



Evaluation Protocol

MiniLit – Building Better Readers: A literacy program for Year 1 students with low reading ability

15 December 2016

Evaluators

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Human Research Ethics Committee at the Royal Children’s Hospital, Melbourne

- HREC 36301A
- Version 3, 15th November 2016

Statement of compliance

This document is a protocol for a research project. This study will be conducted in compliance with all stipulation of this protocol, the conditions of the ethics committee approval, the NHMRC National Statement on ethical Conduct in Human Research (2007) and the Note for Guidance on Good Clinical Practice (CPMP/ICH-135/95).

Evaluation Summary

Year levels	1, second year of Primary school in NSW
Number of students	Screen = 1200, RCT = 300
Number of schools	20
Design	Efficacy randomised controlled trial
Primary outcome	Reading at 12 months post-randomisation



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Background

Importance of Early Literacy for Later Academic Achievement

Literacy is fundamental for educational and life skills. Literacy ability has been linked to school completion rates, enrolment in further education, occupational income and long-term health outcomes. A key component of literacy is the ability to read, a skill often taught when children start primary school. Learning to read is a complex process that involves the recognition of both graphemes and morphemes, or the constituent parts of words and their meanings. A critical aspect of reading ability, known as decoding (1-3), is a foundational skill that the acquisition of all future learning is founded on. Difficulties with decoding often means that the child has difficulty with, or is unable to, link a particular sound with a particular word in written form. Consequently, the child will be unable to read and derive the meaning of the word and subsequently the text (i.e. comprehension)(2).

If problems with decoding and subsequently reading more generally are not addressed early in a child's educational life they will continue throughout childhood to adulthood. Reading policy sits at the purview of both the federal and state governments due to the large economic impact of literacy ability to both the individual and the society. A country that increases their national reading scores by 1% is expected to see an increase in labour productivity and GDP per capita by 2% (4). Because children from low socio-economic backgrounds are also more likely to have low reading ability during the early years of school, redressing low reading ability may additionally provide a pathway to reducing socio-economic inequities more generally

MiniLit intervention

One intervention, which has early promising findings in addressing literacy deficits during the early years of primary school, is the 'MiniLit' program. This program fits within the Tier 2 segment of the Response to Intervention (RTI) framework for providing support for children with additional learning needs. Broadly, the RTI framework consists of general classroom instruction for all students (Tier 1), specialised, out of classroom, small group interventions for children with additional learning needs (Tier 2), and one-to-one specialised interventions for children who require the greatest support (Tier 3).

Based on the RTI framework, MiniLit targets the bottom 25% of readers in Year 1 through 80 intensive and targeted 1-hour lessons. The intervention focuses on improving children's literacy by targeting 5 key areas; (1) phonemic awareness; (2) phonics; (3) fluency; (4) vocabulary; and (5) comprehension. Lessons are typically delivered over 20 weeks, to groups of four students who come out of the regular class for the lesson. The lessons are delivered by either trained teachers or trained paraprofessionals under teacher supervision. At present, MiniLit is currently delivered in 277 NSW public primary schools. A description of the intervention is shown in the Table 1.



Table 1: Overview of the MiniLit intervention

Overview	
Who	MiniLit program targets the bottom 25% of readers in Year 1
How	The MiniLit program is delivered through a student withdrawal from class.
Rationale of MiniLit and its elements	The MiniLit program is a Tier 2 intervention which aims to increase reading ability of the bottom 25% of readers in Year 1 through 80 intensive 1-hour lessons. The key skills targeted by MiniLit include (i) phonemic awareness; (ii) phonics; (iii) fluency; (iv) vocabulary; and (v) comprehension.
Intervention materials and procedures	<p>MiniLit comprises individual student learning resources for literacy delivered through paper-based materials. The program comprises 80 structured lessons that take around 20 weeks to complete, with four lessons of up to 60 minutes per week. The program includes regular measures to monitor the progress of the students. The intervention is offered in groups, with a maximum of 4 students in each group.</p> <p>The MiniLit program is divided into two levels of forty lessons each that students complete according to a placement test included in the program. As a consequence, some students will not complete all 80 lessons depending on where they place in the program.</p> <p>Level 1: Teaching the basics of letter/sound knowledge and decoding skills for Consonant-Vowel-Consonant (CVC) words</p> <p>Level 2: Extending word attack knowledge by teaching commonly used digraphs and longer words</p> <p>Training to facilitate the MiniLit program requires a two-day MiniLit Professional Development Workshop. During the workshop, either qualified teachers or paraprofessionals will receive Professional Development in the area of effective reading instruction by MiniLit Course Instructors. It is based on a combination of theory, live demonstration videos, and small group role-play.</p>

