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A health-education intervention to improve outcomes for outcomes for children with emotional and behavioural difficulties: a pilot randomised controlled trial.

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Protocol

A health-education intervention to improve outcomes for outcomes for children with emotional and behavioural difficulties: a pilot randomised controlled trial.

HELP - Health & Education Linking Project

Protocol Version & Date: 3.8, dated 7/1/27

Roles and responsibilities

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Statement of Compliance

This clinical trial will be conducted in compliance with all stipulation of this protocol, the conditions of the ethics committee approval, the NHMRC National Statement on ethical Conduct in Human Research (2007 and all updates), the Integrated Addendum to ICH E6 (R1): Guideline for Good Clinical Practice E6 (R2), dated 9 November 2016 annotated with TGA comments and the NHMRC guidance Safety monitoring and reporting in clinical trials involving therapeutic goods (EH59, 2016).
ABSTRACT

Introduction
One in seven (14%) children aged 4-17 years old meet criteria for a mental illness over a 12 month period. The majority of these children have difficulty accessing clinical assessment and treatment despite evidence demonstrating the importance of early intervention. Schools are increasingly recognised as universal platforms where children with mental health concerns could be identified and supported. However, educators have limited training or access to clinical support in this area.

Methods and analysis
This study is a pilot randomised controlled trial of a co-designed health and education model aiming to improve educator identification and support of children with emotional and behavioural difficulties. Twelve Victorian government primary schools representing a range of socio-educational communities will be recruited from metropolitan and rural regions, with half of the schools being randomly allocated to the intervention. Caregivers and educators of children in grades 1-3 will be invited to participate. The intervention is likely to involved regular case-based discussions and paediatric support.

Ethics and dissemination
Informed consent will be obtained from each participating school, educator and caregiver. Participants are informed of their voluntary participation and ability to withdrawal at any time. Participant confidentiality will be maintained and data will be secured on a password protected, restricted access database on the Murdoch Children’s research Institute (MCRI) server. Results will be disseminated via peer reviewed journals and conference presentations. Schools and caregivers will be provided with a report of the study outcomes and implications at the completion of the study.

| Data category                  | Information                                                                 |
|-------------------------------|-----------------------------------------------------------------------------|
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| Date of registration in primary registry | 31/5/21                                                                     |
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| Contact for scientific queries| william.garvey@rch.org.au                                                   |
| Public title                  | HELP - Health & Education Linking Project                                   |
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| Countries of recruitment      | Australia                                                                   |
Keywords
Child development, Mental health, Paediatric, Education, Collaboration

ARTICLE SUMMARY

Strengths and limitations

• There is limited evidence for the effectiveness of mental health interventions in primary schools.
• This study is the first to assess direct collaboration between primary school educators and clinicians that aims to empower educators to identify and support children with emotional and behavioural difficulties.
• Given the limited evidence of such models, this study is a pilot and limited to 12 primary schools over a 6 month period to assess educator acceptability and feasibility.
• The 12 primary schools represent a broad range of participants as recruitment involves metropolitan and rural settings as well as varying levels of socio-educational advantage.
• The intervention is co-designed with schools to ensure the educators needs are accounted for in the design.

INTRODUCTION

Background and rationale
Childhood is a critical period of development and has lasting impacts on health and well-being throughout the life course.\(^1\)

Emotional and behavioural difficulties are common in children and can be an early sign of mental illness. Over half of adult mental illness begins prior to 14 years of age\(^2\), and 1 in 7 Australian children meet diagnostic criteria for a mental illness over a 12-month period.\(^5,7\) While this national survey included children aged 4 to 17 years of age, evidence demonstrates that many childhood mental health problems become evident at a much younger age.\(^6\) Emotional difficulties include problems with anxiety, worrying and being withdrawn, while behavioural difficulties include hyperactivity and aggression.\(^9\) Prevention, early identification and intervention with evidence-based practices has been shown to reduce these problems.\(^3,10\) Unfortunately many children, especially those living in lower socioeconomic status (SES) settings, do not receive adequate support.\(^11,12\) This is in part because the individuals supporting children on a daily basis, such as caregivers and educators, may not be able to identify that a child needs help. Many children therefore miss out on support due to a lack of health literacy regarding childhood development and wellbeing. Health professionals hold a great deal of expertise in assessing and managing child mental health problems but access to healthcare may be difficult. Barriers such as siloed services, complex referral pathways, long wait times and high costs mean that many families have difficulty accessing the help they require.\(^4,5\) Public health systems are experiencing increased presentations and referrals of children with emotional and behavioural difficulties, with families experiencing wait times in excess of 12 months to access support.\(^14\) This can result in worsening mental health, poor educational outcomes, and family dysfunction.\(^7,13\) In addition, many children with emotional and behavioural difficulties, such as those with internalising symptoms due to anxiety, are either missed entirely or incorrectly diagnosed.\(^12\)

Schools are an integral aspect of daily life for children, but educators often lack support from the health system regarding how best to identify and manage children with emotional and behavioural difficulties. Improved collaboration between the health and education system could combine the strengths of both to best support these children. While paediatricians are key providers of
identification, assessment and treatment of Australian children with emotional and behavioural difficulties, fewer than 10% of children over 4 years of age will visit a paediatrician in a 12-month period. However, almost every child spends at least 25 hours per week in primary school. The education system is therefore well placed to ensure that these children are identified early and receive the support they need. Educators have an important and unique role in this area, but need to be better supported to detect and respond to problems early, and there are concerns that many schools lack evidence-based approaches to supporting children.

The Victorian government has implemented a strategy to strengthen mental health capacity in secondary schools, but this does not help the large numbers (approx. 84,000 per annum) of children whose difficulties emerge in primary school. Primary schools need to be supported to ensure that children are identified early, have access to evidence-informed interventions within the school environment, and can be referred to appropriate health and other services when school support is deemed insufficient. Families of children who require further assessment and treatment often need help navigating a complex and fragmented service system so as not to risk increased wait times or face mismatched referrals. Ideally all this needs to be designed collaboratively with each school, informed by an understanding of the student cohort and knowledge of local community services and resources.

Two relevant models of collaboration exist within the education and health sectors. Communities of Practice is an approach which has been adopted by the Victorian Department of Education and Training whereby school networks share knowledge, experiences and resources. Project ECHO is a similar model of inter-professional education and case-based learning used in clinical medicine to improve access to specialist expertise. Both models address the challenges of knowledge deficits and organisational silos. Aspects of each could be utilised to improve communication and provide a shared learning experience for the health and education professionals who support children with emotional and behavioural difficulties.

Objectives
The primary objective is to evaluate the feasibility and acceptability of a structured health and education collaborative model designed to improve outcomes for children with emotional and behavioural difficulties. The secondary objective is to assess the identification and support of students with emotional and behavioural difficulties in intervention schools compared to control schools.

Trial design
Pilot randomised controlled trial of a co-designed structured health and education collaborative model aiming to improve educator identification and management of children with emotional and behavioural difficulties and family uptake of services to these difficulties.

Hypotheses
We hypothesise that the structured health and education collaborative model intervention will be feasible and acceptable to educators and caregivers (primary outcome). We also hypothesise that educators in intervention versus control schools will more accurately identify and support children with emotional and behavioural difficulties using standardised measures, implementation of evidence-based strategies and health service use (secondary outcome).

METHODS AND ANALYSIS
Study setting

The study is in Victorian primary schools. Caregivers and educators of students in grades 1 (the second year of formal schooling in Australia), 2 and 3 are recruited to assess children early in their school education. Educators of preparatory grade (i.e. first year of schooling) students are not recruited because of their varying experiences of preschool education and the need to allow time for them to settle into the school environment and routine. Metropolitan and rural primary schools are recruited to test the feasibility and acceptability across diverse settings.

Eligibility criteria

The Australian school sector is made up of government (65.6%), Catholic (19.4%) and independent (15%) schools. To ensure consistency in supports within the education system, only Government schools are invited to participate. Schools are recruited from the Local Government Area of the City of Yarra (metropolitan) and the Wimmera Southern Mallee (rural). Schools must have a minimum of 40 students across grades 1, 2 and 3. Special schools (schools that provide specialist and intensive support in a dedicated setting for students with moderate to high learning and support needs) are excluded. Caregivers and educators of students completing grade 1, 2 or 3 in 2021 are invited to participate. Caregivers who have insufficient English to complete the surveys and who do not have access to interpreter services to support completion of the survey are excluded.

Patient and public involvement

The public was first involved in the project when community leaders within both communities were informed of the concept in early 2019. The lead paediatrician has worked in both communities for a number of years and frequently engages with families, educators and clinicians through this work. The community leaders assist with school recruitment and in shaping the project through conversation early in the design process. Once schools are recruited multiple caregiver information sessions are held at each of the 12 schools, both online and in person. Caregivers are asked to comment on the project in regards to their experience in supporting their children’s development and wellbeing.

Intervention

The intervention schools receive two key strategies.

- Paediatrician (author WG)-led, regular (frequency co-designed) one hour videoconference seminar program with case-based discussions covering topics of interest as selected by participating educators. The program incorporates evidence-based approaches to identification and management of children with emotional and behavioural difficulties.

- Paediatric support to help identify, support and navigate health services for children whom educators perceive have emotional and behavioural difficulties.

Half of the participating schools are randomly allocated to the intervention (intervention group). At the beginning of the project WG (a paediatrician with 12 years of clinical experience) meets with each school allocated to the intervention to co-design the program for terms 3 and 4. Based on other research about improving collaboration, the program involves discussions about certain topics (e.g., anxiety, learning difficulties) selected by each school. This leads to a discussion of how to best use evidence to support children with these difficulties in the school environment. In addition, WG provides assistance to help identify, support and navigate health services for children who require assessment and therapy outside of the school environment. The individual school utilises its normal communication pathway to discuss this with caregivers. The other half of the schools (control...
group) operate as they usually do with no regular case discussion and knowledge of how best to navigate the healthcare system left to educators.

Outcomes
Outcomes are assessed by caregiver and educator-completed surveys at baseline and again at the completion of the trial period (6 months). Educators in both arms complete baseline and follow up surveys for participating children only (caregivers have submitted consent and baseline surveys). Educators in the intervention group are also asked to take part in a focus group at the completion of the intervention (see table 1).

The primary outcome of the study is the feasibility and acceptability of the structured health and education collaborative model from the perspectives of educators and caregivers. This is measured using both quantitative and qualitative methods:

- Quantitative
  - Number and proportion of eligible (i) educators and (ii) caregivers who consent take part in the pilot.
  - Number and proportion of eligible educators who participate in the case based discussions.
  - Number and proportion of eligible educators who utilise paediatric support to discuss how best to support individual students outside of the case-based discussions
  - Study-designed survey items asking educators about acceptability of the program (intervention group only).
  - Educator confidence in supporting children with emotional and behavioural difficulties measured using the school mental health self-efficiency teacher survey (SMH-SETS)20.
  - Open-ended questions about educators’ experience of the program, relevance of the content, usefulness of experience and suggestions for improvement.

- Qualitative
  - Educator perspectives of whether the model has impacted their ability to identify and support children with emotional and behavioural difficulties.

Secondary outcomes will measure in the intervention versus control groups:
  - Accuracy of educator identification of child emotional and behavioural difficulties compared with the standardised measure of each child’s emotional and behavioural symptoms.
  - Caregiver health service use for child emotional and behavioural problems.
Table 1. Primary and secondary outcomes.

| Outcome                        | Variable                              | Measure                                                                 | Participant group | Collection point |
|-------------------------------|---------------------------------------|-------------------------------------------------------------------------|-------------------|------------------|
| Primary                       | Feasibility                           | Study recruitment & retention                                          | Caregiver         | Baseline         |
|                               |                                       |                                                                         |                   | 6 months         |
| Primary                       | Acceptability                         | Intervention participation                                              | Educator          | ✔️               |
|                               |                                       |                                                                         |                   | ✔️               |
| Primary                       | Acceptability                         | Study designed measures                                                |                   | ✔️               |
|                               |                                       |                                                                         |                   | ✔️               |
| Primary                       | Confidence supporting students         | School Mental Health Self-Efficiency Teacher Survey (SMH-SETS)           |                   | ✔️               |
|                               | with emotional and behavioural         |                                                                         |                   | ✔️               |
|                               | difficulties                           |                                                                         |                   | ✔️               |
| Secondary                     | Accuracy and timing of emotional and   | Strengths and Difficulties Questionnaire (SDQ)                          | Caregiver         | ✔️               |
|                               | behavioural difficulties              |                                                                         |                   | ✔️               |
|                               |                                       |                                                                         | Educator          | ✔️               |
|                               |                                       |                                                                         |                   | ✔️               |
| Secondary                     | Health service use                     | Study designed-measures                                                | Caregiver         | ✔️               |
|                               |                                       |                                                                         |                   | ✔️               |

To determine whether the intervention leads to earlier and more accurate assessments of child emotional and behavioural difficulties, caregivers and educators are asked at each time-point (baseline and 6 months later) a single item question as a measure of overall child emotional and behavioural difficulties, namely: “Thinking about your child’s mental health and wellbeing over the last 6 months, has [child’s name] been thriving, coping, struggling or always overwhelmed?” This response is dichotomised (thriving/coping vs struggling/always overwhelmed) and compared against a validated measure of child emotional and behavioural difficulties to determine the sensitivity and specificity of the single item question. The Strengths and Difficulties Questionnaire (SDQ) is a reliable and validated measure, already used in Victoria’s School Entry Health Questionnaire. It is a screening questionnaire for 3 – 16-year-olds, in which caregivers or educators rate 25 items. It provides a total score and subscale scores including emotional symptoms, conduct problems, hyperactivity/inattention, peer relationship problems and prosocial behaviour. “Normal”, “borderline” and “abnormal” ranges exist for total difficulties and each of the subscales. We determine the sensitivity and specificity of the single item measure against the SDQ total borderline/clinical cut point, as reported by educators and caregivers at baseline and at follow up.

Health service use is measured by caregiver report asking the following questions: “Did the teacher suggest a referral to a health service (e.g., GP, paediatrician) for your child because of emotional or behavioural concerns?”. If yes “did you engage with that health service?” If no, “why not?” The baseline survey also collects child (e.g., age, sex, existing emotional and behavioural support) and caregiver (e.g. relationship to child, highest level of education, household income) demographic data.
Measurement of participant compliance

All participants are asked to complete the surveys and measurement of compliance is carried out at each of the data collection points (baseline & 6 months). Any surveys not submitted result in a reminder email or sms being sent to the relevant educator/caregiver. Surveys that have not been submitted will result in the relevant educator/caregivers being contacted by WG to discuss any difficulties completing the survey and assess ongoing participation in the trial.

The time commitment for individual educators includes the co-design focus groups (90 minutes), seminar case discussions (one hour per fortnight/month depending on co-design; intervention group only) and survey completion (10-15 minutes per student i.e., up to 4 to 6 hours at each data collection point). The primary objective of this research project is to assess the acceptability and feasibility of such an intervention in the context of the educators’ workload. Student wellbeing however is a core component of school responsibility, as detailed in the Royal Commission into Victoria’s mental health system, and schools and educators have expressed their willingness to take part in this pilot and complete relevant surveys.

Participant timeline

Schools were first enrolled in April 2021 and randomly allocated to the control or intervention group in May (see figure 1) Baseline survey collection took place in June with follow up surveys planned for January 2022. Co-design workshops occurred with intervention schools in June 2021 and reflection focus groups with the same schools will take place in February 2022.

see figure 1

Sample size

As this is a feasibility and acceptability pilot, a formal sample size calculation is not required. However, with a sample of 432 from 720 eligible (60% enrolment of eligible families presuming 12 schools with an average of 20 students in each of grades 1,2 and 3), will provide meaningful data to ascertain the feasibility and acceptability of the intervention and study measures. Further, results will inform a sample size calculation of a planned future, adequately powered randomised controlled trial to test the effectiveness and cost-effectiveness of this intervention.

Recruitment

School recruitment

Schools are recruited through established relationships with existing community networks and invited to participate in the study. The paediatrician leading the study has been a member of both communities in a professional capacity for over two years; this assists with school and health service participation. The leadership team at each school, including the principal, assist in selecting the individual educators for the co-design process. This include the educators who will be receiving the intervention, along with any members of the school team involved in supporting children with emotional and behavioural difficulties (e.g., student wellbeing team). Each participating school is asked to complete a School Participant Information Statement and Consent Form (see Appendix A).

Student recruitment

Educators distribute the Caregiver Study Interest Form (see Appendix B) where caregivers can state whether they do or do not wish to learn more about the study. In addition to this form, school communication networks are utilised to inform caregivers about the study (e.g., school newsletter, caregiver information evening, flyers on the school campus). Interested families have two weeks to return form after which time WG collects the forms of those families who have opted in. At the end of the two weeks, the classroom educator provides information about how many of the potential...
participants did not return the form. This demonstrates how many potential caregivers could be enrolled if families who did not opt out were contacted in the future.

The study team then phones caregivers who have opted in to hear more about the study. They explain the study further, answer any questions they might have, and ensure they meet inclusion criteria. Eligible and interested caregivers are emailed the baseline survey and Caregiver Participant Information Statement and Consent Form (see Appendix C) to return when completed. Should this “opt-in” approach to recruitment yield insufficient caregivers, an “opt out” approach is taken. We start with an “opt-in” approach first as this is the preference of the study’s ethics committee. Educators who have students enrolled in the study via Caregiver survey completion will be provided with the Educator Participant Information Statement and Consent Form (see Appendix D).

Allocation
A statistician not directly involved in the analysis of the trial results prepares the randomisation schedule. Randomisation is stratified by region and tertile (see figure 2 below). The Index of Community Socio-Educational Advantage (ICSEA) is used to allocate each participating school into a relative tertile where the 1st tertile is the least advantaged third of schools and the 3rd tertile is the most advantaged third of schools.\(^{23}\) The ICSEA score calculation is made up of the socio-educational advantage (SEA) plus remoteness and percentage of Indigenous student enrolment. The SEA is calculated using parental occupation and education. Schools in each region are paired based on their ICSEA score and within each pair, randomly allocated to either the control or intervention group. Allocation occurs after schools have consented to participate in order to ensure that the study includes a broad range of primary schools. Blinding is not possible given that educators (and caregivers) will be aware of their allocation based on participation in the intervention.

see figure 2

Data collection methods
As demonstrated in the participant timeline, measurements are collected at baseline and 6 months post baseline survey completion. Baseline surveys are collected during school term 2, in which caregiver and educator surveys are conducted for each student in the control and intervention schools. Follow up surveys are completed 6 months after the baseline measurements. At this time caregivers and educators are asked to again complete the single item measurement, the Strengths and Difficulties Questionnaire and the SMH-SETS (educators only). In addition, the follow up survey will ask caregivers and educators about health service referral and uptake. Participants complete surveys either via a link to a REDCap survey database or using paper surveys which are then transferred to the REDCap database once submitted.\(^{24,25}\) (see Appendix E and F for caregiver and educator surveys).

Data management & monitoring
All data collected is re-identified and stored in the restricted access folder on the Murdoch Children’s Research Institute (MCRI) server. This database is password protected and only the study investigators have access to this data. Confidentiality of the participants is maintained at all times. As per the Australian Code for the Responsible Conduct of Research, data is stored for a minimum of 5 years. To protect participant privacy, all data collected is re-identifiable with only the research team able to match participant names with ID numbers and stored on a secure network drive within the MCRI that is only accessible by the study investigators. Any paper forms used are scanned and stored on the secure network drive and subsequently destroyed. Given that this is a pilot a data monitoring committee is not required.
Statistical methods
Sample characteristics, participation rates and educator and caregiver reports of feasibility and acceptability are described using simple statistics (e.g. number and proportion of caregivers who take part in the pilot).

To determine the usefulness of the single-item question about child mental health, we determine the sensitivity, specificity, and positive and negative predictive values of the dichotomised response versus the educator-completed SDQ borderline/abnormal total score cut point for students in each group. We do this at baseline and at follow up to determine if educators in the intervention group are more likely to recognise symptoms of emotional and behavioural problems in their students than educators in the control group. The single item question completed by caregivers is also evaluated using the same method of comparison to the educator SDQ total score.

For our secondary outcomes, an intention-to-treat analysis at the level of the child is conducted. Educator and caregiver reported total SDQ score differences between baseline and 6 months is calculated. Mean differences between the intervention and control groups is then compared using t-tests for each of the educator and caregiver scores. To calculate effect sizes (ESs), change scores are standardised to a mean of 0 and a SD of 1. ESs are considered as small, ~0.20 SD; moderate, ~0.50 SD; and large, ~0.80 SD. A mixed effects model is used to assess the effect of the intervention. Given this study is a pilot, both linear and logistic regression modelling is used to assess which method is the most appropriate for a larger study. Analysis is completed using Stata 16.0.26

Harms
Participants are provided with contact details for the lead investigator (WG) and the Director of Research Ethics & Governance at The Royal Children’s Hospital Melbourne. They are advised to report any adverse events and such events will be reported to the Ethics committee once the study team is aware that they have occurred.

ETHICS AND DISSEMINATION

Research and ethics approval
This study was approved by the Royal Children’s Hospital Human Research and Ethics Committee (#67653) and the Victorian Department of Education Research in Schools Ethics Committee (#2021_004349) on the 16th of March 2021. Informed caregiver consent will be obtained via a written or online participant information and consent form.

Protocol amendments
This study will be conducted in compliance with the current version of the protocol. Any change to the protocol document or Informed Consent Form that affects the scientific intent, study design, participant safety, or may affect a participant’s willingness to continue participation in the study is considered an amendment, and therefore will be written and filed as an amendment to this protocol and/or informed consent form. All such amendments will be submitted to the HREC, for approval prior to becoming effective.

Consent
Selected schools are contacted via email and/or phone with an invitation to participate in the study. This correspondence includes the Participant Information and Consent Form (PICF, see appendix section). A signed consent form is obtained for each participating school principal, individual educator and caregiver.
Following family recruitment (described in 3.7) all participants are informed of their voluntary participation and ability to withdrawal their involvement at any time. In addition, each participant is informed of their anonymity in regard to the study including any publications resulting from the research. The lead investigator provides the PICF to the caregiver. This document describes the purpose of the trial, the procedures to be followed, and the risks and benefits of participation.

The research team conducts informed consent discussion and checks the participant comprehend the information provided. The research team member answers any questions about the trial.

Participants are invited to provide consent following a phone call discussion about the study. Participants are given the choice of an online link or paper copy of the consent form to complete along with the baseline survey in the same format.

It is documented in the participant’s record that consent has been provided. When all the inclusion/exclusion criteria have been addressed and the eligibility of the participant confirmed, the participant will be assigned to a trial group, based on the group that their child’s school is randomised to.

Confidentiality
Participant confidentiality is strictly held in trust by the participating investigators, research staff, and the sponsoring institution and their agents. The study protocol, documentation, data and all other information generated is held in strict confidence. No information concerning the study or the data will be released to any unauthorised third party, without prior approval by the participant and written approval of the sponsoring institution.

Declaration of interests
No competing interests to declare

Access to data
Only the research team have access to the data via a password protected secure database.

Dissemination policy
Results will be submitted for publications in peer-reviewed journals and presented at relevant conferences. Principal Investigator William Garvey holds the primary responsibility for publication of the results of the study in accordance to the study publication and dissemination plan to be developed. A report of study outcomes and implications will be delivered to partner organisations and relevant stakeholders.

We will send a summary of the study results to each participating school and caregiver but no individual students will be identified. We will prepare a study report which can be distributed as schools see appropriate.

Contributorship statement
Dr William Garvey conceived and wrote the manuscript with ongoing input from Professor Harriet Hiscock and Professor Frank Oberklaid. All authors contributed to refinement of the study protocol and approved the final manuscript.

Competing interests
The authors declare they have no competing interests.

Funding
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Data sharing statement
Data may be obtained from a third party and are not publicly available. Access to deidentified participant data can be requested by contacting helpinprimaryschools@mcri.edu.au. Reuse will only be permitted with written confirmation and must be cited in any use such as publication.

Figure legend
Figure 1. Flow chart of trial timeline
Figure 2. School pairing by region and ICSEA ranking
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Abbreviations
ESs: Effect Sizes; ICSEA: Index of Community Socio-Educational Advantage; MCRI: Murdoch Children’s research Institute; SEA: socio-educational advantage; SES: Socio-Economic Status; SD: Standard Deviation; SDQ: Strengths and Difficulties Questionnaire; SMH-SETS: School Mental Health Self-Efficacy Teacher Survey; WG: William Garvey

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Word count
4180 words.
Figure 1. Flow chart of trial timeline
Figure 1. Flow chart of trial timeline

For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml
Figure 2. School pairing by region and ICSEA ranking

C = control school  I = intervention school
Appendix A - School Participant Information Statement and Consent Form

**HREC Project Number:** 67653

**Short Name of Project:** Health & Education Linking Project (HELP) - supporting child emotional and behavioural development

**Full Name of Project:** Improving outcomes for children with emotional and behavioural difficulties through a school-based intervention: a pilot randomised controlled trial.

**Principal Researcher:** Dr William Garvey, paediatrician

**Version Number:** 1.3  **Version Date:** 24/04/21

Dear <principal>,

Thank you for taking the time to read this Participant Information Statement and Consent Form. We would like to invite your school to take part in a research project that is explained in this form.

This form is 5 pages long. Please make sure you have all the pages.

**What is an Information Statement and Consent Form?**

An Information and Consent Form tells you about the research project. It explains what the research project involves. This information is to help you decide whether or not you would to take part in the research. Please read it carefully.

Before you decide if you want to take part or not, you can ask us any questions you have about the project. You may want to talk about the project with your family, friends or health care worker.

**Taking part in the research project is up to you**

It is your choice whether you take part in the research project. You do not have to agree if you do not want to.

**Signing the form**

If you want to take part in the research, please sign the consent form at the end of this document. By signing the form you are telling us that you:

- understand what you have read
- had a chance to ask questions and received satisfactory answers
- consent to taking part in the project.
- We will give you a copy of this form to keep.
What is the research project about?

Emotional and behavioural difficulties are common in primary school children and they can have a big impact on their development, learning and well being. We know that they can be an early sign of mental health issues and therefore it is essential that we support all children who experience these difficulties where they live their lives, including at school. It is important to understand how schools and health services can best support the needs of these children, so that they are able to reach their full potential. In this project, we hope to learn more about how education and health can work together to support all children regarding their emotional and behavioural development.

Who is running the project?

My name is William Garvey and I am a paediatrician at the Royal Children’s Hospital (RCH) and researcher at the Murdoch Children’s Research Institute (MCRI). The study team is also made up of other clinicians and researchers at the RCH and MCRI. The study will be conducted in 12 schools, 6 in a metropolitan Melbourne region and 6 in a rural Victoria region. Over the study period we will be assessing a model that involves educators and a paediatrician working together to better support children with emotional and behavioural difficulties in primary school.

Why am I being asked to take part?

You are being asked because it is hoped educators and families in your school are willing to take part in the project. Research shows that 10-20% of children experience significant emotional and behavioural difficulties but often they can be difficult to identify. This study will aim to measure all children in a classroom to make sure it represents the normal population as best possible. Many children in the study will not experience significant emotional and behavioural difficulties but they will also help us understand how the positive role the school environment plays in child development and well being. Educators are integral to best understanding how to support children in the school environment.

What do I need to do in this project?

Principals who agree for their school to participate are being asked to collaborate with and support educators to make sure their involvement is clear and the time commitment is feasible. The project will involve educators and each child’s caregiver completing 2 surveys per child over an 8 month period later this year. The surveys will ask questions about educators experience such as number of years teaching and additional formal training. They will also be asked questions about how each child has seemed recently regarding their emotions and behaviour. Each child’s caregiver will be asked similar questions at the same 2 time points. Caregivers will also be asked about health service use. Each survey is expected to take 10-15 minutes to complete so for a teacher with 25 students participating the time commitment would be approximately 4-6 hours at each of the 2 survey time points. However it will be less if fewer families take part.

Half of the participating schools will be randomly allocated to the intervention. This will be a form of collaboration in which the paediatrician and teacher work together to ensure that the best evidence is used to support all children in the classroom. At the beginning of the project I will meet with each school allocated to the intervention to co-design the program for terms 2, 3 and 4 in 2021. This will take place in term 2 at your school at a time that suits you and the other participating members of your school team (e.g., other educators, principal, wellbeing officer). It will be a single session lasting approximately 90 minutes and will focus on how you can work with a paediatrician to better identify and support children with emotional and behavioural difficulties. Based on other research looking at improving collaboration, it is likely that the program will involve weekly to fortnightly discussions about certain topics (e.g., anxiety, learning difficulties) selected by each school. Educators will also discuss students from their classroom, without identifying the individual, who are experiencing difficulties related to the topic. This will lead to a discussion of how to best use the latest and most reliable evidence to support children with these difficulties in the school environment. In addition, the paediatrician will also help identify, support and navigate health services for children who require assessment and therapy outside of the school environment. These sessions will be held either
at your school or via video conferencing (e.g., zoom) depending on your school’s preference. The other half of the schools will operate as they usually do so we can compare the intervention to normal practice.

**Can I withdraw from the project?**

You can stop taking part in the project at any time. You just need to tell us so. You do not need to tell us the reason why. If you leave the project we will use any information already collected unless you tell us not to.

**What are the possible benefits for me and other people in the future?**

The possible benefits for your school and others in the future include a better understanding of how to best identify and support children with emotional and behavioural difficulties in the classroom. Given how common these problems are and the impact they have on the child and those around them the potential for improvement is significant.

**What are the possible risks, side-effects, discomforting and/or inconveniences?**

The intervention will be a collaborative approach to using evidence-based practice in the school environment to help identify and support children with emotional and behavioural difficulties. This is unlikely to pose any significant risk and no side-effects but the project will be closely monitored for unexpected outcomes. The only inconvenience is educators completing the survey 2 times over the 8 month time period. The survey should take 10-15 minutes to complete per student.

**What will be done to make sure my information is confidential?**

All data collected will be re-identified and stored in the restricted access folder on the MCRI server. This database will be password protected and only the study investigators will have access to this data. Confidentiality of the participants will be maintained at all times, except as required by law, to ensure selected schools and individual participants remain anonymous throughout and after completion of the investigation. As per the Australian Code for the Responsible Conduct of Research, data will be stored for a minimum of 5 years.

**Will we be informed of the results when the research project is finished?**

We will send a summary of the study results to each participating school and caregiver but no individual students or educators will be identified. We will prepare a study report which can be distributed as schools see appropriate. Results be submitted for publications in peer-reviewed journals and presented at relevant conferences.

**Who should I contact for more information?**

If you would like more information about the project, please contact:

Name: Billy Garvey

Contact telephone: 9345 5851

Email: william.garvey@rch.org.au

You can contact the Director of Research Ethics & Governance at The Royal Children’s Hospital Melbourne if you:
- have any concerns or complaints about the project
- are worried about your rights as a research participant
- would like to speak to someone independent of the project.

The Director can be contacted by telephone on (03) 9345 5044.
Consent Form

HREC Project Number: 67653

Research Project Title: Improving outcomes for children with emotional and behavioural difficulties through a school-based intervention: a pilot randomised controlled trial.

Version Number: 1.3    Version Date: 24/4/21

- I have read this information statement and I understand its contents.
- I understand what my child and I have to do to be involved in this project.
- I understand the risks my child could face because of their involvement in this project.
- I voluntarily consent for my child to take part in this research project.
- I have had an opportunity to ask questions about the project and I am satisfied with the answers I have received.
- I understand that this project has been approved by The Royal Children’s Hospital Melbourne Human Research Ethics Committee. I understand that the project is required to be carried out in line with the National Statement on Ethical Conduct in Human Research (2007).
- I understand I will receive a copy of this Information Statement and Consent Form.

