


BMJ Open Sleep IntervEntion as Symptom Treatment for ADHD (SIESTA)-Blended CBT sleep intervention to improve sleep, ADHD symptoms and related problems in adolescents with ADHD: Protocol for a randomised controlled trial

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ABSTRACT

Introduction Adolescents with attention deficit hyperactivity disorder (ADHD) experience a more disrupted sleep and more sleep problems compared with typically developing adolescents. This is particularly concerning, because disrupted sleep is related to worsened clinical, neurocognitive and functional outcomes and leads to increased ADHD symptom impairment. Due to the specific difficulties adolescents with ADHD experience, a tailored sleep treatment is needed. Therefore, our lab developed a cognitive behavioural treatment—Sleep IntervEntion as Sympom Treatment for ADHD (SIESTA)—that integrates sleep training with motivational interviewing, and planning/organisational skills training with the aim of improving sleep problems in adolescents with ADHD.

Methods and analysis A randomised, controlled, investigator-blinded monocentre trial is used to test whether SIESTA in combination with treatment as usual (TAU) for ADHD results in greater improvement in sleep problems than TAU only. Adolescents (aged 13–17 years) with ADHD and sleep problems are included. They complete measurements before treatment (pre-test), approximately 7 weeks after the pre-test (post-test), and approximately 3 months after the post-test (follow-up). The assessment includes questionnaires filled out by adolescents, parents and teachers. Additionally, sleep is assessed by actigraphy and sleep diaries at all time-points. Primary outcomes include objectively and subjectively measured sleep architecture (specified as total sleep time, sleep onset latency, sleep efficiency and number of awakenings), subjectively measured sleep problems and sleep hygiene. Secondary outcomes include ADHD symptoms, comorbidities and functional outcomes. To analyse the data, a linear mixed effects model will be used with an intent-to-treat approach.

Ethics and dissemination The study activities, informed consent and assent forms have been approved by the Ethical Committee Research UZ/KU Leuven (study ID S64197). If proven effective, the intervention will be

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ This cognitive behavioural sleep intervention targeting sleep hygiene (Sleep IntervEntion as Sympom Treatment for ADHD (SIESTA)) is specifically developed for adolescents with attention deficit hyperactivity disorder (ADHD) with the aim of reducing their sleep problems.
- ⇒ Using a randomised controlled trial design, the effect of SIESTA in combination with treatment as usual (TAU) for ADHD as compared with TAU only for ADHD is assessed on sleep-related and ADHD-related outcomes both on the short term and the middle long term.
- ⇒ The SIESTA treatment manual and the assessment protocol of the randomised controlled trial were fine-tuned for the target audience based on a pilot study including focus groups with adolescents with ADHD and separately with their parents.
- ⇒ This is a single-blinded study which could lead to a potential bias in the results of the study.
- ⇒ COVID-19-related restriction measures in Flanders (Belgium) impacted the assessment protocol of the study.

implemented throughout Flanders. Therefore, an advisory board consisting of societal partners in healthcare is appointed at the start of the project, giving advice throughout the project and assistance with implementation afterwards.

Trial registration number NCT04723719.

INTRODUCTION

Up to 72% of adolescents with attention deficit hyperactivity disorder (ADHD) experience sleep problems.¹ A systematic review by Lunsford-Avery *et al*² and a meta-analysis

done by our research group show that adolescents with ADHD have a more disrupted sleep and experience more sleep problems compared with their typically developing peers.^{2,3} This is particularly concerning, because disrupted sleep is related to worsened clinical, neurocognitive and functional outcomes in adolescents with ADHD and leads to increased ADHD symptom impairment.⁴ Therefore, more information on the effectiveness of sleep interventions specifically for adolescents with ADHD would be beneficial and may inform treatment guidelines for ADHD, as these often note problems in sleep in ADHD but lack evidence supporting specific intervention guidelines for ADHD.^{5,6} Although it is still unclear which factors underlie worsened sleep and sleep problems in adolescents with ADHD, inadequate sleep hygiene practices are likely to be an important factor.⁷ Sleep hygiene entails various modifiable factors and behaviours that influence sleep (ie, sleep practices, physiological factors like caffeine and alcohol use, sleep environment) and thus is an important intervention target to improve disrupted sleep.

Up to now, there is no evidence-based cognitive behavioural treatment (CBT) aimed at improving sleep specifically for adolescents with ADHD. A proof of principle is available in children with ADHD,⁸⁻¹² in typically developing adolescents^{13,14} and in adults with ADHD and sleep problems.¹⁵ However, treatments for adolescents with ADHD have received little attention so far. This might be due to the difficulty of providing treatment for adolescents in general and adolescents with ADHD in particular. For children with ADHD, parent-mediated interventions have been proven to be effective. However, they generally do not work for adolescents due to a growing need for autonomy.¹⁶ Furthermore, adolescents with ADHD are known to have motivational difficulties, which are seen by enhanced treatment drop-out and non-compliance to treatment.¹⁷ Moreover, they have severe problems with planning and organisation in daily life,¹⁸ and resisting immediate temptations.¹⁹ These difficulties are likely to affect their sleep; due to organisational difficulties they do not manage to get enough sleep, or may not be able to resist immediate temptations such as mobile phones or social media. Given the specificity of this developmental phase in ADHD, interventions may need to be adapted both towards the developmental phase and the disorder. Therefore, experts in the field of sleep, psychopathology and functional disabilities recommend that sleep disorders should be treated together with functional disabilities such as ADHD symptoms, as they are interactively and bidirectionally related to each other.^{20,21}

Recently, one small-scale pilot study has been published that shows that the existing CBT-based Transdiagnostic Sleep and Circadian Intervention for Youth²² resulted in improvements in sleep, mental health symptoms and daily life executive functioning in 14 adolescents with ADHD.²³ However, the parents of the participants were all highly educated and participants themselves were very motivated, which is likely not to be a representation of all

adolescents with ADHD.²³ Thus, there still is a clear need for a sleep treatment specifically developed for adolescents with ADHD, tailored to their specific difficulties with motivation and planning and organisation. Therefore, our lab developed a CBT intervention—Sleep IntervEntion as Symptom Treatment for ADHD (SIESTA)—that integrates sleep training with motivational interviewing, and planning/organisational skills with the aim of improving sleep problems in adolescents with ADHD.^{24,25} To tailor the intervention optimally towards the needs of adolescents with ADHD and enhance feasibility of the assessment and study protocol of our randomised controlled trial (RCT), we piloted our SIESTA intervention and the study protocol in eight adolescents with ADHD and sleep problems.²⁶ Fine-tuning of the intervention and study protocol was based on the outcomes of the pilot study and feedback from adolescents with ADHD and parents from focus groups.

The objective of this study is to test the effectiveness of SIESTA in combination with treatment as usual (TAU) for ADHD symptomatology compared with TAU only in an RCT. SIESTA is expected to improve sleep architecture measured both objectively and subjectively; specified as total sleep time (TST), sleep onset latency (SOL), sleep efficiency (SE) and number of awakenings (NoA), sleep problems and sleep hygiene practices (primary outcomes). Regarding secondary outcomes, SIESTA is expected to improve ADHD symptoms, comorbid symptoms and functional outcomes. Both primary and secondary outcomes are expected to show greater improvement in the SIESTA group, both on the short term (post-test) and middle long term (approximately 3 months follow-up), than in the TAU-only group.

METHODS AND ANALYSIS

Study design

A randomised, controlled, investigator-blinded mono-centre trial is used to test whether SIESTA in combination with TAU results in greater improvement in sleep than TAU only in adolescents with ADHD. This trial was preregistered at ClinicalTrials.gov (Identifier: NCT04723719; all items from the WHO Trial Registration Data Set are further elaborated on in this registration) and we adhered to the Standard Protocol Items: Recommendations for Interventional Trials recommendations when drafting this protocol (see online supplemental 1).²⁷ This study consists of five waves of recruitment, always following the same procedure (figure 1); January–March 2021, September–October 2021, January–March 2022, September–October 2022 and January–March 2023. We aimed to be outreaching and provide treatments close to where the adolescents live, therefore our therapists travel to different locations in Flanders (Leuven, Antwerp, Hasselt, Brussels, Gent and Roeselare). These different locations in rural and urban areas are chosen to remove barriers for accessibility and to be able to include a diverse sample.

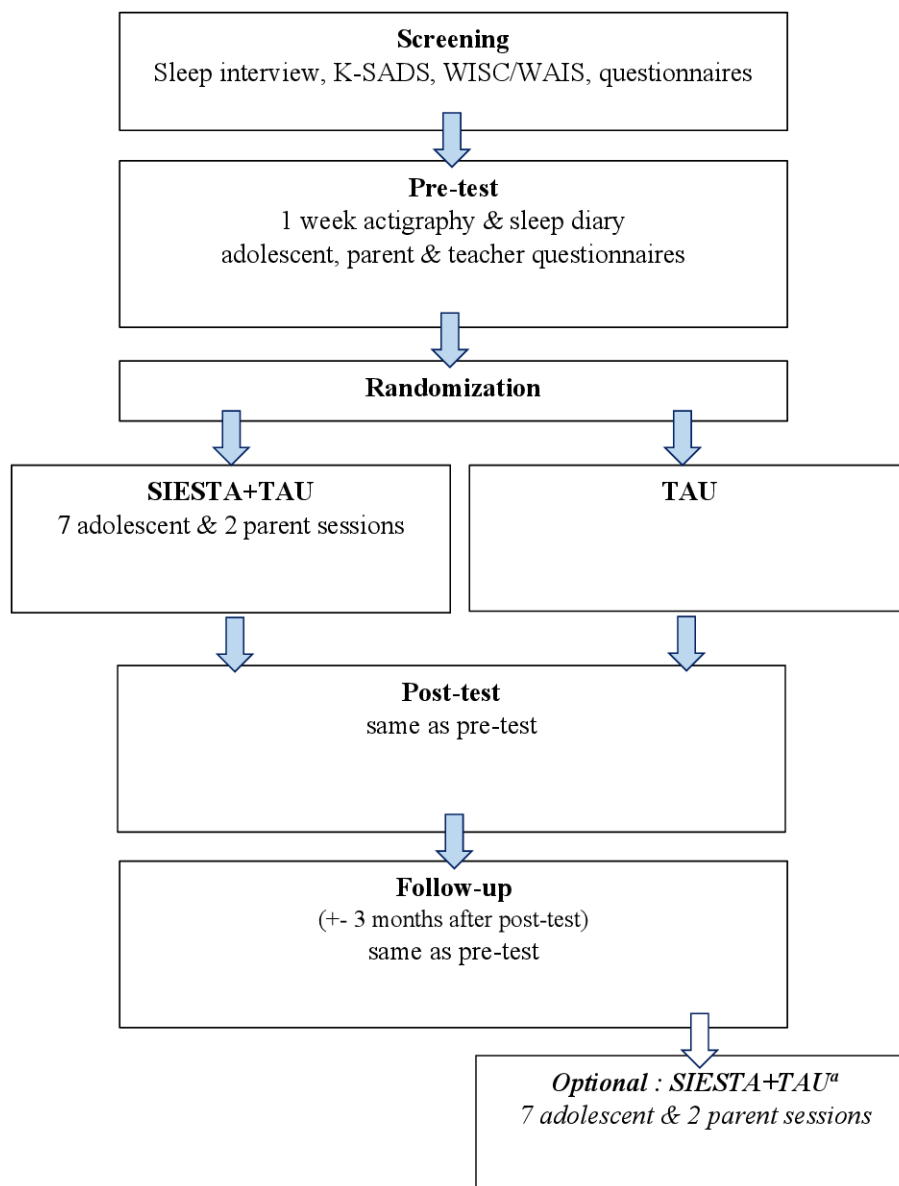


Figure 1 Study procedure. K-SADS, Kiddie Schedule for Affective Disorders and Schizophrenia for school-aged children (6–18 years) Present and Lifetime version based on the Diagnostic and Statistical Manual of Mental Disorders, fifth edition;⁵³ SIESTA, Sleep IntervEntion as Symptom Treatment for ADHD; TAU, treatment as usual; WISC, Wechsler Intelligence Scale for Children, fifth edition;⁵⁴ WAIS, Wechsler Adult Intelligence Scale, fourth edition.⁵⁵ *Those randomised to TAU can voluntary choose to receive SIESTA after the last follow-up. These treatments after the last follow-up are not part of the study protocol anymore.

Participants

Inclusion and exclusion criteria can be found in [table 1](#).

