

## 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	c. 514 pupils identified as struggling readers (based on estimated average of 9 per school)  (c. 1600 pupils tested at pre-test – half of c. 3200, based on average of 56/ per school, 28/ class, 2 classes/ school; 800 tested at post-test)
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		
1.0	06/06/2018	N/A

<sup>1</sup>Department of Education, University of York

<sup>2</sup>York Trials Unit, University of York

## INTERVENTION

Lexia, a computer-based independent learning system (ILS), was originally developed in the US to help pupils with dyslexia. Lexia Reading Core5<sup>®</sup> 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<sup>®</sup> 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 for a period of 24 weeks/two full terms. 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 3 sessions per week for at least 12 weeks. Pupils identified by researchers as struggling readers, approximately 9 per school, will be randomised within school to take part in Lexia Reading Core5<sup>®</sup> 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 will be to ensure the children are on task, monitor progress, scaffold learning with paper-based resources where necessary and manage the software. The intervention will be 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<sup>®</sup> platform, and regular communication with schools.

Table 1: TIDieR

Aspect of TIDieR	Exemplification relating to the evaluation
<b>Brief name</b>	Lexia Reading Core5 <sup>®</sup> (a computer-based Independent Learning System (ILS) for Reading provided by LexiaUK <sup>®</sup> )
<b>Why: Rationale, theory and/or goal of essential elements of the intervention</b>	The research evidence for the programme is mixed although it does show evidence of promise. In addition, Lexia Reading Core5 <sup>®</sup> , 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 <sup>®</sup> in the UK.
<b>Who: Recipients of the intervention</b>	Struggling readers in Year 2
<b>What: Physical or informational materials used in the intervention</b>	The following are provided for each school: <ul style="list-style-type: none"> <li>Initial training via online conference facilities</li> </ul>

	<ul style="list-style-type: none"> <li>• Ongoing support for teachers, including ongoing online web-based training</li> <li>• Programme software</li> <li>• Off-line, paper-based resources</li> <li>• Technical support</li> </ul>
<b>What: Procedures, activities and/or processes used in the intervention</b>	<ul style="list-style-type: none"> <li>• Teachers/Teaching assistants trained in the Lexia Reading Core5®</li> <li>• Senior member of staff (eg Headteacher) present at the first two training sessions to encourage school support and implementation</li> <li>• Lexia Reading Core5® accessed by pupils via PC or tablets</li> <li>• Teachers utilise reports to monitor student performance</li> <li>• Where additional need is identified pupils receive paper-based resources and scaffolded teaching</li> </ul>
<b>Who: Intervention providers/implementers</b>	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.
<b>How: Mode of delivery</b>	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.
<b>Where: Location of the intervention</b>	Schools will be advised that children should be withdrawn from the classroom for Lexia Reading Core5® sessions. This is to facilitate the level of teacher/teaching assistant monitoring and support required by the programme.
<b>When and how much: Duration and dosage of the intervention</b>	The Lexia Reading Core5® intervention will be scheduled for use 4 times a week for 30 minutes (including 10 minutes setup time) over 24 weeks. For compliance pupils must have completed at least 3 sessions per week for 12 weeks (ie 36 sessions in total) and use of off-line resources should be limited to less than 1 hour per week.
<b>Tailoring: Adaptation of the intervention</b>	Given that this is an adaptive programme adaptations are not advised.
<b>How well (planned): Strategies to maximise effective implementation</b>	<p>In order to maximise the effectiveness of the implementation the following strategies will be adopted:</p> <ul style="list-style-type: none"> <li>• Teachers/teaching assistants to take part in on-line training sessions</li> <li>• A member of the school senior leadership to attend at least 2 of the online training sessions delivered via conference facilities</li> <li>• On-going support provided to facilitating teachers and teaching assistants</li> <li>• 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</li> <li>• Where possible data from the software will be used to assess implementation</li> </ul>

## 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<sup>®</sup> 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 alphabetic 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<sup>®</sup> in Northern Ireland which found effects for blending and non-word reading in 4-6 year old pupils (O'Callaghan et al., 2016). The proposed 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<sup>®</sup> in improving struggling readers' reading skills during Year 2?

The secondary research questions are:

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

## **Design**

The trial will be 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 will comprise of struggling readers within Year 2 in evaluation schools in the academic year 2018-19.

## **Randomisation**

Schools will only be eligible for randomisation after:

- Signing a Memorandum of Understanding (MOU), which will include permission for the evaluation team to access school data generated by the Lexia Reading Core5<sup>®</sup> 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 has been completed;
- All teachers in Year 2 have completed an on-line pre-randomisation survey.

Block randomisation, with variable block sizes, stratified by school will be used. Pupils will be randomly allocated 1:1 to receive either the intervention or teaching as usual. An independent trial statistician at the York Trials Unit will be responsible for generating the allocation schedule, using STATA (StataCorp., 2017). Pupils from each school will be randomised in a single batch to ensure allocation concealment from schools prior to randomisation.

Randomisation will be completed before the end of the Summer Term 2018.

## **Participants**

Schools will be eligible to participate if they:

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

Initial recruitment will focus on schools in the North East and Yorkshire and Humber regions.<sup>1</sup> Schools from outside these areas will be accepted to the trial in groups, providing there is a sufficient number to enable cost-effective data collection. The overall sample of schools will include a higher than average proportion of disadvantaged schools (ie an average of 29% or above EverFSM as defined in the National Pupil Database).

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

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

Pupils will be eligible to participate providing:

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

Class teachers will be asked to provide the names of the half of the Year 1 pupils with the lowest attainment. These children will be 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. Pupils who receive a standard age score (SAS) of 85 or less in any of the three subtests of the WRMT-R/NU (word recognition, decoding and comprehension - corresponding to the subsets named above) will be eligible to participate in the trial. It is felt important that this eligibility is determined independent of the teacher to ensure consistency across participating schools.

### ***Incentives***

Participating schools will receive a two-year licence for the Lexia Reading Core5<sup>®</sup> 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<sup>®</sup> to the Year 2 pupils selected to receive Lexia Reading Core5<sup>®</sup> during the study. Should the school 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***

We propose to recruit 57 schools. This number of schools is considered realistic given the capacity of the delivery team and the additional processes established to ensure compliance. The sample will comprise pupils in Year 2 during the academic year 2018-19. Assuming an average of 56 pupils in the school (28 per class, 2-form entry), we estimate an average of 9 pupils per school will be identified as struggling readers. This is based on administration of a similar assessment, the York Assessment for Reading Comprehension (YARC: Snowling et al., 2011), with similar pupils in a previous study (Tracey et al., 2017) which found that 17% of pupils were struggling readers, as identified by the YARC. If we assume a pre and post-test correlation of 0.6 between the baseline and post-test of the WRMT, then with 80% power the detectable effect size is 0.20 allowing for 10% pupil level attrition (StataCorp. 2017. *Stata Statistical Software: Release 15*. College Station, TX: StataCorp LLC). Given that the Lexia Reading Core5<sup>®</sup> programme is based on a computer which the child works on individually to interact with the program we anticipate contamination risk being low although we will work closely with the developers to explore ways in which this can be monitored.

At the time of writing, 50 schools had been recruited to the trial, with an average FSM of 29.3%. Based on this estimate, we might conservatively expect 3 of the struggling readers per school to be eligible for FSM; therefore, in this subgroup, 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 be eligible for FSM. For example, with an average of 6 FSM pupils per school, the MDES would be approximately 0.26 (*ceteris paribus*). The table below reflects this uncertainty.

		OVERALL	FSM
<b>MDES</b>		0.2	0.2-0.36
<b>Pre-test/ post-test correlations</b>	level 1 (pupil)	0.6	0.6
	level 2 (class)	-	-
	level 3 (school)	-	-
<b>Intracluster correlations (ICCs)</b>	level 2 (class)	N/A	N/A
	level 3 (school)	N/A	N/A
<b>Alpha</b>		0.05	0.05
<b>Power</b>		0.8	0.8
<b>One-sided or two-sided?</b>		two	Two
<b>Average cluster size</b>		9	3-9
<b>Number of schools</b>	Intervention	57	57
	Control	57	57
	<b>Total</b>	57	57
<b>Number of pupils</b>	Intervention	257	86-257
	Control	257	86-257
	<b>Total</b>	514	172-514

### **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 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.<sup>2</sup>

### ***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 will 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.

### ***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.

### ***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

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<sup>2</sup> 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.



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<sup>®</sup> 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 will be 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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 also 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 will be 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 will indicate their participation in the evaluation of Lexia Reading Core5<sup>®</sup>. An information sheet will be 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 will be 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 will be responsible, with Louise Elliott, for the day-to-day management and coordination of the trial, working closely with the programme developers.

#### ***Louise Elliott (Co-Principal Investigator)***

Louise Elliott will be responsible, with Louise Tracey, for the day-to-day management and coordination of the trial, working closely with the programme developers.

**Caroline Fairhurst (Co-Investigator)**

Caroline Fairhurst will undertake the randomisation and the statistical analysis of the trial.

A part-time project support officer will be recruited for the duration of the trial to liaise with schools, upload and monitor the teacher surveys, schedule the assessments and the school observation visits and maintain the project database.

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

**Delivery Team**

Dr Maria Cockerill, Queen’s University Belfast

Maria will be 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 will be responsible for the management and coordination for the trial, working closely with the programme evaluators.

Rob Kay, LexiaUK®

Rob will be responsible for the delivery of the programme licence, training and support to schools during the trial.

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

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

**Risks**

<b>Risk</b>	<b>Preventative measures</b>	<b>Likelihood</b>
Insufficient schools recruited	<ul style="list-style-type: none"> <li>• Emphasise that Lexia Reading Core5® is a promising intervention</li> <li>• Work closely with the delivery team and utilise our combined experience of recruitment</li> <li>• All schools will obtain the software as within-school randomisation proposed</li> </ul>	Low
Attrition	<ul style="list-style-type: none"> <li>• At recruitment all schools will be required to sign a MOU</li> <li>• Implementation and training burden is low</li> <li>• All schools will receive the intervention</li> <li>• Regular newsletter contact throughout the project</li> <li>• Over recruit by 15% to allow for some unavoidable attrition</li> </ul>	Low
High attrition from intervention or poor implementation	In the first year of purchasing the programme schools are provided with a level of enhanced	Low

	support to ensure strong implementation which should mitigate against withdrawal	
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) will have overall responsibility for the project. coordination and communication. They will establish areas of lead based on their current 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 (4 <sup>th</sup> June-14 <sup>th</sup> July)	
		June /July	Rolling randomisation	
2018-2019	Autumn Term 2018	September	Intervention starts for 24 weeks	
	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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