# Efficacy Trial of the ParentChild+ programme

Evaluation Report

September 2022

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# About the evaluator

The project was independently evaluated by a team from the University of York and Leeds Beckett University: Louise Tracey (York), Carole Torgerson (York, formerly at Durham University), Erin Dysart (York) Caroline Fairhurst (York), Nicole Gridley (Leeds Beckett) and Charlie Welch (York).

The lead evaluators were Louise Tracey and Carole Torgerson.

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# Acknowledgements

# Executive summary

## The project

ParentChild+ is an intensive 15-month home visiting programme primarily for low-income families with a 2–3-year-old child. The programme was originally developed in the US and is delivered in the UK by the charitable organisation Family Lives. During the twice weekly (30-minute) visits, trained home visitors model reading, conversation and play activities to parents using books and educational toys that are gifted to the family as part of the programme. These activities seek to increase parent–child interaction, promote positive behaviours and encourage early literacy skills with the overall aim to enhance the home learning environment (HLE) and foster academic success.

This project was an efficacy randomised controlled trial (RCT); 283 families took part with 141 families receiving the intervention and 142 continuing with 'usual care' acting as a comparison group for the research. The implementation and process evaluation (IPE) used a descriptive design with data collection methods consisting of observations, interviews, focus groups and surveys. The trial started in July 2019 and completed with endline assessments finishing in September 2021. Families were able to take part in the trial if they lived in Barnsley, Doncaster, Sheffield, or Rotherham, were eligible for, but not taking up, Free Early Learning (FEL) places for 2-year-olds or lived in targeted areas within these local authorities (LAs). There were 129 children (46%) eligible for FEL in the sample of participating families.

The trial and programme delivery were paused for 4-months from the end of March 2020 to the end of July 2020, due to the coronavirus pandemic and first national lockdown. Whilst programme delivery was paused, contact between families and home visitors was maintained through weekly phone calls. Once delivery resumed it did so in a Covid-impacted environment with further local and national lockdowns, leading to a third of home visits being required to be provided online to facilitate social distancing. This was the first-time remote delivery for ParentChild+ had been provided and researched. The project was co-funded with the financial support of the Department for Education and SHINE.

## Key conclusions

Table 1: Key conclusions

| | |
|---|---|
| 1. | Children in families who received ParentChild+ made the equivalent of 2 fewer months' progress in receptive vocabulary development, on average, compared to children in families who did not receive the programme. This result has a moderate to high security rating. |
| 2. | Secondary outcomes gave inconsistent results: ParentChild+ had a low to moderate negative impact on children's communication, fine motor skills and personal-social behaviour in families who received the programme compared to those who did not, as reported by parents who completed the Ages & Stages Questionnaire (ASQ). There is some uncertainty in this finding given many children scored highly on the assessment (ceiling effects). In contrast, parents' ratings of children's home learning environment suggested the programme had a significant moderate impact on this outcome for those who received ParentChild+ than those who did not receive the programme. |
| 3. | Exploratory analysis suggested children in families who received ParentChild+, and were eligible for FEL places, made the equivalent of 3 fewer months' progress in receptive vocabulary development, compared to children in similar families who did not receive the programme. This result has lower security given the smaller number of children in the analysis. |
| 4. | The majority of parents were positive about the programme, spoke highly of the home visitors and reported that they 'strongly agreed' participation had increased their knowledge and confidence with supporting their child's learning and behaviour, and they could apply what they had learnt with their other children. |
| 5. | Semi-structured video observations of parent–child interactions with 28 families before and after programme delivery found no noticeable differences between families who received the programme compared to those who did not, except on two of the 13 categories which highlighted control families exhibited more parent acknowledgements and child spontaneous vocalisations. |

## EEF security rating

These findings have a moderate to high security rating. This was an efficacy trial, which tested whether the intervention worked under developer-led conditions with 283 families. Although the number of children where receptive language assessments were not completed at the end of the research was fairly high (23% of children who were randomised), sufficient analysis is presented to suggest that different approaches to missing data result in no important differences in the conclusions.

## Additional findings

Children in families who received ParentChild+ made, on average, 2 fewer months' progress in receptive language development compared to children in families who did not receive the programme. This is our best estimate of impact,

which has a moderate to high security rating. As with any study, there is always some uncertainty around the result: the possible impacts of this programme range from highly negative effects of five months' less progress to small positive effects of up to one month's additional progress. Similarly, results from analysis of Ages & Stages Questionnaire (ASQ) data reported by parents for the domains of communication, fine motor skills and personal–social behaviour suggest low to moderate negative impacts of the programme. These secondary analyses have lower security than the headline finding given the number of children who scored at the higher end of the assessment (ceiling effects). In other words, the ASQ when used here could not distinguish well between groups of children because so many scored the maximum values on the measurement.

Four additional exploratory analyses looked at subgroups within the main sample and their receptive vocabulary outcomes following programme delivery. Families who received ParentChild+ and were eligible for FEL places (89 children or 40% of the cohort with endline data), made the equivalent of 3 fewer months' progress in receptive vocabulary development, compared to children in similar families who did not receive the programme. This result has lower security compared to the headline finding, given the smaller number of children included in the analysis. Analysis suggested there was some evidence that the intervention was less detrimental to receptive vocabulary for children who had better baseline communication skills. Finally, there was some weak evidence, given the very small number of children, that the programme was less effective for children learning EAL (18 children) but more effective among children who had a Child in Need (CiN) plan (9 children).

Adherence to the programme was high, even though a proportion of the programme was delivered through the Covid-19 pandemic and its influence was considered the biggest barrier to implementation. Of the 141 families allocated to receive the intervention, 45 (32%) received at least all 92 programme visits, 88 (62%) received at least 78 programme visits (85% of the programme) and 10 (7%) did not receive any. However, sensitivity analysis suggests that additional home visits resulted in children having slightly worse receptive vocabulary outcomes compared to those who had fewer visits. Just over a third of visits were delivered online rather than face-to-face, to support social distancing. Online visits are not typical for the ParentChild+ programme and had not been implemented before the pandemic. It is hard to know the extent to which the delivery mode of the visits influenced the study's findings. Additionally, 38 out of 224 families completed endline assessment online rather than face-to-face. However, there were equal numbers in the treatment and control group who experienced the online assessments, and sensitivity analysis suggests mode of assessment did not impact the headline findings for the trial.

The evaluation explored whether parents' behaviour changed following take up of the programme. On the one hand parent report suggested the quality of the HLE significantly improved, with the treatment group reporting an average score of 31, compared to parents who did not receive the programme whose average score was 27.4. Analysis of these scores suggested the programme had a moderate impact on the HLE. However, semi-structured video observations with 28 families before and after programme delivery found no noticeable differences between families who received the programme compared to those who did not, except on two of the 13 categories which highlighted control families exhibited more parent acknowledgements and child spontaneous vocalisations.

The majority of parents were positive about the programme, spoke highly of the home visitors and reported that they 'strongly agreed' participation had increased their knowledge and confidence with supporting their child's learning and behaviour. Parents particularly enjoyed that the programme facilitated time with their child and building a relationship with their home visitor; in fact, 90% of those who completed the endline survey suggested they 'strongly agreed' they had a good relationship with their home visitor. Parents found it easy to fit the programme into their daily routine with flexibility on the part of the parent and home visitor a key facilitator of delivery.

## Cost

The average cost of ParentChild+, if delivered within a local area for three years, and the cost averaged over three years is £3146 per family. The cost rating is therefore very high. This finding was calculated by taking the average cost per family of the programme as delivered in this trial for year 1 (£3579), and the average cost of the programme in year 2 (£2930) and year 3 (£2930) for delivery implemented under 'normal' non-pandemic circumstances.

## Impact

Table 2: Summary of impact on primary outcome

| Primary outcome | Effect size (95% confidence interval) | Estimated months' progress | EEF security rating | No. of pupils | p-value | EEF cost rating |
|---|---|---|---|---|---|---|
| Receptive vocabulary | −0.14 (−0.36 to 0.09) | −2 | 🔒🔒🔒 | 223 | 0.21 | £££££ |
| Receptive vocabulary (FEL) | −0.22 (−0.56 to 0.11) | −3 | − | 89 | 0.20 | |

# Introduction

## Background

There is evidence of the effectiveness of the ParentChild+ programme from the United States (US); Studies conducted in the US show positive effects on cognitive outcomes for pre-school children from disadvantaged backgrounds. The Early Intervention Foundation identifies three RCTs as providing rigorous evidence for the programme (https://guidebook.eif.org.uk/programme/parentchildplus#about-the-evidence). 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 = 0.32) and resulted in higher language scores (ES = 0.37). It also improved some aspects of self-regulation, and children were less likely to display problem behaviours. In addition, an RCT by Madden, O'Hara & Levenstein (1984) found improved cognitive outcomes for children aged 21 to 33 months old. Other, quasi-experimental studies have indicated that the programme improved children's school readiness (Mann et al., 2009; Manz et al., 2016). At the time this evaluation was set up, the programme was being piloted in the UK; however, prior to this study it had not previously been evaluated using an RCT design in this country. The overarching aim of this trial was to assess the efficacy 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 over time (Sylva et al., 2012; Asmussen et al., 2016). Pre-school skills differences between advantaged and disadvantaged children have been found to be predominantly in language and communication skills (Hart & Risley, 1995; Phillips & Lonigan, 2009; Marmot, 2010). Lee (2011) also found that vocabulary size at age two significantly predicted subsequent language and literacy development up to the fifth grade (aged 9–10 years). It has been well established that the HLE, in comparison to other environments, is particularly important for child development including cognitive ability in general, and language and literacy development in particular (Sylva et al., 2004; Tarelli & Stubbe, 2010; Niklas & Schneider, 2013).

The introduction of the provision of government-funded childcare to disadvantaged 2-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 the Reception year (aged 4–5), as measured by the Early Years Foundation Stage (EYFS) profile (Teager & McBride, 2018). Yet, overall, national take-up of this free provision was approximately 72% in 2018 and 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 LAs 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 was able to explore take-up in one LA above the national average in take-up rate, two at the national average rate and one considerably below the national average rate. These LAs were selected for participation in the study as a result of collaboration between the programme delivery team (DT: Family Lives) and South Yorkshire Futures[1] aiming to reduce social inequality in the region.

When the current evaluation was funded, ParentChild+ did not yet have impact data in the UK; however, other, less-intensive programmes aimed at working with parents to improve the HLE were known to have some (limited) evidence of effectiveness. For example, Wood et al. (2015) found that a six-week, one and a half hours a week intervention with parents and children (Early Words Together) improved children's spoken language (as measured by the Pearson Preschool Language Scale), with particular improvements noted in girls' attainment (although this study was a pre-post design with no control group). The intensity of visits and provision of resources involved in the programme suggested, therefore, that, in theory, ParentChild+ had the potential to demonstrate effectiveness in improving the HLE and consequently children's early language and literacy development in a UK-based sample. However, programmes such as this face challenges in terms of 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 can be overcome. By improving child cognitive development, particularly language and literacy skills, prior to formal school entry, the potential for long-term gains in

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[1] South Yorkshire futures are a social mobility partnership, led by Sheffield Hallam University, who aim to improve education for young people in South Yorkshire.

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 an RCT design, is particularly important in terms of stakeholder decision-making regarding implementation and potentially wider rollout.

This is a two-arm efficacy RCT with random allocation at family level to evaluate this intervention against usual care, alongside an impact evaluation and an embedded IPE. At the time the evaluation was funded, the ParentChild+ programme was being piloted in the UK and, therefore, it seemed reasonable to move to the next stage of evaluation using an efficacy trial design.

## Intervention

ParentChild+ (previously known as the Parent–Child Home Programme), is an intensive home visiting programme developed in the US in the 1960s. The programme aims to: increase parent–child interaction; promote positive behaviours; encourage language and other emerging literacy skills; enhance the HLE; 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, paid 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 3 outlines the aspects of the template for description and replication (TIDieR) framework, which gives details of the intervention, including how, when, where and by whom the intervention was delivered.

Due to the delivery of the intervention taking place during the coronavirus pandemic (Covid-19) there was a four-month pause of the delivery of the intervention from the end of March 2020 to the end of July 2020. During this pause, home visitors remained in contact via phone, email or video call with intervention families who wanted their support. However, the level of this support was variable and not as intended by the programme. A survey was developed and distributed to understand what this support looked like to facilitate the IPE (see below). Newsletters were sent to families in both the intervention and control groups to keep them informed about the intervention delivery and the progress of the evaluation throughout the lockdown. Disruption to delivery also continued beyond this four-month pause (see below).

**Changes to the delivery of the intervention due to the Covid-19 pandemic**

Changes were made to the delivery of the intervention for all families during the pandemic and following lockdown restrictions[2] (easing of social distancing): some participants continued to receive the intervention on a face-to-face basis and some participants received the intervention through virtual means such as video calls (and a small number ceased receiving the programme altogether). Due to the nature of local lockdowns, all families received a mixture of both face-to-face and virtual visits. During national or local lockdowns all visits were completed online (with the exception of the four-month pause where the intervention stopped). At other times, families and home visitors used their own discretion to determine whether visits were done online or face-to-face, and this remained in place for the remainder of the programme. Where families opted for online visits, toys and books were dropped off in advance of the session.

Table 3: TIDieR framework

| 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, free childcare places, and their 2–3-year-old children. Recipients also include those who are not entitled to free childcare places but do live within Lower Super Output Areas. |
| **What**: Physical or informational materials used in the intervention | Manualised programme. Educational books and toys provided weekly and used for modelling good practice. |

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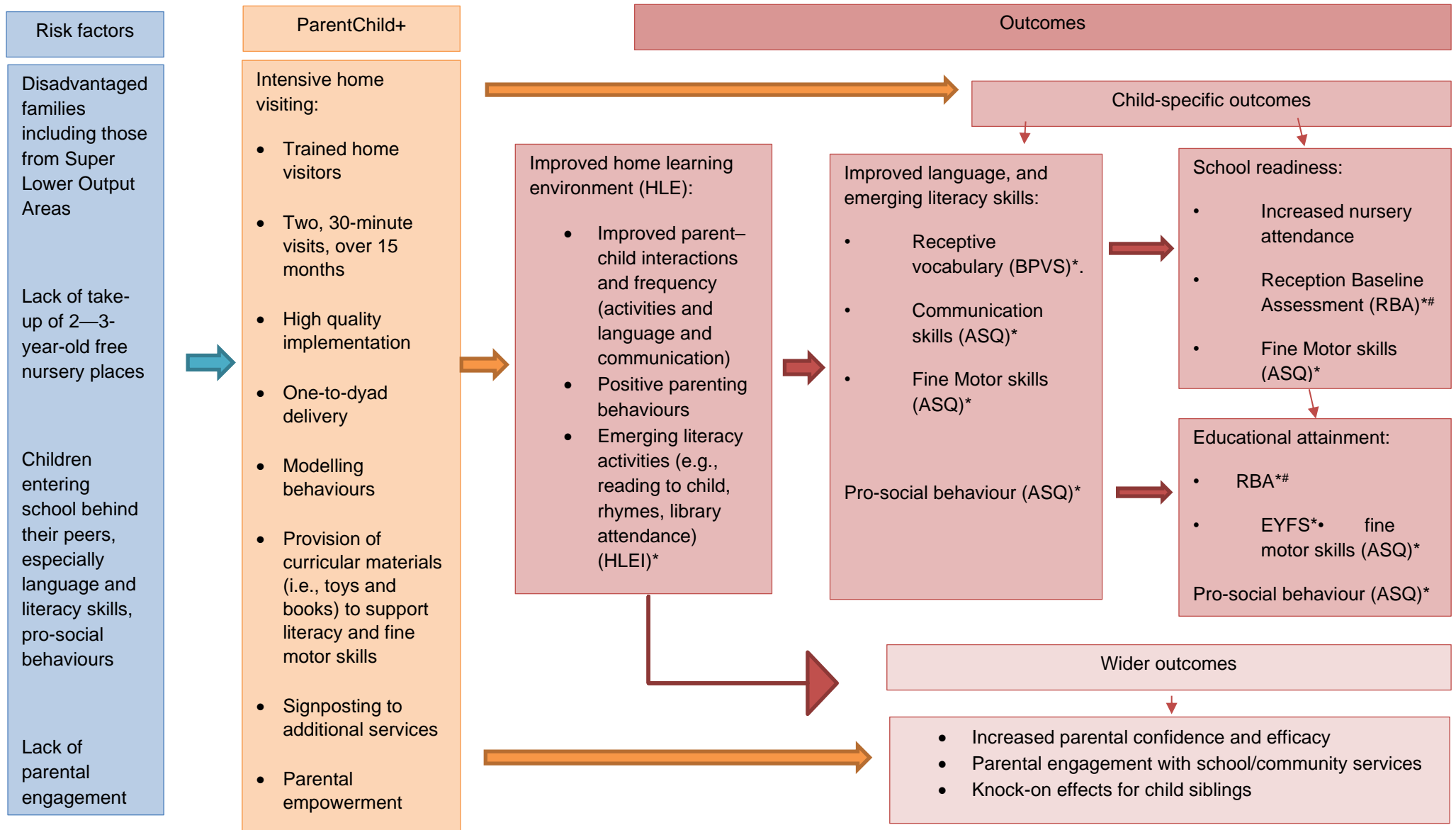[2] National lockdowns occurred: (1) March-June 2020; (2) November 2020; and (3) January-March 2021. There were lockdown restrictions in-between these three periods with a tiered system also operating resulting in local lockdowns. From March to July 2021 England went through a phased exit from lockdown. For further details see: https://researchbriefings.files.parliament.uk/documents/CBP-9068/CBP-9068.pdf

| | |
|---|---|
| **What**: Procedures, activities and/or processes used in the intervention | Home visitors modelling HLE activities in the home. In the first weekly visit, a new resource (i.e., a toy or book) is gifted and use of it modelled by the home visitor. This was to then be reviewed in the second weekly visit. Other activities during the visit to be determined by home visitor according to perceived individual needs of the family and interests of the child. |
| **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[3] |
| **Tailoring**: Adaptation of the intervention | <ul><li>Adaptations according to home language.</li><li>If safeguarding issues are apparent, then two home visitors attend.</li><li>If twins, then intervention delivered collectively for one hour as opposed to 30 minutes.</li><li>Delivery can become community-based (i.e., not in the home) if safeguarding issues for either the child or the researcher.</li><li>If child carer changes (e.g., due to foster care) the programme follows the child and accepts a change in primary carer.</li><li>If a parent is missing for one week, the programme can be delivered to another adult present in the household.<br>Where delivery can no longer be done on a face-to-face basis in the home, it will be done virtually (as a result of Covid-19).</li></ul> |
| **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. |

A logic model for the programme was co-developed by the delivery and evaluation teams (ETs). Figure 1 presents that logic model, highlighting the outcomes measured by the impact evaluation. In the logic model, four risk factors are identified to target families for the intervention: namely disadvantaged families, in particular; disadvantaged families with low uptake of 2–3-year-old nursery places; children likely to enter school behind in language and literacy skills and pro-social behaviour; and/or low take-up of wider LA provision. The ParentChild+ programme is an intensive home-visiting programme with a variety of components, including training of the visitors to implement the programme, provision of regular visits with curricular materials (toys and books) to support literacy and fine motor skills, and modelling of skills to parents/families, including playing with the toys and books and language interactions. High quality implementation of ParentChild+ is hypothesised to impact on receptive vocabulary (primary impact outcome), communication skills and fine motor skills, mediated through an improved HLE. ParentChild+ is also hypothesised to increase parental confidence and efficacy and greater engagement with local community and school services. The IPE explored the contextual and causal factors surrounding the outcomes measured by the impact evaluation and the wider parental and HLE outcomes expected as a result of the programme

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[3] Excluding the four-month pause in delivery due to Covid-19.

Figure 1 – ParentChild+ Evaluation Logic Model

| Risk factors | ParentChild+ | Outcomes |
|---|---|---|

**Risk factors**

Disadvantaged families including those from Super Lower Output Areas

Lack of take-up of 2—3-year-old free nursery places

Children entering school behind their peers, especially language and literacy skills, pro-social behaviours

Lack of parental engagement

**ParentChild+**

Intensive home visiting:

- Trained home visitors
- Two, 30-minute visits, over 15 months
- High quality implementation
- One-to-dyad delivery
- Modelling behaviours
- Provision of curricular materials (i.e., toys and books) to support literacy and fine motor skills
- Signposting to additional services
- Parental empowerment

**Outcomes**

**Child-specific outcomes**

Improved home learning environment (HLE):

- Improved parent–child interactions and frequency (activities and language and communication)
- Positive parenting behaviours
- Emerging literacy activities (e.g., reading to child, rhymes, library attendance) (HLEI)*

Improved language, and emerging literacy skills:

- Receptive vocabulary (BPVS)*.
- Communication skills (ASQ)*
- Fine Motor skills (ASQ)*

Pro-social behaviour (ASQ)*

School readiness:

- Increased nursery attendance
- Reception Baseline Assessment (RBA)*#
- Fine Motor skills (ASQ)*

Educational attainment:

- RBA*#
- EYFS*• fine motor skills (ASQ)*

Pro-social behaviour (ASQ)*

**Wider outcomes**

- Increased parental confidence and efficacy
- Parental engagement with school/community services
- Knock-on effects for child siblings

*Impact evaluation outcome measures

# Not included in this evaluation

# Evaluation objectives

**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 ASQ?
- What is the impact of the ParentChild+ programme on the HLE as measured by the HLE 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 EYFS profile)? This research question is not included in this report, due to the timescale of the study.

**Implementation and process evaluation (IPE) research questions**

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

1. To what extent was the programme implemented as planned?

   1.1 What training was received and were there any implementer factors in programme delivery?

   1.2 What was the number and length of sessions delivered?

   1.3 Was there any variation in implementation and, if so, why?

2. What is the desirability, acceptability and need for the programme within local communities?

   2.1 Who was the programme delivered to – was this the target population?

   2.2 Were there any parental factors resulting in barriers to, or facilitators of, programme delivery?

   2.3 Were there any programme factors resulting in barriers to, and facilitators of, programme delivery (e.g., intensity of programme, home visitor–parent relationship)?

   2.4 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 LAs not being blind to condition)?

3. To what extent did the ParentChild+ programme impact on the HLE, particularly on parent–child verbal interactions? What were the wider outcomes of the programme?

4. What was the impact in terms of parental self-reported confidence and efficacy?

   4.1 To what extent did participation result in parents taking up the free nursery offer and encourage attendance at pre-school settings by participating children?

   4.2 To what extent did the programme result in increased parent (and child) engagement with wider community services?

   4.3 Were there any diffusion effects of programme delivery (e.g., on other family members including child's siblings and other adults in the household)?

5. How did parents feel the continued contact during the Covid-19 lockdown supported them and what support was offered?[4]

The ParentChild+ Protocol and SAP for the study can be found by clicking on the links or on the EEF website https://educationendowmentfoundation.org.uk/projects-and-evaluation/projects/parentchild

## Ethics and trial registration

Ethical approval for this study was obtained through the Education Ethics Committees at the University of York, Durham University and Leeds Beckett University. We also complied with any ethical approval processes required by the participating LAs.

All outputs (including the statistical database, reports and publications) were anonymised. No participant or setting is identifiable in the report. The statistical database holds only non-identifiable data.

5% of the assessments at baseline were randomly selected and double-checked, to assess reliability and consistency. All scores were inputted twice to ensure accuracy. Confidentiality was maintained and no one outside of the evaluation team had access to the database, which is held securely on the University of York and Leeds Beckett University servers. Full consent was obtained from parent/carer participants, including for depositing data to archive at the end of the trial and the possibility of linking to the national pupil database (NPD) to conduct follow-up analysis. Given that visits by data collectors took place in the home, we had in place standard operating procedures (SOPs) to ensure researcher safeguarding.

The trial is registered with the ISTRCN: ISRCTN96216897 (https://doi.org/10.1186/ISRCTN96216897).

Agreement to participate in the trial was obtained using the following strategy: recruitment was conducted by the delivery team (DT) and targeted disadvantaged families with children aged 2–3 years who were eligible for, but not taking up, the two-year-old free nursery place offer. Recruitment of disadvantaged families also included families who were not entitled to free childcare places but did live in Lower Layer Super Output Areas (LLSOAs).[5] Parents/carers were identified through collaboration with LAs. The DT coordinators worked with LA 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.

All the relevant documentation is included in Appendix 2 (e.g., memorandum of understanding, information sheets, withdrawal forms, privacy notices).

## Data protection

Data were handled in accordance with the general data protection regulations (GDPR). Personal data were processed under Article 6 Section (e) of the GDPR ('Tasks carried out in the public interest') as the research was conducted to support education provision in the UK (and Special Category data under Article 9(2)(j)). A Data Protection Impact Assessment (DPIA) was conducted (approved by the Data Protection Officer, University of York, 24/04/2019) and data sharing agreements were put in place with the University of York, Family Lives and the participating LAs.

## Project teams

**The evaluation team (ET)**

The ET was responsible for the design, conduct and reporting of the evaluation, including: writing the protocol and SAP; registering the trial; writing consents, data sharing agreements and privacy notices and gaining ethical approval; all data collection, analysis and writing up of the final report.

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[4] This research question was added in response to Covid-19.
[5] Layer Super Output Areas typically include about 650 households. 'Lower' Layer Super Output Area (LLSOA) refers to an area where, at the aggregation level, there were high levels of disadvantage, although a family living within a LLSOA is not necessarily itself disadvantaged.

Dr Louise Tracey (Co-Principal Investigator, University of York). Louise was responsible for the day-to-day management and coordination of the trial, working closely with the programme developers and supervising the trial coordinator. She led on the protocol and the report writing and contributed to the IPE.

Professor Carole Torgerson (Co-Principal Investigator, University of York). Carole worked closely with Louise to design and oversee the conduct of the trial. She provided overall quality assurance and expertise in mitigating any potential biases and their risks, having had experience in dealing with both in past evaluations. She contributed to the report writing (both impact evaluation and the IPE).

Dr Erin Dysart (trial coordinator, University of York). Erin undertook the day-to-day running of the project, including managing data collection, liaising with Family Lives, LAs and individual participants, and processing data in line with data protection regulations and study protocols. She also assisted in conducting aspects of the IPE and in writing up the report.

Caroline Fairhurst (Co-Investigator and senior statistician, York Trials Unit, University of York). Caroline supervised all the work of the trial statistician, including replicating the primary analyses for quality assurance purposes, and reviewed the final report.

Dr Nicole Gridley (Co-Investigator, Leeds Beckett University). Nicole devised the home observation measure, previously used for the Early Words Together (Nuffield Foundation Project: 43028) study with a similar age group. She conducted the training in using the measure, trained the trial coordinator to code the data and undertook reliability checks. She also contributed to the report writing.

Charlie Welch (trial statistician, York Trials Unit, University of York). Charlie undertook the randomisation, wrote the statistical analysis plan (SAP), conducted all the statistical analyses, and contributed to the report writing. Additionally, Charlie was responsible for uploading the trial data to the EEF archive following the trial.

Additional support was provided at various times of the study by Sarah Compton, Ciara Robinson and Caity Fox-Smith.

**The delivery team (DT)**

The DT was responsible for liaising with LAs to identify potential study participants, recruiting participants, delivering the programme and liaising with the ET in order to ensure the smooth-running of the evaluation and associated data collection activities.

Pamela Park (Deputy CEO, Family Lives). Pamela had overall responsibility for the delivery of the contract with the EEF.

Caroline Fanshawe (Senior Area Manager and Head of Local Services, Family Lives). Caroline oversaw the operational delivery of the ParentChild+ programme and worked closely with the ET to plan and manage the approach, schedule and resourcing. She liaised with the LAs and South Yorkshire Futures and worked with the team leaders Tina Cranshaw (March 2019 to September 2020) and Amy Wilson (from September 2020) to recruit, train and manage the staff DT.

Tina Cranshaw and Amy Wilson (Team Leaders, Family Lives and ParentChild+ across South Yorkshire). Tina and Amy managed the team of three coordinators and twelve home visitors who recruited families and conducted the home visits in order to deliver the ParentChild+ programme.

# Methods

## Trial design

This was a two-armed efficacy RCT with random allocation at family level to evaluate the ParentChild+ intervention against usual care, with an embedded IPE. A summary of the trial design can be found in Table 4.

Table 4: Trial design

| Trial type and number of arms | | Two-armed efficacy trial. |
|---|---|---|
| Unit of randomisation | | Family level |
| Stratification variables | | Local authority |
| **Primary outcome** | **Variable** | Receptive vocabulary |
| | **Measure (instrument, scale)** | British Picture Vocabulary Scale (BPVS-III) (0 – 168) |
| **Secondary outcome(s)** | **Variable(s)** | Communication skills |
| | **Measure(s) (instrument, scale)** | Communication subscale of the Ages & Stages Questionnaire (ASQ) (0–60) |
| | **Variable(s)** | Personal–social skills |
| | **Measure(s) (instrument, scale)** | Personal–social skills subscale of the ASQ (0–60) |
| | **Variable(s)** | Fine motor skills |
| | **Measure(s) (instrument, scale)** | Fine motor skills subscale of the ASQ (0–60) |
| | **Variable(s)** | Home learning environment (HLE) |
| | **Measure(s) (instrument, scale)** | HLE Index (0–56) |

## Participant selection

Recruitment was conducted by the delivery team (DT). Given that recruitment was to a RCT as opposed to the programme *per se*, the evaluation team (ET) worked closely with the DT to ensure that participants were clear about involvement in the study (to reduce the potential for later attrition). Recruitment targeted disadvantaged families with children aged 2–3 years who were eligible for, but not taking up, the 2-year-old free nursery place offer. Recruitment of disadvantaged families also included families who were not entitled to free childcare places but did live in Lower Layer Super Output Areas (LLSOA) in the lowest 20% of the population, based on deprivation related to: income, employment, education skills and training, health and disability, crime, barriers to housing and services and living environment. Parents/carers were identified through collaboration with LAs. The DT coordinators worked with LA 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 local team staff to promote and generate referrals to the study.

A minimum threshold for spoken English language fluency was applied as an inclusion criterion as this could potentially impact on the 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 have been available).

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

Children experiencing language delay were included, providing that they met the other eligibility criteria (eligible for, but not taking up, the two-year-old free nursery place offer or living in a LLSOA). Children were not excluded due to having special needs if it was felt that the family could benefit from inclusion, and providing the other criteria were met.

Where LAs chose to use referral routes into the programme they were requested to prioritise disadvantaged families who were eligible for, but not taking up, free childcare places.

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

Eligible families were classed as recruited when they had:

1.  signed a consent form;
2.  agreed to participate in the programme, if offered;
3.  completed the pre-test measures; and
4.  met the minimum English language threshold (as described above).

We ensured that one parent/carer or a close family member who regularly cared for the programme child was identified to complete the programme and the measures at pre- and post-test. This was the person completing the consent form if they were the main parent/carer. However, we monitored (through the DT) the extent to which both parents and/or close family members were involved in the programme and, if delivery was extended to both parents or other close family members, the ET collected IPE data from both parents or close family members where applicable. In instances where a close family member was to complete the programme, consent was gained by the main parent/carer.

**Incentives for participating parents**

We offered a £10 High Street voucher in exchange for participation at the pre-test stage of data collection to all participating parents or close family members in the study. During the post-test stage intervention families were offered a £10 High Street voucher while control families were offered a £20 High Street voucher for completion of post-test measures. The vouchers were given to those parents/carers or close family members who were directly involved in the programme. We feel that this was justified by the additional burden of the parent self-completion measures and the additional £10 to the control group was justified as they had not received the intervention. In addition, we offered 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 IPE below). As a further incentive, three toys carefully selected by the DT were provided to the control group at the midpoint of trial participation; this was coordinated by the ET. An incentive (£5 voucher) was also provided by the ET to families who informed the team of a change of address, to enable families to be tracked during the progress of the trial. To encourage participation in the parent interviews, parents opting to complete the interview were entered into a £50 voucher draw.

# Impact evaluation

**Outcome measures**

*Primary outcome*

The primary child outcome was the **British Picture Vocabulary Scale (BPVS-III; Dunn, Dunn and NfER, 2009)** administered one-to-one by independent assessors blind to group allocation, 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 other US evaluations of ParentChild+ (ParentChild+, undated). 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 assessor 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 (EAL). It is also easy to administer and takes a relatively short time to complete, enabling children to remain focused during the assessment period. The BPVS-III has proven to be highly correlated with later literacy acquisition (Dunn, Dunn & NfER, 2009). It is standardised for children aged 3–16 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 (Dunn et al., 1997). Consequently, we expected it to be suitable to be administered to two-year-olds, but we conducted a pilot of the BPVS-III prior to its use to confirm its suitability for this study. The pilot took place with 10 children aged between 18 months and three years, recruited from two local playgroups in order to confirm that there was no floor effect. We aimed to have a mixture of children for whom English is an additional language (EAL) and children who are eligible for the two-year-old free nursery places. In the event, only one child was EAL and asking about eligibility for the two-year-old free nursery places was deemed inappropriate. The measure was regarded as suitable because (1) all children gave at least one response (and raw scores were planned to be used); (2) there was variation in response; and (3) no floor effects were detected. The BPVS-III formed the primary pre-test/post-test and was administered by data collectors from the University of York prior to randomisation and following intervention 18-months later. Data collectors were recruited and trained by the University of York ET. They all had prior experience of working with young children and either held, or were working towards, a degree or MSc in psychology.

*Secondary outcomes*

**Ages & Stages Questionnaire®, Third edition (ASQ®-3; Squires & Bricker, 2009).** The ASQ has been used in a number of US evaluations of ParentChild+ (Astuto & Allen, 2018a; Astuto & Allen, 2018b). 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 was completed at pre-test and post-test. The ASQ-3 was 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). Fine motor skills are also associated with early handwriting (as measured by the literacy subscale of the EYFS) and considered a part of a rich HLE (e.g., through the encouragement of drawing and painting) (Melhuish, 2010). Consequently, only three of the five subscales were administered to reduce participant burden: communication, personal–social, and fine motor skills (18 items, 6 in each subscale). Data were collected for three subscales of the ASQ-3 with the responses in each scale being used to generate a score between 0 and 60. The ASQ-3 was administered prior to the BPVS-III to allow the data collectors to build rapport with the children. As the ASQ-3 is mainly based on parent feedback, this enabled the data collectors to have some engagement with the children whilst, at the same time, minimising child fatigue.

The HLE was assessed using the **Home Learning Environment (HLE) Index (Melhuish et al., 2001**), at pre-test and post-test. This 14-item self-report measure was adapted to become an 8-item measure to reduce the burden on participants and reduce the overall testing time. The 8-item 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. The responses to the eight items of the HLE Index were combined to give an overall score between 0 and 56, with higher scores being indicative of a more positive HLE.

The ongoing Covid-19 pandemic resulted in some participants being followed up for the primary and secondary outcomes online (via video conferencing software), rather than in person as planned. Due to this, the measures used were transformed for online administration: the BPVS-III was uploaded onto a PowerPoint (with thanks to teams at the University of Manchester and Durham University for sharing this) and a spreadsheet was developed by Louise Elliott and Imogen Fountain (York Trials Unit, University of York) to record the data. Online administration of the BPVS-III meant that parents were needed to facilitate administration and were asked to confirm what number picture the child had pointed to. To reduce bias, the data collectors were asked to advise parents that they were able to see which picture the child had pointed to, but they needed the parent to confirm this. The ASQ®-3 was administered via the data collectors, with the help of the parents, and responses were recorded directly onto a bespoke spreadsheet. While this was a parent-administered measure during pre-test, there was no way of accurately recording the data if this was not partly administered by the data collector. The HLE Index was added to a parent post-test survey, designed to collect data for the IPE on Qualtrics. These data collection methods were piloted by the data collectors with five volunteers who had age-appropriate children to gather feedback. These administration techniques were used for both online and face-to-face post-test data collection. To aid with the online testing methods, the EEF provided additional funding to cover the costs of laptops for data collectors and, where needed, data and/or laptops for families.

To aid completion of parent-report measures (i.e., the HLE Index and the ASQ-3), these were delivered to families by data collectors who provided time for independent completion during their visit at pre-test. At post-test, as described above, the HLE index was sent to the parent with the post-test survey prior to the administration of the BPVS-III and the ASQ-3 was administered via the data collectors. Data collectors were 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-completed although we do have an independently administered primary outcome. However, the evaluation team feel that this still provides valuable results, given that previous studies have shown that parents can be reliable sources in reporting their child's abilities (Bennett, 2017).

## Sample size

Sample size calculations were conducted using Stata v15.0. Although the unit of randomisation was family/household, in the vast majority of families there was only one eligible child. Therefore, the sample size was conducted as for an individually randomised trial. Multiple eligible children within a household were allowed to take part, and in these cases we used the mean of the available scores obtained within the household for statistical analyses. The DT estimated that they would have capacity to support 160 families in the intervention (40 in each of four geographical regions including those from LLSOAs). Using equal randomisation, we planned to recruit and randomise 320 families (160 families in each condition to make full use of the DT ability to deliver the intervention). 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 at analysis) gives a minimum detectable effect size (MDES) of 0.25 for 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.

The planned recruitment target was not met; a total of 283 families were randomised (141 intervention, 142 control). Under the same assumptions about attrition and correlation between repeated measurements as used for planning (i.e., 20% attrition and r = 0.7), this sample size gives an MDES of 0.27 for 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 = 0.05) and 20% (i.e., power = 80%), respectively.

**Randomisation**

Once parents consented to participate and all baseline testing had been completed, the households were randomly allocated 1:1 to receive either the intervention or usual care (control). Block randomisation was used with variable block sizes, and was stratified by LA (Barnsley, Doncaster, Sheffield and Rotherham). As rolling recruitment was conducted, the unique participant/household ID numbers were sent to the statistician in possession of the allocation schedule in batches on a regular basis. These ID numbers were then placed in a random order (within each stratum) and matched against the next available allocations. The allocations were then communicated to the participants and the DT was sent a list of those participants allocated to the intervention. At pre-test, data collectors were blind to condition as pre-test took place prior to randomisation. At post-test data collectors were not given any information about what group (control or intervention) parents were in. However, as control participants were given an additional £10 High Street voucher, data collectors would have been aware which group families were in, and thus were not blind to condition.

# Statistical analyses

The statistical analyses followed the most recent EEF guidance, and were described in detail in a SAP. It was originally planned to prepare this within three months of the last participant being randomised. However, due to the pause in intervention delivery, development of the SAP was granted a four-month extension by the EEF. Analyses were conducted in Stata/SE v17.0 for Windows. All analyses were conducted following intention-to-treat (ITT) principles, using two-sided statistical tests at the 5% significance level. This means that participants were analysed according to the group to which they were assigned (either intervention or control), regardless of adherence to that condition (i.e., participants allocated to receive the intervention were analysed within the intervention group even if they did not fully participate in the programme). Where participants withdrew from the intervention, this was not classed as withdrawal from the study and participants were asked to continue participating in the follow-up data collection.

A CONSORT flow-diagram was produced to show the flow of households and participants through the trial. Baseline data were summarised descriptively, both as randomised and as included in the primary analysis, with no formal between-group comparisons being undertaken. The number of intervention sessions received, the approximate duration, and the type of session (e.g., face-to-face, virtual etc.) were summarised descriptively for participants in the intervention group. The extent to which families/households were clustered by home visitor was also summarised. Both adjusted and unadjusted summaries of the outcome measures are presented, with appropriate p-values and 95% confidence intervals (CIs) given for all between-group comparisons. Hedges' g effect sizes were also given for between-group comparisons, together with appropriate 95% CIs, unless explicitly stated otherwise in the SAP (see published SAP for details of effect-size point and interval estimation).

**Primary analysis**

Linear regression was used to compare follow-up BPVS-III scores between the two groups, with fixed effects for group allocation, LA, baseline (raw) BPVS-III score (linear term) and age (linear term). Robust standard errors were used to relax the assumption of homoscedastic errors. Participants with either age missing or baseline BPVS-III score missing had these baseline measurements imputed with the estimated conditional mean of the observed measurements prior to model fitting (see SAP for details of the estimation of these conditional means). Hence all participants with non-missing BPVS-III scores at follow-up were included in the primary analysis model. The estimated between-group difference in mean follow-up BPVS-III score from this model was reported, together with two-sided Wald method 95% CIs and p-value. The effect size was estimated using Hedges' g together with a bias-corrected non-parametric bootstrap 95% CI.

*Further analyses of primary outcome*

Further analyses of the primary outcome were conducted to investigate treatment effect heterogeneity due to variation in adherence to the programme, and to assess the sensitivity of the results of the primary analysis to variation in the missing data assumptions:

*Adherence*

We conducted an exploratory analysis of the primary outcome to estimate the extent to which variation in the 'dose' of the programme delivered resulted in treatment-effect heterogeneity. This was done by fitting a linear 'dose–response' model, where the number of sessions delivered (for households allocated to either group) is taken to be a proxy for dose of programme received. Here, the number of sessions delivered is taken to be the number of home visits (either online or in person) conducted outside of the pause in intervention delivery due to the Covid-19 pandemic. 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) was 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 were 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. The point estimate for the dose effect is reported, together with a 95% CI calculated using the model-based standard errors implemented by Stata's *ivregress 2sls* command.

*Missing data*

The possible impact of missing data on the conclusions drawn from the primary analysis was explored with a range of different methods. Baseline variables associated with missing primary outcome data were identified using penalised logistic regression, and the primary analysis model was refitted including these as additional covariates. More than 5% of cases were excluded from the primary analysis due to missing data; hence, the missing at random (MAR) assumption, and possible influence of data observed post-randomisation (e.g., compliance data) were explored using multiple imputation (see published SAP for details). Briefly, we used a multiply imputed dataset (100 imputations) generated using multiple imputation by chained equations. The 100 imputed datasets were each analysed using the same substantive analysis model as used for the primary analysis, with estimates being combined using Rubin's rules. Further information relating to the imputation is given in Appendix 3. Finally, the sensitivity of results to the outcome data being missing not at random (MNAR) was explored using a pattern mixture modelling approach. This approach imputes missing outcome data under various systematic departures from MAR (in each group individually and across both groups), and then the observed and imputed outcome measurements are analysed using the same substantive analysis model as used for the primary analysis.

*Subgroup analyses*

Four other pre-specified exploratory analyses of the primary outcome were conducted to investigate the possibility of treatment effect heterogeneity. Variation in treatment effect was explored across different levels of the following four baseline characteristics: CiN 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); whether or not the child/children are entitled to free early learning, both obtained from the individual LAs; EAL (again, a binary classification), obtained from parents' answers on the pre-test parental survey, and baseline score on the ASQ communication subscale. Baseline score for the ASQ was used for the latter subgroup analysis because, unlike the BPVS-III, it is age-standardised for children as young as one month, and therefore appropriate for the developmental stage of participating children at baseline. The communication subscale was 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 was investigated by examining whether or not the inclusion of the main effect (if not already present), and its interaction with the randomised group, in the model used for the primary analysis, lead to a significant improvement in model fit based on a likelihood ratio test. Estimates of differences between groups within each subgroup (or over a reasonable range of values for the ASQ-3 communication subscale) from the models including interactions were reported, together with 95% CIs and p-values. Effect sizes based on Hedges' g and non-parametric bootstrap 95% CIs were also reported by subgroup.

**Secondary analysis**

The three subscales of the ASQ-3 were analysed individually using three linear regression models, adjusting for allocation, baseline score, age and LA. Any missing baseline scores were imputed with the strata-specific mean prior to analysis. Hence, all participants with non-missing scores at follow-up were included in the models.

The HLE Index score was analysed using a linear regression model adjusting for allocation, baseline score, age and LA. Any missing baseline scores were imputed with the strata specific mean prior to analysis. Hence, all participants with a non-missing HLE Index score at follow-up were included in the model.

**Mediation analysis**

One of the proposed mechanisms by which the intervention seeks to improve language skills and school readiness is by fostering a positive HLE. We conducted an exploratory analysis to investigate the decomposition of the treatment effect obtained for the primary analysis into direct effects (i.e., effects of allocation that are not mediated by the HLE) and indirect effects (i.e., effects of allocation that are mediated by the HLE). Further details of the assumed causal model and analysis methods are given in Appendix 3.

**Estimation of effect sizes**

Standardised effect sizes are reported for all between-group comparisons, unless otherwise stated. Effect sizes are given in terms of Hedges' g, together with bias-corrected non-parametric bootstrap 95% CIs (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 is given by

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

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

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

where $\hat{\delta}$ is some estimate of the difference in means between groups, and $s_1{}^2$ and $s_2{}^2$ are the bias-corrected estimates of the variance of the outcome measurements in the intervention and control groups respectively. Specific details/figures relating to the calculation of effect sizes for the primary and secondary outcome analyses are given in Tables 15b and 17b respectively.

## Implementation and process evaluation (IPE)

In line with EEF guidance (Humphrey et al., 2016) the IPE aimed 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 ET and DT. Figure 1 presents the logic model, highlighting the outcomes measured by the impact evaluation. The IPE explored the contextual and potential 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 was light-touch but rigorous. The IPE also explored lessons on recruiting from this population.

Due to the coronavirus pandemic, a four-month hold was put on the intervention. During this time, participants in the intervention group were offered support by the FL team (the type of support offered was addressed in the ET's Covid-19 report, see Appendix 4) and participants in the intervention and control groups were kept up to date through the issuing of newsletters which were sent to participants during April 2020 and July 2020. Further newsletters were sent during October 2020 and January 2021. The IPE additionally aimed to explore the impact of maintaining relationships with participants during the lockdown period and the effect of this on the programme.

**Data collection methods**

A pragmatic and mixed-method of data collection approach was adopted to answer the IPE questions. It included:

*Routinely collected programme data*

The ET and DT worked closely to establish ways to ensure implementation of the programme as planned. This included 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, were also shared. These consisted of a telephone call and a scripted checklist routinely gathered to monitor programme delivery (subsequently rated as exemplary, adequate/ satisfactory and inadequate, as rated by Family Lives), detail on home visitor–parent/child relationships, and possible spillover effects of the programme. In addition, demographic information was collected from all participants at the recruitment stage of the study.

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

*Interviews/focus groups/questionnaires*

**Focus groups with DT/ home visitors.** The ET conducted focus groups with the DT, all site coordinators (n = 4) and a sample of the trained home visitors (n = 4; one for each area) during July 2021, to understand the implementation of the programme as planned and as occurred. The relationship between the home visitors and families was also explored alongside possible barriers to implementation. Finally, implementer factors, including the profile of the coordinators and home visitors, were explored.

**Interviews with LA leads.** Interviews were conducted with a representative from three of the four LAs, during July 2021, to discuss the desirability, acceptability and need for the programme as well as challenges encountered within the LA context. The interviews also explored recruitment barriers and how these barriers were overcome to allow the ET to capture lessons on recruiting from this population. These interviews were conducted via Zoom (a software for online video conferencing) or telephone to minimise participant burden.

**Interviews with parents.** A small number of interviews were undertaken with a subsample 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, were also explored. Possible spillover effects were also explored relating to the reach of the programme (i.e., possible impact on siblings). This sample was purposively selected to include a range of attendance patterns. However, it should be noted that parents agreeing to take part in the interview were likely to be more engaged with the intervention. These interviews were conducted via Zoom or telephone to minimise participant burden.

**Bespoke parent questionnaire**. This consisted of a brief questionnaire covering access to local networks, including attendance at local group activities (e.g., playgroups), linking of families to social and educational services (e.g., library attendance), and take-up of the two-year-old or three-year-old nursery provision, in line with the impact expectations relating to parents. It also included parent self-report of confidence and efficacy (using Likert scales). This was administered at the same time as the post-test parent self-complete measures during February to August 2021. Accessibility and desirability of the programme were also explored (see Appendix 1).

**Questionnaire regarding support given during the epidemic.** Developed in response to the Covid-19 pandemic (and specifically the national lockdown period at the beginning of the pandemic), this consisted of an online questionnaire, which was developed on Qualtrics (online survey software) and sent to all intervention and control group families. The questionnaire for intervention participants focused on how the support they received from FL helped them during a time of crisis and probed what kind of support they received. The questionnaire also asked both groups about support they may have sought from outside agencies (agencies other than FL) (see Appendix 4).

**Home observation.** In order to assess the impact of the programme on the HLE, an independent HLE observation conducted within the home was completed with a subsample of participating parents randomly assigned to the intervention condition (n = 31) and the control condition (n = 17). Observations were completed once at pre-test and once at post-test between July 2019 and February 2020, and February 2021 to August 2021, respectively. Whilst to some extent this group was self-selected (due to the optional nature of this aspect of the study), where possible we sought to monitor participants across the recruitment phase to ensure they were selected evenly from across the LAs. 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 enabled rich and diverse descriptive findings to be summarised and directly compared with quantified outcomes. It is particularly important given the programme aims to increase parent–child interaction and promote positive behaviours. The process involved 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 involved 10 minutes of the parent and child interacting during free-play, followed by 10 minutes of shared book reading. Videos were coded to form frequency counts to provide an overall assessment of parent–child verbal and non-verbal behaviours relating to the HLE. Analysis of the data looked at potential changes in positive parenting verbalisations (praise, labelling, educational questions) versus more directive, critical verbalisations. For the child, we looked at any potential changes in the overall quantity of verbalisations, as well as the number of verbalisations instigated by the child. If the programme were to have any effect on parent–child interactions, we would expect to see increases across parental categories that are more positive in nature, laden with language content, and/or that encouraged greater verbal participation from the child. The 11 parental and two child categories coded in the observational measure were:

- **Direct text reading**: Any parental verbalisation that is clearly read verbatim from a book.
- **Acknowledgements**: A brief verbal response to the child's verbalisation or behaviour that contains no content other than a simple yes or no response to a question, or that communicates a recognition of something the child has said or done, with no descriptive content.
- **Statements**: A parental declarative sentence or phrase that gives an account of the objects, or people in the situation or the activity occurring during the observation. It provides a description, and does not imply an action or behaviour to be completed by the child.
- **Commands**: Any clearly stated order, demand, or direction in a declarative form (i.e., it tells the child what to do rather than asking them).
- **General questions**: A comment expressed in question form. It gives an account of the objects or people in the situation or the activity occurring during the interaction. The question follows a child's activity rather than attempting to lead it.
- **Educational questions**: A question that seeks to test a child's language comprehension by asking them to point to something, or their expressive language by asking them to attempt to label something themselves or to problem solve different situations.
- **Labelling**: Any attempts made by the parent to label objects/people/body parts etc. whilst holding the child's attention.
- **Praise**: A non-specific or specific verbalisation that expresses approval or favourable judgement on an activity, product or attribute of the child, or a statement that encourages the child to continue their activity.
- **Affirmations**: Any parent verbalisation that merely repeats the child's verbalisation (reflection), or that expands upon a child's verbalisation but still maintains the same content/message (expansion).
- **Prohibitions**: Any critical statement that finds fault with the activities, products or attributes of the child, or any command that is used to stop a child's behaviour.
- **Nursery rhymes**: Any parental verbalisation that is a nursery rhyme or song.
- **Child spontaneous vocalisations**: Any vocalisation made by the child that is not in response to a previous verbalisation made by the parent. Spontaneous vocalisations are coded when the child speaks without prompt to speak.
- **Child responses**: Any verbalisation that is in direct response to a preceding verbalisation from the parent.

Coding was conducted by one researcher, the trial coordinator (Dr Dysart), who was trained by the coding scheme developer Dr Gridley. Training to be competent in using the observational coding scheme took place over three full days. Coders are considered competent once they have consistently reached ≧75% agreement with the primary coder of the tool. This competency level is considered standard best practice within the field (Yoder & Symons, 2010), and is utilised across a number of other coding schemes, including those from which this tool was devised. Inter-rater and intra-rater reliability checks were performed periodically throughout the study on a 20% random sample of available videos to ensure coder agreement remained high during dense periods of coding, and to limit coder drift. Inter-rater reliability checks were performed by Dr Gridley. Intra-rater reliability checks were performed by Dr Dysart with a minimum of a four-week break between the first viewing and the second viewing in order to reduce observer bias.

Due to the lockdown implemented because of the Covid-19 pandemic, observations (n = 7) which form part of the post-test were carried out online, via Zoom, for February and March 2021. Two of these observations were not coded due to poor quality recording. This left five online observations which were used for the evaluation. Following the first online observation, both coders checked the observation for quality and gave feedback to the data collectors. Two observations carried out on Zoom were included in the inter-rater reliability check at post-test.

**IPE analysis**

Process evaluation data (summarised in Table 5) were:

- transcribed and coded in NVivo using pre-agreed 'parent codes' relating to the logic model and the IPE research questions (LA leads, DT, site coordinators, home visitor and parent interviews). 'Child codes' were subsequently developed within these to provide relevant detail focused on participants' experiences and views. Coding was conducted by one researcher to ensure consistency and checked by another researcher for the report;

- a subsample of 20% of parent–child videotaped observations were randomly selected from all available videos and subject to double-coding to ensure at least 75% inter-rater reliability agreement was maintained between the primary coder and the developer during the coding period;

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

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

Table 5. IPE methods overview

| Research methods | Data collection methods | Participants/ data sources | Data analysis methods | Research questions addressed | Implementation/ logic model relevance |
|---|---|---|---|---|---|
| Survey (post) | Online survey | Parents/carers | Quantitative descriptive analysis including frequency counts and proportions | RQ: 2.2, RQ: 2.3, RQ: 2.4, RQ: 4.1, RQ: 4.2, RQ: 4.3, RQ: 4.4, RQ: | IPE and logic model<br><br>Improved parent–child interactions and frequency (activities and language and communication)<br><br>Positive parenting behaviours<br><br>Emerging literacy activities (e.g., reading to child, rhymes, library attendance) (HLEI)<br><br>Increased parental confidence and efficacy<br><br>Parental engagement with school/community services<br><br>Knock-on effects for child siblings<br><br>Increased nursery attendance |
| Survey (Covid-19) | Online survey | Parents/carers | Quantitative descriptive analysis including frequency counts and proportions | RQ: 4.5 | IPE |

| | | | | | |
|---|---|---|---|---|---|
| Focus groups (LA leads/ Area coordinators/home visitors) | Focus groups | LA leads<br><br>Area coordinators<br><br>Home visitors | Thematic analysis | RQ: 1.1, RQ: 1.3, RQ: 2.1, RQ: 2.2, RQ: 2.3, RQ: 2.4, RQ: 4.2, RQ: 4.3, RQ: 4.4, RQ: 4.5 | IPE and logic model<br><br>Disadvantaged families including those from Super Output Areas<br><br>Lack of take-up of 2–3-year-old free nursery places<br><br>Children entering school behind their peers, especially language and literacy skills, pro-social behaviours<br><br>Lack of parental engagement with wider provision within LAs |
| Interviews (parents) | Interviews | Parents/carers | Thematic analysis | RQ: 2.2, RQ: 2.3, RQ: 2.4, RQ: 4.1, RQ: 4.2, RQ: 4.3, RQ: 4.4 | Logic model<br><br>Intensive home visiting:<br><br>Trained home visitors<br><br>Two 30-minute visits, over 15 months. High quality implementation<br><br>One-to-dyad delivery<br><br>Modelling behaviours<br><br>Provision of curricular materials (i.e., toys and books) to support literacy and fine motor skills<br><br>Signposting to additional services<br><br>Parental empowerment |
| Observations (parent/child interaction) | Observations | Parent/Child | Quantitative descriptive analysis including frequency counts and proportions | RQ:3 | Logic model:<br><br>Improved parent–child interactions and frequency (activities and language and communication)<br><br>Positive parenting behaviours<br><br>Emerging literacy activities |

## Costs

As per EEF guidelines, the DT provided to the ET a cost per child for the intervention as delivered during the Covid-19 pandemic (approximately 15 months) and included details regarding dosage of the programme received over this time period, and in addition a cost per child which would apply during 'normal' delivery by comparison. These costs included 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 used these data to estimate the costs of continuing to roll out the programme over a three-year period. Additional costs of implementation were systematically identified in the IPE. Cost implications were identified according to current EEF guidelines through discussions with the DT and home visitor feedback.

## Timeline

The trial timeline is illustrated in Table 6.

Table 6: Timeline

| Dates | Activity | Staff responsible / leading |
|---|---|---|
| January 2019 | Train and recruit site coordinators | Family Lives |
| April 2019 | Agree protocol, write consents and gain ethical approval | University of York |
| April 2019 | Recruit and train baseline data collectors | University of York |
| April 2019 | Recruit home visitors | Family Lives |
| May 2019 | Train home visitors | Family Lives |
| July 2019 to March 2020 | Identify and recruit families | Family Lives/Local Authorities |
| July 2019 to March 2020 | Pre-test | University of York/Leeds Beckett |
| July 2019 to March 2020 | Randomisation | York Trials Unit |
| July 2019 to August 2021 | Programme delivery | Family Lives |
| July 2019 to August 2021 | Implementation and process evaluation | University of York/Leeds Beckett |
| July 2019 to July 2021 | Parental engagement activities such as newsletters | University of York/Family Lives |
| January 2020 to September 2020 | Write SAP | York Trials Unit |
| April 2020 to June 2020 | Covid-19 pause and parental survey | University of York |
| December 2020 to January 2021 | Recruit and train post-test data collectors | University of York |
| January 2021 to August 2021 | Post-test | University of York/Leeds Beckett |
| September 2021 to February 2022 | Analysis and draft Final Report submitted | University of York/York Trials Unit/Leeds Beckett |

# Impact evaluation results

## Participant flow including losses and exclusions

A total of 2531 families (households) were assessed for eligibility, of which 2228 (88.0%) were found to be ineligible. The remaining 303 families were approached for consent, of which 20 (6.6%) did not consent to trial participation. Of the 283 families that consented to trial participation, 278 (98.2%) had one participating child and five (1.8%) had two participating children. Between 25th July 2019 and 26th February 2020, the 283 consenting families (288 eligible children) completed baseline data collection and were randomised: 141 (49.8%) to the intervention (i.e., the ParentChild+ programme); and 142 (50.2%) to the control group. The distribution of allocations within each LA (the stratification factor) is detailed in Table 7. Of the 141 families allocated to the ParentChild+ programme, 131 (92.9%) received at least one programme session, 88 (62.4%) received ≥85% of the planned 92 sessions and 45 (31.9%) received ≥92 sessions. Of the 283 families randomised, 226 (79.9%) were followed up: 111 (78.7%) in the intervention group and 115 (81.0%) in the control group. A total of 223 (78.8%) families had primary outcome data (BPVS-III score) at follow-up available and were included in the primary analysis (109 (77.3%) intervention, 114 (80.3%) control). The flow of participating families through the trial is illustrated in Figure 2, and the availability of outcome data at baseline and follow-up is detailed in Table 8.

Table 7: Allocations by LA (the stratification factor)

| Local authority, n (%) | Control (N = 142) | Intervention (N = 141) | Total (N = 283) |
|---|---|---|---|
| Barnsley | 35 (24.6) | 35 (24.8) | 70 (24.7) |
| Sheffield | 33 (23.2) | 32 (22.7) | 65 (23.0) |
| Doncaster | 40 (28.2) | 40 (28.4) | 80 (28.3) |
| Rotherham | 34 (23.9) | 34 (24.1) | 68 (24.0) |

Table 8: Availability of primary and secondary outcome data at baseline and follow-up

| | Baseline | | | Follow-up | | |
|---|---|---|---|---|---|---|
| | Control (N = 142) | Intervention (N = 141) | Total (N = 283) | Control (N = 142) | Intervention (N = 141) | Total (N = 283) |
| BPVS-III, n (%) | 132 (93.0) | 131 (92.9) | 263 (92.9) | 114 (80.3) | 109 (77.3) | 223 (78.8) |
| ASQ-3 (communication), n (%) | 133 (93.7) | 132 (93.6) | 265 (93.6) | 114 (80.3) | 111 (78.7) | 225 (79.5) |
| ASQ-3 (fine motor), n (%) | 129 (90.8) | 132 (93.6) | 261 (92.2) | 114 (80.3) | 110 (78.0) | 224 (79.2) |
| ASQ-3 (personal–social), n (%) | 129 (90.8) | 129 (91.5) | 258 (91.2) | 114 (80.3) | 111 (78.7) | 225 (79.5) |
| HLE Index, n (%) | 131 (92.3) | 133 (94.3) | 264 (93.3) | 113 (79.6) | 104 (73.8) | 217 (76.7) |

Figure 2: Participant flow diagram (figures are at the family/household level unless otherwise stated)
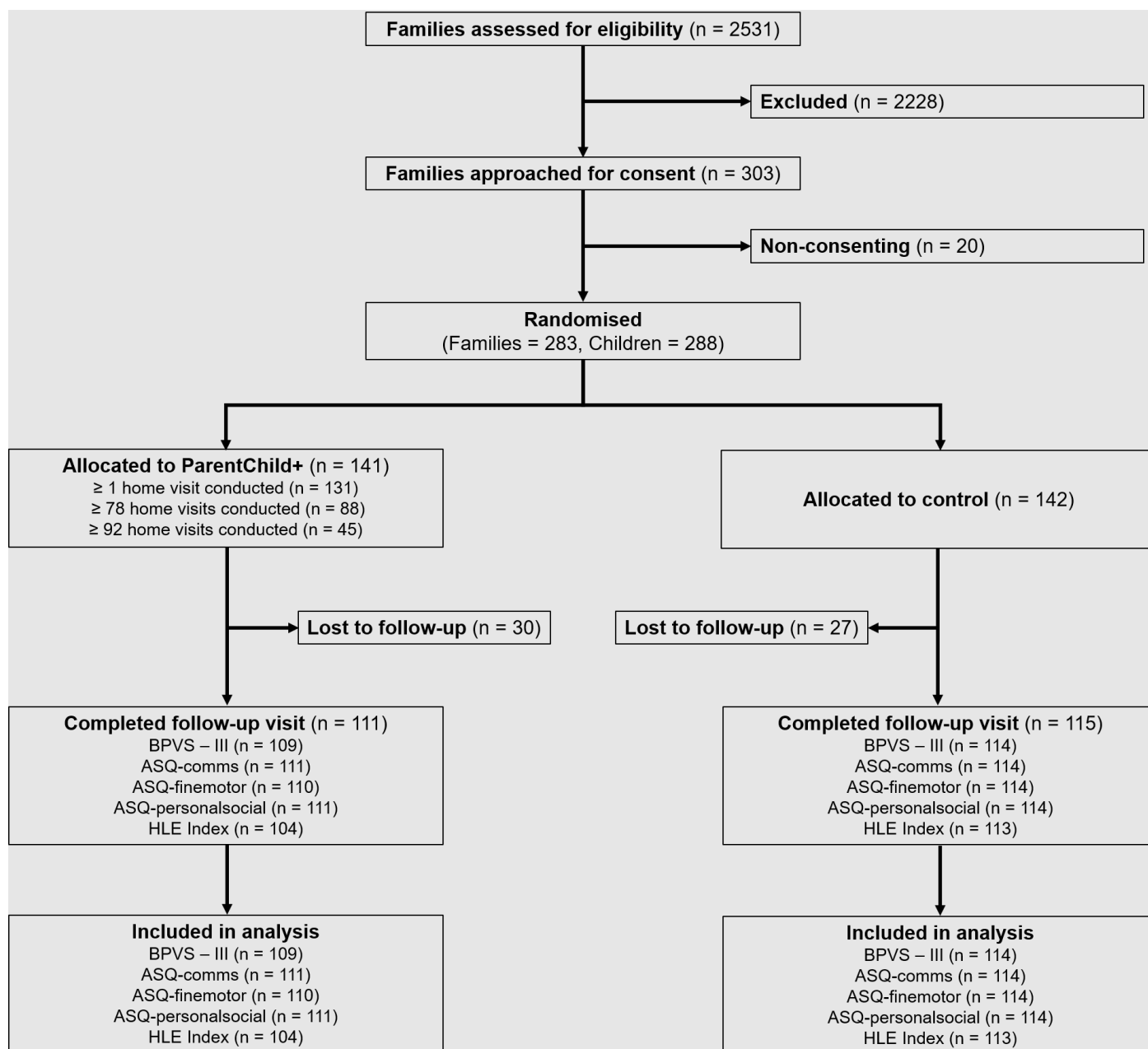


## Attrition

The observed attrition (with respect to the primary outcome) was 21.2%: 22.7% in the intervention group and 19.7% in the control group (see Table 9). The overall sample (Pearson) correlation between the 208 observed pairs of baseline and follow-up measurements of the primary outcome was 0.58. This is somewhat lower than the estimate of 0.7 used in the sample size calculation, and even the upper 95% confidence limit is lower than this value (see Table 10). The apparently lower correlation between repeated measurements of the primary outcome could be wholly or partly the result of floor effects in the BPVS-III baseline measurements (see Figure 3). Such floor effects are quite plausible given that the age of the children in the sample (particularly at baseline) was at or below the lower end of the age range that the BPVS-III is targeted at. Given the number of observed follow-up primary outcome measurements, and assuming that the true population correlation between baseline and follow-up measurements of this outcome is equal to the observed sample (Pearson) correlation, the MDES with Type 1 and 2 error rates of 5% and 20% is 0.31. The observed (Pearson) correlations between pairs of baseline and follow-up measurements of the primary and secondary outcomes are given in Table 10. Details of the MDES (and related quantities) are given in Table 11.

Table 9: Family-level attrition (with respect to the primary analysis)

|  | Control | Intervention | Total |
|---|---|---|---|
| **Number of families randomised** | 142 | 141 | 283 |
| **Number of families included in primary analysis** | 114 | 109 | 223 |
| **Number of families lost (% of randomised)** | 28 (19.7) | 32 (22.7) | 60 (21.2) |

Table 10: Pearson correlation between observed pairs of baseline and follow-up measurements of the outcomes

|  | Control (N = 142) | Intervention (N = 141) | Total (N = 283) |
|---|---|---|---|
| **BPVS-III** |  |  |  |
| N | 106 | 102 | 208 |
| ρ (95% CI*) | 0.57 (0.43 to 0.69) | 0.60 (0.45 to 0.71) | 0.58 (0.48 to 0.67) |
| **ASQ-3 (communication)** |  |  |  |
| N | 107 | 103 | 210 |
| ρ (95% CI*) | 0.67 (0.55 to 0.76) | 0.68 (0.56 to 0.77) | 0.67 (0.59 to 0.74) |
| **ASQ-3 (fine motor)** |  |  |  |
| N | 103 | 103 | 206 |
| ρ (95% CI*) | 0.47 (0.31 to 0.61) | 0.35 (0.17 to 0.51) | 0.41 (0.28 to 0.51) |
| **ASQ-3 (personal–social)** |  |  |  |
| N | 103 | 101 | 204 |
| ρ (95% CI*) | 0.56 (0.41 to 0.68) | 0.67 (0.55 to 0.77) | 0.62 (0.53 to 0.70) |
| **HLE** |  |  |  |
| N | 105 | 98 | 203 |
| ρ (95% CI*) | 0.60 (0.46 to 0.71) | 0.59 (0.44 to 0.70) | 0.58 (0.48 to 0.67) |

*95% CIs based on Fisher's z-transformation.

Table 11: Minimum detectable effect sizes for the trial as planned and as realised[*]

|  | As planned | As randomised | As observed |
|---|---|---|---|
| **Alpha** | 0.05 (two-sided) | 0.05 (two-sided) | 0.05 (two-sided) |
| **Power** | 80% | 80% | 80% |
| **Pre/post correlation** | 0.7 | 0.7 | 0.58 |
| **Control group – randomised** | 160 | 142 | 142 |
| **Control group – effective** | 128 (20% attrition) | ~113 (20% attrition) | 114 (19.72% attrition) |
| **Intervention group – randomised** | 160 | 141 | 141 |
| **Intervention group – effective** | 128 (20% attrition) | ~112 (20% attrition) | 109 (22.70% attrition) |
| **MDES** | 0.25 | 0.27 | 0.31 |

* Assuming that the true population correlation between baseline and follow-up measurements of the primary outcome is equal to the observed sample Pearson correlation.

# Participant characteristics

Prior to randomisation, participating children were administered the BPVS-III by trained data collectors, and parents/carers completed the relevant subscales of the ASQ-3 questionnaire and the HLE Index. A number of other participant-level characteristics (e.g., age, sex etc.) and family/household-level characteristics (e.g., home ownership, household income etc.) were collected using a bespoke questionnaire completed by the parents/carers. Summaries of participant-level characteristics are given in Tables 12 and 13 (prior to pooling of data from households with more than one participating child). Further detailed tabular and graphical summaries of both family/household and participant-level characteristics (both as randomised and as included in the primary analysis) are given in Appendix 5.

As expected, at randomisation the proportion of EAL children and CiN in each group was approximately equal. The mean age in each group was approximately equal, as were the mean scores for the secondary outcomes. There was a slight difference between groups in baseline BPVS-III score, with the mean score in the control group being one point higher ('better') than in the control group. However, the interval estimate for the 'effect' size easily contained 0, suggesting this difference is highly compatible with purely random error (as would be expected given randomisation). However, there were a number of categorical baseline characteristics that differed somewhat between groups. For example, the proportions of children that were male and entitled to a free nursery place were substantially higher in the intervention group than in the control group. There were also a number of other household-level baseline characteristics that showed some degree of imbalance between groups (see Appendix 5). These include home ownership (40% in the control group and 33% in the intervention group) and low income (35% on income support or earning less than £10,000/year in the control group vs 44% in the intervention group). If these characteristics are associated with worse outcomes, then these imbalances may indicate that the intervention group had slightly worse prognosis (treated or otherwise) than the control group. This, in turn, would be expected to shift any treatment effect point estimates in favour of the control group. However, two things should be noted. Firstly, these imbalances do not appear to have resulted in any concerning difference between groups in the baseline measurements of the primary and secondary outcomes. Secondly, if these factors are associated with variation in outcome between groups, then this variation should also manifest within groups – resulting in larger standard errors. Hence the interval estimates and tests reported in subsequent sections are valid (or at least are not made invalid by the observed imbalance), even if the point estimates favour the control group to a greater degree than might have been observed in the absence of these imbalances.

Table 12: Categorical baseline characteristics of the 288 participating children*

| Child-level (categorical) | Control group (N = 145) | | Intervention group (N = 143) | |
|---|---|---|---|---|
| | n/N (missing) | Count (%) | n/N (missing) | Count (%) |
| Male | 135 (10) | 64 (47.4) | 134 (9) | 86 (64.2) |
| EAL | 136 (9) | 12 (8.8) | 134 (9) | 13 (9.7) |
| CiN | 116 (29) | 5 (4.3) | 118 (25) | 7 (5.9) |
| Free Early Learning | 137 (8) | 56 (40.9) | 143 (0) | 73 (51.0) |

* Prior to pooling of data from households with more than one participating child.

Table 13: Continuous baseline characteristics of the 288 participating children*

| Child level (continuous) | Control group (N = 145) | | Intervention group (N = 143) | | Hedges' g (95% CI**) |
|---|---|---|---|---|---|
| | n/N (missing) | Mean (SD) | n/N (missing) | Mean (SD) | |
| Age | 145 (0) | 2.4 (0.3) | 143 (0) | 2.4 (0.3) | 0.04 (–0.19 to 0.27) |
| BPVS-III | 135 (10) | 17.7 (10.7) | 133 (10) | 16.7 (10.1) | –0.10 (–0.34 to 0.14) |
| ASQ-3 communication | 136 (9) | 44.2 (16.6) | 134 (9) | 44.0 (16.4) | –0.01 (–0.25 to 0.23) |
| ASQ-3 personal–social | 132 (13) | 41.3 (14.6) | 134 (9) | 40.4 (14.7) | –0.06 (–0.30 to 0.18) |
| ASQ-3 fine motor | 132 (13) | 45.0 (13.2) | 131 (12) | 44.8 (13.7) | –0.01 (–0.25 to 0.23) |
| HLE Index | 134 (11) | 29.9 (10.9) | 135 (8) | 29.3 (10.6) | –0.05 (–0.29 to 0.18) |

* Prior to pooling of data from households with more than one participating child.

**Confidence limits based on non-central t-distribution.

# Outcomes and analysis

**Primary analysis**

Baseline and follow-up BPVS-III scores for participating children in the same household were pooled prior to analysis by taking the mean of the available scores for a given family/household. It should be noted that all participating households with more than one child were households with children of the same age i.e., twins. Summaries of the observed baseline and follow-up scores for the primary outcome (after pooling) are given in Table 14. Histograms of the marginal distributions of the observed baseline and follow-up BPVS-III scores are given in Figure 3. As discussed in the previous section, the observed mean BPVS-III score at baseline was around one point lower ('worse') in the intervention group than in the control group. The (unadjusted) mean BPVS-III score observed at follow-up was nearly five points lower in the intervention group than in the control group. The results of the planned analysis of the primary outcome are given in Table 15a, and the details required for the effect-size calculation are given in Table 15b. The estimated difference (intervention–control) in BPVS-III score from the primary analysis model is –2.90 (95% CI –7.47 to 1.67, p = 0.21). The Hedges' g (standardised) effect size based on the estimated difference from the primary analysis model and the pooled marginal variance of the observed outcome measurements is –0.14 (95% CI –0.36 to 0.09). Therefore, conditional on all measurement and modelling assumptions, the data are most compatible with the hypothesis that allocation to the intervention results in slightly reduced receptive vocabulary (as measured by the BPVS-III) compared with usual practice. They also suggest that hypotheses positing the intervention improves BPVS-III score at follow-up by a standardised Hedges' g effect size of more than about 0.1 are reasonably implausible. However, uncertainty remains. For example, (taken alone) these results suggest the observed data would be relatively unsurprising if the intervention truly had no effect on follow-up BPVS-III scores, or if it truly reduced these scores by around 5.8 points. That is, the observed data contain approximately the same (limited) amount of information against both of these hypothesised treatment effects.

Table 14: Observed baseline and follow-up BPVS-III scores*

|  | Control (N = 142) | Intervention (N = 141) | Total (N = 283) |
|---|---|---|---|
| **Baseline BPVS-III** |  |  |  |
| N | 132 | 131 | 263 |
| Mean (SD) | 17.7 (10.8) | 16.7 (10.1) | 17.2 (10.4) |
| Median (Q1**, Q3**) | 17.5 (10.0, 22.5) | 16.0 (10.0, 22.0) | 16.5 (10.0, 22.0) |
| Min, Max | 0.0, 55.0 | 1.0, 54.0 | 0.0, 55.0 |
| **Follow-up BPVS-III** |  |  |  |
| N | 114 | 109 | 223 |
| Mean (SD) | 52.1 (19.5) | 47.3 (21.8) | 49.8 (20.8) |
| Median (Q1, Q3) | 54.5 (43.0, 64.0) | 50.0 (32.0, 64.0) | 53.0 (36.0, 64.0) |
| Min, Max | 0.0, 94.0 | 0.0, 87.0 | 0.0, 94.0 |

* Prior to pooling of data from households with more than one participating child.

** Q1 = Lower (first) quartile, Q3 = Upper (third) quartile.

Figure 3: Marginal distributions of the observed baseline and follow-up BPVS-III scores*
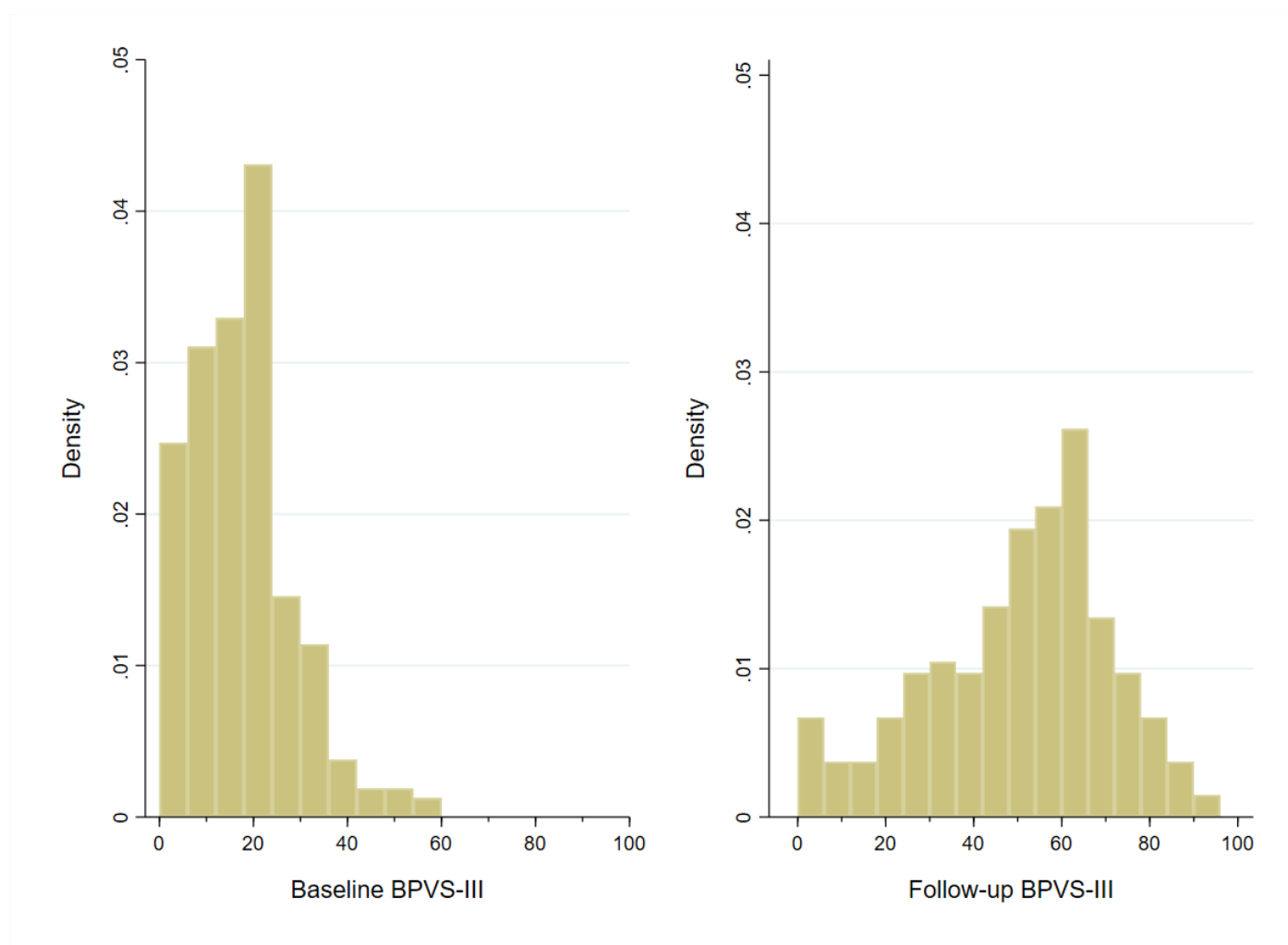


*After pooling of data from households with twins.

Table 15a: Results of the planned primary analysis

| Outcome | Intervention mean (SD) | Control mean (SD) | Adjusted difference d (95% CI*) | p-value* | Effect size g (95% CI**) |
|---|---|---|---|---|---|
| **BPVS-III** | 47.3 (21.8) | 52.1 (19.5) | −2.90 (−7.47 to 1.67) | 0.21 | −0.14 (−0.36 to 0.09) |

*p-value for a Wald test of the hypothesis $H_0: \delta = 0$, based on heteroscedasticity-consistent standard errors.
**Based on non-parametric bootstrap (2500 replicates).

Table 15b: Primary outcome effect size calculation details

| Outcome | Adjusted difference | Intervention | | Control | | Pooled variance | Effect size g (95% CI**) |
|---|---|---|---|---|---|---|---|
| | | N (missing) | Variance* | N (missing) | Variance* | | |
| **BPVS-III** | −2.90 | 109 (32) | 476.1 | 114 (28) | 381.2 | 427.6 | −0.14 (−0.36 to 0.09) |

*Bessel-corrected estimate of marginal variance of the observed outcome measurements.
**Based on non-parametric bootstrap (2500 replicates).

**Secondary analyses**

For each of the secondary outcomes, baseline and follow-up scores for participating children in the same household were pooled prior to analysis by taking the mean of the available scores for a given family/household (required for five households). Summaries of the observed baseline and follow-up scores (after pooling) are given in Table 16. For each

of the secondary outcomes, the mean baseline scores were slightly lower ('worse') in the intervention group compared to the control group, although these differences were all less than one point. At follow-up, mean scores for each of the ASQ subscales were lower ('worse') in the intervention group by around 2 to 3.5 points, in contrast to the HLE Index, where the mean score was larger ('better') in the intervention group by around 3.5 points (compared with the control group). At both time points, ceiling effects were evident for all of the ASQ subscales, with many scores at or close to the maximum score of 60 (between 14% and 28% showing ceiling effects on ASQ subscales at baseline and between 13% and 34% at post-testing. This is higher than would be expected on a standardised measure for this age group. See *Sensitivity analyses* section below for further discussion/analysis). The results of the planned analyses of the secondary outcomes are given in Table 17a, and the details required for the effect-size calculations are given in Table 17b. For each of the three ASQ subscales, the estimated differences (intervention–control) in expected scores from the planned analysis models are approximately –2 to –3 points, resulting in (standardised) Hedges' g effect sizes of approximately –0.15 to –0.2. Hence, conditional on all the various measurements and modelling assumptions, the data are not inconsistent with the hypothesis that allocation to the intervention results in slightly lower scores for these developmental outcomes compared to allocation to treatment as usual. Again, some uncertainty remains for these outcomes. Hypotheses positing the intervention causes both slight increases and moderately sized reductions in ASQ scores (compared to usual care) are reasonably plausible, based on the observed data. For the HLE Index, the estimated difference (intervention – control) in expected score at follow-up is 3.60 (95% CI 1.06 to 6.13, p = 0.01), and the estimated (standardised) effect size is 0.31 (95% CI 0.10 to 0.54). Therefore, in contrast to both the primary outcome and the ASQ outcomes, the data are most compatible with the hypothesis that the intervention results in small to moderately sized improvements in the HLE (as measured by the HLE Index) compared to usual practice.

Table 16: Summaries of the observed baseline and follow-up scores for the secondary outcomes*

| | Control (N = 142) | Intervention (N = 141) | Total (N = 283) |
|---|---|---|---|
| **Baseline ASQ (communication)** | | | |
| N | 133 | 132 | 265 |
| Mean (SD) | 44.5 (16.3) | 43.8 (16.4) | 44.2 (16.3) |
| Median (Q1, Q3) | 50.0 (35.0, 60.0) | 50.0 (35.0, 60.0) | 50.0 (35.0, 60.0) |
| Min, Max | 0.0, 60.0 | 0.0, 60.0 | 0.0, 60.0 |
| **Follow-up ASQ (communication)** | | | |
| N | 114 | 111 | 225 |
| Mean (SD) | 49.7 (13.7) | 47.6 (14.4) | 48.6 (14.0) |
| Median (Q1, Q3) | 55.0 (45.0, 60.0) | 50.0 (40.0, 60.0) | 55.0 (45.0, 60.0) |
| Min, Max | 0.0, 60.0 | 0.0, 60.0 | 0.0, 60.0 |
| **Baseline ASQ (fine motor)** | | | |
| N | 129 | 132 | 261 |
| Mean (SD) | 41.3 (14.5) | 40.4 (14.8) | 40.9 (14.6) |
| Median (Q1, Q3) | 45.0 (30.0, 50.0) | 45.0 (30.0, 50.0) | 45.0 (30.0, 50.0) |
| Min, Max | 5.0, 60.0 | 0.0, 60.0 | 0.0, 60.0 |
| **Follow-up ASQ (fine motor)** | | | |
| N | 114 | 110 | 224 |
| Mean (SD) | 42.5 (15.0) | 39.0 (17.1) | 40.8 (16.1) |
| Median (Q1, Q3) | 45.0 (35.0, 55.0) | 45.0 (25.0, 55.0) | 45.0 (30.0, 55.0) |
| Min, Max | 0.0, 60.0 | 0.0, 60.0 | 0.0, 60.0 |
| **Baseline ASQ (personal–social)** | | | |
| N | 129 | 129 | 258 |
| Mean (SD) | 45.1 (12.9) | 44.7 (13.7) | 44.9 (13.3) |
| Median (Q1, Q3) | 45.0 (40.0, 55.0) | 50.0 (35.0, 55.0) | 45.0 (40.0, 55.0) |
| Min, Max | 5.0, 60.0 | 10.0, 60.0 | 5.0, 60.0 |
| **Follow-up ASQ (personal–social)** | | | |
| N | 114 | 111 | 225 |
| Mean (SD) | 50.0 (12.3) | 47.8 (14.0) | 48.9 (13.2) |

| | | | |
|---|---|---|---|
| Median (Q1, Q3) | 55.0 (45.0, 60.0) | 50.0 (45.0, 60.0) | 55.0 (45.0, 60.0) |
| Min, Max | 0.0, 60.0 | 0.0, 60.0 | 0.0, 60.0 |
| **Baseline HLE Index** | | | |
| N | 131 | 133 | 264 |
| Mean (SD) | 29.9 (11.0) | 29.3 (10.6) | 29.6 (10.8) |
| Median (Q1, Q3) | 31.0 (21.0, 38.0) | 29.0 (21.0, 38.0) | 29.0 (21.0, 38.0) |
| Min, Max | 5.0, 56.0 | 7.0, 56.0 | 5.0, 56.0 |
| **Follow-up HLE Index** | | | |
| N | 113 | 104 | 217 |
| Mean (SD) | 27.4 (11.5) | 31.0 (11.7) | 29.1 (11.7) |
| Median (Q1, Q3) | 28.0 (19.0, 35.0) | 32.0 (22.0, 39.0) | 30.0 (20.0, 38.0) |
| Min, Max | 2.0, 52.0 | 0.0, 56.0 | 0.0, 56.0 |

* Prior to pooling of data from households with more than one participating child.


Table 17a: Results of the planned analyses of the secondary outcomes

| Outcome | Intervention mean (SD) | Control mean (SD) | Adjusted difference d (95% CI*) | p-value* | Effect size g (95% CI**) |
|---|---|---|---|---|---|
| ASQ-3 (communication) | 47.6 (14.4) | 49.7 (13.7) | –2.08 (–4.83 to 0.68) | 0.14 | –0.15 (–0.35 to 0.04) |
| ASQ-3 (fine motor) | 39.0 (17.1) | 42.5 (15.0) | –3.14 (–7.10 to 0.81) | 0.12 | –0.20 (–0.46 to 0.04) |
| ASQ-3 (personal–social) | 47.8 (14.0) | 50.0 (12.3) | –1.94 (–4.76 to 0.87) | 0.17 | –0.15 (–0.35 to 0.08) |
| HLE Index | 31.0 (11.7) | 27.4 (11.5) | 3.60 (1.06 to 6.13) | 0.01 | 0.31 (0.10 to 0.54) |

*p-value for a Wald test of the hypothesis $H_0: \delta = 0$, based on heteroscedasticity-consistent standard errors.
**Based on non-parametric bootstrap (2500 replicates).


Table 17b: Secondary outcome effect-size calculation details

| Outcome | Adjusted difference | Intervention | | Control | | Pooled variance | Effect size g (95% CI**) |
|---|---|---|---|---|---|---|---|
| | | N (missing) | Variance* | N (missing) | Variance* | | |
| ASQ-3 (communication) | –2.08 | 111 (30) | 206.3 | 114 (28) | 187.1 | 196.6 | –0.15 (–0.35 to 0.04) |
| ASQ-3 (fine motor) | –3.14 | 110 (31) | 292.1 | 114 (28) | 224.9 | 257.9 | –0.20 (–0.46 to 0.04) |
| ASQ-3 (personal–social) | –1.94 | 111 (30) | 194.7 | 114 (28) | 151.5 | 172.8 | –0.15 (–0.35 to 0.08) |
| HLE Index | 3.60 | 104 (37) | 136.6 | 113 (29) | 132.3 | 134.4 | 0.31 (0.10 to 0.54) |

*Bessel-corrected estimate of marginal variance of the observed outcome measurements.
**Based on non-parametric bootstrap (2500 replicates).


**Sensitivity analyses**

*Baseline primary outcome data collection errors*

Following baseline data collection, we identified six instances where the baseline BPVS-III administration was stopped prematurely (primarily due to administrator error), meaning the scores obtained were likely to be lower than would have

been obtained had there been no premature stopping. Two of the six instances occurred for households that were subsequently allocated to control and four for households that were subsequently allocated to the intervention. The primary analysis was based on the recorded baseline scores for these six families, and the decision was taken (prior to outcome data collection/review) to repeat the primary analysis treating these baseline scores as missing, and impute them (and any other completely missing baseline BPVS-III scores) following the same procedure as used for the primary analysis (see the published SAP for further information). The estimated difference in expected follow-up BPVS-III score from the fitted model with these baseline data set to missing is –2.43 (95% CI –6.95 to 2.09, p = 0.29) and the estimated Hedges' g effect size is –0.12 (95% CI –0.33 to 0.11). These baseline scores were also treated as missing (and multiply imputed along with other missing data) as part of the sensitivity analyses reported in the section on *Missing data* below.

*Follow-up testing medium*

The ongoing Covid-19 pandemic resulted in some participants being followed up for the primary and secondary outcomes online (via video conferencing software), rather than in person (as planned). Summaries of the testing medium and the level of support given to the participating children that completed the BPVS-III at follow-up (both remotely and in person) are given in Table 18. As can be seen from Table 18 (and as expected by the trial team) the proportions of households/participants being followed in person/remotely are approximately equal across the two groups. There are, however, some differences in the level of support received during follow-up BPVS-III completion (as assessed by the data collectors), with children in the intervention group generally receiving greater support from the parent/carer.[6] This may have been due to an increase in confidence by parents in supporting their children as a result of taking part in the intervention, although this was not measured in the planned analysis. Despite the expectation that the two groups would be exchangeable with respect to follow-up testing medium, two additional analyses were planned (prior to review of any outcome data): one to investigate the potential influence of follow-up testing medium on the estimated treatment effect; and another to investigate outcome and treatment effect heterogeneity associated with this. For the first analysis, we simply refitted the primary analysis model, excluding BPVS-III outcome data from those families that were followed up online (see Table 19a). This results in a slightly larger estimated difference between groups (and slightly wider interval estimates) than the analysis including these families, although inference is largely unaffected. For the second analysis, we used the same analysis set as used for the primary analysis, but added the main effect of follow-up testing medium and its interaction with allocation as explanatory variables (see Table 19b). There is some weak evidence that the treatment effect differed by follow-up type strata, with a moderately sized positive (i.e., favouring the intervention group) treatment-effect estimate for online follow-up and a moderately sized negative (i.e., favouring the control group) treatment-effect estimate for in-person follow-up. However, the estimates are very imprecise (due to the small effective sample size) and the interval estimates suggest the data are also reasonably compatible with the opposite conclusion, or indeed that the treatment effect was close to zero in both follow-up type strata. In other words, face-to-face follow-up did not appear to have a detrimental effect or improve scores.

Table 18: Follow-up testing type and data collector-assessed level of support received during BPVS-III administration (participant-level data for those participants that completed the BPVS-III at follow-up)

| | Control (N = 117) | Intervention (N = 111) | Total (N = 228) |
|---|---|---|---|
| **Follow-up testing medium, n (%)** | | | |
| Face-to-face | 98 (83.8) | 92 (82.9) | 190 (83.3) |
| Online | 19 (16.2) | 19 (17.1) | 38 (16.7) |
| **Support given during BPVS-III test administration, n (%)** | | | |
| No support | 46 (39.3) | 31 (27.9) | 77 (33.8) |
| Low support | 37 (31.6) | 31 (27.9) | 68 (29.8) |
| Medium support | 20 (17.1) | 21 (18.9) | 41 (18.0) |
| High support | 9 (7.7) | 23 (20.7) | 32 (14.0) |
| Missing | 5 (4.3) | 5 (4.5) | 10 (4.4) |

---

[6] Data collectors assessed the level of support given from parents/carers on four levels: no support = the child completed the assessment independently; low support = completed the assessment with prompts from the parent using the same language as the data collector; medium support = completed with prompts from parent using guiding language; and high support = completed with support from parents which guided child to make the correct selection.

Table 19a: Estimates from primary analysis model excluding families/participants that completed follow-up online

| Total sample size (families) | Adjusted difference d (95% CI*) | p-value* | Effect size g (95% CI**) |
|---|---|---|---|
| 186 | –3.74 (–8.74 to 1.26) | 0.14 | –0.18 (–0.44 to 0.02) |

*p-value for a Wald test of the hypothesis $H_0: \delta = 0$, based on heteroscedasticity-consistent standard errors.
**Based on non-parametric bootstrap (2500 replicates).

Table 19b: Estimates from model including follow-up testing medium and its interaction with randomised group as predictors

| Level | Adjusted difference d (95% CI*) | p-value* | Effect size g (95% CI**) |
|---|---|---|---|
| Face-to-face | –4.01 (–9.02 to 1.00) | 0.12 | –0.19 (–0.44 to 0.05) |
| Online | 3.03 (–7.31 to 13.37) | 0.56 | 0.16 (–0.42 to 0.79) |

*p-value for a Wald test of the hypothesis $H_0: \delta = 0$, based on heteroscedasticity-consistent standard errors.
**Based on non-parametric bootstrap (2500 replicates).

*Missing data*

The availability of BPVS-III data is summarised in Table 20. Just over 25% of participating households were missing a BPVS-III score at baseline or follow-up, with around 1–2% missing BPVS-III scores at both time points. Of the 226 households that were followed up (either face-to-face or online), 223 had an available BPVS-III score. Three households were followed up, but did not provide BPVS-III outcome data (all of these were followed up face-to-face). The primary analysis included all households that had a valid BPVS-III score at follow-up, with single imputation implemented for any cases that had missing baseline scores (see published SAP for details). The estimates from the primary analysis are valid under the assumption that the missing outcome data are MAR with respect to the variables included in the primary analysis model. To relax this assumption, we assessed whether various baseline characteristics were associated with missing primary outcome data (see published SAP for details), and supplemented the covariate set used in the primary analysis model with these predictors of missingness. This identified three baseline characteristics for which there was reasonably strong evidence of an association with missing outcome data (see Appendix 6 for details); home ownership (tenant or homeowner), caregiver employment (employed or unemployed/retired) and income (≤£20,000 or >£20,000). These three binary terms were added to the primary analysis model, and this model refitted. Results are given in Table 21. The estimated treatment effects (on both the original scale and the standardised difference scale) are slightly smaller than those obtained for the primary analysis but are broadly comparable. In addition, this change in estimates could be at least partially explained by the exclusion of 23 households with non-missing BPVS-III follow-up data from the analysis model, due to these households having missing data for one or more of the additional covariates (i.e., home ownership, employment status and income) in the second model.

Table 20: Availability of BPVS-III data at baseline and follow-up

| BPVS-III data availability, n (%) | Control (N = 142) | Intervention (N = 141) | Total (N = 283) |
|---|---|---|---|
| Baseline and follow-up | 106 (74.6) | 102 (72.3) | 208 (73.5) |
| Baseline only | 26 (18.3) | 29 (20.6) | 55 (19.4) |
| Follow-up only | 8 (5.6) | 7 (5.0) | 15 (5.3) |
| Neither | 2 (1.4) | 3 (2.1) | 5 (1.8) |

Table 21: Estimates from model including additional baseline predictors of missing BPVS-III follow-up data (complete cases only)

| Number of households | Adjusted difference d (95% CI**) | p-value** | Effect size g (95% CI***) |
|---|---|---|---|
| 200* | –1.93 (–6.66 to 2.80) | 0.42 | –0.09 (–0.32 to 0.14) |

*23 households missing one or more of the additional baseline characteristics included in the model (see above).

**p-value for a Wald test of the hypothesis $H_0: \delta = 0$, based on heteroscedasticity-consistent standard errors.
***Based on non-parametric bootstrap (2500 replicates).

To further relax the assumption that the missing baseline and outcome data were MAR, and to allow for the possible influence of post-randomisation predictors of missingness on outcomes, we used multiple imputation. Multiple imputation involves using the characteristics of those who are missing to identify those of similar characteristics who are not missing and then imputing values from those who are not missing to those who are missing. Results obtained using the multiply imputed data are given in Table 22. The estimated treatment effects (on both the original and Hedges' g scales) are slightly larger in absolute value than the estimates obtained for the primary analysis, with small to moderately sized differences in favour of control being reasonably plausible based on the observed and imputed data. Despite the slight increase in treatment-effect estimate (in absolute terms), the point and interval estimates are broadly comparable with those obtained for the primary analysis, and inference concerning the effectiveness of the intervention is relatively unaffected. Further information relating to the imputation is given in Appendix 2.

Table 22: Estimates obtained using multiply imputed data

| Adjusted difference d (95% CI*) | p-value* | Effect size g (95% CI**) |
| --- | --- | --- |
| −3.86 (−8.31 to 0.59) | 0.09 | −0.19 (−0.41 to 0.03) |

*Based on Rubin's rules.
**Based on Rubin's rules applied to effect-size point estimates and bootstrap standard errors obtained for each imputed dataset.

To investigate departures from the assumption that missing primary outcome data are MAR, we performed a delta-based sensitivity analysis using a pattern mixture model. Treatment-effect estimates for $\delta = 0$ (i.e., expected value of the unobserved BPVS-III scores is the same as the expected value of the observed BPVS-III scores conditional on the covariates in the substantive model) to $\delta = -10$ (i.e., expected value of the unobserved BPVS-III scores is 10 points less than the expected value of the observed BPVS-III scores conditional on the covariates in the substantive model) in increments of one are provided in Table 23. This table shows that the estimated treatment effect is reasonably stable across a broad range of departures from MAR. Even if it is assumed that the departures from MAR only affect the control group (with the missing data in the intervention group being MAR), then the point estimates still favour the control group, even if these departures are assumed to be quite extreme.

Table 23: Estimated treatment effects from the delta-based sensitivity analysis of the primary outcome

| $\delta$ | Treatment effect (95% CI) | | |
| --- | --- | --- | --- |
| | Intervention group only | Control group only | Both groups |
| −10 | −5.15 (−9.84 to −0.47) | −0.89 (−5.57 to 3.79) | −3.14 (−7.87 to 1.60) |
| −9 | −4.93 (−9.60 to −0.25) | −1.09 (−5.76 to 3.58) | −3.12 (−7.83 to 1.60) |
| −8 | −4.70 (−9.37 to −0.04) | −1.29 (−5.95 to 3.37) | −3.09 (−7.79 to 1.61) |
| −7 | −4.48 (−9.14 to 0.18) | −1.49 (−6.15 to 3.16) | −3.07 (−7.75 to 1.61) |
| −6 | −4.25 (−8.90 to 0.40) | −1.69 (−6.34 to 2.96) | −3.04 (−7.71 to 1.63) |
| −5 | −4.03 (−8.67 to 0.62) | −1.89 (−6.54 to 2.75) | −3.02 (−7.68 to 1.64) |
| −4 | −3.80 (−8.44 to 0.84) | −2.09 (−6.73 to 2.54) | −3.00 (−7.64 to 1.65) |
| −3 | −3.58 (−8.21 to 1.06) | −2.30 (−6.93 to 2.34) | −2.97 (−7.61 to 1.67) |
| −2 | −3.35 (−7.99 to 1.28) | −2.50 (−7.13 to 2.14) | −2.95 (−7.58 to 1.69) |
| −1 | −3.13 (−7.76 to 1.51) | −2.70 (−7.33 to 1.93) | −2.92 (−7.56 to 1.71) |
| 0 | −2.90 (−7.53 to 1.73) | −2.90 (−7.53 to 1.73) | −2.90 (−7.53 to 1.73) |

*Post hoc sensitivity analysis of ASQ data*

Ceiling effects were evident across all the ASQ subscales, with many scores equal or close to the maximum score of 60 (see Figure 4). This ceiling clearly violates the assumptions of the planned analysis of this outcome (as reported

above). To investigate the sensitivity of the estimated treatment effects for the ASQ outcomes to departures from the assumptions of the planned analyses, we carried out post hoc semi-parametric rank-based analyses of these outcomes that are likely to be more robust to the ceiling effects and skew evident in the observed ASQ data. These semi-parametric analyses are based on proportional odds models, with the same fixed effects as included in the planned analyses of these outcomes (i.e., treatment group, LA, age and baseline score). The fitted models were then used to derive estimated differences in expected follow-up score (for each of the ASQ outcomes) at each level of LA, holding age and baseline score at the mean values of the observed measurements. The estimated treatment effects for each outcome at each level of LA are reported in Table 24. The reported 95% CIs and p-values are based on delta-method standard errors. From Table 24, it can be seen that the estimates from the semi-parametric analyses are broadly comparable with the estimates obtained from the planned analyses of these outcomes, although some minor attenuation of treatment effects is evident, particularly for the communication and fine motor subscales.

Figure 4: Histograms of observed ASQ baseline and follow-up data
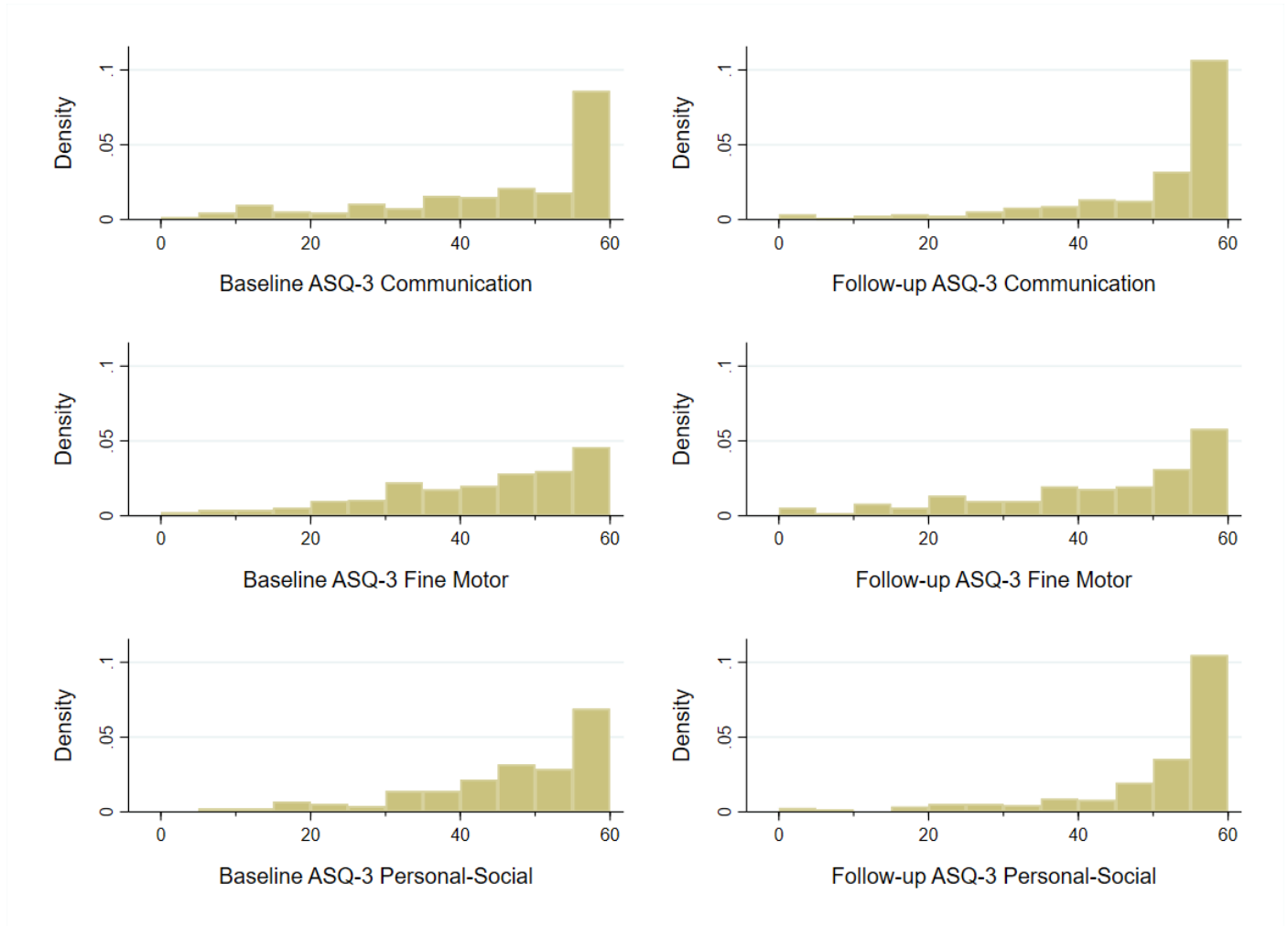
Table 24: Results of post hoc semi-parametric analyses (based on proportional odds models) of the ASQ subscales. Estimated differences in expected value from the fitted proportional odds models are presented by LA, with age and baseline score held at the mean of the observed measurements.[7]

| Outcome | Local authority | Adjusted difference d (95% CI*) | p-value* |
|---|---|---|---|
| ASQ (communication) | Barnsley | −1.63 (−4.28 to 1.01) | 0.23 |
| | Sheffield | −1.78 (−4.67 to 1.11) | 0.23 |
| | Doncaster | −1.49 (−3.90 to 0.93) | 0.23 |
| | Rotherham | −1.55 (−4.06 to 0.95) | 0.22 |
| ASQ (fine motor) | Barnsley | −2.95 (−7.04 to 1.14) | 0.16 |
| | Sheffield | −2.78 (−6.65 to 1.09) | 0.16 |
| | Doncaster | −2.93 (−7.00 to 1.13) | 0.16 |
| | Rotherham | −2.76 (−6.58 to 1.07) | 0.16 |
| ASQ (personal–social) | Barnsley | −2.02 (−4.83 to 0.78) | 0.16 |
| | Sheffield | −1.93 (−4.65 to 0.79) | 0.16 |
| | Doncaster | −1.79 (−4.30 to 0.72) | 0.16 |
| | Rotherham | −1.74 (−4.18 to 0.70) | 0.16 |

*Based on delta method standard errors.

**Adherence to programme**

The planned number of home visits for each household allocated to the ParentChild+ programme was 92. Of the 141 households allocated to the intervention, 45 (31.9%) received at least 92 home visits and 88 (62.4%) received at least 78 home visits (85% of planned). There were 10 (7.1%) households that did not receive any home visits. The distribution of home visits delivered in the intervention group is illustrated in Figure 5. We conducted an exploratory analysis of the primary outcome to explore whether 'dose' of the programme received is a possible source of treatment effect heterogeneity (where number of sessions delivered is taken to be a proxy for dose). We planned to use inverse probability weights to make the MAR assumption more tenable (see published SAP for further details). Due to missing data in some of the baseline variables used to estimate the inverse probability weights (particularly Child in Need status), the inclusion of these weights led to 55 households with non-missing primary outcome data being excluded from the model. We therefore present estimates of the incremental effect of each additional dose for models with and without inverse probability weights (see Table 25). Additional information relating to the two-stage estimator (results of the first-stage regression and tests of instrument strength) are given in Appendix 3. Given the point estimate of the effect of allocation is negative, and the fact that only households in the intervention group received home visits (i.e., the only non-adherent behaviour was households allocated to the intervention not receiving visits as planned), it is unsurprising that the point estimate of the incremental effect is negative. These results suggest the data are most compatible with the hypothesis that each additional home visit resulted in slightly worse performance on the BPVS-III at follow-up, and therefore that number of sessions received may be the source of some treatment-effect heterogeneity (i.e., that the treatment effect varies by number of sessions delivered). However, conditional on the various measurement and modelling assumptions there is relatively weak evidence of any strong linear dose–response relationship. Furthermore, the analysis undertaken rests on a number of strong assumptions (e.g., number of sessions being a reasonable measure of dose of programme received, randomisation affecting outcome only through treatment received, the relationship between dose and outcome being linear, etc.), meaning the results should be interpreted with caution.

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[7] Estimates are presented by LA since the fitted model assumes the treatment effect is additive on the log-odds scale (i.e., constant differences in logit(Pr(Y y)) and therefore relative on the probability scale. Hence the estimated probabilities Pr(Y = y | Intervention, X) and Pr(Y = y | Control, X) and quantities derived thereof (in this case E(Y | Intervention, X) − E(Y | Control, X)) depend on the covariates X (in this case baseline score, age and LA). The estimates reported here are based on baseline score and age being equal to the means of the observed values (for the whole sample), and LA being equal to each of the values specified.

Figure 5: Distribution (expressed as frequency) of the number of home visits delivered (outside of Covid-19 pause period) to households allocated to the intervention group
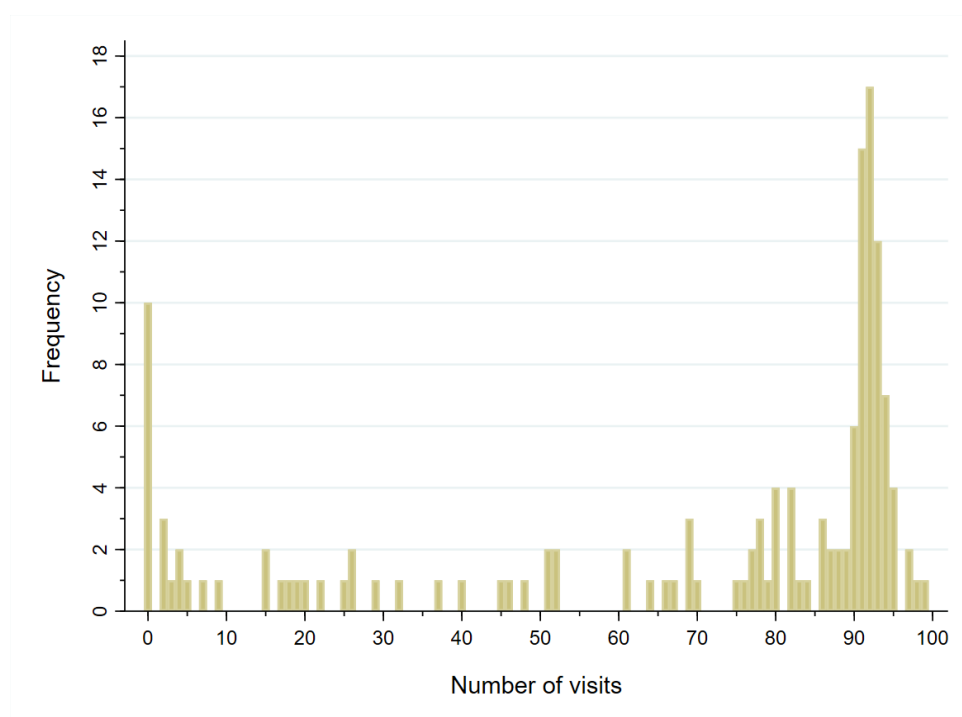


Table 25: Estimates of incremental effect of each home visit (linear relationship assumed) on the primary outcome

| Inverse probability weights used? | N (households) | Point estimate (95% CI) | p-value |
|---|---|---|---|
| Yes | 168 | –0.05 (–0.11 to 0.02) | 0.16 |
| No | 223 | –0.04 (–0.10 to 0.01) | 0.14 |

**Subgroup analyses**

We conducted four pre-specified exploratory analyses of the primary outcome to investigate treatment effect heterogeneity associated with EAL status, baseline ASQ communication subscale score, CiN status and FEL entitlement. As the subgroup analysis is based on small numbers, and there is some overlap between EAL, CiN and FEL status, these results should be interpreted with caution.

*English as an Additional Language (EAL)*

The majority of families and participating children in the sample spoke English as their first language. The proportion of families with observed primary outcome data where the participating child(children) was(were) EAL/not EAL is given in Table 26 by randomised group. Estimates of the treatment effects and effect sizes by EAL subgroup are given in Table 27. As expected, given the relatively sparse data in some of the EAL by allocation strata, the estimates by EAL subgroup are very imprecise and should be interpreted with caution. However, there is some (weak) evidence that the effectiveness of the intervention varied between the two strata, with little difference between groups observed among non-EAL families, but potentially quite large differences (in favour of the control group) observed among EAL families, although the latter is based on a very small number of families.

Table 26: Family-level child EAL status (families/households that had available follow-up BPVS-III data only)

| EAL, n (%) | Control (N = 114) | Intervention (N = 109) | Total (N = 223) |
|---|---|---|---|
| No | 100 (87.7) | 91 (83.5) | 191 (85.7) |
| Yes | 7 (6.1) | 11 (10.1) | 18 (8.1) |
| Missing | 7 (6.1) | 7 (6.4) | 14 (6.3) |

Table 27: Treatment effect and effect-size estimates by EAL status

| | Adjusted difference d (95% CI*) | p-value* | Effect size g (95% CI**) |
|---|---|---|---|
| **Not EAL** | 0.09 (–4.74 to 4.92) | 0.97 | 0.00 (–0.22 to 0.23) |
| **EAL** | −26.69 (–41.14 to −12.24) | 0.00 | −1.70 (–2.76 to –0.72) |

*p-value for a Wald test of the hypothesis $H_0: \delta = 0$, based on heteroscedasticity-consistent standard errors.
**Based on non-parametric bootstrap (2500 replicates).

*Baseline ASQ communication subscale score*

Treatment effect and effect-size estimates across the range of possible baseline ASQ communication subscale scores are given in Table 28. Based on the estimates in Table 28, there is some evidence that the intervention had a less negative effect on receptive vocabulary (as measured by the BPVS-III) among participants with better baseline communication development (compared with the control condition). However, this gradient is not particularly strong, and again estimates are imprecise in some ranges/regions of the parameter space, owing to sparse data (particularly at the lower end of the baseline ASQ communication scores).

Table 28: Treatment effect and effect-size estimates by baseline communication development

| Baseline ASQ-3 communication subscale score | Adjusted difference d (95% CI*) | p-value* | Effect size g (95% CI**) |
|---|---|---|---|
| 0 | –4.91 (–18.08 to 8.27) | 0.46 | –0.24 (–0.89 to 0.42) |
| 10 | –4.42 (–15.04 to 6.19) | 0.41 | –0.21 (–0.75 to 0.33) |
| 20 | –3.94 (–12.13 to 4.25) | 0.34 | –0.19 (–0.60 to 0.23) |
| 30 | –3.45 (–9.52 to 2.61) | 0.26 | –0.17 (–0.47 to 0.14) |
| 40 | –2.97 (–7.64 to 1.70) | 0.21 | –0.14 (–0.37 to 0.08) |
| 50 | –2.48 (–7.19 to 2.22) | 0.30 | –0.12 (–0.34 to 0.10) |
| 60 | –2.00 (–8.15 to 4.15) | 0.52 | –0.10 (–0.39 to 0.20) |

*p-value for a Wald test of the hypothesis $H_0: \delta = 0$, based on heteroscedasticity-consistent standard errors.
**Based on non-parametric bootstrap (2500 replicates).

*Child in Need (CiN) status*

The majority of participating children were not on a CiN plan, although a substantial minority of participants (~19% of those randomised) were missing this information.[8] The proportion of households with observed primary outcome data where the participating child(children) was(were) on a CiN plan is given in Table 29. Estimates of treatment effects (on both the original and standardised effect-size scales) by CiN status subgroup are given in Table 30. Given the extent of missing data and the sparse data in some strata, these estimates should be interpreted with caution. However, there is some (very weak) evidence that the effectiveness of the intervention varied between the two strata, based on a very

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[8] CiN information was provided by LAs. For some families this data was missing in the data files.

small number. The observed data are compatible with the hypothesis that among children that are not on a CiN plan, the intervention results in small reductions in BPVS-III score compared with treatment as usual. The data are also most compatible with the hypothesis that among children who are on a CiN plan, the intervention results in small increases in BPVS-III score. However, the estimate for this stratum is very imprecise (due to the extremely sparse data), and the data are reasonably compatible with hypotheses positing both large positive, and large negative effects of intervention.

Table 29: Family-level CiN status (families/households with available BPVS-III follow-up data only)

| CiN, n (%) | Control (N = 114) | Intervention (N = 109) | Total (N = 223) |
|---|---|---|---|
| No | 87 (76.3) | 83 (76.1) | 170 (76.2) |
| Yes | 4 (3.5) | 5 (4.6) | 9 (4.0) |
| Missing | 23 (20.2) | 21 (19.3) | 44 (19.7) |

Table 30: Treatment effect and effect size estimates by CiN status

| | Adjusted difference d (95% CI*) | p-value* | Effect size g (95% CI**) |
|---|---|---|---|
| **Not CiN** | −5.40 (−10.63 to −0.17) | 0.04 | −0.25 (−0.50 to −0.01) |
| **CiN** | 4.11 (−16.82 to 25.05) | 0.70 | 0.20 (−0.94 to 1.75) |

*p-value for a Wald test of the hypothesis $H_0: \delta = 0$, based on heteroscedasticity-consistent standard errors.
**Based on non-parametric bootstrap (2500 replicates).

*Free early learning (FEL)*

Around 50% of the households randomised were entitled to FEL. The number and proportion of households with non-missing BPVS-III follow-up data that were entitled to FEL is detailed in Table 31. Estimates of treatment effects (on both the original and standardised effect size scales) by FEL entitlement subgroup are given in Table 32. The estimates by FEL entitlement strata are imprecise due to the relatively small effective sample size. However, there is little evidence of substantial treatment-effect heterogeneity associated with FEL entitlement status. Point estimates in each stratum are broadly comparable, and suggest the data are most compatible with hypotheses positing small negative effects of intervention in both subgroups. However, the interval estimates suggest that the observed data are reasonably compatible with hypothesis positing small positive effects of intervention in one or both strata, as well as moderate-to-large negative effects in one or both strata.

Table 31: Household FEL entitlement (households with non-missing BPVS-III follow-up scores only)

| FEL entitlement, n (%) | Control (N = 114) | Intervention (N = 109) | Total (N = 223) |
|---|---|---|---|
| No | 70 (61.4) | 58 (53.2) | 128 (57.4) |
| Yes | 38 (33.3) | 51 (46.8) | 89 (39.9) |
| Missing | 6 (5.3) | 0 (0.0) | 6 (2.7) |

Table 32: Treatment effect and effect size estimates by free early learning entitlement status

| | Adjusted difference δ (95% CI*) | p-value* | Effect size g (95% CI**) |
|---|---|---|---|
| **No FEL entitlement** | −1.87 (−7.91 to 4.18) | 0.54 | −0.09 (−0.40 to 0.20) |
| **FEL entitlement** | −4.78 (−12.19 to 2.62) | 0.20 | −0.22 (−0.56 to 0.11) |

*p-value for a Wald test of the hypothesis $H_0: \delta = 0$, based on heteroscedasticity-consistent standard errors.
**Based on non-parametric bootstrap (2500 replicates).

**Mediation analysis**

Estimates of the natural direct and indirect effects of allocation are given in Table 33. Given the results of the primary analysis, the results of the analysis of the HLE Index and the small positive correlation between BPVS-III and HLE scores at follow-up (r = 0.1), it is unsurprising that the indirect effect of allocation is close to zero, with the majority of the total effect of allocation being via the direct allocation–outcome pathway. However, the estimates are reasonably uncertain, with the data being quite compatible with the hypothesis that the direct effect (and total effect) is zero, as well as hypotheses posting small positive, or moderately sized negative, direct effects of allocation.

Table 33: Estimates of the natural direct and indirect effects (NDE and NIE) of allocation

| Effect | Estimate (95% CI*) | p-value* |
|---|---|---|
| NDE | –2.05 (–7.05 to 2.94) | 0.42 |
| NIE | –0.10 (–1.27 to 1.07) | 0.86 |
| Total effect (marginal)** | –2.15 (–7.01 to 2.70) | 0.38 |

*Based delta method standard errors.
**Differs from estimate obtained for the primary analysis due to different covariate sets, weighting and variance estimation.

# Implementation and process evaluation results

The IPE is reported below using EEF IPE reporting guidelines, and incorporating the IPE research questions. There are three main sections:

- **Compliance**. This section addresses the extent to which the programme was implemented as planned (RQ1), including the home visitor training received (RQ1.1), the number and length of sessions delivered (RQ1.2) and variation in implementation from the TIDieR framework (Table 3) (RQ1.3). It also looks at the support intervention parents felt they received via the programme during the Covid-19 lockdown (RQ4.5).
- **Fidelity**. This section examines factors relating to the feasibility of programme delivery. In particular, it partially explores the desirability, acceptability and need for the programme within local communities (RQ2), with a focus on who the programme was delivered to (RQ2.1) and parental and programme factors including barriers to, and facilitators of, programme delivery (RQ2.2 and RQ2.3).
- **Perceived outcomes**. This completes the exploration on desirability, acceptability and need for the programme (RQ2) by reporting on usual parenting practice prior to the programme and how or if this changed as a result of participating in the programme (RQ2.4). It also examines the extent to which the ParentChild+ programme impacted on the HLE, particularly on parent–child verbal interactions (RQ3) and wider outcomes of the programme (RQ4), including the impact on parental self-reported confidence and efficacy (RQ4.1), the extent to which participation resulted in take up of the free nursery offer and encouraged attendance at pre-school settings (RQ4.2), the extent to which the programme resulted in increased engagement with wider community services (RQ4.3), and possible diffusion effects of the programme (RQ4.4).

Finally, the IPE addresses the main and subsidiary research questions by integrating them with the data from all data collection and analysis sources. However, first the recruitment to, and participation in, the IPE is discussed.

## IPE Recruitment and Participation

The ParentChild+ programme is designed to support the language development of those who are at risk of suffering the negative effects of deprivation which may ultimately mean that, without additional support, children may not be school ready by the time they start school. Thus, a key part of overall recruitment was to specifically target these individuals (as outlined in the *Fidelity* section of the *IPE* and also in the impact evaluation section of the report). Moreover, it is important, as part of the IPE, to capture the views of as many participants as possible to ensure the IPE is reflective. A range of methods were used to capture this information from participants, LA leads, area coordinators and home visitors, as outlined below. Routine data collection and data collected for the impact evaluation were also used as part of the IPE.

**Post-intervention survey**

All parents in the intervention and control groups were asked to complete the post-intervention survey immediately prior to post-testing (between February 2021 and August 2021). A total of 236 responses to the survey were recorded. Of these, 10 responses were removed as they were either duplicated answers (i.e., the respondents had completed the survey twice, in which case the first survey response, identified during data cleaning, was used) or the survey was blank (i.e., no responses were given). This left 219 responses (n = 219), 113 from families in the control group (n = 113) and 106 from families in the intervention group (n = 106). From the 106 responses from the intervention group, nine were from families who had withdrawn from the intervention (but not from the evaluation). For the purpose of analysis, the withdrawn intervention respondents were not looked at separately from the intervention group due to low numbers, but they were still included in the analysis.

**Parent telephone interviews**

A sample of parents allocated to the intervention group (n = 20) were recruited to attend a Zoom or telephone interview via direct email asking for their participation or via a tick box at the end of the evaluation survey (administered between February 2021 and August 2021). Participants were selectively chosen from the list of interested participants. We selected parents at different timepoints of the evaluation (i.e., those who had completed the visits, those who had not yet completed visits and those who had withdrawn from the intervention). Participants who volunteered to give an interview were entered into a £50 High Street voucher prize draw.

**Home visitor focus group**

Home visitors (n = 3), from three of the four LA areas, were recruited via email and the focus group took place via Zoom during June 2021. No home visitors from the fourth LA responded to requests to join the focus group. This was a change from the proposed one-to-one interviews, as this was perceived more suitable due to Covid-19 restrictions and also allowed home visitors to share experiences with each other as well as with the ET.

**Area coordinator focus group**

All four Family Lives area coordinators (one from each area) were recruited for the focus group which took place via Zoom during July 2021.

**Local authority (LA) lead interviews**

LA lead interviews (n = 3) were conducted with three of the four participating LAs. LA leads were emailed and asked for their participation in the interview. Three LA leads agreed to be interviewed and there was no response from the fourth. The interviews took place via Zoom during May 2021.

**Observations**

A sample of parents allocated to the intervention (n = 31) and control groups (n = 17) was recruited for the observations via a tick box on the consent form completed at the time of recruitment. The number of participants recruited were slightly more than proposed in the protocol (n = 30 intervention, n = 15 control), to allow for any issues with recordings. The final sample size was n = 22 intervention group and n = 15 control group. Participants were selected on a rolling basis both prior to, and following, randomisation and were selected according to LA.

Training in the administration of the coding system was undertaken in the summer of 2019 over three days to reach inter-rater reliability levels of 75+%. Further standardisation checks were undertaken on four videos in the summer of 2020 to check for, and minimise, coder drift.

Further quality assurance procedures were undertaken throughout the coding of the full dataset. Intra- and inter-rater reliability was sought on 20% of all observations. Intra-rater reliability (n = 14) measured using intra-class correlations (ICCs) ranged between 0.925 and 1.00, and inter-rater reliability (n = 14) ranged between 0.688 to 0.992. The category yielding the lowest ICC (prohibitions) was also the category with the lowest number of occurrences.

**Covid-19 survey**

A link to a survey asking about support families may have had during the Covid-19 lockdown was included in the July 2020 newsletter. Additionally, the survey link was also emailed out separately to encourage further responses. Overall, 57 control, 41 intervention, and four undisclosed allocation families (total n = 102) responded to the survey.

## Compliance

Box 1: Compliance key findings

Routine programme data gathered from the developers showed that:
1. training given to home visitors was comprehensive and attendance was 100%
2. over half of all intervention families (62%) reached the minimum compliance threshold (78 sessions) for intervention visits
3. during Covid-19 lockdowns sessions moved online, but throughout the intervention face-to-face sessions were the most common form of delivery
4. consequently, this also means that over a third of families did not receive the minimum compliance threshold number of sessions and over a third of sessions were delivered online, which was not delivery as intended.

Successful delivery of the ParentChild+ programme was dependent on three main factors: training of the home visitors and attendance at training, the number of sessions of the programme delivered to intervention families, and any variation in implementation which may have impacted on the ability of intervention families to comply. This section describes these three elements in further detail. Further information can be found under '*Adherence to programme*' in the Impact Evaluation Results section above.

**Home visitor training and attendance**

This section addresses RQ1: To what extent was the programme implemented as planned? It is particularly relevant to RQ 1.1 What training was received and were there any implementer factors in programme delivery?

All home visitors, across the three recruitment phases, attended all modules and sessions. Recruitment was conducted in three timepoints as recruitment of families increased. Training was delivered over two days, covering two modules and 11 sessions (overview in Table 34). Sessions lasted between 30 and 80 minutes (average 52 minutes) and each module ended with a review of the topic covered. Two members of the ET attended both days' training during the first recruitment phase, to ensure all points from the training were covered. Additionally, the ET also gave a 30-minute presentation about RCTs to all home visitors to ensure the randomisation process was understood and, as home visitors played a part in the recruitment of participants, to help home visitors manage the expectations of participants. It should, however, be noted that training did not cover online delivery of the programme which, due to the pandemic, was the mode of delivery for over a third of programme sessions (35%).

Table 34: Home visitor training overview

| Session/Module | Expected time | Main training points | Point covered Y/N |
|---|---|---|---|
| Module 1, Session 1 – Introduction to the course | 60 minutes | • Welcome and introductions<br>• Introduction to the course<br>• Icebreaker activity | Y |
| Module 1, Session 2 – Introduction to PC+ | 45 minutes | • PC+ philosophy, history and logic model<br>• Core components of PC+ | Y |
| Module 1, Session 3 – What is an RCT? What happens? Who does what? | 50 minutes | • What is an RCT?<br>• Funding<br>• Role of the ET<br>• Timescales and recruitment | Y |
| Module 1, Session 4 – Role of the home visitor | 30 minutes | • Role and expectations<br>• Home visitor relationship with parent and child<br>• Verbal interactions with parent and child<br>• Parent as the child's most important teacher | Y |
| Module 1, Session 5 – Home environments | 60 minutes | • What does a rich HLE look and feel like?<br>• Types of issues faced by families and why programme is needed<br>• What is meant by 'our own map of the world'? | Y |
| Module 1, Session 6 – Exploring attitudes, values and prejudice | 50 minutes | • Equality, cultural awareness, attitudes and being non-judgemental, and how own values affect behaviour and responses. | Y |
| Module 2, Session 7 – Child development | 80 minutes | • Core components of PC+<br>• Importance of the first 1000 days<br>• 1001 critical days manifesto and two-year offer<br>• Theory of child development<br>• EYFS resource for parents<br>• Attachment | Y |
| Module 2, Session 8 – PC+ processes and paperwork | 50 minutes | • Overall processes<br>• Paperwork | Y |
| Module 2, Session 9 – Introduction to Child Behaviour Traits (CBT) and Parent and Child Together (PACT) | 60 minutes | • Parent and Child Together assessment measures<br>• Child Behaviour Traits assessment measures<br>• Documents for guidance | Y |
| Module 2, Session 10 – PACT in practice | 40 minutes | • Activity and video<br>• Compare and discuss | Y |
| Module 2, Session 11 – ParentChild+ best practice home visiting and exploring boundaries | 45 minutes | • Video – Best practice home visits<br>• Activity on what can and can't be shared with parents | Y |

**Programme sessions delivered**

This section addresses RQ1: To what extent was the programme implemented as planned? It is particularly relevant to RQ 1.2: What was the number and length of sessions delivered?

Compliance for the intervention was defined as receiving 85% (n = 78) of the 92 sessions. This definition was agreed as appropriate by Family Lives, EEF and the evaluation team. Of 141 intervention families recruited, 88 families (62%) had 78+ intervention sessions, 43 families (31%) had between one and 77 intervention sessions, and 10 families (7%) had zero intervention sessions. A breakdown of the percentage of intervention sessions reached can be found in Figure 6. The data indicate that just over half of all families reached the minimum session threshold.

Figure 6: Percentage of intervention sessions reached
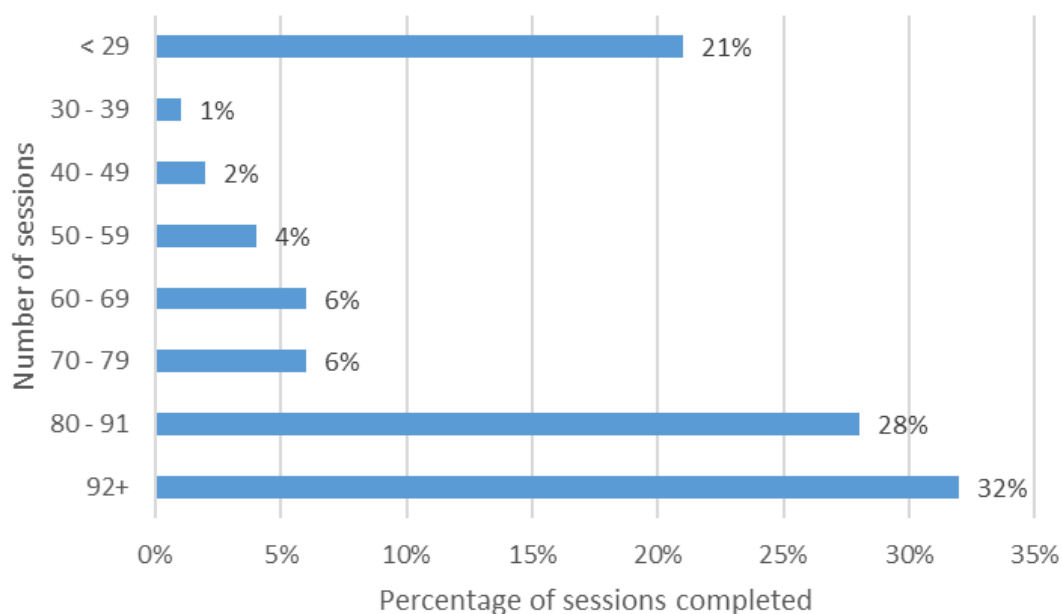


**Variation in implementation due to Covid-19**

This section addresses RQ1: To what extent was the programme implemented as planned? It is particularly relevant to RQ1.3: Any variation in implementation and, if so, why?

Due to the Covid-19 pandemic a contingency of online sessions was utilised from June 2020 and continued to be used, where needed (e.g., for families or home visitors in isolation), for the remainder of the project. Over the duration of the intervention, the majority of sessions were delivered on a face-to-face basis (n = 6158). However, over a third of sessions were delivered online, which was not delivery as intended and not an area home visitors (understandably) were trained in (n = 3396).

# Fidelity

Box 2: Fidelity key findings

Interview/focus group responses from parents, LA leads, home visitors and area coordinators, along with post-test survey responses from parents, lead to the following key conclusions:

- there is a need for ParentChild+ within the LA areas due to poor take-up of nursery provision and several risk factors which mean children enter school with poor language and general development. The ParentChild+ evaluation specifically targeted (and recruited) these families (specifically EAL- and CiN-status families) though not all families would have chosen to engage. It is important to note that one of the inclusion criteria for the programme was a minimal threshold for English language which could have impacted on the number of EAL families within the programme.
- the challenges encountered in terms of recruiting families appeared to be twofold: families not understanding the purpose of the research and staffing levels needed to build enough of a relationship with the family to get them to sign up to the programme.
- the majority of parents found the intervention easy to fit into their daily routine, largely because of their own flexibility, but parents' own lack of knowledge with and a lack of access to technology was a barrier once delivery was moved online during the Covid-19 pandemic, as was children's engagement with an on-screen presence compared to face-to-face interactions.
- the family's relationship with their home visitor was a strong facilitator in programme delivery along with the home visitor's flexibility in arranging/rearranging sessions.
- a small number of families interviewed made comments that suggested that some parents may not have been fully aware of the purpose of the intervention.
- the majority of families clearly appreciated the support (e.g., signposting to services, giving advice on activities to do with children) offered through Family Lives during the Covid-19 pandemic but it is important to note that intervention families were being provided with activities to do with their children during lockdown. This could mean that some families were essentially still receiving elements of the intervention during this time.

To understand how ParentChild+ worked in practice, we sought to investigate four main areas where fidelity could be of importance: the target group and whether the target group was reached, parental factors to programme delivery, programme factors to programme delivery, how the additional support offered to intervention families during the Covid-19 lockdown may have supported intervention families, and the potential impact on the intervention on the whole.

**Target group**

This section addresses RQ2: What is the desirability, acceptability and need for the programme within local communities? It is particularly relevant to RQ 2.1: Who was the programme delivered to – was this the target population?

The ParentChild+ programme was aimed at two groups: those families who were eligible for, but not taking up, free nursery places and, following lower than expected recruitment, those families who live in LLSOAs. Interviews with LA leads (n = 3) probed into the desirability and acceptability of the programme, nursery place take up within the LA areas as well as existing LA provision and recruitment issues.

Regarding the desirability and acceptability of the programme and existing provision, all three LAs reported that while there is generally good take up of provision offered to the target families, EAL families tend to be the families not taking up the local provision offered. For example, one reported that:

> *'20% of eligible families don't take up the offer of provision. Reasons are cultural, and tend to be in multi-ethnic areas. Where families have not taken up existing provision, the children are less school ready' (LA 2).*

Importantly, another LA lead also said:

> *'Children in these localities are likely to be growing up in poverty, and may be experiencing a range of hidden harms, for example, parents affected by substance abuse, unemployment, domestic abuse, mental health issues' (LA 3).*

This suggests that the target families of most concern are those from multi-ethic areas and those children who may be listed as CiN. Data provided in the impact evaluation suggests that, from the sample recruited for ParentChild+, 8.8%

of the control group were EAL and 9.7% of the intervention group were EAL, meaning that only a small percentage of EAL families were involved in the research. Additionally, only a small percentage of the sample recruited (4.0%) were classed as having CiN status, although there was a high percentage of missing data (19.7%). This suggests that, while target families were recruited (those entitled to, but not taking up, a free nursery place and those from LLSOA), the families of most concern to the LAs were not as well recruited. It is important to note here that one of the inclusion criteria for the programme was a minimal threshold for English language which would have impacted on the number of EAL families within the programme.

It was therefore also important to understand any issues with recruitment faced by the LAs, as this would help inform future research. One LA suggested that it was difficult to explain the purpose of the control group to participants and why they may not get the intervention if recruited, indicating that the research itself was a possible barrier. The LAs also reported that they had believed recruitment in general would be easier. LA 1 and LA 2 talked about the initial barriers to recruitment, which included staffing issues and having to expand the geographical area. With regards to recruiting, one LA stated:

> *'It was by sharing the information of those parents that didn't take up the offer [of childcare places] and people ringing around and just building a relationship up with the parent. Really explaining the programme, building that relationship up and building that confidence up with the parent, to get them engaged' (LA 1).*

Thus, the issue of recruiting families appeared to be twofold: families not understanding the purpose of the research and staffing levels needed to build enough of a relationship with the family to get them to sign up to the programme.

In addition, it was important to understand the need for ParentChild+ within each of the LA areas. LA 1 suggested that, although take-up of existing provision is high, the LA would like it to be higher. The LA wanted to see if ParentChild+ would work – hence involvement in the evaluation. Critically, the LA said it did not have the resources to offer what PC+ offers. LA 2 suggested it was vital to get families into existing local services when their children are at an early age, to improve speech, language and communication and they believed that the ParentChild+ programme could help:

> *'School readiness is a concern in some areas of the LA, and some parents do not understand the importance of this. There is a lack of understanding of the best ways to support their children. The families most at risk are those with a low level of educational qualifications and poor English language skills' (LA 2).*

One LA also talked about the importance of engaging families with provision early as soon as a need is identified:

> *'It is challenging to engage with families. The LA understands that some families choose not to engage with the provision. The LA works in partnership with charities, who provide funding for specific initiatives, for example resource packs taken into families as they recognise the need for children to be school ready. Current provision is targeted to individual needs. A priority is parents' knowledge, skills and understanding' (LA3).*

There is a clear need for provision in the LAs to ensure parents understand the importance of their child(ren) being school ready. However, reaching families is clearly an ongoing issue. In terms of recruitment for the RCT, it is possible that this was a hindrance and, in its absence, LA recruitment may have been higher.

**Parental factors in programme delivery**

This section addresses RQ2: What is the desirability, acceptability and need for the programme within local communities? In particular, it addresses RQ 2.2: Were there any parental factors resulting in barriers to, or facilitators of, programme delivery?

As part of the evaluation survey, we asked participants to rate how they found fitting in the weekly sessions. Participants were asked to rate this on a scale of 1–10 (1 being extremely easy and 10 being extremely hard). 79% of participants rated fitting in the weekly sessions between one and three, 14% of participants rated between 4 and 6 and 7% rated between 7 and 10 suggesting that the majority of participants who completed the questionnaire found the visits easy to fit into their daily routine. To probe this further we asked the reasons for the answers given. The results indicated that parents' own flexibility supported the facilitation of weekly visits whereas the Covid-19 pandemic and working patterns hindered their ability to be able to stick to the scheduled weekly visits. In particular, the move to online sessions was

mentioned by some participants, due to their own inexperience with technology or technical issues, as well as their child's (lack of) engagement with online delivery, as affecting the sessions.

To understand further parental factors to programme delivery we looked at the reasons parents gave for withdrawing from the programme (see Table 35). Reasons were provided by the Family Lives area coordinators.

Table 35: Reasons for withdrawing from the intervention

| Reasons for withdrawal from intervention | Number of participants* |
|---|---|
| Withdrawn from intervention and research | 4 |
| No contact or lack of engagement | 13 |
| Ill health | 4 |
| Child attending nursery | 2 |
| Parent too busy/working | 6 |
| Covid-19 | 2 |
| Child not benefiting from intervention | 1 |
| Didn't want to continue | 2 |
| Other | 1 |

* More than one response could be given.

Overall, the data suggest that the programme, while intensive, can be modified if parents can be flexible as to when the sessions take place. Busy working/life schedules can also make fitting in the weekly visits more difficult. The area coordinators also emphasised the difficulties faced in day-to-day life by many of the families that could make programme delivery problematic:

> 'they also had so much going on personally for them … there was so much social care intervention, health intervention, other things that was so much more pressing for them, you know? Needing to visit food banks, needing to go and put electricity on because they'd not had any for that morning to get the kids up and get them ready for school then give them breakfast' (Area Coordinator).

**Programme factors influencing programme delivery**

This section addresses RQ 2: What is the desirability, acceptability and need for the programme within local communities? In particular, it addresses RQ 2.3: Were there any programme factors resulting in barriers to, and facilitators of, programme delivery (e.g., intensity of programme, home visitor–parent relationship)?

As part of the evaluation survey, we asked participants about their relationship with the home visitor. Specifically, parents were asked to rate how they agreed with the statement *'I feel I have a good relationship with my home visitor'*. Participants were asked to rate on a 5-point scale from strongly agree to strongly disagree. Results showed that 90% of participants strongly agreed they had a good relationship with their home visitor, 8% said they agreed, 1% stated they neither agreed nor disagreed and 1% said they disagreed. Thus, the relationship with the home visitor was deemed to be a strong facilitator in the delivery of the programme. The importance of building a strong relationship with parents and their children during home visits was also mentioned frequently in the focus groups (by area coordinators and home visitors). Area coordinators also mentioned, where possible, deliberately 'matching' families with 'the right' home visitor:

> 'I think as a role of coordinator that's been so key in allowing the programme to go to completion because if they'd not been matched with the right home visitor, it could have been so different' (Area coordinator).

In relation to length of session (mean = 29.7 minutes), during the interviews parents commented that a 30-minute session was a good amount of time. One parent commented:

*'If you've ever tried keeping a toddler entertained for more than half an hour on one item it's not easy to do. That's one of the good things about having so many items used within the programme: he can interact with an item for 10 or 15 minutes … So, the 30–40-minute home visits were a good length to keep him focused on one task' (PT0173).*

However, where visits were done online, or continued online after the Covid-19 lockdown due to parental concerns or positive Covid-19 cases, one parent stated:

*'When it came to the video calls I think it was a little bit long because he just doesn't really have that attention span to sit there for a long period of time like longer than maybe five minutes. So, when it was trying to say to them, "He needs to sit and play with these toys or read this story", I think for him he was like, "I've read it once, that's it; I'm done and dusted, I'll see you later", like, "I'm done now", and he was like, "I'm not bothered about anything else". And he didn't really want to sit there and have the conversation with them, he just wanted to go off and play with his own toys. So, for the video calls I think it was a bit long but when it was face-to-face it was fine' (PT0363).*

The difficulties of getting a young child to engage with online delivery was mentioned by some interviewees, which was exacerbated (as in this case) when that child had SEND.

We also asked parents, during the interviews, their opinions on the frequency of sessions. The majority of parents interviewed said that the frequency of the sessions was suitable for them and this was mainly due to the flexibility of the home visitors. One parent commented:

*'the times and the days we got were absolutely fine for us. If they weren't, we always said to them, "Look, we're really sorry, we can't do this day for whatever reason," and they were always really accommodating to us' (PT0329).*

A second parent also said:

*'I think the timing of the visits has been spot on. It's usually been decided by me myself or the home visitor. I think it just depends if something pops up and obviously you've got to change things. You just work around it' (PT0377).*

Thus, most parents were clearly appreciative of the flexibility of the home visitors. However, two participants said that two weekly sessions were not easy to organise, with one parent commenting:

*'I suppose it felt a little bit full-on when it was twice a week' (PT0363),*

and another parent said:

*'It were, like, it wasn't the regular set times, slot times, and that's what made it a bit difficult with [child], because I like a routine or whatever. And sometimes it were, like, you couldn't plan your day because, you know, or your week, because I like to plan the week, but I couldn't plan the week until we knew when [home visitor] were going to ring. I mean, she does give me a few days' notice, etc., or she'll give me a week's notice, but sometimes… But I mean, we've all got to understand that we were all in the same boat anyway, so I mean, that weren't really too difficult, no' (PT0331).*

One parent also said that they found the home visitor to be inflexible stating:

*'I don't think there was very much support if we needed to take a week off if [child] was finding it a little bit overwhelming; I don't think there was very much support for that, so it didn't really meet my expectations of support through it kind of thing' (PT0363).*

**Other factors to programme delivery**

An important part of the ParentChild+ programme is about the home visitors modelling to parents how to interact with their child(ren). This aspect of the IPE addresses RQ2: What is the desirability, acceptability and need for the programme

within local communities? During parent interviews, two parents indicated that they had received the intervention in this way, with one parent commenting:

> *'And we would go back and forth in terms of where I would take control and then I'd take a step back and [home visitor] would come in and she'd kind of navigate us and direct us' (PT0214).*

However, three parents also made comments about feeling happy to leave their child with the home visitor, with one parent saying

> *'I trust them, so I can leave them with [child] without worry' (PT0129),*

and another parent stating:

> *'I'm not really sure if it's necessarily supported me as a parent because I feel like there wasn't really the support there for me; it was more the support there for [child]. So, I don't really feel like it's really supported myself as a parent in a way' (PT0363).*

This may have an implication for the evaluation as this suggests that some parents may not have been fully aware of the purpose of the intervention. In the focus groups, the home visitors and area coordinators echoed these sentiments:

> *'it's about encouraging parents not to sit back and just let you do it all, because I think in the beginning my parents definitely did, and they didn't really understand the parent part of the programme I don't think. Like the Parent+ bit' (Home Visitor).*

In contrast, however, many more parents discussed having the time to spend with their child that the programme facilitated as one of the aspects of the programme they most enjoyed, as well as the relationship they built with the home visitor (as discussed above).

**Support during the Covid-19 pandemic**

The full Covid-19 survey results report can be found in Appendix 4. Below is a short summary of the findings, which address RQ5: How did parents feel the continued contact during the Covid-19 lockdown supported them and what support was offered? The results also address RQ 1.3: Any variation in implementation and, if so, why? and RQ4: What was the impact in terms of parental self-reported confidence and efficacy?

The main aim of the Covid-19 survey was to assess parents' sources of educational support for their child, and the support that families in the intervention group had received from Family Lives during the lockdown period. A total of 102 families took part in the study out of a potential 283 participating families. The sample represents approximately a third (36%) of the overall trial sample, and therefore we cannot be confident that the findings within this survey are representative of the experiences of all the families enrolled in the larger RCT. In addition, the families who completed the survey are more likely to have been more engaged in the research programme.

Of the 41 intervention families who took part in the survey, 38 families (93%) reported contact with Family Lives, 22 of which reported twice-weekly contact, which is the same amount of contact families would have received as part of the intervention during delivery outside of the pandemic, although the amount of time spent for each contact is not clear. Thirteen families also reported once-weekly contact with Family Lives. From the data provided, 80% of this contact involved Family Lives providing parents/carers with ideas for activities to do with their children. This has important implications with respect to the evaluation as it means that some families were essentially still getting similar support to that being provided as part of the intervention although this support did not involve interacting with the parent and child together, but this is not accounted for in the number of sessions recorded for the impact evaluation. Essentially, this means that some families, at the end of the intervention, will have had more sessions than those recorded, although the nature of the sessions was not as intended by the programme. However, as reported above, in the interviews parents reported difficulties in online provision, particularly with engaging young children with this form of delivery. In addition, a third of interviewees indicated having some form of technical challenge with the online sessions, primarily related to the online platform used (either Zoom or Microsoft Teams) or internet connectivity. In addition, of those interviewees who reported the form of technology used for online delivery, half reported using their phone which brought its own difficulties in terms of the size of the screen:

> *'I was trying to hold my phone up somewhere or stand it up so they could see both kids' (PT02039).*

Overall, it is important to note that almost 60% of families in the intervention group also said that the contact they had with Family Lives was generally discussing the difficulties of the lockdown. As one area coordinator described it:

> *'[We knew we were] going to have certain issues going on in personal lives, particularly working with families as closely as we do, so there was a bit more of a focus on how to sort of help someone get through those issues, what could we do to signpost, advise and support' (Area coordinator).*

Families clearly appreciated the support from the home visitors in what was a very difficult time. It is therefore important to acknowledge the work done by Family Lives during the lockdown, as it was clearly helpful to many families and it may well have had a positive impact on engagement with the programme and the retention of intervention families. The home visitors, however, felt that it had a mixed impact on engagement with the programme:

> *'some weeks we are not reaching like our full potential because of the parent not wanting to do the virtual session … But on a positive, we've all got families that respond better to virtual than face-to-face … In some ways it's brought us closer' (Home visitors).*

In order to understand what activities families had been doing during the lockdown period, we asked all families to list five activities they did with their child(ren) in a typical week. Activities were then grouped into five categories: educational activities, physical activities, fine motor skill activities, play and screen time. Across the intervention group and the control group, family activities were generally similar across all categories, although control families seemed to have more variation in the activities they were doing compared to intervention families. Additionally, control group families reported doing more walking, more roleplay and general play and had slightly more screen time compared to intervention families. This is important for the evaluation as it demonstrates that intervention families may have been doing other activities (possibly those suggested by Family Lives) during the lockdown period. A further finding suggested that families had little screen time with their children during lockdown. (For further details see Appendix 4.)

The data suggest that families in the control group were less likely to seek support than those in the intervention group. The intervention group were more likely to seek some level of support. It may be that positive experiences of the programme encouraged participants to actively seek and engage with other forms of help. Families from intervention and control groups reported seeking support from Twinkle, local online group sessions, YouTube and school websites (where families also had older children). However, there seemed to be differences between control and intervention groups with other support accessed. Intervention families reported using more apps that directly helped with maths and literacy, such as Times tables rock stars and ABC mouse. Control group families reported using more BBC Bitesize and phonics-based websites.

# Perceived outcomes

Box 3: Perceived outcomes key findings

Interview/focus group responses from parents, home visitors and area coordinators, along with post-test survey responses from parents, data collected on the HLE and observations looking at parent–child interactions lead to the following conclusions:

- activities measured by the HLE Index, and the time spent doing activities in the home were equivalent, at pre-test, across control and intervention groups.
- attendance for external group activities and educational services was similar across control and intervention groups, at both time points (pre-test and post-test), as was attendance at nursery (which included all families eligible for a free nursery place and all families living in LLSOAs).
- overall, activities done with children in both the home and externally were similar across both groups at pre-test, so the evaluators are confident that any differences found at post-test would be as a result of the intervention (with the exception of any chance differences).
- child behaviour and achievement, as perceived by the parent, was largely consistent across both control and intervention groups.
- the impact on the home learning environment, as measured by the HLE Index, did show small to moderately sized increases in the HLE Index. In contrast, observation data showed noticeable differences between groups at follow-up on only two categories: parent acknowledgements and child spontaneous vocalisation. In both cases, families in the control sample were exhibiting greater frequencies within these categories.
- attendance for group external activities dropped from the start of the research programme (for both control and intervention groups), though this appeared largely to be because of Covid-19.
- changes in attendance for social and educational services either dropped or stayed the same, with the exception of the increase in attendance at parent and toddler swimming groups (though the increase was small and only seen for the control group) and attendance at portage (in which attendance increased for both groups). Covid-19 was the biggest contributor for the drop in attendance. However, it is also clear that some families had taken up using some services due to referrals from schools and nurseries. Thus, it is unclear whether the intervention programme, in the absence of Covid-19, would have impacted on attendance for social and educational (other than nursery) services.
- slightly more intervention families than control families have sent their children to nursery since the start of the research 18 months ago.
- the majority of parents spoke highly about the programme and the home visitors and said that they could use what they had learnt during the programme with other children in their family and that other adults in the household were also taking on some of the techniques learnt.
- parents' experiences of the programme were very positive for the large majority of the parents interviewed.
- the programme had a clear impact on parents' self-reported confidence and efficacy.

In this section we look at some key outcomes, as outlined in the ParentChild+ logic model, using data collected as part of the IPE. Specifically, we explore usual parenting practices and the changes perceived by parents in both the intervention and control groups, the impact on the home learning environment from data collected during observations of parent–child interactions (and data gathered using the HLE Index), wider outcomes in terms of changes in attendance of community activities and the take-up of nursery places. From intervention families, we look at perceived diffusion effects, the experience of the programme, and also the impact on self-reported efficacy and confidence. These are discussed in turn below in more detail.

**Usual parenting practices**

Below we present what usual practice looked like for intervention and control families in terms of the home learning environment (as measured by the HLE Index: (Melhuish, 2010). We also draw on data from the post-test survey to understand similarities and differences between groups in terms of the attendance at external group activities (e.g., playgroups), and social and educational services (e.g., family centre-led baby clinics), and also child attendance at nursery prior to taking part in the programme.

*Usual practice in the home at pre-test*

Control and intervention families completed the HLE Index during pre-test (between July 2019 and January 2020) to establish what activities were done in the home with children and how often they were done. A score was given for each item on the scale and data were calculated as a raw score. For the purposes of the IPE, we calculated the average at pre-test in intervention and control groups. From the original sample in the control group (n = 142), 131 (92%)

participants completed the HLE Index at pre-test with an average score of 30. From the original sample in the intervention group (n = 141), 133 (94%) participants completed the HLE Index at pre-test with an average score of 29. These results address the IPE RQ 2.4 What was usual parenting practice in the absence of the programme (i.e., at pre-test)? It can be inferred from the results that both groups were equivalent in terms of the HLE Index at pre-test. The questions asked as a part of the HLE index included number of times read to a child, singing with the child and amount of time child spent drawing and painting (Index items can be found in Appendix 5). For example, when broken down by item it can be seen that, at post-test:

- 95% of parents/carers reported that someone at home read to their child, and of these, 55% reported that this occurred at least once a day;
- 92% reported that someone in their home taught the child songs, poems or nursery rhymes, nearly half of whom (49%) stated that this occurred daily; and
- 93% reported that their child did draw and paint at home, but less than a quarter (24%) reported that this happened daily.

*Usual practice for external activities at pre-test*

Control and intervention families were asked to complete the evaluation survey at post-test (between January 2021 and August 2021). The survey asked about attendance for external activities (attendance at group activities, attendance at social and education services and nursery attendance) prior to the research programme (i.e., the previous 18 months). Participants could select between attended regularly, attended sometimes, attended infrequently and did not attend. For all group activities, which included church groups, family centre groups, specialist groups and parent carer groups, levels of attendance were similar in both intervention and control groups (see Table 36).

Table 36: Cumulative participant attendance for external activities

| Participant attendance | Control N = 113 | Intervention N = 106 |
|---|---|---|
| Regular attendance | 18% | 18% |
| Some attendance | 17% | 14% |
| Infrequent attendance | 11% | 12% |
| Non attendance | 54% | 56% |

For attendance at educational services, which included library groups, swim sessions, baby clinics, portage, speech and language and health visiting, again this was largely similar across both intervention and control groups (see Table 37).

Table 37: Cumulative participant attendance at educational services

| Participant attendance | Control N = 113 | Intervention N = 106 |
|---|---|---|
| Regular attendance | 8% | 9% |
| Some attendance | 11% | 14% |
| Infrequent attendance | 9% | 11% |
| Non attendance | 72% | 66% |

With regards to nursery attendance, again the figures were similar across control (25%) and intervention groups (21%). It should be noted that all families (not just families who were eligible for, but not taking up free nursery places), were included in this analysis for the purpose of understanding usual practice.

Given the figures in both control and intervention groups are similar throughout, it is reasonable to assume that usual practice was the same across control and intervention groups prior to the research programme. Thus, any differences in practice in terms of educational services found at post-test could be deemed to be as a result of the intervention (with the exception of any chance differences). However, there is also the possibility that taking part in the evaluation itself encouraged parents allocated to the control condition to be more aware of, and to seek out, opportunities to support their children's development.

As part of the evaluation survey, we wished to establish if there were any changes in the behaviour or achievement of the children, as perceived by the parents in both intervention and control groups over the previous 18 months. This addresses RQ 2.5: How did parenting practices change as a result of taking the ParentChild+ programme? Were there any changes as a result of being in the control condition?

In the first instance, we asked about changes in behaviour (see Appendix 1 for the framing of these questions). In the second instance we asked about changes in achievement. We then asked about changes in the relationship between the child and the parent. Finally, we asked about changes in language. For each question the respondents could select strongly agree, somewhat agree, neither agree nor disagree, somewhat disagree, or strongly disagree. This also addresses RQ3: To what extent did the ParentChild+ programme impact on the HLE, particularly on parent–child verbal interactions?

Three control families and one intervention family did not answer this set of questions. Thus, data from 110 participants in the control group (n = 110) and 105 participants in the intervention group (n = 105) were analysed for this section. Results for each question asked are displayed in Tables 38 to 41.

Table 38: Parent responses for improvements in child's behaviour

| Group | Strongly agree | Somewhat agree | Neither agree nor disagree | Somewhat disagree | Strongly disagree |
|---|---|---|---|---|---|
| Control (N = 110) | 30% | 25% | 30% | 13% | 3% |
| Intervention (N = 105) | 44% | 27% | 25% | 3% | 2% |

Table 39: Parent responses for improvements in educational achievement

| Group | Strongly agree | Somewhat agree | Neither agree nor disagree | Somewhat disagree | Strongly disagree |
|---|---|---|---|---|---|
| Control (N = 110) | 56% | 31% | 9% | 3% | 1% |
| Intervention (N = 105) | 66% | 25% | 8% | 1% | 1% |

Table 40: Parent responses for improvements in relationship with child

| Group | Strongly agree | Somewhat agree | Neither agree nor disagree | Somewhat disagree | Strongly disagree |
|---|---|---|---|---|---|
| Control (N = 110) | 49% | 24% | 26% | 0% | 1% |
| Intervention (N = 105) | 46% | 29% | 22% | 2% | 2% |

Table 41: Parent responses to improvements in child's language

| Group | Strongly agree | Somewhat agree | Neither agree nor disagree | Somewhat disagree | Strongly disagree |
|---|---|---|---|---|---|
| Control (N = 110) | 58% | 27% | 12% | 1% | 2% |
| Intervention (N = 105) | 65% | 19% | 14% | 0% | 3% |

Two of the questions on the survey asked parents about improvements seen in child behaviour and educational achievement, and responses were slightly more positive in the intervention group than in the control group. However, in the other two questions regarding improvements in the relationship with the child and child's language, results were similar across both control and intervention groups. These results suggest that any improvements seen by parents could be as a result of ParentChild+ but other factors could not be ruled out (e.g., general development or unconscious bias from those parents who participated in the programme). The home visitors in their focus group were keen to point out individual cases within their caseload as examples of successful outcomes of the programme. These tended to focus on language and communication, behaviour and educational achievement. Many examples were of children perceived to have some form of developmental delay or special educational needs which would not necessarily have been captured in the parent survey, for example:

> *'he is being assessed for autism, but he couldn't concentrate for more than ten seconds. And by the time we'd finished he could do a whole session and give me eye contact and speak. He didn't have any language when I first started'* (Home visitor).

**Impact on the home learning environment (HLE)**

*HLE Index*

Control and intervention families completed the HLE Index during post-test (between January 2021 and August 2021) to establish what activities were done in the home with children and how often they were done. As with the pre-test data for the IPE, we calculated the average based on the raw score. From the original sample in the control group (n = 142) 113 responses were collected, with an average score of 27. In the intervention group, from the original sample (n = 141) 104 responses were collected, with an average score of 31. This addresses the IPE RQ 3: To what extent did the ParentChild+ programme impact on the HLE, particularly on parent–child verbal interactions?

As the HLE impact has already been covered in the Impact analysis secondary outcome analysis, we reiterate the findings of the HLE Index: For the HLE Index, the estimated difference (intervention – control) in expected score at follow-up is 3.60 (95% CI 1.06 to 6.13, $p = 0.01$), and the estimated (standardised) effect size is 0.31 (95% CI 0.10 to 0.54). Therefore, the data are highly compatible with the hypothesis that the intervention results in small to moderately sized improvements in the home learning environment (as measured by the HLE Index) compared to usual practice.

*Observation*

As outlined in the measures section, the process involved a 20-minute semi-structured videotaped observation in the home (or on Zoom, in the case of online data collection) 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 involved 10-minutes of the parent and child interacting during free-play, followed by 10 minutes of shared book reading. Videos were coded to form frequency counts to provide an overall assessment of parent–child verbal and non-verbal behaviours relating to the HLE.

Observations lasted an average of 19.52 (*SD* = 1.97) minutes at baseline and 17.25 (*SD* = 4.69) minutes at follow-up. Follow-up observations took place on average 19.04 months (*SD* = 0.90) after baseline.

*Subsample characteristics*

A total of 48 parent–child dyads provided consent to take part in the observational component of the study. Retention of parents from consent to follow-up was 58%. Participant information for observations can be found in Figure 7. The age of the children at baseline was 2.35 years (*SD* = 0.32) and at follow-up 3.97 years (*SD* = 0.36).

Figure 7: Observation participant flow diagram
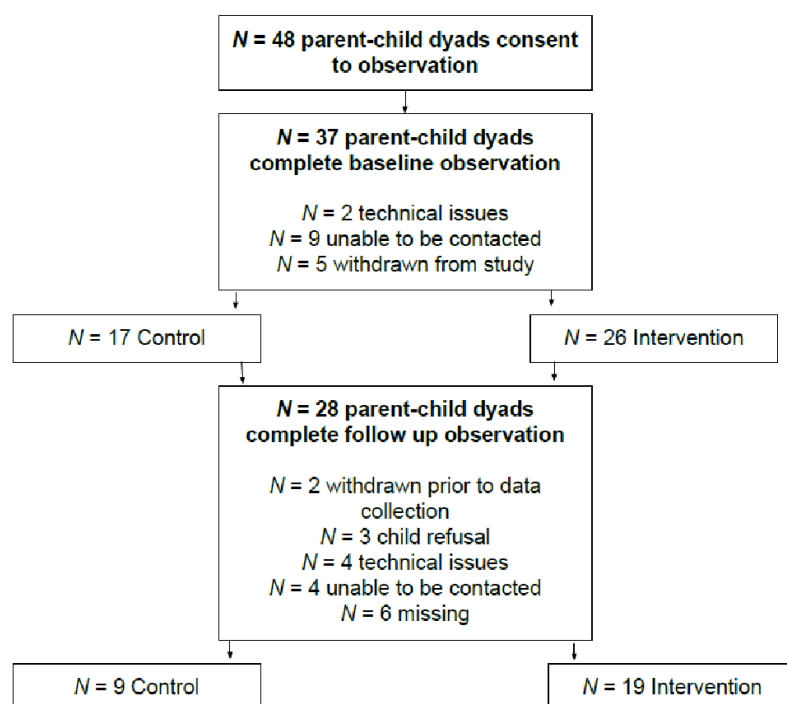


Initial analysis was conducted on all cases where data were available at either baseline or follow-up. No noticeable differences were observed between groups in overall time spent in either reading or play at follow-up. No noticeable differences were observed between the two groups across any of the 13 parent–child categories at baseline. The only observable differences found between groups at follow-up were parent acknowledgements and child spontaneous vocalisation. In both cases, families in the control sample were exhibiting greater frequencies within these categories. No significant differences were observed for the parent categories of direct text reading, statements, commands, general questions, educational questions, labelling, praise, affirmations, prohibitions, and nursery rhymes. The non-significant child category was child responses.

A second analysis was conducted only on cases where there was data available at both baseline and follow-up for each dyad. No noticeable differences were observed between groups in overall time spent in either reading or play at baseline or follow-up. Analysis indicated no differences between groups on any category of observed behaviour at baseline. Observable differences were found between groups at follow-up on parent acknowledgements with the control sample exhibiting more of this category than the intervention group.

As a whole group (intervention and control combined), reductions were observed for parental commands and child spontaneous vocalisations There was also an increase in child responses to parental verbalisations. These findings speak to expected developmental changes in parent–child language use associated with this age range i.e., a reduction in parental direction and an increase in conversational turn-taking. Tables presenting the data can be found in Appendix 7.

**Wider outcomes**

The IPE RQs 3 and 4 address wider outcomes: What were the wider outcomes of the programme? Specifically, 4.2: To what extent did the programme result in increased parent (and child) engagement with wider community services? It is worth noting, however, that during the pandemic access to many additional services was curtailed, pandemic delivery measures varied by location/provider and engagement may not have been possible, although this would have impacted on both control and intervention groups.

In terms of wider outcomes, the home visitors focused their perceived impact of the programme on nursery attendance and on access to wider service provision. For example:

> *'I've got two families they are being assessed for autism, and maybe three families that work with speech and language' (Home visitor).*

*'something like 85% with our families [in our LA] have now sent the children to nursery because we've encouraged them to send them to nursery' (Home visitor).*

This was explained in terms of the relationships formed through the programme with parents:

*'I think that is massive that they have trust in other professionals because they've got a relationship with us' (Home visitor).*

To assess potential changes between control and intervention groups following the research programme, we asked about attendance at a range of different locally provided services in the post-test evaluation survey. It was hypothesised that, as parents became more aware of their child(ren)'s learning needs, attendance with wider community services would increase. We looked individually at the different types of group activities and calculated the percentage difference between pre- and post-test. Tables 42 to 51 report the percentages of attendance for each type of group activity.

*Attendance at community/church groups*

Table 42: Parent-reported attendance at community/church groups pre- and post-test

| | Group | |
|---|---|---|
| **Attendance at baseline** | **Intervention (N = 106)** | **Control (N = 113)** |
| Attended regularly | 24% | 35% |
| Attended sometimes | 18% | 18% |
| Attended infrequently | 12% | 11% |
| I did not attend | 46% | 37% |
| **Attendance at the end of research** | | |
| Attended regularly | 9% | 8% |
| Attended sometimes | 8% | 8% |
| Attended infrequently | 6% | 9% |
| I did not attend | 77% | 75% |

Regular attendance at community/church groups dropped for both groups (control and intervention) during the evaluation period. The percentage difference (decrease in both groups) in regular attendance was higher in the control group (–77%) than in the intervention group (–60%). The percentage difference (increase in both groups) of those not attending local groups was greater in the control group (102%) than the intervention group (67%). Thus, the results show that attendance to community/church groups did not increase following the research programme which would be expected given these groups typically focus on younger children.

*Attendance at family centre playgroups*

Table 43: Parent-reported attendance at family centre playgroups pre- and post-test

| | Group | |
|---|---|---|
| **Attendance at baseline** | **Intervention (N = 106)** | **Control (N = 113)** |
| Attended regularly | 27% | 27% |
| Attended sometimes | 22% | 23% |
| Attended infrequently | 17% | 17% |
| I did not attend | 34% | 34% |
| **Attendance at the end of research** | | |
| Attended regularly | 8% | 4% |
| Attended sometimes | 15% | 14% |
| Attended infrequently | 6% | 8% |
| I did not attend | 71% | 73% |

Regular attendance at family centre playgroups dropped for both groups; the percentage decrease was greater in the control group (–83%), than in the intervention group (–69%). The percentage difference (increase in both groups) of those not attending family centre playgroups was greater in the control group (118%) than in the intervention group (108%). Thus, the results show that attendance at family centre playgroups did not increase following the research programme.

*Attendance at specialist groups*

Table 44: Parent-reported attendance at specialist groups pre- and post-test

| Attendance at baseline | Group | |
|---|---|---|
| | Intervention (N = 106) | Control (N = 113) |
| Attended regularly | 13% | 8% |
| Attended sometimes | 4% | 15% |
| Attended infrequently | 8% | 8% |
| I did not attend | 75% | 69% |
| **Attendance at the end of research** | | |
| Attended regularly | 1% | 4% |
| Attended sometimes | 4% | 3% |
| Attended infrequently | 5% | 2% |
| I did not attend | 91% | 92% |

Regular attendance at specialist groups, such as sensory classes, dropped for both groups; the percentage decrease was greater in the intervention group (–93%) than in the control group (–56%). The percentage difference (increase in both groups) of those not attending local groups was 33% and 22% in the control and intervention groups, respectively. Thus, the results show that attendance at specialist groups did not increase following the research programme.

*Attendance at parent/carer support groups/forums*

Table 45: Parent-reported attendance at parent/carer support groups pre- and post-test

| Attendance at baseline | Group | |
|---|---|---|
| | Intervention (N = 106) | Control (N = 113) |
| Attended regularly | 8% | 4% |
| Attended sometimes | 11% | 12% |
| Attended infrequently | 10% | 9% |
| I did not attend | 71% | 76% |
| **Attendance at the end of research** | | |
| Attended regularly | 3% | 3% |
| Attended sometimes | 9% | 2% |
| Attended infrequently | 8% | 6% |
| I did not attend | 79% | 89% |

Regular attendance at support groups dropped for both groups; the percentage decrease was greater in the intervention group (–63%), than in the control group (–25%). The percentage difference (increase in both groups) of those not attending support groups was 17% and 12% in the control and intervention groups, respectively. Thus, the results show that attendance at support groups did not increase following the research programme.

**Reasons for changes in attendance at groups**

The results from the survey show that in all cases, attendance at external groups dropped from the start of the research programme. Respondents were asked to describe the reason for changes in attendance. A count analysis was undertaken and revealed six main themes: four highlighted the reasons for the drop in attendance as Covid-19, health,

time and child attendance at nursery;[9] one theme was no change; and one theme highlighted reasons for more attendance (developmental needs).

With regard to a drop in attendance, 110 respondents said this was either wholly or partly to do with Covid-19, 51 respondents said their child now attends nursery, 10 respondents reported time being an issue, either because they were working or they had other responsibilities, and seven respondents reported changes due to ill health of either a parent or a child; 10 respondents reported no change. Four respondents attended more for the perceived developmental needs of their child.

The data collected clearly shows that Covid-19 was the biggest contributor towards the drop in attendance at external group activities closely followed by the fact that many of the children were now attending nursery. Thus, it is unclear whether the intervention would have had an impact on attendance at external groups.

*Attendance at library groups*

Table 46: Parent-reported attendance at library groups pre- and post-test

| | Group | |
| --- | --- | --- |
| **Attendance at baseline** | **Intervention (N = 106)** | **Control (N = 113)** |
| Attended regularly | 9% | 19% |
| Attended sometimes | 24% | 14% |
| Attended infrequently | 12% | 8% |
| I did not attend | 55% | 59% |
| **Attendance at the end of research** | | |
| Attended regularly | 4% | 4% |
| Attended sometimes | 8% | 7% |
| Attended infrequently | 11% | 8% |
| I did not attend | 76% | 81% |

Regular attendance at library groups dropped for both groups; the percentage decrease was greater in the control group (–76%) than in the intervention group (–60%). The percentage difference (increase in both group) of those not attending support groups was 36% and 40% in the control and intervention groups, respectively. Thus, the results show that attendance at library groups did not increase following the research programme.

*Attendance at parent and toddler swim sessions*

Table 47: Parent-reported attendance at parent and toddler swim sessions pre- and post-test

| | Group | |
| --- | --- | --- |
| **Attendance at baseline** | **Intervention (N = 106)** | **Control (N = 113)** |
| Attended regularly | 9% | 4% |
| Attended sometimes | 10% | 8% |
| Attended infrequently | 14% | 12% |
| I did not attend | 66% | 75% |
| **Attendance at the end of research** | | |
| Attended regularly | 8% | 5% |
| Attended sometimes | 10% | 9% |
| Attended infrequently | 9% | 6% |
| I did not attend | 72% | 80% |

Regular attendance at swim sessions dropped only for the intervention group (–10% percentage difference). In the control group, there was a percentage increase in regular attendance (of 20%) although in effect these numbers were

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[9] It should be noted that by the end of the programme/post-test, most children would have already turned three so would be entitled to a free nursery place.

small (N = 1). There was a small percentage increase of those not attending swim sessions in both the control and intervention groups (6% and 9% respectively). However, it is possible that, for families in the intervention group, participating in the twice-weekly sessions constrained their time for such activities.

*Attendance at clinics*

Table 48: Parent-reported attendance at clinics pre- and post-test

| | Group | |
|---|---|---|
| **Attendance at baseline** | **Intervention (N = 106)** | **Control (N = 113)** |
| Attended regularly | 8% | 4% |
| Attended sometimes | 13% | 12% |
| Attended infrequently | 11% | 13% |
| I did not attend | 67% | 71% |
| **Attendance at the end of research** | | |
| Attended regularly | 3% | 3% |
| Attended sometimes | 3% | 3% |
| Attended infrequently | 7% | 4% |
| I did not attend | 88% | 91% |

There was a greater percentage decrease in regular attendance at baby clinics in the intervention group (–67%) than in the control group (–40%). There was a similar percentage decrease in those not attending baby clinics in the control and intervention groups (29% and 31% respectively). Thus, the results show that attendance to clinics did not increase following the research programme.

*Attendance at portage*

Table 49: Parent-reported attendance at portage pre- and post-test

| | Group | |
|---|---|---|
| **Attendance at baseline** | **Intervention (N = 106)** | **Control (N = 113)** |
| Attended regularly | 3% | 3% |
| Attended sometimes | 3% | 3% |
| Attended infrequently | 2% | 3% |
| I did not attend | 92% | 94% |
| **Attendance at the end of research** | | |
| Attended regularly | 2% | 2% |
| Attended sometimes | 3% | 1% |
| Attended infrequently | 1% | 3% |
| I did not attend | 94% | 95% |

Regular attendance at portage (an educational home visiting service for children with special educational needs (SEND)) dropped equally for both the control group and the intervention group (both –33%). There was a small percentage increase in those not attending portage in the control and intervention groups (1% and 2% respectively). Thus, the results show that attendance to portage decreased slightly in both intervention and control groups.

*Attendance at speech and language*

Table 50: Parent-reported attendance at speech and language pre- and post-test

| | Group | |
|---|---|---|
| **Attendance at baseline** | **Intervention (N = 106)** | **Control (N = 113)** |
| Attended regularly | 10% | 6% |
| Attended sometimes | 7% | 6% |
| Attended infrequently | 7% | 4% |
| I did not attend | 76% | 84% |
| **Attendance at the end of research** | | |
| Attended regularly | 8% | 6% |
| Attended sometimes | 8% | 5% |
| Attended infrequently | 6% | 3% |
| I did not attend | 78% | 86% |

Regular attendance at speech and language services dropped only for the intervention group (–18%) and remained the same for the control group (0% change). The percentage increase in those not attending speech and language services was the same in both control and intervention groups (both 2%). Thus, the results show that attendance at speech and language services, in both groups, stayed relatively stable across the two time points.

*Attendance for health visitor*

Table 51: Parent-reported attendance with health visitor pre- and post-test

| | Group | |
|---|---|---|
| **Attendance at baseline** | **Intervention (N = 106)** | **Control (N = 113)** |
| Attended regularly | 13% | 14% |
| Attended sometimes | 25% | 20% |
| Attended infrequently | 19% | 16% |
| I did not attend | 42% | 50% |
| **Attendance at the end of research** | | |
| Attended regularly | 9% | 8% |
| Attended sometimes | 12% | 11% |
| Attended infrequently | 14% | 7% |
| I did not attend | 64% | 74% |

Regular attendance for health visitor services dropped in both groups; the percentage decrease was greater in the control group (–44%) than in the intervention group (–29%). There was a similar percentage increase in those not attending health visitor services in the control and intervention groups (50% and 51% respectively). Thus, the results show that attendance with home visitors did not increase following the research programme.

**Reasons for changes in attendance for social and educational services**

Overall, changes in attendance for social and educational services either dropped or stayed the same, with the exception of the increase in attendance at parent and toddler swimming groups (though the increase was only seen for the control group) and attendance at portage (in which attendance increased for both groups). To understand more about the reasons for changes in attendance over 18 months, respondents were asked to describe the reason for changes in attendance. A count analysis was undertaken and revealed seven main themes. Five themes related to drop in attendance: Covid-19, nursery attendance, services no longer required, age of the child, lack of time or money. One theme related to no change in attendance and one theme related to more attendance: referrals to specialist services. 100 respondents said they did not attend due to Covid-19. 16 respondents said they did not attend due to their child being at nursery or school. 17 respondents said they no longer required the services with the main reason given as the age of the child. Eight respondents said non-attendance was due to lack of time or money. 31 respondents reported

there had been no change in their attendance. 10 respondents stated that their child had been referred to specialist services and so they were now attending those specialist services.

The data collected clearly shows that Covid-19 was the biggest contributor towards the drop in attendance at social and educational services. However, it is also clear that some families had taken up using some services due to referrals from schools and nurseries. Thus, it is unclear whether the intervention programme, in the absence of Covid-19, would have impacted on attendance for social and educational services.

*Attendance at nursery*

The IPE RQ 4.1 addresses take-up of the offer of a nursery place: To what extent did participation result in parents taking up the free nursery offer and encourage attendance at pre-school settings by participating children?

In the control group, at the start of the research 18 months prior, 25% of respondents reported sending their child to nursery compared to 21% of the intervention group. At the end of the research 88% of control families and 83% of intervention families sent their child to nursery. The percentage increase in families sending their child to nursery was slightly higher in the intervention group (300%) compared to the control group (250%). It should be noted here that this data includes all participating families, which include LLSOA families whose child(ren) were not entitled to a free nursery place.

We also asked all participants how nursery attendance had changed. Two control families reported their children now going to nursery for fewer hours, compared to none of the intervention group. 36% of control families reported no change in hours of nursery attendance, compared to 37% of intervention families. The biggest change was reported in families sending their children for more hours, both in the control group and in the intervention group (62% and 63% respectively).

To understand more about how many hours children attend nursery, we asked families whether they sent their children for less than five hours, between six to 14 hours, or more than 15 hours. Only families that reported sending their children to nursery answered this question (98 control, 88 intervention). 2% of control families sent their children for less than 5 hours per week. 32% of control families and 27% of intervention families sent their child to nursery between six to 14 hours per week. Finally, 68% of control families sent their child to nursery for 15 plus hours per week, compared to 73% of intervention families.

The results show that slightly more intervention families than control families have sent their children to nursery since the start of the research 18 months ago. From these, a slightly higher number of intervention families, compared to controls, sent their children for 15 plus hours. While we report slightly higher increases in intervention families sending their child(ren) to nursery, the higher number of control families also sending their child(ren) to nursery would suggest, as noted above, that most children would have already turned three so would be entitled to a free nursery place. Thus, we cannot be sure of the impact of the intervention.

**Diffusion effects**

The IPE RQ 4.3 addresses possible diffusion effects: Were there any diffusion effects of programme delivery (e.g., on other family members including child's siblings and other adults in the household)?

Four participants from the original sample taking part in the post-test survey (n = 106) did not answer these questions, leaving a sample of n = 102. Parents were asked to rate their response on a 5-point scale; strongly agree, somewhat agree, neither agree nor disagree, somewhat disagree, or strongly disagree. All intervention participants were asked whether they agreed with the statement 'I have been able to apply what I have learnt to my other children'. 63% of participants strongly agreed with the statement, 18% somewhat agreed, 10% neither agreed nor disagreed, 6% somewhat disagreed and 4% strongly disagreed. It should be noted here that not all parents would have had more than one child. Home visitors often also reported a positive impact on other siblings as a result of the family's involvement in the programme. In contrast, sometimes other siblings could also be a hindrance to programme delivery:

> *'siblings for us all has been massive because some of them have got younger ones which are very demanding and they do impact on the delivery of the session because if mum's off trying to sort the other one out all… it does have an impact on the session' (Home visitor).*

All intervention participants were also asked whether they agreed with the statement 'Other adults in the household have used techniques learned from the programme'. 39% of participants strongly agreed with the statement, 26% somewhat agreed, 30% neither agreed nor disagreed, 1% somewhat disagreed and 4% strongly disagreed.

**Experience of the programme**

During parent interviews, we asked parents about their experience of the ParentChild+ programme. The majority of parents spoke highly about the programme, with many parents commenting on the overall positive experience:

> *'Yeah, it's been great; we've loved it. We're a bit sad it's coming to an end actually' (PT0154).*

> *'[I]t's been good, it's been wonderful. The experience, the opportunity, has been good for us as a family, especially during Covid. – and I guess we're going to bring this up – where there was no nursery so at least we had something to look forward to, and for that it was a bit of a game-changer for us, which we appreciated' (PT0214).*

> *'If it weren't for the programme we would never have had the doors open to what we have had them open to. That's why we're so thankful' (PT0361).*

Parents also spoke positively about the home visitors and the support they offered:

> *'She [the home visitor] was quite supportive; she would update me on everything like, "Oh yeah, we're doing this and this". She always texts me beforehand as well before we actually meet to tell me roughly what they're doing and to obviously make sure there are no symptoms or anything in our house, which I think is quite helpful because sometimes I forget that she's coming that day. But she always tells me what they're going to do or something beforehand' (PT0239).*

> *'Just thank you for letting me be a part of it and thank you to the visitor because she's been absolutely great' (PT0452).*

Only one parent interviewed, however, commented that they hadn't continued with the parenting practice after the programme finished:

> *'No, we are not doing any activities now. It was just with the Teacher [home visitor]. I still can read at home. We just go for a walk now to the garden because she told us to at least go for a walk, so I just take her for the walk' (PT0403).*

**Parent confidence and efficacy**

Parent confidence and efficacy was measured via survey responses in which intervention parents (n = 102) answered five questions. Parents were asked to rate on a 5-point scale: strongly agree, somewhat agree, neither agree nor disagree, somewhat disagree, or strongly disagree. Table 52 shows parent responses for each of the questions asked. The results show that the programme had a clear impact on parental confidence and perceived efficacy. This was confirmed in the home visitor focus group, where they highlighted an increase in parental confidence. The area coordinators also described the programme as 'empowering' parents. These results address IPE RQ4: what was the impact in terms of parental self-reported confidence and efficacy?

Table 52: Parent responses to questions on parent confidence and efficacy

| Statement | Strongly agree | Somewhat agree | Neither agree nor disagree | Somewhat disagree | Strongly disagree |
|---|---|---|---|---|---|
| Being a part of the programme has helped me to think of new things to do to support my child's development | 87% | 11% | 2% | 0% | 0% |
| Being part of the programme has helped me to overcome daily challenges I face with my child | 65% | 17% | 13% | 2% | 4% |
| Being a part of the programme has given me confidence in my own abilities as a parent | 71% | 14% | 14% | 1% | 1% |
| I feel the programme has helped me to be more patient with my child | 64% | 17% | 17% | 2% | 1% |
| Being a part of the programme as increased my knowledge about how my child learns | 72% | 19% | 5% | 0% | 6% |

# Cost

Table 53 gives the comparative costs of delivering ParentChild+ using three different models.[10] All models are calculated assuming delivery to 132 families and exclude additional overhead costs.

Variable costs for delivering the programme include: lead-in time required to set up if this is in a new or existing area; amount of recruitment and training new staff required; the proportion of virtual and face-to-face delivery which affects travel and staffing costs; balance of bought toys against use of free materials; geography of the area being delivered in and associated staff travel costs.

Model 1 is the cost per family of delivering ParentChild+ within the RCT, recruiting 283 families for the control and intervention conditions, including a period of time during the pandemic (four-month extension to delivery and all associated extra costs).

Model 2 is the cost per family of delivering ParentChild+ under 'normal' circumstances (i.e., excluding the four-month pause) using the same proportion of virtual and face-to-face delivery as for the RCT.

Model 3 is the cost per family of delivering ParentChild+ under 'normal' circumstances with 100% face-to-face delivery in the home.

Model 4 is the cost per family of delivering ParentChild+ under 'normal' circumstances with 100% face-to-face delivery in the home, excluding initial set-up costs. These initial set-up costs included: staff recruitment (advertising, HR time, interview costs, induction and training); staff time (up to 3 months) to link with LAs and other partners, set up referral pathways, recruit service users, and set up monitoring and reporting processes.

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[10] As provided by Family Lives.

Table 53: Comparison costs of delivering the ParentChild+ intervention

| Item | Model 1 – RCT[11] | Model 2 – Normal duration with hybrid delivery | Model 3 – Normal duration with 100% face-to-face delivery | Model 4 – Normal delivery with 100% face-to-face and no set-up costs |
|---|---|---|---|---|
| Staff salaries (see below for details) | 752,957 | 375,632 | 409,674 | 383,505 |
| Staff recruitment, training, induction, meetings and disclosure and barring service (DBS) check | 9544 | 7400 | 8450 | 1283 |
| Staff travel and subsistence | 34,654 | 28,050 | 54,250 | 52,500 |
| Staff phones, IT equipment and Microsoft Teams | 22,954 | 12,019 | 13,979 | 8770 |
| Project costs (Staysafe, checking in and out*) | 2800 | 2240 | 2800 | 2800 |
| Accommodation and office costs (postage, stationery, printed materials, storage, refreshments) | 3949 | 4509 | 4509 | 4209 |
| Toys and books | 39,226 | 30,360 | 30,360 | 30,360 |
| **Total** | **866,084** | **460,210** | **524,022** | **483,427** |
| Cost per family (over 22, 18 and 15 months) | £6561 (22 months starting from implementation of intervention) | £3486 (18 months) | £3970 (18 months) | £3662 (15 months) |
| Cost per family in start-up year (Model 1) reduced to 12 months and cost per family in 'Normal' delivery (with no set up costs (model 4) reduced to 12 months | £3579 (12 months from implementation) | | | £2930 (12 months) |

*For safety, all home visitors check in and out of each home visit with the Family Lives central support team. For ParentChild+ an app on phones called Staysafe was used. This enables the support team to know where they are and that they are safe and have left the house as scheduled.

Table 54 provides further details around staffing assumptions.

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[11] Models 1, 2 and 3 include three months of set-up costs.

Table 54: Staffing for the RCT and two comparative models of ParentChild+ delivery

| Model 1 – RCT | Model 2 – Normal duration with hybrid delivery | Model 3 – Normal duration with 100% face-to-face delivery |
|---|---|---|
| 1 × senior area manager on 14 hrs p/w for 30 months<br>1 × team leader for 27 months on 35 hrs p/w<br>3 × area coordinators for 25 months on 35 hrs p/w<br>Average 11 × home visitors (Early Learning Specialists) for average 20 months each (includes the 4 months extension for first lockdown) on 28 hrs p/w | 1 × senior area manager on 7 hrs p/w for 18 months<br>1 × team leader for 18 months on 35 hrs p/w<br>2 × area coordinators on 28 hrs p/w for 17 months<br>9 home visitors (Early Learning Specialists) for 15 months on 28 hrs p/w | 1 × senior area manager on 7 hrs p/w for 18 months<br>1 × team leader for 18 months on 35 hrs p/w<br>2 × area coordinators on 28 hrs p/w for 17 months<br>11 × home visitors (Early Learning Specialists) for 15 months on 28 hrs p/w |

Table 55 presents the cumulative costs per family of ParentChild+ if delivered over three years. Costs for the first year are taken from the intervention model delivered during the evaluation (Model 1), while ongoing delivery in subsequent years is assumed to revert to fully face-to-face home visits and without the pandemic-induced four-month pause (Model 4).

Table 55: Cumulative costs per family of ParentChild+ (assuming delivery over three years)

|  | Year 1 | Year 2 | Year 3 |
|---|---|---|---|
| ParentChild+ | £3579 | £2930 | £2930 |

This yields an overall cost per family per year of £3146 over three years.

# Conclusion

Table 56: Key conclusions

1. Children in families who received ParentChild+ made the equivalent of 2 fewer months' progress in receptive vocabulary development, on average, compared to children in families who did not receive the programme. This result has a moderate to high security rating.

2. Secondary outcomes gave inconsistent results: ParentChild+ had a low to moderate negative impact on children's communication, fine motor skills and personal-social behaviour in families who received the programme compared to those who did not, as reported by parents who completed the Ages & Stages Questionnaire (ASQ). There is some uncertainty in this finding given many children scored highly on the assessment (ceiling effects). In contrast, parents' ratings of children's home learning environment suggested the programme had a significant moderate impact on this outcome for those who received ParentChild+ than those who did not receive the programme.

3. Exploratory analysis suggested children in families who received ParentChild+ and were eligible for FEL places made the equivalent of 3 fewer months' progress in receptive vocabulary development, compared to children in similar families who did not receive the programme. This result has lower security given the smaller number of children in the analysis.

4. The majority of parents were positive about the programme, spoke highly of the home visitors and reported that they 'strongly agreed' participation had increased their knowledge and confidence with supporting their child's learning and behaviour, and they could apply what they had learnt with their other children.

5. Semi-structured video observations of parent–child interactions with 28 families before and after programme delivery found no noticeable differences between families who received the programme compared to those who did not, except on two of the 13 categories which highlighted control families exhibited more parent acknowledgements and child spontaneous vocalisations.

## Impact evaluation and IPE integration

**Interpretation**

The results of the primary impact analysis do not support the prior evidence of the effectiveness of the programme or the research hypotheses. The evidence of positive effects on disadvantaged children's receptive vocabulary, self-regulation and behaviour from two previous RCTs undertaken in the US (Astuto, 2014) was not replicated in this RCT. In the logic model, high quality implementation of ParentChild+ with well-targeted families was hypothesised to improve this child specific outcome. However, the results suggest that there is a small negative effect of the programme on the BPVS-III (Hedges' g −0.14). Whilst the upper 95% bound is positive, its size is only 0.09, which is a relatively small difference. In contrast, the lower 95% bound is −0.36, which is a rather larger difference. The results are consistent with an interpretation that allocation to the intervention leads to slightly reduced receptive vocabulary (as measured by the BPVS-III), compared with usual practice. However, due to the uncertainty around the estimate of effect, this result suggests the intervention has truly made little difference at all on receptive vocabulary, or it has truly reduced BPVS-III scores by around 5 points.

The 'true' effect of the intervention could be zero. However, an alternative explanation for this negative result could be as a result of a source of bias having been introduced. There are two main ways that bias could have been introduced. Firstly, the randomisation may have been inadequate, which could potentially introduce selection bias at randomisation. However, this is unlikely to have happened in this RCT as the allocation was undertaken by an independent statistician and the allocation was concealed. Furthermore, baseline measures appear to be approximately in balance. Secondly, attrition can introduce the potential for post-randomisation selection bias. Whilst attrition in this RCT on the primary outcome was approximately 20%, the levels of attrition were similar between the two groups (intervention and control groups) and, therefore, it is unlikely the attrition introduced sufficient bias to change a positive, statistically significant, effect size to the small non-statistically significant negative effect size observed here. In addition, in the sensitivity analyses, imputation of missing data undertaken under various assumptions did not find different results. The direction and magnitude of estimated Hedges' g effect sizes using the imputed data for the missing data under all assumptions did not change substantially. Further alternative explanations for the negative impact on primary outcome include the explanation that the 'true' effect of the intervention on child outcomes is a longer-term effect and, therefore, could not be observed immediately post-test, but could only be observed through longitudinal outcomes as suggested in the logic model; and the intervention and outcome measures were not delivered as planned during the time of the pandemic. In the logic model an impact on academic longitudinal outcomes as observed on RBA and EYFS is hypothesised. There

is evidence from the secondary outcome (HLE Index) and the IPE that the HLE improved in the intervention families and also parental confidence and efficacy, both of which factors could be observed in positive longer term impact outcomes. Finally, the impact of the Covid-19 pandemic could have had a detrimental impact in respect of the primary outcome. For example, although delivery of PC+ online and assessment online was not perceived to be detrimental in the IPE, in truth, it may have negatively impacted on the primary impact outcome. The IPE demonstrated that some children were struggling with concentration when delivery was online, which inevitably would have impacted on delivery. Modelling behaviour and other key ingredients of the PC+ intervention visits may have been more challenging to do online.

The results of the secondary impact analyses are inconsistent. The HLE Index demonstrated a small to moderate statistically significant effect of ParentChild+ (effect size 0.31), with 95% bounds between 0.1 and 0.54. Therefore, in contrast to both the primary outcome and the three ASQ outcomes (secondary outcome), the effect on HLE suggests small to moderately sized improvements in the HLE (as measured by the HLE Index) compared to usual practice. However, this positive effect should not be over-interpreted, due to it being a secondary outcome and the fact that there were a total of four secondary measures making up the secondary outcomes.

The results of the three ASQ subscales all demonstrated small, non-statistically significant negative effects (ASQ-3 communication –0.15 CI –0.35 to 0.04; ASQ-3 fine motor –0.20 CI –0.46 to 0.04; ASQ-3 personal–social –0.15 CI −0.35 to 0.08). These results should be interpreted cautiously due to the fact they are from multiple measures of one of the secondary outcomes and also the CIs are wide. However, the upper bounds of the 95% confidence intervals are all very low -– just above zero, whereas the lower bounds of the 95% confidence intervals are rather larger – around 0.35 to 0.45. In addition, ceiling effects were evident across all the ASQ subscales, with many scores equal or close to the maximum score of 60, and the measures themselves are self-reported and not blind, unlike the primary outcome measure.

There was some limited evidence that the mode of follow-up testing (in person or online) was associated with differences in treatment effect, with a moderate positive (i.e., favouring intervention) effect for online testing and a moderate negative (i.e., favouring control) effect for in person testing. Table 19b appears to show a qualitative interaction in how the testing was delivered – online or in person. However, this result should be interpreted with caution due to the small sample size, and a result in the opposite direction or a result of no difference cannot be ruled out. Also, the interaction test was not statistically significant (p = 0.24).

For the analyses investigating adherence, the estimates of the incremental effect of each additional home visit on the expected value of the primary outcome were –0.05 (95% CI –0.11 to 0.02) and –0.04 (95% CI –0.10 to 0.01) for analyses with and without inverse probability weights respectively. Taken by themselves, these estimates suggest that, on average, each additional home visit resulted in a slightly worse outcome, and might therefore be a source of treatment effect heterogeneity. It's possible that this apparent negative dose–response relationship could be the result of the disruption caused by Covid-19 and the resulting move to online delivery. However, these estimates should be treated with caution. Firstly, they are based on a model assuming the relationship between dose of programme (as measured by home visits received) is linear. While this linearity assumption is necessary for the identification of the causal effect of programme dose on outcome in the absence of multiple instruments (and/or other strong assumptions about the absence of selection effects), it is unlikely to be exactly correct. Secondly, missing data (in the outcome data and/or baseline data used to calculate inverse probability weights) may have introduced bias. Given these uncertainties, and the lack of any obvious a priori reason that the intervention would be actively harmful to children's receptive vocabulary, it seems most likely that there is simply little-to-no causal relationship between programme dose and expected outcome.

A subgroup analysis was undertaken to compare EAL and non-EAL subgroups on outcomes. The majority of the families spoke English as their first language, and this would have been as a result of the English language threshold used as an exclusion criterion during recruitment. There is limited evidence that the effectiveness of the programme differed by subgroup, with little difference between intervention and control groups among non-EAL families (0.00 CI –0.22 to 0.23) but potentially quite large differences (in favour of the control group) observed among EAL families (–1.70 CI –2.76 to –0.72). This limited evidence suggests that the programme is less effective in families with EAL. However, the estimates by the EAL subgroup analysis are very imprecise and based on very small numbers, and should therefore be interpreted with caution.

Other subgroup analyses looked at baseline communication, 'child in need' (CiN) status and FEL. There was some evidence that the intervention was less detrimental to receptive vocabulary (as measured by the BPVS-III) among participants with better baseline communication development (as measured by the ASQ), but this limited result is derived from estimates which are imprecise, particularly at the lower end of the baseline (ASQ communication) scores. For CiN status, there was some evidence that for children *not* on a CiN plan, the intervention results in a small reduction in BPVS-III score compared with usual practice, whereas for children who are on a CiN plan, the intervention results in a small increase in BPVS-III score. However, the estimate for these results is very imprecise (due to the extremely small sample) and it should be noted that there is some overlap between subgroups (i.e., between CiN status and FEL entitlement). There is little evidence of a substantial treatment effect for FEL entitlement status.

The results of the IPE address three key areas: compliance with all the features and components of the programme; fidelity of the programme, particularly in terms of the need for the programme, focusing on success in recruiting the target sample and exploring barriers and facilitators of programme delivery; and perceived outcomes in terms of desirability and acceptability, focusing on the impact on the HLE.

In terms of compliance, as defined by this evaluation, the programme was largely implemented as planned, including: the home visitors receiving comprehensive training which was compliant with what was outlined in the logic model (100% compliance); the majority of families receiving the target number and length of sessions (over 62% of families reached the minimum threshold for compliance); but with some variation in implementation from the TIDieR framework due to the Covid-19 pandemic. Although more than one-third of the sessions moved to online delivery at the time of the first lockdown, and although some post-tests had to be undertaken online, the parents in the intervention families felt they received very good support via the programme during the Covid-19 lockdown, although this was not always in line with that intended by the programme. In-person delivery and assessment of outcomes was predominant. However, the impact of disruption due to the pandemic and the move to online delivery, cannot be accurately measured. Results cannot be directly related to delivery as originally intended due to the changes implemented because of the restriction imposed by the Covid-19 pandemic lockdowns and temporary halting of face-to-face research in universities, which impacted on some of the outcome assessments.

In terms of fidelity, the programme was found to be desirable and acceptable by parents, and the three LA leads who were interviewed agreed there was a need for it in their LA. There was a clearly demonstrated need for an intervention such as ParentChild+ within the LA areas due to poor take-up of nursery provision and the risk that children in these LAs are entering school with poor language and general development. The ParentChild+ evaluation specifically targeted these families (in particular EAL and CiN-status families), though not all families would have chosen to engage and it is possible that these families may have been more challenging to recruit. The inclusion criterion for eligibility for the programme was a minimal threshold for English language which could have impacted on the number of EAL families within the programme. The subgroup analysis comparing families characterised as EAL and non-EAL and which provided limited evidence that the programme is less effective in EAL families suggests that the targeting of EAL families for the programme could be re-examined in the light of the limited evidence.

Some barriers to recruitment included a few families not fully understanding the purpose of the research and the possibility that increased staffing levels may be needed to build a relationship with some families to facilitate recruitment. Greater involvement of the ET to help to overcome the former, and increased resources to facilitate the latter, could be considered in any future evaluations. Some parents' limited knowledge of technology was an initial barrier once delivery moved online, although enhanced support offered during the pandemic was greatly appreciated and led to the positive relationships with the home visitors continuing throughout this period.

In terms of perceived outcomes, usual parenting practice prior to the programme was similar across intervention and control groups, and this did not change as a result of participating in the programme. The ParentChild+ programme impacted on the HLE (as demonstrated by the positive effect size for this secondary outcome obtained in the impact evaluation) but did *not* impact on the HLE as demonstrated by the observations undertaken on the observation subsample. The fact that no differences between control and intervention groups were observed could have been as a result of chance due to the small number in this sample, and also the fact that there was very high attrition from consent to a sample with both pre- and post-test data. Strengths of the observations include the independence and quality assurance of the coding and analysis; limitations of the observations include the small number in the sample and the challenges of undertaking some of the observations online. The results of the observation measure should be treated with caution and strong conclusions should not be drawn. Impacts on wider outcomes of the programme were

demonstrated in terms of parental self-reported confidence and efficacy. However, participation in ParentChild+ did not result in increased take up of the free nursery offer or encourage attendance at pre-school settings or in increased engagement with wider community services, although this may have been largely due to the pandemic and reluctance of families to engage with other external activities during this time. Perceived diffusion effects of the programme were reported. The majority of parents spoke highly about the programme and the home visitors and said that they could use what they had learnt during the programme with other children in their family and that other adults in the household were also taking on some of the techniques learnt. It is possible that these positive perceptions could lead to the demonstration of positive longer term impact effects on child outcomes, despite scant evidence of this on the immediate post-test outcomes, and this could be explored in a longitudinal follow-up on academic outcomes measures at school.

**Limitations and lessons learned**

The programme ParentChild+ was originally developed in the US for delivery in the US by the Family Lives developers. For this RCT evaluation, ParentChild+ was delivered in four LAs in England (South Yorkshire). The context for the delivery of ParentChild+ is, therefore, very different in England, particularly in terms of the landscape of provision in LAs, communities and schools. This is a potential limitation of the evaluation and may partially explain why the positive results seen in US-based evaluations (Astuto, 2014) were not replicated here (e.g., see Robling et al., 2015). In addition, the results are inconsistent with the results from an evaluation by Wood et al. (2015), which formed part of the rationale for the intervention and found that a six-week, one and a half hours a week intervention with parents and children (Early Words Together) improved children's spoken language (as measured by the Pearson Preschool Language Scale), with particular improvements noted in girls' attainment. However, in the evaluation reported here, an imbalance in gender was found at baseline, with similar percentages of males and females in the control group, but a higher percentage of males in the intervention group and a subgroup analysis of impact varying by gender was not pre-specified and not undertaken.

A further limitation of this evaluation is the variation in the number of visits, and the issue that embedding a programme within LA provision takes time. For example, the family/home visitor relationship may take time to build into a firm relationship. In the evaluation, development of these relationships may have been different in a context without the Covid-19 pandemic and changes in home visitors during the implementation of the 15-month programme.

In terms of potential threats to internal validity: the randomisation was adequate; attrition may have been a threat, but this is unlikely as attrition was evenly balanced between the groups (19.7% in the control group and 22.7% in the intervention group). Subjectivity is implicit in the ASQ subscales due to them all being self-reported. In addition, the secondary outcomes were not blind to condition (intervention or control) and there was evidence of ceiling effects in the ASQ. By definition, subjectivity is also implicit in the IPE because the outcomes depend on self-report.

Some lessons about the delivery of both intervention and outcome assessments in the time of the Covid-19 pandemic have been learned.

The specific contribution of this study to the body of relevant evidence is a rigorously designed and well-conducted RCT (impact evaluation) with embedded IPE which gives estimates of the effect of a US-developed intervention on a primary vocabulary outcome and on secondary outcomes with insights into implementation and process outcomes in a sample of families in England. The results of this evaluation would have limited generalisability to similar families in similar LAs with high levels of disadvantage due to the high levels of uncertainty in the impact estimates.

Finally, as indicated above, the impact of the pandemic, occurring as it did in the midst of this evaluation, cannot be ignored. In addition to the more immediate impacts on intervention delivery and outcome measures, there were wider impacts on families which would have had an impact on the HLE and child outcomes. A report from the Joseph Rowntree Foundation found that poverty levels, already rising prior to the pandemic, brought deeper hardships to those already struggling (Joseph Rowntree Foundation, 2021). Poorer parental mental health was reported as was increased concern by parents about their children's wellbeing and behavioural issues (Children's Commissioner, 2020; Waite et al., 2021). Evidence suggests that children in Reception in the academic year 2020/21 were not necessarily 'school ready' as a result of the pandemic, with the proportion of children achieving a 'good level of development' and 'at least expected' in all the early learning goals of the EYFSP, including in communication and language, by the end of the academic year lower than their pre-pandemic counterparts (Tracey et al., 2022).

# Future research and publications

A future research question that needs answering is whether an impact of the programme is demonstrated on long-term outcomes as outlined in the logic model and which were not explored as part of the study. To do this would require longer term data analysis using NPD data (educational attainment using RBA and EYFS):

> *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)?*

The RBA assessment is currently being piloted and we are unsure of the range and nature of the data that would be available (i.e., 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 would be available or one broken down into the different domains. The longer term educational attainment data could 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 subscales would need to be analysed using ordinal regression, adjusting for allocation, LA and other key baseline covariates thought to be related to outcome. All analyses would need to be detailed in a SAP, prior to the data being accessed or any analysis performed.

Given the strength of the programme theory of change and its theoretical basis, it may also be worth exploring further the reasons why no impacts on the primary outcome (receptive vocabulary) were found in this trial. In addition to the EEF report, two further publications resulting from the evaluation are planned: a journal article describing the context for the RCT, design and methods, results and implications; and a journal article describing the challenges and opportunities of undertaking evaluations during the Covid-19 pandemic.

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# Appendix A: EEF cost rating

Figure 8: Cost rating

| Cost rating | Description |
|---|---|
| £ £ £ £ £ | *Very low:* less than £80 per pupil per year. |
| £ £ £ £ £ | *Low:* up to about £200 per pupil per year. |
| £ £ £ £ £ | *Moderate:* up to about £700 per pupil per year. |
| £ £ £ £ £ | *High:* up to £1200 per pupil per year. |
| £ £ £ £ £ | *Very high:* over £1200 per pupil per year. |

# Appendix B: Security classification of trial findings

**OUTCOME:** *BPVS-III*

| Rating | Criteria for rating | | | Initial score | Adjust | | Final score |
|---|---|---|---|---|---|---|---|
| | **Design** | **MDES** | **Attrition** | | | | |
| 5 🔒 | Randomised design | ≤ 0.2 | 0–10% | | | | |
| 4 🔒 | Design for comparison that considers some type of selection on unobservable characteristics (e.g., RDD, diff-in-diffs, matched diff-in-diffs) | 0.21–0.29 | 11–20% | | | | |
| 3 🔒 | Design for comparison that considers selection on all relevant observable confounders (e.g., Matching or regression analysis with variables descriptive of the selection mechanism) | 0.30–0.39 | 21–30% | 3 | Adjustment for threats to internal validity [0] | | 3 |
| 2 🔒 | Design for comparison that considers selection only on some relevant confounders | 0.40–0.49 | 31–40% | | | | |
| 1 🔒 | Design for comparison that does not consider selection on any relevant confounders | 0.50–0.59 | 41–50% | | | | |
| 0 🔒 | No comparator | ≥0.6 | >50% | | | | |

| Threats to validity | Risk rating | Comments |
|---|---|---|
| **Threat 1: Confounding** | moderate | Randomisation was carried out independently. Some imbalance observed on key characteristics at baseline, including pre-test scores (effect size –0.1), in favour of the control group. Regression models adjust for baseline attainment. |
| **Threat 2: Concurrent interventions** | low | No evidence of concurrent interventions. |
| **Threat 3: Experimental effects** | low | Being invited to participate in the study may have made parents/carers allocated to the control group more aware of how they could help their children but there is no evidence from the IPE that this was a factor. |
| **Threat 4: Implementation fidelity** | moderate | Fidelity was high, allowing for the unavoidable impact of Covid-19 which resulted in a four-month pause to delivery. While 62% of families achieved the minimum threshold of 78 visits during the intervention period, some visits were carried out online rather than face-to-face as intended, which may have influenced the ability to model interactive behaviour to participants as the programme intends. It is difficult to assess how much effect the pause or mixed mode of delivery had, or the extent to which lockdowns and other Covid disruption may have affected the outcomes. |
| **Threat 5: Missing data** | low | Although the level of attrition was fairly high (>21%), sufficient analysis is presented to suggest that different approaches to missing data result in no important differences in the conclusions |
| **Threat 6: Measurement of outcomes** | moderate | Outcome measures are well chosen. The primary outcome was administered by trained assessors, blind to allocation. Some testing was carried out online rather than face-to-face as intended. Although similar numbers of treatment and control children were assessed online, this could have introduced bias through differential levels of support |

| | | provided by parents/carers to complete assessments. Models excluding outcome data from remote assessments yield a slightly larger negative effect size (–0.18), although this is measured with less precision given the smaller sample. |
|---|---|---|
| **Threat 7: Selective reporting** | low | Protocol and SAP were followed as far as possible, given difficulties raised by Covid-19. Deviations are clearly noted. |

- **Initial padlock score:** 3 padlocks – Well-conducted-RCT with MDES at randomisation of 0.27 and attrition of 21%
- **Reason for adjustment for threats to validity**: No adjustment for threats to validity
- **Final padlock score:** initial score adjusted for threats to validity = 3 padlocks

## Appendix 1: ParentChild+ Evaluation Survey

# ParentChild+ Evaluation Survey

Q40 Thank you for taking the time to complete this survey. We really appreciate your participation in the research and your responses will help us to understand any changes that have taken place over the last 18 months since we started the research. Please answer all questions as accurately as possible. Once the survey has been submitted and the assessments with you and your child have been completed we will send you a £10 gift voucher to thank you for your participation in the ParentChild+ research.  Erin & Louise (On behalf of The University of York Evaluation Team).

Page Break

*

Q1 Your child's full name

_____

Q6 Thinking back to before the start of the research (18 months ago), what was your attendance like at the following local group activities?

| | Attended regularly | Attended sometimes | Attended infrequently | I didn't attend |
|---|---|---|---|---|
| Community/Church play groups | ○ | ○ | ○ | ○ |
| Family Centre play groups | ○ | ○ | ○ | ○ |
| Specialist groups such as baby massage or baby sensory | ○ | ○ | ○ | ○ |
| Parent/Carer support groups/forums | ○ | ○ | ○ | ○ |

Q52 What is your attendance like now at the following group activities?

| | Attend regularly | Attend sometimes | Attend infrequently | I don't attend |
|---|---|---|---|---|
| Community/Church play groups | ○ | ○ | ○ | ○ |
| Family Centre play groups | ○ | ○ | ○ | ○ |
| Specialist groups such as baby massage or baby sensory | ○ | ○ | ○ | ○ |
| Parent/Carer support groups/forums | ○ | ○ | ○ | ○ |

Q61 What has been the reason(s) for any change in attendance at the group activities?

_____

Page Break

Q7 Thinking back to the start of the research (18 months ago) what was your attendance at the following social and educational services?

| | Attended regularly | Attended sometimes | Attended infrequently | I didn't attend |
|---|---|---|---|---|
| Library groups such as rhyme time, story time | ○ | ○ | ○ | ○ |
| Parent and Toddler swim sessions | ○ | ○ | ○ | ○ |
| Family Centre led baby clinics e.g. info sessions around sleep/toileting/weaning/breast feeding/behaviour | ○ | ○ | ○ | ○ |
| Portage | ○ | ○ | ○ | ○ |
| Speech and Language Therapy | ○ | ○ | ○ | ○ |
| Health Visiting Services | ○ | ○ | ○ | ○ |

Q62 What is your attendance like now for the following social and educational services?

| | Attend regularly | Attend sometimes | Attend infrequently | I don't attend |
|---|---|---|---|---|
| Library groups such as rhyme time, story time | ○ | ○ | ○ | ○ |
| Parent and Toddler swim sessions | ○ | ○ | ○ | ○ |
| Family Centre led baby clinics e.g. info sessions around sleep/toileting/weaning/breast feeding/behaviour | ○ | ○ | ○ | ○ |
| Portage | ○ | ○ | ○ | ○ |
| Speech and Language Therapy | ○ | ○ | ○ | ○ |
| Health Visiting Services | ○ | ○ | ○ | ○ |

Q63 What has been the reason(s) for any change in attendance at social and educational services?

_____

Q8 My child attend a nursery or childminder 18 months ago

○ True

○ False

Q59 My child now attends a nursery or a childminder

○ True

○ False

Q60 In what way has your child's attendance at a nursery or child minder changed?

○ There has been no change

○ My child attends for more hours now compared to 18 months ago

○ My child attends for less hours now compared to 18 months ago

Q41 How often does you child attend at a nursery/childminder?

○ Less than 5 hours per week

○ Between 6 to 14 hours per week

○ 15+ hours per week

End of Block: Access to local networks

Q54 Which group was your child placed into?

○ My child was placed in the intervention group (Group A) but we did not receive any home visits

○ My child was placed in the intervention group (Group A) and we received some home visits

○ My child was placed in the intervention group (Group A) and we received most home visits/we finished the programme.

○ My child was placed in the control group (Group B) so we were not eligible to receive home visits.

Q10 Please read the following statements and indicate how strongly you agree or disagree with them

|  | Strongly agree | Somewhat agree | Neither agree nor disagree | Somewhat disagree | Strongly disagree |
|---|---|---|---|---|---|
| My child(ren) enjoyed the ParentChild+ sessions with the Home Visitor | ○ | ○ | ○ | ○ | ○ |
| I feel I have a good relationship with my Home Visitor | ○ | ○ | ○ | ○ | ○ |
| I have learnt a great deal about my parenting since joining the programme | ○ | ○ | ○ | ○ | ○ |
| I have been able to apply what I have learnt to my other children | ○ | ○ | ○ | ○ | ○ |
| I feel that my child(ren) and I talk a lot more since starting the programme. | ○ | ○ | ○ | ○ | ○ |
| Other adults in the household have used techniques learned from the programme | ○ | ○ | ○ | ○ | ○ |

Q11 Please indicate how you found fitting in the weekly sessions with the Home Visitors (0 being not hard at all to 10 being extremely hard)

Not hard at all        Extremely hard

0   10   20   30   40   50   60   70   80   90   100

| Fitting in weekly sessions with Home Visitors | |
|---|---|

Q42 What is the reason for your answer to the question above?

_____

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Q44 What did you/your child enjoy most about the programme sessions?

_____

Q45 What did you/your child enjoy least about the programme sessions?

_____

Q46 Would you recommend the ParentChild+ programme to others in the future?

○ Yes

○ Maybe

○ No

Q48 How helpful did you find the books and toys you were given as a part of the research?

○     Very helpful

○     Helpful

○     Neither helpful nor unhelpful

○     unhelpful

○     very unhelpful

Page Break

Q58 Please indicate how much you agree or disagree with the following statements.

| | Strongly agree | Agree | Somewhat agree | Neither agree nor disagree | Somewhat disagree | Disagree | Strongly disagree |
|---|---|---|---|---|---|---|---|
| Being a part of the programme has helped me to think of new things to do to support my child's development | ○ | ○ | ○ | ○ | ○ | ○ | ○ |
| Being part of the programme has helped me to overcome daily challenges I face with my child | ○ | ○ | ○ | ○ | ○ | ○ | ○ |
| Being a part of the programme has given me confidence in my own abilities as a parent | ○ | ○ | ○ | ○ | ○ | ○ | ○ |
| I feel the programme has helped me to be more patient with my child | ○ | ○ | ○ | ○ | ○ | ○ | ○ |
| Being a part of the programme as increased my knowledge about how my child learns | ○ | ○ | ○ | ○ | ○ | ○ | ○ |

**End of Block: Group questions**

**Start of Block: Changes**

Q49 We would like to ask you about any changes you have seen in your child over the last 18 months.

Q51 Please read the following questions and indicate how strongly you agree with them

|  | Strongly agree | Somewhat agree | Neither agree nor disagree | Somewhat disagree | Strongly disagree |
|---|---|---|---|---|---|
| I have seen improvements in my child's behaviour | ○ | ○ | ○ | ○ | ○ |
| I have seen improvements in my child's educational achievement | ○ | ○ | ○ | ○ | ○ |
| My relationship with my child has improved | ○ | ○ | ○ | ○ | ○ |
| My child's language has improved considerably | ○ | ○ | ○ | ○ | ○ |

**End of Block: Changes**

**Start of Block: Home Learning Environment**

Q23 Does anyone at home ever read to your child?

○ Yes

○ No

Q24 How often does someone at home read to your child?

○ Occasionally or less than once a week

○ Once a week

○ Several times a week

○ Once a day

○ More than once a day

Q25 Does anyone at home ever take your child to the library?

○ Yes

○ No

Q26 How often does someone at home take your child to the library? </span>

○ On special occasions

○ Once a month

○ Once a fortnight

○ Once a week

Q28 Does anyone at home ever teach your child a sport, dance, or physical activities?

○ Yes

○ No

Q27 How often does someone at home</span> teach your child a sport, dance, or physical activities?

○ Occasionally, or less than once a week

○ 1 or 2 days a week

○ 3 times a week

○ 4 times a week

○ 5 times a week

○ 6 times a week

○ 7 times a week/constantly

---

Q29 Does your child ever play with letters at home?

○ Yes

○ No

---

Q32 How often does your child play with letters at home?

○ Occasionally, or less than once a week

○ 1 or 2 days a week

○ 3 times a week

○ 4 times a week

○ 5 times a week

○ 6 times a week

○ 7 times a week/constantly

---

Q33 Does anyone at home ever help your child learn the ABC or the alphabet?

○ Yes

○ No

---

Q31 How often does someone at home help your child learn the ABC or the alphabet?

○ Occasionally, or less than once a week

○ 1 or 2 days a week

○ 3 times a week

○ 4 times a week

○ 5 times a week

○ 6 times a week

○ 7 times a week/constantly

---

Q34 Does anyone at home ever teach your child numbers or counting?

○ Yes

○ No

---

Q35 How often does someone at home teach your child numbers or counting?

○ Occasionally, or less than once a week

○ 1 or 2 days a week

○ 3 times a week

○ 4 times a week

○ 5 times a week

○ 6 times a week

○ 7 times a week/constantly

---

Q36 Does anyone at home ever teach your child any songs, poems, or nursery rhymes?

○ Yes

○ No

---

Q37 How often does someone at home teach your child any songs, poems, or nursery rhymes?

