

Trial Evaluation Protocol

Parents and Children Together (PACT)

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Education
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PROJECT TITLE	Parents and Children Together (PACT)
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TRIAL DESIGN	Two-arm randomised controlled trial with random allocation at pupil level
PUPIL AGE RANGE AND KEY STAGE	3-4 year olds (preschool)
NUMBER OF SCHOOLS	48
NUMBER OF PUPILS	480
PRIMARY OUTCOME	Improvements to language development (assessed using a broad language latent variable) at post-test
SECONDARY OUTCOME	Improvements to the child's home learning environment measured by the Home Learning Environment Index at post-test Improvements to language development, measured by the CELF-PreSchool-2. Early literacy skills, measured by letter sound knowledge, early word reading and sound deletion (taken from YARC) School readiness, measured by BESSI

Protocol version history

VERSION	DATE	REASON FOR REVISION
1.0 [original]		

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Intervention

A detailed description of the Parents and Children Together (PACT) intervention is provided in Table 1.

Table 1: Description of the intervention using ‘The Template for Intervention Description Replication (TiDieR) framework

TIDIER FRAMEWORK	DESCRIPTION
Name of intervention	Parents and Children Together (PACT)
Why? Rationale	<p>Oral language skills provide the foundation for formal education and play a critical role in learning to read (Hulme <i>et al.</i>, 2015). Children from low income backgrounds are at risk of delayed language development and educational disadvantage. Interventions that promote oral language in the early years have considerable potential to enhance children’s learning and development, particularly for those from deprived socio-economic backgrounds. PACT is an early language teaching programme (PACT) for parents/carers to deliver to their pre-school child (aged 3-4 years). Results from a within-school randomised controlled trial reported the PACT programme led to significant gains in oral language skills immediately post-test, which were maintained six months later. The trial also reported improvements in some early literacy skills at delayed follow-up (Burgoyne <i>et al.</i>, 2018a 2018b).</p>
Who? Recipients	<p>Primarily the intervention will be evaluated with pre-school children and their parents/carers. Eligible families will have a 3-year old child attending the nursery, parents/carers must have a sufficient level of English to access the programme materials, the child should not have a suspected or diagnosed developmental or learning difficulties and must not have a sibling or step sibling within the same class. Parents/carers are ultimately responsible for engaging with PACT and delivering the content to their child.</p> <p>Nursery level implementers/providers: 1-2 nursery staff in each setting will be trained to support the project (recruitment, training and supporting families taking part) and monitor compliance informally through regular discussions with parents/carers and children.</p>
What? Materials used	<p>PACT is a manualised teaching programme (now published by the Book Trust, The UK’s largest reading charity) consisting of 30 weeks of teaching materials organised into 5-week blocks designed for use by parents/carers in the home with their pre-school children. The sessions are scripted, and all teaching resources needed to deliver the programme daily are provided to parents/carers. The programme incorporates three key components designed to promote children’s early language development:</p> <ol style="list-style-type: none"> 1) Shared reading: Parents/carers read books with their child using strategies which support verbal interaction and active engagement. 2) Vocabulary instruction: Selected words are taught using interactive activities to promote new word learning. 3) Narrative (storytelling): Activities include sequencing, summarizing and telling/retelling stories.
What? Procedures, activities and/or processes	<p>The 30-week programme consists of six 5-week teaching ‘blocks’ that each encompass a different theme which aligns to common early-years themes including: (1) Animals, (2) The World Around Us, (3) Journeys, (4) The Body, (5) Home, and (6) Places and People.</p> <p>Each PACT ‘block’ includes four story books including traditional stories (e.g. The Gingerbread Man), well known modern classics (e.g. The Gruffalo), fact-based storybooks (e.g. The Pond) and books that may be new/unfamiliar to families (e.g. 5 Minutes Peace). Each book has a corresponding activity book including all activities and related resources to enable parents/carers to deliver a scripted 20 minutes interactive learning session, five times a week. Each block also</p>

	<p>contains a 'Bringing it all Together' activity book which features consolidation and theme-level activities.</p> <p>Teaching sessions are the same as the previous trial and 'start with a brief introduction to give parents time to settle the child and get them ready to focus on the activities. Parents/carers and children then read the book together. Following the principles of dialogic reading, parents/carers [are] asked to support their child to play an active role in shared reading by following their child's interest, asking questions, and linking the story to their child's experience. Vocabulary activities focus on learning a new word from the book or theme. New words include a range of word types and [are] selected to be useful across different contexts. Parents/carers then support children's story knowledge and storytelling skills by helping them to order pictures from the story, describe what is happening in the pictures from the story, and retell stories. The teaching sessions end with a recap of the content, praise for the child and a sticker reward.' (Burgoyne <i>et al.</i> 2018a, p8)</p> <p>Each PACT session should last around 20 minutes and should include all listed activities and should follow a consistent structure and routine. The content of weeks 1-4 activities focuses on introducing new content, and week five encourages parents/carers and children to revise and build on learning from the previous 4 weeks. Nominated caregivers are requested to complete a daily record form through a mobile application to gauge session completion and whether the pair enjoyed it. In any cases where families are unable to use the mobile app, paper copies of this form will be provided.</p>
Who? Providers/implementers	<p>PACT is designed to be delivered by a trained caregiver (e.g. parent/guardian, grandparents, older sibling) in the home. Nominated caregivers are required to attend a small group ($n=5-10$) developer-led training session lasting 1.5-2 hours in their child's nursery or one which is geographically close. Trained nursery staff cascade the session to any parents/carers unable to attend the developer-led training.</p> <p>Within each nursery, a staff member will be nominated to support parents/carers to deliver the programme, including attending a one day developer-led training course at Manchester University.</p>
How? Mode of delivery	<p>PACT is designed to provide parents/carers with teaching strategies/activities, materials and resources to support language development. Training is provided by the developer in nursery settings, and support for families is provided through nurseries, specifically by the trained PACT Lead.</p>
Where? Location of delivery	<p>PACT families will be recruited within school nurseries and Local Authority (LA) maintained nursery schools located within socially disadvantaged LAs (Manchester and Lancashire) identified by low Indices of Multiple Deprivation (IMD) rankings. Eligible nursery schools are those that are state-funded, with nurseries that have provision for children 3+.</p>
When and how much? Duration and dosage	<p>PACT teaching sessions are to be delivered for 20 minutes, five days a week for 30 weeks. In total, there is content for 150 home-based teaching sessions. Parents/carers receive six PACT activity packs at five-weekly intervals across the duration of the 30-week programme.</p>
Tailoring and adaptation	<p>The PACT materials have been improved and updated since the initial trial (Burgoyne <i>et al.</i>, 2018a, 2018b) and have been published for use in the EEF-funded trial by Book Trust (the UK's largest reading charity).</p> <p>PACT is a manualised teaching programme and optimal treatment fidelity is emphasised. Nonetheless, parents/carers are encouraged to make surface adaptations (e.g. prompts used during book reading) to tailor the programme to individual children.</p>

