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SLEEP - An intervention with weighted blankets for children with Attention Deficit Hyperactivity Disorder (ADHD) and sleep problems: study protocol for a randomised control trial

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Abstract:

Introduction and objectives;

Children with Attention Deficit Hyperactivity Disorder (ADHD) have an increased risk of sleep problems. Weighted blankets are one possible non-pharmacological intervention for these problems in this group of children, however, the effectiveness of weighted blankets is insufficiently investigated. This study aims to investigate the effectiveness of weighted blankets in terms of sleep, health-related outcomes, and cost-effectiveness, as well as to explore children´s and parents´ experiences of a sleep intervention with weighted blankets.

Methods and analysis;

This study is a randomised placebo-controlled crossover trial comparing the effect of weighted fiber blankets (active) with fiber blankets without weight (placebo). The study period is 4 weeks for each condition respectively, and then an 8-week follow-up. A total of 80 children diagnosed with ADHD, with sleep problems, will enter the study. The primary outcomes are sleep and cost-effectiveness. The secondary outcomes are health-related quality of life, ADHD symptoms, psychological distress, and anxiety. Interviews with a subsample of the participating children and parents will be conducted for exploring the experiences of the intervention.

Ethics and dissemination.

Ethical approval of the trial has been obtained from the Swedish Ethical Review Authority (No. 2019-02158) and conforms to the principles outlined in the Declaration of Helsinki (WMA, 2013). Results will be reported as presentations at peer-review conferences, in articles in peer-review journals, and in meetings with healthcare providers.

Trial Registration number: NCT04180189

Strength and limitations of this study

- The scientific evidence on the effectiveness of weighted blankets is insufficient.
- The results from this randomised controlled trial will provide new evidence of the efficacy, cost-effectiveness, and experiences of the intervention.
- The design used to evaluate the intervention of weighted blankets in the trial may be applied to other healthcare settings and may lead to the development of systematic evaluations of the intervention in local contexts.
- Weighted blankets are prescribed to patients in healthcare as a non-pharmacological intervention for sleep problems, the results from this study make it also applicable to other categories of patients than children with ADHD.
- Potential limitations include loss to follow-up during the multiphase study and that the trial is only implemented at one Department of Child and Adolescent Psychiatry in the southern part of Sweden, which may limit generalisability of specific study findings to other populations and settings.

Introduction

Children with Attention Deficit Hyperactivity Disorder (ADHD) have an increased risk of poor health outcomes compared to healthy children.[1 2] The increased risk is especially apparent among girls.[3] Between 25 and 50% of children with ADHD have sleeping problems,[1 2] commonly including bedtime resistance, night-waking, early morning awakening, and co-sleeping.[4] Sleep is important for everyday functioning and essential for health and wellbeing,[5-7] and sleep deprivation is associated with reduced quality of life,[8] an increased risk of physical and mental health consequences[9 10] as well as increased risk-taking behavior.[11-13] Further, poor sleep negatively affects performance[10] and relationships in school,[14] which has consequences for school results and transition into adulthood and working life.[15 16] Sufficient sleep duration and quality is, on the other hand, associated with better attention, behavior and cognitive functions, and better physical and mental health.[17 18]

The use of pharmacological treatment for sleep problems is common and has increased dramatically among children with ADHD in the last 10 years, although often with unfavorable side effects. [2 11 19] There is some evidence of the benefit of the commonly used Melatonin compared with placebo, but the degree of benefit is uncertain. [20] There are various types of non-pharmacological interventions for children with ADHD to manage sleep problems, which are not associated with the side effects associated with pharmacological treatment. However, due to clinical heterogeneity, poor study quality, and the lack of randomised controlled trials (RCTs),[20-23] the evidence base for the effectiveness of non-pharmacological interventions is inconclusive. There is thus a need for high-quality studies to evaluate the clinical effect and cost-effectiveness of non-pharmacological sleep interventions.

Weighted blankets are currently prescribed as a supplement to or replacement of pharmacological treatment for sleep problems among children with ADHD. The effectiveness of weighted blankets in this context has received little research attention and has generally had insufficient scientific quality,[21 24 25] with only one randomized controlled trial.[26] This latter study had a randomized, placebo-controlled crossover design with a four-week follow up for each type of blanket. The population consisted of 67 children, aged 5-16 years, with autism spectrum disorders and the result showed that the weighted blanket, compared with the control blanket, did not increase total sleep time, sleep-onset latency, or sleep efficiency as measured by actigraphy. However, parents and children favored the weighted blanket and the weighted blankets were well tolerated.[26] In a pilot study including only two children with an

autism spectrum disorder, the use of weighted blankets improved the sleep quality, justifying the need for additional robust research.[27] A case-control study without randomisation included 21 children, aged 8–13 years, with ADHD and 21 matched healthy children as a control group showed some small positive effects on sleep onset latency.[28] In summary, these studies do not provide conclusive evidence of the effect [25], economic impact[20 21] or children's and parents' experiences of weighted blankets for children with ADHD on sleep problems. Thus, more RCT studies are needed to explore this issue further. Given the societal cost and the quality of life implications of sleep interventions, the cost-effectiveness of this non-pharmacological intervention also needs to be investigated.[20]

Objectives

This study targets children with newly diagnosed ADHD and sleep problems, and aims to 1) evaluate the effect of an intervention with weighted blankets on sleep and other health-related outcomes; 2) evaluate the cost-effectiveness of weighted blankets, and 3) explore children´s and parents´ experiences of the sleep intervention with weighted blankets.

Methods

Study design

This is a randomised, placebo-controlled crossover trial investigating the effects of an intervention with fiber-weighted blankets in children with ADHD. The study period is 4 months, including 2 x 4 weeks of intervention with weighted blankets and placebo, followed by an 8-week follow-up (figure 1). The study investigates the effect of the intervention in terms of 1) sleep and health; 2) cost-effectiveness and 3) experiences of sleep and health-related outcomes. The qualitative part will be performed using an explorative design based on interviews from a subsample of the included children and their parents. The interviews will be conducted at the end of the 4-month intervention in order to gain knowledge of the children's and parents' experiences of using these fiber-weighted blankets. The protocol is based on the Standard Protocol Items for Randomized Trials (SPIRIT).[29]

Patient and public involvement

The study design has been planned together with healthcare professionals at the included Department of Child and Adolescent Psychiatry (DCAP). The end-users, i.e children, have

however not been consulted during the planning phase. The results will be communicated to the healthcare services after the research period.

Participants and recruitment

Children attending the ADHD unit at DCAP in the southern part of Sweden during 2020-2021 will be asked to participate in the study. The ADHD unit does not admit children with complex neuropsychiatric or psychiatric comorbidities. Recruitment of participants started in January 2020 and is estimated to be completed during autumn 2021. All children aged 6-15 years, recently diagnosed with ADHD with sleep problems verified by selected questions from the Child's Sleep Habits Questionnaire (CSHQ)[30] will be approached for participation in the study. Children will be excluded if they have already used weighted blankets as a sleep intervention, or if they have received a new prescription or change of pharmacological treatment for sleep problems.

First, eligible children and their parents will be informed verbally about the study by their doctor or nurse at the DCAP. They will then receive written information about the study and be approached by healthcare professionals about participation. After the researchers have received written consent, the participants will be contacted by telephone and the research project leader will provide more detailed information about the study. The participants will be informed that they are about to try two different types of fiber blankets. The participants will be encouraged to contact the researchers if further questions arise.

Intervention

The participants (n=80) will be randomly assigned into two groups using simple randomisation with stratification [31]. A total of 80 sheets with the letter A (Intervention) or the letter B (Control) will be printed out and put into each envelope. The sealed envelopes will be mixed and one of the researchers will pick an envelope randomly for each child. The letter A or B indicates if the child will start with a fiber-weighted blanket (active) or with a fiber blanket without weight (placebo). After four weeks with either the active intervention (A) or placebo (B) the children will change blanket (if starting with active, the child will change into placebo, and vice versa). After this 8-week period, the child will decide which of the two blankets (active or placebo) that they want to retain.

Fiber-weighted blankets from Novista of Sweden (Novista.se) will be used in this study. The weight in the blankets is derived from longitudinal polyester fibers that make it flexible. The

blanket size is 150 x 210 cm, which is a standard size for children and adults in Sweden. The weight of each blanket will be individually tailored (weight between 6 to 10 kg) for the children, based on age, sex, height, weight, degree of sleep problems, and subtypes of ADHD according to the clinical practice of two independent experienced occupational therapists. The fiber blankets without weight (controls) have been designed for the project so that both active and placebo blankets have the same design. The weight is the only aspect that distinguishes them.

Data assessment

Data will be assessed at baseline (prior to the intervention), and during the 4th, 8th, and 16th weeks of the study. A seven-day objective measurement of sleep will be conducted during these measurement periods. Self-reported data will also be gathered through completion of a questionnaire by the parent and child respectively (Table 1).

Interviews with a purposeful sample of children (n = 25) and parents (n = 25) will be held after the intervention period in order to understand the experiences of the intervention's impact on sleep and health-related outcome.

1. *Methods for investigating the health effects of weighted blankets*

Primary outcome

The primary outcome is *objectively measured* and *self-reported sleep*. Variables of interest from the *objectively measured sleep* are: *Sleep onset latency (SOL),* which refers to the period of time between turning lights out to go to sleep (timing identified by marker from the event button, or self-reported time in daily SMS) and falling asleep; *Total sleep time (TST)*, which is equal to the time of total sleep episode minus the awake time; *Sleep efficiency (SE),* which is the total sleep time expressed as a percentage; *wake after sleep onset (WASO),* referring to periods of wakefulness occurring after sleep onset.

Objectively measured sleep will be assessed using actigraphy. This method for assessing sleep has been shown to be a valid in several studies,[32] and has shown to be strongly associated with polysomnographic measures with a correlation coefficient of at least 0.85 in healthy individuals.[33] Measurements from at least 5-7 nights have been recommended.[34] Motionwatch 8 (Camntech.Ltd.), a triaxial accelerometer using MEMs technology, capable of sensing motions in a resultant force range of 0.01 g to 8 g[35] is used in this study,. The

actigraph registers total gross motor activity for analysis of sleep-wake patterns and has good validity for measuring sleep[35]. Recordings will be taken in 30-second epochs.

Participants will be instructed to wear the watch on their non-dominant wrist, for seven consecutive nights. If not worn during the day, the parent and child will be instructed to put on the watch in the early evening, or in good time prior to going to bed. The participant is instructed to push an event-button when they decide to go to sleep, e.g. when they stop reading a book or turn off the lights. Then they are told to push the button again when they wake up in the morning. In addition to marking the event of going to sleep and waking up by pressing the button, the parents will answer questions daily (by text message): 1) What time did the child go to bed yesterday? 2) How long time do you estimate the time for the child to fall asleep from the time the child went to bed? (hours; minutes); 3) What time did the child wake up today?

The variables of interest from the *self-reported sleep* will be assessed by CSHQ[30], and Insomnia Severity Index (ISI).[36]

The CSHQ assesses parental reported sleep and consists of 33 items related to eight subscales; 1*) Bedtime resistance*, 2) *Sleep onset delay*, 3) *Sleep duration*, 4) *Sleep anxiety*, 5) *Night wakings*, 6) *Parasomnias,* 7) *Sleep-disordered breathing*, and 8) *Daytime sleepiness*. Each item is rated on a three-point scale: "usually" if the sleep behavior occurred five to seven times/week; "sometimes" for two to four times/week; and "rarely" for zero to one time/week. A higher score indicates more sleep problems. The scale has good reliability and validity.[30]

Insomnia will be assessed by ISI, which comprises seven items for the children to respond to: 1) Severity of sleep-onset, 2) Sleep maintenance, 3) Early morning awakening problems, 4) Satisfaction with current sleep pattern, 5) Interference with daily functioning, 6) Noticeability of impairment attributed to the sleep problem, and 7) Level of distress caused by the sleep problem. Each item is rated on a five-point Likert scale ranging from "not at all" (scored at 0) to "extremely" (scored at 4). Total scores range from 0 to 28, with high scores meaning greater insomnia severity. ISI is a reliable and valid instrument for quantifying perceived insomnia severity and measures insomnia in treatment research.[36] The ISI will be slightly modified in order to better correspond to a child's language.

Secondary outcomes

The children's general well-being will be assessed by the Child Outcome Rating Scale (CORS),[37] which is an overall measure of psychological distress. It was developed to give children a voice in the services they receive. CORS comprises four items where the child evaluates; 1) Me (How am I doing?), 2) Family (How are things in my family?), 3) School (How am I doing at school?), 4) Everything (How is everything going?). Each item is rated on a 100-millimeter Visual Analog Scale with smiley and sad faces as anchors. CORS has good reliability and moderate validity.[37]

The children's anxiety will be assessed by The short State-Trait Anxiety Inventory for children (short-STAI).[38 39] Short-STAI includes six items.[40] Each item is rated on a four-point Likert scale ranging with 1 = "not at all," 2 = "somewhat," 3, = "moderately", and 4 = "very much." The total score range from 6 to 24 points, with 6 points indicating no anxiety and 24 points indicating the highest level of anxiety. Short-STAI has good reliability and validity for children.[38]

The children's ADHD symptoms - hyperactivity/impulsivity, inattention and oppositional - will be assessed by the parents using The Swanson, Peland, and Nolan Scale (SNAP-IV).[41] The SNAP-IV consists of 30 items and is divided into three subscales: inattention (nine items), hyperactivity/impulsivity (nine items), and oppositional (eight items) and four supplementary questions regarding oppositional (two questions) and ADHD (two questions). Items are rated on a four-point Likert scale range 0 = "not at all", 1 = "just a little", 2 = "quite a bit", and 3 = "very much". Items for inattention and hyperactivity/impulsivity can be combined to create a "combined ADHD" score.[42] Higher scores represent more problem symptoms. The SNAP-IV is a robust and valid measure of outcome for research studies, for example, in randomized controlled trials.[43]

The parents' general well-being will be assessed by the Outcome Rating Scale (ORS),[44] which is a general mental health assessment of the past week in four items; 1) Personal wellbeing, 2) Interpersonal relationships, 3) Social relations and, 4) Overall sense of well-being. Each item is rated on a 100-millimeter Visual Analog Scale with anchors from 0 (negative) to 100 (positive). ORS is a reliable and valid instrument.[37 45]

Family situation and parental mood will be assessed by the Brief Child and Family Phone Interview (BCFPI),[46 47] which comprises two subscales.The subscale ´family situation` contains three items rated on a four-point Likert scale range 1 = never, 2 = sometimes, 3 =

often, 4 =always. The subscale ´parental mood` contains six items based on the question "How often during the past week has the parent experienced…?" rated on a four-point scale; < 1 day, 1-2 days, 3-4 days, >5 days. BCFPI has good reliability and validity.[46 47]

In addition, sociodemographic data and assessment of the *health-related quality of life* in children (EQ-5D-Y)[48] and parents (EQ-5D-3L)[49] will be conducted.

2. *Methods for investigating the cost-effectiveness of weighted blankets*

The health economic evaluation is a within-trial cost-utility analysis with a societal perspective after a follow-up period of 16 weeks. An incremental cost-effectiveness ratio (ICER) reporting costs per QALYs (quality-adjusted life-years) is calculated based on differences in societal costs (implementation costs and societal consequences) and quality of life when using either the fiber-weighted blankets or placebo blankets. No discounting of costs and health effects will be performed due to the short follow-up period. A number of sensitivity analyses are planned, including a probabilistic analysis with bootstrapped differences of major societal consequences as well as of the ICER.

The *societal cost consequences* combine parent-reported data on resource consumption with clinical register data to estimate the differences in societal costs between the two study arms at baseline and 16 weeks. The parent-reported resource consumption survey questions are based on a Swedish adaptation of the TIC-P instrument[50-52] and consider the past two months. The questions include school absence for the child (in numbers of full days, half days, and 1-2 hours), work absence for one parent (in numbers of full days (8 hours), three-quarters of a day (6 hours), half a day (4 hours) and one-quarter of a day (2 hours)), work productivity of the parent (in ten levels from no work accomplished to hardly no decreased work capacity) and healthcare appointments (nine types of healthcare including e.g. school healthcare, primary care, and emergency care). The clinical register data include the number of appointments at the DCAP and prescribed pharmacological therapy. The cost of the resource consumption items from the parent survey and the clinical register will be estimated according to Swedish published data on the average costs for healthcare appointments from SALAR (the Swedish Association of Local Authorities and Regions) and occupation-specific healthcare wages including wage taxes from Statistics Sweden. The cost of parents' work absence and decreased productivity will be estimated using average Swedish hourly wages including wage taxes from Statistics Sweden while the cost of child school absence is estimated according to estimated schooling costs from The Swedish National Agency for Education. The cost of

prescribed pharmacological therapy will be estimated according to listed prices at the Dental and Pharmaceutical Benefits Agency.

The *implementation costs,* i.e. the prescription of the weighted blankets, includes the healthcare region's purchasing price for weighted blankets, child psychiatrist time for prescription, physiotherapist time for tailoring as well as parent and child time. The healthcare costs will be estimated based on data from SALAR and Statistics Sweden while the visiting and traveling time for the parent and child will be estimated according to data from Statistics Sweden and The Swedish National Agency for Education, as above.

Quality of life estimates for calculating *QALYs* over the 16 week follow-up period will be taken from the parent-reported EQ-5D instrument valued with a Swedish tariffs value set.[53] There is currently no appropriate value set for the child version of EQ-5D (i.e. EQ-5D-Y), so in a sensitivity analysis, the VAS-ratings will be used and added to the parent estimated QALYs.

EQ-5D is a generic health-related quality of life instrument[49] measuring the parents' health comprising five dimensions; 1) Mobility, 2) Self-care, 3) Usual activities, 4) Pain/discomfort, and 5) Anxiety/Depression. Each dimension is divided into three levels; No problems, Some or moderate problems, Extreme problems. In addition to the five dimensions, a 100-millimeter vertical Visual Analog Scale with endpoints of 100 means "best imaginable health state" and 0 means "worst imaginable health state. The total score ranges from 0 to 1 where a higher score indicates a better health-related quality of life. EQ-5D-3L is frequently used in Sweden and for economic evaluations and is considered a reliable and valid instrument.[53] For the economic evaluation, the Swedish value set will be used to calculate the parent QALYs.[53]

EQ-5D-Y measures health-related quality of life "today" for children and young people and is developed from the standard adult EQ-5D [48]. EQ-5D-Y comprises five items; 1) Walking about (mobility), 2) Looking after myself (self-care), 3) Doing usual activities (usual activities), 4) Having pain or discomfort (pain and discomfort), and 5) Feeling worried, sad or unhappy (anxiety and depression). Each item is divided into three levels; No problems, Some problems, and A lot of problems. The EQ-5D-Y also includes an easily understandable modified vertical Visual Analogue Scale of EQ-5D, where the respondent rates the overall health status with the endpoints from 0 (the worst health state the child can imagine and 100 (the best health state the child can imagine).[48] EQ-5D-Y has good reliability and validity.[54] As

no value set currently exists that can enable us to calculate QALYs based on the EQ-5D-Y items[55] the VAS ratings will be used to estimate the children QALYs.

Table 1. Overview of the questionnaires included in the study

	Assessed by children reports	**Assessed by parents' reports**
Socioeconomic variables		Children: Age, gender, country of birth, Parents: age gender, country of birth, civil status, level of education, and work situation
Sleep habits	Insomnia Severity Index (ISI) [36]	Child's Sleep Habits Questionnaire (CSHQ) [30]
General well-being	Children Outcome Rating Scale (CORS) [37]	Outcome Rating Scale (ORS) [37 44]
Anxiety	State-Trait Anxiety Inventory (STAI) [38 39]	
ADHD symptoms		Swanson, Peland and Nolan Scale (SNAP IV) [41 42]
Family situation and parental mood		The Brief Child and Family Phone Interview (BCFPI) [46 47]
Health-related quality of life	EQ-5D-Y [48 54]	EQ-5D-3L [49 53]
Resource consumption		School absence (children), work productivity and absence (parents), and healthcare consumption according to Swedish adaptation [51 52] of the TIC-P instrument [50]

3. *Methods for investigating the experiences of weighted blankets*

The qualitative data will consist of individual interviews with children and their parents in the intervention study. An open interview guide with initial questions will be used to ensure similar data from all participants. The initial questions focus the experiences of sleep for children with ADHD, experiences of how the sleep intervention with fiber-weighted blankets influences the children's sleep, and health-related outcomes as well as the family situation. *Questions to the children*: "How do you usually sleep?", "In what way can it be difficult to sleep?", "How does sleep differ if you sleep well or badly?", "What is important for you to be able to sleep?", "How do you experience the two different blankets you have used?", "How do you experience the fiber-weighted blanket?", "Can you describe your sleep since you started using the fiber-weighted blankets?". *Questions to the parents*: "What does sleep mean for your child?", "How does your child usually sleep?", "What is important for your child to be able to sleep?", "How is your child's life affected by sleep?", "How do you experience the

two different blankets your child has used?", "How do you experience the fiber-weighted blanket?", Can you describe your child's sleep since he/she started using the fiber-weighted blankets?", How is your child's well-being since he/she started using the fiber-weighted blankets?", How has the situation for the family and you as a parent been affected since your child started using the fiber-weighted blanket?" *Follow-up questions* will be used to encourage children and parents to develop the answers: "Please tell me more", "How do you mean?" or "What do you have in mind when you say ...?" All interviews will be performed at the University in a quiet room. The interviews will be digitally recorded and transcribed verbatim.

Statistical Power

A power analysis was made based on estimated changes in the primary outcome variable *sleep onset latency* (SOL). Estimations of mean and standard deviations were made based on previous studies of SOL in children. Mean SOL is expected to differ substantially with age among children. Gringras et al. (2014) investigated children 5 to 16 years of age and found a mean value of 76,5 minutes of SOL with a standard deviation of 46,1.[26] Hvolby and Bilenberg (2011) studied SOL in children 8 to 13 years of age and reported a mean value of 23,1 minutes of SOL with a standard deviation of 9,4.[28]

Previous studies investigating the effect of similar interventions on SOL has found a 40% decrease in SOL after the intervention [28]. The power calculation of this study is based on the assumption that a 30% decrease in SOL is a clinically relevant improvement. In this study, including children 6 to 15 years of age, estimating a mean of 35 minutes SOL and a standard deviation of 15, the power analysis demonstrated that 58 children (29 in each group) will be a sufficient number if accepting a 30% difference between groups in SOL with 80 % power. To allow for a 25% dropout, 80 children (40 in each group) will be enrolled in the study.

Data analysis

Statistical analyses will be performed using SPSS version 24 for Windows. The intervention will be evaluated in terms of effect and cost comparison. Differences in objectively and subjectively measured sleep, anxiety, and health-related quality of life will be analysed by paired t-test and by independent sample t-test for between group analyses. Differences in resource consumption will be analyzed via non-parametric bootstrap analyses.[56] The qualitative data from interviews will be analyzed with inductive qualitative content analysis.[57]

Ethics and dissemination

The study is approved by the Swedish Ethical Review Authority (No. 2019-02158) and conforms to the principles outlined in the Declaration of Helsinki.[58] The study will fulfill requirements for research: information, consent, confidentiality, and safety of the participants and is guided by the ethical principles: autonomy, beneficence, non-maleficence, and justice.[59] All participation and data collection will be performed confidentially. Children and parents will receive written and oral information and give their informed consent. The participants will be informed that they can withdraw from the project at any time without having to justify why. Data will be collected in depersonalized form and keys that link data with personal information will be stored separately and only accessible to the project leader. All personal data will be registered according to the General Data Protection Regulation (GDPR2016/679)[60] and the data will be stored in accordance with the Archive Act in Sweden (SFS1990:782).[61] This study is registered at http://clinicaltrials.gov under identification number NCT04180189. The results of this study will be communicated to the included participants, healthcare providers, and companies, in manuscripts submitted to peer-reviewed journals, as well as in presentations at national and international peer-review conferences.

Discussion

Weighted blankets are prescribed to patients in healthcare in Sweden and are widely used as a non-pharmacological intervention for sleep problems, even though there is no evidence for the positive effects of the intervention. The few previous studies investigating the effect of weighted blankets for children with ADHD had not shown conclusive results and to date, there are too few high-quality studies to be able to conclude anything about the evidence base for the intervention. [25-28] The results from this RCT will thus be important for providing new evidence of the efficacy, cost-effectiveness, and experiences of the use of weighted blankets to address sleeping problems among children with ADHD.

We included sleep, both objective and subjective measures, as the primary outcome measure for the RCT. We will also investigate the effectiveness of weighted blankets on health-related outcomes, evaluate the cost-effectiveness, and explore children´s and parents´ experiences of effects. The cost-effectiveness of weighted blankets is highly relevant to investigate though

this has not previously been studied.[21] The cost and benefits of the intervention need to be taken into consideration when implementing the method in healthcare settings.

One strength of the study is its design and the relatively large number of participants. This will be the first randomised placebo-controlled crossover trial investigating the effects of fiber-weighted blankets in children with ADHD. Another strength is the use of both objective and subjective measures for sleep. Although subjectively measured sleep is highly relevant to assess and evaluate, objectively measured sleep has the advantages of being free from subjective expectations in relation to the intervention, and less sensitive to recall bias. Furthermore, the evaluation of health-related outcomes as well as different variables to evaluate cost-effectiveness is a strength of this study. Similarly, the inclusion of a qualitative approach in the design to increase the understanding of both children's and parents' experiences of effects is also a strength. This latter aspect is of great relevance as children's perspectives are seldom taken into account in research.

There are, however, a few methodological challenges with this study. Assessing self-reported data from children is difficult for several reasons. Some of the questionnaires in this study are designed for the parent to respond on behalf of the child (e.g. CSHQ). This may be a good approach for younger children, but depending on the habits around bedtime, the parents may only have (at best) a reasonably good perception of how the child`s sleep was (for example, if sleeping in separate bedrooms). Under these circumstances, the parent and the child are instructed to fill in the questionnaire together to get a more reliable assessment. Another potential bias is the placebo blankets. Although the participants are only informed they are trying two different kinds of blankets, most of them have heard of weighted blankets through media or their health providers, and there is a risk they will have higher expectations on the weighted blanket, than the fiber blanket without weight.

We anticipate the project will make several scientific contributions to the research on health-related outcomes, sleep, and cost-effectiveness for sleep interventions. These findings will be relevant for children with ADHD in particular, but will also be relevant for other target groups and other settings. Finally, the design used to evaluate the intervention of weighted blankets in this trial may if proven feasible and effective be applied to other healthcare settings and may support systematic evaluation of the intervention in clinical practice.

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Author Contribution IL wrote the first draft of the manuscript. PS and IL conceived the study idea, obtained the funding, and are the guarantors of the study. JN, IL, KA, and PS contributed to the study design. IL and KA were primarily responsible for the statistical analysis plan. PJ was responsible for the health economic analysis plan. All authors read and approved the final version of the manuscript.

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Competing interests None declared.

Patient consent for publication Not required.

Availability of data and materials: Not applicable. The data will not be shared as ethics approval for the study requires that data files and the transcribed interviews are kept in locked files, accessible only to the researchers.

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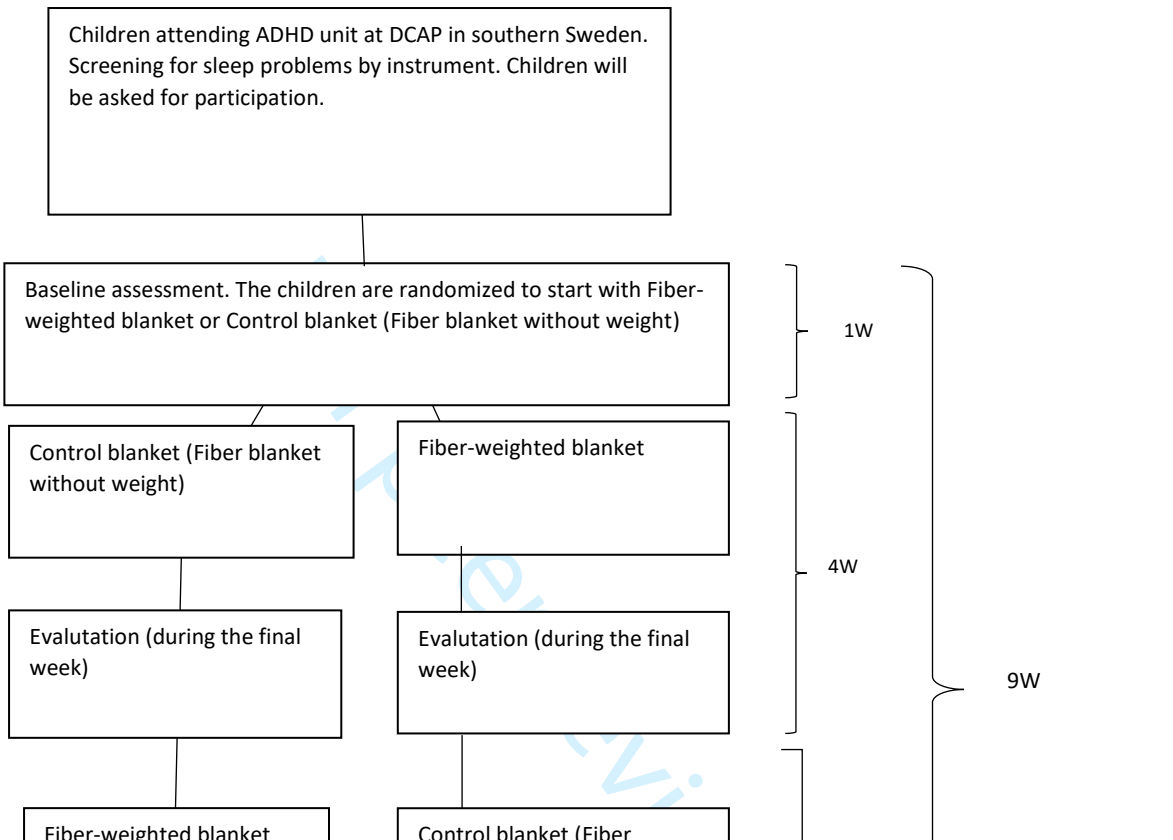
Figure 1. Flowchart RCT. The time between requirement, randomisation, intervention, and follow-up

