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Kia Timata Pai (Best Start): a study protocol for a cluster randomised trial with early childhood teachers to support children’s oral language and self-regulation development

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ABSTRACT

Introduction Oral language skills are associated with children’s later self-regulation and academic skills; in turn, self-regulation in early childhood predicts successful functioning later in life. The primary objective of this study is to evaluate the separate and combined effectiveness of an oral language intervention (Enhancing Rich Conversations, ENRICH) and a self-regulation intervention (Enhancing Neurocognitive Growth with the Aid of Games and Exercise, ENGAGE) with early childhood teachers and parents for children’s oral language, self-regulation and academic functioning.

Methods and analysis The Kia Timata Pai (Best Start) study is a cluster randomised controlled trial with teachers and children in approximately 140 early childhood centres in New Zealand. Centres are randomly assigned to receive either oral language intervention only (ENRICH), self-regulation intervention only (ENGAGE), both interventions (ENRICH+ENGAGE) or an active control condition. Teachers’ and parents’ practices and children’s oral language and self-regulation development are assessed at baseline at age 1.5 years and approximately every 9 months to age 5, and academic performance at age 6. Teacher–child interactions will also be videotaped each year in a subset of the centres. Children’s brain and behaviour development and parent–child interactions will be assessed every 6 months to age 6 years in a subgroup of volunteers.

Ethics and dissemination The Kia Timata Pai trial and the two substudies (Video Project; Brain and Behaviour Development) have been approved by the University of Otago Human Ethics Committee (Health; H20/116), and reviewed for cultural responsiveness by: the Ngai Tahu Research Committee (University of Otago), the Māori Advisory Group (University of Auckland, Liggin Institute) and an internal cultural advisory group. Results will be disseminated in international and national peer-reviewed academic journals and communicated to local, national and international organisations serving early childhood teachers, parents and young children. Data will be available via communication with the corresponding author.

Trial registration number ACTRN12621000845831.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The size and longitudinal design of this cluster randomised controlled trial across early childhood will enable the assessment of the singular and combined effects of teacher-led oral language and self-regulation interventions on the development of children’s oral language in English and te reo Māori, self-regulation and academic functioning.

⇒ The trial represents a partnership between a large provider of early childhood education (BestStart), an external implementation service (Methodist Mission Southern) and a consortium of academics (Emotion Regulation Aotearoa/New Zealand) to provide a culturally responsive intervention with codesigned implementation with the early childhood education provider (BestStart); the use of a single national provider simplifies codesign and the implementation of the intervention.

⇒ The efficacy of the interventions is assessed at multiple levels: via teacher and parent reports, behavioural observations and measures of brain development (EEG/ERP).

⇒ Because of the large size of the main trial, those assessments are restricted to teacher-report and parent-report instruments.

⇒ The single-provider feature with BestStart restricts the ability to collect primary outcomes on children who leave this service provider during early childhood.

INTRODUCTION

Self-regulation comprises the ability to regulate one’s thoughts, feelings and actions. Self-regulation skills are developing rapidly in early childhood and predict later academic functioning and life success. Clinically relevant
difficulties in these skills predict negative outcomes across domains of functioning, including psychological and physical health across the lifespan. Self-regulation difficulties are linked to later problems in academic, occupational and socioemotional functioning. Therefore, it is vital to design preventive measures that can be implemented during early childhood when these skills are rapidly developing.

A successful play-based preventive intervention called ENGAGE (Enhancing Neurocognitive Growth with the Aid of Games and Exercise) aims to improve children's cognitive, emotional and behavioural self-regulation through children’s games (eg, Simon Says) that are interpersonal in nature and teach a range of skills. ENGAGE leads to improvements in parent-rated behaviour problems equivalent to a gold-standard parent-management programme (Triple P), with treatment gains maintained 12 months later. In an intervention in 28 early childhood education centres (ECEs) in Auckland New Zealand, ENGAGE was demonstrated to lower levels of hyperactivity, aggression and inattention across a cohort of 940 preschool children relative to a wait-list control period.

Self-regulation can also be fostered by enhancing children’s oral language development. The way adults talk with children during everyday activities (book-reading, mealtimes, play) advances children’s early language and cognitive development, which in turn enhances their self-regulation. Book-sharing and conversing about everyday experiences are two evidence-based methods that improve children’s oral language skills. For instance, a combined reading-and-conversation programme developed in New Zealand with parents and teachers called Tender Shoots improves preschool children’s oral narrative, early literacy and socioemotional skills up to 1 year after the intervention when compared with activity-based controls. Critically, children’s academic skills at school entry predict their later academic and socioemotional functioning.

Oral language is developing rapidly in the toddler years. Therefore, oral language interventions at this age can produce stronger benefits than similar interventions at older ages, but such interventions are rare. Previous oral language interventions have focused primarily on training either parents or teachers to engage in the interactions, but not both. The few combined interventions that have been conducted indicate larger benefits for preschool children when both parents and teachers are using the techniques compared with home-only or school-only. We have developed a shared reading-and-conversation programme for even younger children with both teachers and parents called ENRICH (Enhancing Rich Conversations; see table 1 and figure 1).

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### Table 1. Books in English and Te Reo Māori and Cards for ENRICH and ENRICH+ Interventions

