

Trial Evaluation Protocol

The REAL Programme

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PROJECT TITLE	The REAL Programme
DEVELOPER (INSTITUTION)	National Children's Bureau
EVALUATOR (INSTITUTION)	NatCen Social Research
PRINCIPAL INVESTIGATOR(S)	Fatima Husain
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TRIAL DESIGN	Two-arm cluster randomised controlled efficacy trial with random allocation at nursery level.
PUPIL AGE RANGE AND KEY STAGE	Early years, ages 3 to 5
NUMBER OF SCHOOLS	120 nurseries
NUMBER OF PUPILS	960
PRIMARY OUTCOME	Early Literacy (Preschool Early Literacy Indicators)
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

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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 project¹ 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 framework³ 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. Practitioners have the option to conduct an additional two visits up to a maximum of 10 home visits. Each visit lasts up to one hour. The visits require at least one parent, guardian or carer of the child to be present for all home visits. 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 literacy. Practitioners are encouraged to be

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.

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.

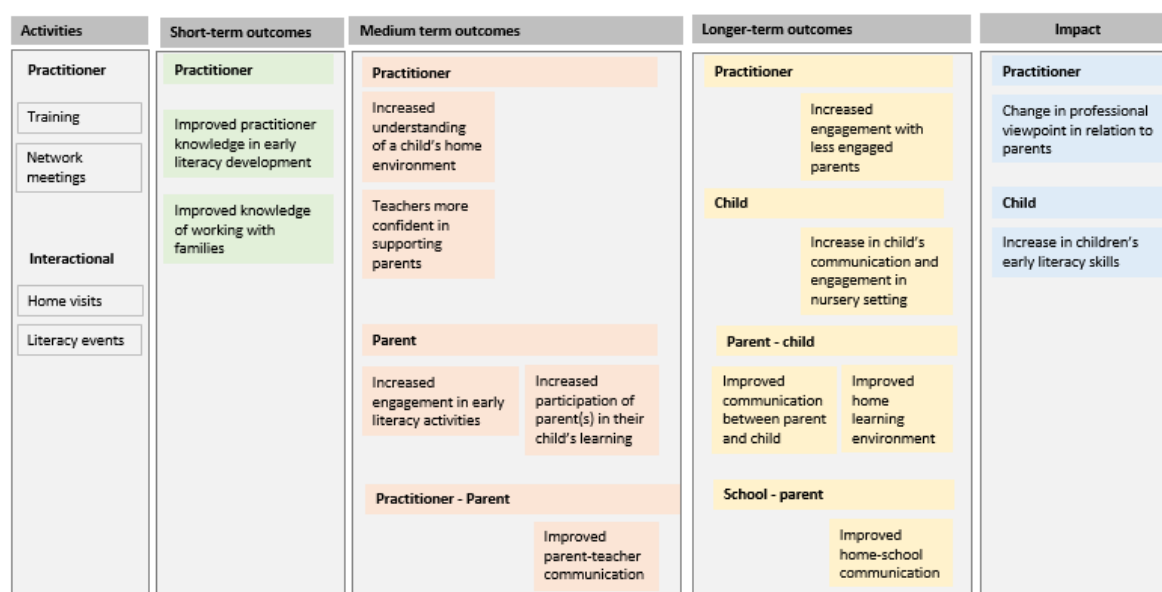
During the trial, the REAL Programme will be delivered over four school terms, starting when the children are in the Spring term of the nursery year and concluding when they are in the Spring term of Reception year at primary school. The practitioner will continue to conduct home visits with families during the Reception year as part of the intervention, unless the child moves to another school outside of the local area. Eight children and their families in each nursery setting will be involved in the trial.

As part of the intervention, practitioners will arrange up to four group literacy events, open to the eight children selected for the intervention, in addition to all nursery class parents and their child who are not participating in The REAL Programme. Termly network meetings for practitioners delivering the programme will be facilitated by NCB.

The trial will take place in the North of England, with three to four Local Authorities selected for participation. Within each Local Authority, a REAL Local Authority Lead will be responsible for recruiting schools for the trial, attending and contributing to the network meetings and coordinating The REAL Programme across schools in their area.

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



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 years⁴ in addition to academic

⁴ 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:

achievement⁵. 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 education⁶. Other related research has shown that parents' interactions with children could also be influenced by the child's gender^{7 8}.

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 achievements⁹. The quality of the HLE has been shown to be equally as important as socioeconomic factors¹⁰. Previous studies also found that programmes with similar characteristics did not demonstrate an impact on early literacy skills in the medium term¹¹.

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 England¹². 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 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 2017.¹³ 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

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/738725/SEED_Impact_Age_4_Report_September_2018.pdf

⁵ 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.

⁶ 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.

⁷ 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.

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

⁹ 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.

¹⁰ 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/>

¹¹ 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.

¹² *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

¹³ Sylva, K., Jelley, F., & Goodall, J. (2018) *Making it REAL. An Evaluation of the Oldham Making It REAL Project*. The Sutton Trust.

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 programme¹⁴. 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

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?

Design

The evaluation will be conducted as a two-arm cluster (nursery-level) 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)¹⁵.

A randomised controlled trial (RCT) uses randomisation to assess the causal impact of an intervention. Random assignment of nurseries 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.

One hundred and twenty nurseries will be recruited to participate in the trial. Nurseries agreeing to participate in the trial will be allocated to one of the two groups, treatment or

¹⁴ *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

¹⁵ 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

control. Of the 120 nurseries recruited to the trial, 60 nurseries will be randomly allocated to the treatment arm and 60 to control (August 2019). The allocation of settings to treatment and control will be communicated to the nurseries by NatCen only after baseline testing is complete. Nurseries assigned to the control condition implement a business-as-usual approach to teaching literacy. As incentivisation, REAL will offer £5,600 to treatment schools and £1,000 to control schools taking part in the trial. This incentive to treatment schools aims to support schools to take part by partially covering the cost of teacher cover for the half day a week required to be spent on this project.

Trial type and number of arms		Two-arm cluster randomised controlled trial with random allocation at nursery level
Unit of randomisation		Nursery
Stratification variable		Geographical area
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) ¹⁶ -Sheffield Early Literacy Development Profile (SELDP) ¹⁷

Randomisation

After agreeing to participate, nurseries will be allocated to one of either the treatment or control groups using stratified randomisation by geographical area. Stratified randomisation ensures balance at setting level across trial arms and across strata after randomisation. This stratification helps to control for potential variations in nursery characteristics and programme implementation across geographical areas, and thus decrease the variance and improve the precision of the impact estimator. The allocation ratio between treatment and control for the expected sample size of 120 nurseries will be a 1:1 ratio.

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

Participants

Nurseries will be recruited by NCB in the North of England drawing on a population of nurseries across 3-4 local authority areas. Recruitment and retention support will be

¹⁶ The HLE scale is constructed utilizing a 12-item psychometrically validated questionnaire to reflect parental practices at home related to pupils' literacy skills development.

¹⁷ 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.

provided by a local authority staff member focused on early years education. 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 practitioner 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 (or act as a control) 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 3-4 in 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 10 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, so from the initial pool of 10 children, 8 children will be finally recruited to the trial. A maximum of 960 children will engage in the trial across all 120 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, and 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 (if their nursery is randomised to the treatment group) 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

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.

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 cluster randomised trial with random assignment at nursery level. It sets out MDES estimates for 8 pupils per nursery intended to be retained in the trial and a total sample size of 120 nurseries in the trial at randomisation.

		OVERALL	FSM
MDES		0.24	0.27
Pre-test/ post-test correlations	level 1 (pupil)	0.5*	0.5*
	level 2 (nursery)	0.1	0.1
Intraclass correlations (ICCs)	level 2 (nursery)	0.15**	0.15**
Alpha		0.05	0.05
Power		0.8	0.8
One-sided or two-sided?		2	2
Average cluster (nursery) size		8	4***
Number of schools	Intervention	60	60
	Control	60	60
	Total	120	120
Number of pupils	Intervention	480	240***
	Control	480	240***
	Total	960	480***

* Pre-test correlations informed by the Family Skills trial evaluation, previously conducted by NatCen, where the pre-pot test correlation was equivalent to 0.54 for the CEM BASE assessment¹⁸.

** We assumed an intraclass correlation of 0.15, also informed by the Family Skills Trial Evaluation, where the intra-class correlation at analysis stage was equivalent to 0.15¹⁹.

¹⁸ 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>

¹⁹ Please refer to the following link for this trial final report:

https://educationendowmentfoundation.org.uk/public/files/Projects/Evaluation_Reports/Family_Skills.pdf

**Proportion of FSM (Early Years Pupil Premium) children anticipated to be well above the national average for FSM pupils for primary schools: 14.4%²⁰. 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 mixed effects model, and indicate that this study is powered to detect an effect of 0.24 standard deviations or greater with the proposed sample of 120 nurseries.

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.

PELI has been psychometrically validated. The reliability and validity of this instrument has been investigated in previous studies (see Kaminski, Abbott, Bravo-Aguayo, Latimer and Good, 2014²¹). The concurrent and predictive validity of the PELI were examined by correlating the PELI subtests and the PCS with two criterion measures, the CELF-P²² and

²⁰ As in Department for Education, Schools, Pupils and their Characteristics: January 2018 - National Tables

²¹ 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.

²² Clinical Evaluation of Language Fundamentals-Preschool. See: Wiig, Secord, & Semel (2004). Clinical evaluation of language fundamentals: Preschool-2. New York, NY: Pearson.

the DIBELS Next²³, 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)²⁴ 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 February/March 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 nurseries 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.

Compliance and other measures

Using a template set out by NatCen, NCB will collect data on the number of home visits conducted 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. A household/parent will 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, 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.

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 delivering the REAL Programme (treatment group) with those from the group delivering business-as-usual (control group).

In order to estimate the impact of the intervention, the primary analysis will use a two-level, mixed effects model, accounting for baseline attainment of children as measured by the PELI assessment (PELI composite score).

²³ 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/>

²⁴ 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.

The basic form of the model is,

$$PELL_{ij} = \beta_0 + \beta_1 Baseline_{ij} + \beta_2 Intervention_j + \beta_3 Regional\ hub + u_j + e_{ij}$$

Where pupils (i) are clustered in nurseries (j). The intervention effect is estimated by β_2 . β_3 represents the regional strata at randomisation, u_j the school random-effect 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.

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 practice, 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 will be defined as six effective home visits and will be measured through data provided by NCB.

Other additional analyses

Alternative models will be estimated in order to assess the impact of the intervention.²⁵ 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:

²⁵ 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.

- 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, nursery type, child's gender and term of birth.
- A single-level OLS regression model, using cluster-robust standard errors. The variables included will be the same as the primary analysis model: baseline attainment, treatment allocation and regional hub.
- 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:

$$SELDP_{ij} = \beta_0 + \beta_1 Baseline_{ij} + \beta_2 Intervention_j + \beta_3 Regional\ hub + u_j + e_{ij}$$

Where pupils (i) are clustered in nurseries (j). The intervention effect is estimated by β_2 . β_3 represents the regional strata at randomisation, u_j the school random-effect 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 section²⁶, we will also report a measure of the effect of the intervention on the home learning environment, using this measure. For this purpose, and since we will not have a follow-up measure for the control group, we will follow a before-after approach, where changes overtime for individuals in the treatment group are assessed. For this purpose, a two-level, mixed effects model, accounting for baseline measures utilizing the HLEI assessment (overall score) will be used.

The basic form of the model in this case is:

$$HLEI_{ijt} = \beta_0 + \beta_1 Baseline_{ijt-1} + \beta_2 Intervention_j + \beta_3 Regional\ hub + u_j + e_{ijt}$$

Where pupils (i) are clustered in nurseries (j) and (t-1) represents time before and (t) time after the intervention. The intervention effect is estimated by β_2 . β_3 represents the regional strata at randomisation, u_j the school random-effect and e_{ijt} the error term.

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.

²⁶ See page 18.

Implementation and process evaluation

A process study will be carried out alongside the impact study 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?
3. What is the per-pupil cost of the intervention?

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 will complement the impact evaluation and offer explanations for any observed effects. 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
- *Responsiveness* – explore engagement with REAL including parents receiving practitioners in the home, 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

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 three 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.