Figure 1. Flowchart RCT. The time between requirement, randomisation, intervention, and follow-up



SPIRIT
STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description
Administrative information		
Title	1	*SLEEP - An intervention with weighted blankets for children with Attention Deficit Hyperactivity Disorder (ADHD) and sleep problems: study protocol for a randomised control trial*
Trial registration	2a	Trial Registration number: NCT04180189
	2b	Trial Registration number: NCT04180189
Protocol version	3	2020-11-30 no. 1
Funding	4	This work was supported by the Knowledge Foundation and Region Halland. Page 13
Roles and responsibilities	5a	Ingrid Larsson[1] (IL) wrote the first draft of the manuscript. Petra Svedberg[1] (PS) and IL conceived the study idea, obtained the funding, and are the guarantors of the study. IL, Katarina Aili[1] (KA), Jens Nygren[1] (JN), and PS contributed to the study design. IL and KA were primarily responsible for the statistical analysis plan. Pia Johansson[1] (PJ) was responsible for the health economic analysis plan. All authors read and approved the final version of the manuscript [1] School of Health and Welfare, Department of Health and Nursing, Halmstad University, Halmstad, Sweden. Page 13
	5b	Knowledge Foundation and Region Halland, Page 13
	5c	Neither the DCAP in Region Halland and the company Novista of Sweden AB nor the funders have any role in the study design, data collection, management, analysis, or interpretation of the data. Page 13
Introduction		
Background and rationale	6a	Previous research does not provide conclusive evidence of the effect, economic impact or children's and parents' experiences of weighted blankets for children with ADHD on sleep problems. Pages 1-2
	6b	Thus, more RCT studies are needed to explore this issue further. Given the societal cost and the quality of life implications of sleep interventions, the cost-effectiveness of this non-pharmacological intervention also needs to be investigated. Pages 1-2

Objectives	7	This study targets children with newly diagnosed ADHD and sleep problems, and aims to 1) evaluate the effect of an intervention with weighted blankets on sleep and other health-related outcomes; 2) evaluate the cost-effectiveness of weighted blankets, and 3) explore children´s and parents´ experiences of the sleep intervention with weighted blankets. Page 2
Trial design	8	This is a randomised, placebo-controlled crossover trial investigating the effects of an intervention with fiber-weighted blankets in children with ADHD. The study period is 4 months, including 2 x 4 weeks of intervention with weighted blankets and placebo, followed by an 8-week follow-up. Page 2

Methods: Participants, interventions, and outcomes

Study setting	9	Children attending the ADHD unit at DCAP in the southern part of Sweden. Page 3
Eligibility criteria	10	All children aged 6-15 years, recently diagnosed with ADHD with sleep problems verified by selected questions from the Child's Sleep Habits Questionnaire (CSHQ) will be approached for participation in the study. Children will be excluded if they have already used weighted blankets as a sleep intervention, or if they have received a new prescription or change of pharmacological treatment for sleep problems. Page 3
Interventions	11a	The participants (n=80) will be randomly assigned into two groups. The child will start with a fiber-weighted blanket (active) or with a fiber blanket without weight (placebo). After four weeks with either the active intervention (A) or placebo (B) the children will change blanket (if starting with active, the child will change into placebo, and vice versa). After this 8-week period, the child will decide which of the two blankets (active or placebo) that they want to retain. Pages 3-4
Outcomes	12	The primary outcome is objectively measured and self-reported sleep. Secondary outcomes: *The children's general well-being* will be assessed by the Child Outcome Rating Scale (CORS), *The children's anxiety* will be assessed by The short State-Trait Anxiety Inventory for children (short-STAI), *The children's ADHD symptoms* - hyperactivity/impulsivity, inattention and oppositional - will be assessed by the parents using The Swanson, Peland, and Nolan Scale (SNAP-IV), *The parents' general well-being* will be assessed by the Outcome Rating Scale (ORS), *Family situation and parental mood* will be assessed by the Brief Child and Family Phone Interview (BCFPI), H*ealth-related quality of life* in children (EQ-5D-Y) and parents (EQ-5D-3L) Pages 4-9
Participant timeline	13	Children attending the ADHD unit at DCAP in the southern part of Sweden during 2020-2021 will be asked to participate in the study. Page 3

Sample size	14	The power calculation of this study is based on the assumption that a 30% decrease in SOL is a clinically relevant improvement. In this study, including children 6 to 15 years of age, estimating a mean of 35 minutes SOL and a standard deviation of 15, the power analysis demonstrated that 58 children (29 in each group) will be a sufficient number if accepting a 30% difference between groups in SOL with 80 % power. To allow for a 25% dropout, 80 children (40 in each group) will be enrolled in the study. Page 10
Recruitment	15	Children attending the ADHD unit at DCAP in the southern part of Sweden during 2020-2021 will be asked to participate in the study. Page 3

Methods: Assignment of interventions (for controlled trials)

Allocation:

Sequence generation	16a	The participants (n=80) will be randomly assigned into two groups using simple randomisation with stratification [31]. A total of 80 sheets with the letter A (Intervention) or the letter B (Control) will be printed out and put into each envelope. The sealed envelopes will be mixed and one of the researchers will pick an envelope randomly for each child. The letter A or B indicates if the child will start with a fiber-weighted blanket (active) or with a fiber blanket without weight (placebo). Page 3

Methods: Data collection, management, and analysis

Data collection methods	18a	Data will be assessed at baseline (prior to the intervention), and during the 4th, 8th, and 16th weeks of the study Page 3
Statistical methods	20a	Statistical analyses will be performed using SPSS version 24 for Windows. The intervention will be evaluated in terms of effect and cost comparison. Differences in objectively and subjectively measured sleep, anxiety, and health-related quality of life will be analysed by paired t-test and by independent sample t-test for between group analyses. Differences in resource consumption will be analyzed via non-parametric bootstrap analyses. Page 10
	20b	The qualitative data from interviews will be analyzed with inductive qualitative content analysis. Page 10

Ethics and dissemination

Research ethics approval	24	The study is approved by the Swedish Ethical Review Authority (No. 2019-02158) and conforms to the principles outlined in the Declaration of Helsinki. Page 11

Consent or assent	26a	Children and parents will receive written and oral information and give their informed consent. The participants will be informed that they can withdraw from the project at any time without having to justify why. Page 11
Confidentiality	27	All participation and data collection will be performed confidentially. Page 11
Declaration of interests	28	None declared. Page 13
Access to data	29	Only the researches have access to the data. Page 13
Dissemination policy	31a	The results of this study will be communicated to the included participants, healthcare providers, and companies, in manuscripts submitted to peer-reviewed journals, as well as in presentations at national and international peer-review conferences. Page 11

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

BMJ Open

SLEEP - An intervention with weighted blankets for children with Attention Deficit Hyperactivity Disorder (ADHD) and sleep problems: study protocol for a randomised control trial

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SLEEP - An intervention with weighted blankets for children with Attention Deficit Hyperactivity Disorder (ADHD) and sleep problems: study protocol for a randomised control trial

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Abstract:

Introduction and objectives;

Children with Attention Deficit Hyperactivity Disorder (ADHD) have an increased risk of sleep problems. Weighted blankets are one possible non-pharmacological intervention for these problems in this group of children. However, the effectiveness of weighted blankets is insufficiently investigated. This study aims to investigate the effectiveness of weighted blankets in terms of sleep, health-related outcomes, and cost-effectiveness, as well as to explore children´s and parents´ experiences of a sleep intervention with weighted blankets.

Methods and analysis;

This study is a randomised placebo-controlled crossover trial comparing the effect of weighted fibre blankets (active) with fibre blankets without weight (control). Children aged 6-13 years, recently diagnosed with uncomplicated ADHD with verified sleep problems were included in the study. The study period is 4 weeks for each condition respectively, and then an 8-week follow-up. A total of 80 children diagnosed with ADHD and sleep problems, will enter the study. The primary outcomes are sleep and cost per QALY (quality-adjusted life-years). The secondary outcomes are health-related quality of life, ADHD symptoms, psychological distress, and anxiety. Interviews with a subsample of the participating children and parents will be conducted for exploring the experiences of the intervention.

Ethics and dissemination.

Ethical approval of the trial has been obtained from the Swedish Ethical Review Authority (No. 2019-02158) and conforms to the principles outlined in the Declaration of Helsinki (WMA, 2013). Results will be reported as presentations at peer-review conferences, in articles in peer-review journals, and meetings with healthcare providers.

Trial Registration number: NCT04180189

Strength and limitations of this study

- The scientific evidence on the effectiveness of weighted blankets is insufficient.
- The results from this randomised controlled trial will provide new evidence of the efficacy, cost-effectiveness, and experiences of the intervention.
- The design used to evaluate the intervention of weighted blankets in the trial may be applied to other healthcare settings and may lead to the development of systematic evaluations of the intervention in local contexts.
- Weighted blankets are prescribed to patients in healthcare as a non-pharmacological intervention for sleep problems, the results from this study make it also applicable to other categories of patients than children with ADHD.
- Potential limitations include loss to follow-up during the multiphase study and that the trial is only implemented at one Department of Child and Adolescent Psychiatry in the southern part of Sweden, which may limit generalisability of specific study findings to other populations and settings.

Introduction

Children with Attention Deficit Hyperactivity Disorder (ADHD) have an increased risk of poor health outcomes compared to healthy children.[1 2] The increased risk is especially apparent among girls.[3] Between 25 and 50% of children with ADHD have sleep problems,[1 2] commonly including bedtime resistance, night- and, early morning awakening, and co-sleeping.[4] Sleep is important for everyday functioning and essential for health and wellbeing.[5-7] Sleep deprivation is associated with reduced quality of life,[8] an increased risk of various physical and mental health consequences[9 10] as well as increased risk-taking behavior.[11-13] Further, poor sleep negatively affects performance[10] and relationships in school,[14] which has consequences for school results and transition into adulthood and working life.[15 16] Sufficient sleep duration and quality is, on the other hand, associated with improved attention, behaviour and cognitive functions, as well as physical and mental health.[17 18]

The use of pharmacological treatment for sleep problems is common and has increased dramatically among children with ADHD in the last 10 years, although often with unfavourable side effects. [2 11 19] There is evidence supporting the commonly used melatonin compared with placebo, but the degree of benefit is uncertain. [20] There are various types of non-pharmacological interventions for children with ADHD to manage sleep problems, which are not associated with the side effects associated with pharmacological treatment. However, due to clinical heterogeneity, poor study quality, and lack of randomised controlled trials (RCTs),[20-23] the evidence for the effectiveness of non-pharmacological interventions is inconclusive. Thus, there is a need for high-quality studies to evaluate the clinical effect and cost-effectiveness of non-pharmacological sleep interventions.

Weighted blankets are currently prescribed as a supplement to or replacement of pharmacological treatment for sleep problems among children with ADHD. The effectiveness of weighted blankets in this context has received little research attention and has generally had insufficient scientific quality,[21 24 25] with only one randomized controlled trial.[26] This latter study had a randomised, placebo-controlled crossover design with a four-week follow-up for each type of blanket. The population consisted of 67 children, aged 5-16 years, with autism spectrum disorders. Weighted blankets, compared with the control blanket, did not increase total sleep time, sleep-onset latency, or sleep efficiency as measured by actigraphy. However, parents and children preferred the weighted blanket, and the weighted blankets were well tolerated.[26] In a pilot study including only two children with an autism spectrum

disorder, the use of weighted blankets improved the sleep quality, justifying the need for additional robust research.[27] A case-control study without randomisation included 21 children, aged 8–13 years, with ADHD and 21 matched healthy children as a control group showed some small positive effects of the weighted blankets on sleep onset latency.[28] In summary, these studies do not provide conclusive evidence of the effect [25], economic effectivess[20 21] or children's and parents' experiences of weighted blankets for children with ADHD on sleep problems. Thus, an RCT evaluating weighted blankets for children with ADHD and sleep problems is timely. Given the societal cost and the quality of life implications of sleep interventions, the cost-effectiveness of this non-pharmacological intervention also needs to be investigated.[20] The hypothesis of this RCT is that weighted blankets will improve objectively measured and self-reported sleep compared to control blankets in children with ADHD.

Objectives

This study targets children with newly diagnosed ADHD and sleep problems, and aims to 1) evaluate the effect of an intervention with weighted blankets on sleep and other health-related outcomes; 2) evaluate the cost-effectiveness of weighted blankets, and 3) explore children´s and parents´ experiences of the sleep intervention with weighted blankets.

Methods

Study design

This is a randomised, placebo-controlled crossover trial investigating the effects of an intervention with fibre-weighted blankets in children with ADHD. The study period is 4 months, including 2 x 4 weeks of intervention with weighted blankets and control blankets, followed by an 8-week follow-up (figure 1). The study investigates the effect of the intervention in terms of 1) sleep and health; 2) cost-effectiveness, and 3) experiences of sleep and health-related outcomes. The qualitative part will be performed using an explorative design based on interviews from a subsample of the included children and their parents. The interviews will be conducted at the end of the 4-month intervention in order to gain knowledge of the children's and parents' experiences of using these fibre-weighted blankets. The protocol is based on the Standard Protocol Items for Randomized Trials (SPIRIT).[29]

Patient and public involvement

The design of the study and the preparation and formulation of this protocol has been co-produced with healthcare professionals at the child and adolescent mental health service (CAMHS). This includes being involved in; planning inclusion and exclusion criteria for the informants, preparing the arrangement for the intervention and selecting which questionnaires to be used to measure outcome variables for children and parents. The project manager has had regular meetings with the healthcare professionals at CAMHS throughout the preparation of the study. A pilot study, with seven children and their parents, has been performed to validate the design, the interventions, and the questionnaires used. As part of this, we asked children and parents about their opinion of the intervention and also asked them for suggestions for improvements. This resulted in a few minor adjustments. The research project has been discussed with occupational therapists (who prescribe weighted blankets in Sweden) and representatives from the national occupational therapy association. The project and preliminary results have been and will be communicated through popular science reports, research conference contributions, and research papers to the healthcare services, occupational therapists, patient groups, and researchers during the research period.