Patient and public involvement

The intervention, study design and research questions were developed with adolescents with ADHD in mind as the researchers have extensive (clinical) experience with ADHD. To fine-tune and adapt SIESTA and the study design to the needs and perceptions of adolescents with ADHD and their parents, a pilot study (n=8) preceded the RCT.²⁸ Adolescents with ADHD and sleep problems and their parents who received the pilot version of SIESTA gave feedback on the intervention and addressed points of improvement in focus groups. Focus groups

were conducted separately with adolescents and parents. Regarding the intervention, feedback was given on the duration, complexity, feasibility, suitability, relevance and representation of ADHD in the materials used in treatment. Regarding the study design and assessment protocol, feedback was given on the (amount of) questionnaires, usability and feasibility of the sleep diary, and actigraphy.

Randomisation and blinding

Participants are randomly assigned to either the treatment (SIESTA+TAU) or control (TAU) group with a 1:1 allocation stratified by ADHD medication use (yes/no) and location (Leuven, Antwerp, Hasselt, Brussels, Gent,

**Table 1** Inclusion and exclusion criteria

Inclusion	Exclusion
<ul style="list-style-type: none"> ▶ 13–17 years old ▶ Attending secondary education ▶ ADHD diagnosis* ▶ Sleep problems†: <ul style="list-style-type: none"> (≥3 days/week and lasting ≥3 months) – Sleep onset >20 min – And/or wake up time after sleep onset >30 min – And/or <7 hours sleep – And at least one inadequate sleep hygiene practice – And distress reported by adolescent and/or parent ▶ IQ ≥80‡ ▶ Stable use of ADHD medication (4 weeks before screening) 	<ul style="list-style-type: none"> ▶ Comorbid disorders: <ul style="list-style-type: none"> – Conduct disorder* – Autism spectrum disorder§ – Depressive disorder with suicide risk or active suicidality* ▶ Sleep disorders†: <ul style="list-style-type: none"> – Narcolepsy – Sleep breathing disorder – Restless leg syndrome ▶ Substance abuse¶ (except nicotine), however substance use is not an exclusion criterion ▶ Physical or medical problems (and medication) causing sleep problems ▶ Medication for sleep, anxiety or depression ▶ Melatonin use (2-week washout of melatonin before participation) ▶ Acute crisis situation at home ▶ CBT sleep intervention participation (<6 months ago)

*Verified by the semi-structured interview K-SADS-PL DSM-5 with the parents.⁵³

†Determined in an extensive sleep interview based on the DSM-5 and International Classification of Sleep Disorders – Third Edition (ICSD-3) criteria with parents and adolescents.^{20 56}

‡Verified by the subtests Vocabulary and Matrix reasoning from the Wechsler Intelligence Scale for Children for adolescents aged 13–16 years or the Wechsler Adult Intelligent Scale for adolescents aged 17 years.^{54 55}

§As indicated by the parents.

¶Verified by the subscale ‘Disorders in the use of substances and behavioural addictions’ of the Measurements in the Addictions for Triage and Evaluations-Youth.⁵⁷

ADHD, attention deficit hyperactivity disorder; CBT, cognitive behavioural treatment; K-SADS-PL DSM-5, Kiddie Schedule for Affective Disorders and Schizophrenia for school-aged children (6–18 years) Present and Lifetime version based on the Diagnostic and Statistical Manual of Mental Disorders, fifth edition.

Roeselare) using permuted blocks of random sizes.^{29 30} We randomise per location to ensure practical feasibility for our therapists of the KU Leuven (ie, there is a maximum amount of adolescents that can be treated per location). Randomisation is done by an independent researcher who is not involved in the study in any way. Due to the nature of the psychological treatment, neither participants nor clinicians can be blinded to allocation. Researchers who are responsible for the practical side of the study (LK, FM) are not blinded to allocation, however, the principal investigator (SvdO) and the other researchers DB, BB and MD are blinded throughout the study.

Intervention and comparison

SIESTA is based on a CBT sleep intervention for typically developing adolescents and a CBT intervention focused on motivational planning for adolescents with ADHD, both developed by (among others) the project applicants.^{31 32} The training follows a structured workbook for the adolescent which can be used during sessions and at home.²⁴ The instructions for the therapist are described in a therapist manual.²⁵ SIESTA consists of seven individual sessions with the adolescents, and two parental sessions. An overview of the content of the sessions can be found in [table 2](#). This RCT uses as control condition TAU for ADHD symptomatology. In Flanders, TAU for ADHD primarily consists of medication with stimulants.

