

BMJ Open Sleep well – be well study: improving school transition by improving child sleep: a translational randomised trial

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ABSTRACT

Introduction: The transition to primary school appears crucial for a child's future academic and psychological well-being. Addressing conditions which negatively affect children during this period, such as poor sleep, may improve these outcomes. Sleep problems are common and in a previous efficacy randomised controlled trial, we demonstrated that sleep problems can be identified and improved using school-based screening followed by a brief behavioural intervention. This trial will determine whether the same intervention is beneficial and cost-effective when delivered by an existing school-based health workforce.

Methods/design: We will recruit 334 children with sleep problems from approximately 40 schools after screening for behavioural sleep problems in the first year of formal education (Grade Prep). Schools in Melbourne, Australia will be invited to participate from a randomly ordered list of eligible schools and we will approach all caregivers of Grade Prep children. Children who have a parent-reported moderate or severe sleep problem will be randomised into either 'usual care' or 'intervention' groups. Trained nurses from the Primary School Nursing programme will deliver the sleep intervention programme. *Intervention:* Two to three contacts between the nurse and the parent; initial 45 min face-to-face meeting or phone call, 15 min phone call 2 weeks later and an optional second 30 min face-to-face meeting. *Follow-up:* 6 and 12 months postrandomisation using parent and teacher surveys and child face-to-face assessments. *Primary outcome:* child psychosocial functioning at 6 months. *Secondary outcomes:* child psychosocial functioning at 12 months and child sleep, behaviour, working memory, academic achievement and parent mental health at 6 and 12 months. Cost-effectiveness analysis will compare incremental costs to difference in child psychosocial functioning at 6 months.

Registration: International Standard Randomised Controlled Trial Number Register (ISRCTN92448857).

BACKGROUND

The start of school, when a child moves from the preschool environment to formal learning, is a crucial developmental transition.

ARTICLE SUMMARY

Strengths and limitations of this study

- First effectiveness trial to determine whether a brief, behavioural sleep intervention has benefits when delivered by an existing school based health workforce.
- A random sample of schools from a broad range of socioeconomic areas.
- Blinding of teacher and academic outcomes to avoid bias.
- An economic analysis which will inform policy and funding decisions related to the program's value.
- Limited generalisability to non-English speaking families, as school nurses do not have the capacity to deliver the intervention in other languages.
- Sleep problems identified through parent report and not objective measures.

About a quarter of Australian children start school with limitations in 'school readiness' attributes that may make for a poorer school transition.¹ A poor school transition can then lead to lower school achievement scores,² a higher likelihood of not completing high school³ and poor relationships with peers and teachers.^{4 5}

A successful transition to school is not determined solely by the child's academic ability, but also by five core attributes collectively referred to as 'school readiness'.^{1 4 6} These comprise child physical health and well-being, social competence, emotional maturity, language and cognitive skills and approach to learning. These attributes reflect the sum of a child's biology and exposures throughout the infant and preschool years. However, their daily expression—and thus a child's subsequent pathway—can be affected by immediate factors including the child's well-being (eg, insufficient sleep, poor iron intake) and/or family functioning (eg, parent mental health, marital conflict).

Most interventions designed to improve school transition have focused on its early



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determinants in the infant and preschool years. While highly appropriate, these neglect the immediate impact that ongoing daily burdens—such as poor sleep—may impose on a child who is just starting school.^{5–7} Identifying readily remediable threats to a child's functioning in the first 6 months of school could optimise the transition to formal education. One promising possibility is identifying and managing sleep problems, because of their very high prevalence and the fact that many sleep problems can be very readily treated using brief, parent-oriented behavioural interventions.^{8–9}

Up to 40% of children experience problems with sleep during the early years of school,^{10–14} and these problems are associated with significant healthcare costs.¹⁵ The most common sleep problems are behavioural in nature and include problems going to bed, trouble sleeping alone and waking during the night.^{16–18} Children with these problems are more likely to have more social and emotional problems,^{12–14} externalising (eg, hyperactivity) behavioural problems,^{12–14–19} decreased classroom learning motivation and school functioning,^{10–16–17–20–21} poorer memory formation and recall^{22–24} and poorer parent mental health^{19–25}—all crucial to a child's daily school functioning. These outcomes can occur with a reduction of as little as 30 min in total average sleep time at any given age.²⁶

These findings collectively provide a firm rationale for a trial to determine whether systematically identifying and treating sleep problems at school entry improves psychosocial and learning outcomes in children's first year of formal schooling. In other words, if children sleep better, do they adapt better to their new school environment?

