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

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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>
</thead>
<tbody>
<tr>
<td>1st meeting (screening)</td>
<td></td>
<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>
</tr>
<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>
</tr>
<tr>
<td>Chronic Sleep Reduction Questionnaire (CSRQ)</td>
<td>adolescent</td>
<td>4</td>
</tr>
<tr>
<td>Children Sleep Habits Questionnaire (CSHQ)</td>
<td>parent(s)/guardian</td>
<td>5</td>
</tr>
<tr>
<td>Quick Delay Questionnaire (QDQ)</td>
<td>adolescent</td>
<td>1</td>
</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>
<td>2</td>
</tr>
<tr>
<td>Conflict Behavior Questionnaire (CBQ)</td>
<td>parent(s)/guardian</td>
<td>4</td>
</tr>
<tr>
<td>Disruptive Behavior Disorder Rating Scale (DBDRS)</td>
<td>parent(s)/guardian</td>
<td>6</td>
</tr>
<tr>
<td>Cognition And Motivation in Everyday Life (CAMEL)</td>
<td>parent(s)/guardian</td>
<td>6</td>
</tr>
<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 save 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.
Informed Consent Form (ICF) parent(s)/guardian(s)
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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: Tienestraat 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.
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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 ticked 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” (GDPR). 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>
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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: _______________________________________________