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Sleeping Sound with Autism Spectrum Disorder (ASD)

Submission date
03/03/2017

Recruitment status
No longer recruiting

Registration date
13/03/2017

Overall study status
Completed

Last Edited
05/06/2024

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Autism Spectrum Disorder (ASD) is a disorder characterised by severe and persistent social, communication, and behavioural problems. Individuals with ASD are at great risk of emotional and behavioural problems during childhood, and, as adults, have poor mental health and occupational functioning outcomes. Children with ASD often suffer from sleep problems, such as difficulty falling asleep, resisting going to bed and being tired in the morning. Sleep disturbance has been shown to cause anxiety and behavioural problems in children with ASD. Despite the promise of behavioural sleep interventions for children with ASD, few studies have examined their efficacy in this condition. Up to 85% of children with ASD experience sleep problems, compared to 20-30% of children in the general population. A previous small study run by the Royal Children's Hospital (Australia) in 2013 found that a programme that includes two or three sleep sessions with a trained staff helped children with ASD improve their sleep problems, wellbeing and daily functioning. This study aims to investigate whether a larger group of children with ASD may benefit from this treatment by comparing children who receive the programme with children who do not.

Who can participate?
Families of children aged 5-12 years and children who have turned 13 and who are attending Primary School (all genders).

What does the study involve?
Parents are contacted about the study to see if their child is eligible. This involves asking questions about their child's autism symptoms, wellbeing and daily functioning. If eligible to take part, they complete a survey which includes questions about their child's autism, sleeping problems, and about their child and family's wellbeing. Participants are then randomly allocated to one of two groups. Those in the first group are included in the sleep programme which involves attending two 50-minute face-to-face sessions and a follow up phone call with a psychologist or paediatrician who has been trained to help manage sleep problems two weeks after the sessions. At the sleep sessions, the psychologist assesses the child's sleep and provides parents with some strategies to help manage their child's sleep. Those in the second group continue with care as usual and do not attend the intervention sessions. Both groups are asked to complete surveys at 3 and 6 months after treatment, and additionally all parents are asked to

bring their child in for a learning assessment at 6 months. With the families' consent, the participants' school teacher is asked to complete surveys at the start of the study, and at the 3 and 6 months follow-up. If additional funding support is available, parent and teacher surveys will also be completed at 12 months.

What are the possible benefits and risks of participating?
Participants may benefit from the strategies and information provided about managing sleep problems. There are no notable risks with participating.

Where is the study run from?
1. Deakin University Melbourne Campus (Australia)
2. The Royal Children's Hospital (Australia)

When is the study starting and how long is it expected to run for?
January 2016 to May 2019
(Updated 20/05/2019, previously: December 2019)

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

Who is the main contact?
Professor Nicole Rinehart
nicole.rinehart@deakin.edu.au

Study website
http://www.sleepingsoundASD.com.au

Contact information

Type(s)
Public

Contact name
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Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
36154A

Study information

Scientific Title
Tailoring a brief sleep intervention for autism spectrum disorder: a randomised controlled trial

Acronym
SSASD

Study objectives
Current study hypothesis as of 18/02/2019:
This study aims to examine the efficacy of a brief behavioural sleep intervention (Sleeping Sound) in treating sleep problems in primary school children aged 5-13 years with ASD.

Compared with a treatment as usual comparison group, children with ASD who receive the Sleeping Sound intervention will show greater improvements in the following areas:

1. Reductions in overall child sleep problem severity including reductions in total sleep disturbance, and problems initiating and maintaining sleep at 3 months post randomisation (post intervention; primary outcome time point)
2. Improvements in child and primary caregiver functioning at 3 and 6 months post randomisation, including improvements in sleep hygiene and severity of sleep problem by parent report, improved daytime sleepiness by teacher report, decreased emotional and behavioural problems reported by parents and teachers, decreased social-communicative symptoms reported by parents, increased cognitive performance, academic achievement and school attendance, increased child quality of life on parent report, decreased parent stress and mental health symptoms and increased parent quality of life and work attendance
3. That the behavioural sleep intervention will be a cost-effective treatment when compared with TAU from a societal and health care perspective, by comparing the costs and benefits (expressed in quality-adjusted life years (QALYs) between the two arms of the trial over the period of the study

