**Draft Protocol**

**LEAP: Language, ENGAGE and Play.**

**Building self-regulation through Play**

**Study Protocol**

**Version: 3 Date: 25th February 2020**

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# RESEARCH TEAM

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# GLOSSARY OF TERMS & ABBREVIATIONS

|  |  |
| --- | --- |
| BASC-3 | Behaviour Assessment System for Children: Version 3 |
| CELF-P 2 | Pre-school Clinical Evaluation of Language Fundamentals (Aus and NZ version) |
| CF | Consent form |
| COL | Community of Learning |
| ECEC | Early Child Care and Education Centre |
| ENGAGE | **E**nhancing **N**eurobehavioural **G**ains with the **A**id of **G**ames and **E**xercise |
| IQ | Intelligence quotient |
| LEAP | **L**anguage, **E**NGAGE **a**nd **P**lay |
| MMS | Methodist Mission South |
| MoE | Ministry of Education |
| MABC-2 | Movement Assessment Battery for Children: Version 2 |
| NGO | Non-governmental organisations |
| NZ | New Zealand |
| OT | Occupational therapist |
| PIS | Participant information sheet |
| PT | Physiotherapist |
| SDQ | Strengths and Difficulties Questionnaire |
| SLT | Speech language therapist |
| WTS | Welcome to School |

# PROTOCOL SUMMARY

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| --- | --- |
| TITLE | LEAP: Language, ENGAGE and Play: Building self-regulation through Play |
| FUNDING | Cure kids, A+ Charitable Trust and AUT Faculty Research Development Fund |
| STUDY PERIOD | 15-months |
| RESEARCH AIMS | To compare the effect on self-regulation of **ENGAGE**, a games-based program delivered by teachers in a community of primary schools, with **LEAP**: an adapted program with intentional language, intentional motor skill development and cultural components. |
| RESEARCH OBJECTIVES | 1. To adapt **ENGAGE** to include intentional language, intentional motor skill development and intentional Te Ao Māori and Pacific world views and tikanga. This adaptation is **LEAP**: **Language, ENGAGE and Play** 2. To assess the impact of **LEAP** on self-regulation skills 3. To compare the impact of **LEAP** on self-regulation skills with that of **ENGAGE** 4. To examine the feasibility of using M-ABC as a developmental screen in new entrant children 5. To assess the impact of **LEAP** on motor planning, fine motor skills and gross motor skills. 6. To compare teacher and child engagement with LEAP with that of ENGAGE. |
| STUDY DESIGN & METHODOLOGY | An open cohort non-randomised cluster design will be used to examine the intervention effects of intentional language and intentional motor skills in **LEAP** with the self-regulation skills in a teacher-led whole of classroom play-based program **ENGAGE**. **ENGAGE** has been implemented across all study schools in 2020 and will continue in 2021. Half the schools will implement adapted ENGAGE: **LEAP** from term 2. Changes in executive function/self-regulation for children enrolled in schools using **ENGAGE** will be compared with children enrolled in schools using **LEAP**. |
| ELIGIBILITY CRITERIA | The principals from all primary schools in the Manaiakalani Communities of Learning are using **ENGAGE** as part of their usual classroom practice. The eligible population is year 1 and 2 children enrolled in the participating schools. All children will participate in the games. Parental consent will be obtained for use of standard school data and behaviour assessments both pre-and post-**ENGAGE**. Additional consent will be obtained for the children enrolled in the schools implementing **LEAP** for the supplemental assessments. |

# STUDY PROTOCOL

## Study summary

Self-regulation is a set of internal skills that control thoughts, emotions and behaviours. The inability to self-regulate is associated with behavioural, emotional, social, and learning difficulties in childhood; followed by later criminality, poverty, poor job performance, low life satisfaction and physical and mental health difficulties.1-4 The Dunedin Longitudinal Study clearly shows self-regulation is more important than IQ for health, social and economic outcomes: even after adjusting for socioeconomic status.2,5,6

Self-regulation is a skill and can therefore improve with training. **ENGAGE**, a play-based program developed by University of Otago researchers, has found promise in improving self-regulation in pre-schoolers.7-9 **ENGAGE** was trialled in 40 ECECs and 12 primary schools in 2019-20 with improvements in behaviour and self-regulation. Many centres are now using **ENGAGE** as part of usual classroom practice.

