

# Cognitive Behavioral Therapy and Mindfulness Based stress Reduction Therapy for Anxiety and Depression Symptoms in Adults with Autism Spectrum Disorders

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The central question is: are the recently published treatment methods (a) cognitive behavioral therapy (CBT-ASD) (Schuurman 2011), and mindfulness based stress reduction (MBSR-ASD) (Spek 2011) effective interventions to reduce anxiety and depression...

<b>Ethical review</b>	Not approved
<b>Status</b>	Will not start
<b>Health condition type</b>	Developmental disorders NEC
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON36888

### Source

ToetsingOnline

### Brief title

CBT and MBSR in adults with ASD

### Condition

- Developmental disorders NEC

### Synonym

autism, pervasive developmental disorders

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Dimence (Deventer)

**Source(s) of monetary or material Support:** Fonds Psychische Gezondheid;patientenvereniging

## Intervention

**Keyword:** autism, cognitive behavioral therapy, mindfulness, symptoms

## Outcome measures

### Primary outcome

the 2 primary outcome measures are depression and anxiety scores on the HADS

### Secondary outcome

the secondary outcome measures are the negative and positive affect scores on the GMS, the degree into which the personal goals have been attained, and the change on the social responsivity.

## Study description

### Background summary

The discomfort for adults with autism spectrum disorder is often unnecessarily high because of untreated comorbid anxiety and depression symptoms. Autism itself is characterized by an impaired social interaction, communication problems and by stereotyped patterns and restricted interests. This results in a dysfunctional interaction with others in the environment. This leads to people with autism being met with a lack of understanding, rejection or too high expectations. Because of a cumulative effect of these negative experiences, the risk of developing anxiety or depression increases. These symptoms are often not recognized because of the autism-associated inability to express feelings and emotions adequately, thereby aggravating the anxiety or depressive symptoms.

Autism spectrum disorders are often comorbid with other psychiatric problems. Lugnegård (2011) reported that 70% of adults with Asperger's Disorder experience at least one depressive episode and that 50% fulfilled the criteria for an anxiety disorder (Lugnegård, Hallerbäck, & Gillberg, 2011). Due to the different presentation of anxiety and depression in ASD, there is probably

insufficient treatment because all symptoms are attributed to ASD. Despite the high degree of impairment that anxiety and mood symptoms cause, treatment interventions for adults with ASD have hardly been studied. From the perspective of clients this calls for studies in which promising interventions (like cognitive behavioral therapy (CBT-ASD) and mindfulness based stress reduction (MBSR-ASD)) are systematically researched in an outpatient population. In order to inform clients better about the treatment possibilities and to be able to advise them appropriately, it is important to study whether (a) CBT-ASD or MBSR-ASD are effective methods and (b) whether the effectiveness is correlated with client related factors. ,

Hypotheses:

Cognitive behavioral therapy (CBT-ASD)

1. completing a CBT-ASD is associated with a reduction of the anxiety and depression symptoms in adults with ASD.
2. completing a CBT-ASD is associated with a reduction of the suffering and an increase of positive feelings and social functioning in adults with ASD.
3. the effect of CBT-ASD is positively correlated with the level of education.

Mindfulness based stress reduction (MBSR-ASD):

1. completing a MBSR-ASD is associated with a reduction of the anxiety and depression symptoms in adults with ASD.
2. completing a MBSR-ASD is associated with a reduction of the suffering and an increase of positive feelings and social functioning in adults with ASD.
3. the effect of MBSR-ASD is not correlated with the level of education.

## **Study objective**

The central question is: are the recently published treatment methods (a) cognitive behavioral therapy (CBT-ASD) (Schoorman 2011), and mindfulness based stress reduction (MBSR-ASD) (Spek 2011) effective interventions to reduce anxiety and depression in adults with autism spectrum disorders?

Secondary questions are:

- (a) Can anxiety and depression symptoms be reduced in adults with ASD by treatment with CBT-ASD?
- (b) Can anxiety and depression symptoms be reduced in adults with ASD by treatment with MBSR-ASD?
- (c) Does the daily suffering reduce or do positive feelings and social functioning increase after treatment with CBT-ASD or MBSR-ASD?
- (d) Are personal goals attained after completing CBT-ASD or MBSR-ASD?
- (e) Are there client related factors that can predict a reduction of symptoms associated with CBT-ASD or MBSR-ASD?
- (f) What is the cost effectiveness of both methods?

## **Study design**

It concerns a randomised prospective cohort study of two existing treatment protocols (MBSR-ASD and CBT-ASD)

## Study burden and risks

The burden for participants consists of completing questionnaires at four stages. Not all questionnaires are required each time. The total time required amounts to 3 hours. (see protocol annex 2). It concerns the following questionnaires:

The degree of anxiety and depression is assessed with the Dutch version of the Hospital Anxiety and Depression Scale (HADS) (Zigmond & Snaith, 1983). This questionnaire contains 14 items. Completion requires 5 to 10 minutes.

The Mindful Attention Awareness Scale (MAAS) is a process measure for mindfulness and measures the frequency of everyday mindful experiences (Brown & Ryan, 2003). This questionnaire contains 15 items. Completion requires 10 to 12 minutes.

The process measure for cognitive change is quantified by the Irrational Beliefs Inventory (IBI). It consists of 50 items. Completion requires 10 to 15 minutes.

The social relatedness scale (SRS) is a well validated self-report instrument with 65 items that quantifies autistic symptoms and can be used to measure change in social functioning after treatment (Constantino, et al., 2003). Completion requires 15 to 20 minutes.

The degree of suffering is determined with the Dutch translation of the Global Mood Scale (GMS). This instrument has 10 items and gives an indication of the positive and negative affects resulting from physical and psychological problems (Watson & Pennebaker, 1989). Completion takes about 5 minutes.

Adults with ASD form a heterogeneous group. By asking participants to formulate their personal goals prior to randomization, it is possible to express the success of an intervention on an individual level, without negative influences of heterogeneity. The degree in which the goals are reached is measured with the Global Attainment Scale (GAS) (Kiresuk & Sherman, 1968). The GAS is a reliable and valid measure of personal (Schlosser, 2004). Therapists are blind to the personal goals.

## Contacts

### Public

Dimence (Deventer)

Singel 13  
7201 HV Deventer  
NL

### Scientific

Dimence (Deventer)

Singel 13

## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

- adults (older than 18) with an autism spectrum disorder (ASD)
- normal intelligence with reasonable verbal comprehension
- able to practice daily and to carry out homework tasks
- score of 8 or above on the anxiety or depression scale of the Hospital Anxiety and Depression Scale (HADS)

### Exclusion criteria

- previous treatment with mindfulness or cognitive behavioral therapy for ASD
- too sensitive for a grouptherapy
- a current psychotic or manic psychiatric condition or under influence of alcohol or drugs
- a reasonable expectation of major changes during the intervention period (e.g. moving house, pregnancy, change of jobs)

## Study design

### Design

Study type: Observational non invasive

Intervention model: Parallel

Allocation: Randomized controlled trial  
Masking: Open (masking not used)

**Primary purpose:** Treatment

## Recruitment

NL  
Recruitment status: Will not start  
Enrollment: 180  
Type: Anticipated

## Ethics review

Not approved  
Date: 22-11-2012  
Application type: First submission  
Review commission: IRB Nijmegen: Independent Review Board Nijmegen (Wijchen)

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

### Other (possibly less up-to-date) registrations in this register

ID: 26280  
Source: NTR  
Title:

### In other registers

Register	ID
CCMO	NL40743.072.12
OMON	NL-OMON26280