Participants and recruitment

Children attending the ADHD unit at CAMHS in the southern part of Sweden during 2020-2021 will be asked to participate in the study. This ADHD unit is designed to assess and if indicated initiate treatment of children with uncomplicated DSM-5 ADHD in order to increase effectiveness and reduce waiting lists. About one-half of the patients with newly diagnosed ADHD are seen in this unit. The local community CAMHS team serves children with suspected ADHD along with comorbidities needing primary intervention or where families suffer from substantial psychosocial stress. Patients in the ADHD unit receive psychoeducation in groups and medication with fewer follow-ups than usual, which is not sufficient for the more complicated cases[30]. Recruitment of participants started in January 2020 and is estimated to be completed during autumn 2021. All children aged 6-13 years, recently diagnosed with uncomplicated ADHD with sleep problems verified by three selected questions from the Child's Sleep Habits Questionnaire (CSHQ)[31] will be approached for participation in the study. Sleep problem is considered to be present if the child 1) seldom (0-1 times per week) or sometimes (2-4 times per week) fall asleep within 20 minutes after going to bed; 2) usually (5-7 times per week) or sometimes (2-4 times per week) sleep too little or 3) wake up several times per night. In addition to this, they need to report that the sleep difficulty in question is a problem. In addition, parents and children should understand (written and

spoken) the Swedish language. Children will be excluded if they have already used weighted blankets as a sleep intervention, or if they have received a new prescription or change of pharmacological treatment for sleep problems. Children diagnosed with DSM-5 ADHD and not started on a stimulant and with sleep difficulties above the threshold will be invited to get further information about the study at the three hours assessment visit. Children diagnosed with DSM-5 ADHD and started on a stimulant will again be reviewed for inclusion criteria at the medication follow-up after about 4 weeks.

First, eligible children and their parents will be informed verbally about the study by their doctor or nurse at the CAMHS. They will then receive written information about the study and be approached by healthcare professionals about participation. After the researchers have received written consent, the participants will be contacted by telephone and the research project leader will provide more detailed information about the study. The participants will be informed that they are about to try two different types of fibre blankets. The participants will be encouraged to contact the researchers if further questions arise.

Intervention

The participants (n=100) will be randomly assigned into two groups using simple randomisation with stratification [32]. A total of 80 sheets with the letter A (Intervention) or the letter B (Control) will be printed out and put into each envelope. The sealed envelopes will be mixed and one of the researchers will pick an envelope randomly for each child. The letter A or B indicates if the child will start with a fibre-weighted blanket (active) or with a fibre blanket without weight (control). After four weeks with either the active intervention (A) or control (B), the children will change blanket (if starting with active, the child will change into control, and vice versa). After this 8-week period, the child will decide which of the two blankets (active or control) that they want to retain.

Fibre-weighted blankets from Novista of Sweden (Novista.se) will be used in this study. The weight in the blankets is derived from longitudinal polyester fibres permitting flexibility. The blanket size is 150 x 210 cm, which is a standard size for children and adults in Sweden. The weight of each blanket will be individually tailored (weight between 6 to 10 kg) for the children, based on age, sex, height, weight, degree of sleep problems, and subtypes of ADHD according to the clinical practice of two independent experienced occupational therapists. The fibre blankets without weight (controls) have been designed for the project so that both active

and control blankets have the same design. The weight is the only aspect that distinguishes them.

Data assessment

Data will be assessed at baseline (prior to the intervention), and during the 4th, 8th, and 16th weeks of the study. The measurements are performed during the last of the four weeks to minimize the risk for bias due to carry-over effects. A seven-day objective measurement of sleep will be conducted during these measurement periods. Self-reported data will also be gathered through the completion of a questionnaire by the parent and child respectively (Table 1).

Interviews with an adequate sample of children (n=25) and parents (n=25) will be conducted after the intervention period in order to understand the experiences of the intervention's impact on sleep and health-related outcome.

1. *Methods for investigating the health effects of weighted blankets*

Primary outcome

The primary outcome is *objectively measured* and *self-reported sleep*. Variables of interest from the *objectively measured sleep* are: *Sleep onset latency (SOL),* which refers to the period of time between turning lights out to go to sleep (timing identified by marker from the event button, or self-reported time in daily text messages) and falling asleep; *Total sleep time (TST)*, which is equal to the time of total sleep episode minus the awake time; *Sleep efficiency (SE),* which is the total sleep time expressed as a percentage; *wake after sleep onset (WASO),* referring to periods of wakefulness occurring after sleep onset.

Objectively measured sleep will be assessed using actigraphy. This method for assessing sleep has been shown to be valid in several studies,[33] and has shown to be strongly associated with polysomnographic measures with a correlation coefficient of at least 0.85 in healthy individuals.[34] Measurements from at least 5-7 nights have been recommended.[35] Motionwatch 8 (Camntech.Ltd.), a triaxial accelerometer using MEMs technology, capable of sensing motions in a resultant force range of 0.01 g to 8 g[36] is used in this study. The actigraph registers total gross motor activity for analysis of sleep-wake patterns and has good validity for measuring sleep[36]. Recordings will be taken in 30-second epochs.

Participants will be instructed to wear the watch on their non-dominant wrist, for seven consecutive nights. If not worn during the day, the parent and child will be instructed to put on the watch in the early evening, or in good time prior to going to bed. The participant is instructed to push an event-button when they decide to go to sleep, e.g. when they stop reading a book or turn off the lights. Then they are told to push the button again when they wake up in the morning. In addition to marking the event of going to sleep and waking up by pressing the button, the parents will answer questions daily (by text message): 1) What time did your child go to bed yesterday? 2) How long time do you estimate the time for your child to fall asleep from the time your child went to bed? (hours, minutes); 3) What time did your child wake up today?

The variables of interest from the *self-reported sleep* will be assessed by CSHQ[31], and Insomnia Severity Index (ISI).[37]

The CSHQ assesses parental reported sleep and consists of 33 items related to eight subscales; 1*) Bedtime resistance*, 2) *Sleep onset delay*, 3) *Sleep duration*, 4) *Sleep anxiety*, 5) *Night wakings*, 6) *Parasomnias,* 7) *Sleep-disordered breathing*, and 8) *Daytime sleepiness*. Each item is rated on a three-point scale: "usually" if the sleep behavior occurred five to seven times/week; "sometimes" for two to four times/week; and "rarely" for zero to one time/week. A higher score indicates more sleep problems. The scale has good reliability and validity.[31]

Insomnia will be assessed by ISI, which comprises seven items for the children to respond to: 1) Severity of sleep-onset, 2) Sleep maintenance, 3) Early morning awakening, 4) Satisfaction with current sleep pattern, 5) Interference with daily functioning, 6) Noticeability of impairment attributed to the sleep problem, and 7) Level of distress caused by the sleep problem. Each item is rated on a five-point Likert scale ranging from "not at all" (scored at 0) to "extremely" (scored at 4). Total score ranges from 0 to 28, with higher scores indicating greater severity. ISI is a reliable and valid instrument for quantifying severity of perceived insomnia and measures insomnia in treatment research.[37] The ISI will be slightly modified in order to better correspond to a child's language.

Secondary outcomes

The children's general well-being will be assessed by the Child Outcome Rating Scale (CORS),[38] which is an overall measure of psychological distress. It was developed to give

children a voice in the services they receive. CORS comprises four items where the child evaluates; 1) Me (How am I doing?), 2) Family (How are things in my family?), 3) School (How am I doing at school?), 4) Everything (How is everything going?). Each item is rated on a 100-millimeter Visual Analog Scale with smiling and sad faces as anchors. CORS has good reliability and moderate validity.[38]

The children's anxiety will be assessed by The short State-Trait Anxiety Inventory for children (short-STAI).[39 40] Short-STAI includes six items.[41] Each item is rated on a four-point Likert scale ranging with 1 = "not at all," 2 = "somewhat," 3, = "moderately", and 4 = "very much." The total score range from 6 to 24 points, with 6 points indicating no anxiety and 24 points indicating the highest level of anxiety. Short-STAI has good reliability and validity for children.[39]

The children's ADHD symptoms - hyperactivity/impulsivity, inattention and oppositional - will be assessed by the parents filling in The Swanson, Peland, and Nolan Scale (SNAP-IV).[42] The SNAP-IV consists of 30 items and is divided into three subscales: inattention (nine items), hyperactivity/impulsivity (nine items), and oppositionality (eight items) and four supplementary questions regarding oppositionality (two questions) and ADHD (two questions). Items are rated on a four-point Likert scale range 0 = "not at all", 1 = "just a little", 2 = "quite a bit", and 3 = "very much". Items for inattention and hyperactivity/impulsivity can be combined to create a "combined ADHD" score.[43] Higher scores represent more symptoms. The SNAP-IV is a robust and valid measure of outcome for research studies and often used in RCTs.[44]

The parents' general well-being will be assessed by the Outcome Rating Scale (ORS),[45] which is a general mental health assessment of the past week in four items; 1) Personal wellbeing, 2) Interpersonal relationships, 3) Social relations and, 4) Overall sense of well-being. Each item is rated on a 100-millimeter Visual Analog Scale with anchors from 0 (negative) to 100 (positive). ORS is a reliable and valid instrument.[38 46]

Family situation and parental mood will be assessed by the Brief Child and Family Phone Interview (BCFPI),[47 48] BCFPI is a structured parent interview for triage at intake and for follow-up evaluation of community care at CAMHS. It consists of 36 symptom items and another 36 items to assess function, adversity, and family stress grouped into 12 subscales. The subscale ´family situation` contains three items rated on a four-point Likert scale range 1

= never, 2 = sometimes, 3 = often, 4 =always. The subscale ´parental mood` contains six items based on the question "How often during the past week has the parent experienced…?" rated on a four-point scale; < 1 day, 1-2 days, 3-4 days, >5 days. BCFPI has good reliability and validity.[47 48]

Health-related quality of life will be assessed for children with EQ-5D-Y[49] and parents with EQ-5D-3L[50]. EQ-5D-Y measures health-related quality of life "today" for children and young people and is developed from the standard adult EQ-5D [49]. EQ-5D-Y comprises five items; 1) Walking about (mobility), 2) Looking after myself (self-care), 3) Doing usual activities (usual activities), 4) Having pain or discomfort (pain and discomfort), and 5) Feeling worried, sad or unhappy (anxiety and depression). Each item is divided into three levels; No problems, Some problems, and A lot of problems. The EQ-5D-Y also includes an easily understandable modified vertical Visual Analogue Scale of EQ-5D, where the respondent rates the overall health status with the endpoints from 0 (the worst health state the child can imagine and 100 (the best health state the child can imagine)[49]. EQ-5D-Y has good reliability and validity.[51] EQ-5D is a generic health-related quality of life instrument[50] measuring the parents' health comprising five dimensions; 1) Mobility, 2) Self-care, 3) Usual activities, 4) Pain/discomfort, and 5) Anxiety/Depression. Each dimension is divided into three levels; No problems, Some or moderate problems, and extreme problems. In addition to the five dimensions, a 100-millimeter vertical Visual Analog Scale with endpoints of 100 means "best imaginable health state" and 0 means "worst imaginable health state is included. The total score ranges from 0 to 1 where a higher score indicates a better health-related quality of life.

In addition, sociodemographic data, resource consumption and will be collected via the survey at baseline and the 4th, 8th, and 16th weeks of the study.

Table 1. Overview of the questionnaires included in the study

	Assessed by children reports	**Assessed by parents' reports**
Socioeconomic variables		Children: Age, gender, country of birth, Parents: age gender, country of birth, civil status, level of education, and work situation
Sleep habits	Insomnia Severity Index (ISI) [37]	Child's Sleep Habits Questionnaire (CSHQ) [31]
General well-being	Children Outcome Rating Scale (CORS) [38]	Outcome Rating Scale (ORS) [38 45]
Anxiety	State-Trait Anxiety Inventory (STAI) [39 40]	

ADHD symptoms		Swanson, Peland and Nolan Scale (SNAP IV) [42 43]
Family situation and parental mood		The Brief Child and Family Phone Interview (BCFPI) [47 48]
Health-related quality of life	EQ-5D-Y [49 51]	EQ-5D-3L [50 52]
Resource consumption		School absence (children), work productivity and absence (parents), and healthcare consumption according to Swedish adaptation [53 54] of the TIC-P instrument [55]

2. *Methods for investigating the cost-effectiveness of weighted blankets*

The health economic evaluation is a within-trial cost-utility analysis with a societal perspective based on the data collected at the 8-week follow-up, with the primary outcome costs per QALY (quality-adjusted life-years). An incremental cost-effectiveness ratio (ICER) with a 4 week time horizon is calculated based on differences in societal costs (implementation costs and societal consequences) and quality of life when using either the fibre-weighted blankets or control blankets. No discounting of costs and health effects will be performed due to the short follow-up period. A number of sensitivity analyses are planned, including probabilistic analyses with bootstrapped differences of individual-level data on major societal consequences and quality of life, as well as of the ICER.

The *societal cost consequences* combine parent-reported data on resource consumption with clinical register data to estimate the differences in societal costs between the two study arms at baseline and 8 weeks. The parent-reported resource consumption survey questions are based on a Swedish adaptation of the TIC-P instrument[53-55] and consider the past two months. The questions include school absence for the child (in numbers of full days, half days, and 1-2 hours), work absence for one parent (in numbers of full days (8 hours), three-quarters of a day (6 hours), half a day (4 hours) and one-quarter of a day (2 hours)), work productivity of the parent (in ten levels from no work accomplished to hardly no decreased work capacity) and healthcare appointments (nine types of healthcare including e.g. school healthcare, primary care, and emergency care). The clinical register data include the number of appointments at the CAMHS and prescribed pharmacological therapy. The cost of the resource consumption items from the parent survey and the clinical register will be estimated according to Swedish published data on the average costs for healthcare appointments from SALAR (the Swedish Association of Local Authorities and Regions) and occupation-specific healthcare wages

including wage taxes from Statistics Sweden. The cost of parents' work absence and decreased productivity will be estimated using average Swedish hourly wages including wage taxes from Statistics Sweden while the cost of child school absence is estimated according to estimated schooling costs from The Swedish National Agency for Education. The cost of prescribed pharmacological therapy will be estimated according to listed prices at the Dental and Pharmaceutical Benefits Agency.

The *implementation costs,* i.e. the prescription of the weighted blankets, include the healthcare region's purchasing price for weighted blankets, child psychiatrist time for prescription, physiotherapist time for tailoring as well as parent and child time. The healthcare costs will be estimated based on data from SALAR and Statistics Sweden while the visiting and traveling time for the parent and child will be estimated according to data from Statistics Sweden and The Swedish National Agency for Education, as above.

