Trial Evaluation Protocol
The REAL Programme

Evaluator: NatCen Social Research
Principal investigator: Svetlana Speight (from May 2020 onwards), Fatima Husain (until May 2020)

Education
Endowment
Foundation

PROJECT TITLE	The REAL Programme
DEVELOPER (INSTITUTION)	National Children's Bureau
EVALUATOR (INSTITUTION)	NatCen Social Research
PRINCIPAL INVESTIGATOR(S)	Svetlana Speight (from May 2020 onwards), Fatima Husain (until May 2020)
PROTOCOL AUTHOR(S)	Fatima Husain, Svetlana Speight, Hannah Piggott, Robert Wishart, Rukmen Sehmi, Sarah Morris, Martina Vojtkova, Berenice Scandone
TRIAL DESIGN	Two-arm cluster randomised controlled efficacy trial with random allocation at pupil level. (Impact evaluation cancelled, IPE only)
PUPIL AGE RANGE AND KEY STAGE	Early years, ages 3 to 5
NUMBER OF SCHOOLS	53 nurseries
NUMBER OF PUPILS	730
PRIMARY OUTCOME	Early Literacy (Preschool Early Literacy Indicators - PELI)
SECONDARY OUTCOMES	- Home learning environment (Home Learning Environment Index - HLEI) - Emergent writing skills (Sheffield Early Literacy Development Profile - SELDP).
BASELINES	For primary outcome: PELI For secondary outcomes: HLEI, SELDP

Protocol version history

VERSION	DATE	REASON FOR REVISION
1.0	04 June 2019	N/A
2.0	18 December 2019	Redesign of evaluation approach
2.1	17 July 2020	Changes to timetable and approach related to Covid-19
3.0	24 May 2021	Impact evaluation cancelled based on the methodological risks and ethical challenges of continuing with the RCT in the light of the Covid-19 pandemic. IPE design adjusted to address changes to delivery plans and cancellation of impact evaluation.

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Intervention

The REAL Programme (Raising Early Achievement in Literacy) has been designed by National Children's Bureau (NCB). The programme aims to help practitioners (usually nursery teachers or reception teachers) to build parents' knowledge and confidence in creating a home learning environment that supports and encourages their children's early literacy and development. The original REAL project[1] was developed in the 1990's and has previously been evaluated through a feasibility trial as part of the Sutton Trust's Engagement Fund in 2017.[2]

The REAL Programme, developed by Professors Peter Hannon and Cathy Nutbrown, is based on the ORIM framework[3] and sets out four ways parents can create a home learning environment that supports children's early literacy development:

1. Creating **O**pportunities for children's literacy development, for example by making children books, CDs and writing material available and accessible in the home environment;
2. **R**ecognising and encouraging children's literacy milestones;
3. **I**nteracting with children positively and supporting real-life literacy tasks and;
4. Acting as **M**odels of literacy users, so children see parents use literacy in everyday life.

Early years practitioners delivering The REAL Programme are required to attend a four-day CPD training course (split into two sessions consisting of two days per session). The training covers the emergent literacy approach to children's knowledge reading and writing, understanding and interpretation of the ORIM framework and how this can be used during interactions with parents and families with confidence, practitioner reflections on working with parents and families and planning techniques for delivery of The REAL Programme. Practitioners receive a training pack, containing the ORIM framework grid, a pack of ideas for structuring home visits, research sheets, DVDs containing examples of home visits and literacy events, and other planning materials.

The trained practitioner then carries out a minimum of eight home visits to families of children needing additional support with early language and literacy development, who have been selected at random to receive the intervention. Practitioners have the option to conduct an additional two visits up to a maximum of 10 . Due to the Covid-19 pandemic, from September 2020, all 'home visits' were conducted remotely via telephone or video calls. Each visit lasts up to one hour. The visits require at least one parent, guardian or carer of the child to be present. The selected child should also be present for the home visits. Each home visit is guided by the ORIM framework grid, which is completed by the practitioner and may be shared with families to support them to think about how they can use it to support their child's early

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[1] http://www.real-online.group.shef.ac.uk/index.html
[2] Sylva, K., Jelley, F., and Goodall, J. (2018) Making it REAL. An Evaluation of the Oldham Making It REAL Project. *The Sutton Trust.*
[3] Nutbrown, C., Hannon, P. and Morgan, A. (2005) Early literacy work with families: policy, practice and research, London: SAGE.

literacy. Practitioners are encouraged to be reflective and reactive in designing the structure and content of the home visits, which may vary according to the practitioner's assessment of the needs of the children and their families. At the end of the visit, practitioners may leave parents or carers with instructions for activities to carry out with the child.

During the trial, The REAL Programme will be delivered over five school terms, starting when the children are in the Spring term of the nursery year and concluding when they are in the Summer term of Reception year at primary school.[4] The practitioner will continue to conduct home visits with families during the Reception year as part of the intervention, unless the child moves to another school outside of the local area. At each nursery setting, practitioners will identify 8-16 children who they think will benefit from the intervention. Of these, around half of the children and their parents/carers at each setting will be selected at random to receive the intervention. The other selected children will form the control group.

In the original intervention design, practitioners were expected to arrange up to four group literacy events, open to the parents of the eight children selected for the intervention. However, due to the Covid-19 pandemic and social distancing guidance, these events did not take place. Termly network meetings for practitioners delivering the programme will be facilitated by NCB.

The trial will take place in the North of England, with ten Local Authorities selected for participation. Within some of the Local Authorities, a REAL Local Authority Lead will be responsible for running the local network..

The logic model for The REAL Programme developed in collaboration with the developer is set out in Figure 1.1.

Figure 1.1. Logic model for The REAL Programme

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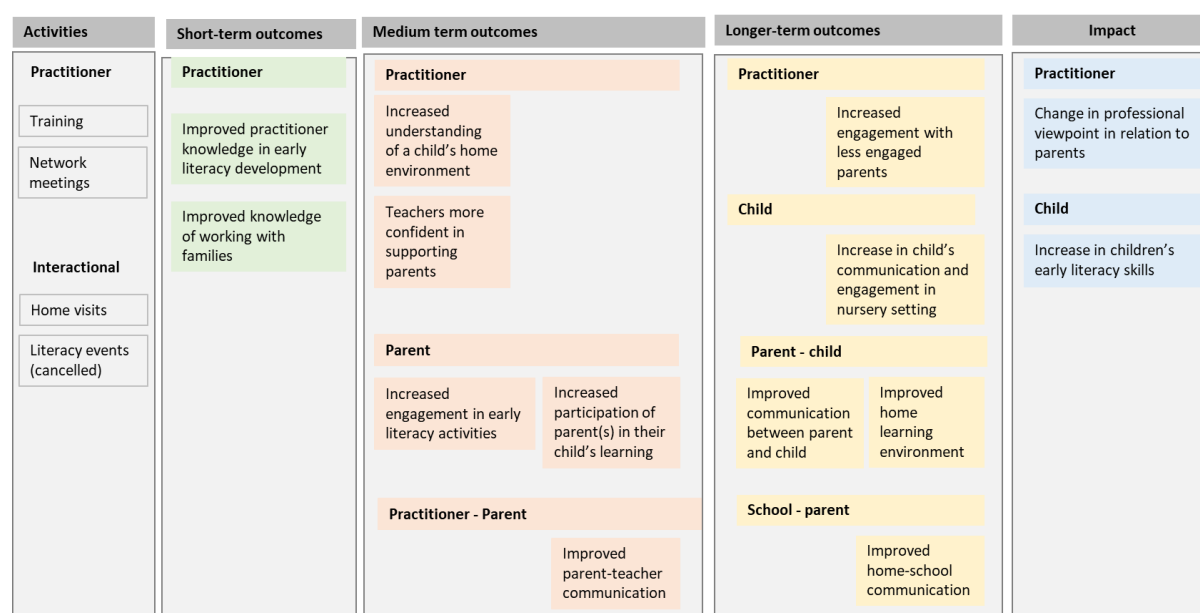
[4] Note that the programme was originally intended to be delivered over four school terms (from Spring term 2019-20 to Spring term 2020-21), but the lockdown and school closures implemented in March 2020 due to the spread of COVID-19 meant programme activities had to be paused and delivery was only over three and a half terms. There was no programme delivery in the Summer term 2019-2020, and delivery was extended to the Summer term 2020-21 until May half-term.

Study rationale and background

Existing research supports the notion that parental involvement in children's early literacy skills development has been associated with higher level cognitive scores, more prosocial behaviour and better behavioural self-regulation in early years[5] in addition to academic achievement[6]. A literature review of the impact of parental involvement on pupil achievements identified that the extent and form of parental involvement is shaped by socioeconomic factors including social class and parental level of education[7]. Other related research has shown that parents' interactions with children could also be influenced by the child's gender[8] [9].

Although evidence suggests that for families with lower parental education levels, parental involvement plays a role in higher aspirations among students, it does not necessarily have an impact on academic achievements[10]. The quality of the HLE has been shown to be equally as important as socioeconomic factors[11]. Previous studies also found that programmes with similar characteristics did not demonstrate an impact on early literacy skills in the medium term[12].

The Department for Education published a policy paper in 2018 outlining a behaviour change approach aimed at improving the home learning environment, coproduced with the National Literacy Trust and Public Health England[13]. This paper supports the ambition set by the Secretary of State for Education to halve the proportion of children who do not achieve expected levels in the 'communication and language' and 'literacy' areas of learning at the end of the reception year by 2028 and is part of a wider social mobility programme. The approach focuses on three concepts to driving behaviour change, developing a model called 'Chat, Play, Read', summarising how parents can create a positive HLE and support professionals working with families. Recognised barriers to supporting children's early language and literacy development include capability, opportunity and motivational barriers and interventions in poorer communities to increase the support for parents using existing

[5] Melhuish, E., and Gardiner, J. (2018) *Study of Early Education and Development (SEED): Impact Study on Early Education Use and Child Outcomes up to age four years*. Research Report. Available at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/738725/SEED _Impact_Age_4_Report_September_2018.pdf

[6] McNeal Jr, R. B. (2014). Parent involvement, academic achievement and the role of student attitudes and behaviors as mediators. *Universal Journal of Educational Research*, *2*(8), 564-576.

[7] Desforges, C. & Abouchaar, A. (2003) *The Impact of Parental Involvement, Parental Support and Family Education on Pupil Achievements and Adjustment: A literature review.* Research Report 433. London: DfES.

[8] Gilkerson, J., Richards, J. A., & Topping, K. J. (2017). The impact of book reading in the early years on parent–child language interaction. *Journal of Early Childhood Literacy*, *17*(1), 92–110.

[9] Johnson K., Caskey M., Rand K., (2014) Gender differences in adult-infant communication in the first months of life. *Pediatrics* 134: 1–8.

[10] Hill, N. E., Castellino, D. R., Lansford, J. E., Nowlin, P., Dodge, K. A., Bates, J. E., & Pettit, G. S. (2004). Parent academic involvement as related to school behavior, achievement, and aspirations: Demographic variations across adolescence. *Child development*, *75*(5), 1491-1509.

[11] Sylva, K., Melhuish, E., Sammons, P., Siraj-Blatchford, I., & Taggart, B. (2004a). *The Effective Provision of Pre-School Education (EPPE) Project: Final Report: A Longitudinal Study Funded by the DfES 1997-2004.* London: Institute of Education, University of London/ Department for Education and Skills/Sure Start. Found at: http://discovery.ucl.ac.uk/10005309/

[12] Sim SSH, Berthelsen D, Walker S, et al. (2014) A shared reading intervention with parents to enhance young children's early literacy skills. *Early Child Development Care* 184(11), 1531–1549.

[13] *Improving the home learning environment. A behaviour change approach* (2018). *HM Government and National Literacy Trust.* Available at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/756020/Improving_the_home_learning_environment.pdf

workforces to deliver messages, prompts and resources were identified as activities to help overcome these barriers.

A feasibility trial of Making It REAL (renamed as The REAL Programme for the current evaluation) was carried out as part of the Sutton Trust's Engagement Fund in 2017.[14] Making It REAL aimed to support practitioners to build parents' knowledge and confidence to create an early home learning environment, supporting their children with reading and writing. The study, involving ten nursery settings in Oldham, concluded that a larger trial of REAL would be needed to provide more robust evidence of effectiveness. The report highlighted promising results using the Home Learning Environment Index, demonstrating a significant effect of the intervention on HLE scores, while recognising the small sample and stated that a larger, more robust trial to demonstrate impact would be needed.

As part of the government's drive to close the 'word gap' in early years, the Department for Education are investing £5 million to trial 'what works' in the home learning environments in the North of England, focusing on implementing evidence-based practice into the programme[15]. Based on the evidence from the feasibility trial, the EEF has selected The REAL Programme as a promising intervention aimed at reducing the development gap in key language and literacy skills at an early age.

Impact evaluation

The impact evaluation of The REAL Programme was cancelled in March 2021 based on the risks and ethical challenges of continuing with the RCT in the light of the Covid-19 pandemic, and its implications for programme implementation and data collection. These factors included:

- Outcome measurement: there were perceived risks and ethical concerns with outcome testing, around sending external assessors to settings during the Covid-19 pandemic and burden for school staff.
- Fidelity: due to Covid-19, home visits paused in March 2020 and were conducted remotely from September 2020. The Covid-19 pandemic also reduced Early Years' staff capacity to engage with the programme. The intervention developers, evaluators and EEF shared concerns that the impact evaluation findings would not be reflective of The REAL Programme in a typical academic year.

Appendix 1 of this protocol outlines the intended impact evaluation design as of the start of the 2020/21 academic year.

Implementation and process evaluation

A process study will be carried out to address the following high level research questions:

1. How is The REAL Programme delivered, and what are the facilitators and barriers to delivery?
2. What are the perceived benefits of the programme for EY practitioners, families and children?

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[14] Sylva, K., Jelley, F., & Goodall, J. (2018) *Making it REAL. An Evaluation of the Oldham Making It REAL Project*. The Sutton Trust.
[15] *Unlocking Talent, Fulfilling Potential. A plan for improving social mobility through education* (2017). Department for Education. Available at:
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/667690/Social_Mobility_Action_Plan_-_for_printing.pdf

3. What are the implications of Covid-19 for delivery and perceived impacts?
4. What can be learnt for future delivery of The REAL Programme?

The process study will take a mixed-methods approach that provides valuable and in-depth information on the delivery of The REAL Programme as well as how the intervention is received. A number of primary and sub-dimensions of the implementation will be assessed. These include:

- *Reach* – appraise whether the population that would benefit from the intervention actually received it and any barriers to this
- *Responsiveness* – explore engagement with REAL including parents engaging in activities and making changes to the home learning environment
- *Appropriateness* – identify whether the intervention was considered credible and relevant
- *Fidelity* – assess delivery as intended, including *dosage* and *quality* of delivery as well as identify any *adaptations*
- *Optimisation* – establish the core elements and ideal/acceptable dosage of the intervention
- *Sustainability* – examine whether the intervention can be continued within a setting.

(a) Methods

The proposed approach will gather both breadth of data through surveys and depth of data using a purposive sampling strategy focused on nursery settings. Reviewing the four broad research questions set out above, the logic model and detailed information about the intervention gathered during the IDeA workshop with NCB, we will identify specific areas of interest for investigation. The research questions, primary and sub-dimensions outlined above and selected areas of interest based on our review of the logic model and intervention will be used to develop our research instruments - topic guides and surveys. This approach will ensure that we capture rich data for carrying out analyses on key implementation dimensions.

The process study will offer rich insights into the delivery of The REAL Programme, gathering data from a range of participants involved including practitioners and parents. The findings from the process evaluation will provide understanding of families' home learning environment, identify whether the intervention was delivered as anticipated, barriers and facilitators of the intervention and perceived benefits for practitioners and families.

Surveys

1. Survey of REAL practitioner at baseline and post-intervention
Across all settings we will carry out an online survey with the practitioner who was trained in The REAL Programme at two points in time, in October 2019 before baseline testing of pupils takes place and at the end of the intervention in June 2021.

1) The baseline survey will capture information on the key challenges in relation to early literacy development of children, their level of experience, reasons for taking part in REAL, how parents were approached about REAL, previous or additional early literacy interventions the nursery is engaged in and what 'Business as Usual' looks like in relation to interaction with parents.

2) The post-intervention survey will seek the REAL practitioner's retrospective assessment of intervention delivery, including their views on REAL delivery once

children moved to Reception year. We will also include questions about how the delivery of visits changed because of school closures due to Covid-19. This will cover what remote visits involved, which means of communication were used and the issue of building relationships with parents in the context of not visiting their homes. We will gather practitioners' views about supporting early literacy during school closures and how the REAL programme was used for that, including what worked well and less well. Finally, we will collect information about perceived impacts of the intervention on children, parents and the practitioners themselves (including on confidence, skills and attitudes), and perceptions of trends in the attainment gap for children.

The survey will take no longer than 15 minutes to complete at a convenient time for practitioners. The survey will be simple to use and will be designed using BUILD software.

2. Compliance data collection

At the end of each term, and with the support of NCB, we will issue a short proforma to practitioners to gather data on the number, frequency and content of interactions with both treatment and control parents. Data on interactions with control parents will only be collected until March 2021, to reflect the cancellation of the impact evaluation and avoid unnecessary burden on REAL practitioners. For each treatment parent/child we will seek information on the number of home visits conducted during the term and the length of each visit. If any visits were planned and cancelled, we will ask for reasons for cancellation. In relation to control parents we will ask about relevant interactions beyond formal meetings that have been conducted with each parent. This will include informal chats about literacy and language development, formal requests for meetings and documents shared.

3. Parent surveys – measuring the Home Learning Environment

A 12 item paper based HLE measure[16] will be administered by practitioners in nurseries by the key point of contact. It will take no longer than 10 minutes to complete and will be administered at three points in time as follows:

Baseline - September/October 2019: once the nursery has identified eligible pupils and at the point of introducing the programme to parents, we expect nurseries to hold a face-to-face meeting to introduce parents to the programme where the HLE measure will be administered to a parent/carer for each child taking part in the trial. The key contact in schools will collect completed questionnaires and return them to NatCen by recorded delivery. At baseline the HLE measure will be supplemented by around five socio-demographic questions.

Beginning of reception year – September/October 2020: the HLE measure will be administered to parents of all children included in the trial by the REAL practitioner or their new school at the beginning of the autumn term. This survey will also allow us to capture changes in HLE as a result of the coronavirus crisis. The completed questionnaires will be returned to NatCen by recorded delivery. A key risk for the mid-point HLE is reaching control parents as practitioners delivering the REAL programme may not have direct contact with parents of control children. The risk is particularly

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[16] Niklas, F., Nguyen, C., Cloney, D., Tayler, C., and Adams, R. (2016) Self-report measures of the home learning environment in large scale research: measurement properties and associations with key developmental outcomes. Learning Environments Research 19(2):181-202.   DOI 10.1007/s10984-016-9206-9

great for children who have moved schools for their reception year. NatCen and NCB will work with the designated key contact in each school to maximise response rates.

Post-intervention – April-May 2021: the post-intervention survey will only be administered to parents in the treatment group. The survey will replicate questions around the HLE and the influence of Covid-19 from waves 1 and 2. This will provide longitudinal data on the parents' assessment of the home learning environment, which is central to The REAL Programme. The survey will also include additional questions on experiences of taking part in The REAL Programme, including any barriers to taking part and views on the usefulness of activities.

Responses to the HLE measure will be entered using a data entry system and 10% of cases will be subject to quality assurance checks. NatCen will send reminders to nurseries and schools to encourage completion and return of the completed questionnaires to NatCen.

Administering the survey to parents
Written guidance will be provided by NatCen to nursey and school staff on what to say to parents and how to administer the survey. To minimize burden on parents, we have considered the following:

- *Survey length:* the survey is very short and easy to complete
- *Research burden on nurseries:* as only 8 - 16 parents from each setting will take part, we believe the burden on nurseries/schools administering the survey will be minimal.
- *Confidentiality*: parents will be given envelopes to place the completed questionnaire in and seal it before giving it to the main contact at the nursey/school to return to NatCen.
- *Return of surveys:* Nurseries/schools will be provided with an addressed pre-paid envelope to return completed questionnaires to NatCen.

Qualitative research

Observations of practitioner training
To gather information on coverage of training and practitioners' responsiveness to it, the research team will observe the two two-day long training sessions for the 53 practitioners delivering The REAL Programme. Observation of these sessions will provide detailed information on what the practitioners will be asked to do and the full range of materials available to them. It will also give us insights into the specificity and flexibility of The REAL Programme in how it is communicated to practitioners. The observations will offer additional detailed insights of the intervention, which will be explored in more depth during interviews with practitioners and parents. Observations will be conducted in January 2020.

The researchers observing the practitioner training will be provided with an observation template, which will be based on the training agenda, research questions and knowledge of the intervention to date.

Observations of network events
Termly events to share learning will be organised by the developer. The research team will observe three network events – in the 2020 Autumn term, 2021 Spring term, and at the end of the programme. Attendance at these events will build understanding of delivery issues

encountered by practitioners and how these are addressed. Moreover, these sessions will provide valuable information on knowledge exchange and changes to practice discussed by practitioners. Observation data will be captured using an observation template, developed based on the objectives of the network events.

Depth research on nursery-parent interactions

We propose to carry out in-depth research in a sub-sample of eight nurseries that will span intervention delivery using a case-study approach. Nursery settings will be purposively selected based on findings from the baseline nursery survey and key sampling criteria to include: geographical location, and role and level of experience of the practitioner selected to take part. For each setting, the following phases of research activities will be carried out.

- *Early implementation:* **interviews with REAL practitioners** on planning and early delivery. These will be conducted by telephone and will take place in spring-summer 2020. We will also seek support from the managers to arrange visits with practitioners and seek appropriate permission from parents to do so. Eight interviews will be conducted.
- *End of intervention delivery:* towards the end of intervention delivery in May-June 2021 we will carry out **telephone interviews with parents and practitioners**. We will re-contact the practitioners interviewed in spring-summer 2020 for this stage of the research and will seek to speak to 16 parents of children in the treatment group – 2 parents for each of the practitioners interviewed.

Wider experiences of delivery

In addition to the practitioner interviews during the in-depth case-study research, we propose to conduct **in-depth telephone interviews** with 12 practitioners to gain a broader view of experiences of The REAL Programme delivery. These interviews will be conducted alongside the case-study end of intervention interviews (May-June 2021). We will gather retrospective views on REAL, including remote delivery (how the remote delivery affected what could and could not be achieved in terms of the intervention's goals/logic model), perceived skills development and perceived benefits to children and parents. We will also ask practitioners about the level of contact with the Local Authority specifically for The REAL Programme. We will sample practitioners purposively, based on the Local Authority they are based in, whether they are a Reception or nursery teacher, and selected data from the baseline nursery survey, such as the proportion of children for whom the setting received Pupil Premium funding and of children with EAL.

Analysis

All qualitative interview data will be digitally recorded with permission from participants and professionally transcribed. Framework in NVivo will be used to manage the data and carry out within and cross-setting analysis. The first step is to develop an analytical framework, based on the topic guide and review by the researchers involved in data collection. This framework is entered into NVivo, which follows a case-based approach, where transcripts are individually coded and entered into NVivo using a consistent framework, a process defined as 'charting'. Quality control checks are carried out across each researcher involved in data collection and charting.

Descriptive and cross-tab analysis of survey data will be conducted using SPSS. The data from the HLE measure will also be converted into SPSS and analysed longitudinally, cross-sectionally and comparatively.

Triangulation of all data and thematic synthesis by the main implementation domains will provide a comprehensive assessment of implementation. The process evaluation will also use compliance data on the number of home visits and the length of visits to provide a description of compliance.

