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 Symptom 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 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.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- This cognitive behavioural sleep intervention targeting sleep hygiene (Sleep IntervEntion as Symptom 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.

INTRODUCTION

Up to 72% of adolescents with attention deficit hyperactivity disorder (ADHD) experience sleep problems.1 A systematic review by Lunsford-Avery et al2 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.\(^5\)\(^6\) 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,\(^8\)\(^9\)\(^10\)\(^11\)\(^12\) 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 Youth\(^22\) 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 monocentre 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.
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. 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, Gent).
The instructions for the therapist are described for the adolescent which can be used during sessions and at both developed by (among others) the project application motivational planning for adolescents with ADHD, developing adolescents and a CBT intervention focused on motivational planning. SIESTA is based on a CBT intervention for typically developing adolescents. In Flanders, TAU for ADHD, attention deficit hyperactivity disorder; CBT, cognitive behavioural treatment; KU Leuven (ie, there is a maximum 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. The training follows a structured workbook for the adolescent which can be used during sessions and at home. The instructions for the therapist are described in a therapist manual. 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, 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. Participants use the event marker button on the actigraph to indicate lights out and getup times. 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. TST, ADHD, attention deficit hyperactivity disorder; CBT, cognitive behavioural treatment; 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.

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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. This is a validated self-report questionnaire with acceptable internal consistency (sleepiness; $\alpha=0.70$; sleep/wake problem behaviours; $\alpha=0.75$). To measure sleep deprivation, the Chronic Sleep Reduction Questionnaire is used. This self-report questionnaire is validated, and has good internal consistency ($\alpha=0.85$ in clinical and $\alpha=0.87$ in control sample). Children Sleep Habits Questionnaire is used to gain insight in parents’ perception of their children’s sleep. 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).

**Sleep hygiene**

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

**Secondary outcomes**

**ADHD symptoms**

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

**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. To evaluate symptoms of anxiety, the revised version of the Screen for Child Anxiety Related Emotional Disorders (SCARED-R) is administered. The SCARED-R is a validated, self-report questionnaire with good psychometric properties. The self-report Child Depression Inventory is administered to assess depressive symptoms. Again, this is a validated questionnaire with good internal consistency ($\alpha=0.88$).

**Functional outcomes**

Parent-adolescent conflict is measured using the Conflict Behaviour Questionnaire. This is a validated, parent-reported questionnaire with acceptable to good internal consistency (appraisal of parent; $\alpha=0.73$; appraisal of dyad; $\alpha=0.89$). To evaluate adolescents’ educational achievement, parents complete the Homework Problems Checklist (HPC) and teachers complete the Classroom Performance Scale (CPS). Both questionnaires are validated and have an excellent internal consistency (HPC: $\alpha$ 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. 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=SIESTA+TAU; 0=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. 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) 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, sleep parameters 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, conduct, or reporting, or dissemination plans of this research. Refer to the ‘Methods’ section for further details.

Patient consent for publication Not applicable.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data are available on reasonable request.

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36 Mestdagh M, Verdonck S. M-path(version 2.5.7) [app]. google play store 2019.


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<td>Trial identifier and registry name. If not yet registered, name of intended registry</td>
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<tr>
<td>Protocol version</td>
<td>3</td>
<td>Date and version identifier</td>
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<td>Funding</td>
<td>4</td>
<td>Sources and types of financial, material, and other support</td>
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<td>Roles and responsibilities</td>
<td>5a</td>
<td>Names, affiliations, and roles of protocol contributors</td>
<td>1, 13</td>
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<tr>
<td></td>
<td>5b</td>
<td>Name and contact information for the trial sponsor</td>
<td>13</td>
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<td></td>
<td>5c</td>
<td>Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities</td>
<td>13</td>
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<td></td>
<td>5d</td>
<td>Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)</td>
<td>12</td>
</tr>
</tbody>
</table>
### Introduction

**Background and rationale**
- 6a Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention
- 6b Explanation for choice of comparators

**Objectives**
- 7 Specific objectives or hypotheses

**Trial design**
- 8 Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)

### Methods: Participants, interventions, and outcomes

**Study setting**
- 9 Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained

**Eligibility criteria**
- 10 Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)

**Interventions**
- 11a Interventions for each group with sufficient detail to allow replication, including how and when they will be administered
- 11b Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)
- 11c Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)
- 11d Relevant concomitant care and interventions that are permitted or prohibited during the trial

**Outcomes**
- 12 Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended

**Participant timeline**
- 13 Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)
Sample size 14 Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations

Recruitment 15 Strategies for achieving adequate participant enrolment to reach target sample size

Methods: Assignment of interventions (for controlled trials)

Allocation:

Sequence generation 16a Method of generating the allocation sequence (e.g., computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (e.g., blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions

Allocation concealment mechanism 16b Mechanism of implementing the allocation sequence (e.g., central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned

Implementation 16c Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions

Blinding (masking) 17a Who will be blinded after assignment to interventions (e.g., trial participants, care providers, outcome assessors, data analysts), and how

