Sleep for attention by attention to sleep

Published: 09-09-2019
Last updated: 15-05-2024

To investigate the effect of sleep treatment on ADHD, mood and sleep quality.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON54573

Source
ToetsingOnline

Brief title
Sleep for attention

Condition

- Other condition
- Sleep disorders and disturbances

Synonym
Sleep disorders ; Attention-deficit/hyperactivity disorder (ADHD)

Health condition

ADHD

Research involving
Human

Sponsors and support

Primary sponsor: Parnassia Bavo Groep (Den Haag)
Source(s) of monetary or material Support: Nederlands Slaap Instituut,Parnassia Bavo Groep (Den Haag),PsyQ en Nederlands Slaap Instituut

Intervention

Keyword: Attention-deficit/hyperactivity disorder, Polysomnography, Randomized controlled trial, Sleep disorders

Outcome measures

Primary outcome

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.

Secondary outcome

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 description

Background summary

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.

Study objective

To investigate the effect of sleep treatment on ADHD, mood and sleep quality.

Study design

Open-label randomized controlled trial

Intervention

Participants have a routine sleep screening using the HSDQ. After a positive screen, they are asked to participate. Participation means 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 aimed at improving the sleep, irrespective of the underlying sleep disorder; (2) treatment as usual (TAU) for ADHD consisting of psyco-education, coaching, pharmacological therapy,, aimed to improving the ADHD and daily functioning; or (3) a combined treatment of sleep and TAU. At three time points the ADHD symptoms, sleep and mood are evaluated objectively and subjectively.

Study burden and risks

The participants will have standard screening for sleep disorders and diagnostic assessment for sleep disorders using home-PSG. To have the PSG at home is more comfortable than in a sleep lab, as is currently the common practice. For the current study, the home-PSG is equally valuable as lab-PSG. The sleep treatments in case of a sleep diagnosis is standard treatment for those with sleep disorders. TAU for ADHD does not include sleep treatment. The combined treatment for sleep and ADHD is novel in the current study. The burden for the participants is regarded to be low as each of the three interventions involves regular treatment for their assessed sleep disorder and ADHD. For the current study, the participants fill out a set of questionnaires and do the computerized objective QbTest (for the severity of ADHD symptoms) at three time points (3 x 40 minutes); wear an actometer (measuring sleep and wake) during a week at two time points; and have an second (re-test) home-PSG at the end of the intervention period. The assessments are non-invasive.

Contacts

Public
Parnassia Bavo Groep (Den Haag)

Carel Reinierszkade 197
Den Haag 2593 HR
NL
Scientific
Parnassia Bavo Groep (Den Haag)

Carel Reinierszkade 197
Den Haag 2593 HR
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion 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

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
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-03-2020
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO

Date:	09-09-2019
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	26-11-2021
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	31-10-2022
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	26-06-2023
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 20912
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL68572.058.18
OMON	NL-OMON20912

Study results

Date completed: 04-10-2023

Actual enrolment: 70

Summary results
Trial is onging in other countries