

# Mindfulness training in adults with Attention Deficit Hyperactivity Disorder\*

## A randomised, controlled study.

Published: 09-09-2009

Last updated: 06-05-2024

To study the effects of Mindfulness training in adults with ADHD on ADHD symptoms and comorbidity with affective and anxiety symptoms. Also, the feasibility of Mindfulness training will be evaluated in this specific patientgroup and the effect on...

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

## Summary

### ID

NL-OMON33974

### Source

ToetsingOnline

### Brief title

Mindfulness training in adults with ADHD

### Condition

- Cognitive and attention disorders and disturbances

### Synonym

ADHD, attention deficit disorder

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Sint Radboud

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** ADHD, attention, Mindfulness

## Outcome measures

### Primary outcome

Conners' Adult ADHD Rating Scale-Investigator Rated: Screening Version

(16)18-item Total ADHD symptom score is the primary outcome measure

### Secondary outcome

Conners' Adult ADHD Rating Scale Observer Screening Version (CAARS-O-S)(16) 18

item total ADHD symptom score, ADHD index, ADHD inattentive subscale, ADHD

hyperactivity/impulsivity subscale

Conners' Adult ADHD Rating Scale Self Report Screening Version (CAARS-S-S) (15)

18 item total ADHD symptom score ADHD index, ADHD inattentive subscale, ADHD

hyperactivity/impulsivity subscale

Beck Depression Inventory (11) Total BDI II-NL score

STAI anxiety (12,13) Total STAI Anxiety score

Mindfulness vragenlijst (FFMQ)(17) Total Mindfulness Questionnaire score

Outcome questionnaire (OQ) (15) Total OQ score

Attention Network Test (ANT) 15 min (18) conflict effect, orienting effect,

alerting effect, Mean Reaction Time for Correct Trials

32 channels Electroencephalogram 60 min (EEG) (19,20) frequency bands; theta

power: 3,5-7,5 Hz; alpha power: 7,5-12,5 Hz; beta power: 12,5-25 Hz

## Study description

## **Background summary**

Attention Deficit Hyperactivity Disorder (ADHD) is a childhood-onset psychiatric condition that often continues into adulthood. Yet there is an continued interest in novel non-pharmacological interventions besides pharmacological treatment in ADHD to optimize outcomes for patients. Mindfulness trainingsprogram has emerged as a new approach for stress reduction and an important innovation in treating psychiatric disorders such as to prevent relapse by recurrent depressive disorders and anxiety disorders. A recent feasibility study has shown positieve outcomes for ADHD symptoms.

## **Study objective**

To study the effects of Mindfulness training in adults with ADHD on ADHD symptoms and comorbidity with affective and anxiety symptoms. Also, the feasibility of Mindfulness training will be evaluated in this specific patientgroup and the effect on the quality of life.

## **Study design**

It is a controlled, randomised study in which 96 patients who have given written informed consent, are randomised in either mindfulness training(n=48), or the waitinglist control group (n=48). The trainingprogram includes 12 weekly sessions in a group of 12 participants and 2 4 weekly sessions. The primary and secondary outcome measures will be taken at the beginning (week 0), in the end (week 20) . Attention tasks will be measured by neuropsychological test. A follow-up measure will take place 2 months after the end of the study for the Mindfulness traininggroup.

## **Intervention**

Training program is conform Mindfulness Based Cognitive Therapy protocol which is used to prevent a relapse in depressive disorder and developed by Teasdale, Williams and Seagal. This program is adjusted for the ADHD patientgroup and includes 12 weekly sessions with the duration of 2,5 hours per sessionand 2 4 weekly sessions instead of 8 sessions of 2,5 hours per session and involves educative information about ADHD.

## **Study burden and risks**

Mindfulness traininggroup:  
Time investment: 7,5 hours (3x2,5 hours) for CAARS-Investigator Rated Interview, to administer study instruments and neuropsychological test (ANT) and Electroencephalogram  
35 hours for participation on the sessions (14x2,5 hours) in 20 weeks during

the study

60 hours of practicing Mindfulness skills

Total: 102,5 hours

Waitinglistgroup:

Time investment: 5 hours (2x2,5 hours) for CAARS-Investigator Rated Interview,  
to administer study instruments and neuropsychological test (ANT) and

Electroencephalogram

Total: 5 hours

## Contacts

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### Scientific

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

patients 18 years of age or older,

diagnosed with ADHD (meets DSM IV criteria for one or other subtype of ADHD)

Capable of speaking and writing in Dutch

## Exclusion criteria

substance abuse/dependence within the past 6 months, a history of psychotic illness, bipolar I disorder, mental retardation, severe borderline or antisocial personality disorder, conduct disorder and chronic suicidal or self-injurious behavior.

## Study design

### Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

### Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	14-09-2009
Enrollment:	96
Type:	Actual

### Medical products/devices used

Registration:	No
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## Ethics review

Approved WMO	
Date:	09-09-2009

Application type: First submission  
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	NL25843.091.09