<table>
<thead>
<tr>
<th>ENRICH (1.5–3 years)</th>
<th>ENRICH+ (3–5 years)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Phase 1 books</strong></td>
<td></td>
</tr>
<tr>
<td>The Noisy Book</td>
<td>Pukeko Shoes</td>
</tr>
<tr>
<td>by Soledad Bravi</td>
<td>by Janet Martin</td>
</tr>
<tr>
<td>Hoihoi Turturi transl. by Ruia Aperahama</td>
<td>and Marigold Janezic</td>
</tr>
<tr>
<td><strong>Phase 1 cards</strong></td>
<td></td>
</tr>
<tr>
<td>Overview of ENRICH, Phase 1</td>
<td>Overview of ENRICH+, Phase 1</td>
</tr>
<tr>
<td>Kai Time</td>
<td>Kai Time</td>
</tr>
<tr>
<td>Book Time</td>
<td>Book Time</td>
</tr>
<tr>
<td>Nappy Time</td>
<td>Greetings/Farewells</td>
</tr>
<tr>
<td>Play Time</td>
<td>Play Time</td>
</tr>
<tr>
<td>Group Time</td>
<td>Group Time</td>
</tr>
<tr>
<td><strong>Phase 2 books</strong></td>
<td></td>
</tr>
<tr>
<td>Mahi/Actions</td>
<td>Abigail Fantail</td>
</tr>
<tr>
<td>by Kitty Brown and Kirsten Parkinson</td>
<td>by Janet Martin</td>
</tr>
<tr>
<td>Kare ia-roto/Feelings by Kitty Brown and Kirsten Parkinson</td>
<td>and Marigold Freeman</td>
</tr>
<tr>
<td>Who’s Driving? by Lea Timmers</td>
<td>Gorilla Loves Vanilla by Chae Strathie and Nicola O’Byrne</td>
</tr>
<tr>
<td>Ma Wai e Hautu transl. by Karena Kelly</td>
<td>Kuwi’s Huhu Hunt by Katherine O. Merewether</td>
</tr>
<tr>
<td><strong>Phase 2 cards</strong></td>
<td></td>
</tr>
<tr>
<td>Overview of ENRICH, Phase 2</td>
<td>Overview of ENRICH+, Phase 2</td>
</tr>
<tr>
<td>Kai Time</td>
<td>Kai Time</td>
</tr>
<tr>
<td>Book Time</td>
<td>Book Time</td>
</tr>
<tr>
<td>Nappy/Toilet Time</td>
<td>Greetings/Farewells</td>
</tr>
<tr>
<td>Play Time</td>
<td>Play Time</td>
</tr>
<tr>
<td>Group Time</td>
<td>Group Time</td>
</tr>
<tr>
<td><strong>Phase 3 books</strong></td>
<td></td>
</tr>
<tr>
<td>Louie the Tui</td>
<td>Te Hipo Huna, transl. by Karena Kelly</td>
</tr>
<tr>
<td>by Janet Martin and Ivar Treskon</td>
<td>by Katherine O. Merewether</td>
</tr>
<tr>
<td>The Three Billy Goats Gruff by Paul Galdone</td>
<td></td>
</tr>
<tr>
<td>Jumblebum by Chae Strathe and Ben Cort</td>
<td></td>
</tr>
<tr>
<td>That’s NOT a Hippopotamus! by Juliette MacIver and Sarah Davis</td>
<td></td>
</tr>
<tr>
<td>Te Hipo Huna, transl. by Karena Kelly</td>
<td></td>
</tr>
<tr>
<td><strong>Phase 3 cards</strong></td>
<td></td>
</tr>
<tr>
<td>Overview of ENRICH+, Phase 3</td>
<td>Overview of ENRICH+, Phase 3</td>
</tr>
<tr>
<td>Kai Time</td>
<td>Kai Time</td>
</tr>
<tr>
<td>Book Time</td>
<td>Book Time</td>
</tr>
<tr>
<td>Greetings/Farewells</td>
<td>Greetings/Farewells</td>
</tr>
<tr>
<td>Play Time</td>
<td>Play Time</td>
</tr>
<tr>
<td>Group Time</td>
<td>Group Time</td>
</tr>
</tbody>
</table>

ENRICH, Enhancing Rich Conversations.
Objective
To determine if an intervention, over and above the usual early childhood curriculum, that targets development of oral language plus self-regulation (ENRICH plus ENGAGE) has greater benefits on the development of children’s oral language, self-regulation and academic functioning than interventions that target either oral language (ENRICH) or self-regulation (ENGAGE).

Methods and Analysis
Study design
This study is an open-label, cluster designed four-armed randomised controlled trial (RCT) with children aged 13–30 months at outset, their parents and their teachers at BestStart early childhood centres in New Zealand. ECEs are randomly assigned to the ENRICH and/or ENGAGE interventions or an Active Control group; teacher and family participation in the study is voluntary at all stages. Interventions are implemented with a factorial design. Professional development with teachers and workshops with parents began after baseline when children were 13–30 months. Interventions will continue until children are 5 years of age, and children will be followed until they are 6 years of age (see figure 1 and figure 2; online supplemental file 1). Consistent with the national early childhood curriculum, the ENRICH intervention is book- and conversation-based to foster toddlers’ oral language skills in English and te reo Māori, with ENRICH+ an advanced version for preschoolers to support oral language in English and te reo Māori, and early literacy (see table 1 and online supplemental file 1). The ENGAGE intervention is games-based to foster preschool children’s self-regulation skills (see table 2 and online supplemental file 1). Recall that oral language is a pathway to self-regulation. Parents can also enrol with their children in a Brain and Behaviour Development substudy (see figure 1 and online supplemental file 2).

ECEs, and participants, will be randomised into the following four arms:
1. Oral language only: ENRICH (1.5–3 years) and ENRICH+ (3–5 years).
2. Self-regulation only: ENGAGE (3–5 years).
3. Combined: ENRICH (1.5–3 years) and ENRICH+ (3–5 years) and ENGAGE (3–5 years).

Figure 1 The Kia Tīmata Pai (Best Start) schedule of enrolment, interventions and assessments. The timeline of participant enrolment, the interventions administered during the study and the assessments conducted at specific time points. This schedule provides an overview of the study design and the key elements involved in the research process. Notes: Specific measures are listed at a particular time-point if there is change in the measure used across time due to ensure they remain developmentally-appropriate. ‘X’ indicates that a particular set of measures was used at that time point. EEG/ERP & eye-tracking measures: Resting, Auditory, Working Memory (WM), Flanker, Disengagement, and Visually-evoked potential. Behavioural executive functioning: WM, Inhibition, and Categorisation, CBRS, Child Behavior Rating Scale; ECBQ, Early Childhood Behavior Questionnaire; ECE, Early childhood education; IDI, Integrated Data Infrastructure; NZCDI, New Zealand Communicative Development Inventories; PELI, Preschool Early Literacy Indicators; PROLL, Parent Rating of Oral Language and Literacy; TROLL, Teacher Rating of Oral Language and Literacy. Parent-child interactions: No toy play, Toy play, Divided attention, and Shared past event narrative.
4. Active control: Curriculum as usual plus child development webinars.

The Kia Tīmata Pai trial contains two nested substudies: (1) the Video Project: a video teacher–child interaction substudy to measure implementation within 24 ECE centres randomly selected from participating centres in two large cities (Auckland: 12; Christchurch: 8), two small cities (Dunedin: 1; Invercargill: 2), and a rural region (1); and (2) the Brain and Behaviour Development substudy on a subset of children (n=235) who volunteered to participate in additional neurophysiological and behavioural testing at university laboratories in either Auckland or Christchurch, New Zealand.

Teachers are being trained in the interventions using a ‘train the trainer’ model. First, teacher managers (called professional practice leaders) within the BestStart early childhood organisation are being trained online and in person in the implementation of the ENRICH and ENGAGE interventions by the research team. These professional practice leaders have at least 10 years of experience in early childhood education. The professional practice leaders subsequently conduct training workshops with the ECE teachers, again via online and in-person delivery, who then implement the techniques with children in their centres.

Professional development workshops for the toddler phase of ENRICH (from approximately 1.5–3 years of age) were delivered in 2021 and 2022. Professional development workshops for ENRICH+ and ENGAGE took place in early 2023 when study children were approximately 3 years old (ie, at the start of the preschool phase, which extends from approximately 3–5 years of age).

Professional practice leaders will receive booster training sessions approximately every 9 months throughout the course of the study; these leaders will then deliver booster training sessions to teachers. As part of the study, professional practice leaders are required to document the delivery of teacher workshops and follow-ups with centres to answer questions. Every time teachers in either ENRICH or ENGAGE conditions receive new training, parents of children in intervention conditions are invited to learn about the new techniques through online information evenings and recorded video links.

