

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

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

Samenvatting

ID

NL-OMON22798

Bron

Nationaal Trial Register

Verkorte titel

Insomnia treatment in forensic patients

Aandoening

Chronic insomnia

Ondersteuning

Primaire sponsor: GGZ Drenthe Mental Health Institute, Zorgondersteuningsfonds

Overige ondersteuning: Zorgondersteuningsfonds, the Netherlands

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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))

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	01-06-2017
Aantal proefpersonen:	110
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies	
Datum:	08-08-2019
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7943
Ander register	METC, Isala Zwolle, the Netherlands : 16.0356

Resultaten