

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

Submission date 11/12/2007	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 24/01/2008	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 31/12/2020	Condition category 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

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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 measure

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

Secondary outcome measures

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

Overall study start date

01/02/2008

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

Age group

Child

Sex

Both

Target number of participants

2,380

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)

Sponsor details

Centre for Community Child Health

Royal Children's Hospital

Flemington Road Parkville

Victoria

Australia

3052

Sponsor type

Hospital/treatment centre

Website

<http://www.mcri.edu.au/>

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

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

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?
Results article	results	01/10/2011	31/12/2020	Yes	No