Sleep for attention by attention to sleep

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20912

Source
NTR

Brief title
Sleep for attention

Health condition

ADHD in adults
Sleep disorders

Sponsors and support

Primary sponsor: PsyQ Expertise Center Adult ADHD, The Hague.
Source(s) of monetary or material Support: PsyQ Expertise Center Adult ADHD, The Hague; Nederlands Slaap Instituut, Amersfoort.

Intervention

Outcome measures

Primary outcome

The comparison of the reduction on the ADHD-RS between treatment arms

Secondary outcome

The comparison of the reduction on the objective ADHD symptoms using the QbTest, and the

depressive symptoms using the QIDS between treatment arms.

The study will also provide the opportunity to examine the following:
a. The baseline EEG characteristics and the hypnograms of the total group of adults with ADHD.
b. The evaluation of each treatment arm on the improvement of subjective sleep quality using the PSQI, and also objective sleep using the Actiwatch and home-PSG characteristics (EEG and hypnogram).
c. The types and severities of sleep disorders and their indicated treatments in adults with ADHD.
d. The effect of TAU on the objective sleep parameters from the Actiwatch and home-PSG

Study description

Background summary

Rationale: Attention-deficit/hyperactivity disorder (ADHD) is highly associated with a delayed circadian rhythm, which is prevalent in 73-78% of children and adults with ADHD. Also sleep disorders such as restless legs syndrome, sleep-disordered breathing, and insomnia are increased in ADHD. The persistence of ADHD symptoms from childhood into adulthood is even predicted by sleep problems. Sleep problems are currently seldom diagnosed and treated in psychiatry. Sleep problems increase cognitive symptoms of ADHD. Treating sleep problems is hypothesized to decrease the severity of ADHD.
Objective: To investigate the effect of sleep treatment on ADHD, mood and sleep quality.
Study design: Open-label randomized controlled trial
Study population: N=60 adults with ADHD who screen positive for a sleep disorder.
Intervention (if applicable): Participants will have a sleep screening using the HSDQ, clinical assessment and polysomnography (PSG) at home. Then, they are randomized for a 12-week intervention of (1) a protocolled sleep treatment for their sleep disorder; (2) treatment as usual (TAU) for ADHD; or (3) a combined treatment of sleep and TAU. At three time points the ADHD symptoms, sleep and mood are evaluated objectively and subjectively.
Main study parameters/endpoints: Each intervention is evaluated for its effect on the reduction of self-reported and objective ADHD symptoms, mood symptoms, and sleep quality. Treatment of sleep is hypothesized to lead to a reduction of ADHD symptoms. The combined treatment of sleep and ADHD is expected to have the highest effect on ADHD. The data will give insight into any treatment effect on the objective PSG signals, and also a cluster analysis for sleep and ADHD will be possible in order to examine if sleep parameters are related to behavioural or psychiatric aspects in ADHD.

Study objective

(1) The stand-alone treatment of sleep problems will have a clinically significant effect on the reduction of ADHD symptoms in adults with ADHD.
(2) The concurrent treatment of sleep problems and usual care is more effective than usual

care to treat ADHD in adults with ADHD.
(3) The concurrent treatment of sleep problems and usual care is more effective than the stand-alone treatment of sleep problems to reduce ADHD symptoms in adults aith ADHD.

Study design

The study is 14 weeks in total.
T0: baseline measurements at week 1. Then, the 12-week interventions start.
T1: a mid-term evaluation of the ADHD and mood symptoms at week 7.
T2: the final week of the study period, at week 14.

Intervention

A 12-week intervention of: (1) a protocolled sleep treatment for their sleep disorder; (2) treatment as usual (TAU) for ADHD; or (3) a combined treatment of sleep and TAU.

Contacts

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Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria: age 18-50 years, diagnosed ADHD (or ADD), understanding of the Dutch language, a positive screening on the HSDQ for at least one of the following sleep disorders: DSPS, RLS / PLMS, sleep-disordered breathing, and/or insomnia.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study: comorbid disorders that require immediate treatment, psychotic disorder, mental retardation, pregnancy or active wish to conceive (in females), use of ADHD or sleep medication in the prior month, history of sleep treatment, and any morbidity affecting sleep (e.g. diabetes).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2019
Enrollment:	60
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 54573
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL7489
CCMO	NL68572.058.18
OMON	NL-OMON54573

Study results