also be completed at pre-test. The ASQ-3 will be used to identify whether or not the programme increased verbal and non-verbal interaction, developed positive behaviours and encouraged early literacy skills. In addition, fine motor skills are supported by the programme and have been associated with school readiness and reading outcomes in the early stages of schooling (Cameron et al., 2012). They are also associated with early handwriting (as measured by the literacy sub-scale of the EYFS) and considered a part of a rich Home Learning Environment (e.g. through the encouragement of drawing and painting) (Melhuish, 2010). Consequently only three of the five subscales will be administered: communication, personal-social, and fine motor to reduce participant burden (18 items, 6 in each subscale).

- The Home Learning Environment will be assessed using the **Home Learning Environment (HLE) Index** (Melhuish, 2010). This 16-item self-reported measure includes items which relate to activities undertaken with the child and their frequency. Items correspond to concrete parenting behaviours based on evidenced relationships to children's development. This scale has been previously used in the National Evaluation of Sure Start and the Millennium Cohort Study.

Both these measures will be administered at pre-test as well as post-test.

To aid completion of parent-report measures, these will be delivered to families by data collectors who will provide time for independent completion during their visit. They will be trained to assist parents/carers to complete the measures if needed. Given the nature of the sample we recognise that much of the data is self-complete although we do have an independently-administered primary outcome. We feel that this will still provide valuable results (cf. Bennett, S., 2017).

The recruitment and data collection flow chart can be found in the Appendix.

We also intend to follow children into the school system with permission to access NPD data at a later stage. To do this, we would need to obtain signed parental consent so that the Local Authorities can share information on school destination using existing information from the project, including child name, date of birth and home postcode. We plan to include in the Memorandum of Understanding and the Data Sharing Agreement with Local Authorities agreement to provide details on child's school destination in February 2021 and February 2022. These two data collection points reflect the expectation that the recruited cohort will enter school in either September 2021 or September 2022 (depending on age at, and month of, recruitment). Allocation of school places is generally conducted prior to February in the preceding academic year. Analysis of NPD data will be conducted as part of a longer term follow up done in addition to the present evaluation. It is anticipated that the focus will be on the Reception Baseline Assessment, which measures communication, language, literacy skills and maths, to assess school readiness and emergent literacy skills. A longer term follow-up is also anticipated. Given that the KS1 assessments will become optional in 2023 (the year our older cohort of children will enter Year 2) and that the phonics assessment administered in Year 1 only measures one discreet aspect of the skills needed in learning to read we anticipate this being the

Early Years Foundation Stage profile, focusing on communication and language, personal, social and emotional development, and literacy attainment.

Analysis plan

The statistical analysis will follow the most recent EEF guidance, and will be described in detail in a Statistical Analysis Plan (SAP) prepared within three months of the last participant being randomised. All analyses will be conducted following intention-to-treat (ITT) principles, using two-sided statistical tests at the 5% significance level. This means that participants will be analysed according to the group they were assigned to (either intervention or control) regardless of adherence to that condition or not (i.e. participants allocated to receive the intervention will be analysed within the intervention group even if they do not participate in the programme). Where participants withdraw from the programme this shall not be classed as withdrawal from the study and participants will be asked to continue participating in the data collection and data processing aspects of the study. Baseline data will be summarised descriptively, both as randomised and as included in the primary analysis, with no formal comparisons being undertaken. Both adjusted and unadjusted summaries of the outcome measures will be presented, with p-values and appropriate 95% confidence intervals (CI) given for all between group comparisons.

A CONSORT diagram will be produced to show the flow of households and participants through the trial.

Primary Analysis

Linear regression will be used to compare raw BPVS-III scores between the two groups. Group allocation, baseline (raw) BPVS-III score, age and Local Authority will be included as fixed effects in the model. Participants with either age missing or baseline BPVS-III score missing will have these imputed with the relevant strata specific mean. Hence all participants with non-missing BPVS-III scores at follow up will be included, as randomised, in the primary analysis model. The BPVS-III is a norm-referenced test and standardised for children aged 3 years to 16 years and 11 months. However the children being recruited as part of this trial will all be less than three years old at baseline, meaning no age standardised scores exist. Hence the inclusion of age as a covariate. The inclusion of age as a covariate is also likely to increase the precision of the estimate of the treatment effect. Inferences regarding the effectiveness of the ParentChild+ programme will be based on the adjusted difference in mean score between the two groups suggested by this model. Effect size will be summarised using Hedges' g and associated 95% CI.

Further analyses of primary outcome

Further analyses of the primary outcome will be conducted to investigate the possible influence of non-compliance on the result of the primary analysis, and to assess the sensitivity of the primary analysis to variation in the missing data assumptions.

