PROJECT TITLE	Trial of the ParentChild+ programme
DEVELOPER (INSTITUTION)	Family Lives
EVALUATOR (INSTITUTION)	University of York, Durham University and Leeds Beckett University
PRINCIPAL INVESTIGATOR(S)	Dr Louise Tracey and Prof. Carole Torgerson
SAP AUTHOR(S)	Charlie Welch and Caroline Fairhurst
TRIAL DESIGN	Two arm, parallel group RCT, with 1:1 randomisation at the household-level, stratified by local authority
CHILD AGE RANGE	2 – 3 years (at baseline)
TARGET SAMPLE SIZE	320 households
ACTUAL SAMPLE SIZE	283 households randomised
PRIMARY OUTCOME MEASURE AND SOURCE	British Picture Vocabulary Scale (BPVS-III) collected by blinded assessors at baseline and follow-up
SECONDARY OUTCOME MEASURE AND SOURCE	• Communication, personal-social skills and fine motor skills sub-scales of the Ages & Stages Questionnaire (ASQ-3) collected by blinded assessors at baseline and follow-up • Home Learning Environment Index collected by blinded assessors at baseline and follow-up

SAP version history

VERSION	DATE	REASON FOR REVISION
1.0	22/1/2021	--

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Introduction

The aim of this trial is to assess the effectiveness of ParentChild+ on child language skills, child behaviour, school readiness and parent-child interaction, among 2-4-year-old children in disadvantaged families. The statistical analysis will be primarily concerned with child language skills, child behaviour, the home learning environment and school readiness, with parent-child interaction being analysed separately. The primary research question is

- What is the impact of ParentChild+ on children's receptive vocabulary as measured by their score on the third edition of the British Picture Vocabulary Scale (BPVS-III)?

The secondary research questions are

- What is the impact of ParentChild+ on verbal/non-verbal interaction, developing positive behaviours and early literacy skills, as measured by the Ages and Stages Questionnaire (ASQ-3)?
- What is the impact of ParentChild+ on the home learning environment as measured by the Home Learning Environment Index (HLEI)?
- What are the longer-term impacts of ParentChild+, as measured by the statutory school-based assessments (i.e. the Reception Baseline Assessment (RBA) and the Early Years Foundation Stage Profile (EYFSP))?

The BPVS-III, ASQ-3 and HLEI data are collected at baseline and follow up by trial data collectors. Data collection takes approximately 30 – 40 minutes. During the intervention delivery phase of the project there was a pause in all intervention delivery activities of approximately four months due to the COVID-19 pandemic. Follow up was delayed by four months to accommodate this pause. After the pause, intervention delivery was via both face-to-face home visits (as originally intended) and virtually using online video-conferencing software (to enable continued intervention delivery to those participants who were unable or unwilling to have in-person home visits).

Design overview

Trial design, including number of arms		Two arm, parallel group RCT, with 1:1 randomisation stratified by local authority
Unit of randomisation		Participating households
Stratification variables (if applicable)		Local Authority (4 levels – Barnsley, Doncaster, Rotherham, Sheffield)
Primary outcome	Variable	Receptive vocabulary
	Measure	BPVS-III (raw score)
Secondary outcomes	Variable	Communication skills
	Measure	ASQ-3 (Communication subscale raw score)
	Variable	Personal-social skills
	Measure	ASQ-3 (Personal-social skills subscale raw score)
	Variable	Fine motor skills
	Measure	ASQ-3 (Fine motor skills subscale raw score)
	Variable	Home learning environment
	Measure	HLEI (Total score)
Baseline covariates for primary analysis		• Local authority (4 levels – Barnsley, Doncaster, Rotherham, Sheffield) • Baseline BPVS-III (raw score) • Age at baseline visit
Baseline covariates for secondary analyses		• Local authority (4 levels – Barnsley, Doncaster, Rotherham, Sheffield) • Baseline score of outcome measure (Communication, Personal-social skills, Fine motor skills or Home Learning Environment Index) • Age at baseline visit

Sample size

Sample size calculations were undertaken using Stata version 15 [1]. Although the unit of randomisation is households, in the vast majority of these there will be only one eligible child (five (1.8%) of the 283 households randomised have more than one eligible child participating). Therefore the sample size calculation was conducted as for an individually randomised trial. Multiple eligible children within a household will be allowed to take part, and in these cases the means of the available scores obtained within the household will be used for the analysis. The delivery team estimated that they would have capacity to support 160 families in the intervention (40 in each of 4 geographical regions). Hence the target sample size was 320 families, randomised 1:1 to either the intervention or treatment as usual. Assuming 20% attrition at follow up (n=64) and that scores obtained at baseline and follow up are approximately bivariate normal with a correlation of 0.7, the effective sample size (n=256) gives a minimum detectable effect size 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% and 20%, respectively. The actual number of households/families randomised was 283.

The estimate of the correlation between the baseline and follow up measurements of 0.7 was based on correlations observed for similar outcome measures used in previous education trials undertaken by York Trials Unit. For example, the correlation between baseline and follow up measurements of the Clinical Evaluation of Language Fundamentals Preschool Assessment Expressive Vocabulary raw scores observed in the EEF funded evaluation of EasyPeasy was 0.75 [1]. A study by Camilleri and Law [2] also provides some evidence that the correlation between repeated measurements of the BPVS is likely to be substantial. The correlation between measurements of the BPVS taken 6 months apart observed in this study was 0.90, although this is based on only 37 pairs of observations. We therefore assume a correlation of 0.7 is a reasonably conservative estimate.

The number of available scores for each of the outcome measurements will be reported by allocation, and in total at each time point. The minimum detectable effect sizes (with type 1 and 2 error rates of 5% and 20% respectively) will be reported for the planned sample size, the actual sample size recruited and the sample size included in the primary analysis, assuming the observed correlation between repeated measurements of the BPVS-III to be the true correlation between repeated measurements in this population. For each outcome, the correlation between the baseline and follow-up measurements will be reported, with 95% confidence intervals based on Fisher's transformation. Templates of tables described in this section are given in Appendix A. The minimum detectable effect sizes for the sample size specified in the protocol (320 households) and the sample size actually recruited (283 households) are given in Table 1.