Quality of life estimates for calculating *QALYs* over the 4 weeks period will be taken from the parent-reported EQ-5D instrument valued with a Swedish tariffs value set.[52] EQ-5D-3L is frequently used in Sweden and for economic evaluations and is considered a reliable and valid instrument.[52] There is currently no appropriate value set for the child version of EQ-5D (i.e. EQ-5D-Y), so in a sensitivity analysis, the VAS ratings will be used and added to the parent estimated QALYs. The QALYs during 4 weeks will be calculated based on the mean changes in quality of life of the two study arms, with an instant change assumed when initiating use of the fibre-blanket.

3. *Methods for investigating the experiences of weighted blankets*

The qualitative data will consist of individual interviews with children and their parents in the intervention study. An open interview guide with initial questions will be used to ensure similar data from all participants. The initial questions refer to the experiences of sleep for children with ADHD, experiences of how the sleep intervention with fibre-weighted blankets influences the children's sleep, and health-related outcomes as well as the family situation. *Questions to the children*: "How do you usually sleep?", "In what way can it be difficult to sleep?", "How does sleep differ if you sleep well or badly?", "What is important for you to be able to sleep?", "How do you experience the two different blankets you have used?", "How do you experience the fibre-weighted blanket?", "Can you describe your sleep since you started using the fibre-weighted blankets?". *Questions to the parents*: "What does sleep mean for your child?", "How does your child usually sleep?", "What is important for your child to

be able to sleep?", "How is your child's life affected by sleep?", "How do you experience the two different blankets your child has used?", "How do you experience the fibre-weighted blanket?", Can you describe your child's sleep since he/she started using the fibre-weighted blankets?", How is your child's well-being since he/she started using the fibre-weighted blankets?", How has the situation for the family and you as a parent been affected since your child started using the fibre-weighted blanket?" *Follow-up probes* will be used to encourage children and parents to elaborate on the answers: "Please tell me more", "How do you mean?" or "What do you have in mind when you say ...?" All interviews will be performed at the University in a quiet room. The interviews will be digitally recorded and transcribed verbatim.

Statistical Power

A power analysis was made based on estimated changes in the primary outcome variable *sleep onset latency* (SOL). Estimations of mean and standard deviations were made based on previous studies of SOL in children. Mean SOL is expected to differ substantially with age among children. Gringras et al. (2014) investigated children 5 to 16 years of age and found a mean value of 76,5 minutes of SOL with a standard deviation of 46,1.[26] Hvolby and Bilenberg (2011) studied SOL in children 8 to 13 years of age and reported a mean value of 23,1 minutes of SOL with a standard deviation of 9,4.[28]

Previous studies investigating the effect of similar interventions on SOL have found a 40% decrease in SOL after the intervention [28]. The power calculation of this study is based on the assumption that a 30% decrease in SOL is a clinically relevant improvement. In this study, including children 6 to 13 years of age, estimating a mean of 35 minutes SOL and a standard deviation of 15, the power analysis demonstrated that 58 children (29 in each group) will be a sufficient number if accepting a 30% difference between groups in SOL with 80 % power. To allow for a 25% dropout, 80 children (40 in each group) will be enrolled in the study.

Data analysis

Statistical analyses will be performed using SPSS version 24 for Windows. The intervention will be evaluated in terms of effect and cost comparison. Differences in objectively and subjectively measured sleep, anxiety, and health-related quality of life will be analysed by paired t-test and by independent sample t-test for between group analyses. Differences in societal costs will be analysed via non-parametric bootstrap analyses on individual-level data

and reported as credibility intervals.[56] The qualitative data from interviews will be analysed with inductive qualitative content analysis.[57]

Ethics and dissemination

The study is approved by the Swedish Ethical Review Authority (No. 2019-02158) and conforms to the principles outlined in the Declaration of Helsinki.[58] The study will fulfill requirements for research: information, consent, confidentiality, and safety of the participants and is guided by the ethical principles: autonomy, beneficence, non-maleficence, and justice.[59] All participation and data collection will be performed confidentially. Children and parents will receive written and oral information and parents give their informed consent in writing. The participants will be informed that they can withdraw from the project at any time without having to justify why. Data will be collected in anonymised form and keys that link data with personal information will be stored separately and only accessible to the project leader. All personal data will be registered according to the General Data Protection Regulation (GDPR2016/679)[60] and the data will be stored in accordance with the Archive Act in Sweden (SFS1990:782).[61] This study is registered at http://clinicaltrials.gov under identification number NCT04180189. The results of this study will be communicated to the included participants, healthcare providers, and companies, in manuscripts submitted to peer-reviewed journals, as well as in presentations at national and international peer-review conferences.

Discussion

Weighted blankets are prescribed to patients in healthcare in Sweden and are widely used as a non-pharmacological intervention for sleep problems, even though evidence for the effects of weighted blankets is lacking. The few previous studies investigating the effect of weighted blankets for children with ADHD have not shown conclusive results and to date, there are too few high-quality studies to support the intervention. [25-28] The results from this RCT will thus be important for providing new evidence of the efficacy, cost-effectiveness, and experiences of the use of weighted blankets to address sleep problems among children with ADHD.

Some methodological considerations can be highlighted. A strength in this research is that this study will be the first randomised placebo-controlled crossover trial investigating the effects

of fibre-weighted blankets in children with ADHD. Another strength is the use of both objective and subjective measures for sleep. Although subjectively measured sleep is highly relevant to assess and evaluate, objectively measured sleep has the advantages of being free from subjective expectations in relation to the intervention, and less sensitive to recall bias. Furthermore, the evaluation of cost-effectiveness of weighted blankets is highly relevant though this has not previously been studied.[21] The costs and benefits of the intervention need to be taken into consideration when implementing the intervention in healthcare settings. Similarly, the inclusion of a qualitative approach in the design to increase the understanding of both children's and parents' experiences of effects is another strength. This latter aspect is of great relevance as children's perspectives are seldom taken into account in research.

There are, however, a few methodological challenges with this study. Assessing self-reported data from children is difficult for several reasons. Some of the questionnaires in this study are designed for the parent to respond on behalf of the child (e.g. CSHQ). This may be a good approach for younger children, but depending on the habits around bedtime, the parents may only have (at best) a reasonably good perception of how the child`s sleep was (for example, if sleeping in separate bedrooms). Under these circumstances, the parent and the child are instructed to fill in the questionnaire together to get a more reliable assessment. Another potential bias is the control blankets. The difference in weight will be obvious for parents and also for children. The participants are only informed they are trying two different kinds of blankets. However, most have learned about weighted blankets through media or their health providers, possibly affecting expectations in favour of the weighted blanket

We anticipate the project will make several scientific contributions to the research on health-related outcomes, sleep, and cost-effectiveness for non-pharmacological sleep interventions. such as weighted blankets. These findings will be essential for healthcare professionals in their practice though evidence today for the effects of weighted blankets is scarce. The results will also be relevant for children with ADHD in particular, but will also be relevant for other target groups and other settings.

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Author Contribution IL, JN and PS contributed to the conception of the study, obtained the funding, and are the guarantors of the study. IL, KA, JN, PJ, HJ and PS contributed to the study design. IL and KA were primarily responsible for the statistical analysis plan. PJ was responsible for the health economic analysis plan. IL and PS were responsible for the qualitative analysis plan. IL drafted the manuscript and KA, JN, PJ, HJ and PS revised the manuscript critically for important intellectual content, All authors read and approved the final version of the manuscript.

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Competing interests None declared.

Patient consent for publication Not required.

Availability of data and materials: Not applicable. The data will not be shared as ethics approval for the study requires that data files and the transcribed interviews are kept in locked files, accessible only to the researchers.

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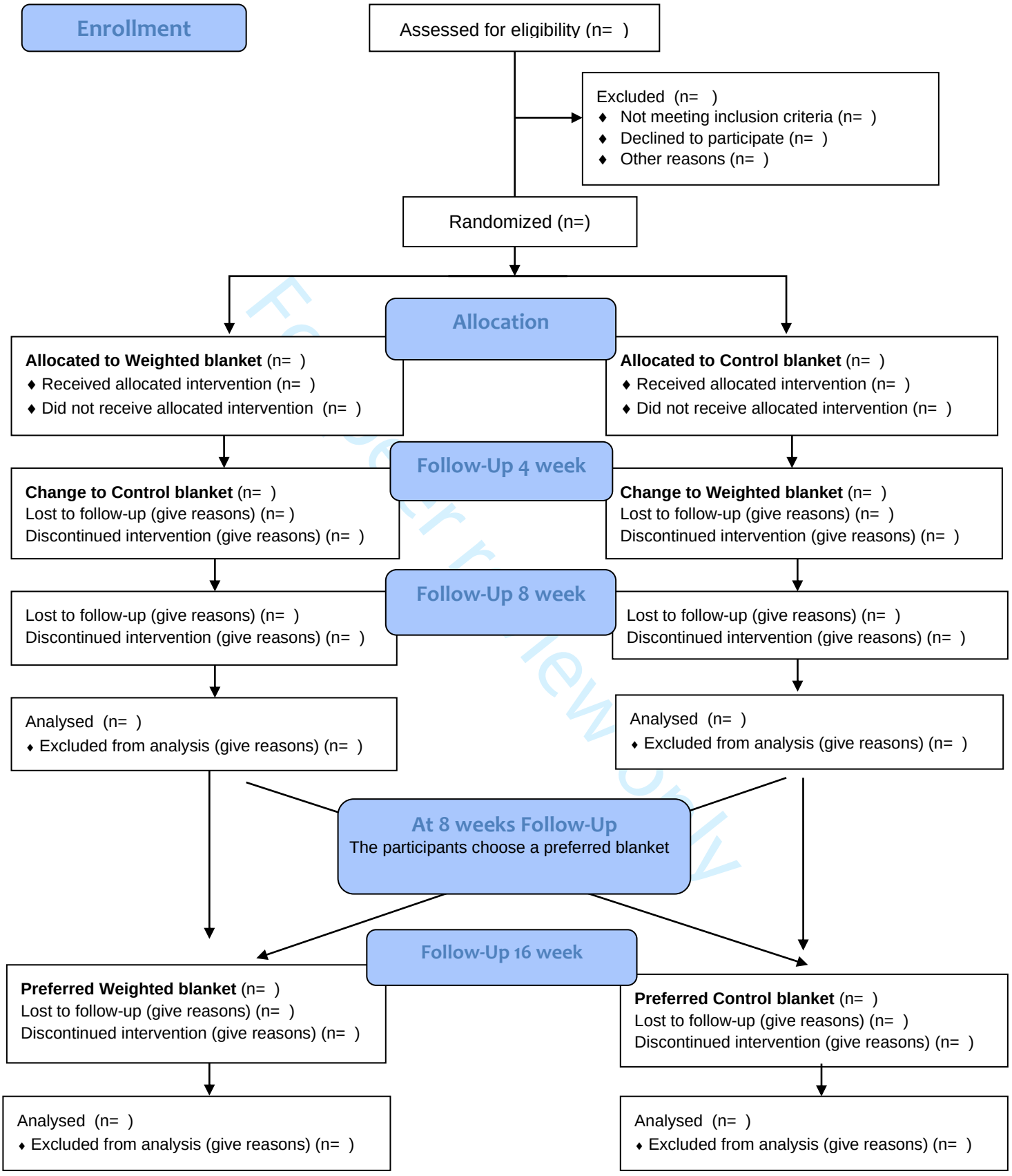
Figur 1 CONSORT Flow Diagram over the SLEEP trial



SPIRIT
STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description
Administrative information		
Title	1	*SLEEP - An intervention with weighted blankets for children with Attention Deficit Hyperactivity Disorder (ADHD) and sleep problems: study protocol for a randomised control trial*
Trial registration	2a	Trial Registration number: NCT04180189
	2b	Trial Registration number: NCT04180189
Protocol version	3	2020-11-30 no. 1
Funding	4	This work was supported by the Knowledge Foundation and Region Halland. Page 13
Roles and responsibilities	5a	Ingrid Larsson[1] (IL) wrote the first draft of the manuscript. Petra Svedberg[1] (PS) and IL conceived the study idea, obtained the funding, and are the guarantors of the study. IL, Katarina Aili[1] (KA), Jens Nygren[1] (JN), and PS contributed to the study design. IL and KA were primarily responsible for the statistical analysis plan. Pia Johansson[1] (PJ) was responsible for the health economic analysis plan. All authors read and approved the final version of the manuscript [1] School of Health and Welfare, Department of Health and Nursing, Halmstad University, Halmstad, Sweden. Page 13
	5b	Knowledge Foundation and Region Halland, Page 13
	5c	Neither the DCAP in Region Halland and the company Novista of Sweden AB nor the funders have any role in the study design, data collection, management, analysis, or interpretation of the data. Page 13
Introduction		
Background and rationale	6a	Previous research does not provide conclusive evidence of the effect, economic impact or children's and parents' experiences of weighted blankets for children with ADHD on sleep problems. Pages 1-2
	6b	Thus, more RCT studies are needed to explore this issue further. Given the societal cost and the quality of life implications of sleep interventions, the cost-effectiveness of this non-pharmacological intervention also needs to be investigated. Pages 1-2

Objectives	7	This study targets children with newly diagnosed ADHD and sleep problems, and aims to 1) evaluate the effect of an intervention with weighted blankets on sleep and other health-related outcomes; 2) evaluate the cost-effectiveness of weighted blankets, and 3) explore children´s and parents´ experiences of the sleep intervention with weighted blankets. Page 2
Trial design	8	This is a randomised, placebo-controlled crossover trial investigating the effects of an intervention with fiber-weighted blankets in children with ADHD. The study period is 4 months, including 2 x 4 weeks of intervention with weighted blankets and placebo, followed by an 8-week follow-up. Page 2

Methods: Participants, interventions, and outcomes

Study setting	9	Children attending the ADHD unit at DCAP in the southern part of Sweden. Page 3
Eligibility criteria	10	All children aged 6-15 years, recently diagnosed with ADHD with sleep problems verified by selected questions from the Child's Sleep Habits Questionnaire (CSHQ) will be approached for participation in the study. Children will be excluded if they have already used weighted blankets as a sleep intervention, or if they have received a new prescription or change of pharmacological treatment for sleep problems. Page 3
Interventions	11a	The participants (n=80) will be randomly assigned into two groups. The child will start with a fiber-weighted blanket (active) or with a fiber blanket without weight (placebo). After four weeks with either the active intervention (A) or placebo (B) the children will change blanket (if starting with active, the child will change into placebo, and vice versa). After this 8-week period, the child will decide which of the two blankets (active or placebo) that they want to retain. Pages 3-4
Outcomes	12	The primary outcome is objectively measured and self-reported sleep. Secondary outcomes: *The children's general well-being* will be assessed by the Child Outcome Rating Scale (CORS), *The children's anxiety* will be assessed by The short State-Trait Anxiety Inventory for children (short-STAI), *The children's ADHD symptoms* - hyperactivity/impulsivity, inattention and oppositional - will be assessed by the parents using The Swanson, Peland, and Nolan Scale (SNAP-IV), *The parents' general well-being* will be assessed by the Outcome Rating Scale (ORS), *Family situation and parental mood* will be assessed by the Brief Child and Family Phone Interview (BCFPI), H*ealth-related quality of life* in children (EQ-5D-Y) and parents (EQ-5D-3L) Pages 4-9
Participant timeline	13	Children attending the ADHD unit at DCAP in the southern part of Sweden during 2020-2021 will be asked to participate in the study. Page 3

Sample size	14	The power calculation of this study is based on the assumption that a 30% decrease in SOL is a clinically relevant improvement. In this study, including children 6 to 15 years of age, estimating a mean of 35 minutes SOL and a standard deviation of 15, the power analysis demonstrated that 58 children (29 in each group) will be a sufficient number if accepting a 30% difference between groups in SOL with 80 % power. To allow for a 25% dropout, 80 children (40 in each group) will be enrolled in the study. Page 10
Recruitment	15	Children attending the ADHD unit at DCAP in the southern part of Sweden during 2020-2021 will be asked to participate in the study. Page 3

Methods: Assignment of interventions (for controlled trials)

Allocation:

Sequence generation	16a	The participants (n=80) will be randomly assigned into two groups using simple randomisation with stratification [31]. A total of 80 sheets with the letter A (Intervention) or the letter B (Control) will be printed out and put into each envelope. The sealed envelopes will be mixed and one of the researchers will pick an envelope randomly for each child. The letter A or B indicates if the child will start with a fiber-weighted blanket (active) or with a fiber blanket without weight (placebo). Page 3

Methods: Data collection, management, and analysis

Data collection methods	18a	Data will be assessed at baseline (prior to the intervention), and during the 4th, 8th, and 16th weeks of the study Page 3
Statistical methods	20a	Statistical analyses will be performed using SPSS version 24 for Windows. The intervention will be evaluated in terms of effect and cost comparison. Differences in objectively and subjectively measured sleep, anxiety, and health-related quality of life will be analysed by paired t-test and by independent sample t-test for between group analyses. Differences in resource consumption will be analyzed via non-parametric bootstrap analyses. Page 10
	20b	The qualitative data from interviews will be analyzed with inductive qualitative content analysis. Page 10

Ethics and dissemination

Research ethics approval	24	The study is approved by the Swedish Ethical Review Authority (No. 2019-02158) and conforms to the principles outlined in the Declaration of Helsinki. Page 11

Consent or assent	26a	Children and parents will receive written and oral information and give their informed consent. The participants will be informed that they can withdraw from the project at any time without having to justify why. Page 11
Confidentiality	27	All participation and data collection will be performed confidentially. Page 11
Declaration of interests	28	None declared. Page 13
Access to data	29	Only the researches have access to the data. Page 13
Dissemination policy	31a	The results of this study will be communicated to the included participants, healthcare providers, and companies, in manuscripts submitted to peer-reviewed journals, as well as in presentations at national and international peer-review conferences. Page 11

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

BMJ Open

SLEEP - An intervention with weighted blankets for children with Attention Deficit Hyperactivity Disorder (ADHD) and sleep problems: study protocol for a randomised control trial

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SLEEP - An intervention with weighted blankets for children with Attention Deficit Hyperactivity Disorder (ADHD) and sleep problems: study protocol for a randomised control trial

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Abstract:

Introduction and objectives;

Children with Attention Deficit Hyperactivity Disorder (ADHD) have an increased risk of sleep problems. Weighted blankets are one possible non-pharmacological intervention for these problems in this group of children. However, the effectiveness of weighted blankets is insufficiently investigated. This study aims to investigate the effectiveness of weighted blankets in terms of sleep, health-related outcomes, and cost-effectiveness, as well as to explore children´s and parents´ experiences of a sleep intervention with weighted blankets.

Methods and analysis;

This study is a randomised placebo-controlled crossover trial comparing the effect of weighted fibre blankets (active) with fibre blankets without weight (control). Children aged 6-13 years, recently diagnosed with uncomplicated ADHD with verified sleep problems were included in the study. The study period is 4 weeks for each condition respectively, and then an 8-week follow-up. A total of 100 children diagnosed with ADHD and sleep problems, will enter the study. The primary outcomes are sleep and cost per QALY (quality-adjusted life-years). The secondary outcomes are health-related quality of life, ADHD symptoms, psychological distress, and anxiety. Interviews with a subsample of the participating children and parents will be conducted for exploring the experiences of the intervention.

Ethics and dissemination.

Ethical approval of the trial has been obtained from the Swedish Ethical Review Authority (No. 2019-02158) and conforms to the principles outlined in the Declaration of Helsinki (WMA, 2013). Results will be reported as presentations at peer-review conferences, in articles in peer-review journals, and meetings with healthcare providers.

Trial Registration number: NCT04180189

Strength and limitations of this study

- The scientific evidence on the effectiveness of weighted blankets is insufficient.
- The results from this randomised controlled trial will provide new evidence of the efficacy, cost-effectiveness, and experiences of the intervention.
- The design used to evaluate the intervention of weighted blankets in the trial may be applied to other healthcare settings and may lead to the development of systematic evaluations of the intervention in local contexts.
- Weighted blankets are prescribed to patients in healthcare as a non-pharmacological intervention for sleep problems, the results from this study make it also applicable to other categories of patients than children with ADHD.
- Potential limitations include loss to follow-up during the multiphase study and that the trial is only implemented at one Department of Child and Adolescent Psychiatry in the southern part of Sweden, which may limit generalisability of specific study findings to other populations and settings.

Introduction

Children with Attention Deficit Hyperactivity Disorder (ADHD) have an increased risk of poor health outcomes compared to healthy children.[1 2] The increased risk is especially apparent among girls.[3] Between 25 and 50% of children with ADHD have sleep problems,[1 2] commonly including bedtime resistance, night- and, early morning awakening, and co-sleeping.[4] Sleep is important for everyday functioning and essential for health and wellbeing.[5-7] Sleep deprivation is associated with reduced quality of life,[8] an increased risk of various physical and mental health consequences[9 10] as well as increased risk-taking behavior.[11-13] Further, poor sleep negatively affects performance[10] and relationships in school,[14] which has consequences for school results and transition into adulthood and working life.[15 16] Sufficient sleep duration and quality is, on the other hand, associated with improved attention, behaviour and cognitive functions, as well as physical and mental health.[17 18]

The use of pharmacological treatment for sleep problems is common and has increased dramatically among children with ADHD in the last 10 years, although often with unfavourable side effects. [2 11 19] There is evidence supporting the commonly used melatonin compared with placebo, but the degree of benefit is uncertain. [20] There are various types of non-pharmacological interventions for children with ADHD to manage sleep problems, which are not associated with the side effects associated with pharmacological treatment. However, due to clinical heterogeneity, poor study quality, and lack of randomised controlled trials (RCTs),[20-23] the evidence for the effectiveness of non-pharmacological interventions is inconclusive. Thus, there is a need for high-quality studies to evaluate the clinical effect and cost-effectiveness of non-pharmacological sleep interventions.

Weighted blankets were beingprescribed in Sweden as a supplement to or replacement of pharmacological treatment for sleep problems among children with ADHD. However, the practice was recently stopped due to lack of evidence supporting the practice. The effectiveness of weighted blankets in this context has received little research attention and has generally had insufficient scientific quality,[21 24 25] with only one randomized controlled trial.[26] This latter study had a randomised, placebo-controlled crossover design with a four-week follow-up for each type of blanket. The population consisted of 67 children, aged 5-16 years, with autism spectrum disorders. Weighted blankets, compared with the control blanket, did not increase total sleep time, sleep-onset latency, or sleep efficiency as measured by actigraphy. However, parents and children preferred the weighted blanket, and the weighted

blankets were well tolerated.[26] In a pilot study including only two children with an autism spectrum disorder, the use of weighted blankets improved the sleep quality, justifying the need for additional robust research.[27] A case-control study without randomisation included 21 children, aged 8–13 years, with ADHD and 21 matched healthy children as a control group showed some small positive effects of the weighted blankets on sleep onset latency.[28] In summary, these studies do not provide conclusive evidence of the effect [25], economic effectivess[20 21] or children's and parents' experiences of weighted blankets for children with ADHD on sleep problems. Thus, an RCT evaluating weighted blankets for children with ADHD and sleep problems is timely. Given the societal cost and the quality of life implications of sleep interventions, the cost-effectiveness of this non-pharmacological intervention also needs to be investigated.[20] The hypothesis of this RCT is that weighted blankets will improve objectively measured and self-reported sleep compared to control blankets in children with ADHD.

Objectives

This study targets children with newly diagnosed ADHD and sleep problems, and aims to 1) evaluate the effect of an intervention with weighted blankets on sleep and other health-related outcomes; 2) evaluate the cost-effectiveness of weighted blankets, and 3) explore children´s and parents´ experiences of the sleep intervention with weighted blankets.

Methods

Study design

This is a randomised, placebo-controlled crossover trial investigating the effects of an intervention with fibre-weighted blankets in children with ADHD. The study period is 4 months, including 2 x 4 weeks of intervention with weighted blankets and control blankets, followed by an 8-week follow-up (figure 1). The study investigates the effect of the intervention in terms of 1) sleep and health; 2) cost-effectiveness, and 3) experiences of sleep and health-related outcomes. The qualitative part will be performed using an explorative design based on interviews from a subsample of the included children and their parents. The interviews will be conducted at the end of the 4-month intervention in order to gain

knowledge of the children's and parents' experiences of using these fibre-weighted blankets. The protocol is based on the Standard Protocol Items for Randomized Trials (SPIRIT).[29]

Patient and public involvement

The design of the study and the preparation and formulation of this protocol has been co-produced with healthcare professionals at the child and adolescent mental health service (CAMHS). This includes being involved in; planning inclusion and exclusion criteria for the informants, preparing the arrangement for the intervention and selecting which questionnaires to be used to measure outcome variables for children and parents. The project manager has had regular meetings with the healthcare professionals at CAMHS throughout the preparation of the study. A pilot study, with seven children and their parents, has been performed to validate the design, the interventions, and the questionnaires used. As part of this, we asked children and parents about their opinion of the intervention and also asked them for suggestions for improvements. This resulted in a few minor adjustments. The research project has been discussed with occupational therapists (who prescribe weighted blankets in Sweden) and representatives from the national occupational therapy association. The project and preliminary results have been and will be communicated through popular science reports, research conference contributions, and research papers to the healthcare services, occupational therapists, patient groups, and researchers during the research period.

Participants and recruitment

Children attending the ADHD unit at CAMHS in the southern part of Sweden during 2020-2021 will be asked to participate in the study. This ADHD unit is designed to assess and if indicated initiate treatment of children with uncomplicated ADHD according to DSM-5[30] in order to increase effectiveness and reduce waiting lists. About one-half of the patients with newly diagnosed ADHD are seen in this unit. The triaging unit selected patients ages 6-12 when the structured Brief Child and Family Phone Interview (BCFPI) interview suggested a probable diagnosis of ADHD. Exclusion criteria for referral to this unit were significant comorbidity requiring immediate treatment, severe parental stress, and intellectual impairment requiring more comprehensive interventions. The diagnostic assessment was based on written information from the present school (teacher report form and open questions about school functioning), the BCFPI, interview with parent and the child, and observing the child during the two hours assessment. The diagnostic schedule was inspired by and a short form of Kiddie Schedule for Affective Disorders and schizophrenia – Present and Lifetime version (K-SADS-

PL) to cover ADHD, externalizing and tic disorders as well as anxiety and affective disorders while infrequent diagnoses were not screened [31]. Patients in the ADHD unit received psychoeducation in groups and medication with fewer follow-ups than usual, and insufficient for the more complicated cases[32]. Recruitment of participants started in January 2020 and is estimated to be completed during autumn 2021. All children aged 6-13 years, recently diagnosed with uncomplicated ADHD with sleep problems verified by three selected questions from the Child's Sleep Habits Questionnaire (CSHQ)[33] will be approached for participation in the study. Sleep problem is considered to be present if the child 1) seldom (0-1 times per week) or sometimes (2-4 times per week) fall asleep within 20 minutes after going to bed; 2) usually (5-7 times per week) or sometimes (2-4 times per week) sleep too little or 3) wake up several times per night. In addition to this, they need to report that the sleep difficulty in question is a problem. In addition, parents and children should understand (written and spoken) the Swedish language. Children will be excluded if they have already used weighted blankets as a sleep intervention, or if they were currently on and wished to stay on melatonin for sleep problems. Children diagnosed with ADHD and not started on a stimulant and with sleep difficulties above the threshold will be invited to get further information about the study at the three hours assessment visit. Children diagnosed with ADHD and started on a stimulant will again be reviewed for inclusion criteria at the medication follow-up after about 4 weeks.

First, eligible children and their parents will be informed verbally about the study by their doctor or nurse at the CAMHS. They will then receive written information about the study and be approached by healthcare professionals about participation. After the researchers have received written consent, the participants will be contacted by telephone and the research project leader will provide more detailed information about the study. The participants will be informed that they are about to try two different types of fibre blankets. The participants will be encouraged to contact the researchers if further questions arise.

Intervention

The participants (n=100) will be randomly assigned into two groups using simple randomisation with stratification [34]. A total of 100 sheets with the letter A (Intervention) or the letter B (Control) will be printed out and put into each envelope. The sealed envelopes will be mixed and one of the researchers will pick an envelope randomly for each child. The letter A or B indicates if the child will start with a fibre-weighted blanket (active) or with a fibre blanket without weight (control). After four weeks with either the active intervention (A) or control (B), the children will change blanket (if starting with active, the child will change

into control, and vice versa). After this 8-week period, the child will decide which of the two blankets (active or control) that they want to retain.

Fibre-weighted blankets from Novista of Sweden (Novista.se) will be used in this study. The weight in the blankets is derived from longitudinal polyester fibres permitting flexibility. The blanket size is 150 x 210 cm, which is a standard size for children and adults in Sweden. The weight of each blanket will be individually tailored (weight between 6 to 10 kg) for the children, based on age, sex, height, weight, degree of sleep problems, and subtypes of ADHD of two independent experienced occupational therapists. The fibre blankets without weight (controls) have been designed for the project so that both active and control blankets have the same design. The weight is the only aspect that distinguishes them.

Data assessment

Data will be assessed at baseline (prior to the intervention), and during the 4th, 8th, and 16th weeks of the study. The measurements are performed during the last of the four weeks to minimize the risk for bias due to carry-over effects. A seven-day objective measurement of sleep will be conducted during these measurement periods. Self-reported data will also be gathered through the completion of a questionnaire by the parent and child respectively (Table 1).

Interviews with an adequate sample of children (n=25) and parents (n=25) will be conducted after the intervention period in order to understand the experiences of the intervention's impact on sleep and health-related outcome.

1. *Methods for investigating the health effects of weighted blankets*

Primary outcome

The primary outcome is *objectively measured* and *self-reported sleep*. Variables of interest from the *objectively measured sleep* are: *Sleep onset latency (SOL),* which refers to the period of time between turning lights out to go to sleep (timing identified by marker from the event button, or self-reported time in daily text messages) and falling asleep; *Total sleep time (TST)*, which is equal to the time of total sleep episode minus the awake time; *Sleep efficiency (SE),* which is the total sleep time expressed as a percentage; *wake after sleep onset (WASO),* referring to periods of wakefulness occurring after sleep onset.

Objectively measured sleep will be assessed using actigraphy. This method for assessing sleep has been shown to be valid in several studies,[35] and has shown to be strongly associated with polysomnographic measures with a correlation coefficient of at least 0.85 in healthy individuals.[36] Measurements from at least 4-7 nights have been recommended.[37] Motionwatch 8 (Camntech.Ltd.), a triaxial accelerometer using MEMs technology, capable of sensing motions in a resultant force range of 0.01 g to 8 g[38] is used in this study. The actigraph registers total gross motor activity for analysis of sleep-wake patterns and has good validity for measuring sleep[38]. Recordings will be taken in 30-second epochs.

Participants will be instructed to wear the watch on their non-dominant wrist, for seven consecutive nights. If not worn during the day, the parent and child will be instructed to put on the watch in the early evening, or in good time prior to going to bed. The participant is instructed to push an event-button when they decide to go to sleep, e.g. when they stop reading a book or turn off the lights. In addition to marking the event of going to sleep and waking up by pressing the button, the parents will answer questions daily (by text message): 1) What time did your child go to bed yesterday?; 2) How long time do you estimate the time for your child to fall asleep from the time your child went to bed? (hours, minutes); 3) What time did your child wake up today?; 4) Was your child restless and moved around a lot during sleep? (not at all restless, a little restless, moderately restless, very restless); 5) Was your child restless when falling asleep? (not at all restless, a little restless, moderately restless, very restless)

The variables of interest from the *self-reported sleep* will be assessed by CSHQ[33], and Insomnia Severity Index (ISI).[39]

The CSHQ assesses parental reported sleep and consists of 33 items related to eight subscales; 1*) Bedtime resistance*, 2) *Sleep onset delay*, 3) *Sleep duration*, 4) *Sleep anxiety*, 5) *Night wakings*, 6) *Parasomnias,* 7) *Sleep-disordered breathing*, and 8) *Daytime sleepiness*. Each item is rated on a three-point scale: "usually" if the sleep behavior occurred five to seven times/week; "sometimes" for two to four times/week; and "rarely" for zero to one time/week. A higher score indicates more sleep problems. The scale has good reliability and validity.[33]

Insomnia will be assessed by ISI, which comprises seven items for the children to respond to: 1) Severity of sleep-onset, 2) Sleep maintenance, 3) Early morning awakening, 4) Satisfaction with current sleep pattern, 5) Interference with daily functioning, 6) Noticeability of

impairment attributed to the sleep problem, and 7) Level of distress caused by the sleep problem. Each item is rated on a five-point Likert scale ranging from “not at all” (scored at 0) to “extremely” (scored at 4). Total score ranges from 0 to 28, with higher scores indicating greater severity. ISI is a reliable and valid instrument for quantifying the severity of perceived insomnia and measures insomnia in treatment research.[39] The ISI will be slightly modified in order to better correspond to a child’s language.

Secondary outcomes

The children's general well-being will be assessed by the Child Outcome Rating Scale (CORS),[40] which is an overall measure of psychological distress. It was developed to give children a voice in the services they receive. CORS comprises four items where the child evaluates; 1) Me (How am I doing?), 2) Family (How are things in my family?), 3) School (How am I doing at school?), 4) Everything (How is everything going?). Each item is rated on a 100-millimeter Visual Analog Scale with smiling and sad faces as anchors. CORS has good reliability and moderate validity.[40]

The children’s anxiety will be assessed by The short State-Trait Anxiety Inventory for children (short-STAI).[41 42] Short-STAI includes six items.[43] Each item is rated on a four-point Likert scale ranging with 1 = "not at all," 2 = "somewhat," 3, = "moderately”, and 4 = "very much." The total score range from 6 to 24 points, with 6 points indicating no anxiety and 24 points indicating the highest level of anxiety. Short-STAI has good reliability and validity for children.[41]

The children’s ADHD symptoms - hyperactivity/impulsivity, inattention and oppositional - will be assessed by the parents filling in The Swanson, Peland, and Nolan Scale (SNAP-IV).[44] The SNAP-IV consists of 30 items and is divided into three subscales: inattention (nine items), hyperactivity/impulsivity (nine items), and oppositionality (eight items) and four supplementary questions regarding oppositionality (two questions) and ADHD (two questions). Items are rated on a four-point Likert scale range 0 = “not at all”, 1 = “just a little”, 2 = “quite a bit”, and 3 = “very much”. Items for inattention and hyperactivity/impulsivity can be combined to create a “combined ADHD” score.[45] Higher scores represent more symptoms. The SNAP-IV is a robust and valid measure of outcome for research studies and is often used in RCTs.[46]

The parents' general well-being will be assessed by the Outcome Rating Scale (ORS),[47] which is a general mental health assessment of the past week in four items; 1) Personal wellbeing, 2) Interpersonal relationships, 3) Social relations and, 4) Overall sense of well-being. Each item is rated on a 100-millimeter Visual Analog Scale with anchors from 0 (negative) to 100 (positive). ORS is a reliable and valid instrument.[40 48]

Family situation and parental mood will be assessed by the Brief Child and Family Phone Interview (BCFPI),[49 50] BCFPI is a structured parent interview for triage at intake and follow-up evaluation of community care at CAMHS. It consists of 36 symptom items and another 36 items to assess function, adversity, and family stress grouped into 12 subscales. The subscale ´family situation` contains three items rated on a four-point Likert scale range 1 = never, 2 = sometimes, 3 = often, 4 =always. The subscale ´parental mood` contains six items based on the question "How often during the past week has the parent experienced…?" rated on a four-point scale; < 1 day, 1-2 days, 3-4 days, >5 days. BCFPI has good reliability and validity.[49 50]

Health-related quality of life will be assessed for children with EQ-5D-Y[51] and parents with EQ-5D-3L[52]. EQ-5D-Y measures health-related quality of life "today" for children and young people and is developed from the standard adult EQ-5D [51]. EQ-5D-Y comprises five items; 1) Walking about (mobility), 2) Looking after myself (self-care), 3) Doing usual activities (usual activities), 4) Having pain or discomfort (pain and discomfort), and 5) Feeling worried, sad or unhappy (anxiety and depression). Each item is divided into three levels; No problems, Some problems, and A lot of problems. The EQ-5D-Y also includes an easily understandable modified vertical Visual Analogue Scale of EQ-5D, where the respondent rates the overall health status with the endpoints from 0 (the worst health state the child can imagine and 100 (the best health state the child can imagine)[51]. EQ-5D-Y has good reliability and validity.[53] EQ-5D is a generic health-related quality of life instrument[52] measuring the parents' health comprising five dimensions; 1) Mobility, 2) Self-care, 3) Usual activities, 4) Pain/discomfort, and 5) Anxiety/Depression. Each dimension is divided into three levels; No problems, Some or moderate problems, and extreme problems. In addition to the five dimensions, a 100-millimeter vertical Visual Analog Scale with endpoints of 100 means "best imaginable health state" and 0 means "worst imaginable health state is included. The total score ranges from 0 to 1 where a higher score indicates a better health-related quality of life.

ADHD diagnosis and subtype as well as comorbidities will be extracted from the clinical records. In addition, symptom load from ADHD inattention or/and hyperactivity/impulsivity

pharmacological treatment, sociodemographic data, resource consumption and will be collected via the survey at baseline and the 4th, 8th, and 16th weeks of the study.

Table 1. Overview of the questionnaires included in the study

	Assessed by children reports	**Assessed by parents' reports**
Socioeconomic variables		Children: Age, gender, country of birth, Parents: age gender, country of birth, civil status, level of education, and work situation
Sleep habits	Insomnia Severity Index (ISI) [39]	Child's Sleep Habits Questionnaire (CSHQ) [33]
General well-being	Children Outcome Rating Scale (CORS) [40]	Outcome Rating Scale (ORS) [40 47]
Anxiety	State-Trait Anxiety Inventory (STAI) [41 42]	
ADHD symptoms		Swanson, Peland and Nolan Scale (SNAP IV) [44 45]
Family situation and parental mood		The Brief Child and Family Phone Interview (BCFPI) [49 50]
Health-related quality of life	EQ-5D-Y [51 53]	EQ-5D-3L [52 54]
Resource consumption		School absence (children), work productivity and absence (parents), and healthcare consumption according to Swedish adaptation [55 56] of the TIC-P instrument [57]

2. *Methods for investigating the cost-effectiveness of weighted blankets*

The health economic evaluation is a within-trial cost-utility analysis with a societal perspective based on the data collected at the 8-week follow-up, with the primary outcome costs per QALY (quality-adjusted life-years). An incremental cost-effectiveness ratio (ICER) with a 4 week time horizon is calculated based on differences in societal costs (implementation costs and societal consequences) and quality of life when using either the fibre-weighted blankets or control blankets. No discounting of costs and health effects will be performed due to the short follow-up period. A number of sensitivity analyses are planned, including probabilistic analyses with bootstrapped differences of individual-level data on major societal consequences and quality of life, as well as of the ICER.

The *societal cost consequences* combine parent-reported data on resource consumption with clinical register data to estimate the differences in societal costs between the two study arms at baseline and 8 weeks. The parent-reported resource consumption survey questions are

based on a Swedish adaptation of the TIC-P instrument[55-57] and consider the four weeks. The questions include school absence for the child (in numbers of full days, half days, and 1-2 hours), work absence for one parent (in numbers of full days (8 hours), three-quarters of a day (6 hours), half a day (4 hours) and one-quarter of a day (2 hours)), work productivity of the parent (in ten levels from no work accomplished to hardly no decreased work capacity) and healthcare appointments (nine types of healthcare including e.g. school healthcare, primary care, and emergency care). The clinical register data include the number of appointments at the CAMHS and prescribed pharmacological therapy. The cost of the resource consumption items from the parent survey and the clinical register will be estimated according to Swedish published data on the average costs for healthcare appointments from SALAR (the Swedish Association of Local Authorities and Regions) and occupation-specific healthcare wages including wage taxes from Statistics Sweden. The cost of parents' work absence and decreased productivity will be estimated using average Swedish hourly wages including wage taxes from Statistics Sweden while the cost of child school absence is estimated according to estimated schooling costs from The Swedish National Agency for Education. The cost of prescribed pharmacological therapy will be estimated according to listed prices at the Dental and Pharmaceutical Benefits Agency.

The *implementation costs,* i.e. the prescription of the weighted blankets, include the healthcare region's purchasing price for weighted blankets, administration and transportation from the assistive technology centre, child psychiatrist time for referral to an occupational therapist, occupational therapist time for assessment, prescription and tailoring as well as parent and child time. The healthcare costs will be estimated based on data from SALAR and Statistics Sweden while the visiting and traveling time for the parent and child will be estimated according to data from Statistics Sweden and The Swedish National Agency for Education, as above.

Quality of life estimates for calculating *QALYs* over the 4 weeks period will be taken from the parent-reported EQ-5D instrument valued with a Swedish tariffs value set.[54] EQ-5D-3L is frequently used in Sweden and for economic evaluations and is considered a reliable and valid instrument.[54] There is currently no appropriate value set for the child version of EQ-5D (i.e. EQ-5D-Y), so in a sensitivity analysis, the VAS ratings will be used and added to the parent estimated QALYs. The QALYs during 4 weeks will be calculated based on the mean changes in quality of life of using weighted blankets vs control blankets, with an instant change assumed when initiating use of the weighted blankets.

3. *Methods for investigating the experiences of weighted blankets*

The qualitative data will consist of individual interviews with children and their parents in the intervention study. An open interview guide with initial questions will be used to ensure similar data from all participants. The initial questions refer to the experiences of sleep for children with ADHD, experiences of how the sleep intervention with weighted blankets influences the children's sleep, and health-related outcomes as well as the family situation. *Questions to the children*: "How do you usually sleep?", "In what way can it be difficult to sleep?", "How does sleep differ if you sleep well or badly?", "What is important for you to be able to sleep?", "How do you experience the two different blankets you have used?", "How do you experience the weighted blanket?", "Can you describe your sleep since you started using the weighted blankets?". *Questions to the parents*: "What does sleep mean for your child?", "How does your child usually sleep?", "What is important for your child to be able to sleep?", "How is your child's life affected by sleep?", "How do you experience the two different blankets your child has used?", "How do you experience the weighted blanket?", Can you describe your child's sleep since he/she started using the weighted blankets?", How is your child's well-being since he/she started using the weighted blankets?", How has the situation for the family and you as a parent been affected since your child started using the weighted blanket?" *Follow-up probes* will be used to encourage children and parents to elaborate on the answers: "Please tell me more", "How do you mean?" or "What do you have in mind when you say ...?" The interviews will be digitally recorded and transcribed verbatim.

Statistical Power

A power analysis was made based on estimated changes in the primary outcome variable *sleep onset latency* (SOL). Estimations of mean and standard deviations were made based on previous studies of SOL in children. Mean SOL is expected to differ substantially with age among children. Gringras et al. (2014) investigated children 5 to 16 years of age and found a mean value of 76,5 minutes of SOL with a standard deviation of 46,1.[26] Hvolby and Bilenberg (2011) studied SOL in children 8 to 13 years of age and reported a mean value of 23,1 minutes of SOL with a standard deviation of 9,4.[28]

Previous studies investigating the effect of similar interventions on SOL have found a 40% decrease in SOL after the intervention [28]. The power calculation of this study is based on the assumption that a 30% decrease in SOL is a clinically relevant improvement. In this study,

including children 6 to 13 years of age, estimating a mean of 35 minutes SOL and a standard deviation of 15, the power analysis demonstrated that 58 children (29 in each group) will be a sufficient number if accepting a 30% difference between groups in SOL with 80 % power. To allow for a 40% dropout, 100 children (50 in each group) will be enrolled in the study.

