Investigating the best treatment for the Delayed Sleep Phase Syndrome in adults with Attention-Deficit/Hyperactivity Disorder and it’s effect on health and appetite

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22013

Source
Nationaal Trial Register

Brief title
FASE

Health condition

English:
Attention-Deficit/Hyperactivity Disorder (ADHD)
Delayed Sleep Phase Syndrome (DSPS)

Dutch:
ADHD
Verlate slaapfase syndroom

Sponsors and support

Primary sponsor: Marc Blom, PhD, Director PsyQ The Hague
Source(s) of monetary or material Support: Fonds NutsOhra
PsyQ Research Fund

PsyQ Expertise Center Adult ADHD

Intervention

Outcome measures

Primary outcome

The phase shift of the sleep/wake cycle as evaluated by the time of DLMO directly after treatment.

Secondary outcome

Improvement of appetite hormones

Improvement of diabetic parameters

Improvement of biomarker profiles

Improvement of cardiovascular parameters

Improvement of sleep parameters

Improvement of quality of life

Decrease of ADHD symptoms

Decrease of intake of carbohydrate-rich food

Treatment satisfaction

Study description

Background summary

About 80% of adults with Attention-Deficit/Hyperactivity Disorder (ADHD) have chronic sleep-onset problems and the majority of them has a Delayed Sleep Phase Syndrome (DSPS). DSPS is characterized by chronic sleep dept, which has negative consequences for physical health and is associated on the long term with weight gain, obesity, diabetes, hypertension, metabolic syndrome, cardiovascular disease, and even cancer. This study investigates the best treatment of DSPS (melatonin, placebo or melatonin and light therapy), and will determine whether patients with ADHD and DSPS have suboptimal biomarkers of chronic diseases like diabetes. Fifty-one adults with ADHD and DSPS will be recruited from the PsyQ

Outpatient clinics in the Netherlands.

Study objective

This study will investigate the best treatment of Delayed Sleep Phase Syndrome (melatonin, placebo or melatonin and light therapy), and will determine whether patients with ADHD and DSPS have blood values that may indicate susceptibility for chronic diseases like diabetes.

The results will give insight into the association between DSPS, ADHD, and chronic conditions such as diabetes, and may serve as a model for the increase in obesity and metabolic syndrome in the general population, in which sleep loss is common due to the extended use of artificial light.

Study design

All outcomes will be measured at baseline, directly after treatment and three weeks after treatment.

Methods of measurement:

Improvement of appetite hormones - blood

Improvement of diabetic parameters -blood

Improvement of biomarker profiles -blood

Improvement of cardiovascular parameters – ECG/ Ambulant Blood Pressure Monitor

Improvement of sleep parameters -actigraphy

Improvement of quality of life -questionnaire

Decrease of ADHD symptoms - questionnaire

Decrease of intake of carbohydrate-rich food -questionnaire

Treatment satisfaction -questionnaire

Intervention

Patients will be randomized for sleep education, plus:

(1) 0.5 mg of melatonin daily,

(2) 0.5 mg of placebo daily, or

(3) 0.5 mg of melatonin daily, plus 30 minutes of light therapy in the morning between 7 and 8 AM.

Each treatment takes three weeks; the Melatonin intake will be three hours before the patient's individually determined Dim-Light Melatonin Onset (DLMO), and will be advanced during the treatment period.

Contacts

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Eligibility criteria

Inclusion criteria

- Age between 18 and 55 years old

- Diagnosis ADHD

- Diagnosis DSPS

Exclusion criteria

- Psychotic illness

- Untreated mood disorder

- Untreated anxiety disorder

- Alcohol intake > 2U/day, or for woman >15U/week, for men >21 U/week

- Use of cannabis or harddrugs within one month prior to study participation

- Suspected dementia, anamnestic disorder or other cognitive disorder

- Mental retardation

- Use of the following medication within one month prior to study participation: psychostimulants, melatonin, mirtazapin, sleep medication, antipsychotics, clonidin, benzodiazepins, bèta-blockers

- Insufficient fluency of the Dutch language

- Evening or night shift work

- Travel over >2 time zones two weeks prior to study participation (because of possible jet lag)

- Pregnancy or breast feeding

- Having young children who may disturb night rest

- Type 2 diabetes mellitus

- Light therapy one month prior to study particatipation

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	16-05-2013
Enrollment:	51
Type:	Anticipated

Ethics review

Positive opinion

Date:	17-05-2013
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 46908
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL3831
NTR-old	NTR3999
CCMO	NL39579.058.12
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON46908

Study results