By offering rich insights into the delivery of The REAL Programme, gathering data from a range of participants involved including practitioners, school nursery leads and parents, the process study will provide contextual data to broaden our understanding of the findings from the impact evaluation. The findings from the process evaluation will provide data in order to identify whether the intervention was delivered as anticipated, barriers and facilitators of the intervention and perceived benefits for practitioners and families in addition to the primary outcomes.

Surveys

1. *Survey of early year lead/reception teacher*

Across all treatment settings we will carry out an online survey at two points in time, in October 2019, around the time that nurseries are in the process of identifying eligible children and at the end of the intervention in January/February 2021.

- 1) The baseline survey will capture information on the key challenges experienced by the nursery in relation to early literacy development of children, the level of experience of practitioners, reasons for taking part in REAL and previous or additional early literacy interventions the nursery is engaged in.
- 2) The post-intervention survey will seek early year lead/reception teachers' retrospective assessment of intervention delivery, find out if additional literacy interventions were delivered, seek views on REAL delivery once children moved to Reception year, capture views on the time and cost burden on nursery settings.

2. Parent surveys – measuring the Home Learning Environment

A 12 item paper based HLE measure²⁷ will be administered by practitioners in treatment nurseries and by the key point of contact in control settings. It will take no longer than 5 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 eligible child in treatment and control schools. 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.

End of nursery year – June/July 2020: the HLE measure will be administered to parents by the key point of contact in control schools and by practitioners in treatment groups after the last home visit of the school year. The completed questionnaires will be returned to NatCen by recorded delivery.

Post-intervention – January/February 2021: practitioners will administer the HLE measure to parents immediately after the last home visit. At this point in time, children will have moved to Reception year and contacting parents who were in control nurseries will be very difficult as we will not have a key point of contact to administer the measure. Therefore the post-intervention HLE measure will only be administered to parents of children in the treatment group. The end-of-year and post-intervention surveys will include around five additional questions on experiences of taking part in The REAL Programme. This survey will provide longitudinal data on the parents' assessment of the home learning environment, which is central to The REAL Programme.

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 to encourage completion and return of the completed questionnaires to NatCen.

Administering the survey to parents

²⁷ 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

Written guidance will be provided by NatCen to nursery 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 - 10 parents from each setting will take part, we believe the burden on nurseries 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 nursery to return to NatCen.
- *Return of surveys*: Nurseries will be provided with an addressed pre-paid envelope to return completed questionnaires to NatCen.

3. Surveys of intervention practitioners

We will conduct an online survey with practitioners towards the end of the intervention delivery period, providing overarching perspectives from a range of practitioners involved in delivering The REAL Programme. The survey will capture information about perceived changes in practitioner skills and confidence in relation to supporting parents, experiences of conducting home visits, awareness of changes to the home learning environment in relation to early literacy, and perceived benefits of the intervention to children and parents. 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.

4. Survey capturing 'Business as Usual'

The key point of contact in Control settings will be asked to complete a short online survey (no longer than 10 minutes) at the end of the intervention period. This will capture settings' retrospective views on their efforts to improve early literacy development, support parents, and influence the home learning environment.

To gain an in-depth understanding of the experiences of intervention delivery, we will aim to gather the views of a wide range of practitioners and carry out in-depth research focused on a small number of nurseries.

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 60 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 two network events – during the second and third term of REAL delivery.

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.

Observations of literacy events

Practitioners will be expected to deliver up to four literacy events, open to the eight children selected for the intervention and their parents, in addition to all nursery class parents and their child who are not participating in The REAL Programme. The research team will observe two of these events – during the second and third term of REAL delivery – to gain insights into the content and structure of the events, level of adaptation and the interaction between parents and practitioners, including issues raised by parents and key areas of discussion. Observation data will be captured using an observation template, developed based on the objectives of the literacy events.

REAL Local Authority Lead interviews

In each of the local areas, the developer has engaged a local authority staff member to support school recruitment at the start and retention throughout. It is expected that this staff member will play an important role in keeping primary school engaged when children in nursery move to Reception year. We expect this member of staff to facilitate evaluation activities. LA staff will sign a separate MoU giving their commitment to supporting the delivery of REAL and associated evaluation activities. We will conduct six LA staff interviews at the start of the evaluation in October 2019 and toward the end in January 2021. These interviews will provide insight into school level commitment to REAL and overarching contextual issues in relation to early years interventions.