	<p>Nursery staff may choose to adapt the level of interaction with parents/carers and children in relation to the PACT programme e.g., prompting their use, talking to parents/carers about engaging with the materials.</p> <p>In the previous PACT trial (Burgoyne <i>et al.</i>, 2018a, 2018b), (a) settings were encouraged to hold 'celebration events' (at weeks 10, 20 and 30) to celebrate families achievements and success on the programmes, and (2) participants were also given a £10 voucher on completing each 10-week block of the programme to thank them for their participation. Neither of these are being implemented within the context of this trial due to concerns over the scalability of the incentives and centrally coordinated celebration events. Parents will, instead, received £10 for each child assessment time-point completed. Parents/carers will also receive project newsletters every 10 weeks. Children will receive certificates to thank them for their participation.</p>
<p>How well (planned?): strategies to maximise effectiveness</p>	<p>Strategies to maximise implementation effectiveness include:</p> <p>(a) Nurseries providing sufficient support to PACT families: Nurseries can send more than one staff member to the developer-led training to mitigate issues relating to the continuation of the programme associated with staff absence. PACT Leads will be informed of suggestions and recommendations on how to support nominated caregivers during their training. PACT Leads will be advised to hold some form of weekly drop-in session(s) for the first 1-3 weeks of the programme delivery to monitor nominated caregiver progress with the programme, allow for troubleshooting and model any activities that parents/carers are unsure of. After these initial three weeks of the programme, PACT Leads will be asked to provide ongoing support to nominated caregivers in a form that suits their setting and their families, e.g. continue with drop in sessions, contact via email or text message, and asking parents/carers about it when they drop off their child. PACT Leads will also be the ones who provide a new PACT pack to nominated caregivers at each 5-week interval. The PACT Lead will be encouraged to use this opportunity to talk with their PACT families to take an interest in their progress.</p> <p>(b) Offering families flexibility for training sessions and delivery of the programme: Nurseries will inform families that more than one caregiver can attend training and administer the programme to their child. Offering to train more than one parent/carer is likely to increase the frequency of programme delivery. Multiple dates/times for training located in the child's nursery, or a location close to it, will be offered to encourage nominated parent/carer(s) attendance. Mop-up training will be provided by the setting's trained PACT Lead should parents/carers be unable to attend a developer-led session. During training, the nominated parent/carer(s) will be encouraged to aim to deliver the programme at a similar time each day and give the programme a name that they use with their child to get the child to more easily understand the routine.</p>

Study rationale and background

Vocabulary acquisition is a key element of early infant development and continues to be an important factor throughout childhood. Bergelson and Swingley (2012) reported that babies appear to start learning the sound forms of whole words within the first few months of life and they understand the meanings of several common nouns from the age of six months. At around the age of 18 months, young children's vocabulary begins to expand rapidly and it is estimated that they learn words at a rate of one every two waking hours; a trend that will continue to adolescence (Pinker, 1994). In addition to vocabulary acquisition, infants need to learn about the features of spoken language such as where words begin and end, and realise that these units carry a meaning. This phonological knowledge underpins vocabulary acquisition and growth.

Moving on to learning to read, Harrison (2004) suggested that children need different types of knowledge as precursors:

- Knowledge and understanding of the world; Knowledge of how our language works;
- Knowledge of conventions of print; Phonological awareness; Decoding, oral reading fluency and reading comprehension are beginning to be acquired by many children by 5 years of age.

Evidence indicates that parenting and educational environment in the early years have a powerful influence on language development. The quality of the home learning environment and educational resources within the home are important factors (Melhuish *et al.* 2008b) and there is a link between this quality and socio-economic status (Foster *et al.* 2005). We observe children from disadvantaged backgrounds entering school with lower levels of attainment than their more socioeconomically advantaged peers (Tymms *et al.* 2014) and this trend persists throughout primary school (Merrell, Little and Coe, 2014); development and skills at the start of school are predictive of later outcomes (See, for example, Tymms, Merrell and Bailey, 2017).

PACT provides teaching sessions and materials for parents/carers to use with their children to develop their language skills. Previous research suggests that through its structured programme to enhance the home learning environment, PACT could positively impact on the quality of the home learning environment, leading to gains in language development.

Impact Evaluation

Research questions

1. What is the impact of the PACT intervention on the language development of children aged 3-4 years old, as measured using a broad language latent variable [Primary Outcome]
2. What is the impact of PACT on the early literacy skills of children aged 3-4? [Secondary Outcome]
3. What is the impact of PACT on the home learning environment of children aged 3-4 years old as measured using the Home Learning Environment Index? [Secondary Outcome]
4. What is the impact of the PACT intervention on the school readiness of children aged 3-4? [Secondary Outcome]

Research questions 1 and 3 will be investigated immediately following the intervention (immediate post-testing). Ten months after the completion of the intervention, research questions 1, 2 and 4 will be investigated (delayed post-testing).

Design

Table 2: Study design summary

Trial type and number of arms		Two-armed randomised controlled efficacy trial
Unit of randomisation		Pupil level
Stratification variables (if applicable)		Pre-test completeness
Primary outcome	Variable	Language development
	measure (instrument, scale)	A latent language variable combining Clinical Evaluation of Language Fundamentals Preschool 2 UK (CELF-Preschool UK – sentence structure and expressive vocabulary subscales), BPVS-3, APT and Listening Comprehension.
Secondary outcome(s)	variable(s)	(1) Early Literacy skills, (2) Home Learning Environment, (3) School Readiness
	measure(s) (instrument, scale)	(1) CELF Preschool 2 UK Core Language Standardised Score (sentence structure, expressive vocabulary and word structure subscales), YARC (letter sound knowledge, early word reading and sound deletion) (2) Home Learning Environment Index, (3) BESSI

We propose a two-armed randomised controlled efficacy trial delivered under ideal conditions with allocation at pupil level. Pupils will be allocated into one of two groups on a 1:1 ratio to:

- Intervention – pupils allocated to receive the PACT programme
- Control – pupils allocated to 'business as usual' plus equivalent incentive cost of materials (approximately £130) in books to parents/carers on completion of the immediate post-test

The within-school randomised design has recognised limitations, particularly relating to the potential risk of contamination between the groups. The books included in the programme could be passed between parents/carers in the PACT group to the control group, however the developers advised the core of the programme is the accompanying activities and resources which after initial completion would not be particularly useful as some of the materials are single use. Additionally, the staff training could encourage change of practice within the setting, however the developers intend the training to focus on the theory of the programme and how best to support parents/carers in its delivery, none of which is expected to create new knowledge significant enough to influence classroom based practice. Following these discussions and reassurances with the developers and EEF, the evaluation team deemed the risk of contamination to be low and out-weighted by the advantages of the within-setting design providing greater power and a lower minimum detectable effect, than a between-setting design. The evaluation team will work with the developers to make sure that consistent and clear messages are being communicated at both school and parent/carer recruitment stages to mitigate risk of potential contamination between the intervention and control group.

Randomisation

Randomisation will be completed independently by the trial statistician who has no involvement in the recruitment of schools or parents/carers. All participating pupils will be allocated into one of two groups (intervention or control) on a 1:1 ratio. The within-school randomised study design poses a higher risk of baseline imbalances between groups. Randomisation will be undertaken to ensure the two groups (control and intervention) are balanced on pre-test completion status as follows:

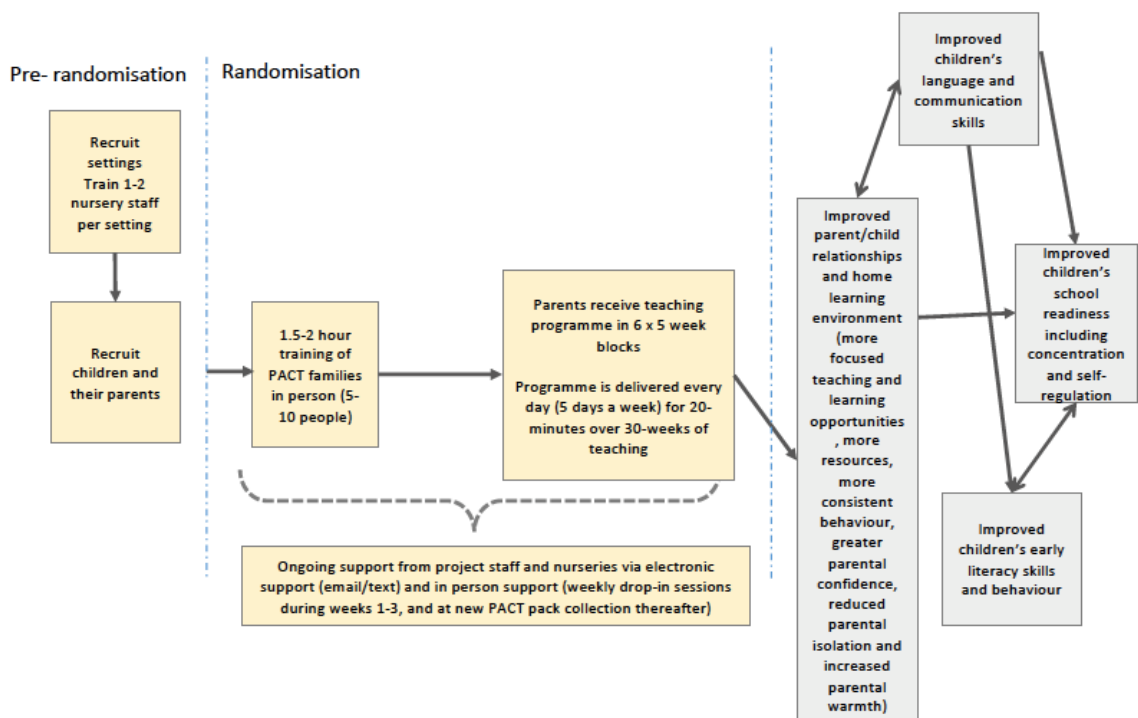
- (1) 'Pre-test complete' which will include all children who complete all assessments which form the latent language variable (CELF Expressive Vocabulary, CELF Sentence Structure, Listening Comprehension, BPVS-3, APT) and the CELF Word Structure measure.
- (2) 'Partial pre-test complete' which includes at a minimum both the completion of CELF expressive vocabulary and the CELF sentence structure
- (3) No pre-test data available

