

# Treatment of anxiety disorders in children with Autism Spectrum Disorders (ASD).

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON22241

### Source

NTR

### Health condition

ASD refers to conditions that share a core triad of impairments consisting of qualitative impairments in social interaction, verbal and non-verbal communication, and repetitive and stereotyped patterns of interest and behavior (APA, 2001). ASD is estimated to occur in 0.6% of the population (Fombonne, 2005), however, there is considerable heterogeneity of symptom presentation. Furthermore, psychiatric comorbidity is very common among children with ASD (e.g. De Bruin et al., 2007). Of interest to the present study are comorbid anxiety disorders, which are estimated to occur in nearly 40% of the children with ASD (van Steensel, