Effects of melatonin treatment, light therapy, and sleep improvement in children with Delayed Sleep Phase Syndrome

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Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28494

Bron
Nationaal Trial Register

Aandoening

Delayed Sleep Phase Disorder, Delayed Sleep Phase Syndrome, DSPD, DSPS, sleep onset insomnia

Ondersteuning

Primaire sponsor: University, hospital
Overige ondersteuning: Pharma Nord

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

behaviour problems and cognitive functioning

Toelichting onderzoek

Achtergrond van het onderzoek

There is much evidence that quality and quantity of sleep is related to psychosocial and behavioural outcomes in children. Although there is a large amount of evidence indicating that sleep restriction leads to impaired functioning, much less evidence is available for the effects of sleep improvement. The current study aims to examine the psychosocial, behavioural, and cognitive effects of sleep improvement in children with insufficient sleep due to Delayed Sleep Phase Syndrome (DSPS).
The general aim of the present study is to investigate, in a longitudinal-experimental design, the effects of melatonin treatment and light therapy in children on sleep, health, and various psychosocial, behavioural, and cognitive outcomes. A second aim is to investigate whether improvements in psychosocial, behavioural and cognitive outcomes can be attributed to improved sleep, or to melatonin or light therapy itself. Third, relationships between children's sleep, functioning, and parenting will be examined.

Doel van het onderzoek

The general aim of the present study is to investigate, in a longitudinal-experimental design, the effects of melatonin treatment and light therapy in children on sleep, health, and various psychosocial, behavioural, and cognitive outcomes. A second aim is to investigate whether improvements in psychosocial, behavioural and cognitive outcomes can be attributed to improved sleep, or to melatonin or light therapy itself. Third, relationships between children's sleep, functioning, and parenting will be examined.

Onderzoeksopzet

After 4 weeks treatment and 12 weeks follow-up

Onderzoeksproduct en/of interventie

The study has an experimental design with 3 groups: "melatonin", "placebo melatonin", and "light therapy". Children are randomly assigned to one of the groups. After a baseline period of one week, children receive melatonin treatment, placebo melatonin, or light therapy for four weeks. A follow-up takes place 12 weeks later.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- The child is between 7 and 12 years old,
and

- The child has chronic sleep onset problems, which is indicated by:

a. complaint of inability to fall asleep at the desired clock time (Sleep onset later than 20:45 h in children aged 7 years and for older children 15 minutes later per year until and including age 12, and a latency between lights-off time and sleep onset (sleep onset latency) of more than 30 minutes),

b.
the symptoms are present for at least 4 nights a week, for at least 1 month during a regular school period,
and

- Dim Light Melatonin Onset (DLMO, the clock time at which the endogenous melatonin secretion reaches the threshold of 4 pg/ml) later than 19:45 h in children aged 7 years and

for older children 15 minutes later per year until and including age 12,
and

- the sleep problems result in problems with daytime functioning . Children should have the following symptoms:

a) sleepiness/tiredness during the day
and at least one of the following:

b) external behaviour problems

c) internal behaviour problems

d) problems with functioning at school.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- pervasive developmental disorder

- chronic pain

- known disturbed hepatic or renal function

- Roter or Dubin-Johnson syndrome

- epilepsy

- use of stimulants, neuroleptics, benzodiazepines, clonidine, antidepressants, hypnotics, or â-blockers within 4 weeks before enrolment

- total IQ <80.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind

Controle:	Placebo

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-09-2013
Aantal proefpersonen:	192
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	26-06-2013
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 39468
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3884
NTR-old	NTR4045
CCMO	NL38852.018.12
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON39468

Resultaten

Samenvatting resultaten
N/A