Teachers in ENRICH centres were trained in 2021 and 2022 and provided with new resources for the toddler phase of the study (two sets of informational cards, six new books and instructional videos; see table 1). In the preschool phase of the study, teachers in both ENRICH+ and ENGAGE conditions have begun to receive new training and resources (sets of informational cards and/or books and instructional videos) approximately every 9 months (see table 1).

Teachers in ENRICH centres are encouraged to use the intervention techniques as often as possible throughout the day in any language both they and the child speak during five routines: mealtimes, book times, nappy changes, play and group time. Provided books are all commercially available, but contain conversation

Table 2  
*Examples of ENGAGE games and activities*

<table>
<thead>
<tr>
<th>Targeted domain</th>
<th>ENGAGE game or activity (3–5 years)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Emotional/feelings</td>
<td>▶ Relaxing Yoga</td>
</tr>
<tr>
<td></td>
<td>▶ Deep Breathing</td>
</tr>
<tr>
<td></td>
<td>▶ Drawing</td>
</tr>
<tr>
<td>Cognitive/thinking</td>
<td>▶ Object Copy</td>
</tr>
<tr>
<td></td>
<td>▶ Puzzles</td>
</tr>
<tr>
<td></td>
<td>▶ Cups Memory</td>
</tr>
<tr>
<td></td>
<td>▶ Beading</td>
</tr>
<tr>
<td></td>
<td>▶ Snap</td>
</tr>
<tr>
<td></td>
<td>▶ Card Memory</td>
</tr>
<tr>
<td>Behavioural/doing</td>
<td>▶ Ball Games</td>
</tr>
<tr>
<td></td>
<td>▶ Musical Statues</td>
</tr>
<tr>
<td></td>
<td>▶ Animal Speeds</td>
</tr>
<tr>
<td></td>
<td>▶ Skipping</td>
</tr>
<tr>
<td></td>
<td>▶ Ball and Spoon Race</td>
</tr>
<tr>
<td></td>
<td>▶ Simon Says</td>
</tr>
<tr>
<td></td>
<td>▶ Hop Scotch</td>
</tr>
</tbody>
</table>

*Adapted with permission from Healey and Healey9 (2019; table 1). ENGAGE, Enhancing Neurocognitive Growth with the Aid of Games and Exercise.*

Figure 2  
Schematic diagram of study design. This schematic diagram provides a visual representation of the study design, depicting the sequential flow of participant selection, randomisation, allocation to intervention groups and the subsequent assessments conducted throughout the study period. ENRICH, Enhancing Rich Conversations; ENGAGE, Enhancing Neurocognitive Growth with the Aid of Games and Exercise.
prompts on each page that have been specially designed and inserted for this study. In ENRICH+, teachers will be encouraged to select two books per week to read three times each, plus to continue to have enriched conversations on a daily basis during greetings/farewells, mealtimes, play times and group time. Teachers in ENGAGE centres are encouraged to use the games for 30 min a day.

In the toddler phase of the study (1.5–3 years), teachers in centres in the ENGAGE-only arm and the Active Control arm participated in two webinars on childhood nutrition, a topic chosen in consultation with BestStart. In the preschool phase, teachers in the Active Control arm will also receive child development webinars every 9 months on children’s friendships, a topic chosen in consultation with BestStart. All webinars are recorded and delivered by Ph.D.-level child development experts for approximately 1 h each including questions. Parents of children in the ENGAGE-only arm (toddler phase) and the active-control arm of the study are invited to these webinars or to watch recordings, at their leisure.

Participants: eligibility criteria, study setting and consent process
The Kia Timata Pai trial is a collaboration with a large national early childhood education organisation in New Zealand called BestStart. Beginning on 4 May 2021 and with a second cohort recruited from March to June 2022, managers from 138 ECEs invited teachers and parents of all children in the target age range (originally from 17 to 24 months but changed to 13–30 months at enrolment) to consent to participate via an online link or paper forms at the centre (see online supplemental file 3). There are no gender, ethnic, language or socioeconomic restrictions to participation. All enrolled children (13–30 months at enrolment; M=20.6 months; SD=3.4) are being exposed to the interventions within their ECE. Data are being collected only on those children whose families granted consent. The final wave of data collection for the early childhood phase is planned to end in December 2025, and the final age 6 assessment is planned to end in January 2027.

Implementation checks
Intervention fidelity is being monitored: (1) via fortnightly teacher self-ratings of the frequency of their delivery of the techniques and each study child’s engagement in the techniques and (2) via videotaped teacher–child interactions once a year in the 24 centres in the Video Project (approximately 100 children and their teachers each year). These implementation checks will serve as an audit on trial conduct and are being overseen by Methodist Mission Southern, a coinvestigator body that is independent of the sponsoring organisation (ERANZ).

Outcomes
Primary
Our primary outcomes are children’s oral language, self-regulation and early literacy (see figure 1). In the toddler phase (1.5–2.25 years), we are measuring increases in vocabulary size and syntax with the New Zealand Communicative Development Inventories (short forms) in English, te reo Māori, Samoan, Tongan, Mandarin, and Cantonese for parents, and for teachers in English and te reo Māori and increases in the effortful control subscale and decreases in the negative emotionality subscale of the Early Childhood Behavior Questionnaire. In the preschool phase (3–5 years), we will measure increases in English oral language (semantic, phonological, syntactic and pragmatic) and literacy (letter recognition, print concepts and writing) with the Teacher Rating of Oral Language and Literacy, and the adapted companion Parent Rating of Oral Language and Literacy. Children’s competence in producing words and phrases in te reo Māori will be measured via teacher and parent report. Finally, global teacher ratings will assess improvement of children’s oral language, literacy, self-regulation and social skills from ages 3 to 6.

Secondary
Children’s B4 school check at age 4.5 years will be accessed through the Ministry of Health to assess improvements in school readiness. Medical practitioners rate children’s cognitive, physical, and socioemotional development. Children’s Integrated Data Infrastructure (IDI) will also be accessed at age 6 years and beyond to provide long-term data on improvements in education, health and employment outcomes. The IDI is administrative data held by the New Zealand government on a range of outcomes. Parents and teachers are self-reporting their early learning practices at each assessment wave. Teachers are also reporting on their own proficiency in te reo Māori, an official language of New Zealand and a target focus of ENRICH and ENRICH+ (see table 1).

Each year, approximately 100 children and their teachers in the Video Project classrooms are being videotaped for a total of 25 min (5 min per targeted routine). The videotapes will be transcribed and then coded for the quantity and quality of speech by coders who are blind to centre condition. Two waves of video observation data were collected in 2021 and 2022, with two more waves planned in 2023 and 2024.

Every 6 months, the children participating in the Brain and Behaviour Development substudy are being administered additional neurophysiological measures (electroencephalography (EEG)/event-related potential (ERP) and eye-tracking) and behavioural measures of executive functioning (working memory, inhibition and categorisation), oral language and literacy (vocabulary, story comprehension, phonological awareness and letter recognition); and a parent–child interaction measure (see figure 1 and online supplemental file 2). Analysts and coders are blind to children’s centre condition. The
first through third waves of data are now complete, with the fourth wave ongoing.

