Mindfulness training for youth with ADHD: Improving self-control and ADHD symptoms

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

Summary

ID

NL-OMON43975

Source
ToetsingOnline

Brief title
MindChamp: Mindfulness for Children with ADHD and Mindful Parenting

Condition

- Cognitive and attention disorders and disturbances

Synonym
Attention deficit hyperactivity disorder (ADHD), hyperkinetic disorder

Research involving
Human

Sponsors and support

Primary sponsor: Karakter
Source(s) of monetary or material Support: Horizon 2020 Marie-Sklodowska Curie Training Network grant

Intervention

Keyword: ADHD, mindfulness, RCT, self-control

Outcome measures

Primary outcome

Our primary outcome measure consists of parent ratings of child self-control on the Behaviour Rating Inventory of Executive Function (BRIEF), which involves standardised ecologically-valid ratings of everyday self-control.

Secondary outcome

Other measures of child self-control, child behaviour, parental self-control, parental behaviour, and other measures (e.g. quality of life).

Study description

Background summary

Deficits in self-control (e.g. planning, delay of gratification, inhibition of responses) are a key problem in attention deficit hyperactivity disorder (ADHD). However, although existing interventions for ADHD are effective in reducing the core symptoms of ADHD, they all have limited effects on improving self-control in ADHD. Further, residual symptoms and impairment remain. Hence, there is need for new interventions that target shortcomings in existing interventions for ADHD. Effective strategies to improve children*s self-control come with the potential to substantially benefit the child*s further development, and to significantly lower negative academic, health, wealth, social and public safety outcomes linked to poor self-control. A promising approach is the use of mindfulness, an innovative non-pharmacological therapeutic intervention.

Study objective

Our primary objective is to evaluate the effectiveness of mindfulness training in improving self-control of youth with ADHD. As secondary objectives, we aim to quantify the effectiveness in reducing ADHD symptoms, reducing comorbid (e.g. ASD) symptoms, reducing impairment of functioning, and improving outcomes

in the parents of youth with ADHD.

Study design

We will provide mindfulness training as an add-on to care-as-usual (CAU). This will optimise CAU for ADHD. We will randomly assign 100 children with ADHD and their parents to mindfulness training (N=50) (plus CAU), and to control condition (CAU-only) (N=50). Data from children and parents will be collected at baseline, endpoint and at 6-month follow-up, and will include assessments of self-control, ADHD symptoms, comorbid symptoms, impairment, and parental outcomes (e.g. parental self-control, parenting). We will also collect saliva samples from children at baseline and at endpoint.

Intervention

We will use the MYmind mindfulness training, which uses a standardised protocol based on mindfulness-based cognitive therapy. It consists of 8 weekly group sessions of 90 minutes for youth with ADHD, and parallel mindful parenting training for the parents. For eight weeks after the last session the families undergo home self-practice, followed by a single 90 minutes joint parent-child booster session. This booster session signifies study endpoint. CAU usually consists of behavioural interventions and/or medication.

Study burden and risks

The risks and discomforts are estimated as low. Burden for all participants are the recurrent non-invasive assessments. For children these include diagnostic assessment (baseline only), questionnaires, behaviour observation, and cognitive tests (baseline, endpoint, follow-up); for parents these include diagnostic assessment (baseline only), questionnaires and cognitive tests (baseline, endpoint, follow-up).
Benefits for the participants are good monitoring of treatment effect and the possibility to receive mindfulness training free of charge, which is currently not covered by health insurance. If the mindfulness training proves effective, they will receive additional treatment for their disorder targeting deficits that are not covered by CAU. A further benefit is that this study will allow optimisation of CAU.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

(1) Child has a clinical diagnosis of ADHD according to the Diagnostic and Statistical Manual of Mental Disorders; DSM-IV or DSM-5 system, and confirmed by a structured interview (K-SADS).
(2) 8-16 years old.
(3) At least one parent willing to participate.
(4) ADHD medication dose is stable, or there is an informed decision on not taking ADHD medication.
(5) Child and parent have an estimated IQ >= 80.
(6) Child and parent have adequate mastery of Dutch language.
(7) We allow for psychiatric comorbidities except psychosis, bipolar illness, active suicidality, untreated posttraumatic stress disorder or substance use, provided ADHD is the primary diagnosis in the child; similarly, we allow for psychopathology in the parents, except psychosis, bipolar disorder, active suicidality, untreated posttraumatic stress disorder or substance use.
(8) Not participating in another intervention study.

Exclusion criteria

none

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-02-2016
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	28-01-2016
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	26-07-2016
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO	

Date:	30-11-2016
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	20-02-2017
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	14-09-2017
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	NL53815.091.15

Study results

Results posted: 10-12-2021

First publication
10-12-2021