17b If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant’s allocated intervention during the trial

Methods: Data collection, management, and analysis

Data collection methods 18a Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (e.g., duplicate measurements, training of assessors) and a description of study instruments (e.g., questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol

18b Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols
### Data management

- **19** Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol

### Statistical methods

- **20a** Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol
- **20b** Methods for any additional analyses (eg, subgroup and adjusted analyses)
- **20c** Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)

### Methods: Monitoring

#### Data monitoring

- **21a** Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed
- **21b** Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial

#### Harms

- **22** Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct

#### Auditing

- **23** Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor

### Ethics and dissemination

#### Research ethics approval

- **24** Plans for seeking research ethics committee/institutional review board (REC/IRB) approval

#### Protocol amendments

- **25** Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)
<table>
<thead>
<tr>
<th>Item</th>
<th>Description</th>
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<tr>
<td>26a</td>
<td>Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)</td>
<td>11</td>
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<tr>
<td>26b</td>
<td>Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable</td>
<td>NA</td>
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<tr>
<td>27</td>
<td>How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial</td>
<td>10</td>
</tr>
<tr>
<td>28</td>
<td>Financial and other competing interests for principal investigators for the overall trial and each study site</td>
<td>13</td>
</tr>
<tr>
<td>29</td>
<td>Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators</td>
<td>10 (data management plan)</td>
</tr>
<tr>
<td>30</td>
<td>Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation</td>
<td>12</td>
</tr>
<tr>
<td>31a</td>
<td>Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions</td>
<td>12-13</td>
</tr>
<tr>
<td>31b</td>
<td>Authorship eligibility guidelines and any intended use of professional writers</td>
<td>13</td>
</tr>
<tr>
<td>31c</td>
<td>Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code</td>
<td>10 (data management plan)</td>
</tr>
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</table>

**Appendices**

<table>
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<th>Item</th>
<th>Description</th>
<th>Pages</th>
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<td>32</td>
<td>Model consent form and other related documentation given to participants and authorised surrogates</td>
<td>Supplement 2, 3</td>
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<tr>
<td>33</td>
<td>Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable</td>
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*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons “Attribution-NonCommercial-NoDerivs 3.0 Unported” license.*
Title of study:
SIESTA: Sleep IntervEntion as Symptom Treatment for ADHD – Blended CBT sleep intervention to improve sleep, ADHD symptoms and related problems in adolescents with ADHD

Contractor: KULeuven; Oude Markt 13, 3000 Leuven (sponsored by TBM fund of Scientific Research Fund – Flanders (FWO))

Research institute: ADHD-consultation of UPC KU Leuven; Herestraat 49, 3000 Leuven

Medical ethics committee: Research Ethics Committee UZ/KU Leuven

Name + contact information researchers:

<table>
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<tr>
<th>Name</th>
<th>Email</th>
<th>Phone</th>
</tr>
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<tr>
<td>Elien Beerts</td>
<td><a href="mailto:elien.beerts@upckuleuven.be">elien.beerts@upckuleuven.be</a></td>
<td>0490 58 48 23</td>
</tr>
<tr>
<td>Yana Vlaeyen</td>
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<td>0491 72 87 34</td>
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<td>Lena Keuppens</td>
<td><a href="mailto:lena.keuppens@kuleuven.be">lena.keuppens@kuleuven.be</a></td>
<td>016 32 17 34</td>
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<td>Finja Marten</td>
<td><a href="mailto:finja.marten@kuleuven.be">finja.marten@kuleuven.be</a></td>
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<tr>
<td>Prof. Dr. Saskia van der Oord</td>
<td><a href="mailto:saskia.vanderoord@kuleuven.be">saskia.vanderoord@kuleuven.be</a></td>
<td>016 32 58 24</td>
</tr>
<tr>
<td>Prof. Dr. Dieter Baeyens</td>
<td><a href="mailto:dieter.baeyens@kuleuven.be">dieter.baeyens@kuleuven.be</a></td>
<td>016 32 60 68</td>
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<tr>
<td>Prof. Dr. Marina Danckaerts</td>
<td><a href="mailto:marina.danckaerts@kuleuven.be">marina.danckaerts@kuleuven.be</a></td>
<td>016 34 38 21</td>
</tr>
</tbody>
</table>

Name & surname: ___________________________________________

Date of birth: ______________________________________________

Intro

We know that about 75% of adolescents with ADHD have sleep problems. This can include difficulty falling asleep when going to bed, waking up during the night or feeling very tired during the day. This in turn can make other things more difficult, such as not being able to pay attention, being easily distracted, organizing your schoolwork and how you feel. Reducing these sleep problems will also reduce their effects. It can possibly even reduce your ADHD symptoms.

We have come up with a training for this, which we are researching in a study. We hope that you want to participate in this training and the study that goes with it. In this letter we want to explain what you can expect from this study and officially ask you to participate.

To see if you qualify for the training, we are going to ask you, your parents and one of your teachers to fill out some questionnaires. You will also fill out a sleep diary and wear a watch that measures your sleep. If you qualify, there are two options; you can either participate in the training immediately or participate in the training 6 months later. The training lasts 7 to 10 weeks, during which you attend here weekly and your parents also attend 2 times.

In this cognitive behavioral training you will work with a trainer to look at how you can improve your sleep by focusing on planning, sleep behavior and motivation. This training will not cost you any money, because you will also participate in the research that accompanies it. Before you get the training and after you finish it, we will ask you and your parents to fill out questionnaires so we can see if the training works well.

By participating, you can help test this training for adolescents with ADHD. By participating you are both helping yourself and others. You will also receive a compensation of 50 euros if you participate in the full study.
Informed Assent Form (IAF) participants
SIESTA RCT
S64197

Legend to figure:
Informed consent/assent = an informed consent that you and your parents/guardians sign to participate in this study
Screening = measurements we take to determine if you can participate in the study
Exclusion = decision that you cannot participate in the study
Pretest = the measurements that precede the training to determine the effectiveness of the training afterwards
Randomization = the point in time at which it will be randomly determined whether you will be able to participate in the training program immediately or 6 months later
Training group = if you are in this group after randomization, you will start the training immediately after the pretest
Control group = if you are in this group after randomization, you can start the training in 6 months time if you still wish to do so
Posttest = the measurements which will take place after the training in order to determine the effectiveness of the training by comparing pretest and posttest measurements
Follow-up = the measurements which will take place 4-5 months after the training in order to determine the medium term effectiveness of the training by comparing posttest and follow-up measurements

Informed consent

- I have received an explanation of the nature, purpose, duration, and foreseeable effects of the study.

- I know that my participation consists of the following elements:
  - contact form
  - questionnaires on general skills, sleep, reward sensitivity, depressed mood, physical development, gaming, substance abuse and anxiety in daily life
  - a short version of an intelligence test (if not already done recently; WISC/WAIS)
  - wear an actigraph (a watch that measures sleep) three times for one week
  - keep a sleep diary alongside the actigraph
  - interview about sleep
  - depending on the results of the interviews and the questionnaires it will be decided whether I can participate in the sleep training of 7 sessions
  - observations
  - a short satisfaction questionnaire about the training

- I know that my parents' participation will consist of:
  - contact form
  - questionnaires on general skills, homework, sleep, behavioral problems, cognition and motivation in daily life.
  - interview (K-SADS)
  - interview about sleep
  - two sessions during the sleep training

- To know how I am doing at school, the researchers will contact one of my teachers to fill out a questionnaire about school. I prefer the following teacher for this purpose:

----------------------------------------------------------------------------------------------------------------------

- I give the researchers permission to access my patient record to consult the information needed for this study into a separate, encrypted database.
- I know that if I am qualified for the training, I may be able to attend the training immediately or after 6 months.
- I know that some sessions may be filmed for supervision of the trainer. I know that I will be unrecognizable and that the camera will be aimed at the trainer. After the supervision, the recording will be destroyed. The videos are only going to be viewed by the researchers to see if the trainer is following protocol properly.
- I agree to cooperate with the investigator and will notify him/her if I experience unexpected or unusual effects/symptoms.
- I know that in the case of Serious Adverse Events, for example, if I have suicidal thoughts, the researchers will contact my psychologist or other caregivers.
- I am aware that my trainer is going to receive some of the information from the first appointment.
- I or others may benefit from this study in the following ways:
  - Participation may improve the treatment of sleep problems in adolescents with ADHD.
  - Depending on the results of the screening, the decision will be made whether I can participate in the sleep training.

- I know that there are normally no risks involved in completing the questionnaires and the standardized interviews and tests, but any participation in a study involves a small risk. In general, of course, it may happen that I get tired during the study. The researchers will then take a break or see how best to remedy this.
- I know that if needed psychological help can be provided at any time during the study.
- The results of this study may be used for scientific purposes and may be published. My name will not be used in this process. Moreover, care will be taken to ensure coding and confidentiality of my data.
Informed Assent Form (IAF) participants
SIESTA RCT
S64197

- The study data about me will be processed in coded form and retained for 25 years after the end of the study.
- I understand what is expected of me during this study.
- I am participating in this study of my own free will.
- I will receive a reimbursement of up to 50 euros if I complete the questionnaires and the sleep diary before and after the fully completed training and if I wore the actigraph.
- I am aware that this study was approved by an independent Research Ethics Committee UZ/KU Leuven.
- I am aware that all information is going to be treated confidentially. This is in accordance with the General Data Protection Regulation (GDPR). They ensure that data is protected and not allowed to be passed on to just anyone. I know that I can find more information about this in my parents’ informed consent.
- I know that I am insured through the study in case of damage and/or injury arising from the study. I know that if I want more information about this, it is in my parents’ informed consent.
- I may withdraw from the study at any time without giving a reason for this decision and know that no harm will come to me as a result. The data collected up to that point will be retained.
- For any questions, complaints and further follow-up, after my participation I know I can contact:
  - Researchers: see first page at top
  - Ethics committee: ec@uzleuven.be
  - Privacy committee: privacy@kuleuven.be
  - Data protection authority: contact@apd-gba.be

☐ I have read and understood the information above and have received answers to all my questions about this study. I agree to participate.

