The effect of protocolled cognitive behavioural therapy for insomnia (CBT-I) on sleep, vigilance, working memory and aggressive behaviour.

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In this study, the objective is to examine the effect of protocolled cognitive behavioural therapy for insomnia (CBT-I) in adolescents with complex psychiatric problems and sleeping problems (problems falling asleep, staying asleep and/or waking up...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Sleep disorders and disturbances
Study type	Interventional

Summary

ID

NL-OMON49746

Source
ToetsingOnline

Brief title
Effect of CBT-I on sleep, vigilance, working memory and aggression

Condition

- Sleep disorders and disturbances

Synonym
insomnia, Sleeping problems

Research involving
Human

Sponsors and support

Primary sponsor: GGZ Eindhoven (Eindhoven)

Source(s) of monetary or material Support: GGzE

Intervention

Keyword: Aggressive behaviour, Cognitive behavioural therapy, Sleep, Working memory

Outcome measures

Primary outcome

The study parameters are:

(1) the decrease in minutes 'awake in bed' on the sleep calendar

(2) the improvement in vigilance

(3) the improvement in working memory

(4) the decrease in aggressive behaviour on a behavioural questionnaire

Secondary outcome

Not applicable.

Study description

Background summary

Sleeping problems in adolescents have received little attention, even though several studies show that the prevalence of these problems in adolescents is high. Moreover, the prevalence in adolescents with psychiatric problems is even higher: up to 60-80% of adolescents with ADHD or autism suffer from sleeping problems. Poor sleep is related to impairment of cognitive and psychological functioning and behavioural problems. Therefore, it is important to pay more attention to the treatment of sleeping problems, especially in adolescents with both (complex) psychiatric and sleeping problems.

Study objective

In this study, the objective is to examine the effect of protocolled cognitive behavioural therapy for insomnia (CBT-I) in adolescents with complex psychiatric problems and sleeping problems (problems falling asleep, staying asleep and/or waking up too early) on their vigilance, working memory,

aggressive behaviour and self-reported sleep efficiency.

Study design

A stepped wedge trial design is used including 31 adolescents admitted at The Catamaran, a hospital for youth forensic psychiatry and orthopsychiatry. In order to collect data, all adolescents will report their sleep on a sleep calendar during a week. Sixteen adolescents with sleeping problems will enrol into the intervention and form the experimental group. They will receive treatment with CBT-I, while computerized tests targeting vigilance and working memory and a behavioural questionnaire will be used to evaluate the effect of treatment. The other adolescents, without sleeping problems, form the control group. They will only report their sleep once more on a sleep calendar during a week in the last week (week 17) of the study.

Intervention

Adolescents in the experimental group will receive, in four clusters of four, a weekly, protocolled, CBT-I session with a total duration of six weeks. Every four adolescents will be individually treated but they will start at the same moment with their treatment. Every morning, the adolescents fill out a sleep calendar about their night*s sleep. Every three weeks and in total six times, vigilance and working memory will be measured with computerized tasks. Every six months, the adolescents in the experimental group and their key worker (*zaakwaarnemer*) complete a behavioural questionnaire as part of care as usual during their admission at The Catamaran. The score on aggressive behaviour before and after treatment will be used in this study.

Study burden and risks

No health risks are involved in participating in this study. The assumption is that the adolescents in the experimental group will directly benefit from participation because their sleeping problems will decrease. The main burden is their investment in time. The total burden is approximately three hours for each participant in the experimental group and 14 minutes for the participants in the control group in the time period of 17 weeks.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Age 16 up to and including 22 years
Having problems with falling asleep, staying asleep or waking up too early
Sleep efficiency is less than 85% on a self-reported sleep calendar

Exclusion criteria

Sleeping problems due to a Delayed Sleep Phase Disorder (DSPS)

Study design

Design

Study type: Interventional

Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	03-12-2020
Enrollment:	31
Type:	Actual

Ethics review

Approved WMO

Date:	14-07-2020
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

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	NL73980.028.20