Trial Evaluation Protocol

Lexia

Evaluator: University of York

Principal investigators: Louise Tracey & Louise Elliott

PROJECT TITLE	Lexia Reading Core5®
DEVELOPER (INSTITUTION)	Queen's University Belfast, Lexia UK
EVALUATOR (INSTITUTION)	University of York
PRINCIPAL INVESTIGATOR(S)	Louise Tracey & Louise Elliott
PROTOCOL AUTHOR(S)	Louise Tracey, Louise Elliott & Caroline Fairhurst
TRIAL DESIGN	Two-armed within-school individual randomised controlled trial (efficacy)
PUPIL AGE RANGE AND KEY STAGE	5-7 years, KS1
NUMBER OF SCHOOLS	57
NUMBER OF PUPILS	697 pupils identified as struggling readers (average of 12 per school)
PRIMARY OUTCOME	Reading ability (WRMT-III composite)
SECONDARY OUTCOMES	Word recognition, decoding, comprehension, fluency (WRMT-III subtests); KS1 Reading (raw scores)

Protocol version history

VERSION	DATE	REASON FOR REVISION
1.1	01/02/2019	Trial protocol updated following completion of recruitment and randomisation, and in conjunction with preparation of the Statistical Analysis Plan: • The criteria for pupil eligibility changed because fewer children than anticipated were fulfilling the original selection criteria. • The number of pupils recruited per school was increased from 9 to maximum of 14 because schools suggested that they could manage up to 7 Lexia pupils. • The randomisation method was changed from using variable block sizes in the stratified block randomisation,

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		to use a fixed block size of 2 to ensure no more than 7 pupils were allocated to receive the Lexia intervention in any one school. • Calculation of treatment effect size was changed in the light of the most recent EEF guidance.
1.0	06/06/2018	N/A

INTERVENTION

Lexia, a computer-based independent learning system (ILS), was originally developed in the US to help pupils with dyslexia. Lexia Reading Core5® is designed for wider use and provides personalised, adaptive learning for a wide range of ability levels at primary school age. Pupils begin with a diagnostic test and are placed at an appropriate level and work independently, typically having three to four 20-minute sessions per week (not including set-up time). The system is able to keep track of users' progress in real-time. Facilitators (Teachers and/or teaching assistants) are provided with reports to monitor pupils' performance and, where appropriate, paper-based activities are suggested from within the system. Facilitators need to give pupils initial guidance on using the programme, teach and reinforce some units, and oversee and monitor pupil progression. Online training and support is offered. The programme is most commonly used in UK schools as an in-school supplement to target struggling readers although it can also be used as a whole class intervention or as a school-provided, home-use supplement to teaching. Lexia Reading Core5® has been adapted to the UK context (eg. using UK-English audio and spellings) and is currently being used in over 3,000 schools.

The programme will be delivered from September 2018 throughout the academic year. Schools are expected to schedule 4 sessions of 30 minutes (including 10 minutes setup time) per week. To meet the minimum requirements for compliance pupils must do a minimum of 60 minutes (excluding setup time) per week for at least 12 non-consecutive weeks. Pupils identified by researchers as struggling readers, up to 14 per school, were randomised within school to take part in Lexia Reading Core5® or to the control group. Each pupil will work independently during the intervention with one adult (either a teacher or teaching assistant) supervising the pupils. The adult's role is to ensure the children are on task, monitor progress, scaffold learning with paper-based resources where necessary and manage the software. The intervention is delivered in-school only as, although some schools currently provide the programme for use at home, we want to ensure that pupils without wider access to IT are not disadvantaged. In-school provision will also ensure more consistency of implementation fidelity.

The aim of this evaluation is to assess how effective Lexia Reading Core5® is in improving the reading skills of struggling readers in Key Stage 1 (KS1). The research will also address the possible impact of Lexia Reading Core5® on pupils eligible for Free School Meals (FSM). As this is an efficacy trial, we will work closely with the delivery team to establish ways to ensure implementation of the programme as planned across all schools eg through the monitoring of usage data available from the Lexia Reading Core5® platform, and regular communication with schools.

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Table 1: TIDieR

Aspect of TIDieR	Exemplification relating to the evaluation
Brief name	Lexia Reading Core5® (a computer-based Independent Learning System (ILS) for Reading provided by LexiaUK©)
Why: Rationale, theory and/or goal of essential elements of the intervention	The research evidence for the programme is mixed although it does show evidence of promise. In addition, Lexia Reading Core5®, and other programmes which provide an ILS, are popular with schools for instructional purposes. This evaluation would be the first large-scale randomised controlled trial of Lexia Reading Core5® in the UK.
Who: Recipients of the intervention	Struggling readers in Year 2
What: Physical or informational materials used in the intervention	The following are provided for each school: • Initial training via online conference facilities • Ongoing support for teachers, including ongoing online web-based training • Programme software • Off-line, paper-based resources • Technical support
What: Procedures, activities and/or processes used in the intervention	• Teachers/Teaching assistants trained in the Lexia Reading Core5® • Senior member of staff (eg Headteacher) present at the first two training sessions to encourage school support and implementation • Lexia Reading Core5® accessed by pupils via PC or tablets • Teachers utilise reports to monitor student performance • Where additional need is identified pupils receive paper-based resources and scaffolded teaching
Who: Intervention providers/implementers	As an ILS Lexia Reading Core5® is designed to provide personalised learning to each of the pupils selected. Teachers/teaching assistants (TAs) will facilitate and monitor implementation and provide instruction as required. Teachers/TAs will be trained to set up pupils on the Lexia Reading Core5® system and understand the data provided by the programme. LexiaUK© will provide this training virtually via online conference facilities.
How: Mode of delivery	Delivery of Lexia Reading Core5® to the struggling readers in the intervention group eg. during guided reading sessions, can occur on a PC or tablet computer, under the supervision of trained personnel.
Where: Location of the intervention	Schools will be advised that children should be withdrawn from the classroom for Lexia Reading Core5® sessions. This

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	is to facilitate the level of teacher/teaching assistant monitoring and support required by the programme.
When and how much: Duration and dosage of the intervention	The Lexia Reading Core5® intervention should be scheduled for use 4 times a week for 30 minutes (including 10 minutes setup time) over the academic year. For compliance, pupils must have completed a minimum of 60 minutes (excluding set-up time) per week for at least 12 non-consecutive weeks
Tailoring: Adaptation of the intervention	Given that this is an adaptive programme, adaptations are not advised.
How well (planned): Strategies to maximise effective implementation	In order to maximise the effectiveness of the implementation the following strategies will be adopted: • Teachers/teaching assistants to take part in on-line training sessions • A member of the school senior leadership to attend at least 2 of the online training sessions delivered via conference facilities • On-going support provided to facilitating teachers and teaching assistants • Pupil data will be monitored to keep track of compliance and identify those who do not receive the minimum dosage (i.e. non-compliers). LexiaUK© will contact schools via email in the first instance if non-compliance is detected • Where possible data from the software will be used to assess implementation

SIGNIFICANCE

In 2016 the percentage of pupils not reaching the expected standard in reading at KS1 was 26%. For pupils receiving FSM the figure was 40% (DfE, 2016). Early literacy problems can hinder children's knowledge and development, with long-term consequences for their educational outcomes. Consequently, there is a need for identifying the most promising approaches in KS1 and the early years (Higgins, Katsipataki & Coleman, 2014). Remedial and tutorial use of technology has been identified as being particularly practical for lower attaining pupils, those with special educational needs or those from disadvantaged backgrounds in providing intensive support to enable them to catch up with their peers (Higgins, Xiao & Katsipataki, 2012). A review of the effectiveness of educational technology applications in improving the reading achievement of struggling readers in elementary schools in the US also suggested that such approaches show promise (Cheung & Slavin, 2012).

Lexia Reading Core5® is currently used in over 3,000 schools in the UK. Other programmes implementing an ILS approach are also popular with schools for instructional purposes. Previous RCTs of earlier versions of Lexia in the US found 'potentially positive effects' on alphabetics and comprehension but no discernible effects on fluency and general reading achievement (What Works Clearinghouse, 2009). These studies typically took place over a six-month period. As such, this programme shows promise. Although some studies of Lexia have been conducted in the UK these have generally been small-scale (Brooks, 2016). There has been one randomised controlled trial (RCT) of Lexia Reading Core5® in Northern Ireland which found effects for blending and non-word reading in 4-6 year old pupils (O'Callaghan et al., 2016). This efficacy trial provides an opportunity to evaluate the programme using a large-scale RCT within the UK context, using outcomes which measure all-round reading ability.

Methods

Research questions

The primary research question is:

> How effective is Lexia Reading Core5® in improving struggling readers' reading skills during Year 2?

