

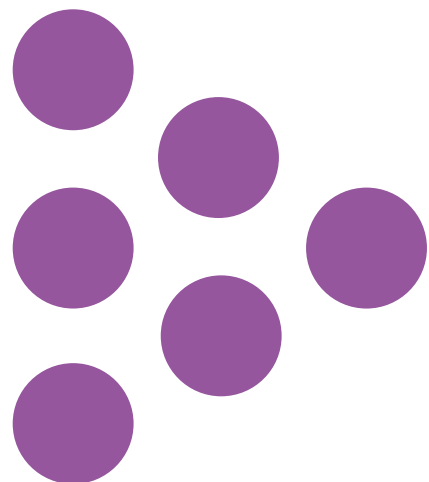


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Randomised Controlled Trial (RCT) of Families Connect

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Protocol (updated)



Contents

1	Evaluation design summary	4
2	About the intervention	5
3	Evaluation aims	11
4	Evaluation design	13
5	Sample size	14
6	Eligibility and recruitment	17
7	Baseline	20
8	Randomisation	21
9	Outcome measurement	22
10	Process evaluation	24
11	Cost evaluation	27
12	Analysis	28
13	Reporting and other outputs	29
14	Consent and ethical conduct	30
15	Data security and data sharing	32
16	Personnel	33
17	Risks	33
18	Timetable	34
19	References	38
	Appendix A: A Theory of Change for Families Connect	41



Protocol updates March 2019

Section 5, p.17: a booster recruitment phase to ensure the randomised sample meets the sample size requirements for a powered trial.

Section 10, p.26: a note that one of the five case studies in the process evaluation will be carried out in the booster phase.

Section 12, p.28: a note that randomisation block will be flagged in the analysis dataset.

Section 18, p.34-37: timetable updates, to take account of the booster phase.



1 Evaluation design summary

Age range	4 – 6 year olds (Reception and Year 1 in England and Wales; P1 and P2 in Scotland; Y1 and Y2 in Northern Ireland)
Number of schools	25 schools ¹
Number of children	400 pupils (16 per school) ²
Design	Family-randomised efficacy trial ³
Primary outcome	Pupils' receptive vocabulary using the BPVS3 ⁴ six months after programme delivery
Secondary outcomes	Pupils' receptive vocabulary using the BPVS3 immediately after programme delivery Pupils' maths attainment using the PUMA ⁵ immediately and six months after programme delivery Pupils' social and emotional outcomes using the teacher-completed SDQ ⁶ and CSS ⁷ questionnaire immediately and six months after delivery
Other outcomes	Increased confidence and engagement in child's learning as measured by parental perceptions of parent efficacy, home learning environment and parent role construction scales using a parent questionnaire ⁸ administered at baseline and immediately after programme delivery

¹ The design is based on analysing results from 400 pupils from 25 schools (16 pupils per school). For pragmatic reasons the number of schools involved in the trial may be increased, with fewer pupils per school (i.e. in some schools it may be challenging to recruit 16 families to the trial).

² For pragmatic reasons, the trial will over-recruit to 440 pupils.

³ Whilst the trial will analyse at the pupil level, it will be necessary to randomise by family (so that families with more than one child taking part can be allocated to either intervention or control, so that they can take part as a family unit and avoid contamination across trial arms).

⁴ Dunn, L.M., Dunn, L.M., Burge, B. and Styles, B. (2009). British Picture Vocabulary Scale (3rd Ed. BPVS3). GL/Assessment. www.gl-assessment.co.uk.

⁵ Colin McCarty, Caroline Cooke, (2015). Progress in Understanding Maths Assessment (PUMA). [RS Assessment, from Hodder Education](#)

⁶ Goodman, R. (1997). 'The strengths and difficulties questionnaire: A research note', *Journal of Child Psychology and Psychiatry*, **38**, 52, 52-58.

⁷ Child Softer Skills Questionnaire developed by Save the Children UK (SCUK).

⁸ Hoover-Dempsey and Sandler, 2005; Sylva *et al.*, 2008; Melhuish *et al.*, 2001.

2 About the intervention

2.1 Strategic purpose

Families Connect is a parental engagement programme that has been designed by Save the Children UK (SCUK) to develop the skills and confidence of families in disadvantaged areas, and provide them with the resources to actively engage their children in learning in the home. Families Connect builds on SCUK's extensive experience of running parental engagement programmes. It is aligned with SCUK's strategic mission to transform the early years for disadvantaged children in the UK by bringing innovative solutions to scale, embedding sustainable approaches into the fabric of families' lives, and influencing policy to ensure change is realised for children into the future. SCUK's focus is on filling the gaps in evidence about what will make the biggest difference for disadvantaged children.

2.2 Intervention overview

What is the focus of Families Connect?

Families Connect focuses on families with children aged 4-6, and is delivered in schools with a high proportion of disadvantaged children across all four countries of the UK. Disadvantage is measured by levels of Free School Meals (FSM) (or Pupil Equity Fund (PEF) in Scotland). The programme uses play as a vehicle for learning and interaction with parents and between parents and children. It focuses on three key areas: social and emotional development; literacy and language development; and numeracy and mathematics.

What are the programme aims?

Families Connect aims to:

- stimulate the home learning environment, including increasing the confidence and skills of parents and carers, and enhancing the activities they do together with their children and the knowledge of how they support learning
- model how to approach, engage and work with families (parental engagement)
- create opportunities for schools and parents to build relationships.

The final intended outcome of Families Connect is to ensure that children living in poverty will have a greater chance of reaching their potential and do better at school.

How is Families Connect delivered?

Families Connect is delivered through a series of two-hour sessions in school over eight weeks (known as a 'programme cycle'). The timings of the sessions are flexible to suit the families involved (for example, during school, after school or straddling the end of the school day). The programme is delivered by trained Community Practitioners (CPs) – professionals who work with families and children, and who are usually teachers, teaching assistants or family support workers from the school. SCUK trains the CPs over two days to deliver the eight sessions independently in their school. The CPs are provided with programme implementation support

including coaching calls and site visits to ensure that they are confident and supported in their delivery.

Who takes part in Families Connect?

The programme is open to all families in a school with children aged 4-6. Schools and trained CPs use school newsletters, texts and coffee mornings to tell families about the programme. Some informal invitations and targeting of families that schools feel would particularly benefit takes place through conversations with teachers and parent advocates (for example parents who have been on the programme previously or who have friendships and networks amongst parents throughout the early years). Parents who would particularly benefit may include those who are not engaged with the school, those whose children need additional support at home, those where the transition from nursery to school was problematic, or parents who lack confidence. (Section 6.3 on recruiting families contains further information about how this will be approached for the trial, to ensure that all relevant families have the opportunity to hear about and take part in the trial. Opt-in and withdrawal procedures are documented in Section 14.)

About ten families take part in a cycle of Families Connect. The family members involved are a parent or parents and their child(ren) aged 4-6. Other family members or carers can also attend where appropriate to ensure continuity for the family and child (for example a grandparent or other main carer). Older and younger siblings do not attend. As the sessions are usually in school time, older siblings are in school; and schools organise a crèche to look after younger siblings during the sessions.

What is the programme design?

A child's home environment can have a significant impact on their early learning and future development (Sylva *et al.*, 2004 and 2008). Home learning is known to be one of the biggest influences on child outcomes – more important even than learning at preschool (Dearden *et al.*, 2010). Evidence shows that parental engagement in their children's learning contributes to readiness to learn and has a positive impact on their educational outcomes (Kiernan and Mensah, 2011), and that parental involvement in children's education is one of the strongest predictors of school success and exerts a powerful impact on school attainment and adjustment (Desforget and Abouchaar, 2003). However, some parents do not feel they have the skills, or confidence to make a difference at home and schools can lack the resources and expertise to effectively engage parents in their children's early learning. Families Connect is designed to develop these skills and confidence, and provide parents living in areas of disadvantage with resources to actively engage their children in learning at home. Feedback from parents who participated in Families and Schools Together (FAST) has informed the development of Families Connect, to provide more support for their children's learning in three key areas – literacy and language development, numeracy, and social and emotional development - and uses play as the vehicle for learning and interaction. To our knowledge, no other family learning programme currently provides support in these key developmental areas, delivered in this way.

According to the programme manual, the programme’s design is based on evidence that activities such as parent-child conversations, storytelling and number games are associated with improvement achievement at age five (Whitehurst and Lonigan, 1998; Nord *et al.*, 2000; Wade and Moore, 2000). The eight sessions, set out in Box 1, were developed by experts to ensure they are grounded in theory and existing good practice around children’s learning.

Box 1: Programme overview		
Social and emotional development	Week 1: Focus on Feelings Week 2: The Importance of Praise Week 3: The Importance of Listening	Julie Casey – educational psychologist who co-developed the SEAL Programme (Social Emotional Aspects of Learning).
Literacy and language development	Week 4: Book Talk Week 5: Beyond the Page	The National Literacy Trust – a national charity dedicated to raising UK literacy levels.
Numeracy and mathematics	Week 6: The Importance of Counting Week 7: Number Talk	Edge Hill University – pioneers of the Every Child Counts programme to help boost attainment in mathematics.
	Week 8: Celebration and Evaluation	

What do the sessions involve?