The Manaiakalani Kahui ako, a well-established group of schools in Tāmaki, the Auckland suburbs of Glen Innes, Point England and Panmure, trialled **ENGAGE** in 2020 and has committed to continuing **ENGAGE** as part of their self-regulation achievement challenge.10

Recent work by the A+ funded Welcome to School (WTS) studies has identified high levels of language disadvantage in Tāmaki new entrants: 26% have language skills less than the 1st centile11-14 At this level, children were functioning below the 3-year-old level and had difficulty understanding basic instructions in the classroom. Given the high prevalence of language disadvantage, low working memory and poor motor planning in Tāmaki new entrants,11-14 researchers are collaborating to adapt **ENGAGE** to an appropriate level for the children.

This project brings together a range of experts from health, education, and the community to collaborate using participatory research. An occupational therapist, physiotherapist, speech therapist and neuropsychologist will join with teachers, cultural advisors and **ENGAGE** trainers to amend the current games: **LEAP**: **Language, ENGAGE and Play**. Resultant games will be engaging, developmentally scaffolded, and culturally appropriate.

Adaptations to improve specific language, memory and motor skills are expected to augment the effect on self-regulation, however, this needs to be tested. As all primary schools in the Manaiakalani COL have committed to continuing **ENGAGE** as part of their self-regulation achievement challenge, and have established relationships with the Welcome to School Research team, the COL is ideally suited to an intervention trial testing the adaptation of **ENGAGE**. As such, principals have agreed half the Manaiakalani schools will continue with **ENGAGE** and half will implement the adaptions as **LEAP**. Improvements in self-regulation for children in schools implementing **ENGAGE** will be compared to improvements for children in schools implementing **LEAP**. All schools will then continue with the games that document the most improvement.

## Funding

Cure kids, A+ Charitable Trust and AUT Faculty Research Development Fund.

## Background and rationale

**Self-regulation** is a set of internal skills that control our thoughts, emotions, and behaviours, and are most-commonly exercised when we are presented with challenging, stressful, or emotionally stimulating situations. Self-regulation includes:

* Cognition (attention, memory and other functions) **– THINKING**
* Emotion (recognising emotions, tolerance of frustration and anger) **– FEELING**
* Behaviour (hyperactivity/impulsivity) **– DOING**

**Children aren’t born with these skills, but they have the potential to develop them if given the right support to build these skills**. The Centre for the Developing Child notes that if “children do not get what they need from their relationships with adults and conditions,… their skill development can be seriously delayed or impaired”.15 Environments in which children experience adverse events such as neglect, abuse, and/or violence may expose children to toxic stress; this can weaken the development of self-regulation (and executive functioning).

Graphical user interface, text, application, chat or text message

Description automatically generatedAcquiring “executive function” and “self-regulation” skills is important to help enable children to learn, plan, focus, remember instructions, switch tasks and control impulses. These skills are critical to learning, achievement, and behaviour.

Self-regulation is a skill, and as such it can be developed with training. **ENGAGE**: **Enhancing Neurobehavioural Gains with the Aid of Games and Exercise** was developed by Dione Healey at the University of Otago using play-based games to improve self-regulation.7-9 **ENGAGE** has been successfully trialled among preschool children with attentional difficulties and found to be as effective as Triple P in reducing parent-rated problem behaviours in pre-schoolers (i.e., Hyperactivity, Attention Problems, and Aggression); with gains maintained over a 12-month follow-up.

**ENGAGE** consists of a toolbox of teacher-led games 30 minutes each day for a term (8-9 weeks). The games are common games used in childhood and allow adaptation with increasing levels of complexity. They target:

* Thinking / cognitive self-regulation and memory (e.g., cups memory, sorting),
* Feeling / emotional self-regulation (e.g., relaxation), and
* Doing / behavioural self-regulation (musical statues, Simon says).

It has since been adapted and trialled in 40 Early Child Care and Education Centres (ECECs) in Auckland and Dunedin. Early results suggest it is enjoyable, feasible and resulted in improved behaviour and self-regulation.9 Based on this early success; the Ministry of Education (MoE) contracted Methodist Mission South (MMS) to roll out **ENGAGE** for years 1-2 in 30 primary schools over 2020. This again showed overall improvement in behaviour and self-regulation.

The Manaiakalani Kahui ako, one of the longest standing Communities of Learning (COL), introduced **ENGAGE** in 2020 as part of their achievement challenge for developing self-regulation.10 Recent work by the A+ funded Welcome to School (WTS) studies has identified high levels of language disadvantage in Tāmaki new entrants: 26% have language skills less than the 1st centile.11-14 At this level, children were functioning below the 3-year-old level and had difficulty understanding basic instructions in the classroom. The language skills were related to social disadvantage: not to English as another language.14 The WTS follow-up study 18 months after school entry revealed persisting low language, low levels of self-regulation, difficulties with motor planning and fine motor skills, and low visuo-spatial and verbal working memory. The combination of these factors compounds these children’s difficulties, particularly as they live in a community with significant socioeconomic disadvantage.16

The language disadvantage has significant impacts on social pragmatics and children’s ability to identify feelings and emotions, participate in games, and develop friendships and learning skills.14,17-21 These factors in combination with the low working memory and poor motor planning, require **ENGAGE** to be taught at the developmental level of the children, incorporating any strengths and weaknesses with appropriate progressions. Failure to do so will potentially negate any impact of the intervention.

To gain the most from **ENGAGE**, and get the best outcomes for the tamariki, it is essential the games match the developmental, emotional, and cultural needs of the children. Whilst the games are ones commonly used in NZ, they are relatively Eurocentric. We are therefore specifically incorporating structured play aka. ‘games’, from Te Ao Māori and Pacific world views. A different range of cultural adaptations, themes, language, and constructs will then be available for different communities. The games will be adapted by a range of experts to incorporate intentional language, intentional motor planning, and cultural adaptations to develop **LEAP**: **Language, ENGAGE and Play**. Resultant games will be engaging, developmentally scaffolded, and culturally appropriate. The additional effect on self-regulation of the adaptations will then be tested in an intervention trial across the Manaiakalani group of schools.

Improving early self-regulation, particularly in communities with significant socioeconomic disadvantage, has the potential for significant future improved educational, social and health outcomes and cost-savings for children, whānau, communities and society.2

## Overall aim

The project will examine the effect on self-regulation of **LEAP**, ENGAGE with intentional language, motor planning and cultural adaptations, in comparison with the effect of **ENGAGE** on self-regulation in the Manaiakalani community of primary schools in Auckland.

## Objectives

1. To adapt **ENGAGE** to include intentional language, intentional motor skill development and intentional Te Ao Māori and Pacific world views and tikanga. This adaptation is **LEAP**: **Language, ENGAGE and Play**.
2. To assess the impact of **LEAP** on self-regulation skills
3. To compare the impact of **LEAP** on self-regulation skills with that of **ENGAGE**
4. To examine the feasinility of using M-ABC as a developmental screen in new entrant children
5. To assess the impact of **LEAP** on motor planning, fine motor skills and gross motor skills
6. To compare teacher and child engagement with **LEAP** with that of **ENGAGE**.

## Study design

The study is designed as an open cohort, parallel, non-randomised cluster intervention trial to examine the effects of intentional language, intentional motor skill and cultural adaptations in **LEAP** with the self-regulation skills in **ENGAGE:** a teacher-led whole of classroom play-based program to improve self-regulation. **ENGAGE** will be part of the usual classroom teaching across 10 Manaiakalani schools in term 1 2021. The non-randomised allocation of schools to either ENGAGE or LEAP program can be a potential source of bias

Adaptations will occur during two multidisciplinary workshops. The adapted games: **LEAP**, will be implemented from term 2 in a subset of schools with the remaining schools continuing with **ENGAGE**. The effect of **LEAP** on self-regulation will be compared to the effect of **ENGAGE**.

## 

## Study setting

Multisite intervention in Manaiakalani COL in Tamaki: the suburbs of Glen Innes, Panmure Bridge and Point England. This is a multicultural community with significant socioeconomic disadvantage. 25% children are Māori, 65% Pacific (25% Tongan, 15% Samoan,10% Cook Island Māori and 5% Other Pacific) and 10% Other ethnicities. Participating schools include: Glen Innes, Glenbrae, Glen Taylor, Panmure Bridge, Point England, Ruapotaka, St Patricks, St Pius X, Tamaki, and Stonefields.