The secondary research questions are:

1. How effective is Lexia Reading Core5® in improving struggling readers' word recognition skills during Year 2?
2. How effective is Lexia Reading Core5® in improving struggling readers' decoding skills during Year 2?
3. How effective is Lexia Reading Core5® in improving struggling readers' comprehension skills during Year 2?
4. How effective is Lexia Reading Core5® in improving struggling readers' fluency skills during Year 2?
5. How effective is Lexia Reading Core5® in improving struggling readers' outcomes in KS1 national reading assessments?
6. How effective is Lexia Reading Core5® in improving struggling readers' reading skills during Year 2 for FSM pupils?

Design

This is a two-armed within-school individual level RCT. This provides the ideal counterfactual as it avoids the issue of variation between schools and randomisation controls for selection bias. As the intervention is delivered via a computer one-to-one, the possibility of diffusion is reduced. Our sample comprises of struggling readers within Year 2 in evaluation schools in the academic year 2018-19.

Randomisation

Schools were eligible for randomisation after:

- Signing a Memorandum of Understanding (MOU), which included permission for the evaluation team to access school data generated by the Lexia Reading Core5® software;
- Providing specified data requested in the MOU (including pupil UPNs, pupils' FSM status, KS1 Reading raw and scaled scores) and contact details for their head teacher, lead contact and class teachers;
- All baseline testing of potentially struggling readers for identification purposes had been completed;
- All teachers in Year 2 had completed an on-line pre-randomisation survey.

Block randomisation, with a fixed block size of 2 stratified by school, was used to ensure that no more than 7 pupils were allocated to receive the Lexia intervention in any one school. Pupils were randomly allocated 1:1 to receive either the intervention or teaching as usual. An independent trial statistician at the York Trials Unit was responsible for generating the allocation schedule, using STATA (StataCorp., 2017). Pupils from each school were randomised in a single batch to ensure allocation concealment from schools prior to randomisation.

Randomisation was completed before the end of the Summer Term 2018.

Participants

Schools were eligible to participate if they:

- Had approximately 50 pupils per year group;
- Were not involved in another EEF trial focusing on KS1 literacy or aiming to achieve change at a whole school level;
- Were not currently using Lexia Reading Core5®, or had used Lexia Reading Core5® in the past 12 months
- Met the technological requirements to support an IT-based intervention (the intervention can be run on iPads); and
- Were willing to implement the intervention with respect to the random allocation (i.e. only with those pupils assigned to the intervention group).

Initial recruitment focussed on schools in the North East and Yorkshire and Humber regions.[1] Schools from outside these areas were accepted to the trial in groups, providing there was a sufficient number to enable cost-effective data collection. The overall sample of schools includes a higher than average proportion of disadvantaged schools (ie an average of 29% or above EverFSM as defined in the National Pupil Database).

Schools were recruited by the delivery team, with support from the evaluation team.

Pupils were eligible to participate providing:

- They were identified as a struggling reader; and
- A withdrawal of data form was not received from the parent.

Class teachers were asked to provide the names of the half of the Year 1 pupils with the lowest attainment. These children were independently assessed by the administration of the Word Identification, Word Attack and Passage Comprehension subtests of the Woodcock Reading Mastery Tests – Revised Normative Update (WRMT-R/NU) by assessors recruited and trained by the University of York. Originally, it was planned that pupils who received a standard age score (SAS) of 85 or less in any of the three subtests of the WRMT-R/NU at pre-test would be eligible to participate in the study. This was amended after pre-testing took place because fewer children than anticipated were fulfilling the original selection criteria and schools indicated a higher than expected capacity to deliver the Lexia programme. Consequently, eligible pupils were defined as those with pre-test WRMT-R/NU scores less than or equal to the 12th lowest ranking pupil's score for that school (up to a maximum of 14 per school). It was felt important that eligibility was determined independent of the teacher to ensure consistency across participating schools.

Incentives

Participating schools receive a two-year licence for the Lexia Reading Core5® program at the reduced cost of £500 plus VAT per school for use with 30 pupils. This licence fee is non-refundable; however, it is contingent on the school delivering Lexia Reading Core5® to the Year 2 pupils selected to receive Lexia Reading Core5® during the study. Should the school

[1] As identified by the previous government office regions (GORs): http://webarchive.nationalarchives.gov.uk/20080728100253/http://www.dcsf.gov.uk/rsgateway/leas.shtml.

withdraw from the evaluation during the period of the study the licence will be terminated. The programme can be used for additional pupils outside of Year 2 during the study and with any pupils within the school (including Year 2) for the remainder of the licence to bring the total usage to 30 pupils.

