investigating the efficacy of cognitive behavioral therapy in patients with substance use disorder and comorbid ADHD. A randomized controlled trial with cognitive behavioral therapy.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON37930

Source
ToetsingOnline

Brief title
nvt

Condition

- Other condition
- Cognitive and attention disorders and disturbances

Synonym
ADHD, attention-deficit hyperactivity disorder

Health condition

verslaving

Research involving
Human

Sponsors and support

Primary sponsor: Arkin (Amsterdam)
Source(s) of monetary or material Support: fonds Nuts Ohra

Intervention

Keyword: ADHD, cognitive behavioral therapy, SUD (substance use disorder)

Outcome measures

Primary outcome

During the trial, the Dutch version of the ADHD rating scale will be completed

three times (at the start of the trial, at the end, and at follow-up (3 months

after the last CBT session).

Secondary outcome

- TLFB (Time Line Follow Back): self-report measure for substance use

- Beck Depression Inventory (BDI)

- Beck Anxiety Inventory (BAI)

- EQ-5: quality of life

- TIC-P (health care consumption and production losses)

- neurocognitive task: Stroop

- Urine checks (cocaine, amphetamines, XTC, opioids, cannabis, benzodiazepines,

alcohol)

Study description

Background summary

For references in this text: see reference list in research protocol.
Attention Deficit Hyperactivity Disorder (ADHD) is characterised by symptoms of inattention, hyperactivity and impulsivity. The prevalence among children and adolescents is approximately 5% (1). Recently there has been growing awareness of the fact that ADHD can persist in adulthood. Moreover, it becomes clear that ADHD is a highly comorbid disorder, with high rates of, for example, substance use disorder (SUD). Biederman et al (2) found a significantly higher life time risk for psychoactive substance use disorders in ADHD adults compared with non ADHD controls (52% versus 27%). According to Wilens and colleagues (3), 17-45% of adult ADHD patients have histories of alcohol abuse or dependency, and 9-30% of ADHD patients have histories of drug abuse or dependency. Rasmussen et al (4) also investigated the presence of alcohol- and drug abuse among untreated ADHD patients, and found that 37% of the untreated men and 18% of untreated women had problems of alcohol abuse; moreover, 45% of these men and 29% of these women reported drug abuse. This combination of ADHD and SUD is a very invalidating and interfering problem as the prognosis of addiction is negatively influenced by ADHD. For example, Arias and collegues (5) showed that patients with ADHD and SUD become addicted at earlier age, use more substances and are admitted to inpatient clinics more often than addicted patients without ADHD. ADHD is also associated with increased risk of relapse in substance use (Carrol and Rounsaville, 6). It is estimated that 20% of the patients with SUD have ADHD (7). However, diagnosing ADHD in this population is difficult because of partly overlapping symptoms and because there is no validated instrument for diagnosing ADHD in this patientgroup. Also, a validated screening instrument for ADHD in substance-abusing patients is not available yet. To make an accurate estimation of the prevalence of ADHD in SUD patients, a European study, EASP, has been designed by ICASA. In this study, a screening instrument will also be validated. Arkin participates in this European study with the Jellinek addiction treatment centre. We expect to find a high number of SUD patients with comorbid ADHD. This will raise new questions, as an adequate treating program for this patientgroup is not available.
One of the treatment options for patients with ADHD en SUD is medication. Numerous studies have demonstrated the effectiveness of medication (especially stimulant medication) for adult patients with ADHD (8). The findings for patients with ADHD and SUD however, are at best inconsistent (9-15), but results of randomized trials are, almost without exception, disappointing. Moreover, medication is contra-indicated in the case of continued or relapsing substance use. In addiction, relapse is common.
Another treatment option for adults with ADHD is Cognitive Behavioral Therapy (CBT). Although the experience is limited, there is beginning evidence for the effect of cognitive behavioural therapy for adult patients with ADHD (16-30). However, this therapy has not yet been investigated in patients with comorbid substance use disorders.
The current proposal is designed to contribute to developing adequate treatment options for patients with ADHD and SUD.

Study objective

The objective of this study is to investigate the acceptance, feasibility and efficacy of cognitive behavioral therapy in reducing ADHD symptoms for adult patients with ADHD and SUD. We will also investigate how substance use and craving are influenced by ADHD treatment with cognitive behavioral therapy. The research questions are:
1. Does Cognitive Behavioral Therapy (CBT) reduce self-reported ADHD symptoms in a population of treatment seeking adult patients with SUD and comorbid ADHD, compared to Treatment As Usual (TAU)?
2. Does ADHD treatment with CBT lead to reduced substance use or increased abstinence in adult patients with ADHD and SUD, compared to TAU?

Study design

The research questions will be investiged using a randomized controlled trial design. Patients will be randomized for adding cognitive behavioral therapy to standard addiction treatment. Allocation to either condition will be performed in a blinded way, but treatment itself is of course not blinded to patients, clinicians or investigators.

Intervention

All patients receive addiction treatment. Moreover, patients are randomzed to 2 conditions: Treatment as Usual, or Treatment as Usual plus Cognitive Behavioral Therapy (CBT). This CBT consists of 7 individual sessions for adult ADHD patients, as desigend by Safren et al. Addiction treatment consists of 8 sessions, both in the CBT condition as in the TAU condition. In the TAU condition, patients receive 1 session psycho-education on ADHD, and 1 session with a theme of choice. Medication for ADHD is not provided during the trial. Patients who use a stable dosage of medication for ADHD, and still experience ADHD symptoms, are allowed to enter the trial and continue their medication. ADHD symptoms and substance use will be monitored during the trial.

Study burden and risks

The burden for participants in this research project consists of:
- attending 5 extra one-hour-sessions of cognitive behavioral therapy for ADHD (for 50% of the participants)
- completing questionnaires at three moments (for all participants).
There are no risks associated with this research project.

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

- age 18-60 years
- current DSM-IV diagnosis of adult ADHD
- current DSM-IV diagnosis of Substance Use Disorder
- able to provide written informed consent and to comply with all study procedures.

Exclusion criteria

- severe neurological or psychiatric disorders (e.g. Parkinson's disease, dementia, epilepsy, psychosis, bipolar depression) that require psychotropic medications.
- inability to read/ write Dutch language

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-07-2011
Enrollment:	150
Type:	Actual

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL31127.018.10