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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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Manuscripts

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3 *SLEEP - An intervention with weighted blankets for children with Attention Deficit*
4 *Hyperactivity Disorder (ADHD) and sleep problems: study protocol for a randomised control*
5 *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 performance¹⁰ 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

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3 autism spectrum disorder, the use of weighted blankets improved the sleep quality, justifying
4 the need for additional robust research.²⁷ A case-control study without randomisation included
5 21 children, aged 8–13 years, with ADHD and 21 matched healthy children as a control group
6 showed some small positive effects on sleep onset latency.²⁸ In summary, these studies do not
7 provide conclusive evidence of the effect²⁵, economic impact^{20 21} or children's and parents'
8 experiences of weighted blankets for children with ADHD on sleep problems. Thus, more
9 RCT studies are needed to explore this issue further. Given the societal cost and the quality of
10 life implications of sleep interventions, the cost-effectiveness of this non-pharmacological
11 intervention also needs to be investigated.²⁰
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21 Objectives

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

34 *Study design*

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

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57 The study design has been planned together with healthcare professionals at the included
58 Department of Child and Adolescent Psychiatry (DCAP). The end-users, i.e children, have
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3 however not been consulted during the planning phase. The results will be communicated to
4 the healthcare services after the research period.
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6 7 *Participants and recruitment* 8

9 Children attending the ADHD unit at DCAP in the southern part of Sweden during 2020-2021
10 will be asked to participate in the study. The ADHD unit does not admit children with
11 complex neuropsychiatric or psychiatric comorbidities. Recruitment of participants started in
12 January 2020 and is estimated to be completed during autumn 2021. All children aged 6-15
13 years, recently diagnosed with ADHD with sleep problems verified by selected questions
14 from the Child's Sleep Habits Questionnaire (CSHQ)³⁰ will be approached for participation in
15 the study. Children will be excluded if they have already used weighted blankets as a sleep
16 intervention, or if they have received a new prescription or change of pharmacological
17 treatment for sleep problems.
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20 First, eligible children and their parents will be informed verbally about the study by their
21 doctor or nurse at the DCAP. They will then receive written information about the study and
22 be approached by healthcare professionals about participation. After the researchers have
23 received written consent, the participants will be contacted by telephone and the research
24 project leader will provide more detailed information about the study. The participants will be
25 informed that they are about to try two different types of fiber blankets. The participants will
26 be encouraged to contact the researchers if further questions arise.
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29 *Intervention* 30

31 The participants (n=80) will be randomly assigned into two groups using simple
32 randomisation with stratification³¹. A total of 80 sheets with the letter A (Intervention) or the
33 letter B (Control) will be printed out and put into each envelope. The sealed envelopes will be
34 mixed and one of the researchers will pick an envelope randomly for each child. The letter A
35 or B indicates if the child will start with a fiber-weighted blanket (active) or with a fiber
36 blanket without weight (placebo). After four weeks with either the active intervention (A) or
37 placebo (B) the children will change blanket (if starting with active, the child will change into
38 placebo, and vice versa). After this 8-week period, the child will decide which of the two
39 blankets (active or placebo) that they want to retain.
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41 Fiber-weighted blankets from Novista of Sweden (Novista.se) will be used in this study. The
42 weight in the blankets is derived from longitudinal polyester fibers that make it flexible. The
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3 blanket size is 150 x 210 cm, which is a standard size for children and adults in Sweden. The
4 weight of each blanket will be individually tailored (weight between 6 to 10 kg) for the
5 children, based on age, sex, height, weight, degree of sleep problems, and subtypes of ADHD
6 according to the clinical practice of two independent experienced occupational therapists. The
7 fiber blankets without weight (controls) have been designed for the project so that both active
8 and placebo blankets have the same design. The weight is the only aspect that distinguishes
9 them.
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15 *Data assessment*

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18 Data will be assessed at baseline (prior to the intervention), and during the 4th, 8th, and 16th
19 weeks of the study. A seven-day objective measurement of sleep will be conducted during
20 these measurement periods. Self-reported data will also be gathered through completion of a
21 questionnaire by the parent and child respectively (Table 1).
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26 Interviews with a purposeful sample of children (n = 25) and parents (n = 25) will be held
27 after the intervention period in order to understand the experiences of the intervention's
28 impact on sleep and health-related outcome.
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32 *1. Methods for investigating the health effects of weighted blankets*

33 *Primary outcome*

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36 The primary outcome is *objectively measured and self-reported sleep*. Variables of interest
37 from the *objectively measured sleep* are: *Sleep onset latency (SOL)*, which refers to the period
38 of time between turning lights out to go to sleep (timing identified by marker from the event
39 button, or self-reported time in daily SMS) and falling asleep; *Total sleep time (TST)*, which is
40 equal to the time of total sleep episode minus the awake time; *Sleep efficiency (SE)*, which is
41 the total sleep time expressed as a percentage; *wake after sleep onset (WASO)*, referring to
42 periods of wakefulness occurring after sleep onset.
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51 Objectively measured sleep will be assessed using actigraphy. This method for assessing
52 sleep has been shown to be a valid in several studies,³² and has shown to be strongly
53 associated with polysomnographic measures with a correlation coefficient of at least 0.85 in
54 healthy individuals.³³ Measurements from at least 5-7 nights have been recommended.³⁴
55 Motionwatch 8 (Camntech.Ltd.), a triaxial accelerometer using MEMs technology, capable of
56 sensing motions in a resultant force range of 0.01 g to 8 g³⁵ is used in this study,. The
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actigraph registers total gross motor activity for analysis of sleep-wake patterns and has good validity for measuring sleep³⁵. 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 CSHQ³⁰, 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

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

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

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

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

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57 *Family situation and parental mood* will be assessed by the Brief Child and Family Phone
58 Interview (BCFPI),^{46 47} which comprises two subscales. The subscale 'family situation'
59 contains three items rated on a four-point Likert scale range 1 = never, 2 = sometimes, 3 =
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3 often, 4 =always. The subscale 'parental mood' contains six items based on the question
4 "How often during the past week has the parent experienced...?" rated on a four-point scale;
5 < 1 day, 1-2 days, 3-4 days, >5 days. BCFPI has good reliability and validity.^{46 47}
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9 In addition, sociodemographic data and assessment of the *health-related quality of life* in
10 children (EQ-5D-Y)⁴⁸ and parents (EQ-5D-3L)⁴⁹ will be conducted.
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13 2. Methods for investigating the cost-effectiveness of weighted blankets

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16 The health economic evaluation is a within-trial cost-utility analysis with a societal
17 perspective after a follow-up period of 16 weeks. An incremental cost-effectiveness ratio
18 (ICER) reporting costs per QALYs (quality-adjusted life-years) is calculated based on
19 differences in societal costs (implementation costs and societal consequences) and quality of
20 life when using either the fiber-weighted blankets or placebo blankets. No discounting of
21 costs and health effects will be performed due to the short follow-up period. A number of
22 sensitivity analyses are planned, including a probabilistic analysis with bootstrapped
23 differences of major societal consequences as well as of the ICER.
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30 The *societal cost consequences* combine parent-reported data on resource consumption with
31 clinical register data to estimate the differences in societal costs between the two study arms
32 at baseline and 16 weeks. The parent-reported resource consumption survey questions are
33 based on a Swedish adaptation of the TIC-P instrument⁵⁰⁻⁵² and consider the past two months.
34 The questions include school absence for the child (in numbers of full days, half days, and 1-2
35 hours), work absence for one parent (in numbers of full days (8 hours), three-quarters of a day
36 (6 hours), half a day (4 hours) and one-quarter of a day (2 hours)), work productivity of the
37 parent (in ten levels from no work accomplished to hardly no decreased work capacity) and
38 healthcare appointments (nine types of healthcare including e.g. school healthcare, primary
39 care, and emergency care). The clinical register data include the number of appointments at
40 the DCAP and prescribed pharmacological therapy. The cost of the resource consumption
41 items from the parent survey and the clinical register will be estimated according to Swedish
42 published data on the average costs for healthcare appointments from SALAR (the Swedish
43 Association of Local Authorities and Regions) and occupation-specific healthcare wages
44 including wage taxes from Statistics Sweden. The cost of parents' work absence and
45 decreased productivity will be estimated using average Swedish hourly wages including wage
46 taxes from Statistics Sweden while the cost of child school absence is estimated according to
47 estimated schooling costs from The Swedish National Agency for Education. The cost of
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3 prescribed pharmacological therapy will be estimated according to listed prices at the Dental
4 and Pharmaceutical Benefits Agency.
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7 The *implementation costs*, i.e. the prescription of the weighted blankets, includes the
8 healthcare region's purchasing price for weighted blankets, child psychiatrist time for
9 prescription, physiotherapist time for tailoring as well as parent and child time. The healthcare
10 costs will be estimated based on data from SALAR and Statistics Sweden while the visiting
11 and traveling time for the parent and child will be estimated according to data from Statistics
12 Sweden and The Swedish National Agency for Education, as above.
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18 *Quality of life* estimates for calculating *QALYs* over the 16 week follow-up period will be
19 taken from the parent-reported EQ-5D instrument valued with a Swedish tariffs value set.⁵³
20 There is currently no appropriate value set for the child version of EQ-5D (i.e. EQ-5D-Y), so
21 in a sensitivity analysis, the VAS-ratings will be used and added to the parent estimated
22 *QALYs*.
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28 EQ-5D is a generic health-related quality of life instrument⁴⁹ measuring the parents' health
29 comprising five dimensions; 1) Mobility, 2) Self-care, 3) Usual activities, 4) Pain/discomfort,
30 and 5) Anxiety/Depression. Each dimension is divided into three levels; No problems, Some
31 or moderate problems, Extreme problems. In addition to the five dimensions, a 100-millimeter
32 vertical Visual Analog Scale with endpoints of 100 means "best imaginable health state" and
33 0 means "worst imaginable health state. The total score ranges from 0 to 1 where a higher
34 score indicates a better health-related quality of life. EQ-5D-3L is frequently used in Sweden
35 and for economic evaluations and is considered a reliable and valid instrument.⁵³ For the
36 economic evaluation, the Swedish value set will be used to calculate the parent *QALYs*.⁵³
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45 EQ-5D-Y measures health-related quality of life "today" for children and young people and is
46 developed from the standard adult EQ-5D⁴⁸. EQ-5D-Y comprises five items; 1) Walking
47 about (mobility), 2) Looking after myself (self-care), 3) Doing usual activities (usual
48 activities), 4) Having pain or discomfort (pain and discomfort), and 5) Feeling worried, sad or
49 unhappy (anxiety and depression). Each item is divided into three levels; No problems, Some
50 problems, and A lot of problems. The EQ-5D-Y also includes an easily understandable
51 modified vertical Visual Analogue Scale of EQ-5D, where the respondent rates the overall
52 health status with the endpoints from 0 (the worst health state the child can imagine and 100
53 (the best health state the child can imagine).⁴⁸ EQ-5D-Y has good reliability and validity.⁵⁴ As
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no value set currently exists that can enable us to calculate QALYs based on the EQ-5D-Y items⁵⁵ 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