Date:

Name and signature participant  Name and signature researcher
Title of study: SIESTA: Sleep IntervEnion as Symptom Treatment for ADHD - Blended CBT sleep intervention to improve sleep, ADHD symptoms and related problems in adolescents with ADHD

Sponsor: KULeuven; Oude Markt 13, 3000 Leuven (sponsored by TBM fund of Scientific Research Fund – Flanders (FWO))
Research institute: ADHD-consultation of UPC KU Leuven; Herestraat 49, 3000 Leuven
Medical ethics committee: Ethics Committee Research UZ/KU Leuven

Information letter for parent(s)/guardian(s) of participants in scientific research

1 Introduction:

Scientific research has shown that in adolescents with Attention Deficit Hyperactivity Disorder (ADHD) there is a sharp increase in problems in daily life (for example, with planning and organizing) and in other problems besides ADHD. For example, up to 75% of adolescents with ADHD experience sleep problems, such as difficulty falling asleep and/or waking up a lot during the night. This in turn, can affect a whole range of other domains, for example, difficulty paying attention, being easily distracted, difficulty organizing school work and his/her mood. It is therefore essential to treat these sleep problems as well as all other problems.

We have developed an intervention for this. This cognitive behavioral training focuses on planning, sleep behavior and motivation. The training consists of 7 individual sessions with the adolescent and 2 sessions with parents/guardians. By participating in this study, your son/daughter will receive this training for free (either immediately or 6 months later, the training lasts about 10 weeks). On top of that, your son/daughter will receive up to 50 euros for participating in the training and completing all parts of the study (actigraph, sleep diary, questionnaires).

2 Description of the study:

At the start of the study, we collect information about your son/daughter using questionnaires, which are filled in by themselves, you as parent(s)/guardian(s), and a teacher. In addition, an abbreviated intelligence test (WISC/WAIS) is administered to your son/daughter, we interview you (K-SADS) and ask about his/her sleep patterns. If some of this information can be found in your son/daughter's medical file, we can - with your permission - extract this information from the file. Furthermore, your son/daughter's sleep will be measured for one week using a watch that measures sleep (actigraph) and at the same time he/she will fill in a sleep diary every day.

Based on this information, we will evaluate whether your son/daughter can participate in the study. If so, we will ask your son/daughter, you as parent(s)/guardian(s) and a teacher to complete more questionnaires. The intervention itself consists of 7 individual sessions with your son/daughter and 2 sessions with you, during which we work on changing sleep patterns and sleep hygiene. Planning and motivation is also addressed. If, based on this information, your son/daughter can participate, a randomization will take place. This randomization determines whether your son/daughter will receive the training immediately or 6 months later. If the result of the randomization is that your son/daughter receives the training 6 months later, you will then be asked again if you are still interested.
More detailed information can be found under item 3: Details of the study.

Important for this study is to obtain complete information of as many adolescents as possible. Therefore, if you decide to participate, we ask that you cooperate in all parts of the study. Nevertheless, your participation is completely voluntary and you can stop at any time without having to provide an explanation. All your data will be treated in a confidential manner. We are covered by insurance in case you experience any damage as a result of participating in the study.

3 Details of the study:

Legend:
Informed consent/assent = an informed consent that you and your son/daughter sign to participate in this study
Screening = measurements we take to determine if your son/daughter can participate in the study
Exclusion = decision that your son/daughter cannot participate in the study
Pretest = the measurements that precede the training to determine the effectiveness of the training
Informed Consent Form (ICF) parent(s)/guardian(s)
SIESTA RCT
S64197

afterwards

Randomization = it is determined by chance whether your son/daughter can participate in the training immediately or 6 months later
Training group = if your son/daughter is placed in this group after randomization, he/she will start the training immediately after the pretest
Control group = if your son/daughter is in this group after randomization, he/she can start the training in 6 months if he/she still wishes to do so
Posttest = the measurements that will take place after the training in order to determine the effectiveness of the training by comparing pretest and posttest measurements
Follow-up = the measurements that will take place 4-5 months after the training in order to determine the medium long-term effectiveness of the training by comparing posttest and follow-up measurements

3.1 Tests:

3.1.1 Questionnaires

We will ask your son/daughter, you and a teacher to fill in questionnaires about your son/daughter. Which questionnaires actually need to be filled in, depends on his/her age and also on questionnaires that may have already been filled in recently and can be found in the patient file. In the table below you will find an overview of all the questionnaires used in the study and who will fill them in. If you have completed all the required questionnaires at all study points, your son/daughter will be reimbursed up to a maximum of 50 Euros.

<table>
<thead>
<tr>
<th>Questionnaire</th>
<th>Informant</th>
<th>Duration in minutes</th>
</tr>
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<tbody>
<tr>
<td>1st meeting (screening)</td>
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<td></td>
</tr>
<tr>
<td>Basic information</td>
<td>Parent(s)/guardian</td>
<td>2</td>
</tr>
<tr>
<td>Basic information</td>
<td>adolescent</td>
<td>2</td>
</tr>
<tr>
<td>Holland Sleep Disorders Questionnaire (HSDQ)</td>
<td>adolescent</td>
<td>4</td>
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<tr>
<td>Measurements in the Addictions for Triage and Evaluation - Youth (MATE-Y)</td>
<td>adolescent</td>
<td>2</td>
</tr>
<tr>
<td>Physical Development Scale (PDS)</td>
<td>adolescent</td>
<td>3</td>
</tr>
<tr>
<td>Clinical Videogaming Addiction Test (C-VAT)</td>
<td>adolescent</td>
<td>3</td>
</tr>
<tr>
<td>2nd, 3rd and 4th meeting (pre-, post, follow-up measurement)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Adolescent Sleep Hygiene Scale (ASHS) (+ School Sleep Habits Survey (SSHS))</td>
<td>adolescent</td>
<td>7</td>
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<tr>
<td>Chronic Sleep Reduction Questionnaire (CSRO)</td>
<td>adolescent</td>
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</tr>
<tr>
<td>Children Sleep Habits Questionnaire (CSHQ)</td>
<td>parent(s)/guardian</td>
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<tr>
<td>Quick Delay Questionnaire (QDQ)</td>
<td>adolescent</td>
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</tr>
<tr>
<td>Child Depression Inventory (CDI-2)</td>
<td>adolescent</td>
<td>4</td>
</tr>
<tr>
<td>Screen for Child Anxiety Related Emotional Disorders (SCARED-NL)</td>
<td>adolescent</td>
<td>5</td>
</tr>
<tr>
<td>Homework Problems Checklist (HPC)</td>
<td>parent(s)/guardian</td>
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<tr>
<td>Confict Behavior Questionnaire (CBQ)</td>
<td>parent(s)/guardian</td>
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<tr>
<td>Disruptive Behavior Disorder Rating Scale (DBDERS)</td>
<td>parent(s)/guardian</td>
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<tr>
<td>Cognition And Motivation in Everyday Life (CAMEL)</td>
<td>parent(s)/guardian</td>
<td>6</td>
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<tr>
<td>Classroom Performance Survey (CPS)</td>
<td>teacher</td>
<td>2</td>
</tr>
</tbody>
</table>
3.1.2 Kiddie Schedule for Affective Disorders and Schizophrenia (K-SADS)

The K-SADS is an interview that is administered to you as parent(s)/guardian(s) (your son/daughter does not need to be present for this). The questions you will be asked during the administration of the K-SADS are the same for every participant. The answers you give will be converted into numbers by the researcher and entered into a computer. In this way, the K-SADS not only allows us to collect a lot of information, but also to calculate scores. Administration of the K-SADS takes about 1 hour and takes place at UZ Leuven (Gasthuisberg), at PraxisP (the academic clinical center of the Faculty of Psychology and Educational Sciences, KU Leuven) or in case of an outbreak of COVID-19 or if desired digitally (via Mynexuzhealth or the platform of PraxisP, with Skype for Business as backup). If a K-SADS was administered within the last two years, this part of the study may be omitted.

3.1.3 Sleep interview

During a sleep interview your son/daughter and you will be asked questions to get a detailed overview of his/her sleep. Different aspects of sleep will be discussed, such as sleep pattern, any difficulty he/she may have falling asleep or waking up at night, sleep hygiene, daytime sleepiness, etc. This interview is structured and based on the characteristics that are essential for a good interview about sleep as described in the literature and will take up to one hour. This will also be conducted at UZ Leuven (Gasthuisberg) or PraxisP (KU Leuven). In the case of an outbreak of COVID-19 or if you wish, the sleep interview can be conducted digitally (via Mynexuzhealth or via the platform of PraxisP, with Skype for Business as backup).

3.1.4 Abbreviated intelligence test

An abbreviated intelligence test (WISC/WAIS) consists of several assignments that your son/daughter must try to do to the best of his/her ability. A researcher accompanies him/her in a quiet room, explains the assignments to him/her and scores the answers. The abbreviated intelligence test is administered at UZ Leuven (Gasthuisberg) or PraxisP (KU Leuven) and takes approximately 0.5 hours. Your son/daughter does not need to prepare for the abbreviated intelligence test. If an intelligence test has been taken in the past two years, this part of the study may be omitted. In the case of an outbreak of COVID-19 or if you wish, this part can be done digitally (through Mynexuzhealth or through PraxisP's platform, with Skype for Business as a backup).

3.1.5 Sleep diary

Your son/daughter will be asked to keep a sleep diary three times for one week (at the first appointment, 6-10 weeks later and after 4-5 months). In the sleep diary he/she has to indicate the times when he/she went to bed, fell asleep, woke up and got up. Completing the sleep diary takes up to 3 minutes. It is filled in using m-Path and two reminders are sent each day at moments of their choice.

3.1.6 Actigraph (watch that measures sleep)

During the week in which your son/daughter fills in the sleep diary, he/she will be given a watch that measures his/her sleep. The watch will track when he/she goes to bed, falls asleep, wakes up and gets up. The data will then be used (along with the sleep diary) to calculate your son/daughter's sleep time. We will ask your son/daughter to do this three times (same as sleep diary). Together with your son/daughter and you, we will make arrangements on how to organize this in the most convenient way.
3.2 Study process

Before having to decide whether you want to participate in this study, you will get sufficient time to go through this information letter, to think about it, to discuss it with others, and if necessary, to ask for additional information. We will also explain the entire study during the first contact via the telephone. In case you still have questions, you can always contact one of the researchers: Elien, Yana, Lena and Finja (at the end of the document, you can find the contact details). After receiving the information, you have to decide whether you want to participate. In case you do, you have to fill in the form of approval (at the end of the document) and deliver the signed document to one of the researchers.

If you decide to participate in this research, one of the researchers, who is working at UZ Leuven (Elien Beerts), will look in the patient file of your son/daughter to retrieve all available information and copy it into a coded data file (coded means that the name is connected to a number and all data will be saved using that number instead of the entire name). Additionally, it will be checked whether some parts of the research can be skipped (questionnaires, K-SADS, sleep interview, or shortened intelligence test). Your son/daughter, you as parent(s)/guardian(s) and one teacher will be invited via e-mail to fill in online questionnaires. On top of that, we will schedule a moment for the K-SADS, the sleep interview and the shortened intelligence test. During that appointment, your son/daughter will also receive information about the sleep diary and the watch that is measuring sleep. In case of an outbreak of COVID-19, you will receive the watch via a courier and the use of the clock and the sleep diary will be explained via Mynexuzhealth (or the platform of PraxisP, backup Skype for Business).

If your son/daughter fulfills all criteria to participate in the training, we will schedule the sessions for the intervention. This happens either directly after the second appointment (pretest) or half a year later, depending on the group your son/daughter is randomized to. These sessions can be recorded to be used during supervision for the trainers. The audio recordings will also be used by the researchers to assess integrity and reliability of the training, given by the trainer. Only the trainer, the supervisor and the researchers will listen to the recordings and directly after supervision, the fragments will be deleted. After 6-10 weeks, your son/daughter will be asked again to wear the watch and fill in the sleep diary, and again 4-5 months later. Additionally, all of you will be asked again to fill in questionnaires.

3.3 Data storage

The coded results of the research will be retained for 25 years, counting from either the publication of results or the ending of subsidiary of the project, to ensure the validity of the research (RDM policy, KU Leuven). All results will be stored in a safe locality at the KU Leuven.

3.3.1 Reuse of data

Within the scope of this research, there are always new developments and insights. Therefore, it might happen that the results of this research will be published again within a different research, and within the 25 years that the data is kept. This research will then be within the field of the current study and will thus focus on sleep problems of adolescents with ADHD. Any additional research outside of the trial, must be approved by a Belgian recognized ethics committee.
3.4 Benefits and possible risks:

3.4.1 Benefits:
One benefit of participating in this research is the fact that your son/daughter will receive a training tackling his/her sleep problems for free. Next to that, we will be able to improve the training based on your experiences. Additionally, you will get a reimbursement: your son/daughter will receive maximally 50 euros if they wear the watch before and after the training and fill in the questionnaires and sleep diaries. If it seems during the research that additional research and/or treatment is needed, we will discuss this with you and provide you with the contact details of a doctor or health professional that you can contact.

3.4.2 Possible risks:
Normally there are no risks connected to filling in the questionnaires and the standardized interviews and tests, however, every participation in a study includes a small risk. In general, it can happen that you get tired during the research. Then we will have a little break or figure out how we can help best. Additionally, there is always the possibility of psychological help. Lastly, there is always the possible risk that there are problems with the measurements to ensure the confidentiality of personal data.

4 Costs:
Participation in this research will not result in any additional costs for you.

5 Reimbursement:
You will receive a reimbursement for participation in this research of maximally 50 euros (after you have filled in the questionnaires and the sleep diary, and worn the watch before and after the training).

6 Participation and withdrawal:
Participation in the study is completely voluntarily.

Your decision of giving consent, to the usage and processing of your data and/or images for this case report, is completely voluntary. If you refuse, no further actions need to be done. You don’t have to sign anything or justify your decision. Also, you can always withdraw your consent, without any reason. Your decision won’t affect the quality of your further relation with the researchers or teacher in any manner. In case you do not want to participate anymore, we will keep the coded data that has been collected before your withdrawal.

You can ask questions about the possible and/or known risks or disadvantages at any time. If data is retrieved during the study that might have an influence on your willingness to continue participating, we will inform you. If you experience any disadvantage based on your participation in this study, there will be a suitable consequence.

