# Mindfulness for adolescents with autism spectrum disorders * a series of single case studies

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Other condition |
| **Study type** | Observational non invasive |

## Summary

### ID

NL-OMON43953

**Source**
ToetsingOnline

**Brief title**
Mindfulness for adolescents with ASD * a series of single case studies

### Condition

- Other condition
- Mood disorders and disturbances NEC

**Synonym**
Autism spectrum disorder / Autism / ASD

**Health condition**

Autisme spectrum stoornissen

**Research involving**
Human

## Sponsors and support

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

## Intervention

**Keyword:** Adolescent, Autism spectrum disorder, Mindfulness, Single case experimental design

## Outcome measures

### Primary outcome

Individualized daily measures of internalizing symptoms are the primary outcome measures.

### Secondary outcome

Secondary outcome measures are daily reported process variables: time spent on formal mindfulness practices, mindful awareness, worry, rumination, stress, compassion, self-compassion, and sleep. A multi-informant design is used, with subjects and their parents as informants. Daily measures will be completed during baseline period, training, follow-up till 9 weeks after training, and 1 year follow-up during 1 week. Additional measurement occasions will be pre-training (just before training), post-training (directly after training), and at two follow-up occasions (9 weeks and 1 year after training).

# Study description

### Background summary

Although the effects of Mindfulness Training (MFT) in adults are well established, research on the effects of MFT in adolescents with Autism Spectrum Disorder (ASD) 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 have positive effects for adolescents with ASD and clinically elevated internalizing symptoms.

### Study objective

The main objective of the study is to investigate whether a 9 week MFT for adolescents with ASD and clinically elevated internalizing symptoms, reduces adolescent's internalizing symptoms. Secondary objective is to investigate the process of change.

### Study design

A single case experimental design with a multiple baseline across subjects will be used to investigate how changes unfold over time. In addition, pre-training, post-training, and follow-up measures will be conducted.

### Intervention

Subjects receive MFT that consists of 9 weekly 1.5 hour individual sessions. Their parents receive one session Mindful Parenting Training (MPT) and will take part in the last session and the booster session with their child for 30 minutes.

### Study burden and risks

Daily measures will be completed during baseline period, training, follow-up till 9 weeks after training, and 1 year follow-up during 2 weeks. This is between 147 and 168 days in total. The daily measures will last three minutes per day, which is considered feasible to fill in every day for adolescents and their parents. Participants could benefit from getting insight in their daily functioning and the effect of MFT on their personal goals by completing the daily measures. Additional measurement occasions will be at 4 occasions: pre-training (before start training), post-training (directly after training), and at two follow-up occasions (9 weeks and 1 year after training), and last 40 to 50 minutes each time. The questionnaires can be completed online, so participants can do it in the comfort of their home environment. The information provided by the questionnaires and daily measures are essential for investigating the effectts of MFT for this target group. Participation in this study carries no risks. This study can only be carried out with including adolescents between 14 and 17 years old next to adolescents aged 18 till 21 years old, because the MFT protocol is developed for the developmental phase of adolescence, which starts after 11 years and lasts into young adulthood. Children between 14 and 17 years old in early and middle adolescence could benefit from the MFT protocol, but evidence for the effects of the MFT training can only be provided if this group is included in this study investigating the protocol. A related research protocol that included the same population and MFT

has been evaluated and approved by the Medical Ethical Committee of the Academical Medical Centre (AMC), project number NL43720.018.13.

## 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)
Elderly (65 years and older)

### Inclusion criteria

Inclusion criteria are (1) a DSM diagnosis of ASD verified by the Autism Diagnostic Observation Schedule - Generic (ADOS-G), (2) clinically elevated internalizing symptoms as verified by at least one internalizing diagnosis on a semi-structured diagnostic interview (e.g. Anxiety Disorders Interview Schedule, ADIS), and a (sub) clinical score on CBCL and YSR internalizing problems; (3) an estimated IQ of 80 or higher, (3) adolescents have to be between 14 and 21 years old.

### Exclusion criteria

Participants are excluded from participation when (1) inadequate mastery of the language in which the training is conducted by the child or parents, (2) severe behavioral problems established by a conduct disorder (CD) on the ADIS-C, (3) presence of current suicidal risk, (4) presence of current non-treated psychotic disorders, (5), participating in another ongoing psychological intervention (apart from *stable* medication), and (6) living away from family home.

## Study design

### Design

**Study type:** Observational non invasive

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|---|---|
| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Treatment |

### Recruitment

NL

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|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 09-05-2016 |
| Enrollment: | 6 |
| Type: | Actual |

## Ethics review

Approved WMO

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| Date: | 20-11-2015 |
| Application type: | First submission |
| Review commission: | METC Amsterdam UMC |

Approved WMO

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| Date: | 05-07-2016 |
| 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 | NL54211.018.15 |