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 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 early years leads/reception teachers** on planning and early delivery. These will be conducted by telephone and will take place in spring 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.
- *On-going delivery:* this phase of the research will be carried out in the Summer term of 2020. It will comprise a **visit to the nursery** to carry out a **face-to-face interview with the REAL practitioner**, after which we will accompany the practitioner on a home visit to **observe the practitioner-parent session**. We would seek to do this half-way through the intervention, during the 4th home visit. This is an experimental approach, but will provide methodological insights to explore the optimal methods for understanding the home learning environment. Although evidence points towards associations between early literacy development and the home learning environment, there is a data gap in understanding how this works in practice. We will develop a thematic proforma, developed using data from training observations and early

implementation interviews. Based on the proforma we will take mental notes and only write down key words so as not to distract the practitioner, parent(s) and child. To minimise observer bias, researchers carrying out the observations will be briefed in best practice approaches to conducting non-participation observations and parents will be told in advance about the purpose of the observation. The things we will want to observe are the environment, presence of the eligible child, any interactions with the child, the tone of the conversations, body language and expressions of both parent and practitioner, materials used in discussions, and any materials given to parents. Immediately after the observation, we will note down the observations.

- *End of intervention delivery:* towards the end of intervention delivery in the Autumn term of the 20/21 school year, when eligible children have just started Reception year, we will carry out **telephone interviews with parents**. We will seek to speak to 16 parents – 2 parents for each of the practitioners interviewed during the on-going delivery phase. These interviews will last no longer than 30 minutes.

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 towards the end of the intervention to gather retrospective views on REAL, perceived skills development and perceived benefits to children and parents. These interviews will be a follow-up to the practitioner survey. We will use emerging survey findings to identify a sample of practitioners. The sampling approach for selection of participants for interview will consider a range of views on delivery, include those delivering the programme through children's transition to primary school, and will select practitioners with different views on home visits. The interviews will be semi-structured, following an overarching topic guide while taking into account survey responses, exploring specific perspectives observed in the data in more depth.

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.

Cost evaluation

We propose to collect cost data consistent with EEF guidelines²⁸. There will be two sources of cost data:

- *Costs of delivery by NCB*: A cost-proforma will be sent to NCB to calculate the cost of delivering training and for any support for nurseries offered by NCB or Local Authority Leads.
- *The post-intervention early years lead/reception teacher survey* (described above) will gather the cost of participation such as the hours of supply cover needed for staff to plan and carry out home visits.

An estimate of the overall cost of the intervention during the trial will capture the costs of implementation (such as training), staff costs and hourly rate of supply staff alongside the practitioners' log of time spent during home visits. The per pupil cost over three years will be estimated on the basis of annual average net costs to settings divided by the number of participating children.

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 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.

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 will be registered with the International Standard Randomised Controlled Trial Number (ISRCTN) (register the trial at: www.controlled-trials.com).

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

²⁸https://educationendowmentfoundation.org.uk/uploads/pdf/EEF_guidance_to_evaluators_on_cost_evaluation_1.pdf

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 and Formara Print+ who will print personalised testing materials.

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 Fatima Husain	Research Lead	Overall study lead and senior oversight of process evaluation
Sarah Morris	Senior Researcher	Project manager, all research stages and testing
Hannah Piggott	Senior Researcher	Project manager, all research stages and testing
Helen Burridge	Researcher	Working on all study stages
Phoebe Averill	Researcher	Working on all study stages
Luca Tiratelli	Research Assistant	Working on all study stages
Evaluation Team		
Martina Votjkova	Head of Evaluation	Senior oversight of the impact evaluation
Rodrigo Torres	Research Director	Lead, impact evaluation
Rukmen Sehmi	Senior Analyst	Impact evaluation analysis

National Children's Bureau are delivering the intervention. Helen Wheeler and Ellie Suggate-Francis 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. One REAL Local Authority Lead for each local authority included in the trial will assist with recruitment and coordination of the intervention and will support the network meetings.

Risks

The main risks to the project identified at the protocol stage are set out in the table below. NatCen will maintain a risk log for the duration of the study.

Risk	Likelihood / impact	Mitigation / Contingency
Difficulties recruiting the required number of suitable school nurseries	Likelihood: Medium	The NCB team will need to recruit 120 schools. NatCen will provide clear, concise information on the evaluation requirements for communication with schools and be on hand to answer questions at the MOU signing stage. NatCen will also have a dedicated website and contact email/phone number to ensure the study is legitimate. Regular meetings with NCB will ensure progress can be monitored.
	Impact: High	
Low levels of compliance among parents	Likelihood: Medium	Low levels of compliance (i.e. not meeting 6 home visits) may result in lack of statistical power for the impact analysis. NatCen will draft clear information leaflets for the evaluation, outlining required activities. NatCen and NCB will review the parent leaflets drafted explaining the evaluation. NCB will meet with parents in advance of the implementation delivery to fully explain the programme and answer any questions. Practitioners will be trained in engaging parents to participate in home visits.
	Impact: High	
Nursery level attrition	Likelihood: Low	This will be addressed by setting out clearly the requirements for the trial in the MoU; staging payments of incentive with a larger proportion to be paid upon completion of the post-intervention research tasks; and providing schools with clear instructions at the start of the project on what needs to be done and when.
	Impact: High	
Pupil level attrition,	Likelihood: Low	There is a risk of pupil level attrition in general. For example, pupil absence during testing. Speech and

particularly transitioning to Reception year	Impact: Medium	Language Therapists will carry out one mop up visit per school to mitigate this risk. Further risk of attrition could be due to the transition of children into the Reception year. NCB will collect updated pupil data in the Summer term, with the name and contact details for the school where they will be attending Reception. NCB will make contact with the school and they will be asked to sign an MOU. We will aim to follow children to their new school unless they move out of area.
Nursery staff unable to find the time for interviews	Likelihood: Medium	Research activities involved for the evaluation are clearly outlined in the MoU. NatCen researchers are experienced in making appointments for observations and interviews. We will aim to schedule face to face interviews to time them with observation of parent visits. Alternatively, we can offer telephone interviews where this is not feasible at a time that is convenient for them. Nurseries selected for in-depth research will be given a £50 book voucher as a token of appreciation for participation.
	Impact: Medium	

Timeline

Dates	Activity	Staff responsible/leading
Jan-Mar 2019	Finalise recruitment materials, number of schools to be recruited	NCB
Mar-Jun 2019	Recruit schools, sign MOUs	NCB, REAL LA Leads
Aug 2019	Randomisation of schools (without informing them of allocation)	NatCen
Sep-mid Oct 2019	Pupil identification for treatment schools, parent information leaflets handed out, pupil lists sent to NatCen Parent HLE (1) questionnaires administered Early year lead/reception teacher survey (1) administered	NCB, schools, NatCen
Oct 2019	Interviews with REAL LA leads	NatCen, REAL LA Leads
Nov-Dec 2019	Baseline assessment of pupils	SLTs, NatCen
Dec 2019	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 early year leads/reception teachers conducted	NatCen
	Observations of network events	NatCen, NCB
	Observations of literacy events	NatCen, NCB
May-Jul 2020	Parent HLE (2) surveys administered – treatment and control schools	Schools, NatCen
	School visits by evaluation team – practitioner interviews, observations of practitioner-parent session	
Sep 2020	Children move to Reception year, updated pupil lists sent to NatCen	NCB, schools
Oct 2020	Telephone interviews with parents	NatCen
Nov-Dec 2020	Survey of intervention practitioner administered	NatCen
	Observations of network events	NatCen, NCB
	Observations of literacy events	NatCen, NCB
Jan-Feb 2021	Early year lead/reception teacher survey (2) administered	Schools, NatCen
	Survey capturing ‘business as usual’ administered	
	In-depth interviews with practitioners conducted	
Feb 2021	Interviews with REAL LA Leads	NatCen, REAL LA Leads
Feb-Mar 2021	Post-intervention assessment of pupils	SLTs, NatCen
	Parent HLE (3) surveys administered – treatment schools	Schools, NatCen
May-Aug 2021	Analysis and reporting	NatCen
Sep 2021	First draft of the report submitted to the EEF	NatCen
Autumn 2021	EYFSP attainment data available in the NPD	
	TO BE DISCUSSED AND POTENTIALLY COMMISSIONED SEPARATELY:	
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)	