Table 1: Sample size overview

		Protocol	Randomisation
Minimum Detectable Effect Size (MDES)		0.25	0.27
Pre/post correlations		0.7	0.7
Attrition		20%	20%
Alpha		0.05	0.05
Power		0.8	0.8
One-sided or two-sided?		Two-sided	Two-sided
Number of children	Intervention	160	141
	Control	160	142
	Total	320	283

Analysis

All outcomes will be analysed once, at the trial's conclusion, using Stata version 16 [3]. The flow of households/participants through the trial will be presented in a CONSORT diagram (see Appendix B). Analyses will be conducted following intention-to-treat (ITT) principles, meaning that participants will be analysed according to the group to which they were assigned, regardless of subsequent adherence to that condition. For each of the five continuous outcomes, baseline and follow up data will be summarised descriptively in terms of the non-missing sample size, mean, standard deviation, median, interquartile range and minimum and maximum. Differences between groups at follow-up will be reported adjusted for local authority (the stratification factor) and other pre-specified covariates (see details below) together with appropriate 95% confidence intervals and p-values. Effect sizes will be reported for all between group comparisons, unless otherwise stated. Effect size will be given in terms of Hedges' g, together with bias corrected non-parametric bootstrap 95% confidence interval (2500 replicates). Let n_1 and n_2 be the size of the intervention and control groups respectively (i.e. the number of observed outcomes after pooling of data from households with multiple eligible and participating children). Hedges' g will be calculated based on Hedges' unbiased estimator for effect size [4], given by

$$g = d \times \frac{\Gamma\left(\frac{m}{2}\right)}{\sqrt{\frac{m}{2}}\,\Gamma\left(\frac{m-1}{2}\right)} \qquad (1)$$

where $m = n_1 + n_2 - 2$, and d is defined as

$$d = \frac{\hat{\delta}}{\sqrt{\frac{(n_1 - 1){s_1}^2 + (n_2 - 1){s_2}^2}{m}}} \qquad (2)$$

where $\hat{\delta}$ is some estimate of the difference in means between groups, and s_1 and s_2 are the observed sample standard deviations of the outcome measurements in the intervention and control group respectively.

Baseline data

Baseline data will be summarised descriptively by trial arm and overall, both as randomised and as included in the primary analysis model, as shown in the templates of tables in Appendix C. Continuous data will be summarised in terms of the non-missing sample size, mean, standard deviation, median, interquartile range, minimum and maximum. Categorical data will be summarised in terms of counts and percentages. For the rare cases where there are multiple eligible and participating children in a given household, each child's baseline information will be included in these summaries on an individual basis (to avoid difficulties encountered in pooling categorical baseline data which varies within household). No between group comparisons of baseline data will be undertaken, except unadjusted Hedges' g effect sizes will be presented for the differences between groups in the non-missing baseline scores obtained for the outcomes. Descriptive summaries and histograms of baseline scores for the outcome measures will also be presented after the data from households with multiple participating children are pooled. Some of the categorical baseline characteristics (of participating children) feature "rare" categories and reporting such data stratified by treatment group may therefore present a possible risk of disclosure. If a given categorical baseline characteristic leads to cells with frequencies less than four, then these categories will either be combined (where it is appropriate to do so) or the precise cell counts will be suppressed and reported as "<4".

Primary analysis

The primary outcome for this study is BPVS-III score [5] at 19 months post randomisation (the planned 15 month follow up plus an additional four months due to the COVID-19 pause period). For the vast majority of households, this will be the single integer score between 0 and 168 obtained by the participating child within the household. For the rare cases where there are multiple eligible and

participating children in a given household, the available scores will be pooled by taking their mean, with this pooled score then being treated as the observation for that household. A similar logic will be applied for the continuous covariates included in the model. The categorical covariates included in the model all vary at the level of the household so no pooling will be necessary. The household BPVS-III scores will be modelled using a univariate linear regression model with the variables given in Table 2 included as explanatory variables (assuming linear relationships between continuous covariates and outcome), together with a heteroscedasticity robust variance estimator.

Table 2: Primary analysis model terms and interpretation

Term	Interpretation	Type	Details
Z_i	Randomised allocation for household i	Binary	Indicator variable (Control = 0, Intervention = 1)
LA_i	Local authority in which household i was situated at baseline	Categorical	4 levels (Barnsley, Doncaster, Rotherham, Sheffield) Included in the model via three indicator variables with Barnsley used as the reference category.
$\mathrm{baseline}_i$	Baseline BPVS-III score for household i	Continuous (linear)	Score between 0 and 168 (mean-centred) Where there are multiple eligible and participating children in household i, the baseline score for this household will be taken to be the mean of the available scores.
age_i	Age at baseline for household i	Continuous (linear)	Age in months (mean-centred) Where there are multiple eligible and participating children in household i, the age at baseline for this household will be taken to be the mean of the available ages.

All randomised households/participants have complete data on local authority and age at baseline. If a participating household has a non-missing BPVS-III score at follow up, but is missing a BPVS-III score at baseline, then these missing baseline values will be imputed using conditional mean imputation as follows.

1. If the household has non-missing baseline HLEI and ASQ-3 Communication subscale scores, then the missing baseline BPVS-III scores will be imputed using the predicted values obtained from a regression of the observed baseline BPVS-III scores on local authority (as above), age (as above), baseline HLEI score (0-56 linear relationship assumed), and baseline ASQ-3 Communication subscale score (0-60, linear relationship assumed)

2. If the household has a non-missing baseline HLEI score (respectively ASQ-3 Communication subscale score), then the missing baseline BPVS-III scores will be imputed using the predicted values obtained from a regression of the observed baseline BPVS-III scores on local authority (as above), age (as above) and baseline HLEI score (baseline ASQ-3 Communication subscale score)

3. If the household is also missing both HLEI and ASQ-3 Communication subscale scores at baseline, then the missing baseline BPVS-III scores will be imputed using the predicted values obtained from a regression of the observed baseline BPVS-III scores on local authority (as above) and age (as above) only

The fitted analysis model will use importance weighting to ensure any cases that have an imputed baseline BPVS-III score receive a lower weight than cases that have an observed baseline BPVS-III score [6]. Cases that had a missing baseline BPVS-III score (prior to imputation) will be assigned a weight of $1 - {r_i}^2$, where r_i is the sample correlation between baseline and available follow up BPVS-III measurements among the complete cases in randomised group i. Complete cases with an observed baseline BPVS-III score will be assigned a weight of 1.

Conditional normality will be assessed using a normal quantile-quantile plot. If this plot suggests serious violation of the assumption of conditional normality, then the outcome measurements will be log-transformed (using the natural logarithm with a value of 1 added to the original scores to account for any scores of zero prior to taking the logarithm) and the same model will be fitted to the transformed scores. An estimate of the between group difference in mean score (on the original scale), conditional on representative values of the covariates (mean values for age and baseline score and at each level of local authority) will be derived from this model, with standard errors obtained using the delta method. If severe model misspecification is still evident for the model with log-transformed response, then a semi-parametric ordinal logit regression model will be fitted with the same covariate specification detailed in Table 2. This model will be used to estimate the between group difference in mean score (on the original scale), conditional on representative values of the covariates (mean values for age and baseline score and at each level of local authority) [7]. The adequacy of the logit link will be assessed, with an alternative link (probit, log-log or complementary log-log) being used if the logit link appears severely misspecified. The reporting of the results from the primary analysis is outlined in Appendix D.