Current evidence for MiniLit

A number of studies have examined the impact of the MiniLit program on the reading ability of students participating in the program. Although these previous studies have shown promising benefits in terms of effect sizes on children’s reading ($d = 1.1$ to 1.8), results are derived from differences between pre- and post-training scores. In addition, there has been limited efficacy and effectiveness studies that compare children who complete MiniLit to those who receive “business as usual” classroom teaching or alternative RTI Tier 2 interventions. The current evidence for MiniLit consists of studies performed by the developer, including a small within-school, wait-list randomised controlled trial of the MiniLit program demonstrating its positive impact (5-8). Therefore, these promising findings now need to be evaluated in a large scale RCT to determine the impact of the program on student

outcomes when scaled to system-level implementation. In addition, it is important to evaluate the process indicators that can predict the outcomes of the intervention, as well as the implementation cost-benefit.

Research questions

The overarching question of this project is whether the MiniLit intervention, offered to Year 1 students identified as being in the bottom 25% of readers, improves student reading and literacy outcomes 12 months post-randomisation?

Primary objective

The primary research aim of this project is:

1. To determine, for Year 1 students in the bottom 25% of readers, whether students who receive MiniLit have better reading outcomes at 12 months post-randomisation, compared to those who have usual classroom teaching

We therefore hypothesise that students who receive the MiniLit intervention will have better mean reading ability scores on the Australian Edition of the York Assessment of Reading for Comprehension - Passage Reading (YARC – PR) at 12 months post-randomisation, compared to students who receive ‘business as usual’.

Secondary objectives

The secondary aims are:

1. To determine student reading outcomes in both intervention and control groups 6 months (short term) post-randomisation.
2. To determine the proportion of students with ‘low reading ability’ in both intervention and control (‘business as usual’) groups at 6 and 12 months post-randomisation
3. To determine the implementation enablers and barriers that are predictive of program success and sustainability (see process evaluation below).
4. To determine the cost per student, and cost-effectiveness of the intervention (see economic evaluation below).

Ethics

The project will have primary ethics approval from the Human Research Ethics Committee at the Royal Children’s Hospital, Melbourne. It will also have ethics approval from the Melbourne Graduate School of Education at the University of Melbourne and research approval from the NSW Department of Education.

Registration

The project will be registered on the Australian New Zealand Clinical Trials Registry (www.anzctr.org.au/).

Funding

This study is being funded by Evidence for Learning, which is non-for-profit as part of Social Ventures Australia.

Roles and responsibilities

The study is a partnership between the Murdoch Children's Research Institute and Melbourne Graduate School of Education, with the administrative base to be MCRI. The NSW Department of Education will provide in-kind support to conduct the research, such as in school recruitment. MiniLit will provide in-kind support to train staff members at participating schools to deliver the intervention and providing required intervention materials.

All findings from this study will be reported independently of NSW Department of Education and MiniLit.

Efficacy randomised control trial

Design

This is an efficacy stage randomised controlled trial of the MiniLit intervention, nested within a cross-sectional screening project. Results will be reported according to CONSORT guidelines and the extension report of non-pharmacologic interventions.

School recruitment

All primary schools within NSW will be eligible to participate if they meet the following criteria:

- Year 1 student population of over 70 students
- Be located within 50kms of the metropolitan centre of Sydney, Newcastle or Wollongong.
- Have a socio-economic status in the top two quartiles (i.e. most disadvantaged locations) This is determined by the NSW Department of Education's "Family Occupation and Education Index (FOEI). This index takes into account the parents' education level and occupation for each student.

(www.cese.nsw.gov.au/publications-filter/family-occupation-and-education-index-foei-2013)

Based on data from 2016, there will be 134 primary schools who meet these criteria and therefore will be invited via email by the NSW Department of Education to provide an Expression of Interest (EOI) to participate in the project. All schools will be provided with the School Information Sheet to outline the project's aims, rationale and expectations for participating schools. To express their interest, schools will complete a signed School Consent Form and return it to the research team.

From the EOI list, an independent statistician not involved in the project will select a total of 20 schools using a randomisation sequence stratified by SES category. Schools will be informed of their selection via email from the project team and the NSW Department of Education.

Child recruitment using opt-out process

Student recruitment for the project will be conducted using an informed opt-out process, as approved by the NSW Department of Education. The opt-out process will cover the initial screening for low reading ability and for children with a readability in the bottom 25th percentile (see below), it will also cover the randomization and data collection associated with the main randomized controlled trial.

Three weeks before the screening process, the students' school will provide parents of all Year 1 students who meet our eligibility criteria with the Parent Information Statement (PIS).

This includes information about the project's aims, time requirements and expectations. Parents will be able to contact the research team via a provided phone number or email if they have any concerns or wish their child not to participate. They will also be provided information about the project's website.

To increase the likelihood that parents receive the information before the study commences, a notification will be placed in the school newsletter to inform parents of Year 1 students that their school is involved in the study and that the PIS has been sent home with all Year 1 students. Teachers will also be encouraged to inform parents about the PIS in their general interactions with families. In addition, all parents will be sent a second parent information statement 2 weeks after the initial letter is sent home. The PIS will also be translated into the five most common languages other than English at the participating schools to increase its accessibility to parents of Year 1 students. The translated documents will be provided by the NSW Department of Education once schools have been selected to participate in the project to ensure languages are specific to this project population. Teachers will be able to provide translated versions of the PIS to families they believe require the translated version to understand the requirements of the study.

Exclusion criteria

Students will be excluded from the screening and trial stage if they have:

- severe disabilities (e.g. cerebral palsy, vision/hearing impairments) that do not allow them to participate in the intervention.
- students with Language Background Other Than English (LBOTE) whose English Language abilities does not allow them to participate in the intervention. Although this will affect the generalisability of the findings to such students, the aim of the project is to establish efficacy and the intervention can only be delivered in English.

The classroom teacher will be responsible for determining which children are excluded from the study based on the above criteria. Teachers are often responsible for identifying children who may not be suitable to enroll in certain support services that schools offer. Teachers will be asked to keep a record of any children they have excluded from their class, and which exclusion criteria/s the child met. This will allow the research team to track the proportion of children who are being excluded.

Screening for low reading ability

All Students in Year 1 at a participating school will be screened for low reading ability using the Australian Edition of the York Assessment of Reading for Comprehension – Passage Reading (YARC – PR). The initial assessments will be conducted by the classroom teacher in one-to-one testing conditions with each child. The test takes about 10 minutes per child to complete. The teacher will not be trained to score the assessments or convert the raw scores to ability or standardized scores.

Teachers will provide the research team with the completed assessment sheets. The research team will score each assessment to create a raw score, which will be converted to standardized scores using the scoring program provided with the measure. Students identified as being in the bottom 25th centile of readers according to the measure's published standardised data will be eligible for randomisation. Given that there are three subscales available, children will be eligible for the study if they are in the bottom 25th centile on at least two subscales. This definition aligns with the recommendations of the MiniLit developers as to how the target population of low readers is identified.

All caregivers of children who complete the screening assessment will be provided with a summary of their child's reading ability. Parents will be able to contact the research team to discuss any concerns they may have about their child's assessment scores or they may also wish to discuss them with the classroom teacher. Teachers commonly speak to parents about their child's academic progress and are comfortable explaining findings and placing them in context of the child's overall academic performance.

Randomisation

Eligible students within each school will be individually randomised to the 'MiniLit' (intervention) or 'business as usual' (control) group, stratified by school. No student-level variables will be included in the randomisation protocol. Contamination will be reduced by control students not being identified to teachers or being able to access the MiniLit program. The randomisation will be conducted by a statistician who is independent of the research team. The research team will notify parents by mail of their child's results post-randomisation, including group allocation and the remaining steps of the project.

MiniLit intervention

Children randomised to the intervention group will receive the MiniLit program.

A nominated staff member/s at each school will attend a two-day training to enable them to be able to deliver the intervention. The training will be delivered by MiniLit, and will cover the rationale for the intervention, the reading domains in which the intervention is targeting, how to deliver the content during the MiniLit lessons as well as how to tailor the intervention to the child's specific needs. The training will occur in Term 1 2017 and the staff members nominated to be trained to deliver the intervention will be determined by school leadership. During Term 2 and 3 in 2017, children receiving the program will be removed from class for 1 hour per day. Working with the trained MiniLit teacher, groups of up to 4 children will complete each MiniLit lesson in an appropriate quiet area in the school. If there are more than 4 children at a school randomized to the MiniLit group, two groups will be used and children will be grouped based on their initial reading ability. This practice is also part of the standard MiniLit intervention protocol.

Blinding

Allocation of individual students to MiniLit versus Business as Usual groups will be concealed from members of the research team involved in outcome assessments for the duration of the project. Because school staff, teachers and students will not be blinded, they will be asked not to disclose student randomisation status to the research staff when the research staff conduct assessments at their schools. However, in cases of disclosure, this information will be recorded in the project database and 'unblinding' will be examined as a potential confounding variable in the outcome analyses.

Outcome measures

At 6 and 12 months post-randomisation, all children in the RCT will complete a 30-minute assessment of their reading and literacy ability. All assessments will be conducted with a trained research assistant, blinded to the child's intervention status. The measures used in the assessments are described in detail below.