A Complier Average Causal Effect (CACE) analysis will be conducted to obtain an estimate of the average causal effect of receiving the programme as planned, while accounting for measured and unmeasured confounding between treatment adherence and outcome. For the purposes of this trial, compliance will be defined dichotomously as delivery of 78 of the 92 programme sessions (85%) with each session being approximately 30 minutes long. This is based on compliance as defined by, and used for routine data analysis by the original developers in the US. An additional compliance analysis based on continuous data (ie. number of overall sessions completed) will also be conducted.

The possible impact of missing data on the conclusions drawn from the primary analysis will be explored with a range of different methods. Available reasons for withdrawal/missingness will be examined to inform whether these are plausibly related to outcome or not. Baseline variables associated with missing primary outcome data will be identified using logistic regression, and the primary analysis model will be refitted including these as additional covariates in order to make the missing at random (MAR) assumption more plausible. If greater than or equal to 5% of cases are excluded from the primary analysis due to missing data, then the MAR assumption, and possible influence of data observed post randomisation (e.g. compliance data) will be explored using multiple imputation. Finally the sensitivity of results to the outcome data being missing not at random (MNAR) will be explored using a pattern mixture modelling approach.

Secondary Analyses

Data will be collected for three subscales of the ASQ-3 with the responses in each scale being used to generate a score between 0 and 60. These will be analysed individually using three linear regression models adjusting for allocation, baseline score and local authority. Any missing baseline scores will be imputed with the strata specific mean prior to analysis. Hence all participants with non-missing scores at follow up will be included in the models.

The responses to the 16 items of the Home Learning Environment Index will be combined to give an overall score, with higher scores being indicative of a more positive home learning environment. This score will be analysed using a linear regression model adjusting for allocation, baseline score and local authority. Any missing baseline scores will be imputed with the strata specific mean prior to analysis. Hence all participants with a non-missing Home Learning Environment Index score at follow up will be included in the model.

Subgroup Analyses

Four pre-specified exploratory analyses of the primary outcome will be conducted to investigate the possibility of treatment effect heterogeneity. Variation in treatment effect will be explored across different levels of the following four baseline characteristics; Children in Need status, (a binary classification of whether or not the child/children in the household have ever been a “Child in Need” at any time in their life up until baseline), English as an Additional Language (again a binary classification),baseline score on the ASQ communication subscale and whether or not the child/children are entitled to a free nursery place. Baseline score for the ASQ will be used for this subgroup analysis because, unlike the BPVS-III, it is age standardised for children as young as 1 month, and therefore appropriate for the developmental stage of participating children at baseline. The communication subscale will be used as it aligns more closely with the construct measured by the BPVS-III than either of the other two ASQ scales that are being collected.

In all four cases treatment effect heterogeneity will be investigated by examining whether or not the inclusion of the main effect (if not already present), and its interaction with randomised group, in the model used for the primary analysis leads to a significant improvement in model fit based on a likelihood ratio test. If the inclusion of such interactions does lead to improved model fit, then this model will be used to assess between group differences within strata and provide associated inference.

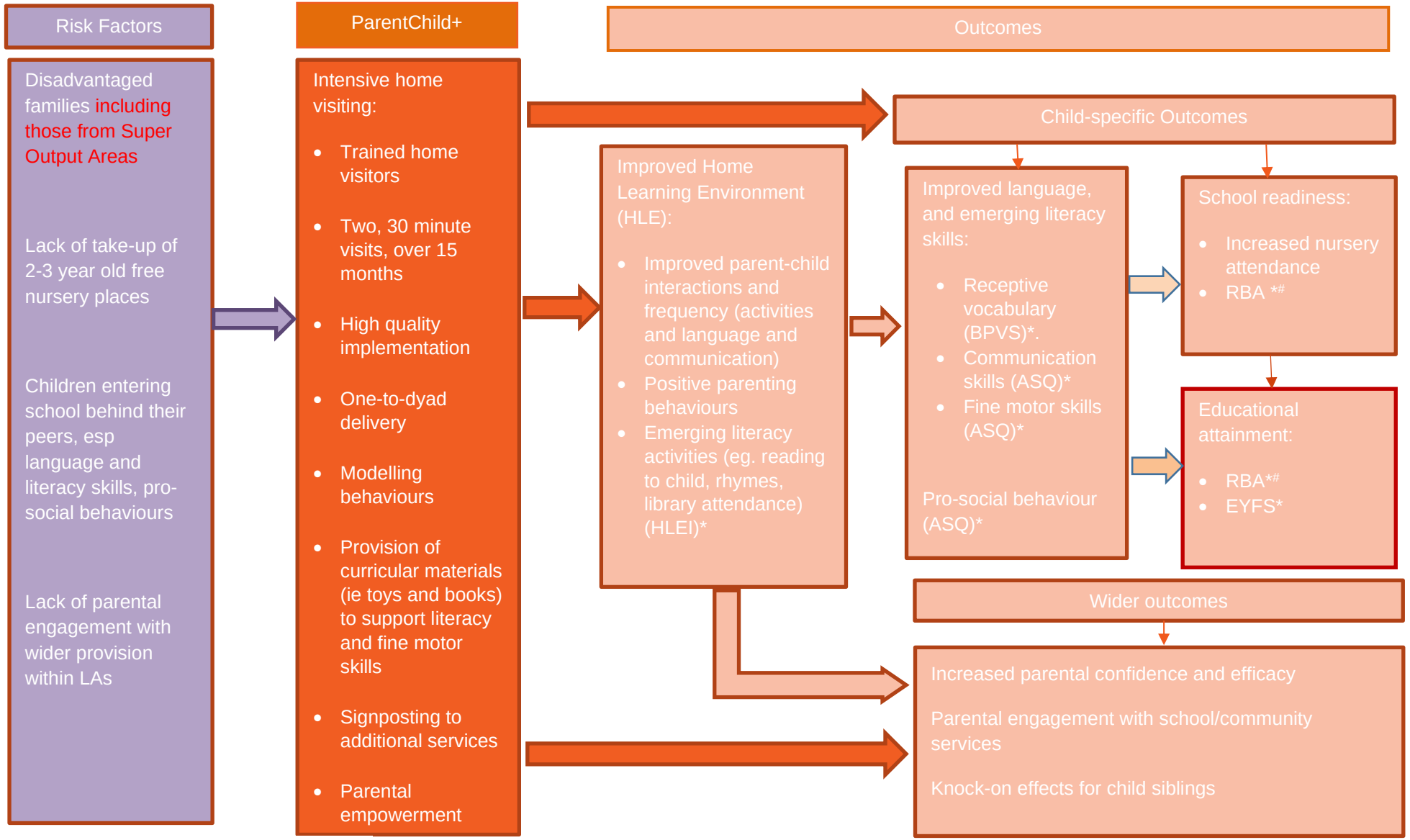
Finally, longer term data analysis is anticipated using NPD data. It is currently anticipated that the RBA assessment, will initially be used. However, this measure is currently being piloted and we are unsure of the range and nature of the data that will be available (ie. it is currently scored out of 45 and covers maths, language, communication and literacy skills). In particular,