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

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23 A power analysis was made based on estimated changes in the primary outcome variable
24 *sleep onset latency* (SOL). Estimations of mean and standard deviations were made based on
25 previous studies of SOL in children. Mean SOL is expected to differ substantially with age
26 among children. Gringras et al. (2014) investigated children 5 to 16 years of age and found a
27 mean value of 76,5 minutes of SOL with a standard deviation of 46,1.²⁶ Hvolby and Bilenberg
28 (2011) studied SOL in children 8 to 13 years of age and reported a mean value of 23,1
29 minutes of SOL with a standard deviation of 9,4.²⁸
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36 Previous studies investigating the effect of similar interventions on SOL has found a 40%
37 decrease in SOL after the intervention²⁸. The power calculation of this study is based on the
38 assumption that a 30% decrease in SOL is a clinically relevant improvement. In this study,
39 including children 6 to 15 years of age, estimating a mean of 35 minutes SOL and a standard
40 deviation of 15, the power analysis demonstrated that 58 children (29 in each group) will be a
41 sufficient number if accepting a 30% difference between groups in SOL with 80 % power. To
42 allow for a 25% dropout, 80 children (40 in each group) will be enrolled in the study.
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48 *Data analysis*

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

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3 this has not previously been studied.²¹ The cost and benefits of the intervention need to be
4 taken into consideration when implementing the method in healthcare settings.
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7 One strength of the study is its design and the relatively large number of participants. This
8 will be the first randomised placebo-controlled crossover trial investigating the effects of
9 fiber-weighted blankets in children with ADHD. Another strength is the use of both objective
10 and subjective measures for sleep. Although subjectively measured sleep is highly relevant to
11 assess and evaluate, objectively measured sleep has the advantages of being free from
12 subjective expectations in relation to the intervention, and less sensitive to recall bias.
13 Furthermore, the evaluation of health-related outcomes as well as different variables to
14 evaluate cost-effectiveness is a strength of this study. Similarly, the inclusion of a qualitative
15 approach in the design to increase the understanding of both children's and parents'
16 experiences of effects is also a strength. This latter aspect is of great relevance as children's
17 perspectives are seldom taken into account in research.
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26 There are, however, a few methodological challenges with this study. Assessing self-reported
27 data from children is difficult for several reasons. Some of the questionnaires in this study are
28 designed for the parent to respond on behalf of the child (e.g. CSHQ). This may be a good
29 approach for younger children, but depending on the habits around bedtime, the parents may
30 only have (at best) a reasonably good perception of how the child's sleep was (for example, if
31 sleeping in separate bedrooms). Under these circumstances, the parent and the child are
32 instructed to fill in the questionnaire together to get a more reliable assessment. Another
33 potential bias is the placebo blankets. Although the participants are only informed they are
34 trying two different kinds of blankets, most of them have heard of weighted blankets through
35 media or their health providers, and there is a risk they will have higher expectations on the
36 weighted blanket, than the fiber blanket without weight.
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46 We anticipate the project will make several scientific contributions to the research on health-
47 related outcomes, sleep, and cost-effectiveness for sleep interventions. These findings will be
48 relevant for children with ADHD in particular, but will also be relevant for other target groups
49 and other settings. Finally, the design used to evaluate the intervention of weighted blankets
50 in this trial may if proven feasible and effective be applied to other healthcare settings and
51 may support systematic evaluation of the intervention in clinical practice.
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3 **Acknowledgments** We thank Dr. Håkan Jarbin at the Department of Child and Adolescent
4 Psychiatry (DCAP) in Region Halland for his helpful discussions about study design and
5 recruiting. We also thank the healthcare professionals at the DCAP in Region Halland for
6 assistance with study recruitment from their sites. We are grateful for the assistance provided
7 by Novista of Sweden AB to provide the study with fiber blankets with and without weights.
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11 **Author Contribution** IL wrote the first draft of the manuscript. PS and IL conceived the
12 study idea, obtained the funding, and are the guarantors of the study. JN, IL, KA, and PS
13 contributed to the study design. IL and KA were primarily responsible for the statistical
14 analysis plan. PJ was responsible for the health economic analysis plan. All authors read and
15 approved the final version of the manuscript.
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20 Region Halland (Grant no. HALLAND-940226). Neither the DCAP in Region Halland and
21 the company Novista of Sweden AB nor the funders have any role in the study design, data
22 collection, management, analysis, or interpretation of the data.
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25 **Competing interests** None declared.
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27 **Patient consent for publication** Not required.
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30 **Availability of data and materials:** Not applicable. The data will not be shared as ethics
31 approval for the study requires that data files and the transcribed interviews are kept in locked
32 files, accessible only to the researchers.
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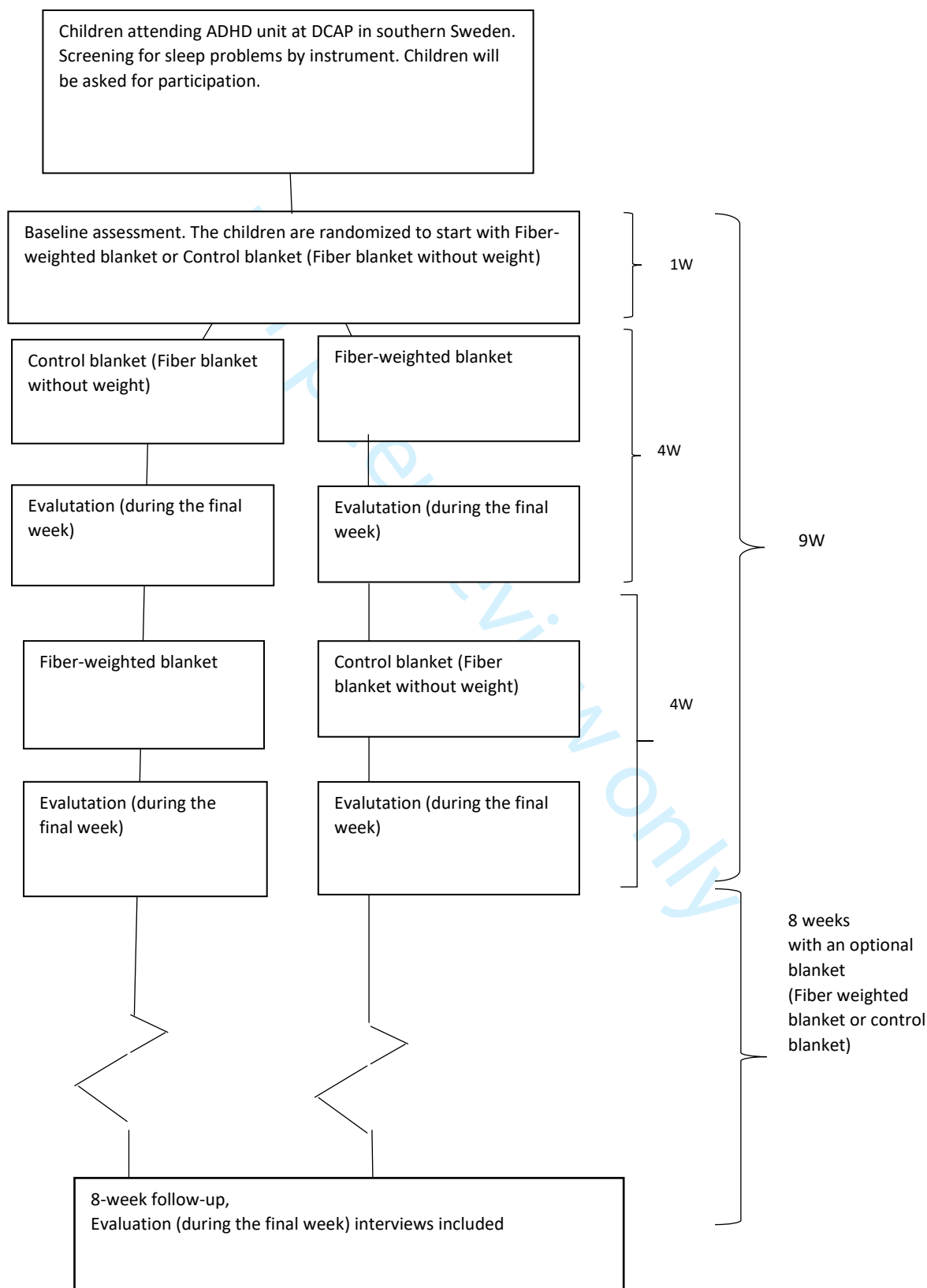
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Figure 1. Flowchart RCT. The time between requirement, randomisation, intervention, and follow-up

