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Sleeping Sound with Attention deficit hyperactivity disorder (ADHD)

Submission date
22/10/2014

Recruitment status
No longer recruiting

Registration date
17/11/2014

Overall study status
Completed

Last Edited
21/01/2019

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Attention deficit hyperactivity disorder (ADHD) is a behavioural disorder, the symptoms of which include not paying attention, hyperactivity and impulsive behaviour. Symptoms occur at an early age but often improve at the patient grows older. Children with ADHD can also suffer from sleep problems, where the child either has difficulty getting to sleep or frequently wakes up during the night. This symptom, however, is often overlooked. Up to 70% of children with ADHD experience sleep problems, compared with 20-30% of children in the general population. In 2010 we ran a two year study to test a new behavioural sleep programme (intervention) for children with ADHD and sleeping problems (ISRCTN68819261). The study took place from 21 paediatric practices across Victoria, Australia and the programme found to have a beneficial effect. A lack of sleep can have an effect on a persons memory and make them more forgetful. Six months into the trial, we tested the effect of childrens memory using the Working Memory Test Battery for Children and found that their memory had improved. Here, we want to investigate the feasibility and cost-effectiveness of delivering this behavioural sleep intervention at the population level through paediatricians and child psychologists in Victoria and Queensland, Australia.

Who can participate?
Children aged 5-12 years with paediatrician diagnosed ADHD from paediatric practices in Victoria and Queensland.

What does the study involve?
Participating paediatricians are randomly allocated to either a intervention or control group and all their participating patients are allocated to that group with them. Those paediatricians allocated to the control group have further contact with the research team. Those paediatricians allocated to the intervention group are trained by the research team in how to treat children using a brief behavioural sleep intervention. If paediatricians have a large number of patients enrolled in the study the participants are randomly allocated to receive treatment either by their paediatrician or by a psychologist (who is trained to how treat children using the intervention). After training the health professionals deliver the 2 session intervention to participating families. Families of children attending a paediatrician randomly allocated to the control group receive usual care which involves seeing their paediatrician as per usual regarding their childs

ADHD. Paediatricians typically see children with ADHD every 6 months to check their height, weight, blood pressure and re-issue a script for medication (valid for 6 months), where necessary. Families are followed up at 3 and 6 months after the intervention to see how the intervention is helping.

What are the possible benefits and risks of participating?
It is assumed that the strategies and information provided to parents in the intervention group will help manage their child's sleep problems. There are no direct benefits of participation for those in the control group. No risks or side-effects are anticipated. Participants allocated to the intervention group may be inconvenienced by the need to attend 2 x 45-60 minute sessions with their paediatrician or psychologist.

Where is the study run from?
The study is being led by the Murdoch Childrens Research Institute in Victoria and has a second site located in Queensland at the Mater Research Institute and University of Queensland. Deakin University are providing support with the health economics evaluation.

When is study starting and how long is it expected to run for?
November 2014 to December 2017

Who is funding the study?
National Health and Medical Research Centre (Australia)

Who is the main contact?
Prof. Harriet Hiscock
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Study website
http://www.rch.org.au/ccch/for_researchers/Sleeping_Sound_with_ADHD/#Sleeping_Sound_2

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1058827

Study information

Scientific Title
Does a brief, behavioural sleep intervention, delivered by trained paediatricians and psychologists improve sleep, ADHD symptom severity and behaviour for children with ADHD? A cluster-randomised, translational trial

Acronym
SSADHD

Study objectives
Hypotheses as of 30/08/2016:
Compared to control children receiving standard care:
1. At 3 and 6 months post-randomisation, a brief, behavioural sleep intervention delivered by paediatricians/clinical psychologists will:
1.1. Decrease prevalence (primary outcome) and severity (secondary outcome) of child sleep problems
1.2. Improve child ADHD symptoms as rated by primary caregivers and teachers
1.3. Improve functioning in other child (ADHD symptoms, QoL, behaviour, working memory, executive functioning, learning, academic achievement, school attendance) and primary caregiver (mental health, parenting, work attendance) outcome domains
2. The intervention will be cost effective. We will first present a cost-consequences analysis, then proceed to cost-effectiveness analysis against the primary outcome measure as primary economic analysis. Secondary economic analysis will include cost-utility analysis against CHU9D-based Quality of Life Years.

