Mindfulness in child and adolescent psychiatry

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

Summary

ID

NL-OMON38850

Source
ToetsingOnline

Brief title
Mindfulness in child and adolescent psychiatry

Condition

- Other condition
- Psychiatric and behavioural symptoms NEC

Synonym
Attention Deficit Hyperactivity Disorder (ADHD) + Autism Spectrum Disorder (ASD)

Health condition

Attention Deficit Hyperactivity Disorder + Autism Spectrum Disorder

Research involving
Human

Sponsors and support

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

Intervention

Keyword: ADHD, ASD, Mindfulness, Youngsters

Outcome measures

Primary outcome

Primary outcome measure for study populations 1, 2, 3, 4 and 5 is attention problems.

Secondary outcome

Secondary outcome measures are anxiety and depression symptoms, stress, fatigue, quality of life, family emotion regulation, and mindfulness for study population 1, 2, 3, 4 and 5. Population specific outcome measures are hyperactivity and impulsivity in study populations 1 and 2; rumination and problems in social interaction and communication in study population 3 and 4; and self-compassion, acceptence and experiential avoidance in study population 5.

Study description

Background summary

Although the effects of Mindfulness Training (MFT) in adults are well established, research on the effects of MFT in child and adolescent psychiatry is a relatively new domain. Based on proven effectiveness in adults as well as promising results from pilot studies in children and adolescents, it is hypothesized that the use of MFT will be effective in children and adolescents with ADHD and ASD. Also for Mindful Parenting Training (MPT) it is hypothesized

it will have positive effects on both parent and child.

Study objective

The main objective of the study is to investigate whether an 8 week MFT for children and adolescents with Attention Deficit Hyperactivity Disorder (ADHD) or Autism Spectrum Disorder (ASD) as well as an 8 week MPT for parents, would be effective in reducing psychiatric symptoms and increasing mindfulness.

Study design

A non-experimental pre-post design with two follow-up measurements will be used, with a within group waitlist condition to control for time effects.
A multi-informants design is used, with subjective as well as objective measurements. Measurement occasions will be at waitlist (8 weeks prior to training), pre-training (1 week prior to training), post-training (directly after training), and at two follow-up occasions (8 weeks and 1 year after post-training).

Intervention

Subjects from study population 1, 2, 3 and 4 receive MFT that consists of 8 weekly 1.5 hour group sessions. During the MFT of study population 1, 2, 3 and 4, parents receive 8 weeks parallel MPT (pMPT). Subjects from study population 5 are parents who join the MPT without their children. They attend the 8 weeks 3 hour group sessions.

Study burden and risks

Subjects of populations 1, 2, 3 and 4 participate in MFT, which consists of 8 weekly 1.5 hour group sessions. Their parents follow pMPT which also consist of 8 weekly 1.5 hour group sessions. Subject of population 5 participate in 8 weekly 3 hour sessions of MPT.
Children and adolescents need to spend an additional 15 minutes daily on their homework, whereas parents need to spend an additional 30 minutes each day. The burden is considered minimal, as our clinical impressions as well as standardized evaluation forms indicate that the meditation brings them quietness, that the yoga exercises are fun to do, and the time they need to spend is considered reasonable. Often patients are very motivated for this training, as mindfulness enables them to do something about their attention problems, anxiety and depressive symptoms themselves, without the use of medication. Compliance to the MFT as well as response rate at the different measurement occasions is very high. The questionnaires can be completed online, so participants can do it in the comfort of their home environment. Only for the computer task the child/adolescent needs to come to the treatment center. Participation in mindfulness training carries no risks.

The Mindfulness research lines as described in this study have been evaluated and approved by the Ethical Committee of the Department of Child Development and Education, Faculty of Social and Behavioral Sciences, University of Amsterdam.

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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

In order to be eligible to participate in this study, a subject must meet all of the following criteria:;For study populations 1 and 2:
Inclusion criteria for the ADHD group are (1) a DSM-IV diagnosis of ADHD established with the

parent and child version of the Anxiety Disorders Interview Schedule for Children (ADIS-C), (2) an estimated IQ of 80 or higher, (3) participants have to be able to attend the first session, with a minimum of at least 6 out of 8 sessions, and (4), at least one parent has to be able to attend the parent sessions and (5), participants have to be between 9 and 12 years old (elementary school) for the children group and between 12 and 18 years old (secondary school) for the adolescent group. ;For study population 3 and 4:
Inclusion criteria for the ASD group are (1) a DSM-IV diagnosis of ASD confirmed by the Autism Diagnostic Observation Schedule - Generic (ADOS-G), (2) an estimated IQ of 80 or higher, (3) participants have to be able to attend the first session, with a minimum of at least 6 out of 8 sessions, and (4), at least one parent has to be able to attend the parent sessions, and (5), participants have to be between 9 and 12 years old (elementary school) for the children group and between 12 and 23 years old (secondary school and beyond) for the adolescent group.;For study population 5:
Inclusion criteria for the MPT are (1) the experience of childrearing stress, (2) either a DSM-IV diagnosis of the parent or the child, (3) an estimated IQ of 80 or higher, and (4), participants have to be able to attend the first session, with a minimum of at least 6 out of 8 sessions.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:;For study populations 1 and 2:
Participants are excluded from participation when (1) inadequate mastery of the Dutch language by the child or parents, (2) severe behavioral problems established by a CD on the ADIS-C, (3) comorbid developmental disorder (autistic), and (4), participating in another ongoing psychological intervention (apart from *stable* medication). ;For study population 3 and 4:
Participants are excluded from participation when (1) inadequate mastery of the Dutch language by the child or parents, (2) severe behavioral problems established by the ADIS-C, (3) presence of suicidal risk, (4) presence of non-treated psychotic disorders, and (5), participating in another ongoing psychological intervention (apart from *stable* medication). ;For study population 5:
Participants are excluded from participation when (1) inadequate mastery of the Dutch language and (2), participating in another ongoing psychological intervention (apart from *stable* medication).

Study design

Design

Study type: Interventional
Masking: Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-07-2013
Enrollment:	625
Type:	Actual

Ethics review

Approved WMO Date:	20-06-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	12-07-2016
Application type:	Amendment
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	NL43720.018.13