A Brief Parent-based Sleep Intervention for ADHD Children

This study is currently recruiting participants.

Verified August 2017 by Dr. Shirley Xin Li, The University of Hong Kong

Sponsor:
The University of Hong Kong

Collaborator:
Chinese University of Hong Kong

Information provided by (Responsible Party):
Dr. Shirley Xin Li, The University of Hong Kong

ClinicalTrials.gov Identifier:
NCT03263156

First received: August 23, 2017
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Purpose

Sleep problems are very common in children with ADHD, with a prevalence rate as high as 73%, and often pose significant challenges and stress to the families. Sleep problems in ADHD children are strongly associated with the exacerbation of daytime symptoms, impaired physical health, and poor parental mental health. The present study is a randomised controlled trial to compare the effects of a parent-based sleep intervention for children with ADHD (aged 6-12). Eligible participants will be randomised to either intervention (two face-to-face consultation sessions and one follow-up phone call) or waiting-list control condition. Assessments will be conducted at pre-treatment (baseline), one-week after the intervention (post-treatment), and 3 months after the intervention.

<table>
<thead>
<tr>
<th>Condition</th>
<th>Intervention</th>
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</thead>
<tbody>
<tr>
<td>ADHDInsomnia</td>
<td>Behavioral: Sleep hygiene practices and behavioural intervention</td>
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</table>

Study Type: Intervventional

Study Design: Allocation: Randomized
Intervention Model: Parallel Assignment
Masking: None (Open Label)
Primary Purpose: Treatment
Official Title: Effects of a Brief Parent-based Sleep Intervention for Children With Attention Deficit Hyperactivity Disorder

Resource links provided by NLM:

MedlinePlus related topics: Healthy Sleep

U.S. FDA Resources

Further study details as provided by Dr. Shirley Xin Li, The University of Hong Kong:

Primary Outcome Measures:
- Child: Change of child's sleep [Time Frame: Baseline, 1-week and 3-month posttreatment]
  Change of the child's sleep measured by the Children's Sleep Habits Questionnaire (CSHQ), and sleep problems rated by parent (none, mild, moderate, severe)

Secondary Outcome Measures:
- Child: Change of daytime sleepiness [Time Frame: Baseline, 1-week and 3-month posttreatment]
  Pediatric Daytime Sleepiness Scale (PDSS) - parent report

- Child: Change of other sleep measures [Time Frame: Baseline, 1-week and 3-month posttreatment]
  Daily sleep diary and actigraphic assessment for consecutive seven days

- Child: Change of ADHD symptoms [Time Frame: Baseline, 1-week and 3-month posttreatment]
  Strengths and Weaknesses of ADHD Symptoms (SWAN) - parent report

- Child: Change of child's behaviour & other clinical symptoms [Time Frame: Baseline, 1-week and 3-month posttreatment]
  Strengths and Difficulties Questionnaire - parent report; Child Behavior Checklist (CBCL) - parent report

- Child: Change of quality of life [Time Frame: Baseline, 1-week and 3-month posttreatment]
  Pediatric Quality of Life Inventory 4.0 - parent proxy report (PedsQL) - parent report

- Child: Change of cognitive performance (sustained attention) [Time Frame: Baseline, 1-week and 3-month posttreatment]
  Continuous Performance Test (CPT)

- Child: Change of cognitive performance (auditory attention span) [Time Frame: Baseline, 1-week and 3-month posttreatment]
Digit Span

- Child: Change of cognitive performance (working memory) [ Time Frame: Baseline, 1-week and 3-month posttreatment ]
  N-back

- Child: Change of cognitive performance (cognitive processing) [ Time Frame: Baseline, 1-week and 3-month posttreatment ]
  Letter-digit substitution task

- Child: Change of cognitive performance (cognitive flexibility) [ Time Frame: Baseline, 1-week and 3-month posttreatment ]
  Bergs Card Sorting Test (BCST)

- Child: Change of cognitive performance (planning skills) [ Time Frame: Baseline, 1-week and 3-month posttreatment ]
  Tower of London (TOL)

- Change of parental self-reported sleep quality [ Time Frame: Baseline, 1-week and 3-month posttreatment ]
  Pittsburgh Sleep Quality Index (PSQI)

- Change of parental insomnia symptoms [ Time Frame: Baseline, 1-week and 3-month posttreatment ]
  Insomnia Severity Index (ISI)

- Change of parental daytime sleepiness [ Time Frame: Baseline, 1-week and 3-month posttreatment ]
  Epworth Sleepiness Questionnaire (ESS)