* 1. ***Intervention***

**LEAP**: **ENGAGE** adapted according to the language, motor skills and culture of the children with developmentally appropriate scaffolding.

Intentional Language: Adaptations will be guided by baseline assessments as well as the Welcome to School (WTS) projects which include comprehensive data on language and working memory.8-10 Assessments will be undertaken by an experienced paediatric speech language therapist (SLT).

Intentional motor skills: Gross motor skills are relative strengths for Tamaki children, but some have difficulty with motor planning and fine motor skills.8,9 This, in combination with difficulties with emotional regulation and impulse control, can result in disruptive behaviour.22 An occupational therapist (OT) will assess baseline skills and ensure **LEAP** scaffolds motor-skills and motor-planning in a developmentally appropriate way.

Cultural adaptations: The Manaiakalani kahui ako is a multicultural community with 90% of children identifying as Māori or Pacific. We are using the opportunity to consult cultural experts, specifically incorporating structured play aka. ‘games’, from Te Ao Māori and Pacific world views and integrating adaptations from cultural leads from the school communities e.g., using coconut shells instead of cups in the memory games, ensuring children lie with heads in the same direction acknowledging tikanga re feet not being placed next to another persons’ head.

Teacher adaptations: **ENGAGE** is adapted as required by teachers. We will incorporate adaptations and suggestions from teachers experienced with **ENGAGE** in new entrant classrooms to develop a new baseline of games.

* 1. ***Outcome measures***

Methodist Mission South (MMS), the non-governmental organisation (NGO) contracted to provide training and support for **ENGAGE**, requires data for two measures of self-regulation: teacher reported behaviour rating scales (BASC and SDQ) immediately before and after the intervention. The effect on self-regulation will be examined by comparing high level measures obtained with **LEAP** to the same measures obtained with **ENGAGE**. As teachers provide behaviour ratings both before and after the 8-9-week period of games they themselves implement, there is potential for unconscious provider bias. **LEAP** therefore has a suite of subjective and objective measures across several domains at baseline and follow-up. To examine whether gains continue with ongoing use of the games, we have added a third time point for the behaviour measures. All measures and their timing are detailed in appendix 1.

Baseline measures in all schools:

* Student demographics
* School demographics
* School Entry Assessment (concepts about print, letter identification, word reading, word writing)
* Behavioural Measures
  + The Behaviour Assessment System for Children (BASC-3): A comprehensive measure of both adaptive and problem behaviours in the school setting, home and community. Provides scores, centiles, and T-scores for standard populations. MMS use the total score and the scores for hyperactivity, attention, and aggression.
  + The Strengths and Difficulties Questionnaire (SDQ). A behavioural screening questionnaire for children 3–16 years with 25 questions across five scales (emotional, conduct, hyperactivity/inattention, peer-relationship and prosocial). Completed by the parent and classroom teacher.

Outcomes measures in all schools:

* Primary outcome measure: Self-regulation: BASC-3. Scores for Hyperactivity, Attention Problems and Aggression on the parent and teacher-rated BASC-3.

Secondary outcome measures in all schools:

* Self-regulation: SDQ. Total and subscale scores on the parent and teacher rated SDQ. Actual scores and proportion of children in each category: close to normal, slightly raised, high, very high (slightly low, low, very low for prosocial score).
* Reading comprehension: Reading levels, 6-year-net (print concepts, word knowledge and comprehension).
* Other: Attendance data to explore dose response to intervention. Principals will provide information about supplemental student learning and behaviour support
* Teacher feedback and suggestions about improvements (appendix 3).