Outcome measures

Primary outcomes

Objective sleep architecture: TST, SOL, SE and NoA

Sleep is registered with wrist actigraphy (Motionwatch, CamNtech) as objective measurement. Participants wear an actigraph for five school nights and two weekend nights, as based on previous research,³³ this is sufficient to be able to compute reliable sleep architecture estimates. Actigraphy has been reliably used in adolescents with sleep problems and has been shown to be sensitive to treatment effects.^{13 33 34} Participants use the event marker button on the actigraph to indicate lights out and getup times.³⁵ If they forget to press the button, those time points are extracted from the sleep diary data. Using these data, TST (time asleep between sleep onset and sleep offset), SOL (time from lights out to sleep onset), SE (percentage of time spent asleep TST while in bed TiB) and NoA (number of times awake after sleep onset and before sleep offset) are calculated.

Subjective sleep architecture

Sleep is registered with a sleep diary as subjective measurement. The adolescents fill out the sleep diary for five school nights and two weekend nights, keeping track of lights out, sleep onset, sleep offset and getup via an ecological momentary assessment app m-Path.³⁶ TST,

Table 2 Overview of the adolescent and parent sessions of SIESTA

Session 1	Psychoeducation on sleep in adolescents with ADHD. Focus on goal setting and adolescent motivation.
Session 2	In-depth psychoeducation on sleep hygiene (sleep practices, physiological factors like caffeine and alcohol use, sleep environment). Adolescent sleep behaviour research: What does the adolescent already know and what more information is needed?
Session 3	Adjustments to align better with healthy sleep practices. Discussing trying out an alarm and relaxation exercises.
Parent session 1	Psychoeducation on sleep in adolescents with ADHD. Discussing and creating realistic expectations of parents towards the intervention and their adolescent.
Session 4	Aimed at drawing up a functional and topographical analysis of the sleep problem and specify the goals of <i>session 1</i> based on that. An individualised sleep plan is made to target their sleep problem.
Session 5	An extra plan can be added to the sleep plan: this can focus on rumination, planning and organisation, circadian rhythm and motivation.
Session 6	The sleep plan is finalised. Making sure it is adapted towards the adolescent.
Parent session 2	Finding a balance between controlling and letting go of the sleep of the adolescent. Positive communication about the sleep of the adolescent.
Session 7	Relapse prevention.
ADHD, attention deficit hyperactivity disorder; SIESTA, Sleep IntervEntion as Symptom Treatment for ADHD.	

SOL, SE and NoA are calculated analogous to the actigraph data.

Sleep problems

Sleep problems are measured using two self-report and one parent-reported questionnaire. The following two subscales of the School Sleep Habits Survey are used: sleepiness and sleep/wake problem behaviours.³⁷ This is a validated self-report questionnaire with acceptable internal consistency (sleepiness; $\alpha=0.70$; sleep/wake problem behaviours; $\alpha=0.75$).³⁸ To measure sleep deprivation, the Chronic Sleep Reduction Questionnaire is used.³⁹ This self-report questionnaire is validated, and has good internal consistency ($\alpha=0.85$ in clinical and $\alpha=0.87$ in control sample).⁴⁰ Children Sleep Habits Questionnaire is used to gain insight in parents' perception of their children's sleep.⁴¹ This is a validated, parent-reported questionnaire with acceptable internal consistency ($\alpha=0.78$ in clinical and $\alpha=0.68$ in control sample) and acceptable test-retest reliability (0.62–0.79).⁴¹

Sleep hygiene

Sleep hygiene is measured with the revised Adolescent Sleep Hygiene Scale.⁴² This is a validated self-report questionnaire with adequate to good internal consistency (total scale $\alpha=0.84$ and subscales $\alpha=0.60$ – 0.81).⁴²

Secondary outcomes

ADHD symptoms

Inattention and hyperactivity-impulsivity subscales of the Disruptive Behaviour Disorder Rating Scale (DBDRS) are used to measure ADHD symptoms.⁴³ This parent-reported questionnaire is validated, and the internal consistency of the scales in a Flemish sample is good for inattention and hyperactivity-impulsivity.⁴³