- Change of parental sleep parameters as measured by actigraphy [ Time Frame: Baseline, 1-week and 3-month posttreatment ]
  Actigraphic sleep parameters

- Change of parental sleep hygiene practice [ Time Frame: Baseline, 1-week and 3-month posttreatment ]
  Sleep Hygiene Index (SHI)

- Change of parental stress [ Time Frame: Baseline, 1-week and 3-month posttreatment ]
  Parental Stress Index - Short Form (PSI-SF)

- Change of parental mood symptoms [ Time Frame: Baseline, 1-week and 3-month posttreatment ]
  Depression Anxiety Stress Scales - 21 item (DASS-21)
- Change of parental daytime fatigue [Time Frame: Baseline, 1-week and 3-month posttreatment]
  Multidimensional Fatigue Inventory (MFI)

- Parent's satisfaction to the treatment [Time Frame: Baseline, 1-week and 3-month posttreatment]
  Treatment satisfaction rating scale

Estimated Enrollment: 60

Actual Study Start Date: April 1, 2017

Estimated Study Completion Date: March 31, 2019

Estimated Primary Completion Date: March 31, 2019 (Final data collection date for primary outcome measure)

<table>
<thead>
<tr>
<th>Arms</th>
<th>Assigned Interventions</th>
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<tbody>
<tr>
<td>Experimental: Intervention group</td>
<td>Behavioral: Sleep hygiene practices and behavioural intervention</td>
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<tr>
<td>The intervention will involve two face-to-face consultation sessions and one follow-up phone call with parents to help them learn sleep hygiene practices and specific behavioural strategies to improve their child's sleep and follow up on the progress.</td>
<td>The first session will involve the provision of sleep-related psycho-education (e.g. sleep hygiene practices) and specific strategies to tackle problematic sleep-related behaviours, as well as collaborative goal setting and development of management plan tailored to the child's sleep problem for the next two weeks. The second session will involve a review of the sleep diary and a reinforcement of learned strategies, and focus on problem-solving to tackle any issues that have emerged from implementing the behavioural strategies at home. A follow-up phone call will be made two weeks later to provide parents with an opportunity to ask any further questions and to consolidate learned strategies and further troubleshoot.</td>
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<tr>
<td>No Intervention: Waiting-list control</td>
<td>Children in the waiting-list control group will receive usual clinical care.</td>
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Eligibility

Ages Eligible for Study: 6 Years to 12 Years (Child)

Sexes Eligible for Study: All

Accepts Healthy Volunteers: No

Criteria
Inclusion Criteria:

- Aged 6-12 years old;
- With a clinical diagnosis of ADHD (any subtype), as confirmed by the Diagnostic Interview Schedule for Children-version-IV (DISC-IV);
- With parent-reported insomnia (difficulty initiating sleep and/or maintaining sleep).

Exclusion Criteria:

- Children with a serious medical condition (e.g. severe cerebral palsy) or intellectual disability (IQ<70);
- Children with a neurological and/or medical condition that may lead to disordered sleep;
- Suspected clinical sleep disorders (e.g. obstructive sleep apnea, OSA) that may potentially contribute to a disruption in sleep continuity and quality, as assessed by the Children's Sleep Habits Questionnaire (CSHQ). If the child is suspected of a clinical sleep disorder, he/she will be referred to appropriate services;
- Children who are already receiving specialised help (behavioural intervention) for their sleep from a psychologist or at a specialized sleep clinic.

Contacts and Locations
Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT03263156

Contacts
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Locations

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Sponsors and Collaborators
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Investigators
Principal Investigator: Shirley Xin Li, PhD,DClinPsy
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Study Documents (Full-Text)
More Information

Responsible Party: Dr. Shirley Xin Li, Assistant Professor, The University of Hong Kong
ClinicalTrials.gov Identifier: NCT03263156
Other Study ID Numbers: 30160604
Study First Received: August 23, 2017
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Individual Participant Data (IPD) Sharing Statement:
Plan to Share IPD: No

Studies a U.S. FDA-regulated Drug Product: No
Studies a U.S. FDA-regulated Device Product: No

Keywords provided by Dr. Shirley Xin Li, The University of Hong Kong:
sleep
ADHD
behavioural intervention
insomnia

Additional relevant MeSH terms:
Sleep Initiation and Maintenance Disorders
Attention Deficit Disorder with Hyperactivity
Sleep Disorders, Intrinsic
Dyssomnias
Sleep Wake Disorders
Nervous System Diseases
Mental Disorders
Attention Deficit and Disruptive Behavior Disorders
Neurodevelopmental Disorders

ClinicalTrials.gov processed this record on August 28, 2017