Whilst randomising based on pre-test scores would be desirable, it is not possible due to timing of the pre-test assessments, the required data entry time and delivery of the PACT programme requiring the majority of the academic year (30 weeks). The evaluation team will inform the developer of pupil allocation, who will relay this information to schools and parents/carers. As the developers are tasked with the collection and entry of post-test data, best practice would have been to blind them to pupil allocation to reduce the introduction of bias; however, this it is not feasible as it would prevent the delivery of the intervention under ideal conditions. We discuss this further in later sections.

Participants

Participant allocation throughout the trial is summarised by the PACT Logic Model, detailed in Figure 1.

Figure 1: PACT Logic Model



NURSERIES

A sample of 400 pupils from 40 schools with nursery classes is required to power the analysis. So, initial recruitment will target 450 pupils from 450 schools to compensate for a possible 10% attrition in a number of schools both during the course of the programme and at post-testing. This level of over recruitment will account for some of the attrition experienced in the developer's earlier trial (Burgoyne *et al.* 2018a, funded by Nuffield Foundation) which reported 24% attrition. However, every effort will be made to avoid attrition from the programme and the outcome measurement. The recruitment target here is based on the maximum capacity of the developer's ability to deliver the intervention within this trial's timeframe.

At the time of writing (June 2019), the developer had recruited 48 schools. This would assume 480 pupils recruited across these schools.

The evaluation team worked with the developers to recruit school nurseries to the project. The developers held recruitment events publicised through the Local Authority and conduct mail outs. Eligible schools are:

- a) State funded
- b) Located in areas with high scores on the Indices of Multiple Deprivation (including Rochdale, Lancashire and Tameside)
- c) Agree to all study requirements outlined in the Memorandum of Understanding (MoU) which describe their commitment to the delivery of PACT and participation of a minimum number of families ($n=4$) to the trial and administration of measures
- d) Agreeing and signing a project specific Data Sharing Agreement (DSA)

Each school will be responsible for nominating at least one (but up to two) staff member(s) to become the 'PACT Lead' and manage the school and parent/carer's participation in the trial. The staff member(s) will be required to attend one of two available full day training sessions hosted by the developers at Manchester University in April 2019. The staff training day will give an overview of the trial design and timetable, a detailed insight into the PACT materials and how to use them, the underpinning educational theory and will offer suggestions and recommendations on how to recruit and support participating parents/carers. Staff are not required to cascade training to other staff members within the school, except in circumstances where the staff member leaves during the trial and therefore needs to handover responsibility to another member of staff in the school. This can also happen in cases where schools have two nominated PACT Leads but only one attends the training. Schools will be encouraged to send two staff members (the nominated school liaison plus another staff member) to attend the developer-led training to mitigate for the potential of staff absence throughout the course of the trial. Staff training is considered an integral part of the programme; therefore, if a school does not attend training, they will be withdrawn from the trial prior to randomisation. Whilst staff time and travel will not be reimbursed, all schools will receive £500 as compensation for such expenses incurred to participate in the trial, including resourcing to complete trial paperwork, recruitment of parents/carers, coordinating one-to-one assessments pre- and post-tests. Schools can opt to receive this payment in two instalments, £250 at the end of nursery and £250 at the end of the trial. We believe this £500 payment will promote retention of settings throughout the trial, often an issue within early years' trials. Each PACT Lead will get a full set of the PACT materials (six PACT activity packs) in order to help them support parents/carers completing PACT; they will be informed not to use the PACT pack for within school teaching. Nurseries will be requested to provide specific data on participating pupils including their Unique Pupil Number (UPN), Early Years Pupil Premium (EYPP) status, English as an Additional Language (EAL) status, nursery attendance data and school destination data.

PARENTS/CARERS AND CHILDREN

Nurseries will be responsible for promoting the project to parents/carers. Nursery staff will be requested to provide trial information (developed by the evaluation team and the developers) to all parents/carers of children who are three or due to turn three years old by September 2019 and are pre-registered to start nursery in September 2019. Schools will be advised of the requirements for the project; this will include that someone within a recruited family must be able to access the resources by having a basic level of English. Parents with twins/(step) siblings in the same academic year or children with suspected or diagnosed developmental or learning difficulty are not eligible to take part. Developers will collect data on how many eligible parents/carers within each nursery were approached to take part. The nurseries will support the completion and collection of parent/carer participant agreement forms. The parent/carer participation form will request parents/carers to provide their child's personal data, including their name, date of birth, sex, school, address, nursery attendance information and if English is an Additional Language. Nurseries will return hardcopies of the participation form to the developers, who will in turn provide scanned copies to the evaluators alongside a spreadsheet of pupil-level information. Nurseries will be requested to aim to recruit around 10 parents/carers to the trial, with no maximum limit assuming eligibility criteria is met. Nurseries who do not recruit a minimum of four parents/carers will be withdrawn prior to randomisation.

The parents/carers will be informed of their random allocation (intervention or control) by letter given to them by the nursery, sent by the developers. Parents/carers allocated to the control group will be informed when they will receive the equivalent incentive cost of materials (approximately £130) in books (completion of the immediate post-test) and those in the PACT group will be informed about the next steps within the trial. Parents/carers randomly assigned to the PACT group will be required to attend a 1.5-2 hour small group (parents/carers representing 5-10 children) developer-led training session. The developers intend to ‘pair’ nurseries which are geographically close to one another and hold the parent training session at one of the two locations. A variety of training dates and times spanning weekday mornings, afternoons, and evenings will be offered to parents/carers. The training session will cover the design of the trial, provide a detailed overview of the PACT materials, how to implement them in the home and how to adapt them to the individual learning needs of their child. The developers have informed schools that they may need to provide childcare for parents whilst they are attending a PACT training session. If caregivers are unable to attend a developer-led training, they will receive the training session by the PACT Lead within the nursery. Nursery staff will be requested to report to the developers when cascade training has occurred, who will consequently pass this information to the evaluation team. Parents/carers who do not attend any form of training will not receive the intervention but their child will be assessed (assuming parental/carer permission to do so remains in place).