Principal Name ____________________________________________________________________________
Principal Signature ____________________________________________________________________________
Date ______________________________________________________________________________________

Name of Witness to Participant’s Signature ____________________________________________________________________________
Witness Signature ____________________________________________________________________________
Date ______________________________________________________________________________________

Declaration by researcher: I have explained the project to the participant who has signed above. I believe that they understand the purpose, extent and possible risks of their involvement in this project.

Research Team Member Name ____________________________________________________________________________
Research Team Member Signature ____________________________________________________________________________
Date ______________________________________________________________________________________

Note: All parties signing the Consent Form must date their own signature.
Appendix B - Caregiver Study Interest Form

Dear caregiver,

Your child’s school is taking part in a research project with the Murdoch Children’s Research Institute. This project is testing a new way of working with teachers to better support children’s social and emotional health and wellbeing. We hope as many families as possible take part. The project is being run by Dr. Billy Garvey, a paediatrician (children’s doctor) at The Royal Children’s Hospital.

To learn more about the project, please tick the “I would like to hear more information” box below. By ticking this, your child’s school will pass your name and contact phone number to Dr Billy Garvey (children’s doctor) who is leading the project. They will not share any child contact details. Dr Garvey will use this information to telephone you, explain more about the study and see if you would like to take part. At this point, you can decide whether you want to take part. If you do not want to, we will destroy your data (i.e., name and contact number).

If you do not wish to hear more about the project, please tick the “I would not like my contact details passed on” box below. This means your child’s school will not pass any contact details to Dr Billy Garvey and we will not contact you.

I would like to hear more information about the project from the research team at MCRI
I would not like my contact details passed onto the research team at MCRI

| Parent/Guardian Name | Contact number | Parent/Guardian Signature | Date |
|----------------------|----------------|---------------------------|------|
Appendix C - Caregiver Participant Information Statement and Consent Form

HREC Project Number: 67653

Short Name of Project: Health & Education Linking Project (HELP) - supporting child emotional and behavioural development

Full Name of Project: Improving outcomes for children with emotional and behavioural difficulties through a school-based intervention: a pilot randomised controlled trial.

Principal Researcher: Dr William Garvey, paediatrician

Version Number: 1.4 Version Date: 24/04/21

Dear <insert parent/guardian’s name>,

Thank you for taking the time to read this Information Statement and Consent Form. We would like to invite your child to take part in a research project that is explained in this form.

This form is 4 pages long. Please make sure you have all the pages.

What is an Information Statement and Consent Form?

An Information and Consent Form tells you about the research project. It explains what the research project involves. This information is to help you decide whether or not you would like your child to take part in the research. Please read it carefully.

Before you decide if you want your child to take part or not, you can ask us any questions you have about the project. You may want to talk about the project with your family, friends or health care worker.

Taking part in the research project is up to you

It is your choice whether or not your child takes part in the research project. You do not have to agree if you do not want to.

Signing the form

If you would like your child to take part in the research, please sign the consent form at the end of this document. By signing the form you are telling us that you:

• understand what you have read

• had a chance to ask questions and received satisfactory answers

• consent to your child taking part in the project.
What is the research project about?

Emotional and behavioural difficulties are common in children and they can have a big impact on their development, learning and well being. We know that they can be an early sign of mental health issues. It is important to understand how schools and health services can best support the needs of these children, so that they are able to reach their full potential. In this project, we hope to learn more about how education and health can work together to support all children in their emotional and behavioural development.

Who is running the project?

My name is William Garvey and I am a paediatrician (children’s doctor) at the Royal Children’s Hospital (RCH) and researcher at the Murdoch Children’s Research Institute (MCRI). The study team is also made up of other paediatricians and researchers at the RCH and MCRI. The study will be conducted in 12 schools, 6 in a metropolitan Melbourne region and 6 in a rural Victoria region. We will be assessing a model that involves educators and a paediatrician working together to better support children with emotional and behavioural difficulties in primary school.

Why is my child being asked to take part?

Your child is being asked to participate because your child’s school has agreed to take part in the study. Research shows that 10-20% of children experience significant emotional and behavioural difficulties but often they can be difficult to identify. This study aims to include all children in a classroom to make sure our project helps as many children as possible. Many children in the study will not experience these difficulties but they will also help us understand the positive role the school environment plays in child development and well being.

What does my child need to do in this project?

The project will involve you and your child’s teacher completing 2 surveys over an 8 month period. The surveys will ask questions about your family such as number of people, their age and sex. You will also be asked questions about your child’s emotions and behaviour. You will also be asked about services or help you may have used if your child’s emotional and behavioural issues. Each survey should take 10-15 minutes.

Half of the participating schools will be randomly allocated to the intervention which will be a form of collaboration in which the paediatrician and teacher work together to ensure that the best evidence is used to support all children in the classroom. We will work with the school to develop a design for this project to best meet the needs of all students. Based on other research looking at improving collaboration, it is likely that the program will involve discussions about certain topics (e.g., anxiety, learning difficulties) selected by each school. This will lead to a discussion of how to best use the latest and most reliable evidence to support children with these difficulties in the school environment. In addition, there will be assistance provided to teachers to help navigate health services for children who require assessment and support outside the school. The other half of the schools will operate as they usually do so we can compare the intervention to normal practice.

Can my child stop taking part in the project?

Your child can stop taking part in the project at any time. You just need to tell us so. You do not need to tell us the reason why. If your child leaves the project we will use any information already collected unless you tell us not to.

What are the possible benefits for my child and other people in the future?

The possible benefits for your child and others in the future include a better understanding of how to best identify and support children with emotional and behavioural difficulties in the classroom. Given how common these problems are and the impact they have on the child and those around them, the potential for improvement is significant.
What are the possible risks, side-effects, discomfor.ng and/or inconveniences?

If your child is in a school randomly allocated to the intervention group they will have indirect exposure to the intervention as it involves helping their teacher to help identify and support children with emotional and behavioural difficulties. Therefore, there are no significant risks and no side-effects to be concerned about if you decide to participate. Across the two groups, the only inconvenience is having to complete the survey 2 times over the 8 month time period. The survey should only take 10-15 minutes to complete.

What will be done to make sure my child’s information is confidential?

All data collected will be re-iden7fied and stored in the restricted access folder on the MCRI server. This database will be password protected and only the study investigators will have access to this data. Confidentiality of the participants will be maintained at all times, except as required by law, to ensure selected schools and individual participants remain anonymous throughout and after completion of the investigation. As per the Australian Code for the Responsible Conduct of Research, data will be stored for a minimum of 5 years.

Will we be informed of the results when the research project is finished?

You will have access to your individual information if requested. In addition, we will send a summary of the study results to each participating school and caregiver but no individual students will be identified. We will prepare a study report which can be distributed as schools see appropriate. Results be submited for publications in peer-reviewed journals and presentations.

Who should I contact for more information?

If you would like more information about the project, please contact:

Name: Billy Garvey
Contact telephone: 9345 5851

Assessed for eligibility

Excluded (n= 726)
• Did not opt in (714)
• Unable to contact (425)

Allocation May 2021

Randomised to control or intervention

Control arm
6 schools

Co-design workshop June 2021

6 schools (128 students)
Caregiver survey

Baseline survey July 2021

6 schools
Caregiver survey

Follow up survey Jan 2022

6 schools
Caregiver survey

Reflection focus groups Feb 2022

Intervention arm
6 schools

6 schools

6 schools (273 students)
Caregiver survey

6 schools
Caregiver survey

6 schools
Consent Form

HREC Project Number: 67653

Research Project Title: Improving outcomes for children with emotional and behavioural difficulties through a school-based intervention: a pilot randomised controlled trial.

Version Number: 1.4

Email: william.garvey@rch.org.au

You can contact the Director of Research Ethics & Governance at The Royal Children's Hospital Melbourne if you:

• have any concerns or complaints about the project
• are worried about your rights as a research participant
• would like to speak to someone independent of the project.

The Director can be contacted by telephone on (03) 9345 5044.

• I have read this information statement and I understand its contents.
• I understand what my child and I have to do to be involved in this project.
• I understand the risks my child could face because of their involvement in this project.
• I voluntarily consent for my child to take part in this research project.
• I have had an opportunity to ask questions about the project and I am satisfied with the answers I have received.
• I understand that this project has been approved by The Royal Children's Hospital Melbourne Human Research Ethics Committee. I understand that the project is required to be carried out in line with the National Statement on Ethical Conduct in Human Research (2007).
• I understand I will receive a copy of this Information Statement and Consent Form.

Parent/Guardian Name

Parent/Guardian Signature

Date

Name of Witness to Participant’s Signature

Witness Signature

Date
Declaration by researcher: I have explained the project to the participant who has signed above. I believe that they understand the purpose, extent and possible risks of their involvement in this project.

Research Team Member Name

Research Team Member Signature

Date

Note: All parties signing the Consent Form must date their own signature.

Appendix D - Educator Participant Information Statement and Consent Form

HREC Project Number: 67653

Short Name of Project: Health & Education Linking Project (HELP) - supporting child emotional and behavioural development

Full Name of Project: Improving outcomes for children with emotional and behavioural difficulties through a school-based intervention: a pilot randomised controlled trial.

Principal Researcher: Dr William Garvey, paediatrician

Version Number: 1.5 Version Date: 24/04/21

Dear <educator>,

Thank you for taking the time to read this Participant Information Statement and Consent Form. We would like to invite you to take part in a research project that is explained in this form.

This form is 5 pages long. Please make sure you have all the pages.

What is an Information Statement and Consent Form?
An Information and Consent Form tells you about the research project. It explains what the research project involves. This information is to help you decide whether or not you would to take part in the research. Please read it carefully.

Before you decide if you want to take part or not, you can ask us any questions you have about the project. You may want to talk about the project with your family, friends or health care worker.

**Taking part in the research project is up to you**

It is your choice whether you take part in the research project. You do not have to agree if you do not want to.

**Signing the form**

If you want to take part in the research, please sign the consent form at the end of this document. By signing the form you are telling us that you:

- understand what you have read
- had a chance to ask questions and received satisfactory answers
- consent to taking part in the project.
- We will give you a copy of this form to keep.

**What is the research project about?**

Emotional and behavioural difficulties are common in primary school children and they can have a big impact on their development, learning and well being. We know that they can be an early sign of mental health issues and therefore it is essential that we support all children who experience these difficulties where they live their lives, including at school. It is important to understand how schools and health services can best support the needs of these children, so that they are able to reach their full potential. In this project, we hope to learn more about how education and health can work together to support all children regarding their emotional and behavioural development.

**Who is running the project?**

My name is William Garvey and I am a paediatrician at the Royal Children’s Hospital (RCH) and researcher at the Murdoch Children’s Research Institute (MCRI). The study team is also made up of other clinicians and researchers at the RCH and MCRI. The study will be conducted in 12 schools, 6 in a metropolitan Melbourne region and 6 in a rural Victoria region. Over the study period we will be assessing a model that involves educators and a paediatrician working together to better support children with emotional and behavioural difficulties in primary school.

**Why am I being asked to take part?**

You are being asked to take part because it is hoped students in your class will participate in the project. Research shows that 10-20% of children experience significant emotional and behavioural difficulties but often they can be difficult to identify. This study will aim to measure all children in a classroom to make sure it represents the normal population as best possible. Many children in the study will not experience significant emotional and behavioural difficulties but they will also help us understand how the positive role the school environment plays in child development and well being. Educators are integral to best understanding how to support children in the school environment.

**What do I need to do in this project?**
The project will involve you and each child’s caregiver completing 2 surveys per child over an 8 month period later this year. The first surveys will ask questions about your experience such as number of years teaching and additional formal training. In the subsequent surveys, you will also be asked questions about how each child has seemed recently regarding their emotions and behaviour. Each child’s caregiver will be asked similar questions at the same 3 time points. Caregivers will also be asked about health service use. Each survey is expected to take 10-15 minutes to complete so for a teacher with 25 students participating the time commitment would be approximately 4-6 hours at the 2 survey time points. However it may be less than this if only some families in your class take part.

Half of the participating schools will be randomly allocated to the intervention. This will be a form of collaboration in which the paediatrician and teacher work together to ensure that the best evidence is used to support all children in the classroom. At the beginning of the project I will meet with each school allocated to the intervention to co-design the program for terms 2, 3 and 4 in 2021. This will take place in term 2 at your school at a time that suits you and the other participating members of your school team (e.g., other educators, principal, wellbeing officer). It will be a single session lasting approximately 90 minutes and will focus on how you can work with a paediatrician to better identify and support children with emotional and behavioural difficulties. Based on other research looking at improving collaboration, it is likely that the program will involve weekly to fortnightly discussions about certain topics (e.g., anxiety, learning difficulties) selected by each school. Educators will also discuss students from their classroom, without identifying the individual, who are experiencing difficulties related to the topic. This will lead to a discussion of how to best use the latest and most reliable evidence to support children with these difficulties in the school environment. In addition, the paediatrician will also help identify, support and navigate health services for children who require assessment and therapy outside of the school environment. These sessions will be held either at your school or via video conferencing (e.g., zoom) depending on your schools preference. The other half of the schools will operate as they usually do so we can compare the intervention to normal practice.

Can I withdraw from the project?

You can stop taking part in the project at any time. You just need to tell us so. You do not need to tell us the reason why. If you leave the project we will use any information already collected unless you tell us not to.

What are the possible benefits for me and other people in the future?

The possible benefits for you and others in the future include a better understanding of how to best identify and support children with emotional and behavioural difficulties in the classroom. Given how common these problems are and the impact they have on the child and those around them, the potential for improvement is significant.

What are the possible risks, side-effects, discomforting and/or inconveniences?

The intervention will be a collaborative approach to using evidence-based practice in the school environment to help identify and support children with emotional and behavioural difficulties. This is unlikely to pose any significant risk and no side-effects but the project will be closely monitored for unexpected outcomes. The only inconvenience is having to complete the survey 3 times over the 8 month time period which will take up to 6 hours, depending on the number of families in your classroom who take part.

What will be done to make sure my information is confidential?

All data collected will be re-identified and stored in the restricted access folder on the MCRI server. This database will be password protected and only the study investigators will have access to this data. Confidentiality of the participants will be maintained at all times, except as required by law, to ensure selected schools and individual participants remain anonymous throughout and after completion of the investigation. As per the Australian Code for the Responsible Conduct of Research, data will be stored for a minimum of 5 years.

Will we be informed of the results when the research project is finished?
You will have access to your individual information if requested. In addition, we will send a summary of the study results to each participating school and caregiver but no individual students or educators will be identified. We will prepare a study report which can be distributed as schools see appropriate. Results be submitted for publications in peer-reviewed journals and presented at relevant conferences.

**Who should I contact for more information?**

If you would like more information about the project, please contact:

Name: Billy Garvey  
Contact telephone: 9345 5851  
Email: william.garvey@rch.org.au

You can contact the Director of Research Ethics & Governance at The Royal Children's Hospital Melbourne if you:
- have any concerns or complaints about the project
- are worried about your rights as a research participant
- would like to speak to someone independent of the project.

The Director can be contacted by telephone on (03) 9345 5044.

### Consent Form

| HREC Project Number: | 67653 |
|----------------------|-------|
| Research Project Title: | Improving outcomes for children with emotional and behavioural difficulties through a school-based intervention: a pilot randomised controlled trial. |
| Version Number: | 1.5 |
| Version Date: | 24/4/21 |

- I have read this information statement and I understand its contents.
- I understand what I have to do to be involved in this project.
- I understand the risks I could face because of my involvement in this project.
- I voluntarily consent to take part in this research project.
- I have had an opportunity to ask questions about the project and I am satisfied with the answers I have received.
- I understand that this project has been approved by The Royal Children’s Hospital Melbourne Human Research Ethics Committee. I understand that the project is required to be carried out in line with the National Statement on Ethical Conduct in Human Research (2007).
- I understand I will receive a copy of this Information Statement and Consent Form.

