

Trial Evaluation Protocol [PACT]

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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 by LanguageScreen:.) at delayed (12 months) post-test
SECONDARY OUTCOME	Improvements to the child's home learning environment measured by the Home Learning Environment Index at post-test Improvements to different components of language development (assessed by LanguageScreen subtest scores) at delayed post-test School readiness, measured by BESSI at delayed post-test

Protocol version history

VERSION	DATE	REASON FOR REVISION
1.2 [<i>latest</i>]		
2.1	09/11/2021	<p>Due to disruption to the intervention and evaluation delivery due to Covid-19 the following revisions were made:</p> <ul style="list-style-type: none"> • TIDierR framework updated with the revised delayed timeline for delivery of the PACT intervention • Research questions were updated to reflect the revised data collection timeframe and use of LanguageScreen app to collect data instead of face to face language assessments • Design updated to reflect change to primary and secondary outcomes • Change to 'Control' condition with incentive being given at end of nursery when books were appropriate rather than collecting of immediate post-testing data which was not possible • Removal of discussion of potential bias with developer collecting post-testing data as evaluator is now collecting this data • Addition of additional incentives to schools for data collection at delayed post-test due to additional burden of LanguageScreen assessment • Update to 'Outcome measures' section to reflect changes to outcome data collection due to Covid restrictions including change from researcher collected face-to-face outcome measures to LanguageScreen and changes to Home Learning Environment data collection due to issues with validity of questions during covid restrictions. Inclusion of table to show differences from original protocol. • Evaluation team now responsible for post-test data collection instead of developer team • Added detail of prize draw incentive for additional HLE survey • Analysis section updated to reflect change in outcomes and timeframe for collection • Addition of Covid-19 research question in IPE • Additional parent survey to collect data about impact of Covid-19 on implementation of PACT • Conflict of interest statement updated as risk of assessment bias reduced by change in design and data collection • Update to risk table due to Covid-19 situation and resulting changes to project design • Updated timeline due to other described project changes <p>Updates to other areas of the protocol due to progress through the trial</p> <ul style="list-style-type: none"> • Updates to nursery recruitment numbers and locations in Participants section

		<ul style="list-style-type: none"> • Addition of £10 voucher for parents for each child assessment missed from original protocol • Description of BESSI and HLE data collection now included • Updated description of compliance data gathering and CACE analysis due to more detail being available about PACTapp data. • Update to include analysis methods for IPE • Update to cost evaluation section based on new EEF guidance on cost evaluation since the writing of the original protocol • Small updates to IPE data collection methods <p>Updates to project team personnel due to staff changes during the project</p>
1.0 [original]	26/7/2019	[leave blank for the original version]

Table of contents

Protocol version history	2
Table of contents	3
Intervention	5
Study rationale and background	9
Impact Evaluation	9
Research questions	9
Design	11
Randomisation	11
Participants	12
NURSERIES	12
PARENTS/CARERS AND CHILDREN	13
Sample size calculations	14
Outcome measures	15
PRIMARY.....	15
SECONDARY.....	Error! Bookmark not defined.
DELIVERY OF OUTCOME ASSESSMENTS	18
CHALLENGES OF ASSESSMENT IN THE EARLY YEARS	20
Analysis plan	20
PRIMARY OUTCOME	20
SECONDARY OUTCOME	21
SUBGROUPS	21
CACE ANALYSIS	21
Implementation and process evaluation	21
Research Questions (mapped to IPE dimensions)	21
Theory of Change	23

Design	24
Methods.....	24
COLLECTION OF AVAILABLE ADMINISTRATIVE DATA	24
OBSERVATIONS	25
USUAL PRACTICE SURVEYS	25
PACT LEAD INTERVIEWS	26
PARENT/CARER INTERVIEWS	26
DEVELOPER INTERVIEW	26
Cost evaluation.....	26
Ethics and registration	27
Data protection.....	27
Conflict of Interest.....	28
Personnel.....	28
DELIVERY TEAM	28
EVALUATION TEAM.....	28
Risks.....	30
Timeline.....	34
References.....	36

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	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).
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.

<p>What? Procedures, activities and/or processes</p>	<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 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>
<p>Who? Providers/implementers</p>	<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>
<p>How? Mode of delivery</p>	<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>
<p>Where? Location of delivery</p>	<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>

<p>When and how much? Duration and dosage</p>	<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> <p>Due to Covid-19, nursery closures and ongoing restrictions meant an interruption to the delivery of the PACT Packs. While the fifth PACT Pack was sent to settings just before the first Covid-19 lockdown in March 2020 (two weeks earlier than planned), the sixth pack was not sent to nurseries until the end of May 2020 (originally planned to be beginning May). The intervention delivery period was expected to end mid June when post-testing would have begun, however, due to the delay to the delivery of the sixth pack and the disrupted delivery period during lockdown, the intervention delivery period was extended by 10 weeks until end August 2020 to capture the full picture of what families had been able to deliver.</p>
<p>Tailoring and adaptation</p>	<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>
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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

Due to Covid-19 restrictions in schools and in universities, it has been necessary to change from researcher-delivered face-to-face assessment of children in schools to assessment which can be delivered by staff in schools. Covid-19 restrictions also meant that the collection of data immediately after completion of the intervention was not possible. It has therefore been necessary to adapt the impact evaluation research questions:

1. What is the impact of the PACT intervention on the language development of participating children, as measured using a language latent variable, assessed by LanguageScreen app delivered by school staff at the end of the first year of school (reception year) (12 months after the intervention period)? [Primary Outcome]
2. What is the impact of PACT on the Expressive vocabulary, Receptive vocabulary, Listening comprehension, and Sentence repetition (LanguageScreen sub-set items) of participating children? [Secondary Outcome]
3. What is the impact of PACT on the home learning environment of participating children at the end of nursery and after two months in school as measured using the Home Learning Environment Index? [Secondary Outcome]

4. What is the impact of the PACT intervention on the school readiness of participating children as measured at the end of the first year of school? [Secondary Outcome]

Research questions 1, 2 and 4 will be investigated when the children are at the end of their first year (reception) in school – 12 months after the scheduled end of the PACT programme (delayed post-test). The original protocol had a 10 month delayed post-test however a pragmatic decision was made to postpone the delayed post-testing by a couple of months to the end of the school year, due to continuing covid restrictions and changes to the assessment. Research question 3 (using parent completed measures) will be investigated immediately after the scheduled end of the PACT Programme and 5 months later. The five months later data collection was initially planned to be collected at the same time as postponed immediate post-testing language assessment but ongoing covid restrictions prevented this taking place and it was only possible to collect HLE data then.

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 LanguageScreen sub-scale scores (Expressive vocabulary, Receptive vocabulary, Listening comprehension, and Sentence repetition).
Secondary outcome(s)	variable(s)	(1) Early language skills, (2) Home Learning Environment, (3) School Readiness
	measure(s) (instrument, scale)	(1) LanguageScreen sub-scale scores: Expressive vocabulary (EV), Receptive vocabulary (RV), Listening comprehension (LC) and Sentence repetition (SR) (2) Home Learning Environment Index, (3) Brief Early Skills and Support Index (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 at the end of nursery [previous protocol stated that receiving book incentives would be dependent on completion of immediate post-test however, as it was not possible to complete immediate post-testing at the end of nursery, books were issued to all control group families at the planned time at the end of nursery and when the books were still age appropriate for the children.]

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. The issue will be followed in the IPE analysis.

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:

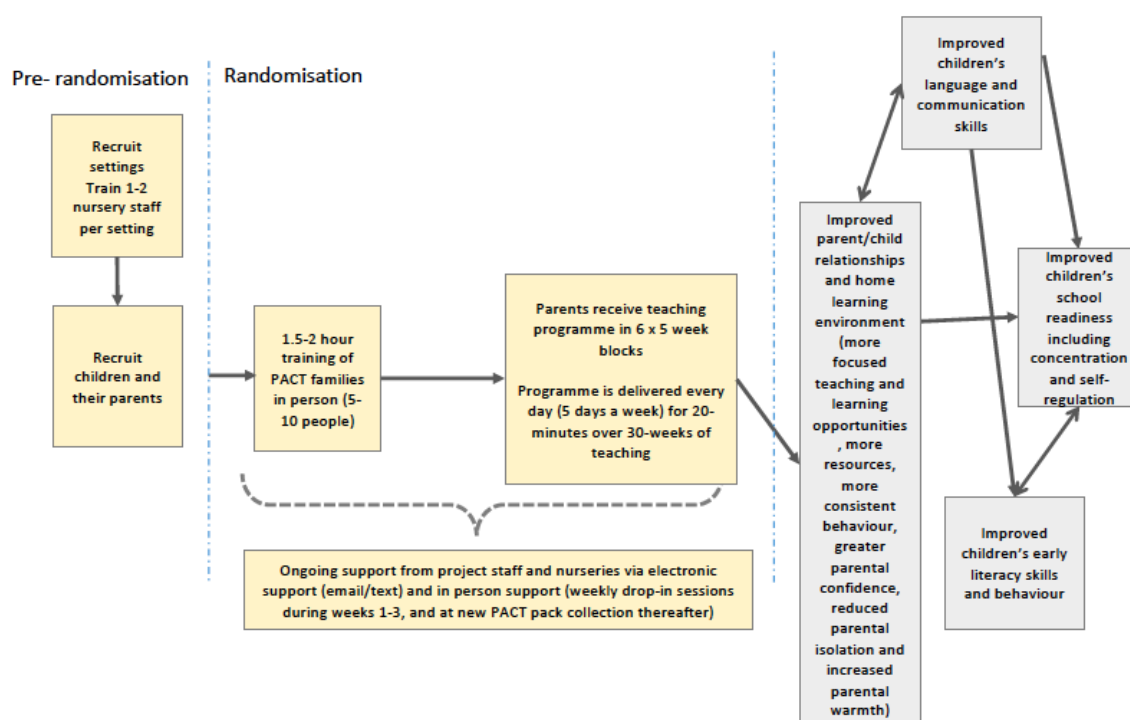
- (1) 'Pre-test complete' which will include all children who complete all assessments which form the latent language variable (CELF Expressive Vocabulary, CELF Sentence Structure, Listening Comprehension, BPVS-3, APT) and the CELF Word Structure measure.
- (2) 'Partial pre-test complete' which includes 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.

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 480 pupils from 48 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 end of the school recruitment phase (June 2019) 48 schools had been recruited. Three schools were unable to recruit the minimal number of pupils and withdrew from the study. These were replaced by 2 new schools from a waiting list. At the time of randomisation, the developer had recruited 47 schools with 450 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 Warrington, Bolton, 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.

A number of children moved to schools not signed up to the project when they transitioned from nursery to school (reception). To incentivise these new schools to allow and facilitate data collection about the participating children these schools were offered £100 in vouchers for Early Years School Equipment per child they assessed with LanguageScreen and BESSI. For children in schools that originally signed up to the project, schools were offered £10 voucher for Early Years School Equipment per child assessed with LanguageScreen (with a minimum of £50 for each school). This was in addition to the above monetary incentive due to the additional burden on the school of the LanguageScreen assessment compared to the researcher-delivered assessments originally planned.

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). Parents will receive a £10 shopping voucher each time their child is assessed.

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

***Total number of school remains at 48 as this is a within-school randomisation**

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 MDES.

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

#	Significance Leve (α)	Power (1- β)	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, MDES 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 project originally planned to use the language latent variable at immediate post-test, as defined by the developer's previous PACT trial (Burgoyne 2018) which would have allowed for direct comparison to the results of this trial. This was to be measured by 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.

These measures were collected at the baseline/pre-test timepoint by face-to-face visits to schools by researchers.

However, the Covid-19 pandemic, the associated nursery and school closures as well as ongoing government, school and university restrictions to limit contact with other people, have meant that the project has been unable to collect planned measures of language ability at the immediate post-intervention point. These continued restrictions have also made it impossible to send researchers into schools to collect data from children at the delayed post-test time point. In order to collect some data of the participating children's language ability we plan to use the LanguageScreen (languagescreen.com) assessment in June/July 2021 (delayed post-testing).

This assessment was suggested by EEF as it is being used in the trial of the Nuffield Early Language Intervention (NELI) and is a standardised app-based assessment which is delivered by a member of school staff. The LanguageScreen assessment (delivered by OxEd assessment: https://oxedandassessment.com/language_screen) is made up of four subtests: Receptive Vocabulary (23 items where the child chooses which of 4 pictures matches a spoken word), Expressive Vocabulary (24 items asking the child to name pictures), Listening Comprehension (listening to 3 stories each followed by a series of questions about the story tapping understanding – 16 items) and Sentence Repetition (14 items repeating verbatim a series of spoken sentences). It is administered using an app on a tablet by a member of staff in the child's school. Full instructions are included within the app for the delivery of the assessment without the need for training. Verbal instructions and items for the child are played aloud through the app. This should minimise variability in the delivery of the assessments across all the settings. The four assessments are presented in a set order and take around 25 minutes to complete. The assessment administrator marks on the app whether the child answers correctly or not for questions where the child gives a verbal answer. Data from the app is uploaded to the LanguageScreen website automatically and results are generated automatically by LanguageScreen. A standardised and raw score for each subtest as well as an overall raw and standardised score are provided. We will use a latent variable formed from the four subtests standardised scores as described in West et al. 2021.

LanguageScreen assessment scores correlated strongly ($r=.95$) with a latent variable created from scores on standardised researcher-delivered measures (CELF-Preschool – Expressive Vocabulary subtest and APT information and grammar scores included in this study as well as CELF-Preschool

Recalling Sentences subtest not included in this study) in a previous study of more than a thousand participants (West et al 2021). This gives a strong indication that the LanguageScreen assessment is measuring the same constructs as the latent variable in the West et al study and should be a good alternative measure for this research given the similarity of assessments.

The primary outcome measure will therefore be a latent variable created using LanguageScreen subscale scores at delayed post-test.

SECONDARY

LanguageScreen subtests scores of Receptive Vocabulary, Expressive Vocabulary, Listening Comprehension and Sentence Repetitions as collected at delayed post-test will be used as individual secondary outcomes.

The **Brief Early Skills & Support Index** (or **BESSI**) questionnaire (measured at the 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 4/5/7 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 intervention period (i.e. during the immediate post-testing period). As Covid-19 may have affected what the normal Home Learning Environment looked like with children being home-schooled, nurseries closed and parents potentially furloughed or working from home, at immediate post-test we asked parents/carers to complete the Home Learning Environment questions for the period right before lockdown when life was more normal and for the time of completing the questionnaire in June when Covid restrictions were in place. We also added in a Home Learning Environment data collection point in November when the child was now in reception. This was to investigate whether there were any prolonged changes in Home Learning Environment beyond the intervention period (as the intervention period was extended until the end of August).

Due to the covid-related restrictions above we will not be able to collect the planned Early Literacy Skills or the additional CELF secondary measures stated in the original protocol as these would both have required researchers to deliver these assessments.

