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Sleep well be well: improving school transition by improving child sleep

Submission date
19/07/2012

Recruitment status
No longer recruiting

Registration date
17/08/2012

Overall study status
Completed

Last Edited
22/01/2018

Condition category
Nervous System Diseases

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

Plain English summary of protocol

Background and aims
Sleep problems are common in children in the first year of elementary school, known as Grade Prep in Victoria, Australia. Around 1 in 4 Prep children have a sleep problem which can include problems settling to sleep, waking overnight or being tired in the morning. These problems have been linked with social and emotional difficulties and also poorer learning. A sleep education program has previously been demonstrated to reduce child sleep problems and have positive benefits for childrens social and emotional problems as well as reduce parent mental health symptoms. This study aims to test whether the one-on-one sleep help program, when delivered by an existing school health workforce, can improve not only childrens sleep but their behaviour, learning and quality of life and family wellbeing too.

Who can participate?
Parents of Grade Prep children who report their child has a sleep problem. Parents will be approached through 47 randomly selected primary schools in the Southern School Region of metropolitan Melbourne. Primary schools will come from the Government and Catholic education sectors.

What does the study involve?
Participants will be randomly allocated to either the sleep education or the usual care group. Those in the sleep education group will receive a behavioural sleep education program, delivered by a trained primary school nurse from the Victorian Primary School Nursing program in the Southern Region of Melbourne. The intervention involves three components:

Part 1: 45-minute one-on-one consultation session (generally face-to-face, but may be done over the phone in case of the parent and nurse being unable to find a mutually convenient time to meet)
Part 2: 20-minute phone call 2 weeks later
Part 3: 30-minute one-on-one consultation session (optional)

Topics covered will include: overview of sleep problems, role of sleep and different types of strategies that can be used for different sleep problems. Parents will complete a sleep management plan for their child under the guidance of the school nurse, writing down the

strategies they feel appropriate for their child's sleep problem and that they are comfortable implementing. Those in the usual care (control) group will not receive the intervention.

What are the possible benefits and risks of participating?
If parents are in usual care group, they may not benefit from taking part in the study. However, their information will help us to find out how useful our sleep program is. If parents are in the sleep help group, the information they get may help them manage their childs sleep problem. Improving sleep may help their childs school performance, health and behaviour. We dont think the study has any risks, side effects or discomforts for you or your child. If the child does not want to take part in their assessment when we visit, we wont go ahead. Parents may choose not to complete some questions on the survey if you feel uncomfortable or upset about them.

Where is the study run from?
Murdoch Childrens Research Institute (Australia)

When is the study starting and how long is it expected to run for?
February 2013 to December 2016

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

Who is the main contact?
Associate Professor Harriet Hiscock
harriet.hiscock@rch.org.au

Study website
http://www.rch.org.au/ccch/research-projects/sleep-well-be-well/

Contact information

Type(s)
Scientific

Contact name
Dr Harriet Hiscock

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Centre for Community Child Health
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Parkville
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3052

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1024203

Study information

Scientific Title
Improving school transition by improving child sleep: a translational randomised trial

Study objectives
Current hypothesis as of 15/09/2014:
In a population of children in their first year of primary school with parent-reported sleep problems, we hypothesise that:
1. At 6 and 12 months post-randomisation, a brief child sleep intervention delivered by school nurses, will:
1.1. Improve child psychosocial functioning (primary outcome: parent-reported PedsQL at 6 months)
1.2. Decrease prevalence of child sleep problems (secondary outcome)
1.3. Improve other secondary outcomes relevant to child functioning, including childrens sleep hygiene practices, sleep patterns, behaviour, academic skills, school adjustment, and the primary caregivers mental health.
2. A structured training and education package emphasising brief, standardised behavioural management strategies will lead to a sustained increase in knowledge, competency and confidence of school nurses in addressing sleep problems in new school entrants.
3. The intervention will be cost effective.

Previous hypothesis:
In a population of children in their first year of primary school with parent-reported sleep problems, we hypothesise that:
1. At 3, 6 and 12 months post-randomisation, a brief child sleep intervention delivered by school nurses, will:
1.1. Improve child psychosocial functioning (primary outcome: parent-reported PedsQL at 6 months)
1.2. Decrease prevalence of child sleep problems (secondary outcome)
1.3. Improve other secondary outcomes relevant to child functioning, including childrens sleep hygiene practices, sleep patterns, behaviour, academic skills, school adjustment, and the primary caregivers mental health.
2. A structured training and education package emphasising brief, standardised behavioural management strategies will lead to a sustained increase in knowledge, competency and confidence of school nurses in addressing sleep problems in new school entrants.
3. The intervention will be cost effective.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Human Research Ethics Committee at the Royal Childrens Hospital in Melbourne, Australia, 13/07/2012, ref: 32146

Study design
Translational randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Quality of life

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
Child behavioural sleep problems

Interventions
Current interventions as of 11/07/2016:
47 primary schools in the Southern School Region of Melbourne will be involved. Most schools will be involved on two occasions, in 2013 and 2014.

