BMJ Open is committed to open peer review. As part of this commitment we make the peer review history of every article we publish publicly available.

When an article is published we post the peer reviewers’ comments and the authors’ responses online. We also post the versions of the paper that were used during peer review. These are the versions that the peer review comments apply to.

The versions of the paper that follow are the versions that were submitted during the peer review process. They are not the versions of record or the final published versions. They should not be cited or distributed as the published version of this manuscript.

BMJ Open is an open access journal and the full, final, typeset and author-corrected version of record of the manuscript is available on our site with no access controls, subscription charges or pay-per-view fees (http://bmjopen.bmj.com).

If you have any questions on BMJ Open’s open peer review process please email info.bmjopen@bmj.com
Can a teacher-led mindfulness intervention for new school entrants improve child outcomes: A school cluster randomised controlled trial

<table>
<thead>
<tr>
<th>Journal:</th>
<th>BMJ Open</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manuscript ID:</td>
<td>bmjopen-2019-036523</td>
</tr>
<tr>
<td>Article Type:</td>
<td>Protocol</td>
</tr>
<tr>
<td>Date Submitted by the Author:</td>
<td>19-Dec-2019</td>
</tr>
<tr>
<td>Complete List of Authors:</td>
<td>Quach, Jon L.; Univ Melbourne, Deery, Ben; Univ Melbourne Kern, Peggy; The University of Melbourne Clinton, Janet; Univ Melbourne Gold, Lisa; Deakin University, Deakin Health Economics Orsini, Francesca; Murdoch Childrens Research Institute, Clinical Epidemiology and Biostatistics Unit Sciberras, Emma; Murdoch Childrens Research Institute, Centre for Community Child Health</td>
</tr>
<tr>
<td>Keywords:</td>
<td>Community child health &lt; PAEDIATRICS, Child &amp; adolescent psychiatry &lt; PSYCHIATRY, PUBLIC HEALTH</td>
</tr>
</tbody>
</table>
I, the Submitting Author has the right to grant and does grant on behalf of all authors of the Work (as defined in the below author licence), an exclusive licence and/or a non-exclusive licence for contributions from authors who are: i) UK Crown employees; ii) where BMJ has agreed a CC-BY licence shall apply, and/or iii) in accordance with the terms applicable for US Federal Government officers or employees acting as part of their official duties; on a worldwide, perpetual, irrevocable, royalty-free basis to BMJ Publishing Group Ltd (“BMJ”) its licensees and where the relevant Journal is co-owned by BMJ to the co-owners of the Journal, to publish the Work in this journal and any other BMJ products and to exploit all rights, as set out in our licence.

The Submitting Author accepts and understands that any supply made under these terms is made by BMJ to the Submitting Author unless you are acting as an employee on behalf of your employer or a postgraduate student of an affiliated institution which is paying any applicable article publishing charge (“APC”) for Open Access articles. Where the Submitting Author wishes to make the Work available on an Open Access basis (and intends to pay the relevant APC), the terms of reuse of such Open Access shall be governed by a Creative Commons licence – details of these licences and which Creative Commons licence will apply to this Work are set out in our licence referred to above.

Other than as permitted in any relevant BMJ Author’s Self Archiving Policies, I confirm this Work has not been accepted for publication elsewhere, is not being considered for publication elsewhere and does not duplicate material already published. I confirm all authors consent to publication of this Work and authorise the granting of this licence.
CAN A TEACHER-LED MINDFULNESS INTERVENTION FOR NEW SCHOOL ENTRANTS IMPROVE CHILD OUTCOMES: A SCHOOL CLUSTER RANDOMISED CONTROLLED TRIAL

Jon Quach (PhD) 1,2, jon.quach@unimelb.edu.au  
Ben Deery (DPsych) 1, b.deery@unimelb.edu.au  
Peggy L. Kern (PhD) 1, peggy.kern@unimelb.edu.au  
Janet Clinton (PhD) 1, jclinton@unimelb.edu.au  
Lisa Gold (PhD) 3, lisa.gold@deakin.edu.au  
Francesca Orsini (MBio) 4, Francesca.orsini@mcri.edu.au  
Emma Sciberras (DPsych) 5,6 emma.sciberras@deakin.edu.au

1 Melbourne Graduate School of Education, The University of Melbourne  
2 Policy, Equity and Translation, Murdoch Childrens Research Institute  
3 Health Economics, Deakin University  
4 Clinical Epidemiology and Biostatistics Unit, Murdoch Childrens Research Institute  
5 School of Psychology, Deakin University  
6 Health Services Research, Murdoch Childrens Research Institute

Word count: 3981 words

Key words: mindfulness, school-based intervention, primary schools

CORRESPONDING AUTHOR

Dr Jon Quach  
Melbourne Graduate School of Education, The University of Melbourne  
Level 4, 100 Leicester Street, Carlton, Victoria 3010  
Australia
Email: jon.quach@unimelb.edu.au

FUNDING STATEMENT:

This study is funding by an Australian Research Council Discovery Award (DP190100504). Associate Professor Sciberras is funded via a National Health Medical Research Council Career Development Fellowship (GNT1110688).

CONFLICTS OF INTEREST:

Dr Ben Deery developed the intervention, but does not receive any commercial or non-commercial financial entitlements. All other authors have no conflicts of interest to declare.

AUTHOR CONTRIBUTION:

All authors are investigators on the successful funding grant for this project, with Dr Quach as the lead investigator. They have all contributed to the study’s design as well as this protocol’s drafting and finalization. All authors have reviewed and approved this submitted version.
ABSTRACT

Introduction

The first years of school are critical in establishing a foundation for positive long-term academic, social and well-being outcomes. Mindfulness-based interventions may help students transition well into school, but few robust studies have been conducted in this age group. We aim to determine whether compared to controls, children who receive a mindfulness intervention within the first years of primary school have better:

1. Immediate attention/short-term memory at 18-months post randomization (primary outcome).
2. Inhibition, working memory, and cognitive flexibility at 18 months post-randomization.
3. Socio-emotional wellbeing, emotion-regulation, and mental health-related behaviors at 6- and 18-months post randomization.
4. Sustained changes in teacher practice and classroom interactions at 18-months post randomization.

Furthermore, we aim to determine whether the implementation predicts the efficacy of the intervention, and the cost effectiveness relative to outcomes.

Methods and Analysis

This cluster randomised controlled trial will be conducted in 22 primary schools in disadvantaged areas of Melbourne, Australia. 826 students in the first year of primary school will be recruited to detect between groups differences of Cohen’s d=0.25 at the 18-month follow-up.

Parent, teacher and child-assessment measures of child attention, emotion-regulation, executive functioning, socio-emotional well-being, mental health-related behavior and learning, parent mental well-being, teacher well-being will be collected 6- and 18-months post-randomisation. Implementation factors will be measured throughout the study.

Intention-to-treat analyses, accounting for clustering within schools and classes, will adopt a two-level random effects linear regression model to examine outcomes for the intervention versus control students. Unadjusted and analyses adjusted for baseline scores, baseline age, gender and family socio-economic status will be conducted.
**Ethics and Dissemination:** Ethics approval has been received by the Human Research Ethics Committee at the University of Melbourne. Findings will be reported in peer-review publications, national and international conference presentations and research snapshots directly provided to participating schools and families.

**STRENGTHS AND LIMITATIONS**

- Provide the first efficacy trial findings for a whole-class mindfulness intervention delivered across the first two years of primary school
- Understand the implementation factors associated with the trial outcomes
- Understand the cost-benefits of the intervention in relation to the trial outcomes
- Use of blinded measures consisted of child, parent and teacher-reported measures across multiple domains proposed to change through a mindfulness intervention
INTRODUCTION

The first years of school are critical for establishing firm foundations for positive child social, psychological and academic development. Children’s ability to regulate their attention, emotions, and behavior, and to follow classroom instructions during this period predicts school adjustment, participation and success. Similar to other countries, data from the Australian Early Development Census (AEDC) found that 22.4% of children commence school developmentally vulnerable. These vulnerabilities are highest in regards to (commonly relate to) behavioral and emotional difficulties, with children in disadvantaged areas three times more likely to experience these difficulties. Children who transition poorly into school are at increased risk for a host of detrimental outcomes, including behavioral and emotional problems, poor peer and teacher relationships, and low academic performance. These difficulties can persist throughout their schooling years and impact upon long-term educational, economic, social, physical and mental health outcomes. Thus, identifying evidence-based approaches to help children develop attention and emotional regulation skills is critical in proactively supporting children’s mental health and academic performance.

Contemplative practices such as mindfulness, has rapidly gained popularity in both practice and research and has potential to be used in classrooms to help children transition to school and to support ongoing learning. Mindfulness is broadly defined as the awareness that arises from paying purposeful attention to the present moment, non-judgmentally, with acceptance or curiosity. Numerous mindfulness-based programs have been developed for children and adults to build attention, self-monitoring, self-regulation, and mental flexibility. Such programs propose that individuals can become more ‘mindful’ by learning and practicing mindful skills and activities.

The interest in mindfulness-based interventions has been matched with studies, reviews, and meta-analyses examining the effectiveness of these interventions. Studies find that interventions can have positive effects on attention, executive functioning, social behavior and mindfulness in children and adults. However, reviews have also raised numerous concerns. Comparison groups are often weak or non-existent, selective samples are used, measures rely predominantly on self-report, methods are inconsistent (making it difficult to directly compare study effects), and programs are often poorly defined and vary in their components, resulting in programs that are often quite different. Only a limited number of rigorous randomised control
trials (RCTs) have examined the impact of mindfulness interventions using objective outcome measures assessed over time. Further, systematic reviews have identified very few studies that have been conducted with children under 8 years,\textsuperscript{13, 14} and to our knowledge, no large-scale rigorous studies exist at the early primary school level.

Even for the school-based interventions with stronger evidence, it is unknown whether their effectiveness can be maintained when implemented at large scale. Many mindfulness programs involve the use of electronic/smart devices (e.g., audio recorded instructions), which the teacher is expected to facilitate/lead, and children are expected to engage in. Little emphasis is given to equipping teachers with the theoretical and practical knowledge underlying the activities, or on providing strategies for incorporating mindfulness into their day-to-day teaching practices. Yet teacher pedagogy and student-teacher relationships are critical for learning.\textsuperscript{27} For instance/example, a recent mindfulness intervention study following children from preschool to school suggested that observed executive functioning and later vocabulary and literacy benefits only emerged when teachers embedded these skills within their usual classroom practices over a long period of time, well beyond the standard 8-12-week period of most mindfulness interventions.\textsuperscript{28}

Given the complexity of implementing interventions in schools,\textsuperscript{29} it is also important to understand the quality, fidelity and dosage of the mindfulness intervention that children are exposed to, especially when promising interventions are implemented at scale.\textsuperscript{30-32} When mindfulness programs are poorly implemented or taught without appropriate theoretical and practical training, a range of unintended and adverse consequences can occur.\textsuperscript{15} Further, it is critical to determine the financial and time costs required to achieve positive outcomes, to ensure that limited time and resources schools have available are well spent. There are clear gaps between the levels of interest, evidence and investment in mindfulness-based interventions and best practices for doing so. Addressing these gaps will have both national and international implications for the use of mindfulness intervention within early primary school classrooms.

Addressing the lack of empirically based mindfulness programs for early years education, the intervention used in this study directly trains teachers on mindfulness theory and practice and provides a structured approach for embedding mindfulness activities into everyday teaching practices to improve student outcomes. Initial support for the intervention was established through a pilot RCT involving 109 children from 6 classrooms in 4 preschool centers in disadvantaged
areas of Melbourne, Australia. Preliminary data at immediate post-intervention, indicated intervention children had better immediate attention/short term memory (measured via the Corsi Block-tapping task, effect size Cohen’s d=0.29; Digit Span Forward task, d=0.24), behavior regulation (measured via Less is More, d=0.34), and mental health-related behaviors (measured via the Teacher Strengths and Difficulties Questionnaire - Externalizing, d=0.45), compared to control children. Qualitative data demonstrated that teachers believed that the program was effective for themselves, their children and their colleagues, and reported parents wanted to know more about the program and the activities. They also continued to embed mindfulness into their classroom after the program finished.

The current study uses a rigorous RCT cluster design to build on these promising findings to examine whether the same intervention remains effective when implemented within early primary school classrooms at larger scale. We will provide an in-depth examination of child, teacher and school level factors that promote and reduce the intervention’s success. We will also consider the costs and economic benefits of the intervention. We hypothesize that the intervention will be associated with:

5. Improvements in child immediate attention/short-term memory assessed via blinded direct assessment 18-months post randomization (primary outcome).
6. Improvements in executive functioning measured via blinded direct assessment of inhibition, working memory, and cognitive flexibility, 18 months post-randomization.
7. Improved socio-emotional wellbeing, emotion-regulation, and mental health-related behaviors, reported by parents and teachers, 6- and 18-months post randomization.
8. Sustained changes in teacher practice and classroom interactions assessed via blinded raters at 18-months post randomization.

Furthermore, we hypothesize that the quality and dosage of implementation will predict the efficacy of the intervention, and the intervention will be cost effective relative to outcomes.

METHODS
Pre-registration and Ethics

The study is registered with the Australian New Zealand Clinical Trials Registry (ACTRN12619000326190). Ethics approval was obtained from the Human Research Ethics Committee at the University of Melbourne (Ethics ID: 1853492), Australia, and approval for the
study was provided by the Victorian Department of Education and Training (DET) and Catholic Education Melbourne (CEM).

**Patient and Public Involvement**
No patient involved

**Design**
This is a cluster RCT with an embedded process and economic evaluation (see Figure 1). This will inform the benefits of the intervention compared to current practice, identify for whom and under what conditions the intervention is beneficial, and provide an indication of the cost-benefits of the intervention. Results will be reported per the CONSORT guidelines for non-pharmacologic interventions.\\(^{33}\)

**Participants**
All Foundation children (i.e., the first year of primary school, ages 5-6) at participating schools with parental consent will be invited to participate in the data collection, provided the child and parents have sufficient English language abilities to complete the measures. Although this will affect generalizability, the majority of measures have not been validated for other languages. Children without consent will still be exposed to the intervention as part of their school’s wellbeing approach but not complete the measures.

**Sample size**
The estimated sample size across all stages of the study are shown in Figure 2.

Given the hypotheses of the trial and measures collected in our pilot study as well as in published meta-analyses,\\(^{13, 14}\) we anchored our sample size calculations on detection of a minimum effect size of 0.25 standard deviations (SD) between the treatment and control groups at 18-months post-randomization in a two-arm parallel trial with 80% power and a two-tailed 5% Type I error. The sample size applies across all measures collected at 18-months post randomization, based on the number of SDs rather than on the actual outcome distributions.

To account for the clustering effect within classes (ICC=0.02) and schools (ICC=0.02), and an attrition rate of 20% by the end of the study, our planned sample size is 413 children per
condition (826 total). To achieve this, we estimate we will recruit 22 schools to participate (11 per condition). This assumes an average of 2.5 Foundation Year classes at each school, and 65% of parents providing consent for data collection (16 per class, 40 per school). The final number of schools will be dependent on student population, the number of classes within each school and class size of the recruited schools.

**School selection and recruitment**

Primary schools from metropolitan Melbourne, Australia, with disadvantaged student populations will be recruited. This will be determined by approaching schools with a high proportion of children starting primary school developmentally vulnerable in ‘emotional maturity’ and ‘social competence’ domains as defined by the AEDC. The AEDC is a national census completed every three years by classroom teachers for children in the first year of primary school, including 2015 and 2018. Data are available for >98% of Australian children during data collection years. Therefore, the AEDC provides accurate estimates of the number of children with developmental vulnerabilities for/at each school. Where AEDC data are not available, other government or administrative datasets that measure school disadvantage will be used to select eligible schools.