The primary outcome will be measured using the York Assessment of Reading for Comprehension – Passage Reading (YARC – PR) at 6 months (secondary outcome) and 12 months (primary outcome) post-randomisation.

The YARC – PR is an individually administered paper-based assessment of children's reading attainment from age five to 11. The YARC – PR provides 3 subtest scores: (i) Accuracy, (ii) Reading Rate and (iii) Comprehension. The test provides raw scores for each subtest in the early reading component which can be converted to a standard score (Mean = 100, Standard Deviation = 15), percentile rank and age equivalents.

The measure assesses the student using one of two parallel tests of graded passages (A and B) with 8 accompanying comprehension questions. The assessment is conducted individually by a trained research assistant and takes about 10 minutes per student.

For this project, students will be eligible for the trial if they have a standard score of 90 or below, which equates to the bottom 25% percentile on at least two of the three subtests. This cut point is in line with the design of the original design of the intervention to target low readers in the bottom 25% percentile. For the primary outcomes, differences between groups will be measured using standard scores. The YARC – PR standard scores have been previously used to identify low progress readers in research and clinical practice. This cut point will also be used at 6 and 12 months post-randomisation to determine the proportion of students who have “low reading ability” in the intervention versus control groups.

In addition, the secondary outcome measures will be:

- **Wheldall Assessment of Reading Lists (WARL)** is a tool to identify children’s reading ability. This assessment takes approximately 5 minutes per child and yields a mean raw score as a count of how many words correctly identified in 1 minute, averaged over three separate lists.
- The **YARC - Early Reading (YARC – Early)** assesses phonological skills, alphabetic knowledge and individual word reading and yields four subtests, which are (i) Letter Sound Knowledge, (ii) Early Word Recognition, (iii) Sound Deletion and (iii) Sound Isolation. The measure is individually administered and takes approximately 15 minutes to complete per child. The test provides raw scores for each subtest in the early reading component which can be converted to a standard score ($m=100$, $sd=15$), percentile rank and age equivalents. A phoneme awareness composite can also be calculated by the combining of scores on the Sound Isolation and Sound Deletion subtests.
- **Children's Test of Nonword Repetition (CN REP)** assesses aspects of phonological memory and working memory that are important for language ability and predictive of children’s reading ability. The measure takes approximately 3 minutes to administer per child and has been standardised and validated for children between 4 and 8 years who are attending mainstream schools (mean 100, SD 15).

The time points for administering each measure are shown in Table 2 below.

Table 2: Project measures

Measure	Construct	Method	Timepoint		
			Baseline	6-mths ¹	12-mths ¹
York Assessment of Reading for Comprehension – Passage Reading	Reading	Child Assessment	♦ ²	♦	♦
Wheldall Assessment of Reading Lists	Reading	D	♦	♦	♦
York Assessment of Reading for Comprehension – Early Reading	Reading	D	♦	♦	♦
Children's Test of Nonword Repetition	Phonological memory	D	♦	♦	♦

1 Post-randomisation, 2 Conducted by classroom teacher

Data collection

Data collection will involve face-to-face, direct child assessments.

For face-to-face assessments, a trained research assistant will conduct the assessments with the student during school hours in a room allocated by the school. All requirements for assessment for child safety as required by the NSW Department of Education will be adhered to.

A fundamental principle of RCTs is that all outcome data are collected by research staff who are fully blind to whether students are in the control or intervention group in the study. This will reduce intentional and unintentional bias that can occur in the way that a research assistant conducts the assessments. School staff and teachers will be asked to not disclose information about any student's randomisation status during this assessment. However, those that do disclose information will be recorded in the project database and this 'unblinding' will be examined as a potential confounding variable in the outcome analyses.

Sample size calculations

The final sample size was based on the capacity of the MiniLit developers considering training and resource requirements for this efficacy project. The participant flow is shown in the Figure 1.