Each session involves a range of activities, techniques and games that parents and carers discuss, try out and practise with their children, in order to consider how they can introduce them into their home environments. Half of each session is for parents only; and half is for parents and children together. As set out in Box 2, each session is made up of six sections which are delivered consistently each week, but with some flexibility in order to allow the programme to be delivered either during school, after school or straddling the end of the school day.

Box 2: Session structure (example within school or straddling the end of school day)			
Part 1	Reflection Time	Ice breaker, pause for a moment, and reflection on information and activities from previous week.	20 mins
Part 2	The Science Bit	Discussion and learning on why this week’s topic is important to help children’s learning and relating to parents’ own experiences.	20 mins
Part 3	Trying it Out	Facilitator models games/activities, parents try out in pairs, and consider how they might adapt to their own children.	25 mins
Children join			

Part 4	Snack Time	Snack to provide energy and focus for children; quality time for parents and children; conversation around a <i>Talk Topic</i> poster prompt.	20 mins
Part 5	Doing it Together	Parent led games/activities with their children, children see parent as the lead figure, facilitator on hand to provide support.	20 mins
Part 6	Reward and Close	Stickers for Reward Charts, inclusive activity to signal close.	15 mins

What are the expected outcomes and impact of the programme?

The intended long-term effects of Families Connect are that children will have a greater chance of achieving their potential and doing better at school, as their parents will do more in the home to support their learning. The programme does this by developing the skills and confidence of parents and carers who take part, and provides them with the resources needed to actively engage their children in learning in the home. A Theory of Change for the programme is provided in Appendix A: this is a working document that is regularly reviewed by SCUK as the programme develops. The intended outcomes of Families Connect can be summarised as follows⁹:

Intended outcomes for children:

- Improvements in child's softer skills in regards to education and motivation to learn
- Improvements in child's social and emotional skills
- Improvements in child's communication skills
- Improvements in child's interest in and understanding of literacy and numeracy

Intended outcomes for parents

- Improvements in parent/child communication
- Increase in understanding and empathy for their child's learning
- Increase in parental motivation, and parents' confidence, to support their child's learning
- Increase in communication between parents and school

Intended outcomes for schools:

- Increase in parental engagement in the school community

⁹ Note, the primary and secondary outcomes for the RCT efficacy trial focus on some but not all of these outcomes areas. The outcomes selected for the RCT are those most pertinent to the current state of development of Families Connect and taking into account previous evidence. Some of these areas will be explored in the implementation and process evaluation only (rather than with outcome measures).

- Strengthening of relationships between the school and parents
- Positive changes within the school environment.

As set out in section 3, the trial will focus on measuring outcomes for children and for parents. It will not measure outcomes for schools, but will explore these qualitatively. As described above, the programme provides training on parental engagement to school staff, and through the programme itself aims to support parents, via trained school practitioners, to support their child's learning.

2.3 Existing delivery and evidence

Since the programme started in Autumn 2014, SCUK has delivered 340 cycles of Families Connect in over 250 schools in areas of disadvantage across the UK, directly reaching more than 3,000 children, and with a much further indirect reach of siblings and classmates through working with parents, carers and schools.

Evaluation of Families Connect has been conducted in-house to date. SCUK has tested the intended outcomes of language and social and emotional development through a mixed methods approach examining both quantitative data collected through GL Assessment's British Picture Vocabulary Scale (BPVS3) (Dunn *et al.*, 2009) and parent and teacher questionnaires which included the Strengths and Difficulties Questionnaire (Goodman, 1997), child softer skills scales (developed in-house by SCUK) and parent efficacy and home learning environment scales (Hoover-Dempsey and Sandler, 2005; Sylva *et al.*, 2008), and data collected via qualitative interviews. Using a pre, post and follow up approach SCUK have considered the immediate and longer-term outcomes for parents and children. Results of this in-house evaluation to date show improvements in the BPVS scores from pre to 3 month follow up that are evident in children who received the programme, with no statistically significant change in comparison children in the same time period. In addition, parents consistently report that Families Connect has a positive impact on how they and their child interact at home following the programme, and they report that they can also perceive its influence on other members of the family ([Save the Children, 2017](#)).

NFER has conducted further analyses on these Families Connect datasets, and the findings are reported in a document that has been used to inform the protocol (Rennie and Styles, 2018).

2.4 Implementation protocol for the trial

Section 2.2 has set out an overview of the Families Connect intervention. This section sets out a protocol for the intervention, as it is to be delivered in this trial. This is necessary, as the programme is under continuous development, and SCUK wish to trial a version of Families Connect under defined parameters. Further details can be found in Box 3 Implementation protocol overview (below), and with reference to the Families Connect Delivery Manual (2016).

Box 3: Implementation protocol overview

Which schools can take part in Families Connect?	Primary schools with Reception and Year 1 classes, in schools with over 20% free school meals (FSM) eligibility in England, and over 25% FSM eligibility in Wales; with Y1 and Y2 in schools in Northern Ireland with over 40% FSM eligibility; and with P1 and P2 in Scotland, in areas of disadvantage determined in consultation with the local SCUK manager. Schools may need to be medium to large, in order to recruit the number of families required (see Section 3).
Which families can take part in Families Connect?	Families with a child/children in Reception or Year 1 (in England and Wales) (the equivalent of P1/P2 in Scotland and Y1/Y2 Northern Ireland) in academic year 2018/19. Families must not have taken part in Families Connect before (for example with an older sibling).
Who will deliver Families Connect?	SCUK's usual criteria for practitioners will apply (as set out in the Facilitator Role Description and Person Specs in the Delivery Manual). Amongst other criteria, the CPs should have a commitment to working in partnership with parents, experience of working with groups of parents in an informal manner, and a commitment to providing feedback and evaluation support to the programme. For the trial, the Community Practitioners (facilitators) must not be any of the trial children's regular class teachers or teaching assistants.
How many CPs will be trained?	Two CPs from each school should attend the training. One must be a member of teaching or teaching assistant staff from the school, and one could be another teacher/TA or a family support worker.
What coaching / visit support will be provided?	This will involve a site visit and/or coaching call from the trainer which happens in either week 2, 3 or 4. Under special conditions (i.e. trainer perceives it is necessary to support delivery) site visits can happen at week 1.
Can repeat cycle schools take part?	Yes, as long as the children and families in the trial have not taken part in Families Connect before. To avoid contamination through parental engagement practice/resources having been embedded in the school, repeat schools in the trial will be restricted to 2 nd cycles only (i.e. schools on their 3 rd cycle or more of Families Connect will not take part).

How much adaptation is allowed?	Sessions will be expected to run as per the Delivery Manual. The timing of sessions is flexible, i.e. within the school day, after the school day, or straddling the end of the school day. The ordering of the 8-week sessions is flexible only for the order of the literacy and numeracy blocks, i.e. the three sessions on social and emotional development must be delivered first. If the CPs/parent group feel numeracy is more suitable next, the two numeracy sessions can happen before the two literacy sessions. The programme will always end with the Week 8 celebration and evaluation.
What are the minimum requirements for attendance?	Families are expected to attend at least one week from each of the three sections of the programme (i.e. one on social and emotional development, one on literacy/language, and one on numeracy), and a minimum of five sessions in total.
What resources will schools need to provide?	Schools will need to provide: crèche facilities (if needed), snacks, and workshop materials (e.g. dice, magnifying glasses, stickers) ¹⁰ . We estimate total costs of £800 - £1500, with the maximum including the cost of external crèche facilities. SCUUK will provide all the printed materials schools will need.

3 Evaluation aims

SCUUK has carried out development, feasibility and evaluation work on Families Connect, and is now embarking on scale-up and considering optimal delivery models. This efficacy evaluation aims to provide a robust measure of programme impact, and contribute crucial implementation and process evaluation results for future optimisation of delivery at scale across the UK. It aims to inform future research, including a potential effectiveness trial of Families Connect. The study will also contribute to the evidence base available to policy makers and developers of similar programmes to improve early years' education, and be used to advocate for the importance of parental engagement in the early years education of disadvantaged children.

The main research questions for this UK-wide RCT evaluation are set out below around impact, implementation, and further development.

1. Impact – to what extent is Families Connect achieving its intended outcomes, and to what extent would this warrant further investment and research?

¹⁰ A small budget will be available to support schools with purchasing some resources.

The programme intends to impact on the literacy and language development, numeracy development, and social and emotional development of children. The study will explore the following research questions through analysis of outcome measures in the trial (see Section 9 for further detail):

- Does the programme make a difference to children’s literacy and language development?
- Does the programme make a difference to children’s numeracy development?
- Does the programme make a difference to children’s social and emotional development?
- Does the programme make a difference to parental engagement with children’s learning?

The evaluation will also explore which schools, CPs, families and children take part in the programme during the trial – in order to understand the school demographic in terms of disadvantage, any repeat cycle schools, and family demographics. It will also explore fidelity and engagement in terms of how much training is received, how many sessions parents attend, who attends (which family member/parent), and who drops out and why? Particular research questions will include:

- Did families take part in at least one session from the three areas of the programme, as intended? How many sessions did families take part in across the 8-weeks? (these are the two main dosage fidelity measures for the trial, see Section 10)
- Does programme participation in terms of attendance have an effect on the primary outcome? (see section on 9 for details of CACE analysis)

In addition, the process evaluation will further explore *perceived* outcomes, including what difference teachers, parents and where appropriate children themselves feel the programme has made to: children’s learning; to parents’ confidence, communication and support of their child’s learning and whether they continue to use the activities and approaches with their child(ren); to schools’ capacity to work with families; to parents’/families’ engagement with school; and to children’s home learning environments, as indicators of longer-term impact.

