

Study title: Effects of a brief parent-based sleep intervention for children with attention deficit hyperactivity disorder

Research Protocol V1.2

Date: 29th September 2016

Background and Significance

Sleep disturbances as a common complaint in children with ADHD and the associated consequences

Attention deficit hyperactivity disorder (ADHD) is the most common psychiatric disorder with childhood onset,¹ affecting approximately 5% of children and adolescents worldwide,² and 3.9% in Hong Kong.³ It is characterized by impairment caused by inattention, impulsivity, and/or hyperactivity. At least one comorbid psychiatric disorder is present in 87% of children with ADHD.⁴ Among the array of comorbidities, sleep problems and the associated impairments have long been recognized as one of the most common issues. Sleep problems have been reported in 25-73% of children with ADHD.⁵⁻⁶ Local data also indicate that non-medicated ADHD children experienced significantly more sleep difficulties than normally developing children.⁷

The impacts of sleep problems on ADHD children can be far-reaching. Presence of sleep problems ranging from mild to severe predicts lower psychosocial functioning even after controlling for other potential confounders, including comorbidities, demographic characteristics, and severity of ADHD symptoms.⁸ Moderate-to-severe sleep problems are strongly associated with the severity of ADHD symptoms and impaired physical wellbeing of the child; parents with an ADHD child with comorbid sleep problems are 2.7 times more likely to be clinically depressed, stressed, or anxious.⁶

Evidence-based treatments for sleep problems in ADHD

Within the complex and multidirectional relationship between sleep and ADHD, poor sleep hygiene has been found to be a significant contributor. A previous study has shown that sleep problems in ADHD are generally behavioural in nature, primarily occurring at or around sleep onset.⁹ Behavioural interventions have been found to be effective in managing sleep problems in children in the general population,¹⁰ as well as in children with special needs (e.g. those with neurodevelopmental disorders).¹¹⁻¹³ Hence, behavioural interventions have been suggested as the first-line treatment for ADHD children experiencing sleep problems.¹⁴ In fact, standard behavioural techniques, such as graduated extinction and bedtime fading, have shown to be highly effective in managing sleep problems in children with ADHD.¹⁰

Significance

We expect that this parent-based behavioural sleep intervention will improve the sleep quality of children with ADHD, which in turn may lower inattention/hyperactivity impairment, reduce parental stress and improve the child's daily functioning.

Objectives and Hypothesis of the study

To assess the effect of a brief parent-based sleep behavioural intervention on the sleep quality as well as other aspects of functioning and mental health of children with ADHD and their parents.

Compared to children with ADHD and insomnia receiving treatment as usual, the group of children with ADHD and insomnia receiving the parent-based intervention will have better sleep and functioning as well as parental mental health at post-intervention and follow-up at 3 months.

Study Design/Methodology

Study Sites

Alice Ho Miu Ling Nethersole Hospital, TaiPo, N.T., Hong Kong

Sleep Research Clinic & Laboratory, Department of Psychology, The University of Hong Kong

Study Population

Parents of children who meet all the following inclusion criteria and none of the exclusion criteria will be our target participants.

Inclusion criteria:

ADHD with sleep problem(s)

- 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:

1. Children with a serious medical condition (e.g. severe cerebral palsy) or intellectual disability (IQ<70);
2. Children with a neurological and/or medical condition that may lead to disordered sleep;
3. 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;

4. Children who are already receiving specialized help for their sleep from a psychologist or at a specialized sleep clinic.

A total of 60 families will be invited to participate in this programme and will be randomized into intervention group and waitlist-control group (30 families each).

Subject Recruitment Plans and Consent Process

Patients at the child psychiatric clinic of Alice Ho Miu Ling Nethersole Hospital who potentially meet the inclusion criteria will be invited to take part in the study by the attending psychiatrists. Recruitment will be also conducted in the community (e.g. via posters, mass emails).

Potential interested parents will be contacted via phone and a brief assessment will be conducted to ascertain the presence and severity of sleep problems. For those who report that their child has insomnia, they will be asked several questions to establish whether the problem meets the International Classification of Sleep Disorders criteria.

Potential participants will then be invited to attend a face-to-face interview. First, consent will be obtained from the carer/parent of the targeted child with a Cantonese consent form provided with sufficient time for reading and enquiry. Potential participants will then be screened using CSHQ for presence of sleep problems (exclusion criteria) and DISC-IV to further confirm the ADHD diagnosis.