○ Occasionally, or less than once a week

○ 1 or 2 days a week

○ 3 times a week

○ 4 times a week

○ 5 times a week

○ 6 times a week

○ 7 times a week/constantly

---

Q38 Does your child ever paint or draw at home?

○ Yes

○ No

---

Q39 How often does your child paint or draw at home?

○ Occasionally, or less than once a week

○ 1 or 2 days a week

○ 3 times a week

○ 4 times a week

○ 5 times a week

○ 6 times a week

○ 7 times a week/constantly

**End of Block: Home Learning Environment**

**Start of Block: Interview**

Q40 We are asking intervention families if they would like to take part in an interview to share their experiences of participating in the ParentChild+ programme. All families who wish to be considered for an interview will be placed into a prize draw to receive £50 of high street vouchers. We only need 20 families to share their experiences so you may not get selected for an interview however you will still be entered into the prize draw. We are interested in hearing from all families placed in the intervention group so even if you did not complete the programme, we would still like to interview you. Once we have interviewed 20 parents the prize draw will close. We will announce the winner in September 2021. Please indicate below whether or not you would like to be considered for an interview.

○ Yes, I would like to be considered for an interview

○ No, I would not like to be considered for an interview

**End of Block: Interview**

## Appendix 2 – Ethics documentation



**Data Protection Impact Assessments**

**(formerly known as Privacy Impact Assessments)**

**Primary contacts**

Durham Burt

**Data Protection Officer**

dataprotection@york.ac.uk

**Step 1: Identify the need for a DPIA**

**Explain broadly what the project aims to achieve and what type of processing it involves. You may find it helpful to refer to or link to other documents, such as a project proposal or ethics application form. Summarise why you identified the need for a DPIA.**

**Project description**

An evaluation of the ParentChild+ programme using a randomised control trial (RCT) design. Four Local Authorities will be recruited to implement the ParentChild+ programme over the period July 2019- February 2021. The programme is targeted at families eligible for, but not taking up, the free 2 year old nursery places. 80 families will be recruited in each Local Authority to participate in the evaluation, with half allocated to the intervention and half to 'parenting as usual'.

A DPIA is needed as we will be processing special category data (Children in Need status). We will also combine data from multiple sources (LA data, NPD data and individual data collected specifically for the study).

**Step 2: Describe the processing**

**Describe the nature of the processing: how will you collect, use, store and delete data? What is the source of the data? Will you be sharing data with anyone? You might find it useful to refer to a flow diagram or another way of describing data flows. What types of processing identified as likely high risk are involved?**

1. Local Authorities will provide information regarding eligible families to Family Lives (eligible families being those eligible for, but not taking up, the free 2 year old nursery places). Family Lives will use this data to identify and recruit families. This data will not be shared with UoY.
2. UoY will draft and issue the consent form. This will be fully GDPR compliant and approval will be obtained from the Education Department Ethics Committee.
3. Once families are recruited and consented UoY will obtain data relating to Children in Need Status from the LA (access to this data will be included in the consent).
4. At the end of the study children's school destination will be obtained from the LA (again, this will be included in the participant consent).

Data will be transferred via the UoY's secure Drop Off service or via Qualtrics on-line survey software. It will be merged with data collected as part of the study. This data (including data collected by the research team, Children in Need status and school destination) will not be shared with Family Lives. However, where participants are allocated to the intervention condition their names and contact details will be shared with Family Lives in order to facilitate programme delivery. Consent to do so will be included in the participant consent form. Data will be pseudoanonymised by the use of ID numbers with the identifying key stored on a separate server. In the longer term an anonymous version of the project database (containing participant data) will be uploaded onto the EEF data archive for use by other researchers.

**Describe the scope of the processing: what is the nature of the data, and does it include special category or criminal offence data? How much data will you be collecting and using? How often? How long will you keep it? How many individuals are affected? What geographical area does it cover?**

Family Lives will obtain data on eligible families including contact address, phone numbers and, possibly, email addresses as well as Children in Need information. This data will not be shared with UoY. Once participating families have consented to take part in the study their Children in Need status will be shared by Family Lives with UoY via UoY secure Drop Off service. In addition, child's school destination will be collected in February 2021 and 2022. All data will be stored by UoY until November 2025 in a pseudonymised dataset with the key kept on a separate filestore.

**Describe the context of the processing: what is the nature of your relationship with the individuals? How much control will they have? Would they expect you to use their data in this way? Do they include children or other vulnerable groups? Are there prior concerns over this type of processing or security flaws? Is it novel in any way? What is the current state of technology in this area? Are there any current issues of public concern that you should factor in? Are you signed up to any approved code of conduct or certification scheme (once any have been approved)?**

UoY will only process data for individuals who have provided consent. Participants will be fully informed with an appropriate GDPR compliant participant information sheet. All participants also will be provided with information regarding how to withdraw their data and the timescale for doing so. Consent will be obtained in line with ethical expectations and with ethical approval from the Department of Education Ethics Committee. This will not, however, form the legal basis for processing participant data. We intend to process under Article 6(1) (e) and Special Category data under Article 9(2) (j) of the GDPR.

**Describe the purposes of the processing: what do you want to achieve? What is the intended effect on individuals? What are the benefits of the processing for you, and more broadly?**

The purpose of processing the data is twofold:

1. To enable sub-analysis of the impact of the ParentChild+ programme for those identified as being of Children in Need status compared to those not classified as such.
2. To link with NPD data to identify potential longer-term impacts of the programme.

This will have no impact on individuals (other than if they have taken part in the programme or not) but should inform policy and local (possibly national) practice if positive (or otherwise) results are found. This is an area of key concern policy-wise given that free two-year old nursery places are provided for disadvantaged children but not taken up by some families. The programme is designed to fill that gap.

**Step 3: Consultation process**

**Consider how to consult with relevant stakeholders: describe when and how you will seek individuals' views – or justify why it's not appropriate to do so. Who else do you need to involve within your organisation? Do you need to ask your processors to assist? Do you plan to consult information security experts, or any other experts?**

Consultation with:

- Local Authorities – we have discussed with the relevant Local Authorities in a series of conference calls and email exchanges to ensure all parties are clear of the process and to refine those processes in line with the needs of all LAs involved.
- Family Lives – discussed the process for transferring and sharing of data (the data sharing will be one-way (Family Lives to UoY). UoY will not share the project database with Family Lives.
- The University's Data Protection Officer consulted regarding any agreements and data processing
- University Contract Officer consulted regarding Data Sharing Agreements
- Participants not to be consulted directly prior to the consent process. However, the evaluation team has extensive experience of working with disadvantaged families and all consents, and data collection will be designed to be clear, and to minimise burden to participants. Potential participants will be issued with information about the project to enable them to make an informed decision on whether to take part or not.

**Step 4: Assess necessity and proportionality**

> **Describe compliance and proportionality measures, in particular: what is your lawful basis for processing? Does the processing actually achieve your purpose? Is there another way to achieve the same outcome? How will you prevent function creep? How will you ensure data quality and data minimisation? What information will you give individuals? How will you help to support their rights? What measures do you take to ensure processors comply? How do you safeguard any international transfers?**

We intend to process this under Article 6(1)(e)[12] and Special Category data under Article 9(2)(j)[13] of the GDPR. Processing is designed to minimise burden to participants and use of Local Authority data is the only way in which we can access this information which is important for assessing the impact of the programme and for targeting the programme to its intended audience. Participating families will be consented and the use of this data will be included in this consent. Participating families will be given information relating to how to withdraw their data and a timescale for doing so. Family Lives will transfer data to UoY rather than vice versa although we will ensure that such transfers are via the University of York secure Drop off service. The Data Sharing Agreement sets out the arrangements for safe transfer and sharing of data. Function creep will be prevented as the purpose for processing will be clearly articulated to participants prior to sign-up. The research team have carefully determined the project scope and will gather the minimum amount of data necessary to achieve the stated purpose. Pseudonymisation will be used to minimise risk of identification and data outputs will be carefully prepared to ensure individuals are not identified.

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[12] "(e) processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller".
[13] "(j) processing is necessary for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes in accordance with Article 89(1) based on Union or Member State law which shall be proportionate to the aim pursued, respect the essence of the right to data protection and provide for suitable and specific measures to safeguard the fundamental rights and the interests of the data subject."

**Step 5: Identify and assess risk**

| Describe the source of risk and nature of potential impact on individuals. Include associated compliance and corporate risks as necessary. | Likelihood of harm | Severity of harm | Overall risk |
|---|---|---|---|
| Access to sensitive personal data (Children in Need Status). Data will be stored in accordance with University policy and accepted best practice, https://www.york.ac.uk/it-services/security/. All data password protected and stored on a separate server by ID code. The key to this stored separately. Data to be transferred from Family Lives to UoY via secure Drop Off service. Data will not be stored on removeable media and/or laptops/tablets. | Low | Significant | Low |
| Access to children's school destination data. Data to be transferred by LAs to UoY via the University's secure Drop off service. Data to be linked using a unique, anonymous identifying code. The key to the code to be stored on a separate server. | Low | Significant | Low |
| Identification during research output. Pseudonymisation will be used to minimise risk of identification and data outputs will be carefully prepared to ensure individuals are not identified (following ONS Safe Researcher Policies and guidelines on reporting of data). | Low | Significant | Low |
| Function creep. The purpose for processing will be clearly articulated to participants prior to sign-up. The research team have carefully determined the project scope and will gather the minimum amount of data necessary to achieve the stated purpose. Pseudonymisation will be used to minimise risk of identification and data outputs will be carefully prepared to ensure individuals are not identified. | Low | Low | Low |
| Excessive sharing of data. The data will be password-protected, with access provided only to team members with responsibility for processing the data. | | Low | |

| | Low | | Low |
|---|---|---|---|
| | | | |

**Step 6: Identify measures to reduce risk**

**Identify additional measures you could take to reduce or eliminate risks identified as medium or high risk in step 5**

| Risk | Options to reduce or eliminate risk | Effect on risk | Residual risk | Measure approved |
|---|---|---|---|---|
| Children in Need status revealed | Stored by code number and with consent of participants. Data will not be stored on removeable media and/or laptops/tablets. | Reduced | Reduced | Yes/no |
| Child's school destination revealed | Stored by code number and with consent of participants. Linkage by code number only. Key to ID numbers stored on password-protected separate filestore. | Reduced | Reduced | |
| Identification during research output. | Pseudonymisation will be used to minimise risk of identification. Data outputs will be reviewed to identify risk and carefully prepared to ensure individuals are not identified (following ONS Safe Researcher Policies and guidelines on reporting of data). Where concerns are raised individual data will not be included in the data output. | Reduced | Reduced | |

## DATA SHARING AGREEMENT

This Agreement is made on the Effective Date, between:

**Parties**

(1)  **UNIVERSITY OF YORK**, a body incorporated in England and Wales by Royal Charter with registration number RC000679 whose principal offices are at Heslington, York, YO10 5DD (the 'University); and

(2)  **FAMILY LIVES,** Family Lives, 15-17 The Broadway, Hatfield, Herts, AL9 5HZ, Registered company number 3817762 ('Family Lives); and

(3)  [Insert contracting name and registered number and address of the Local Authority] (the 'Local Authority').

Each known as a 'Party' and together as the 'Parties'.

**Background**

A.  The University is conducting a Project on behalf of the Funding Body.

B.  This Agreement will set out the arrangements between the Parties for the sharing of Personal Data for the agreed purposes in relation to the Project.

C.  The Appendices to this Agreement set out the Project specific information relating to the data sharing arrangements.

The Parties, intending to be legally bound, agree as follows:

**1.  Definitions and interpretation**

1.1.  The definitions in Appendix 1 shall apply to this Agreement.

1.2.  The headings of the articles and clauses in this Agreement are for convenience only and have no legal effect.

1.3.  References in this Agreement to any statute or statutory provision include reference to the same as amended, re-enacted, or replaced from time to time.

**2.  Arrangement between the parties**

2.1.  Each Party shall be solely responsible for its own Processing of the Personal Data and ensuring that the Personal Data is processed in compliance with the Data Protection Laws.

2.2.  Each Party shall act as a Data Controller in respect of the Processing of the Personal Data on its own behalf and each shall be a Data Controller of the Personal Data acting individually and in common as further set out in the Data Processing Particulars (Appendix 2).

2.3.  Each Party shall assist the other Party(s) in complying with all applicable requirements of the Data Protection Laws in relation to the processing of the Personal Data.

**3.  Purpose of the data sharing and data to be shared**

3.1.  The Parties agree to share Personal Data for the agreed purpose set out in in the Data Processing Particulars.

3.2.   The Parties will share the minimum amount of data necessary for agreed purpose. A breakdown of the Personal Data being shared is set out in Appendix 3.

**4.   Legal Basis for sharing Information**

4.1.   Under the Data Protection Laws a Data Controller must identify a legal basis for Processing Personal Data and, where applicable, an additional condition for processing Special Category Data.

4.2.   The legal basis for each of the Parties Processing under this Agreement is set out in the Data Processing Particulars.

4.3.   Each Party will ensure it is not subject to any prohibition or restriction which would:

4.3.1.   prevent or restrict it from disclosing or transferring the Personal Data to the other Party(s) as required under this Agreement;

4.3.2.   prevent or restrict it from granting the other Party(s) access to the Personal Data as required under this Agreement; or

4.3.3.   prevent or restrict the Party(s) from Processing the Personal Data, as envisaged under this Agreement.

4.4.   Each Party will ensure that all privacy notices have been given/updated (and/or, as applicable, consents obtained) and are sufficient in scope to enable each Party to Process the Personal Data as required in order to obtain the benefit of its rights and to fulfil its obligations under this Agreement in accordance with the Data Protection Laws.

**5.   Access and individuals' rights**

5.1.   The Parties recognise that Data Subjects have the following general rights under Data Protection Laws: a right to be informed; a right of access; a right to rectification; a right to erasure; a right to restrict processing; a right to data portability; a right to object; and rights in relation to automated decision making and profiling.

5.2.   Where a Party (the Receiving Party) receives a Data Subject request related to any of the rights in 5.1 or correspondence from the ICO which relates directly or indirectly to the Processing of Personal Data under this Agreement the Receiving Party shall promptly, and in any event within 48 hours of receipt, provide to the other Party(s) a copy of such Data Subject request or ICO correspondence and reasonable details of the circumstances giving rise to it. The Parties will take necessary steps, as required by Data Protection Laws, to comply with the request.

5.3.   In addition to providing the notice referred to in 5.2 each Party shall provide the other Party(s) with all reasonable co-operation and assistance required by the other Party(s) in relation to any such Data Subject request or ICO correspondence;

5.4.   In the event that a Party (the Receiving Party) receives a request under the Freedom of Information Act 2000 to disclose the Personal Data, the Receiving Party will notify and consult the other Party(s). The decision to disclose (in full or in part) or not will rest with the Receiving Party.

**6.   Governance and security**

6.1.   Each Party shall:

6.1.1.   Maintain appropriate technical and organisational measures to safeguard the Personal Data from unauthorised or unlawful processing, accidental loss,

destruction or damage. Any agreed technical and organisational security measures particular to this Agreement are set out in Appendix 4;

6.1.2. Provide the other Party(s) with all information necessary to demonstrate compliance with the terms of this Agreement. This includes a general right to audit, inspect or otherwise verify the steps taken;

6.1.3. Ensure that all Personal Data disclosed or transferred to, or accessed by, the other Party(s) is accurate and up-to-date, as well as adequate, relevant and not excessive to enable a Party to Process the Personal Data as envisaged under this Agreement;

6.1.4. Take reasonable steps to ensure the reliability of any of its personnel who have access to the Personal Data;

6.1.5. Not do anything which shall damage the reputation of the other Party(s) or that Party's relationship with the Data Subjects;

6.1.6. Not transfer the Personal Data it is processing to a Restricted Country unless agreed by the Parties, or as set out in the Data Processing Particulars and subject to doing so in accordance with the Data Protection Laws;

6.1.7. Hold the information contained in the Personal Data confidentially and under at least the conditions of confidence as a Party holds Personal Data Processed by it other than the Personal Data;

6.1.8. Not disclose the Personal Data to a third party (including a sub-contractor) in any circumstances without the other Party(s) prior written consent, save in relation to disclosures to Permitted Recipients.

## 7. Data breach management

Each Party shall:

7.1. Where required to do so make due notifications to the ICO; the ICO MUST be notified of any appropriately evaluated data breach within 72 hours.

7.2. Notify the other Party(s) in writing without undue delay and, in any event, within twenty-four (24) hours of it becoming aware of any actual or suspected Personal Data Breach in relation to the Personal Data received from the other Party(s) and shall, within such timescale to be agreed by the Parties (acting reasonably and in good faith):

7.2.1. implement any measures necessary to restore the security of compromised Personal Data; and

7.2.2. support the other Party(s) to make any required notifications to the ICO and/or other equivalent relevant regulator and affected Data Subjects.

## 8. Term and Termination

8.1. This Agreement shall commence on the Effective Date and expire at the end of the Term, unless terminated earlier as provided below or extended with Agreement of the Parties.

8.2. A Party may terminate this Agreement upon written notice in the event that a Party is in material breach of this Agreement and such breach has not been remedied within thirty (30) days' notice of the breach from the non-breaching Party(s).

8.3. Termination or expiry of this Agreement shall not affect the survival of any clauses or provisions herein which are stated, or which by their nature are intended, to continue after termination or expiry.

**9. General provisions**

9.1. No one who is not a party to this Agreement is intended to or may benefit from its terms.

9.2. This Agreement and the attached appendix constitutes the entire agreement between the Parties with respect to the subject matter of this Agreement and supersedes all prior and contemporaneous agreements or communications.

9.3. The Parties may not amend this Agreement, except by a written agreement of authorised representatives of the Parties.

9.4. This Agreement (and all non-contractual liability arising from it) is governed by, and is to be construed in accordance with, the laws of England and Wales. The English Courts will have exclusive jurisdiction to deal with any dispute which arises out of, or in connection with, this Agreement and the Parties irrevocably submit to such jurisdiction.

9.5. This Agreement may be executed in any number of counterparts, each of which shall be an original, but all of which together shall constitute one legal document. Signatures transmitted in an Adobe Portable Document Format (PDF) file attached to an email shall be acceptable to bind each Party and shall not affect the validity of the Agreement in any way.

The Parties have signed this Agreement by their respective duly authorised representatives.

**SIGNED FOR AND ON BEHALF OF**
**The University of York**

Signed: _____

Name:    _____

Title:     _____

Date:     _____

**SIGNED FOR AND ON BEHALF OF**
**Family Lives**

Signed: _____

Name:    _____

Title:     _____

Date:     _____

**SIGNED FOR AND ON BEHALF OF**
**[Local Authority]**


Signed: _____

Name:     _____

Title:      _____

Date:      _____

**APPENDIX 1 - DEFINITIONS**

**Project specific definitions**

| | |
|---|---|
| **"Term"** | This Agreement will commence on the Effective Date and will continue until the project database held by the University is destroyed at the end of 2025. |
| **"Funding Body"** | The Education Endowment Foundation. |
| **"Project"** | Evaluation of the ParentChild+ Programme. |
| **"Nominated Representatives"** | For the University: Dr Louise Tracey |
| | Family Lives Representative shall be: Caroline Fanshawe |
| | Local Authority Representative shall be: [INSERT] |

**General definitions**

| | |
|---|---|
| **"Agreement"** | This data sharing agreement, its attachments, and any agreed amendments. |
| **"Data Protection Laws"** | The General Data Protection Regulation (EU) 2016/679 (the 'GDPR') and Data Protection Act 2018 and all applicable laws and regulations including any successor legislation relating to the processing of the personal data and privacy, including where applicable the guidance and codes of practice issued by the UK ICO. |
| **"Data Controller", "Data Processor", "Data Subject", "Personal Data Breach", "Personal Data", "Processing", "Special Category Data"** | Shall have the meanings as defined by the Data Protection Laws. |
| **"Data Processing Particulars"** | In relation to any Processing under this Agreement the information as set out in Appendix 2 which shall include: the subject matter, duration, nature and purpose, types and categories of data, legal basis and permitted recipients. |
| **"Effective date"** | The date that this Agreement has been signed by all the Parties. |

**"ICO"**                               Means the UK Information Commissioner's
                                        Office, or any successor or replacement body
                                        from time to time.

**APPENDIX 2**

**DATA PROCESSING PARTICULARS**

| | |
|---|---|
| **The subject matter of the Processing** | The subject matter of the Processing is to conduct the independent evaluation of the effectiveness of the ParentChild+ programme (the Project) funded by the Education Endowment Foundation (EEF). <br><br> The EEF is an independent charity founded in 2011 with funding from the Department of Education. Its aim is to build the evidence for what works in raising children's attainment. Consequently, evaluations are conducted to demonstrate the impact of its projects on attainment. EEF evaluations require data on the background characteristics of children (including free school meals eligibility) and their attainment – from schools, from the National Pupil Database (NPD), and, in the case of this study, from Local Authorities. Ultimately, the EEF aims to track all its pupils longitudinally using the NPD and link with data collected directly from its evaluations. This data will be stored in an EEF data archive (held by FFT Education), with the aim to eventually make it publicly available in an anonymised form for further research for the benefit of the wider education and research communities. |
| **Duration of the Processing** | The Parties will Process the Personal Data during the Term. |
| **The nature and purpose of the Processing** | The parties agree to share data for the following purposes only: <br><br> The Local Authority will provide information regarding eligible families to Family Lives (eligible families being those in the Local Authority named who are eligible for, but not currently taking up, the offer of a free 2 year old nursery place). This information will only be provided once the local authority has discharged its responsibility to the data subjects to inform them of how their data will be processed. <br><br> Family Lives will use this data to identify and recruit families to the Project. This data from the Local Authority will only be shared with Family Lives not with the University. <br><br> Once families are recruited and consented the University will obtain data relating to the Children in Need Status (as defined under section 17 of the Children Act 1989) from the Local Authority (access to this data will be included in the consent issued by the University). <br><br> At the end of the study children's school destination will be obtained from the Local Authority (this will be included in the participant consent issued by the University). <br><br> Further detail is provided in Appendix 3. |
| **The type of Personal Data being Processed** | As set out in Appendix 3. |
| **The categories of Data Subjects** | The Personal Data concerns parents/carers and their children. |
| **University's legal basis for Processing** | In line with the University's charter which states that it will advance learning and knowledge by teaching and research, the University processes personal data for research purposes under Article 6 (1) (e) of the GDPR: |

| | |
|---|---|
| | Processing is necessary for the performance of a task carried out in the public interest<br><br>Special category data is processed under Article 9 (2) (j):<br><br>Processing is necessary for archiving purposes in the public interest, or scientific and historical research purposes or statistical purposes<br><br>Research will only be undertaken where ethical approval has been obtained from the University of York Education Ethics Committee, where there is a clear public interest and where appropriate safeguards have been put in place to protect data. |
| **Family Lives legal basis for processing** | Family Lives will process information based upon Article 6 (1) (e) of the GDPR:<br><br>Processing is necessary for the performance of a task carried out in the public interest. |
| **Local Authorities legal basis for Processing** | The Local Authority will process and share information based upon the following article 6 GDPR clauses:<br><br><br>[Local Authority to complete] |
| **Permitted Recipients** | As detailed in Appendix 4 – 'Access'.<br><br>At the end of the evaluation, the University, as evaluators, are expected to submit data directly to the EEF data archive, held by the Fisher Family Trust (FFT). When the data is transferred to the FFT, the EEF becomes the data controller and is responsible for determining the purpose and means of the data processing. The non-anonymised evaluation data may be shared by the EEF with the Department for Education and, in an anonymised form, with the Office for National Statistics and potentially other research teams. The EEF processes personal data from evaluations on the basis of legitimate interests, according to the General Data Protection Regulation (GDPR), Article 6, paragraph 1(f), Further information about how the data is processed by the EEF can be found in their privacy notice: https://educationendowmentfoundation.org.uk/public/files/Grantee_guide_and_EEF_policies/Evaluation/Data_protection/Privacy_notice_-_EEF_evaluations.pdf. |
| **Transfer of data to a Restricted Country** | Although it is not anticipated, there is potential that where deemed appropriate the University may utilise a cloud storage solution provided by Google which means that data can be located at any of Google's globally spread data centres. However, the University has data protection compliant arrangements in place with this provider. For further information see, https://www.york.ac.uk/it-services/google/policy/privacy/ |

## APPENDIX 3 - DESCRIPTION OF DATA

| Item | Purpose/Use | Source | When collected | Format |
|---|---|---|---|---|
| Eligible family details (Parent/carer name, child name, child date of birth, Children in need status) | To allow Family Lives to recruit families to the study | Local Authorities | April-November 2019 | Encrypted Excel spreadsheet |
| Participating family details (Parent/carer name, child name, child date of birth, Children in Need Status, family demographics) | To facilitate the conduct of the research and to be used in statistical analysis | Family participant consent forms Local Authorities | April-November 2019 | Paper record forms Encrypted Excel spreadsheet |
| Routinely collected programme data (attendance, withdrawal, cancellation and mid-programme questionnaire) | To allow for compliance analysis and process evaluation | Collected by Family Lives | July 2019-March 2021 | Encrypted Excel spreadsheet |
| NPD Data: pupil details (including FSM status and anonymised Pupil Matching Reference) | To be used in the long term statistical analysis | Local Authorities (School destination) National Pupil Database (NPD) | February 2021 February 2022 | Encrypted Excel spreadsheet Text file downloaded from NPD secure data portal |
| Audio Recordings of interviews with local authority leads, parents and members of Family Lives | To allow the evaluation team researchers to assess stakeholder views of the programme | Collected by evaluation team researchers | July 2019-March 2021 | Audio file |

# APPENDIX 4 - SECURITY ARRANGEMENTS

I. The parties agree to take the following steps to ensure data accuracy: the pupil data provided by the Local Authority at the start of the study will be imported into a database and cross-checked with the original to ensure consistency. A dedicated member of the University team will ensure that all research data collected during the study is correctly completed, assigned and input.

II. Electronic data sent by the Local Authority to the Family Lives and University of York teams will be encrypted and transferred via the University of York's DropOff service: https://www.york.ac.uk/it-services/services/dropoff/

III. In the unlikely event of any occurrence where personal information is e-mailed between parties both recipient and transmitter domain will be TLS compliant.

IV. Emails relating to the study and project participants by Family Lives, University of York and Durham University will be TLS

V. All NPD data and video recordings will be destroyed 1 year after completion of the evaluation (March 2022). All other individual data stored at University of York will be destroyed at the end of 2025.

VI. All electronic data will be stored on central servers with access through authorised network computers or via the secure Remote Desktop using the University of York encrypted VPN. No data will be stored on portable devices.

VII. Families' personal details will be held separately from all other data. Participant families will be allocated a unique identifier (FamilyId) that will be used to label all data collected by the evaluation team.

VIII. The University wide information security policy is publicly available at: https://www.york.ac.uk/media/it-services/docs/policy/policies/InformationSecurityPolicy.pdf

| Item | Transfer to/from evaluation team | Storage | Access | Destruction |
|---|---|---|---|---|
| Eligible family details (Parent/carer name, child name, child date of birth, Children in Need status) | N/A | Password protected files on Family Lives servers | Restricted to Family Lives | January 2020 |
| Participating family details (Parent/carer name, child name, child date of birth, Children in Need Status, family demographics) | Encrypted and sent by the University of York's DropOff service | In a password protected database on the university servers | Restricted to University of York | November 2025 |
| Routinely collected programme data (attendance, withdrawal, cancellation and mid-programme questionnaire) | Encrypted and sent by Family Lives via the University of York's DropOff service | In a password protected database on the university servers | Restricted to University of York | November 2025 |

| Item | Transfer to/from evaluation team | Storage | Access | Destruction |
|---|---|---|---|---|
| NPD Data: pupil details (including FSM status and anonymised Pupil Matching Reference) | Txt file downloaded from NPD secure data portal, password required | In a restricted electronic folder on the university servers. | Restricted to members of the evaluation team | One year after the end of the evaluation (November 2022) |
| Audio Recordings of interviews with local authority leads, parents and members of Family Lives | With the researcher on paper and password protected voice recorder | Paper interview notes will be held in locked filing cabinets stored in a room with restricted access. The notes will be transcribed by the researcher and stored on university servers. The audio files will be uploaded to university servers and deleted from the voice recorder. | Restricted to members of the evaluation team and the transcription service. The transcription service will not have information about the participants. | Audio recordings will be deleted one year after the end of the evaluation (November 2022). Electronic and hard-copy files will be deleted at the end of 2025. |

# MEMORANDUM OF UNDERSTANDING (MoU)

# Evaluation of the ParentChild+ programme

This Memorandum of Understanding (MOU) is between the Local Authority named on the signature page of this agreement, the University of York (the 'University') and Family Lives. This MoU explains what your Local Authority's participation in this study will entail. If you agree to take part and accept the terms and conditions outlined, please sign a copy of this form and return by email or post to the contact provided at the end of this letter.

During this project, you will be working with the Family Lives team (supported by Sheffield Hallam University and South Yorkshire Futures), hereafter referred to as the 'Delivery Team', who are responsible for identifying suitable families, training home visitors and for programme delivery and with researchers from the University of York (supported by researchers at Durham University and Leeds Beckett University), hereafter referred to as the 'Evaluation Team', who are carrying out an independent evaluation of the project.

**Aim of the programme**

ParentChild+ is an intensive home visiting programme delivered in the UK by Family Lives. It has an extensive US evidence-base indicating improvements in receptive vocabulary, self-regulation, behaviour and school readiness. The aim of the programme is to enhance the home learning environment and improve children's readiness for school. The programme involves twice-weekly visits to selected participating families by specially trained home visitors over a 15 month period (to a total of 92 sessions). Each week the home visitor takes a free, age appropriate toy or book and models with the parent how to read and play with their child. The target audience is families who are eligible for, but not currently taking up, the offer of a free 2 year old nursery place.

**Aims of the evaluation**

**The aim of the evaluation is to assess the impact of the ParentChild+ programme on child language skills, child behaviour, school readiness and parent-child interaction. Funded by the Education Endowment Foundation, the evaluation will research the effectiveness of ParentChild+ in a sample of 320 families. The results of the research will contribute to our understanding of the potential value of using the ParentChild+ programme to improve children's development and parenting skills.  The impact of ParentChild+ will be evaluated and compared with "usual practice", i.e. usual parenting practices, using a randomised controlled trial design (RCT). This means that those participants recruited to the study will be randomly allocated to either receive the programme (160 families) or to be in a control group which does not receive the programme (160 families). Random allocation is felt to be the best and fairest way of investigating what effect the ParentChild+ programme has on children and parenting behaviours as compared with changes associated with child development more generally.**

**Structure of the evaluation**

The evaluation involves four Local Authorities in the South Yorkshire region (Barnsley, Doncaster, Rotherham and Sheffield). Each Local Authority will assist in identifying eligible parents for the study. Recruitment will be of eighty families per Local Authority with children aged 2-3 who are eligible for, but not taking up, the 2-year free nursery offer, with Children in Need being prioritised for recruitment. There will be a minimum threshold for parents' English language fluency in order to ensure that parents fully understand the evaluation process and this will be assessed by the Delivery and Evaluation Teams based on ability to understand and complete the necessary paperwork related to the study with assistance from a data collector. Children with language delay and special educational needs will be included in the study providing they/their family meets the other eligibility criteria. Families will be identified between April and November 2019.

After families have been identified they will be approached to participate in the study. Once consent is received from eligible families the University of York will arrange for baseline testing to occur. This will involve a home visit by a trained data collector who will complete a short receptive language assessment with the child (approximately 5-10 minutes; BPVS), and will help the parent/carer to complete the Ages and Stages Questionnaire (the focus of which would be verbal and non-verbal interaction, positive behaviours and early literacy skills; ASQ). A small subsample of participants (10 per Local Authority) will be approached to have a 20 minute home observation video session but this will involve a separate consent process.

Once the baseline data is received, families will be randomly allocated to receive the ParentChild+ programme or to continue with 'usual practice' (40 families in each Local Authority in each condition). It is important that potential participant families understand and consent to this process. Randomisation will take place on a rolling basis from July to December 2019. Families will be informed of their allocation within a week of randomisation with programme delivery for those families allocated to receive ParentChild+ commencing approximately 2 weeks later.

Participant families who are allocated to receive the programme will do so over a 15 month period and those allocated to the control condition will be provided with three toys at the mid-point of the project to encourage continued participation. Approximately 16 months after the baseline assessment has taken place families will be post-tested using the BPVS, the ASQ and the Home Learning Environment Questionnaire Index (HLEQ). A subsample of parents will also be asked to take part in a 20-minute home observation and a telephone interview. Family Lives will conduct routine data collection based on usual programme practice. This includes data relating to sessions completed, withdrawal from the programme (including any known reasons for withdrawal), reasons for cancellation of home visits (when provided) and data from the mid-point programme interviews with participating parents conducted by the Lead Coordinator. This data will be shared with the evaluation team via the Data Sharing Agreement.

The Evaluation Team also plans to link project data with information from the National Pupil Database in the longer term, to assess any longer-term impacts of the programme. Consent for this will be included in overall consent from project participants.

**Responsibilities of the Delivery Team:**

- Work closely with the relevant Local Authority teams to facilitate shared working and a joined-up approach to recruiting families for ParentChild+, alongside access to nursery provision.

- Deliver the ParentChild+ programme of home visits to those participant families allocated to receive the programme.
- Share data with the Evaluation Team in line with a signed Data Sharing Agreement.
- Treat any data provided by the Local Authority with the strictest confidence and in line with the Data Sharing Agreement and Data Protection regulations (as outlined above).
- Act as the first point of contact for any questions about the intervention.

**Responsibilities of the Evaluation Team:**

- Act as the first point of contact for any questions about the evaluation.
- Organise a data sharing agreement to be put in place with LAs and Family Lives.
- Conduct the random allocation of participants.
- Provide information about the trial for participants.
- Conduct baseline and post-test assessments with participants.
- Conduct home observations and/or telephone interviews with a subsample of participants.
- Collect data and relevant consent from parents in order to link to the National Pupil Database for possible long-term follow-up.
- Provide the incentives for control parents as a thank you for taking part in the study.
- Analyse the data from the project.
- Disseminate the research findings through the EEF report and at conferences and through academic papers.
- Upload anonymised data from the trial onto the EEF/FFT data archive.

**Requirement for Local Authorities:**

- Between April and December 2019, provide details of children eligible but not currently taking up the 2-year of nursery provision offer for disadvantaged children. This data will include (from different sources): child's name, child's Date of Birth, parent name; address, parent telephone number, & Children in Need Status.
- Where possible, work closely with the Delivery Team to promote the programme, facilitate shared working and a joined-up approach to recruiting families for ParentChild+ alongside access to nursery provision.
- Agree to the Evaluation Team obtaining data on the evaluation cohort's attainment results and other characteristics such as FSM status, from the National Pupil Database, and will provide details of known school destination and/or child UPNs to enable this to be achieved (Febru ary 2021 and February 2022).
- At the earliest opportunity, notify the Delivery Team if there are any issues which could prevent the effective implementation of the intervention.
- Members of Local Authorities involved in the project will provide valid addresses and telephone contact numbers (and where possible email addresses) of eligible families to the Evaluation and Delivery Teams and agree to check communications from the Delivery Team regularly during the period of the research.
- Inform the Delivery and Evaluation Teams immediately of any change in contact details either within the Local Authority or of eligible/participating parents.
- Facilitate the delivery of the intervention programme by providing meeting, training and interviewing facilities
- Participate in an interview with a member of the Evaluation Team to discuss accessibility and desirability of implementing the programme.

*Use of Data*

All family data and any other personal data used for the Project will be treated with the strictest confidence and will be used and stored in accordance with all applicable data protection laws including the General Data Protection Regulation (EU) 2016/679 (the GDPR) and the Data Protection Act 2018 (the Data Protection Legislation).

The parties agree that a data sharing agreement will be put in place between the University, Family Lives and each Local Authority which will include the details of the types of personal data being shared, the purpose and duration of that sharing and the responsibilities each party has in relation to that information.

The University and Family Lives will be deemed as Data Controllers (as defined by the Data Protection Legislation) with regard to the personal data used for this Project. Accordingly the University will, in the form of a privacy notice/participation sheet, provide information to individuals about the use of their personal data which we may hold and use for this Project. Individual participants will also be provided with the option of withdrawal from the research and details of the process to do so.

The University's privacy notice/information sheet is compliant with the requirements of the GDPR including a clear statement of the University legal basis for processing their personal data, which will be for the performance of a task carried out in the public interest. This is in line with the University's charter which states learning and knowledge will be advanced through teaching and research. If any special category data is processed by the University then this would be under the legal basis of archiving purposes in the public interest, or scientific and historical research purposes or statistical purposes.

For the purpose of the research, named data will be linked with information about participants provided by the Local Authority and with information provided by the National Pupil Database (NPD). Confidentiality will be maintained and no one outside the Delivery Team or the Evaluation Team will have access to the study database. This will be stored until completion of the study in 2021. It will then be shared with the Department for Education, the EEF's archive manager and, in an anonymised form, the Office for National Statistics, the EEF's archive manager and potentially other research teams. The central database held by the Evaluation Team will then be deleted. Further matching to NPD and other administrative data may take place during subsequent research.

The University is committed to the principle of data protection by design and default and will collect the minimum amount of data necessary for the project. In addition, we will anonymise or pseudonymise data wherever possible. All results will be anonymised so that no individual local authorities, individual families or children will be identifiable in the report or dissemination of any results. Results may also be used in presentations and for teaching purposes.

If you have any questions about the participant information sheet or concerns about how the data is being processed, please feel free to contact Dr Louise Tracey by email (louise.tracey@york.ac.uk) or by telephone on +44 (0)1904 323460, or the Chair of Ethics Committee via email education-research-administrator@york.ac.uk. If you are still dissatisfied, please contact the University's Data Protection Officer at dataprotection@york.ac.uk

## Local Authority agreement

I agree for my Local Authority _____to take part in the Evaluation of the ParentChild+ programme.

Local Authority / Lead Name: _____

Local Authority / Lead Signature: _____ Date: ____/____/_____

Local Authority/Lead Email Address: _____

**Main Contact Details (if different from above):**

Main Contact Name: _____

Main Contact Role: _____

Main Contact Email Address: _____

Main Contact Phone Number: _____

**Evaluation Team, University of York**

Lead Researcher Name: Louise Tracey

Lead Researcher Signature: _____ Date: ____/____/_____

Lead Researcher Email Address: louise.tracey@york.ac.uk

**Delivery Team, Family Lives**

Main Contact Name: Caroline Fanshawe

Main Contact Signature: _____ Date: ____/____/_____

Main Contact Email Address: carolinef@familylives.org.uk

**Thank you for agreeing to take part in this research. Please return this form to:**

Dr Louise Tracey, Department of Education, University of York, York, YO10 5DD or email a scanned copy to
louise.tracey@york.ac.uk

**General Data Protection Regulation (GDPR) Information Sheet**

**On what basis will you process my data?**

Under the General Data Protection Regulation (GDPR), the University must identify a legal basis for processing personal and, where appropriate, an additional condition for processing special category data.  In line with our charter, which states that we advance learning and knowledge by teaching and research, the University processes personal data for research purposes under Article 6 (1)(e) of the GDPR:

*Processing is necessary for the performance of a task carried in the public interest*

Special category data is processed under Article 9 (2)(j):

*Processing is necessary for archiving purposes in the public interest or scientific and historical research purposes or statistical purposes*

Research will only be undertaken where ethical approval has been obtained, where there is a clear public interest and where appropriate safeguards have been put in place to protect data.

In line with ethical expectations and to comply with common law duty of confidentiality, we will seek your consent to participate where appropriate.  This consent will not, however, be our legal basis for processing your data under GDPR.

**How will you use my data?**

Data will be processed for research purposes as outlined in this notice and the participation information letter.

**Will you share my data with 3rd parties?**

Personal data will be accessible to the project team at the University of York only, unless you are allocated to receive the programme in which case contact details will be shared with Family Lives.  Anonymised data may be accessed by Durham University and Leeds Beckett University for analysis purposes only.  At the end of the study your child's data will be shared with the Department for Education, the EEF, FFT Education (EEF's data processor for the EEF data archive) and, in an anonymised form, potentially with other research teams. Further matching to NPD data may take place during subsequent research.  Anonymised data may be reused by the research team or other third parties for secondary research purposes. With your permission we will also inform your Local Authority that you are participating in the study and/or programme

**What is the Education Endowment Foundation (EEF)?**

The EEF is an independent charity founded in 2011 with funding from the Department of Education. Its aim is to build the evidence for what works in raising attainment. Ultimately, this means demonstrating the impact of its projects on children's attainment. All EEF evaluations require data on the background characteristics of pupils and their attainment – from local authorities or schools and from the NPD. Ultimately, the EEF aims to track all its pupils longitudinally using the NPD and link with data collected directly from its evaluations. This data will be stored in an

EEF data archive (held by FFT Education), with the aim to eventually make it publicly available in an anonymised form for further research for the benefit of the wider education and research communities.

**Why do the researchers want to look at data from the National Pupil Database (NPD)?**

The NPD is a government database where information about all pupils in English schools and their exam results (e.g. SATs) are stored. Looking at data on the NPD will allow the researchers to compare the attainment of pupils in schools who did and did not receive the Family Lives ParentChild+ programme. To obtain data from the NPD we need to ask your Local Authority to provide your child's unique pupil number. The funder of the research (EEF) has also asked us to collect information about free school meal eligibility, because they are interested in exploring the reach of the interventions that they fund. All data will be transferred securely by local authorities to the evaluation team with your consent.

**How will you keep my data secure?**

The University will put in place appropriate technical and organisational measures to protect your personal data and/or special category data.  For the purposes of this project all information, including video recordings, collected as part of the sub-study observations, will be stored securely by code number.  Any identifiable information will be stored separately from the data.  Information will be treated confidentially and shared on a need to know basis only.  The University is committed to the principle of data protection by design and default and will collect the minimum amount of data necessary for the project.  In addition, we will anonymise or pseudonymise data wherever possible.

**Will you transfer my data internationally?**

No.  Data will be held within the European Economic Area in full compliance with data protection legislation.

**Will I be identified in any research outputs?**

No.  Any dissemination of the research findings (e.g. through reports, academic publications and presentations) will be in an anonymous format.

**How long will you keep my data?**

Any individually identifiable data will be destroyed by November 2025.  At the end of the study your child's data will be shared with the Department for Education, the EEF, FFT Education (EEF's data processor for the EEF data archive) and, in an anonymised form, with other research teams and potentially the UK Data Archive. Further matching to NPD data may take place during subsequent research.

**What rights do I have in relation to my data?**

Under GDPR, you have a general right of access to your data, a right to rectification, erasure, restriction, objection or portability.  You also have a right to withdraw at any point prior to April 2021.  Please note, not all rights apply where data is processed purely for research purposes.  For further information see, https://www.york.ac.uk/records-management/generaldataprotectionregulation/individualsrights/.

**Questions or concerns**

If you have any questions about this GDPR information sheet or concerns about how your data is being processed, please contact Louise Tracey (louise.tracey@york.ac.uk) in the first instance.  If you are still dissatisfied, please contact the University's Data Protection Officer (dataprotection@york.ac.uk).

**Right to complain**

If you are unhappy with the way in which the University has handled your personal data, you have a right to complain to the Information Commissioner's Office.  For information on reporting a concern to the Information Commissioner's Office, see www.ico.org.uk/concerns.

