

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

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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

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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?
Results article	results	20/01/2015		Yes	No