Mindfulness training versus treatment as usual in adults with attention deficit hyperactivity disorder (ADHD)

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To examine the (cost)effectiveness of mindfulness versus treatment as usual (TAU) in adults with Attention Deficit Hyperactivity Disorder (ADHD).

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

Summary

ID

NL-OMON41102

Source
ToetsingOnline

Brief title
Mindfulness training in adults with ADHD

Condition

- Cognitive and attention disorders and disturbances

Synonym
ADHD, Attention deficit hyperactivity disorder

Research involving
Human

Sponsors and support

Primary sponsor: Radboudumc
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: ADHD, executive functions, Mindfulness, quality of life

Outcome measures

Primary outcome

quality of life measured with the Outcome Questionnaire (OQ 45.2; Lambert et al., 1996)

Secondary outcome

- investigator and self-report ADHD symptoms (CAARS-IR en CAARS-SV; Adler et al., 2008)

- executive functioning (BRIEF-A; Goia et al., 2000)

- mindfulness skills (short form of the FFMQ; Bohlmeijer et al., 2011)

- self-compassion (short form of the SCS; Raes et al., 2011)

- health and well-being (SF-12; Ware et al., 1996)

- health care and societal costs (TiC-P; Institute for Medical Technology Assessment, 2010)

- neuropsychological test battery containing of cognitive tasks all measuring neurocognitive functions (Working memory task, Motivation x activation reinforcement learning task, Probabilistic reversal learning task, Pavlovian to instrumental transfer task, Demand selection task)

Study description

Background summary

Attention Deficit Hyperactivity Disorder (ADHD) is a common neurodevelopmental disorder with a high persistence into adulthood. Patients with ADHD are

primarily offered stimulant medication. However, not all patients are willing to take medication, some suffer from unacceptable side-effects and for many medication does not reduce their symptoms to the degree they would wish for. Therefore, there is a strong need for effective psychosocial interventions that are both accessible to a large group of patients and have been shown to be cost-effective, such as mindfulness training.

The current study aims at investigating whether individual mindfulness training is superior to the usual treatment in terms of an improvement of quality of life and executive functioning and a decrease of ADHD symptoms, health care and societal costs.

Study objective

To examine the (cost)effectiveness of mindfulness versus treatment as usual (TAU) in adults with Attention Deficit Hyperactivity Disorder (ADHD).

Study design

Randomised controlled trial comparing mindfulness in addition to TAU with TAU alone. Baseline and end of treatment assessments, consisting of an interview and online neuropsychological tests, will be done by blinded assessors and by online self-report questionnaires. After 3 months, patients allocated to the TAU condition will be offered mindfulness as well. At 3 and 6 months after completion of the training, follow-up assessments will take place by online self-report questionnaires.

Intervention

We have developed a treatment protocol of mindfulness for ADHD based on both the MBCT (Mindfulness-Based Cognitive Therapy; Segal, Williams & Teasdale, 2013) and the MAPs-training (Mindful Awarenss Practices; Zylowska, 2012). This intervention will be compared to the treatment as usual, usually consisting of farmacotherapy with psychostimulants and psycho-education.

Study burden and risks

This study involves capacitated adults and examines a therapeutic intervention. Participation is free of charge. There are no indications that there are risks related to the intervention. During the training participants can become more conscious of their ADHD related symptoms, like restlessness and a lack of attention. This might be confronting for the participant. However, we do not expect this to be harmful. Patients allocated to the mindfulness condition can use their medication for ADHD during the intervention, like psychosimulants. Participating in this study can be time consuming, as participants will be interviewd, will perform neuropsychological tasks and will fill out several

questionnaires at different time points.

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
• Primary diagnosis of ADHD, according to the criteria of DSM-5 based on a structured psychiatric interview for ADHD (the DIVA)
• Willing to be randomized to either mindfulness training or treatment as usual only.
• Capable of filling out questionnaires in Dutch.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
• Being under 18 years of age
• Psychotic symptoms
• Depressive disorder with psychotic symptoms or suicidality
• Active manic episode
• Borderline or antisocial personality disorder
• Substance dependence
• Autistic disorder
• Tic disorder with vocal tics
• Learning difficulties or other cognitive impairments
• Not being able to understand or use the Dutch language
• Former participation in MBSR or MBCT

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-09-2014
Enrollment:	120
Type:	Actual

Ethics review

Approved WMO

Date:	03-07-2014
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	26-05-2015
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL48776.091.14