Comorbidities

Symptoms of multiple comorbidities are measured using self-report, parent-reported and teacher-reported questionnaires. The oppositional defiant disorder subscale of the parent-reported DBDRS is used.⁴³ To evaluate symptoms of anxiety, the revised version of the Screen for Child Anxiety Related Emotional Disorders (SCARED-R) is administered.⁴⁴ The SCARED-R is a validated, self-report questionnaire with good psychometric properties.⁴⁵ The self-report Child Depression Inventory 2 is administered to assess depressive symptoms.⁴⁶ Again, this is a validated questionnaire with good internal consistency ($\alpha=0.88$).⁴⁶

Functional outcomes

Parent-adolescent conflict is measured using the Conflict Behaviour Questionnaire.⁴⁷ This is a validated, parent-reported questionnaire with acceptable to good internal consistency (appraisal of parent; $\alpha=0.73$; appraisal of dyad; $\alpha=0.89$).⁴⁸ To evaluate adolescents' educational achievement, parents complete the Homework Problems Checklist (HPC)⁴⁹ and teachers complete the Classroom Performance Scale (CPS).⁵⁰ Both questionnaires are validated and have an excellent internal consistency (HPC: α ranging from 0.90 to 0.92; CPS: academic competence; $\alpha=0.98$; interpersonal competence; $\alpha=0.91$).

Sample size estimates

A recent study in typically developing adolescents with sleep problems found large effects ($\beta=0.91$) at post-test of a CBT sleep treatment as compared with waitlist controls on their primary sleep-related outcome measure (objectively measured) and a medium effect size for reduction of ADHD symptoms.^{13 14} Based on this research, moderate to large effect sizes can be expected for SIESTA in combination with TAU for ADHD on sleep outcomes



as compared with TAU for ADHD only. Therefore, using G*power we calculated with this large effect size a power of 0.8 and an α of 0.5 for our desired sample size. There are at least 40 participants per condition needed for analysing the data implementing a linear mixed effects model. However, to anticipate for possible drop-out or lack of response on assessment (although expected to be minimal due to inclusion of motivational interviewing and the pilot study) and as the effect size of the ADHD outcome is medium and not large ($d=0.55$), an additional 15% will be recruited, resulting in a total of 92 participants, with 46 participants per condition.

DATA MANAGEMENT

Each participant will receive a unique code that allows to link the data of a participant over time, as well as to link all data of adolescents, parents, teachers and clinicians. After each assessment, the pseudonymised data are uploaded immediately from the researchers' computers to secure network shared drives, whereas paper data are in locked archive cabinets. After all waves have been completed and all data have been linked, the dataset containing the names and codes is deleted. It is assured that data are stored securely. During the study, data are stored on secure network drives in the KU Leuven data centre. The secure network drives are hosted by the central Information and Communication: Technology and Systems (ICTS) services and managed by the IT service. More information on data management can be found in our Data Management Plan 'Blended CBT sleep intervention to improve sleep, ADHD symptoms and related problems in adolescents with ADHD—FWO DMP title' on <http://DMPonline.kuleuven.be> (this also includes further information regarding access to data and dissemination policy).

Statistical analysis

The analyses are based on an intent-to-treat approach, whereby participants are analysed as a function of the condition to which they had been assigned. A longitudinal linear mixed effects model will be applied, with the variance components error correlation structure among the repeated measures over pre-test, post-test and follow-up. The model contains a random intercept varying over participants, a fixed effect of time (pre-test, post-test and follow-up), a random slope for time varying over participants, a fixed effect of condition ($1=\text{SIESTA+TAU}$; $0=\text{TAU}$) and an interaction effect between time and condition. We will correct for multiple testing in the multilevel analyses. Additionally, the potential impact of COVID-19 restrictions is taken into account by including wave as a level in the multilevel analyses. Effect sizes are computed by calculating the difference in change scores for SIESTA+TAU as compared with TAU only between post-treatment/follow-up and pre-test and dividing this amount by the pooled SD of the change scores for SIESTA+TAU and TAU only. CIs for effect sizes are computed

using procedures delineated by Odgaard and Fowler.⁵¹ Although participants are instructed to be off sleep medication and to not change their ADHD medication, they may not comply. Therefore, this is thoroughly assessed both at post-test and follow-up. This allows for potential sensitivity analyses in the sleep medication free sample, and those that did not change ADHD medication.