Sample size calculations

Table 3: Summary of sample size calculations for the actual number of schools recruited (as of June 2019)

		OVERALL
MDES		0.18
Pre-test/ post-test correlations	level 1 (pupil)	0.60
	level 2 (class)	
	level 3 (school)	
Intracluster correlations (ICCs)	level 2 (class)	
	level 3 (school)	10%
Alpha		0.05
Power		0.8
One-sided or two-sided?		Two-sided
Average cluster size		10
Number of schools	Intervention	48
	Control	48
	Total	48
Number of pupils	Intervention	240
	Control	240
	Total	480

Sample size calculations to reflect a within school randomisation design. Based on the maximum capacity for delivery by the developer 48 schools are recruited and randomised with 480 children in total (i.e., 10 per school), along with 5% Type I error, 80% Power, 10% intra-school correlation, 60% pre-post test correlation and 2-sided test. Using these assumptions (scenario 3b in table 1 below), the

sample size will detect a minimum difference of 0.18 standard deviation between the PACT and control group. The intra-cluster correlation of 10% is based on the average value observed in EEF trials (Xiao *et al*, 2016). We have assumed 0.60 for correlation between pre-test and post test score as Burgoyne *et al*. (2018a, 2018b) found previously.

Table 4 presents what would happen if we vary some of these assumptions using a more conservative pre-post test correlation (0.25) and varying the number of schools recruited to the trial. Using our preferred assumptions (scenario 1b) recruiting 48 schools (480 participants) would allow us to detect a minimum effect size of 0.18. Assuming 16.7% dropout in number of schools (i.e if the number of schools recruited dropped to 40) the minimum detectable effect size would rise 0.20.

We believe that initial recruitment should target 48 schools to counter for the significant level of school attrition at the baseline assessment (pre-randomisation) stage that we have seen in other early years trials. In case recruitment exceeds the targeted number of schools and are retained throughout the study, it would increase power of the study to detect smaller MDSES.

Table 4. MDSES using a variety of assumptions and recruitment scenarios

#	Significance Level (α)	Power ($1-\beta$)	Pre-post correlation (R^2)	# pupil (n)	Effect size			
					# schools (J = 30)	# schools (J = 35)	# schools (J = 40)	# schools (J = 48)
1a	0.05	0.80	0.25	10	0.31	0.29	0.27	0.25
1b	0.05	0.80	0.60	10	0.24	0.22	0.20	0.18

Person randomised, multisite, MDSES vs Power

Alpha (α) = Level of significance

beta (β) = Acceptable level of type II error

10 families per school

*Used effect size variability estimate =0.05

Software used: Optimal Design

Outcome measures

PRIMARY

The proposed primary outcome measure is the language latent variable at immediate post-test, as defined by the developer's previous PACT trial (Burgoyne 2018a, 2018b), which will allow for direct comparison to the results of this trial and allow a latent variable to be utilised in the analysis. This will be measured through the use of:

- (a) The **Clinical Evaluation of Language Fundamentals Preschool 2 UK (CELF-Preschool 2 UK)** subscale scores of sentence structure and expressive vocabulary. CELF-Preschool 2 UK provides a measure for expressive and receptive language skills in young children. This is a standardised and validated assessment with the proposed age group and UK sample.
- (b) The **British Picture Vocabulary Scale – 3 (BPVS-3)**, is a standardised measure of receptive vocabulary appropriate to 3 year olds. The programme activities specifically target vocabulary learning and involve increased exposure to a variety of books and resources. This measure consists of a set of pictures from which the child is asked to point to the picture representing a given word.
- (c) The **Action Picture Test (APT)** is a standardised test that requires children to give samples of spoken language in response to picture stimuli. The test considers grammatical structures used and the expressive vocabulary used. The test is suitable to use with children between the ages

of 3 and 8 and provides normed scores. It is quick and simple to administer and inexpensive to purchase.

- (d) **Listening Comprehension** as measured by a task developed by the developer team used previously across a variety of projects. In this assessment children listen to a recording of a short story. The tester then asks eight comprehension questions and records the child's response verbatim for later scoring by the research team using detailed scoring guidance. The test takes approximately three minutes to administer. Materials for this will be provided by the developer at no additional cost.

SECONDARY

The **CELF–Preschool-2 UK word structure subtest** will also be measured at pre-testing and immediate post-test to create a **CELF-Preschool-2 UK Core language standardised score** as a secondary outcome. This subtest measures the child's knowledge of grammatical rules in a sentence-completion task and takes approximately 7-8 minutes to administer. In addition to being a secondary outcome for this trial, the score will also be used for comparison to other EEF early years' language evaluations.

Early Literacy Skills (measured at the 10 month delayed post-test) will involve measures of letter-sound knowledge, early word reading and sound deletion (taken from the **YARC assessment**). In the previous trial of PACT the largest effect sizes were found at delayed post-test on these measures which are indicators of early literacy skills rather than the pre-literacy language skills measured by the other outcomes.

The **Brief Early Skills & Support Index** (or **BESSI**) questionnaire (measured at the 10 month delayed post-test) will be used to evaluate school readiness. BESSI is a simple but reliable questionnaire which assesses how well children are making the transition to school. This questionnaire has been developed and validated for reception and nursery children. Teachers will be asked to complete this questionnaire for children in the project at delayed post-test.

The **Home Learning Environment Index** (HLE; Melhuish et al, 2008) which was developed as part of the EPPE study, and has been used in several large studies including the Millennium Cohort Study, National Evaluation of Sure Start (NESS) and a study of the Home Learning Environment by the Scottish Government (Melhuish, 2010). The HLE asks parents/carers to report the frequency of seven routine activities which are conceptually linked to learning (including being read to, going to the library, playing with numbers, painting and drawing, being taught letters, being taught numbers and songs/poems/rhymes). These seven items were positively linked with predicting under and over achievement at aged 5 (Melhuish *et al.* 2008). Frequency of the seven activities is coded on a 0 to 7 scale). Previously, this index was used in surveys conducted over the phone, however, for the PACT trial, the questions will be added to the usual practice survey for parents/carers at the beginning of the trial and immediately following the teaching period (i.e. during the immediate post-testing period).

Table 5 summarises when each of the measures will be collected.

DELIVERY OF OUTCOME ASSESSMENTS

It has been agreed that the developers will manage the collection, entry and coding of all data relating to the impact evaluation within the trial – baseline, post-test and at delayed post-test. Strategies will be put in place to ensure that the majority of actual collection and all coding of data is conducted blind to treatment allocation. The developer will recruit and provide comprehensive training to a team of Research Assistants (RAs) to collect assessment data. The developers will coordinate all assessment arrangements and logistics unblinded. However, the RAs who will be conducting the assessments on a one-to-one basis with participating children will be blinded to allocation. In addition to off-site training, the developer will provide additional on-site training to RAs by attending the first assessments with each RA. The RA will observe the developer carrying out assessments with two children. The RA will then be subsequently observed assessing two children by the developer. This process is included to ensure quality control of the RAs; however, will mean that in a small number of cases, the assessments

will not be carried out blind. Information regarding who carried out each assessment will be collected and used in the analysis.

At each testing point RAs will be instructed that assessments are to be conducted in the pre-specified order as listed in Table 5. Pre- and post-test assessments will take place in the child’s nursery and will take approximately 30 minutes to complete across two testing sessions with a break in between. Repeat visits along with further mop-up visits are planned by the developer as pupil absence on the planned day of testing is common in early years settings. For the delayed post-test, children will have moved from nursery to school and may not be at the same school. Wherever possible, delayed post-testing will be conducted in the child’s school. However, where this is not possible, the RA will seek to assess children at home. At delayed post-test assessments will take approximately 40 minutes, which will be split across two sessions with a break in between. RAs will be required to record any deviation from this procedure, which has been discussed and agreed between the developer and evaluator.

Table 5: List of assessments at each assessment time-point.