2. Implementation – what conditions and other factors support the implementation of Families Connect and how well was it implemented?

The evaluation will explore whether the programme was delivered as intended (implementation fidelity), and assess how well and the extent to which key conditions, support and intervention features were in place to support delivery (implementation quality). Research questions and lines of enquiry will build on existing knowledge and research by SCUK into the key features of Families Connect that are believed to contribute to successful implementation and to sustaining and embedding the approach (SCUK, internal report). They will include:

- What are the key programme features, approaches and conditions for successful implementation in schools? (including pre-conditions in schools¹¹, school leadership, school culture, implementation training and support)
 - To what extent were these implemented? How does the delivery model support these key features? What delivery and implementation challenges and barriers were there?
 - How well were the implementation criteria (to be developed by SCUK as part of the project) delivered? To what extent do these seem to relate to outcomes? Which appear to be core and which appear to be adaptable?
- 3. Development, embedding and scale up – what further support and development is needed for embedding and scale up? What barriers and enablers are likely to be encountered in scale up?**

Elements of Families Connect have been designed to ensure embedding the approach (such as ‘keeping it going’), and scalability such as group based training of community practitioners to deliver the programme in school. Research questions around further development, embedding and scale-up will include:

- What further implementation support by SCUK and/or schools is needed to implement Families Connect well? What further support is needed for optimal delivery?
- Does the programme need to be developed in any way to support embedding the approach and sustain the outcomes? What is schools’ capacity to embed the approach?
- How might the model be adapted for scale-up? What adaptations are perceived to work at scale (for example group based training of community practitioners to deliver the programme in school, and views to inform the development of a cascade model for co-facilitators)?

4 Evaluation design

The evaluation involves four overall strands of work:

Strand 1: Secondary analysis of existing data: to confirm outcome measures, sample sizes and inform the protocol.

Strand 2: Small-scale efficacy RCT: using in-school randomisation with a waitlist control; involving at least 400 families across at least 25 schools; focusing on children aged 4 – 6; in schools with school level FSM > 20%; baseline and two follow-ups measuring vocabulary numeracy, and social/emotional outcomes; one follow-up measuring parents’ confidence and engagement in their child’s learning.

Strand 3: Process evaluation: four strands exploring: programme model; implementation and fidelity; schools’ experiences; and parents’ views/home learning environment. Informed by

¹¹ There is a special focus on schools in this study, as previous evaluations of Families Connect have not focused on investigating how the school context supports the programme, and it is felt by the SCUK delivery team that school context is important to the programme.

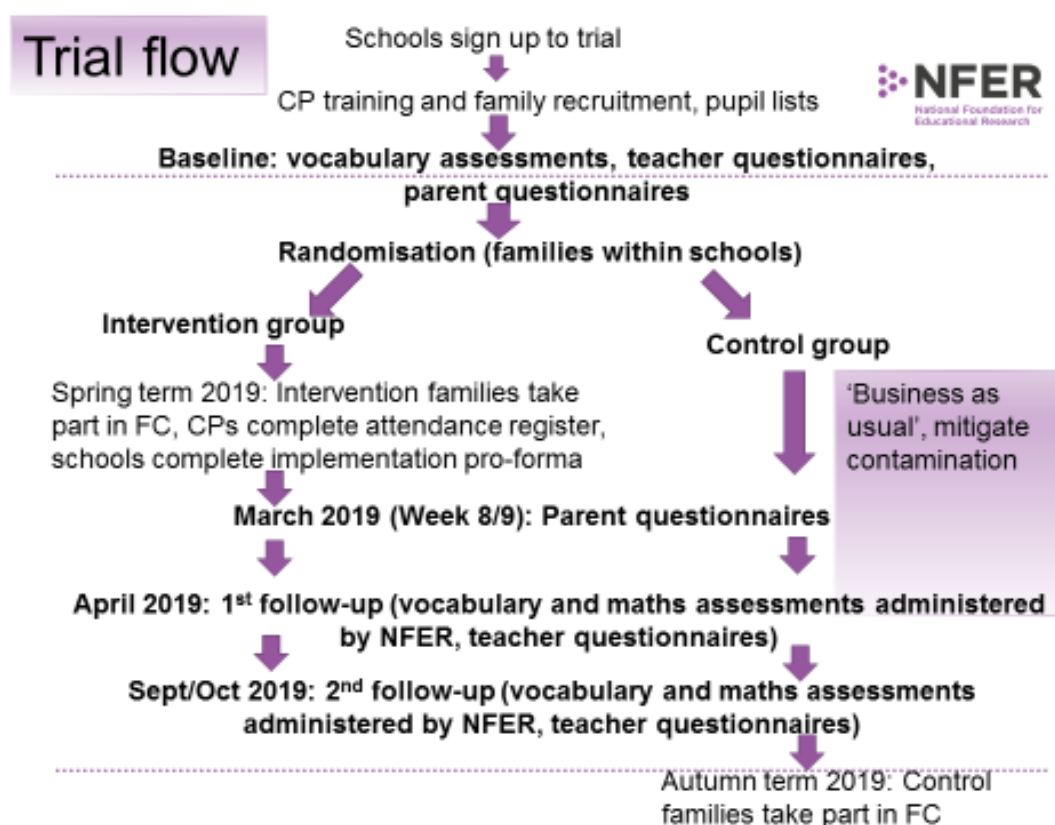
Humphrey *et al.*'s (2016) guidance for implementation and process evaluation and the EEF guidance 'Putting Evidence to Work- A School's Guide to Implementation' by Sharples *et al.* (2018)¹².

Strand 4: Costs evaluation: to establish the costs of the intervention to schools, and the cost per pupil per year.

A technical report on the secondary analysis undertaken (Strand 1) and results can be found in a separate technical appendix (Rennie and Styles, 2018).

The overall flow of the trial (Strand 2) is shown in Figure 1 below.

Figure 1: Trial Flow



5 Sample size

The trial is designed to measure 400 families from 25 schools (16 families per school). This is based on both sample size calculations, and pragmatic delivery reasons – the intervention is usually delivered in groups of between eight and ten families. 16 families per school will allow

¹² <https://educationendowmentfoundation.org.uk/tools/guidance-reports/a-schools-guide-to-implementation/>

two groups of eight to take part – one as the intervention group, one as the waitlist control. A minimum of 12 families per school is recommended for pragmatic delivery reasons. This will result in more schools needing to be recruited, however this will not have an impact on the power calculations as this is a family level randomised trial¹³. Sample size calculations, informed by the secondary analysis, are presented below.

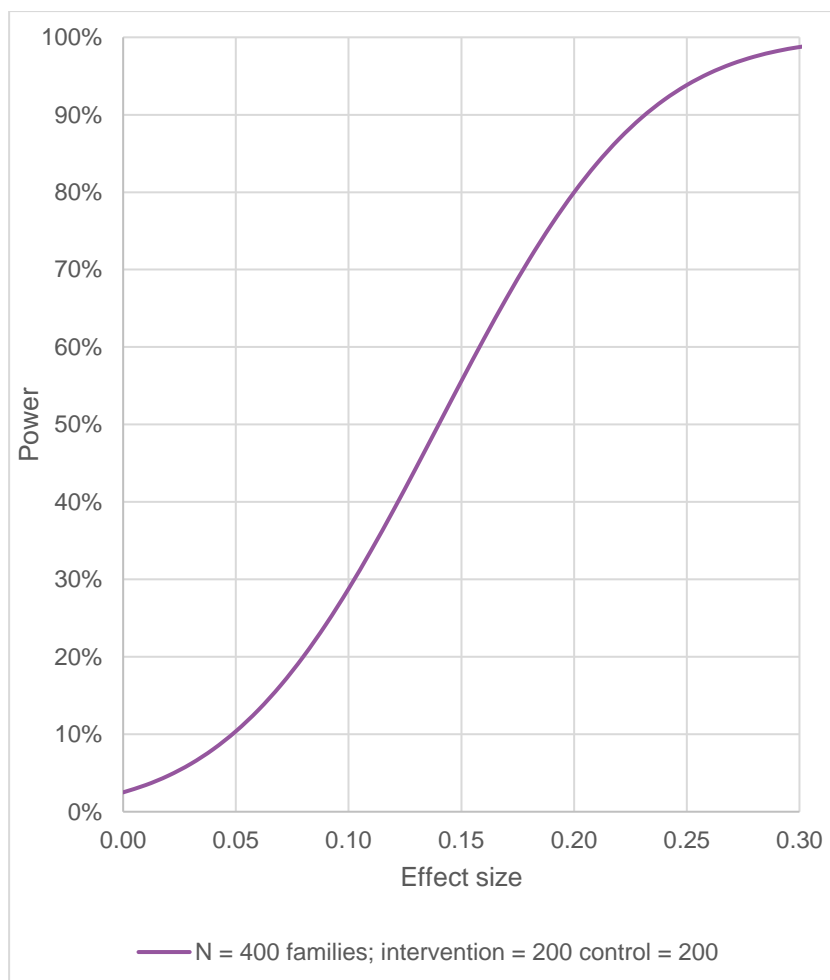
On the basis of existing SCUUK data and NFER secondary analysis of that data (Rennie and Styles, 2018) the following assumptions were used:

- a correlation between pre and both post-BPVS3 scores of 0.7 (secondary data analyses revealed correlations between baseline and follow up of .75 and .76 ($p = <.001$) depending on sample used (see Rennie and Styles, 2018, Technical Appendix on Secondary Data Analysis)
- an anticipated effect size of 0.2 (secondary analyses revealed a Hedge's G quasi-effect size of 0.29)
- no design effect through randomising within schools and only being concerned with internal validity
- probability 0.05 of a Type I error
- 80 per cent power.