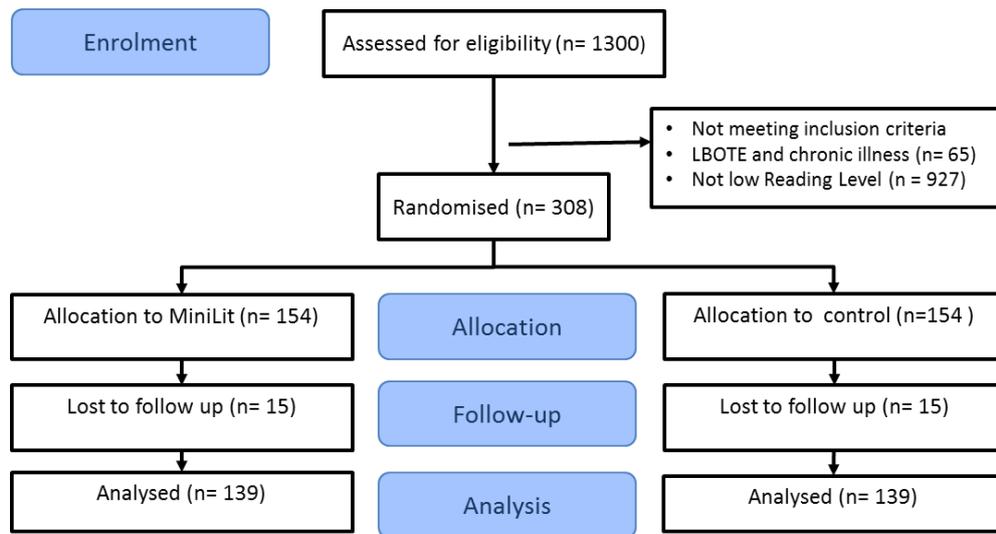


Figure 1: Participant flow chart

Overall, 20 schools will be involved in this project. Assuming an average of 65 students per school, 1300 students will be enrolled across all participating schools. We estimate that 5% of students (N = 65) will not be eligible for the project based on our inclusion criteria. It is estimated that 25% of students will be identified as 'low readers' (N = 308) and thus eligible for the project. With an attrition rate of 10% over the 1 year of the project, a final sample of 278 students (N = 139 per group) will have analysable data.

Based on an intention-to-treat analysis, the final sample size will be able to detect an effect size of 0.34 in scores on the primary outcome, with 80% power at a 5% level of significance.

This sample size calculation does not take into account the effect of clustering for SES category at the school level (which will decrease power and increase detectable effect size) or the correlation of the pre- and post-test scores (which will increase power and decrease detectable effect size).

Analysis plan

The baseline characteristics of the participants and schools will be summarised by group. Categorical variables will be presented as frequency and proportion values in each category. Continuous variables will be presented by means and standard deviations (SDs) for unskewed data, medians and interquartile ranges for skewed data, and ranges.

Data analysis for the project will be performed by a statistician in CEBU at MCRI.

Statistical analysis will follow standard methods for randomised controlled trials. The primary analysis will be by intention-to-treat and will include all randomised participants where outcome data are available.

The primary outcome is student reading outcomes at 12 months post-randomisation, as measured by the YARC – PR. The primary analysis will use a multivariate linear regression to examine the YARC – PR score (continuous) at 12 months post-randomisation for the intervention students, compared to students in the control group. Both unadjusted and adjusted analyses will be conducted. For adjusted analyses, two models will be conducted. The first will account for baseline assessment scores whilst the second will also include student age, gender and family SES as a priori confounders. Family SES will be determined using the NSW Department of Education’s Student Educational Advantage score, which is derived from parent education level and occupation. This will be provided by the NSW Department of Education. Clustering of students within schools and MiniLit groups will be accounted for in the models using regression techniques that respect these structures. Findings between groups will be presented as mean differences with 95% Confidence Intervals, p-values and Hedge’s g effect sizes.

For secondary outcomes, continuous variables will be analysed using linear regression and categorical data will use logistic regression. Unadjusted and adjusting findings will be presented according to the models described in the primary outcome analyses. Given the pragmatic sample size, sub-group analyses will only be conducted if the sub-group has over 40 students per group (25% of the final sample).

In addition to the intention-to-treat analyses, all analyses will be repeated to enable findings to be compared to those from a “per protocol” analysis. The “per protocol” for the intervention group will be defined as students who have attended 90% of their MiniLit lessons during Term 2 and 3. For the control students, per protocol will be defined as not receiving any MiniLit sessions. This comparison will be included as part of the implementation and process evaluation described in the next section.

The frequency and patterns of missing data will be examined and sensitivity analyses will be performed comparing the results of analyses restricted to students with complete data and analyses where missing data are imputed using a conservative approach.

Implementation and process evaluation

The implementation and process evaluation will explore both the theory of change related to the MiniLit program and dimensions of implementation including fidelity, dosage, quality, differentiation, and monitoring of control/comparison conditions that may influence the theory of change. The implementation and process evaluation will seek to understand barriers and enablers of the MiniLit implementation process that may impact the effectiveness of the program as determined by the results of the RCT. There are two phases to the implementation and process evaluation:

Phase 1 – case studies of ‘exemplar’ MiniLit schools

Schools participating in Phase 1 will be current schools who are implementing MiniLit and who have been identified as being ‘exemplar’ schools in terms of their implementation and student outcomes, as determined by the MiniLit developers. Recruiting schools for this phase will involve an EOI process that will be coordinated by the MiniLit developers. A program developer workshop and case studies will provide comprehensive information regarding the program and its implementation in these schools. These activities will inform Phase 2.