Suitable participants with insomnia will then be randomized into the two groups of intervention and wait-list control. The intervention will involve two fortnightly individual consultation sessions. The first session will focus on (1) a thorough assessment of the nature of the child's sleep problem, followed by (2) the provision of sleep-related psycho-education about normal sleep based on the child's developmental level, sleep hygiene, specific strategies known to be effective in tackling problematic sleep-related behaviours in children, and (3) collaborative goal setting and development of management plan tailored to the child's sleep problem for the next two weeks. Parents will also be asked to complete a sleep diary to monitor their child's sleep patterns in the following 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. Families will be provided with information sheets and leaflets designed for this programme, which will include information about sleep hygiene, common sleep problems, and strategies for managing specific sleep problems in children with ADHD. 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.

Measurements

Child-related Measures

Sleep Problems & Daytime Functioning

Children's Sleep Habits Questionnaire (CSHQ) – parent report.¹⁵ A validated 50-item parent-report measure of difficulties initiating and maintaining sleep over past week in children of age 4-12 (Cronbach's alpha=0.79). Items are rated on a three-point scale from "rarely" to "usually", and scores range from 33 to 99. The validated Chinese version will be used.¹⁶

Pediatric Daytime Sleepiness Scale (PDSS) – parent report. A validated 8-item self-report scale to measure daytime sleepiness in children and adolescents (Cronbach's Alpha=0.80).¹⁷ The Chinese version has been validated.¹⁸

Actigraphy. Assessed with Actiwatch 2 (Philips Respironics, Murrysville, PA), a small motion sensor attached to the non-dominant wrist to measure body movements. Indicators such as total sleep time, sleep onset latency, wake after sleep onset, and sleep efficiency (ratio of time asleep to time spent in bed) will be measured. Movement patterns can then be analysed in terms of sleep and wake times according to established scoring rules.¹⁹

Sleep diaries – parent report. Daily primary caregiver report of child sleep during the two 7-days sessions of actigraph measurement.

ADHD Diagnosis & Symptoms

Diagnostic Interview Schedule for Children – Version-IV (DISC-IV) – parent report. To confirm the diagnosis of attention deficit/hyperactivity disorder (ADHD) based on DSM-IV.²⁰ DISC-IV was validated locally.²¹ Functional impairment scores to achieve a full DSM-IV diagnosis were included, according to published scoring algorithms for the DISC-IV, equivalent to one severe or at least two intermediate impairments in six domains of daily functioning.²²

Strengths and Weaknesses of ADHD Symptoms (SWAN) – parent report. The Chinese version of SWAN rating scale is an 18-item questionnaire for assessment of ADHD symptoms, validated locally for Chinese children in Hong Kong.²³ Parents are asked to compare the child's inattention and hyperactivity behaviours with children of the same age using a 7-point scale. Scores range from -3 (far better than peers) to +3 (far worse than peers), with 0 denoting average behaviour. The total scale score had excellent internal consistency (Cronbach's Alpha=0.90), test-retest reliability, and good discriminant validity in differentiating ADHD clinic sample from community sample.²³

Behaviour, Other Clinical Symptoms & Functioning

Child Behavior Checklist (CBCL) – parent report. A validated 118-item measure assessing mental health problems in children and includes both externalizing and internalizing problems.²⁴ The validated Chinese version will be used.²⁵

Pediatric Quality of Life Inventory 4.0 – parent proxy report (PedsQL) – parent report.²⁶ A validated 23-item measure of quality of life for children aged 2-18 (Cronbach's alpha=0.86). A psychosocial health summary score is generated from 15 items, with scores ranging from 0 to 100 (higher scores indicating better quality of life). Items are rated on a 5-point scale from "never" to "almost always" as based on behaviour of child in the past month. A validated Chinese version by the research trust will be used (NB: the English version is attached, currently acquiring the Chinese version).

Strengths and Difficulties Questionnaire – parent report. The Strengths and Difficulties Questionnaire (SDQ) is a screening questionnaire designed by Goodman²⁷ to identify psychological maladjustment in children and adolescents. There are five domains: conduct problems, inattention-hyperactivity, emotional problems, peer problems and pro-social behaviour. Each domain contains five questions on a 3-point Likert scale. The difficulties score is the sum of all items except those on pro-social behaviour. An impact supplement scale looks at how the psychological problems of the children impact his/her surroundings. A Chinese version of SDQ is available and has proved reliable and valid.