we are unsure whether only a composite score will be available or one broken down into the different domains. The longer term educational attainment data will be drawn from the (1) communication and language, (2) personal, social and emotional development and (3) literacy areas of learning of the EYFS. For each area of learning, the individual EYFS sub scales will be analysed using ordinal regression, adjusting for allocation, local authority and other key baseline covariates thought to be related to outcome. All analyses will be detailed in a statistical analysis plan, prior to the data being accessed or any analysis performed.

Implementation and process evaluation

In line with EEF guidance (Humphrey et al., 2016) the implementation and process evaluation (IPE) aims to explore the relationship between delivery and programme outcomes, in particular to provide greater context and understanding of the results of the impact evaluation. A logic model for the programme was co-developed by the Evaluation Team and Delivery Team. Figure 1 presents that logic model, highlighting the outcomes measured by the impact evaluation. The IPE will explore the contextual and causal factors surrounding these outcomes and the wider outcomes expected as a result of the programme. Given the proposed burden on parents for the impact evaluation (particularly relating to programme participation and self-complete measures) the process evaluation will be light-touch but rigorous. The IPE will also explore lessons on recruiting from this population.

Figure 1: ParentChild+ Evaluation Logic Model



*Impact evaluation outcome measures

Research Questions

The research questions the IPE seeks to investigate are as follows:

1. To what extent was the programme implemented as planned?
    - What training was received and were there any implementer factors in programme delivery?;
    - What was the number and length of sessions delivered?; and
    - Any variation in implementation and, if so, why?
2. What is the desirability, acceptability and need for the programme within local communities?
    - Who was the programme was delivered to – was this the target population?;
    - Were there any parental factors resulting in barriers to, or facilitators of, programme delivery?;
    - Were there any programme factors resulting in barriers to, and facilitators of, programme delivery (eg. intensity of programme, home visitor-parent relationship)?; and
    - What was usual parenting practice in the absence of the programme? How did this change as a result of taking the ParentChild+ programme? Were there any changes as a result of being in the control condition (especially in the light of local authorities not being blind to condition)?
3. To what extent did the ParentChild+ programme impact on the HLE, particularly on parent-child verbal interactions?
4. What were the wider outcomes of the programme?
    - What was the impact in terms of parental self-reported confidence and efficacy?;
    - To what extent did participation result in parents taking up the free nursery offer and encourage attendance at pre-school settings by participating children?;
    - To what extent did the programme result in increased parent (and child) engagement with wider community services?; and
    - Were there any diffusion effects of programme delivery (e.g. on other family members including child's siblings and other adults in the household)?

METHODS

There will be a pragmatic and mixed-method approach. It will include:

- **Routinely collected programme data**

The Evaluation Team (ET) and Delivery Team (DT) will work closely to establish ways to ensure implementation of the programme as planned. This includes data relating to programme delivery, in particular, data relating to sessions completed, withdrawal from the programme (including any known reasons for withdrawal) and reasons for cancellation of home visits (when provided). Data from the mid-point programme interviews with participating parents, conducted by the Lead Coordinator, will also be shared. These consist of a telephone call and a scripted checklist routinely gathered to monitor programme delivery (subsequently rated as exemplary, adequate/ satisfactory and inadequate), detail on home visitor-parent/child relationships, and possible spill over effects of the programme. In addition, demographic information will be collected from all participants at the recruitment stage of the study.

The ET will also attend a small number (n=2) of training sessions to understand the programme and work of the home visitors more fully. This will enable the ET to therefore assess and monitor programme implementation.

- **Interviews**

A number of interviews will be conducted at the end of programme delivery with the following key stakeholders:

DT/ home visitors. The ET will conduct interviews with the DT, all site coordinators (n=4) and a sample of the trained home visitors (n=4; one for each area) to understand the implementation of the programme as planned and as occurred. The relationship between the home visitors and families will also be explored alongside possible barriers to implementation. Finally, implementer factors, including the profile of the coordinators and home visitors will be explored.

Interviews with local authority leads. Interviews will be conducted with a member from each of the local authorities (n=4) to discuss the desirability, acceptability and need for the programme as well as challenges within the local authority context. The interviews will also explore recruitment barriers and how these barriers were overcome to allow ET to capture lessons on recruiting from this population.

Interviews with parents. A small number of interviews will be undertaken with a sub-sample of intervention parents at post-test (n=20) to understand attitudes towards the programme; completion of sessions; perceived changes in practice; and aspects of the programme they found easiest and most challenging to implement. Barriers/challenges to completing the programme and acceptability of the programme, including intensity will also be explored. Possible spill over effects will also be explored relating to the reach of the programme (i.e. possible impact on siblings). This sample will be purposively selected to include a range of attendance patterns. These interviews will be conducted via telephone to minimise participant burden.

- **Bespoke parent questionnaire**.

This will consist of a brief questionnaire covering access to local networks, including attendance at local group activities (e.g. play groups), linking of families to Social & Educational services (e.g.

library attendance), take-up of the two-year old or three year old nursery provision, in line with the impact expectations relating to parents. It will also include parent self-report of confidence and efficacy (using Likert scales). This would be administered at the same time as the post-test parent self-complete measures. Accessibility and desirability of the programme will also be explored.

In order to assess the impact of the programme on the HLE an independent **HLE observation** within the home will be conducted with a sub-sample of participating parents randomly assigned to the intervention condition (30) and the control condition (15) at pre- and post-test (n=45). Whilst to some extent this group will be self-selected (due to the optional nature of this aspect of the study) where possible they we will seek to monitor participants across the recruitment phase to ensure they are selected evenly from across the Local Authorities and where possible include a representative sample in terms of quantifiable demographics (e.g. age of parent, socio-economic circumstance, EAL, number of additional children, marital status). This is a novel approach to combining a qualitative outcome assessment from a RCT with a quantified (primary) outcome. Because the outcomes of the intervention are not as tightly defined as in other areas of educational progress (e.g., performance at KS2 or GCSE) observing the parents and children and coding their activity will enable rich and diverse rigorous qualitative findings to be summarised and directly compared with quantified outcomes. It is particularly important given the program aims to increase parent-child interaction and promote positive behaviours. The process will involve a 20-minute semi-structured videotaped observation in the home of the parent interacting with their child to assess targeted parenting behaviours. Developed by Dr Gridley, based on the Play and Reading Observation Tool (PAROT; Pye, 2015) and the Dyadic Parent-Child Interaction Coding Scheme (DPICS; Robinson and Eyberg, 1981) the observation will involve 10-minutes of the parent and child interacting during free-play, followed by 10 minutes of shared book reading. Videos will be coded to form frequency counts to provide an overall assessment of parent-child verbal and non-verbal behaviours relating to the HLE. It is planned to analyse the data to look at potential changes in positive parenting verbalisations (praise, labelling, educational questions) versus more directive, critical verbalisations. For the child, we will look at any potential changes in the overall quantity of verbalisations, as well as the number of verbalisations which are instigated by the child. Coding will be conducted by the Trial Co-ordinator (Dr Dysart), trained by Dr Gridley, who will also conduct the inter-rater reliability checks. Training to be competent in using the observational coding scheme takes place over three full days. Coders are considered competent once they have reached 75% agreement with the primary coder. Inter-rater and intra-rater reliability checks are performed periodically throughout the coding process on a 20% random sample of available videos to ensure coder agreement remains high during dense periods of coding, and to limit coder drift.

A summary of the IPE is provided in Table 2 below.

Table 2: IPE Research Questions and Methods

Research Question	METHOD								
	Routine programme data	Attendance at training	Face-to-face Interviews				Parent Telephone interviews	Parent question-naires	Home Observation
			Delivery Team	Site co-ordinators	Home visitors	Local Authority leads			
1. To what extent was the programme implemented as planned?									
• What training was received and were there any implementer factors in programme delivery?		X	X	X	X				
• What was the number and length of sessions delivered?	X								
• Any variation in implementation and, if so, why?			X	X	X				
2. What is the desirability, acceptability and need for the programme within local communities?									
• Who was the programme was delivered to?	X	X				X			
• Were there any parental factors resulting in barriers to, or facilitators of, programme delivery?	X				X		X	X	
• Were there any programme factors resulting in barriers to, and facilitators of, programme delivery?	X		X	X	X		X	X	
• What was usual parenting practice in the absence of the programme? How did this change as a result of taking the ParentChild+ programme? Were there any changes as a result of being in the control condition?						X	X	X	

Research Question	METHOD								
	Routine programme data	Attendance at training	Face-to-face Interviews				Parent Telephone interviews	Parent question-naires	Home Observation
			Delivery Team	Site co-ordinators	Home visitors	Local Authority leads			
3. To what extent did the ParentChild+ programme impact on the HLE, particularly on parent-child verbal interactions?									X
4. What were the wider outcomes of the programme?									
• What was the impact in terms of parental confidence and efficacy?							X	X	
• To what extent did participation result in parents taking up the free nursery offer?					X	X	X	X	
• To what extent did the programme result in increased parent engagement with wider community services?				X	X		X	X	
• Were there any diffusion effects of programme delivery?					X		X	X	

Analysis

Process evaluation data will be (where applicable):

- Transcribed and coded in NVivo using pre-agreed 'parent codes' relating to the logic model and the IPE research questions (Local Authority leads, Delivery Team, site coordinators, home visitor and parent interviews). 'Child codes' will subsequently be developed within these to provide relevant detail focused on participants' experiences and views;

- Checked to ensure at least 75% inter-rater reliability on a sub-sample (N = 20% of all videotaped observations) of records (where coded);

- Inputted twice and checked for quality assurance purposes (routinely-collected data and bespoke parent questionnaire)

Analysis will be triangulated to provide a fuller picture of the implementation of the programme from the point of view of all stakeholders.

Cost evaluation

As per EEF guidelines, the evaluation team will provide a cost per child for the intervention (approximately 15 months), and include detail regarding dosage of the programme received over this time period. These costs will include home visitor recruitment and training (including any subsequent additional recruitment and training over the period of the trial), travel costs and provision of materials. We will use this data to estimate the costs of continuing to roll the programme over a three year period. Additional costs of implementation will be systematically identified in the process evaluation. Cost implications will be identified according to current EEF guidelines through discussions with the Delivery Team and home visitor feedback.

Ethics and registration

Ethical approval for this study will be sought through the Education Ethics Committees, University of York, Durham University and Leeds Beckett University. We will also comply with any ethical approval processes required by the participating Local Authorities.

All outputs (including the statistical database, reports and publications) will be anonymised. No participant or setting will be identifiable in the report or dissemination of results. The statistical database will hold non-identifiable data.

Five per cent (5%) of the assessments will be randomly selected and double-checked, to assess reliability and consistency. All scores will be input twice to ensure accuracy. Confidentiality will be maintained and no one outside of the evaluation team will have access to the database which will be held securely on the department servers. Full consent will be obtained from parent/carer participants including depositing data at the end of the trial and the possibility of linking to the NPD to conduct follow-up analysis. Given that visits by data

collectors will take place in the home, we have in place SOPs to ensure researcher safeguarding.

The trial will be registered with the ISTRCN.

Data protection

Data will be handled in accordance with the General Data Protection Regulations (GDPR). Personal data will be processed under Article 6 Section (e) of the GDPR ('Tasks carried out in the public interest') as the research is being conducted to support education provision in the UK (and, if applicable, Special Category data under Article 9(2)(j)). A Data Protection Impact Assessment (DPIA) has been conducted (approved by Data Protection officer, University of York, 24/04/2019) and Data Sharing Agreements will be put in place with the University of York, Family Lives and the participating Local Authorities.

Personnel

The Evaluation Team is responsible for the conduct of the evaluation, including writing the protocol and SAP, registering the trial, writing consents, data sharing agreements and privacy notices and gaining ethical approval, data collection, analysis and writing the final report.

The Evaluation Team comprises:

Dr Louise Tracey (Co-PI). Louise will be responsible for the day-to-day management and coordination of the trial, working closely with the programme developers and supervising the trial co-ordinator. She will lead on the protocol and the report writing and contribute to the Implementation and Process Evaluation (IPE).

Professor Carole Torgerson (Co-PI). Carole will work closely with Louise to design the trial, including the unique approach to providing blinded impact and process outcomes and provide overall quality assurance and expertise in mitigating any potential biases and their risks, having had experience in dealing with both in past evaluations. She will contribute to the report writing and the IPE.