Table 5 summarises when each of the measures will be collected and how this compares to the original protocol.

DELIVERY OF OUTCOME ASSESSMENTS

It was originally agreed that the developers would manage the collection, entry and coding of all data relating to the impact evaluation within the trial – baseline, immediate post-test and at delayed post-test- with strategies put in place to ensure collection and coding of data is done blinded to treatment allocation. Pre-test/baseline outcome assessment was collected in this way by the developer team through researchers visiting the schools, prior to randomisation. However, for post-testing, as we will no longer collect any data from researcher-delivered face-to-face measures which would have been coordinated by the developer team, the responsibility for collecting outcome assessment data will now be with the evaluation team who will provide instruction and support to schools to collect LanguageScreen assessment data at the delayed post-testing point in June/July 2021.

Schools will deliver LanguageScreen using the LanguageScreen app on a tablet or large phone. The app guides the assessment, reading allowed all the questions and text. The adult in the school supporting the assessment delivery, decides whether the child has responded correctly or incorrectly and presses the appropriate button. There is guidance in each section for the adult delivering the assessment. Assessors using the app will be encouraged to use a practice code to do a run through of the assessment in advance of assessing any children. The assessment takes between 10 and 20 minutes to complete for each child. It will not be possible to blind the assessor to the intervention allocation of the child, therefore there is the potential for bias in the completion of the assessments. However, as children are now in school rather than nursery, it will be likely that the assessor doing the assessment will not be a member of staff involved in the delivery of the PACT programme. The app delivery of the assessment is very structured and leaves little room for varying the delivery of the assessment so we expect potential bias to be minimised.

For the baseline assessment data-collection the developer recruited and provided training to a team of Research Assistants (RAs) to collect assessment data. Training for RAs consisted of an off-site training session day plus additional on-site training where the RA observed the delivery of two assessments by the developer and then the developer observed the delivery of the assessment by the RA. This step was included to quality control the RAs and provide immediate feedback if needed. The assessments were conducted in the pre-specified order and took approximately 30 minutes to complete per child with a break in between sessions.

Table 5: List of assessments at each assessment time-point and revisions from original protocol.

Pre-test		Immediate Post-test		Delayed Post-test	
Original protocol	Revised post-covid Protocol	Original protocol	Revised post-covid protocol	Original protocol	Revised post-covid protocol
Language Measures with pupils in schools					
CELF sentence structure (MU - RA delivered)	As planned	CELF sentence structure (MU - RA delivered)	Not possible due to COVID-19 context	CELF sentence structure (MU - RA delivered)	LanguageScreen (DU – school staff delivered)
CELF expressive vocabulary (MU – RA delivered)	As planned	CELF expressive vocabulary (MU – RA delivered)	Not possible due to COVID-19 context	CELF expressive vocabulary (MU – RA delivered)	
Listening comprehension (MU – RA delivered)	As planned	Listening comprehension (MU – RA delivered)	Not possible due to COVID-19 context	Listening comprehension (MU – RA delivered)	
BPVS III (MU – RA delivered)	As planned	BPVS III (MU – RA delivered)	Not possible due to	BPVS III (MU – RA delivered)	

			COVID-19 context		
Renfrew Action Picture Test (MU – RA delivered)	As planned	Renfrew Action Picture Test (MU – RA delivered)	Not possible due to COVID-19 context	Renfrew Action Picture Test (MU – RA delivered)	
CELF word structure (MU – RA delivered)	As planned	CELF word structure (MU – RA delivered)	Not possible due to COVID-19 context	YARC Letter Sound Knowledge, Early Word Reading, Sound Deletion (MU – RA delivered)	
Parent completed measures					
Home Learning Environment Index (HLE)	As planned	Home Learning Environment Index (HLE)	Home Learning Environment Index (HLE) in June 2020 & Nov 2021	-	
Reception staff completed measures					
				Brief Early Skills & Support Index (BESSI)	As planned

Parents/carers will be asked to give permission for the RA delivered assessments to be audio recorded (now pre-test only). All RA delivered assessments, where permission has been given, will be audio recorded for the evaluation team to perform quality assurance 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. For the delivery of LanguageScreen at delayed post testing, the developer team will prepare the data for the participating pupils and do initial communication with schools about the upcoming assessment period. The evaluator team will upload all the pupil information into the assessment software and will liaise with schools during the testing period to support their delivery of LanguageScreen. Should schools have difficulties with accessing the LanguageScreen assessment on their hardware the evaluation team will be able to courier tablets to schools for schools to conduct the assessments.

For the delivery of BESSI, schools will be emailed a link to an online survey which they need to complete for all the relevant pupils in their settings. They will be asked that a member of staff who knows the child completes the BESSI for that child. For schools who have difficulties accessing the online survey, a paper copy will be provided that they can copy for each pupil and return by post. Instructions for completing BESSI will be sent at the same time as those for LanguageScreen.

The HLE data will be collected as part of usual practice surveys to parents using [onlinesurveys.ac.uk](https://www.onlinesurveys.ac.uk). These will be sent via email to the parent/carer email addresses at each time point. Where these have not been completed within the requested timeframe or where a bounce back is received from the email account, paper copies of the survey will be posted to the parent. For the additional data collection time point – November 2020 – a prize draw incentive of four Amazon vouchers will be added in to encourage participation in an additional element.

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.

COMPLIANCE DATA

Parents/carers in the PACT intervention group will be asked to record their delivery of each of the PACT sessions by completing the PACTapp on their phone/tablet. This app records the date that the sessions are completed and whether they enjoyed the session. If any parents/carers have difficulties with being able to download or use the app they can complete paper record forms. These forms will be returned to the school PACT lead who will return any paper forms to the developer team who will in turn share these forms with the evaluator team. For the CACE analysis we will use the total number of PACT sessions completed by each intervention participant. The PACTapp doesn't record which specific week within a 5-week pack the daily sessions were completed and only gives data of the number of day 1/2/3/4/5 sessions completed per pack. We therefore assume that each session is only completed once and only include a maximum of 5 sessions (1 per week) for each day 1/2/3/4/5 session per pack disregarding any data over and above this.

Analysis plan

A detailed statistical analysis plan (SAP) will be agreed before the analysis of delayed post-test data. An original SAP was drafted and sent for comment in March 2020 but never published due to the arrival of Covid-19 and changes to the project which resulted from the Covid-19 disruption.

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

This section has been updated due to the changes to the outcome measures as described above. Further detail of the analysis can be found in the SAP.

The primary outcome considering a latent language variable derived by combining 4 variables from scores on LanguageScreen sub-tests (1.Expressive vocabulary, 2.Receptive vocabulary, 3.Listening comprehension, 4. Sentence repetition) will be analysed on a continuous scale using a confirmatory factor analysis model. The pre-test language latent variable (formed from the assessment collected at pre-test) will be used for baseline adjustment using ANCOVA 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 (Burgoyne 2018). This modelling approach enables estimation of impacts of PACT across the different components of language development as measured by the latent outcome. It assumes that the language skills may be better assessed as a latent construct that uses shared variance of the sub-tests and can reflect important elements of language skills that may be difficult to measure relying on observed variables. 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 (Cham *et al.*, 2017).

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 conditional variance of the outcome data to ensure consistency of results with the latent variable model, where the confidence interval for the effect of the intervention will be based on conditional variance. The immediate (HLE) and delayed impacts (HLE, LanguageScreen, BESSI) of the PACT intervention on the secondary outcomes will be analysed using a multilevel model accounting for intra-school correlation. Exploratory analysis comparing the difference between the immediate impact of the intervention and five-month follow up for the HLE 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

Compliance data on the number of PACT sessions completed will be collected from parents/carers in the PACT intervention group. Compliance will be measured using a continuous score of the number of sessions that parents/carers recorded as complete using the PACT App or paper record forms returned to the schools. Parents/carers were asked to record that they had completed a session immediately after doing it and to indicate their child's level of enjoyment for the session. Paper record forms were completed where parents/carers were not able to access the PACT App. The maximum number of sessions possible for completion was 150 (if all sessions were completed) and the minimum number is zero (if no sessions were recorded as completed). This compliance data will be used in a complier Average Causal Effect (CACE) analysis which will be implemented using instrumental variable approach to assess whether there was greater impact of the intervention for those that completed more sessions.

Self-reported compliance data will also 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. This will be explored in the IPE.

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 nurseries 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)