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Cognitive Performance

Continuous Performance Test (CPT).²⁹ A computerised attention test designed by the Psychology Experiment Building Language, adopting the Conners Continuous Performance task (CCPT). A constant series of letter stimuli appear on the screen, participant must respond to all stimuli except for the letter X. The task takes approximately 14 minutes to complete. This task is used for measuring visual sustained attention, response inhibition, and reaction time.

Digit Span.³⁰ A computerised digit span task developed by the Psychology Experiment Building Language. A string of number is presented to participants both visually and auditory. Participants are then asked to key in the number string presented to them earlier. This task takes approximately 3 minutes to complete. This task is used for measuring auditory attention span.

N-back. A computerised visual working memory task, adapted from the dual n-back task designed by the Psychology Experiment Building Language.³¹ The n-back task consists of three different load levels (1-back, 2-back, and 3-back). Continuous audio and visual information are presented to participants. Participants are asked to response to the stimulus if the target is identical to the one immediately preceding one (1-back), identical to the one presented two trails back (2-back), and identical to the one presented three trails back (3-back). It consists of 59 test trails and task takes

approximately 8 minutes to complete. This task is used for measuring auditory and visual working memory.

Letter-digit task.³² A computerized version of letter digit substitution task developed by the Psychology Experiment Building Language. Nine letters and nine digits are paired at the top of the screen and the child is requested to press the digits on the keyboard corresponding to a test set of the nine symbols presented in a mixed order. It consists of 30 trails and it takes approximately 3 minutes to complete. This task is used for measuring cognitive processing.

Bergs Card Sorting Test (BCST).³³ A computerised version of card sorting test adapted from Wisconsin Card Sorting Test, designed by the Psychology Experiment Building Language. BCST contains 64 screen images (cards). A number of cards are presented to the participants. Participants are asked to sort the cards depending on the particular rule. They do not know how to match, however feedback are given whether a particular match is right or wrong. This task takes approximately 3 minutes to complete. This task is used for measuring cognitive flexibility.

Tower of London (TOL).³⁴ A computerised version of the TOL task developed by the Psychology Experiment Building Language, based on Shallice (1982)³⁵ TOL paradigm. Participants are asked to move coloured discs one by one from an initial state to match a goal state, within limited moves. There are a total of 12 trails for this task. This task is used for measuring planning skills.

Parent-related Measures

Sleep

Pittsburgh Sleep Quality Index (PSQI). A validated 19-item measure used to assess sleep habits, quality, and quantity, producing a total score and seven sub-scores in sleep quality, sleep onset latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleep medication, and daytime dysfunction (Cronbach's Alpha=0.83).³⁶ The validated Chinese version will be used.³⁷

Insomnia Severity Index (ISI). A validated 7-item measure for detecting changes in perceived sleep difficulties, with high convergence between patient and clinician ratings (Cronbach's Alpha=0.74).³⁸ Items are rated on a 5-point scale from "not at all" to "extremely". Total score ranges from 0-28 and higher scores indicate greater insomnia severity. The Chinese version has been validated.³⁹

Sleep Hygiene Index (SHI). A validated 13-item measure designed to assess sleep hygiene (Cronbach's alpha=0.66).⁴⁰ Items are rated on a 5-point scale from "never" to "always". Total scores range from 0 to 52, with high scores indicating poorer sleep hygiene.

Epworth Sleepiness Questionnaire (ESS). A validated 8-item measure to assess daytime sleepiness in terms of the likelihood of falling asleep while engaged in eight different activities

(Cronbach's Alpha=0.74).⁴¹ Items range from 0-3 and the total score ranges from 0-24. Higher scores indicate greater sleep propensity in daily life. The Chinese version has been validated.⁴²

Actigraphy. As above.

Mental Health

Parental Stress Index – Short Form (PSI-SF). A validated 36-item measure on parental distress, parent-child dysfunctional interaction, and difficult child (Cronbach's Alpha=0.81).⁴³ The validated Chinese version will be used.⁴⁴

Depression Anxiety Stress Scales – 21 item (DASS-21). A validated 21-item measure on adult mental health, looking at depression, anxiety, and stress (Cronbach's Alpha=0.95).⁴⁵ Items are rated on a four-point scale from "not at all" to "most of the time", with higher scores representing more mental health difficulties. A validated Chinese version will be used.⁴⁶

Multidimensional Fatigue Inventory (MFI). A validated 20-item measure devised to measure fatigue; dimensions include general fatigue, physical fatigue, mental fatigue, reduced motivation, and reduced activity (Cronbach's Alpha=0.84).⁴⁷ The Chinese version has been validated.⁴⁸

Other Information

Demographics & health history. Each family will complete a brief questionnaire so as to provide sample characteristics of the child (demography, family characteristics, medical history). Prescribed medication(s) of the child at the time of study will be documented and recorded.

Evaluation survey. Each family will be invited to complete a brief evaluation survey to provide feedback on the usefulness and arrangement of the intervention.

Measures on sleep, ADHD symptoms, other clinical symptoms and functioning, and cognitive performance of the child, as well as parental sleep and mental health will be administered at the following time-points for the intervention and waitlist-control group: before the intervention programme (baseline); after the intervention (one-week after the follow-up call to assess the short-term effects of the intervention). The above measurements will be additionally conducted for the intervention group at 3 months after the intervention to assess any long-term effects of the treatment.

Statistical Analysis Plan

Sample Size Determination and Power

The primary outcome is the child's sleep based on parental report (e.g. CSHQ, sleep problems rated by parents), as a measure of intervention efficacy. Secondary outcomes include other sleep measures (e.g. actigraphic parameters, daytime sleepiness), daytime functioning, quality of life and other

clinical symptoms and behavior of the child, as well as parental sleep and mental health. A previous representative study found an effect size of -0.8 for CSHQ at 3 months follow-up, which would require 26 families in each arm to have 80% power at the two-sided 5% level of significance to detect this effect.⁴⁹ To allow for 15% loss to follow-up, we require 30 families in each group.

Analysis Plan

Preliminary descriptive analysis will be conducted to compare the two groups (intervention, wait-list control) for any baseline differences in sleep and functioning characteristics. Subsequent analysis will be conducted on an intention to treat basis. For child- and parent-related measures, changes between baseline and post-intervention as well as between baseline and follow-up at 3 months will be computed. Mean differences in change at 95% confidence interval in outcomes between intervention and control arms will be estimated with regression models, adjusting for covariates as well as baseline scores for each specific measure if there are any group differences.⁵⁰ Potential covariates to be considered include the child's age, sex, medication use (yes or no), and family socioeconomic status (measured by monthly family income). As for computing effect sizes, changes in each outcome will be standardized to a mean of 0 and standard deviation of 1, before repeating the regression analyses. Effect sizes are interpreted as small, moderate and large for standard deviations of ~0.20, 0.50, and .80 respectively.⁵¹

Declaration of Helsinki

The study will follow the ethical principles under the Declaration of Helsinki. The right of all individuals to self-determination and the right to make informed decisions regarding participation in research, both initially and during the course of the research are respected. Participants' welfare would take precedence over the interests of science and society, and ethical consideration would take precedence over laws and regulations.

Privacy and confidentiality

Participants' names will be kept on a password-protected database and will be linked only with a study identification number for this research. There are no patient identifiers. Data will be stored in a locked office of the investigators and maintained for a minimum of three years after the completion of the study.

Risk/Benefit to participants

This study does not present any risks to the participants. Selected participants will all receive a behavioural sleep intervention and related education materials.

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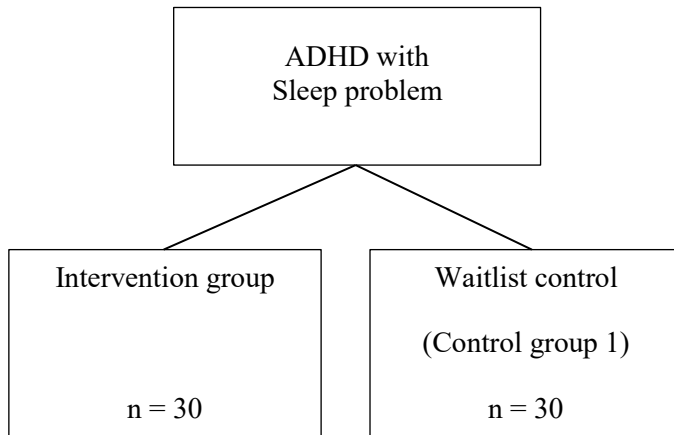
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Appendix

Figure 1.



Recruitment criteria (for psychiatrists' reference):

Inclusion criteria:

- 6-12 years old (of both genders)
- ADHD (any subtype)
- With insomnia (difficulty initiating and/or maintaining sleep)

Excluding those with the following condition

- Serious medical condition (e.g. severe cerebral palsy) or intellectual disability (IQ<70)
- Neurological and/or medical condition that may lead to disordered sleep
- Clinical sleep disorders (e.g. obstructive sleep apnea, OSA)
- Receiving specialized help (behavioural intervention) for their sleep from a psychologist or at a specialized sleep clinic