Caroline Fairhurst (CI) and statistician Charlie Welch. Charlie will undertake the randomisation, write the Statistical Analysis Plan (SAP), conduct the statistical analysis, and contribute to the report writing. Additionally, Charlie will be responsible for uploading the trial data to the FFT archive following the trial. He will be supervised in this by experienced senior statistician, Caroline Fairhurst.

Dr Nicole Gridley (CI). Nicole has devised the home observation measure, currently being used for the EWT study with a similar age group. She will conduct the training in using the measure, train the Trial Co-ordinator to code the data and undertake reliability checks.

Dr Erin Dysart (Trial Co-ordinator). Erin will undertake the day-to-day running of the project, including managing data collection, liaising with Family Lives, Local Authorities and individual participants, and processing data in line with data protection regulations and study protocols. She will also assist in conducting the IPE.

Dr Xiaofei Qi (Co-opted researcher). Xiaofei will contribute to the IPE, with a particular emphasis on the Quality Assurance aspects.

The Delivery Team is responsible for liaising with Local Authorities to identify potential study participants, recruiting participants, delivering the programme and liaising with the Evaluation Team in order to ensure the smooth-running of the evaluation and associated data collection activities.

The Delivery Team comprises:

Pamela Park (Deputy CEO, Family Lives). Pamela will have overall responsibility for the delivery of the contract with the Education Endowment Foundation.

Caroline Fanshawe (Senior Area Manager, Family Lives). Caroline will oversee the operational delivery of the ParentChild+ programme and work closely with the Evaluation Team to plan and manage the approach, schedule and resourcing. She will liaise with the Local Authorities and South Yorkshire Futures and work with the Team Leader (Tina Cranshaw) to recruit, train and manage the staff delivery team.

Tina Cranshaw (Team Leader, Family Lives and ParentChild+ across South Yorkshire). Tina will manage the team of three Coordinators and twelve Home Visitors who will recruit families and conduct the home visits in order to deliver the ParentChild+ programme.

Risks

We foresee the main risks to be recruitment and attrition. We will work closely with the DT to ensure effective recruitment. We have accounted for 20% attrition in the sample size. Strategies to minimise attrition will include:

- regular contact with parents to maintain engagement. We plan to contact parents every three months throughout the project with a brief newsletter and a Freepost card to be completed in the case of a change of address. We will provide a £5 high street voucher as a thank you for notifying change of address. We think these strategies will be particularly important for the control group.

- providing a mid-point incentive to control parents to continue participation in the trial.

- offering flexible times to conduct assessments. Given that the recruitment will be focused in South Yorkshire, by recruiting a team of data collectors in this area we will be able to offer such flexibility cost effectively. We currently have Standard Operating Procedures (SOPs) in place for contacting parents for a similar study using both telephone and text messaging which we find to be effective means of communication;

- appointment of an advisory committee of experts (and parents) to advise further strategies.

Similar strategies to minimise attrition could be implemented to assist with longer-term follow-up. For wider consideration of the risks and our plans to mitigate them see below.

Risk	Preventative measures	Likelihood
Insufficient participating parents recruited	Work with DT to ensure recruitment strategy is clear and that all participating parents understand what participation involves. Incentives offered. Monitoring by ET and EEF at agreed recruitment time points. DT work closely with Local Authorities to ensure they engage fully and assist with recruitment of families. Regular meetings held to report on progress and resolve issues and challenges.	High
Attrition	Use of regular communication, including tracking of participating parents and incentives for continued participation, including a small monetary incentive for completing the post-test measures. Strategies adopted to encourage longer-term follow up. Use of expert advisory committee.	High
Home visiting staff turnover	Attendance by ET at extra training sessions to ensure consistency of training. Family Lives policies and procedures followed to ensure staff are motivated, engaged and supported.	Medium
Scheduling visits/missed appointments	Suitability interviews prior to consent to ensure participants understand the commitment to the programme. Participants sign an agreement relating to their responsibility to the programme. Visit times offered as best as possible to match family lifestyles. Home visitors work with families to establish a routine to enable visits to occur regularly.	High
Local Authority not blind to condition leading to extra support to control group participants	Local Authorities encouraged not to boost provision for control participants due to the nature of the research design. Interviews with LA leads and the bespoke parent questionnaire at post-test will also explore the extent to which possible alternative provision was targeted at this group.	Medium
Missing Outcome Data	The amount of missing outcome data will be driven principally by attrition at the follow up time point. As alluded to previously strategies will be put in place to ensure that this remains as low as possible. All outcome data is being collected during visits by trained data collectors who will administer the primary outcome and will be able to assist participants with the completion of the measures. We therefore expect missingness due to poor completion of questionnaires to be minimal. Rules to allow for small amounts of missing data in the ASQ and HLE will be implemented to	Low

	make full use of all available information. Sensitivity analyses exploring the impact of missing data will also be conducted.	
Project Management across Universities	Louise Tracey will be the substantive PI and has extensive experience of managing large scale RCTs and evaluations in similar areas. The team as a whole has worked successfully together on other evaluations.	Low
Capacity	A Trial Co-ordinator will be appointed to build capacity. We would anticipate having a person in place prior to the pre-test (April 2019). During the initial set-up phase, we have 3 experienced RSOs with the skills and expertise to conduct the initial set up phase i.e. consent forms and ethical approval.	Low