With these assumptions the model requires a minimum of 400 families to be randomised into two equally sized groups and analysed for the trial. These families will be distributed across approximately 25 schools based on an average attendance of eight families per cycle and therefore 16 per school including controls. The power curve is displayed below in Figure 2.

¹³ This may however have a practical and budgetary impact on data collection and test administration with schools – and there will be an upper limit to the number of schools that can be included within the budget.

Figure 2. Power curve



The emphasis of any efficacy trial is on internal rather than external validity. However, it will be important to ascertain that any effects (and modes of delivery) seen are not unique to individual UK countries. For this reason, and since Save the Children arranges its administration of Families Connect by these geographical areas, the sample of 25 schools will be taken across the following regions: North of England, South of England, Wales, Scotland and Northern Ireland (five schools from each). Although an under-representation of England in terms of population size, this sampling design will assist in establishing any strengths and weaknesses in the administration across the five areas.

It is important to stress this is the required analysed intention-to-treat sample size for the trial, with data points at baseline, follow-up 1 and follow-up 2. In order to achieve this, SCUK will aim to recruit an additional school per region (i.e. '25+5', so a total of 30 schools, six schools per region) and up to 20 families per school to allow for some pre- and post-randomisation drop out. Should it not be possible to recruit this number of families per school, it would be possible to have a larger number of schools in the trial each with fewer families (for example, an

analysed sample of 30 schools each with a minimum of 13 families would achieve a MDES of 0.2; in this case we would recommend recruiting up to 16 families per school to allow for drop-out but retain power). There may be budgetary implications and delivery practicalities of going to a higher number of schools than this. Loss to follow-up measurement will be minimised by using NFER test administrators to carry out the primary outcome measurement at both follow-up timepoints. This means that only full school withdrawal, individual family withdrawal, or pupil absence on the day should result in loss to follow-up. The latter can be as high as six per cent in schools with a disadvantaged intake ([DfE National Statistics](#)). To allow for this we will ensure that at least 440 families go forward to be randomised. Section 6 provides further details on recruitment strategies.

Due to difficulties recruiting schools initially, a booster recruitment phase of around 50 families was commissioned in January 2019. By this time some 378 families (391 children) had been recruited and randomised to the trial. The booster recruitment will ensure sufficient power, as calculated above, by randomising at least 440 pupils in the trial. The schools will be recruited from Scotland (where there is delivery capacity, due to lower recruitment from this region in the initial phase) and also from Northern England (again with delivery capacity across two regional areas – North West and North East). Eligibility and recruitment criteria will be as per the initial sample – as set out in Section 6 below. Baseline data collection and randomisation will also be carried out in the same way as for the main group (see Sections 7 and 8). Families randomised to the intervention group in the booster phase will start the intervention in the summer term of 2019. (The control group families in the booster phase will receive the intervention in the spring term 2020.) All pupil results will be analysed together, with the two blocks being taken into account in the models.

6 Eligibility and recruitment

Recruitment is required at three levels for Families Connect: i) school recruitment, ii) recruiting Community Practitioners to be trained to deliver the programme, iii) family recruitment. The criteria and strategies for each of these are outlined below.

6.1 School eligibility and recruitment

The following school eligibility criteria will apply to the trial.

- **School type and year groups:** Primary schools in the state maintained sector (including those with academy status) with Reception and Year 1 classes (or the equivalent Y1 and Y2 classes in Northern Ireland, and P1 and P2 classes in Scotland) will be eligible for the trial. Special educational needs schools and private schools will not be eligible.
- **Disadvantage:** School-level FSM eligibility greater than 20 per cent in England, greater than 25 per cent in Wales, greater than 40 per cent in Northern Ireland, and in areas of disadvantage in Scotland based on Pupil Equity Funding and local consultant knowledge, will take part in the trial.

- **Geography:** Using the preferred 25+5 sample size scenario outlined in Section 5 above, six schools will be recruited from each region, namely, the North of England, the South of England, Wales, Northern Ireland and Scotland. These schools can plausibly come from anywhere within each region, although it is possible that they may be in locations in proximity to SCUK Programmes Managers and Trainers so that schools can attend central training and PMs/Trainers can visit schools to provide on-site coaching support as required by the programme.
- **School size:** As up to 20 families may be needed per school to take part, it is likely that schools will be medium to large in size, rather than small one-form entry schools. Where a cluster of small schools that normally work together to pool resources want to take part to facilitate numbers, NFER will consider how feasible it is to include them as one cluster/site (delivery in such a case should be combined at one site).
- **School first language:** Schools must be English speaking, as the primary outcome for the trial (BPVS3) is administered in English and requires English vocabulary responses. Welsh-only speaking schools will not be eligible to take part in the trial.
- **Previous experience of Families Connect:** Schools must be new to Families Connect or have only run it once before in their school. If schools have previously run Families Connect more than once, they cannot take part in the trial. This is so that no school in the trial has already embedded parental engagement approaches or regularly or widely uses the resources associated with Families Connect within the school. (Of course, schools will have varying levels of parental engagement experience – information about this will be collected through a baseline and end-point pro-forma – see Section 10 Process Evaluation.)

SCUK is responsible for school recruitment. Promotion and recruitment strategies will include: advertising the trial on the SCUK and NFER websites, SCUK PMs visits to schools to promote the programme, PMs meetings with headteachers to discuss the programme, and SCUK approaching schools that have previously run one cycle of Families Connect to ascertain interest in running it again. Promotion and recruitment materials will include: a promotion leaflet for schools designed jointly by SCUK and NFER, a School Trial Information Sheet designed by NFER, a Families Connect School Partnership Agreement, a Memorandum of Understanding for the trial annexed to the Agreement and a Privacy Notice including data sharing arrangements for the trial. SCUK will also provide schools with a selection of T-shirts, balloons and gate banners to help promote Families Connect. All schools joining the trial will identify a member of staff to be the main point of contact throughout the trial. The headteacher will sign the school MoU, which will clearly set out the schools' requirements for the trial in terms of school and pupil/family level data collection. They will identify a key point of contact for the trial (e.g. a CP). They will return the MoU to SCUK who will pass the relevant information to NFER.

SCUK will provide a list of all approached and recruited schools to NFER including postcode and the school contact details for those that have signed the MoU. NFER will then assign

school IDs to each recruited school in the trial and share this list with SCUUK and where relevant with QUB.

6.2 Community Practitioner eligibility and recruitment

Each school will identify two members of staff to be trained by SCUUK as Community Practitioners (CPs) to deliver Families Connect in their school. These staff must be teachers, teaching assistants or family support workers from within each school who do not teach Reception or Year 1 in England/Wales (Y1/Y2 in Northern Ireland; P1/P2 in Scotland) in 2018/19. Schools will need to release them to take part in a two-day training event in the autumn term 2018. However if the school already has trained CPs due to a previous cycle of Families Connect, the CPs will attend a refresher session and be provided with details of the current trial.

NFER will hold briefing sessions about the RCT for CPs at training events and via webinar. Trial materials for CPs will include the School Trial Information Sheet, a Do's and Don'ts Trial Briefing Sheet, a copy of the MoU and a Privacy Notice. Schools will provide the contact details of their CPs to SCUUK, who will share these with NFER and where relevant with QUB.

6.3 Family eligibility and recruitment

- **Age group:** Families with child(ren) in Reception or Year 1 in England/Wales (Y1/Y2 in Northern Ireland; P1/P2 in Scotland) in 2018/19 are eligible for the trial.
- **Disadvantage:** Families Connect is a universal programme. It is open to all and often runs with a mix of families from different backgrounds. This efficacy trial will not test the best combination of families (that may be better suited to a future school-randomised trial), but will aim to collect data on levels of disadvantage, for example household income (collected on a parent questionnaire using income bands) or FSM/Pupil Equity Fund eligibility of the families joining to monitor whether at least 20 per cent of them are from disadvantaged backgrounds.
- **More than one child:** Where a family has more than one child in Reception and/or Year 1 in England/Wales (Y1/Y2 in Northern Ireland, P1/P2 in Scotland) (for example twins) all eligible children can attend¹⁴. Hence randomisation will be at a family level (rather than pupil level) – as each family will need to attend either the intervention or the control group delivery sessions (to avoid contamination within families).

¹⁴ Note that where twins take part, a parent or carer for each child can take part in the sessions. Where a family has siblings in both year groups, usually just one child takes part (although it is possible for two to take part where two parents/carers also take part). For the trial, this must be decided before randomisation, and will be requested that it is the oldest child (to avoid any selection bias, and so that the younger sibling may have the opportunity to take part in a further cycle of Families Connect if run at the school).