IPE methods overview

Research methods	Data collection methods	Participants/ data sources (type, number)	Data analysis methods	Implementation/ logic model relevance
Quantitative	Survey (baseline)	REAL practitioners (53)	Descriptive analysis	Programme relevance and appeal; early implementation; usual practice
Quantitative	Survey (endline)	REAL practitioners (43)	Descriptive analysis	Programme delivery; fidelity and dosage; perceived outcomes
Quantitative	Compliance monitoring forms	REAL practitioners	Descriptive analysis	Fidelity and dosage
Quantitative	Survey (baseline)	Treatment and control parents (730)	Descriptive analysis	Home learning environment
Quantitative	Survey (interim)	Treatment and control parents (643)	Descriptive analysis	Home learning environment
Quantitative	Survey (endline)	Treatment parents (285)	Descriptive analysis	Home learning environment
Qualitative	Observations	Practitioner training (2)	Thematic analysis	Programme delivery; fidelity
Qualitative	Observations	Network events (3)	Thematic analysis	Programme delivery; fidelity
Qualitative	Case-study interviews (early implementation)	Practitioners (8)	Thematic analysis	Programme relevance and appeal; early implementation; usual practice
Qualitative	Case-study interviews (endline)	Practitioners (8)	Thematic analysis	Programme delivery; perceived outcomes
Qualitative	Case-study interviews (endline)	Parents (16 – 2x8 settings)	Thematic analysis	Programme delivery; perceived outcomes
Qualitative	Interviews (endline)	Practitioners (12)	Thematic analysis	Programme delivery; perceived outcomes

Ethics and registration

NatCen's research information leaflet setting out the evaluation requirements for the evaluation will be sent to schools at recruitment stage. Schools that sign an MoU and addendum (which outlines the new design approach for the evaluation and updated requirements for schools) will send out a parent information leaflet to parents/carers of the children selected for the programme. The information leaflet will explain the study; the research activities for the trial, data linkage to the National Pupil Database (NPD), the transfer and storage of anonymised data to the EEF's archive, managed by FFT Education through the Office for National Statistics. Parents/carers will be able to withdraw their child from data linkage at any point during the study by contacting NatCen. The leaflet will also include information on the testing process. NatCen will maintain a database of withdrawals and delete the appropriate level of pupil data as soon as a withdrawal is communicated.

The developers will provide practitioners with guidance on how to explain the selection and randomisation process for participation in The REAL Programme.

Ethical approval for this study will be sought from NatCen's Research Ethics Committee in advance of research activities in the autumn term of 2019. The NatCen REC will review the study design to confirm compliance with internal ethical standards.

The trial has been registered with the International Standard Randomised Controlled Trial (Trial number: ISRCTN 23292431).

Data protection

NatCen will store and handle all data securely and confidentially in line with the GDPR. Only the research team will have access to the data collected as part of the evaluation. School and pupil-level data will be transferred to NatCen via a secure FTP. Reports and other publications arising from this research will not identify any individual nursery, school, staff member, parent or pupil. Nurseries or individual staff who no longer wish to take part in the evaluation can request to have their data deleted at any point prior to the submission of the draft report.

NatCen will be the data controller and will additionally process data until the data is submitted to the EEF archive and has successfully passed archive quality checks, at which point EEF will become the data controller and FFT Education become a data processor. The legal basis for NatCen's processing of the data is 'legitimate interest'. We've carried out a legitimate interests assessment and have determined that pupil, parent, staff and nursery level data will be collected and processed on the basis of legitimate interest because the independent evaluation will feed into necessary evidence around what works for children's early literacy development in the Early Years and the home learning environment, which is currently an important area of policy focus for DfE. In addition, we've balanced the impact our processing might have against the reason for us conducting this study and we do not believe the impact would override our interest in any way. No special category data will be collected as part of the evaluation. We will issue a privacy notice to all concerned parties, which will also be published on the study website (www.natcen.ac.uk/real).

Additional data processors will include McGowan Transcriptions who will transcribe qualitative interviews, Formara Print+ who will print personalised testing materials and registered Speech and Language Therapists who will be recruited by Medacs.

All data will be securely deleted from NatCen's network six months after the end of the project.

Personnel

The project will be led by researchers in the Children and Families Team, working closely with impact evaluation experts in NatCen's Evaluation Team. Speech and Language Therapists will be recruited using agencies to conduct the assessments with children. Data entry processes will be coordinated through NatCen's Data Unit and postage and printing will be handled by the Logistics Team.

Details of the NatCen evaluation teams are outlined below.

Staff name	Role	Description of responsibilities
Children and Families Team		
Dr Svetlana Speight	Research Lead (May 2020 onwards)	Overall study lead and senior oversight of process evaluation
Dr Fatima Husain	Research Lead (until May 2020)	Overall study lead and senior oversight of process evaluation
Sarah Morris	Research Director	Project manager, all research stages and Testing
Hannah Piggott	Senior Researcher	Project manager, all research stages and Testing
Berenice Scandone	Senior Researcher	Project manager, all research stages and Testing
Helen Burridge	Researcher	Working on all study stages
Molly Mayer	Researcher	Working on all study stages
Harriet Read	Research Assistant	Working on all study stages
Evaluation Team		
Martina Votjkova	Head of Evaluation	Senior oversight of the impact evaluation
Robert Wishart	Senior Analyst	Lead, impact evaluation
Anysia Nguyen	Analyst	Impact evaluation analysis

National Children's Bureau are delivering the intervention. Helen Wheeler, Ellie Suggate-Francis and Gill Holden are leading on the design and delivery. Professor Cathy Nutbrown from the University of Sheffield will lead on the training design and delivery for nursery teachers. In some local authorities, a REAL Local Authority Lead will assist with recruitment and coordination of the intervention and will support the network meetings.

Risks

Main risks to the project were initially identified at the protocol stage in v1.0. Risks have been updated since NatCen was requested to redesign the evaluation methodology and again, after the Covid-19 pandemic affected the delivery of the programme and the trial

further. The updated list of risks is set out in the table below. NatCen will maintain a risk log for the duration of the study.

1. **Logistical and practical risks**

Risk	Likelihood / impact	
Difficulties **recruiting** the required number of suitable **schools and pupils per nursery** for the redesigned RCT	**Likelihood: Medium**	The NCB team will need to recruit a minimum of 60 schools for the new power calculations with an average of 12 3 year olds whose parents are willing to participate in the programme and the evaluation.
	Impact: High	Different numbers recruited will result in different power calculations (for example, 50 settings and 10 children per setting will affect the MDES estimates provided and require a new power calculation). Given the difficulties in recruitment for the trial to date, there is a risk that the required number of nurseries and pupils per nursery will not be reached. This will affect the ability to detect an effect.
Attrition of schools	**Likelihood: High**	Schools who have already signed MoUs will be asked to sign an addendum to the MoU, which will be sent on Monday 1 July 2019 to schools. Asking schools to re-sign an agreement carries an inherent risk of drop-out
	Impact: High	
	Impact: High	Asking schools to sign a redesign which places additional burden on the school of managing more children (and their parents) in the trial and trying to maintain half of them in control conditions) will risk further drop-out. Evaluation activities – requiring more children to be tested and practitioners to administer more HLE surveys (to include all parents) may also lead to drop-out. Moreover, Speech and Language Therapists (SLTs) will need to spend a longer time at each setting to test more children, which may be inconvenient for the setting. Given that there are only around 10-12 schools days left and the last week of schools is quite busy, schools may not sign the addendum in time, which will result in their exclusion from the trial (and thereby reduce the number of settings in the programme affecting the power of the trial).
Not enough **eligible children** per school	**Likelihood: Medium**	The nurseries recruited may not have the required number of children aged 3 to take part.