7 Ethics Committee
This study was reviewed and approved by the Ethics Committee Research UZ/KU Leuven. It will be operated in accordance with the ethical principles set out in the latest version of the “Helsinki Declaration”, which has been developed to protect participants of clinical studies, and the “Good Clinical Practices”. In no way should the favorable opinion of the Ethics Committee Research UZ/KU Leuven be interpreted as an incentive to take part in this study.
If you have any questions relating to your rights as a patient in a study, you can contact the patient rights ombudsman of your institution on this telephone number: +32 16 34 48 18 (between 8:30 and 16:30 o’clock). If necessary, he/she can put you in contact with the ethics committee.

8 Confidentiality:
In accordance with the Belgian law from 22 August 2002 regarding the rights of the patient and the General Data Protection Regulation (GDPR) (EU) 2016/679 from 27 April 2016 regarding the protection of the processing of personal data of humans and the free circulation of those data, we will respect your personal privacy.

All information collected during this study will be coded. The key to these codes will only be accessible to the researchers, so only they will be able to trace your son/daughter’s research data back to the personal data. The key for coding the data will be removed after the data collection of the study. Only then, will the data be analyzed. Only the coded data will be used in any documentation, reports or publications (in medical journals or conferences) about the study. Confidentiality of the data is thereby guaranteed at all times. Both personal data and data concerning the health of your son/daughter will be processed and kept for at least 25 years. The data controller is KU Leuven, who is also the sponsor. The research team of the KU Leuven will have access to your personal data relevant to the research (among others questionnaire material, intelligence research, clinical interviews) of the UZ Leuven. Limited information from the sleep interview, K-SADS and the results from the questionnaires (HSDQ and MATE-Y) from the first appointment will be reported back to the trainer involved. Furthermore, in case of Serious Adverse Events or a crisis situation, for example suicidality, (already involved) care providers can be contacted by the researchers.

The (coded) research data may be transmitted to Belgian or other regulatory authorities, to the relevant ethics committees, to other physicians/psychologists and/or institutions working with the sponsor. They may also be transmitted to other sites of the sponsor in Belgium and in other countries where the norms for protection of personal data may be different or less strict. This is always done in coded form as explained above. Your consent to participate in this study therefore also means that you agree to your encoded medical data being used for purposes described in this information form and to be transferred to the above-mentioned people and/or institutions. The sponsor will use the collected data in the context of the study in which you are participating, but also wants to be able to use them in the context of other studies on the same disorder as yours. Outside the context described in this document, your data can only be used if an ethics committee has given its approval.

If you withdraw your consent to participate in the study, the coded data already collected before your withdrawal will be retained. This will ensure the validity of the study. No new data will be transmitted to the sponsor.

Representatives of KU Leuven, auditors, the Ethics Committee Research UZ/KU Leuven and the competent authorities have direct access to your files to check the procedures of the study and/or the data, without violating confidentiality. These people are bound by professional secrecy or by a confidentiality agreement. This can only be done within the limits permitted by the relevant laws. By signing the consent form, after prior explanation, you agree to this access.

If you have any questions about how we use your data or if you want to stop further processing, you can always contact your physician-researchers at the following contact address: Tiensestraat 102 - box 3720, 3000 Leuven. If you have any further concerns or complaints, you can contact the KU Leuven privacy team at privacy@kuleuven.be.
Informed Consent Form (ICF) parent(s)/guardian(s)
SIESTA RCT
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You have the right to complain about how your information is handled to the Belgian supervisory authority responsible for enforcing data protection laws:

Data Protection Authority (DPA)
Drukpersstraat 35 – 1000 Brussels
Tel. +32 2 274 48 00
E-mail: contact@apd-gba.be
Website: www.gegevensbeschermingsautoriteit.be

9 Insurance in case of damage:

Any participation in a study involves a risk, however small. The sponsor is liable - even in the absence of fault - for the damage to the participant or, in the event of his/her death, to his/her successors, if it is directly or indirectly related to his/her participation in the study. Consequently, you do not need to demonstrate fault. For this purpose, KU Leuven has an insurance policy with no fault liability in accordance with article 29 of the law of experiments on the human person of 7 May 2004 (Amlin Insurance SE; policy number 299.053.700). We therefore request that you report every new health problem to the physician-investigator. He/she can provide you with additional information about possible treatments. If the medical examiner believes that there may be a connection with the study, he/she will inform the sponsor of the study who will initiate the declaration procedure with the insurance company. The latter will, if it deemed necessary, appoint an expert to make a judgment on the connection between your new health complaints and the study.

In the event of disagreement with the medical examiner or with the expert appointed by the insurance company, and at any time if you consider it necessary, you or, in the event of your death, your successors may sue the insurer directly in Belgium (Amlin Insurance SE; policy number 299.053.700; Vanbreda Risk & Benefits NV, Plantin en Moretuslei 297, 2140 Antwerp).