Intervention delivery

The number of sessions received, the approximate duration, and the type of session (e.g. face-to-face, virtual etc.) will be summarised descriptively for participants in the intervention group. The extent to which families/households are clustered within home visitors will also be summarised descriptively. If over 80% of households followed up (in the intervention arm) are nested within a unique home visitor cluster, then a sensitivity analysis of the primary outcome allowing for clustering by home visitor in the intervention arm will be implemented using a heteroscedastic partially nested mixed effect model as outlined in [8]. This model will adjust for the same fixed effects as the primary analysis (with identical imputation of missing baseline BPVS-III scores as implemented in the primary analysis) and will be fitted using restricted maximum likelihood estimation with the Kenward – Roger degrees of freedom correction being implemented. Clustering by home visitor in the intervention group will be accounted for using a treatment by home visitor cluster random slope, and individual level residual variances will be allowed to vary by randomised group. Any households which are not nested in a unique home visitor cluster will be considered nested within the cluster of the home visitor from whom they received the most sessions. The treatment effect from this model will be reported, together with the appropriate 95% CI and p-value. The effect size will also be reported together with a bias-corrected non-parametric bootstrap 95% CI (2500 replicates).

Adherence

We will conduct an exploratory analysis of the primary outcome to investigate whether “dose” of programme delivered is a source of treatment effect heterogeneity. This will be done by fitting a linear “dose”-response model, where the number of sessions delivered is taken to be a proxy for dose of programme received. Here the number of sessions delivered is the number of visits (of any kind) conducted outside of the pause in intervention delivery due to the COVID-19 pandemic (23/03/2020 to 22/06/2020). Due to the possibility of unmeasured common causes of both the number of programme sessions delivered and outcome, a two-stage least squares estimator (with random allocation as the instrument), will be used to estimate the incremental effect of each additional session assuming a linear relationship between this variable and the outcome. The baseline covariates included in the primary analysis model will be included in the first and second stage regressions estimated as part of the two-stage least squares estimator, together with the same imputation of missing baseline values as implemented for the primary analysis. Missing outcome measurements are assumed to be missing at random, and inverse probability weights (truncated at the 1st and 99th percentile) will be used as part of the two-stage estimator. The probability of having a valid BPVS-III score at follow up will be estimated using a Firth logistic regression model [9] including the following baseline variables;

- Treatment group (binary – control vs intervention)
- Baseline BPVS-III score (continuous, modelled using linear term)
- Baseline Home Learning Environment Index score (continuous, modelled using linear term)
- Child in need status (binary – Yes vs No)

The point estimate for the "dose" effect will be reported, together with a 95% CI calculated using the model based standard errors implemented by Stata's ivregress 2sls command. No effect size statistics will be reported. The results of the first stage regression, and the F-statistic and p-value for an F-test of the strength of the instrument (namely randomisation) will also be reported.

Errors in baseline BPVS-III data collection

The BPVS-III is comprised of 14 sets of 12 items [5]. The test proceeds until the child being tested makes 8 or more errors in a set of 12 items, at which point the test is stopped. Once a set is commenced, all items in the set should be administered. During the baseline data collection there were a few cases of this instrument being terminated prematurely, due to either data collector error, or due to the child or parent being unwilling to continue with the test. The scores obtained in these cases will be used for the purposes of the primary analysis. The sensitivity of the results to these cases will be investigated by refitting the primary analysis model with these cases (as well as any other missing baseline values) being imputed and down-weighted as for the primary analysis.

Heterogeneity and measurement error in BPVS-III due to testing medium

Due to ethical constraints as a result of the COVID-19 pandemic, a proportion of follow up data collection will not be conducted by data collectors in person in the participant's homes (as planned), but will be undertaken by data collectors online using video-conferencing software. The proportion of participants who undergo remote follow up (i.e. via video-conferencing software) is expected to be small, and will be independent of randomised group as well as any participant characteristics. However, variation in the testing procedure may still be a source of additional variation and/or error in the BPVS-III follow up measurements obtained (as the result of either random or systematic measurement error). We therefore plan to include additional sensitivity analyses to investigate the possible influence of both variation in testing procedure and measurement error on the results of the primary analysis.

The proportion of participants that complete remote follow-up will be summarised by group. It is anticipated that children completing the BPVS-III remotely may receive greater support from their parent/carer during administration of this assessment, than would be expected if the follow-up data collection were being undertaken in person. The level of support given during administration will be ranked using a four level ordinal scale (see below), and will be summarised by randomised group.

No support – No support of any form was given to the child being assessed

Low – The carer repeated the questions in the same way the data collector administered them

Medium – The carer repeated the questions and added additional words (e.g. "the" or "a")

High – The carer gave direct clues (e.g. "You have one of those", "What do you drink out of?" etc.)

Firstly, the primary analysis model will be re-fitted including only households who completed in-person follow-up data collection. Given that receipt of in-person vs remote follow up will be unrelated to either randomised group or potential outcome, the ordinary least squares estimator of the treatment effect should not be affected by selection bias, and will be unaffected by any bias due to measurement error resulting from remote follow-up data collection. Cases with observed follow up BPVS-III measurements, but missing baseline BPVS-III measurements will have the missing baseline measurement imputed and will be down-weighted as in the primary analysis. The treatment effect estimates, p-values and effect size estimates obtained from this model will be reported in an identical manner to the reporting of the results of the primary analysis.

Secondly, the primary analysis model will be re-fitted (including all households with available BPVS-III outcome data), with an additional binary covariate indicating follow-up type received (in-person or remote) and its interaction with randomised group in the linear predictor. The inclusion of these terms will help account for variation in outcome due to testing medium, as well as any possible variation in the influence of remote testing across randomised groups. This model will be used to obtain treatment effect

estimates, p-values and effect size estimates by follow-up type strata, with results being reported as for the primary analysis.

Note that methods to formally account for measurement error resulting from remote follow up (particularly measurement error that differs by randomised group) will not be employed due to the lack of an external calibration sample (i.e. a set of children similar to the children included in the trial cohort, with both remote and in-person BPVS-III scores available).

Missing data

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 summarised. Baseline variables associated with missing/observed primary outcome data will be identified using a series of univariable Firth logistic regression models [9]. The following baseline variables will be assessed;

- Child EAL (binary – Yes vs No)
- Child in need status (binary – Yes vs No)
- ASQ-3 communication subscale score at baseline (continuous)
- ASQ-3 personal-social subscale score at baseline (continuous)
- Home learning environment index score (continuous)
- Caregiver EAL (binary – Yes vs No)
- Home ownership (binary – tenant vs homeowner)
- Caregiver employment (binary – employed vs unemployed/retired)
- Household income (binary – ≤£20000 vs >£20000)

Any baseline variables that are found to improve model fit (compared with the model with all parameters other than the intercept constrained to zero (as opposed to omitted)) in a likelihood ratio test of size 10% will be added to the primary analysis model, and this model refitted. Missing values of continuous baseline covariates will be imputed with the local authority specific mean prior to model fitting. Cases with missing values for categorical covariates will be omitted. The difference between groups from the model including additional predictors of missingness will be reported, together with an appropriate 95% CI and p-value. The effect size will also be reported together with a bias-corrected non-parametric bootstrap 95% CI (2500 replicates).

