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Getting it Right from the Start (GIRFTS): protocol for a stepped-wedge cluster randomised controlled trial of a school-based framework to improve children's oral language and reading outcomes

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ABSTRACT

Introduction Strong oral language and reading skills are important for child development. The response to intervention (RTI) framework supports schools to apply evidence-based practices and interventions to proactively meet the learning needs of all students and identify and support students at risk of learning difficulties. Getting it Right from the Start (GIRFTS) aims to implement a codesigned RTI framework in the first 2 years of formal schooling (foundation and grade 1) to improve oral language and reading skills. GIRFTS includes an implementation evaluation.

Methods and analysis GIRFTS is a stepped-wedge cluster randomised trial conducted in Victoria, Australia, over 3 years. Clusters are primary schools. The intervention is to implement tiers 1 and 2 of the RTI framework into foundation and grade 1 according to RTI principles. The primary outcome is reading comprehension by the start of grade 2. Secondary outcomes include listening comprehension, word and non-word reading and phonological awareness. An implementation evaluation will also be conducted with the study to understand schools' RTI implementation process and enablers and barriers to implementation. Strategies used by schools to overcome implementation challenges will also be investigated.

Ethics and dissemination This trial was approved by the Royal Children's Hospital Human Research Ethics Committee (HREC/58832/RCHM-2019). Investigators will communicate the results to stakeholders, collaborators and participating schools and teachers through presentations and publications.

Trial registration numbers ISRCTN91164066, ACTRN12622000146796.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Poor oral language and reading ability are associated with negative physical and mental health in adults.

WHAT THIS STUDY ADDS

⇒ We anticipate that this study will demonstrate that implementation of a response to intervention framework supported by an implementation support partner can improve oral language and reading skills in early primary school children.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ This study can potentially change educational instruction, policies and practice by demonstrating a systematic and effective approach through which oral language and reading in young students can be improved across the social gradient.

INTRODUCTION

Education is a social determinant of health.[1 2] Poorer health outcomes—such as disease prevalence and mental health—are generally observed in populations of lower education whereas better outcomes are observed in more educated populations.[3–5] This inequality is not resolved with age or by location[6] and can have a generational impact.[7–9] To receive the advantages offered by education, children need the skills that enable learning. This includes developing oral language and reading skills which then become the main mechanism for further study.[10] Poor oral language skills, which precede the development of literacy, have been observed more frequently in young offenders.[11] Although not causal, poor literacy skills in adults have been linked to poorer health, including diseases such as diabetes, hypertension, HIV infection, prostate cancer, depression and other emotional conditions, even after variables

such as age and sex have been controlled.[12–15] Certainly, difficulties in language and literacy represent a significant determinant of later health and learning outcomes.

There is growing support for addressing early oral language and reading development through a public health lens of intervention and prevention because of its widespread and inequitable impact.[16–19] Prevention and early intervention efforts targeting oral language and literacy skills can yield high economic impact, particularly for disadvantaged children,[20] placing less burden on education and health systems later in life. Importantly, a public health approach could apply the concept of 'proportionate universalism', whereby addressing oral language and literacy difficulties is done through a systems lens that enables the intensity of support to be tailored to the specific needs of children.[21 22] One such platform that enables population-level intervention is schools. This is due to their near-universal reach and ability to provide ongoing support over an extended period.

An education framework which has been proposed to be important for improving student oral language and literacy outcomes via a concurrent-tiered approach similar to proportionate universalism is the response to intervention (RTI) framework. RTI is commonly described as three tiers, offering increasing levels of support.[23 24] Tier 1 represents high-quality evidence-based whole-of-classroom instruction provided to all students. Tier 2 is more intensive teaching support, often provided in small groups targeting specific skills. Tier 3 is even more intensified support in a one-on-one format. The principles that drive RTI and make it a dynamic and responsive framework to improve student outcomes are: (a) early identification of students needing additional support through screening; (b) student data analysis informing the selection of appropriate interventions; (c) multitiered supports dependent on student needs and (d) progress monitoring to measure impact.[23 24] When implemented with fidelity, RTI improves student outcomes.[25] Reading difficulties can be reduced when high-quality whole-of-class teaching is supplemented with targeted small-group interventions for at-risk learners.[26]

This research protocol is for the Getting it Right from the Start (GIRFTS) study, a stepped-wedge cluster randomised controlled trial with an embedded implementation evaluation. The project aims to:

1. Determine the impact of a codesigned whole-of-class (tier 1) and small-group (tier 2) intervention approach, compared with 'business as usual', in the first 2 years of school on students' oral language and reading outcomes.
2. Evaluate implementation process including enablers and barriers and its relationship with student outcomes.