Sample size calculations

Proposed

We initially proposed to recruit 57 schools. This number of schools was considered realistic given the capacity of the delivery team and the additional processes established to ensure compliance. Assuming an average of 56 pupils in the school (28 per class, 2-form entry), we estimated that an average of 9 pupils per school would be identified as struggling readers based on achieving a standard age score of 85 or less in any of the three subtests of the WRMT-R/NU at pre-test. This was based on administration of a similar assessment, the York Assessment for Reading Comprehension (Snowling 2011), with similar pupils in a previous study (Tracey et al. 2014), which found that 17% of pupils were struggling readers, as identified by the YARC. Assuming a pre and post-test correlation of 0.6 between the baseline and post-test of the WRMT, with 80% power, the minimum detectable effect size (MDES) with this sample size would be 0.20 allowing for 10% pupil level attrition (StataCorp., 2017). The model that will be used to analyse the data will adjust for any potential within school correlation but this was not incorporated in the sample size calculation.

The schools recruited to the trial had an average FSM of 29.2% overall. Based on this estimate, we might conservatively have expected 3 of the struggling readers per school to be eligible for FSM; therefore, in this subgroup, ceteris paribus, the MDES would be 0.36. However, it is likely that FSM status and being a struggling reader are correlated, so a higher proportion of the 9 identified struggling readers might have been eligible for FSM. For example, with an average of 6 FSM pupils per school, the MDES would be approximately 0.26 (ceteris paribus).

Actual

A total of 57 schools were recruited. All eligible pupils with pre-test WRMT-R/NU score less than or equal to the 12th lowest ranking pupil in the class were randomised (1:1) to either receive the Lexia intervention or teaching as usual. Based on this selection criteria, 697 pupils in total (mean 12.2 per school, range 12-13) were randomised. Assuming a pre- and post-test correlation of 0.6 and 10% pupil-level attrition, the MDES with this sample size would be 0.18 with 80% power for the overall study.

For the FSM subgroup, since the recruited schools had an average of 29.2% FSM pupils, we could conservatively estimate an average of four randomised pupils to be eligible for FSM in each recruited school. Using otherwise identical parameters to those described above, the MDES in this subgroup would be 0.31 with 80% power. However, there could be more than four randomised pupils in each school eligible for FSM as FSM status is correlated to pre-test scores. Depending on the percentage of FSM pupils among the randomised pupils, MDES with 80% power could be as low as 0.18.

Table 2: Sample size calculations

		Proposed		Actual	
		OVERALL	FSM	OVERALL	FSM
MDES		0.20	00.36	0.18	0.31
Pre-test/ post-test correlations	level 1 (pupil)	0.6	0.6	0.6	0.6
	level 2 (class)	-	-	-	-
	level 3 (school)	-	-	-	-
Intracluster correlations (ICCs)	level 2 (class)	N/A	N/A	N/A	N/A
	level 3 (school)	N/A	N/A	N/A	N/A
Alpha		0.05	0.05	0.05	0.05
Power		0.8	0.8	0.8	0.8
One-sided or two-sided?		Two	Two	Two	Two
Average cluster size		9	3	12.2	4
Number of schools	intervention	57	57	57	57
	control	57	57	57	57
	total	57	57	57	57
Number of pupils	intervention	257	86	348	114
	control	257	86	349	114
	total	514	172	697	228

Outcome Measures

The primary outcome measure is a composite of the raw scores of four subtests of the WRMT-III (Word Identification, Word Attack, Passage Comprehension, and Oral Reading Fluency) (Woodcock, 2011) for Year 2 pupils. The WRMT-III is a standardised measure suitable for ages 4 years 6 months to 79 years 11 months. The WRMT-III will be administered one-to-one with each child by a trained administrator. It is paper-based and the proposed sub-tests will take approximately 20-25 minutes in total to administer to each child. Administration of the WRMT-III at post-test will be conducted by trained administrators who

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are blind to group allocation to avoid the potential for ascertainment bias. The WRMT-III subtests measure word recognition (Word Identification), decoding (Word Attack), comprehension (Passage Comprehension) and fluency (Oral Reading Fluency). This is considered an appropriate measure as these subtests identify the key areas in which readers typically struggle and those that Lexia Reading Core5® targets. The composite score constructed from these subtests will reflect overall reading ability.