# Appendix 3: Adherence and Mediation

## Adherence

**Table 1:** Results of first stage regression (analysis including inverse probability weights, N = 168)

| Term | Coef. | Robust SE | p-value | 95% CI |
|---|---|---|---|---|
| Allocation | | | | |
|   Intervention | 82.39 | 2.23 | <0.001** | 77.98 to 86.80 |
| Local authority | | | | |
|   Sheffield | -0.02 | 3.49 | 0.996 | -6.92 to 6.88 |
|   Doncaster | 3.02 | 2.88 | 0.297 | -2.68 to 8.71 |
|   Rotherham | 7.58 | 2.75 | 0.006 | 2.16 to 13.01 |
| BPVS-III score at baseline* | 0.19 | 0.13 | 0.162 | -0.08 to 0.45 |
| Age (years) at baseline* | -1.67 | 4.69 | 0.722 | -10.94 to 7.59 |
| Intercept | -2.38 | 1.96 | 0.226 | -6.25 to 1.49 |

*Mean centred
**Partial R-squared = 0.8882 (p < 0.0001)

**Table 2:** Results of first stage regression (analysis excluding inverse probability weights, N = 223)

| Term | Coef. | Robust SE | p-value | 95% CI |
|---|---|---|---|---|
| Allocation | | | | |
|   Intervention | 79.66 | 2.15 | <0.001 | 75.41 to 83.90 |
| Local authority | | | | |
|   Sheffield | 0.24 | 3.23 | 0.941 | -6.13 to 6.61 |
|   Doncaster | -2.41 | 3.14 | 0.443 | -8.60 to 3.78 |
|   Rotherham | 6.35 | 2.67 | 0.018 | 1.08 to 11.61 |
| BPVS-III score at baseline* | 0.16 | 0.12 | 0.189 | -0.08 to 0.39 |
| Age (years) at baseline* | -2.36 | 4.43 | 0.594 | -11.09 to 6.36 |
| Intercept | -0.91 | 2.00 | 0.650 | -4.85 to 3.03 |

*Mean centred
**Partial R-squared = 0.8685 (p < 0.0001)

## Mediation analysis

The assumed causal model or the exploratory mediation analysis is given in Figure xx1. The key assumptions/features of this causal model are:

- No confounding of allocation (Z) and outcome (Y). This follows from random allocation of treatment)

- Confounding of follow-up HLE index and BPVS-III scores is negligible conditional on the observed baseline covariates X (BPVS-III score, HLE index score, Local authority, age, English as an Additional Language and household income (binary - ≤£20000 or >£20000)). This is illustrated in Figure xx1 by the absence of any common causes of the follow-up HLE index score (the mediator M) and Y.

- The effect of the mediator on outcome is not constrained to be equal across treatment groups (i.e. the model explicitly allows for treatment by mediator interaction in the outcome regression). This is made explicit in Figure xx1 by the arrow from Z to the arrow between M and Y.

Point and interval estimates of the natural direct and indirect effects were obtained using the user written Stata command `paramed`.

**Figure 1:** Assumed causal model for exploratory mediation analysis. Here X denotes measured baseline covariates (see above) and nodes Z, M and Y denote random allocation, HLE index score at follow-up and BPVS-III score at follow-up respectively
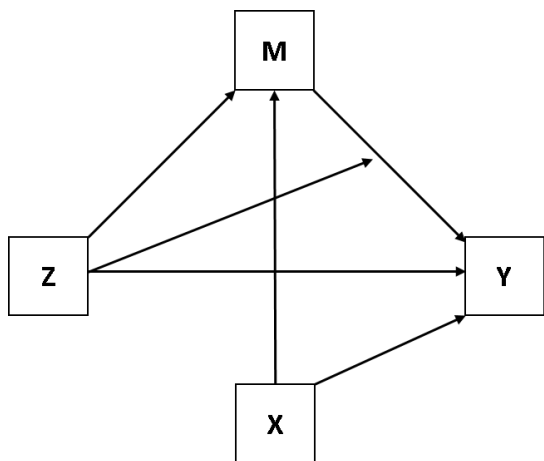
**Appendix 4: ParentChild+ Covid-19 Families Evaluation Survey Report**

# ParentChild+ COVID-19 Families Evaluation Survey Report

September 2020 V 0.4

Katrina d'Apice, Erin Dysart, Louise Tracey, Nicole Gridley & Carole Torgerson

# Contents

# Overview

The ParentChild+ families survey was developed to look into the support families may have had during the first Covid19 pandemic lockdown. The survey had two aims: 1) to assess parents' sources of educational support for their child during the first COVID-19 lockdown, and 2) to assess the support that families in the intervention group had received from Family Lives during the first lockdown. Due to the national lockdown the home visits for intervention families were paused for a period of four months. However, during this four-month pause Family Lives remained in contact with many of the intervention families in order to maintain engagement and provide support for families. As part of the intervention, families would have normally had two 30-minute face to face sessions per week with a home visitor. As evaluators we were keen to establish what the support during the four-month pause of the programme looked like. Additionally, due to the disruption of the first lockdown for all families, we were keen to establish whether families had sought advice from organisations other than Family Lives on how to support their child(ren)'s development during this period. Descriptive statistics are reported.

# Methodology

## Procedure

All families (n=283) that were enrolled in the ParentChild+ research programme were invited to take part in the online survey (appendix 1) via a link that was emailed to them. The survey included questions about household composition, childcare, and working practices. The parents were also asked to state the types of activities they had undertaken with their child(ren) and the educational support they had sought from organisations. In addition, the intervention group families were asked to report the frequency of contact with Family lives and select the type of support received from 4 options, the parents were able to choose multiple forms of support. Parents completed the survey online between 17th July 2020 and 1st September 2020. Data were analysed, and descriptive statistics were reported by group allocation.

## Participants

Overall, 102 families (57 control, 41 intervention, 4 undisclosed allocation) responded to the survey. The programme children within these families were aged on average 2 years (range = 2 to 4 years). Most families (n = 89) reported English as their primary language at home. Additional primary languages included Polish (n = 3), Urdu (n = 1) and Bengali (n = 1). One family reported a bilingual language environment that included both English and Punjabi. Seven families did not state the primary language that they spoke at home.

The proportion of survey respondents speaking each language is comparable to the overall sample of families that reported their primary languages spoken at home during the pre-test visit. For example, English was the primary language spoken by 94% of the survey respondents compared to 85% of the overall sample of families. Polish was reported as the primary language in 3% of families from both the survey respondents and the full sample of families. Urdu was the primary language reported by 3% of the overall sample, but only 1% of the survey respondents. By contrast, Bengali was spoken by a larger proportion of the survey respondents compared to the overall sample, 1% and 0.4% respectively.

## Household Composition

Three families had two children enrolled in the study. Thus, four children from two households were aged 2 years and two children from one household were aged 3 years. In cases where two children are enrolled in the study, the parents were asked to count both children as a single child in the description about household size below.

For 28 families, the programme child was the only child living in the family home during lockdown. In 43 families the programme child had one other sibling under the age of 18 living at home. A total of 23 families had three children living in the household, three families had four children, and five families reported five or more children living at home during lockdown. Table 1 summarises the age of the study children and those children that lived in the same home as the study children during the lockdown.

**Table 1. Age of Children in Households**

| Number of Children in Household | Age of Children | | | | | |
|---|---|---|---|---|---|---|
| | 0 to 2 years | 3 to 4 years | 5 to 7 years | 8 to 11 years | 12 to 14 years | 15 to 17 years |
| One child (n=28) | 18 | 10 | - | - | - | - |
| Two children[1] (n=43) | 31 | 23 | 15 | 5 | 0 | 1 |
| Three Children (n=43) | 20 | 17 | 14 | 9 | 4 | 4 |
| Four Children (n=3) | 4 | 2 | 1 | 3 | 2 | 0 |
| Five Children (n=5) | 8 | 1 | 4 | 4 | 4 | 2 |

Note. [1]one family did not state the study child's age. [2] one family that reported 5 children in the household did not state the ages of the fourth and fifth child.

Mothers from 88 families (37 intervention, 48 control group, 3 didn't report group allocation) had primary caregiver duties for the majority of the time during lockdown, whereas only seven fathers (2 intervention, 5 control group) reported primary responsibility for the care of their children during this time. Childcare was shared between the mother and father in three families (all control group), and one intervention family responded that the grandmother did the majority of childcare during lockdown. School/nursery providers were the main source of childcare for only two families (1 intervention, 1 control group).

Of the families that completed the survey, nine families reported that the primary caregiver also worked from home during lockdown (four intervention and five control group). From these nine families, seven were mothers who also worked from home during lockdown, five of whom worked part-time and two who did not report whether the work was full or part-time. One was a father who worked part-time, and one was a primary caregiver stated as 'other' who also worked part-time. Thus, it is assumed from the information given that all other primary caregivers (n= 92) were not working from home at the same time as looking after their child(ren).

Parents were asked to state the number of adults, aged over 18, that were in the household during the lockdown (in addition to the primary caregiver if they were a member of the household).

| **Intervention Group** | **Control Group** |
|---|---|
| • 2 parents reported no additional adults in the household (i.e., a single parent family). | • No parents reported that they were the only adult in the household. |
| • 20 parents lived with one other adult. | • 20 parents lived with one other adult. |
| • 18 parents lived with 2 other adults. | • 37 parents lived with 2 other adults. |
| • 1 parent lived with 3 other adults. | • No parents lived with 3 other adults. |

The parents were asked to report if the additional adults in the household also worked from home during the lockdown.

| **Intervention Group** | **Control Group** |
|---|---|
| *First Additional Adult* | *First Additional Adult* |
| • 28 did not work from home, this may have been either because they were not working or because they were key workers who worked outside the home. | • 44 did not work from home, this may have been either because they were not working or because they were key workers who worked outside the home. |

- 10 did work from home.
  - 9 worked full time
  - 1 worked part time

***Second Additional Adult***

- 17 did not work from home.

- 2 did work from home.
  - Both full time

***Third Additional Adult***
- 1 did work from home.
  - Unknown if this was full or part time

- 13 did work from home.
  - 9 worked full time
  - 4 worked part time

***Second Additional Adult***

- 29 did not work from home.

- 8 did work from home.
  - 3 full time
  - 5 part time

***Third Additional Adult***
- None reported.

# Results

## Contact with Family Lives

Families completing the survey were asked to state whether they were in the intervention (Group A) or the control arm (Group B). Families who indicated they were in Group A, were additionally asked about the contact they had with Family Lives during the lockdown. Of the 41 intervention families, 38 (93%) reported that they had been in contact with Family Lives during this time (only three parents stated they had no contact). More than half of these families (n = 22) reported that they had been in contact with Family Lives twice a week during lockdown. A further 13 families reported contact frequency of once a week, and two families stated that they had contact with Family Lives less than once a week. One family did not answer this question.

The parents were asked to report how the Home Visitor from Family Lives supported them during lockdown by selecting options from a list, each parent could choose multiple options (Figure 1). 4 families chose all 4 options, 8 families chose 3 options, 12 families chose 2 options and 12 families only chose 1 option. 1 family did not answer this question.

The most common option "providing ideas for activities to do with my child(ren)" was reported by 33 parents. "Generally discussing difficulties of the Covid19 lockdown" was noted by 24 parents, and "giving advice on where to seek support from outside agencies e.g. financial support, mental health support" was chosen by 12 parents. In addition, seven parents selected "providing ways in which to deal with behavioural issues" as a form of support that was provided.

Other forms of support included catching up and checking on family's wellbeing, for example "[our Home Visitor was] *extremely friendly, reassuring and helpful.*" One parent commented that the Home Visitor from Family Lives is "*second to none and we will be eternally grateful for the support, empathy and compassion she has shown to our family*!" Another parent stated that "*having that regular phone call each week during lockdown has been amazing.. even like a lifeline to the outside world at times. Not only to discuss what my little ones* [have] *been up to but for me as well*."

**Figure 1. The percentage of different types of support parents report receiving from Family Lives during lockdown. Multiple types of support were received by some families.**
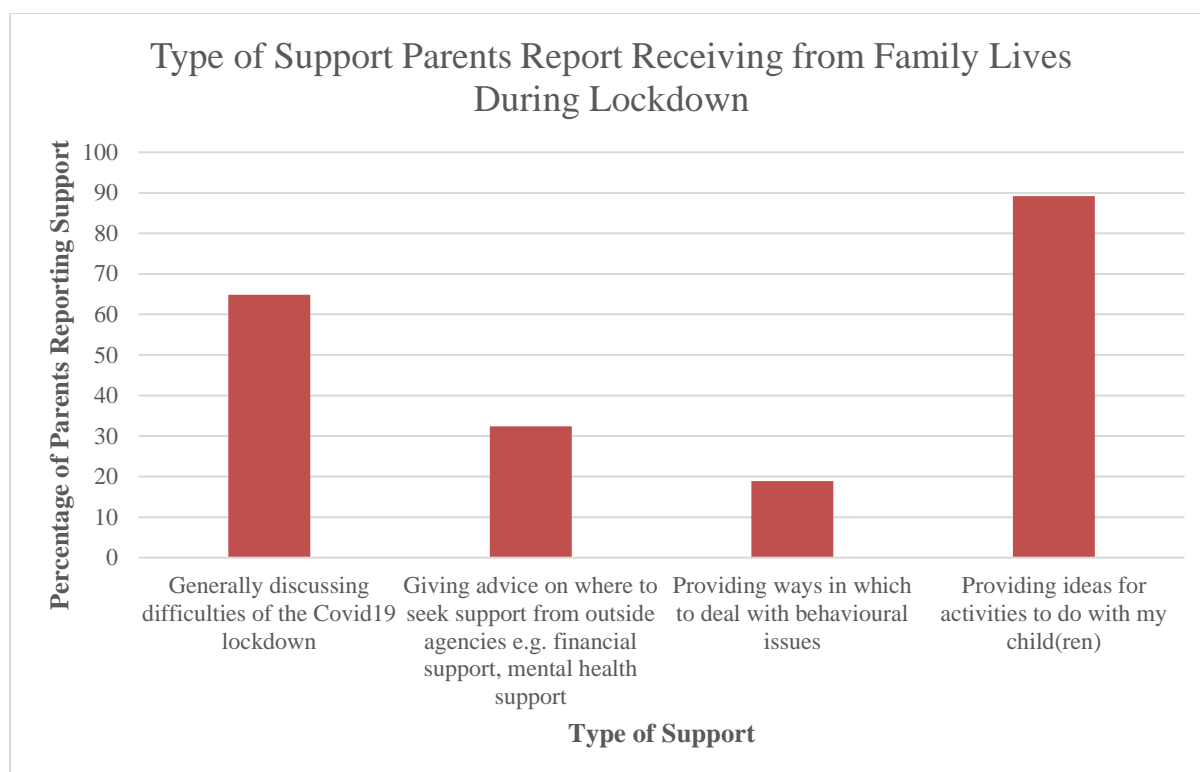


**Usefulness of Support Received by Family Lives**

The majority of parents reported that the support they received from Family Lives during the Covid19 lockdown was either very helpful or helpful (19 and 13 parents respectively). Only one parent stated that the support was neither helpful nor unhelpful. Several parents commented in more detail about the support they had received from Family Lives:

"*My home visitor never missed a call and we looked forward to her calls each week.*"

"*In a time where support wasn't there from family it was good to have when thing's felt difficult.*"

"*It has been a bit of normality for both me and my child to speak with our visitor every week throughout the lock down, we have been provided with activities to do which have been brilliant. Also a Facebook page has been set up where we can share things we have been up to and see what others are doing with their children, there are also activities posted on there for us to try with our children which we have really enjoyed trying. Our visitor has been amazing and always kept in touch checking that we are all okay too it's been nice to know that we've always had someone checking in on us.*"

"*The person who works with us as part of this programme has been amazing and is a truly wonderful teacher to my child.*"

"*I honestly never thought that an outside organisation could be of help as much as Family Lives has been especially during Lockdown. I'm a very independent individual and previously worked in a nursery for many years and thought I had lots of my own ideas to educate my child. But Family Lives has helped my take that experience to another level. I have nothing but praise for my home visitor and appreciate all the activity ideas, weekly calls and now video calls. Thank you to everyone involved in keeping everything up and running during this crazy time.*"

# Activities Undertaken During Lockdown

All parents (control and intervention) were asked to state five activities they had been doing with their children during lockdown. The activities that parents reported were categorised into five themes:

- Educational Activities
- Physical Activities
- Fine motor skill Activities
- Play
- Screen Time

### Educational Activities

Reading was the most common of all activities with over half of parents (53 out of 90 answering this question) stating that they read with their child during lockdown. Maths, such as counting, numbers and shapes were mentioned by 16 parents. Emphasis on word learning, for example, learning the alphabet, sounds, and spellings were reported by eight parents. Vocabulary development in the form of singing (e.g. nursery rhymes) was noted as an activity by eight parents. Schoolwork was an activity undertaken in six households, and general learning (e.g. learning flash cards) took place in two households. Figure 2 show the activities undertaken by families in the intervention and the waiting control group for all themes.

### Physical Activities

Walking was the most common outside activity, with 44 parents reporting that they walked with their children during lockdown. Outside play, such as in the garden or trampolining, was mentioned by 34 parents, and gardening (e.g. growing vegetables) was reported by 12 parents. An additional two parents stated that riding bikes was an activity they did with their children during lockdown, and a further three parents stated that dancing was an activity undertaken during lockdown.

### Fine Motor Skill Activities

Fine motor skill activities took place in many households during lockdown, with 32 parents reporting engaging in arts and crafts with their child. Parents commented that painting, drawing, and baking/ cooking were activities undertaken in their homes (n = 32, 21, and 29 parents respectively). In addition, messy play which included sand and water play was reported as an activity by 26 families. Games and puzzles were played in 18 families, building, such as LEGO, Duplo, or forts were present in 15 families' activities and Play-Doh was specifically mentioned by 13 families.

### Play

Role play (e.g. cooking, imaginary play, dressing up, dolls tea party) was mentioned by 19 families. In addition, general play (e.g. with toys) was reported by 17 families.

### Screen Time

Watching television and films was reported by nine families.

**Figure 2. Activities undertaken by families during lockdown per group.**
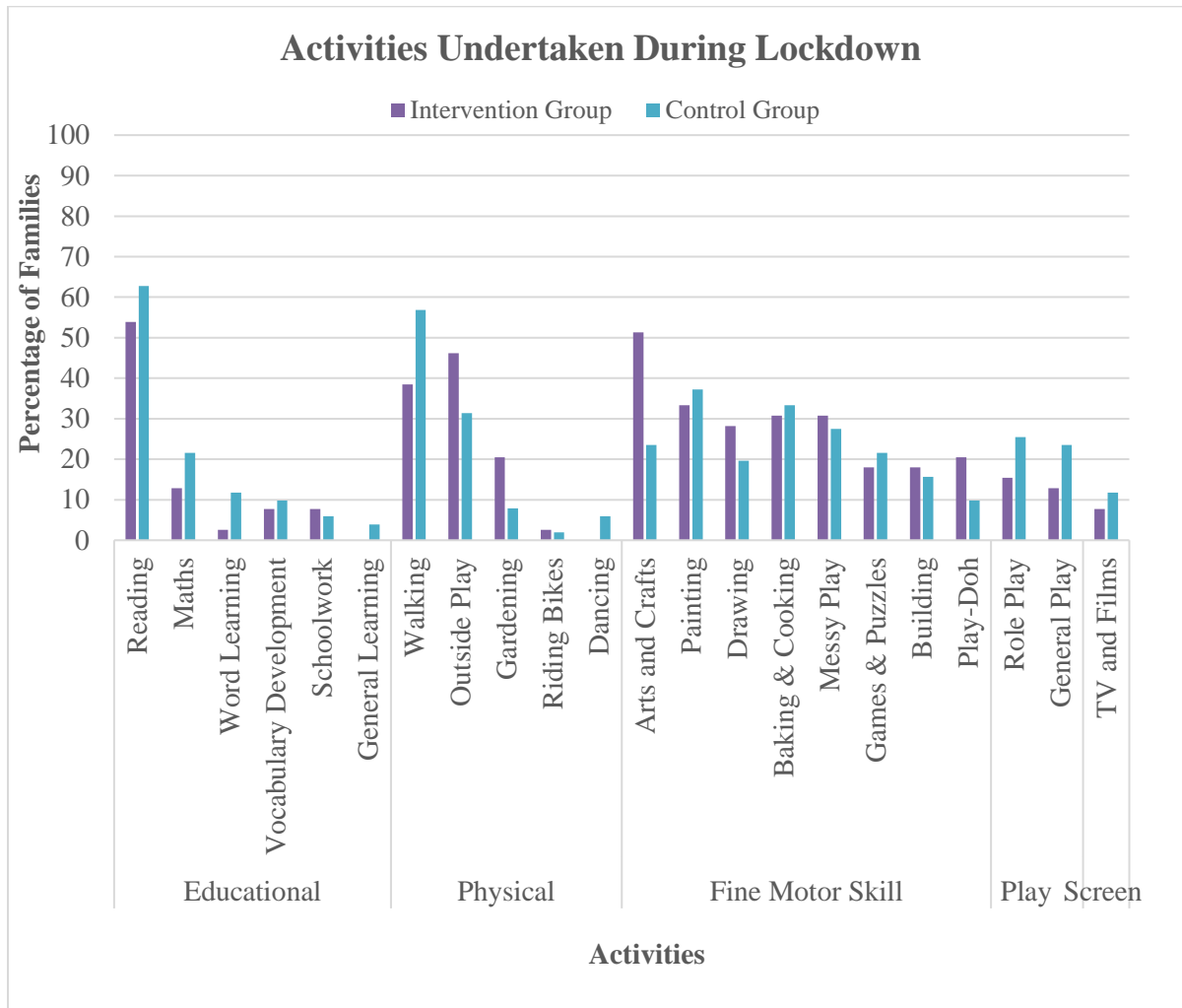


## Support from Organisations (other than Family Lives)

All parents were asked to state if they had sought support from organisations during the lockdown. It is important to note that the survey did not specify that this question related to organisations other than Family Lives therefore all data relating directly to Family Lives was removed in order for the evaluators to understand what additional support families may have sought. A total of 52 parents reported that they had not looked for support from organisations to help them with educating their child. In contrast, 30 parents sought '*a little*' support from organisations, and 11 parents looked for '*a lot*' of support (see Figure 3 for support sought by each group).

**Figure 3. Percentage of families seeking educational support from organisations during lockdown, per group.**
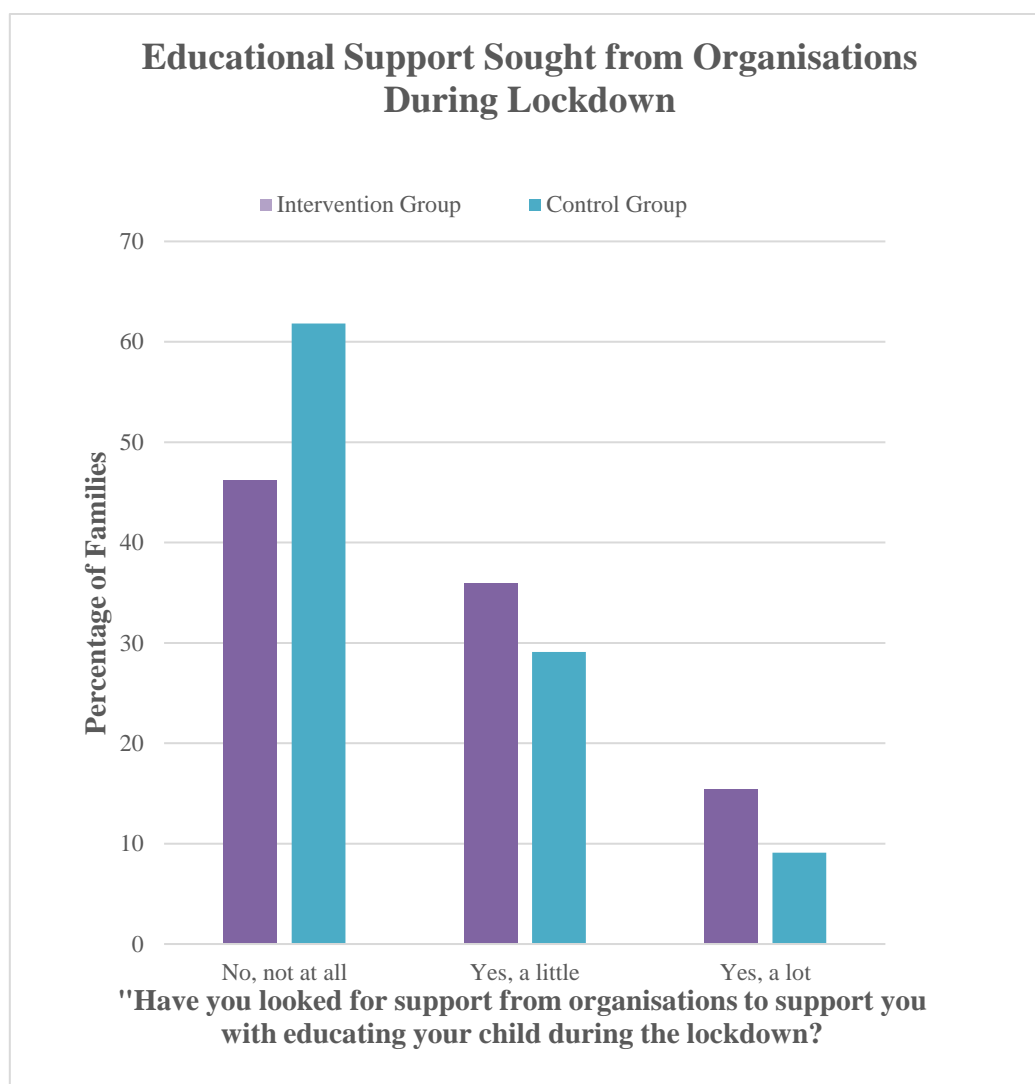


Most parents found that the support they encountered from organisations offering educational activities during the lockdown was either very helpful or helpful (9 and 17 parents respectively). Reasons for these responses were that they kept children entertained and aided development, with the websites Twinkl and Pinterest noted as good sources for educational activities. However, seven parents reported that the support from organisations was neither helpful nor unhelpful because the activity ideas were something they already did, or Pinterest ideas were too old for their child.

A total of 22 families (seven intervention, 15 waiting controls) provided further information on the educational resources that they had accessed during the lockdown (Figure 4). The educational website most frequently accessed by parents during the lockdown was Twinkl, with one parent stating that "it has printable activities". Children's schools were cited as a source for educational resources in four families, all of whom had older children. Several parents also reported accessing Rawmarsh children's centre boogie tots sessions or other local online groups. YouTube videos such as phonics videos, BBC bitesize and family Facebook pages were used by a few parents to access educational resources. Other online resources included Pinterest, ABC Mouse, RMmaths and Jolly phonics.

**Figure 4. The percentage of families in each group accessing different educational resources during lockdown.**



Educational Resources Accessed During Lockdown

■ Intervention Group   ■ Waiting Control Group
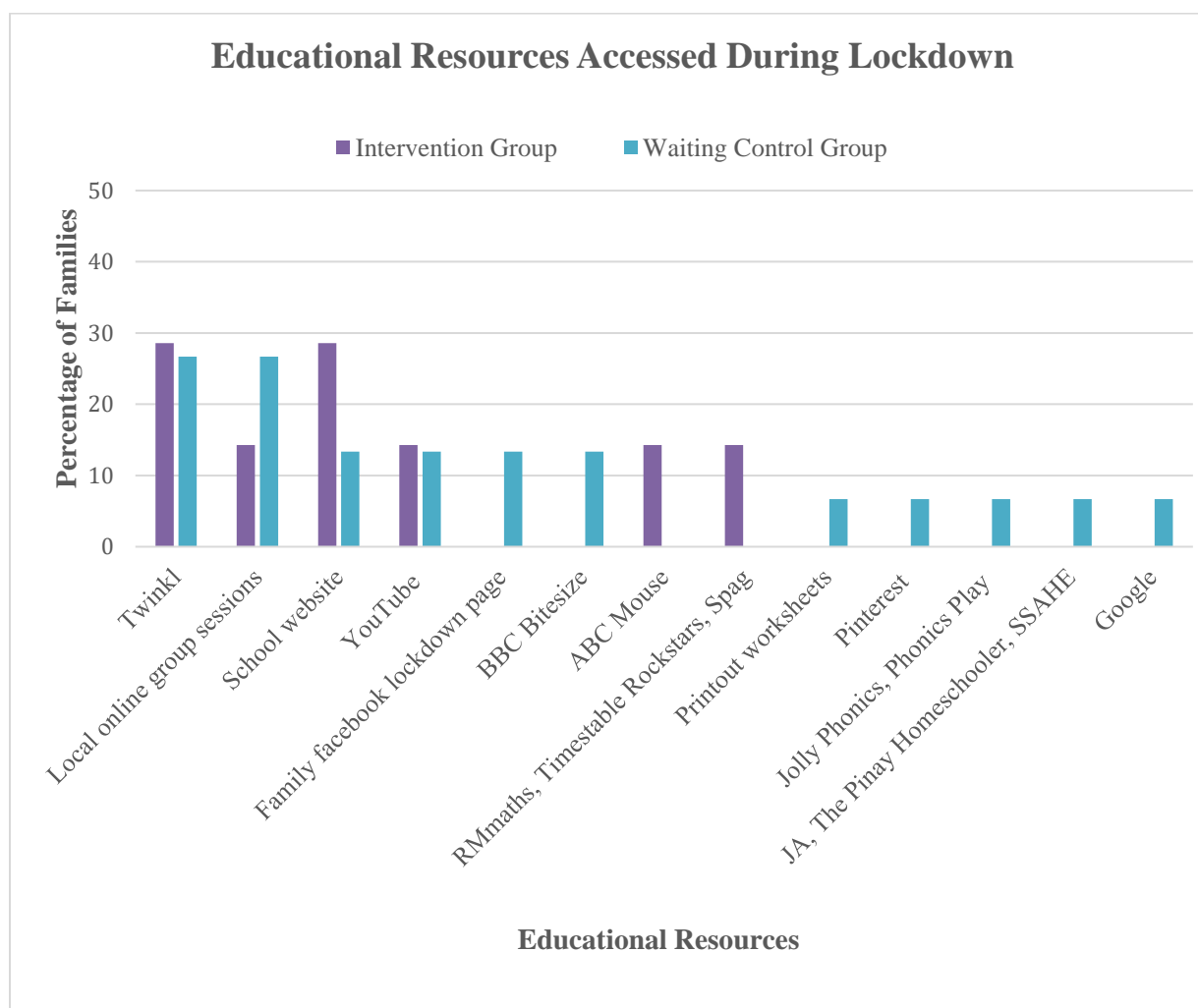
**\*** Percentages are based on 22 families (7 intervention, 15 controls) that reported this information. JA = Jady Alveraz, SSAHE = Sarah Stay At Home Educator.

## Parents' Experiences During Lockdown

The parents were asked to comment about their experiences during lockdown. 12 parents stated that it was "*difficult*", "*hard*", "*lonely*" or "*stressful*", whilst one parent noted that it was hard but was getting easier. A few parents reported that although it was difficult, it was also good to spend time with their families. On a positive note, 5 parents reported that it was "*wonderful*" spending quality time with their families, and a further 3 parents commented that it was "*fun*", for example, "*fantastic, really good quality time exploring, learning, being creative.*"

Several parents mentioned that they had to juggle work and childcare or home-schooling responsibilities. In addition, multiple child households were mentioned as a challenge by a few parents "*it was stressful juggling [the] needs of a 2-year-old and 5-year-old*". By contrast, a few parents reported that not much had changed because they already looked after their child at home, or because it was easy to keep their child entertained.

Four parents reported that the lockdown aided their child's development, for example, "*They have come on so much both emotionally and educationally as so much time that we wouldn't have had.*" However, there were also reports by 4 parents about their child's frustration during the lockdown:

"*It's been very hard having an only child and not being allowed to play with other children. She's been craving social interaction with other children.*"

"*He was getting very frustrated with us, even bored! Which was completely understandable as it was difficult for adults to go through, never mind a two and a half year old.*"

One parent with an autistic child mentioned that the change in routine was particularly challenging for their child. Another parent noted the loss of activities available to them during lockdown "*the main things we have missed is play cafes, trampoline, zoos, swimming lessons.*"

# Summary

The main aim of this survey was to assess parents' sources of educational support for their child, and the support that families in the intervention group had received from Family Lives during the COVID-19 lockdown. It should be noted that the survey may be biased towards those who speak English as a first language as this population accounted for the majority of participants, However, this is reflective of the population taking part in the ParentChild+ research programme., 102 families took part in the study out of a potential 283 participating families. The current sample represents 36% of the overall trial sample, and therefore we cannot be confident that the findings within this survey are representative of the experiences of all the families enrolled in the larger RCT. In addition, the families who completed the survey are more likely to have been more engaged in the research programme.

Of the 41 intervention families who took part in the survey 38 families (93%) reported contact with Family Lives, 22 of which reported twice weekly contact which is the same amount of contact families would have received as part of the intervention although the amount of time spent for each contact is not clear. 13 families also reported once weekly contact with Family Lives. From the data provided 80% of this contact involved Family Lives providing parents/carers with ideas for activities to do with their children. This has important implications with respect to the evaluation as it means that some families were essentially still getting similar support to that being provided as part of the intervention but this is not accounted for in the number of sessions recoded for the impact evaluation. Essentially, this means that some families, at the end of the intervention will have had more sessions that those recorded, and this should be noted in the final evaluation report. One parent also discussed a Facebook page which was set up by Family Lives where activities to do with their child(ren) were posted and shared. Again, this has important implications for the impact evaluation and should be followed up in more detail in the process evaluation. It is important however to balance this point with the positive implications highlighted in the report.

Overall, it is important to note that that almost 60% of families in the intervention group also said that the contact they had with Family Lives was generally discussing the difficulties of the Covid19 lockdown. Families clearly appreciated the support from the home visitors in what was a very difficult time. It is therefore important to acknowledge that the work done by Family Lives during the lockdown as it was clearly helpful to many families and it may well have had a positive impact on engagement of the programme and retention of intervention families. Newsletters were sent out to all families in both April and July. It will be important to address, in the process evaluation, whether families felt that the newsletters were helpful in keeping them up to date with what was happening with the research project and whether they were influential to keep them engaged with the research project, particularly during unprecedented circumstances

In order to understand what activities families had been doing during lockdown we asked all families to list five activities they did with their child(ren) in a typical week. Activities were then grouped into five categories; educational activities, physical activities, fine motor skill activities, play and screen time. Across the intervention group and the control group family activities were generally similar across all categories although control families seemed to have more variation in the activities, they were doing compared to intervention families. Additionally, control group families reported doing more walking, more role play and general play and had slightly more screen time compared to intervention families. This is important for evaluation as it demonstrates that intervention families may have been doing other activities (possibly those suggested by Family Lives) during the lockdown period. This point should be addressed in the bespoke questionnaire which forms part of the process evaluation to look into this further we looked at the support families may have sought from organisations other than Family Lives. A further finding suggested that families had little screen time with their children during lockdown. The bespoke questionnaire should also investigate whether parents were referring to screen time with the adult present.

The findings suggest that families in the control group were less likely to seek support that those in the intervention group. The intervention group were more likely to seek a little or a lot of support. Families from intervention and control groups reported seeking support from Twinkle, local online group sessions, You Tube and school websites (where families also had older children). However, there seemed to be differences between control and intervention groups with other support accessed. Intervention families reported using more apps that directly helped with maths and literacy such as timetables rock stars and ABC mouse. Control group families reported using such as BBC bitesize and Phonics based websites. Importantly, control group families also reported using the Family Facebook lockdown page. This raises

some concerns that will need to be covered in the process evaluation as it is possible that this refers to a Family Lives Facebook page which should only be able to be accessed by intervention families. If control group families have also accessed the Family Lives Facebook page, then they have essentially been accessing part of the ParentChild+ programme which, in turn, could have helped enhance their child(ren)'s language abilities. Again, this should be investigated further in the bespoke questionnaire and interviews with Home Visitors.

The survey additionally asked questions regarding the families experiences of lockdown. It was important for the evaluation team to be able to report on difficultyies families faced during this period. While there were many families who reported difficulties other families also reported on the positive things that had come out of lockdown such as spending quality time with their children with parents also stating that their child(ren) had come on socially and emotionally. These findings are in line with the Save the Children report (2020) which found families enjoyed spending time together. Indeed, research evidence shows that it is the quality and not the quantity of the parent-child interaction that is important for children's development (Sylva et al., 2004). However, it should be noted that the Save the Children report also found that while some children showed great resilience others struggled with their wellbeing and a lack of routine. ParentChild+ families reported the difficulties faced with juggling work and childcare. There were also additional difficulties for children with Special Educational Needs (SEN) with reports of changes in routine causing frustration which has also been found in current literature (e.g. Toseeb et al. 2020) Similarly, other families reported difficulties not having the normal activities to do. An important part of the process evaluation then will be to establish reasons for changes in the home learning environment (as measured by the HLE questionnaire) which have taken place due to the lockdown.

Overall, this report provides an overview of the important support given to intervention families from Family Lives over the lockdown period. It will be important to establish the role of this on parental engagement and retention of families. It will also be important for the process evaluation to establish how much this additional support may have impacted upon the primary outcome measure. Also, of importance will be to establish if control group families were enabled access to the Family lives online lockdown page and consider the implications on primary outcomes measures. Finally, given the very different experiences for families during the lockdown periods it will be important to understand secondary outcome measures within the context of the Covid19 lockdown restrictions and the additional time that families may have had to support their children's development.

# References

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# Appendix 5 – The Family Lives Covid-19 Survey

# ParentChild+ Families Survey

Q1 We would like you to complete the following survey to give us an idea about what you have been doing with your child during the Covid19 lockdown and what support you may have received. We understand how difficult the lockdown has been on all families, especially in terms of social distancing, and we know that you may not have been able to interact with your child as you normally would during these times. We also know that many people have had issues to deal with during this period and may not have been able to focus on the usual things.

 Please answer this survey as honestly as you can. All data collected for this survey will be anonymous.  We will not ask for your name or any other identifying information. Participation in this study is entirely optional. If you do agree to complete the questionnaire you are free to leave any questions unanswered or to stop completing the questionnaire altogether at any point.  Once the questionnaire is submitted the data cannot be withdrawn; as it is anonymous there will be no way to identify your data.

 Please click the arrow to continue

Q2 Please indicate how may children (including the research child), under the age of 18, have been in your household during the Covid19 lockdown (Note; if you have more than one child taking part in the research please count both children as one child)

○ 1  (1)

○ 2  (2)

○ 3  (3)

○ 4  (4)

○ 5+  (5)

Q3
Please state child 1 age (this should be the current age of the child taking part in the research)

○ 1 year  (4)

○ 2 years  (5)

○ 3 years  (6)

○ 4 years +  (7)

Q33 Do you have more than one child taking part in the research? (e.g. you have twins)

○ Yes  (1)

○ No  (2)

Q34 Please state the age of the additional child taking part in the research

○ 1 year  (1)

○ 2 years  (2)

○ 3 years  (3)

○ 4 years +  (4)

Q23
Please state child 2 age

○ 0 to 2 years  (4)

○ 3 to 4 years  (5)

○ 5 to 7 years  (6)

○ 8 to 11 years  (7)

○ 12 to 14 years  (8)

○ 15 to 17 years  (9)

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Q24
Please state child 3 age

○     0 to 2 years  (4)

○     3 to 4 years  (5)

○     5 to 7 years  (6)

○     8 to 11 years  (7)

○     12 to 14 years  (8)

○     15 to 17 years  (9)

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Q25
Please state child 4 age

○     0 to 2 years  (4)

○     3 to 4 years  (5)

○     5 to 7 years  (6)

○     8 to 11 years  (7)

○     12 to 14 years  (8)

○     15 to 17 years  (9)

---

Q26
Please state child 5 age

○   0 to 2 years  (4)

○   3 to 4 years  (5)

○   5 to 7 years  (6)

○   8 to 11 years  (7)

○   12 to 14 years  (8)

○   15 to 17 years  (9)

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Page Break

Q4 Who looked after your child(ren) for the majority of the time during the initial lockdown at the end of March 2020?

○ School/Nursery provider  (1)

○ Mother  (2)

○ Father  (3)

○ Another adult living in the house  (4)

○ other (please state)  (5) _____

---

Q5 Did the person looking after your child during the initial lockdown also work from home during this time?

○ Yes  (1)

○ No  (2)

---

Page Break

Q6 Did the person looking after you child during the initial lockdown work full time or part time hours?

○   Full-time  (1)

○   Part-time  (2)

○   Don't know  (3)

Q7 How many adults (18+ years) have been in your household during the initial lockdown? (if the person looking after your child(ren) was a member of your household please state how many additional adults there were in the household)

○   0  (1)

○   1  (2)

○   2  (3)

○   3  (4)

○   4+  (5)

Page Break

Q8 Did adult 1 work from home during the initial lockdown?

○ Yes  (1)

○ No  (2)

Q27 Did adult 2 work from home during the initial lockdown?

○ Yes  (1)

○ No  (2)

Q28 Did adult 3 work from home during the initial lockdown?

○ Yes  (1)

○ No  (2)

Q29 Did adult 4 work from home during the initial lockdown?

○ Yes  (1)

○ No  (2)

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Page Break

Q9 Did adult 1 work-full time or part-time hours during the initial lockdown?

○   Full-time  (1)

○   Part-time  (2)

○   Don't know  (3)

--------------------------------------------------------------------------------

Q30 Did adult 2 work-full time or part-time hours during the initial lockdown?

○   Full-time  (1)

○   Part-time  (2)

○   Don't know  (3)

--------------------------------------------------------------------------------

Q31 Did adult 3 work-full time or part-time hours during the initial lockdown?

○   Full-time  (1)

○   Part-time  (2)

○   Don't know  (3)

--------------------------------------------------------------------------------

Q32 Did adult 4 work-full time or part-time hours during the initial lockdown?

○ Full-time  (1)

○ Part-time  (2)

○ Don't know  (3)

Q15 Please state which group you are in for the ParentChild+ Research

○ Group A (Intervention group)  (1)

○ Group B (Control group)  (2)

*Skip To: End of Block If Please state which group you are in for the ParentChild+ Research = Group B (Control group)*

*Display This Question:*

*If Please state which group you are in for the ParentChild+ Research = Group A (Intervention group)*

Q11 During the Covid19 lockdown have you been in contact with Family Lives?

○ Yes  (1)

○ No  (2)

*Display This Question:*

*If During the Covid19 lockdown have you been in contact with Family Lives? = Yes*

Q12 On average how many times have you had contact with Family lives during a typical week since the initial lockdown in March began?

○   Twice a week  (1)

○   Once a week  (2)

○   Less than once a week  (3)

---

Q13 How did the Home Visitor from Family Lives support you during the times you had contact (tick as many as apply)?

☐   Generally discussing difficulties of the Covid19 lockdown  (1)

☐   Giving advice on where to seek support from outside agencies e.g. financial support, mental health support (2)

☐   Providing ways in which to deal with behavioural issues  (3)

☐   Providing ideas for activities to do with my child(ren)  (4)

☐   Other (Please state)  (5) _____

---

Q16 How helpful have you found the support given by Family Lives during the Covid19 lockdown?