**Participant and public involvement**

A key feature of the intervention is to codesign implementation with BestStart professional practice leaders. Academics designed the two interventions, but the way the techniques are presented to teachers at each phase is being developed through a codesign process with BestStart leaders, facilitated by implementation leaders at Methodist Mission Southern. The objective is to build on teachers’ existing knowledge and practices to enhance uptake of ENRICH and ENGAGE techniques. BestStart leaders also inform the administration of the fortnightly implementation checks and assessments at each wave.

**Sample size calculation**

Based on previous oral language and self-regulation interventions with early childhood teachers, we anticipate small to medium effect sizes. Power analyses of final-phase primary outcomes suggested a total sample size at baseline of approximately 1600 children (ie, approximately 400 per group, including control group) for the current study to afford precision for estimates with alpha=0.05 and power between 0.75 and 0.90. This sample size of 400 per group at baseline allows for attribution of children over the early childhood phase of the study. This sample size also takes into account multiple predictor variables to allow for up to eight-way analyses within groups for some outcomes at time of final analysis of the early childhood phase at age 5 (see online supplemental file 1 for more detail). We expect to have full data for any analyses involving IDI (Integrated Data Infrastructure) information from age 6 and beyond, because parents have consented to that information being used regardless of whether children stay in their same BestStart centre throughout early childhood.

**Recruitment**

Recruitment of children in the target age range began with a first cohort A from May to August 2021. Due to pandemic-related disruptions, recruitment continued with a second cohort B from March to June 2022 for a total of 1496 children and their parents and 1634 teachers enrolled in the study to date. We excluded 15 children who fell outside the age range of 13–30 months, so the total number of children who will be included in analyses is 1481, with no substantial loss of power for the small to medium effect sizes anticipated. New teachers are being recruited, consented and trained as they begin employment at BestStart (see online supplemental files 13).

**Allocation to conditions (randomisation)**

The procedure for allocating centres to conditions was central randomisation by computer using a 2 (ENRICH vs no ENRICH) × 2 (ENGAGE vs no ENGAGE) factorial design (see figure 2). The method used to generate the sequence was permuted block randomisation by early childhood centre.

**Data collection**

In the Kia Timata Pai main trial, assessments are being administered approximately every 9 months between ages 1.5 and 5 years, and at age 6 years. Teachers and parents are asked to complete instruments to assess children’s oral language and literacy, self-regulation and socioemotional skills (see figure 1), which takes approximately 35 min each wave using REDCap (Research Electronic Data Capture) hosted at the University of Otago. Paper forms are also provided for participants who do not wish to complete the forms online.

In the Video Project, naturally occurring classroom practices at 24 centres are videotaped by researchers every year to age 5 years, which takes approximately 90 minutes in each centre at each assessment wave.

In the Brain and Behaviour Development substudy, a subset of 235 children from the main trial are taking part in additional neurophysiological and behavioural assessments: EEG/ERP, eye-tracking, and behavioural measures of attention, emotion processing, categorisation, cognitive flexibility, inhibitory control, and memory, as well as a parent–child interaction task (see figure 1; online supplemental file 2). For the EEG session, children sit on their parents’ lap and parents are asked to hold their children still. Children’s eyes are 60–70 cm from the Tobii Spectrum eye tracker. The distance was determined using the Position Guide feature in Tobii Pro Lab software.

Data collection for the Kia Timata Pai main trial early childhood phase, the Video Project substudy and the Brain and Behaviour Development substudy are targeted to end in December 2025.

Incentives to complete assessments at each wave in the main trial are in the form of raffles for centres (of 10 US$250 gift cards) and parents (of 10 US$250 gift cards). Parents and children participating in the Brain and Behaviour Development substudy receive a US$20 gift card and small gift at each wave.

**Data management and security**

**Source and format of data**

All raw data files including the reports of teachers and parents are saved as CSV files, and media files including the naturalistic observations from 24 BestStart centres are saved as MTS video files at the University of Otago.

**Data sharing protocol between centres and the university**

Data from all sites are collected by the REDCap server or sent directly to the research manager, Dr. Tugce Bakir-Demir, at University of Otago. Hard copies of any paper forms are couriered to the University of Otago in a secure envelope via New Zealand Couriers.

Data sharing agreements have been established between the University of Otago, University of Auckland and Boston Children’s Hospital. Participants were informed and consented to the data sharing process (see online supplemental file 3).
Data storage, security and access

Raw digital data are stored in REDCap, which is a secure, web-based software platform. Back-ups of the digital data are also on the University of Otago server. Paper forms are securely stored at the research laboratory within the university to which only a limited number of approved researchers in the trial have access.

Raw electrophysiological (EEG/eye-tracking) data are stored encrypted on secure servers within the University of Auckland. Due to the nature of this electrophysiological data, it could not be wholly deidentified prior to processing as it contains audio and video recordings of participants, which are naturally identifying.

Confidentiality

All information that we collect is used only by the research team working on this study. Any raw data (including video data) and personal information will be retained in secure storage for at least 5 years after the end of the project, as required by the University of Otago’s research policy, after which time it will be destroyed. The overall results of the project will be published and will be available in university libraries and public good databases, but each individual participant's information will remain anonymous and confidential.

Statistical analyses

For the primary outcomes of the main trial, we will analyse data only from participants who have remained in their original BestStart centre. All enrolled children will be included in analyses of the B4 School Check and IDI and age 6 follow-up. We will use intention-to-treat analyses for the participants in the Brain and Behaviour Development substudy, who will continue to be followed even if they leave their BestStart centre.

Mixed modelling and moderator/mediator analyses will be conducted to assess children’s oral language and self-regulation outcomes as a function of intervention condition (nested within centres) and as a function of implementation fidelity, adjusting for confounders. If missingness is below 60%, we will test the assumption that missing data are missing completely at random and if necessary apply multiple imputation. We will also run sensitivity analyses that compare the results for each cohort (A and B) with the results for the entire sample.

Ethical considerations

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 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. Therefore, we have determined that there is no need for a formal data monitoring committee.

The University of Otago Human Ethics Committee (Health) approved this study on 23 November 2020 (H20/116). The cultural responsiveness of the project has also been approved by the Ngā Tūhurū Research Advisory Committee in 2020 and again, after minor modifications, in 2022. The cultural appropriateness of assessments and intervention materials is continually monitored by our own Cultural Advisory Group who are drawn from academia, the community and the BestStart provider (currently Amanda Clifford, Elizabeth Schaughency, Mele Tauaopepeu, Karen Salmon, Pip Laufiso, Barbara Backshall and Waveney Lord).

Trial registration status

The study was registered in the Australia/New Zealand Clinical Trial Registry (ACTRN12621000845831) on 22 April 2021, prior to the date of the first enrolment on 4 May 2021. Confirmation of trial registration was delayed (1 July 2021) due to a COVID-19-related backlog. Any amendments to this protocol will be updated on the trial registry.

DISCUSSION

The Kia Tīmata Pai study was developed to promote oral language and self-regulation development in children from 1.5 years of age using interventions that include both teachers and parents. To the best of our knowledge, this study is the first RCT to test the singular and combined effects of oral language and self-regulation interventions on children from such a young age.

Our findings will inform both theory and practice. With respect to theory, we will be able to test our hypothesis that oral language is a key driver of later self-regulation. We will also test our hypothesis that combining oral language and self-regulation interventions will produce the greatest benefits for children’s self-regulation and later academic functioning. Finally, via the Brain and Behaviour Development substudy, we will test our hypothesis that the intervention benefits are mediated by neurophysiological changes in brain development.

With respect to practice, our findings will inform the design of early childhood curricula in New Zealand and internationally, including those with a multilingual focus. In contrast to previous studies focused on predicting negative outcomes, the analyses could identify predictors of future positive outcomes. Critically, each intervention is designed so that it can be readily scaled up to reach larger numbers of early childhood teachers and children—within a short-time frame.

Dissemination

We will disseminate the findings widely via newsletters to early childhood centres and parents twice a year, in-person
and online presentations at national and international conferences, publications in academic journals, blogs and podcasts for professional and trade organisations, oral and written communication to the New Zealand Ministry of Education, and a study website.

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Disclaimer Emotion Regulation Aotearoa New Zealand (ERANZ) is the sponsor for this trial. Members of ERANZ include RP ER, SM, ES, MT, KS, and PG. Please contact corresponding author Professor Elaine Reese, elaine.reese@otago.ac.nz at University of Otago, Department of Psychology, 93 Union Place East, Dunedin, New Zealand 9016, (64) 03 479-8441. The sponsor is responsible for the study design of the main trial; collection, management, analysis, and interpretation of the data; and the decision to submit reports for publication.

Competing interests The principal investigators (RP and ER) and coinvestigators (JK, HG, TB-D, ES, KS, MT, AC, SM, PG, CN, RW and JO’S) report no financial or other competing interests.

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.

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Background

Self-regulation is a vital skill for people of all ages. Self-regulation in early childhood predicts later academic functioning and life success (Moffitt et al., 2011). Poor self-regulation in early childhood is associated with current behaviour problems and with later psychopathology. For example, ADHD is a chronic neurodevelopmental disorder of self-regulation (Mannuzza et al., 2003; Willcutt et al., 2005), and the most common disorder of childhood (APA, 2000) with 12,500 children medicated for ADHD in New Zealand (New Zealand Health Information Service, 2008). ADHD is associated with increases in the risk of academic and employment failure, additional psychopathology, and criminality (Gathje et al., 2008).

Although external interventions using medication (Conners, 2002) and behaviour modification (e.g., parent training; Pelham & Fabiano, 2008) are highly effective treatments for ADHD in the short-term, gains are rarely maintained after the termination of treatment (Molina et al., 2009). Healey and Halperin (2015) developed a novel preschool intervention designed to overcome these shortcomings. ENGAGE (Enhancing Neurocognitive Growth with the Aid of Games and Exercise) aims to improve ADHD symptoms through strengthening neural networks leading to improved self-regulatory skills. ENGAGE employs a range of tasks involving skill areas known to be under-developed in children with ADHD. The tasks are variations of well-known children’s games (e.g., Simon Says) that are interpersonal in nature, and teach a range of physical and mental skills. ENGAGE leads to equivalent improvements in parent-rated behaviour problems as a gold-standard parent-management programme (Triple P), with treatment gains maintained 12 months later (Healey & Healey, 2019).

Another way to foster self-regulation is to enhance children’s oral language development (Salmon et al., 2016). The way adults talk with children during everyday activities (mealtimes, book-reading, play) advances children’s early language and cognitive development (e.g., Gilkerson et al., 2018), which in turn enhances their self-regulation. Oral language skills also support children’s literacy development and their success in school. Tender Shoots is a book-reading and conversation programme for parents and educators to enhance pre-schoolers’ oral language development (Schaughency et al., 2014). Tender Shoots stimulates high-quality conversations between adults and children (Das et al., in prep), which in turn improves children’s oral language, literacy, self-regulation, and socioemotional skills (Das et al., in prep; Reese et al., 2020; Riordan et al., in prep; Schaughency et al., 2020; in prep).

We now need to know if ENGAGE and Tender Shoots together will produce even better outcomes for children than either programme alone. To maximise these benefits, we are trialling a new preparatory phase for toddlers, ENRICH (ENhancing RICH conversations), that will lay the oral language foundations
needed for children to make the most of ENGAGE and Tender Shoots in the preschool years.

Our aim is to conduct a 5-year longitudinal randomised controlled trial (RCT) evaluating the effectiveness of targeting language and self-regulation over time (ENRICH + Tender Shoots + ENGAGE), to targeting language alone (ENRICH + Tender Shoots) or self-regulation alone (ENGAGE), in comparison to the usual BestStart curriculum.

The four arms are thus (400 children in each).
1) Combined: ENRICH (1.5 to 3 years) + Tender Shoots (3 to 5 years) + ENGAGE (3 to 5 years)
2) Language only: ENRICH (1.5 to 3 years) + Tender Shoots (3 to 5 years)
3) Self-regulation only: ENGAGE (3 to 5 years)
4) Control: Existing BestStart curriculum

*Note that groups 1, 2, and 3 will also receive the existing BestStart curriculum.

<table>
<thead>
<tr>
<th>Intervention groups</th>
<th>Wave 1 1.5 – 3 years</th>
<th>Wave 2 3 – 5 years</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>ENRICH</td>
<td>As usual</td>
</tr>
<tr>
<td>Combined</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Language</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Self-regulation</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Control</td>
<td>X</td>
<td></td>
</tr>
</tbody>
</table>

Hypotheses: We expect that with its focus on improving self-regulation, ENGAGE will produce the strongest benefits for self-regulation. But we expect the combination of ENRICH, Tender Shoots, and ENGAGE will lead to the best outcomes for children’s self-regulation and socioemotional skills, because we hypothesise that language development will potentiate the benefits of ENGAGE on children’s self-regulation. We will conduct mediator analyses to assess whether benefits are gleaned through increases self-regulation or language. We also expect that the combination of ENRICH + Tender Shoots, with its focus on improving language, will indeed produce the greatest benefits for children’s language development. These language benefits are expected to extend to children’s reading skills and be maintained through the first year of primary school. We expect that either ENGAGE or ENRICH/Tender Shoots alone will also lead to benefits for self-regulation and oral language, respectively, over the existing BestStart curriculum. From a policy point of view, it would be of interest to see which intervention gives best value for money, or if the combination of the three is worth the extra cost and time. The findings from this study could shape the national early childhood curriculum.
Sampling, Power, Allocation: Our methodologist and data analyst, Dr. Matt Healey (Methodist Mission Southern), will select 140 centres from over 200 BestStart centres to form a nationally representative sample of regions, socioeconomic status, and children’s ethnicity (see attached methodology document). This number of centres is estimated to allow recruitment of the desired number of 1600 children aged 17- to 24-months at the outset. A final sample size of 400 children per group is estimated to provide sufficient power to mitigate the possible effects of cluster variance confounds, interaction effects, predictor variables, and participant attrition. Dr. Healey will then randomly assign each centre to one of the four conditions.