Phase 2 – RCT implementation and process evaluation

Phase 2 will involve all schools participating in the main intervention component of the project. An implementation and process evaluation will be conducted, which will involve the collection of data to: (a) determine fidelity and other dimensions; and (b) support the validation of the proposed theory of change.

Methodology and instrumentation

The implementation and process evaluation will take a mixed methods approach, using both existing program data collection methods and newly developed tools. These tools will be developed following the process evaluation workshop with program developers in late 2016 and using information gathered from case studies of existing MiniLit schools in early 2017.

These activities will inform the overall approach to refining the process evaluation. The protocol will be updated on April 2017 to reflect these refinements.

Process evaluation workshop

This will involve further development of the MiniLit logic model and to deepen the evaluators understanding of the program components.

Case studies of existing MiniLit schools

Before the intervention component of the project commences, the evaluation will examine 2-3 MiniLit schools considered ‘exemplar’ from an implementation perspective. These schools will be randomly selected from a larger group of MiniLit schools nominated for feasibility and opportunity by the program developers and recruited via an EOI process. Data collection methods will include lesson observations and interviews with key personnel.

Theory of change

This component of the process considers the specific mechanisms (or dimensions of implementation) in the intervention that initiate change in the outcome measures: student reading ability. The intention behind identifying the dimensions of implementation is to validate a theory of change for the MiniLit program based on data gathered in the process

evaluation, while also maintaining an open-ended approach so as to not overlook any key insights that might be gained from this aspect of the overall evaluation. A preliminary four step theory of change is shown in Figure 2 below.

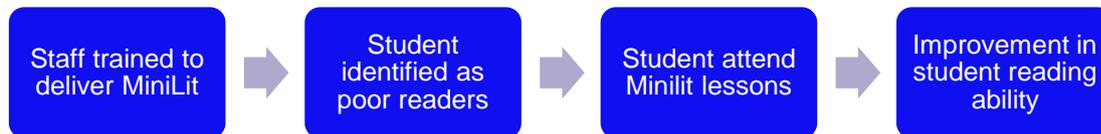


Figure 2: Preliminary four step theory of change

A more detailed logic model will be established with program developers to generate evidence indicators of the dimensions of implementation that influence the main outcome measure (student reading ability). Measures will then be developed with the intent to build a structural model that demonstrates the relationships between the primary outcome, YARK – PR, and dimensions of implementation. Research questions to be considered in this aspect of the evaluation include:

- Did the MiniLit program activities lead to improvements in students' reading ability?
- Did these improvements (if and where they occurred) impact student reading ability as measured by main outcome measures?
- What influence did dimensions of implementation have on program outcomes?

Dimensions of implementation

Fidelity will take a micro view as per EEF guidelines¹ with issues of dosage and quality considered separately. In this project, fidelity will consider procedural adherence to the structure and sequence of activities outlined by MiniLit developers and seek to determine whether adaptations to implementation have occurred. Research questions for this aspect of the evaluation are:

- Did the activities prescribed by MiniLit occur as they were supposed to?
 - Staff delivering the program were trained effectively and as intended by the program
 - Students identified appropriately
 - Lessons occurred with planned frequency in correct content

Where adaptations to these activities and processes occurred, to what extent were they surface (minor) or deep (more substantial i.e. removal of core components)? Specific parameters of surface and deep adaptation will be determined with the MiniLit program developers at the process evaluation workshop.

1

https://educationendowmentfoundation.org.uk/public/files/Evaluation/Setting_up_an_Evaluation/IPE_Guidance_Final.pdf

Data to answer these questions will be collected as implementation data from intervention schools, which will allow an overall fidelity score to be calculated for each school. In addition, an implementation survey for schools post-intervention will investigate any adaptations to implementation.

Dosage: will consider the amount of the intervention implemented both in terms of completeness (dosage delivered) and exposure (dosage received). These two aspects are important to consider as some students may not attend all available MiniLit sessions (for instance due to illness), and will therefore be exposed to a lower number of sessions than the total number of sessions delivered, and the received dosage is different to the delivered dosage. Data representing these measures (such as records of lessons delivered and attendance records of students) will be collected from participating schools.

Quality of implementation will focus on staff preparedness to implement and teach the MiniLit program and the quality of session delivery during implementation. Data to determine quality will include a survey completed by staff following training regarding perceptions of preparedness and self-efficacy to teach MiniLit. Lesson observations will collect data regarding the quality of session delivery against a rubric designed in collaboration with the MiniLit program developers.

Differentiation will determine the extent to which the MiniLit intervention can be distinguished from existing practice within the intervention schools. This will be evidenced via interviews with key school personnel, teachers and school leaders to understand whether other reading interventions are in place and the structure of normal literacy lessons.