- **SEN:** Children with special education needs (SEN) are eligible. Consideration will be needed as to the suitability of the outcome measures, in particular for those with visual impairments for the primary outcome (which uses visual cue cards).
- **EAL:** Where English is spoken by the parent family members as an additional language, schools and CPs will need to make local arrangements to include them in delivery (as per usual practice) and the trial. Parents whose first language is not English may need local support to complete the parent questionnaires (for example translators in situ).

Families Connect will be promoted to families via newsletters, school texts and/or emails to parents, noticeboards, and coffee mornings/afternoons. The coffee morning/afternoons/open evenings are an open event where parents can find out about the programme, talk to CPs or SCUk and where appropriate sign up to the trial (for example, if they have already received information and have had a cooling off period). Schools and trained Community Practitioners will need to provide a range of promotion and recruitment activities, suitable to their family constituents including strategies for those who might not be able to or might not normally attend an event in school time (for example, after school/evening sessions for working parents, a range of written and verbal mediums).

Two areas will need special attention: 1) How schools will identify/select families that they feel would 'particularly benefit' (as stated in Section 2, this will may include schools' knowledge of children where transition from nursery to Reception has been problematic, because a parent has expressed lack of confidence, or because a child is behind age related expectations, for example). 2) Making sure there is a 'cooling off' period between being informed about the trial and signing up. For some families this period will be between receiving information and attending a coffee morning. However, if the coffee morning is the first point a family has seen the information they will need a cooling off period after signing up.

Trial materials for parents will include a participant information sheet/letter (PIS) and an opt-in consent form. A Privacy Notice for parents will also be available. Participation will involve opt-in consent (see Section 14) and a 'cooling' off period of one week after that – after which baseline data will be collected about their child(ren) (see Section 7). Some baseline information about the family will also be collected with their opt-in consent on a parent questionnaire (see Section 7). Participants may withdraw consent for their data to be used in the trial at any point (see Section 14).

7 Baseline

NFER will collect school level information from each school that has signed the MoU for the trial, including school-level FSM (or similar indicator), previous experience of Families Connect,

and prior and anticipated engagement with other parent engagement and early learning programmes. Where this is already known/collected by SCUK, we will not re-collect it.

Parents will provide opt-in consent for their own and their children's data to be used in the trial. At sign up, parents will be asked to provide some information on a questionnaire including family surname(s), household income bracket, parent education level, whether their child has Special Educational Needs (SEN) (yes/no) and whether their child's first language is English (yes/no). The parent questionnaire, administered by SCUK, will include the Parent Perception of Parental Efficacy Scale, the Home Learning Environment Scale and the Parent Role Construction Scale (Hoover-Dempsey and Sandler, 2005; Sylva *et al.*, 2008). Note, SCUK will support with the administration of the parent questionnaire; NFER will conduct all the data processing and analysis of the questionnaire data so as to ensure independence.

Schools will provide a list of all the families (we are expecting up to 20 per school) taking part in the trial to NFER. They will do this via a secure portal, and provide pupil full name, pupil other family surname (if another is used by their family), pupil DoB, gender, pupil-level FSM/Pupil Premium eligibility (or equivalent) if known, and class name/class teacher. NFER will then apply a pupil ID to each pupil in the trial. If more than one child from one family takes part in the trial they will be linked using a family level code. This is for randomisation purposes. Please see further details below.

Each pupil in the trial will then sit a vocabulary assessment (the BPVS3) (pre-labelled with their names and trial ID), administered and scored by SCUK test administrators to minimise burden on schools. Schools will send the papers by secure courier to NFER for scores to be verified and cleaned. Pupils' Reception and/or Year 1 (as appropriate per country) class teachers will also fill out a questionnaire about each pupil in the trial – these questionnaires include the SDQ (Goodman, 1997) and the CSS questionnaire (SCUK developed) – and return these to NFER by secure courier.

Note, a maths assessment will not be administered at baseline, as there is no age-suitable PUMA numeracy development. As numeracy development is a secondary outcome for the trial, this will not be unduly problematic.

8 Randomisation

Randomisation will be at the family-level within schools. This is akin to pupil level, but will be at a family level to account for some families having more than one child in Reception and/or Year 1 in England/Wales (Y1/Y2 in Northern Ireland, P1/P2 in Scotland), e.g. twins (see footnote in section 6.3). Carried out by an NFER statistician, randomisation will be stratified by school. If the number of siblings taking part is over 2% of the trial sample, we will consider using family level as a strata to ensure equal distribution of groups of siblings between intervention and control. This will aid intervention delivery as community practitioners will only be expected to deliver to half of the families during each of the main and waitlist phases.

It must be noted that Year 1 children (Y2 in NI, P2 in Scotland) randomised to control could potentially be seven years old during waitlist intervention delivery. Although Families Connect is aimed at ages four to six this is not important for the present trial as there is no further data collection during the waitlist phase. Moreover, although SCUK focus on children aged 4-6, the programme may still be used for children aged seven as Heckman (2006) states that the attainment gap becomes relatively fixed after the age of eight. Prior to this point interventions are highly beneficial. Additionally, the programme is designed to improve parents' skills that can be adopted during the entire academic career of a child. As Heckman (2011) states, the highest benefit to academic achievement is gained with an early intervention, and sustained high quality educational support. As such, the programme will be suitable for families who receive it early in the following academic year.

9 Outcome measurement

Primary outcome

The primary research question is:

1. What is the impact of Families Connect on age 4 to 6 pupils' receptive vocabulary as measured by the BPVS3 six months after programme delivery?

The British Picture Vocabulary Scale (3rd Ed. BPVS3) (Dunn *et al.*, 2009) was chosen for its strong psychometric and implementation properties. It received ratings of 3/3 and 2/3 from the EEF database of early years' measures¹⁵ for the above properties respectively. Furthermore it has been used in previous Save the Children evaluations and aligns well with the literacy and language focus of the Families Connect programme. It is a one-to-one teacher conducted assessment that measures the child's receptive vocabulary. The assessment will be administered by external test administrators. For this trial the raw score will be used as this still reflects the adaptive aspect of the test.

Secondary outcomes

The secondary research questions are:

1. What is the impact of Families Connect on age 4 to 6 pupils' receptive vocabulary as measured by the BPVS3 immediately after programme delivery?
2. What is the impact of Families Connect on age 4 to 6 pupil's numeracy development as measured by the Hodder PUMA, immediately and 6 months after programme delivery?

¹⁵ <https://educationendowmentfoundation.org.uk/projects-and-evaluation/evaluating-projects/early-years-measure-database/early-years-measures-database/>

3. What is the impact of Families Connect on pupils' social and emotional development as measured by the teacher completed Strengths and Difficulties Questionnaire (SDQ), Goodman, 1997), and the Child Softer Skills (CSS) (developed by SCUUK) scale immediately and 6 months after programme delivery?

The Hodder PUMA test (Progress in Understanding Maths Assessment; McCarty and Cooke, 2015) (PUMA) has been chosen as it is a nationwide standardised test which has been aligned to the national curriculum. It aligns well with the Families Connect programme to improve general attainment in numeracy. As the test is designed to evaluate Reception children in the summer, the youngest reception participants being measured at first follow-up (early summer 2019) may struggle with the test. Teachers and students will be made aware that this is to be expected to mitigate any negative impact this may have on the pupils and schools. Year 1 students, and all students at second follow-up should find the test to be of a suitable difficulty level. The assessment will be administered by external test administrators.

The SDQ (Strengths and Difficulties Questionnaire, Goodman, 1997) was chosen as it is a reliable measure of pupils' emotional and social wellbeing and it has been used in previous Families Connect cycles. The scale consists of 25 items which will be teacher assessed. Similarly, the CSS focuses on social and emotional wellbeing and how this relates to learning behaviour. The scale consists of 12 items, it will be teacher assessed.

Note, that test administrators will be blind to group allocation when administering the BPVS3 and PUMA outcome assessments at both follow-ups. Teachers will not be supplied with a list of group allocation for follow-up SDQ completion. However, it is plausible that they may not be blind to allocation, as they may know which pupils have participated in Families Connect during the spring term and which have not. There may be some bias in how teachers complete the SDQ, which we will acknowledge when writing up the results. Teachers' bias is more likely at follow-up 1 (i.e. with current class teacher) than at follow-up 2 (at the start of a new academic year, with a new teacher). That said, at follow-up 2, class teachers may know less about each child than their previous class teacher, as it will be the start of a new academic year. This will be considered when interpreting the results.

Further outcomes

A further research question is:

1. What is the impact of Families Connect on parental engagement in pupils' learning as measured by the Parental Perceptions of Parent Efficacy (PES), Parent Role Construction (PRC) and the Home Learning Environment KS1 (HLE) scales immediately after programme delivery?

The Home Learning Environment Scale (HLE) is a reliable measure that captures the frequency of a range of general and work specific interactions between parents and pupils

(Sylva *et al.*, 2008). The activities in the scale align well to the activities practiced in the Families Connect programme. It is a parent assessed measure that consist of 12 items.

The Parent Role Construction (PRC) scale is a subscale of the original Parental Role Construction for Involvement Scale (Hoover-Dempsey and Sandler, 2005). It is a reliable measure that captures a parent’s belief about what they should be doing as regards their child’s learning, and can be used as an independent scale. It is a parent assessed measure that consists of 10 items.