If greater than or equal to 5% of cases are excluded from the primary analysis due to missing outcome data, then an analysis using multiply imputed data will be undertaken. At least 100 imputations will be generated using multiple imputation by chained equations with imputation performed separately by randomised group to allow for possible interactions between variables included in the imputation model and randomised group. The imputation model will include the variables specified in Table 3, as well as any baseline variables identified as being associated with missing primary outcome data (see above). Missing values in baseline variables included in the imputation model will be imputed where necessary (after removal of values imputed using simple imputation methods for other analyses).

Table 3: Details of the variables included in the chained equation algorithm together with the univariate imputation method used to impute any missing values

Variable	**Type**	**Details**	**Details of univariate imputation model (if imputation required)**
BPVS-III score at follow up	Continuous	Score between 0 and 168	Predictive mean matching (10 nearest neighbours)
Local authority	Categorical	Four levels (Barnsley, Doncaster, Rotherham, Sheffield)	N/A
BPVS-III score at baseline	Continuous	Score between 0 and 168	Predictive mean matching (10 nearest neighbours)
Age at baseline	Continuous	Age in months	N/A
Child in Need status	Binary	Yes = 1 No = 0	Logistic regression (with penalisation if required)
ASQ-3 Communication subscale score at baseline	Continuous	Score between 0 and 60	Predictive mean matching (10 nearest neighbours)

ASQ-3 Communication subscale score at follow up	Continuous	Score between 0 and 60	Predictive mean matching (10 nearest neighbours)
ASQ-3 Personal-Social subscale score at baseline	Continuous	Score between 0 and 60	Predictive mean matching (10 nearest neighbours)
ASQ-3 Personal-Social subscale score at follow up	Continuous	Score between 0 and 60	Predictive mean matching (10 nearest neighbours)
HLEI score at baseline	Continuous	Score between 0 and 56	Predictive mean matching (10 nearest neighbours)
HLEI score at follow up	Continuous	Score between 0 and 56	Predictive mean matching (10 nearest neighbours)

The few cases where premature termination of the baseline BPVS-III occurred, will have the scores obtained set to missing and these will also be imputed as part of the multiple imputation. The length of burn in used for the chained equation algorithm (i.e. the number of cycles before data are imputed) will initially be determined by examining the trace plots of the algorithm. A Gelman – Rubin $\hat{R}$ statistic will be calculated using 5 chains of double the length suggested by the trace plots, with the second half of each chain being used to double check that the algorithm is likely to have indeed reached a stable state. If $\hat{R}$ is greater than 1.1 then a longer burn in length will be used, and possible reasons for slow/non-convergence will be investigated. A minimum burn in of 10 iterations being used if this appears to be sufficiently many for the algorithm to reach a stable state. Data augmentation/penalisation will be used to impute binary variables should separation occur in any of the univariate models used to impute these data. Imputed data will be analysed using the same model as used for the primary analysis. If the Monte Carlo error for the treatment effect estimate is greater than or equal to 5% of the standard error for the treatment effect estimate, a further 10 imputations will be performed. This will be repeated until the Monte Carlo error is below this threshold. The difference between groups estimated using the multiply imputed data will be reported together with an appropriate 95% CI and p-value. The effect size and 95% CI will be estimated using the "MI Boot" approach described in [10]. Briefly, this involves calculating an estimate of the effect size and a non-parametric bootstrap standard error (1000 replicates) for each imputed dataset, and combining these using Rubin's rules.

The sensitivity of the results of the primary analysis to the outcome data being missing not at random (MNAR) will be explored using a pattern mixture modelling approach as implemented in the `rctmiss` command available from the Boston College Statistical Software Components archive [11]. This command will be used to produce a graph of the change in the coefficient for allocation as the sensitivity parameter in the pattern mixture model varies between 0 (unobserved BPVS-III scores the same as the observed BPVS-III scores conditional on other covariates in the substantive model) and -10 (unobserved BPVS-III scores are 10 points less than the observed BPVS-III scores conditional on other covariates in the substantive model) in steps of one. This will provide some indication of the extent to which the results of the primary analysis are robust to outcome data being missing not at random. The estimated between group difference at each level of the sensitivity parameter will also be reported together with 95% CI and p-value. Effect sizes will not be reported.

Mediation analysis

One of the proposed mechanisms by which the intervention improves language skills and school readiness, is by fostering a positive home learning environment. Quantitative data concerning the home learning environment is collected at baseline and follow up using the Home Learning Environment Index (HLEI), which provides a score between 0 and 56, with higher scores indicating a more positive home learning environment. An exploratory analysis will be conducted, to decompose the intention-to-treat estimate into direct effects (i.e. effects of allocation that are not explained by changes to the home learning environment) and indirect effects (i.e. effects of allocation that can be attributed to changes in the home learning environment). The assumed causal model for this analysis is given in Figure 1. The key assumptions/features are:

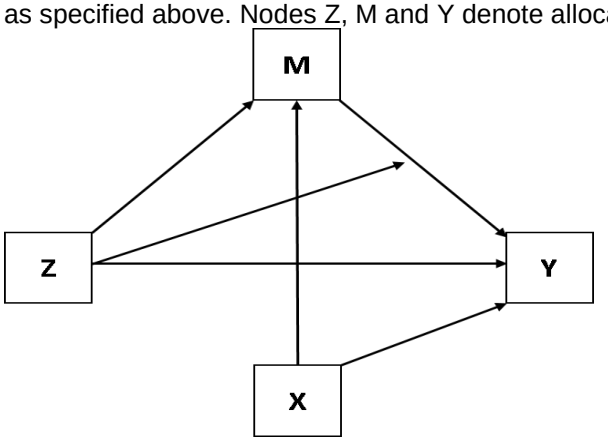
A) Confounding of follow-up HLEI and BPVS-III scores is negligible conditional on observed baseline covariates (BPVS-III score, HLEI score, local authority, English as an Additional Language, age and parental income). This is illustrated in Figure 1 by the absence of any

unmeasured common causes of M and Y. Note parental income will be dropped from the model if it leads to the exclusion of greater than 10% of the cases which would otherwise be included.

B) Allows for treatment by mediator interaction. This is made explicit in Figure 1 by the arrow from Z to the arrow between M and Y.

This model will be fitted using the user written Stata command `paramed` [12]. The point estimates of the natural direct and indirect effects will be reported together with 95% confidence intervals based on standard errors obtained via the delta method.