The law provides that the insurer can be sued either at the court of the place where the harmful events occurred, or at the court of your place of residence, or at the court of the insurer's registered office.

10 Contact:

We would like to thank you in advance for reading this information letter carefully. If you would like additional information about the study or about your rights and obligations, or if you would like to report any potential adverse effects as a result of the study, you may contact us at any time during the course of the study:

Elien Beerts  elien.beerts@upckuleuven.be  0490 58 48 23
Yana Vlaeyen  yana.vlaeyen@uzleuven.be  0491 72 87 34
Lena Keuppens  lena.keuppens@kuleuven.be  016 32 17 34
Finja Marten  finja.marten@kuleuven.be  016 32 01 16
Prof. Dr. Marina Danckaerts  marina.danckaerts@kuleuven.be  016 34 38 21
Prof. Dr. Saskia van Der Oord  saskia.vanderoord@kuleuven.be  016 32 58 24
Prof. Dr. Dieter Baeyens  dieter.baeyens@kuleuven.be  016 32 60 68
Every box has to be ticket if the participant agrees to participate

<table>
<thead>
<tr>
<th>I declare that I have read the document “Information letter for participants of scientific research” and got a copy. I agree with the content of the document and also agree to take part in the study.</th>
</tr>
</thead>
<tbody>
<tr>
<td>I received a copy of the signed and dated informed consent form. I have been informed of the nature, the purpose, the duration, and the expected effects of the study and what is expected of me. I have been informed of the possible risks and benefits of the study. I have had the opportunity to ask any questions that came to mind and have obtained a satisfactory response to my questions.</td>
</tr>
<tr>
<td>I agree to cooperate with the responsible researchers. I will inform them if my son/daughter experiences unexpected or unusual symptoms.</td>
</tr>
<tr>
<td>I understand that the sponsor has taken out an insurance in case I should suffer any damage in connection with my participation in this trial.</td>
</tr>
<tr>
<td>I am aware that this study was reviewed and approved by the independent Ethics Committee Research UZ/KU Leuven. This study will be operated in accordance with the ethical principles set out in the latest version of the “Helsinki Declaration”, which has been developed to protect participants of clinical studies, and the “Good Clinical Practices” (GDP). I am aware that my identity and data will be protected. This approval was in no way the reason to participate in this study.</td>
</tr>
<tr>
<td>I am aware that I can always withdraw my consent, without any reason. This will not affect the quality of my further relation with the researchers in any manner. In case I do not want to participate any longer, the coded data that has been collected before my withdrawal will be kept. Thereby, the validity of the study will be ensured. This is in alignment with the GDPR law due to the fact that the data collection is of general importance. This is also in alignment with the Helsinki Declaration (1964).</td>
</tr>
<tr>
<td>I have been informed that my coded data will be processed and kept during 25 years. I agree with that.</td>
</tr>
<tr>
<td>I have been informed that my coded data, as well as the coded data of my son/daughter, as well as data concerning the health of my son/daughter, will be processed and kept for 25 years. I agree to this.</td>
</tr>
<tr>
<td>I consent to the use of my data for future research within 25 years. This research will continue to focus on sleep problems in adolescents with ADHD.</td>
</tr>
<tr>
<td>I understand that auditors, representatives of the sponsor, the Ethics Committee Research UZ/KU Leuven or competent authorities may wish to inspect the data to verify the information collected. These people are bound by professional secrecy or by a confidentiality agreement. By signing this document, I consent to this inspection.</td>
</tr>
<tr>
<td>Furthermore, I am aware that certain data will be passed on in coded form to the research institution, KU Leuven or other institutes as already mentioned on pages 7 and 8. I give my permission for this. At all times my privacy and the privacy of my son/daughter will be respected.</td>
</tr>
<tr>
<td>I am participating in this study on a voluntary basis.</td>
</tr>
<tr>
<td>I consent to my son/daughter participating in the study.</td>
</tr>
<tr>
<td>I hereby authorize the researchers to access my son/daughter’s patient record, extract from it the information needed for the study described above, and store it in a separate, encrypted database.</td>
</tr>
</tbody>
</table>
Informed Consent Form (ICF) parent(s)/guardian(s)  
SIESTA RCT  
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I hereby give permission to the researchers to receive a copy of WISC/WAIS and/or K-SADS reporting from the past 2 years for the first appointment. This may result in the first appointment being shorter.

I participate in the study including questionnaires, observations and interviews. If applicable, I also participate in the treatment process.

Name of the adolescent: ____________________________________________

Date of birth of the adolescent: ____________________________________

Name of the parent(s)/guardian: ________________________________

Date: __________________________________________________________

Signature of the parent(s)/guardian: ________________________________

Researcher’s statement:

I confirm that I have explained the nature, purpose, and foreseeable effects of the study to the above-named volunteer.

The volunteer agreed to participate by providing his/her personally dated signature.

Name of the person who gave prior explanations:

Date: __________________________________________________________

Signature of the researcher: ________________________________________