Supplemental Baseline and Outcome measures in Intervention schools:

* Self-regulation and working memory measures:
  + Gift wrap task: To evaluate the ability to delay gratification.23,24 Proportion of children who do not peep, and the average time to first peep for those that do.
  + Visuospatial and Auditory/Verbal Working Memory: Corsi Block Test and Number Recall forward and backward.25,26
  + Bear/Dragon: Standardised assessment for cognitive flexibility and inhibitory control.
* Language measures:
  + Pre-school Clinical Evaluation of Language Fundamentals (CELF-P): A comprehensive range of language measures, widely used, NZ norms and good psychometric properties.27 Raw and standardised total language scores and centiles, expressive language scores and receptive language scores.
  + Classroom observation: Observation adapted from MoE classroom observation tool. Used in the WTS studies. Complemented with the CELF pragmatics profile: a scaled assessment of attention and observation of social pragmatics.
* Motor measures:
  + Movement Assessment Battery for Children-Second Edition (MABC-2): a standardised assessment for evaluating gross and fine developmental movement skills in tamariki/children aged 3-16 years,28 and for monitoring their progress in response to intervention and research.29 It evaluates movement competence in the areas of manual dexterity, aiming and catching, and balance, generates both normative data and qualitative information, and has established validity and reliability. Whilst it has been used among typically developing populations internationally, in NZ it is specifically used for assessment and planning intervention among children with motor difficulties referred to child development teams and/or therapists. This provides an opportunity to determine its acceptability and feasibility of M-ABC as a motor assessment tool among a community of more-typically developing 5-year-old children. Outcomes: raw score, standardised score and percentile, significant motor difficulty (at or below the 5th centile), at risk of motor difficulty/impairment (5th-15th centile), and age-appropriate motor skills (greater than 15th centile).
* Other measure collected only at baseline:
  + Language Map (Nelson tool to assess what languages are used for what purpose by all household members e.g., instructional, nurturing etc).

## Participants

* 1. ***Eligible population***

The principals from all primary schools in the Manaiakalani COL are continuing with **ENGAGE** as part of usual classroom pedagogy and have agreed the COL will participate in the trial: either **ENGAGE** or the adaptation of **ENGAGE** and subsequent implementation of **LEAP**. The eligible population is thus children in years 1 and 2 enrolled in the schools in the COL.

* 1. ***Inclusion criteria***

All children will participate as part of usual classroom pedagogy. Children with pre- and post- behaviour measures will be included in the cluster-specific analyses. Children whose parents decline consent to assessment will participate in the **ENGAGE** or **LEAP** as part of usual pedagogy but will not have assessments done or have their data included in the trial.

* 1. ***Exclusion criteria***

Nil (except children whose parents decline consent). There will be no gender, racial/ethnic, language, or socioeconomic restrictions to participation in this study.

* 1. ***Recruitment of participants***

The principals from all primary schools in the Manaiakalani COL have agreed to continue with **ENGAGE** or introduce **LEAP**. Individual children will be recruited at the beginning of the year using a variety of mechanisms including school newsletters/whānau-school hui/teacher invites (first stage consent). Explanation of and consent for, the additional assessments for **LEAP** will after the caregiver/parent has had discussions with a LEAP researcher.

* 1. ***Number of participants***

The number of children anticipated to take part is based on enrolment data from 2019 and 2020.

Estimated 300-320 children across the Manaiakalani Community of Learning, enrolled in the 10 different schools. The number and ethnicity of children enrolled in each Manaiakalani school is detailed in appendix 3.

Approximately half the schools will continue with **ENGAGE** and half will implement **LEAP**: i.e., approx. 150 in each group. Based on participation rate in previous studies and mobility of children to different schools in the Manaiakalani COL, it is anticipated approximately 80% of eligible children will participate and have pre- and post-outcome measures: 120 in **LEAP** and 120 in **ENGAGE**. The numbers may not be equal as we are recruiting to the intervention by schools.

* 1. ***Consent***

Parents’ consent for their child to be part of the Manaiakalani pedagogy improvement process when they enrol their child. Consent to participate in **ENGAGE** is therefore not required as it is a normal part of classroom instruction (having been implemented in 2020).30 Children who are not in the specified age range at commencement of the study, and any other children whose parents do not consent to them taking part, will be included in all activities but will not be involved in the assessment process. Parents of nonparticipating children will be sent an information letter to let them know about the project and about their children’s educators’ participation. We will only collect data on those children whose parents have consented and who meet eligibility criteria.

Informed consent to participate in the intervention trial will be obtained for children and teachers in participating schools. Four different consents will occur:

1. Children in **ENGAGE** schools: Parental consent will be gained to enable routinely collected school data and pre- and post-behaviour data to be used as comparison data for the intervention.
2. Children in **LEAP** schools: Parental consent will be gained to enable routinely collected school data and pre- and post-behaviour data to be used as comparison data for the intervention. Consent will also be obtained for additional assessments (pre- and post-intervention), and participation in **LEAP**.
3. Teachers: Consent will be gained from teachers for their provision of questionnaire data about the children in their class and for feedback via a standard template (appendix 2).
4. Workshop participation: Consent will be obtained from a group of teachers, cultural experts, PT, OT, SLT, ENGAGE developers to participate in the 2 workshops to adapt ENGAGE.

## Potential risks

The proposed study does not involve any medication or invasive procedures and as such risk to children and their families is minimal. The techniques we will teach are all designed to be positive and beneficial for adults and children alike; however, conversations can sometimes become negative, and young children can vary in their engagement with new activities. We anticipate that any of these issues will be within the realm of what teachers normally deal with on an everyday basis, and in fact, the techniques are designed to help educators tackle discussions of everyday negative events in ways that will support children’s coping and emotion regulation, and in ways that will facilitate children’s participation in activities.

Children have been participating in **ENGAGE** games during 2020 with no adverse events. The modifications are expected to make the games more developmentally appropriate and thus less risky. The only potential risk is that children could be identified during the assessments as being developmentally delayed or at risk of delay. The findings will be discussed with the caregivers, and any child identified as requiring additional input will have further assessments and intervention arranged with consent as appropriate.

## Conflicts of interest

There are/are no conflicts of interest to declare.

## Data management

* 1. ***Data collection***

All schools, teachers and students will be assigned unique identifiers. A single electronic, password-protected, database will be hosted on the ADHB server, which meets security and ethical confidentiality requirements. The COL routinely uses Google forms for questionnaires as the most reliable feedback mechanism.