Pre- and Immediate Post-Test	Delayed Post-Test
Completed by Research Assistants Session 1 – with pupils in schools	Completed by Research Assistants Session 1 – with pupils in schools
*CELF sentence structure	*CELF sentence structure
*CELF expressive vocabulary	*CELF expressive vocabulary
*Listening comprehension (Snowy)	*Listening comprehension (Snowy)
-	YARC Letter Sound Knowledge
-	YARC Early Word Reading
-	-
Completed by Research Assistants Session 2 – with pupils in nurseries	Completed by Research Assistants Session 2 – with pupils in nurseries
*BPVS III	*BPVS III
*Renfrew Action Picture Test	*Renfrew Action Picture Test
CELF word structure	CELF word structure
-	Listening comprehension (Sandcastles)
-	YARC Sound Deletion
Completed by parents	-
Home Learning Environment Index (HLE)	-
-	Completed by Reception class teacher
-	Brief Early Skills & Support Index (BESSI)

* Indicate the measures which form the Language Latent Variable

Parents/carers will be asked to give permission for assessments to be audio recorded. All assessments where permission has been given will be audio recorded for the evaluation team to perform quality assurance and bias checks on 10% of the assessments carried out by the RAs, and all of the assessments carried out by the developer team. Raw data scores will be securely transferred to the evaluation team for independent analysis. A testing plan will be developed by the developer and evaluation team and discussed with EEF before testing commences. The testing plan will also detail the measures the developers will undertake to reduce the risk of potential bias from being unblinded to pupil allocation during the assessment period, cleaning and coding of the data. Examples of measures that will be undertaken are that the RAs conducting the assessments in nurseries will be blinded to allocation and will be responsible for making decisions with the nursery as to the order pupils will be tested on the day, rather than this being specified by the developer. The exception to this will be in the situations where the developer attends the first assessments with the RA, as detailed earlier. In these cases, all audio recorded assessments conducted by the developer will be quality assured for unconscious bias. RAs will undertake data entry, cleaning and coding under the direction of the developer. Therefore, pupil IDs will be used along with hidden columns to prevent either the developer or RA being able to identify the allocation of the pupils during these processes. Key decisions around the number of follow up visits to schools will be made in conjunction with the evaluation team.

CHALLENGES OF ASSESSMENT IN THE EARLY YEARS

Limitations of testing in the early years are the young age and temperament of children who may or may not be responsive at the time of testing, potentially leading to missing data. This is particularly the case in September, at the beginning of the school year, when children will be unfamiliar with the environment and school staff. The evaluation team advised testing should ideally take place following a 'settling in period' within the setting. However, due to the length of the programme (30 weeks within a single academic year), this is not possible within the context of this trial. Therefore, testing has been scheduled to take place within the first two weeks of the new academic year.

Analysis plan

A detailed statistical analysis plan (SAP) will be produced within six months of the agreed protocol.

The primary outcome and secondary outcomes will be analysed using the principles of intention to treat, meaning that all schools and pupils will be analysed in the group they were randomised to, irrespective of whether or not they actually get the PACT programme. Statistical significance will be assessed at the 5% level. Point estimates and 95% confidence intervals will be provided as appropriate.

PRIMARY OUTCOME

The primary outcome considering a latent language variable derived by combining Clinical Evaluation of Language Fundamentals Preschool 2 UK (CELF- Preschool UK – sentence structure and expressive vocabulary subscales), BPVS-3, APT and Listening Comprehension will be analysed on a continuous scale using confirmatory factor analysis model. The effect size and its confidence intervals will be estimated as standardised factor loadings from confirmatory factor analysis models. A similar modelling approach was used in the previous trial. Sensitivity analysis will be performed using multilevel structural equation modelling to test whether the estimated effects of the intervention are constant across schools. Missing data in the pre-test and outcomes measures will be accounted for using full information maximum likelihood estimation techniques.

SECONDARY OUTCOME

All non-latent variable secondary outcomes will be analysed using multilevel models with school and school-by-intervention as random effects. The effect size and the associated confidence intervals will be calculated using unconditional variance of the outcome data. The immediate and delayed impacts of the PACT intervention on the secondary outcomes will be analysed using multilevel model accounting for intra-school correlation. Exploratory analysis comparing the difference between the immediate impact of the intervention and ten-month follow up will also be reported.

SUBGROUPS

All the outcome data will be analysed by Early Years Pupil Premium (EYPP) eligibility using interaction model. Effect size for pupils eligible for EYPP will be reported in accordance with EEF requirement.

CACE ANALYSIS

Self-reported compliance data will be collected from parents/carers in both the intervention and control groups as part of the standard intervention delivery and through the usual practice survey. This inventory will capture all educative support provided by parents/carers to their children at home. Compliance data on session delivered based on the PACT app (which sessions and total number of sessions completed) completed by the PACT group will be used in a Complier Average Causal Effect (CACE) analysis. The CACE analysis will be implemented using instrumental variable approach.

Implementation and process evaluation

The process evaluation will take place before and during the full 30-week duration of programme delivery and will monitor implementation fidelity, the processes involved for schools in implementing the

intervention, and the perceptions of relevant stakeholders. Process evaluation activity will be mapped to Humphrey's (2016a, 2016b) eight dimensions, ensuring appropriate coverage of each dimension. Data automatically collected through parent daily record forms (collected via the app) will be used to track implementation fidelity and aspects of parental engagement (described further below).

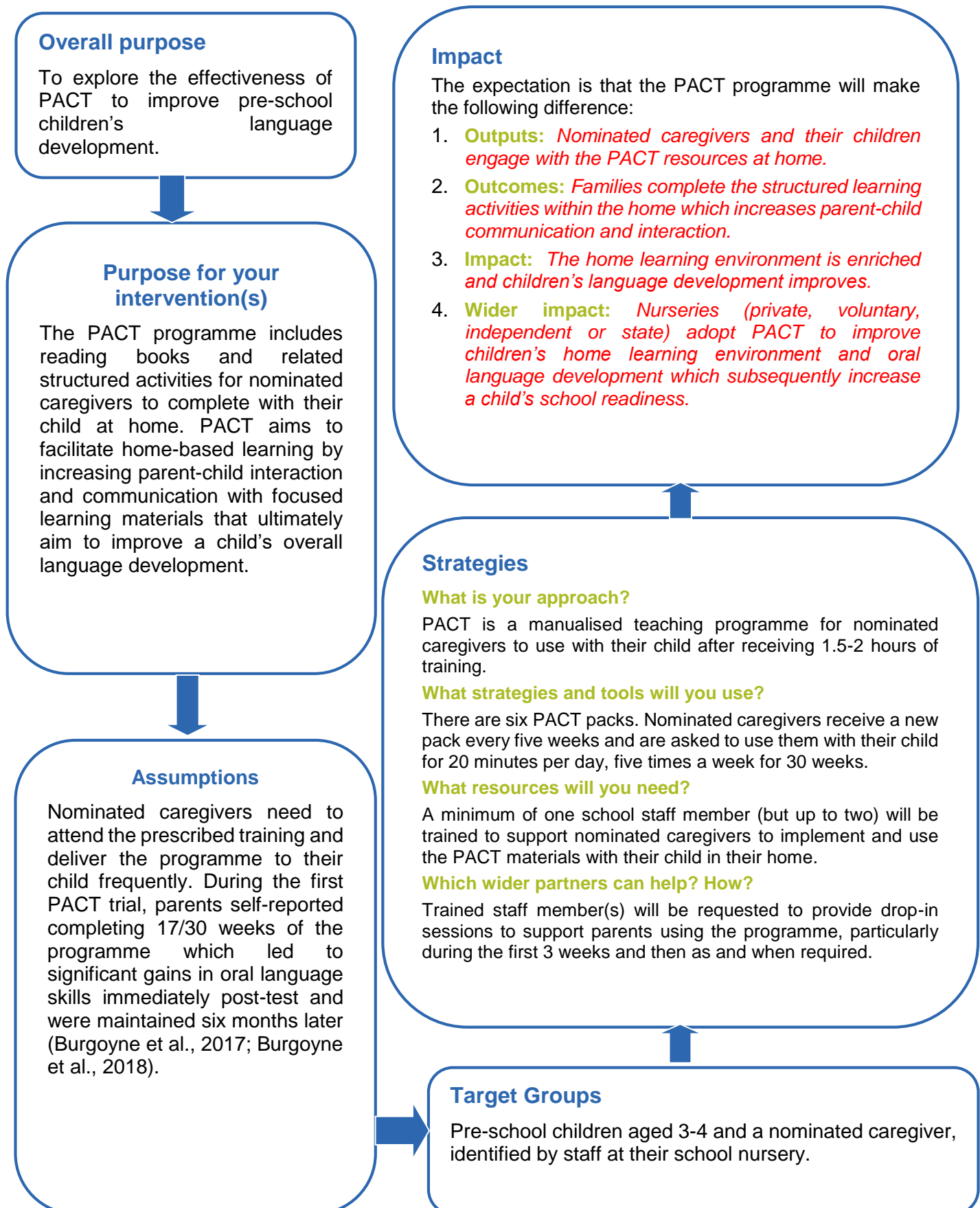
Research Questions (mapped to IPE dimensions)

- To what extent is training delivered to nursery staff (fidelity/quality) and how is this received (responsiveness)?
- To what extent does initial training take place for parents/carers? How is this training delivered? How many parents/carers attend the training sessions? (fidelity)
- To what extent do parents/carers deliver the teaching sessions to their children throughout the 30 weeks of the programme? (fidelity/dosage) What are the reasons for variety in this? (responsiveness)
- How closely do parents/carers follow the teaching session plans? (fidelity, quality, adaptations)
- How do schools support parents/carers? (quality/adaptation) How many support sessions are delivered? (fidelity/dosage) How many and which parents/carers attend these events? (fidelity/reach)
- What is the perceived impact of the intervention by parents/carers and school staff? (responsiveness)
- How does PACT differ from usual practice and control group activity (programme differentiation)?
- What barriers were faced by schools and by nurseries in implementing the intervention?
- Are there any groups of parents/carers that can't access the intervention and why? (reach)
- What constitutes ideal conditions for the delivery of the intervention and was this possible (fidelity)?

Theory of Change

Figure 2 illustrates the PACT Theory of Change model.

Figure 2: PACT Theory of Change model.



Design

The implementation and process evaluation will focus on tracking and monitoring fidelity, dosage, quality and responsiveness at each of the different levels of delivery of the intervention. Table 6 below summarises the level of delivery and research methods that would be used to learn about each level.

Table 6: Research methods for each level of intervention delivery

Level of delivery	Specific activities	Research methods
Support for schools (through developer)	Developer providing training and materials to schools	<ul style="list-style-type: none"> • Observation (2 x PACT Lead training sessions) • PACT Lead Interview (10 x 2 time points) • Developer interview (1) • Delivery/attendance administrative data • PACT Lead survey
Training and support for parents/carers (through developer and school)	Delivery of training to parents/carers through developer and school Delivery of training materials to parents/carers Dedicated support sessions hosted by schools Ongoing support for parents/carers	<ul style="list-style-type: none"> • Observation (parent/carer training – 1 x observation of each of the 3 trainers) • PACT Lead Interview (10) • Parent interview (20 x 2 time points) • Delivery/attendance administrative data • Parent/carer survey • PACT Lead survey
Parent/carer delivery of intervention	Delivery of the teaching sessions by parent/carer to child across the intervention period	<ul style="list-style-type: none"> • Parent/carer interviews (20 x 2 time points) • Parent/carer survey • Parent/carer self-report tracking of session delivery
Child responsiveness	Child's responsiveness to the intervention materials and teaching sessions	<ul style="list-style-type: none"> • Parent/carer interviews (20 x 2 time points) • Parent/carer survey

Methods

COLLECTION OF AVAILABLE ADMINISTRATIVE DATA

Attendance at developer-led training sessions (both school PACT Leads and parent/carers) will be collected by the developers and passed to the evaluation team. PACT Leads will be requested to inform the developer team of any instances where they have delivered training to parent/carers themselves.

As part of the PACT intervention, parent/carers are requested to complete an online daily record form. This will be delivered through an app; however, paper copies of the form will also be made available for parents who are unable or unwilling to use the app. This will be completed by parents/carers at the end of each PACT session to indicate its completion and if they/their child enjoyed the session.

Data collected through the app will be sent electronically to Manchester University. Paper versions of the record forms are returned to schools by parents/carers and collected by school staff when new PACT packs are distributed at each 5-week interval. The usage information collected through the record form app/paper version will be monitored by the developers who will contact the school to encourage parent re-engagement if there is an indication parents/carers are not engaging with the intervention.

This is to ensure that as far as possible the intervention is delivered under ideal conditions as this is an efficacy trial to establish 'can the intervention work?'. The developers will then send the forms to the evaluation team where they will be used as a measure of fidelity.

OBSERVATIONS

Using semi-structured observation schedules, the evaluation team will observe both staff training sessions and conduct three observations of parent/carer developer-led training sessions (one observation of each member of the developer training team).

STAFF ATTITUDES SURVEY

Whilst attending the developer-led training, school staff members will be requested to complete an initial attitudes and demographic survey. The survey will ascertain the staff member's role within the school, their rationale for signing up to PACT (if applicable), their perceived potential impact of the programme and their confidence in recruiting families and delivering the required administration and support for the programme. The survey will be distributed at the end of the training session and collected back in by the evaluation team. The survey will take approximately 10 minutes to complete.

USUAL PRACTICE SURVEYS

Schools will be requested to complete a 'Usual Practice' survey at baseline and post-test detailing their usual practice for providing support to parents generally, and also specifically around language development. This will also help to understand whether there was any spill-over or compensation rivalry in the control group.

Parents/carers will also be asked to complete a 'Usual Practice' survey at baseline and at immediate post-test asking them to detail the types and frequency of home learning activities.

PACT LEAD INTERVIEWS

We will conduct telephone interviews with ten randomly selected PACT Leads early in the intervention delivery and again at the end of delivery. Interviews will capture resource usefulness and acceptability, intervention delivery and the perceived impact of PACT. Here (as well as in the PACT Lead post-intervention survey) we will also gather details on the costs to schools (e.g. monetary, staff time) associated with implementing PACT.

PARENT/CARER INTERVIEWS

Telephone interviews will be conducted with 20 parents/carers implementing PACT at two time-points over the course of the intervention. Information gathered from the parent pre-test Usual Practice survey will be used to select parents/carers with a variety of characteristics. The telephone interviews will explore the acceptability and delivery of PACT and how it was used and adapted in individual circumstances, including any barriers that may have been faced. The interviews will also explore if the programme has had an impact on parents' understanding of child development and parents' attitudes and engagement with their child and their child's learning. The interviews will also seek to gauge any changes to the level of parent-nursery interactions as a result of implementing the PACT programme. Interviews will last approximately 15-30 minutes, and will take place at a time to be determined, most convenient to the parents. Agreement will be gained for participation. For participating in both interviews, parents/carers will receive a £15 Love2Shop voucher.

DEVELOPER INTERVIEW

An interview with the developers will be conducted at the end of the programme to explore their views relating to the delivery of the intervention, discuss further development of/changes to it, perceived impact of the intervention, implementation fidelity including actual barriers, future plans, including information on costs to be included in the cost evaluation in line with recent guidance from the EFF.

Cost evaluation

Data on intervention costs will be collected from the developers as well as from schools participating in the PACT Lead interviews, through interviews as part of the process evaluation, and will be used to conduct a cost evaluation in line with recent guidance from the EEF.

Ethics and registration

Ethical approval for the evaluation has been received from Durham University's School of Education Ethics Committee on 12/12/2018.

Agreement to participate was sought from each school to take part in the overall trial via a Memorandum of Understanding. Their participation in the trial was dependent upon their agreement to participate in the evaluation and subsequent data sharing with the EEF. Agreement to participate will also be sought from: relevant school staff for observations, interviews and surveys; from parents/carers for child assessments, observations, interviews and surveys as part of the process evaluation; and from the developer for the interview at the end of the trial.