○ Very Helpful  (1)

○ Helpful  (2)

○ Neither helpful nor unhelpful  (3)

○ Unhelpful  (4)

○ Very unhelpful  (5)

○ Please state a reason for your answer  (6) _____

**End of Block: Block 4**

**Start of Block: Block 5**

Q17 Please list up to 5 activities you (or the person looking after your child) have been doing with your child(ren) in a typical week during lockdown

○ Activity 1  (1) _____

○ Activity 2  (2) _____

○ Activity 3  (3) _____

○ Activity 4  (4) _____

○ Activity 5  (5) _____

Q18 Have you looked for support from organisations to support you with educating your child (the child who is part of the research) during the lockdown? (such as looking for educational activities online)?

○ Yes, alot  (1)

○ Yes, a little  (2)

○ No, not at all  (3)

---

*Skip To: Q21 If Have you looked for support from organisations to support you with educating your child (the chil... = No, not at all*

---

Q19 How helpful have you found the support you have found from organisations offering educational activities during the Covid19 lockdown?

○ Very helpful  (1)

○ Helpful  (2)

○ Neither helpful nor unhelpful  (3)

○ Unhelpful  (4)

○ Very Unhelpful  (5)

○ Please give a reason for your answer  (6) _____

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Q20 What educational resources have you accessed during the Covid19 lockdown? (please state the organisation name, if you know it, and the activity)

_____

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Q21 What language do you usually speak at home?

○ English  (1)

○ Punjabi  (2)

○ Urdu  (3)

○ Bengali  (4)

○ Pashto  (5)

○ German  (6)

○ Spanish  (7)

○ Polish  (8)

○ Russian  (9)

○ Slovakian  (10)

○ Other (please state)  (11) _____

End of Block: Block 5

Start of Block: Block 6

Q22 Please leave any other comments about your experiences during lockdoown

_____

End of Block: Block 6

# Appendix 6: Further baseline data summaries

**Table 1**: Household baseline characteristics as randomised and as included in the primary analysis

| | Randomised | | | Included in primary analysis | | |
|---|---|---|---|---|---|---|
| | **Control**<br>(N = 142) | **Intervention**<br>(N = 141) | **Total**<br>(N = 283) | **Control**<br>(N = 114) | **Intervention**<br>(N = 109) | **Total**<br>(N = 223) |
| **Local authority, n (%)** | | | | | | |
| Barnsley | 35 (24.6) | 35 (24.8) | 70 (24.7) | 27 (23.7) | 27 (24.8) | 54 (24.2) |
| Sheffield | 33 (23.2) | 32 (22.7) | 65 (23.0) | 29 (25.4) | 24 (22.0) | 53 (23.8) |
| Doncaster | 40 (28.2) | 40 (28.4) | 80 (28.3) | 33 (28.9) | 30 (27.5) | 63 (28.3) |
| Rotherham | 34 (23.9) | 34 (24.1) | 68 (24.0) | 25 (21.9) | 28 (25.7) | 53 (23.8) |
| **Care-giver's first language, n (%)** | | | | | | |
| English | 113 (79.6) | 112 (79.4) | 225 (79.5) | 91 (79.8) | 84 (77.1) | 175 (78.5) |
| Other | 20 (14.1) | 20 (14.2) | 40 (14.1) | 16 (14.0) | 18 (16.5) | 34 (15.2) |
| Missing | 9 (6.3) | 9 (6.4) | 18 (6.4) | 7 (6.1) | 7 (6.4) | 14 (6.3) |
| **Home ownership, n (%)** | | | | | | |
| Owned | 57 (40.1) | 46 (32.6) | 103 (36.4) | 52 (45.6) | 41 (37.6) | 93 (41.7) |
| Rented | 73 (51.4) | 84 (59.6) | 157 (55.5) | 53 (46.5) | 60 (55.0) | 113 (50.7) |
| Missing | 12 (8.5) | 11 (7.8) | 23 (8.1) | 9 (7.9) | 8 (7.3) | 17 (7.6) |
| **Home type, n (%)** | | | | | | |
| Detached | 16 (11.3) | 8 (5.7) | 24 (8.5) | 13 (11.4) | 7 (6.4) | 20 (9.0) |
| Semi-detached | 69 (48.6) | 67 (47.5) | 136 (48.1) | 59 (51.8) | 49 (45.0) | 108 (48.4) |
| Terrace | 40 (28.2) | 50 (35.5) | 90 (31.8) | 30 (26.3) | 40 (36.7) | 70 (31.4) |
| Flat | 6 (4.2) | 5 (3.5) | 11 (3.9) | 4 (3.5) | 4 (3.7) | 8 (3.6) |
| Missing | 11 (7.7) | 11 (7.8) | 22 (7.8) | 8 (7.0) | 9 (8.3) | 17 (7.6) |
| **Employment, n (%)** | | | | | | |
| Employed full-time | 10 (7.0) | 8 (5.7) | 18 (6.4) | 6 (5.3) | 7 (6.4) | 13 (5.8) |
| Self-employed or employed part-time | 36 (25.4) | 40 (28.4) | 76 (26.9) | 32 (28.1) | 36 (33.0) | 68 (30.5) |
| Unemployed or Long term sick | 69 (48.6) | 72 (51.1) | 141 (49.8) | 53 (46.5) | 49 (45.0) | 102 (45.7) |
| Other | 16 (11.3) | 11 (7.8) | 27 (9.5) | 15 (13.2) | 9 (8.3) | 24 (10.8) |
| Missing | 11 (7.7) | 10 (7.1) | 21 (7.4) | 8 (7.0) | 8 (7.3) | 16 (7.2) |
| **Household income, n (%)** | | | | | | |
| On income support | 26 (18.3) | 26 (18.4) | 52 (18.4) | 15 (13.2) | 15 (13.8) | 30 (13.5) |
| £0 - £5000 | 15 (10.6) | 27 (19.1) | 42 (14.8) | 13 (11.4) | 22 (20.2) | 35 (15.7) |
| £5001 - £10000 | 8 (5.6) | 9 (6.4) | 17 (6.0) | 7 (6.1) | 5 (4.6) | 12 (5.4) |
| £10001 - £15000 | 22 (15.5) | 18 (12.8) | 40 (14.1) | 20 (17.5) | 14 (12.8) | 34 (15.2) |
| £15001 - £20000 | 21 (14.8) | 18 (12.8) | 39 (13.8) | 17 (14.9) | 17 (15.6) | 34 (15.2) |
| £20001 - £30000 | 23 (16.2) | 16 (11.3) | 39 (13.8) | 21 (18.4) | 13 (11.9) | 34 (15.2) |
| £30000+ | 15 (10.6) | 13 (9.2) | 28 (9.9) | 12 (10.5) | 13 (11.9) | 25 (11.2) |
| Missing | 12 (8.5) | 14 (9.9) | 26 (9.2) | 9 (7.9) | 10 (9.2) | 19 (8.5) |
| **Number of participating children in household, n (%)** | | | | | | |
| 1 | 139 (97.9) | 139 (98.6) | 278 (98.2) | 111 (97.4) | 107 (98.2) | 218 (97.8) |
| 2 | 3 (2.1) | 2 (1.4) | 5 (1.8) | 3 (2.6) | 2 (1.8) | 5 (2.2) |
| **Number of non-participating children in household, n (%)** | | | | | | |
| 0 | 33 (23.2) | 26 (18.4) | 59 (20.8) | 29 (25.4) | 23 (21.1) | 52 (23.3) |
| 1 | 50 (35.2) | 54 (38.3) | 104 (36.7) | 41 (36.0) | 39 (35.8) | 80 (35.9) |
| 2 | 26 (18.3) | 32 (22.7) | 58 (20.5) | 22 (19.3) | 23 (21.1) | 45 (20.2) |
| 3+ | 24 (16.9) | 20 (14.2) | 44 (15.5) | 15 (13.2) | 17 (15.6) | 32 (14.3) |
| Missing | 9 (6.3) | 9 (6.4) | 18 (6.4) | 7 (6.1) | 7 (6.4) | 14 (6.3) |
| **Number of adults in household, n (%)** | | | | | | |
| 1 | 23 (16.2) | 35 (24.8) | 58 (20.5) | 15 (13.2) | 21 (19.3) | 36 (16.1) |
| 2 | 100 (70.4) | 87 (61.7) | 187 (66.1) | 87 (76.3) | 73 (67.0) | 160 (71.7) |
| 3+ | 10 (7.0) | 10 (7.1) | 20 (7.1) | 5 (4.4) | 8 (7.3) | 13 (5.8) |
| Missing | 9 (6.3) | 9 (6.4) | 18 (6.4) | 7 (6.1) | 7 (6.4) | 14 (6.3) |

**Table 2:** Baseline scores for the primary and secondary outcomes as randomised and as included in the primary analysis (after pooling of data from households with multiple participating children)

| | Randomised | | | Included in primary analysis | | |
|---|---|---|---|---|---|---|
| | **Control** (N = 142) | **Intervention** (N = 141) | **Total** (N = 283) | **Control** (N = 114) | **Intervention** (N = 109) | **Total** (N = 223) |
| **BPVS-III** | | | | | | |
| N | 132 | 131 | 263 | 106 | 102 | 208 |
| Mean (SD) | 17.7 (10.8) | 16.7 (10.1) | 17.2 (10.4) | 18.5 (11.3) | 16.9 (10.1) | 17.7 (10.8) |
| Median (Q1, Q3) | 17.5 (10.0, 22.5) | 16.0 (10.0, 22.0) | 16.5 (10.0, 22.0) | 18.0 (10.0, 23.0) | 15.5 (10.0, 22.0) | 16.5 (10.0, 23.0) |
| Min, Max | 0.0, 55.0 | 1.0, 54.0 | 0.0, 55.0 | 0.0, 55.0 | 1.0, 51.0 | 0.0, 55.0 |
| **ASQ (Comms)** | | | | | | |
| N | 133 | 132 | 265 | 107 | 102 | 209 |
| Mean (SD) | 44.5 (16.3) | 43.8 (16.4) | 44.2 (16.3) | 43.9 (16.8) | 44.1 (16.2) | 44.0 (16.5) |
| Median (Q1, Q3) | 50.0 (35.0, 60.0) | 50.0 (35.0, 60.0) | 50.0 (35.0, 60.0) | 50.0 (35.0, 60.0) | 50.0 (35.0, 60.0) | 50.0 (35.0, 60.0) |
| Min, Max | 0.0, 60.0 | 0.0, 60.0 | 0.0, 60.0 | 0.0, 60.0 | 0.0, 60.0 | 0.0, 60.0 |
| **ASQ (Fine Motor)** | | | | | | |
| N | 129 | 132 | 261 | 103 | 102 | 205 |
| Mean (SD) | 41.3 (14.5) | 40.4 (14.8) | 40.9 (14.6) | 41.3 (14.1) | 40.6 (14.6) | 40.9 (14.3) |
| Median (Q1, Q3) | 45.0 (30.0, 50.0) | 45.0 (30.0, 50.0) | 45.0 (30.0, 50.0) | 45.0 (30.0, 50.0) | 45.0 (30.0, 50.0) | 45.0 (30.0, 50.0) |
| Min, Max | 5.0, 60.0 | 0.0, 60.0 | 0.0, 60.0 | 5.0, 60.0 | 0.0, 60.0 | 0.0, 60.0 |
| **ASQ (Personal-Social)** | | | | | | |
| N | 129 | 129 | 258 | 103 | 100 | 203 |
| Mean (SD) | 45.1 (12.9) | 44.7 (13.7) | 44.9 (13.3) | 44.7 (13.2) | 44.7 (13.9) | 44.7 (13.5) |
| Median (Q1, Q3) | 45.0 (40.0, 55.0) | 50.0 (35.0, 55.0) | 45.0 (40.0, 55.0) | 45.0 (40.0, 55.0) | 50.0 (35.0, 55.0) | 47.5 (40.0, 55.0) |
| Min, Max | 5.0, 60.0 | 10.0, 60.0 | 5.0, 60.0 | 5.0, 60.0 | 10.0, 60.0 | 5.0, 60.0 |
| **HLE** | | | | | | |
| N | 131 | 133 | 264 | 106 | 103 | 209 |
| Mean (SD) | 29.9 (11.0) | 29.3 (10.6) | 29.6 (10.8) | 30.5 (11.2) | 29.3 (10.4) | 29.9 (10.8) |
| Median (Q1, Q3) | 31.0 (21.0, 38.0) | 29.0 (21.0, 38.0) | 29.0 (21.0, 38.0) | 33.0 (20.0, 39.0) | 29.0 (21.0, 38.0) | 31.0 (21.0, 38.0) |
| Min, Max | 5.0, 56.0 | 7.0, 56.0 | 5.0, 56.0 | 5.0, 56.0 | 7.0, 50.0 | 5.0, 56.0 |

**Figure 1:** Baseline BPVS-III scores (after pooling data from households with multiple participating children)
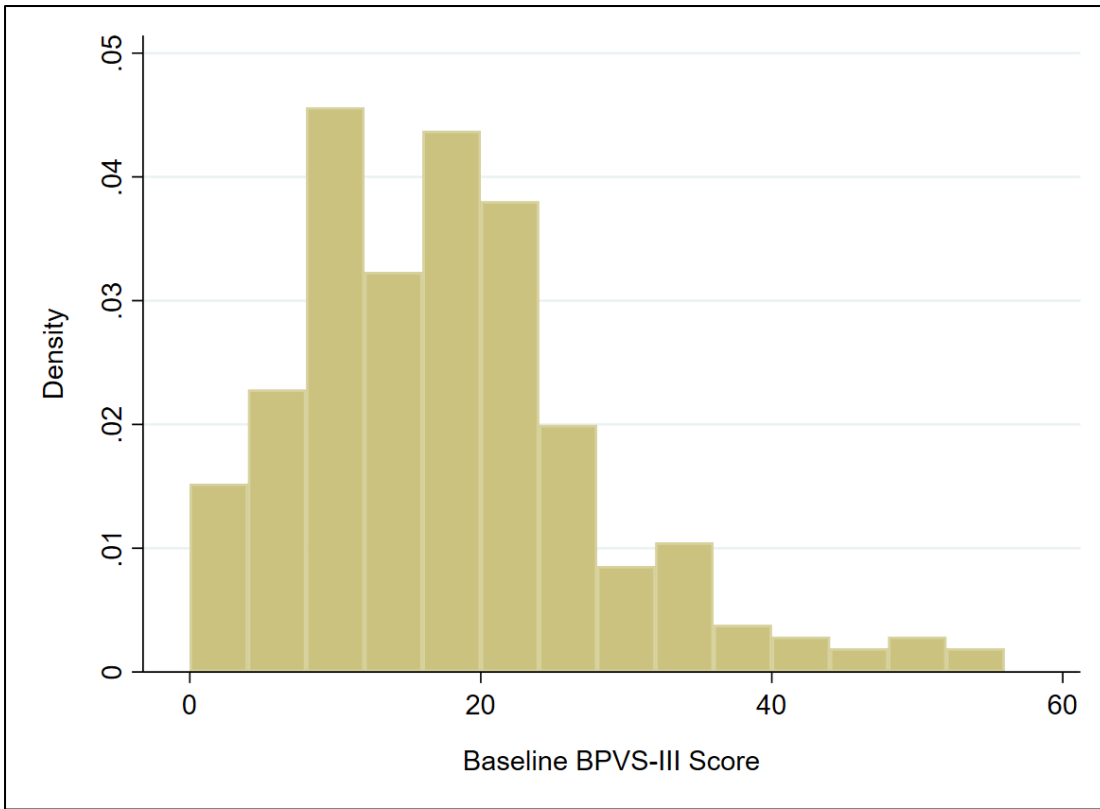


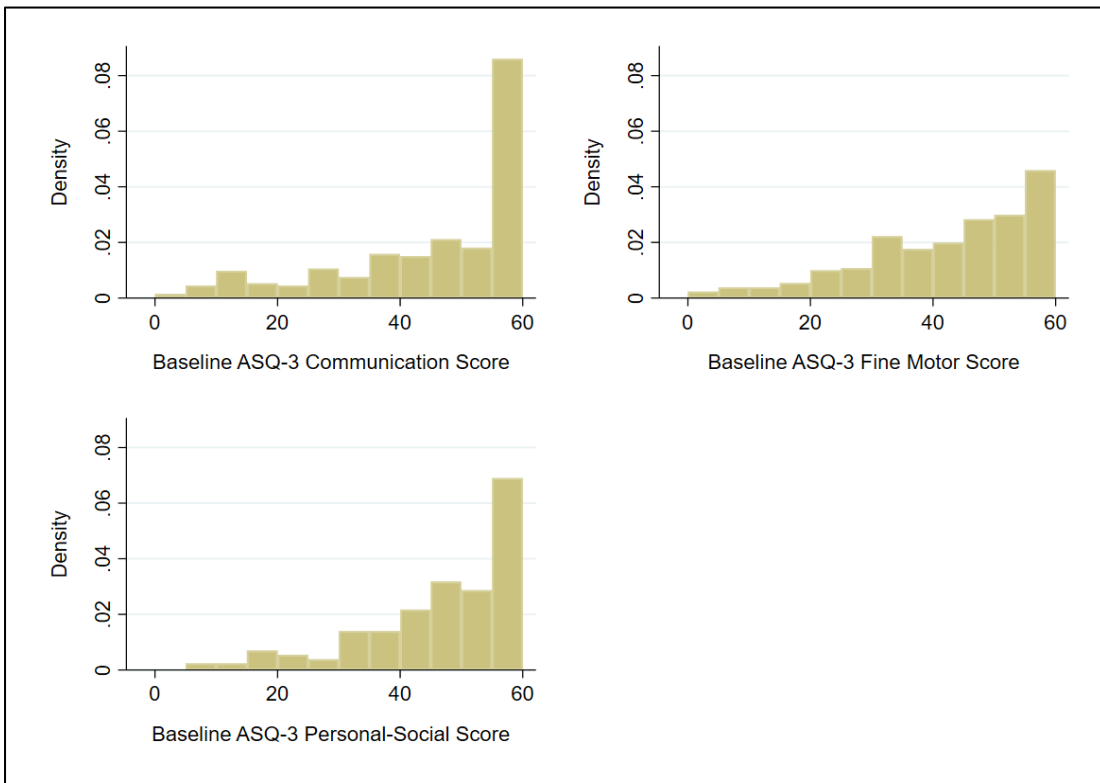**Figure 2:** Baseline ASQ subscale scores (after pooling data from households with multiple participating children)
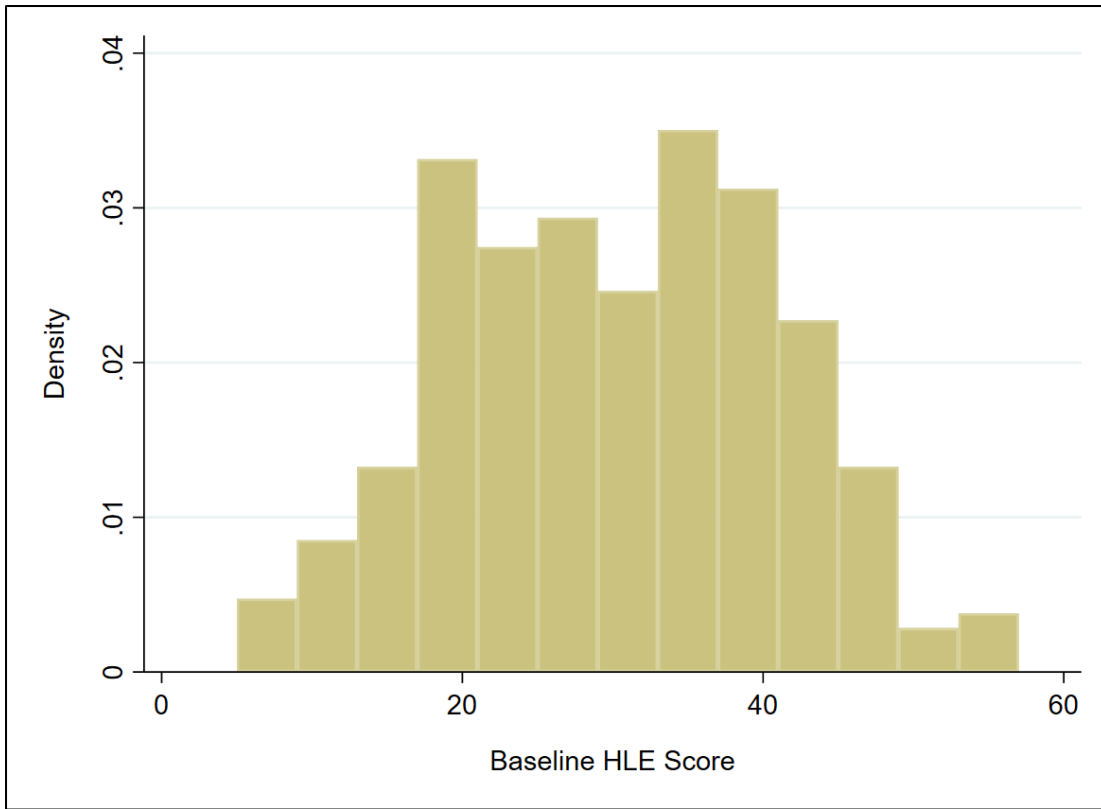
**Figure 3:** Baseline HLE index scores (after pooling data from households with multiple participating children)

# Appendix 7: Missing data analyses

**Table 1:** Association between pre-specified baseline variables (excluding baseline Child in Need status) and the probability of observed/missing primary outcome data

| Baseline variable | p-value* | Added to analysis model |
|---|---|---|
| Child in need status (Yes or No) | 0.72 | No |
| Child EAL status | 0.56 | No |
| Caregiver EAL status | 0.34 | No |
| Baseline ASQ Communication subscale score | 0.77 | No |
| Baseline ASQ Personal-social subscale score | 0.65 | No |
| Baseline HLE index score | 0.40 | No |
| Home ownership (binary – tenant/homeowner) | 0.00 | Yes |
| Employment (binary – Employed or Unemployed/retired) | 0.05 | Yes |
| Income (binary - ≤£20000 or >£20000) | 0.04 | Yes |

*p-value from likelihood ratio tests of Firth logistic regression models with/without the relevant term constrained to zero. Term included in supplementary model (and imputation model) if $p<0.1$

**Figure 1:** Mean of imputed follow-up BPVS-III scores over 200 cycles of the chained equation algorithm (five chains). The mean of the observed data is given by the red horizontal line
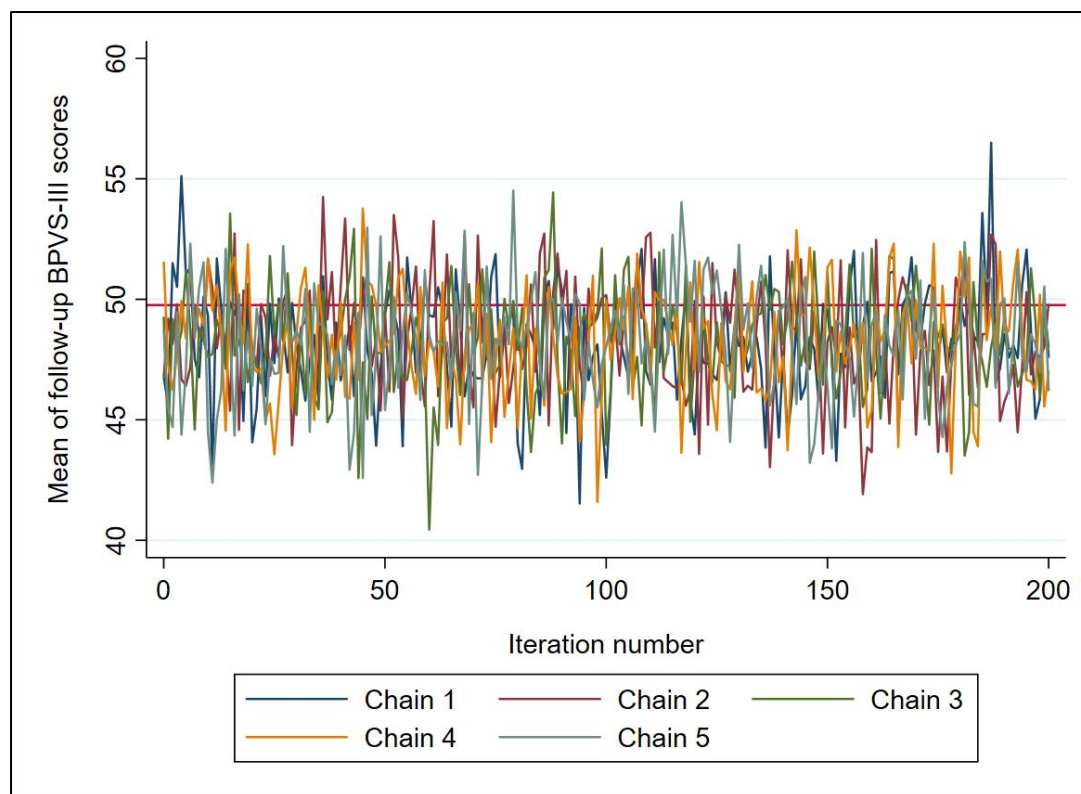
**Figure 2:** Standard deviation of imputed follow-up BPVS-III scores over 200 cycles of the chained equation algorithm (five chains). The standard deviation of the observed data is given by the red horizontal line
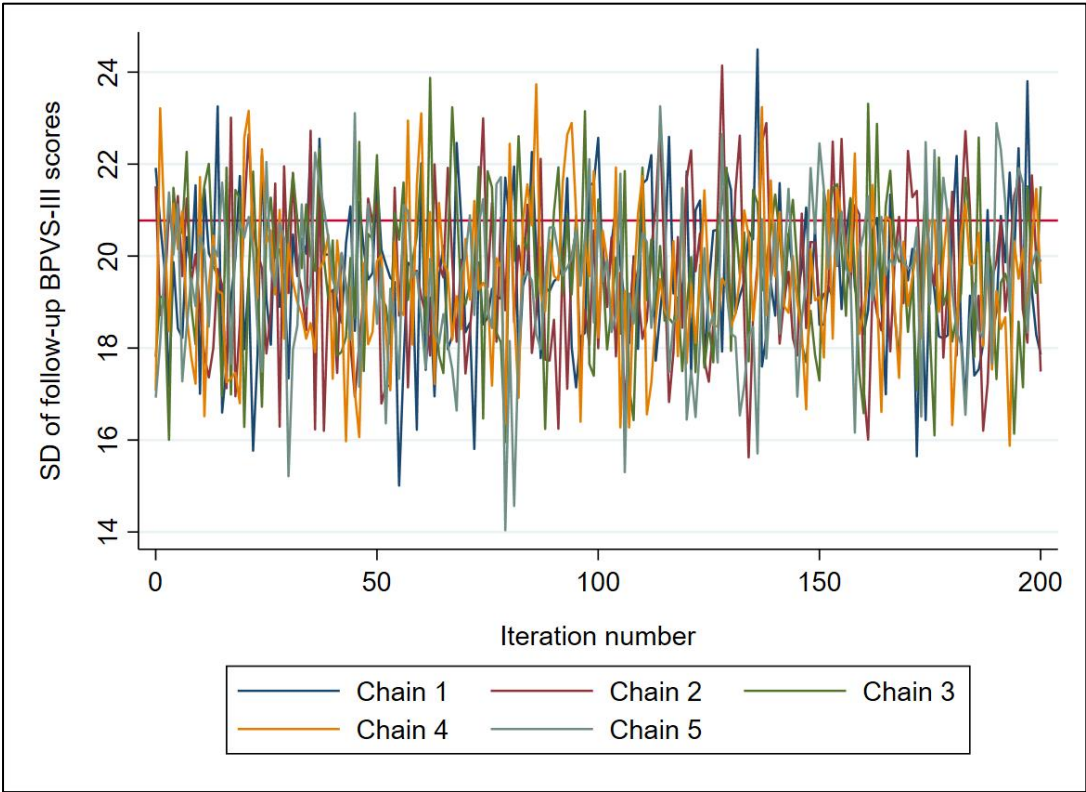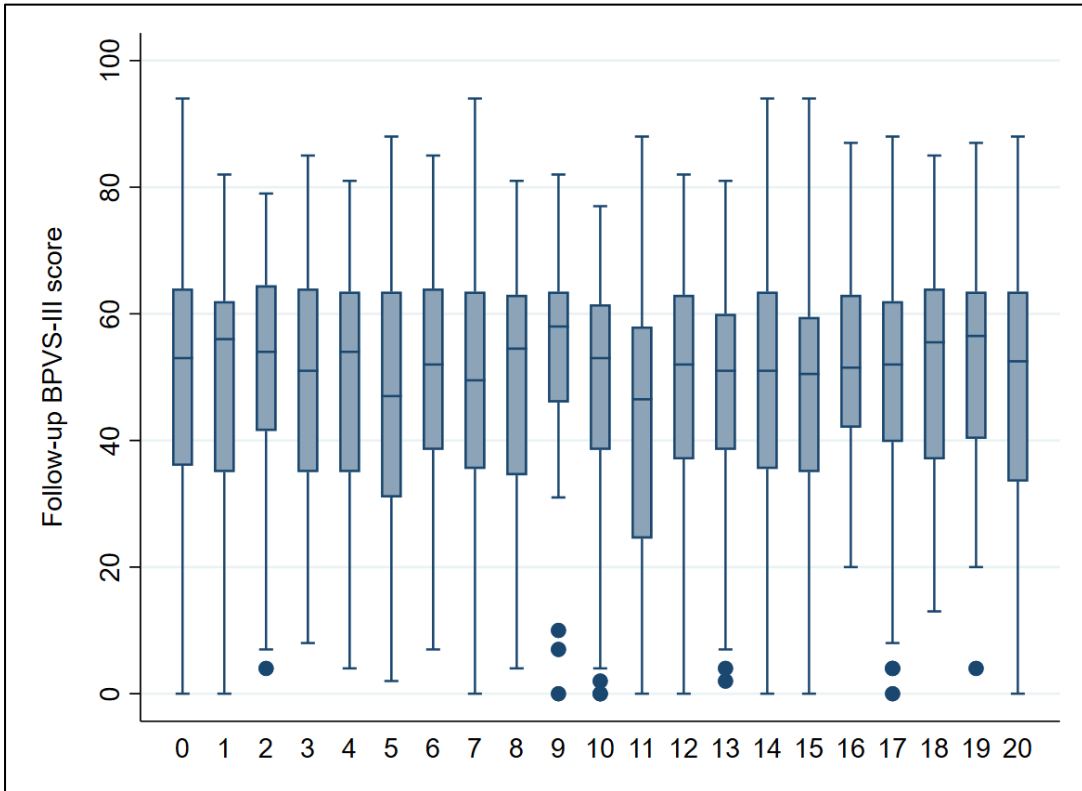
**Figure 3:** Observed (0) and imputed (1 - 20) follow-up BPVS-III scores (100 imputations generated, but only 20 imputations shown)

# Appendix 8: Observation analysis

Key:

DTR = Direct text reading

ACK = Acknowledgments

STATE = Statement

COM = Command

GQ = General question

EQ = Educational question

LABEL = Labelling

PRAISE = Praise and encouragement

AFF = Affirmation

PRO = Prohibition

NURSERY = Nursery rhyme

SP = Spontaneous vocalisation

Res = Response

Vocal = vocalisation

Table 1 Intra-rater reliability n=14

|  | alpha | P value |
|---|---|---|
| DTR | .993 | <.001 |
| ACK | .970 | <.001 |
| STATE | .975 | <.001 |
| COM | .962 | <.001 |
| GQ | .969 | <.001 |
| EQ | .972 | <.001 |
| LABEL | .989 | <.001 |
| PRAISE | .996 | <.001 |
| AFF | .968 | <.001 |
| PRO | .925 | <.001 |
| NURSERY | 1..00 | - |
| SP |  |  |
| Res |  |  |
| Vocal |  |  |

Table 2 Inter-rater reliability n=14

|  | alpha | P value |
|---|---|---|
| DTR | .918 | <.001 |
| ACK | .902 | <.001 |
| STATE | .903 | <.001 |
| COM | .976 | <.001 |
| GQ | .932 | <.001 |
| EQ | .974 | <.001 |
| LABEL | .978 | <.001 |
| PRAISE | .987 | <.001 |
| AFF | .868 | <.001 |

| | | |
|---|---|---|
| PRO | .928 | <.001 |
| NURSERY | .927 | <.001 |
| SP | | |
| Res | | |
| Vocal | | |

## Means by groups (whole sample)

| | Intervention | | Control | |
|---|---|---|---|---|
| | Time 1 (n = 22) | Time 2 (n = 19) | Time 1 (n = 15) | Time 2 (n = 9) |
| DTR | 14.86 (8.24) | 16.53 (8.03) | 15.47 (5.68) | 14.89 (4.13) |
| ACK | 25.09 (12.48) | 22.05 (13.29) | 26.67 (15.03) | 33.00 (10.01) |
| STATE | 42.19 (17.11) | 37.52 (17.26) | 48.07 (19.79) | 50.67 (21.51) |
| COM | 71.68 (27.68) | 28.16 (16.46) | 76.93 (41.89) | 39.00 (21.16) |
| GQ | 38.82 (18.38) | 40.74 (21.37) | 38.60 (20.54) | 44.33 (26.02) |
| EQ | 23.14 (17.61) | 18.21 (15.03) | 21.40 (2304) | 17.22 (14.20) |
| LABEL | 23.41 (17.97) | 17.74 (19.88) | 38.80 (72.65) | 9.22 (7.77) |
| PRAISE | 6.45 (6.35) | 6.33 (6.92) | 10.33 (11.27) | 7.56 (7.76) |
| AFF | 11.86 (9.51) | 8.00 (6.74) | 11.33 (10.51) | 11.78 (8.68) |
| PRO | 2.86 (3.99) | 1.26 (1.96) | 4.20 (5.68) | 1.22 (1.48) |
| NURSERY | .14 (.64) | .42 (1.30) | .67 (1.44) | .22 (.44) |
| All SP | 44.82 (34.18) | 16.63 (13.34) | 36.87 (25.31) | 33.44 (24.53) |
| All RES | 63.63 (27.52) | 81.00 (42.78) | 61.67 (29.51) | 86.56 (26.48) |
| ALL VOC | 108.45 (43.11) | 97.63 (50.33) | 98.53 (39.13) | 120.00 (35.24) |
| Reading | 7.92 (2.36) | 7.00 (3.04) | 9.01 (1.56) | 7.80 (1.69) |
| Playing | 11.49 (1.93) | 9.76 (2.97) | 11.18 (1.44) | 11.12 (1.35) |
| Total observation time | 19.41 (2.04) | 16.77 (5.06) | 20.20 (.37) | 18.92 (1.95) |

## Paired t-tests – per protocol whole sample (N = 24)

| | Time 1 | Time 2 | t | P value |
|---|---|---|---|---|
| DTR | 14.83 (7.06) | 15.63 (7.39) | -.469 | .643 |
| ACK | 27.71 (14.04) | 25.08 (13.79) | .699 | .491 |
| STATE | 44.13 (17.61) | 42.21 (18.94) | .480 | .636 |
| COM | 75.38 (38.71) | 30.46 (19.23) | 5.740 | <.001*** |
| GQ | 41.25 (21.12) | 43.04 (22.70) | -.312 | .757 |
| EQ | 24.46 (19.90) | 18.37 (15.58) | 1.135 | .268 |
| LABEL | 36.13 (57.78) | 13.08 (13.59) | 1.883 | .072 |
| PRAISE | 7.83 (10.04) | 6.71 (7.57) | .493 | .627 |
| AFF | 12.38 (10.58) | 8.71 (7.06) | 1.775 | .089 |
| PRO | 2.50 (3.82) | 1.17 (1.85) | 1.588 | .126 |
| NURSERY | .38 (1.17) | .21 (.65) | .659 | .517 |
| All SP | 42.25 (29.60) | 23.00 (20.25) | 2.987 | .007** |
| All RES | 59.71 (27.24) | 80.29 (37.58) | -2.488 | .021* |
| ALL VOC | 101.96 (43.61) | 103.29 (48.04) | -.126 | .901 |
| Reading | 8.10 (2.39) | 7.02 (2.80) | 1.371 | .184 |
| Playing | 11.42 (1.81) | 10.23 (2.79) | 1.804 | .084 |
| Observation Time | 19.52 (1.97) | 17.25 (4.69) | 2.114 | .046* |

## Independent t-tests at baseline (ITT)

| | Intervention Time 1 (n = 22) | Control Time 1 (n = 15) | t | P |
|---|---|---|---|---|
| DTR | 14.86 (8.24) | 15.47 (5.68) | .246 | .807 |
| ACK | 25.09 (12.48) | 26.67 (15.03) | .347 | .731 |
| STATE | 42.91 (17.11) | 48.07 (19.79) | .845 | .404 |
| COM | 71.68 (27.68) | 76.93 (41.89) | .460 | .648 |
| GQ | 38.82 (18.38) | 38.60 (20.54) | -.034 | .973 |

| | | | | |
|---|---|---|---|---|
| EQ | 23.14 (17.61) | 21.40 (2304) | -.260 | .797 |
| LABEL | 23.41 (17.97) | 38.80 (72.65) | .957 | .345 |
| PRAISE | 6.45 (6.35) | 10.33 (11.27) | 1.337 | .190 |
| AFF | 11.86 (9.51) | 11.33 (10.51) | -.160 | .874 |
| PRO | 2.86 (3.99) | 4.20 (5.68) | .842 | .406 |
| NURSERY | .14 (.64) | .67 (1.44) | 1.521 | .137 |
| All SP | 44.82 (34.18) | 36.87 (25.31) | -.767 | .448 |
| All RES | 63.64 (27.52) | 61.67 (29.51) | -.208 | .837 |
| ALL VOC | 108.45 (43.11) | 98.53 (39.13) | -.713 | .481 |
| Reading | 7.92 (2.36) | 9.01 (1.56) | 1.569 | .126 |
| Playing | 11.49 (1.93) | 11.18 (1.44) | -.527 | .602 |
| Observation time | 19.41 (2.04) | 20.20 (.37) | 1.467 | .151 |

**Independent t-tests at follow-up (ITT)**

| | Intervention Time 2 (n = 19) | Control Time 2 (n = 9) | t | P |
|---|---|---|---|---|
| DTR | 16.53 (8.03) | 14.89 (4.13) | -.573 | .572 |
| ACK | 22.05 (13.29) | 33.00 (10.01) | 2.186 | .038* |
| STATE | 37.52 (17.26) | 50.66 (21.51) | 1.739 | .094 |
| COM | 28.15 (16.46) | 39.00 (21.16) | 1.485 | .150 |
| GQ | 40.73 (21.37) | 44.33 (26.02) | .388 | .701 |
| EQ | 18.21 (15.03) | 17.22 (14.20) | -.165 | .870 |
| LABEL | 17.73 (19.88) | 9.22 (7.77) | -1.231 | .229 |
| PRAISE | 6.31 (6.92) | 7.55 (7.76) | .426 | .674 |
| AFF | 8.00 (6.74) | 11.77 (8.68) | 1.263 | .218 |
| PRO | 1.26 (1.96) | 1.22 (1.48) | -.055 | .956 |
| NURSERY | .42 (1.30) | .22 (.44) | -.442 | .662 |
| All SP | 16.63 (13.34) | 33.44 (24.53) | 2.366 | .026* |
| All RES | 81.00 (42.78) | 86.55 (26.48) | .356 | .724 |
| ALL VOC | 97.63 (50.33) | 120.00 (35.24) | 1.196 | .242 |
| Reading | 7.00 (3.04) | 7.80 (1.69) | .726 | .474 |
| Playing | 9.76 (2.97) | 11.12 (1.35) | 1.293 | .207 |
| Observation time | 16.77 (5.06) | 18.92 (1.95) | 1.218 | .234 |

**Independent t-tests at baseline (Per Protocol)**

| | Intervention Time 1 (n = 16) | Control Time 1 (n = 8) | t | P |
|---|---|---|---|---|
| DTR | 15.38 (7.79) | 13.75 (5.62) | -.523 | .606 |
| ACK | 26.50 (11.58) | 30.13 (18.72) | .587 | .563 |
| STATE | 41.00 (16.10) | 50.38 (19.93) | 1.243 | .227 |
| COM | 73.19 (29.17) | 79.75 (54.77) | .384 | .705 |
| GQ | 41.31 (20.17) | 41.13 (24.38) | -.020 | .984 |
| EQ | 23.81 (15.88) | 25.75 (27.52) | .220 | .828 |
| LABEL | 23.19 (17.77) | 62.00 (95.62) | 1.603 | .123 |
| PRAISE | 5.25 (6.33) | 13.00 (14.14) | 1.877 | .074 |
| AFF | 12.25 (10.49) | 12.63 (11.48) | .080 | .937 |
| PRO | 2.81 (4.49) | 1.88 (2.03) | -.558 | .583 |
| NURSERY | .19 (.75) | .75 (1.75) | 1.114 | .277 |
| All SP | 43.37 (27.91) | 40.00 (34.66) | -.258 | .799 |
| All RES | 61.37 (27.13) | 56.37 (29.02) | -.416 | .681 |
| ALL VOC | 104.75 (42.31) | 96.37 (48.57) | -.436 | .667 |
| Reading | 7.60 (2.56) | 9.09 (1.76) | 1.472 | .155 |
| Playing | 11.56 (1.93) | 11.14 (1.61) | -.521 | .607 |

| | | | | |
|---|---|---|---|---|
| Observation time | 19.16 (2.34) | 20.24 (.40) | 1.273 | .216 |

**Independent t-tests at follow-up (Per Protocol)**

| | *Intervention Time 2 (n = 16)* | *Control Time 2 (n = 8)* | *t* | *P* |
|---|---|---|---|---|
| DTR | 16.43 (8.74) | 14.00 (3.38) | -.754 | .459 |
| ACK | 21.06 (13.66 | 33.12 (10.69) | 2.177 | .040* |
| STATE | 37.50 (15.38) | 51.62 (22.49) | 1.805 | .085 |
| COM | 26.56 (16.81) | 38.25 (22.49) | 1.435 | .165 |
| GQ | 42.93 (20.84) | 43.25 (27.60) | .031 | .975 |
| EQ | 19.18 (16.23) | 16.75 (15.10) | -.354 | .726 |
| LABEL | 14.81 (15.56) | 9.62 (8.21) | -.877 | .390 |
| PRAISE | 5.93 (7.49) | 8.25 (7.99) | .697 | .493 |
| AFF | 7.31 (5.52) | 11.50 (9.24) | 1.396 | .177 |
| PRO | 1.25 (2.08) | 1.00 (1.41) | -.305 | .763 |
| NURSERY | .18 (.75) | .25 (.46) | .215 | .832 |
| All SP | 17.37 (14.48) | 24.25 (26.09) | 2.055 | .052 |
| All RES | 77.68 (42.13) | 85.50 (28.10) | .472 | .642 |
| ALL VOC | 95.06 (51.58) | 119.75 (37.67) | 1.198 | .244 |
| Reading | 6.77 (3.26) | 7.53 (1.60) | .622 | .544 |
| Playing | 9.72 (3.20) | 11.25 (1.38) | 1.280 | .214 |
| Observation time | 16.49 (5.47) | 18.78 (2.06) | 1.136 | .268 |