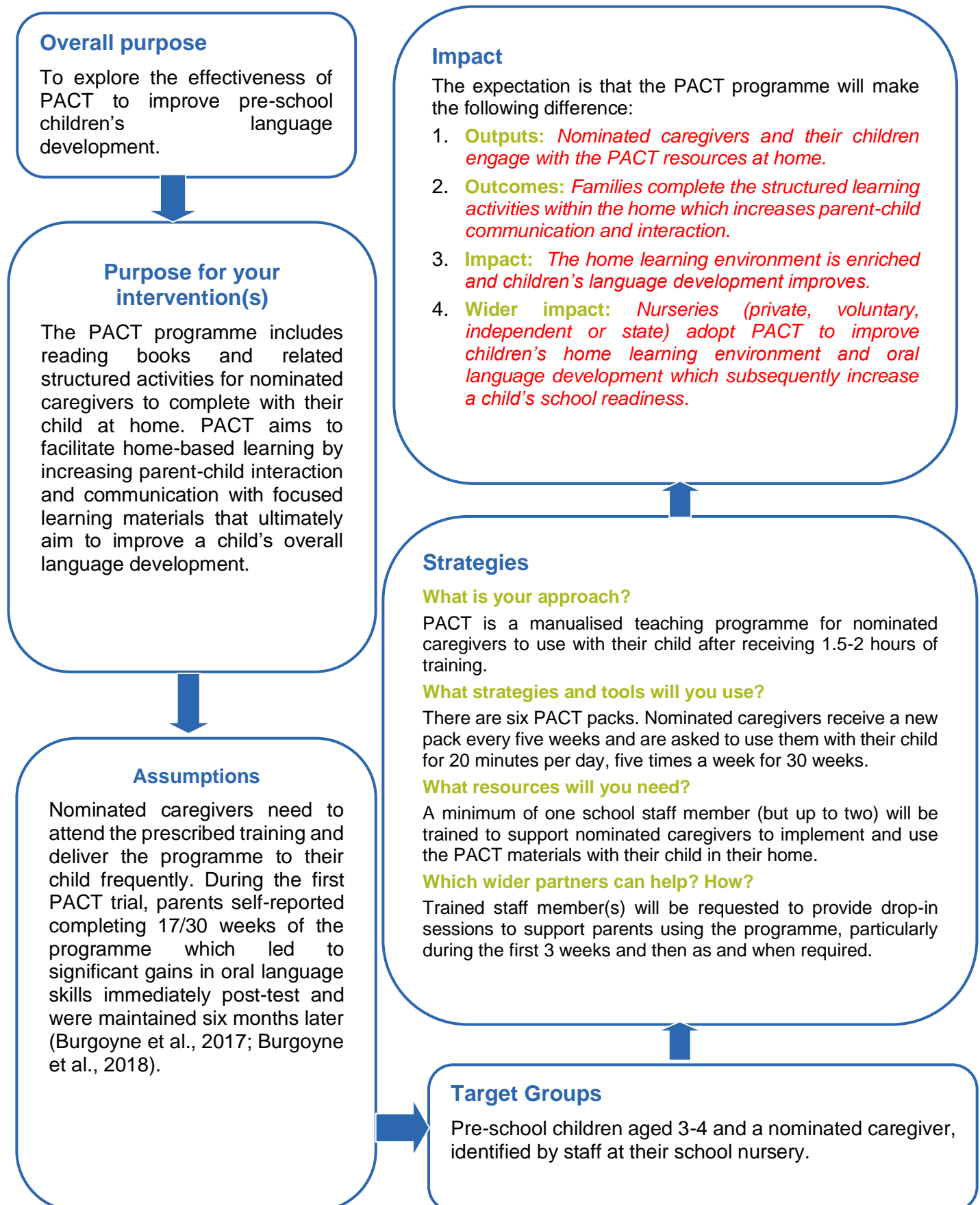
1. To what extent is training delivered to nursery staff (fidelity/quality) and how is this received (responsiveness)?
2. To what extent does initial training take place for parents/carers? How is this training delivered? How many parents/carers attend the training sessions? (fidelity)

3. 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)
4. How closely do parents/carers follow the teaching session plans? (fidelity, quality, adaptations)
5. 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)
6. What is the perceived impact of the intervention by parents/carers and school staff? (responsiveness)
7. How does PACT differ from usual practice and control group activity (programme differentiation)?
8. What barriers were faced by schools and by parents/carers in implementing the intervention?
9. Are there any groups of parents/carers that can't access the intervention and why? (reach)
10. What constitutes ideal conditions for the delivery of the intervention and was this possible (fidelity)?
11. How did Covid-19 affect the delivery of PACT? (added for the Post-covid protocol revision)

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, reach 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	Research questions
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 (3 timepoints) 	1, 2
Training and support for parents/carers (through developer and school)	Recruitment of parents 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 • Parent interview (20 x 2 time points) • Delivery/attendance administrative data • Parent/carer survey • PACT Lead survey 	2, 5, 6, 7, 8, 9, 10, 11
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 • Parent/carer survey • Parent/carer Phone App / paper record data 	3, 4, 6, 7, 8, 9, 10, 11
Child responsiveness	Child's responsiveness to the intervention materials and teaching sessions	<ul style="list-style-type: none"> • Parent/carer interviews • Parent/carer survey 	6

Methods summary and analysis

COLLECTION OF AVAILABLE ADMINISTRATIVE DATA

Attendance at developer-led training sessions (both nursery 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. Attendance numbers for developer-delivered training will be reported in answering RQs 1 and 2 along with the number of parents/carers who were trained by the PACT lead rather than the developer. This gives detail about the extent to which training was delivered and attended as defined by the programme.

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. The data collected from both the record forms and the app will be matched to the pupil database using Excel. The app records the number of day 1 sessions, day 2 sessions, day 3 sessions, day 4 sessions and day 5 sessions for each PACT Pack (which lasts for 5 weeks). The PACT app data did not contain which week the data referred to, thus it was not possible to match the exact session that was completed within the pack without modifying the data. The week data had to be entered into the dataset by hand to cover each sets of days 1/2/3/4/5 based on the timestamp of when the session had been completed. In our analysis we will discount where parents/carers have recorded any session more than once. We will then be able to create a total number of sessions completed for each PACT Pack to look at the change in delivery over the course of the intervention as well as a total number of PACT sessions completed. We will use descriptive statistics to analyse and report on the number of PACT sessions completed. The total number of sessions completed will also be used in the CACE analysis.

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). Observations will be looking at the content of the training sessions, the response to the sessions and the consistency of training sessions delivered by different trainers.

SURVEYS

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

Nurseries 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. At immediate post-test separate surveys will be delivered to the control and intervention groups. Both will include the Home Learning Environment index. The intervention group will be asked to provide feedback on the delivery of the intervention while the control group will be asked about their usual practice to do with reading at home and home learning as well as access to the intervention materials to assess contamination.