Previous study hypothesis:
Children with ASD who receive the Sleeping Sound intervention will show reductions in sleeping problems, emotional and behavioural problems, social-communicative symptoms, as well as increased cognitive and academic performance and quality of life post intervention compared to children who receive treatment as usual. It is further hypothesised that parents of children who receive the intervention will have decreased parent mental health symptoms than those who receive treatment as usual, and that the Sleeping Sound intervention will be cost-effective compared to the usual treatment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Current ethics approval as of 18/02/2019:
Royal Children's Hospital Human Research Ethics Committee, 22/07/2016, ref: HREC/16/RCHM /73
Deakin University #2017-130
Victorian Department of Education and Early Childhood Development Approval #2016_003134
Catholic Education Office Approval (Melbourne #0501)

Previous ethics approval:
Royal Children's Hospital Human Research Ethics Committee, 22/07/2016, ref: HREC/16/RCHM /73

Study design
Multi-site randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

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
Autism Spectrum Disorder

Interventions
Current interventions as of 18/05/2018:
Parents are contacted about the project and to see if their child is eligible for the project. This involves asking questions about their child's autism symptoms, wellbeing and daily functioning. If eligible to take part, they complete a survey about their child's autism and sleep, and about

their child and family's wellbeing. Upon receiving the completed consent form and baseline survey, families are randomised to either the behavioural sleep intervention group or the comparison group. Treatment allocation is determined sequentially, according to a computer-generated block randomisation sequence, with blocks of randomly varying size. Given the relatively fewer diagnoses of Autism Spectrum Disorder (ASD) among girls, randomisation is stratified by gender to ensure equal representation of girls in both study arms.

1. Behavioural sleep intervention (intervention group):
Participants in the intervention group are offered two 50 minute face-to-face, fortnightly sleep consultations, with a further follow up phone call two weeks with a trained psychologist or paediatrician after the consultations. The intervention is delivered by trained study-employed clinicians with experience working with children with ASD. These visits are free of charge. During the first consultation, the clinician assesses the child's 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 child's sleep problem. Parents are asked to complete a sleep diary between the first and second consultation. The second consultation and follow-up phone call are used to review the sleep diary, reinforce suggested strategies and troubleshoot any problems encountered.

2. Usual care (control group):
Participants in the control group are able to access the usual care for ASD from their child's paediatrician and/or other health services.

All families complete surveys at baseline and then again at 3 and 6 months follow up time points post-randomisation. At 6 months all parents are asked to bring their child in for a learning assessment. With families consent, the participants' school teacher is asked to complete surveys at the start of the study, and at 3 and 6 months follow up. The National Assessment Program — Literacy and Numeracy (NAPLAN) results for the child are accessed to review educational outcomes, as well as the child's Medicare records are accessed in order assess which health services they have used. If additional funding support is available, parent and teacher surveys will also be completed at 12 months.

Previous interventions:
Parents are contacted about the project and to see if their child is eligible for the project. This involves asking questions about their child's autism symptoms, wellbeing and daily functioning. If eligible to take part, they complete a survey about their child's autism and sleep, and about their child and family's wellbeing. Upon receiving the completed consent form and baseline survey, families are randomised to either the behavioural sleep intervention group or the comparison group. Treatment allocation is determined sequentially, according to a computer-generated block randomisation sequence, with blocks of randomly varying size. Given the relatively fewer diagnoses of Autism Spectrum Disorder (ASD) among girls, randomisation is stratified by gender to ensure equal representation of girls in both study arms.

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The second consultation and follow-up phone call are used to review the sleep diary, reinforce suggested strategies and troubleshoot any problems encountered.

2. Usual care (control group):
Participants in the control group are able to access the usual care for ASD from their child's paediatrician and/or other health services.

At six months all parents are asked to bring their child in for a learning assessment. All families complete surveys at baseline and then again at three, six and 12 months follow up time points post-randomisation. With families consent, the participants' school teacher is asked to complete surveys at the start of the study, and at three, six and 12 months follow up. The National Assessment Program — Literacy and Numeracy (NAPLAN) results for the child are accessed to review educational outcomes, as well as the child's Medicare records are accessed in order assess which health services they have used.