ETHICS AND DISSEMINATION

Ethical considerations

The study application was submitted to the Ethical Committee Research UZ/KU Leuven (study ID S64197). The study activities and informed consent forms have been approved. The study will be conducted according to ethical principles based on the Helsinki Declaration, Good Clinical Practice, national regulatory mandatory instructions and this protocol. General Data Protection Regulation ((European Union (EU) 2016/679 of 27 April 2016; <https://eur-lex.europa.eu/eli/reg/2016/679/oj>) will be applied as the adolescents and their parents are informed about the study and the informed assent and consent form are presented in understandable language before participation. Adolescents are asked to assent to participate in the study (online supplemental 2). Additionally, consent from the parent is required for participation (online supplemental 3).

Safety considerations

Once a year throughout the clinical trial, a progress report is submitted to the Ethical Committee Research UZ/KU Leuven containing an overview of all serious adverse events (as defined by the Ethical Committee Research UZ/KU Leuven)⁵² that occurred during the reporting period and taking into account all new available safety information received during the reporting period. Adverse events will be recorded and systematically assessed during the sessions of the treatment. If adverse events are reported, these will be documented in a separate document by the therapists who provide the treatment and reported to the Ethical Committee Research UZ/KU Leuven, both directly after the report and annually in a summary. The following minimum information is recorded for each adverse event: (1) description, (2) start and stop, (3) severity and seriousness, (4) causality assessment to the study treatment and (5) outcome.

Dissemination plan

Implementation is a major part of this project. To this end, an advisory board is involved from the start of the project; they meet twice yearly in the first and last year, and yearly in the second and third year of the project and on demand. This board consists of important societal representatives of mental healthcare in Flanders, that is, the advisory board consists of representatives of private practices, the Flemish Behaviour Therapy Association, the ADHD reference network Flanders, the specialised sleep centre UZ Leuven, the patient organisation ADHD ZitStil, Sig vzw

(educational organisation rehabilitation centres), the Belgian Association for Sleep Research and Sleep Medicine and the European ADHD Guidelines group. Also, the project partners are involved in governmental organisations relating to mental healthcare policy (eg, members of the Hoge Gezondheidsraad ADHD; expert advisory board to the minister of health in Belgium; members of the European ADHD Guidelines Group). Both the project applicants and the advisory board will join forces across four lines of (mental) healthcare for optimal implementation when SIESTA is proven effective: line (1) governmental organisations and mental healthcare policy makers/non-discriminatory transfer to the EU, line (2) mental healthcare organisations, specialised sleep centres and a network of sleep experts in Flanders, line (3) clinicians and other professionals working with adolescents with ADHD and/or individuals with sleep problems and line (4) patient organisations, adolescents with ADHD and their parents. These combined efforts will lead to an optimal implementation of the following products and knowledge acquired by this project if proved effective: a workbook and therapist manual of SIESTA, a training module for clinicians wanting to provide SIESTA and a website containing all information and training materials regarding SIESTA for adolescents, parents, clinicians, mental health organisations and governmental organisations. Additionally, results of the study will be communicated to other researchers via publications in academic journals and presentations at conferences.

CONCLUSION

Up to 72% of adolescents with ADHD experience sleep problems, which are likely to be bidirectionally causally related to increased ADHD symptom impairment, oppositional and depressive symptomatology and functional impairments. Therefore, we developed a new CBT sleep intervention specifically for adolescents with ADHD, integrating motivational interviewing, planning and organisational skills and sleep hygiene interventions, named SIESTA. This protocol describes an RCT which is conducted to investigate whether SIESTA in combination with TAU is more effective than TAU only in improving sleep hygiene practices, sleep problems, ADHD symptoms and related problems in adolescents with ADHD.

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Contributors LK, FM, DB, BB, MD and SvdO substantially contributed to the design or analysis of the study, helped with revision of the article, gave final approval of the version to be published and agreed to be accountable for all aspects of both the study and the article.

Competing interests MD is participating in a Takeda-sponsored clinical trial in attention deficit hyperactivity disorder. All other authors have no conflict of interest.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the 'Methods' section for further details.

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