Timeline

	2019				2020				2021		
	Jan-March	April-June	July-Sept	Oct-Dec	Jan-March	April-June	July-Sept	Oct-Dec	Jan-March	April-June	July-Nov
Recruit & Train site co-ordinators											
Agree protocol, write consents and gain ethical approval											
Identify & recruit families (with support from ET)											
Recruit and train data collectors											
Pre-test											
Randomisation											
Recruit Home Visitors (HV)											
Train HV											
Write SAP											
Programme delivery											
Implementation & Process Evaluation											
Parental engagement activities											
Post-test											
Analysis & write final report											

Key:

	Delivery Team
	Evaluation Team

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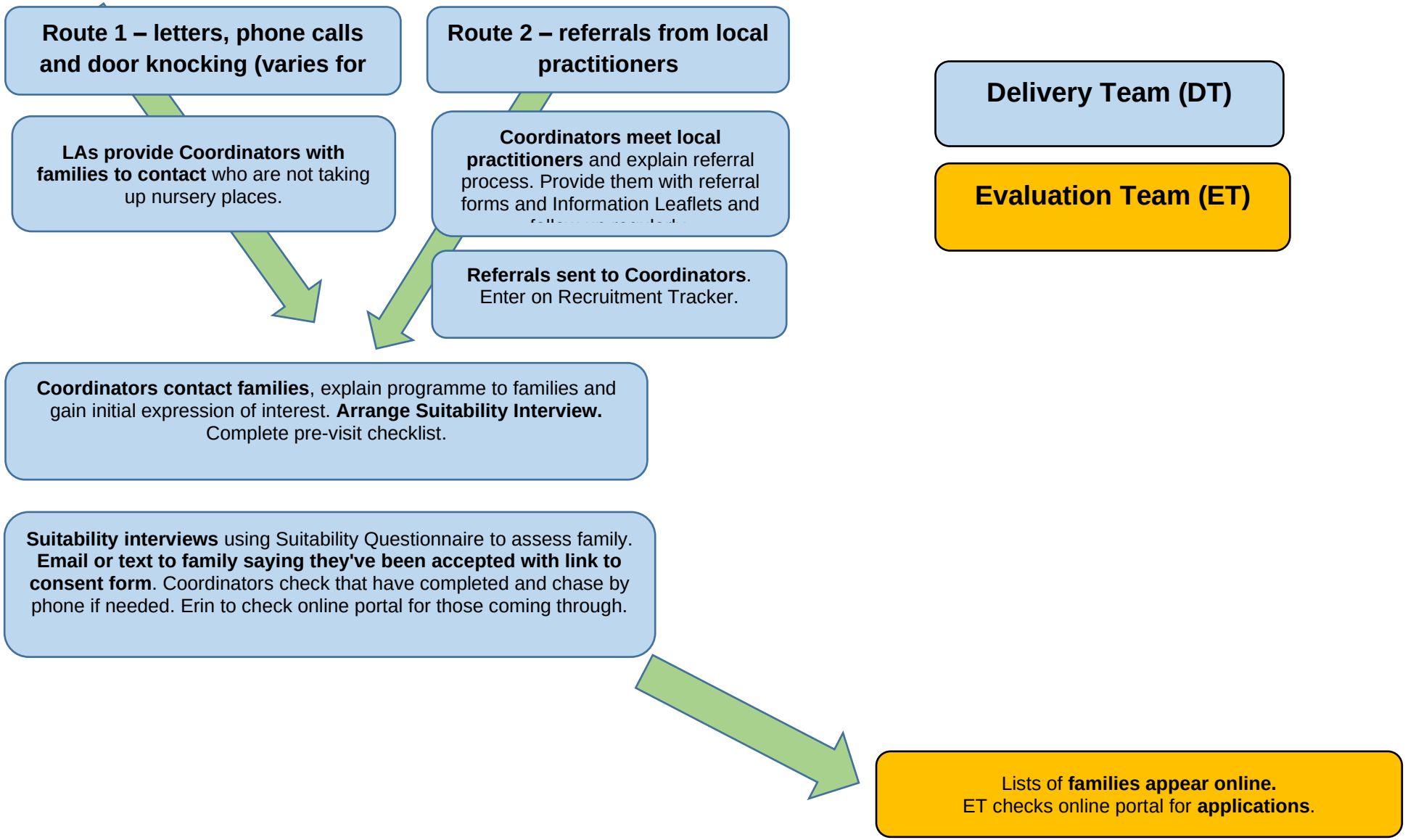
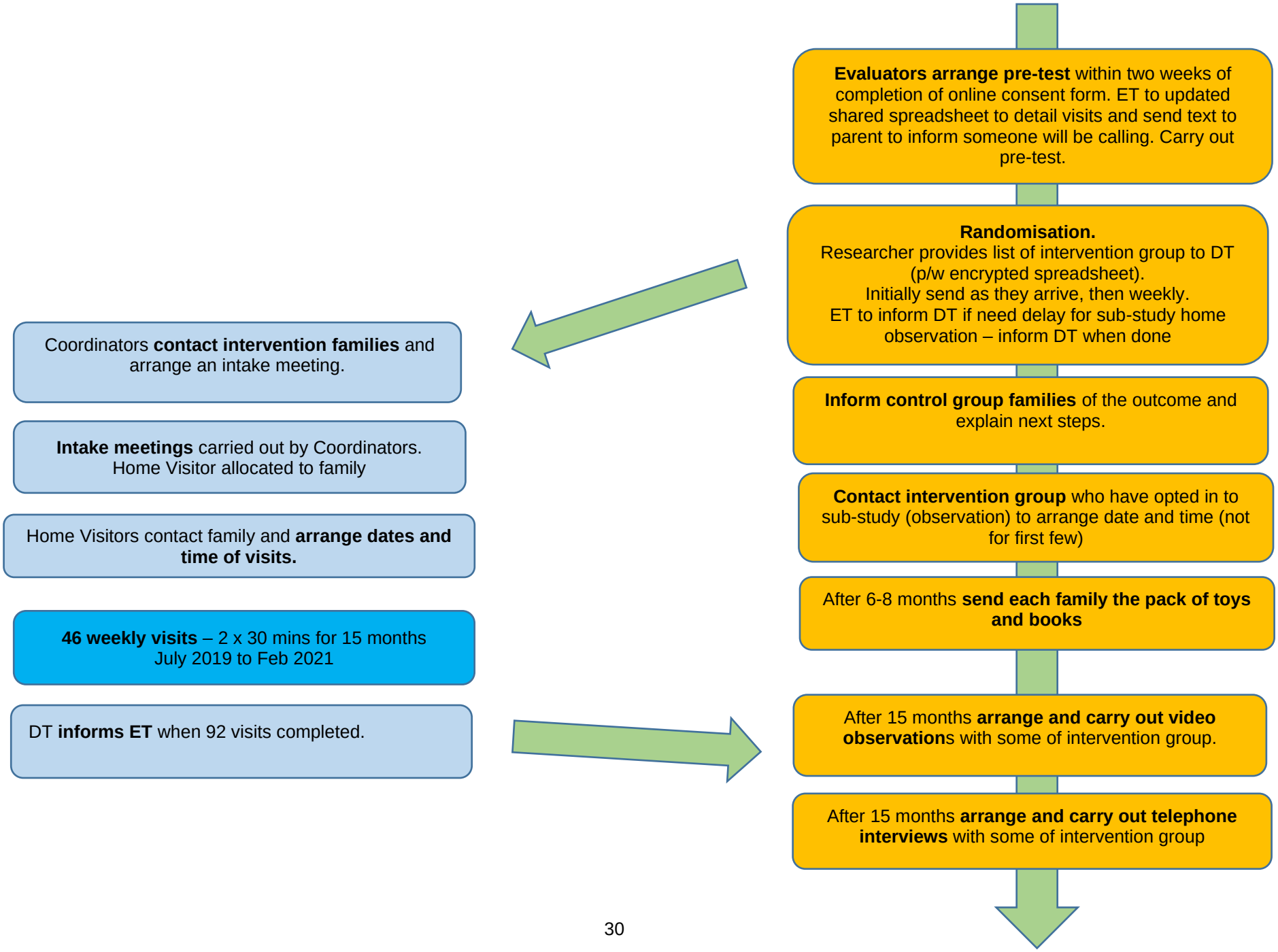
Appendix: ParentChild+ Evaluation Flow chart




Evaluators arrange pre-test within two weeks of completion of online consent form. ET to updated shared spreadsheet to detail visits and send text to parent to inform someone will be calling. Carry out pre-test.
Randomisation.
Researcher provides list of intervention group to DT (p/w encrypted spreadsheet).
Initially send as they arrive, then weekly.
ET to inform DT if need delay for sub-study home observation – inform DT when done
Inform control group families of the outcome and explain next steps.
Contact intervention group who have opted in to sub-study (observation) to arrange date and time (not for first few)
After 6-8 months **send each family the pack of toys and books**
After 15 months **arrange and carry out video observation**s with some of intervention group.
After 15 months **arrange and carry out telephone interviews** with some of intervention group
Coordinators **contact intervention families** and arrange an intake meeting.
Intake meetings carried out by Coordinators.
Home Visitor allocated to family
Home Visitors contact family and **arrange dates and time of visits.**
46 weekly visits – 2 x 30 mins for 15 months
July 2019 to Feb 2021
DT **informs ET** when 92 visits completed.