Data analysis

Statistical analyses will be performed using SPSS version 24 for Windows. The intervention will be evaluated in terms of effect and cost comparison. Differences will be evaluated with an intention to treat analysis. Objectively and subjectively measured sleep, anxiety, and health-related quality of life will be evaluated with a paired t-test or equivalent non-parametric tests and by independent sample t-test for between group analyses of carry-over and period effect. Children included are stable on medication before inclusion and are encouraged not to initiate other sleep adjustments during the study period. ADHD symptoms and sleep problems are thus considered to be stable over the 4+4 cross-over period minimizing any period effects. The weighted blanket is only active under actual use and the treatment effect is not likely to be carried over. Linear mixed effect model will be used for evaluating the effect on sleep problems over time. Differences in societal costs will be analysed via non-parametric bootstrap analyses on individual-level data and reported as credibility intervals.[58] The qualitative data from interviews will be analysed with inductive qualitative content analysis.[59]

Ethics and dissemination

The study is approved by the Swedish Ethical Review Authority (No. 2019-02158) and conforms to the principles outlined in the Declaration of Helsinki.[60] The study will fulfill requirements for research: information, consent, confidentiality, and safety of the participants and is guided by the ethical principles: autonomy, beneficence, non-maleficence, and justice.[61] All participation and data collection will be performed confidentially. Children and parents will receive written and oral information and parents give their informed consent in writing. The participants will be informed that they can withdraw from the project at any time without having to justify why. Data will be collected in anonymised form and keys that link data with personal information will be stored separately and only accessible to the project leader. All personal data will be registered according to the General Data Protection Regulation (GDPR2016/679)[62] and the data will be stored in accordance with the Archive Act

in Sweden (SFS1990:782).[63] This study is registered at http://clinicaltrials.gov under identification number NCT04180189. The results of this study will be communicated to the included participants, healthcare providers, and companies, in manuscripts submitted to peer-reviewed journals, as well as in presentations at national and international peer-review conferences.

Discussion

Weighted blankets are prescribed to patients in healthcare in Sweden and are widely used as a non-pharmacological intervention for sleep problems, even though evidence for the effects of weighted blankets is lacking. The few previous studies investigating the effect of weighted blankets for children with ADHD have not shown conclusive results and to date, there are too few high-quality studies to support the intervention. [25-28] The results from this RCT will thus be important for providing new evidence of the efficacy, cost-effectiveness, and experiences of the use of weighted blankets to address sleep problems among children with ADHD.

Some methodological considerations can be highlighted. A strength is that this study will be the first randomised placebo-controlled crossover trial investigating the effects of fibre-weighted blankets in children with ADHD. Another strength is the use of both objective and subjective measures for sleep. Although subjectively measured sleep is highly relevant to assess and evaluate, objectively measured sleep has the advantages of being free from subjective expectations in relation to the intervention, and less sensitive to recall bias. Furthermore, the evaluation of cost-effectiveness of weighted blankets is highly relevant though this has not previously been studied.[21] The costs and benefits of the intervention need to be taken into consideration when implementing the intervention in healthcare settings. Similarly, the inclusion of a qualitative approach in the design to increase the understanding of both children's and parents' experiences of effects is another strength. This latter aspect is of great relevance as children's perspectives are seldom taken into account in research.

There are, however, a few methodological challenges with this study. Assessing self-reported data from children is difficult for several reasons. Some of the questionnaires in this study are designed for the parent to respond on behalf of the child (e.g. CSHQ). This may be a good approach for younger children, but depending on the habits around bedtime, the parents may only have (at best) a reasonably good perception of how the child`s sleep was (for example, if sleeping in separate bedrooms). Under these circumstances, the parent and the child are

instructed to fill in the questionnaire together to get a more reliable assessment. Another potential bias is the control blankets. The difference in weight will be obvious for parents and also for children. The participants are only informed they are trying two different kinds of blankets. However, most have learned about weighted blankets through media or their health providers, possibly affecting expectations in favour of the weighted blanket

We anticipate the project will make several scientific contributions to the research on health-related outcomes, sleep, and cost-effectiveness for non-pharmacological sleep interventions. such as weighted blankets. These findings will be essential for healthcare professionals in their practice though evidence today for the effects of weighted blankets is scarce. The results will also be relevant for children with ADHD in particular, but will also be relevant for other target groups and other settings.

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Author Contribution IL, JN and PS contributed to the conception of the study, obtained the funding, and are the guarantors of the study. IL, KA, JN, PJ, HJ and PS contributed to the study design. IL and KA were primarily responsible for the statistical analysis plan. PJ was responsible for the health economic analysis plan. IL and PS were responsible for the qualitative analysis plan. IL drafted the manuscript and KA, JN, PJ, HJ and PS revised the manuscript critically for important intellectual content, All authors read and approved the final version of the manuscript.

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Competing interests None declared.

Patient consent for publication Not required.

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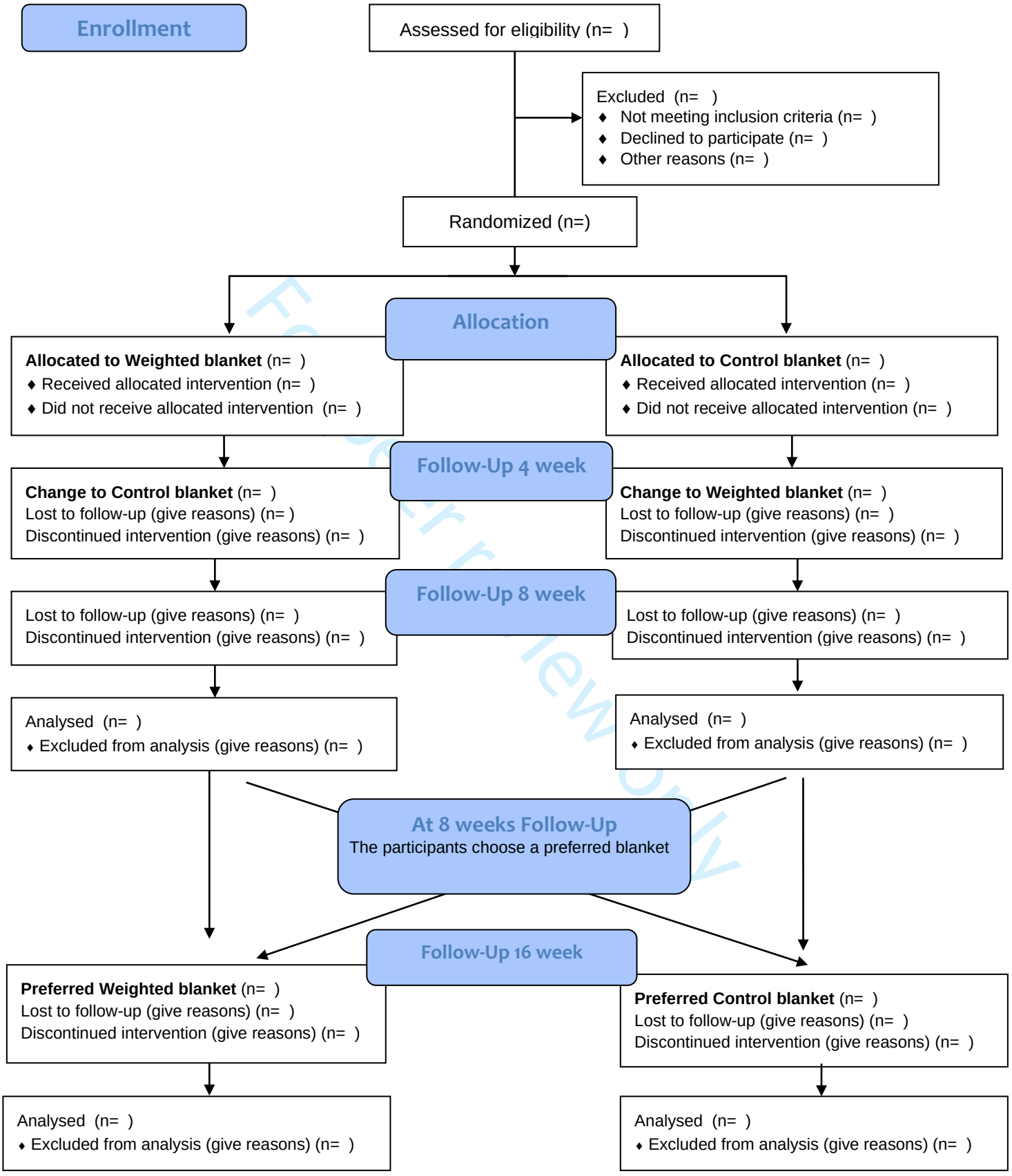
Figur 1 CONSORT Flow Diagram over the SLEEP trial



SPIRIT
STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description
Administrative information		
Title	1	*SLEEP - An intervention with weighted blankets for children with Attention Deficit Hyperactivity Disorder (ADHD) and sleep problems: study protocol for a randomised control trial*
Trial registration	2a	Trial Registration number: NCT04180189
	2b	Trial Registration number: NCT04180189
Protocol version	3	2020-11-30 no. 1
Funding	4	This work was supported by the Knowledge Foundation and Region Halland. Page 13
Roles and responsibilities	5a	Ingrid Larsson[1] (IL) wrote the first draft of the manuscript. Petra Svedberg[1] (PS) and IL conceived the study idea, obtained the funding, and are the guarantors of the study. IL, Katarina Aili[1] (KA), Jens Nygren[1] (JN), and PS contributed to the study design. IL and KA were primarily responsible for the statistical analysis plan. Pia Johansson[1] (PJ) was responsible for the health economic analysis plan. All authors read and approved the final version of the manuscript [1] School of Health and Welfare, Department of Health and Nursing, Halmstad University, Halmstad, Sweden. Page 13
	5b	Knowledge Foundation and Region Halland, Page 13
	5c	Neither the DCAP in Region Halland and the company Novista of Sweden AB nor the funders have any role in the study design, data collection, management, analysis, or interpretation of the data. Page 13
Introduction		
Background and rationale	6a	Previous research does not provide conclusive evidence of the effect, economic impact or children's and parents' experiences of weighted blankets for children with ADHD on sleep problems. Pages 1-2
	6b	Thus, more RCT studies are needed to explore this issue further. Given the societal cost and the quality of life implications of sleep interventions, the cost-effectiveness of this non-pharmacological intervention also needs to be investigated. Pages 1-2

Objectives	7	This study targets children with newly diagnosed ADHD and sleep problems, and aims to 1) evaluate the effect of an intervention with weighted blankets on sleep and other health-related outcomes; 2) evaluate the cost-effectiveness of weighted blankets, and 3) explore children´s and parents´ experiences of the sleep intervention with weighted blankets. Page 2
Trial design	8	This is a randomised, placebo-controlled crossover trial investigating the effects of an intervention with fiber-weighted blankets in children with ADHD. The study period is 4 months, including 2 x 4 weeks of intervention with weighted blankets and placebo, followed by an 8-week follow-up. Page 2

Methods: Participants, interventions, and outcomes

Study setting	9	Children attending the ADHD unit at DCAP in the southern part of Sweden. Page 3
Eligibility criteria	10	All children aged 6-15 years, recently diagnosed with ADHD with sleep problems verified by selected questions from the Child's Sleep Habits Questionnaire (CSHQ) will be approached for participation in the study. Children will be excluded if they have already used weighted blankets as a sleep intervention, or if they have received a new prescription or change of pharmacological treatment for sleep problems. Page 3
Interventions	11a	The participants (n=80) will be randomly assigned into two groups. The child will start with a fiber-weighted blanket (active) or with a fiber blanket without weight (placebo). After four weeks with either the active intervention (A) or placebo (B) the children will change blanket (if starting with active, the child will change into placebo, and vice versa). After this 8-week period, the child will decide which of the two blankets (active or placebo) that they want to retain. Pages 3-4
Outcomes	12	The primary outcome is objectively measured and self-reported sleep. Secondary outcomes: *The children's general well-being* will be assessed by the Child Outcome Rating Scale (CORS), *The children's anxiety* will be assessed by The short State-Trait Anxiety Inventory for children (short-STAI), *The children's ADHD symptoms* - hyperactivity/impulsivity, inattention and oppositional - will be assessed by the parents using The Swanson, Peland, and Nolan Scale (SNAP-IV), *The parents' general well-being* will be assessed by the Outcome Rating Scale (ORS), *Family situation and parental mood* will be assessed by the Brief Child and Family Phone Interview (BCFPI), H*ealth-related quality of life* in children (EQ-5D-Y) and parents (EQ-5D-3L) Pages 4-9
Participant timeline	13	Children attending the ADHD unit at DCAP in the southern part of Sweden during 2020-2021 will be asked to participate in the study. Page 3

Sample size	14	The power calculation of this study is based on the assumption that a 30% decrease in SOL is a clinically relevant improvement. In this study, including children 6 to 15 years of age, estimating a mean of 35 minutes SOL and a standard deviation of 15, the power analysis demonstrated that 58 children (29 in each group) will be a sufficient number if accepting a 30% difference between groups in SOL with 80 % power. To allow for a 25% dropout, 80 children (40 in each group) will be enrolled in the study. Page 10
Recruitment	15	Children attending the ADHD unit at DCAP in the southern part of Sweden during 2020-2021 will be asked to participate in the study. Page 3

Methods: Assignment of interventions (for controlled trials)

Allocation:

Sequence generation	16a	The participants (n=80) will be randomly assigned into two groups using simple randomisation with stratification [31]. A total of 80 sheets with the letter A (Intervention) or the letter B (Control) will be printed out and put into each envelope. The sealed envelopes will be mixed and one of the researchers will pick an envelope randomly for each child. The letter A or B indicates if the child will start with a fiber-weighted blanket (active) or with a fiber blanket without weight (placebo). Page 3

Methods: Data collection, management, and analysis

Data collection methods	18a	Data will be assessed at baseline (prior to the intervention), and during the 4th, 8th, and 16th weeks of the study Page 3
Statistical methods	20a	Statistical analyses will be performed using SPSS version 24 for Windows. The intervention will be evaluated in terms of effect and cost comparison. Differences in objectively and subjectively measured sleep, anxiety, and health-related quality of life will be analysed by paired t-test and by independent sample t-test for between group analyses. Differences in resource consumption will be analyzed via non-parametric bootstrap analyses. Page 10
	20b	The qualitative data from interviews will be analyzed with inductive qualitative content analysis. Page 10

Ethics and dissemination

Research ethics approval	24	The study is approved by the Swedish Ethical Review Authority (No. 2019-02158) and conforms to the principles outlined in the Declaration of Helsinki. Page 11

Consent or assent	26a	Children and parents will receive written and oral information and give their informed consent. The participants will be informed that they can withdraw from the project at any time without having to justify why. Page 11
Confidentiality	27	All participation and data collection will be performed confidentially. Page 11
Declaration of interests	28	None declared. Page 13
Access to data	29	Only the researches have access to the data. Page 13
Dissemination policy	31a	The results of this study will be communicated to the included participants, healthcare providers, and companies, in manuscripts submitted to peer-reviewed journals, as well as in presentations at national and international peer-review conferences. Page 11

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.