	Impact: High	Schools with small numbers of 3 year olds may not select children based on the eligibility criteria agreed, which may affect trial results.
Impact on timetable for NatCen's receipt of **pupil lists**	**Likelihood: High**	NatCen will need pupil lists sooner than in the previous design, due to new logistical challenges (e.g. ensuring SLTs recruited can cover testing of additional children, scheduling of testing of more children than expected and randomising). NatCen will also need to allow time for randomisation before testing and extend the timetable for testing, due to scheduling and testing of a larger number of pupils per school.
	Impact: High	NCB are concerned that schools may not be able to approach and gain consent from parents by Friday 13 September in order to send NatCen pupil lists. If pupil lists cannot be sent to NatCen by 13 September, NatCen will not be able to create and send out packs to SLTs with the names of schools and children in time for SLTs to book and conduct the baseline testing during the testing window.
Difficulties with recruitment of enough SLTs to conduct baseline testing	**Likelihood: High**	Delay in recruitment of schools and expansion of Local Authorities included in the trial to date has impacted on the timetable for recruitment of SLTs. The redesign at this late stage means that NatCen may not be able to recruit enough SLTs to conduct the tests in a compressed time window as there will be variability in number of pupils requiring testing, resulting in variability in testing time required per SLT.
	Impact: High	Late changes to the LA may also result in a shortfall of SLTs required to attend the training sessions in September and conduct the testing. This will mean NatCen are not able to conduct tests with all of the children selected to be involved in the study, or incur additional expenses of training SLTs at a later date, due to delays in recruitment.
Booking and conducting baseline tests	**Likelihood: Medium**	There may be high levels of attrition because the SLTs are not able to conduct >10 assessments at each setting unless the testing period is expanded.
	Impact: High	NatCen will need to allow additional time for SLTs to schedule and conduct the tests (potential impact on cost).

Lack of support from the developer to ensure that the trial runs smoothly	**Likelihood: High**	The re-design requires adjustments to the timeline particularly in acquiring pupil lists in September. We know from other early years projects that settings make occupancy decisions early (during the previous school year) and for new children visits may take place any time from April to July before they start in September.
	Impact: High	The developer's support in ensuring that the trail can get started as intended and to minimise attrition will be instrumental to managing the re-design at such a late stage of planning.
Additional training sessions may need to be held for SLTs working on REAL – increased costs for the trial	**Likelihood: Medium**	The aim was for The REAL Programme and Hanen LLLI to hold joint training sessions for SLTs, in order to minimise overall cost of the trials. Redesigning the evaluation approach at a late stage of implementation, which leads to amended specifications for SLT recruitment, may result in not all SLTs for The REAL Programme being available to attend the briefings in early September.
	Impact: High	In addition, recruitment of 'REAL champion' SLTs to conduct the training for the assessments during the training sessions has been postponed due to redesign. This late change may result in lack of availability for REAL champions and training by the assessment provider in advance of the full training sessions in early September.
Attrition of individual children per school for post-intervention testing in the control group	**Likelihood: High**	Previously, settings in the control groups would have been required to provide details of the reception classes that children had moved to. The re-design will involve practitioners retaining contact with the children in the intervention group but no contact with children in the control group.
	Impact: High	We will need practitioners to additionally arrange the post-test with children in the control group, and inform the developer of instances where children in the control settings are moving to different schools. NatCen will need to know from the developer whether the new school is participating in The REAL Programme (therefore they can participate in the post-testing at the new school).
COVID-19 second wave	**Likelihood: Medium**	

Risk	Likelihood / impact	
	Impact: High	If a second wave of the pandemic means schools are closed or it is not possible for practitioners to conduct home visits, this will mean the programme cannot be delivered as planned.
COVID-19 leads to additional attrition of nurseries/schools or pupils	**Likelihood: Medium**	COVID-19 and the impacts of school closures during lock-down may mean schools are no longer willing to put time and resources into the programme or evaluation
	Impact: High	COVID-19 may also mean that parents are unwilling for practitioners to come in to their home as part of the programme. NCB will maintain consistent contact with nurseries/schools to try to prevent additional attrition

2. Ethical risks

Risk	Likelihood / impact	
Concerns for parents about reasons for inclusion in the intervention	**Likelihood: Medium**	The parents of children assigned at random for the treatment group may be concerned about reasons for their child being selected. They may worry that the teacher thinks they are not providing adequate support for their children.
	Impact: High	This risk is exacerbated by the new design, as some children in the same setting won't be selected Settings will need additional guidance from the developers in explaining the randomised nature of selection for the trial to practitioners and how to communicate this to parents.
Concerns for parents about their child not being included in the intervention	**Likelihood: Medium**	The parents of children assigned at random for the control group may be concerned that they and their child will receive less support than those selected for the intervention.

	Impact: High	This risk is exacerbated by the new design, as some children in the same setting will be selected. Schools will need additional guidance from the developers in explaining the randomised nature of selection for the trial.
Increased burden on practitioners	**Likelihood: High**	Practitioners will need to communicate to half of the eligible parents that they will not receive the intervention. This carries a higher risk of parent drop-out than would be in the original design. This is much easier to do at a setting level. Practitioners will be required to maintain 'BAU' with treatment parents which may be difficult.
Children identified as eligible and 'in need' of the intervention are not provided with any additional support	**Likelihood: Medium**	The control group in each school will be identified as likely to benefit from the intervention but will not be receiving any support. This may lead to ethical concerns for teachers and therefore potential implications for the trial if they offer additional support to children and families in the control group.
	Impact: High	
Children identified as eligible may not all be 'in need' of the intervention and therefore may not stand to benefit from it	**Likelihood: High**	The increased number of eligible children per nursery needed for a family-level randomised design may result in "mis-targeting" and inclusion of some children that are not in need of the intervention in the trial sample. These children are less likely to benefit from the intervention, which could result in an under-estimate of the true average treatment effect for those in need.
	Impact: Medium	
Placing research burden on schools, parents and children with a low likelihood of finding an effect	**Likelihood: Low**	If the recruitment risks outlined in the section above are realised, the trial may not recruit enough settings and pupils, reducing the power of the RCT design.
	Impact: High	It would be unethical to place research burden on already time pressured schools, parents and children with the prior knowledge that the trial is unlikely to be able to assess whether there is an impact.

	Likelihood: High	Practitioners may not be able to maintain 'business as usual' with the control group children. It may be that they apply the same practice as they do for treated children, or may show 'distance' to control children and their parents. Certainly if increasing practitioner confidence to interact with parents is an outcome (current logic model) then it is unclear how practitioners are to 'revert to original levels of confidence' with control parents.
Non-compliance and contamination	Impact: Medium	Parents assigned to the control group may attend the literacy events intended for treatment-group parents. In such a case, the trial would not be able to reliably evaluate the effect of the entire programme, only the effect of some aspects thereof such as the provision of home visits. Finally, trained practitioners may inadvertently or deliberately choose to undermine the treatment allocation by delivering home visits to control-group families.

Timeline

Dates	Activity	Staff responsible/ leading
Jan-Mar 2019	Finalise recruitment materials, number of schools to be recruited	NCB
Mar-Jul 2019	Recruit schools, sign MOUs	NCB, REAL LA Leads
Sep-mid Oct 2019	Pupil identification for the trial, parent information leaflets handed out, pupil lists sent to NatCen Parent HLE (1) questionnaires administered – control and treatment REAL practitioner survey (1) administered	NCB, schools, NatCen
Oct-Dec 2019	Baseline assessment of pupils	SLTs, NatCen
Dec 2019	Randomisation of pupils	NatCen
Jan 2020	Schools informed of randomisation (after baseline testing)	NCB
Jan 2020	NCB delivers The REAL Programme training to practitioners – observations conducted by NatCen	NCB, NatCen

Jan 2020	Schools start delivering The REAL Programme	Schools
Mar-Apr 2020	Interviews with REAL practitioners conducted	NatCen
April – August	REAL Programme paused due to COVID-19 school closures	
Sep – Dec 2020	Children move to Reception year, updated pupil lists sent to NatCen Parent HLE (2) surveys administered – treatment and control Observations of network events	NCB, schools NatCen
April – May 2021	Parent HLE (3) survey administered – treatment Telephone interviews with treatment parents	Schools, NatCen
June 2021	REAL practitioner survey (2) administered In-depth interviews with REAL practitioners conducted	Schools, NatCen
Aug-Nov 2021	Analysis and reporting	NatCen
Dec 2021	First draft of the report submitted to the EEF **TO BE DISCUSSED AND POTENTIALLY COMMISSIONED SEPARATELY:**	NatCen
Spring 2022	Addendum report on EYFPS delayed attainment: Spring 2022 - possibly including exploratory setting-level analysis to tease out any potential impact of practitioners being away for so long from intervention settings and/ or potential positive spill-over)	

Appendix 1: Impact evaluation – cancelled March 2021

(b) Research questions

The overarching aims of the impact evaluation of The Real Programme (REAL) are to answer the following principal research questions:

1. What is the impact on children's early literacy skills of participation in The REAL Programme?
2. How do the impacts differ by gender and social disadvantage as measured by Early Years Pupil Premium?
3. What are the effects of the programme on the home learning environment?

(c) Design

The evaluation will be conducted as a two-arm multi-site family-level[17] randomised controlled efficacy trial of REAL on the early literacy development of children aged 3 to 5 years old. The primary outcome of interest is early literacy development as measured by the Preschool Early Literacy Indicators (PELI) assessment. We will also be reporting emergent writing skills as a secondary outcome making use of the Sheffield Early Literacy Development Profile (SELDP). Both assessments will be administered to all participants at baseline and at the end of the intervention. An additional secondary outcome will be a measure of student's home learning environment (HLE), assessed through a 12-item instrument proposed by Niklas, et al. (2014)[18].

A randomised controlled trial (RCT) uses randomisation to assess the causal impact of an intervention. Random assignment of children within participating EY settings to treatment and control ensures that the groups have comparable baseline characteristics, meaning that most differences in outcomes between the groups at the end of the trial can be in expectation attributed to the intervention itself.

Fifty three nurseries have been recruited to participate in the trial. Nurseries agreeing to participate in the trial will identify 8-16 children eligible to receive the intervention. Within each participating nursery, families of eligible children that agree to participate in the trial will be allocated to one of the two groups, treatment or control with half of the families randomly allocated to the treatment arm half to control (December 2019). The allocation of families to treatment and control will be conducted and communicated to participating parents by nurseries only after baseline testing of all children participating in the trial is complete.

Note, the evaluation was originally designed as a two-armed cluster (nursery-level) randomised controlled efficacy trial involving 120 nurseries due to a number of benefits of nursery-level randomisation over family-level randomisation in the context of the REAL programme. The original design had lower risk of spillovers, contamination and non-compliance with treatment assignment, lower risk of mis-targeting of the programme to those not in need, and fewer ethical concerns relating to withholding treatment in the control group. However, the evaluation design was revised due to difficulties experienced by the developers in recruiting a sufficient number of nurseries into the trial to enable nursery-level

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[17] By family, we refer here to the eligible child (or children, e.g., in the case of twins) and their primary carer(s), typically their parents. Since part of the intervention consists of home visits involving the whole family, it would not be feasible to conduct randomisation at individual (child-) level since all eligible children in the household will invariably be exposed to the home visits.

[18] Niklas, F., Nguyen, C., Cloney, D., Tayler, C., and Adams, R. (2016) Self-report measures of the home learning environment in large scale research: measurement properties and associations with key developmental outcomes. *Learning Environments Research* 19(2): 181-202. DOI 10.1007/s10984-016-9206-9

randomisation. The Risks section briefly outlines some of the key risks associated with the revised design. These have been considered by EEF and the NCB (the programme developer), and an agreement reached to proceed with the trial despite these.

Trial type and number of arms		Two-arm multisite randomised controlled trial with random allocation at family level
Unit of randomisation		Family
Stratification variable		Nursery
Primary outcome	Variable	Early literacy development
	measure (instrument, scale)	Preschool Early Literacy Indicators assessment (PELI)
Secondary outcome(s)	variable(s)	-Home learning environment -Emergent writing skills
	measure(s) (instrument, scale)	-Home Learning Environment Index (HLEI)[19] -Sheffield Early Literacy Development Profile (SELDP)[20]

(d) Randomisation

Following baseline assessment of participating children, participating families will be allocated to one of either the treatment or control groups using blocked randomisation by nursery. This blocked randomisation helps to control for potential variations in nursery characteristics and programme implementation across geographical areas, and thus decreases the variance and improves the precision of the impact estimator. It will also ensure an equal allocation of families within each nursery into treatment and control groups safeguarding against the need to resource the delivery of the programme to more than 8 children and their parent(s)/carer(s) per nursery. The allocation ratio between treatment and control within each nursery will be a 1:1 ratio, and consequently the expected allocation ratio across the total expected sample size of 650 children at randomisation is expected to be approximately 1:1.

A unique identifier will be assigned to each nursery (block) and family unit prior to randomisation. The software Stata will be used to undertake blocked randomisation, choosing a seed and drawing a random number from a uniform distribution (using the command *egen*) for each defined block. All steps will be recorded using *do* and *log* files. Analysts will be blinded to the identity of nurseries and families at the time of randomisation, and group allocation identifiers will subsequently be merged with nursery and family data.

(e) Participants

Nurseries will be recruited by NCB in the North of England drawing on a population of nurseries across 8-10 local authority areas. In some of the areas recruitment and retention support will be provided by a local authority staff member focused on early years education.

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[19] The HLE scale is constructed utilizing a 12-item psychometrically validated questionnaire to reflect parental practices at home related to pupils' literacy skills development.
[20] The SELDP is an early literacy assessment developed by the University of Sheffield. It contains a writing component subscale for assessing children's emergent writing skills.

The LA staff will be appointed by the developer. The following eligibility criteria apply to nurseries:

> i. Type of nursery: only school-based nurseries will be eligible to take part.
>
> ii. Prior REAL involvement: nurseries and practitioners should not have any prior exposure to The REAL Programme.
>
> iii. Availability: the school's Early Years coordinator, in conjunction with the school headteacher, will identify one qualified EYFS teacher to undertake training and be able to commit a half day per week to focus on programme delivery (should the nursery be assigned to receive the intervention). All nurseries also need to have identified a key point of contact to support evaluation activities.

Nurseries will also be required to sign a Memorandum of Understanding (MOU) confirming their commitment to deliver the programme and engage in evaluation activities.

Children eligible to take part in the programme will be identified by nurseries. Children eligible to take part will be aged 3in August 2019. Practitioners will select children needing additional support in early literacy based on their prior knowledge of the child and of the child's parent(s)/carers. In some cases, this may be based on a home visit or on a more formal assessment of the child. Practitioners will be asked to keep a record of the criteria they use to identify eligible children. After this information is collected, nurseries' response patterns will be analysed. In case there are important differences in the recruitment patterns utilised across nurseries, this information will be used for later analyses (e.g. subgroup analysis only for nurseries using formal assessment for recruitment).

Each nursery will initially identify children who they think are eligible to take part in the trial. Their parents/main carers will be approached one by one inviting them to take part in the trial. A maximum of 730 children will engage in the trial across all 53 nurseries (restricted by delivery team capacity).

Parents of eligible children will be invited to take part in the trial. NatCen will provide an information leaflet for the nursery, and a parent information sheet along with our privacy notice so that all nurseries and parents are fully aware of the requirements of the evaluation. Only one parent/main carer per household will be named as the pupil representative for all the purposes of the trial. However, for practical reasons, more than one adult per household will be allowed to participate in the activities of the trial (home visits). The representative of each child will be invited to take part in a face-to-face meeting where the practitioner will inform the parent/main carer of the nursery's involvement in the trial, the possibility of receiving an early literacy intervention, explain how the randomisation process will work,) and that the trial will involve the processing of personal data and future linking of trial test results to their child's Early Years Foundation Stage Profile (EYFSP). Parents/main carers who agree verbally to take part and do not withdraw their pupil from data processing will be considered recruited into the trial sample.

Once recruitment of parents into the trial sample is completed, nurseries, in addition to recording the selection criteria used to identify eligible children, will be required to provide the following information on children:

- Unique Pupil Number (UPN)
- First name, Last name
- Date of birth
- Whether in receipt of Early Years Pupil Premium (EYPP)

For research purposes, the following parent/main carer data will be collected:

- First name, Last name
- Contact details
- Name of eligible child (or children)[21]

This information will be collected in a template specified by NatCen. Information on the nursery and practitioner taking part in the programme will also be collected. NCB will collect and collate this data as well as information from pupils' representatives (parents/main carer) and share it with NatCen using a secure server. For research purposes, a unique identifier will be assigned to nurseries, children, parents, and practitioners. This data will be stored in a secure server at NatCen and only used for research purposes during this trial.

(f) Sample size calculations

The below table represents the intention-to-treat minimum detectable effect size (MDES) that can be achieved with the available sample size (overall and for Pupil Premium children only) for a two-armed multisite randomised trial with random assignment at family level. At student enumeration (prior to baseline outcome assessment and randomisation), 53 nurseries were participating in the trial, with an average of 14 families recruited per nursery (harmonic mean). The calculations below set out MDES estimates for an average of13 pupils per nursery (harmonic mean) and a total sample size of 50 nurseries retained in the trial at randomisation (assuming a 5 per cent attrition at nursery level and 6.5 per cent attrition at pupil level between recruitment and randomisation).

		OVERALL	FSM
MDES		0.18	0.32
Pre-test/ post-test correlations	level 1 (pupil)	0.5*	0.5*
	level 2 (nursery)	0	0
Intracluster correlations (ICCs)	level 2 (nursery)	0	0
Alpha		0.05	0.05
Power		0.8	0.8
One-sided or two-sided?		2	2
Average cluster (nursery) size		13	4***
Number of nurseries	Total	50	50
Number of pupils	Intervention	325	100***
	Control	325	100***
	Total	650	200***

* Pre-test correlations informed by the Family Skills trial evaluation, previously conducted by NatCen, where the pre-post test correlation was equivalent to 0.54 for the CEM BASE assessment[22]. However, note that our sample size calculations include estimates of the proportion of variance explained through the included covariates (such as baseline attainment), also known as R-squared. To our knowledge, there is no straightforward way to translate expected pre-test/post-test correlation into the expected R-squared for multiple linear regression or multi-level

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[21] In case multiple children within a family meet the eligibility criteria (e.g., in the case of twins), all eligible children will be included in the trial sample.
[22] CEM BASE Reception Baseline Assessment assesses vocabulary acquisition, letter and word recognition, comprehension, and understanding of reading fundamentals: https://www.cem.org/our-solution-base

models so the R-squared values we use are approximations only. In this case, we assumed an R-squared at level one equal to 0.35.

**Proportion of FSM (Early Years Pupil Premium) children anticipated to approximately 30%, above the national average for FSM pupils for primary schools of 14.4%[23]. The latter since participating pupils will be selected according to their levels of need, and areas chosen for the intervention are amongst those presenting high levels of vulnerability.

The MDES calculations were undertaken using PowerUp! for a two-level fixed effects model with treatment assignment at level 1 (child level) and nursery fixed effects at level two, and indicate that this study is powered to detect an effect of 0.18 standard deviations or greater with the recruited sample of 53 nurseries and 14 children per nursery.

(g) Outcome measures

The primary outcome, early literacy, will be measured using the Preschool Early Literacy Indicators (PELI) assessment. PELI is a psychometrically tested assessment embedded within a set of 10 child-friendly storybooks, of which two will be selected (one for baseline testing and one for the end of intervention testing). The story books specifically address five early literacy dimensions: phonological awareness, alphabet knowledge, vocabulary, oral language, and comprehension. PELI was chosen as an appropriate instrument as it measures dimensions of early literacy that are closely linked to those addressed by the REAL programme intervention.

PELI is comprised of four subtests (Alphabet Knowledge, Phonological Awareness, Vocabulary and Oral Language and Listening Comprehension). The Alphabet Knowledge score is coded from the number of letters of the English alphabet named correctly by the child (0 to 26). Phonological Awareness is assessed utilizing a series of pictures that the child needs to recognize and name; it is marked with a score that ranges from 0 to 15. To assess Vocabulary and Oral Language a series of items from some of these pictures are chosen. The score for each item the child tells about ranges from 0 to 5 based on the quality of the response, with one-word responses receiving 1 point and grammatically correct compound sentences receiving 5 points. The Vocabulary and Oral Language total score ranges from 0 to 35. The listening comprehension scale is comprised of a total of nine questions and children receive 2 points for each correct response and 1 point for each partially correct response. Scores on the Listening Comprehension subtest range from 0 to 23.

The PELI composite score (PCS) is a combination of the individual PELI subtests and represents the overall skill level of the child. To ensure that the PCS reflects each subtest equally, weights are applied to the subtest scores resulting in a composite score where all subtests have the same importance. The weights are applied as follows:

- Alphabet knowledge: two
- Listening comprehension: four
- Phonological awareness: four
- Vocabulary and Oral Language: three

The PELI composite score therefore has a range of 0-309, though the expected values are dependent on the pupil's age and the timing of assessment in an academic year. Kaminski et al (2014) report that on average, a three to four year old at the start of the academic year has a mean of 111.92 (SD: 60.08); by the end of the academic year this increases to a mean

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[23] As in Department for Education, Schools, Pupils and their Characteristics: January 2018 - National Tables

of 178.81 (SD 67.99). By comparison a four to five year old at the end of the academic year will have a mean score of 220.34 (SD 57.07).

PELI has been psychometrically validated. The reliability and validity of this instrument has been investigated in previous studies (see Kaminski, Abott, Bravo-Aguayo, Latimer and Good, 2014[24]). The concurrent and predictive validity of the PELI were examined by correlating the PELI subtests and the PCS with two criterion measures, the CELF-P[25] and the DIBELS Next[26], showing good results. The alternate form reliability of various PELI forms for the PELI composite score ranges from .87 to .96 (Kaminski et al. 2014).

The secondary outcome will be writing and will be measured using the writing component of the Sheffield Early Literacy Development Profile (SELDP)[27] developed by the programme designers. The SELDP writing component is being used at the request of the developer. Since this measure has not been psychometrically validated, the final outcome (score) for all individuals in the writing component of the SELDP will be analysed. If distributional assumptions for simple linear regression are met (normality of the outcome variable), the writing component will be part of the regression analyses. Otherwise, descriptive statistics will be produced comparing the scores of children under the intervention with those in the control group.

Given the technical complexities of assessing individuals utilising these instruments, both PELI and the writing component of the SELDP assessment will be administered by Speech and Language Therapists (SLTs) at baseline in November/December 2019 and post-intervention in June 2021. PELI takes around 15 minutes to administer and we expect the SELDP writing component to take up to 10 minutes maximum. To reduce the risk of marking bias, baseline testing will take place before families are randomised to treatment or control groups. All Speech and Language Therapists will be trained by NatCen on how to mark both assessments before the beginning of the trial.

(h) Compliance and other measures

Given family-level randomisation, there is a non-trivial risk of non-compliance in both the treatment and control groups.

Given that nurseries will identify a number of children in need of the intervention whose families will be assigned at random to the control group, there is a risk of two-sided non-compliance. Firstly, some control group families might receive the intervention if practitioners conduct home visits with these families despite their assignment to the control group.. Collecting data on whether and which control group parents have been exposed to aspects of the intervention is thus crucial to estimate a valid complier average causal effect of the intervention. The specific context of Covid-19 will present additional challenges for home visits. For example, government social distancing guidelines may prevent non-household

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[24] Kaminski, R. A., Abbott, M., Bravo Aguayo, K., Latimer, R., & Good, R. H. (2014). The Preschool Early Literacy Indicators: Validity and Benchmark Goals. *Topics in Early Childhood Special Education*, *34*(2), 71–82.

[25] Clinical Evaluation of Language Fundamentals-Preschool. See: Wiig, Secord, & Semel (2004). Clinical evaluation of language fundamentals: Preschool-2. New York, NY: Pearson.

[26] DIBELS Next First Sound Fluency (FSF). Good, Kaminski, Cummings, Dufour-Martel, Petersen, Powell-Smith, & Wallin (2010). *DIBELS Next*. Eugene, OR: Dynamic Measurement Group. Available from http://dibels.org/

[27] More information about this instrument can be found in Nutbrown, C. (1997) *Recognising Early Literacy Development: Assessing Children's Achievements*. London: Sage Publications. Appendix 1.

members entering the home, or parents may be reluctant to let teachers into their homes. Therefore, there is an increased likelihood that some families may not receive the envisaged amount of home visits. The impact of this will be assessed using the compliance analysis.

