

# Sleep Well - Be Well: A randomised controlled trial of a brief behaviour intervention for child sleep problems in Melbourne school children

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<b>Registration date</b> 24/01/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 31/12/2020	<b>Condition category</b> Signs and Symptoms	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**Protocol serial number**  
N/A

## Study information

**Scientific Title**

Sleep Well - Be Well: A randomised controlled trial of a brief behaviour intervention for child sleep problems in Melbourne school children

## **Acronym**

"Sleep Well - Be Well" Study

## **Study objectives**

In a sample of school children with parent reported sleep problems, a sleep intervention will result in:

1. A lower proportion of children with parent-reported sleep problems at 3, 6 and 12 months
2. Better mean child scores on concentration, behaviour and health-related quality of life at 3, 6 and 12 months
3. Better mean child scores on learning at 6 months
4. Better mean parent scores on parent mental health at 3, 6 and 12 months
5. The intervention will be feasible and acceptable for parents and schools

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

1. Royal Children's Hospital Ethics Committee. Date of approval: 11th November 2007 (ref: HREC 27132 A)
2. Victorian Department of Education and Early Childhood Development. Date of approval: 11th November 2007 (ref: SOS 003739)

## **Study design**

Study 1: Observational; Study 2: Interventional (Randomised controlled trial)

## **Primary study design**

Interventional

## **Study type(s)**

Treatment

## **Health condition(s) or problem(s) studied**

Sleep problems in children

## **Interventions**

30 State primary schools across Melbourne are involved.

Study 1: Observational - Questionnaire distribution to 2,380 Melbourne school students

Study 2: Interventional - Invited parents from Part 1 to participate in the randomised controlled trial

Study 2: Randomised controlled trial:

Part 1: 45-minute one-on-one consultation session

Part 2: 20-minute phone call 1 week later

Part 3: 30-minute one-on-one consultation session (optional)

Topics covered will include: overview of sleep problems, role of sleep, types of sleep problems and an individual plan for the specific child sleep problems reported by the parent. The

strategies will focus on establishing good sleep hygiene including having a set bedtime and bedtime routine, keeping the child's bedroom comfortable, and avoiding TV/computers in the bedroom. Parents will complete a sleep plan for their child under the guidance of the nurse /psychology student, writing down the strategies they feel appropriate for their child's sleep problem.

Control group: No intervention ("Usual care" group)

## **Intervention Type**

Other

## **Phase**

Not Specified

## **Primary outcome(s)**

How much is your child's sleeping pattern or habits a problem for you?(none/mild/moderate/severe) (Timepoints: B, 3, 6, 12)

B = Baseline

E = Enrolment

3 = 3 Month follow-up

6 = 6 Month follow-up

12 = 12 Month follow-up

## **Key secondary outcome(s)**

1. Children's Sleep Habits Questionnaire (Abbreviated) a validated 33-item questionnaire which focuses on dyssomnias, parasomnias and sleep-disordered breathing problems in children aged 4-12 years old (Timepoints: E, 6, 12)
2. Paediatric Quality of Life Inventory™ (PedsQL™) - a validated 23-item questionnaire measuring quality of life which focuses on the child's physical, emotional, social and school functioning (Timepoints: B, 3, 6, 12)
3. Strength and Difficulties Questionnaire - a validated 25-item questionnaire that focuses on the child's emotional conduct, hyperactivity, inattention, peer relationship and prosocial behavior (Timepoints: B, 6, 12)
4. Depression Anxiety Stress Scale (Abbreviated) - a validated 21-item self report instrument designed to measure the three related negative emotional states of depression, anxiety and tension/stress of the parent (Timepoints: B, 3, 6, 12)
5. Conners' Parent Rating Scale - Revised: Short form - a validated 27-item questionnaire that measures a child's behaviour in the areas of opposition, cognitive problems/inattention, hyperactivity and Attention-Deficit/Hyperactivity Disorder (ADHD) Index (Timepoints: E, 3, 6, 12)
6. Weschler Individual Achievement Test (WIAT)-II Australian (Abbreviated) - A face-to-face assessment tool which identifies basic academic skills and intervention needs in children. It has three subtests of spelling, word reading and numerical operations (Timepoint: 6)
7. Impact on parent work life, measured through parent report of how many times they were late or missed work due to their child's sleep problem (Timepoints: E, 3, 6, 12)

B = Baseline

E = Enrolment

3 = 3 Month follow-up

6 = 6 Month follow-up

12 = 12 Month follow up

**Completion date**

01/06/2009

## Eligibility

**Key inclusion criteria**

1. All students who are attending the first year of primary school will be distributed a survey and asked to be part of the study at baseline.
2. Primary care givers will be invited to participate in the study if the baseline questionnaire is returned, and that they indicate that the child has a moderate or severe sleep problem.

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Child

**Sex**

All

**Total final enrolment**

1512

**Key exclusion criteria**

1. Children with major malformations or medical conditions (e.g., blindness, Down's Syndrome).
2. Parents with insufficient English to complete questionnaires.
2. Parents of children who score high in the sleep apnoea questionnaire items from the Child Sleep Habits Questionnaire at baseline will be contacted by Dr Hiscock to clarify the nature of their sleep problem. If Dr Hiscock is concerned that the child may have sleep apnoea, she will explain this to the family and suggest they are reviewed in the Sleep Clinic at the Centre for Community Child Health. These children will be excluded from the intervention study as behavioural interventions are not standard treatment for sleep apnoea. Based on data from prevalence studies, we anticipate that only 2% or about 40 children may have this problem.

**Date of first enrolment**

01/02/2008

**Date of final enrolment**

01/06/2009

## Locations

**Countries of recruitment**

Australia

**Study participating centre**  
Centre for Community Child Health  
Parkville  
Australia  
3052

## Sponsor information

**Organisation**  
Murdoch Childrens Research Institute (MCRI) (Australia)

**ROR**  
<https://ror.org/048fyec77>

## Funder(s)

**Funder type**  
Hospital/treatment centre

**Funder Name**  
Royal Children's Hospital (Australia) - Centre for Community Child Health

## Results and Publications

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**  
Not provided at time of registration

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/10/2011	31/12/2020	Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes