

Randomized controlled trial of the effects of cognitive behavioral therapy for insomnia on sleep, impulsivity and aggression in forensic psychiatric patients

No registrations found.

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

Summary

ID

NL-OMON22798

Source

NTR

Brief title

Insomnia treatment in forensic patients

Health condition

Chronic insomnia

Sponsors and support

Primary sponsor: GGZ Drenthe Mental Health Institute, Zorgondersteuningsfonds

Source(s) of monetary or material Support: Zorgondersteuningsfonds, the Netherlands

Intervention

Outcome measures

Primary outcome

Insomnia severity as measured by self report questionnaire (ISI). Objective sleep efficiency as measured by actigraphy.

Secondary outcome

General psychopathology and level of impulsivity and aggression as measured by self report questionnaires (SCL-90, BIS and AQ)

Objective evaluation of level of impulsivity as measured by neuropsychological testing (Stop Signal Task and Iowa Gambling Task)

Taxation of risk of possible aggressive incidents by the treating physician (START)

Study description

Background summary

Background: Many patients with psychiatric disorders experience sleeping problems. Sleep disorders can be both cause and consequence of psychiatric disorders, and contribute strongly to daily dysfunction and diminished quality of life. Treating sleeping problems positively affects the course of psychiatric illness. In forensic psychiatric patients, treatment of sleeping disorders could be even more important, considering the association between quality and quantity of sleep on one hand, and impulsivity and aggression on the other. Poor sleep is a potential risk factor for impulsive and aggressive behavior. Our hypothesis is that treatment of sleeping problems in forensic psychiatric patients ameliorates sleep and general psychopathology, and reduces impulsivity and aggression.

Objective: Evaluating the effects of cognitive behavioral therapy for chronic insomnia (CBT-I) on sleep, general psychopathology, impulsivity and aggression in forensic psychiatric patients.

Study design: In this randomized controlled intervention study, subjects will undergo a 6-week protocolled treatment for insomnia. Criteria for chronic insomnia will be assessed during a diagnostic interview. Severity of insomnia, as well as the absence of other co-occurring sleeping disorders will be evaluated with the Sleep Diagnosis Questionnaire (SDQ). Furthermore, a minimum score of 1 is required on the impulsivity item and hostility item of the HKT-30 (a Dutch adaptation of the HCR-20, a risk taxation instrument), to be able to evaluate treatment effects. Additional information on psychiatric diagnosis and current use of (hypnotic) medication will be extracted from the medical files. Subsequently, subjects will be randomly assigned to either the intervention or a waiting list condition. Subjective evaluation of sleep, general psychopathology and level of impulsivity and aggression will be measured before and after treatment using four self report questionnaires: the Insomnia Severity Index (ISI), Symptom Checklist 90 (SCL-90), Barratt Impulsiveness Scale (BIS), and Aggression Questionnaire (AQ) respectively. Objective data on sleep characteristics and level of impulsivity will be obtained by actigraphy and two neuropsychological tests (Stop Signal Task and Iowa Gambling Task). Moreover, the treating physician will assess the possible occurrence of aggression by using the Short Term Assessment of Risk and Treatability (START, a risk taxation instrument). A follow-up evaluation will be carried out seven weeks

post-intervention.

Study objective

Poor sleep is a potential risk factor for impulsive and aggressive behavior. Our hypothesis is that treatment of sleeping problems in forensic psychiatric patients ameliorates sleep and general psychopathology, and reduces impulsivity and aggression.

Study design

weeks 0 (pre-treatment), 7 (post-treatment), 14 (follow-up), (21 (only for waiting list: post-treatment))

Intervention

Cognitive behavioral therapy for insomnia (CBT-i) versus waiting list

Contacts

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Eligibility criteria

Inclusion criteria

Male subjects between 18 and 55 years of age, currently under treatment by a forensic psychiatric facility.

Chronic insomnia (assessed by interview and Sleep Diagnosis Questionnaire (SDQ))

Exclusion criteria

Comorbid sleep disorders as RLS or sleep apnea (assessed by interview and Sleep Diagnosis Questionnaire (SDQ))

No objective impulsivity or hostility ((assessed by HKT-30)

Severe concurrent psychiatric illness or behavioral disorders requiring acute safety measures, interfering with ability to participate

Insufficient understanding of the Dutch language, disabling them to complete the questionnaires and neuropsychological task

Study design

Design

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

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-06-2017
Enrollment:	110
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion	
Date:	08-08-2019
Application type:	First submission

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
NTR-new	NL7943
Other	METC, Isala Zwolle, the Netherlands : 16.0356

Study results