Behavioural sleep education program, delivered by a trained primary school nurse from the Victorian Primary School Nursing program in the Southern Region of Melbourne.

Intervention:
Part 1: 45-minute one-on-one consultation session (added 20/11/2013: generally face-to-face, but may be done over the phone in case of the parent and nurse being unable to find a mutually convenient time to meet)
Part 2: 20-minute phone call 2 weeks 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 school nurse, writing down the strategies they feel appropriate for their child's sleep problem.

Control group: No intervention ('usual care' group)

Previous interventions:
40 primary schools in the Southern School Region of Melbourne will be involved on two occasions, in 2013 and 2014.

Behavioural sleep education program, delivered by a trained primary school nurse from the Victorian Primary School Nursing program in the Southern Region of Melbourne.

Intervention:
Part 1: 45-minute one-on-one consultation session (added 20/11/2013: generally face-to-face, but may be done over the phone in case of the parent and nurse being unable to find a mutually convenient time to meet)
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 school nurse, writing down the strategies they feel appropriate for their child's sleep problem.

Control group: No intervention ('usual care' group)

Intervention Type
Behavioural

Primary outcome measure
Current primary outcome measures as of 15/09/2014:
Parent-reported child psychosocial functioning measured at 6-month follow-up by the 23-item PedsQL4.0 Psychosocial Health Summary score (5-7 year old version)

The choice of psychosocial well-being as our primary outcome reflects the current literature on longitudinal impacts of poor sleep and our own trial-based evidence that improving sleep has psychosocial benefits likely to be important to school functioning.

Previous primary outcome measures:
Parent-reported child psychosocial functioning measured at enrolment, 3-, 6- and 12-month follow up by the 23-item PedsQL4.0 Psychosocial Health Summary score (5-7 year old version)

The choice of psychosocial well-being as our primary outcome reflects the current literature on longitudinal impacts of poor sleep and our own trial-based evidence that improving sleep has psychosocial benefits likely to be important to school functioning.

Secondary outcome measures
Current secondary outcome measures as of 11/07/2016:
Parent-reported secondary measures. Measured at enrolment, 6 and 12 months post randomisation.
1. Prevalence of child sleep problems
2. Child sleep behaviours: 33-item Child Sleep Habits Questionnaire, a validated measure of disorders initiating/maintaining sleep with a clinical cut point for dichotomous analyses.
3. Sleep hygiene: study-developed measure
4. Child behaviour: 25-item Strengths and Difficulties Questionnaire (SDQ), 4-16 years. Yields Prosocial and Total Problems scores, plus 4 subscales (hyperactivity/inattention, conduct, emotional, peer relationships)
5. Parent mental health: 21-item Depression Anxiety Stress Scale, a validated measure which

yields scores for Depression, Anxiety and Stress
6. Strategies/information received from school nurses (intervention parents, 6 months only). Overall satisfaction, usefulness, frequency and ease of use of sleep information and strategies.

Blinded direct assessment and child report (6 and 12 months post randomisation) of:
1. Basic academic skills: Wechsler Individual Achievement Test 2ndEd Abbreviated; 3 subscales (spelling, reading and math) transformed to standard scores (mean 100, SD 15).
2. Psychosocial functioning: Researcher-administered 5-7 year old self-report PedsQL4.0.44
3. Working memory: Automated Working Memory Assessment (digit recall, dot matrix, Mister X and backwards digit recall subscales)
4. Quality of life of child: Child Health Utilities 9D (child self-report)

Blinded teacher report (6 and 12 month post randomisation) of:
1. Academic achievement: 22-item teacher-reported Academic Rating Scale; 3 subscales (language/literacy, mathematical thinking, approach to learning).
2. Child behaviour: Teacher version of the Strengths and Difficulties Questionnaire.
3. Teacher-child relationship: 15-item teacher-reported Student-Teacher Relationship Scale short form which yields subscale scores for conflict and closeness.

Economic analysis (6 and 12 months post randomisation) including:
1. Quality of life of parent, measured by the EQ-5D (parent self-report)
2. Health service use. Parents will report any other help for their childs sleep from health services (e.g. school nurse, GP, paediatrician etc). Resource use data (retrospectively from parents and prospectively from school nurses, teachers and research team) will be valued using existing unit cost estimates (market prices, Medical Benefits Schedule fee rates, etc.).

Previous secondary outcome measures:
Parent-reported secondary measures. Measured at enrolment, 3, 6 and 12 months post randomisation.
1. Prevalence of child sleep problems
2. Child sleep behaviours: 33-item Child Sleep Habits Questionnaire, a validated measure of disorders initiating/maintaining sleep with a clinical cut point for dichotomous analyses.
3. Sleep hygiene: study-developed measure
4. Child behaviour: 25-item Strengths and Difficulties Questionnaire (SDQ), 4-16 years. Yields Prosocial and Total Problems scores, plus 4 subscales (hyperactivity/inattention, conduct, emotional, peer relationships)
5. Parent mental health: 21-item Depression Anxiety Stress Scale, a validated measure which yields scores for Depression, Anxiety and Stress
6. Strategies/information received from school nurses (intervention parents, 6 months only). Overall satisfaction, usefulness, frequency and ease of use of sleep information and strategies.

Blinded direct assessment and child report (6 and 12 months post randomisation) of:
1. Basic academic skills: Wechsler Individual Achievement Test 2ndEd Abbreviated; 3 subscales (spelling, reading and math) transformed to standard scores (mean 100, SD 15).
2. Psychosocial functioning: Researcher-administered 5-7 year old self-report PedsQL4.0.44

Blinded teacher report (6 and 12 month post randomisation) of:
1. Academic achievement: 27-item teacher-reported Academic Rating Scale; 3 subscales (language/literacy, mathematical thinking, approach to learning).
2. Child behaviour: Teacher version of the Strengths and Difficulties Questionnaire.
3. Teacher-child relationship: 28-item teacher-reported Student-Teacher Relationship Scale which yields a total score and three subscales for conflict, closeness and dependency.

Economic analysis (3, 6 and 12 months post randomisation) including:
1. Quality of life of child and parent, measured by Health Utilities Index-3 (parent self-report and parent-proxy child report versions, 6 and 12 months only). Widely-used, 15-item generic health measure generates preference-based single scores and quality-adjusted life years.
2. Health service use. Parents will report any other help for their childs sleep from health services (e.g. school nurse, GP, paediatrician etc). Resource use data (retrospectively from parents and prospectively from school nurses, teachers and research team) will be valued using existing unit cost estimates (market prices, Medical Benefits Schedule fee rates, etc).

Overall study start date
01/02/2013

Completion date
30/12/2016

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 upon return of their baseline questionnaire if they indicate that their child has a moderate or severe sleep problem

Participant type(s)
Mixed

Age group
Child

Sex
Both

Target number of participants
5000 initially approached, of which 418 will be eligible to be randomised

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
3. Parents of children who score high in the sleep apnoea questionnaire items from the Child Sleep Habits Questionnaire at baseline. The families will be contacted by Associate Professor Hiscock to clarify the nature of their sleep problem. If Associate Professor 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 at The Royal Childrens Hospital in Melbourne. 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% of children may have this problem.

Added 15/09/2014:
4. We will exclude individual children from enrolment in the RCT if they have a sibling that has already been enrolled (if two siblings become eligible at the same time, e.g. twins, we will ask parents to select one sibling for inclusion)

Date of first enrolment
25/02/2013

Date of final enrolment
23/10/2014

Locations

Countries of recruitment
Australia

Study participating centre
Royal Children's Hospital
Parkville
Australia
3052

Sponsor information

Organisation
Murdoch Childrens Research Institute (Australia)

Sponsor details
Murdoch Childrens Research Institute
Royal Children's Hospital
Flemington Road
Parkville
Australia
3052

Sponsor type
Hospital/treatment centre

Website
http://www.mcri.edu.au/

ROR
https://ror.org/048fyec77

Funder(s)

Funder type
Research council

Funder Name
National Health and Medical Research Council (ref: 1024203)

Alternative Name(s)
NHMRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Australia

Results and Publications

Publication and dissemination plan
Publications are current under review in high impact journals with the aim of publishing them in 2018.

Intention to publish date
12/01/2018

Individual participant data (IPD) sharing plan
Requests for individual level data can be sent to Professor Harriet Hiscock (harriet.hiscock@rch.org.au) at the Centre for Community Child Health, Royal Children's Hospital, Australia. Requests will be considered individually and be subject to approval from the Human Research Ethics Committee at the Royal Children's Hospital.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	28/10/2013		Yes	No
Basic results		20/12/2017	22/01/2018	No	No