Figure 1: Causal model assumed for mediation investigation. X denotes measured baseline covariates as specified above. Nodes Z, M and Y denote allocation and HLEI and BPVS-III scores at follow up.



Subgroup analyses

Four pre-specified exploratory subgroup 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 any participating child in a given household has ever been a child in need at any time in their life prior to the baseline visit.
- **English as an additional language**
  A binary classification defined in terms of the main language spoken at home with the child.
- **Baseline score for the ASQ-3 communication subscale**
  Score between 0 and 60 (if there are multiple participating children within a given household then the mean of the available scores will be used).
- **Entitlement to a free nursery place**
  A binary classification of whether or not any participating child in the household is entitled to a free nursery place.

Treatment effect heterogeneity for each of these four covariates will be investigated by examining whether or not the inclusion of an interaction between the covariate and randomised group in the primary analysis model (together with the main effect of the covariate), leads to improvement in model fit based on a likelihood ratio test of size 20%. If the inclusion of the interaction term does appear to improve model fit (at the level specified), then the estimated coefficient(s) for the interaction term(s) will be presented together with 95% CIs and p-values, and the model including the interaction (and the main effect of the covariate) will be used to derive treatment contrasts at each level (where feasible) of the baseline covariate under consideration, together with 95% CIs and p-values. Contrasts will be given for every level of categorical covariates. For the ASQ-3 communication subscale, contrasts will be given over the range of scores from 10 to 50 in increments of 10. Effect sizes will be given in terms of Hedges' g, together with bias-corrected non-parametric bootstrap 95% CIs (2500 replicates).

Secondary outcome analysis

Ages and Stages Questionnaire – 3

Participating children will be tested using three subscales of the Ages and Stages Questionnaire (ASQ-3) [13] at both baseline and follow up. The three subscales that will be used are the communications subscale, personal-social skills subscale and fine motor skills subscale. All subscales are scored between 0 and 60, with higher scores indicating better development. The ASQ-3 is age standardised, meaning that children will complete different versions of the instrument depending on the age at which they are tested. The versions of the ASQ-3 used in this study are: 24 months, 27 months, 30 months, 33 months, 36 months, 42 months, 48 months and 54 months. Item level missingness will be dealt with according to the rules for missingness given in the ASQ-3 Users Guide. If a sub-scale has one or two missing items, the sub-scale score will be calculated by summing the scores for the non-missing items, and multiplying the resulting score by 1.2 if there is one item missing, and 1.5 if there are two items missing. If a participant has more than two missing items in a given sub-scale, then the sub-scale is not scored for the participant, and the data score is treated as missing.

The three subscales will be analysed using univariate linear regression models adjusting for allocation, local authority, age and the baseline score for the relevant subscale. If a household has an available score at follow-up, but the baseline score is missing, then the missing score will be imputed prior to analysis, following a similar approach to that implemented for the primary analysis (i.e. conditional mean imputation). Those with imputed baseline data will be down-weighted in the analysis model in a similar manner to the weighting implemented for the primary analysis. The assumptions of the models will be checked using diagnostic plots of the estimated residuals, with log-transformation of the outcome and/or robust standard errors used if the model assumptions are seriously violated. The fitted models will be used to derive adjusted differences between groups, 95% confidence intervals, p-values and effect sizes in terms of Hedges' g (together with a bootstrap 95% confidence interval).

Home Learning Environment Index

Parents of participating children will complete the Home Learning Environment Index (HLEI, see Appendix E) at both baseline and follow up. Responses to the eight items on this questionnaire are then summed to generate a score between 0 and 56, where higher scores indicate a more positive home learning environment. If there are fewer than three items missing, then the missing items will be imputed with the mean of the scores for the non-missing items, and the overall score calculated by summing the scores for all eight items. If there are three or more items missing, then the overall score will be treated as missing.

HLEI score will be analysed using a univariate linear regression model, adjusting for allocation, local authority, age and baseline HLEI score. If a household has an available score at follow-up, but the baseline score is missing, then the missing score will be imputed prior to analysis, following a similar approach to that implemented for the primary analysis (i.e. conditional mean imputation). Those with imputed baseline data will be down-weighted in the analysis model in a similar manner to the weighting implemented for the primary analysis. The assumptions of the models will be checked using diagnostic plots of the estimated residuals, with log-transformation of the outcome and/or robust standard errors used if the model assumptions are seriously violated. The fitted model will be used to derive adjusted difference between groups, 95% confidence interval, p-value and effect size in terms of Hedges' g (together with a bootstrap 95% confidence interval).

Longer term follow-up using data obtained from the National Pupil database

In addition to the analyses conducted as part of the ParentChild+ evaluation, we would also like to investigate the longer term impact of the programme on children's development using EYFSP data obtained from the National Pupil Database (NPD). Parental consent to access information relating to school destination was obtained as part of the trial recruitment and consent process. Note that the results of the within trial analyses specified in previous sections will be reported prior to any analysis of EYFSP data. These data would be obtained and analysed as part of a secondary follow-up study (pending funding).

Early Years Foundation Stage Profile

Participating children will be assessed according to the Early Years Foundation Stage Profile (EYFSP) at the end of their first year of school, with these data being obtained from the National Pupil Database (NPD) by the research team. The children in the ParentChild+ evaluation cohort will enter Reception in either September 2020 or September 2021 and will be assessed according to one of two versions of the EYFSP, hereafter referred to as "old" and "new" [14, 15] The new version is due to become statutory for students entering reception in September 2021 (delayed a year due to the COVID-19 pandemic); however, numerous schools are "early adopters", and will complete the new version of this assessment for children who entered reception in September 2020. Hence, trial participants who enter Reception in 2021, and those who entered Reception in September 2020 at an early adopter school (if any) will be assessed according to the new version. Trial participants who entered Reception in September 2020 at schools that are not early adopter schools will be assessed according to the old version.

Both versions of the EYFSP consist of 17 Early Learning Goals (ELGs), although there are differences in the ELGs between versions (see Table 4). Further information can be found in [14] and [15]. For the old version, children are assigned a score of "Emerging", "Expected" or "Exceeding" for each ELG. For the new version, children are assigned a score of either "Emerging" or "Expected" for each ELG. In order to combine EYFSP data from both versions, the "Expected" and "Exceeding" categories in the old version would be combined so each participant would have EYFSP data consisting of 17 binary (Emerging or Expected) responses (one for each ELG).