The Parent Efficacy Scale (PES) is a reliable measure of parents’ beliefs about their ability to influence their child’s educational outcomes (Hoover-Dempsey and Sandler, 2005). It is a parent assessed measure that consists of seven items.

Note that SCUK will support with the administration of the parent questionnaire at follow-up; CPs/staff members will not be blind to allocation, but will receive instructions to support only with logistical administration of the questionnaire. NFER will conduct the data processing and analysis so as to ensure independent analysis.

10 Process evaluation

10.1 Approach and strands

The trial will include a process evaluation to explore participants’ and deliverers’ views on the programme as delivered during the trial. The process evaluation will adopt a theory-based approach (Chen, 1990; Donaldson, 2007) designed to gather information on key steps in the theory of change (ToC) developed for this intervention. It will also be informed by implementation and process evaluation guidelines (Humphrey *et al.*, 2016).

Previous evaluations of Families Connect conducted by SCUK have focused on capturing experiential and observational views of the programme, for example through parents’/families’ views and anecdotes and presenting vignettes. According to these, parents’ experiences of the programme are very positive (Bradley *et al.*, 2016; Bizas *et al.*, 2017) This process evaluation will take Save the Children’s previous evaluation of Families Connect further by: including programme designers and deliverers in the evaluation; evaluating implementation fidelity; and identifying the key ingredients in the model and any implications of adapting the model for further scale up. The process evaluation will have four strands, as set out in Box 4 below.

Box 4: Implementation and process evaluation methods and research questions	
Data Collection Method	Research Questions
Strand 1: understanding the programme model (incl. what further support to develop)	
Programme theory of change workshop	

Interviews with up to six programme managers at both the start and end of the trial	What does the training, support and delivery involve? What are the key features of the programme? What can be adapted? How is it different to other programmes?
Strand 2: exploring implementation (incl. implementation fidelity, any adaptations and why)	
School and family recruitment information, and family attendance registers	Who takes part and why? How many and which sessions did families attend?
School implementation pro-formas and end-point pro-formas	Was the training and programme delivered as intended? What are the features of effective implementation? How well were they perceived to have been implemented? Were any changes made to the programme? What happened in the control group?
Observations of training (one per region, five in total), post-training interviews with trainers (five in total) and CPs (up to 10 in total)	Was the training delivered as intended? How well did it prepare CPs for delivery?
Strand 3: exploring schools' experiences (incl. a focus on the factors and conditions that support schools to deliver Families Connect)	
School visits and observations (one per region, five in total) with site interviews (up to two school staff, up to two pairs of children and up to two CPs at each site) (up to 10 SLT, up to 10 pairs of children, and up to 10 CPs in total)	What are the key features of effective implementation? How well were they perceived to have been implemented? Who takes part and why? Are participants engaged with and enjoying the programme? How is it different to other practice? Were any changes made to the programme?
Telephone interviews with school senior leaders (two per region, not site visit schools; 10 in total)	What are the key features of effective implementation? How is the programme different to other practice?
Strand 4: focus on parents and home learning environment (incl. perceived outcomes)	
Interviews following up to three parents per region up to three times (e.g. site visit, follow-up and longer-term follow-up by telephone) (up to 15 parents in total)	Who takes part and why? Are participants engaged with and enjoying the programme? What are the key effective features of the programme? How is it different to other practice?

The evaluation will be mindful of burden on schools, and where SCUK have already evaluated topics in detail we will draw on these findings rather than replicate. The table below sets out the methods, sample sizes and research questions/areas to be covered by the process evaluation.

10.2 Levels of data collection

It is helpful to think of the process data collection on three levels according to coverage and depth:

All schools will provide baseline and end-point information on any prior or current parental engagement or home learning programmes other than Families Connect during the trial period. This will also cover information about any control group contamination. All schools will provide attendance logs for **all their intervention families** – this will be collated by Community Practitioners. In addition, SCUK will collect monitoring information about all schools in terms of coaching visits, and implementation quality (the latter at post-programme site visits).

A sub-sample of schools (10; about two-fifths) will contribute to the collection of school-level experiences and exploration of the implementation criteria, through telephone interviews with senior leaders.

A small number of schools (five in total, one per region), will form the focus of deeper data collection from deliverers and participants (CPs, school staff, parents, children) through interviews, observations and site visits. In addition, a **sub-sample of parents** from the site visit schools (up to three parents per site) will be followed up at up to two further time points over the course of the trial.

10.3 School/participant selection for the process evaluation?

We plan to select observation sites randomly within each region. We also plan to observe a range of sessions across the three topic areas (rather than observe the same session across all sites), in order to capture experiences across the programme. We will invite a range of participants to take part as needed – some randomly, some based on relevance/role, some based on opportunity. Participation is always a voluntary invitation and based on participants' consent. A participant or whole school can withdraw from participating in the process evaluation interviews/observations at any point (see section 14). Where possible (bearing in mind budget and effort), we will replace them with another school/participant to ensure breadth and coverage of views. Note that one of these five case study sites will be in the booster phase; with four taking place in the initial phase.

10.4 Measuring fidelity

Fidelity will be monitored in a number of ways:

Implementation fidelity – SCUK will monitor the number of training and coaching sessions delivered at each site, as well the delivery of the 8-week sessions and the order in which they are delivered. This will provide implementation fidelity information for the trial team.

Participation fidelity – CPs will take an attendance register at each of the 8-weeks. Participation fidelity will include a record of whether a family has attended at least one session from each of the three topic foci (i.e. social and emotion, literacy and maths), and how many sessions in total they attended. These figures will be used in the CACE analysis (section 12.1).

Implementation quality – SCUK will ask schools to complete a core criteria pro-forma towards the end of the 8-week programme, to assess how well the programme was implemented (this will cover a range of aspects from programme training and support, to conditions in the school environment).

10.5 IPE team and responsibilities

In terms of data collection, NFER will be responsible for process data collection in three regions: the North of England, the South of England and Wales. QUB will be responsible for process data collection in two regions: Northern Ireland and Scotland. SCUK and CPs will be responsible for fidelity and quality data collection (i.e. completion of attendance logs, QA monitoring such as number of coaching visits, and site feedback forms focusing on implementation criteria) – and will provide this information to NFER and where relevant to QUB.

In terms of instrument design, NFER will take a lead on programme and school-focused instruments (for example, interview schedules for school staff, CPs, Programmes Managers). QUB will take a lead on instruments and evaluation follow-up strategies for parents and children.

In terms of IPE analysis, NFER will take a lead on analyses of fidelity data, observation data, and interview data from school staff, CPs and Programmes Manager. QUB will take a lead on analysing interview data from parents and children.

11 Cost evaluation

The study will include an evaluation of the costs of Families Connect that assumes schools are paying for the entire cost of the intervention; although the intervention is currently offered to schools free of charge. The evaluation will explore the cost of programme delivery in terms of training costs incurred by Save the Children, delivery costs for the Community Practitioners and direct, marginal costs to the schools themselves. Methods to collect this information will include completion of pro-forma templates in advance of interviews with Programmes Managers at Save the Children and school senior leaders. We will follow published guidance on cost evaluation ([EEF, 2016](#)). We will estimate the cost per pupil per school year, as if the programme had been repeated over three years, and use this to calculate cost per unit effect size. This will aid decisions about the suitability of the intervention for a future effectiveness trial and options for scale-up. Furthermore, it can feed directly into future sample size calculations as cost per unit effect size could then be compared to interventions for the same age group as published on the EEF's Teaching and Learning Toolkit¹⁶, for example.

¹⁶ <https://educationendowmentfoundation.org.uk/evidence-summaries/teaching-learning-toolkit>

12 Analysis

12.1 Statistical analysis

Full detail of the analysis will be included in a Statistical Analysis Plan that will be reviewed by the independent advisory group statistician. A summary of the analysis is included here.

The primary intention-to-treat (ITT) analysis of BPVS3 scores will be a single level regression. This will test for an overall Families Connect effect over the Business as Usual (BaU) control group. A flag for randomisation block will be included in the dataset. The dependent variable for the regression will be the raw BPVS3 score 6 months after programme delivery with the following covariates:

- an indicator of whether the pupil is assigned to the intervention group
- pupil prior attainment as measured by the BPVS3 at baseline
- dummies for school.

The effect size will be presented as Hedges g .

The secondary ITT analysis of BPVS3 scores will be the same analysis as the primary ITT, however, it will use the raw BPVS3 scores measured immediately after programme delivery as the dependent variable. This will test for short term effects of Families Connect over BaU.

The impact of Families Connect on BPVS3 scores will further be investigated through the use of a multi-level model with time point at level 1 and pupil at level 2. Baseline measurements and group will be included as covariates. This analysis will have increased power to investigate the effect of Families Connect over BaU.

A subsequent model will be used as above with an interaction between time and intervention. This model will test whether any effect has enhanced or attenuated over time.

Subgroup analyses will be conducted using household level income (as a measure of deprivation), and using SEN, using interaction terms.

The remainder of the secondary outcomes, i.e. PUMA, SDQ, CSS and the parental engagement scales, will be analysed in a similar way as specified in the Statistical Analysis Plan. For the SDQ, the CSS and the parental engagement scales a baseline measurement will be used as a covariate. For the PUMA test, the baseline measurement of the BPVS3 will act as the covariate as no baseline Maths tests were available for the appropriate age group on this trial. An indicator of group allocation will be included in all models. Effect sizes will be presented in the same way as for the primary outcome measure.