The Evaluation Team has registered the trial with ISRCTN (www.isrctn.com) following agreement of the original protocol. The registration number is ISRCTN16848772 and can be accessed at <https://doi.org/10.1186/ISRCTN16848772>.

Data protection

The legal basis for processing the personal data accessed and generated by the trial is Public Task covered by GDPR Article 6 (1) (e) public task, which states that; "the processing is necessary for you to perform a task in the public interest or for your official functions, and the task or function has a clear basis in law." No special category data will be collected as part of this project.

We have carried out a Data Protection Impact Assessment (DPIA) identifying the privacy risks associated with the processing of personal data and for implementing appropriate controls to manage those risks. A privacy notice has been provided to all schools and participants in the trial detailing the processing and storage of data for the evaluation of the trial.

Data quality will be ensured through adherence to a detailed data management plan. Quality assurance checks on data sets along with data minimisation will ensure that only required and up to date information is held by the evaluation team. Wherever possible, project identification codes rather than participant names will be used to improve confidentiality and increase data security. Project data will be stored electronically on secure servers and electronic devices authorised by Durham University with paper copies of project data stored in locked cabinets in the project office in the School of Education Durham University. If parents/carers agree, their child's information will be linked with the National Pupil Database (NPD) (held by the Department for Education) and shared with EEF, and their data contractor FFT Education for long term follow up of pupil progress by EEF. No sensitive personal information will be shared outside of Durham University.

The roles and responsibilities for the trial for Durham University and the University of Manchester have been identified and a data sharing agreement implemented which includes a description of the nature of the data being collected and how it will be shared, stored, protected and reported by each party.

Conflict of Interest

The evaluation team highlighted to EEF a possible conflict of interest arising from the developers being tasked with conducting the data collection at post- and delayed post-test due to the risk of unconscious bias. A detailed testing plan is to be produced by the developer and the evaluation team to ensure, as far as possible, data collection and entry is conducted blind to treatment allocation and the evaluation team will undertake rigorous quality assurance checks during post-testing assessments to monitor unconscious bias.

Personnel

DELIVERY TEAM

Dr Kelly Burgoyne (PI): Kelly is a Lecturer in Language Disorders at The University of Manchester. Her research is focused on cognitive development, particularly the development of reading and language skills, and the nature and causes of children's learning difficulties. Kelly has particular experience in the development and evaluation of interventions to support children's reading and language development.

Recent projects include a large-scale longitudinal study of Australian school children; the development and evaluation of a parent/carer-delivered early language teaching programme for pre-school children; and studies of the role of pattern understanding in reading and arithmetic development.

Steph Hargreaves (Research Assistant): Steph is a Research Assistant at The University of Manchester. Her qualifications include a BSc and a Masters of Research in Psychology. Steph has good knowledge of randomised controlled trials because of her experience in NHS clinical research. Steph supported many child language acquisition studies during her previous role at the Child Study Centre in Manchester, which is part of the ESRC International Centre for Language and Communicative Development (LuCiD) research collaboration investigating how children learn to communicate using language.

EVALUATION TEAM

The team includes members of the Durham University and University of York Evaluation panels.

Vic Menzies (PI). Vic is an experienced education trials coordinator and researcher with experience of running large trials in nurseries (EasyPeasy, Maths Champions), primary (Shared Maths Project, Hallé SHINE on Manchester, Peer Tutoring in Maths in Scotland) and secondary schools (Project Based Learning, ICCAMS 2 Project, SHINE in Secondaries). Prior to moving to Durham, Vic's previous research included studies of early number development in Scotland and the effect of phonological awareness and training on children's early reading skills. As PI she will lead the impact, process and cost evaluation elements, contributing expertise to the design and conduct of this evaluation as well as to the writing of the final report. While Vic is on maternity leave Helen Cramman (Research Team Lead) will be PI on the project.

Dr Helen Cramman, Research Team Lead, has experience of leading and delivering large-scale evaluation research projects along with managing large trials, including EEF EasyPeasy. Helen has experience of leading studies in the early years with projects including an Innovate UK funded project for teaching computer science to reception pupils. She has published on the development of language and number skills in the early years (Boreboom 2018, Copping 2017, Cramman, 2018). Helen also has experience of providing CPD to primary educators. Helen will provide high-level advice and support to the PI throughout the project as well as taking over the PI role while Vic Menzies is on maternity leave.

Dr Adetayo Kasim, is a senior statistician. He has experience of a wide range of trials, including currently a large NIHR - HTA 'parent/carer mediated' intervention in children on Autistic Spectrum Disorder (ASD) with repetitive behaviours. Given the similarities between this and PACT, he will be able to provide invaluable expertise for the general design of the evaluation, as well as the more specific statistical analysis plan.

Dr Lyn Robinson-Smith, is a Senior Research Fellow based at the York Trials Unit, University of York. Lyn is an experienced trial manager and researcher and has led and delivered large trials in the early years (Maths Champions Evaluation, EasyPeasy). Her expertise and interest lie in conducting research in early years settings to improve attainment for disadvantaged children and robust trial design. Lyn will assist in preparing the protocol and provide ongoing advice to the project team drawing on her RCT experience and early years work, particularly while Vic is on maternity leave.

Professor Christine Merrell has published extensively in the area of young children's development and has many years of experience in developing assessments for use with children in the early years

and primary school. She will provide valuable experience and expertise for the process evaluation as well as the interpretation of the quantitative findings and process evaluation.

Dr Julie Rattray is a lecturer in Education and Psychology. Her research interests include conceptual development, and early development and learning. Julie will support the delivery of the assessments.

Dr Nasima Akhter is Assistant Professor (Research) in quantitative methods. Her areas of interest and expertise include the evaluation of complex interventions and health inequality. Nasima will conduct the impact analysis for the project and contribute to the report writing.

Jessica Hugill is a research assistant, experienced in delivering large scale RCTs (ICCAMS and Maths Champions) and the development of implementation and process evaluation measures. Jess has a background in Psychology and is an experienced Primary School teacher. Jess will conduct the IPE activity and liaise with schools and the developers for their delivery of the assessments.

Sarah Hallett is Senior Research Officer and has significant experience in the coordination and delivery of large-scale projects with multiple partners. Sarah has coordinated more than 2000 assessments across school and early year settings across two EEF funded evaluations (Maths Champions and EasyPeasy) and has specific expertise in data management. Sarah will provide support relating to project management, data management processes and reviewing the developer's assessment plans during the project setup phase.

Risks

Table 7 details the foreseen risks to the evaluation and methods of mitigation.

Table 7: Risks to the evaluation

Risk	Detail	Mitigation
Recruitment of schools	<p>Schools might not be interested in participating.</p> <p>Recruitment may take longer than anticipated.</p> <p>Schools may be willing to sign-up to the trial but not sign the Data Sharing Agreement.</p> <p>Schools may drop-out</p>	<p>We are currently offering schools £500 for participating, which we deem sufficient and appropriate participation incentive. Barriers to participation could be explored should recruitment be low.</p> <p>Hold additional recruitment events.</p> <p>Inform schools of the DSA prior to sign-up and discuss with schools where necessary. Over recruit, if possible, to account for any drop-out post-recruitment due to schools not agreeing to sign the DSA.</p> <p>Have a reserve list of schools interested in taking part in the trial to approach and replace drop-out school, if early enough within the trial.</p>
Staff training	<p>Low uptake of training which could lead to increased attrition.</p>	<p>Set dates and make schools aware of these as early as possible. Offer multiple training dates for schools to select a suitable date.</p> <p>Encourage schools to nominate two staff member to attend training, to mitigate in case of absence of one staff member.</p>
Low and/or delayed recruitment of parents/pupils	<p>Low uptake of parents/pupils taking part. Each nursery needs to recruit a minimum of 4 parents/pupils per nursery for continued participation.</p>	<p>Provide quality training to each nursery's PACT Lead so they feel confident in speaking to parents/carer about the benefits of the intervention and participating in the trial.</p> <p>Provide parents/carers with quality information about the trial/intervention (information sheets).</p> <p>Parents/carers are made aware of information and that they can withdraw their child/themselves from the trial at any time, without a reason.</p> <p>Parents/carers assured of their own and their child's anonymity and</p>

	<p>Under current trial plans, parents/carers will be recruited from pre-registration lists during summer 2019 meaning the child will just be starting at the school in September. Some nursery schools may have low numbers of pre-registered children who are eligible for the trial. Recruiting new parents/carers at the beginning of school year could impact on the pre-testing schedule.</p>	<p>confidentiality of data via parental information sheets and participation forms.</p> <p>Liaise with schools regularly during summer to remind them to invite any new pre-registered parents/children to take part in the trial.</p>
Pre-test data collection	<p>Schools are not responsive to dates supplied for trained assessors to go visit</p> <p>The timeline is tight between pre-testing and randomisation.</p> <p>Children are absent on the day of the assessment visit.</p> <p>Assessments are lost either before being received by the developers, or data is lost from databases at Manchester.</p>	<p>Developers to speak to Headteacher and encourage response.</p> <p>Evaluation and delivery teams to update on progress and concerns regularly through frequent teleconferences.</p> <p>Arrange more than one nursery assessment visit to 'mop-up' missed assessments.</p> <p>Manchester have a data management plan in place which includes the mechanism for RAs returning assessment forms securely back to the development team and have electronic data back-up arrangements.</p>
Within school randomisation	<p>Within school randomisation design weakens validity of results.</p> <p>There is a risk of contamination as parents/carer in the intervention group could give parents/carers in the control group their PACT pack.</p>	<p>Schools are required to recruit a minimum of n=4 parents/children to continue their participation in the trial. There is no upper limit on how many parents/children can take part in the trial within any one school. Minimising at randomisation for pre-test completion will help provide some balance to control/intervention groups.</p> <p>Parents/carers will be informed at developer-led training that PACT packs should not be shared. Several of the materials in the PACT packs are single use, making sharing less useful to parents.</p>

Randomisation assignment process	Staff unavailable to carry out randomisation Tight timeline	Ensure backup staff are available to do this Randomisation could be completed in back-up (of schools who have completed pre-test), if necessary, to adhere as close to timeline as possible.
Parent/carer training	Low uptake of training which could lead to reduced uptake of intervention/increased attrition.	Set dates and make schools and parents/carers aware of these as early as possible. Offer multiple training dates for parents/carers to select a suitable date. Encourage more than one parent/carer from each household to attend developer-led training, to mitigate if one parent/carer is absent on the day of developer-led training. Sufficiently train school staff to deliver parent/carer training in the event they cannot attend the developer-led training.
Delivery of the intervention	The PACT Lead might leave the school. This might lead to the disruption of communication channels and might cause parents/carers to disengage.	Encourage schools to send more than one staff member to the developer-led training. In the event that a key PACT Lead leaves the school, they will be advised to cascade their knowledge on the intervention to another staff member. The developers will provide telephone support/training if necessary, should this situation arise.
Retention of schools	Schools become unresponsive or withdraw from the project at any time.	Developer team to develop strong relationship with schools through regular contact. Communicate directly with schools to offer help to overcome their reasons for withdrawal, where necessary. EEF prepare a letter to the school's head teacher to encourage they remain in the trial.
Retention of participants	Parents/carers withdraw from the intervention.	Address parent/carer withdrawal at developer-led staff training, and help staff to mitigate this. Keep parental evaluation requirements to a minimum. PACT Leads to engage with, establish relationship and motivate parents/carers.

Risk of unconscious bias to trial data	There is a risk of unconscious bias to the trial with post-test and delayed-post test data collection being undertaken by the developers. Developers will organise data collection visits and collate the final data spreadsheets.	<p>Developers cannot be blinded to allocation in order to preserve the intervention being conducted under ideal conditions. The developers will arrange data collection visits, however any decisions to cease data collection visits to a setting (e.g. because the school is unresponsive or an RA has already visited the school multiple times) will be made by the evaluation team. This will help to mitigate the risk of unconscious bias that could present when organising post-test data collection visits.</p> <p>Whilst the developers will be organising visits, the data collection will be conducted by blinded RAs, except in the initial assessments where the developer will also attend and carry out assessments with children. The RAs will also enter their own data.</p> <p>Evaluation team to conduct quality assurance checks on 10% of all audio recorded assessments conducted by RAs. All audio recorded assessments conducted by the developer to be quality assured for unconscious bias</p>
Post-test data collection	<p>Schools lose interest in the trial and don't grant permission for post-testing</p> <p>Selected children are absent on the day of the assessments.</p>	<p>Schools can receive half of the incentive payment (£250) on completion of immediate post-testing.</p> <p>Developers to arrange more than one nursery assessment visit to 'mop-up' missed assessments.</p>
Analysis of data	Durham staff unable to analyse data, e.g., Long-term illness or loss of key staff.	Durham will discuss possible extension to delivery date with EEF. Durham will seek support from Faculty.
Interpretation of findings	Level of involvement/engagement of PACT Leads within schools could vary between locations and impact on results.	It is likely this will be reflected when the developers communicate with schools, particularly when PACT packs are due to be dispatched and also on weekly record forms. Parental engagement can be considered in the CACE analyses.
Production of final report	Durham staff unable to produce report, e.g. long-term illness, or loss of key staff.	Durham will discuss possible extension to delivery date with EEF. Durham will aim to assign other staff to the project.

Timeline

Dates	Activity	Staff responsible/ leading
Jul/Aug 18	Set up meetings	All
Sept 18 – July 19	Protocol development	Evaluator
Oct 18	Ethics application	Evaluator
Oct 18 - Apr 19	Recruit and train settings	Developer (with support from evaluator)
Apr 19 - Sept 19	Recruit parents/carers and children	Developer (with support from evaluator)
Mid Sept 19 - Oct 19	Pre-testing - CELF Preschool-2 (Sentence Structure, Expressive Vocabulary, Word Structure), BPVS-3, APT, Listening Comp (Snowy)	Developer
	HLE, Usual Practice Surveys	Evaluator
Early Oct 19	Randomisation	Evaluator
End Oct	Training for parents	Developer (observation by evaluator)
Oct 19 - Jun 19	Parents/carers deliver programme (30 weeks)	Developer
Dec/Jan 20	1 st PACT Lead & Parent phone interviews	Evaluator
Apr/May 20	2 nd Parent/carer phone interview	Evaluator
May 20	2 nd PACT Lead phone interviews	Evaluator
Jun 20	Parent/carer survey	Evaluator
Jun 20	PACT Lead survey	Evaluator
Jun 20 - Jul 20	Immediate post-testing - CELF Preschool-2 (Sentence Structure, Expressive Vocabulary, Word Structure), BPVS-3, APT, Listening Comp (Snowy)	Developer
	HLE, Usual Practice Survey	Evaluator
Jul 20- Aug 20	Developer interview	Evaluator
Jul 20- Oct 20	Data analysis	Evaluator
Sept 20 to Nov 20	Follow up where children attend school	Developer
Sept 20 to Nov 20	Report writing	Evaluator
30 Nov 20	Submit draft final report	Evaluator
May 21	Agree final report (based on data from immediate post-test)	Evaluator
May 21	10 month delayed post-test - CELF Preschool-2 (Sentence Structure, Expressive Vocabulary, Word Structure), YARC (Letter Sound Knowledge, Early Word Reading, Sound Deletion), BPVS-3, APT, Listening Comp (Snowy), Listening Comprehension (Sandcastle)	Developer
	BESSI	
June 21 to Aug 21	Data analysis	Evaluator

Sept 21	Report addendum writing	Evaluator
Oct 21	Submit report addendum	Evaluator
Oct 21	Submission of all data to FFT archive	Evaluator

References

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