METHOD AND ANALYSIS

Trial design

GIRFTS is a stepped-wedge cluster randomised controlled trial, where clusters are defined as schools, which involves an initial period where no clusters (schools) are exposed to the intervention, followed by regular intervals where groups of clusters (defined as a cohort) transition from control to intervention.[27] This process continues until all schools have been exposed to the intervention. Specifically, all schools in the study are in the control condition, that is, business as usual, during the school year 2021 (period 0). Then, one cohort (comprising nine schools) switches to the intervention at the beginning of 2022 (period 1) while the other cohort continues with business as usual for the whole school year. At the beginning of the school year 2023, the other cohort also switches to the intervention, while the first cohort continues delivering the intervention for another year (period 2). Hence, the study design consists of three periods and two cohorts and each period is one Australian school year (end January–December). Schools will be randomised into one of two cohorts by an independent researcher (see table 1).

SETTING

This trial will be conducted in Victoria, Australia, in the first 2 years of formal schooling (foundation and grade 1) in participating schools. Schools will be sourced from the Victorian Department of Education (DE) and the Melbourne Archdiocese Catholic Schools (MACS). Schools from DE North-East Victoria Region, DE North-West Victoria Region and MACS that meet the following criteria will be eligible, as they represent schools in more socioeconomically disadvantaged areas that are more

Table 1 Trial design

Cohort	School	Period 0 (2021)	Period 1 (2022)	Period 2 (2023)	2024
1	No. 1–9		★	●	■
2	No. 10–18		★	●	■

The trial design consists of two cohorts with nine schools each and three periods of one school year duration (four terms, 9–11 weeks per term). Control periods are unshaded, intervention periods are shaded in grey. Data collection for each period occurs at the start of the year immediately following that period. Therefore, data collection to reflect period 0 occurs at ★. Data collection to reflect period 1 occurs at ●. Data collection to reflect period 2 occurs at ■.

Table 2 GIRFTS professional learning content

Professional learning	Time commitment	Content
Response to intervention	2–3 hours	► Differentiation ► Multitiered interventions ► Data-based decision-making ► Using research evidence ► Universal screening ► Progress monitoring
SOLAR	6 hours	► Oral language as the basis for learning to read ► The Simple View of Reading ► Linguistics for reading instruction ► Approaches to phonics instruction

SOLAR, Science of Language and Reading.

likely to have students with poorer oral language and reading skills.[28]

- 2018 school Index of Community Socio-Educational Advantage value is ≤1100.
- 2018 school Australian Early Development Census results[29]—language and cognitive domain vulnerability rate of ≥10%.

PARTICIPANT RECRUITMENT

Students

Consent will be sought from parents/guardians before data collection and facilitated by schools. For each period, parent and student data will be collected on consenting students at the start of grade 2, as a reflection of the previous year when they were in grade 1. Parents/guardians can request to withdraw consent at any time. There are no exclusion criteria. Parent information statements will be available in other languages.

School staff and ISPs

Informed consent will be sought from school leaders, foundation and grade 1 teachers and intervention staff. Staff will be invited to participate in surveys and focus groups. School staff can withdraw consent at any time.

Implementation support partners (ISPs) who will be assigned to each participating school will be recruited from the education sectors (DE and MACS). ISPs will have an undergraduate or master's degree in a relevant field (eg, teaching, speech pathology) and a strong evidence-based understanding of how children acquire language and reading skills. Informed consent will be obtained from each ISP to participate in focus groups and collect materials related to performing the ISP role.

Randomisation

Computer-generated block randomisation with blocks of size 2, stratified by school sector (DE North-East Victoria Region, DE North-West Victoria Region and MACS) will be completed by a statistician independent of the project. Participating schools will be randomised into one of two cohorts. Cohort allocation will be shared with key research team personnel and ISPs. School principals will be emailed their allocation before the commencement of the study.

All data collectors and statisticians will be blinded to cohort allocation until the end of the trial.

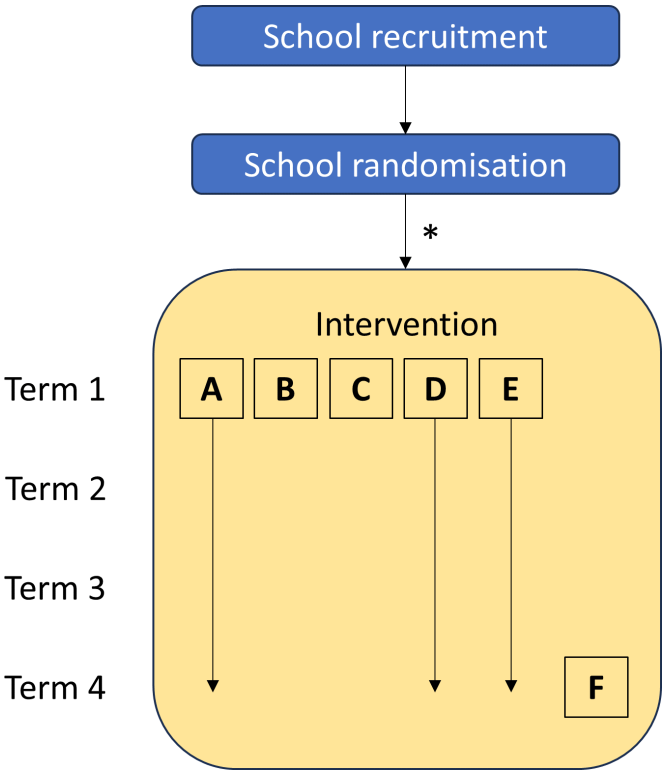

Figure 1 GIRFTS study timeline. Blue represents school recruitment and randomisation activities. Yellow represents intervention activities. A=ISP support; B=SOLAR short course; C=RTI professional learning; D=online resources; E=communities of practice; F=reflection and planning meeting. *After all schools in both cohorts complete period 0 (baseline), cohort 1 will commence the intervention (yellow), and cohort 2 will continue their 'business as usual' for one school year (period 1). In period 2, cohort 1 will repeat the intervention (yellow), except for activities C and D if the staff member had completed them in the previous year, and cohort 2 will commence the intervention (yellow). Refer to table 1 for periods and study design. GIRFTS, Getting it Right from the Start; ISP, implementation support partner; RTI, response to intervention; SOLAR, Science of Language and Reading.

Intervention

Over the intervention periods, schools will implement tier 1 and tier 2 of an RTI framework for oral language and reading in foundation and grade 1 over the full school year. The school year is from late January to mid-December and is split into four terms of 9–11 weeks. Tier 3 will not be a focus for this study. All foundation and grade 1 teachers will be expected to implement an RTI framework, and all their students are expected to receive

Table 3 Student outcome measures

Outcome measures	Administration	Skills assessed	Australian norms	Grade norms	Scaled/ standard average score	Data collection timepoint	Validity and reliability data
CUBED: Narrative Language Measures (NLM) Listening subtest	Individually	Listening comprehension of an oral narrative. Students retell a story and comprehension questions probe their vocabulary and inference skills.	Not available	Not available	Not available	Baseline (2022) Period 1 (2023) Period 2 (2024)	Petersen & Spencer, (2016)[32]
Sutherland Phonological Awareness Test-Revised (SPAT-R), subtests 4–9	Individually	Ability to identify beginning and ending sounds in words, blend and segment sounds in words and manipulate sounds.	Not available	1–4*	Not available	Baseline (2022) Period 1 (2023) Period 2 (2024)	Neilson, 2003[33]
Test of Word Reading Efficiency–Second Edition (TOWRE-2) List B	Individually	Efficiency of pronouncing printed words and phonemically regular non-words accurately and fluently (ie, word and non-word reading skills).	6.0–12.99 years	1–6	90–110	Baseline (2022) Period 1 (2023) Period 2 (2024)	Torgesen *et al* (2012)[34]
The Clinical Evaluation of Language Fundamentals–Australian and New Zealand Standardised Fifth Edition (CELF-5). Subtest: Following Directions	Individually	Ability to interpret spoken directions of increasing length and complexity.	5; 0–21;11 years	Not available	8–12	Baseline (2022) Period 1 (2023) Period 2 (2024)	Wigg *et al* (2017)[35]
Reading Progress Test 1 (RPT1)	Group	Reading comprehension of written text.	Not available	F-6	89–111	Baseline (2022) Period 1 (2023) Period 2 (2024)	Vincent *et al* (2004)[36]

F represents foundation students, first year of school. RPT1 will be the primary outcome. CUBED:NLM, SPAT-R subtests 4-9, TOWRE-2 and CELF-5: Following directions will be secondary outcomes. Assessments will be administered in the order presented in the table.
*Subtest grade criterion with 25th percentile cut-off score.

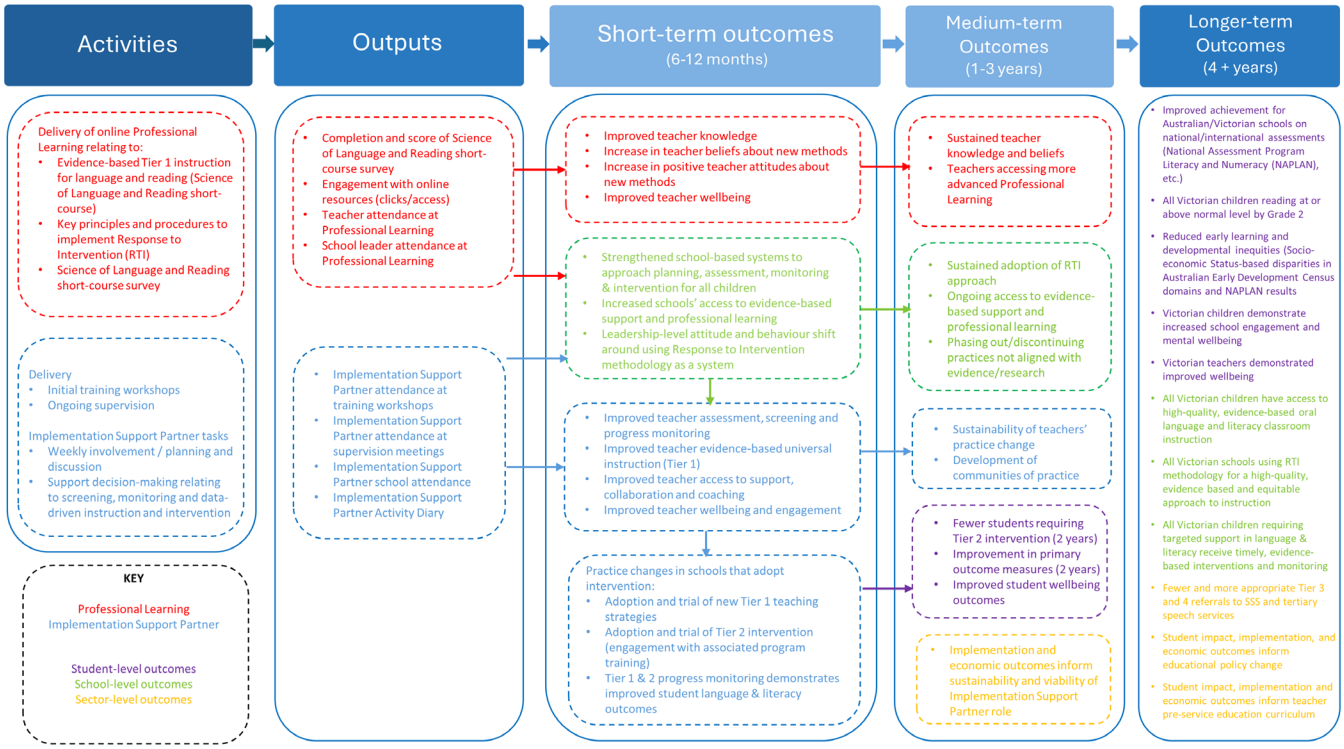

Figure 2 Program logic for Getting it Right from the Start (GIRFTS).

the intervention. Students will be between 5 and 7 years old.

Schools will be supported to select and implement evidence-based whole-class tier 1 teaching practices and specific tier 2 interventions. Schools will select appropriate assessment tools and interventions for their context with guidance from their ISP, through a co-design approach. The study will provide additional support in the form of professional learning that includes short courses, training and online resources, and school implementation planning meetings.

Implementation support partner

A dedicated ISP will work with schools 1 day (7 hours) per week over the implementation period to support their school's development and execution of an RTI framework including choice and training for tier 1 instructional approaches and tier 2 interventions. ISP's activities are expected to include planning, reflection, professional learning, and observation and coaching in the classroom. ISPs will not provide direct student support.