The secondary outcome measures will be the raw scores of the individual subtests of the WRMT-III and the KS1 reading raw scores. The KS1 reading raw scores will be securely transferred from schools in an encrypted excel spreadsheet for the Year 2 pupils as the National Pupil Database only holds data on whether pupils are 'working towards', 'working at' or 'working above' the standard expected at the end of KS1.

Raw scores in the WRMT-R/NU pre-test administered before the intervention begins (as described above) will be used as baseline measures of prior attainment.[2]

Analysis plan

The statistical analysis proposed follows the most recent EEF guidance (EEF, 2015b). A detailed statistical analysis plan will be prepared by the trial statistician within three months of randomisation. The proposed analysis is provided in brief below.

All analyses will be conducted in Stata (v15 or later, to be confirmed in the final report) on an intention to treat basis, using two-sided significance at the 5% level. Baseline data will be summarised by trial arm and presented descriptively. No formal comparison of baseline data will be undertaken, except to report the differences in WRMT-III pre-test scores as a Hedges' g effect size.

Primary Analysis

The primary analysis will investigate any difference in the WRMT-III composite reading score between the two groups. The analysis will take the form of a linear mixed model at the pupil-level with outcome score as the response variable. Group allocation and pre-score will be included as fixed effects in the model. Potential clustering at the school level will be controlled for by including school as a random effect. The treatment effect size was intended to be calculated based on the adjusted mean difference between the intervention and control group, and the total variance (between plus within school variance), obtained from the linear mixed model. However, following the most recent EEF guidance, effect sizes will be calculated by dividing the adjusted mean difference between the intervention and control group by the pooled variance obtained from an unconditional model. A 95% CI for the effect size will be calculated by dividing the 95% confidence limits for the adjusted mean difference by this same variance. All parameters used in these calculations will be provided in the final report.

CACE Analysis

A Complier Average Causal Effect (CACE) analysis for the primary outcome will be considered to account for pupil engagement with the intervention (in terms of number of online sessions completed). An instrumental variable (IV) approach will be taken using randomised group as the IV.

[2] It was originally intended to use the WRMT-III for the baseline measure. However, for pragmatic reasons (Pearson being unable to supply the tests in time) the WRMT-N/RU was chosen. The WRMT-N/RU does not include the Oral Reading Fluency measure which will only be administered at post-test.

Missing data
A mixed effect logistic regression model will be run to predict the presence of missing primary outcome (composite WRMT-III reading score) data including group allocation and pre-test score. The impact of missing data on the primary analysis will be assessed by repeating the analysis on a data set where missing data has been completed using multiple imputation.

Subgroup Analysis
Pupil UPNs, as obtained during the recruitment period (see Randomisation above) will be used to access additional data relating to pupil characteristics from the National Pupil Database (ie. EverFSM). The effect of the intervention on pupils who are eligible for FSM will be assessed via the inclusion of FSM status (the EverFSM indicator (EVERFSM_6_P) in the NPD) and an interaction term between FSM status and allocation in the primary analysis model. Additionally, the primary analysis will be repeated on the subgroup of FSM pupils.

Secondary Analysis
The secondary outcomes of the individual WRMT-III subtest scores and KS1 Reading raw score will be analysed as described for the primary outcome, using the pre-test score of the subtest as the measure of prior attainment in the model (composite WRMT-III pre-test score will be included in the model for the outcome of KS1 Reading).

Implementation and process evaluation methods
Background
Current evidence suggests that the effective use of technology in schools is heavily influenced by school and teacher factors. Higgins et al. (2012) indicate 'it seems probable that more effective schools and teachers are more likely to use digital technologies more effectively than other schools'. They also suggest it is 'the pedagogy of the application of technology in the classroom which is important: the how rather than the what' (p.3). Our process evaluation seeks to provide a useful understanding of the programme and its use in schools. It will also, where possible, inform and explain the findings of the impact evaluation.

Research questions
The process evaluation seeks to answer the following research questions:

1. What is the relationship between the fidelity of the intervention and the impact on pupil outcomes?
2. How much variability occurred in implementation of the intervention across different settings in respect of:
    a. dosage (number and frequency of overall sessions)
    b. school factors such as physical space/place of intervention
    c. teacher factors, including supervision of the sessions and use of paper-based resources
    d. potential or actual perceived barriers to implementation
3. The reach of the intervention (including use of training and support provided)
4. The nature of teaching as usual (ie. the control conditions) - what support was offered to those pupils not allocated to the intervention group.