If a school or families drop out of the trial, multiple imputation and sensitivity analysis may be carried out to handle missing data.

CACE analyses will be based on the fidelity indicators of dosage (attending at least one session from each of the three topic areas; and total number of sessions attended) and if

appropriate using implementation fidelity measures (as collected by SCUUK). This will yield quantitative measure(s) of fidelity that can be used in multi-level models of vocabulary.

12.2 Qualitative data analysis

Qualitative data collected through interviews and observations will be analysed thematically, against a thematic framework based on the IPE research questions outlined in Section 3 (informed by the IPE dimensions in Humphrey *et al.*, 2016) and the Families Connect implementation quality criteria/indicators (to be developed by SCUUK ahead of implementation data collection). The framework will also allow for emergent themes to surface from the data. Qualitative data will also be collated by data subjects (e.g. trainers' views, CPs' views, parents' views) and triangulated across data subjects where possible.

13 Reporting and other outputs

The trial will be registered at the [ISRCTN Registry](#) and the protocol and Statistical Analysis Plan will be published on the NFER website. The former will be published before randomisation takes place and the latter within three months of randomisation.

The final report, which will include findings and recommendations for future implementation, will be published on both the Save the Children, NFER and Queen's University Belfast's websites, and will be written to CONSORT-SPI standards (Montgomery *et al.*, 2018).

Other outputs, dissemination and engagement activities will utilise a range of channels including partners' websites, social media channels and newsletters targeted specifically at schools.

In addition, quantitative data produced through the course of the research will be uploaded to the [UK Data Archive](#) to ensure that the data is housed securely and is available for future researchers. This process will be informed by a Data Management Plan in accordance with the [UK Data Archive guidelines/checklists](#).

The project team will develop a detailed communications plan to reach key stakeholders and audiences with the findings from the study. The findings from this evaluation will be used by Save the Children to improve Families Connect and other parental engagement programmes. They will inform future research, including a potential effectiveness trial of Families Connect. The study will also contribute to the evidence base available to others developing, delivering or embedding similar programmes to improve early years' education, will be available to policy makers, and used to advocate for the importance of parental engagement in the early years' education of disadvantaged children.

14 Consent and ethical conduct

14.1 Ethical review

Save the Children has an Ethics Committee composed of experts with a specific focus on research ethics involving children. The Committee consists of representatives from a number of countries (including Canada, Lebanon, UK and the US) with different sectorial and geographical expertise. The Ethics Committee is independent from Save the Children and has the power to veto a research project if they find it unethical.

Similarly, the Code of Practice Group at NFER ensures appropriate ethical review of any research undertaken by the organisation, monitors and adjudicates on matters requiring ethical scrutiny and develops policies and guidance to facilitate the protection of research participants.

The research conducted by Queen's University Belfast will conform fully to the University's Code of Conduct and Integrity in Research (Queen's University Belfast, 2014) and the Concordat to Support Research Integrity (Universities UK, 2012); and will be carried out under the ethical approval granted by the other two organisations.

The proposed research has received ethical clearance from NFER's Code of Practice Group during the Grant Application stage (January – June 2017).

In addition to abiding by the three organisations' ethics reviews and Codes of practice, this protocol makes particular reference to a number of considerations around consent and ethical conduct. These are outlined below.

14.2 Informed consent

Families participating in Families Connect sign opt in consent forms prior to taking part in, and providing data for, Families Connect. The forms ensure that all families taking part are fully aware of the nature and demands of the programme and provide their informed consent. They also allow for further analysis of data for development purposes. Furthermore, the consent form specifies that any data collected is kept confidential, and all reporting is done in a way that anonymises results. These Families Connect Programme consent forms will be adapted to include information about the trial and evaluation requirements. All participants in the programme will be given letters/information sheets about how their data will be gathered, used and stored, and this will be reiterated at each point data is gathered. Consent is given by parents for data to be collected relating to their children.

The parent information sheet/letter and consent forms will include information about the provision of de-identified data to both the UK Data Archive and to the SCUK programmatic data archive, and to give an opt-in for their data to be gathered and stored in this way. Information about how data will be de-identified and archived will also be included in the training that is given to community practitioners so that they are equipped to answer questions from families on this if necessary.

Note, the project will not provide qualitative data generated through the process evaluation to the UK Data Archive. Based on the small number of schools that will be involved in this element of the study we do not believe that anonymity could be guaranteed.

14.3 Safeguarding of children and families involved in the trial

All NFER, QUB and SCUUK staff involved in this project will have current enhanced DBS checks. As SCUUK is the PI, they state that they will ensure that all partners are aware of, and adhere to, SCUUK Child Safeguarding Policy. Additionally, the administration of BPVS3 (a test that is carried one-to-one with children) will be carried out according to the guidelines set by GL Assessment, with further adherence to child safeguarding policies set by participating schools, helping us ensure that there is no risk or threat to children. The NFER test administrators who will administer the BPVS3 and the maths test at the second follow-up are all qualified teachers with current enhanced DBS checks.

14.4 Compliance with data protection legislation

Save the Children, NFER and Queen's University Belfast comply with all relevant legislation including the new GDPR regulations from May 2018. Data collected will have been obtained with the explicit consent of the individuals. This will be necessary under the GDPR as some of the data will be classed as 'special' and therefore not suitable for processing under other lawful conditions that preclude consent. In addition, the information will not be available publicly in an identifiable way. NFER is registered with the Data Protection Registrar for all aspects of their work, which they presently conduct according to the eight principles of the 1998 Data Protection Act. They are ISO27001-certified and their Data Security Policy is designed around ISO27001 requirements. Similarly, all data gathered by Queen's University Belfast will be stored securely and anonymously, in line with the requirements of the Data Protection Act and GDPR.

Currently Families Connect programmatic data is stored for seven years based on funder requirements. Any hard copies of data will be securely stored in Save the Children facilities and soft copies in Save the Children UK servers. Trial outcome data will be de-identified before it is shared and stored by SCUUK. Save the Children systems are fully compliant with both current and upcoming data protection regulations. Access to data stored within Save the Children will be regulated and only available to members of the project team.

14.5 Withdrawals

A family, child or whole school can withdraw from the intervention and/or the trial at any point. We will ask for consent at the start of the trial to collect evaluation data for all randomised children/families even if they do not attend all of the programme. However, a family/child can withdraw their consent for their data to be used in the trial at any point, including all of their data up to the point of withdrawal if they so request. Withdrawals can be made by informing their CP/school, NFER or SCUUK. A Privacy Notice will provide contact details for withdrawals and data subject requests.

15 Data security and data sharing

15.1 Data security

We will be processing data classed as ‘special’ under GDPR (for example data obtained from the SDQ) and we will be doing this after opt-in consent by the parents. Pupil names and dates of birth from consenting families will be uploaded to NFER via a secure school web portal. A flag will be used to identify siblings and twins. On receipt of this data, NFER will allocate each child a unique pupil identifier for the project. This resulting file will link a pupil ID with their name and date of birth. It will reside on a secure drive only accessible by a small number of named researchers working on the trial. The unique pupil ID will be used across all outcome and fidelity measures.

In order to make completion of tests and questionnaires easier for teachers and administrators, they will be pre-populated with pupils’ names and dates of birth (plus linked bar code and unique ID) before sending out to schools.

In order to ensure the correct data is collated and matched for each participant, all data cleaning and matching will be carried out on files using pupil names, DoBs and IDs. This will be done on a secure drive only accessible by a small number of named researchers working on the trial.

All analysis will be undertaken on a secure drive, accessible by a small number of named researchers working on the trial. In order to minimise the risk of a data breach as regards special personal data, the SDQ data file will be analysed on a file with IDs only (names and DoBs will be removed).

All datafile outputs for the SCUK programmatic archive and the UK Data Archive will be de-identified, including having the unique pupil ID removed.

15.2 Data sharing

SCUK and NFER will be joint Data Controllers for the RCT evaluation.

- NFER will be data processors for the impact elements of the trial.
- NFER and QUB will be data processors for the IPE (section 10.5 sets out the roles and responsibilities of NFER and QUB in terms of data collection geography, and data subject analyses).
- SCUK will be data processors for recruitment information, attendance data and implementation criteria data, prior to sharing with NFER for further analysis.

A Data Sharing Agreement will be in place between the three organisations, and a Privacy Notice reflecting this will be available for schools. Personal data will be shared between NFER and SCUK via secure portal, and between NFER and QUB via secure portal. Data sharing with schools will also happen via secure school portals. Portals will be deleted shortly after use.

16 Personnel

The Principal Investigator for this study is Dr Christine Bradley, Evaluation and Research Advisor, SCUK. Co-investigators are Dr Ben Styles, Head of NFER's Education Trials Unit, and Dr. Aideen Gildea (School of Social Sciences, QUB). They will be supported by Nikolaos Bizas (Evaluation and Research Advisor, SCUK). Day-to-day trial management will be overseen by Pippa Lord, Senior Trials Manager (NFER), supported by Kathryn Hurd (Head of Survey Support, NFER) and Michael Neaves (Researcher and schools liaison, NFER). Other team members are: Caroline Sharp (Research Director and in charge of QA for the process evaluation), Constance Rennie (Statistician, NFER) and Kelly Kettlewell (Research Manager and undertaking the process evaluation).

In addition, the Families Connect programme will be supported by experienced SCUK Programmes Managers based in in-country teams, specialist Families Connect trainers, and a management group including the Heads of the country teams, Head of Early Learning Services and the Head of Programme Development and Quality at SCUK.

An external Advisory Group will be involved at key stages in the project to provide advice on development, delivery, analysis and outputs. All members of the Advisory Group will be provided with a Terms of Reference Document, outlining the meetings and an invitation to support in dissemination activity.

17 Risks

Each organisation will conduct a risk assessment for the project in accordance with their organisations' requirements, and will keep these up to date. In addition, a recognition of joint risks will be shared in Partnership/Data Sharing Agreements. The main and joint risks relating to trial design are summarised in Table 1 below.

Table 1: Risks and countermeasures

Risk	Effect	Countermeasures and contingencies
Insufficient schools and/or families recruited to the study	Will affect power for the trial	SCUK focused recruitment strategy; focus on medium to large schools rather than one-form entry; can recruit more schools each with fewer families.
Data attrition (pupil data)	Will affect ITT analysis	NFER Test Administrators are collecting follow-up 1 and follow-up 2 pupil data to ensure minimal drop out from data collection. Loss to longer-term follow-up will be mitigated through keeping in touch with schools, CPs and

		parents at the end of the academic year 2018/2019 and start of 2019/20 academic year.
Contamination (e.g. families switch groups, control group families adopt FC approaches, materials/resources are shared outside of the intervention group)	Will affect fidelity and potential to measure impact	<p>NFER and QUB will hold RCT briefing sessions for CPs in person and via webinar. They will receive a Do's and Don'ts checklist including: CPs and families to avoid sharing experiences, tips or resources with control group families and other teachers; encourage the control group to wait until the autumn term to find out more and take part with a trained CP. Explain that no families/children miss out.</p> <p>Families will receive information about the purpose of the trial; and a Do's and Don'ts handout once randomised.</p> <p>All families will receive an ID, and CPs will check that families attend the correct sessions according to group allocation.</p> <p>Schools will complete an end-point pro-forma which will include information about possible contamination.</p>

18 Timetable

Table 2: Project timetable

Activity	Month	Purpose
Theory of Change workshop	July/Aug 2018	To map process methods and questions to theory and implementation plan.
Further analysis of existing Save the Children data	July-Aug 2018	To advise trial protocol
Telephone interviews with programme designers/manager	July-Aug 2018	To understand programme design and intended implementation
Trial protocol and recruitment materials	Aug-Sept 2018	To recruit schools

Recruitment of schools	Sept-Nov 2018	To allow sample size target to be met
Publication of the trial protocol	Oct-Nov 2018	Open science
Save the Children trains the Community Practitioners; observe training sessions and interviews with community practitioners	Nov 2018	Observations and interviews to understand intended delivery, preparedness to deliver, and assess perceived quality
Recruitment of families; consent and parent questionnaires Devise monitoring logs	Nov-early Dec 2018	To allow sample size target to be met Logs to assess fidelity; and costs
Baseline testing by schools and SCUK administrators Finalise statistical analysis plan	Early Jan 2019	In advance of randomisation to guarantee an unbiased measure Measurement and analyses specified prior to randomisation
Randomisation of families within schools	Mid-late Jan 2019	Random allocation of families to intervention/control
Community practitioners deliver Families Connect	End Jan-early Apr 2019	Delivery of the 8 session programme
Recruit booster sample schools and families; consent and baseline parent questionnaires	End Jan – Early March 2019	To ensure sample size is sufficient at randomisation for a powered trial
Booster sample baseline testing by schools and SCUK administrators	Mid-March 2019	In advance of booster sample randomisation
Booster sample randomisation	End March 2019	Random allocation of families to intervention/control
Delivery observations and post-delivery school staff and community practitioner interviews; paired interviews with children; interviews with parents	March 2019	To explore implementation of the programme, including fidelity

Follow-up parent questionnaires and fidelity measures	End Mar-early Apr 2019	To explore parental outcomes, and dosage, fidelity and implementation measures for the trial
1 st follow-up testing by NFER test administrators (schools complete the SDQs)	Apr-early May 2019	Determine effect immediately after programme
Delivery to booster intervention families	Apr-June 2019	Delivery (one case study from the main phase to be conducted in the booster phase in order that process data is collected from this phase).
Follow-up booster parent questionnaires, fidelity measures, and 1 st booster follow-up pupil testing by NFER administrators (schools complete the SDQs)	End June – July 2019	To explore parental outcomes and dosage; and to determine effect immediately after programme.
Phone interviews with parents	June-Sept 2019	To understand effect on parents and on the home learning environment
Telephone interviews with school senior leaders	June 2019	To explore factors that support the programme (e.g. conditions in schools), challenges, and factors for scale up, and explore implementation quality further
Telephone interviews with programme designers/ managers/ practitioners	June-July 2019	To understand delivery, fidelity, adaptability, challenges and barriers/enablers for scale up
2 nd follow-up testing by NFER test administrators (schools complete the SDQs)	Sept-early Oct 2019	Determine effect five months from programme delivery
Waitlist control families receive Families Connect	Oct-Dec 2019	Must be after 2 nd follow-up testing is complete
2 nd booster phase follow-up by NFER test administrators (schools complete the SDQs)	Jan 2020	Determine effect five/six months from programme delivery
Booster waitlist control families	Late Jan – March 2020	Must be after 2 nd follow-up testing is complete

Data capture, analysis and reporting	Feb-May 2020	Draft report by end May 2020
Final report	2020	Publication and ongoing dissemination

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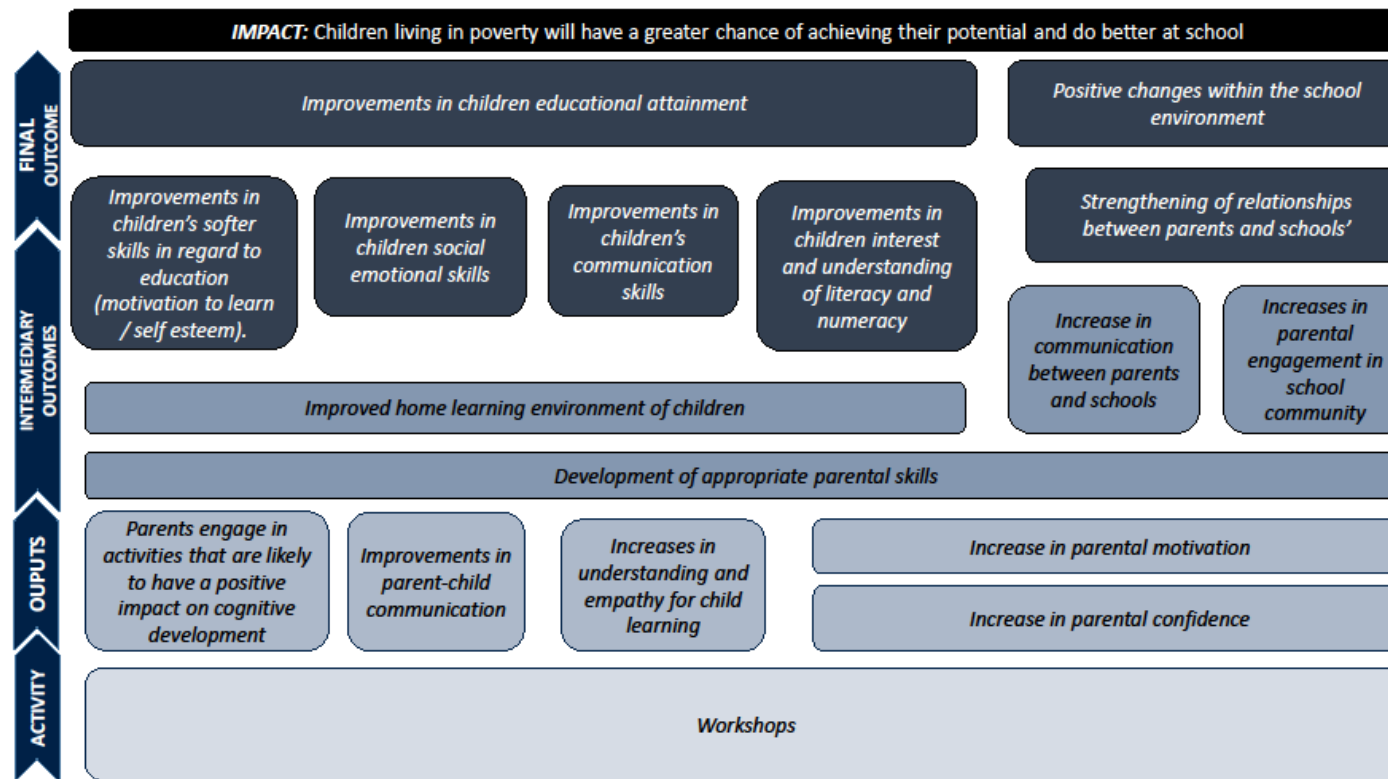
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Appendix A: A Theory of Change for Families Connect



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