The school recruitment approach is similar to those used in previous school-based longitudinal studies and intervention trials conducted by members of the research team. Australian schools are clustered into three sectors: Government (69%), Catholic (19.2%), and Independent (11.8%). To balance representation with study time and resources, we will include government and Catholic schools.

Although DET and CEM have provided approval for research within schools, each school’s leadership has independent responsibility to approve which projects they choose their schools to participate in. Drawing on the DET and CEM network of schools, we will first present our study at each area’s school leadership network meetings or similar engagement event, providing background on the study and an overview of what would be expected of the school, teachers, parents, and children. Principals will be able to indicate interest in participating in the study without fully committing. By doing this, we limit the burden of approaching schools in which school leadership do not wish to participate. If a sufficient number of schools express interest, we will proceed with selection and randomization. Based on our prior experiences working with
primary schools in the region, we estimate that 87 (75%) will express interest in being a part of
the study, with the main reason for declining being time commitments and participation in other
research projects. If additional schools are needed, we will directly contact remaining schools in
the area until the number of required schools has been achieved.

Recruitment will be stratified by school sector type to ensure a representative sample from
both sectors. Of those selected, we will approach the school’s principal to ascertain their agreement
to participate. If the principal declines, we will contact the next randomly selected school on the
list, repeating until we reach the required sample size.

We will then meet with all Foundation and Grade 1 teachers at participating schools to
describe the purpose and requirements of the project, expected time commitments, and recruitment
process and answer any questions they may have. The teachers will be provided with an
information sheet detailing their expected involvement, a consent form, and a brief survey.

**Student recruitment and consent**

Before we begin student recruitment at each school, we will work with each school to
publicise the trial, raising parental awareness and interest in the study through notifications in
school newsletters, posters on classroom doors and sending advance-notice postcards to the homes
of eligible children. Teachers will then send a recruitment pack to each family. The pack will
contain an information sheet detailing the study, a consent form, a brief survey and an envelope.
Parents will be asked to return the completed consent forms and survey in the sealed envelope to
a secure box in the child’s classroom.

Consent for the study will be specific to the data collection. Because the intervention
focuses on embedding simple play-based activities into teachers’ daily practice and classrooms, it
would be unethical and impractical to have children without consent be removed from the
classroom, when teachers are implementing the mindfulness-based activities and games. Children
are commonly/frequently exposed to similar changes in teacher practice following teacher
professional development (PD) or when teachers make explicit decisions to implement a new
pedagogical approach or wellbeing curriculum in their classroom.

**Randomization**
After the parent and teacher surveys have been completed, schools, stratified by school sector, will be randomized to control or intervention in block sizes ranging from two to four. To reduce the potential for contamination effects, the randomization will be conducted by a researcher independent of the study team, and group allocation will be concealed from research team members involved in the direct outcome assessments. All intervention schools will complete a Memorandum of Understanding, agreeing not to share the intervention resources with control schools, and control schools will not have access to the intervention training or manual.

**Mindfulness Intervention**

Training and troubleshooting support for the mindfulness intervention will be provided by the program developer. Children will be exposed to the intervention across two consecutive academic school years, Foundation and Grade 1.

For intervention schools, Foundation and Grade 1 teachers will attend one PD day in 2020 and 2021 respectively, which will provide the theoretical and practical foundations of the program and instructions for implementing the program. Teachers will be provided with an implementation manual (available by request), which includes a schedule of activities, lesson plans, communication templates/examples, sample activities, parent homework sheets, audio/music and film suggestions, and training slides. Participants will review the materials, watch examples, practice a selection of activities, and will be able to ask questions to ensure clear understanding of the program and implementation.

Following the PD, the teachers will be expected to embed the 12-week intervention into their classrooms, using the manual to help them to learn, practice, incorporate, and reflect on the activities and strategies. The mindfulness program involves three core practice components, (i) mindful games/activities; (ii) mindful routines/transitions/moments; and (iii) use of props/books/music/art, which can be used within the classroom and integrated with normal teaching activities. For each week, it is recommended that teachers:

1. Engage in two mindfulness activities per day at least four times per week, utilizing suggested props, games, or art/music, and trying to anchor these around key routines or transition periods during the day (e.g., on classroom arrival/departure, after lunch/recess, before a test/specialist class, snack or mealtimes, moving between classrooms).
2. Read suggested storybooks each week and discuss with children possible connections to mindfulness and related skills/concepts. The manual includes a list of popular children's storybooks (commonly available in schools or easily accessed) with guidance for discussion.

3. Identify and embed spontaneous ‘mindful moments’ into their daily classroom routines, transitions and class time, such as using ‘slow motion’ walking to the library, or watching rain drops race down classroom window. Teachers will also be asked to establish, if possible, a ‘Mindful Space’ in the classroom to provide an ongoing reminder and/or display of mindfulness tools, while also creating a place for children to engage in mindful activities during class time. The space may include a variety of mindful props (e.g., mind jar), games (e.g., rock balancing), activities (e.g., mindful drawing), and storybooks. Intervention schools will be provided with all required props, books, games and other resources (e.g., door/wall posters) to implement the key elements of the program.

Throughout the 12-week program, teachers will also be encouraged to:

1. Discuss the intervention’s implementation during their team’s regular meetings, led by participating teachers, to reflect on the intervention’s progress, implementation, and support needs, providing peer support and a shared commitment to the program. In Year 2 of the study, Foundation teachers will continue to participate in these meetings, providing their own reflections and experiences to the Grade 1 teachers, potentially aiding sustainability through a train-the-trainer type approach.

2. Contact the research team for additional implementation support, trouble shooting, or advice/coaching, if required

3. Share examples of mindful activities, artwork and discussions with parents, enabling connections and modelling between school, home, and ongoing support.

Following the 12-week intervention, we will conduct a 1-hour meeting with teachers to allow reflection on learnings from the past 12 weeks and to help develop an ongoing implementation plan if they chose.

**Outcome data collection and research assistant blinding**

Outcome assessments will be conducted 6 (end of Foundation for the children) and 18 months (end of Grade 1) post randomization. At each occasion, parents and teachers will be asked
to complete surveys. Children will complete face-to-face direct assessments at baseline and 18 months post randomization during school hours by trained research assistants blinded to the school’s group allocation.

**Measures**

Measures are summarized in Table 1, which have chosen to attempt to measure proximal and distal outcomes that align with our intervention’s theory of change, which have been informed by our pilot findings and existing systematic reviews.\(^\text{13, 14, 17}\)

The primary outcome is labelled as child visuo-spatial short-term memory, as measured by the Corsi Block Tapping Forward Raw Score at 18-months post-randomization.\(^\text{41}\) We have referred to this as short-term memory, however, previous psychological and cognitive sciences research have also used forward block span as a measure of immediate attention (the same applies for Digit Span Forwards and verbal short-term memory), with such terms often used somewhat interchangeably. Other research highlights difficulties in separating short term memory and immediate attention conceptually and experimentally, hence they strongly overlap.\(^\text{42, 43}\)

The study includes secondary outcomes across multiple domains. Examining multiple outcomes aligns with the UK Medical Research Council guidelines for interventions that are complex in nature and likely to result in possible impact across a diversity of domains.\(^\text{44}\) It is particularly important that sufficient data are measured to enable comparability across mindfulness-based school programmes, as programmes frequently vary in their content, setting and target population. Because of the wide variety of measures, while each outcome will be analysed individually, findings and interpretations will consider the consensus of evidence for the data provided. This will involve careful examination and consideration of the magnitude, direction and statistical significance of the responsiveness estimated for each outcome. Due to the increased potential for false-positive findings arising through analysis of multiple outcomes, patterns will be interpreted cautiously and in context with one another, rather than in isolation.

**Process evaluation**

The implementation and process evaluation will use a mixed-methods approach, drawing on data collected via teacher surveys and teacher interviews. It will explore the intervention’s theory of change and the extent to which the dimensions of implementation impact the program’s
effectiveness, as well as the enablers and barriers to its implementation. Fidelity, quality and adaptation of the intervention’s activities over the 12-week manualised implementation will be examined via fortnightly surveys completed by intervention teachers. Sustainability, enablers and barriers of the intervention will be examined via teacher interviews and surveys at 6- and 18-month post-randomization. Factors will be examined at the student, teacher and school levels where appropriate.

The wellbeing practices of the control schools will also be examined to document any practice similarities (i.e., the presence of mindfulness practices/elements or other social-emotional learning [SEL] programs) and differences (e.g., the use of mindfulness audio-recorded sessions versus pedagogy-based approaches) when compared to our intervention.

**Economic Evaluation**

Costs associated with the intervention training and delivery will be prospectively and retrospectively recorded, including costs for delivery, material/prop resources required by the schools, and time spent on the program. Resources used in training and ongoing support will be prospectively recorded by the research team, and all intervention teachers will prospectively record time and resources used in intervention delivery and report these through the process evaluation. Teacher surveys will include retrospective report from control teachers of time and resources used on SEL related activities.

Using surveys, teachers in intervention and control schools will retrospectively report in-school additional support at 3 and 18-months post-randomization, and at each time point parents will recall out-of-school health and education service use over the previous year.

Resource use will be presented in natural units as well as valued in 2021 Australian dollars using local (state) and national unit cost estimates (e.g., education department salary scales, Medicare Benefits Schedule). Costs will be presented as costs per student from a government payer perspective.

Analyses will involve: (i) a cost-consequences analysis, which will compare incremental costs of the intervention (costs accrued in the intervention arm, from intervention and resource use over the period of follow-up, compared to costs accrued in the control arm) to all primary and secondary outcomes, expressed in their natural units of measurement; and (ii) cost-effectiveness,
assessed against the primary outcome measure and presented as cost per point change in child attention. Impact of missing data will be assessed through multiple imputation (described below).

**Statistical Analysis**

All participants and school demographic and baseline continuous outcomes will be presented as mean and SD (or medians and interquartile ranges for skewed data), whilst categorical outcomes will be presented as absolute and relative frequencies by group. Statistical analysis will follow standard methods for cluster randomized trials and the primary analysis will be by intention to treat. Multiple imputation will be conducted separately in the two arms using chained equations applied to all outcomes simultaneously, including baseline measures as auxiliary variables. Fifty imputed datasets will be generated. All analyses will be conducted using Stata.

The primary outcome is student visual-spatial short-term memory/immediate attention at 18 months post-randomization. The effect of the intervention on the Corsi Block Tapping Forward raw score at 18 months compared to control children will be examined adopting a linear mixed model, which will include the stratification factor used during randomization (school sector) as a fixed effect term and two random effect terms (school and class) to account for the clustering structure of the data. The effect of intervention on the primary outcome at 18 months will then be adjusted by the student baseline Corsi Block Tapping Forward score, age at baseline, gender, family socio-economic status and child IQ, which will be included in the above model as fixed effect terms.

For all the outcomes collected at 18 months, the effect of the intervention will be estimated using generalized linear mixed models (linear or logistic according to the nature of the outcome), which will include control variables (i.e., school sector, the corresponding outcome measure at baseline, age at baseline, gender, family socio-economic status, child IQ and time of assessment) as fixed effect terms and the same random effect terms mentioned above. For outcomes collected at 6-months and at 18-months, the same generalized linear mixed models described above will be adopted, with the addition of a third random effect term (i.e., student), to account for the repeated measures over time (the nature of the outcome), which will include control variables as fixed effect terms and the same random effect terms mentioned above with the addition of a third random effect term (i.e., student), to account for the repeated measures within children.
DISSEMINATION PLAN

Once the study is completed, we will publish our findings in international peer-reviewed child health journals and present at national and international conferences. In addition, we will send participating schools and parents a short report of our findings. A copy of the report will also be sent to relevant government departments.

- **Annual school and parent newsletter:** To maintain engagement throughout the study, we will send annual newsletters to all participating schools and families that will provide a progress update, and summary of any new findings which have been published.

- **A participating school seminar:** Recognising the time and resource contributed by participating schools, it is important findings are presented to schools in a timely manner. We will hold, and record, a half-day seminar at the primary institution within 6 months of the study’s completion to present findings and enable dialogue about implications.
REFERENCES


**Table 1: Description of measures and timepoints**

<table>
<thead>
<tr>
<th>Measure</th>
<th>Domain</th>
<th>Scoring description</th>
<th>Method of assessment</th>
<th>Baseline</th>
<th>Intervention</th>
<th>6-mth</th>
<th>18-mth</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Primary Outcome</strong></td>
<td></td>
<td>Have a specific scoring description to determine the specific outcome.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Corsi Block Forward Tapping Task(^{41})</td>
<td>Visuo-spatial short term memory/immediate attention</td>
<td>Raw scores for longest recall span will be used to determine visual short term memory / immediate attention</td>
<td>Child Assessment</td>
<td>●</td>
<td></td>
<td></td>
<td>●</td>
</tr>
<tr>
<td><strong>Secondary Outcomes</strong></td>
<td></td>
<td>Have a specific scoring description to determine the specific outcome.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>CHILD</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Digit Span Forward(^{41})</td>
<td>Verbal immediate attention/short term memory</td>
<td>Raw scores for longest recall span will be used to determine verbal immediate attention</td>
<td>Child Assessment</td>
<td>●</td>
<td></td>
<td></td>
<td>●</td>
</tr>
<tr>
<td>Corsi Block Backward Tapping Task(^{41})</td>
<td>Visuo-spatial working memory</td>
<td>Use of raw scores, indicating longest backward recall span</td>
<td>Child Assessment</td>
<td>●</td>
<td></td>
<td></td>
<td>●</td>
</tr>
<tr>
<td>Digit Span Backwards(^{41})</td>
<td>Verbal working memory</td>
<td>Use of raw scores, indicating longest backward recall span</td>
<td>Child Assessment</td>
<td>●</td>
<td></td>
<td></td>
<td>●</td>
</tr>
<tr>
<td>NIH Toolbox, Flanker Inhibitory Control and Attention Test(^{46})</td>
<td>Inhibitory control, Attention</td>
<td>Raw scores range from 0 – 10, with standard scores mean = 100 (SD = 15) used in reporting</td>
<td>Child Assessment</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td>●</td>
</tr>
<tr>
<td>NIH Toolbox, Dimensional Change Card Sort</td>
<td>Cognitive flexibility</td>
<td>Raw scores</td>
<td>Child Assessment</td>
<td>●</td>
<td></td>
<td></td>
<td>●</td>
</tr>
<tr>
<td>Sustained Attention to Response Task</td>
<td>Sustained attention</td>
<td>Standard scores mean = 100 (SD = 15)</td>
<td>Child Assessment</td>
<td>●</td>
<td></td>
<td></td>
<td>●</td>
</tr>
<tr>
<td>Strengths and Difficulties Questionnaire (SDQ)(^{47})</td>
<td>Child mental-health related behavior</td>
<td>A 25-item validated measure for children aged 4 to 16 years; with higher scores representing higher levels of behavior/mental health difficulties. Measure reports subscales for internalizing difficulties (5 items), externalizing difficulties (10 items) and Total Difficulties (20 items).</td>
<td>Parent and teacher survey</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td>●</td>
</tr>
<tr>
<td>Measure</td>
<td>Domain</td>
<td>Description</td>
<td>Source</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>------------------------------------------------------------------------</td>
<td>---------------------------------------------</td>
<td>-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td>------------------------------------------------------------------------</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Affective Reactivity Index</td>
<td>Emotion-regulation</td>
<td>A 7-item measure, with a range of 0 – 14, with higher scores representing greater irritability.</td>
<td>Parent</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Childhood Executive Functioning Inventory (CHEXI)⁴⁸</td>
<td>Executive Functioning Behaviour</td>
<td>A 24-item measure validated for children aged 4 to 12 years. Each item is scored 1 – 5, with higher scores representing greater difficulties. It yields 2 subscales: Inhibition (11-items) and working memory (13-items).</td>
<td>Parent and teacher survey</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ECLS-K Approaches to Learning⁴⁹</td>
<td>Learning Behaviour</td>
<td>A 6-item subscale from the Social Rating Scale used in Early Childhood Longitudinal Study-Kindergarten (ECLS-K). Items were designed to assess various aspects of a child’s approach to learning, such as organization, working independently and task completion. The possible score range was 1 - 6, with higher scores indicating better approaches to learning.</td>
<td>Teacher survey</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Interpersonal Mindfulness in Parenting (IEM-P)⁵⁰</td>
<td>Mindful parenting, parent-child interaction (4 subscales)</td>
<td>10-item measure, with subscales for awareness and present-centred attention (4 items), non-judgement (3-items) and non-reactivity (3-items).</td>
<td>Parent survey</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Short Warwick Edinburgh Mental Well-Being Scale (SWEMWBS)⁵¹</td>
<td>Mental well-being</td>
<td>7-item scale which yields a single score ranging from 7 to 35, with higher scores representing better well-being</td>
<td>Parents</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Kessler-6 (K-6)⁵²</td>
<td>Psychological distress</td>
<td>A 6-item, self-reported and validated measure of mental health distress, with higher scores indicating greater psychological distress.</td>
<td>Parents</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>TEACHER</strong></td>
<td><strong>Measures</strong></td>
<td><strong>Description</strong></td>
<td><strong>Raters</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mindfulness in Teaching (MIT) Scale</td>
<td>Teacher mindfulness</td>
<td>14-item self-report measure, with Teacher Intrapersonal Mindfulness (9-items, range 9 - 45) and Teacher Interpersonal Mindfulness subscales (7-items, range 7 - 35), with higher scores representing more negative outcomes</td>
<td>Teachers</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Student-Teacher Relationship Scale – Short Form (STRS-SF)</td>
<td>Quality of Student-Teacher Relationships</td>
<td>14-item measure, with possible score range was 28 to 75, with higher scores representing a more positive relationship between the teacher and the child.</td>
<td>Teachers</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Short Warwick Edinburgh Mental Well-Being Scale (SWEMWBS)</td>
<td>Mental well-being</td>
<td>7-item scale which yields a single score ranging from 7 to 35, with higher scores representing better well-being</td>
<td>Teachers</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Kessler-6 (K-6)</td>
<td>Psychological distress</td>
<td>A 6-item, self-reported and validated measure of mental health distress, with higher scores indicating greater psychological distress.</td>
<td>Teachers</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CLASS</td>
<td>Classroom environment/quality, Teacher-Student interactions</td>
<td>Widely used observational rater tool (1 hr) that assesses dimensions of classroom interactions linked to student achievement and classroom quality (Emotional Support, Classroom Organisation, and Instructional Support)</td>
<td>Research Assistant</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>CONFOUNDERS</strong></th>
<th><strong>Measures</strong></th>
<th><strong>Description</strong></th>
<th><strong>Raters</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Woodcock Johnson – 3rd Edition</td>
<td>General cognitive/intellectual and non-verbal ability</td>
<td>Standard scores will be used, with mean 100, SD = 15</td>
<td>Child</td>
<td></td>
</tr>
<tr>
<td>Family demographics</td>
<td></td>
<td></td>
<td>Parents</td>
<td></td>
</tr>
<tr>
<td>Teacher demographics</td>
<td></td>
<td></td>
<td>Teachers</td>
<td></td>
</tr>
<tr>
<td>Recruitment</td>
<td>Intervention</td>
<td>Control</td>
<td></td>
<td></td>
</tr>
<tr>
<td>-------------</td>
<td>--------------</td>
<td>---------</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>A B C D</td>
<td>E F</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Randomization</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline assessments</td>
</tr>
<tr>
<td>Intervention in Grade Prep</td>
</tr>
<tr>
<td>6-month follow-up</td>
</tr>
<tr>
<td>Intervention in Grade 1</td>
</tr>
<tr>
<td>18-month follow-up</td>
</tr>
</tbody>
</table>

**Description of key study activities**

- **A**: Parent information statement and written consent form distributed to all parents of all children in Grade Prep at participating schools.
- **B**: Parent survey reporting on child self-regulation, executive functioning and behavior.
- **C**: Teacher survey on child executive functioning and behavior.
- **D**: Teacher self-report survey on own mental well-being, classroom practice and knowledge and attitude of mindfulness.
- **E**: Objective child assessments for Corsi Block Tapping Task, Digit Recall and NIH Flanker.
- **F**: Objective child assessment for Ravens.
- **G**: Intervention: Consisting of one day expert professional development, 12 weeks of manualized intervention delivery, fortnightly teacher meetings and online community.
- **H**: Process Evaluation Measures, including measures of implementation quality, quantity and fidelity. Teacher interviews to understand implementation barriers and enablers.
- **I**: Observation of classroom environment using CLASS Observation Tool.

*Figure 1: Graphical representation of key study components*
Figure 2: CONSORT participant flow chart – estimated numbers

- **Approach**
  - N = 1156 Children
  - N = 22 Schools (average 52 students per school)

- **Consent and randomisation**
  - N = 826 children (60%)
  - N = 22 Schools
  - N = 56 Teachers, ~ 2.5 per school

- **Allocation**
  - Allocated to Intervention
    - N = 413 Children
    - N = 28 Teachers
    - N = 11 Schools (Clusters)
  - Allocated to Control
    - N = 413 Children
    - N = 28 Teachers
    - N = 11 Schools (Clusters)

- **Intervention in 2020 (Grade Prep)**
  - N = 28 Teachers
  - N = 11 Schools
  - N = 413 Children

- **6Mth Follow-up**
  - N = 413 Parent surveys
  - N = 28 Teacher surveys

- **Intervention in 2021 (Grade 1)**
  - N = 28 Teachers
  - N = 11 Schools
  - N = 413 Children

- **18Mth Follow-up**
  - N = 413 Child assessments
  - N = 413 Parent surveys
  - N = 28 Teacher surveys

- **Analytic Sample**
  - Estimated 20% attrition
    - N = 330 Children
    - N = 56 Teachers
    - N = 11 Schools (clusters)
SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

<table>
<thead>
<tr>
<th>Section/item</th>
<th>Item No</th>
<th>Description</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Administrative information</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Title</td>
<td>1</td>
<td>Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym</td>
<td>1</td>
</tr>
<tr>
<td>Trial registration</td>
<td>2a</td>
<td>Trial identifier and registry name. If not yet registered, name of intended registry</td>
<td>7</td>
</tr>
<tr>
<td></td>
<td>2b</td>
<td>All items from the World Health Organization Trial Registration Data Set</td>
<td></td>
</tr>
<tr>
<td>Protocol version</td>
<td>3</td>
<td>Date and version identifier</td>
<td>1</td>
</tr>
<tr>
<td>Funding</td>
<td>4</td>
<td>Sources and types of financial, material, and other support</td>
<td>2</td>
</tr>
<tr>
<td>Roles and responsibilities</td>
<td>5a</td>
<td>Names, affiliations, and roles of protocol contributors</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>5b</td>
<td>Name and contact information for the trial sponsor</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>5c</td>
<td>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</td>
<td>NA</td>
</tr>
<tr>
<td></td>
<td>5d</td>
<td>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)</td>
<td>NA</td>
</tr>
<tr>
<td><strong>Introduction</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Background and rationale</td>
<td>6a</td>
<td>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</td>
<td>7</td>
</tr>
<tr>
<td></td>
<td>6b</td>
<td>Explanation for choice of comparators</td>
<td>11</td>
</tr>
<tr>
<td>Objectives</td>
<td>7</td>
<td>Specific objectives or hypotheses</td>
<td>7</td>
</tr>
</tbody>
</table>
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, noninferiority, exploratory)

Methods: Participants, interventions, and outcomes

Study setting 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

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

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)

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

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 16b 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

Implementation 16c Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions

Blinding (masking) 17a Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how

17b 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 methods 18a 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

18b 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 19 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

Statistical methods 20a 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

20b Methods for any additional analyses (eg, subgroup and adjusted analyses)
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 21a 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

21b 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 22 Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct

Auditing 23 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 24 Plans for seeking research ethics committee/institutional review board (REC/IRB) approval

Protocol amendments 25 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 26a Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)

26b Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable

Confidentiality 27 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 28 Financial and other competing interests for principal investigators for the overall trial and each study site

Access to data 29 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 30 Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation

Dissemination policy 31a 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

31b Authorship eligibility guidelines and any intended use of professional writers

31c Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code

Appendices

Informed consent materials 32 Model consent form and other related documentation given to participants and authorised surrogates

Biological specimens 33 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

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons “Attribution-NonCommercial-NoDerivs 3.0 Unported” license.
Study Protocol: Can a teacher-led mindfulness intervention for new school entrants improve child outcomes: A school cluster randomised controlled trial

<table>
<thead>
<tr>
<th>Journal</th>
<th>BMJ Open</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manuscript ID</td>
<td>bmjopen-2019-036523.R1</td>
</tr>
<tr>
<td>Article Type</td>
<td>Protocol</td>
</tr>
<tr>
<td>Date Submitted by the Author</td>
<td>09-Feb-2020</td>
</tr>
<tr>
<td>Complete List of Authors</td>
<td>Quach, Jon L.; Univ Melbourne, Deery, Ben; Univ Melbourne Kern, Peggy; The University of Melbourne Clinton, Janet; Univ Melbourne Gold, Lisa; Deakin University, Deakin Health Economics Orsini, Francesca; Murdoch Childrens Research Institute, Clinical Epidemiology and Biostatistics Unit Sciberras, Emma; Murdoch Childrens Research Institute, Centre for Community Child Health</td>
</tr>
<tr>
<td>&lt;b&gt;Primary Subject Heading&lt;/b&gt;</td>
<td>Mental health</td>
</tr>
<tr>
<td>Secondary Subject Heading</td>
<td>Paediatrics, Public health</td>
</tr>
<tr>
<td>Keywords</td>
<td>Community child health &lt; PAEDIATRICS, Child &amp; adolescent psychiatry &lt; PSYCHIATRY, PUBLIC HEALTH</td>
</tr>
</tbody>
</table>
I, the Submitting Author has the right to grant and does grant on behalf of all authors of the Work (as defined in the below author licence), an exclusive licence and/or a non-exclusive licence for contributions from authors who are: i) UK Crown employees; ii) where BMJ has agreed a CC-BY licence shall apply, and/or iii) in accordance with the terms applicable for US Federal Government officers or employees acting as part of their official duties; on a worldwide, perpetual, irrevocable, royalty-free basis to BMJ Publishing Group Ltd (“BMJ”) its licensees and where the relevant Journal is co-owned by BMJ to the co-owners of the Journal, to publish the Work in this journal and any other BMJ products and to exploit all rights, as set out in our licence.

The Submitting Author accepts and understands that any supply made under these terms is made by BMJ to the Submitting Author unless you are acting as an employee on behalf of your employer or a postgraduate student of an affiliated institution which is paying any applicable article publishing charge (“APC”) for Open Access articles. Where the Submitting Author wishes to make the Work available on an Open Access basis (and intends to pay the relevant APC), the terms of reuse of such Open Access shall be governed by a Creative Commons licence – details of these licences and which Creative Commons licence will apply to this Work are set out in our licence referred to above.

Other than as permitted in any relevant BMJ Author’s Self Archiving Policies, I confirm this Work has not been accepted for publication elsewhere, is not being considered for publication elsewhere and does not duplicate material already published. I confirm all authors consent to publication of this Work and authorise the granting of this licence.
STUDY PROTOCOL: CAN A TEACHER-LED MINDFULNESS INTERVENTION FOR NEW SCHOOL ENTRANTS IMPROVE CHILD OUTCOMES: A SCHOOL CLUSTER RANDOMISED CONTROLLED TRIAL

Jon Quach (PhD) 1,2, jon.quach@unimelb.edu.au
Ben Deery (DPsych) 1, b.deery@unimelb.edu.au
Peggy L. Kern (PhD) 1, peggy.kern@unimelb.edu.au
Janet Clinton (PhD) 1, jclinton@unimelb.edu.au
Lisa Gold (PhD) 3, lisa.gold@deakin.edu.au
Francesca Orsini (MBio) 4, Francesca.orsini@mcri.edu.au
Emma Sciberras (DPsych) 5,6 emma.sciberras@deakin.edu.au

1 Melbourne Graduate School of Education, The University of Melbourne
2 Policy, Equity and Translation, Murdoch Childrens Research Institute
3 Health Economics, Deakin University
4 Clinical Epidemiology and Biostatistics Unit, Murdoch Childrens Research Institute
5 School of Psychology, Deakin University
6 Health Services Research, Murdoch Childrens Research Institute

Word count: 3981 words

Key words: mindfulness, school-based intervention, primary schools

CORRESPONDING AUTHOR
Dr Jon Quach
Melbourne Graduate School of Education, The University of Melbourne
Level 4, 100 Leicester Street, Carlton, Victoria 3010
Australia
Email: jon.quach@unimelb.edu.au

FUNDING STATEMENT:

This study is funding by an Australian Research Council Discovery Award (DP190100504). Associate Professor Sciberras is funded via a National Health Medical Research Council Career Development Fellowship (GNT1110688).

CONFLICTS OF INTEREST:

Dr Ben Deery developed the intervention, but does not receive any commercial or non-commercial financial entitlements. All other authors have no conflicts of interest to declare.

AUTHOR CONTRIBUTION:

All authors are investigators on the successful funding grant for this project, with Dr Quach as the lead investigator. All authors have reviewed and approved this submitted version.

- JQ was involved in the study’s design as well as the drafting and finalising of the study protocol. They will have overall responsibility for the study’s conduct.
- BD was involved in the study’s design as well as the drafting and finalising of the study protocol. They also designed the intervention.
- PK was involved in the study’s design as well as the drafting and finalising of the study protocol.
- JC was involved in the study’s design as well as the drafting and finalising of the study protocol.
- LG was involved in the study’s design as well as the drafting and finalising of the study protocol.
- FO was involved in the study’s design as well as the drafting and finalising of the study protocol.
- ES was involved in the study’s design as well as the drafting and finalising of the study protocol.
ABSTRACT

Introduction

The first years of school are critical in establishing a foundation for positive long-term academic, social and well-being outcomes. Mindfulness-based interventions may help students transition well into school, but few robust studies have been conducted in this age group. We aim to determine whether compared to controls, children who receive a mindfulness intervention within the first years of primary school have better:

1. Immediate attention/short-term memory at 18-months post randomization (primary outcome).
2. Inhibition, working memory, and cognitive flexibility at 18 months post-randomization.
3. Socio-emotional wellbeing, emotion-regulation, and mental health-related behaviors at 6- and 18-months post randomization.
4. Sustained changes in teacher practice and classroom interactions at 18-months post randomization.

Furthermore, we aim to determine whether the implementation predicts the efficacy of the intervention, and the cost effectiveness relative to outcomes.

Methods and Analysis

This cluster randomised controlled trial will be conducted in 22 primary schools in disadvantaged areas of Melbourne, Australia. 826 students in the first year of primary school will be recruited to detect between groups differences of Cohen’s d=0.25 at the 18-month follow-up.

Parent, teacher and child-assessment measures of child attention, emotion-regulation, executive functioning, socio-emotional well-being, mental health-related behavior and learning, parent mental well-being, teacher well-being will be collected 6- and 18-months post-randomisation. Implementation factors will be measured throughout the study.

Intention-to-treat analyses, accounting for clustering within schools and classes, will adopt a two-level random effects linear regression model to examine outcomes for the intervention versus control students. Unadjusted and analyses adjusted for baseline scores, baseline age, gender and family socio-economic status will be conducted.
Ethics and Dissemination: Ethics approval has been received by the Human Research Ethics Committee at the University of Melbourne. Findings will be reported in peer-review publications, national and international conference presentations and research snapshots directly provided to participating schools and families.

STRENGTHS AND LIMITATIONS

- Provide the first efficacy trial findings for a whole-class mindfulness intervention delivered across the first two years of primary school
- Understand the implementation factors associated with the trial outcomes
- Understand the cost-benefits of the intervention in relation to the trial outcomes
- Use of blinded measures consisted of child, parent and teacher-reported measures across multiple domains proposed to change through a mindfulness intervention
INTRODUCTION

The first years of school are critical for establishing firm foundations for positive child social, psychological and academic development. Children’s ability to regulate their attention, emotions, and behavior, and to follow classroom instructions during this period predicts school adjustment, participation and success. Similar to other countries, data from the Australian Early Development Census (AEDC) found that 22.4% of children commence school developmentally vulnerable. These vulnerabilities are highest in regards to (commonly relate to) behavioral and emotional difficulties, with children in disadvantaged areas three times more likely to experience these difficulties. Children who transition poorly into school are at increased risk for a host of detrimental outcomes, including behavioral and emotional problems, poor peer and teacher relationships, and low academic performance. These difficulties can persist throughout their schooling years and impact upon long-term educational, economic, social, physical and mental health outcomes. Thus, identifying evidence-based approaches to help children develop attention and emotional regulation skills is critical in proactively supporting children’s mental health and academic performance.

Contemplative practices such as mindfulness, has rapidly gained popularity in both practice and research and has potential to be used in classrooms to help children transition to school and to support ongoing learning. Mindfulness is broadly defined as the awareness that arises from paying purposeful attention to the present moment, non-judgmentally, with acceptance or curiosity. Numerous mindfulness-based programs have been developed for children and adults to build attention, self-monitoring, self-regulation, and mental flexibility. Such programs propose that individuals can become more ‘mindful’ by learning and practicing mindful skills and activities.

The interest in mindfulness-based interventions has been matched with studies, reviews, and meta-analyses examining the effectiveness of these interventions. Studies find that interventions can have positive effects on attention, executive functioning, social behavior and mindfulness in children and adults. However, reviews have also raised numerous concerns. Comparison groups are often weak or non-existent, selective samples are used, measures rely predominantly on self-report, methods are inconsistent (making it difficult to directly compare study effects), and programs are often poorly defined and vary in their components, resulting in programs that are often quite different. Only a limited number of rigorous randomised control
trials (RCTs) have examined the impact of mindfulness interventions using objective outcome measures assessed over time. Further, systematic reviews have identified very few studies that have been conducted with children under 8 years, and to our knowledge, no large-scale rigorous studies exist at the early primary school level.

Even for the school-based interventions with stronger evidence, it is unknown whether their effectiveness can be maintained when implemented at large scale. Many mindfulness programs involve the use of electronic/smart devices (e.g., audio recorded instructions), which the teacher is expected to facilitate/lead, and children are expected to engage in. Little emphasis is given to equipping teachers with the theoretical and practical knowledge underlying the activities, or on providing strategies for incorporating mindfulness into their day-to-day teaching practices. Yet teacher pedagogy and student-teacher relationships are critical for learning. For instance/example, a recent mindfulness intervention study following children from preschool to school suggested that observed executive functioning and later vocabulary and literacy benefits only emerged when teachers embedded these skills within their usual classroom practices over a long period of time, well beyond the standard 8-12-week period of most mindfulness interventions.

Given the complexity of implementing interventions in schools, it is also important to understand the quality, fidelity and dosage of the mindfulness intervention that children are exposed to, especially when promising interventions are implemented at scale. When mindfulness programs are poorly implemented or taught without appropriate theoretical and practical training, a range of unintended and adverse consequences can occur. Further, it is critical to determine the financial and time costs required to achieve positive outcomes, to ensure that limited time and resources schools have available are well spent. There are clear gaps between the levels of interest, evidence and investment in mindfulness-based interventions and best practices for doing so. Addressing these gaps will have both national and international implications for the use of mindfulness intervention within early primary school classrooms.

Addressing the lack of empirically based mindfulness programs for early years education, the intervention used in this study directly trains teachers on mindfulness theory and practice and provides a structured approach for embedding mindfulness activities into everyday teaching practices to improve student outcomes. Initial support for the intervention was established through a pilot RCT involving 109 children from 6 classrooms in 4 preschool centers in disadvantaged
areas of Melbourne, Australia. Preliminary data at immediate post-intervention, indicated intervention children had better immediate attention/short term memory (measured via the Corsi Block-tapping task, effect size Cohen’s d=0.29; Digit Span Forward task, d=0.24), behavior regulation (measured via Less is More, d=0.34), and mental health-related behaviors (measured via the Teacher Strengths and Difficulties Questionnaire - Externalizing, d=0.45), compared to control children. Qualitative data demonstrated that teachers believed that the program was effective for themselves, their children and their colleagues, and reported parents wanted to know more about the program and the activities. They also continued to embed mindfulness into their classroom after the program finished.

The current study uses a rigorous RCT cluster design to build on these promising findings to examine whether the same intervention remains effective when implemented within early primary school classrooms at larger scale. We will provide an in-depth examination of child, teacher and school level factors that promote and reduce the intervention’s success. We will also consider the costs and economic benefits of the intervention. We hypothesize that the intervention will be associated with:

5. Improvements in child immediate attention/short-term memory assessed via blinded direct assessment 18-months post randomization (primary outcome).
6. Improvements in executive functioning measured via blinded direct assessment of inhibition, working memory, and cognitive flexibility, 18 months post-randomization.
7. Improved socio-emotional wellbeing, emotion-regulation, and mental health-related behaviors, reported by parents and teachers, 6- and 18-months post randomization.
8. Sustained changes in teacher practice and classroom interactions assessed via blinded raters at 18-months post randomization.

Furthermore, we hypothesize that the quality and dosage of implementation will predict the efficacy of the intervention, and the intervention will be cost effective relative to outcomes.

**METHODS**

**Pre-registration and Ethics**

The study is registered with the Australian New Zealand Clinical Trials Registry (ACTRN12619000326190). Ethics approval was obtained from the Human Research Ethics Committee at the University of Melbourne (Ethics ID: 1853492), Australia, and approval for the
study was provided by the Victorian Department of Education and Training (DET) and Catholic Education Melbourne (CEM).

**Patient and Public Involvement**

No patient involved

**Design**

This is a cluster RCT with an embedded process and economic evaluation (see Figure 1). This will inform the benefits of the intervention compared to current practice, identify for whom and under what conditions the intervention is beneficial, and provide an indication of the cost-benefits of the intervention. Results will be reported per the CONSORT guidelines for non-pharmacologic interventions.

**Participants**

All Foundation children (i.e., the first year of primary school, ages 5-6) at participating schools with parental consent will be invited to participate in the data collection, provided the child and parents have sufficient English language abilities to complete the measures. Although this will affect generalizability, the majority of measures have not been validated for other languages. Children without consent will still be exposed to the intervention as part of their school’s wellbeing approach but not complete the measures.

**Sample size**

The estimated sample size across all stages of the study are shown in Figure 2.

Given the hypotheses of the trial and measures collected in our pilot study as well as in published meta-analyses, we anchored our sample size calculations on detection of a minimum effect size of 0.25 standard deviations (SD) between the treatment and control groups at 18-months post-randomization in a two-arm parallel trial with 80% power and a two-tailed 5% Type I error. The sample size applies across all measures collected at 18-months post randomization, based on the number of SDs rather than on the actual outcome distributions.

To account for the clustering effect within classes (ICC=0.02) and schools (ICC=0.02), and an attrition rate of 20% by the end of the study, our planned sample size is 413 children per
condition (826 total). To achieve this, we estimate we will recruit 22 schools to participate (11 per condition). This assumes an average of 2.5 Foundation Year classes at each school, and 65% of parents providing consent for data collection (16 per class, 40 per school). The final number of schools will be dependent on student population, the number of classes within each school and class size of the recruited schools.

**School selection and recruitment**

Primary schools from metropolitan Melbourne, Australia, with disadvantaged student populations will be recruited. This will be determined by approaching schools with a high proportion of children starting primary school developmentally vulnerable in ‘emotional maturity’ and ‘social competence’ domains as defined by the AEDC. The AEDC is a national census completed every three years by classroom teachers for children in the first year of primary school, including 2015 and 2018.\(^\text{34}\) Data are available for >98% of Australian children during data collection years. Therefore, the AECD provides accurate estimates of the number of children with developmental vulnerabilities for/at each school. Where AEDC data are not available, other government or administrative datasets that measure school disadvantage will be used to select eligible schools.

The school recruitment approach is similar to those used in previous school-based longitudinal studies and intervention trials conducted by members of the research team.\(^\text{35-39}\) Australian schools are clustered into three sectors: Government (69%), Catholic (19.2%), and Independent (11.8%). To balance representation with study time and resources, we will include government and Catholic schools.

Although DET and CEM have provided approval for research within schools, each school’s leadership has independent responsibility to approve which projects they choose their schools to participate in. Drawing on the DET and CEM network of schools, we will first present our study at each area’s school leadership network meetings or similar engagement event, providing background on the study and an overview of what would be expected of the school, teachers, parents, and children. Principals will be able to indicate interest in participating in the study without fully committing. By doing this, we limit the burden of approaching schools in which school leadership do not wish to participate. If a sufficient number of schools express interest, we will proceed with selection and randomization. Based on our prior experiences working with
primary schools in the region, we estimate that 87 (75%) will express interest in being a part of the study, with the main reason for declining being time commitments and participation in other research projects. If additional schools are needed, we will directly contact remaining schools in the area until the number of required schools has been achieved.

Recruitment will be stratified by school sector type to ensure a representative sample from both sectors. Of those selected, we will approach the school’s principal to ascertain their agreement to participate. If the principal declines, we will contact the next randomly selected school on the list, repeating until we reach the required sample size.

We will then meet with all Foundation and Grade 1 teachers at participating schools to describe the purpose and requirements of the project, expected time commitments, and recruitment process and answer any questions they may have. The teachers will be provided with an information sheet detailing their expected involvement, a consent form, and a brief survey.

**Student recruitment and consent**

Before we begin student recruitment at each school, we will work with each school to publicise the trial, raising parental awareness and interest in the study through notifications in school newsletters, posters on classroom doors and sending advance-notice postcards to the homes of eligible children. Teachers will then send a recruitment pack to each family. The pack will contain an information sheet detailing the study, a consent form, a brief survey and an envelope. Parents will be asked to return the completed consent forms and survey in the sealed envelope to a secure box in the child’s classroom.

Consent for the study will be specific to the data collection. Because the intervention focuses on embedding simple play-based activities into teachers’ daily practice and classrooms, it would be unethical and impractical to have children without consent be removed from the classroom, when teachers are implementing the mindfulness-based activities and games. Children are commonly/frequently exposed to similar changes in teacher practice following teacher professional development (PD) or when teachers make explicit decisions to implement a new pedagogical approach or wellbeing curriculum in their classroom.

**Randomization**
After the parent and teacher surveys have been completed, schools, stratified by school sector, will be randomized to control or intervention in block sizes ranging from two to four. To reduce the potential for contamination effects, the randomization will be conducted by a researcher independent of the study team, and group allocation will be concealed from research team members involved in the direct outcome assessments. All intervention schools will complete a Memorandum of Understanding, agreeing not to share the intervention resources with control schools, and control schools will not have access to the intervention training or manual.

**Mindfulness Intervention**

Training and troubleshooting support for the mindfulness intervention will be provided by the program developer. Children will be exposed to the intervention across two consecutive academic school years, Foundation and Grade 1.

For intervention schools, Foundation and Grade 1 teachers will attend one PD day in 2020 and 2021 respectively, which will provide the theoretical and practical foundations of the program and instructions for implementing the program. Teachers will be provided with an implementation manual (available by request), which includes a schedule of activities, lesson plans, communication templates/examples, sample activities, parent homework sheets, audio/music and film suggestions, and training slides. Participants will review the materials, watch examples, practice a selection of activities, and will be able to ask questions to ensure clear understanding of the program and implementation.

Following the PD, the teachers will be expected to embed the 12-week intervention into their classrooms, using the manual to help them to learn, practice, incorporate, and reflect on the activities and strategies. The mindfulness program involves three core practice components, (i) mindful games/activities; (ii) mindful routines/transitions/moments; and (iii) use of props/books/music/art, which can be used within the classroom and integrated with normal teaching activities. For each week, it is recommended that teachers:

1. Engage in two mindfulness activities per day at least four times per week, utilizing suggested props, games, or art/music, and trying to anchor these around key routines or transition periods during the day (e.g., on classroom arrival/departure, after lunch/recess, before a test/specialist class, snack or mealtimes, moving between classrooms).
2. Read suggested storybooks each week and discuss with children possible connections to mindfulness and related skills/concepts. The manual includes a list of popular children's storybooks (commonly available in schools or easily accessed) with guidance for discussion.

3. Identify and embed spontaneous ‘mindful moments’ into their daily classroom routines, transitions and class time, such as using ‘slow motion’ walking to the library, or watching rain drops race down classroom window.

Teachers will also be asked to establish, if possible, a ‘Mindful Space’ in the classroom to provide an ongoing reminder and/or display of mindfulness tools, while also creating a place for children to engage in mindful activities during class time. The space may include a variety of mindful props (e.g., mind jar), games (e.g., rock balancing), activities (e.g., mindful drawing), and storybooks. Intervention schools will be provided with all required props, books, games and other resources (e.g., door/wall posters) to implement the key elements of the program.

Throughout the 12-week program, teachers will also be encouraged to:

1. Discuss the intervention’s implementation during their team’s regular meetings, led by participating teachers, to reflect on the intervention’s progress, implementation, and support needs, providing peer support and a shared commitment to the program. In Year 2 of the study, Foundation teachers will continue to participate in these meetings, providing their own reflections and experiences to the Grade 1 teachers, potentially aiding sustainability through a train-the-trainer type approach.

2. Contact the research team for additional implementation support, trouble shooting, or advice/coaching, if required

3. Share examples of mindful activities, artwork and discussions with parents, enabling connections and modelling between school, home, and ongoing support.

Following the 12-week intervention, we will conduct a 1-hour meeting with teachers to allow reflection on learnings from the past 12 weeks and to help develop an ongoing implementation plan if they chose.

**Outcome data collection and research assistant blinding**

Outcome assessments will be conducted 6 (end of Foundation for the children) and 18 months (end of Grade 1) post randomization. At each occasion, parents and teachers will be asked
to complete surveys. Children will complete face-to-face direct assessments at baseline and 18 months post randomization during school hours by trained research assistants blinded to the school’s group allocation.

Measures

Measures are summarized in Table 1, which have chosen to attempt to measure proximal and distal outcomes that align with our intervention’s theory of change, which have been informed by our pilot findings and existing systematic reviews.13, 14, 17

The primary outcome is labelled as child visuo-spatial short-term memory, as measured by the Corsi Block Tapping Forward Raw Score at 18-months post-randomization.41 We have referred to this as short-term memory, however, previous psychological and cognitive sciences research have also used forward block span as a measure of immediate attention (the same applies for Digit Span Forwards and verbal short-term memory), with such terms often used somewhat interchangeably. Other research highlights difficulties in separating short term memory and immediate attention conceptually and experimentally, hence they strongly overlap.42, 43

The study includes secondary outcomes across multiple domains. Examining multiple outcomes aligns with the UK Medical Research Council guidelines for interventions that are complex in nature and likely to result in possible impact across a diversity of domains.44 It is particularly important that sufficient data are measured to enable comparability across mindfulness-based school programmes, as programmes frequently vary in their content, setting and target population. Because of the wide variety of measures, while each outcome will be analysed individually, findings and interpretations will consider the consensus of evidence for the data provided. This will involve careful examination and consideration of the magnitude, direction and statistical significance of the responsiveness estimated for each outcome. Due to the increased potential for false-positive findings arising through analysis of multiple outcomes, patterns will be interpreted cautiously and in context with one another, rather than in isolation.

Process evaluation

The implementation and process evaluation will use a mixed-methods approach, drawing on data collected via teacher surveys and teacher interviews. It will explore the intervention’s theory of change and the extent to which the dimensions of implementation impact the program’s
effectiveness, as well as the enablers and barriers to its implementation. Fidelity, quality and adaptation of the intervention’s activities over the 12-week manualised implementation will be examined via fortnightly surveys completed by intervention teachers. Sustainability, enablers and barriers of the intervention will be examined via teacher interviews and surveys at 6- and 18-month post-randomization. Factors will be examined at the student, teacher and school levels where appropriate.

The wellbeing practices of the control schools will also be examined to document any practice similarities (i.e., the presence of mindfulness practices/elements or other social-emotional learning [SEL] programs) and differences (e.g., the use of mindfulness audio-recorded sessions versus pedagogy-based approaches) when compared to our intervention.

**Economic Evaluation**

Costs associated with the intervention training and delivery will be prospectively and retrospectively recorded, including costs for delivery, material/prop resources required by the schools, and time spent on the program. Resources used in training and ongoing support will be prospectively recorded by the research team, and all intervention teachers will prospectively record time and resources used in intervention delivery and report these through the process evaluation. Teacher surveys will include retrospective report from control teachers of time and resources used on SEL related activities.

Using surveys, teachers in intervention and control schools will retrospectively report in-school additional support at 3 and 18-months post-randomization, and at each time point parents will recall out-of-school health and education service use over the previous year.

Resource use will be presented in natural units as well as valued in 2021 Australian dollars using local (state) and national unit cost estimates (e.g., education department salary scales, Medicare Benefits Schedule). Costs will be presented as costs per student from a government payer perspective.

Analyses will involve: (i) a cost-consequences analysis, which will compare incremental costs of the intervention (costs accrued in the intervention arm, from intervention and resource use over the period of follow-up, compared to costs accrued in the control arm) to all primary and secondary outcomes, expressed in their natural units of measurement; and (ii) cost-effectiveness,
assessed against the primary outcome measure and presented as cost per point change in child attention. Impact of missing data will be assessed through multiple imputation (described below).

**Statistical Analysis**

All participants and school demographic and baseline continuous outcomes will be presented as mean and SD (or medians and interquartile ranges for skewed data), whilst categorical outcomes will be presented as absolute and relative frequencies by group. Statistical analysis will follow standard methods for cluster randomized trials and the primary analysis will be by intention to treat. Multiple imputation will be conducted separately in the two arms using chained equations applied to all outcomes simultaneously, including baseline measures as auxiliary variables. Fifty imputed datasets will be generated. All analyses will be conducted using Stata.

The primary outcome is student visual-spatial short-term memory/immediate attention at 18 months post-randomization. The effect of the intervention on the Corsi Block Tapping Forward raw score at 18 months compared to control children will be examined adopting a linear mixed model, which will include the stratification factor used during randomization (school sector) as a fixed effect term and two random effect terms (school and class) to account for the clustering structure of the data. The effect of intervention on the primary outcome at 18 months will then be adjusted by the student baseline Corsi Block Tapping Forward score, age at baseline, gender, family socio-economic status and child IQ, which will be included in the above model as fixed effect terms.

For all the outcomes collected at 18 months, the effect of the intervention will be estimated using generalized linear mixed models (linear or logistic according to the nature of the outcome), which will include control variables (i.e., school sector, the corresponding outcome measure at baseline, age at baseline, gender, family socio-economic status, child IQ and time of assessment) as fixed effect terms and the same random effect terms mentioned above. For outcomes collected at 6-months and at 18-months, the same generalized linear mixed models described above will be adopted, with the addition of a third random effect term (i.e., student), to account for the repeated measures over time (the nature of the outcome), which will include control variables as fixed effect terms and the same random effect terms mentioned above with the addition of a third random effect term (i.e., student), to account for the repeated measures within children.
DISSEMINATION PLAN

Once the study is completed, we will publish our findings in international peer-reviewed child health journals and present at national and international conferences. In addition, we will send participating schools and parents a short report of our findings. A copy of the report will also be sent to relevant government departments.

- **Annual school and parent newsletter:** To maintain engagement throughout the study, we will send annual newsletters to all participating schools and families that will provide a progress update, and summary of any new findings which have been published.

- **A participating school seminar:** Recognising the time and resource contributed by participating schools, it is important findings are presented to schools in a timely manner. We will hold, and record, a half-day seminar at the primary institution within 6 months of the study’s completion to present findings and enable dialogue about implications.
REFERENCES


### Table 1: Description of measures and timepoints

<table>
<thead>
<tr>
<th>Measure</th>
<th>Domain</th>
<th>Scoring description</th>
<th>Method of assessment</th>
<th>Baseline</th>
<th>Intervention</th>
<th>6-mth</th>
<th>18-mth</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Primary Outcome</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Corsi Block Forward Tapping Task&lt;sup&gt;41&lt;/sup&gt;</td>
<td>Visuo-spatial short term memory/immediate attention</td>
<td>Raw scores for longest recall span will be used to determine visual short term memory / immediate attention</td>
<td>Child Assessment</td>
<td></td>
<td>●</td>
<td></td>
<td>●</td>
</tr>
<tr>
<td><strong>Secondary Outcomes</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>CHILD</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Digit Span Forward&lt;sup&gt;41&lt;/sup&gt;</td>
<td>Verbal immediate attention/short term memory</td>
<td>Raw scores for longest recall span will be used to determine verbal immediate attention</td>
<td>Child Assessment</td>
<td>●</td>
<td></td>
<td>●</td>
<td></td>
</tr>
<tr>
<td>Corsi Block Backward Tapping Task&lt;sup&gt;41&lt;/sup&gt;</td>
<td>Visuo-spatial working memory</td>
<td>Use of raw scores, indicating longest backward recall span</td>
<td>Child Assessment</td>
<td>●</td>
<td></td>
<td>●</td>
<td>●</td>
</tr>
<tr>
<td>Digit Span Backwards&lt;sup&gt;41&lt;/sup&gt;</td>
<td>Verbal working memory</td>
<td>Use of raw scores, indicating longest backward recall span</td>
<td>Child Assessment</td>
<td>●</td>
<td></td>
<td>●</td>
<td>●</td>
</tr>
<tr>
<td>NIH Toolbox, Flanker Inhibitory Control and Attention Test&lt;sup&gt;46&lt;/sup&gt;</td>
<td>Inhibitory control, Attention</td>
<td>Raw scores range from 0 – 10, with standard scores mean = 100 (SD = 15) used in reporting</td>
<td>Child Assessment</td>
<td>●</td>
<td></td>
<td>●</td>
<td>●</td>
</tr>
<tr>
<td>NIH Toolbox, Dimensional Change Card Sort</td>
<td>Cognitive flexibility</td>
<td>Raw scores</td>
<td>Child Assessment</td>
<td>●</td>
<td>●</td>
<td></td>
<td>●</td>
</tr>
<tr>
<td>Sustained Attention to Response Task</td>
<td>Sustained attention</td>
<td>Standard scores mean = 100 (SD = 15)</td>
<td>Child Assessment</td>
<td>●</td>
<td>●</td>
<td></td>
<td>●</td>
</tr>
<tr>
<td>Strengths and Difficulties Questionnaire (SDQ)&lt;sup&gt;47&lt;/sup&gt;</td>
<td>Child mental-health related behavior</td>
<td>A 25-item validated measure for children aged 4 to 16 years; with higher scores representing higher levels of behavior/mental health difficulties. Measure reports subscales for internalizing difficulties (5 items), externalizing difficulties (10 items) and Total Difficulties (20 items).</td>
<td>Parent and teacher survey</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td>●</td>
</tr>
<tr>
<td>Affective Reactivity Index</td>
<td>Emotion-regulation</td>
<td>A 7-item measure, with a range of 0 – 14, with higher scores representing greater irritability.</td>
<td>Parent</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>---------------------------</td>
<td>-------------------</td>
<td>-----------------------------------------------------------------</td>
<td>--------</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Childhood Executive Functioning Inventory (CHEXI)</td>
<td>Executive Functioning Behaviour</td>
<td>A 24-item measure validated for children aged 4 to 12 years. Each item is scored 1 – 5, with higher scores representing greater difficulties. It yields 2 subscales: Inhibition (11-items) and working memory (13-items).</td>
<td>Parent and teacher survey</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ECLS-K Approaches to Learning</td>
<td>Learning Behaviour</td>
<td>A 6-item subscale from the Social Rating Scale used in Early Childhood Longitudinal Study-Kindergarten (ECLS-K). Items were designed to assess various aspects of a child’s approach to learning, such as organization, working independently and task completion. The possible score range was 1 - 6, with higher scores indicating better approaches to learning.</td>
<td>Teacher survey</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**PARENT**

<table>
<thead>
<tr>
<th>Interpersonal Mindfulness in Parenting (IEM-P)</th>
<th>Mindful parenting, parent-child interaction (4 subscales)</th>
<th>10-item measure, with subscales for awareness and present-centred attention (4 items), non-judgement (3-items) and non-reactivity (3-items).</th>
<th>Parent survey</th>
</tr>
</thead>
<tbody>
<tr>
<td>Short Warwick Edinburgh Mental Well-Being Scale (SWEMWBS)</td>
<td>Mental well-being</td>
<td>7-item scale which yields a single score ranging from 7 to 35, with higher scores representing better well-being</td>
<td>Parents</td>
</tr>
<tr>
<td>Kessler-6 (K-6)</td>
<td>Psychological distress</td>
<td>A 6-item, self-reported and validated measure of mental health distress, with higher scores indicating greater psychological distress.</td>
<td>Parents</td>
</tr>
</tbody>
</table>
### TEACHER

<table>
<thead>
<tr>
<th>Scale</th>
<th>Description</th>
<th>Target Group</th>
</tr>
</thead>
<tbody>
<tr>
<td>TEACHER Mindfulness in Teaching (MIT) Scale</td>
<td>14-item self-report measure, with Teacher Intrapersonal Mindfulness (9-items, range 9 - 45) and Teacher Interpersonal Mindfulness subscales (7-items, range 7 - 35), with higher scores representing more negative outcomes</td>
<td>Teachers</td>
</tr>
<tr>
<td>Quality of Student-Teacher Relationships</td>
<td>14-item measure, with possible score range was 28 to 75, with higher scores representing a more positive relationship between the teacher and the child.</td>
<td>Teachers</td>
</tr>
<tr>
<td>Short Warwick Edinburgh Mental Well-Being Scale (SWEMWBS)</td>
<td>7-item scale which yields a single score ranging from 7 to 35, with higher scores representing better well-being</td>
<td>Teachers</td>
</tr>
<tr>
<td>Kessler-6 (K-6)</td>
<td>A 6-item, self-reported and validated measure of mental health distress, with higher scores indicating greater psychological distress.</td>
<td>Teachers</td>
</tr>
</tbody>
</table>

### CLASS

| Classroom environment/quality, Teacher-Student interactions | Widely used observational rater tool (1 hr) that assesses dimensions of classroom interactions linked to student achievement and classroom quality (Emotional Support, Classroom Organisation, and Instructional Support) | Research Assistant |

### CONFOUNDERS

<table>
<thead>
<tr>
<th>Scale</th>
<th>Description</th>
<th>Target Group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Woodcock Johnson – 3rd Edition</td>
<td>Standard scores will be used, with mean 100, SD = 15, general cognitive/intellectual and non-verbal ability</td>
<td>Child</td>
</tr>
<tr>
<td>Family demographics</td>
<td></td>
<td>Parents</td>
</tr>
<tr>
<td>Teacher demographics</td>
<td></td>
<td>Teachers</td>
</tr>
<tr>
<td>Recruitment</td>
<td>Intervention</td>
<td>Control</td>
</tr>
<tr>
<td>-------------</td>
<td>-------------</td>
<td>---------</td>
</tr>
<tr>
<td>Baseline assessments</td>
<td>B C D E F</td>
<td></td>
</tr>
<tr>
<td>Randomization</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intervention in Foundation/Grade Prep</td>
<td>G H</td>
<td></td>
</tr>
<tr>
<td>6-month follow-up</td>
<td>B C D</td>
<td>B C D</td>
</tr>
<tr>
<td>End of School Year</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intervention in Grade 1</td>
<td>D G H</td>
<td>D</td>
</tr>
<tr>
<td>18-month follow-up</td>
<td>B C D E I</td>
<td>B C D E I</td>
</tr>
</tbody>
</table>

**Figure key**

- □ Data collection
- ○ Intervention process/data

**Description of key study activities**

- **A**: Parent information statement and written consent form distributed to all parents of all children in Grade Prep at participating schools
- **B**: Parent survey reporting on child self-regulation, executive functioning and behavior
- **C**: Teacher survey on child executive functioning and behavior
- **D**: Teacher self-report survey on own mental well-being, classroom practice and knowledge and attitude of mindfulness
- **E**: Objective child assessments for Corsi Block Tapping Task, Digit Recall and NIH Flanker
- **F**: Objective child assessment for WJ-III
- **G**: Intervention: Consisting of one day expert professional development, 12 weeks of manualized intervention delivery, fortnightly teacher meetings and online community
- **H**: Process Evaluation Measures, including measures of implementation quality, quantity and fidelity. Teacher interviews to understand implementation barriers and enablers
- **I**: Observation of classroom environment using CLASS Observation Tool.

**Figure 1: Graphical representation of key study components**

For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml
Figure 2: CONSORT participant flow chart – estimated numbers
SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

<table>
<thead>
<tr>
<th>Section/item</th>
<th>Item No</th>
<th>Description</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Administrative information</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Title</td>
<td>1</td>
<td>Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym</td>
<td>1</td>
</tr>
<tr>
<td>Trial registration</td>
<td>2a</td>
<td>Trial identifier and registry name. If not yet registered, name of intended registry</td>
<td>7</td>
</tr>
<tr>
<td></td>
<td>2b</td>
<td>All items from the World Health Organization Trial Registration Data Set</td>
<td></td>
</tr>
<tr>
<td>Protocol version</td>
<td>3</td>
<td>Date and version identifier</td>
<td>1</td>
</tr>
<tr>
<td>Funding</td>
<td>4</td>
<td>Sources and types of financial, material, and other support</td>
<td>2</td>
</tr>
<tr>
<td>Roles and responsibilities</td>
<td>5a</td>
<td>Names, affiliations, and roles of protocol contributors</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>5b</td>
<td>Name and contact information for the trial sponsor</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>5c</td>
<td>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</td>
<td>NA</td>
</tr>
<tr>
<td></td>
<td>5d</td>
<td>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)</td>
<td>NA</td>
</tr>
<tr>
<td>Introduction</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Background and rationale</td>
<td>6a</td>
<td>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</td>
<td>7</td>
</tr>
<tr>
<td></td>
<td>6b</td>
<td>Explanation for choice of comparators</td>
<td>11</td>
</tr>
<tr>
<td>Objectives</td>
<td>7</td>
<td>Specific objectives or hypotheses</td>
<td>7</td>
</tr>
</tbody>
</table>
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, noninferiority, exploratory)

Methods: Participants, interventions, and outcomes

Study setting 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

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

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)

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

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 16b 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.

Implementation 16c Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions.

Blinding (masking) 17a Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how.

17b 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 methods 18a 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.

18b 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 19 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.

Statistical methods 20a 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.

20b Methods for any additional analyses (eg, subgroup and adjusted analyses).
<table>
<thead>
<tr>
<th>Item</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>20c</td>
<td>Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)</td>
</tr>
<tr>
<td>21a</td>
<td>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</td>
</tr>
<tr>
<td>21b</td>
<td>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</td>
</tr>
<tr>
<td>22</td>
<td>Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct</td>
</tr>
<tr>
<td>23</td>
<td>Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor</td>
</tr>
<tr>
<td>24</td>
<td>Plans for seeking research ethics committee/institutional review board (REC/IRB) approval</td>
</tr>
<tr>
<td>25</td>
<td>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)</td>
</tr>
<tr>
<td>26a</td>
<td>Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)</td>
</tr>
<tr>
<td>26b</td>
<td>Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable</td>
</tr>
<tr>
<td>27</td>
<td>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</td>
</tr>
<tr>
<td>28</td>
<td>Financial and other competing interests for principal investigators for the overall trial and each study site</td>
</tr>
<tr>
<td>29</td>
<td>Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators</td>
</tr>
</tbody>
</table>
Ancillary and post-trial care 30 Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation NA

Dissemination policy 31a Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions 16

31b Authorship eligibility guidelines and any intended use of professional writers 16

31c Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code 16

Appendices

Informed consent materials 32 Model consent form and other related documentation given to participants and authorised surrogates Appendix

Biological specimens 33 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 NA

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons “Attribution-NonCommercial-NoDerivs 3.0 Unported” license.
CAN A TEACHER-LED MINDFULNESS INTERVENTION FOR NEW SCHOOL ENTRANTS IMPROVE CHILD OUTCOMES? PROTOCOL FOR A SCHOOL CLUSTER RANDOMISED CONTROLLED TRIAL.

<table>
<thead>
<tr>
<th>Journal:</th>
<th>BMJ Open</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manuscript ID</td>
<td>bmjopen-2019-036523.R2</td>
</tr>
<tr>
<td>Article Type:</td>
<td>Protocol</td>
</tr>
<tr>
<td>Date Submitted by the Author:</td>
<td>17-Mar-2020</td>
</tr>
<tr>
<td>Complete List of Authors:</td>
<td>Quach, Jon L.; Univ Melbourne, Deery, Ben; Univ Melbourne Kern, Peggy; The University of Melbourne Clinton, Janet; Univ Melbourne Gold, Lisa; Deakin University, Deakin Health Economics Orsini, Francesca; Murdoch Childrens Research Institute, Clinical Epidemiology and Biostatistics Unit Sciberras, Emma; Murdoch Childrens Research Institute, Centre for Community Child Health</td>
</tr>
<tr>
<td>Primary Subject Heading:</td>
<td>Mental health</td>
</tr>
<tr>
<td>Secondary Subject Heading:</td>
<td>Paediatrics, Public health</td>
</tr>
<tr>
<td>Keywords:</td>
<td>Community child health &lt; PAEDIATRICS, Child &amp; adolescent psychiatry &lt; PSYCHIATRY, PUBLIC HEALTH</td>
</tr>
</tbody>
</table>
I, the Submitting Author has the right to grant and does grant on behalf of all authors of the Work (as defined in the below author licence), an exclusive licence and/or a non-exclusive licence for contributions from authors who are: i) UK Crown employees; ii) where BMJ has agreed a CC-BY licence shall apply, and/or iii) in accordance with the terms applicable for US Federal Government officers or employees acting as part of their official duties; on a worldwide, perpetual, irrevocable, royalty-free basis to BMJ Publishing Group Ltd ("BMJ") its licensees and where the relevant Journal is co-owned by BMJ to the co-owners of the Journal, to publish the Work in this journal and any other BMJ products and to exploit all rights, as set out in our licence.

The Submitting Author accepts and understands that any supply made under these terms is made by BMJ to the Submitting Author unless you are acting as an employee on behalf of your employer or a postgraduate student of an affiliated institution which is paying any applicable article publishing charge ("APC") for Open Access articles. Where the Submitting Author wishes to make the Work available on an Open Access basis (and intends to pay the relevant APC), the terms of reuse of such Open Access shall be governed by a Creative Commons licence – details of these licences and which Creative Commons licence will apply to this Work are set out in our licence referred to above.

Other than as permitted in any relevant BMJ Author’s Self Archiving Policies, I confirm this Work has not been accepted for publication elsewhere, is not being considered for publication elsewhere and does not duplicate material already published. I confirm all authors consent to publication of this Work and authorise the granting of this licence.
CAN A TEACHER-LED MINDFULNESS INTERVENTION FOR NEW SCHOOL ENTRANTS IMPROVE CHILD OUTCOMES? PROTOCOL FOR A SCHOOL CLUSTER RANDOMISED CONTROLLED TRIAL.

Jon Quach (PhD)\textsuperscript{1,2}, jon.quach@unimelb.edu.au
Ben Deery (DPsych)\textsuperscript{1}, b.deery@unimelb.edu.au
Peggy L. Kern (PhD)\textsuperscript{1}, peggy.kern@unimelb.edu.au
Janet Clinton (PhD)\textsuperscript{1}, jclinton@unimelb.edu.au
Lisa Gold (PhD)\textsuperscript{3}, lisa.gold@deakin.edu.au
Francesca Orsini (MBio)\textsuperscript{4}, Francesca.orsini@mcri.edu.au
Emma Sciberras (DPsych)\textsuperscript{5,6} emma.sciberras@deakin.edu.au

\textsuperscript{1} Melbourne Graduate School of Education, The University of Melbourne
\textsuperscript{2} Policy, Equity and Translation, Murdoch Childrens Research Institute
\textsuperscript{3} Health Economics, Deakin University
\textsuperscript{4} Clinical Epidemiology and Biostatistics Unit, Murdoch Childrens Research Institute
\textsuperscript{5} School of Psychology, Deakin University
\textsuperscript{6} Health Services Research, Murdoch Childrens Research Institute

\textbf{Word count:} 3981 words

\textbf{Key words:} mindfulness, school-based intervention, primary schools

\textbf{CORRESPONDING AUTHOR}

Dr Jon Quach

Melbourne Graduate School of Education, The University of Melbourne

Level 4, 100 Leicester Street, Carlton, Victoria 3010 Australia

Email: jon.quach@unimelb.edu.au
FUNDING STATEMENT:

This study is funded by an Australian Research Council Discovery Award (DP190100504). Associate Professor Sciberras is funded via a National Health Medical Research Council Career Development Fellowship (GNT1110688).

CONFLICTS OF INTEREST:

Dr Ben Deery developed the intervention but does not receive any commercial or non-commercial financial entitlements. All other authors have no conflicts of interest to declare.

AUTHOR CONTRIBUTION:

All authors are investigators on the successful funding grant for this project, with Dr Quach as the lead investigator. All authors have reviewed and approved this submitted version.

- JQ was involved in the study’s design as well as the drafting and finalising of the study protocol. They will have overall responsibility for the study’s conduct.
- BD was involved in the study’s design as well as the drafting and finalising of the study protocol. They also designed the intervention.
- PK was involved in the study’s design as well as the drafting and finalising of the study protocol.
- JC was involved in the study’s design as well as the drafting and finalising of the study protocol.
- LG was involved in the study’s design as well as the drafting and finalising of the study protocol.
- FO was involved in the study’s design as well as the drafting and finalising of the study protocol.
- ES was involved in the study’s design as well as the drafting and finalising of the study protocol.
ABSTRACT

Introduction

The first years of school are critical in establishing a foundation for positive long-term academic, social and well-being outcomes. Mindfulness-based interventions may help students transition well into school, but few robust studies have been conducted in this age group. We aim to determine whether compared to controls, children who receive a mindfulness intervention within the first years of primary school have better:

1. Immediate attention/short-term memory at 18-months post randomization (primary outcome).
2. Inhibition, working memory, and cognitive flexibility at 18 months post-randomization.
3. Socio-emotional wellbeing, emotion-regulation, and mental health-related behaviours at 6- and 18-months post randomization.
4. Sustained changes in teacher practice and classroom interactions at 18-months post randomization.

Furthermore, we aim to determine whether the implementation predicts the efficacy of the intervention, and the cost effectiveness relative to outcomes.

Methods and Analysis

This cluster randomised controlled trial will be conducted in 22 primary schools in disadvantaged areas of Melbourne, Australia. 826 students in the first year of primary school will be recruited to detect between groups differences of Cohen’s d=0.25 at the 18-month follow-up.

Parent, teacher and child-assessment measures of child attention, emotion-regulation, executive functioning, socio-emotional well-being, mental health-related behaviour and learning, parent mental well-being, teacher well-being will be collected 6- and 18-months post-randomisation. Implementation factors will be measured throughout the study.

Intention-to-treat analyses, accounting for clustering within schools and classes, will adopt a two-level random effects linear regression model to examine outcomes for the intervention versus control students. Unadjusted and analyses adjusted for baseline scores, baseline age, gender and family socio-economic status will be conducted.
Ethics and Dissemination: Ethics approval has been received by the Human Research Ethics Committee at the University of Melbourne. Findings will be reported in peer-review publications, national and international conference presentations and research snapshots directly provided to participating schools and families.

STRENGTHS AND LIMITATIONS

- Provide the first efficacy trial findings for a whole-class mindfulness intervention delivered across the first two years of primary school, with embedded process and economic evaluations
- Large population-based sample, specifically targeting schools in disadvantage areas of Melbourne, Australia
- Use of multi-informant and blinded outcome measures consisting of child, parent and teacher-reported measures across multiple domains proposed to change through a mindfulness intervention
- Unable to determine potential biological benefits (i.e. reduced stressed related cortisol) of the intervention
INTRODUCTION

The first years of school are critical for establishing firm foundations for positive child social, psychological and academic development. Children’s ability to regulate their attention, emotions, and behaviour, and to follow classroom instructions during this period predicts school adjustment, participation and success. Similar to other countries, data from the Australian Early Development Census (AEDC) found that 22.4% of children commence school developmentally vulnerable. These vulnerabilities are highest in regards to (commonly relate to) behavioural and emotional difficulties, with children in disadvantaged areas three times more likely to experience these difficulties. Children who transition poorly into school are at increased risk for a host of detrimental outcomes, including behavioural and emotional problems, poor peer and teacher relationships, and low academic performance. These difficulties can persist throughout their schooling years and impact upon long-term educational, economic, social, physical and mental health outcomes. Thus, identifying evidence-based approaches to help children develop attention and emotional regulation skills is critical in proactively supporting children’s mental health and academic performance.

Contemplative practices such as mindfulness, has rapidly gained popularity in both practice and research and has potential to be used in classrooms to help children transition to school and to support ongoing learning. Mindfulness is broadly defined as the awareness that arises from paying purposeful attention to the present moment, non-judgmentally, with acceptance or curiosity. Numerous mindfulness-based programs have been developed for children and adults to build attention, self-monitoring, self-regulation, and mental flexibility. Such programs propose that individuals can become more ‘mindful’ by learning and practicing mindful skills and activities.

The interest in mindfulness-based interventions has been matched with studies, reviews, and meta-analyses examining the effectiveness of these interventions. Studies find that interventions can have positive effects on attention, executive functioning, social behaviour and mindfulness in children and adults. However, reviews have also raised numerous concerns. Comparison groups are often weak or non-existent, selective samples are used, measures rely predominantly on self-report, methods are inconsistent (making it difficult to directly compare study effects), and programs are often poorly defined and vary in their components, resulting in programs that are often quite different. Only a limited number of rigorous randomised control
trials (RCTs) have examined the impact of mindfulness interventions using objective outcome measures assessed over time. Further, systematic reviews have identified very few studies that have been conducted with children under 8 years,\textsuperscript{13, 14} and to our knowledge, no large-scale rigorous studies exist at the early primary school level.

Even for the school-based interventions with stronger evidence, it is unknown whether their effectiveness can be maintained when implemented at large scale. Many mindfulness programs involve the use of electronic/smart devices (e.g., audio recorded instructions), which the teacher is expected to facilitate/lead, and children are expected to engage in. Little emphasis is given to equipping teachers with the theoretical and practical knowledge underlying the activities, or on providing strategies for incorporating mindfulness into their day-to-day teaching practices. Yet teacher pedagogy and student-teacher relationships are critical for learning.\textsuperscript{27} For instance/example, a recent mindfulness intervention study following children from preschool to school suggested that observed executive functioning and later vocabulary and literacy benefits only emerged when teachers embedded these skills within their usual classroom practices over a long period of time, well beyond the standard 8-12-week period of most mindfulness interventions.\textsuperscript{28}

Given the complexity of implementing interventions in schools,\textsuperscript{29} it is also important to understand the quality, fidelity and dosage of the mindfulness intervention that children are exposed to, especially when promising interventions are implemented at scale.\textsuperscript{30-32} When mindfulness programs are poorly implemented or taught without appropriate theoretical and practical training, a range of unintended and adverse consequences can occur.\textsuperscript{15} Further, it is critical to determine the financial and time costs required to achieve positive outcomes, to ensure that limited time and resources schools have available are well spent. There are clear gaps between the levels of interest, evidence and investment in mindfulness-based interventions and best practices for doing so. Addressing these gaps will have both national and international implications for the use of mindfulness intervention within early primary school classrooms.

Addressing the lack of empirically based mindfulness programs for early years education, the intervention used in this study directly trains teachers on mindfulness theory and practice and provides a structured approach for embedding mindfulness activities into everyday teaching practices to improve student outcomes. Initial support for the intervention was established through a pilot RCT involving 109 children from 6 classrooms in 4 preschool centres in disadvantaged
areas of Melbourne, Australia. Preliminary data at immediate post-intervention, indicated
intervention children had better immediate attention/short term memory (measured via the Corsi
Block-tapping task, effect size Cohen’s $d=0.29$; Digit Span Forward task, $d=0.24$), behaviour
regulation (measured via Less is More, $d=0.34$), and mental health-related behaviours (measured
via the Teacher Strengths and Difficulties Questionnaire - Externalizing, $d=0.45$), compared to
control children. Qualitative data demonstrated that teachers believed that the program was
effective for themselves, their children and their colleagues, and reported parents wanted to know
more about the program and the activities. They also continued to embed mindfulness into their
classroom after the program finished.

The current study uses a rigorous RCT cluster design to build on these promising findings
to examine whether the same intervention remains effective when implemented within early
primary school classrooms at larger scale. We will provide an in-depth examination of child,
teacher and school level factors that promote and reduce the intervention’s success. We will also
consider the costs and economic benefits of the intervention. We hypothesize that the intervention
will be associated with:

5. Improvements in child immediate attention/short-term memory assessed via blinded direct
assessment 18-months post randomization (primary outcome).
6. Improvements in executive functioning measured via blinded direct assessment of
inhibition, working memory, and cognitive flexibility, 18 months post-randomization.
7. Improved socio-emotional wellbeing, emotion-regulation, and mental health-related
behaviours, reported by parents and teachers, 6- and 18-months post randomization.
8. Sustained changes in teacher practice and classroom interactions assessed via blinded
observations at 18-months post randomization.

Furthermore, we hypothesize that the quality and dosage of implementation will predict the
efficacy of the intervention, and the intervention will be cost effective relative to outcomes.

METHODS

Pre-registration

The study is registered with the Australian New Zealand Clinical Trials Registry
(ACTRN12619000326190).
Patient and Public Involvement
No patient involved

Design
This is a cluster RCT with an embedded process and economic evaluation (see Figure 1). This will inform the benefits of the intervention compared to current practice, identify for whom and under what conditions the intervention is beneficial, and provide an indication of the cost-benefits of the intervention. Results will be reported per the CONSORT guidelines for non-pharmacologic interventions.33

Participants
All Foundation children (i.e., the first year of primary school, ages 5-6) at participating schools with parental consent will be invited to participate in the data collection, provided the child and parents have sufficient English language abilities to complete the measures. Although this will affect generalizability, most measures have not been validated for other languages. Children without consent will still be exposed to the intervention as part of their school’s wellbeing approach but not complete the measures.

Sample size
The estimated sample size across all stages of the study are shown in Figure 2.
Given the hypotheses of the trial and measures collected in our pilot study as well as in published meta-analyses,13,14 we anchored our sample size calculations on detection of a minimum effect size of 0.25 standard deviations (SD) between the treatment and control groups at 18-months post-randomization in a two-arm parallel trial with 80% power and a two-tailed 5% Type I error. The sample size applies across all measures collected at 18-months post randomization, based on the number of SDs rather than on the actual outcome distributions.
To account for the clustering effect within classes (ICC=0.02) and schools (ICC=0.02), and an attrition rate of 20% by the end of the study, our planned sample size is 413 children per condition (826 total). To achieve this, we estimate we will recruit 22 schools to participate (11 per condition). This assumes an average of 2.5 Foundation Year classes at each school, and 65% of parents providing consent for data collection (16 per class, 40 per school). The final number of
schools will be dependent on student population, the number of classes within each school and class size of the recruited schools.

**School selection and recruitment**

Primary schools from metropolitan Melbourne, Australia, with disadvantaged student populations will be recruited. This will be determined by approaching schools with a high proportion of children starting primary school developmentally vulnerable in ‘emotional maturity’ and ‘social competence’ domains as defined by the AEDC. The AEDC is a national census completed every three years by classroom teachers for children in the first year of primary school, including 2015 and 2018. Data are available for >98% of Australian children during data collection years. Therefore, the AEDC provides accurate estimates of the number of children with developmental vulnerabilities for at each school. Where AEDC data are not available, other government or administrative datasets that measure school disadvantage will be used to select eligible schools.

The school recruitment approach is similar to those used in previous school-based longitudinal studies and intervention trials conducted by members of the research team. Australian schools are clustered into three sectors: Government (69%), Catholic (19.2%), and Independent (11.8%). To balance representation with study time and resources, we will include government and Catholic schools.

Although DET and CEM have provided approval for research within schools, each school’s leadership has independent responsibility to approve which projects they choose their schools to participate in. Drawing on the DET and CEM network of schools, we will first present our study at each area’s school leadership network meetings or similar engagement event, providing background on the study and an overview of what would be expected of the school, teachers, parents, and children. Principals will be able to indicate interest in participating in the study without fully committing. By doing this, we limit the burden of approaching schools in which school leadership do not wish to participate. If a enough schools’ express interest, we will proceed with selection and randomization. Based on our prior experiences working with primary schools in the region, we estimate that 87 (75%) will express interest in being a part of the study, with the main reason for declining being time commitments and participation in other research projects. If
additional schools are needed, we will directly contact remaining schools in the area until the number of required schools has been achieved.

Recruitment will be stratified by school sector type to ensure a representative sample from both sectors. Of those selected, we will approach the school’s principal to ascertain their consent to participate (see Supplementary File 1). If the principal declines, we will contact the next randomly selected school on the list, repeating until we reach the required sample size.

We will then meet with all Foundation and Grade 1 teachers at participating schools to describe the purpose and requirements of the project, expected time commitments, and recruitment process and answer any questions they may have. The teachers will be provided with an information sheet detailing their expected involvement, a consent form (see Supplementary File 2), and a brief survey.

**Student recruitment and consent**

Before we begin student recruitment at each school, we will work with each school to publicise the trial, raising parental awareness and interest in the study through notifications in school newsletters, posters on classroom doors and sending advance-notice postcards to the homes of eligible children. Teachers will then send a recruitment pack to each family. The pack will contain an information sheet detailing the study, a consent form (see Supplementary File 3), a brief survey and an envelope. Parents will be asked to return the completed consent forms and survey in the sealed envelope to a secure box in the child’s classroom.

Consent for the study will be specific to the data collection. Because the intervention focuses on embedding simple play-based activities into teachers’ daily practice and classrooms, it would be unethical and impractical to have children without consent be removed from the classroom, when teachers are implementing the mindfulness-based activities and games. Children are commonly/frequently exposed to similar changes in teacher practice following teacher professional development (PD) or when teachers make explicit decisions to implement a new pedagogical approach or wellbeing curriculum in their classroom.

**Randomization**

After the parent and teacher surveys have been completed, schools, stratified by school sector, will be randomized to control or intervention in block sizes ranging from two to four. To
reduce the potential for contamination effects, the randomization will be conducted by a researcher independent of the study team, and group allocation will be concealed from research team members involved in the direct outcome assessments. All intervention schools will complete a Memorandum of Understanding, agreeing not to share the intervention resources with control schools, and control schools will not have access to the intervention training or manual.

**Mindfulness Intervention**

Training and troubleshooting support for the mindfulness intervention will be provided by the program developer. Children will be exposed to the intervention across two consecutive academic school years, Foundation and Grade 1.

For intervention schools, Foundation and Grade 1 teachers will attend one PD day in 2020 and 2021 respectively, which will provide the theoretical and practical foundations of the program and instructions for implementing the program. Teachers will be provided with an implementation manual (available by request), which includes a schedule of activities, lesson plans, communication templates/examples, sample activities, parent homework sheets, audio/music and film suggestions, and training slides. Participants will review the materials, watch examples, practice a selection of activities, and will be able to ask questions to ensure clear understanding of the program and implementation.

Following the PD, the teachers will be expected to embed the 12-week intervention into their classrooms, using the manual to help them to learn, practice, incorporate, and reflect on the activities and strategies. The mindfulness program involves three core practice components, (i) mindful games/activities; (ii) mindful routines/transitions/moments; and (iii) use of props/books/music/art, which can be used within the classroom and integrated with normal teaching activities. For each week, it is recommended that teachers:

1. Engage in two mindfulness activities per day at least four times per week, utilizing suggested props, games, or art/music, and trying to anchor these around key routines or transition periods during the day (e.g., on classroom arrival/departure, after lunch/recess, before a test/specialist class, snack or mealtimes, moving between classrooms).
2. Read suggested storybooks each week and discuss with children possible connections to mindfulness and related skills/concepts. The manual includes a list of popular children's
storybooks (commonly available in schools or easily accessed) with guidance for discussion.

3. Identify and embed spontaneous ‘mindful moments’ into their daily classroom routines, transitions and class time, such as using ‘slow motion’ walking to the library, or watching rain drops race down classroom window.

Teachers will also be asked to establish, if possible, a ‘Mindful Space’ in the classroom to provide an ongoing reminder and/or display of mindfulness tools, while also creating a place for children to engage in mindful activities during class time. The space may include a variety of mindful props (e.g., mind jar), games (e.g., rock balancing), activities (e.g., mindful drawing), and storybooks. Intervention schools will be provided with all required props, books, games and other resources (e.g., door/wall posters) to implement the key elements of the program.

Throughout the 12-week program, teachers will also be encouraged to:

1. Discuss the intervention’s implementation during their team’s regular meetings, led by participating teachers, to reflect on the intervention’s progress, implementation, and support needs, providing peer support and a shared commitment to the program. In Year 2 of the study, Foundation teachers will continue to participate in these meetings, providing their own reflections and experiences to the Grade 1 teachers, potentially aiding sustainability through a train-the-trainer type approach.

2. Contact the research team for additional implementation support, trouble shooting, or advice/coaching, if required

3. Share examples of mindful activities, artwork and discussions with parents, enabling connections and modelling between school, home, and ongoing support.

Following the 12-week intervention, we will conduct a 1-hour meeting with teachers to allow reflection on learnings from the past 12 weeks and to help develop an ongoing implementation plan if they chose.

**Outcome data collection and research assistant blinding**

Outcome assessments will be conducted 6 (end of Foundation for the children) and 18 months (end of Grade 1) post randomization. At each occasion, parents and teachers will be asked to complete surveys. Children will complete face-to-face direct assessments at baseline and 18
months post randomization during school hours by trained research assistants blinded to the school’s group allocation.

**Measures**

Measures are summarized in Table 1, which have chosen to attempt to measure proximal and distal outcomes that align with our intervention’s theory of change, which have been informed by our pilot findings and existing systematic reviews.\textsuperscript{13, 14, 17}

The primary outcome is labelled as child visuo-spatial short-term memory, as measured by the Corsi Block Tapping Forward Raw Score at 18-months post-randomization.\textsuperscript{41} We have referred to this as short-term memory, however, previous psychological and cognitive sciences research have also used forward block span as a measure of immediate attention (the same applies for Digit Span Forwards and verbal short-term memory), with such terms often used somewhat interchangeably. Other research highlights difficulties in separating short term memory and immediate attention conceptually and experimentally, hence they strongly overlap.\textsuperscript{42, 43}

The study includes secondary outcomes across multiple domains. Examining multiple outcomes aligns with the UK Medical Research Council guidelines for interventions that are complex in nature and likely to result in possible impact across a diversity of domains.\textsuperscript{44} It is particularly important that sufficient data are measured to enable comparability across mindfulness-based school programmes, as programmes frequently vary in their content, setting and target population. Because of the wide variety of measures, while each outcome will be analysed individually, findings and interpretations will consider the consensus of evidence for the data provided. This will involve careful examination and consideration of the magnitude, direction and statistical significance of the responsiveness estimated for each outcome. Due to the increased potential for false-positive findings arising through analysis of multiple outcomes, patterns will be interpreted cautiously and in context with one another, rather than in isolation.

**Process evaluation**

The implementation and process evaluation will use a mixed-methods approach, drawing on data collected via teacher surveys and teacher interviews. It will explore the intervention’s theory of change and the extent to which the dimensions of implementation impact the program’s effectiveness, as well as the enablers and barriers to its implementation.\textsuperscript{29} Fidelity, quality and
adaptation of the intervention’s activities over the 12-week manualised implementation will be examined via fortnightly surveys completed by intervention teachers. Sustainability, enablers and barriers of the intervention will be examined via teacher interviews and surveys at 6- and 18-month post-randomization. Factors will be examined at the student, teacher and school levels where appropriate.

The wellbeing practices of the control schools will also be examined to document any practice similarities (i.e., the presence of mindfulness practices/elements or other social-emotional learning [SEL] programs) and differences (e.g., the use of mindfulness audio-recorded sessions versus pedagogy-based approaches) when compared to our intervention.

**Economic Evaluation**

Costs associated with the intervention training and delivery will be prospectively and retrospectively recorded, including costs for delivery, material/prop resources required by the schools, and time spent on the program. Resources used in training and ongoing support will be prospectively recorded by the research team, and all intervention teachers will prospectively record time and resources used in intervention delivery and report these through the process evaluation. Teacher surveys will include retrospective report from control teachers of time and resources used on SEL related activities.

Using surveys, teachers in intervention and control schools will retrospectively report in-school additional support at 3 and 18-months post-randomization, and at each time point parents will recall out-of-school health and education service use over the previous year.

Resource use will be presented in natural units as well as valued in 2021 Australian dollars using local (state) and national unit cost estimates (e.g., education department salary scales, Medicare Benefits Schedule). Costs will be presented as costs per student from a government payer perspective.

Analyses will involve: (i) a cost-consequences analysis, which will compare incremental costs of the intervention (costs accrued in the intervention arm, from intervention and resource use over the period of follow-up, compared to costs accrued in the control arm) to all primary and secondary outcomes, expressed in their natural units of measurement; and (ii) cost-effectiveness, assessed against the primary outcome measure and presented as cost per point change in child attention. Impact of missing data will be assessed through multiple imputation (described below).
Statistical Analysis

All participants and school demographic and baseline continuous outcomes will be presented as mean and SD (or medians and interquartile ranges for skewed data), whilst categorical outcomes will be presented as absolute and relative frequencies by group. Statistical analysis will follow standard methods for cluster randomized trials and the primary analysis will be by intention to treat. Multiple imputation will be conducted separately in the two arms using chained equations applied to all outcomes simultaneously, including baseline measures as auxiliary variables. Fifty imputed datasets will be generated. All analyses will be conducted using Stata.

The primary outcome is student visual-spatial short-term memory/immediate attention at 18 months post-randomization. The effect of the intervention on the Corsi Block Tapping Forward raw score at 18 months compared to control children will be examined adopting a linear mixed model, which will include the stratification factor used during randomization (school sector) as a fixed effect term and two random effect terms (school and class) to account for the clustering structure of the data. The effect of intervention on the primary outcome at 18 months will then be adjusted by the student baseline Corsi Block Tapping Forward score, age at baseline, gender, family socio-economic status and child IQ, which will be included in the above model as fixed effect terms.

For all the outcomes collected at 18 months, the effect of the intervention will be estimated using generalized linear mixed models (linear or logistic according to the nature of the outcome), which will include control variables (i.e., school sector, the corresponding outcome measure at baseline, age at baseline, gender, family socio-economic status, child IQ and time of assessment) as fixed effect terms and the same random effect terms mentioned above. For outcomes collected at 6-months and at 18-months, the same generalized linear mixed models described above will be adopted, with the addition of a third random effect term (i.e., student), to account for the repeated measures over time (the nature of the outcome), which will include control variables as fixed effect terms and the same random effect terms mentioned above with the addition of a third random effect term (i.e., student), to account for the repeated measures within children.

ETHICS AND DISSEMINATION
Ethics approval was obtained from the Human Research Ethics Committee at the University of Melbourne (Ethics ID: 1853492), Australia, and approval for the study was provided by the Victorian Department of Education and Training (DET) and Catholic Education Melbourne (CEM). Active written consent will be provided by each child’s parent/caregiver, whilst all participating teachers will provide active written consent.

Once the study is completed, we will publish our findings in international peer-reviewed child health journals and present at national and international conferences. In addition, we will send participating schools and parents a short report of our findings. A copy of the report will also be sent to relevant government departments.

- **Annual school and parent newsletter**: To maintain engagement throughout the study, we will send annual newsletters to all participating schools and families that will provide a progress update, and summary of any new findings which have been published.

- **A participating school seminar**: Recognising the time and resource contributed by participating schools, it is important findings are presented to schools in a timely manner. We will hold, and record, a half-day seminar at the primary institution within 6 months of the study’s completion to present findings and enable dialogue about implications.
REFERENCES


Table 1: Description of measures and timepoints

<table>
<thead>
<tr>
<th>Measure</th>
<th>Domain</th>
<th>Scoring description</th>
<th>Method of assessment</th>
<th>Baseline</th>
<th>Intervention</th>
<th>6-mth</th>
<th>18-mth</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Primary Outcome</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Corsi Block Forward Tapping Task$^{41}$</td>
<td>Visuo-spatial short-term memory/Immediate attention</td>
<td>Raw scores for longest recall span will be used to determine visual short-term memory / immediate attention</td>
<td>Child Assessment</td>
<td>●</td>
<td></td>
<td>●</td>
<td>●</td>
</tr>
<tr>
<td>Digit Span Forward$^{41}$</td>
<td>Verbal immediate attention/Short term memory</td>
<td>Raw scores for longest recall span will be used to determine verbal immediate attention</td>
<td>Child Assessment</td>
<td>●</td>
<td></td>
<td>●</td>
<td>●</td>
</tr>
<tr>
<td>Corsi Block Backward Tapping Task$^{41}$</td>
<td>Visuo-spatial working memory</td>
<td>Use of raw scores, indicating longest backward recall span</td>
<td>Child Assessment</td>
<td>●</td>
<td></td>
<td>●</td>
<td>●</td>
</tr>
<tr>
<td>Digit Span Backwards$^{41}$</td>
<td>Verbal working memory</td>
<td>Use of raw scores, indicating longest backward recall span</td>
<td>Child Assessment</td>
<td>●</td>
<td></td>
<td>●</td>
<td>●</td>
</tr>
<tr>
<td>NIH Toolbox, Flanker Inhibitory Control and Attention Test$^{46}$</td>
<td>Inhibitory control, Attention</td>
<td>Raw scores range from 0 – 10, with standard scores mean = 100 (SD = 15) used in reporting</td>
<td>Child Assessment</td>
<td>●</td>
<td></td>
<td>●</td>
<td>●</td>
</tr>
<tr>
<td>NIH Toolbox, Dimensional Change Card Sort</td>
<td>Cognitive flexibility</td>
<td>Raw scores</td>
<td>Child Assessment</td>
<td>●</td>
<td></td>
<td>●</td>
<td>●</td>
</tr>
<tr>
<td>Sustained Attention to Response Task</td>
<td>Sustained attention</td>
<td>Standard scores mean = 100 (SD = 15)</td>
<td>Child Assessment</td>
<td>●</td>
<td></td>
<td>●</td>
<td>●</td>
</tr>
<tr>
<td>Strengths and Difficulties Questionnaire (SDQ)$^{47}$</td>
<td>Child mental-health related behaviour</td>
<td>A 25-item validated measure for children aged 4 to 16 years; with higher scores representing higher levels of behaviour/mental health difficulties. Measure reports subscales for internalizing difficulties (5 items), externalizing difficulties (10 items) and Total Difficulties (20 items).</td>
<td>Parent and teacher survey</td>
<td>●</td>
<td></td>
<td>●</td>
<td>●</td>
</tr>
<tr>
<td>Affective Reactivity Index</td>
<td>Emotion-regulation</td>
<td>A 7-item measure, with a range of 0 – 14, with higher scores representing greater irritability.</td>
<td>Parent</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>---------------------------</td>
<td>-------------------</td>
<td>------------------------------------------------------------------------------------------------</td>
<td>--------</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Childhood Executive Functioning Inventory (CHEXI)</td>
<td>Executive Functioning Behaviour</td>
<td>A 24-item measure validated for children aged 4 to 12 years. Each item is scored 1 – 5, with higher scores representing greater difficulties. It yields 2 subscales: Inhibition (11-items) and working memory (13-items).</td>
<td>Parent and teacher survey</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ECLS-K Approaches to Learning</td>
<td>Learning Behaviour</td>
<td>A 6-item subscale from the Social Rating Scale used in Early Childhood Longitudinal Study-Kindergarten (ECLS-K). Items were designed to assess various aspects of a child’s approach to learning, such as organization, working independently and task completion. The possible score range was 1 - 6, with higher scores indicating better approaches to learning.</td>
<td>Teacher survey</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**PARENT**

<table>
<thead>
<tr>
<th>Interpersonal Mindfulness in Parenting (IEM-P)</th>
<th>Mindful parenting, parent-child interaction (4 subscales)</th>
<th>10-item measure, with subscales for awareness and present-centred attention (4 items), non-judgement (3-items) and non-reactivity (3-items).</th>
<th>Parent survey</th>
</tr>
</thead>
<tbody>
<tr>
<td>Short Warwick Edinburgh Mental Well-Being Scale (SWEMWBS)</td>
<td>Mental well-being</td>
<td>7-item scale which yields a single score ranging from 7 to 35, with higher scores representing better well-being</td>
<td>Parents</td>
</tr>
<tr>
<td>Kessler-6 (K-6)</td>
<td>Psychological distress</td>
<td>A 6-item, self-reported and validated measure of mental health distress, with higher scores indicating greater psychological distress.</td>
<td>Parents</td>
</tr>
</tbody>
</table>
### TEACHER

<table>
<thead>
<tr>
<th>Measure</th>
<th>Subscales</th>
<th>Scores</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mindfulness in Teaching (MIT) Scale</td>
<td>Teacher mindfulness</td>
<td>14-item self-report measure, with Teacher Intrapersonal Mindfulness (9-items, range 9 - 45) and Teacher Interpersonal Mindfulness subscales (7-items, range 7 - 35), with higher scores representing more negative outcomes</td>
</tr>
<tr>
<td>Student-Teacher Relationship Scale – Short Form (STRS-SF)</td>
<td>Quality of Student-Teacher Relationships</td>
<td>14-item measure, with possible score range was 28 to 75, with higher scores representing a more positive relationship between the teacher and the child.</td>
</tr>
<tr>
<td>Short Warwick Edinburgh Mental Well-Being Scale (SWEMWBS)</td>
<td>Mental well-being</td>
<td>7-item scale which yields a single score ranging from 7 to 35, with higher scores representing better well-being</td>
</tr>
<tr>
<td>Kessler-6 (K-6)</td>
<td>Psychological distress</td>
<td>A 6-item, self-reported and validated measure of mental health distress, with higher scores indicating greater psychological distress.</td>
</tr>
<tr>
<td>CLASS</td>
<td>Classroom environment/quality, Teacher-Student interactions</td>
<td>Widely used observational tool (1 hr) that assesses dimensions of classroom interactions linked to student achievement and classroom quality (Emotional Support, Classroom Organisation, and Instructional Support)</td>
</tr>
</tbody>
</table>

### CONFOUNDERS

<table>
<thead>
<tr>
<th>Measure</th>
<th>Subscales</th>
<th>Scores</th>
</tr>
</thead>
<tbody>
<tr>
<td>Woodcock Johnson – 3rd Edition</td>
<td>General cognitive/intellectual and non-verbal ability</td>
<td>Standard scores will be used, with mean 100, SD = 15</td>
</tr>
<tr>
<td>Family demographics</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Teacher demographics</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Figures

Figure 1: Graphical representation of key study components

Figure 2: CONSORT participant flow chart – estimated numbers
<table>
<thead>
<tr>
<th>Recruitment</th>
<th>Intervention</th>
<th>Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline assessments</td>
<td>B C D E F</td>
<td></td>
</tr>
<tr>
<td>Randomization</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intervention in Foundation/Grade Prep</td>
<td>G H</td>
<td></td>
</tr>
<tr>
<td>6-month follow-up</td>
<td>B C D</td>
<td>B C D</td>
</tr>
<tr>
<td>End of School Year</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intervention in Grade 1</td>
<td>D G H</td>
<td>D</td>
</tr>
<tr>
<td>18-month follow-up</td>
<td>B C D E I</td>
<td>B C D E I</td>
</tr>
</tbody>
</table>

**Figure key**

- Data collection
- Intervention process/data

**Description of key study activities**

- **A**: Parent information statement and written consent form distributed to all parents of all children in Grade Prep at participating schools
- **B**: Parent survey reporting on child self-regulation, executive functioning and behavior
- **C**: Teacher survey on child executive functioning and behavior
- **D**: Teacher self-report survey on own mental well-being, classroom practice and knowledge and attitude of mindfulness
- **E**: Objective child assessments for Corsi Block Tapping Task, Digit Recall and NIH Flanker
- **F**: Objective child assessment for WJ-III
- **G**: Intervention: Consisting of one day expert professional development, 12 weeks of manualized intervention delivery, fortnightly teacher meetings and online community
- **H**: Process Evaluation Measures, including measures of implementation quality, quantity and fidelity. Teacher interviews to understand implementation barriers and enablers
- **I**: Observation of classroom environment using CLASS Observation Tool.

**Figure 1: Graphical representation of key study components**
Figure 2: CONSORT participant flow chart – estimated numbers
School Consent Form
Melbourne Graduate School of Education

Project: Minds@Play: Understanding the efficacy of integrating mindfulness within teaching practice to improve student outcomes

Responsible Researcher: Dr Jon Quach

Additional Researchers: Prof Janet Clinton, A/Prof Emma Sciberras, A/Prof Lisa Gold, A/Prof Peggy Kern, Ms Francesca Orsini, Dr Ben Deery

Name of School:

Name of Person signing: ____________________________
First name ____________________________ Last name

Role of person signing ____________________________

1. I consent for my school to participate in this project, the details of which have been explained to me, and I have been provided with a written plain language statement to keep.

2. I understand that the purpose of this research is to investigate whether a teacher-led mindfulness intervention can improve student outcomes.

3. I understand that my participation in this project is for research purposes only.

4. I acknowledge that the possible effects of participating in this research project have been explained to my satisfaction.

5. In this project the school will be required to:
   a. Allow teachers to (i) attend the intervention training (if required), (ii) implement the intervention activities (if required) and (iii) complete surveys about students and themselves
   b. Provide a suitable area to conduct the student data collection assessments

6. I understand that my school’s participation is voluntary and that I am free to withdraw from this project anytime without explanation or prejudice and to withdraw any unprocessed data that I have provided.

7. I understand that the data from this research will be stored at the University of Melbourne and will be destroyed after the youngest participant turns 25 years of age.

8. I have been informed that the confidentiality of the information I provide will be safeguarded subject to any legal requirements; my school’s data will be password protected and accessible only by the named researchers.

9. I understand the de-identified research data may be used in future research closely related or in the same general area of research, if the opportunity arises

10. I understand that after I sign and return this consent form, it will be retained by the researcher.

Participant Signature: ____________________________ Date: ____________________________
Teacher Consent Form
Melbourne Graduate School of Education

Project: Minds@Play: Understanding the efficacy of integrating mindfulness within teaching practice to improve student outcomes

Responsible Researcher: Dr Jon Quach

Additional Researchers: Prof Janet Clinton, A/Prof Emma Sciberras, A/Prof Lisa Gold, A/Prof Peggy Kern, Ms Francesca Orsini, Dr Ben Deery

Name of Participant: __________________________________________________________________________

First name __________________________ Last name __________________________________________________________________________

1. I consent for me to take part in this project, the details of which have been explained to me, and I have been provided with a written plain language statement to keep.

2. I understand that the purpose of this research is to investigate whether a teacher-led mindfulness intervention can improve student outcomes.

3. I understand that my participation in this project is for research purposes only.

4. I acknowledge that the possible effects of participating in this research project have been explained to my satisfaction.

5. In this project I will be required to complete surveys about my student’s and my own well-being.

6. I understand that my participation is voluntary and that I am free to withdraw from this project anytime without explanation or prejudice and to withdraw any unprocessed data that I have provided.

7. I understand that the data from this research will be stored at the University of Melbourne and will be destroyed after the youngest child turns 25 years of age.

8. I have been informed that the confidentiality of the information I provide will be safeguarded subject to any legal requirements; my data will be password protected and accessible only by the named researchers.

9. I understand that after I sign and return this consent form, it will be retained by the researcher.

OPTIONAL CONSENT

☐ I do ☐ I do not

I give permission for the de-identified research data to be used in future research closely related or in the same general area of research, if the opportunity arises

Participant Signature: __________________________________________________________________________ Date: __________
Parent/Guardian Consent Form

Melbourne Graduate School of Education

Project: Minds@Play: Understanding the efficacy of integrating mindfulness within teaching practice to improve student outcomes

Responsible Researcher: Dr Jon Quach

Additional Researchers: Prof Janet Clinton, A/Prof Emma Sciberras, A/Prof Lisa Gold, A/Prof Peggy Kern, Ms Francesca Orsini, Dr Ben Deery

Name of Parent/Guardian:

First name

Last name

Name of Child:

First name

Last name

1. I consent for me and my child to take part in this project, the details of which have been explained to me, and I have been provided with a written plain language statement to keep.

2. I understand that the purpose of this research is to investigate whether a teacher-led mindfulness intervention can improve student outcomes

3. I understand that my participation in this project is for research purposes only.

4. I acknowledge that the possible effects of participating in this research project have been explained to my satisfaction.

5. In this project I will be required to complete surveys about my child’s and my own well-being, and that my child will participate in face-to-face activities conducted at their school at each data collection period

6. I understand that my participation is voluntary and that I am free to withdraw from this project anytime without explanation or prejudice and to withdraw any unprocessed data that I have provided.

7. I understand that the data from this research will be stored at the University of Melbourne and will be destroyed after the youngest child turns 25 years of age.

8. I have been informed that the confidentiality of the information I provide will be safeguarded subject to any legal requirements; my data will be password protected and accessible only by the named researchers.

9. I understand that after I sign and return this consent form, it will be retained by the researcher.

OPTIONAL CONSENT

☐ I do ☐ I do not
I give permission to the Victorian Department of Education and Training to release my child’s School Entry Health Questionnaire results to the research team

☐ I do ☐ I do not
I give permission to the Victorian Department of Education and Training to release my child’s English Online results to the research team

☐ I do ☐ I do not
I give permission to the Victorian Curriculum and Assessment Authority to release my child’s Grade 3 NAPLAN results to the research team.

☐ I do ☐ I do not
I give permission for the de-identified research data to be used in future research closely related or in the same general area of research, if the opportunity arises

Participant Signature: ____________________________ Date: ____________
<table>
<thead>
<tr>
<th>Section/item</th>
<th>Item No</th>
<th>Description</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Administrative information</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Title</td>
<td>1</td>
<td>Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym</td>
<td>1</td>
</tr>
<tr>
<td>Trial registration</td>
<td>2a</td>
<td>Trial identifier and registry name. If not yet registered, name of intended registry</td>
<td>7</td>
</tr>
<tr>
<td></td>
<td>2b</td>
<td>All items from the World Health Organization Trial Registration Data Set</td>
<td></td>
</tr>
<tr>
<td>Protocol version</td>
<td>3</td>
<td>Date and version identifier</td>
<td>1</td>
</tr>
<tr>
<td>Funding</td>
<td>4</td>
<td>Sources and types of financial, material, and other support</td>
<td>2</td>
</tr>
<tr>
<td>Roles and responsibilities</td>
<td>5a</td>
<td>Names, affiliations, and roles of protocol contributors</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>5b</td>
<td>Name and contact information for the trial sponsor</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>5c</td>
<td>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</td>
<td>NA</td>
</tr>
<tr>
<td></td>
<td>5d</td>
<td>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)</td>
<td>NA</td>
</tr>
<tr>
<td><strong>Introduction</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Background and rationale</td>
<td>6a</td>
<td>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</td>
<td>7</td>
</tr>
<tr>
<td></td>
<td>6b</td>
<td>Explanation for choice of comparators</td>
<td>11</td>
</tr>
<tr>
<td>Objectives</td>
<td>7</td>
<td>Specific objectives or hypotheses</td>
<td>7</td>
</tr>
</tbody>
</table>
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, noninferiority, exploratory)

Methods: Participants, interventions, and outcomes

Study setting  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

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

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)

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

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:
<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sequence generation</strong></td>
<td>16a</td>
</tr>
<tr>
<td>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.</td>
<td></td>
</tr>
<tr>
<td><strong>Allocation concealment mechanism</strong></td>
<td>16b</td>
</tr>
<tr>
<td>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.</td>
<td></td>
</tr>
<tr>
<td><strong>Implementation</strong></td>
<td>16c</td>
</tr>
<tr>
<td>Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions.</td>
<td></td>
</tr>
<tr>
<td><strong>Blinding (masking)</strong></td>
<td>17a</td>
</tr>
<tr>
<td>Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how.</td>
<td></td>
</tr>
<tr>
<td><strong>Blinding (masking)</strong></td>
<td>17b</td>
</tr>
<tr>
<td>If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant’s allocated intervention during the trial.</td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Data collection methods</strong></td>
<td>18a</td>
</tr>
<tr>
<td>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.</td>
<td></td>
</tr>
<tr>
<td><strong>Data management</strong></td>
<td>18b</td>
</tr>
<tr>
<td>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.</td>
<td></td>
</tr>
<tr>
<td><strong>Data management</strong></td>
<td>19</td>
</tr>
<tr>
<td>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.</td>
<td></td>
</tr>
<tr>
<td><strong>Statistical methods</strong></td>
<td>20a</td>
</tr>
<tr>
<td>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.</td>
<td></td>
</tr>
<tr>
<td><strong>Statistical methods</strong></td>
<td>20b</td>
</tr>
<tr>
<td>Methods for any additional analyses (eg, subgroup and adjusted analyses).</td>
<td></td>
</tr>
</tbody>
</table>
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 21a 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

21b 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 22 Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct

Auditing 23 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 24 Plans for seeking research ethics committee/institutional review board (REC/IRB) approval

Protocol amendments 25 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 26a Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)

26b Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable

Confidentiality 27 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 28 Financial and other competing interests for principal investigators for the overall trial and each study site

Access to data 29 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 30 Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation

Dissemination policy 31a Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions

31b Authorship eligibility guidelines and any intended use of professional writers

31c Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code

Appendices

Informed consent materials 32 Model consent form and other related documentation given to participants and authorised surrogates

Biological specimens 33 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

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons “Attribution-NonCommercial-NoDerivs 3.0 Unported” license.