For peer review only

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





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

Section/item	Item No	Description
Administrative information		
Title	1	<i>SLEEP - An intervention with weighted blankets for children with Attention Deficit Hyperactivity Disorder (ADHD) and sleep problems: study protocol for a randomised control trial</i>
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

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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
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10	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
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18	Methods: Participants, interventions, and outcomes		
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20	Study setting	9	Children attending the ADHD unit at DCAP in the southern part of Sweden. Page 3
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23	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
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32	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
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42	Outcomes	12	The primary outcome is objectively measured and self-reported sleep. Secondary outcomes: <i>The children's general well-being</i> will be assessed by the Child Outcome Rating Scale (CORS), <i>The children's anxiety</i> will be assessed by The short State-Trait Anxiety Inventory for children (short-STAI), <i>The children's ADHD symptoms - hyperactivity/impulsivity, inattention and oppositional -</i> will be assessed by the parents using The Swanson, Peland, and Nolan Scale (SNAP-IV), <i>The parents' general well-being</i> will be assessed by the Outcome Rating Scale (ORS), <i>Family situation and parental mood</i> will be assessed by the Brief Child and Family Phone Interview (BCFPI), <i>Health-related quality of life</i> in children (EQ-5D-Y) and parents (EQ-5D-3L) Pages 4-9
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56	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
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- 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

17 **Methods: Assignment of interventions (for controlled trials)**

18 Allocation:

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- Sequence generation 16a The participants (n=80) will be randomly assigned into two groups using simple randomisation with stratification³¹. 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

32 **Methods: Data collection, management, and analysis**

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- 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

51 **Ethics and dissemination**

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- 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

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2	Consent or assent	26a	Children and parents will receive written and oral information and give
3			their informed consent. The participants will be informed that they can
4			withdraw from the project at any time without having to justify why.
5			Page 11
6			
7	Confidentiality	27	All participation and data collection will be performed confidentially.
8			Page 11
9			
10	Declaration of	28	None declared. Page 13
11	interests		
12			
13	Access to data	29	Only the researches have access to the data. Page 13
14			
15	Dissemination	31a	The results of this study will be communicated to the included
16	policy		participants, healthcare providers, and companies, in manuscripts
17			submitted to peer-reviewed journals, as well as in presentations at
18			national and international peer-review conferences. Page 11
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21 *It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013
22 Explanation & Elaboration for important clarification on the items. Amendments to the
23 protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT
24 Group under the Creative Commons "[Attribution-NonCommercial-NoDerivs 3.0 Unported](https://creativecommons.org/licenses/by-nc-nd/3.0/)"
25 license.
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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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SCHOLARONE™
Manuscripts

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3 *SLEEP - An intervention with weighted blankets for children with Attention Deficit*
4 *Hyperactivity Disorder (ADHD) and sleep problems: study protocol for a randomised control*
5 *trial*
6

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21 **Keywords:** Attention deficit hyperactivity disorder (ADHD), children, intervention, sleep
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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 performance¹⁰ 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

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3 disorder, the use of weighted blankets improved the sleep quality, justifying the need for
4 additional robust research.²⁷ A case-control study without randomisation included 21 children,
5 aged 8–13 years, with ADHD and 21 matched healthy children as a control group showed
6 some small positive effects of the weighted blankets on sleep onset latency.²⁸ In summary,
7 these studies do not provide conclusive evidence of the effect²⁵, economic effectiveness^{20 21} or
8 children's and parents' experiences of weighted blankets for children with ADHD on sleep
9 problems. Thus, an RCT evaluating weighted blankets for children with ADHD and sleep
10 problems is timely. Given the societal cost and the quality of life implications of sleep
11 interventions, the cost-effectiveness of this non-pharmacological intervention also needs to be
12 investigated.²⁰ The hypothesis of this RCT is that weighted blankets will improve objectively
13 measured and self-reported sleep compared to control blankets in children with ADHD.
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25 **Objectives**

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

38 *Study design*

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

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

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32 Children attending the ADHD unit at CAMHS in the southern part of Sweden during 2020-
33 2021 will be asked to participate in the study. This ADHD unit is designed to assess and if
34 indicated initiate treatment of children with uncomplicated DSM-5 ADHD in order to
35 increase effectiveness and reduce waiting lists. About one-half of the patients with newly
36 diagnosed ADHD are seen in this unit. The local community CAMHS team serves children
37 with suspected ADHD along with comorbidities needing primary intervention or where
38 families suffer from substantial psychosocial stress. Patients in the ADHD unit receive
39 psychoeducation in groups and medication with fewer follow-ups than usual, which is not
40 sufficient for the more complicated cases³⁰. Recruitment of participants started in January
41 2020 and is estimated to be completed during autumn 2021. All children aged 6-13 years,
42 recently diagnosed with uncomplicated ADHD with sleep problems verified by three selected
43 questions from the Child's Sleep Habits Questionnaire (CSHQ)³¹ will be approached for
44 participation in the study. Sleep problem is considered to be present if the child 1) seldom (0-
45 1 times per week) or sometimes (2-4 times per week) fall asleep within 20 minutes after going
46 to bed; 2) usually (5-7 times per week) or sometimes (2-4 times per week) sleep too little or 3)
47 wake up several times per night. In addition to this, they need to report that the sleep difficulty
48 in question is a problem. In addition, parents and children should understand (written and
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3 spoken) the Swedish language. Children will be excluded if they have already used weighted
4 blankets as a sleep intervention, or if they have received a new prescription or change of
5 pharmacological treatment for sleep problems. Children diagnosed with DSM-5 ADHD and
6 not started on a stimulant and with sleep difficulties above the threshold will be invited to get
7 further information about the study at the three hours assessment visit. Children diagnosed
8 with DSM-5 ADHD and started on a stimulant will again be reviewed for inclusion criteria at
9 the medication follow-up after about 4 weeks.

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

19 *Intervention*

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

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31 Fibre-weighted blankets from Novista of Sweden (Novista.se) will be used in this study. The
32 weight in the blankets is derived from longitudinal polyester fibres permitting flexibility. The
33 blanket size is 150 x 210 cm, which is a standard size for children and adults in Sweden. The
34 weight of each blanket will be individually tailored (weight between 6 to 10 kg) for the
35 children, based on age, sex, height, weight, degree of sleep problems, and subtypes of ADHD
36 according to the clinical practice of two independent experienced occupational therapists. The
37 fibre blankets without weight (controls) have been designed for the project so that both active
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3 and control blankets have the same design. The weight is the only aspect that distinguishes
4 them.
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6 7 *Data assessment* 8

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10 Data will be assessed at baseline (prior to the intervention), and during the 4th, 8th, and 16th
11 weeks of the study. The measurements are performed during the last of the four weeks to
12 minimize the risk for bias due to carry-over effects. A seven-day objective measurement of
13 sleep will be conducted during these measurement periods. Self-reported data will also be
14 gathered through the completion of a questionnaire by the parent and child respectively (Table
15 1).
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20 Interviews with an adequate sample of children (n=25) and parents (n=25) will be conducted
21 after the intervention period in order to understand the experiences of the intervention's
22 impact on sleep and health-related outcome.
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26 27 1. Methods for investigating the health effects of weighted blankets 28

29 30 *Primary outcome* 31

32 The primary outcome is *objectively measured and self-reported sleep*. Variables of interest
33 from the *objectively measured sleep* are: *Sleep onset latency (SOL)*, which refers to the period
34 of time between turning lights out to go to sleep (timing identified by marker from the event
35 button, or self-reported time in daily text messages) and falling asleep; *Total sleep time (TST)*,
36 which is equal to the time of total sleep episode minus the awake time; *Sleep efficiency (SE)*,
37 which is the total sleep time expressed as a percentage; *wake after sleep onset (WASO)*,
38 referring to periods of wakefulness occurring after sleep onset.
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45 Objectively measured sleep will be assessed using actigraphy. This method for assessing
46 sleep has been shown to be valid in several studies,³³ and has shown to be strongly associated
47 with polysomnographic measures with a correlation coefficient of at least 0.85 in healthy
48 individuals.³⁴ Measurements from at least 5-7 nights have been recommended.³⁵ Motionwatch
49 8 (Camntech.Ltd.), a triaxial accelerometer using MEMs technology, capable of sensing
50 motions in a resultant force range of 0.01 g to 8 g³⁶ is used in this study. The actigraph
51 registers total gross motor activity for analysis of sleep-wake patterns and has good validity
52 for measuring sleep³⁶. Recordings will be taken in 30-second epochs.
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3 Participants will be instructed to wear the watch on their non-dominant wrist, for seven
4 consecutive nights. If not worn during the day, the parent and child will be instructed to put
5 on the watch in the early evening, or in good time prior to going to bed. The participant is
6 instructed to push an event-button when they decide to go to sleep, e.g. when they stop
7 reading a book or turn off the lights. Then they are told to push the button again when they
8 wake up in the morning. In addition to marking the event of going to sleep and waking up by
9 pressing the button, the parents will answer questions daily (by text message): 1) What time
10 did your child go to bed yesterday? 2) How long time do you estimate the time for your child
11 to fall asleep from the time your child went to bed? (hours, minutes); 3) What time did your
12 child wake up today?
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21 The variables of interest from the *self-reported sleep* will be assessed by CSHQ³¹, and
22 Insomnia Severity Index (ISI).³⁷
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26 The CSHQ assesses parental reported sleep and consists of 33 items related to eight subscales;
27 1) *Bedtime resistance*, 2) *Sleep onset delay*, 3) *Sleep duration*, 4) *Sleep anxiety*, 5) *Night*
28 *wakings*, 6) *Parasomnias*, 7) *Sleep-disordered breathing*, and 8) *Daytime sleepiness*. Each
29 item is rated on a three-point scale: “usually” if the sleep behavior occurred five to seven
30 times/week; “sometimes” for two to four times/week; and “rarely” for zero to one time/week.
31 A higher score indicates more sleep problems. The scale has good reliability and validity.³¹
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38 *Insomnia* will be assessed by ISI, which comprises seven items for the children to respond to:
39 1) Severity of sleep-onset, 2) Sleep maintenance, 3) Early morning awakening, 4) Satisfaction
40 with current sleep pattern, 5) Interference with daily functioning, 6) Noticeability of
41 impairment attributed to the sleep problem, and 7) Level of distress caused by the sleep
42 problem. Each item is rated on a five-point Likert scale ranging from “not at all” (scored at 0)
43 to “extremely” (scored at 4). Total score ranges from 0 to 28, with higher scores indicating
44 greater severity. ISI is a reliable and valid instrument for quantifying severity of perceived
45 insomnia and measures insomnia in treatment research.³⁷ The ISI will be slightly modified in
46 order to better correspond to a child’s language.
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54 55 56 *Secondary outcomes*

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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

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3 children a voice in the services they receive. CORS comprises four items where the child
4 evaluates; 1) Me (How am I doing?), 2) Family (How are things in my family?), 3) School
5 (How am I doing at school?), 4) Everything (How is everything going?). Each item is rated on
6 a 100-millimeter Visual Analog Scale with smiling and sad faces as anchors. CORS has good
7 reliability and moderate validity.³⁸
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13 *The children's anxiety* will be assessed by The short State-Trait Anxiety Inventory for
14 children (short-STAI).^{39 40} Short-STAI includes six items.⁴¹ Each item is rated on a four-point
15 Likert scale ranging with 1 = "not at all," 2 = "somewhat," 3, = "moderately", and 4 = "very
16 much." The total score range from 6 to 24 points, with 6 points indicating no anxiety and 24
17 points indicating the highest level of anxiety. Short-STAI has good reliability and validity for
18 children.³⁹
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25 *The children's ADHD symptoms* - hyperactivity/impulsivity, inattention and oppositional -
26 will be assessed by the parents filling in The Swanson, Peland, and Nolan Scale (SNAP-IV).⁴²
27 The SNAP-IV consists of 30 items and is divided into three subscales: inattention (nine
28 items), hyperactivity/impulsivity (nine items), and oppositionality (eight items) and four
29 supplementary questions regarding oppositionality (two questions) and ADHD (two
30 questions). Items are rated on a four-point Likert scale range 0 = "not at all", 1 = "just a
31 little", 2 = "quite a bit", and 3 = "very much". Items for inattention and
32 hyperactivity/impulsivity can be combined to create a "combined ADHD" score.⁴³ Higher
33 scores represent more symptoms. The SNAP-IV is a robust and valid measure of outcome for
34 research studies and often used in RCTs.⁴⁴
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43 *The parents' general well-being* will be assessed by the Outcome Rating Scale (ORS),⁴⁵
44 which is a general mental health assessment of the past week in four items; 1) Personal
45 wellbeing, 2) Interpersonal relationships, 3) Social relations and, 4) Overall sense of well-
46 being. Each item is rated on a 100-millimeter Visual Analog Scale with anchors from 0
47 (negative) to 100 (positive). ORS is a reliable and valid instrument.^{38 46}
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53 *Family situation and parental mood* will be assessed by the Brief Child and Family Phone
54 Interview (BCFPI),^{47 48} BCFPI is a structured parent interview for triage at intake and for
55 follow-up evaluation of community care at CAMHS. It consists of 36 symptom items and
56 another 36 items to assess function, adversity, and family stress grouped into 12 subscales.
57 The subscale 'family situation' contains three items rated on a four-point Likert scale range 1
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= 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-Y⁴⁹ and parents with EQ-5D-3L⁵⁰. EQ-5D-Y measures health-related quality of life "today" for children and young people and is developed from the standard adult EQ-5D⁴⁹. 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 instrument⁵⁰ 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 instrument⁵³⁻⁵⁵ 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

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3 including wage taxes from Statistics Sweden. The cost of parents' work absence and
4 decreased productivity will be estimated using average Swedish hourly wages including wage
5 taxes from Statistics Sweden while the cost of child school absence is estimated according to
6 estimated schooling costs from The Swedish National Agency for Education. The cost of
7 prescribed pharmacological therapy will be estimated according to listed prices at the Dental
8 and Pharmaceutical Benefits Agency.
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14 The *implementation costs*, i.e. the prescription of the weighted blankets, include the
15 healthcare region's purchasing price for weighted blankets, child psychiatrist time for
16 prescription, physiotherapist time for tailoring as well as parent and child time. The healthcare
17 costs will be estimated based on data from SALAR and Statistics Sweden while the visiting
18 and traveling time for the parent and child will be estimated according to data from Statistics
19 Sweden and The Swedish National Agency for Education, as above.
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26 *Quality of life* estimates for calculating *QALYs* over the 4 weeks period will be taken from the
27 parent-reported EQ-5D instrument valued with a Swedish tariffs value set.⁵² EQ-5D-3L is
28 frequently used in Sweden and for economic evaluations and is considered a reliable and valid
29 instrument.⁵² There is currently no appropriate value set for the child version of EQ-5D (i.e.
30 EQ-5D-Y), so in a sensitivity analysis, the VAS ratings will be used and added to the parent
31 estimated *QALYs*. The *QALYs* during 4 weeks will be calculated based on the mean changes
32 in quality of life of the two study arms, with an instant change assumed when initiating use of
33 the fibre-blanket.
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40 3. Methods for investigating the experiences of weighted blankets

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43 The qualitative data will consist of individual interviews with children and their parents in the
44 intervention study. An open interview guide with initial questions will be used to ensure
45 similar data from all participants. The initial questions refer to the experiences of sleep for
46 children with ADHD, experiences of how the sleep intervention with fibre-weighted blankets
47 influences the children's sleep, and health-related outcomes as well as the family situation.
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49 *Questions to the children:* "How do you usually sleep?", "In what way can it be difficult to
50 sleep?", "How does sleep differ if you sleep well or badly?", "What is important for you to be
51 able to sleep?", "How do you experience the two different blankets you have used?", "How
52 do you experience the fibre-weighted blanket?", "Can you describe your sleep since you
53 started using the fibre-weighted blankets?". *Questions to the parents:* "What does sleep mean
54 for your child?", "How does your child usually sleep?", "What is important for your child to
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3 be able to sleep?”, “How is your child’s life affected by sleep?”, “How do you experience the
4 two different blankets your child has used?”, “How do you experience the fibre-weighted
5 blanket?”, Can you describe your child’s sleep since he/she started using the fibre-weighted
6 blankets?”, How is your child’s well-being since he/she started using the fibre-weighted
7 blankets?”, How has the situation for the family and you as a parent been affected since your
8 child started using the fibre-weighted blanket?” *Follow-up probes* will be used to encourage
9 children and parents to elaborate on the answers: “Please tell me more”, “How do you mean?”
10 or “What do you have in mind when you say ...?” All interviews will be performed at the
11 University in a quiet room. The interviews will be digitally recorded and transcribed verbatim.
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20 *Statistical Power*

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23 A power analysis was made based on estimated changes in the primary outcome variable
24 *sleep onset latency* (SOL). Estimations of mean and standard deviations were made based on
25 previous studies of SOL in children. Mean SOL is expected to differ substantially with age
26 among children. Gringras et al. (2014) investigated children 5 to 16 years of age and found a
27 mean value of 76,5 minutes of SOL with a standard deviation of 46,1.²⁶ Hvolby and Bilenberg
28 (2011) studied SOL in children 8 to 13 years of age and reported a mean value of 23,1
29 minutes of SOL with a standard deviation of 9,4.²⁸
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36 Previous studies investigating the effect of similar interventions on SOL have found a 40%
37 decrease in SOL after the intervention²⁸. The power calculation of this study is based on the
38 assumption that a 30% decrease in SOL is a clinically relevant improvement. In this study,
39 including children 6 to 13 years of age, estimating a mean of 35 minutes SOL and a standard
40 deviation of 15, the power analysis demonstrated that 58 children (29 in each group) will be a
41 sufficient number if accepting a 30% difference between groups in SOL with 80 % power. To
42 allow for a 25% dropout, 80 children (40 in each group) will be enrolled in the study.
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48 *Data analysis*