Prior to working with the school, ISPs will receive training provided by experts within the study team and externally. Topics covered include RTI, facilitating change and quality improvement cycles. ISPs will also attend learning communities twice a month with other ISPs.

Professional learning: short courses and training

All teachers of foundation and grade 1 classes, school leaders and intervention staff will be invited to attend professional learning about the RTI framework, language and reading. Professional learning will be strongly encouraged but not mandated. Professional learning commences with the start of implementation.

RTI professional learning will be developed by expert project investigators (JQ and SP) and delivered online.

The Science of Language and Reading (SOLAR) Lab Introductory short course will be offered online through the School of Education at La Trobe University, Victoria, to four staff at each school, each implementing year. With agreement from La Trobe University, schools participating in the project can view SOLAR content together (thus allowing more than four people per school to receive training).

Staff/teachers who join the project part way through will be asked to independently complete professional learning and will be enrolled in the next SOLAR short course.

Table 2 outlines the professional learning course content and anticipated time commitment.

Professional learning: online resources

School staff will be able to access additional professional learning resources through an online learning management system. Resources will be curated to support the choice and delivery of evidence-based tier 1 instructional approaches and tier 2 interventions.

School implementation planning meetings

In term 4 of each implementation year, implementing schools will be invited to a reflection and planning meeting (online). Schools will be encouraged to share and problem solve in a collaborative environment.

Table 4 Implementation data collection tools and time points

Data collection tool	Description	Design	Data collection time point
SOLAR quiz	4–6 multiple choice questions directly related to the SOLAR content of each session. Participants will also be invited to share reflections on the session in a free-text section.	Study designed	After each SOLAR professional learning session (4 in total)
GIRFTS RTI implementation rubric	Representative team of participant teachers/leaders self-rate school performance on 6 components of RTI implementation.	Adapted from existing tools	Beginning-Middle-End-implementation
RTI survey	Participant survey using 5-point scale to measure perspectives on school systems, collaboration, instruction and assessments.	Study designed	Beginning-Middle-End-implementation
Qualitative interviews and focus groups	Gain multiple perspectives on RTI implementation and factors that promote and inhibit the approach (eg, school leadership, teachers, ISPs).	Study designed	End of each implementation year

GIRFTS, Getting it Right from the Start; ISPs, implementation support partners; RTI, response to intervention; SOLAR, Science of Language and Reading.

A diagram outlining the study timeline is shown in figure 1.

Measures and data collection

Student outcome measures

The student outcome measures will be assessed using the five measures outlined in table 3. Measures were selected based on their validity and reliability, sensitivity to change over time, and administration feasibility with a young cohort. The primary outcome will be reading comprehension at the start of grade 2 and will be measured using the Reading Progress Test 1 (RPT1). Secondary outcomes will be listening comprehension, word and non-word reading and phonological awareness at the start of grade 2 and will be measured using CUBED: Narrative Language Measures Listening subtest, Sutherland Phonological Awareness Test-Revised, subtests 4–9, Test of Word Reading Efficiency–Second Edition List B and The Clinical Evaluation of Language Fundamentals–Australian and New Zealand Standardised Fifth Edition Subtest: Following Directions.

Student outcome measures will be collected from both cohorts at the start of the year immediately following each period of the study. This is depicted in table 1 and is relevant to all assessments in table 3.

Assessments will be administered by a team of data collectors, including research assistants and university students from speech pathology, psychology and education. An experienced speech-language pathologist will train all data collectors to administer the assessments.

Student date of birth, gender, terms the student was enrolled at the school and RTI tiers to which the student was exposed will be collected from the school at the end of each year.

Implementation evaluation

The evaluation will be a multi-informant mixed-methods implementation evaluation including longitudinal qualitative data collection. The evaluation will be guided by our interventions' program logic (see figure 2), which was developed at the commencement of the project. Informed by the Consolidated Framework for Implementation Research,[30] the evaluation will capture key implementation domains for both formative and summative evaluation to track adherence to the intervention, inform any improvements and evaluate the implementation process. Implementation data will come from but is not limited to, meeting minutes, relevant activity notes, survey responses and activity diaries. Qualitative data will be collected from interviews and focus groups with school leadership and teachers and ISPs.

Data will be triangulated to develop a detailed description of the RTI implementation process at each school. This evaluation aims to address the following questions: (1) What are the similarities and differences between different school implementation processes to implement RTI? (2) What are the enablers and barriers to implementing RTI and what strategies have schools used to overcome these challenges?