Original hypotheses:
Compared to control children receiving standard care:
1. At 3 and 6 months post-randomisation, a brief, behavioural sleep intervention delivered by paediatricians/clinical psychologists will:
1.1. Decrease prevalence (primary outcome) and severity (secondary outcome) of child sleep problems;
1.2. Improve child ADHD symptoms as rated by primary caregivers and teachers; and
1.3. Improve functioning in child (quality of life, behaviour, working memory, and academic achievement) and primary caregiver (mental health) outcome domains.
2. The intervention will be cost effective. We will first present a cost-consequences analysis, then proceed to cost-effectiveness analysis against the primary outcome measure as primary economic analysis. Secondary economic analysis will include cost-utility analysis against CHU9D-based Quality of Life Years.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Royal Childrens Hospital Human Research Ethics Committee, 13/06/2014; ref: 34072

Study design
Multi-site cluster-randomised controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Hospital

Study type(s)
Quality of life

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

Health condition(s) or problem(s) studied
Attention deficit hyperactivity disorder (ADHD)

Interventions
1. Behavioural sleep intervention (intervention group):
Families in the intervention group will be offered two face-to-face, fortnightly sleep consultations with their paediatrician (or psychologist), with the option for a further follow up phone call. At the first consultation, the clinician will assess the childs sleep problem, elicit parent goals for sleep management, provide information about normal sleep, sleep cycles, and sleep hygiene strategies, and formulate a behavioural sleep management plan tailored to the childs sleep problem. Parents will be asked to complete a sleep diary between the first and second consultation. The second consultation and follow-up phone call will be used to review the sleep diary, reinforce suggested strategies and troubleshoot any problems encountered.

2. Usual care (control group):
Families in the usual care group will be able to access usual care for ADHD from their childs paediatrician and/or other health services.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Parent report of child sleep problem at 3 month follow up

Secondary outcome measures

Child secondary outcome measures include:
1. Sleep: Parent report of child sleep patterns as measured by the Child Sleep Habits Questionnaire at 3 months; sleep problem and patterns at 6 month follow up, teacher report of daytime sleepiness at 3 & 6 month follow up
2. ADHD symptoms (parent and teacher report), measured at 3 & 6 months follow up
2. Psychosocial quality of life (parent report), measured at 6 month follow up
3. Behaviour (parent and teacher report), measured at 3 & 6 months follow up
4. Working memory (blinded, direct assessment), measured at 6 month follow up
5. Academic functioning (blinded, direct assessment), measured at 6 month follow up

Added 30/08/2016:
6. Executive functioning and learning (blinded, direct assessment), measured at 6 month follow up

Parent secondary outcome measures include:
1. Parent mental health, measured at 6 month follow up
2. Parenting behaviours, measured at 6 month follow up

Overall study start date
01/11/2014

Completion date
31/12/2017

Eligibility

Key inclusion criteria
Inclusion criteria as of 13/01/2017
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 (2014):
3.1 Chronic insomnia disorder
3.2 Sleep-wake phase disorder
3.3 Sleep-related anxiety”

Original 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
3.5 Anxiety-associated insomnia

Participant type(s)
Patient

Age group
Child

Lower age limit
5 Years

Upper age limit
12 Years

Sex
Both

Target number of participants
target number of participants to recruit into the study is 320 (160 randomised to intervention; 160 randomised to control).

Key exclusion criteria
Potential participants will be excluded from the study if they meet any of the following conditions:
1. Suspected obstructive sleep apnoea as screened by three obstructive sleep apnoea items from the Child Sleep Habits Questionnaire (CSHQ) and interview with CI Hiscock (paediatrician)
2. Have a major illness (e.g. cerebral palsy) or disability (e.g. intellectual disability)
3. Non-English speaking

Date of first enrolment
28/01/2015

Date of final enrolment
30/10/2016

Locations

Countries of recruitment
Australia

Study participating centre
The Royal Children's Hospital
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Sponsor information

Organisation
Murdoch Children's Research Institute (Australia)

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Sponsor type
Research organisation

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ROR
https://ror.org/048fyec77

Funder(s)

Funder type
Research organisation

Funder Name
National Health and Medical Research Council - Project Grant 1058827

Alternative Name(s)
NHMRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Australia

Results and Publications

Publication and dissemination plan
1. Planned publication in a peer reviewed medical journal
2. Presentation at international conferences

Intention to publish date
30/06/2018

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	04/04/2017		Yes	No
Results article	results	01/01/2020	21/01/2019	Yes	No