Recruitment: Teachers in each centre will recruit parents to enrol their 17- to 24-month-old children in the study. Children with a pervasive developmental disorder or history of brain trauma will be excluded from data collection. We will thus be unable to generalise to children with pervasive developmental disorders or history of brain trauma. All children within the target age group will be exposed to the interventions within their ECE, but data will not be collected on those children whose families have not granted consent. Parents of nonparticipating children attending the centre will be sent an information letter to let them know about the projects and about their children’s educators’ participation. There will be no gender, racial/ethnic, language, or socioeconomic restrictions to participation in this study.

Baseline: Following enrolment in the study and informed consent, parents and teachers will be asked to complete some of the following measures, which will be decided upon in collaboration with BestStart to minimise response burden: the Behavioural Assessment System for Children (BASC-2; a widely used measure of psychosocial functioning; see Appendix 1); the Strengths and Difficulties Questionnaire (SDQ; see Appendix 2), the Children’s Behaviour Questionnaire.
Parents will also be asked to complete a demographic and developmental history questionnaire (see Appendix 5) and the Parenting Stress Index (see Appendix 6) as a baseline measure of stress in relation to parenting their target child, and to report on their tobacco/alcohol/drug use during pregnancy. Teachers will report on the children’s skills using the Teacher Rating of Oral Language and Literacy (TROL; see Appendix 7) and the Child Behaviour Rating Scale (CBRS; see Appendix 8). Teachers will also report on their beliefs and current practices to support children’s self-regulation, language, and (Brackett et al., 2012). We will offer parents and teachers $10 vouchers for each wave of questionnaires that they are asked to complete. We will give children small rewards (stamps, stickers) at individual assessment sessions.

Intervention Phase:
After clusters of centres are randomly assigned to one of the four conditions (with approximately 400 children each), the PIs will hold professional development sessions with 14 professional practice leaders (PPLs) serving around 20 centres each (of which roughly 10 centres for each PPL will be part of the RCT). The PIs will train the PPLs to train the teachers in their participating centres via a training video and resources. A separate training video will be developed for any parents who want to learn the techniques to use at home; this variable will be controlled for in analyses by measuring the number of parents who request the training video and who report using the techniques at home. For the control condition, measures of parents’ existing use of the techniques will be taken. These training sessions will be held in early 2021 for ENRICH, and in 2022 for ENGAGE and Tender Shoots. We will measure implementation through observations of classroom activities, which are expected to be conducted on a daily basis. We will guard against cross-contamination by taking advantage of the existing structure of the BestStart organisation, in which each PPL manages a cluster of centres. Each PPL will be responsible for administering a single condition across their centres, thus limiting the possibility of teachers or parents sharing information about other conditions with other centres. We will also liaise with PPLs throughout the study on ways to prevent cross-contamination across centres in the same region.

Early Childhood Outcomes:
Our main outcome measures will be language, self-regulation, socioemotional, and early literacy development. Approximately every 6 months between ages 2 and 5, we will ask teachers and parents to use the same instruments to assess children’s self-regulation, language, and socioemotional skills. We will supplement these parent- and teacher-report instruments with individually administered assessments to children from age 2.5, such as the following well-validated measures that co-PIs Healey, Reese, and Schaughency have used in previous projects (e.g., project 16/016):

**Oral language and literacy:** Clinical Evaluation of Language Fundamentals, Australian/New Zealand 5th edition: Preschool 2 (CELF-P; Wiig et al., 2017), the Preschool Early Literacy Indicators (PELI, Kaminski et al., 2014),
and children’s narrative comprehension and production (Reese et al., 2010). For bilingual children, we will conduct measures of early literacy and narrative in both languages as often as possible.

**Self-regulation:** The Statues subtest from the Developmental Neuropsychological Assessment (NEPSY-2; Korkman et al., 2007); the Head and Toes Task (Ponitz et al., 2008); selected subtests from the Stanford Binet (SB5; Roid, 2003; e.g., Working Memory); and additional subtests from the Developmental Neuropsychological Assessment (NEPSY-2) such as Comprehension of Instructions and Visuomotor Precision.

**Socioemotional skills:** Emotion knowledge task (Denham, 2006); Challenging Behaviour Task (Bierman et al., 2014).

**B4 School Check:** Not all parents obtain a B4 School Check for their children with GPs (Schluter et al., 2020), but we will request access to this information when available. The B4 School Check is a health and development screening with 4-year-olds that assesses communication and behavioural difficulties. This information will serve as a reference point when comparing the children in our sample to other New Zealand children.

**School Outcomes:** We will invite children’s primary school teachers to complete the same behaviourial, socioemotional, and language and literacy rating scales as the early childhood teachers. If we have the capacity, we will also administer individual assessments, similar to the PELI above, to assess children’s developing literacy skills.

**Internal Data Safety Monitoring Committee**

We will coordinate with BestStart to develop a protocol for monitoring any adverse events. This protocol will involve Methodist Mission Southern regularly checking in on a weekly basis with individual educators and parents to answer questions and provide support, in collaboration with BestStart management and with the study team.

**References**


Riordan, J., Reese, E., Das, S., Carroll, J., & Schaughency, E. (in prep). *Tender Shoots*: Helping parents to have rich conversations with young children to advance early literacy.


Supplemental File 2

Original Protocol for Brain Development Sub-Study, Toddler Phase

1. EEG/ERP Tasks (3 tasks; ~ 30 minutes)
2. Eyetracking (2 tasks; ~ 15 minutes)
3. Behavioral executive function battery (3 tasks; ~15 minutes)
4. Parent-child interaction task (15 minutes)

Task Descriptions:

1. **EEG/ERP** (~ 30 minutes total, allowing 5-10 minutes for netting)
   a. **Resting state EEG** (~5 minutes)
      i. EEG is recorded, for 5 minutes, while children watch a video of a screensaver or moving toys (as a distraction)
   b. **Flanker ERP task** (~8 minutes)
      i. Passive ERP task testing attention, discrimination, novelty detection, and information processing. Stimuli are 5 fish in a row. In “congruent” trials, all of the fish are facing in the same direction”. In “incongruent” trials, one of the five fish is facing in the opposite direction. Eye gaze data will be collected with eye trackers to see how long it takes for children to detect (look at) the fish facing the opposite direction
   c. **Auditory familiar/non-familiar ERP task** (~8 minutes)
      i. Passive ERP task testing attention, discrimination, detection of novelty, and information processing. Stimuli are familiar voices and non-familiar voices. (details still being thought through - familiar voices could be a recording of the mom’s voice. If not possible, a training phase in which the child is familiarized to a voice could be used.

2. **Eyetracking** (~15 minutes, allowing a few minutes for set-up and calibration)
   a. **Disengagement** (~5 minutes)
      i. In each trial, children are presented with a face as the central stimulus. A peripheral stimulus (a geometric shape) is presented to the left or right of the central stimulus (face) with a ~1000 ms delay of onset. There will be a familiar face stimuli (same face for ~70% of trials), and unfamiliar faces (3 different faces - presented 10% of the trials each). The length of time that the children take to shift their eye gaze from the central face target to look at the peripheral target will be measured with the eye tracker.
   ii. **Working memory**: (~5 minutes) 4 boxes task (e.g., Garon et al., 2014) with eye tracking. 1 of 4 doors on screen has a toy behind it. Flap goes down. Flap comes back up, does the child look at the correct door?
3. **Behavioral executive functioning battery** (~15 minutes)
   a. **Glitter wand task** (Devine, Ribner & Hughes, 2019) - attractive toy placed within reach of child; Experimenter tells child not to touch it and then turns around. Time how long the child can resist touching (up to 30 seconds). Testing behavioral inhibition.
   b. **Reverse categorisation** - two sets of objects, each with a different color. There are two boxes, one with each of the colors. Children are given objects (e.g. blocks) one at a time and instructed to place them in the box with the opposite color as the block. Testing cognitive flexibility.
   c. **Spin the pots task** - cups are arranged on a spinning round disk (lazy susan). Experimenter places stickers under all cups except for 1 or 2 while child is watching; covers cups and spins, then uncovers. Child sequentially picks cups that they think have a sticker under them. Testing working memory.

4. **Parent-child interaction task** (~ 15 minutes)
   - No toy play (4 mins)
   - Books + toys free play (4 mins)
   - Divided attention (parent watches an instructional video while the child plays by him/herself) (developed by Ran Wei; 4 mins)
   - Parent-child narrative task (Reese & Newcombe, 2007; talking about a pre-selected shared past event) (3-4 mins)
Kia Timata Pai: Fostering Children’s Oral Language and Self-Regulation

INFORMATION SHEET FOR PARTICIPANTS (PARENTS/WHANAU)

Thank you for your interest and consideration of possible participation for you and your child in our project. Please read this information sheet carefully before deciding whether to participate. If you decide to participate, we thank you. If you decide not to take part, there will be no disadvantage to you, and we thank you for considering our request.

What is the aim of the project?

The aim of this project is to discover the "best start" for young children in early childhood education. This research is a 4-year longitudinal study to compare three new evidence-based professional learning and development (PLD) modules for early childhood kaiako/educators, added to the existing BestStart curriculum. The PLD modules integrate effective techniques for developing children's oral language, literacy, self-regulation, and social-emotional competence, all of which are vital for academic achievement. The programme is expected to contribute to kaiako/educators' professional learning and development and to be beneficial for children's development. Your child's centre may be allocated to receive one of the new PLD modules, or to continue to teach, if in one of the important control groups, in the existing BestStart curriculum.

This project is funded by the Wright Family Foundation. It is a collaborative project between BestStart, Methodist Mission Southern and researchers at the University of Otago, Victoria University Wellington, and University of Auckland.

What Type of Participants are Being Sought?
Participants will be educators and children in their care aged between 17 months and 5 years, and their parents. Your child's kaiako/educators are also being invited to participate.

What will participants be asked to do?

Should you agree to take part in this project with your child, you will be asked to complete questionnaires about your child's health and development, and about your own health, every 6 months until your child turns 5 years old. These questionnaires are expected to take a total of 3 hours across the next 3.5 years. If your child's centre is selected to learn the new techniques, your child's centre will be sharing these practices so that you can learn how to use them at home. To acknowledge your contribution to the project, a small token of appreciation will be offered. Your child may be videotaped as part of our evaluation of classroom practices.

Please be aware that you may decide not to take part in the project without any disadvantage to yourself or your child.

What data or information will be collected and what use will be made of it?

In addition to the information described above, we will also collect general demographics about you and your family (age, ethnicity, gender etc.). The purpose of collecting demographic information is so that we may describe our study sample and further tailor the programme to the needs of individual families. We will also seek access to your child's B4 School Check data (Ministry of Health) and the Integrated Data Infrastructure (IDI; Statistics New Zealand) to add to the information we are able to collect in the centre.
All information that we collect will be used only by the research team working on this study. The overall results of the project may be published and will be available in the University library, but each individual participant's information will remain anonymous and confidential as described below. You are most welcome to request a copy of the results of the project should you wish.

The data collected will be securely stored in such a way that only the research team will be able to gain access to it. Any raw data and personal information (including video data) will be retained in secure storage for at least five years after the end of the project, as required by the University's research policy, after which time it will be destroyed.

Can participants change their mind and withdraw from the project?

Reminder: You and your child may withdraw from participation in the project at any time and without any disadvantage to yourself of any kind.

What if participants have any questions?

If you have any questions about our project, either now or in the future, please feel free to contact any of the following:

Professor Elaine Reese              Professor Richie Poulton
(03) 479-8441                      (03)479-8507

A/P Dione Healey              Dr Elizabeth Schaugency
(03)479-7620                        (03)479-5864

This study has been approved by the University of Otago Human Ethics Committee. If you have any concerns about the ethical conduct of the research, you may contact the Committee through the Human Ethics Committee Administrator (ph(03) 479 8256 or email gary.witte@otago.ac.nz). Any issues you raise will be treated in confidence and investigated and you will be informed of the outcome.
Kia Timata Pai: Fostering Children's Oral Language and Self-Regulation

CONSENT FORM FOR
PARTICIPANTS (PARENTS/WHAN AU)

I have read the Information Sheet concerning this project and understand what it is about. All my questions have been answered to my satisfaction. I understand that I am free to request further information at any stage.

I know that:

1. My participation (and my child’s) in the project is entirely voluntary

2. My child and I are free to withdraw from the project at any time without any disadvantage

3. My child will be assessed every 6 months to age 5 for oral language, self-regulation, and social-emotional skills

4. My child may be videotaped as part of the evaluation of classroom practices
5. I consent to the research team contacting my child's primary school after enrolment for a follow-up assessment at age 6

6. I consent to the research team requesting access to my child's B4 School Check data (Ministry of Health)

9. Information collected in this study may be used for future research. This would include comparing my information and my child's with future information in the Integrated Data Infrastructure (IOI). No individualised results will be used in any reports.

10. The results of the project may be published in media and available in the University of Otago Library (Dunedin, New Zealand) but information will be stored and presented in ways that will protect participants' confidentiality.

I agree to take part in this project.

(Signature of participant)  (Date)
(Child's name) (Date of birth)

Phone number: .................................................................

Address

Street name:

Street number:

Suburb:

City:

Postcode:

This study has been approved by the University of Otago Human Ethics Committee. If you have any concerns about the ethical conduct of the research, you may contact the Committee through the Human Ethics Committee Administrator (ph (03) 479 8256 or email gary.witte@otago.ac.nz). Any issues you raise will be treated in confidence and investigated and you will be informed of the outcome.
Best Leap

A Sub-study to The Best Start Study: Children’s Brain Development

INFORMATION SHEET FOR PARTICIPANTS (PARENTS)

Thank you for considering participating in this sub-study to our larger project to measure children’s brain development. Please read this information sheet carefully before deciding whether or not to participate. If you decide to participate we thank you. If you decide not to take part, there will be no disadvantage to you, and we thank you for considering our request.

What is the Aim of the Project?

The aim of this sub-study is to measure the effects of the new practices on children’s brain development and their behaviour. We would like to learn more about how the program changes children’s attention, cognitive, and social processing.

This project is funded by the international organisation Wellcome LEAP, with collaborators at the Liggins Institute at the University of Auckland, and Boston Children’s Hospital in the U.S.

What Type of Participants are Being Sought?

Participants will be children who are already participating in the larger BestStart study between 17 months and 36 months, and their parents.

What will Participants be Asked to Do?

Should you agree to take part in this project with your child, you will be given taxi or petrol vouchers to visit the Liggins Institute at University of Auckland, or a location closer to your home, for one session every 6 months at times that are convenient for you and your child. Each session will take about one hour. At each session, your child will complete a brain-based measure to assess their neural responses to images and a series of behavioural tasks.

Your child will first look at images on a screen and we will record their eye movements using an eye tracker and their brain activity using electroencephalography (EEG) to record event-related potentials (ERPs). ERPs allow us to measure electrical brain responses to different images.

The eye tracker is made up of a special computer monitor that has a set of infrared cameras built into the edges of the screen. These cameras follow eye movements and will tell us exactly where on the screen your child is looking as they watch the images. In addition, we will record your child’s brain activity with a small cap that is made of stretchy material. Each cap has many sponges on it and inside each sponge is a small recording sensor. We soak the cap in a warm salt water solution so the sponges get soft before we put the cap on the child’s head. As your child’s brain is working, it is constantly giving off small electrical signals, which travel out to the scalp where we can pick them up with the special sensors.

After the eye-tracking and EEG equipment is ready to record, we will have your child sit in front of a computer screen. We will have your child watch a video of moving objects for two minutes while we record their resting brain activity. Next, we will record your child’s eye movements and brain activity in response to a series of images on the screen (for instance, rows of fish with one fish facing the wrong way, or a series of faces). In addition, a digital video will be recorded to help the researcher know when to present new images to your child and to aid data analysis. Your child’s name will not be associated with the video recording and the file
will be accessible only to the investigators of this study. Before starting the behavioural tasks, we will remove the EEG cap from your child’s head and take a short break if necessary.

The last three tasks are behavioural measures of your child’s executive functioning. To measure waiting for a turn, a researcher will place a glitter wand within reach of your child. The researcher will tell your child not to touch it and then will turn around. We will time how long your child can resist touching (up to 30 seconds). To test cognitive flexibility, your child will be shown two sets of blocks, each with a different colour. They are then shown two boxes. Children are given blocks one at a time and instructed to place them in the box with the opposite colour as the block. To test working memory, cups are arranged on a spinning round disk. A researcher places stickers under all cups except for 1 or 2 while your child is watching. Then the researcher covers the cups and spins, then uncovers. Your child will pick cups that they think have a sticker under them.

Please be aware that you may decide not to take part in the project without any disadvantage to yourself of any kind. Even if you decide not to participate in this sub-study, your child can still be part of the larger study.

What Data or Information will be Collected and What Use will be Made of it?

All information that we collect will be used only by the research team working on this study. This includes the University of Otago, the Liggins Institute at the University of Auckland, and Boston Children’s Hospital in the U.S. We will transfer the data (including video recordings) to Boston Children’s Hospital for analysis using secure systems. The overall results of the project may be published and will be available in the University library, but individual participants’ information will remain anonymous and confidential as described below. You are most welcome to request a copy of the results of the project should you wish.

The data collected will be securely stored in such a way that only the research team will be able to gain access to it. At the end of the project any personal information (including video recordings) will be destroyed immediately, except that, as required by the University’s research policy, any raw data on which the results of the project depend will be retained in secure storage at the University of Otago for at least five years.

What are the risks of this research study? What could go wrong?

There are minimal risks posed by these procedures. The study is for research purposes only.

The EEG/ERP technique is a non-invasive technique. If at any time during the session the researcher sees something that you and your doctor should know about, you will be notified and encouraged to see your child’s GP. A researcher will be present with you and your child throughout the testing session and the study will be stopped if your child shows any signs of discomfort. The salt solution that we use is non-toxic and will not hurt your child. We will remove most or all of the salt water with a warm flannel before you leave the lab, but some residual salt may remain until your child has a bath. The sensors we use to record brain activity are held together by a stretchy elastic material which may spring back if your child pulls on it. To ensure that this does not happen, a researcher will sit next to your child during the session and will make sure that their hands are not near the cap.

Can Participants Change their Mind and Withdraw from the Project?

Reminder: You and your child may withdraw from participation in the project at any time and without any disadvantage to yourself of any kind.

What if Participants have any Questions?
If you have any questions about our project, either now or in the future, please feel free to contact any of the following:

**Best Leap Sub-study:**

Sophia Amjad – Research Coordinator
Sonia Byrne – Research Assistant
Anita Trudgen – Research Assistant
The Liggins Institute

Email: kiatimatapai@best-start.org

**The Best Start Study:**

Professor Elaine Reese                                   Professor Richie Poulton
Department of Psychology                                                              Department of Psychology
University Telephone      University Telephone
479-8441                                                                                         479-8507

Associate Professor Dione Healey                      Dr Elizabeth Schaughency
Department of Psychology                                                              Department of Psychology
University Telephone      University Telephone
479-7620                                                                                          479-5864

This study has been approved by the University of Otago Human Ethics Committee. If you have any concerns about the ethical conduct of the research you may contact the Committee through the Human Ethics Committee Administrator (ph +643 479 8256 or email gary.witte@otago.ac.nz). Any issues you raise will be treated in confidence and investigated and you will be informed of the outcome.
Best Leap

A Sub-study to The Best Start: Children’s Brain Development

CONSENT FORM FOR
PARTICIPANTS (PARENTS/GUARDIANS)

I have read the Information Sheet concerning this project and understand what it is about. All my questions have been answered to my satisfaction. I understand that I am free to request further information at any stage.

I know that:-

1. My participation (and my child’s) in the project is entirely voluntary;
2. My child and I are free to withdraw from the project at any time without any disadvantage;
3. My child’s brain development will be assessed every 6 months from 1.5 years (18 months) to 3 years (36 months).
4. I agree for my child to be fitted with the EEG cap.
5. I agree for my child’s eye movements to be videotaped.
6. The data (including video recordings) will be transferred securely to Boston Children’s Hospital for analysis.
7. Personal identifying information (including video recordings) will be destroyed at the conclusion of the project but any raw data on which the results of the project depend will be retained in secure storage at the University of Otago for at least five years.
8. A small token of appreciation will be offered for my participation.
9. The results of the project may be published and available in the University of Otago Library (Dunedin, New Zealand) but information will be stored and presented in ways that will protect participant’s confidentiality.

I agree to take part in this project.
(Signature of parent/guardian)   (Date)

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.............................................................................  ...............................

(Child’s name)   (Date of birth)

Phone number: .............................................................................

Address
   Street name: .............................................................................
   Street number: .............................................................................
   Suburb: .............................................................................
   City: .............................................................................
   Postcode: .............................................................................

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