Table 4 shows the key data collection tools that will be used to interrogate the program logic relating to implementation outcomes.

For cohort 1, the beginning of implementation will be between February and May 2022, mid-implementation between November 2022 and April 2023 and end implementation between November 2023 and April 2024. For cohort 2, the beginning of implementation will be between February and May 2023, mid-implementation between November 2023 and April 2024 and end implementation between November 2024 and April 2025.

Data management and storage

All data will be stored in compliance with Murdoch Children's Research Institute (MCRI) and ethical requirements for data storage. A single, online electronic database (REDCap) will be used to record participant details. It is hosted by the MCRI server and meets ethical

confidentiality requirements. Participant data will be identified by ID code only and stored in the secure electronic database.

Paper assessments or forms will be stored in a locked filing cabinet at the Royal Children's Hospital and available to select researchers. Researchers can access participant details where necessary.

Sample size and power calculations

Sample size calculation is anchored around the detection of a minimum effect size of 0.28 SD in reading comprehension measured via the RPT1 to allow comparisons with other international programs. Sample size calculation was performed using 'The Shiny CRT Calculator' (https://clusterrcts.shinyapps.io/rshinyapp/). The following assumptions will be made; a SD of 1, an intracluster correlation coefficient of 0.02, a cluster autocorrelation of 0.8 and an alpha of 0.05. A total of 16 schools (8 schools in each cohort) and an average number of 35 students per year per school (who give consent and have primary outcome data available) will be required to detect an effect size of 0.28 SD on the RPT1 score between intervention and control groups with a power of 80%. To account for the potential dropout of up to 2 schools during the study, 18 schools (9 in each cohort) will be recruited to the study.

Statistical analysis plan

To estimate the effect of the intervention compared with business as usual on primary and secondary outcomes, statistical methods will consider time effects and clustering effects within school and within class. Statistical methods are described in detail in a statistical analysis plan.[27]

The primary outcome (RPT1) and the secondary outcomes will be calculated for each cell in the stepped-wedge design by aggregating all students' measures in each school during each school year.

Continuous outcomes (including the primary outcome, RPT1) will be analysed using a mixed-effects model with a Gaussian distribution with an identity link function, fitted to data at the students' level. The model will include fixed effects for the intervention group, calendar time (year), school sector, and random effects for school (cluster), and grade 1 class within the school.

If the proportion of missing outcome data is >10% in the primary outcome, missing data in the primary and secondary outcomes will be handled using multiple imputation techniques.

Dissemination

Research findings will be disseminated via state, national and international education and childhood development conferences, high-impact academic journals, publications targeting practising teachers, and inclusion in strategic policy forums such as Australian national ministerial and senior officer councils as demonstrated in our previous research. Individuals who make substantial contributions to the design, conduct, interpretation and reporting of GIRFTS will be made authors.

Patient and public involvement

This trial partners with the education system (DE and MACS) to ensure the suitability of the trial design. A pilot phase informed the conduct and design of the GIRFTS trial.[31] GIRFTS will include a codesigned implementation, which allows participant (school staff) involvement. Participating schools will be invited to project presentations and receive regular updates. Families will receive updates through parent newsletters.

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Contributors The original study design was conceived by JQ, PS, PE, SP, LG, BS, FO and SG. MLS and CS implemented the study design. FO provided statistical expertise. JC and SE provided access to schools in their sectors. MLS and CS drafted the manuscript on the basis of the existing protocol. All authors contributed, refined and approved the final manuscript. SG is the guarantor for this trial and provided oversight for the study. Professional writers are not intended to be used for the reporting of this trial.

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Competing interests PS is the Co-Director of the La Trobe University Science of Language and Reading (SOLAR) Lab. The short course that is part of the intervention described in this paper is delivered by the SOLAR Lab. PS does not receive any financial benefit from SOLAR Lab activities. There are no other competing interests to disclose.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not applicable.

Ethics approval This trial was ethically approved by the Royal Children's Hospital Human Research Ethics Committee (HREC/58832/RCHM-2019). Approval to conduct research in schools was obtained from DE (Research in Schools and Early Childhood Settings, RISEC 2019_004235 and MACS Study Number, 0688). Additional HREC approvals were not required. Investigators will communicate the results to stakeholders, collaborators, and participating schools and teachers through newsletters, presentations, and publications.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement No data are available. The datasets generated during and/or analysed during the current study are not expected to be made available due to not being covered by the ethics approval.

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