* 1. ***Data storage***

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| **Generation and collection – how data will be generated and collected** | **Data generation (source data)**  In this study, the following types of data will be collected:   * Personal identifying information (names, ethnicity, contact details in the event participants request a copy of the final report) * School demographics * School entry assessment data and key academic data. Routinely collected as part of school monitoring of academic progress * Attendance data: routinely collected by schools * Standardised validated assessments: BASC, SDQ, CELF-P, CELF Pragmatic profile, Classroom observation, M-ABC, Gift wrap task, Corsi block test, Number recall, Bear/Dragon * Teacher feedback re games/intervention * Language map: pictorial depiction of languages spoken in the home: collected for each intervention child by the LEAP researcher.   **Source Document Plan**  The source documents for this study include:  The Behaviour Assessment System for Children (BASC-3) (paper)  The Strengths and Difficulties Questionnaire (SDQ) (paper)  Academic and attendance data from schools (digital);  Additional student support from school principals (paper);  Clinical Evaluation of Language Fundamentals (CELF-P-4) and pragmatic profile (paper);  Classroom observation (paper);  Movement ABC-2 (M-ABC-2) (paper);  Self-regulation measures (paper);  Language map (paper);  Demographic questionnaire (paper);  Teacher feedback re games (paper);  and the signed PIS/CFs (paper).  We will maintain a Source Document Plan that will document the source, i.e., original recording, for each data discrete item/category of items collected for the study. This Source Document Plan, signed and dated by the Principal Investigator, will be prepared prior to recruitment of the first participant and will be filed in the site’s Investigator Site File. |
| **Generation and collection**  **Use**  **Storage and access** | **Data capture methods and data use, storage, access, and disclosure during the study**  **Data collection methods**  All schools, teachers and students will be assigned unique identifiers. A single electronic, password-protected, database hosted on the ADHB server, which meets security and ethical confidentiality requirements. Data collection methods are outlined above.  **Access Disclosure**  Consent documents will be collected in hard copy and scanned.  **Use of the data**  Analysis will be conducted with COL-wide data: Intervention and control schools. The baseline characteristics of the students and schools will be summarised: number/proportion in each category for categorical variables and means/SDs, or medians/ranges/IQRs for non-normally distributed data continuous variables.  **Storage and access**  All study-related data will be secured in digital files only accessible by two factor authenticated password and locked physical storage facilities. All data collection will be undertaken in accordance with the National Ethical Standards for Health and Disability Research and Quality Improvement (2019). Files containing private or confidential data will be stored in locations accessible only by appropriate designated members of the research team.  **Specific storage and access procedures:**   * Contact details will be stored digitally along with participant identifier codes, in a password-protected drive accessible only by the research team. * Participant consent and receipt of reimbursement documents will be collected in hard copy by the research team at the time of interviews. Consent documents will be scanned and stored by the research team in a single password-protected file in the Investigator Site Files and the hard copies destroyed. * Hard copy forms will be stored by the research team as described above.   **Disclosure**  The study protocol, documentation, data, and all other information generated will be held in strict confidence. No information concerning the study, or the data will be released to any unauthorised third party. Information will not be released without written permission of the participant. |
| **Methods to reduce identification of participants** | **Data confidentiality**  Participant confidentiality is strictly held in trust by the Principal Investigator. To preserve confidentiality and reduce the risk of identification during collection, analysis and storage of data and information, the following will be undertaken:   1. The number of confidential variables collected for everyone has been minimised. The data collected will be limited to that required to address the objectives. 2. Participant identifiers will be stored separately to the data collected.   This participant code will be linked only to participant names and contact details. All recording forms will be stored and linked to the participant codes. The Principal Investigator is responsible for the storage of a master-file of names and other identifiable data with the participant ID; access to this document will be restricted to the research team and authorised persons as listed previously. The master file will be stored securely, and separately, from study data in locked/ password-protected database with passwords kept separately. |
| **Quality assurance** | **Quality assurance**  Brief meetings will be held with teachers in each school at the beginning of the year to outline the project, objectives, and outcome measures used. A Project manager from ENGAGE and LEAP will monitor rollout and respond to any questions. These PMs will not discuss adaptations or differences across the schools. |
| **Storage post-study ARCHIVE**  **Disposal** | **Archiving - Data and document retention**  **Archiving**  All data will be retained for a period of 10 years after the last child turns 16 years in accordance with HDEC ethics committee requirements, before being destroyed. During the archive period, the Principal Investigator will be the custodian, who will have access to the stored data and outline any procedures that may be followed to dispose of the data at the end of the archival period. Records will not be destroyed without the written consent of the Principal Investigator.  **Destruction**  Following the archive period both data and documents will be destroyed using irreversible methods to ensure that the data is no longer usable. Hardcopies will be disposed of via a confidential shredding process. For electronic data, software that permanently erases data will be utilised. |
| **Long-term custodianship** | **Long-term custodianship (after archive period finished)**  Following the conclusion of the study, all digital data will be archived in a secure network drive for each site. |

## Data analysis

Analysis will be conducted with cluster-wide data. The baseline characteristics of the students and schools will be summarised by intervention group: number/proportion in each category for categorical variables and means/SDs, or medians/ranges/IQRs for non-normally distributed data continuous variables.

* 1. ***Primary outcome analysis***

The primary outcome, the change in the high-level measure of self-regulation, will be summarised by intervention group as a mean/SD. The mean score will be compared between the groups using a two-level random effects linear regression model. Results will be reported as a mean difference between groups together with a 95% CI and p-value. BASC-3. Scores for Hyperactivity, Attention Problems and Aggression on the parent and teacher-rated BASC-3.

* 1. ***Secondary analysis***

Secondary outcomes will be summarised within treatment groups and compared using linear and logistic regression models adjusted for school. SDQ. Total and subscale scores on the parent and teacher rated SDQ. Actual scores and proportion of children in each category: close to normal, slightly raised, high, very high (slightly low, low, very low for prosocial score).

## Ethics

1. This trial will receive HDEC ethics approval and approval by ADHB Research Office and ADHB/WDHB Māori Research Advisor.

## Dissemination

Translation of study results will be facilitated by Manaiakalani Kahui Ako, University of Auckland, Auckland University of Technology, University of Otago, and Starship Community. Findings from this trial will be of national and international significance in health and education sectors.

Dissemination of findings will occur via whānau-school hui, reports to the school’s board of trustees, the Manaiakalani Education Trust, the Ministry of Education, Ministry of Health, Department of Prime Minister and Cabinet, NZ Wellbeing Strategy, Chief Science Advisor, as well as presentations at local, national and international conferences and publications in academic journals.

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