Monitoring of control/comparison group will occur to assist in establishing the counterfactual. Research questions relevant to this component include:

- What was usual teaching/learning? (E.g. are other interventions related to reading being implemented?)

Formative evaluation

The evaluation will also determine aspects of the MiniLit program that could be improved, changes to staff roles involved in the program and staff perspectives on the benefits of MiniLit for students. Research questions in this aspect of the evaluation include:

- What aspects of MiniLit could be improved?
- Does MiniLit assist all students? If not, who benefits more from the program?
- What are the changes to the role of reading support staff in the school?
- How do MiniLit staff members' perspectives of their teaching self-efficacy change as a result of the program?
- Do staff believe the program has benefited students in general?

Economic analysis

The economic evaluation of the intervention will be a two-stage analysis. We will use cost-consequences analysis as a first step to compare any incremental costs of the MiniLit intervention (costs accrued in the intervention group, from resource use over the period of follow-up, compared to costs accrued in the control group) to all primary and secondary outcomes, expressed in their natural units of measurement. We will then conduct a cost-effectiveness analysis to compare incremental costs to differences in scores on the YARC (the primary outcome measure for reading ability).

Measured resource use will be valued using existing unit cost estimates (e.g. education department salary scales, etc.). Uncertainty in cost and outcome data and the sensitivity of economic evaluation results to the chosen methods of evaluation will be tested by extensive sensitivity analyses.



Timeline

Date	Activity	Responsible
Nov 2016	Ethics approval from Human Research Ethics Committee at The Royal Children's Hospital	MCRI / MGSE
Nov 2016	Research approval from the NSW Department of Education	MCRI / MGSE
Dec 2016	Expression of Interest for school participation and selection of participating schools for Phase 1 of the process evaluation	MGSE
Dec 2016	Expression of Interest for school participation and selection of participating schools for the efficacy RCT	DET / MCRI
Jan 2017	Send implied consent form to all students at participating schools	DET / MCRI
Feb to Mar 2017 (School Term 1)	Screening of reading ability of all Year 1 students at participating schools who have not opted out of project	MCRI
Apr 2017	Teachers and paraprofessionals to be trained to be 'MiniLit teachers'	MiniLit / DET
Apr 2017 (Start Term 2)	Commence intervention	MiniLit / DET
Sep 2017 (End Term 3)	End of MiniLit Intervention	MiniLit / DET
Oct 2017 (Start Term 4)	Complete 6 month post-randomisation assessments	MCRI
Apr 2018	Complete 12 month post-randomisation assessments	MCRI
May to Jun 2018	Data cleaning and analysis	MCRI / MGSE
Sep 2018	Report submitted to Social Ventures Australia and NSW Department of Education	MCRI / MGSE

Subject withdrawal

Reasons for withdrawal - student

A student will be withdrawn from the study if parents actively chooses to opt-out of the study. This may be communicated either directly to the research team, or parents can also communicate this via the teacher. If communicated via the classroom teacher, the research team will follow up with the parent to confirm. In both instances, the parent will be asked to complete the opt-out form to confirm withdrawal from the study. This form will be provided to all parents at study commencement, and a copy will also be made available upon request at any timepoint during the study. Parents will be able to withdrawal their child at any point in the study and a reason for withdrawal is not a requirement of opting-out.

Handling of withdrawn data or loss to follow-up - student

In the event that a parent opt-outs of the study, the student will cease to undergo any further scheduled assessments as part of the study. We will confirm with the parent whether they wish to have any data already collected to be used and analysed, or to have all collected data removed as if they were never part of the study. The option to have all collected data to be destroyed and not used as part of the study aligns with the National Statement for research studies using an opt-out consent.

Dissemination of finding

The findings from this study will be presented in a final report to Evidence For Learning in September 2018. All findings will be presented at a group level, and individual child, schools and teachers will not be identified. In addition, findings about specific schools and teachers will also not be presented in the report.

In addition to the report, we will also disseminate our findings in peer-review publications and presentations at national and international conferences. All participating schools and families will also be provided with a 1-page newsletter outlining the study's main findings.

Unforeseen adverse event reporting

We do not anticipate any serious adverse events to occur during this project.

Parents, teachers and schools will be able to contact the research team at any stage during the study if they have any concerns. Contact details for the research team will be clearly listed on all study materials as well as on the study's website.

MiniLit staff members will be able to report to the research team if they have any concerns about individual students involved in the intervention. In addition, research assistants will note if any students experience distress whilst conducting any face-to-face outcome assessments. Research assistants will also receive training on how to manage these

situations as part of their training to conduct outcome assessments in schools. Any specific protocols that are required by the NSW Department of Education will be adhered to.

Any concerns raised by MiniLit teachers and research assistants about an unforeseen adverse event will be discussed by the investigator team at the next scheduled team meeting. These meetings are scheduled to occur twice a month for the duration of the project. Any events will also be included in the project's log book.

Where necessary, concerns will also be communicated to the Human Research Ethics Committee at the Royal Children's Hospital and the NSW Department of Education to ensure they are appropriately addressed.

Administration processes

Data storage

All schools, teachers and students will be given unique numerical identifiers (an ID code) for use throughout the project. A single, online electronic database (RedCap) will record all participant details. It will be hosted by the MCRI server, because it is secure and meets ethical confidentiality requirements. Researchers will have different levels of access to the password protected database and randomisation status of Schools. Researchers will be able to access the details of participants where necessary but not their randomisation status unless necessary to that investigator; and managerial staff will be able to access all levels as required. All participant questionnaire data will be identified by ID code only and be stored in the secure electronic database.

Any written materials will be immediately scanned and also saved with the student's or teacher's record on the electronic database. Paper versions of assessments or forms will be stored in a locked filing cabinet at the Royal Children's Hospital and available only to the relevant research assistant. Aside from the initial consents (NSW DoE), all further data collection material will be identified by unique number only with no identifying information available.

Only project staff directly involved in the analysis of the data will have access to the hardcopy data records and the electronic database. The database linking the participants' identity to their ID code will be maintained electronically on a password-protected file.

Project record retention

All project materials will be stored on the password-protected electronic database or in locked cabinets for until the youngest participant is 25-years-old, e.g. 2039. After that time, hardcopy materials will be destroyed by shredding, and any password protected electronic archives will be permanently deleted.

Confidentiality

Participant confidentiality is strictly held in trust by the participating investigators, research staff, and the sponsoring institution and their agents, and is extended to cover school, teacher, student and parent information relating to the project. The project protocol, documentation, data and all other information generated will be held in strict confidence. No information concerning the project or the data will be released to any unauthorized third party, without prior written approval of the sponsoring institution. The HRECs of the sponsoring institution may inspect all documents and records required to be maintained by the Investigator. All evaluation forms, reports and other records that leave the site will be identified only by the child participant ID Number to maintain subject confidentiality.

Protocol modification

This project will be conducted in compliance with the current version of the protocol. Any change to the protocol document or Informed Consent Form that affects the scientific intent, project design, participant safety, or may affect a participants' willingness to continue participation in the project is considered an amendment, and therefore will be written and filed as an amendment to this protocol and/or informed consent form.

Protocol deviations

All protocol deviations must be recorded in the child record on the secure database by the Research Project Manager. Deviations must also be reported to the CIs. Protocol deviations will be assessed for significance by the Chief Investigators. Those deviations deemed to have a potential impact on the integrity of the project results, participant safety or the ethical acceptability of the trial will be reported to the HREC during the course of the project from 2016-18.

Personnel

Dr Jon Quach

Will take overall responsibility for this project. He is a leading researcher in the area of developing and trialing scalable interventions within existing school systems. He has extensive doctoral and postdoctoral experience in school-based randomised intervention trials, having taken a lead role in over 10 pilot, efficacy and effectiveness trials. The potential benefits of each intervention were examined for (i) feasibility and acceptability, to guide intervention development, (ii) effect sizes, to understand potential benefits and (ii) translational effectiveness, to examine population-level benefits when incorporated into current practice and delivery systems.

Professor Sharon Goldfeld

Will lead the randomised control trial. She is a paediatrician, public health physician, Associate Director at CCCH and Co-Group leader of Child Health Policy, Equity and

Translation at MRCI. She has a decade of experience in state government as a senior policymaker in health and education including Principal Medical Advisor in the Victorian Department of Education. She led the national effort for two of the largest child health data contributions in Australia, both of which have ongoing utility and impact: Children's Headline Indicators (CHI) (AIHW) and the AEDI (now Census) (Australian Government Department of Education). Her complementary and synergistic ARC, NHMRC, government and philanthropy funded research program (\$18 million) brings together a number of secondary analysis studies and intervention randomised controlled trials in health and education that highlight and address issues of equity, particularly those most relevant to the child health and education policy environments.

Associate Professor Janet Clinton

Will lead the process evaluation of this proposal. She is the Director of the CPE and Director of the International Teacher Education Effectiveness Research Hub, at the MGSE. She has wide national and international experience as an evaluator, psychologist, and educator, and has an extensive publication record. Overall, she has led over 85 national and international evaluation projects. Her evaluation work has focused on development of teacher evaluation protocols, as well as using evaluation as a vehicle for change management and building capacity through extensive engagement with key stakeholders.

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