Methods
The research questions above will be answered via a pragmatic and mixed method approach which will include the following elements:

Programme data

The evaluation team will be provided with access to the data files produced by, and for, schools via the software following opt-in permission obtained from schools in the MOU.The Lexia Reading Core5® programme software provides school, class and individual level reports which we will use to gather information relating to implementation, fidelity and dosage. This information is particularly valuable for both the impact and process evaluations as it reduces the potential burden of the research on schools. It will provide information about how often the programme was used and for what length of time, any patterns of usage during the programme delivery period and, if possible, what areas of the adaptive programme showed the greatest amounts of progress over time.

Pre and post teacher survey

All teachers in Year 2 were asked to complete an on-line pre-randomisation survey to establish a full picture of school and teacher contextual factors: literacy teaching in Year 2, what usual/baseline practice for struggling readers looks like in the participating schools, and levels of IT experience, usage, school facilities and IT support. This survey will be re-administered at post-test with additional questions relating to use of the programme (eg. when scheduled and whether delivered in a group timeslot or individual timeslots, what activities other Year 2 pupils are engaged in at that time, training and support used) and associated benefits (eg. 'softer' outcomes in terms of pupils' confidence and engagement) and challenges (eg. IT support, scheduling time in the school day).

School visits

Ten schools will be randomly selected to be visited to form case studies for a more in-depth process evaluation. Visits will be scheduled to coincide with a time when Lexia Reading Core5® is being delivered to observe implementation of the programme, including what space and IT is provided, support offered to children during the Lexia Reading Core5® sessions (eg. teacher or teaching assistant present), number of children in any one session, and pupil engagement. Where possible provision for pupils in the control condition will also be observed. If a school that has withdrawn is selected, we will approach them to ask if they would be willing to be visited, and if not, another participating school will be randomly selected in its place.

In addition, whilst at the school, teacher interviews and pupil focus groups will be conducted, as described below:

- *Teacher Interviews*

  Teachers will be interviewed to establish school and class contextual practices; the timing and space provided for programme delivery, additional support for children using the programme, provision for those struggling readers allocated to the control condition, and the rationale behind these decisions. In addition, there will be discussion about whole class literacy provision for Year 2. Information will also be elicited regarding the ease of use of the Lexia Reading Core5® programme, the training and support used and attitudes towards the programme. If possible, programme data collected will be used to help frame this discussion. If teaching assistants were used for programme delivery they would also be involved in a short discussion regarding delivery.

- *Pupil focus groups*

  We will conduct a small number of focus groups with Year 2 struggling readers allocated to the intervention condition (in 5 out of the 10 schools visited). Framed within our

observation of programme delivery this would allow us to assess pupil experience of using the programme, their perceptions of their learning, pupil engagement and confidence. Although the pupils are young, with the aid of visual aids and prompts we would aim to facilitate a meaningful dialogue between children and researchers (Wall, 2008). Focus groups would have no more than 3-4 students each and last no longer than 20 minutes.

Interview data will be transcribed and imported into the NVivo software. It will be analysed thematically using a deductive approach and triangulated with observation and pupil focus group data. The use of a case study approach will also allow us to understand further the conditions under which implementation is successful within schools.

Costs

The evaluators will report the cost per pupil over a three-year period for the intervention.

The cost of the intervention, including software licences, ongoing support, any pre-requisite resources and time required for staff (head teacher, teachers and teaching assistants) training will be collected from the developers.

Costs relating to any additional materials or resources needed within schools for the intervention will be collected through the teacher survey at the end of the intervention period. Questions will be asked during the teacher interviews to identify any issues around provision/cost of resources.

The survey will also be used to collect information about the teacher and teaching assistant time required to facilitate the intervention. Questions will include time taken delivering the intervention, training time (other than the initial training which will be collected from the developer) and time spent on any other activities related to the intervention.

Ethics and registration

Ethical approval and data protection

Ethical approval for this study was sought through the Education Ethics Committee, University of York.