---

**Educator Name**  
**Educator Signature**  
**Date**
Name of Witness to Participant’s Signature  |  Witness Signature  |  Date

**Declaration by researcher:** I have explained the project to the participant who has signed above. I believe that they understand the purpose, extent and possible risks of their involvement in this project.

Note: All parties signing the Consent Form must date their own signature.

---

**Appendix E - Caregiver Survey**

**About your child (baseline survey only)**

What is your child’s first name?

_____________________________________

What is your child’s surname?

_____________________________________

What is your child’s date of birth?

__ __ / __ __ / __ __

Which school does your child attend?

_____________________________________

Who is your child’s teacher?

_____________________________________

What grade is your child in?
☐ Grade 1  ☐ Grade 2  ☐ Grade 3

Is your child
☐ Male  ☐ Female  ☐ Other  ☐ Prefer not to say

Is your child receiving Program for Students with a disability (PSD) funding?
☐ Yes  ☐ No

Is your child receiving National Disability Insurance Scheme (NDIS) Funding?
☐ Yes  ☐ No

Is your child accessing mental health support outside of school?
☐ Yes  ☐ No

About you and your family *(baseline survey only)*

You are the child's
☐ Biological parent  ☐ Step-parent  ☐ Other

You are
☐ Male  ☐ Female  ☐ Other/prefer not to say

You are currently (select the option that best describes you at the moment)
☐ Single, never married  ☐ Married/de facto  ☐ Widow(er)  ☐ Divorced/separated

What is the highest year of school you have completed?
☐ Year 12  ☐ Year 11  ☐ Year 10 or less

What is the highest qualification you have completed since leaving school?
☐ No further qualification post school  ☐ Trade apprenticeship
☐ Technical diploma/certificate  ☐ University degree
☐ Postgraduate university degree

Do you currently have a partner that lives with you?
Is your partner the child's
☐ Biological parent    ☐ Step-parent Other

Is your partner
☐ Male    ☐ Female    ☐ Other/prefer not to say

What is the highest year of school your partner has completed?
☐ Year 12    ☐ Year 11    ☐ Year 10 or less

What is the highest qualification your partner has completed since leaving school?
☐ No further qualification post school    ☐ Trade apprenticeship
☐ Technical diploma/certificate    ☐ University degree
☐ Postgraduate university degree

What is the main language spoken at home?
☐ English    ☐ Other

What is the total income of everyone in your household per week (or year) before tax?
☐ Nil income
☐ Less than $1,000 (less than $52,000 per year)
☐ $1,000-$1,499 ($52,000-$77,999 per year)
☐ $1,500-$1,999 ($78,000-$103,999 per year)
☐ $2,000-$2,999 ($104,000-$155,999 per year)
☐ $3,000-$3,399 ($156,000-$207,999 per year)
☐ More than $4,000 ($208,000 or more per year)

Contact information

Having your contact details will enable us to contact you directly for the second survey in term 4, and will also enable us to send you updates on the study.

Your first name
_____________________________________

Your surname
_____________________________________
Child functioning (both baseline and follow up survey)

Strengths and difficulties questionnaire (SDQ)

|                                                                 | Not true | Somewhat true | Certainly true |
|-----------------------------------------------------------------|---------|---------------|----------------|
| Considerate of other people's feelings                         | ☐       | ☐             | ☐              |
| Restless, overactive, cannot stay still for long                | ☐       | ☐             | ☐              |
| Often complains of headaches, stomach-aches or sickness        | ☐       | ☐             | ☐              |
| Shares readily with other children, for example toys, treats, pencils | ☐       | ☐             | ☐              |
| Often loses temper                                             | ☐       | ☐             | ☐              |
| Rather solitary, prefers to play alone                          | ☐       | ☐             | ☐              |
| Generally well behaved, usually does what adults request       | ☐       | ☐             | ☐              |
| Many worries or often seems worried                            | ☐       | ☐             | ☐              |
| Helpful if someone is hurt, upset or feeling ill               | ☐       | ☐             | ☐              |
| Constantly fidgeting or squirming                              | ☐       | ☐             | ☐              |
| Has at least one good friend                                   | ☐       | ☐             | ☐              |
| Often fights with other children or bullies them               | ☐       | ☐             | ☐              |
| Often unhappy, depressed or tearful                            | ☐       | ☐             | ☐              |
|                                                                 | Not true | Somewhat true | Certainly true |
|------------------------------------------------------------------|----------|---------------|----------------|
| Generally liked by other children                               | ☐        | ☐             | ☐              |
| Easily distracted, concentration wanders                        | ☐        | ☐             | ☐              |
| Nervous or clingy in new situations, easily loses confidence     | ☐        | ☐             | ☐              |
| Kind to younger children                                         | ☐        | ☐             | ☐              |
| Often lies or cheats                                             | ☐        | ☐             | ☐              |
| Picked on or bullied by other children                           | ☐        | ☐             | ☐              |
| Often volunteers to help others (parents, teachers, other children) | ☐        | ☐             | ☐              |
| Thinks things out before acting                                  | ☐        | ☐             | ☐              |
| Steals from home, school or elsewhere                            | ☐        | ☐             | ☐              |
| Gets along better with adults than with other children           | ☐        | ☐             | ☐              |
| Many fears, easily scared                                       | ☐        | ☐             | ☐              |
| Good attention span, sees work through to the end                | ☐        | ☐             | ☐              |

Over the last 6 months your child has been
☐ Thriving  ☐ Coping  ☐ Struggling  ☐ Always overwhelmed

**Health service use (Follow up survey only)**

Did the teacher suggest a referral to a health service (e.g., GP, paediatrician) for your child because of emotional or behavioural concerns?

☐ Yes  ☐ No

If yes did you engage with that health service?

☐ Yes  ☐ No

If no, why not?

___________________________________________
Appendix F - Educator Survey

Educator demographic information (*Baseline survey only*)

Please enter your first name:

_____________________________________

Please select your gender

- Man
- Woman
- No-binary/gender diverse
- My gender identity isn't listed
- I prefer not to say

Do you currently work

- Part-time
- Full-time

How many years have you been teaching?
## School Mental Health Self-Efficiency Teacher Survey (SMH-SETS)

*(both baseline and follow up surveys)*

| Task Description                                                                 | Strongly disagree | Disagree | Somewhat disagree | Somewhat agree | Agree | Strongly agree |
|----------------------------------------------------------------------------------|-------------------|----------|-------------------|----------------|-------|----------------|
| Recognize when there is a student with an internalizing concern                  | ☐                 | ☐        | ☐                 | ☐              | ☐     | ☐              |
| Recognize when there is a student with an externalizing concern                  | ☐                 | ☐        | ☐                 | ☐              | ☐     | ☐              |
| Recognize when there is a student displaying indicators of exposure to trauma    | ☐                 | ☐        | ☐                 | ☐              | ☐     | ☐              |
| Provide academic instruction to students with an internalizing concern           | ☐                 | ☐        | ☐                 | ☐              | ☐     | ☐              |
| Provide academic instruction to students with an externalizing concern           | ☐                 | ☐        | ☐                 | ☐              | ☐     | ☐              |
| Provide academic instruction to students with diverse backgrounds who have MH concerns | ☐                 | ☐        | ☐                 | ☐              | ☐     | ☐              |
| Consider cultural needs in promoting students' MH                                | ☐                 | ☐        | ☐                 | ☐              | ☐     | ☐              |
| Respond when a student is in crisis                                              | ☐                 | ☐        | ☐                 | ☐              | ☐     | ☐              |
| Respond when a student is displaying aggressive behavior                          | ☐                 | ☐        | ☐                 | ☐              | ☐     | ☐              |
| Respond to a student who is expressing suicidal thoughts                           | ☐                 | ☐        | ☐                 | ☐              | ☐     | ☐              |
| Refer a student to the appropriate school-based MH providers                     | ☐                 | ☐        | ☐                 | ☐              | ☐     | ☐              |
| Offer assistance in the classroom when a student is struggling with a MH concern | ☐                 | ☐        | ☐                 | ☐              | ☐     | ☐              |
Would you participate in the Health & Education Linking Project (HELP) again if offered in the future?

☐ Yes  ☐ No

Would you recommend the Health & Education Linking Project (HELP) to other educators?

☐ Yes  ☐ No

**Individual student survey (one per student) (Both baseline and follow up surveys)**

**Strengths and difficulties questionnaire (SDQ)**

| Question                                                                 | Strongly disagree | Disagree | Somewhat disagree | Somewhat agree | Agree | Strongly agree |
|-------------------------------------------------------------------------|------------------|---------|------------------|---------------|-------|----------------|
| Discuss student MH concerns with parents/guardians                      |                  |         |                  |               |       |                |
| Promote the social skills of students in my classroom                   |                  |         |                  |               |       |                |
| Promote the emotional skills of students in my classroom                |                  |         |                  |               |       |                |

**Acceptably**  
*(Follow up survey only)*

Would you participate in the Health & Education Linking Project (HELP) again if offered in the future?

☐ Yes  ☐ No

Would you recommend the Health & Education Linking Project (HELP) to other educators?

☐ Yes  ☐ No

**Considerate of other people's feelings**

[☐]  [☐]  [☐]  [☐]  [☐]

**Restless, overactive, cannot stay still for long**

[☐]  [☐]  [☐]  [☐]  [☐]

**Often complains of headaches, stomach-aches or sickness**

[☐]  [☐]  [☐]  [☐]  [☐]

**Shares readily with other children, for example toys, treats, pencils**

[☐]  [☐]  [☐]  [☐]  [☐]

**Often loses temper**

[☐]  [☐]  [☐]  [☐]  [☐]

**Rather solitary, prefers to play alone**

[☐]  [☐]  [☐]  [☐]  [☐]

**Generally well behaved, usually does what adults request**

[☐]  [☐]  [☐]  [☐]  [☐]

**Many worries or often seems worried**

[☐]  [☐]  [☐]  [☐]  [☐]

**Helpful if someone is hurt, upset or feeling ill**

[☐]  [☐]  [☐]  [☐]  [☐]

**Constantly fidgeting or squirming**

[☐]  [☐]  [☐]  [☐]  [☐]

**Has at least one good friend**

[☐]  [☐]  [☐]  [☐]  [☐]

**Often fights with other children or bullies them**

[☐]  [☐]  [☐]  [☐]  [☐]
|                                                                 | Not true | Somewhat true | Certainly true |
|------------------------------------------------------------------|----------|---------------|----------------|
| Often unhappy, depressed or tearful                              |          |               |                |
| Generally liked by other children                               |          |               |                |
| Easily distracted, concentration wanders                        |          |               |                |
| Nervous or clingy in new situations, easily loses confidence     |          |               |                |
| Kind to younger children                                        |          |               |                |
| Often lies or cheats                                            |          |               |                |
| Picked on or bullied by other children                          |          |               |                |
| Often volunteers to help others (parents, teachers, other children) |          |               |                |
| Thinks things out before acting                                 |          |               |                |
| Steals from home, school or elsewhere                           |          |               |                |
| Gets along better with adults than with other children           |          |               |                |
| Many fears, easily scared                                      |          |               |                |
| Good attention span, sees work through to the end               |          |               |                |

Over the last 6 months this student has been

☐ Thriving  ☐ Coping  ☐ Struggling  ☐ Always overwhelmed

**Health service recommendation (Follow up survey only)**

Did you suggest a referral to a health service (e.g., GP, paediatrician) for this student because of emotional or behavioural concerns?

☐ Yes  ☐ No
# Reporting checklist for protocol of a clinical trial.

Based on the SPIRIT guidelines.

## Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the SPIRIT reporting guidelines, and cite them as:

Chan A-W, Tetzlaff JM, Gøtzsche PC, Altman DG, Mann H, Berlin J, Dickersin K, Hróbjartsson A, Schulz KF, Parulekar WR, Krleža-Jerić K, Laupacis A, Moher D. SPIRIT 2013 Explanation and Elaboration: Guidance for protocols of clinical trials. BMJ. 2013;346:e7586

| Reporting Item                                      | Page Number |
|-----------------------------------------------------|-------------|
| **Administrative information**                      |             |
| Title                                               | #1          |
| Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym | 1           |
| Trial registration                                  | #2a         |
| Trial identifier and registry name. If not yet registered, name of intended registry | 1           |
| Trial registration: data set                        | #2b         |
| All items from the World Health Organization Trial Registration Data Set | 1           |
| Protocol version                                    | #3          |
| Date and version identifier                         | 1           |
| Funding                                             | #4          |
| Sources and types of financial, material, and other support | 1           |
| Roles and responsibilities: contributorship         | #5a         |
| Names, affiliations, and roles of protocol contributors | 1           |

For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml
Roles and responsibilities: sponsor contact information

Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities

Roles and responsibilities: sponsor and funder

Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)

Introduction

Background and rationale

Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention

Background and rationale: choice of comparators

Explanation for choice of comparators

Objectives

Specific objectives or hypotheses

Trial design

Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, non-inferiority, exploratory)

Methods:
Participants, interventions, and outcomes

Study setting

Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained

n/a
Eligibility criteria

Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)

Interventions:

#11a Interventions for each group with sufficient detail to allow replication, including how and when they will be administered

Interventions:

#11b Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)

Interventions:

#11c Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)

Interventions:

#11d Relevant concomitant care and interventions that are permitted or prohibited during the trial

Outcomes

#12 Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended

Participant timeline

#13 Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)

Sample size

#14 Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations

Recruitment

#15 Strategies for achieving adequate participant enrolment to reach target sample size

Methods: Assignment of interventions (for controlled trials)

Allocation: sequence generation

#16a Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be
provided in a separate document that is unavailable to those who enrol participants or assign interventions

**Allocation concealment mechanism**

- **Mechanism of implementing the allocation sequence** (e.g., central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned

**Allocation: implementation**

- Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions

**Blinding (masking)**

- Who will be blinded after assignment to interventions (e.g., trial participants, care providers, outcome assessors, data analysts), and how

**Blinding (masking): emergency unblinding**

- If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant’s allocated intervention during the trial

**Methods: Data collection, management, and analysis**

**Data collection plan**

- Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (e.g., duplicate measurements, training of assessors) and a description of study instruments (e.g., questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol

**Data collection plan: retention**

- Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols

**Data management**

- Plans for data entry, coding, security, and storage, including any related processes to promote data quality (e.g., double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol

**Statistics: outcomes**

- Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol
Statistics: additional analyses

- Methods for any additional analyses (eg, subgroup and adjusted analyses)

Statistics: analysis population and missing data

- Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)

**Methods: Monitoring**

Data monitoring:

- Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed

Data monitoring:

- Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial

Harms

- Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct

Auditing

- Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor

**Ethics and dissemination**

Research ethics approval

- Plans for seeking research ethics committee / institutional review board (REC / IRB) approval

Protocol amendments

- Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC / IRBs, trial participants, trial registries, journals, regulators)

Consent or assent

- Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)
Consent or assent: Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable

Confidentiality: How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial

Declaration of interests: Financial and other competing interests for principal investigators for the overall trial and each study site

Data access: Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators

Ancillary and post trial care: Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation

Dissemination policy: trial results: Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (e.g., via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions

Dissemination policy: authorship: Authorship eligibility guidelines and any intended use of professional writers

Dissemination policy: reproducible research: Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code

Appendices

Informed consent materials: Model consent form and other related documentation given to participants and authorised surrogates

Biological specimens: Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable

The SPIRIT Explanation and Elaboration paper is distributed under the terms of the Creative Commons Attribution License CC-BY-NC. This checklist was completed on 19 December 2021 using https://www.goodreports.org/, a tool made by the EQUATOR Network in collaboration with Penelope.ai
Protocol: A health-education intervention to improve outcomes for children with emotional and behavioural difficulties: a pilot cluster randomised controlled trial.

| Journal       | BMJ Open                  |
|---------------|---------------------------|
| Manuscript ID | bmjopen-2021-060440.R1    |
| Article Type  | Protocol                  |
| Date Submitted by the Author | 20-May-2022 |
| Complete List of Authors | Garvey, William; Royal Children's Hospital Research Institute, Centre for Community Child Health; Murdoch Children's Research Institute, Health Services  
Schembri, Rachel; Murdoch Children's Research Institute, Clinical Epidemiology & Biostatistics  
oberklaid, frank; The Royal Children's Hospital, Centre for Community Child Health; Murdoch Children's Research Institute  
Hiscock, Harriet; The Royal Children's Hospital, Centre for Community Child Health |
| Primary Subject Heading | Paediatrics |
| Secondary Subject Heading | Public health |
| Keywords | Community child health < PAEDIATRICS, MENTAL HEALTH, Developmental neurology & neurodisability < PAEDIATRICS, PUBLIC HEALTH |
Study Protocol

Protocol: A health-education intervention to improve outcomes for children with emotional and behavioural difficulties: a pilot cluster randomised controlled trial.

HELP - Health & Education Linking Project

Protocol Version & Date: 4.0, dated 29/4/22

Roles and responsibilities
Dr William Garvey\textsuperscript{1,2,3} - primary investigator
Dr Rachel Schembri\textsuperscript{4} - associate investigator
Professor Frank Oberklaid\textsuperscript{1,2,3} - associate investigator
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0409 358 496

Statement of Compliance
This clinical trial will be conducted in compliance with all stipulation of this protocol, the conditions of the ethics committee approval, the NHMRC National Statement on ethical Conduct in Human Research (2007 and all updates), the Integrated Addendum to ICH E6 (R1): Guideline for Good Clinical Practice E6 (R2), dated 9 November 2016 annotated with TGA comments and the NHMRC guidance Safety monitoring and reporting in clinical trials involving therapeutic goods (EH59, 2016).
ABSTRACT

Introduction
One in seven (14%) children aged 4-17 years old meet criteria for a mental illness over a 12 month period. The majority of these children have difficulty accessing clinical assessment and treatment despite evidence demonstrating the importance of early intervention. Schools are increasingly recognised as universal platforms where children with mental health concerns could be identified and supported. However, educators have limited training or access to clinical support in this area.

Methods and analysis
This study is a pilot cluster randomised controlled trial of a co-designed health and education model aiming to improve educator identification and support of children with emotional and behavioural difficulties. Twelve Victorian government primary schools representing a range of socio-educational communities will be recruited from metropolitan and rural regions, with half of the schools being randomly allocated to the intervention. Caregivers and educators of children in grades 1-3 will be invited to participate. The intervention is likely to involved regular case-based discussions and paediatric support.

Ethics and dissemination
Informed consent will be obtained from each participating school, educator and caregiver. Participants are informed of their voluntary participation and ability to withdrawal at any time. Participant confidentiality will be maintained and data will be secured on a password protected, restricted access database on the Murdoch Children’s research Institute (MCRI) server. Results will be disseminated via peer reviewed journals and conference presentations. Schools and caregivers will be provided with a report of the study outcomes and implications at the completion of the study.

| Data category                          | Information                                                                 |
|---------------------------------------|-----------------------------------------------------------------------------|
| Primary registry and trial identifying number | Australian New Zealand Clinical Trials Registry Trial Id: ACTRN12621000652875 |
| Date of registration in primary registry | 31/5/21                                                                     |
| Sources of monetary or material support | NHMRC Postgraduate scholarship for Dr William Garvey grant number 2005394   |
| Primary sponsor                       | The Murdoch Children’s Research Institute, Melbourne, Australia              |
| Contact information for primary sponsor | mcri@mcri.edu.au                                                             |
| Contact for public queries            | helpinprimaryschools@mcri.edu.au                                            |
|                                      | The Murdoch Children’s Research Institute, Melbourne, Australia              |
| Contact for scientific queries        | william.garvey@rch.org.au                                                  |
|                                      | The Royal Children’s Hospital, Melbourne, Australia                         |
ARTICLE SUMMARY

Strengths and limitations

• This study evaluates direct collaborations between primary school educators and clinicians that aim to empower educators to identify and support children with emotional and behavioural difficulties.
• Given the limited evidence of such models, this study is a pilot and limited to 12 primary schools over a 6 month period to assess educator acceptability and feasibility
• The 12 primary schools represent a broad range of participants as recruitment involves metropolitan and rural settings as well as varying levels of socio-educational advantage.
• The intervention is co-designed with schools to ensure the educators’ needs are accounted for in the design.

INTRODUCTION

Background and rationale

Childhood is a critical period of development and has lasting impacts on health and well-being throughout the life course.1

Emotional and behavioural difficulties are common in children and can be an early sign of mental illness. Over half of adult mental illness begins prior to 14 years of age2, and 1 in 7 Australian children meet diagnostic criteria for a mental illness over a 12-month period.3 While this national survey included children aged 4 to 17 years of age, evidence demonstrates that many childhood mental health problems become evident at a much younger age.4,5 Emotional difficulties include problems with anxiety, worrying and being withdrawn, while behavioural difficulties include hyperactivity and aggression.6 Prevention, early identification and intervention with evidence-based practices has been shown to reduce these problems.7,8 Unfortunately many children, especially
those living in lower socioeconomic status (SES) settings, do not receive adequate support.\textsuperscript{9,10} This is in part because the individuals supporting children on a daily basis, such as caregivers (those with parental or legal responsibility)\textsuperscript{11} and educators, may not be able to identify that a child needs help. Many children therefore miss out on support due to a lack of health literacy regarding childhood development and wellbeing. Health professionals have a great deal of expertise in assessing and managing child mental health problems, but timely access to healthcare may be difficult. Barriers such as siloed services, complex referral pathways, long wait times and high costs mean that many families have difficulty accessing the help they require.\textsuperscript{12,13} Public health systems are experiencing increased numbers of presentations and referrals of children with emotional and behavioural difficulties, with families experiencing wait times in excess of 12 months to access support.\textsuperscript{14} This can result in worsening mental health, poor educational outcomes, and family dysfunction.\textsuperscript{3,15} In addition, many children with emotional and behavioural difficulties, such as those with internalising symptoms, are either missed entirely or incorrectly diagnosed.\textsuperscript{10}

Schools are an integral aspect of daily life for children, but educators often lack support from the health system regarding how best to identify and manage children with emotional and behavioural difficulties. Improved collaboration between the health and education sectors could combine the strengths of both to better support these children. While paediatricians frequently assess and treat children with emotional and behavioural difficulties, fewer than 10\% of children over 4 years of age will visit a paediatrician in a 12-month period.\textsuperscript{16} However, almost every child spends at least 25 hours per week in primary school. The education system is therefore well placed to enable these children to be identified early and receive the support they need. Educators have an important and unique role in this area, but need to be better supported to detect and respond to problems early as there are concerns that many schools lack evidence-based approaches to supporting children.\textsuperscript{17}

The Victorian state government has implemented a strategy to strengthen mental health capacity in secondary schools, but this does not help the large numbers (approx. 84,000 per annum) of children whose difficulties emerge in primary school.\textsuperscript{3} Primary schools need to be supported to ensure that children are identified early, have access to evidence-informed interventions within the school environment, and can be referred to appropriate health and other services when school support is deemed insufficient. Families of children who require further assessment and treatment often need help navigating a complex and fragmented service system so as not to risk increased wait times or face mismatched referrals. Ideally all this needs to be designed collaboratively with each school, informed by an understanding of the student cohort and knowledge of local community services and resources.

Two relevant models of collaboration exist within the education and health sectors. Communities of Practice is an approach which has been adopted by the Victorian Department of Education and Training whereby school networks share knowledge, experiences and resources.\textsuperscript{18} Project ECHO is a similar model of inter-professional education and case-based learning used in clinical medicine to improve access to specialist expertise.\textsuperscript{19} Both models address the challenges of knowledge deficits and organisational silos. Aspects of each could be utilised to improve communication and provide a shared learning experience for the health and education professionals who support children with emotional and behavioural difficulties.

Objectives
The primary objective is to evaluate the feasibility and acceptability to educators and caregivers, of a structured health and education collaborative model designed to improve outcomes for children with emotional and behavioural difficulties.

The secondary objective is to assess any difference between intervention and control schools in educator identification and classifications of children as “struggling/always overwhelmed” (single
item question) in those who score in the “borderline/clinical” range on the Strengths and Difficulties Questionnaire (SDQ; validated against clinical diagnosis).

Trial design
Pilot cluster randomised controlled trial of a co-designed structured health and education collaborative model aiming to improve educator identification and management of children with emotional and behavioural difficulties and family uptake of services to assess and manage these difficulties.

Hypotheses
We hypothesise that the structured health and education collaborative model will be feasible and acceptable to educators and caregivers (primary outcome). We also hypothesise that educators in such a model will be able to identify and support children with emotional and behavioural difficulties using standardised measures, implementation of evidence-based strategies and health service use (secondary outcome).

METHODS AND ANALYSIS

Study setting
The study is conducted in Victorian primary schools. Caregivers and educators of students in grades 1 (the second year of formal schooling in Australia), 2 and 3 are recruited to assess children early in their school education. Educators of preparatory grade (i.e. first year of schooling) students are not recruited because of their varying experiences of preschool education and the need to allow time for them to settle into the school environment and routine. Metropolitan and rural primary schools are recruited to test the feasibility and acceptability across diverse settings.

Eligibility criteria
The Australian school sector is made up of government (65.6%), Catholic (19.4%) and independent (15%) schools. To ensure consistency in supports within the education system, only Government schools are invited to participate. Schools are recruited from the Local Government Area of the City of Yarra (metropolitan) and the Wimmera Southern Mallee (rural). Schools must have a minimum of 40 students across grades 1, 2 and 3. Special schools (schools that provide specialist and intensive support in a dedicated setting for students with moderate to high learning and support needs) are excluded. Caregivers and educators of students completing grade 1, 2 or 3 in 2021 are invited to participate. Caregivers who have insufficient English to complete the surveys and who do not have access to interpreter services to support completion of the survey are excluded.

Patient and public involvement
The public was first involved in the project when community leaders within both communities were informed of the concept in early 2019. The lead paediatrician has worked in both communities for a number of years and through this work frequently engages with families, educators and clinicians. The community leaders assist with school recruitment and in shaping the project through conversation early in the design process. Once schools are recruited multiple caregiver information sessions are held at each of the 12 schools, both online and in person. Caregivers are asked to
comment on the project in regards to their experience in supporting their children’s development and wellbeing.

Intervention
The intervention period is 6 months with baseline surveys pre-intervention and a follow up survey at the completion of the intervention period. During the 6 month intervention period schools receive two key strategies.

- Paediatrician (author WG)-led, fortnightly one hour videoconference seminar program with case-based discussions covering topics of interest as selected by participating educators. The program incorporates evidence-based approaches to identification and management of children with emotional and behavioural difficulties.

- Paediatrician support to help identify, support and navigate health services for children whom educators perceive have emotional and behavioural difficulties.

Half of the participating schools are randomly allocated to the intervention (intervention group). At the beginning of the project WG meets with each school allocated to the intervention to co-design the program for terms 3 and 4. Based on other research about improving collaboration, the program involves discussions about certain topics (e.g., anxiety, learning difficulties) selected by each school. This leads to a discussion of how to best use evidence to support children with these difficulties in the school environment. In addition, WG provides assistance to help identify, support and navigate health services for children who require assessment and therapy outside of the school environment. The individual school utilises its normal communication pathways to discuss this with caregivers.

The other half of the schools (control group) operate as they usually do with no regular case discussion and knowledge of how best to navigate the healthcare system left to educators.

Outcomes
Outcomes are assessed by caregiver and educator-completed surveys at baseline and again at the completion of the trial period (6 months). Educators in both arms complete baseline and follow up surveys for participating children only (caregivers have submitted consent and baseline surveys). Educators in the intervention group are also asked to take part in a focus group at the completion of the intervention (see table 1).

The primary outcome of the study is the feasibility and acceptability of the structured health and education collaborative model from the perspectives of educators and caregivers. This is measured using both quantitative and qualitative methods:

- Quantitative
  - Number and proportion of eligible (i) educators and (ii) caregivers who consent take part in the pilot.
  - Number and proportion of eligible educators who participate in the case based discussions.
  - Number and proportion of eligible educators who utilise paediatric support to discuss how best to support individual students outside of the case-based discussions
  - Study-designed survey items asking educators about acceptability of the program.
  - Educator confidence in supporting children with emotional and behavioural difficulties measured using the school mental health self-efficacy teacher survey (SMH-SETS).

- Qualitative
• Open-ended questions about educators’ experience of the program, relevance of the content, usefulness of experience and suggestions for improvement.
• Educator perspectives of whether the model has impacted their ability to identify and support children with emotional and behavioural difficulties.

Secondary outcomes will measure in the intervention versus control groups:
• Accuracy of educator identification of child emotional and behavioural difficulties (study-designed, single item measure) compared with the standardised measure The Strengths and Difficulties Questionnaire (SDQ), a reliable and validated measure, already used in Victoria’s School Entry Health Questionnaire of each child’s emotional and behavioural symptoms.22
• Improvement in emotional and behavioural symptoms at the completion of the intervention, measured by the SDQ, compared to baseline.
• Caregiver health service use for child emotional and behavioural problems.
Table 1. Primary and secondary outcomes.

| Outcome       | Variable                                | Measure                              | Participant group | Collection point |
|---------------|-----------------------------------------|--------------------------------------|-------------------|------------------|
| Primary       | Feasibility                             | Study recruitment & retention        | Caregiver         | ✔️               |
| Primary       | Acceptability                           | Intervention participation           | Educator          | ✔️               |
| Primary       | Acceptability                           | Study designed measures              | Baseline          | ✔️               |
| Primary       | Confidence supporting students          | School Mental Health Self-Efficiency Teacher Survey (SMH-SETS) | 6 months          | ✔️               |
| Secondary     | Accuracy and timing of emotional and    | Strengths and Difficulties Questionnaire (SDQ) | Baseline          | ✔️               |
| Secondary     | Health service use                      | Study designed-measures              | 6 months          | ✔️               |

To determine whether the intervention leads to identification of child emotional and behavioural difficulties, caregivers and educators are asked at each time-point (baseline and 6 months later) a single item question as a measure of overall child emotional and behavioural difficulties, namely: “Thinking about your child’s mental health and wellbeing over the last 6 months, has [child’s name] been thriving, coping, struggling or always overwhelmed?”. This response is dichotomised (thriving/cop ing vs struggling/always overwhelmed) and compared against the SDQ, a validated measure of child emotional and behavioural difficulties to determine the sensitivity and specificity of the single item question. It is a screening questionnaire for 3 – 16-year-olds, in which caregivers or educators rate 25 items. It provides a total score and subscale scores including emotional symptoms, conduct problems, hyperactivity/inattention, peer relationship problems and prosocial behaviour. “Normal”, “borderline” and “abnormal” ranges exist for total difficulties and each of the
We will determine the sensitivity and specificity of the single item measure against the SDQ total borderline/clinical cut point, as reported by educators and caregivers at baseline and at follow up.

Health service use is measured by caregiver report asking the following questions: “Did the teacher suggest a referral to a health service (e.g., GP, paediatrician) for your child because of emotional or behavioural concerns?”. If yes “did you engage with that health service?” If no, “why not?” The baseline survey also collects child (e.g., age, sex, existing emotional and behavioural support) and caregiver (e.g. relationship to child, highest level of education, household income) demographic data.

Measurement of participant compliance
All participants are asked to complete the surveys and measurement of compliance is carried out at each of the data collection points (baseline & 6 months). Any surveys not submitted result in a reminder email or sms being sent to the relevant educator/caregiver. Surveys that have not been submitted will result in the relevant educator/caregivers being contacted by WG to discuss any difficulties completing the survey and assess ongoing participation in the trial.

The time commitment for individual educators includes the co-design focus groups (90 minutes), seminar case discussions (one hour per fortnight/month depending on co-design; intervention group only) and survey completion (10-15 minutes per student i.e., up to 4 to 6 hours at each data collection point). The primary objective of this research project is to assess the acceptability and feasibility of such an intervention in the context of the educators’ workload. Student wellbeing however is a core component of school responsibility, as detailed in the Royal Commission into Victoria’s mental health system, and participating schools and educators have expressed their willingness to take part in this pilot and complete relevant surveys.

Participant timeline
Schools were first enrolled in April 2021 and randomly allocated to the control or intervention group in May (see figure 1) Baseline survey collection took place in June with follow up surveys planned for January 2022. Co-design workshops occurred with intervention schools in June 2021 and reflection focus groups with the same schools will take place in February 2022.

Sample size
As this is a feasibility and acceptability pilot, a formal sample size calculation is not required. However, with a sample of 432 from 720 eligible (60% enrolment of eligible families presuming 12 schools with an average of 20 students in each of grades 1, 2 and 3), will provide meaningful data to ascertain the feasibility and acceptability of the intervention and study measures. Further, results will inform a sample size calculation of a planned future, adequately powered randomised controlled trial to test the effectiveness and cost-effectiveness of this intervention.

Recruitment
School recruitment
Schools are recruited through established relationships with existing community networks and invited to participate in the study. The paediatrician leading the study has been a member of both communities in a professional capacity for over two years; this assists with school and health service participation. The leadership team at each school, including the principal, assist in selecting the individual educators for the co-design process. This include the educators who will be receiving
the intervention, along with any members of the school team involved in supporting children with emotional and behavioural difficulties (e.g., student wellbeing team). Each participating school is asked to complete a School Participant Information Statement and Consent Form (see Appendix A).

**Student recruitment**
Educators distribute the Caregiver Study Interest Form (see Appendix B) where caregivers can state whether they do or do not wish to learn more about the study. In addition to this form, school communication networks are utilised to inform caregivers about the study (e.g., school newsletter, caregiver information evening, flyers on the school campus). Interested families have two weeks to return the form after which time WG collects the forms of those families who have opted in. At the end of the two weeks, the classroom educator provides information about how many of the potential participants did not return the form. This demonstrates how many potential caregivers could be enrolled if families who did not opt out were contacted in the future. Any family who returns forms where opt out has been selected will not be contacted.

The study team then phones caregivers who have opted in to hear more about the study. They explain the study further, answer any questions they might have, and ensure they meet inclusion criteria. Eligible and interested caregivers are emailed the baseline survey and Caregiver Participant Information Statement and Consent Form (see Appendix C) to return when completed. Should this “opt-in” approach to recruitment yield insufficient caregivers, an “opt out” approach is taken as per the Royal Children’s Hospital (RCH) ethics committee and Department of Education approval. We start with an “opt-in” approach first as this is the preference of the study’s ethics committee. Educators who have students enrolled in the study via caregiver survey completion will be provided with the Educator Participant Information Statement and Consent Form (see Appendix D).

**Allocation**
A statistician not directly involved in the analysis of the trial results prepares the randomisation schedule. Randomisation is stratified by region and tertile (see figure 2 below). For each stratum, we have two schools, which have been randomly allocated to treatment and control. This has been done using function sample in R 4.1.0. The Index of Community Socio-Educational Advantage (ICSEA) is used to allocate each participating school into a relative tertile where the 1st tertile is the least advantaged third of schools and the 3rd tertile is the most advantaged third of schools. The ICSEA score calculation is made up of the socio-educational advantage (SEA) plus remoteness and percentage of Indigenous student enrolment. The SEA is calculated using parental occupation and education. Schools in each region are paired based on their ICSEA score and within each pair, randomly allocated to either the control or intervention group. Allocation occurs after schools have consented to participate to ensure that the study includes a broad range of primary schools. Blinding is not possible given that educators (and caregivers) will be aware of their allocation based on participation in the intervention.

see figure 2

**Data collection methods**
As demonstrated in the participant timeline, measurements are collected at baseline and 6 months post baseline survey completion. Baseline surveys are collected prior to the 6 month intervention period, in which caregiver and educator surveys are conducted for each student in the control and intervention schools. Follow up surveys are completed 6 months after the baseline measurements. At this time caregivers and educators are asked to again complete the single item measurement, the Strengths and Difficulties Questionnaire and the SMH-SETS (educators only). In addition, the follow up survey will ask caregivers and educators about health service referral and uptake.
Participants complete surveys either via a link to a REDCap survey database or using paper surveys which are then transferred to the REDCap database once submitted.27,28 (see Appendix E and F for caregiver and educator surveys).

Data management & monitoring
All data collected is de-identified and stored in the restricted access folder on the Murdoch Children’s Research Institute (MCRI) server. This database is password protected and only the study investigators have access to this data. Confidentiality of the participants is maintained at all times. As per the Australian Code for the Responsible Conduct of Research, data is stored for a minimum of 5 years. To protect participant privacy, all data collected is de-identifiable with only the research team able to match participant names with ID numbers and stored on a secure network drive within the MCRI that is only accessible by the study investigators. Any paper forms used are scanned and stored on the secure network drive and subsequently destroyed. Given that this is a pilot study with limited resources, a formal data monitoring committee has not been created. The study team meet frequently however to monitor progress and independent oversight occurs as required by the overseeing University.

Statistical methods
Sample characteristics, participation rates and educator and caregiver reports of feasibility and acceptability are described using summary statistics (e.g. number and proportion of caregivers who take part in the pilot, and educator confidence supporting students with emotional and behavioral difficulties).

To determine the usefulness of the single-item question about child mental health, we determine the sensitivity, specificity, and positive and negative predictive values of the dichotomised response versus the educator-completed SDQ borderline/abnormal total score cut point for students in each group. We do this at baseline and at follow up to determine if educators in the intervention group identify more children with symptoms of emotional and behavioural problems compared to educators in the control group. The single item question completed by caregivers is also evaluated using the same method of comparison to the caregiver SDQ total score.

For our secondary outcomes, an intention-to-treat analysis at the level of the child is conducted. Scores from the SDQ at follow up are dichotomised and compared between the intervention and control groups, with adjustments for baseline SDQ and the randomisation stratification factor (ICSEA). This will be conducted separately for educator and caregiver reported SDQ, using logistic regression. Odds Ratio will be reported with 95% confidence intervals and p values. These analyses will also be repeated using linear regression of the continuous SDQ scores on a standardized scale to provide effect sizes. ESs are considered as small, ~0.20 SD; moderate, ~0.50 SD; and large, ~0.80 SD. Analysis is completed using Stata 17.0.29

Harms
Participants are provided with contact details for the lead investigator (WG) and the Director of Research Ethics & Governance at The Royal Children’s Hospital Melbourne. They are advised to report any adverse events and such events will be reported to the Ethics committee once the study team is aware that they have occurred. Oversight of the pilot includes monthly review meetings with HH and FO - two experienced paediatric researchers who have conducted over 15 RCTs in child health

ETHICS AND DISSEMINATION
Research and ethics approval

This study was approved by the Royal Children’s Hospital Human Research and Ethics Committee (#67653) and the Victorian Department of Education Research in Schools Ethics Committee (#2021_004349) on the 16th of March 2021. Informed caregiver consent will be obtained via a written or online participant information and consent form.

Protocol amendments

This study will be conducted in compliance with the current version of the protocol. Any change to the protocol document or Informed Consent Form that affects the scientific intent, study design, participant safety, or may affect a participant’s willingness to continue participation in the study is considered an amendment, and therefore will be written and filed as an amendment to this protocol and/or informed consent form. All such amendments will be submitted to the HREC, for approval prior to becoming effective.

Consent

Selected schools are contacted via email and/or phone with an invitation to participate in the study. This correspondence includes the Participant Information and Consent Form (PICF, see appendix section). A signed consent form is obtained for each participating school principal, individual educator and caregiver.

Following family recruitment (described in 3.7) all participants are informed of their voluntary participation and ability to withdraw their involvement at any time. In addition, each participant is informed of their anonymity in regard to the study including any publications resulting from the research. The lead investigator provides the PICF to the caregiver. This document describes the purpose of the trial, the procedures to be followed, and the risks and benefits of participation.

The research team conducts informed consent discussion and checks the participant comprehend the information provided. The research team member answers any questions about the trial.

Participants are invited to provide consent following a phone call discussion about the study. Participants are given the choice of an online link or paper copy of the consent form to complete along with the baseline survey in the same format.

It is documented in the participant’s record that consent has been provided. When all the inclusion/exclusion criteria have been addressed and the eligibility of the participant confirmed, the participant will be assigned to a trial group, based on the group that their child’s school is randomised to.

Confidentiality

Participant confidentiality is strictly held in trust by the participating investigators, research staff, and the sponsoring institution and their agents. The study protocol, documentation, data and all other information generated is held in strict confidence. No information concerning the study or the data will be released to any unauthorised third party, without prior approval by the participant and written approval of the sponsoring institution.

Declaration of interests

No competing interests to declare

Access to data
Only the research team have access to the data via a password protected secure database.

**Dissemination policy**
Results will be submitted for publications in peer-reviewed journals and presented at relevant conferences. Principal Investigator William Garvey holds the primary responsibility for publication of the results of the study in accordance to the study publication and dissemination plan to be developed. A report of study outcomes and implications will be delivered to partner organisations and relevant stakeholders.
We will send a summary of the study results to each participating school and caregiver but no individual students will be identified. We will prepare a study report which can be distributed as schools see appropriate.

**Contributorship statement**
Dr William Garvey conceived and wrote the manuscript with ongoing input from Dr Rachel Schembri, Professor Harriet Hiscock and Professor Frank Oberklaid. All authors contributed to refinement of the study protocol and approved the final manuscript.

**Competing interests**
The authors declare they have no competing interests.

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**Data sharing statement**
Data may be obtained from a third party and are not publicly available. Access to deidentified participant data can be requested by contacting helpinprimaryschools@mcri.edu.au. Reuse will only be permitted with written confirmation and must be cited in any use such as publication.

**Figure legend**
Figure 1. Flow chart of trial timeline
Figure 2. School pairing by region and ICSEA ranking
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Abbreviations
ESs: Effect Sizes; ICSEA: Index of Community Socio-Educational Advantage; MCRI: Murdoch Children’s research Institute; SEA: socio-educational advantage; SES: Socio-Economic Status; SD: Standard Deviation; SDQ: Strengths and Difficulties Questionnaire; SMH-SETS: School Mental Health Self-Efficacy Teacher Survey; WG: William Garvey

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Word count
4180 words.
Enrolment April 2021
Assessed for eligibility
12 schools (1008 students)

Excluded (n=726)
• Did not opt in (714)
• Unable to contact (425)

Allocation May 2021
Randomised to control or intervention

Control arm
6 schools

6 schools (128 students)
Caregiver survey
Educator survey

6 schools
Caregiver survey
Educator survey

Intervention arm
6 schools

Co-design workshop June 2021
6 schools
Co-design workshop with educators

Baseline survey July 2021
6 schools (273 students)
Caregiver survey
Educator survey

Follow up survey Jan 2022
6 schools
Caregiver survey
Educator survey

Reflection focus groups Feb 2022
6 schools
Focus group with educators

Figure 1. Flow chart of trial timeline
Figure 2. School pairing by region and ICSEA ranking
Appendix A - School Participant Information Statement and Consent Form

Dear <principal>,

Thank you for taking the time to read this Participant Information Statement and Consent Form. We would like to invite your school to take part in a research project that is explained in this form.

This form is 5 pages long. Please make sure you have all the pages.

What is an Information Statement and Consent Form?

An Information and Consent Form tells you about the research project. It explains what the research project involves. This information is to help you decide whether or not you would to take part in the research. Please read it carefully.

Before you decide if you want to take part or not, you can ask us any questions you have about the project. You may want to talk about the project with your family, friends or health care worker.

Taking part in the research project is up to you

It is your choice whether you take part in the research project. You do not have to agree if you do not want to.

Signing the form

If you want to take part in the research, please sign the consent form at the end of this document. By signing the form you are telling us that you:

- understand what you have read
- had a chance to ask questions and received satisfactory answers
- consent to taking part in the project.
- We will give you a copy of this form to keep.
What is the research project about?

Emotional and behavioural difficulties are common in primary school children and they can have a big impact on their development, learning and well being. We know that they can be an early sign of mental health issues and therefore it is essential that we support all children who experience these difficulties where they live their lives, including at school. It is important to understand how schools and health services can best support the needs of these children, so that they are able to reach their full potential. In this project, we hope to learn more about how education and health can work together to support all children regarding their emotional and behavioural development.

Who is running the project?

My name is William Garvey and I am a paediatrician at the Royal Children’s Hospital (RCH) and researcher at the Murdoch Children’s Research Institute (MCRI). The study team is also made up of other clinicians and researchers at the RCH and MCRI. The study will be conducted in 12 schools, 6 in a metropolitan Melbourne region and 6 in a rural Victoria region. Over the study period we will be assessing a model that involves educators and a paediatrician working together to better support children with emotional and behavioural difficulties in primary school.

Why am I being asked to take part?

You are being asked because it is hoped educators and families in your school are willing to take part in the project. Research shows that 10-20% of children experience significant emotional and behavioural difficulties but often they can be difficult to identify. This study will aim to measure all children in a classroom to make sure it represents the normal population as best possible. Many children in the study will not experience significant emotional and behavioural difficulties but they will also help us understand how the positive role the school environment plays in child development and well being. Educators are integral to best understanding how to support children in the school environment.

What do I need to do in this project?

Principals who agree for their school to participate are being asked to collaborate with and support educators to make sure their involvement is clear and the time commitment is feasible. The project will involve educators and each child’s caregiver completing 2 surveys per child over an 8 month period later this year. The surveys will ask questions about educators experience such as number of years teaching and additional formal training. They will also be asked questions about how each child has seemed recently regarding their emotions and behaviour. Each child’s caregiver will be asked similar questions at the same 2 time points. Caregivers will also be asked about health service use. Each survey is expected to take 10-15 minutes to complete so for a teacher with 25 students participating the time commitment would be approximately 4-6 hours at each of the 2 survey time points. However it will be less if fewer families take part.

Half of the participating schools will be randomly allocated to the intervention. This will be a form of collaboration in which the paediatrician and teacher work together to ensure that the best evidence is used to support all children in the classroom. At the beginning of the project I will meet with each school allocated to the intervention to co-design the program for terms 2, 3 and 4 in 2021. This will take place in term 2 at your school at a time that suits you and the other participating members of your school team (e.g., other educators, principal, wellbeing officer). It will be a single session lasting approximately 90 minutes and will focus on how you can work with a paediatrician to better identify and support children with emotional and behavioural difficulties. Based on other research looking at improving collaboration, it is likely that the program will involve weekly to fortnightly discussions about certain topics (e.g., anxiety, learning difficulties) selected by each school. Educators will also discuss students from their classroom, without identifying the individual, who are experiencing difficulties related to the topic. This will lead to a discussion of how to best use the latest and most reliable evidence to support children with these difficulties in the school environment. In addition, the paediatrician will also help identify, support and navigate health services for children who require assessment and therapy outside of the school environment. These sessions will be held either
at your school or via video conferencing (e.g., zoom) depending on your schools preference. The other half of the schools will operate as they usually do so we can compare the intervention to normal practice.

**Can I withdraw from the project?**

You can stop taking part in the project at any time. You just need to tell us so. You do not need to tell us the reason why. If you leave the project we will use any information already collected unless you tell us not to.

**What are the possible benefits for me and other people in the future?**

The possible benefits for your school and others in the future include a better understanding of how to best identify and support children with emotional and behavioural difficulties in the classroom. Given how common these problems are and the impact they have on the child and those around them the potential for improvement is significant.

**What are the possible risks, side-effects, discomforting and/or inconveniences?**

The intervention will be a collaborative approach to using evidence-based practice in the school environment to help identify and support children with emotional and behavioural difficulties. This is unlikely to pose any significant risk and no side-effects but the project will be closely monitored for unexpected outcomes. The only inconvenience is educators completing the survey 2 times over the 8 month time period. The survey should take 10-15 minutes to complete per student.

**What will be done to make sure my information is confidential?**

All data collected will be re-identified and stored in the restricted access folder on the MCRI server. This database will be password protected and only the study investigators will have access to this data. Confidentiality of the participants will be maintained at all times, except as required by law, to ensure selected schools and individual participants remain anonymous throughout and after completion of the investigation. As per the Australian Code for the Responsible Conduct of Research, data will be stored for a minimum of 5 years.

**Will we be informed of the results when the research project is finished?**

We will send a summary of the study results to each participating school and caregiver but no individual students or educators will be identified. We will prepare a study report which can be distributed as schools see appropriate. Results be submitted for publications in peer-reviewed journals and presented at relevant conferences.

**Who should I contact for more information?**

If you would like more information about the project, please contact:

Name: Billy Garvey

Contact telephone: 9345 5851

Email: william.garvey@rch.org.au

You can contact the Director of Research Ethics & Governance at The Royal Children’s Hospital Melbourne if you:

- have any concerns or complaints about the project
- are worried about your rights as a research participant
- would like to speak to someone independent of the project.

The Director can be contacted by telephone on (03) 9345 5044.
Consent Form

HREC Project Number: 67653

Research Project Title: Improving outcomes for children with emotional and behavioural difficulties through a school-based intervention: a pilot randomised controlled trial.

Version Number: 1.3  Version Date: 24/4/21

• I have read this information statement and I understand its contents.
• I understand what my child and I have to do to be involved in this project.
• I understand the risks my child could face because of their involvement in this project.
• I voluntarily consent for my child to take part in this research project.
• I have had an opportunity to ask questions about the project and I am satisfied with the answers I have received.
• I understand that this project has been approved by The Royal Children’s Hospital Melbourne Human Research Ethics Committee. I understand that the project is required to be carried out in line with the National Statement on Ethical Conduct in Human Research (2007).
• I understand I will receive a copy of this Information Statement and Consent Form.

Principal Name

Principal Signature

Date

Name of Witness to Participant’s Signature

Witness Signature

Date

Declaration by researcher: I have explained the project to the participant who has signed above. I believe that they understand the purpose, extent and possible risks of their involvement in this project.

Research Team Member Name

Research Team Member Signature

Date

Note: All parties signing the Consent Form must date their own signature.
Appendix B - Caregiver Study Interest Form

Dear caregiver,

Your child’s school is taking part in a research project with the Murdoch Children’s Research Institute. This project is testing a new way of working with teachers to better support children’s social and emotional health and wellbeing. We hope as many families as possible take part. The project is being run by Dr. Billy Garvey, a paediatrician (children’s doctor) at The Royal Children’s Hospital.

To learn more about the project, please tick the “I would like to hear more information” box below. By ticking this, your child’s school will pass your name and contact phone number to Dr Billy Garvey (children’s doctor) who is leading the project. They will not share any child contact details. Dr Garvey will use this information to telephone you, explain more about the study and see if you would like to take part. At this point, you can decide whether you want to take part. If you do not want to, we will destroy your data (i.e., name and contact number).

If you do not wish to hear more about the project, please tick the “I would not like my contact details passed on” box below. This means your child’s school will not pass any contact details to Dr Billy Garvey and we will not contact you.

- I would like to hear more information about the project from the research team at MCRI
- I would not like my contact details passed onto the research team at MCRI

| Parent/Guardian Name | Contact number | Parent/Guardian Signature | Date |
|----------------------|----------------|---------------------------|------|
Appendix C - Caregiver Participant Information Statement and Consent Form

HREC Project Number: 67653
Short Name of Project: Health & Education Linking Project (HELP) - supporting child emotional and behavioural development
Full Name of Project: Improving outcomes for children with emotional and behavioural difficulties through a school-based intervention: a pilot randomised controlled trial.
Principal Researcher: Dr William Garvey, paediatrician
Version Number: 1.4 Version Date: 24/04/21

Dear <insert parent/guardian’s name>,

Thank you for taking the time to read this Information Statement and Consent Form. We would like to invite your child to take part in a research project that is explained in this form.

This form is 4 pages long. Please make sure you have all the pages.

What is an Information Statement and Consent Form?

An Information and Consent Form tells you about the research project. It explains what the research project involves. This information is to help you decide whether or not you would like your child to take part in the research. Please read it carefully.

Before you decide if you want your child to take part or not, you can ask us any questions you have about the project. You may want to talk about the project with your family, friends or health care worker.

Taking part in the research project is up to you

It is your choice whether or not your child takes part in the research project. You do not have to agree if you do not want to.

Signing the form

If you would like your child to take part in the research, please sign the consent form at the end of this document. By signing the form you are telling us that you:

- understand what you have read
- had a chance to ask questions and received satisfactory answers
- consent to your child taking part in the project.
What is the research project about?

Emotional and behavioural difficulties are common in children and they can have a big impact on their development, learning and well being. We know that they can be an early sign of mental health issues. It is important to understand how schools and health services can best support the needs of these children, so that they are able to reach their full potential. In this project, we hope to learn more about how education and health can work together to support all children in their emotional and behavioural development.

Who is running the project?

My name is William Garvey and I am a paediatrician (children’s doctor) at the Royal Children’s Hospital (RCH) and researcher at the Murdoch Children’s Research Institute (MCRI). The study team is also made up of other paediatricians and researchers at the RCH and MCRI. The study will be conducted in 12 schools, 6 in a metropolitan Melbourne region and 6 in a rural Victoria region. We will be assessing a model that involves educators and a paediatrician working together to better support children with emotional and behavioural difficulties in primary school.

Why is my child being asked to take part?

Your child is being asked to participate because your child’s school has agreed to take part in the study. Research shows that 10-20% of children experience significant emotional and behavioural difficulties but often they can be difficult to identify. This study aims to include all children in a classroom to make sure our project helps as many children as possible. Many children in the study will not experience these difficulties but they will also help us understand the positive role the school environment plays in child development and well being.

What does my child need to do in this project?

The project will involve you and your child’s teacher completing 2 surveys over an 8 month period. The surveys will ask questions about your family such as number of people, their age and sex. You will also be asked questions about your child’s emotions and behaviour. You will also be asked about services or help you may have used if your child’s emotional and behavioural issues. Each survey should take 10-15 minutes.

Half of the participating schools will be randomly allocated to the intervention which will be a form of collaboration in which the paediatrician and teacher work together to ensure that the best evidence is used to support all children in the classroom. We will work with the school to develop a design for this project to best meet the needs of all students. Based on other research looking at improving collaboration, it is likely that the program will involve discussions about certain topics (e.g., anxiety, learning difficulties) selected by each school. This will lead to a discussion of how to best use the latest and most reliable evidence to support children with these difficulties in the school environment. In addition, there will be assistance provided to teachers to help navigate health services for children who require assessment and support outside the school. The other half of the schools will operate as they usually do so we can compare the intervention to normal practice.

Can my child stop taking part in the project?

Your child can stop taking part in the project at any time. You just need to tell us so. You do not need to tell us the reason why. If your child leaves the project we will use any information already collected unless you tell us not to.

What are the possible benefits for my child and other people in the future?

The possible benefits for your child and others in the future include a better understanding of how to best identify and support children with emotional and behavioural difficulties in the classroom. Given how common these problems are and the impact they have on the child and those around them, the potential for improvement is significant.
What are the possible risks, side-effects, discomfoting and/or inconveniences?

If your child is in a school randomly allocated to the intervention group they will have indirect exposure to the intervention as it involves helping their teacher to help identify and support children with emotional and behavioral difficulties. Therefore, there are no significant risks and no side-effects to be concerned about if you decide to participate. Across the two groups, the only inconvenience is having to complete the survey 2 times over the 8 month time period. The survey should only take 10-15 minutes to complete.

What will be done to make sure my child’s information is confidential?

All data collected will be re-identified and stored in the restricted access folder on the MCRI server. This database will be password protected and only the study investigators will have access to this data. Confidentiality of the participants will be maintained at all times, except as required by law, to ensure selected schools and individual participants remain anonymous throughout and after completion of the investigation. As per the Australian Code for the Responsible Conduct of Research, data will be stored for a minimum of 5 years.

Will we be informed of the results when the research project is finished?

You will have access to your individual information if requested. In addition, we will send a summary of the study results to each participating school and caregiver but no individual students will be identified. We will prepare a study report which can be distributed as schools see appropriate. Results be submitted for publications in peer-reviewed journals and presented at relevant conferences.

Who should I contact for more information?

If you would like more information about the project, please contact:

Name: Billy Garvey

Contact telephone: 9345 5851
Email: william.garvey@rch.org.au

You can contact the Director of Research Ethics & Governance at The Royal Children's Hospital Melbourne if you:

- have any concerns or complaints about the project
- are worried about your rights as a research participant
- would like to speak to someone independent of the project.

The Director can be contacted by telephone on (03) 9345 5044.

Consent Form

HREC Project Number: 67653

Research Project Title: Improving outcomes for children with emotional and behavioural difficulties through a school-based intervention: a pilot randomised controlled trial.

Version Number: 1.4 Version Date: 24/4/21

- I have read this information statement and I understand its contents.
- I understand what my child and I have to do to be involved in this project.
- I understand the risks my child could face because of their involvement in this project.
- I voluntarily consent for my child to take part in this research project.
- I have had an opportunity to ask questions about the project and I am satisfied with the answers I have received.
- I understand that this project has been approved by The Royal Children’s Hospital Melbourne Human Research Ethics Committee. I understand that the project is required to be carried out in line with the National Statement on Ethical Conduct in Human Research (2007).
- I understand I will receive a copy of this Information Statement and Consent Form.

Parent/Guardian Name: ____________________________ Parent/Guardian Signature: ____________________________ Date: ________________

Name of Witness to Participant’s Signature: ____________________________ Witness Signature: ____________________________ Date: ________________
Declaration by researcher: I have explained the project to the participant who has signed above. I believe that they understand the purpose, extent and possible risks of their involvement in this project.

| Research Team Member Name | Research Team Member Signature | Date |
|----------------------------|-------------------------------|------|

Note: All parties signing the Consent Form must date their own signature.

Appendix D - Educator Participant Information Statement and Consent Form

HREC Project Number: 67653
Short Name of Project: Health & Education Linking Project (HELP) - supporting child emotional and behavioural development
Full Name of Project: Improving outcomes for children with emotional and behavioural difficulties through a school-based intervention: a pilot randomised controlled trial.
Principal Researcher: Dr William Garvey, paediatrician
Version Number: 1.5  Version Date: 24/04/21

Dear <educator>,

Thank you for taking the time to read this Participant Information Statement and Consent Form. We would like to invite you to take part in a research project that is explained in this form.

This form is 5 pages long. Please make sure you have all the pages.

What is an Information Statement and Consent Form?
An Information and Consent Form tells you about the research project. It explains what the research project involves. This information is to help you decide whether or not you would to take part in the research. Please read it carefully.

Before you decide if you want to take part or not, you can ask us any questions you have about the project. You may want to talk about the project with your family, friends or health care worker.

**Taking part in the research project is up to you**

It is your choice whether you take part in the research project. You do not have to agree if you do not want to.

**Signing the form**

If you want to take part in the research, please sign the consent form at the end of this document. By signing the form you are telling us that you:

- understand what you have read
- had a chance to ask questions and received satisfactory answers
- consent to taking part in the project.
- We will give you a copy of this form to keep.

**What is the research project about?**

Emotional and behavioural difficulties are common in primary school children and they can have a big impact on their development, learning and well being. We know that they can be an early sign of mental health issues and therefore it is essential that we support all children who experience these difficulties where they live their lives, including at school. It is important to understand how schools and health services can best support the needs of these children, so that they are able to reach their full potential. In this project, we hope to learn more about how education and health can work together to support all children regarding their emotional and behavioural development.

**Who is running the project?**

My name is William Garvey and I am a paediatrician at the Royal Children’s Hospital (RCH) and researcher at the Murdoch Children’s Research Institute (MCRI). The study team is also made up of other clinicians and researchers at the RCH and MCRI. The study will be conducted in 12 schools, 6 in a metropolitan Melbourne region and 6 in a rural Victoria region. Over the study period we will be assessing a model that involves educators and a paediatrician working together to better support children with emotional and behavioural difficulties in primary school.

**Why am I being asked to take part?**

You are being asked to take part because it is hoped students in your class will participate in the project. Research shows that 10-20% of children experience significant emotional and behavioural difficulties but often they can be difficult to identify. This study will aim to measure all children in a classroom to make sure it represents the normal population as best possible. Many children in the study will not experience significant emotional and behavioural difficulties but they will also help us understand how the positive role the school environment plays in child development and well being. Educators are integral to best understanding how to support children in the school environment.

**What do I need to do in this project?**
The project will involve you and each child’s caregiver completing 2 surveys per child over an 8 month period later this year. The first surveys will ask questions about your experience such as number of years teaching and additional formal training. In the subsequent surveys, you will also be asked questions about how each child has seemed recently regarding their emotions and behaviour. Each child’s caregiver will be asked similar questions at the same 3 time points. Caregivers will also be asked about health service use. Each survey is expected to take 10-15 minutes to complete so for a teacher with 25 students participating the time commitment would be approximately 4-6 hours at the 2 survey time points. However it may be less than this if only some families in your class take part.

Half of the participating schools will be randomly allocated to the intervention. This will be a form of collaboration in which the paediatrician and teacher work together to ensure that the best evidence is used to support all children in the classroom. At the beginning of the project I will meet with each school allocated to the intervention to co-design the program for terms 2, 3 and 4 in 2021. This will take place in term 2 at your school at a time that suits you and the other participating members of your school team (e.g., other educators, principal, wellbeing officer). It will be a single session lasting approximately 90 minutes and will focus on how you can work with a paediatrician to better identify and support children with emotional and behavioural difficulties. Based on other research looking at improving collaboration, it is likely that the program will involve weekly to fortnightly discussions about certain topics (e.g., anxiety, learning difficulties) selected by each school. Educators will also discuss students from their classroom, without identifying the individual, who are experiencing difficulties related to the topic. This will lead to a discussion of how to best use the latest and most reliable evidence to support children with these difficulties in the school environment. In addition, the paediatrician will also help identify, support and navigate health services for children who require assessment and therapy outside of the school environment. These sessions will be held either at your school or via video conferencing (e.g., zoom) depending on your schools preference. The other half of the schools will operate as they usually do so we can compare the intervention to normal practice.

Can I withdraw from the project?

You can stop taking part in the project at any time. You just need to tell us so. You do not need to tell us the reason why. If you leave the project we will use any information already collected unless you tell us not to.

What are the possible benefits for me and other people in the future?

The possible benefits for you and others in the future include a better understanding of how to best identify and support children with emotional and behavioural difficulties in the classroom. Given how common these problems are and the impact they have on the child and those around them, the potential for improvement is significant.

What are the possible risks, side-effects, discomforting and/or inconveniences?

The intervention will be a collaborative approach to using evidence-based practice in the school environment to help identify and support children with emotional and behavioural difficulties. This is unlikely to pose any significant risk and no side-effects but the project will be closely monitored for unexpected outcomes. The only inconvenience is having to complete the survey 3 times over the 8 month time period which will take up to 6 hours, depending on the number of families in your classroom who take part.

What will be done to make sure my information is confidential?

All data collected will be re-identified and stored in the restricted access folder on the MCRI server. This database will be password protected and only the study investigators will have access to this data. Confidentiality of the participants will be maintained at all times, except as required by law, to ensure selected schools and individual participants remain anonymous throughout and after completion of the investigation. As per the Australian Code for the Responsible Conduct of Research, data will be stored for a minimum of 5 years.

Will we be informed of the results when the research project is finished?
You will have access to your individual information if requested. In addition, we will send a summary of the study results to each participating school and caregiver but no individual students or educators will be identified. We will prepare a study report which can be distributed as schools see appropriate. Results be submitted for publications in peer-reviewed journals and presented at relevant conferences.

Who should I contact for more information?

If you would like more information about the project, please contact:

Name: Billy Garvey
Contact telephone: 9345 5851
Email: william.garvey@rch.org.au

You can contact the Director of Research Ethics & Governance at The Royal Children's Hospital Melbourne if you:
  • have any concerns or complaints about the project
  • are worried about your rights as a research participant
  • would like to speak to someone independent of the project.
The Director can be contacted by telephone on (03) 9345 5044.

Consent Form

HREC Project Number: 67653
Research Project Title: Improving outcomes for children with emotional and behavioural difficulties through a school-based intervention: a pilot randomised controlled trial.

Version Number: 1.5  Version Date: 24/4/21

• I have read this information statement and I understand its contents.
• I understand what I have to do to be involved in this project.
• I understand the risks I could face because of my involvement in this project.
• I voluntarily consent to take part in this research project.
• I have had an opportunity to ask questions about the project and I am satisfied with the answers I have received.
• I understand that this project has been approved by The Royal Children’s Hospital Melbourne Human Research Ethics Committee. I understand that the project is required to be carried out in line with the National Statement on Ethical Conduct in Human Research (2007).
• I understand I will receive a copy of this Information Statement and Consent Form.

Educator Name ______________________ Educator Signature ______________________ Date _____________
Declaration by researcher: I have explained the project to the participant who has signed above. I believe that they understand the purpose, extent and possible risks of their involvement in this project.

Note: All parties signing the Consent Form must date their own signature.

Appendix E - Caregiver Survey

About your child (baseline survey only)

What is your child’s first name?

_____________________________________

What is your child’s surname?

_____________________________________

What is your child’s date of birth?

__ __ / __ __ / __ __

Which school does your child attend?

_____________________________________

Who is your child’s teacher?

_____________________________________

What grade is your child in?
☐ Grade 1  ☐ Grade 2  ☐ Grade 3

Is your child
☐ Male  ☐ Female  ☐ Other  ☐ Prefer not to say

Is your child receiving Program for Students with a disability (PSD) funding?
☐ Yes  ☐ No

Is your child receiving National Disability Insurance Scheme (NDIS) Funding?
☐ Yes  ☐ No

Is your child accessing mental health support outside of school?
☐ Yes  ☐ No

About you and your family (baseline survey only)

You are the child’s
☐ Biological parent  ☐ Step-parent  ☐ Other

You are
☐ Male  ☐ Female  ☐ Other/prefer not to say

You are currently (select the option that best describes you at the moment)
☐ Single, never married  ☐ Married/de facto  ☐ Widow(er)  ☐ Divorced/separated

What is the highest year of school you have completed?
☐ Year 12  ☐ Year 11  ☐ Year 10 or less

What is the highest qualification you have completed since leaving school?
☐ No further qualification post school  ☐ Trade apprenticeship  ☐ Technical diploma/certificate  ☐ University degree  ☐ Postgraduate university degree

Do you currently have a partner that lives with you?
☐ Yes  ☐ No

Is your partner the child's

☐ Biological parent  ☐ Step-parent Other

Is your partner

☐ Male  ☐ Female  ☐ Other/prefer not to say

What is the highest year of school your partner has completed?

☐ Year 12  ☐ Year 11  ☐ Year 10 or less

What is the highest qualification your partner has completed since leaving school?

☐ No further qualification post school  ☐ Trade apprenticeship

☐ Technical diploma/certificate  ☐ University degree

☐ Postgraduate university degree

What is the main language spoken at home?

☐ English  ☐ Other

What is the total income of everyone in your household per week (or year) before tax?

☐ Nil income

☐ Less than $1,000 (less than $52,000 per year)

☐ $1,000-$1,499 ($52,000-$77,999 per year)

☐ $1,500-$1,999 ($78,000-$103,999 per year)

☐ $2,000-$2,999 ($104,000-$155,999 per year)

☐ $3,000-$3,399 ($156,000-$207,999 per year)

☐ More than $4,000 ($208,000 or more per year)

Contact information

Having your contact details will enable us to contact you directly for the second survey in term 4, and will also enable us to send you updates on the study.

Your first name

_____________________________________

Your surname

_____________________________________

For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml
Child functioning *(both baseline and follow up survey)*

Strengths and difficulties questionnaire (SDQ)

|                                                                 | Not true | Somewhat true | Certainly true |
|------------------------------------------------------------------|----------|---------------|----------------|
| Considerate of other people's feelings                          | ☐        | ☐             | ☐              |
| Restless, overactive, cannot stay still for long                 | ☐        | ☐             | ☐              |
| Often complains of headaches, stomach-aches or sickness          | ☐        | ☐             | ☐              |
| Shares readily with other children, for example toys, treats, pencils | ☐        | ☐             | ☐              |
| Often loses temper                                              | ☐        | ☐             | ☐              |
| Rather solitary, prefers to play alone                           | ☐        | ☐             | ☐              |
| Generally well behaved, usually does what adults request        | ☐        | ☐             | ☐              |
| Many worries or often seems worried                              | ☐        | ☐             | ☐              |
| Helpful if someone is hurt, upset or feeling ill                 | ☐        | ☐             | ☐              |
| Constantly fidgeting or squirming                                | ☐        | ☐             | ☐              |
| Has at least one good friend                                    | ☐        | ☐             | ☐              |
| Often fights with other children or bullies them                 | ☐        | ☐             | ☐              |
| Often unhappy, depressed or tearful                              | ☐        | ☐             | ☐              |
Over the last 6 months your child has been

☐ Thriving  ☐ Coping  ☐ Struggling  ☐ Always overwhelmed

**Health service use (Follow up survey only)**

Did the teacher suggest a referral to a health service (e.g., GP, paediatrician) for your child because of emotional or behavioural concerns?

☐ Yes  ☐ No

If yes did you engage with that health service?

☐ Yes  ☐ No

If no, why not?

_____________________________________

|                          | Not true | Somewhat true | Certainly true |
|--------------------------|----------|---------------|----------------|
| Generally liked by other children |          |               |                |
| Easily distracted, concentration wanders |          |               |                |
| Nervous or clingy in new situations, easily loses confidence |          |               |                |
| Kind to younger children |          |               |                |
| Often lies or cheats     |          |               |                |
| Picked on or bullied by other children |          |               |                |
| Often volunteers to help others (parents, teachers, other children) |          |               |                |
| Thinks things out before acting |          |               |                |
| Steals from home, school or elsewhere |          |               |                |
| Gets along better with adults than with other children |          |               |                |
| Many fears, easily scared |          |               |                |
| Good attention span, sees work through to the end |          |               |                |
Appendix F - Educator Survey

Educator demographic information *(Baseline survey only)*

Please enter your first name:

_____________________________________

Please select your gender

- Man
- Woman
- No-binary/gender diverse
- My gender identity isn't listed
- I prefer not to say

Do you currently work

- Part-time
- Full-time

How many years have you been teaching?
## School Mental Health Self-Efficiency Teacher Survey (SMH-SETS)

*both baseline and follow up surveys*

|                                                                 | Strongly disagree | Disagree | Somewhat disagree | Somewhat agree | Agree | Strongly agree |
|-----------------------------------------------------------------|------------------|----------|-------------------|----------------|-------|----------------|
| Recognize when there is a student with an internalizing concern | ☐                | ☐        | ☐                 | ☐              | ☐     | ☐              |
| Recognize when there is a student with an externalizing concern | ☐                | ☐        | ☐                 | ☐              | ☐     | ☐              |
| Recognize when there is a student displaying indicators of exposure to trauma | ☐                | ☐        | ☐                 | ☐              | ☐     | ☐              |
| Provide academic instruction to students with an internalizing concern | ☐                | ☐        | ☐                 | ☐              | ☐     | ☐              |
| Provide academic instruction to students with an externalizing concern | ☐                | ☐        | ☐                 | ☐              | ☐     | ☐              |
| Provide academic instruction to students with diverse backgrounds who have MH concerns | ☐                | ☐        | ☐                 | ☐              | ☐     | ☐              |
| Consider cultural needs in promoting students' MH | ☐                | ☐        | ☐                 | ☐              | ☐     | ☐              |
| Respond when a student is in crisis | ☐                | ☐        | ☐                 | ☐              | ☐     | ☐              |
| Respond when a student is displaying aggressive behavior | ☐                | ☐        | ☐                 | ☐              | ☐     | ☐              |
| Respond to a student who is expressing suicidal thoughts | ☐                | ☐        | ☐                 | ☐              | ☐     | ☐              |
| Refer a student to the appropriate school-based MH providers | ☐                | ☐        | ☐                 | ☐              | ☐     | ☐              |
| Offer assistance in the classroom when a student is struggling with a MH concern | ☐                | ☐        | ☐                 | ☐              | ☐     | ☐              |
Would you participate in the Health & Education Linking Project (HELP) again if offered in the future?

☐ Yes  ☐ No

Would you recommend the Health & Education Linking Project (HELP) to other educators?

☐ Yes  ☐ No

Individual student survey (one per student) (Both baseline and follow up surveys)

Strengths and difficulties questionnaire (SDQ)

|                                | Not true | Somewhat true | Certainly true |
|--------------------------------|----------|---------------|----------------|
| Considerate of other people's feelings | ☐        | ☐             | ☐              |
| Restless, overactive, cannot stay still for long | ☐        | ☐             | ☐              |
| Often complains of headaches, stomach-aches or sickness | ☐        | ☐             | ☐              |
| Shares readily with other children, for example toys, treats, pencils | ☐        | ☐             | ☐              |
| Often loses temper | ☐        | ☐             | ☐              |
| Rather solitary, prefers to play alone | ☐        | ☐             | ☐              |
| Generally well behaved, usually does what adults request | ☐        | ☐             | ☐              |
| Many worries or often seems worried | ☐        | ☐             | ☐              |
| Helpful if someone is hurt, upset or feeling ill | ☐        | ☐             | ☐              |
| Constantly fidgeting or squirming | ☐        | ☐             | ☐              |
| Has at least one good friend | ☐        | ☐             | ☐              |
| Often fights with other children or bullies them | ☐        | ☐             | ☐              |
| Statement                                                                 | Not true | Somewhat true | Certainly true |
|---------------------------------------------------------------------------|----------|---------------|----------------|
| Often unhappy, depressed or tearful                                       |          |               |                |
| Generally liked by other children                                         |          |               |                |
| Easily distracted, concentration wanders                                  |          |               |                |
| Nervous or clingy in new situations, easily loses confidence              |          |               |                |
| Kind to younger children                                                  |          |               |                |
| Often lies or cheats                                                      |          |               |                |
| Picked on or bullied by other children                                    |          |               |                |
| Often volunteers to help others (parents, teachers, other children)       |          |               |                |
| Thinks things out before acting                                           |          |               |                |
| Steals from home, school or elsewhere                                     |          |               |                |
| Gets along better with adults than with other children                    |          |               |                |
| Many fears, easily scared                                                |          |               |                |
| Good attention span, sees work through to the end                          |          |               |                |

Over the last 6 months this student has been

☐ Thriving  ☐ Coping  ☐ Struggling  ☐ Always overwhelmed

**Health service recommendation (Follow up survey only)**

Did you suggest a referral to a health service (e.g., GP, paediatrician) for this student because of emotional or behavioural concerns?

☐ Yes  ☐ No
Reporting checklist for protocol of a clinical trial.

Based on the SPIRIT guidelines.

**Instructions to authors**

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the SPIRIT reporting guidelines, and cite them as:

Chan A-W, Tetzlaff JM, Gøtzsche PC, Altman DG, Mann H, Berlin J, Dickersin K, Hróbjartsson A, Schulz KF, Parulekar WR, Krleža-Jerić K, Laupacis A, Moher D. SPIRIT 2013 Explanation and Elaboration: Guidance for protocols of clinical trials. BMJ. 2013;346:e7586

| Reporting Item                                      | Page Number |
|----------------------------------------------------|-------------|
| **Administrative information**                     |             |
| Title                                              | #1          | 1           |
| Descriptive title identifying the study design,    |             |
| population, interventions, and, if applicable,     |             |
| trial acronym                                      |             |
| Trial registration                                 | #2a         | 1           |
| Trial identifier and registry name. If not yet     |             |
| registered, name of intended registry              |             |
| Trial registration: data set                       | #2b         | 1           |
| All items from the World Health Organization Trial |             |
| Registration Data Set                             |             |
| Protocol version                                   | #3          | 1           |
| Date and version identifier                       |             |
| Funding                                            | #4          | 1           |
| Sources and types of financial, material, and      |             |
| other support                                     |             |
| Roles and responsibilities: contributorship       | #5a         | 1           |
| Names, affiliations, and roles of protocol         |             |
| contributors                                       |             |
| Roles and responsibilities: | #5b | Name and contact information for the trial sponsor | 1 |
|-----------------------------|-----|--------------------------------------------------|---|
| Roles and responsibilities: | #5c | Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities | 1 |
| Roles and responsibilities: | #5d | Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee) | n/a |

**Introduction**

| Background and rationale | #6a | Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention | 3 |
|--------------------------|-----|-----------------------------------------------------------------------------------------------------------------|---|
| Background and rationale: choice of comparators | #6b | Explanation for choice of comparators | 7 |

**Objectives**

| #7 | Specific objectives or hypotheses | 4 |

**Trial design**

| #8 | Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, non-inferiority, exploratory) | 4 |

**Methods:**

| Participants, interventions, and outcomes | #9 | Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained | 5 |
Eligibility criteria #10 Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)

Interventions: description #11a Interventions for each group with sufficient detail to allow replication, including how and when they will be administered

Interventions: modifications #11b Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving / worsening disease)

Interventions: adherance #11c Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)

Interventions: concomitant care #11d Relevant concomitant care and interventions that are permitted or prohibited during the trial

Outcomes #12 Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended

Participant timeline #13 Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)

Sample size #14 Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations

Recruitment #15 Strategies for achieving adequate participant enrolment to reach target sample size

Methods: Assignment of interventions (for controlled trials)

Allocation: sequence generation #16a Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be
Allocation concealment mechanism  

Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned

Allocation: implementation  

Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions

Blinding (masking)  

Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how

Blinding (masking): emergency unblinding  

If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant’s allocated intervention during the trial

Methods: Data collection, management, and analysis

Data collection plan  

Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol

Data collection plan: retention  

Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols

Data management  

Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol

Statistics: outcomes  

Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol
Statistics: additional analyses

Methods for any additional analyses (eg, subgroup and adjusted analyses)

Statistics: analysis population and missing data

Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)

**Methods: Monitoring**

Data monitoring: formal committee

Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed

Data monitoring: interim analysis

Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial

Harms

Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct

Auditing

Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor

**Ethics and dissemination**

Research ethics approval

Plans for seeking research ethics committee / institutional review board (REC / IRB) approval

Protocol amendments

Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC / IRBs, trial participants, trial registries, journals, regulators)

Consent or assent

Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)
Consent or assent: Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable

Confidentiality: How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial

Declaration of interests: Financial and other competing interests for principal investigators for the overall trial and each study site

Data access: Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators

Ancillary and post trial care: Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation

Dissemination policy: trial results: Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (e.g., via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions

Dissemination policy: authorship: Authorship eligibility guidelines and any intended use of professional writers

Dissemination policy: reproducible research: Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code

Appendices

Informed consent materials: Model consent form and other related documentation given to participants and authorised surrogates

Biological specimens: Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable

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