We therefore propose a number of ways of capturing compliance across the treatment and control groups. Using a template set out by NatCen, NCB will collect data on the number of home visits conducted with treatment group families and the length of each visit. The number of home visits will be used in our analysis of compliance. According to NCB typical home visits last between 30 and 60 minutes. In addition, we will collect registers of all the home literacy events conducted by the nurseries, which will indicate which treatment group parents attended as well as whether and which control group parents attended. To complement this, NatCen will conduct a termly survey to find out what interaction has taken place with treatment parents beyond REAL visits and also with control parents beyond business as usual.

Should the collected data indicate that there is a number of control group families that have participated in at least one literacy event and/or received at least one literacy-oriented home visit, this will be considered evidence of two-sided non-compliance. In such a case, a household in the control group would be defined as non-compliant if they attended at least one literacy event or received at least one literacy-related home visit. The complier average causal effect would therefore estimate the impact of participating in at least one literacy event or receiving at least one literacy-related home visit.

Should the collected evidence suggest that there was one-sided non-compliance only, that is, none of the control families were exposed to literacy-related home visits, we may be able to utilise data on numbers and length of home visit sessions in the treatment group to conduct some more extensive compliance analysis. In such a case, a household/parent would be defined as compliant if at least six effective home visits take place throughout the duration of the trial (out of a total of 10) for each family. A visit in compliance with requirement is expected to last for at least 20 minutes. If the length of one or more visit is substantially below expected (below 20 minutes), these will not be counted as effective visits. For additional statistical analysis when estimating the effectiveness of the intervention under one-sided non-compliance, the number of effective visits will also be treated as a dosage of the intervention (continuous variable), varying from 0 to 10, according to the number of actual visits.

(i) Analysis plan

The primary analysis will estimate the impact of REAL on early literacy as measured by PELI, of children signed-up to the trial (intention-to-treat approach). We will compare the outcomes (PELI composite score) for the group of children whose parents have agreed to take part in the REAL Programme (treatment group) with those offered business-as-usual (control group). To estimate the impact of the intervention, the primary analysis will use a single-level model with nursery fixed-effects, accounting for baseline attainment of children as measured by the PELI assessment (PELI composite score).

The basic form of the model is,

$$PELI_{ij} = \beta_0 + \beta_1 Baseline_{ij} + \beta_2 Intervention_{ij} + \beta_3 Nursery_j + e_{ij}$$

Where subscripts (i) and (j) refer to pupils and nurseries respectively. The intervention effect is estimated by β_2. β_3 represents nursery fixed effects and e_{ij} the error term. In line with the

EEF Analysis guidance, other covariates will not be considered at this stage. The analysis will be implemented in Stata 14 SE-64.

In order to allow for comparability with other studies when reporting the effect size of the impact of the intervention, we will be using standardized scores (z-scores) on the PELI assessment for both baseline attainment and post-intervention attainment measures.

The impact of the intervention will be expressed as a standardised effect size using Hedge's g with 95% confidence intervals. Following EEF guidelines, the unconditional variance in the primary outcome for the pooled sample will be used when computing the Hedge's g statistic.

(j) Subgroup analyses

Subgroup analyses will be performed, to assess whether the treatment effect varies between disadvantaged and non-disadvantaged children, as well as between boys and girls. Two subgroup analyses will be carried out:

1) Subgroup analysis assessing the impact of the intervention on the primary outcome for children eligible for Pupil Premium.
2) Subgroup analysis assessing the impact of the intervention on the primary outcome according to children's gender.

To estimate the subgroup analysis, a separate model utilizing the same covariates as the one detailed in the basic form will be utilized. To perform these analyses, children's information about their early years pupil premium status and gender will be used. NCB will collect this data from nurseries.

It should be noted that both subgroup analyses mentioned are likely to lack enough statistical power due to small sample sizes, so the interpretation of their results may be limited.

Compliance Analysis

The complier average causal effect (CACE) will be estimated to show the effect of REAL on compliers' attainment on the primary outcome. In case of one-sided non-compliance, the CACE is the average effect of the intervention for that group of children whose parents in the treatment group have complied with the programme. As previously detailed, compliance in this case will be defined as six effective home visits and will be measured through data provided by NCB.

In case of two-sided non-compliance, the CACE is the average effect of the intervention for that group of children whose parents have complied with their treatment assignment (i.e., those treatment group children whose parents have complied with the programme and those parents in the control group whose parents have complied with their assignment and not participated in any aspect of the programme). Compliance in this case will be defined as having participated in at least one literacy event or received at least one home visit, measured though attendance registers at the literacy events and a termly survey of practitioners. Our approach to compliance analysis in this case will be outlined in more detail in the Statistical Analysis Plan (SAP).

(k) Other additional analyses

Alternative models will be estimated in order to assess the impact of the intervention.[28] A range of sensitivity analyses will be carried out to explore the robustness of the main findings. The following four analyses will be carried out:

- An unadjusted analysis that will not include baseline covariates.
- A full model, including a wider range of explanatory variables to control for potential imbalance at baseline: EY pupil premium eligibility, child's gender and term of birth.
- A basic form model where the treatment is included as a continuous variable (dosage as number of home visits) instead of a dummy variable (treatment vs. control), to assess whether the impact of the intervention differs according to the number of effective home visits.

Secondary outcomes

If the outcome measure of the writing component for the SELDP assessment proves to be normally distributed, we will be measuring the impact of the intervention following an intention-to-treat approach, estimating a basic model similar to that of the primary outcome analysis:

$$SELDP_{ij} = \beta_0 + \beta_1 Baseline_{ij} + \beta_2 Intervention_{ij} + \beta_3 Nursery_j + e_{ij}$$

Where the subscripts (i) and (j) refer to pupils and nurseries respectively. The intervention effect is estimated by β_2. β_3 represents nursery fixed effects, and e_{ij} the error term. For this measure we will also be using standardized scores (z-scores), reporting confidence intervals at 95% level, and the effect size utilizing hedge's formula as previously described.

Although the home learning environment index (HLEI) will mostly be analysed as part of the process evaluation section[29], we will also report a measure of the effect of the intervention on the home learning environment, using this measure.

The HLEI measure is collected at three time points with intervention and control parents: prior to randomisation, at a mid-point in delivery (the first half of the autumn term of 2020/21) and at the end of the intervention (summer term 2020-21).[30]

HLEI is being collected using a self-completion questionnaire, administered by practitioners soon after school starts in Autumn 2020 to parents in both the intervention and control condition. As practitioners are administering the survey, there is a risk of social desirability bias and acquiescence effects, particularly in the intervention condition and this will be acknowledged in the evaluation report.

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[28] This may include using multiply imputed data sets to ensure the estimated effect is not biased as a result of missing data for outcomes; this may occur if differential loss to follow-up creates an imbalance between trial groups or attrition is high.

[29] See page 18.

[30] Originally, NatCen planned to administer the HLEI at the end of the nursery year (mid-point – June/July 2020) to all parents (intervention and control) and then again at post-intervention (end point – January/February 2021) to parents of intervention children only (as it would be challenging to reach control parents once children moved to primary school).

We will analyse two separate models: one assessing HLEI scores post-intervention (Summer 2021), and the other at mid-point (Autumn 2020, which is closer to the period of schools' complete closures because of Covid-19).

The basic form of the models are as follows:

$$HLEI_{jt+1} = \beta_0 + \beta_1 Baseline_{jt} + \beta_2 Intervention_j + \beta_3 Nursery + e_j$$

$$HLEI_{jt+2} = \beta_0 + \beta_1 Baseline_{jt} + \beta_2 Intervention_j + \beta_3 Nursery + e_j$$

Where (j) refers to families, (t) to the baseline survey, (t+1) the mid-point survey in Autumn 2020/21 and (t+2) to the final survey in Summer 2020/21. The intervention effect will be estimated by β_2. β_3 represents nursery fixed effects and e_i the error term. The results of these models will be interpreted carefully, considering how Covid-19 and school closures may have affected the home learning environment.Since it was considered important to measure changes in the home learning environment (HLE), this analysis will also form a component of the process study and is described in more detail in the following section below.