

Investigating bedtime procrastination and circadian phase in patients with delayed sleep phase disorder

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Sleep disturbances (incl subtypes)
Study type	Observational non invasive

Summary

ID

NL-OMON43738

Source

ToetsingOnline

Brief title

Bedtime procrastination in patients with DSPD

Condition

- Sleep disturbances (incl subtypes)

Synonym

disorder of the biological clock, sleep disorder

Research involving

Human

Sponsors and support

Primary sponsor: Philips Research

Source(s) of monetary or material Support: Philips Research

Intervention

Keyword: bedtime procrastination, circadian phase, delayed sleep phase disorder

Outcome measures

Primary outcome

The primary objective of the study is to investigate whether patients with DSPD suffer more from bedtime procrastination as compared to age- and sex-matched controls.

A1) A comparison of DSPD-patients* average score on the Bedtime Procrastination Scale (BPS) compared to age- and sex-matched healthy controls. A2) To evaluate the correlation between DLMO (Dim Light Melatonin Onset) and the score on the BPS in DSPD patients, to explore the relation between having a late circadian rhythm and the degree of bedtime procrastination.

Secondary outcome

B1) To investigate whether DSPD patients show increased reward dependence as compared to controls.

B2) To evaluate whether subtypes of DSPD patients can be identified with respect to reward dependence, lifestyle behaviour and occurrence of co-morbidities.

B3) To provide insight into needs, wishes and pitfalls of DSPD patients with respect to chronotherapy.

B4) To validate the phase estimation algorithm developed at Philips Research.

Study description

Background summary

Delayed sleep-phase disorder (DSPD) is a circadian rhythm sleep disorder. People with DSPD typically fall asleep some hours after midnight, may experience long sleep onset latencies and have difficulty waking up in the morning. Circadian rhythm disorders are often co-morbid with mental disorders (e.g. depression, anxiety, ADHD, addiction). DSPD is assigned to biological factors (i.e. genetics), to behavioural factors (lifestyle), or both. Chronotherapy treatment strategies should be individually adjusted and may be dependent on the underlying causes of DSPD in the individual. 'Bedtime Procrastination' is one of the factors that supports the development of DSPD. Self-control is a crucial factor in the application of chronotherapy and may be a pitfall of DSPD patients.

Study objective

The current research is set to provide insight into the phenotypic characteristics of DSPD patients in terms of psychological characteristics, occurrence of co-morbidities, and behavioural characteristics such as bedtime routines and lifestyle, and uses this information to increase the effectivity of chronotherapy interventions by developing new treatment strategies targeting the individual's motivation and self-control systems.

Study design

a cross-sectional case-control study

Study burden and risks

Participating in this study is at low risk since the investigational treatment does not involve any invasive procedures or medicinal products. Wrist-worn actigraphy, questionnaires and saliva sampling by spitting in a vial, are non-invasive manners of data collection. The burden for the patient mainly involves the time investment (completing a total of 9 questionnaires, wearing actiwatches during two weeks, and saving one evening to perform salivary DLMO measurements. The DLMO measurement is arranged in such a way that patients can do this measurement in their home setting, instead of the hospital, which reduces the burden. For DSPD patients, the desired treatment outcome is an earlier sleep episode and/or proper management of regular bedtimes. The ultimate aim is to develop new treatment strategies that will provide clear therapeutic benefit for the patient.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

DSPD patients:

-diagnosed with DSPD accruing to the International Classification of Sleep Disorders, ICSD

-age between 18 and 55 years

-score between 6-15 on the Horne Ostberg Chronotype Questionnaire; healthy controls:

-score between 16-32 on the Horne Ostberg Chronotype Questionnaire

-age between 18 and 55 years

-no self-reported (chronic) sleep complaints

Exclusion criteria

- unable to speak and read Dutch.

- vulnerable groups, such as people with psychotic illness, severe intellectual disability, or cognitive dysfunction.
- Shift work or transmeridian flights within 1 month prior to the study
- Presence of other dominant sleep disturbances as apparent from polysomnography examination

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	12-01-2017
Enrollment:	168
Type:	Actual

Ethics review

Approved WMO	
Date:	22-07-2016
Application type:	First submission
Review commission:	METC Slotervaartziekenhuis en Reade (Amsterdam)
Approved WMO	
Date:	05-02-2018
Application type:	Amendment
Review commission:	METC Slotervaartziekenhuis en Reade (Amsterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
CCMO	NL53284.048.15