All outputs (including the statistical database, reports and publications) will be anonymised so that no school or pupil will be identifiable in the report or dissemination of results. Data will be handled in accordance with the General Data Protection Regulations (GDPR) which comes into effect in May 2018. Personal data will be processed under Article 6 Section (e) of the GDPR ('Tasks carried out in the public interest') as the research is being conducted to support education provision in the UK. The statistical database will hold non-identifiable data. 5% of the assessments will be randomly selected and double-checked, to assess reliability and consistency. All scores will be input twice to ensure accuracy. Confidentiality will be maintained and no one outside of the evaluation team will have access to the database which will be held securely on the department servers. KS1 results data will be transferred to the evaluation team from schools using an encrypted Excel spreadsheet.

The MOU signed by the school headteachers indicates their participation in the evaluation of Lexia Reading Core5®. An information sheet was provided to parents via the school to explain the trial and the data that will be collected and with whom it will be shared. For ethical reasons parents were given the opportunity to withhold their child's data from the

evaluation, withhold permission to link to the National Pupil Database and to deposit data at the end of the trial.

Trial Registration
The trial has been registered at the International Standard Randomised Controlled Trial Number registry (ISRCTN). (Number to be confirmed).

Personnel

Evaluation Team

Dr Louise Tracey (Co-Principal Investigator)
Louise Tracey is responsible, with Louise Elliott, for the day-to-day management and coordination of the trial, working closely with the programme developers.

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Caroline Fairhurst (Co-Investigator)
Caroline Fairhurst undertook the randomisation and will conduct the statistical analysis of the trial.

The project support officer, Imogen Fountain, is responsible for liaising with schools, uploading and monitoring the teacher surveys, scheduling the assessments and the school observation visits and maintaining the project database.

The evaluation team is responsible for the design, randomisation, data collection, analysis and reporting of the evaluation.

Delivery Team

Dr Maria Cockerill, Queen's University Belfast
Maria is responsible for recruitment and for the day-to-day management and coordination of the trial, working closely with the LexiaUK© delivery partner and with the programme evaluators.

Professor Allen Thurston, Queen's University Belfast
Allen is responsible for the management and coordination for the trial, working closely with the programme evaluators.

Rob Kay, LexiaUK©
Rob is responsible for the delivery of the programme licence, training and support to schools during the trial.

A part-time research associate was recruited for the duration of the trial to assist the delivery team.

The delivery team are responsible for school recruitment, training and support for the programme.

Risks

Risk	Preventative measures	Likelihood
Insufficient schools recruited	• Emphasise that Lexia Reading Core5® is a promising intervention • Work closely with the delivery team and utilise our combined experience of recruitment • All schools will obtain the software as within-school randomisation proposed	Low
Attrition	• At recruitment all schools required to sign a MOU • Implementation and training burden is low • All schools will receive the intervention • Regular newsletter contact throughout the project • Over recruit by 15% to allow for some unavoidable attrition	Low
High attrition from intervention or poor implementation	In the first year of purchasing the programme schools are provided with a level of enhanced support to ensure strong implementation which should mitigate against withdrawal	Low
School staff turnover	Web-based training takes approximately 3 hours and there is continuing support for the programme by the providers.	Low
Project Management	The PI's (Louise Tracey & Louise Elliott) have overall responsibility for the project, coordination and communication. They have established areas of lead based on their areas of expertise to ensure that the study is conducted with clear responsibilities.	Low

Timeline

School Year	Term	Specific date	Evaluation team	Lexia / QBU
2017-2018	**Spring Term 2018**	**January-May**	Main recruitment period (including MOUs, parental withdrawal) led by QUB / LexiaUK© with input from the evaluation team	
		May-June	Pupil data collection from recruited schools Teacher baseline surveys distributed and collected	
	Summer Term 2018	**April / May / June**		Begin licence issue and online-training for schools
		June	WRMT assessments (pre-test) carried out in schools (4th June-14th July)	
		June /July	Rolling randomisation	
2018-2019	**Autumn Term 2018**	**September**	Intervention starts	
	Spring Term 2019	**January-March**	Process Evaluation Observations, Focus Groups and Interviews	

	Summer Term 2019	**April / May**	Teacher follow-up surveys distributed and collected Process evaluation data coded and analysed	
		June	WRMT assessments (post test) carried out in schools Obtain KS1 data directly from schools	
		July	Checking and inputting assessment data	
2019-2020		**October**	Begin main trial write up pending NPD data	
		October / November	Access NPD data	
		November	Analysis	
		December	First draft of final report	
		May	Final report submitted & Data downloaded to FFT	

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