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:
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. Saskia van der Oord  saskia.vanderoord@kuleuven.be  016 32 58 24
Prof. Dr. Dieter Baeyens  dieter.baeyens@kuleuven.be  016 32 60 68
Prof. Dr. Marina Danckaerts  marina.danckaerts@kuleuven.be  016 34 38 21

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