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51 Statistical analyses will be performed using SPSS version 24 for Windows. The intervention
52 will be evaluated in terms of effect and cost comparison. Differences in objectively and
53 subjectively measured sleep, anxiety, and health-related quality of life will be analysed by
54 paired t-test and by independent sample t-test for between group analyses. Differences in
55 societal costs will be analysed via non-parametric bootstrap analyses on individual-level data
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3 and reported as credibility intervals.⁵⁶ The qualitative data from interviews will be analysed
4 with inductive qualitative content analysis.⁵⁷
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9 **Ethics and dissemination**

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

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45 Weighted blankets are prescribed to patients in healthcare in Sweden and are widely used as a
46 non-pharmacological intervention for sleep problems, even though evidence for the effects of
47 weighted blankets is lacking. The few previous studies investigating the effect of weighted
48 blankets for children with ADHD have not shown conclusive results and to date, there are too
49 few high-quality studies to support the intervention.²⁵⁻²⁸ The results from this RCT will thus
50 be important for providing new evidence of the efficacy, cost-effectiveness, and experiences
51 of the use of weighted blankets to address sleep problems among children with ADHD.
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58 Some methodological considerations can be highlighted. A strength in this research is that this
59 study will be the first randomised placebo-controlled crossover trial investigating the effects
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3 of fibre-weighted blankets in children with ADHD. Another strength is the use of both
4 objective and subjective measures for sleep. Although subjectively measured sleep is highly
5 relevant to assess and evaluate, objectively measured sleep has the advantages of being free
6 from subjective expectations in relation to the intervention, and less sensitive to recall bias.
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8 Furthermore, the evaluation of cost-effectiveness of weighted blankets is highly relevant
9 though this has not previously been studied.²¹ The costs and benefits of the intervention need
10 to be taken into consideration when implementing the intervention in healthcare settings.
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12 Similarly, the inclusion of a qualitative approach in the design to increase the understanding
13 of both children's and parents' experiences of effects is another strength. This latter aspect is
14 of great relevance as children's perspectives are seldom taken into account in research.
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21 There are, however, a few methodological challenges with this study. Assessing self-reported
22 data from children is difficult for several reasons. Some of the questionnaires in this study are
23 designed for the parent to respond on behalf of the child (e.g. CSHQ). This may be a good
24 approach for younger children, but depending on the habits around bedtime, the parents may
25 only have (at best) a reasonably good perception of how the child's sleep was (for example, if
26 sleeping in separate bedrooms). Under these circumstances, the parent and the child are
27 instructed to fill in the questionnaire together to get a more reliable assessment. Another
28 potential bias is the control blankets. The difference in weight will be obvious for parents and
29 also for children. The participants are only informed they are trying two different kinds of
30 blankets. However, most have learned about weighted blankets through media or their health
31 providers, possibly affecting expectations in favour of the weighted blanket
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41 We anticipate the project will make several scientific contributions to the research on health-
42 related outcomes, sleep, and cost-effectiveness for non-pharmacological sleep interventions.
43 such as weighted blankets. These findings will be essential for healthcare professionals in
44 their practice though evidence today for the effects of weighted blankets is scarce. The results
45 will also be relevant for children with ADHD in particular, but will also be relevant for other
46 target groups and other settings.
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3 **Acknowledgments** We thank the healthcare professionals at the CAMHS in Region Halland
4 for assistance with study recruitment from their sites. We are grateful for the assistance
5 provided by Novista of Sweden AB to provide the study with fibre blankets with and without
6 weights.
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10 **Author Contribution** IL, JN and PS contributed to the conception of the study, obtained the
11 funding, and are the guarantors of the study. IL, KA, JN, PJ, HJ and PS contributed to the
12 study design. IL and KA were primarily responsible for the statistical analysis plan. PJ was
13 responsible for the health economic analysis plan. IL and PS were responsible for the
14 qualitative analysis plan. IL drafted the manuscript and KA, JN, PJ, HJ and PS revised the
15 manuscript critically for important intellectual content, All authors read and approved the
16 final version of the manuscript.
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19
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23 collection, management, analysis, or interpretation of the data.
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26 **Competing interests** None declared.
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29 **Patient consent for publication** Not required.
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32 **Availability of data and materials:** Not applicable. The data will not be shared as ethics
33 approval for the study requires that data files and the transcribed interviews are kept in locked
34 files, accessible only to the researchers.
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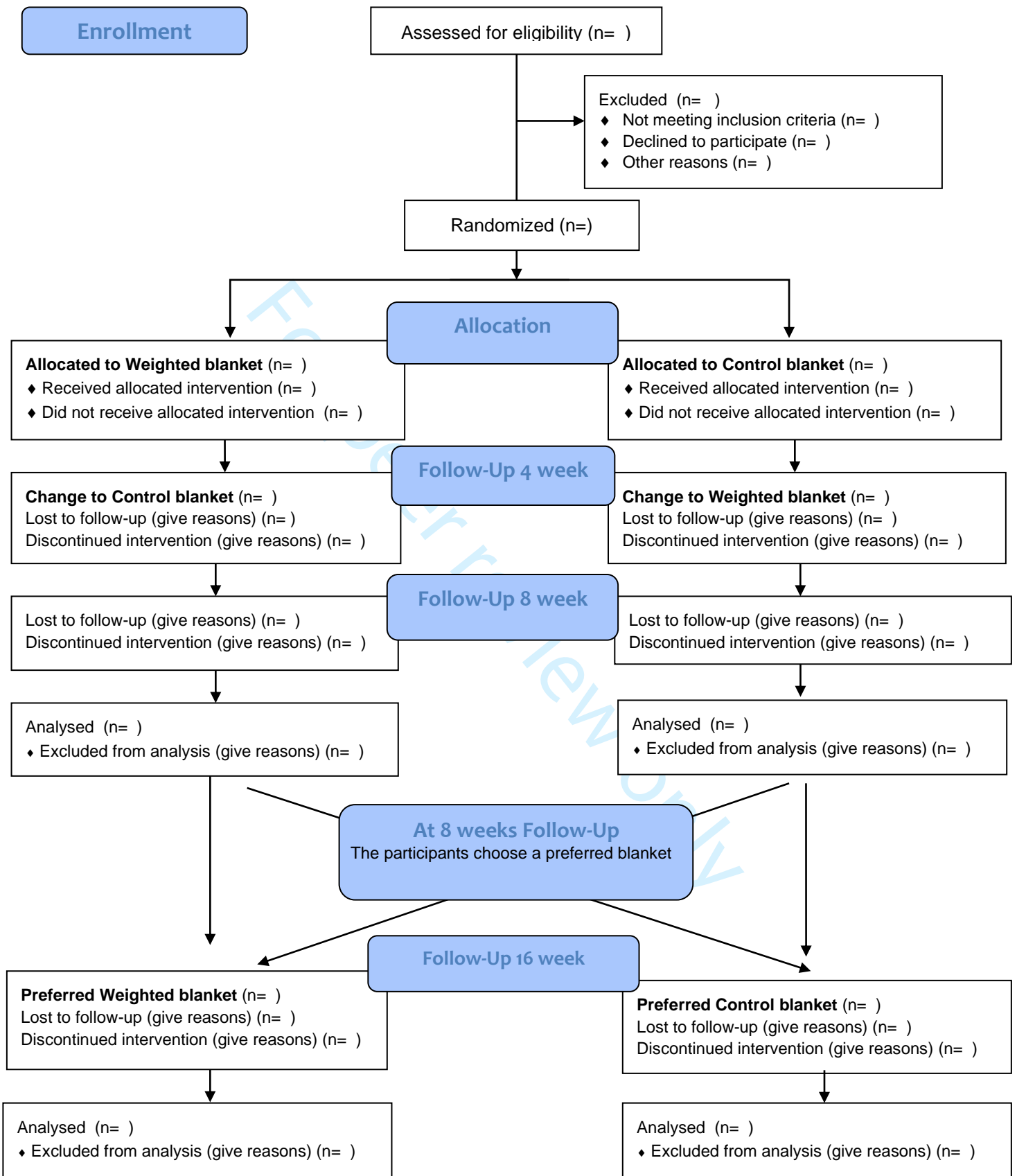
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Figur 1 CONSORT Flow Diagram over the SLEEP trial





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

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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
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10	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
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18	Methods: Participants, interventions, and outcomes		
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20	Study setting	9	Children attending the ADHD unit at DCAP in the southern part of Sweden. Page 3
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23	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
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32	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
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42	Outcomes	12	The primary outcome is objectively measured and self-reported sleep. Secondary outcomes: <i>The children's general well-being</i> will be assessed by the Child Outcome Rating Scale (CORS), <i>The children's anxiety</i> will be assessed by The short State-Trait Anxiety Inventory for children (short-STAI), <i>The children's ADHD symptoms - hyperactivity/impulsivity, inattention and oppositional -</i> will be assessed by the parents using The Swanson, Peland, and Nolan Scale (SNAP-IV), <i>The parents' general well-being</i> will be assessed by the Outcome Rating Scale (ORS), <i>Family situation and parental mood</i> will be assessed by the Brief Child and Family Phone Interview (BCFPI), <i>Health-related quality of life</i> in children (EQ-5D-Y) and parents (EQ-5D-3L) Pages 4-9
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56	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
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- 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

17 **Methods: Assignment of interventions (for controlled trials)**

18 Allocation:

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- Sequence generation 16a The participants (n=80) will be randomly assigned into two groups using simple randomisation with stratification³¹. 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

32 **Methods: Data collection, management, and analysis**

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- 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

51 **Ethics and dissemination**

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- 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

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2	Consent or assent	26a	Children and parents will receive written and oral information and give
3			their informed consent. The participants will be informed that they can
4			withdraw from the project at any time without having to justify why.
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7	Confidentiality	27	All participation and data collection will be performed confidentially.
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10	Declaration of	28	None declared. Page 13
11	interests		
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13	Access to data	29	Only the researches have access to the data. Page 13
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15	Dissemination	31a	The results of this study will be communicated to the included
16	policy		participants, healthcare providers, and companies, in manuscripts
17			submitted to peer-reviewed journals, as well as in presentations at
18			national and international peer-review conferences. Page 11
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21 *It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013
 22 Explanation & Elaboration for important clarification on the items. Amendments to the
 23 protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT
 24 Group under the Creative Commons "[Attribution-NonCommercial-NoDerivs 3.0 Unported](https://creativecommons.org/licenses/by-nc-nd/3.0/)"
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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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Manuscript ID	bmjopen-2020-047509.R2
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Date Submitted by the Author:	13-Oct-2021
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Primary Subject Heading:	Paediatrics
Secondary Subject Heading:	Mental health, Paediatrics
Keywords:	Developmental neurology & neurodisability < PAEDIATRICS, Child & adolescent psychiatry < PSYCHIATRY, SLEEP MEDICINE

SCHOLARONE™
Manuscripts

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3 *SLEEP - An intervention with weighted blankets for children with Attention Deficit*
4 *Hyperactivity Disorder (ADHD) and sleep problems: study protocol for a randomised control*
5 *trial*
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21 **Keywords:** Attention deficit hyperactivity disorder (ADHD), children, intervention, sleep
22 problems, weighted blankets
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25 **Word count: 5251**
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27 **Journal: BMJ Open**
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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 performance¹⁰ 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 being prescribed 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

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3 blankets were well tolerated.²⁶ In a pilot study including only two children with an autism
4 spectrum disorder, the use of weighted blankets improved the sleep quality, justifying the
5 need for additional robust research.²⁷ A case-control study without randomisation included 21
6 children, aged 8–13 years, with ADHD and 21 matched healthy children as a control group
7 showed some small positive effects of the weighted blankets on sleep onset latency.²⁸ In
8 summary, these studies do not provide conclusive evidence of the effect²⁵, economic
9 effectiveness^{20 21} or children's and parents' experiences of weighted blankets for children with
10 ADHD on sleep problems. Thus, an RCT evaluating weighted blankets for children with
11 ADHD and sleep problems is timely. Given the societal cost and the quality of life
12 implications of sleep interventions, the cost-effectiveness of this non-pharmacological
13 intervention also needs to be investigated.²⁰ The hypothesis of this RCT is that weighted
14 blankets will improve objectively measured and self-reported sleep compared to control
15 blankets in children with ADHD.
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28 Objectives

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

41 *Study design*

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43 This is a randomised, placebo-controlled crossover trial investigating the effects of an
44 intervention with fibre-weighted blankets in children with ADHD. The study period is 4
45 months, including 2 x 4 weeks of intervention with weighted blankets and control blankets,
46 followed by an 8-week follow-up (figure 1). The study investigates the effect of the
47 intervention in terms of 1) sleep and health; 2) cost-effectiveness, and 3) experiences of sleep
48 and health-related outcomes. The qualitative part will be performed using an explorative
49 design based on interviews from a subsample of the included children and their parents. The
50 interviews will be conducted at the end of the 4-month intervention in order to gain
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3 knowledge of the children's and parents' experiences of using these fibre-weighted blankets.
4 The protocol is based on the Standard Protocol Items for Randomized Trials (SPIRIT).²⁹
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6 7 *Patient and public involvement* 8

9 The design of the study and the preparation and formulation of this protocol has been co-
10 produced with healthcare professionals at the child and adolescent mental health service
11 (CAMHS). This includes being involved in; planning inclusion and exclusion criteria for the
12 informants, preparing the arrangement for the intervention and selecting which questionnaires
13 to be used to measure outcome variables for children and parents. The project manager has
14 had regular meetings with the healthcare professionals at CAMHS throughout the preparation
15 of the study. A pilot study, with seven children and their parents, has been performed to
16 validate the design, the interventions, and the questionnaires used. As part of this, we asked
17 children and parents about their opinion of the intervention and also asked them for
18 suggestions for improvements. This resulted in a few minor adjustments. The research project
19 has been discussed with occupational therapists (who prescribe weighted blankets in Sweden)
20 and representatives from the national occupational therapy association. The project and
21 preliminary results have been and will be communicated through popular science reports,
22 research conference contributions, and research papers to the healthcare services,
23 occupational therapists, patient groups, and researchers during the research period.
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36 37 *Participants and recruitment* 38

39 Children attending the ADHD unit at CAMHS in the southern part of Sweden during 2020-
40 2021 will be asked to participate in the study. This ADHD unit is designed to assess and if
41 indicated initiate treatment of children with uncomplicated ADHD according to DSM-5³⁰ in
42 order to increase effectiveness and reduce waiting lists. About one-half of the patients with
43 newly diagnosed ADHD are seen in this unit. The triaging unit selected patients ages 6-12
44 when the structured Brief Child and Family Phone Interview (BCFPI) interview suggested a
45 probable diagnosis of ADHD. Exclusion criteria for referral to this unit were significant
46 comorbidity requiring immediate treatment, severe parental stress, and intellectual impairment
47 requiring more comprehensive interventions. The diagnostic assessment was based on written
48 information from the present school (teacher report form and open questions about school
49 functioning), the BCFPI, interview with parent and the child, and observing the child during
50 the two hours assessment. The diagnostic schedule was inspired by and a short form of Kiddie
51 Schedule for Affective Disorders and schizophrenia – Present and Lifetime version (K-SADS-
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3 PL) to cover ADHD, externalizing and tic disorders as well as anxiety and affective disorders
4 while infrequent diagnoses were not screened³¹. Patients in the ADHD unit received
5 psychoeducation in groups and medication with fewer follow-ups than usual, and insufficient
6 for the more complicated cases³². Recruitment of participants started in January 2020 and is
7 estimated to be completed during autumn 2021. All children aged 6-13 years, recently
8 diagnosed with uncomplicated ADHD with sleep problems verified by three selected
9 questions from the Child's Sleep Habits Questionnaire (CSHQ)³³ will be approached for
10 participation in the study. Sleep problem is considered to be present if the child 1) seldom (0-
11 1 times per week) or sometimes (2-4 times per week) fall asleep within 20 minutes after going
12 to bed; 2) usually (5-7 times per week) or sometimes (2-4 times per week) sleep too little or 3)
13 wake up several times per night. In addition to this, they need to report that the sleep difficulty
14 in question is a problem. In addition, parents and children should understand (written and
15 spoken) the Swedish language. Children will be excluded if they have already used weighted
16 blankets as a sleep intervention, or if they were currently on and wished to stay on melatonin
17 for sleep problems. Children diagnosed with ADHD and not started on a stimulant and with
18 sleep difficulties above the threshold will be invited to get further information about the study
19 at the three hours assessment visit. Children diagnosed with ADHD and started on a stimulant
20 will again be reviewed for inclusion criteria at the medication follow-up after about 4 weeks.

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

27 28 29 *Intervention*

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32 The participants (n=100) will be randomly assigned into two groups using simple
33 randomisation with stratification³⁴. A total of 100 sheets with the letter A (Intervention) or
34 the letter B (Control) will be printed out and put into each envelope. The sealed envelopes
35 will be mixed and one of the researchers will pick an envelope randomly for each child. The
36 letter A or B indicates if the child will start with a fibre-weighted blanket (active) or with a
37 fibre blanket without weight (control). After four weeks with either the active intervention (A)
38 or control (B), the children will change blanket (if starting with active, the child will change
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3 into control, and vice versa). After this 8-week period, the child will decide which of the two
4 blankets (active or control) that they want to retain.
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7 Fibre-weighted blankets from Novista of Sweden (Novista.se) will be used in this study. The
8 weight in the blankets is derived from longitudinal polyester fibres permitting flexibility. The
9 blanket size is 150 x 210 cm, which is a standard size for children and adults in Sweden. The
10 weight of each blanket will be individually tailored (weight between 6 to 10 kg) for the
11 children, based on age, sex, height, weight, degree of sleep problems, and subtypes of ADHD
12 of two independent experienced occupational therapists. The fibre blankets without weight
13 (controls) have been designed for the project so that both active and control blankets have the
14 same design. The weight is the only aspect that distinguishes them.
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21 *Data assessment*

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23 Data will be assessed at baseline (prior to the intervention), and during the 4th, 8th, and 16th
24 weeks of the study. The measurements are performed during the last of the four weeks to
25 minimize the risk for bias due to carry-over effects. A seven-day objective measurement of
26 sleep will be conducted during these measurement periods. Self-reported data will also be
27 gathered through the completion of a questionnaire by the parent and child respectively (Table
28 1).
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35 Interviews with an adequate sample of children (n=25) and parents (n=25) will be conducted
36 after the intervention period in order to understand the experiences of the intervention's
37 impact on sleep and health-related outcome.
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41 *1. Methods for investigating the health effects of weighted blankets*

42 *Primary outcome*

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44 The primary outcome is *objectively measured and self-reported sleep*. Variables of interest
45 from the *objectively measured sleep* are: *Sleep onset latency (SOL)*, which refers to the period
46 of time between turning lights out to go to sleep (timing identified by marker from the event
47 button, or self-reported time in daily text messages) and falling asleep; *Total sleep time (TST)*,
48 which is equal to the time of total sleep episode minus the awake time; *Sleep efficiency (SE)*,
49 which is the total sleep time expressed as a percentage; *wake after sleep onset (WASO)*,
50 referring to periods of wakefulness occurring after sleep onset.
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3 Objectively measured sleep will be assessed using actigraphy. This method for assessing
4 sleep has been shown to be valid in several studies,³⁵ and has shown to be strongly associated
5 with polysomnographic measures with a correlation coefficient of at least 0.85 in healthy
6 individuals.³⁶ Measurements from at least 4-7 nights have been recommended.³⁷ Motionwatch
7 8 (Camntech.Ltd.), a triaxial accelerometer using MEMs technology, capable of sensing
8 motions in a resultant force range of 0.01 g to 8 g³⁸ is used in this study. The actigraph
9 registers total gross motor activity for analysis of sleep-wake patterns and has good validity
10 for measuring sleep³⁸. Recordings will be taken in 30-second epochs.

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

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40 The variables of interest from the *self-reported sleep* will be assessed by CSHQ³³, and
41 Insomnia Severity Index (ISI).³⁹

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

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56 *Insomnia* will be assessed by ISI, which comprises seven items for the children to respond to:
57 1) Severity of sleep-onset, 2) Sleep maintenance, 3) Early morning awakening, 4) Satisfaction
58 with current sleep pattern, 5) Interference with daily functioning, 6) Noticeability of
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3 impairment attributed to the sleep problem, and 7) Level of distress caused by the sleep
4 problem. Each item is rated on a five-point Likert scale ranging from “not at all” (scored at 0)
5 to “extremely” (scored at 4). Total score ranges from 0 to 28, with higher scores indicating
6 greater severity. ISI is a reliable and valid instrument for quantifying the severity of perceived
7 insomnia and measures insomnia in treatment research.³⁹ The ISI will be slightly modified in
8 order to better correspond to a child’s language.
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15 *Secondary outcomes*

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18 *The children's general well-being* will be assessed by the Child Outcome Rating Scale
19 (CORS),⁴⁰ which is an overall measure of psychological distress. It was developed to give
20 children a voice in the services they receive. CORS comprises four items where the child
21 evaluates; 1) Me (How am I doing?), 2) Family (How are things in my family?), 3) School
22 (How am I doing at school?), 4) Everything (How is everything going?). Each item is rated on
23 a 100-millimeter Visual Analog Scale with smiling and sad faces as anchors. CORS has good
24 reliability and moderate validity.⁴⁰
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32 *The children’s anxiety* will be assessed by The short State-Trait Anxiety Inventory for
33 children (short-STAI).^{41 42} Short-STAI includes six items.⁴³ Each item is rated on a four-point
34 Likert scale ranging with 1 = "not at all," 2 = "somewhat," 3, = "moderately", and 4 = "very
35 much." The total score range from 6 to 24 points, with 6 points indicating no anxiety and 24
36 points indicating the highest level of anxiety. Short-STAI has good reliability and validity for
37 children.⁴¹
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44 *The children’s ADHD symptoms - hyperactivity/impulsivity, inattention and oppositional -*
45 *will be assessed by the parents filling in The Swanson, Peland, and Nolan Scale (SNAP-IV).*⁴⁴
46 The SNAP-IV consists of 30 items and is divided into three subscales: inattention (nine
47 items), hyperactivity/impulsivity (nine items), and oppositionality (eight items) and four
48 supplementary questions regarding oppositionality (two questions) and ADHD (two
49 questions). Items are rated on a four-point Likert scale range 0 = “not at all”, 1 = “just a
50 little”, 2 = “quite a bit”, and 3 = “very much”. Items for inattention and
51 hyperactivity/impulsivity can be combined to create a “combined ADHD” score.⁴⁵ Higher
52 scores represent more symptoms. The SNAP-IV is a robust and valid measure of outcome for
53 research studies and is often used in RCTs.⁴⁶
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3 *The parents' general well-being* will be assessed by the Outcome Rating Scale (ORS),⁴⁷
4 which is a general mental health assessment of the past week in four items; 1) Personal
5 wellbeing, 2) Interpersonal relationships, 3) Social relations and, 4) Overall sense of well-
6 being. Each item is rated on a 100-millimeter Visual Analog Scale with anchors from 0
7 (negative) to 100 (positive). ORS is a reliable and valid instrument.^{40 48}
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13 *Family situation and parental mood* will be assessed by the Brief Child and Family Phone
14 Interview (BCFPI),^{49 50} BCFPI is a structured parent interview for triage at intake and follow-
15 up evaluation of community care at CAMHS. It consists of 36 symptom items and another 36
16 items to assess function, adversity, and family stress grouped into 12 subscales. The subscale
17 'family situation' contains three items rated on a four-point Likert scale range 1 = never, 2 =
18 sometimes, 3 = often, 4 =always. The subscale 'parental mood' contains six items based on
19 the question "How often during the past week has the parent experienced...?" rated on a four-
20 point scale; < 1 day, 1-2 days, 3-4 days, >5 days. BCFPI has good reliability and validity.^{49 50}
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27 *Health-related quality of life* will be assessed for children with EQ-5D-Y⁵¹ and parents with
28 EQ-5D-3L⁵². EQ-5D-Y measures health-related quality of life "today" for children and young
29 people and is developed from the standard adult EQ-5D⁵¹. EQ-5D-Y comprises five items; 1)
30 Walking about (mobility), 2) Looking after myself (self-care), 3) Doing usual activities (usual
31 activities), 4) Having pain or discomfort (pain and discomfort), and 5) Feeling worried, sad or
32 unhappy (anxiety and depression). Each item is divided into three levels; No problems, Some
33 problems, and A lot of problems. The EQ-5D-Y also includes an easily understandable
34 modified vertical Visual Analogue Scale of EQ-5D, where the respondent rates the overall
35 health status with the endpoints from 0 (the worst health state the child can imagine and 100
36 (the best health state the child can imagine)⁵¹. EQ-5D-Y has good reliability and validity.⁵³
37 EQ-5D is a generic health-related quality of life instrument⁵² measuring the parents' health
38 comprising five dimensions; 1) Mobility, 2) Self-care, 3) Usual activities, 4) Pain/discomfort,
39 and 5) Anxiety/Depression. Each dimension is divided into three levels; No problems, Some
40 or moderate problems, and extreme problems. In addition to the five dimensions, a 100-
41 millimeter vertical Visual Analog Scale with endpoints of 100 means "best imaginable health
42 state" and 0 means "worst imaginable health state is included. The total score ranges from 0 to
43 1 where a higher score indicates a better health-related quality of life.
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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

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3 based on a Swedish adaptation of the TIC-P instrument⁵⁵⁻⁵⁷ and consider the four weeks. The
4 questions include school absence for the child (in numbers of full days, half days, and 1-2
5 hours), work absence for one parent (in numbers of full days (8 hours), three-quarters of a day
6 (6 hours), half a day (4 hours) and one-quarter of a day (2 hours)), work productivity of the
7 parent (in ten levels from no work accomplished to hardly no decreased work capacity) and
8 healthcare appointments (nine types of healthcare including e.g. school healthcare, primary
9 care, and emergency care). The clinical register data include the number of appointments at
10 the CAMHS and prescribed pharmacological therapy. The cost of the resource consumption
11 items from the parent survey and the clinical register will be estimated according to Swedish
12 published data on the average costs for healthcare appointments from SALAR (the Swedish
13 Association of Local Authorities and Regions) and occupation-specific healthcare wages
14 including wage taxes from Statistics Sweden. The cost of parents' work absence and
15 decreased productivity will be estimated using average Swedish hourly wages including wage
16 taxes from Statistics Sweden while the cost of child school absence is estimated according to
17 estimated schooling costs from The Swedish National Agency for Education. The cost of
18 prescribed pharmacological therapy will be estimated according to listed prices at the Dental
19 and Pharmaceutical Benefits Agency.

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

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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 intervention²⁸. 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,

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

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

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43 The study is approved by the Swedish Ethical Review Authority (No. 2019-02158) and
44 conforms to the principles outlined in the Declaration of Helsinki.⁶⁰ The study will fulfill
45 requirements for research: information, consent, confidentiality, and safety of the participants
46 and is guided by the ethical principles: autonomy, beneficence, non-maleficence, and
47 justice.⁶¹ All participation and data collection will be performed confidentially. Children and
48 parents will receive written and oral information and parents give their informed consent in
49 writing. The participants will be informed that they can withdraw from the project at any time
50 without having to justify why. Data will be collected in anonymised form and keys that link
51 data with personal information will be stored separately and only accessible to the project
52 leader. All personal data will be registered according to the General Data Protection
53 Regulation (GDPR2016/679)⁶² and the data will be stored in accordance with the Archive Act
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3 in Sweden (SFS1990:782).⁶³ This study is registered at <http://clinicaltrials.gov> under
4 identification number NCT04180189. The results of this study will be communicated to the
5 included participants, healthcare providers, and companies, in manuscripts submitted to peer-
6 reviewed journals, as well as in presentations at national and international peer-review
7 conferences.
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14 **Discussion**