An additional Usual Practice Survey was administered in November 2020 when it was found out that the post-test period had to be postponed and later cancelled due to Covid-19 lockdowns. This survey included the HLE measure from the impact evaluation as well as questions about continued use of PACT and home activities surrounding reading. This additional survey aimed to capture practice beyond the intervention period (which was moved to August) and any changes to home practice which persisted once children had started in school.

ANALYSIS OF SURVEYS

Descriptive statistics will be generated from the quantitative responses in surveys. For the parent/carer surveys comparisons will be made between the intervention and control group participants to draw out differences both at baseline and changes that may have been caused by the intervention during later surveys. Qualitative responses will be coded inductively and analysed thematically along with the interview data to provide evidence of how PACT was delivered at the different levels and the response to PACT.

INTERVIEWS

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 timepoints 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. 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.

INTERVIEW ANALYSIS

Interviews will be recorded, and transcripts created of each interview. The transcripts will be analysed using NVivo software. A combination of inductive and deductive coding will be used to analyse the data with the first coding being only inductive and a second coding being done using the IPE themes.

Cost evaluation

Data on intervention costs will be collected from the developers through interviews, as well as from the PACT Lead surveys as part of the process evaluation and will be used to conduct a cost evaluation in line with recent guidance from the EFF. As EFF updated their cost evaluation guidance during the project we have added in an additional cost-workshop with the developer. This will take place in summer 2021 and will try to capture the ingredients model of the intervention and what the programme would look like should it be delivered over three years. It will also collect data on the costs of the packs and the training delivered by the developer.

Specifically, questions regarding the amount of time spent by PACT Leads and other setting staff during the intervention as well as other PACT related spending for the nurseries will be included in the post-intervention survey for PACT Leads. Interviews done as part of the IPE will ask PACT Leads to reflect on the activities and time necessary for the delivery of PACT. Parent/carer surveys will also ask parents

to report the amount of time and commitment needed to deliver PACT. Costs to schools will be presented separately from the time requirement on parents/carers to deliver the programme.

Interviews with the developer and the cost evaluation workshop with the developer team will help to break down the costs of the programme by individual ingredients and to establish what the costs would be for schools in terms of the costs of the PACT packs, and the training/support and delivery of the intervention as conducted in the current trial. It will be assumed that the intervention could have been delivered to all the children recruited to the trial (both those in the intervention and control group) for the cost calculations as there was the demand within nurseries to receive the programme and the capacity within the delivery team to deliver this. This seems like a reasonable assumption if the programme was to run outside of the trial.

Ethics and registration

Ethical approval for the evaluation has been received from Durham University's School of Education Ethics Committee on 12/12/2018 with updates at 15/4/2020, 8/8/2020, 27/11/2020 and 16/2/2021 to include the data collection tools and post-covid changes to the delivery of the project.

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 nursery staff for interviews and surveys; from parent/carers for child assessments, 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. Participating schools will also sign a data sharing agreement agreeing that the data collected can be shared between the developer and evaluator teams.

Conflict of Interest

The evaluation team highlighted to EEF a possible conflict of interest arising from the developers being tasked in the original protocol with conducting the data collection at post- and delayed post-test due to the risk of unconscious bias. However, as the assessments and testing plans have changed and the developer team are no longer responsible for collecting post-test data this is no longer a potential conflict of interest.

Personnel

DELIVERY TEAM

Dr Kelly Burgoyne (PI): Kelly is a Lecturer in Psychology and Education 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. Adetayo Kasim left this role in June 2021 and was replaced by Jochen Einbeck.

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. Jessica Hugill left this role in March 2020 and was replaced by Paivi Eerola in June 2020.

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.

Paivi Eerola is a Research Assistant (from June 2020) and is experienced in qualitative research methods through running interviews and surveys and analysing qualitative data. Paivi has supported many evaluations covering a wide age range of pupils. She has published on the social impact of music education in primary school (2014) and widening participation in higher education (Younger & Eerola, 2018). Paivi will collect and analyse the IPE data and liaise with schools for their delivery of the assessments.

Jochen Einbeck is a Professor in statistics and has taken over the role of senior statistician on the project when Adetayo Kasim left at the end of June 2021.

Risks

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

Table 7: Risks to the evaluation

Risk	Detail	Mitigation
Contract negotiations about LanguageScreen may not allow the sharing of the LanguageScreen data with the EEF archive or the developer team	Current agreement with OxEd excludes the sharing of personal data from LanguageScreen outside of the Durham University team unless completely anonymised. This means that it won't be possible to share this with the EEF archive with personal data attached.	Continue conversations with OxEd about the potential to share the data. Plan to share a fully anonymised dataset with the EEF archive for further analysis just without an option to link to NPD.
Schools may not sign updated data sharing agreements needed to use LanguageScreen in time for data collection	Negotiating on data sharing agreements has delayed being able to send out DSAs to schools. These will now only be able to go out 1-2 weeks ahead of the assessment period.	Use of electronic signature through Adobe sign reduces the requirement for schools to print, sign and post back DSAs. Research assistant will contact schools in advance of testing period to make sure that they have received the contract and will be chasing the return of the DSAs in advance of testing period.
Schools may not be able to get the LanguageScreen app to work on their hardware	Some schools reported that their settings have been unable to run the app	The evaluation team will purchase 5 tablets with data that can be couriered to schools to use for assessments.
Covid-19 restrictions may close schools again leading to not being able to collect outcome data	Unlikely scenario that schools will close again. Pupils and staff testing positive for corona virus have to self isolate for two weeks which could take place during the testing period.	Collection of BESSI through online survey which could still be completed by school staff even if schools close.
Attrition from the project at post-testing leads to insecure findings from the trial and low padlock rating	Due to only being able to collect data at delayed post-test, children having moved to different settings when starting school and covid-19 disruption making schools unwilling to participate in post-testing it is likely there will be a high level of attrition for primary outcome data collection	Regular communication with schools regarding the project and the assessment during the assessment period. Use of incentives for completion of LanguageScreen assessments with an amount per child for each assessment. This is higher for schools not previously involved.

		Retrial already ongoing as results from this trial likely to be difficult to interpret and generalise.
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	Low uptake of training which could lead to increased attrition.	<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	Low uptake of parents/pupils taking part. Each nursery needs to recruit a minimum of 4 parents/pupils per nursery for continued participation.	<p>Provide quality training to each nursery's PACT Lead so they feel confident in speaking to parents/carers 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 confidentiality of data via parental</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>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	<p>Staff unavailable to carry out randomisation</p> <p>Tight timeline</p>	<p>Ensure backup staff are available to do this</p>

		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.	<p>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.</p> <p>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.</p> <p>Sufficiently train school staff to deliver parent/carer training in the event they cannot attend the developer-led training.</p>
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.	<p>Encourage schools to send more than one staff member to the developer-led training.</p> <p>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.</p>
Retention of schools	Schools become unresponsive or withdraw from the project at any time.	<p>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.</p> <p>EEF prepare a letter to the school's head teacher to encourage they remain in the trial.</p>
Retention of participants	Parents/carers withdraw from the intervention.	<p>Address parent/carer withdrawal at developer-led staff training, and help staff to mitigate this.</p> <p>Keep parental evaluation requirements to a minimum.</p> <p>PACT Leads to engage with, establish relationship and motivate parents/carers.</p>

Post-intervention data collection	Schools lose interest in the trial and don't grant permission for post-testing Selected children are absent on the day of the assessments.	Schools can receive half of the incentive payment (£250) on completion of immediate post-testing. Schools are compensated for each assessment they do. Nursery/school staff will run LS assessments more freely when children are around. Parents are paid a £10 voucher each time their child is assessed. There is two weeks mop-up period to finish all assessments.
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) HLE, Usual Practice Surveys	Developer Evaluator
Early Oct 19	Randomisation	Evaluator
End Oct	Training for parents	Developer (observation by evaluator)
Oct 19 - Aug 20 (<i>end date</i>)	Parents/carers deliver programme (30 weeks)	Developer

<i>changed from Jun 20)</i>		
Dec 19 - Feb 20 (<i>end date change from Jan 20)</i>)	1 st PACT Lead & Parent phone interviews	Evaluator
Mar 20	COVID-19 RESTRICTIONS BEGIN	
Jun 20	Parent/carer survey	Evaluator
Jun 20	PACT Lead survey	Evaluator
Jun 20	2 nd PACT Lead phone interviews	Evaluator
Jun 20 – Jul 20 (cancelled)	Immediate post-testing scheduled but unable to be completed due to Covid-19	Developer
Jul 20 (<i>delayed from May/Jun 20)</i>)	2 nd Parent/carer phone interview	Evaluator
Jul 20- Aug 20	Developer interview	Evaluator
Jul 20- Jun 21 (<i>end date change from Oct 20)</i>)	IPE Data analysis	Evaluator
Aug 20 – Oct 20 (<i>additional activity</i>)	Piloting remote assessment	Evaluator/Developer
Sept 20 - Nov 20	Follow up where children attend school	Developer
Nov 20 (<i>additional activity</i>)	Additional parent usual practice survey (including HLE)	Evaluator
Dec 20 – Jan 21 (<i>additional activity</i>)	Submit retrial proposal	Developer/Evaluator
Jun 21 – Jul 21 (<i>delayed from May 21)</i>)	Delayed post-test - LanguageScreen (Expressive Vocabulary, Receptive Vocabulary, Listening Comprehension, Sentence Repetition) BESSI	Evaluator
Sept 20 - Aug 21 (<i>end date change from Nov 20)</i>)	IPE Report writing	Evaluator
Aug 21 (<i>additional activity</i>)	Submission of interim IPE Report	Evaluator
Sept 21 (<i>delayed from Jun – Aug 21)</i>)	Data analysis	Evaluator
Oct 21	Report writing	Evaluator
Nov 21	Submit report	Evaluator
Apr 22	Agree final report with EEF	Evaluator
Apr 22	Submission of all data to FFT archive	Evaluator

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