Therefore, we conducted an efficacy randomised controlled trial (RCT) from 2008 to 2010 of a brief behavioural intervention for child sleep problems, identified by universal screening, in the first 6 months of school.¹⁸ The 108 new school entrants in this 'efficacy' trial were recruited from 22 schools in Melbourne, Australia, whose parents reported a moderate or severe child sleep problem. The intervention was delivered by research staff to those identified by a simple universal screen and is designed for public health applicability and sustainability within the school system. Parents and children randomised to the intervention group received a standardised yet flexible intervention, tailored to the child's sleep problems and family preferences. The same process of universal screening followed by targeted intervention will be used in this new trial.

Process evaluation in the efficacy study found that overall, intervention parents rated the strategies highly for treating and coping with the child's sleep problem and ease of use. Follow-up of 85% was achieved in each arm (46 children) at 12 months. Outcomes demonstrated that, relative to controls, intervention children's psychosocial health-related quality of life improved at every follow-up time point (3, 6 and 12 months postrandomisation). Children's sleep habits showed a lasting

improvement, while parents' mental health improved but only transiently (effect sizes 0.25, 0.22 and 0.08 at 3, 6 and 12 months, respectively). Fewer intervention children had a moderate/severe sleep problem at 3 months (33% vs 43%, $p=0.2$) and 6 months (25.5% vs 46.8%, $p=0.03$) but not 12 months (32% vs 33%, $p=0.8$). The success of this small-scale efficacy trial pointed to a larger trial to investigate if this intervention would also be effective and cost-effective in the 'real world'. This is the next step in evidence generation and translation.^{27–28}

We will trial school nurses as the professionals delivering the intervention because their existing presence in primary schools would facilitate a sustainable integration of the intervention into existing health systems, if this trial is successful. School nurses are particularly well placed to implement this intervention for school-entry children, but despite their expertise in normal child health and development, they are not trained to address sleep problems. Instead, they usually refer children with sleep problems outside the school system, for example, to outpatient clinics, which typically have long waiting lists. Our approach could increase the proportion of children who access care while reducing waiting times and redirecting flow, so that only more complex cases receive the more costly secondary and tertiary services. It could also systematically upskill the primary care workforce in a common and burdensome problem.

Building on our efficacy trial, we now aim to determine whether the same intervention, delivered by school nurses in their usual settings, can replicate the benefits of the earlier efficacy trial.¹⁷ If cost-effective, we will have produced a process ready for uptake by schools that could be readily incorporated into the existing school health system.

Therefore, in this translational, population-based trial, delivered in the school setting, we aim to determine

1. Whether a brief, behavioural intervention to manage sleep problems in new school entrants improves psychosocial functioning, sleep and a range of secondary outcomes related to successful school functioning.
2. The costs and cost-effectiveness of such an intervention delivered at the population level.

We hypothesise that, compared with the control children at 6 and 12 months post randomisation, a brief child sleep intervention delivered by school nurses in the first year of schooling will

1. (A) Improve child psychosocial functioning (primary outcome: parent-reported PedsQL at 6 months);
 - (B) Decrease the prevalence of child sleep problems (secondary outcome);
 - (C) Improve other secondary outcomes relevant to child functioning, including children's sleep hygiene practices, sleep patterns, behaviour, academic skills, school adjustment and the primary caregiver's mental health.
2. A structured training and education package emphasising brief, standardised behavioural management

strategies will lead to a sustained increase in knowledge, competency and confidence of school nurses in addressing sleep problems in new school entrants.

3. The intervention will be cost-effective.

METHODS/DESIGN

Design

RCT nested in a population-based, cross-sectional survey. Results will be reported according to Consolidated Standards of Reporting Trials guidelines and the extension report of non-pharmacological interventions.²⁹ Figure 1 shows the components of the trial graphically.³⁰

Setting

We will recruit primary schools in the Southern region of metropolitan Melbourne, Australia. The State of Victoria's Department of Education and Early Child Development (DEECD) groups primary schools in metropolitan Melbourne into four regions. The largest is the Southern region, servicing >14 000 new school entrants annually from diverse socioeconomic and cultural backgrounds in more than 300 primary schools. Primary schools in Australia include State (government-operated) schools, covering 68% of new school entrants in 2012, Catholic schools (22%) and other independent schools (10%). For this study, we will recruit Government and Catholic schools as DEECD school nurses service all Government and Catholic schools and only a limited number of independent schools.

Study structure and timing

We will screen for, recruit and manage sleep problems in children in two waves (each 18 months in duration) beginning 1 year apart to capture the preschool to school transition period of two consecutive cohorts of children. Wave 1 spans school Terms 1–2 (February–July) 2013 (Grade Prep; screening and recruitment) to Terms 3–4 (August–December) 2014 (12-month follow-up), while Wave 2 spans 2014 Terms 1–2 (Grade Prep; screening and recruitment) until 2015 Term 3–4. The last year of the study (mid 2015–mid 2016) will be used for analysis and reporting.

School nurse participation

The Victorian Primary School Nursing Program consists of registered nurses funded by DEECD and is available free to families to provide screening and intervention for health and developmental problems. Children are typically referred into the services through the School Entrant Health Questionnaire (SEHQ), which is a broad-brush health screening tool to detect health, behavioural and developmental problems and is completed by >90% of parents of new school entrants.

Each Southern region school nurse (n=approximately 22) will sign an individual Memorandum of Understanding (MOU), agreeing to train and deliver

the intervention programme during the study. Nurses who join the workforce in 2014 will also be asked to sign the MOU. Similar agreements have underpinned many of our previous successful trials with primary care professionals.³¹

School recruitment

We will randomly order schools with ≥ 50 Grade Prep students in 2012 and sequentially invite them to participate in the study. As the school sectors differ in size, we will construct a randomly ordered invitation list of schools for each sector. Each list will be constructed so that each school nurse will attend a similar number of schools in each sector. Approximately 40 schools will be selected overall, with the total from each sector being proportional to the school sector size (approximately 30 Government schools and 10 Catholic schools).

If a school declines, we will approach the next school on the list, until we reach the required number of schools for each sector (ie, Government and Catholic). Each school will be asked to participate in 2013 and 2014. Each school's principal will be asked to approve participation by signing a school participation form. After the first 20 schools have returned the school participation forms, we will assess the balance of schools and sectors within nurses and adjust the balance, if necessary, by choosing the next school in each list to balance the number of schools across nurses.

Child screening and recruitment

Approximately 6 weeks before the nurse is scheduled to visit a school, teachers will display study advertising posters and distribute a primer postcard briefly introducing the study to primary caregivers of Grade Prep children; both of these strategies have been used in our previous school-based trials to boost response. The following week, teachers will distribute the screening survey (two pages, including questions about sleep problems, eligibility criteria and family contact details) and cover letter to parents, who are asked to return the completed survey to a secure deposit box in the classroom within 2 weeks. To boost recruitment and ascertain response rates, teachers will record surveys distributed and returned for their class, and will distribute a reminder survey after 2 weeks to those yet to return a survey. Research assistants will collect the deposit box and score surveys for trial eligibility.

Parents who report that their child has moderate or severe sleep problems will be contacted by a research assistant to explain the trial. We will mail to interested parents an information pack which will include a Participant Information Sheet, two consent forms (one retained for own records) and a baseline survey (10 pages, taking 20 min to complete). The survey will assess child sleep in more detail and address potential confounders and factors associated with child sleep problems and sociodemographic data. To facilitate enrolment and randomisation before the school nurse

Figure 1 Graphical summary of study design.

1. Time point relative to randomisation	2. Intervention	3. Control
Screening		A
Baseline		B C
Randomisation		
2 weeks	D	
4 weeks	E	
6 weeks	F	
Post-intervention	G	
6 months	H I J K	H J K
12 months	H J K	H J K
A	Survey screening for child sleep problems sent through schools to parents of children in Grade Prep.	
B	Families reporting moderate/severe sleep problems who are interested in the RCT are mailed the RCT baseline survey, Participant Information Statement and consent form.	
C	Nurse pre-intervention quiz to assess nurse knowledge about sleep problems in children	
D	A one-on-one intervention session (45 minute duration) is held between school nurse and parent at the child's school or by telephone. In the session, the nurse will cover normal sleep requirements and importance of good sleep hygiene practices; then select with the parent acceptable strategies for their child's specific behavioural sleep problem, drawing on a menu of flexible yet standardised techniques.	
E	The nurse calls the parent at a pre-arranged time for a 15 minute discussion with the parent to consolidate and, if necessary, modify the selected strategies.	
F	An optional 30 minute on-on-one session can be held between the nurse and parent if required.	
G	Nurse post-intervention quiz to assess nurse knowledge about sleep and competency in delivery sleep strategies to families	
H	Study follow-up survey sent to parents to assess primary and secondary outcomes.	
I	Intervention feedback survey sent to all intervention families to assess the usefulness and acceptability of the intervention and its components	
J	Study follow-up survey sent to teachers to assess primary and secondary outcomes.	
K	Direct assessment of child at school to assess secondary outcomes	

visit, those who have not returned the baseline survey will be sent a reminder letter after 1 week, a reminder text message a further 1 week later, and a reminder call a further 1 week after that.

Exclusion criteria

We will exclude families from enrolment in the RCT if: (1) children have major health problems (as assessed by the screening survey); (2) children have symptoms suggestive of obstructive sleep apnoea (OSA; see below) as this sleep problem is not amenable to behavioural sleep intervention or (3) parents have insufficient English proficiency to complete the surveys and participate in the intervention programme. In addition, we will exclude individual children from enrolment in the RCT if they have a sibling that has already been enrolled (if two siblings become eligible at the same time, eg, twins, we will ask parents to select one sibling for inclusion).

Children with suspected OSA (measured by three items from the Child Sleep Habits Questionnaire in the screening survey) will be telephoned by Dr Hiscock or Dr Wake (paediatricians) to determine if they are likely to have sleep apnoea and to ascertain if the child needs follow-up for OSA. Children with symptoms suggestive of OSA will be ineligible for the RCT and will be encouraged by Dr Hiscock/ Dr Wake to follow-up with their family doctor or paediatrician. Those who are deemed not to have symptoms suggestive of OSA will be invited to participate in the trial as per the recruitment process described above.

Randomisation

An independent statistician from the Clinical Epidemiology and Biostatistics Unit (MCRI) will generate a randomisation schedule with the allocation stratified by the school to ensure balance between the intervention and control arms by school. This schedule

will be used by the statistician to randomise children into either trial arm once written, informed consent has been received. Families will be informed of their group allocation by letter. Nurses will be notified of children allocated to the intervention group and will receive an intervention pack personalised for each family. Families randomised to the control group will be notified by letter and will not receive any sleep services from their school nurse. They will, however, be free to access other services for their child's sleep problem and we will measure the use of such services in the follow-up surveys.

Intervention training

Nurses attend two 3 h training sessions over 3 weeks in March 2013. During these sessions, we train nurses in (1) the intervention content including normal child sleep, sleep hygiene (sleep habits) and sleep intervention strategies; (2) how to individualise sleep strategies to families and (3) use of checklists and activities to be practiced. We use evidence-based education strategies such as role play, feedback and modelling practice. A refresher course will be run prior to Wave 2.

Before starting training, school nurses complete a 'pre-quiz' to establish their baseline knowledge, skills and attitudes in relation to child sleep problems and their management. A 'post-quiz' following training will establish changes in knowledge and encourage reflection on and review of the materials; this will be repeated late in 2014, after the nurse has delivered the programme to all intervention children. Their commitment to the new strategies and their readiness to change practice (both important indicators of successful implementation) will also be assessed.³²

Intervention delivery

The school nurse will arrange a 45 min session to provide the intervention to the parent at the child's school at a mutually convenient time. If a time cannot be arranged to meet in person, the nurse will arrange a mutually convenient time to deliver the first session over the telephone. In the session, the nurse will cover education about normal sleep requirements and the importance of good sleep hygiene practices; then acceptable strategies will be selected with the parent for their child's specific behavioural sleep problem, drawing on a menu of flexible yet standardised techniques. Two weeks later, the nurse will make a 15 min phone call to consolidate and, if necessary, modify the selected strategies. If needed, a final 30 min face-to-face appointment will take place a further 2 weeks later for parents who request a more detailed review and revision of their original sleep problem management plan. This process will be closely monitored for process fidelity and early troubleshooting, so that we can be confident in the event of null findings that this reflects the intervention as planned rather than an avoidable process issue. The intervention protocol is designed to mimic the current

system in which school nurses are alerted to contact families if a health problem is identified through the SEHQ.

Follow-up

We will mail follow-up surveys and email secure links to the online versions (25 min to complete survey(s) at each time-point) to all intervention and control group families 6 and 12 months postrandomisation to determine the short-term and long-term changes, as well as any additional help sought for the child's sleep. We will also seek corroborative information about the sleep habits we would expect to change with an effective intervention, for example, time taken for a child to fall asleep (which correlates strongly with the 'gold standard' objective measure of polysomnography³³). In the 6-month survey, intervention group parents will also describe their perceptions of the intervention. Parents will return the survey in a supplied reply-paid envelope. If not returned, a reminder text message (10 days later), reminder survey packs (a further 1 week later) and reminder calls (a further 1 week later) will be made to families to maximise return rates.

At 6 and 12 months postrandomisation, the child's schoolteacher will complete a brief, blinded survey (4 pages, 10 min to complete) about child behaviour, academic achievement and the student-teacher relationship. The survey will be available in hard copy or online. Teachers will be reminded by letter and/or email to complete the survey. Also at 6 and 12 months, a research assistant will conduct a blinded, 1-h face-to-face assessment with the child at their school. This will extend our measured outcomes beyond sleep and psychosocial outcomes to directly assess academic skills and school adjustment. These are closely linked to later school success³⁴ and can be affected by poor sleep.¹⁴

Measures

The measures used throughout the study are summarised in table 1 below. Measures refer to children and are reported by parents unless otherwise specified.

The *primary outcome* is child psychosocial functioning at 6 months postrandomisation as assessed by the PedsQL V.4.0 Psychosocial Health Summary score³⁵ (5-year-old to 7-year-old version, 23 items). The reason for choosing this as our primary outcome is, as our cited literature shows, that poor sleep has longitudinal effects on psychosocial functioning and our own trial suggests that improving sleep has psychosocial benefits that are likely to be important to school functioning. We also measure psychosocial functioning at 12 months.

Experienced research staff at the Centre for Community Child Health will provide measurement training for face-to-face measures. The training will involve familiarisation with the measure's components, how they are administered and scoring. Mock assessments will be conducted to further familiarise the staff in the presence of the trainer. Staff will observe the assessments being used either in a clinic or as part of

Table 1 Study measures by time point

Measure	Screen	RCT enrolment	6 Months	12 Months
<i>Sleep problem</i> : LSAC question, as described above	▲		▲	▲
<i>Psychosocial functioning</i> : PedsQL 4 ⁴¹ (23 items; 5-year-old to 7-year-old version. (1) Parent report and (2) child self-report—researcher administered at 6 and 12 months)		▲	▲	▲
<i>Sleep behaviours</i> : Child Sleep Habits Questionnaire ⁴² (33 items; measure of disorders initiating/maintaining sleep with a clinical cut point for dichotomous analyses)		▲	▲	▲
<i>Sleep timing</i> : usual bed/sleep/wake time on school/non-school nights		▲	▲	▲
<i>Behaviour</i> : Strengths and Difficulties Questionnaire ⁴³ (SDQ, 4–16 years; 25 items; yields hyperactivity/inattention, conduct, emotional, peer-relationships subscale; and total problems scores and clinical cut points)		▲	▲	▲
<i>Parents' mental health</i> : Depression Anxiety Stress Scale ⁴⁴ (21 items; validated measure that has been very acceptable to parents in our community trials)		▲	▲	▲
<i>Quality of life of child</i> : Child Health Utility 9D (CHU-9D), child self-report version; validated measure with nine dimensions, each with five levels; yields worried, sad, pain, tired, annoyed, schoolwork, sleep, daily routine, activities; generates preference-based single scores and quality-adjusted life years (QALYs)			▲	▲
<i>Quality of life of parent</i> : EuroQol 5D (EQ-5D-5 L), parent self-report version; validated measure with five dimensions, each with five levels and the visual analogue scale EQ-VAS; yields mobility, self-care, usual activities, pain/discomfort, anxiety/depression; generates single index and value sets from EQ-VAS to facilitate calculation of QALYs		▲	▲	▲
<i>Intervention strategies/information</i> : parent-reported, satisfaction, usefulness, frequency and ease of use of sleep information and strategies measured on 10 cm visual analogue scales ³¹			#	
<i>Health service use</i> : parent-reported on other health services sought for child's sleep. Resource use (retrospectively from parents and prospectively from school nurses, teachers and research team) valued using existing unit cost estimates (market prices, Medical Benefits Schedule fee rates, etc)		▲	▲	▲
<i>Academic achievement</i> : Academic Rating Scale (27 items; teacher reported language/literacy, mathematical thinking, approach to learning subscales. Correlates highly with objective achievement ⁴⁵)			▲	▲
<i>Teacher-child relationship</i> : Student-Teacher Relationship Scale ⁴⁶ (28 items; teacher reported; yields a total score and three subscales for conflict, closeness and dependency)			▲	▲
<i>Basic academic skills</i> : Wechsler Individual Achievement Test 2nd ed Abbreviated (20 min); 3 subscales (spelling, reading and math) ⁴⁷ as assessed by a blinded researcher			▲	▲

Time points: screen=screening survey; 0=baseline survey; 6–12 months postrandomisation. ▲Completed by all RCT, # intervention families only.
RCT, randomised controlled trial.

another research project. In addition, the first assessment conducted by each staff member will be observed by a more experienced member of the research team. A fortnightly meeting will be held to enable staff to troubleshoot and to ensure fidelity.

Economic evaluation

The economic evaluation of the intervention will be a two-stage analysis. We will use cost-consequences analysis as a first step to compare any incremental costs of the intervention (costs accrued in the intervention arm,

from intervention and resource use over the period of follow-up, compared with costs accrued in the control arm) to all primary and secondary outcomes, expressed in their natural units of measurement.³⁶ We will then proceed to cost-effectiveness analysis as the primary economic analysis to compare incremental costs to difference in the PedsQL Psychosocial Health Summary score at 6 months, the prespecified primary outcome. As the secondary outcome measures include multiattribute utility measures of child and parent health-related quality of life (table 1), we will present a cost-utility

analysis on the combined parent–child quality-adjusted life years (QALYs) as a secondary economic analysis.³⁷

All analyses will be conducted from health and education service, as well as the broader societal, perspectives, as interventions cost-effective from a service perspective can add substantially to family costs.³⁸ Research assistants will prospectively record resources used in screening and nurses will record resources used in intervention delivery. Parents will retrospectively recall service use for child sleep over the previous year at recruitment and over the past 6 months for the 6-month and 12-month follow-ups. Parental recall of child service, financial and time resource use over periods up to 1 year can capture family resource use inside and outside the formal healthcare sector.³² Measured resource use will be valued using existing unit cost estimates (eg, education department salary scales, Medical Benefit Schedule fee rates). Any costs and outcomes incurred outside of a 1-year time frame will be discounted at 5%.³⁹ Uncertainty in cost and outcome data and sensitivity of economic evaluation results to chosen methods of evaluation will be tested by extensive sensitivity analyses.³⁷

Sample size

Our efficacy trial observed a 0.40 SD improvement in the PedsQL Psychosocial Health Summary score at 6 months (our primary outcome), as well as significantly improved sleep problems and parent mental health. However, we think it worthwhile and prudent to plan for an effect corresponding to a mean difference as small as one-third of SD (0.33 SD) in favour of the intervention arm, which would still be of major public health importance. To achieve 80% power for such a difference, at a 5% level of significance, will require 142 children in each study arm to complete the study. [Figure 2](#) shows the anticipated participant flow.

This assumes a 75% parent response to the screening survey and 11% with a moderate or severe child sleep problem, of whom 80% enter the RCT. Therefore, allowing for 15% attrition, an initial sample size targeting 5060 school entry children for the screening survey will provide the required 142 children per arm at follow-up. Even if attrition were 25%, we would still have 80% power for a difference of 0.35 SD.

We have not included a design effect, because children will be randomised individually. A large difference

in the intervention effect at the level of school nurses and/or schools is expected to decrease the precision of the trial comparison. However, clustering of children within schools is expected to increase the precision of the intervention effect. It is not possible to estimate the magnitude of these effects a priori, so these have not been included in the sample size calculation.

Statistical analyses

All analyses will be based on the intention-to-treat principle at 6 and 12 months postrandomisation.

For aim 1, for continuous standard scores (our primary outcome of child psychosocial functioning at 6 months and most secondary outcomes), we will use linear regression models to estimate the mean difference (and 95% CIs) between the intervention and control groups. For dichotomous outcomes, logistic regression models will be used to estimate the intervention effect as an OR with 95% CIs. All analyses will use regression techniques that respect any non-independence in outcomes from children attending the same school and the school nurse. All analyses will be adjusted for baseline scores wherever possible, in order to increase the precision of comparisons.⁴⁰ We will present results of analyses, both unadjusted and adjusted, for potential confounding factors identified a priori, including child age, gender and socioeconomic status.

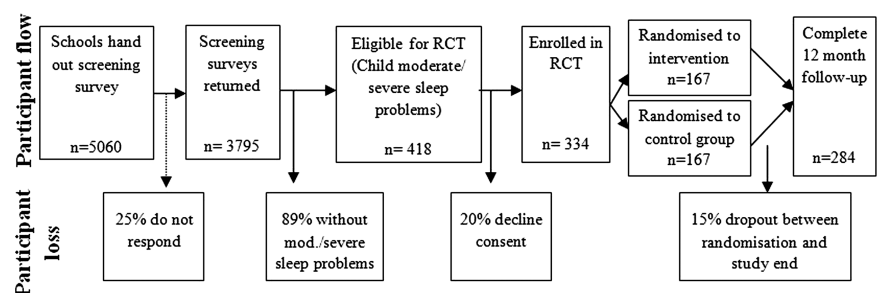
We will address the hypothesis that nurse training and education improves professional knowledge, competency and confidence using simple descriptive and paired prepost statistics.

For aim 2, we will assess the incremental net costs of the intervention at 6 and 12 months postrandomisation. We will then proceed through cost-consequences analysis (as a first step) to a cost-effectiveness analysis against the primary outcome measure (primary economic analysis). Secondary economic analysis will include cost-utility analysis against QALYs.³⁷

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

Figure 2 Anticipated participant flow.



short report of our findings. A copy of the report will also be sent to relevant government departments.

DISCUSSION

School outcomes largely determine a society's social, health and economic capital. A successful transition to school is formative to these outcomes. A child's ability to adapt to school is shaped not only by early life experiences, but also by current health and well-being. Thus, any modifiable problems that prevent an optimal school transition should be addressed systematically and urgently.

Sleep problems are one such issue. Research has already shown that at school entry, sleep problems are common and have serious immediate impacts on how children function. Research has also shown that these sleep problems are treatable, and that treatment improves psychosocial functioning as well as sleep. The next step is to confirm these findings in a definitive cost-effectiveness trial. This effectiveness RCT continues along the translation continuum by trialling the sleep intervention in 'real-world' settings, that is, delivered by primary school nurses through the existing school health screening and intervention framework.

If cost-effective, we expect the following outcomes:

- ▶ The best evidence yet that addressing sleep problems improves early school functioning and adjustment.
- ▶ A ready-to-use intervention that is tailored to the Australian school and policy system and can be replicated internationally.
- ▶ A strong research partnership linking child health, education, economic and policy.

In summary, this trial will make an original and significant contribution to providing children with a healthier start to school life, and may have flow-on effects through their schooling and later life.

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Contributors HH, MW, JQ and LG were responsible for the study's conception and design. SA was involved in the study's data analysis plan and K-LS was involved in the economic evaluation plan. All authors contributed to the preparation of the manuscript and have all approved the final submitted version.

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