

# Can a sleep intervention improve outcomes for children with attention-deficit hyperactivity disorder (ADHD)?

**Submission date**  
22/04/2010

**Recruitment status**  
No longer recruiting

☐ Prospectively registered

☐ Protocol

**Registration date**  
15/06/2010

**Overall study status**  
Completed

☐ Statistical analysis plan

☒ Results

**Last Edited**  
04/02/2015

**Condition category**  
Mental and Behavioural Disorders

☐ 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

Impact of a sleep intervention in children with attention-deficit hyperactivity disorder (ADHD): a randomised controlled trial

## Study objectives

We hypothesise that, compared to the control group, families randomised to the intervention group will report 3, 6 and 12 months post-intervention:

1. Improved child outcomes including:

1.1. Lower (better) mean score on an attention-deficit hyperactivity disorder (ADHD) symptom scale (primary outcome)

1.2. Lower proportion with sleep problems

1.3. Improved mean scores on continuous measures of working memory, behaviour, health-related quality of life, and school attendance

2. Improved primary caregiver outcomes including:

2.1. Lower proportion of mental health problems on an adult mental health scale

2.2. Improved mean scores on continuous measure of work attendance

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Royal Children's Hospital, Melbourne, Australia and Department of Education and Early Childhood Development Human Research Ethics Committees, Victoria, Australia - pending as of 22/04/2010

## Study design

Single-centre randomised controlled trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## 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

Attention-deficit hyperactivity disorder (ADHD)

## Interventions

**Behavioural sleep intervention (intervention group):**

The behavioural sleep intervention will be delivered by a study-employed paediatrician, child psychologist and/or nurse.

Parent(s) and the child will be seen for two x 50 minute consultations to assess and provide strategies to assist their child's sleep problem. The first session will focus on an assessment of the child's sleep problem, providing information about normal sleep and sleep cycles, advice about sleep hygiene, and a tailored plan specific to the sleep diagnosis. For example, sleep onset association disorder, typically associated with the need for parental presence at sleep time, will be managed with adult fading. This technique requires gradual withdrawal of parental presence from the child's bedroom over 7 - 10 days. Limit setting disorder will be managed by ignoring child protests and rewarding compliance with bedtime routines. Delayed sleep phase will be managed by temporarily setting the child's bedtime later, gradually bringing it forward, and waking the child at a pre-set time in the morning to ensure they do not sleep in.

Families will receive written handouts summarising the session content and will complete a written management plan with the clinician. All families will be asked to complete a sleep diary for their child to facilitate recognition of sleep patterns and improvements and to help set further goals.

The second session will be held two weeks later to reinforce strategies and monitor progress. The sleep clinician will contact families by telephone two weeks after the second visit to reinforce strategies, troubleshoot and monitor progress.

**Usual care (control group):**

Families in the usual care group will be able to access usual care for ADHD or their child's sleep from their child's paediatrician and/or other health services.

## **Intervention Type**

Other

## **Phase**

Not Applicable

## **Primary outcome measure**

Child's ADHD symptoms: ADHD Rating Scale IV (parent and teacher report), measured at 3, 6, and 12 months post-randomisation.

## **Secondary outcome measures**

Secondary child outcome measures include:

1. Sleep problem - none, mild, moderate or severe (parent report), measured at 3, 6, and 12 months post-randomisation
2. Children's Sleep Habits Questionnaire (CSHQ), measured at 3, 6, and 12 months post-randomisation
3. Strengths and Difficulties Questionnaire (SDQ) (parent and teacher report), measured at 3, 6, and 12 months post-randomisation
4. Pediatric Quality of Life Inventory (Peds QL), measured at 3, 6, and 12 months post-randomisation
5. Daily Parent Rating of Evening and Morning Behaviour (DMREB), measured at 3, 6, and 12 months post-randomisation
6. School attendance, measured at 3, 6, and 12 months post-randomisation

7. Other sleep help (eg GP, school nurse), measured at 3, 6, and 12 months post-randomisation
8. Working Memory Test Battery for Children (WMTB-C, a face-to-face measure), measured at 6 months post-randomisation

Secondary primary caregiver outcome measures include:

1. Depression Anxiety Stress Scale (DASS), measured at 3 and 6 months post-randomisation
2. Work attendance, measured at 3 and 6 months post-randomisation

**Overall study start date**

01/05/2010

**Completion date**

31/12/2012

## Eligibility

**Key inclusion criteria**

Families of children aged 5 - 12 years (either sex) with caregiver report of:

1. Moderate to severe sleep problems
2. ADHD symptoms meeting Diagnostic and Statistical Manual of Mental Disorders, 4th Edition (DSM-IV) criteria for ADHD (child also needs to have been previously diagnosed with ADHD by a paediatrician)
3. At least one of the following sleep problems as defined by the American Academy of Sleep Medicine diagnostic criteria (2005):
  - 3.1. Sleep onset association disorder
  - 3.2. Limit setting disorder
  - 3.3. Delayed sleep phase
  - 3.4. Primary insomnia or anxiety

**Participant type(s)**

Patient

**Age group**

Child

**Lower age limit**

5 Years

**Upper age limit**

12 Years

**Sex**

Both

**Target number of participants**

248 participants (124 randomised to intervention arm; 124 randomised to control arm)

**Key exclusion criteria**

1. With suspected obstructive sleep apnoea as screened by three obstructive sleep apnoea items from the Child Sleep Habits Questionnaire (CSHQ) and interview with CI Hisock

2. Receiving help from a health professional (e.g. psychologist) specifically for their sleep problem (aside from their treating paediatrician)

**Date of first enrolment**

01/05/2010

**Date of final enrolment**

31/12/2012

## **Locations**

**Countries of recruitment**

Australia

**Study participating centre**

Flemington Road

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## **Sponsor information**

**Organisation**

Murdoch Childrens Research Institute (MCRI) (Australia)

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**Sponsor type**

Research organisation

**Website**

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**ROR**

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

## **Funder(s)**

**Funder type**

Research council

**Funder Name**

National Health and Medical Research Council (NHMRC) (Australia) (ref: 607362)

**Alternative Name(s)**

NHMRC

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

Australia

## 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?
<a href="#">Results article</a>	results	20/01/2015		Yes	No