Table 4: Overview of the Early Learning Goals (ELGs) in the old and new versions of the Early Years Foundation Stage Profile (EYFSP)

Area of Learning	**"Old" EYFSP ELGs** (See Section 6 of 2021 EYFSP handbook for further detail)	**"New" EYFSP ELGs** (See Section 3.4 of 2021 EYFSP early adopter handbook for further detail)
Communication and language development	1. Listening and attention 2. Understanding 3. Speaking	1. Listening, attention and understanding 2. Speaking
Physical development	4. Moving and handling 5. Health and self-care	3. Gross motor skills 4. Fine motor skills
Personal, social and emotional development	6. Self-confidence and self-awareness 7. Managing feeling and behaviour 8. Making relationships	5. Self-regulation 6. Managing self 7. Building relationships
Literacy	9. Reading 10. Writing	8. Comprehension 9. Word reading 10. Writing
Mathematics	11. Numbers 12. Shape, space and measures	11. Number 12. Numerical patterns
Understanding the world	13. People and communities 14. The world 15. Technology	13. Past and present 14. People, culture and communities 15. The natural world

Expressive arts and design	16. Exploring and using media and materials 17. Being imaginative	16. Creating with materials 17. Being imaginative and expressive

The (binary) responses for each of the 17 ELGs would be used to generate two summary scores. A "Total" score between 0 and 17 indicating how many ELGs which were assigned a score of "Expected", and a "Good Level of Development" score between 0 and 12 indicating how many of ELGs 1 – 12 (see Table 3) were assigned a score of "Expected".

Both outcomes would be analysed using ordinal regression models with logit link functions, adjusting for the same covariates as the primary analysis model and an additional binary covariate for version of EYFSP completed. Despite being determined after randomisation, version of EYFSP completed will be unrelated to allocation, hence its inclusion as a covariate would not be expected to introduce selection bias. It is included as a means of accounting for any additional outcome heterogeneity associated with EYFSP version completed. Missing values of continuous baseline covariates would be imputed with local authority specific mean prior to model fitting. For both models, the adequacy of the logit link would be assessed using a plot of the transformed exceedance probabilities against outcome stratified by randomised group, with other link functions considered if the logit link appears to be severely misspecified. Inference concerning differences between randomised groups would be based on the following quantities and graphical displays obtained from the fitted model;

- Odds ratio for allocation, together with two-sided 95% confidence intervals and p-values

- Difference in proportion of participants achieving "Expected" for all ELGs comprising each summary score (conditional on representative values for the other covariates in the model), together with 95% Wald confidence limits based on standard errors obtained via the delta method

- Difference in mean number of ELGs assigned a score of "Expected" (conditional on representative values for the other covariates in the model), together with 95% Wald confidence limits based on standard errors obtained via the delta method

- Plots of the exceedance probabilities (i.e. $\Pr(Y \geq y \mid \text{Group} = \text{Intervention}, X)$ and $\Pr(Y \geq y \mid \text{Group} = \text{Control}, X)$ where Y is a random variable denoting number of ELGs assigned a score of "Expected" and X denotes representative values of the other covariates) against Y stratified by randomised group

- Plot of the difference (Intervention – Control) in exceedance probabilities, and ratio (Intervention/Control) of exceedance probabilities against Y (conditional on representative values for the other covariates in the model), together with 95% Wald confidence limits based on standard errors obtained via the delta method

In addition to the two summary scores outlined above, we would also use the responses to some of the ELGs to generate four binary outcomes relating to specific areas of development. These would be derived and analysed as follows;

Speaking

Both versions of the EYFSP have a specific ELG for Speaking. Responses from both versions would be analysed together in a Firth logistic regression model [7] adjusting for randomised treatment group, local authority, baseline BPVS score, age at baseline and a binary covariate for version of the EYFSP completed. Missing values for continuous baseline covariates would be imputed with the local authority

specific mean prior to model fitting. The odds ratio for allocation would be reported, together with two-sided 95% profile penalised likelihood confidence intervals and p-values.

Writing

Both versions of the EYFSP have a specific ELG for Writing. Responses from both versions would be analysed together in a Firth logistic regression model [7] adjusting for randomised treatment group, local authority, baseline BPVS score, baseline ASQ fine-motor skills score, age at baseline and a binary covariate for version of the EYFSP completed. Missing values for continuous baseline covariates would be imputed with the local authority specific mean prior to model fitting. The odds ratio for allocation would be reported, together with two-sided 95% profile penalised likelihood confidence intervals and p-values.

Listening, attention and understanding

The old version of the EYFSP has two separate ELGs, one for Listening and attention and one for Understanding, whereas the new version has a single ELG for Listening, attention and understanding (Table 3). For participants who complete the old version, a score of 1 (i.e. Expected level of development) would be assigned if the child is meeting expected levels in both the Listening and attention and Understanding ELGs, with a score of 0 (i.e. Emerging) assigned otherwise. This derived binary outcome would be analysed together with the binary responses to the Listening, attention and understanding ELG assigned to participants completing the new version. This outcome would be analysed using a Firth logistic regression model [7] adjusting for randomised treatment group, local authority, baseline BPVS score, age at baseline and a binary covariate for version of the EYFSP completed. Missing values for continuous baseline covariates would be imputed with the local authority specific mean prior to model fitting. The odds ratio for allocation would be reported, together with two-sided 95% profile penalised likelihood confidence intervals and p-values.

Reading and comprehension

The new version of the EYFSP has two separate ELGs relating to reading and comprehension (namely Comprehension and Word reading) whereas the old version has just one ELG (Table 3). For participants who complete the new version, a score of 1 (i.e. Expected level of development) would be assigned if the child is meeting expected levels in both the Comprehension and Word reading, and 0 (i.e. Emerging) otherwise. This derived binary outcome would be analysed together with the binary responses to the Reading ELG assigned to participants completing the old version. This outcome would be analysed using a Firth logistic regression model [7] adjusting for randomised treatment group, local authority, baseline BPVS score, age at baseline and a binary covariate for version of the EYFSP completed. Missing values for continuous baseline covariates would be imputed with the local authority specific mean prior to model fitting. The odds ratio for allocation would be reported, together with two-sided 95% profile penalised likelihood confidence intervals and p-values.

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Appendix A – Sample size and attrition

Table xx: Available outcome measures data. Figures are presented by household (i.e. after pooling of available data from households with multiple participating children).

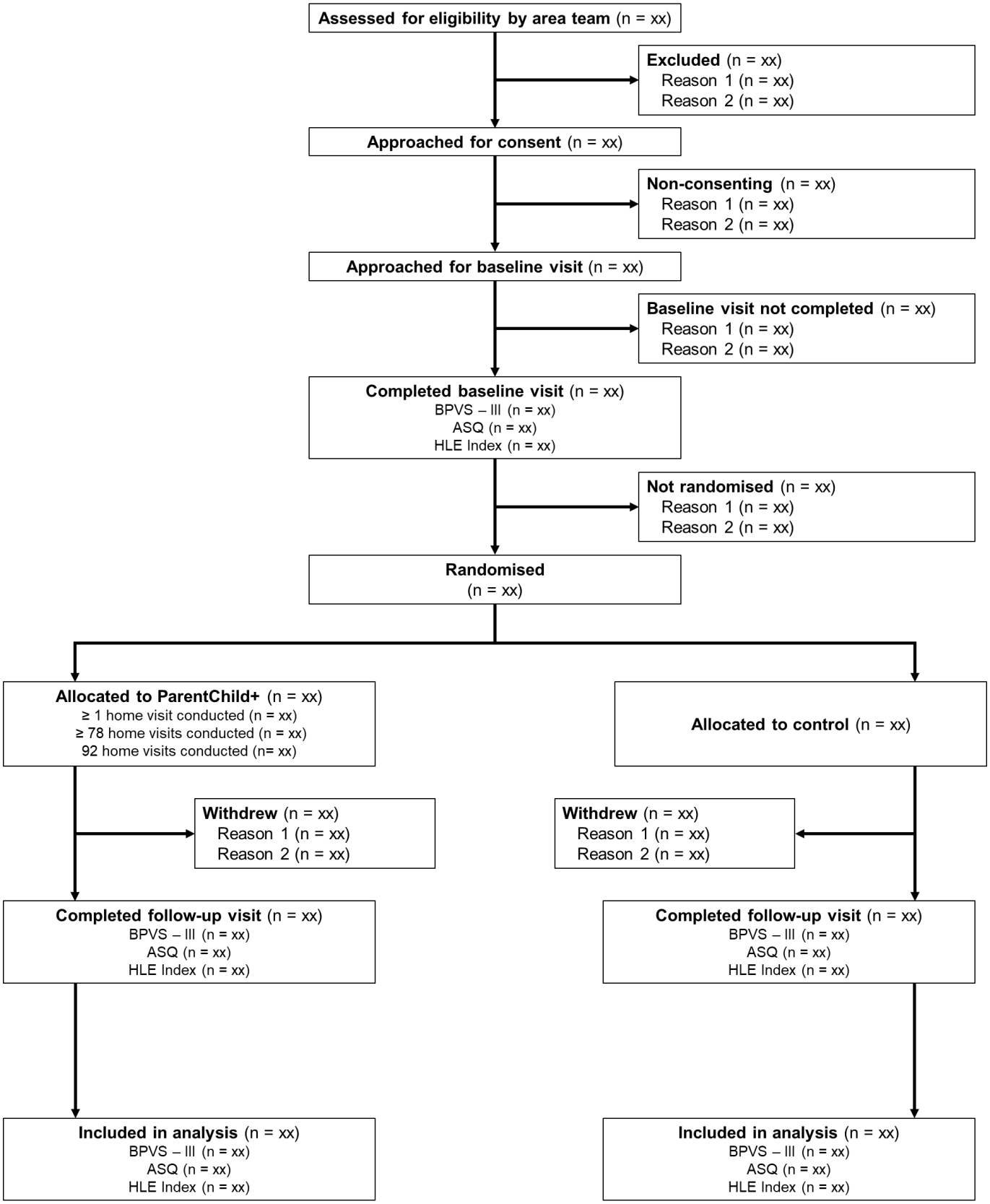
Outcome	Baseline			Follow up		
	Intervention (N = xx)	**Control** (N = xx)	**Total** (N = xx)	**Intervention** (N = xx)	**Control** (N = xx)	**Total** (N = xx)
BPVS-III, N (%)						
ASQ-3 (Communication), N (%)						
ASQ-3 (Personal-Social), N (%)						
ASQ-3 (Fine Motor), N (%)						
HLEI, N (%)						

Table xx: Correlation between baseline and follow up measurements of the outcome measurements, with 95% confidence intervals based on Fisher's z-transformation.

Outcome	**Intervention** (N = xx)	**Control** (N = xx)	**Total** (N = xx)
BPVS-III N ρ (95% CI)			
ASQ-3 (Communication) N ρ (95% CI)			
ASQ-3 (Personal-social) N ρ (95% CI)			
ASQ-3 (Fine motor) N ρ (95% CI)			
HLEI N ρ (95% CI)			

Appendix B – Participant flow diagram

Figure xx: CONSORT flow diagram



Appendix C – Baseline Data Summaries

Table xx: Brief categorical baseline characteristics of participating children (before pooling data from households with multiple participating children).

Child-level (categorical)	Intervention group		Control group	
	n/N (missing)	Count (%)	n/N (missing)	Count (%)
Male				
EAL				
Child in need				
Free nursery place				

Table xx: Brief continuous baseline characteristics of participating children (before pooling data from households with multiple participating children) and “effect size” in terms of Hedges g.

Child-level (continuous)	Intervention group		Control group		“Effect size” (Hedges g)
	n/N (missing)	Mean (SD)	n/N (missing)	Mean (SD)	
Age					
BPVS-III					
ASQ-3 Communication					
ASQ-3 Personal-Social					
ASQ-3 Fine Motor					
HLEI					

Table xx: Detailed categorical baseline characteristics of participating children (before pooling data from households with multiple participating children).

Characteristic	Randomised			Included in primary analysis		
	Intervention (N = xx)	**Control** (N = xx)	**Total** (N = xx)	**Intervention** (N = xx)	**Control** (N = xx)	**Total** (N = xx)
Gender, n (%)						
Male						
Female						
Other						
Prefer not to say						
Missing						
EAL, n (%)						
Yes						
No						
Missing						
Child in need, n (%)						
Yes						
No						
Missing						
Free nursery place, n (%)						
Yes						
No						
Missing						
Home language, n (%)						
English						
Urdu						
Bengali						
Punjabi						
German						
Spanish						
Pushto						
Russian						
Polish						
Slovakian						
Other						
Missing						

Table xx: Detailed continuous baseline characteristics of participating children

Characteristic	Randomised			Included in primary analysis		
	Intervention (N = xx)	**Control** (N = xx)	**Total** (N = xx)	**Intervention** (N = xx)	**Control** (N = xx)	**Total** (N = xx)
Age (years)						
N						
Mean (SD)						
Median (Q1, Q3)						
Min, Max						
BPVS-III*						
N						
Mean (SD)						
Median (Q1, Q3)						
Min, Max						
BPVS-III**						
N						
Mean (SD)						
Median (Q1, Q3)						
Min, Max						
ASQ-3 Communication*						
N						
Mean (SD)						
Median (Q1, Q3)						
Min, Max						
ASQ-3 Communication**						
N						

Characteristic	Randomised			Included in primary analysis		
	Intervention (N = xx)	**Control** (N = xx)	**Total** (N = xx)	**Intervention** (N = xx)	**Control** (N = xx)	**Total** (N = xx)
Mean (SD)						
Median (Q1, Q3)						
Min, Max						
ASQ-3 personal-social*						
N						
Mean (SD)						
Median (Q1, Q3)						
Min, Max						
ASQ-3 personal-social**						
N						
Mean (SD)						
Median (Q1, Q3)						
Min, Max						
ASQ-3 fine motor*						
N						
Mean (SD)						
Median (Q1, Q3)						
Min, Max						
ASQ-3 fine motor**						
N						
Mean (SD)						
Median (Q1, Q3)						
Min, Max						
HLEI*						
N						
Mean (SD)						
Median (Q1, Q3)						
Min, Max						
HLEI**						
N						
Mean (SD)						
Median (Q1, Q3)						
Min, Max						

*Un-pooled (i.e. before pooling data from households with multiple participating children).

**Pooled (i.e. after pooling data from households with multiple participating children).

Table xx: Detailed baseline characteristics of participating households/care-givers.

Characteristic	Randomised			Included in primary analysis		
	Intervention (N = xx)	**Control** (N = xx)	**Total** (N = xx)	**Intervention** (N = xx)	**Control** (N = xx)	**Total** (N = xx)
Local authority, n (%)						
Barnsley						
Doncaster						
Rotherham						
Sheffield						
First language, n (%)						
English						
Urdu						
Bengali						
Punjabi						
German						
Spanish						
Pashto						
Russian						
Polish						
Slovakian						
Missing						
Property ownership, n (%)						
Owned						
Rented						

Characteristic	Randomised			Included in primary analysis		
	Intervention (N = xx)	**Control** (N = xx)	**Total** (N = xx)	**Intervention** (N = xx)	**Control** (N = xx)	**Total** (N = xx)
Missing						
Property type, n (%)						
Detached						
Semi-detached						
Terrace						
Flat						
Missing						
Programme children in household, n (%)						
One						
Two						
Missing						
Employment, n (%)						
Employed full-time						
Self-employed						
Employed part-time						
Unemployed						
Long-term sick						
Retired						
Other						
Missing						
Income, n (%)						
On income support						
£0 - £5,000						
£5,001 - £10,000						
£10,001 - £15,000						
£15,001 - £20,000						
£20,001 - £30,000						
£30,000+						
Missing						
Number of adults in household, n (%)						
One						
Two						
Three						
Four						
Five						
Six						
Non-programme children in household, n (%)						
One						
Two						
Three						
Four						
Five						
Six						

Appendix D – Reporting

Table xx: Descriptive summary of outcome measurements at baseline and follow up. Figures are by household (i.e. after pooling of available data from households with multiple participating children).

Outcome	Baseline			Follow up		
	Intervention (N = xx)	**Control** (N = xx)	**Total** (N = xx)	**Intervention** (N = xx)	**Control** (N = xx)	**Total** (N = xx)
BPVS-III N Mean (SD) Median (Q1, Q3) Min, Max						
ASQ-3 (Communication) N Mean (SD) Median (Q1, Q3) Min, Max						
ASQ-3 (Personal-social) N Mean (SD) Median (Q1, Q3) Min, Max						
ASQ-3 (Fine motor) N Mean (SD) Median (Q1, Q3) Min, Max						
HLEI N Mean (SD) Median (Q1, Q3) Min, Max						

Table xx: Between group comparisons adjusting for local authority and pre-specified prognostic covariates. Figures are presented by household (i.e. after pooling of available data from households with multiple participating children).

Outcome	**Intervention** Mean (SD)	**Control** Mean (SD)	**Adjusted Difference** δ (95% CI)	**p-value**	**Effect size*** g (95% CI)
BPVS-III					
ASQ-3 (Communication)					
ASQ-3 (Personal-social)					
ASQ-3 (Fine motor)					
HLEI					

*Hedges' g, 95% bootstrap CI (2500 replicates).

Table xx: Calculation of effect size point estimate for between group contrasts adjusted for local authority and pre-specified prognostic covariates.

Outcome	**Adjusted difference**	**Intervention**		**Control**		**Pooled variance***	**Effect size**
		N (missing)	**Variance***	**N (missing)**	**Variance***		
BPVS-III							
ASQ-3 (Communication)							
ASQ-3 (Personal-social)							
ASQ-3 (Fine motor)							
HLEI							

*Of outcome measurements

Appendix E – Home Learning Environment Index

Question	Response	Score
Q1 Does anyone at home ever read to your child?	1 – Yes 2 - No	 0
1.a *How often does someone read to your child?*	1 – Occasionally or less than once a week 2 – Once a week 3 – Several times a week 4 – Once a day 5 – More than once a day	1 2 4 6 7
Q2 Does anyone at home ever take your child to the library?	1 – Yes 2 - No	 0
2.a How often does someone at home take your child to the library?	1 – One special occasions 2 – once a month 3 – Once a fortnight 4 – Or, once a week	3 5 6 7
Q3 Does anyone at home ever teach your child a sport, dance, or physical activities?	1 – Yes 2 - No	 0
3.a How often does someone at home teach your child a sport, dance, or physical activities?	1 – Occasionally, or less than once a week 2 – 1 or 2 days a week 3 – 3 times a week 4 – 4 times a week 5 – 5 times a week 6 – 6 times a week 7 – 7 times a week/constantly	1 2 3 4 5 6 7
Q4 Does your child ever play with letters at home?	1 – Yes 2 - No	 0
4.a How often does your child play with letters at home?	1 – Occasionally, or less than once a week 2 – 1 or 2 days a week 3 – 3 times a week 4 – 4 times a week 5 – 5 times a week 6 – 6 times a week 7 – 7 times a week/constantly	1 2 3 4 5 6 7
Q5 Does anyone at home ever help your child learn the ABC or the alphabet?	1 – Yes 2 - No	 0
5.a How often does someone at home help your child learn the ABC or the alphabet?	1 – Occasionally, or less than once a week 2 – 1 or 2 days a week 3 – 3 times a week 4 – 4 times a week 5 – 5 times a week 6 – 6 times a week 7 – 7 times a week/constantly	1 2 3 4 5 6 7
Q6 Does anyone at home ever teach your child numbers or counting?	1 – Yes 2 - No	 0
6.a How often does someone at home teach your child numbers or counting?	1 – Occasionally, or less than once a week 2 – 1 or 2 days a week 3 – 3 times a week 4 – 4 times a week 5 – 5 times a week 6 – 6 times a week 7 – 7 times a week/constantly	1 2 3 4 5 6 7
Q7 Does anyone at home ever teach your child any songs, poems, or nursery rhymes?	1 – Yes 2 - No	 0
7.a How often does someone at home teach your child any songs, poems, or nursery rhymes?	1 – Occasionally, or less than once a week 2 – 1 or 2 days a week 3 – 3 times a week 4 – 4 times a week 5 – 5 times a week 6 – 6 times a week 7 – 7 times a week/constantly	1 2 3 4 5 6 7
Q8 Does you child ever paint or draw at home?	1 – Yes 2 - No	 0
8.a How often does your child paint or draw at home?	1 – Occasionally, or less than once a week 2 – 1 or 2 days a week 3 – 3 times a week 4 – 4 times a week 5 – 5 times a week 6 – 6 times a week 7 – 7 times a week/constantly	1 2 3 4 5 6 7