Sleep for attention by attention to sleep

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(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...

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20912

Bron
NTR

Verkorte titel
Sleep for attention

Aandoening

ADHD in adults
Sleep disorders

Ondersteuning

Primaire sponsor: PsyQ Expertise Center Adult ADHD, The Hague.
Overige ondersteuning: PsyQ Expertise Center Adult ADHD, The Hague; Nederlands Slaap Instituut, Amersfoort.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

(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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-06-2019
Aantal proefpersonen:	60
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 54573
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten