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

Submission date
22/04/2010

Recruitment status
No longer recruiting

Registration date
15/06/2010

Overall study status
Completed

Last Edited
04/02/2015

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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
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

Study type(s)
Treatment

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 conatct families by telephone two weeks after the second visit to reinforce strategies, trouble shoot 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(s)
Child's ADHD symptoms: ADHD Rating Scale IV (parent and teacher report), measured at 3, 6, and 12 months post-randomisation.

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Child

Lower age limit
5 years

Upper age limit
12 years

Sex
All

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
Parkville
Australia
3052

Sponsor information

Organisation
Murdoch Childrens Research Institute (MCRI) (Australia)

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)
National Health and Medical Research Council, Australian Government, NHMRC National Health and Medical Research Council, NHMRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Australia

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	20/01/2015		Yes	No