Intervention Type
Behavioural

Primary outcome measure
Current primary outcome measure as of 18/02/2019:
Parent reports of child sleep problem are measured by the Children's Sleep Habits Questionnaire at baseline and 3 months post randomisation (post intervention).

Previous primary outcome measure as of 18/05/2018:
Parent reports of child sleep problem are measured by the Child Sleep Habits Questionnaire at baseline, 3, and 6 months.

Previous primary outcome measure:
Parent reports of child sleep problem are measured by the Child Sleep Habits Questionnaire at baseline, 3, 6, and 12 months.

Secondary outcome measures
Current secondary outcome measures as of 18/02/2019:
Child secondary outcome measures:
1. Child sleep problems measured by Children's Sleep Habits Questionnaire (parent report measured at baseline and 6 months post randomisation), parent report of sleep problem severity and sleep hygiene (parent report at baseline, 3 and 6 months post randomisation), and Teacher Daytime Sleepiness Questionnaire (teacher report at baseline, 3 and 6 months post randomisation).
2. Emotional and behavioural problems as measured by Strength and Difficulties Questionnaire (parent and teacher reports at baseline, 3 and 6 months post randomisation) and Developmental Behaviour Checklist (parent report at baseline and 6 months)
3. Social-communicative symptoms as measured by Social Communication Questionnaire current form (parent reports at baseline, 3 and 6 months post randomisation)
4. Cognitive and academic performances as measured by the NIH cognitive toolbox and selected measures from the Wide Range Achievement Test 4th Edition (blinded, direct assessments at 6 months post randomisation), linkage to NAPLAN results (standardised national assessment of literacy and numeracy Australian children complete in Grades 3, 5, 7 and 9) and school attendance
5. Quality of life as measured by Child Health Utilities 9D (parent reports at baseline, 3 and 6 months post randomisation).

Parent secondary outcome measures:
1. Parent mental health symptoms are measured using K10 (Kessler 10) at baseline, 3 and 6 months post randomisation.
2. Parent stress is measured using the PSI-4-SF (Parenting stress index, fourth edition, short form) at baseline, 3 and 6 months post randomisation.
3. Parent quality of life measured using the AQoL4D (Adult Quality of Life Questionnaire 4D) at baseline, 3 and 6 months post randomisation and parent-reported work attendance

Economic outcome measure:
Cost-effectiveness of the intervention is measured using a cost-utility and cost-consequence analysis between the two arms of the trial over the period of the study. The inclusion of the CHU9D will allow calculation of quality-adjusted life years (QALYs) as part of a cost-utility analysis, which will be undertaken along with a cost-consequence analysis, whereby the differences in costs between the intervention group and the control group will be compared with the differences in the full suite of study outcomes. Cost measurements include a study designed resource use questionnaire collected at baseline, 3 and 6 months and permission to access Medicare and Pharmaceutical Benefits Scheme data for a time period of 3 months prior to baseline up until the last follow-up assessment.

Previous secondary outcome measures as of 18/05/2018:
Child secondary outcome measures:
1. Emotional and behavioural problems are measured using parent and teacher reports at baseline, 3 and 6 months
2. Social-communicative symptoms are measured using parent and teacher reports at baseline, 3 and 6 months
3. Cognitive and academic performances are measured using blinded and direct assessments at 6 months
4. Quality of life is measured using parent reports at baseline, 3 and 6 months

Parent secondary outcome measures:
1. Parent mental health symptoms are measured using K10 (Kessler 10) at baseline, 3 and 6 months
2. Parent stress is measured using the PSI-4-SF (Parenting stress index, fourth edition, short form) at baseline, 3 and 6 months

Economic outcome measure:
1. Cost-effectiveness of the intervention is measured using a cost-utility and cost-consequence analysis (based from parent reports) at baseline, 3 and 6 months

Previous secondary outcome measures:
Child secondary outcome measures:
1. Emotional and behavioural problems are measured using parent and teacher reports at baseline, 3, 6 and 12 months
2. Social-communicative symptoms are measured using parent and teacher reports at baseline, 3, 6 and 12 months
3. Cognitive and academic performances are measured using blinded and direct assessments at 6 months
4. Quality of life is measured using parent reports at baseline, 3, 6 and 12 months

Parent secondary outcome measures:
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Economic outcome measure:
1. Cost-effectiveness of the intervention is measured using a cost-utility and cost-consequence analysis (based from parent reports) at baseline, 3, 6 and 12 months

Overall study start date
01/01/2016

Completion date
31/12/2019

Eligibility

Key inclusion criteria
Current inclusion criteria as of 18/02/2019:
1. Families of children aged 5-12 years (all genders) (13 years if attending primary school).
2. ASD symptoms meeting criteria for ASD according to the Social Communication Questionnaire. The child must have previously received a conclusive multi-disciplinary diagnosis of Autistic Disorder or Asperger's Disorder (according to Diagnostic and Statistical manual of Mental Disorders, 4th Edition; DSM-IV), or ASD (according to Diagnostic and Statistical manual of Mental Disorders, 5th Edition; DSM-5). A SCQ cut off score of >= 11 will be used.
3. Moderate to severe sleep problems, with at least one of the following sleep problems as defined by the American Academy of Sleep Medicine diagnostic criteria (2013): chronic insomnia (including problems of initiating and maintaining sleep, sleep-onset association, limit-setting, and anxiety-related insomnia) or delayed sleep-wake phase.

Previous inclusion criteria as of 18/10/2017:
1. Families of children aged 5-12 years (all genders) (13 years if attending primary school)
2. ASD symptoms meeting criteria for ASD according to the Social Communication Questionnaire. The child must have previously received a conclusive multi-disciplinary diagnosis of Autistic Disorder or Asperger's Disorder (according to Diagnostic and Statistical manual of Mental Disorders, 4th Edition; DSM-IV), or ASD (according to Diagnostic and Statistical manual of Mental Disorders, 5th Edition; DSM-5). A SCQ cut off score of >= 11 will be used
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3. Moderate to severe sleep problems, with at least one of the following sleep problems as defined by the American Academy of Sleep Medicine diagnostic criteria (2013): chronic insomnia (including problems of initiating and maintaining sleep, sleep-onset association, limit-setting,

and anxiety-related insomnia), delayed sleep-wake phase or parasomnias (including nightmares, sleep terrors and sleepwalking)

Participant type(s)
Patient

Age group
Child

Lower age limit
5 Years

Upper age limit
13 Years

Sex
Both

Target number of participants
The target number of participants to recruit into the study is 234 (117 randomised to intervention, 117 randomised to control).

Total final enrolment
246

Key exclusion criteria
Current exclusion criteria:
1. Intellectual disability
2. Have comorbid medical condition that affects sleep (e.g. nocturnal seizures, blindness), or syndromic genetic (e.g. Fragile X) conditions
3. Suspected obstructive sleep apnoea as screened by three obstructive sleep apnoea items from the Child Sleep Habits Questionnaire (CSHQ) and interview with a paediatrician
4. Non-English speaking

Previous exclusion criteria:
1. Intellectual disability
2. Have comorbid medical (e.g. epilepsy), neuropsychiatric (e.g. Tourette's) or syndromic genetic (e.g. Fragile X) conditions
3. Suspected obstructive sleep apnoea as screened by three obstructive sleep apnoea items from the Child Sleep Habits Questionnaire (CSHQ) and interview with a paediatrician
4. Non-English speaking

Date of first enrolment
01/04/2017

Date of final enrolment
05/04/2019

Locations

Countries of recruitment
Australia

Study participating centre
Deakin University
221 Burwood Highway
Burwood
Victoria
Melbourne
Australia
3125

Study participating centre
The Royal Children's Hospital
50 Flemington Road
Parkville
VIC
Melbourne
Australia
3052

Sponsor information

Organisation
The Royal Children’s Hospital

Sponsor details
The Royal Children's Hospital
Flemington Road
Parkville
Melbourne
Australia
3052

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/02rktxt32

Funder(s)

Funder type
Research council

Funder Name
Australian National Health and Medical Research Centre

Results and Publications

Publication and dissemination plan
Planned publication in a peer reviewed medical journal and planned presentations at local and international conferences.

Intention to publish date
31/12/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Susannah Bellows sleepingsound@deakin.edu.au

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	19/11/2019	22/11/2019	Yes	No
Results article		21/11/2022	26/04/2023	Yes	No
Results article		13/03/2022	26/04/2023	Yes	No
Results article		04/06/2024	05/06/2024	Yes	No