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17 Weighted blankets are prescribed to patients in healthcare in Sweden and are widely used as a
18 non-pharmacological intervention for sleep problems, even though evidence for the effects of
19 weighted blankets is lacking. The few previous studies investigating the effect of weighted
20 blankets for children with ADHD have not shown conclusive results and to date, there are too
21 few high-quality studies to support the intervention.²⁵⁻²⁸ The results from this RCT will thus
22 be important for providing new evidence of the efficacy, cost-effectiveness, and experiences
23 of the use of weighted blankets to address sleep problems among children with ADHD.
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30 Some methodological considerations can be highlighted. A strength is that this study will be
31 the first randomised placebo-controlled crossover trial investigating the effects of fibre-
32 weighted blankets in children with ADHD. Another strength is the use of both objective and
33 subjective measures for sleep. Although subjectively measured sleep is highly relevant to
34 assess and evaluate, objectively measured sleep has the advantages of being free from
35 subjective expectations in relation to the intervention, and less sensitive to recall bias.
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37 Furthermore, the evaluation of cost-effectiveness of weighted blankets is highly relevant
38 though this has not previously been studied.²¹ The costs and benefits of the intervention need
39 to be taken into consideration when implementing the intervention in healthcare settings.
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41 Similarly, the inclusion of a qualitative approach in the design to increase the understanding
42 of both children's and parents' experiences of effects is another strength. This latter aspect is
43 of great relevance as children's perspectives are seldom taken into account in research.
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51 There are, however, a few methodological challenges with this study. Assessing self-reported
52 data from children is difficult for several reasons. Some of the questionnaires in this study are
53 designed for the parent to respond on behalf of the child (e.g. CSHQ). This may be a good
54 approach for younger children, but depending on the habits around bedtime, the parents may
55 only have (at best) a reasonably good perception of how the child's sleep was (for example, if
56 sleeping in separate bedrooms). Under these circumstances, the parent and the child are
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3 instructed to fill in the questionnaire together to get a more reliable assessment. Another
4 potential bias is the control blankets. The difference in weight will be obvious for parents and
5 also for children. The participants are only informed they are trying two different kinds of
6 blankets. However, most have learned about weighted blankets through media or their health
7 providers, possibly affecting expectations in favour of the weighted blanket
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12 We anticipate the project will make several scientific contributions to the research on health-
13 related outcomes, sleep, and cost-effectiveness for non-pharmacological sleep interventions.
14 such as weighted blankets. These findings will be essential for healthcare professionals in
15 their practice though evidence today for the effects of weighted blankets is scarce. The results
16 will also be relevant for children with ADHD in particular, but will also be relevant for other
17 target groups and other settings.
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24 **Acknowledgments** We thank the healthcare professionals at the CAMHS in Region Halland
25 for assistance with study recruitment from their sites. We are grateful for the assistance
26 provided by Novista of Sweden AB to provide the study with fibre blankets with and without
27 weights.
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31 **Author Contribution** IL, JN and PS contributed to the conception of the study, obtained the
32 funding, and are the guarantors of the study. IL, KA, JN, PJ, HJ and PS contributed to the
33 study design. IL and KA were primarily responsible for the statistical analysis plan. PJ was
34 responsible for the health economic analysis plan. IL and PS were responsible for the
35 qualitative analysis plan. IL drafted the manuscript and KA, JN, PJ, HJ and PS revised the
36 manuscript critically for important intellectual content, All authors read and approved the
37 final version of the manuscript.
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43 the company Novista of Sweden AB nor the funders have any role in the study design, data
44 collection, management, analysis, or interpretation of the data.
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47 **Competing interests** None declared.
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50 **Patient consent for publication** Not required.
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52 **Availability of data and materials:** Not applicable. The data will not be shared as ethics
53 approval for the study requires that data files and the transcribed interviews are kept in locked
54 files, accessible only to the researchers.
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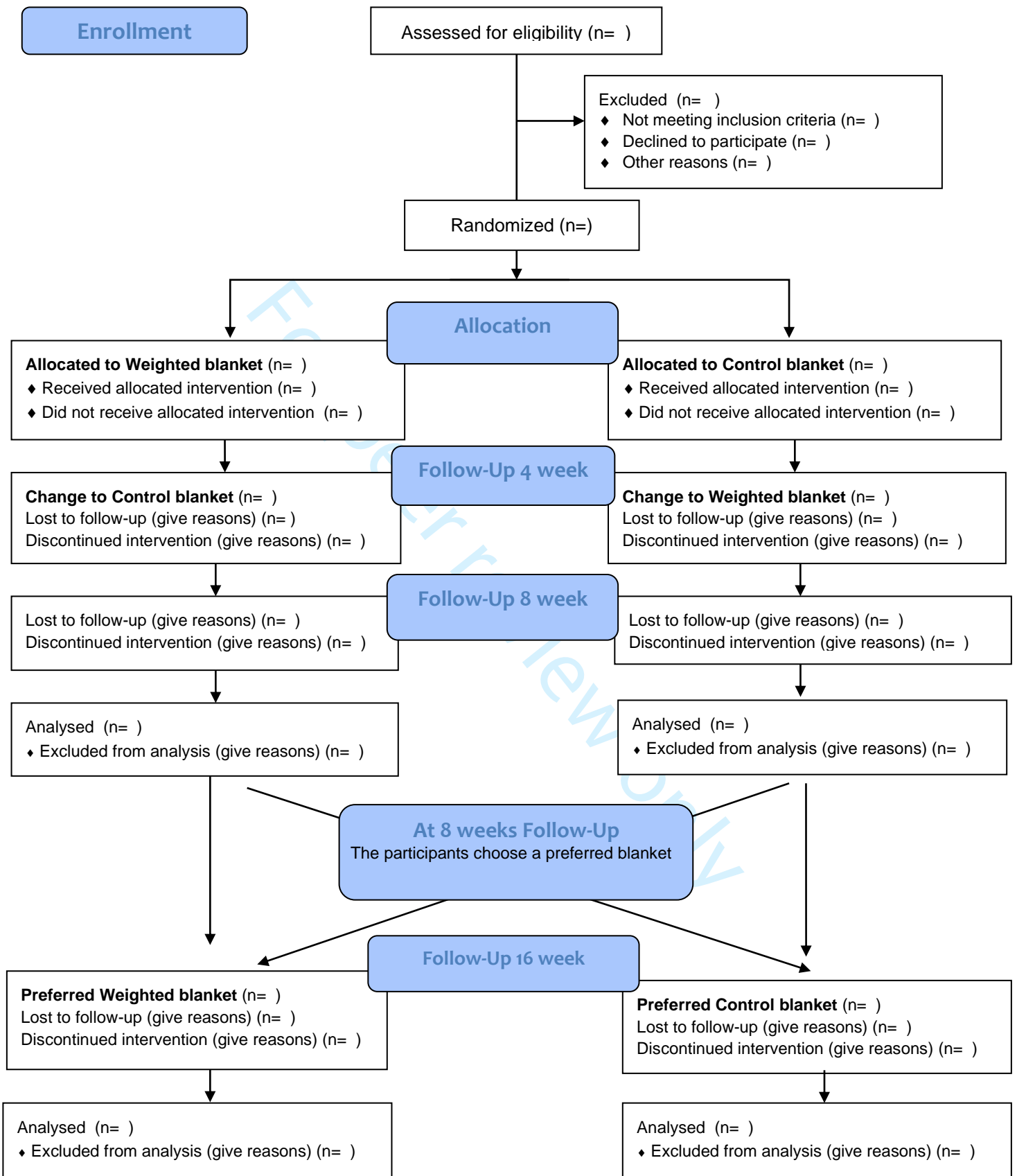
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Figur 1 CONSORT Flow Diagram over the SLEEP trial



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

Section/item	Item No	Description
Administrative information		
Title	1	<i>SLEEP - An intervention with weighted blankets for children with Attention Deficit Hyperactivity Disorder (ADHD) and sleep problems: study protocol for a randomised control trial</i>
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

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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
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10	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
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18	Methods: Participants, interventions, and outcomes		
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20	Study setting	9	Children attending the ADHD unit at DCAP in the southern part of Sweden. Page 3
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23	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
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32	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
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42	Outcomes	12	The primary outcome is objectively measured and self-reported sleep. Secondary outcomes: <i>The children's general well-being</i> will be assessed by the Child Outcome Rating Scale (CORS), <i>The children's anxiety</i> will be assessed by The short State-Trait Anxiety Inventory for children (short-STAI), <i>The children's ADHD symptoms - hyperactivity/impulsivity, inattention and oppositional -</i> will be assessed by the parents using The Swanson, Peland, and Nolan Scale (SNAP-IV), <i>The parents' general well-being</i> will be assessed by the Outcome Rating Scale (ORS), <i>Family situation and parental mood</i> will be assessed by the Brief Child and Family Phone Interview (BCFPI), <i>Health-related quality of life</i> in children (EQ-5D-Y) and parents (EQ-5D-3L) Pages 4-9
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56	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
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- 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:

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- Sequence generation 16a The participants (n=80) will be randomly assigned into two groups using simple randomisation with stratification³¹. 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

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- 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

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- 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

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2	Consent or assent	26a	Children and parents will receive written and oral information and give
3			their informed consent. The participants will be informed that they can
4			withdraw from the project at any time without having to justify why.
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7	Confidentiality	27	All participation and data collection will be performed confidentially.
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10	Declaration of	28	None declared. Page 13
11	interests		
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13	Access to data	29	Only the researches have access to the data. Page 13
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15	Dissemination	31a	The results of this study will be communicated to the included
16	policy		participants, healthcare providers, and companies, in manuscripts
17			submitted to peer-reviewed journals, as well as in presentations at
18			national and international peer-review conferences. Page 11
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21 *It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013
 22 Explanation & Elaboration for important clarification on the items. Amendments to the
 23 protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT
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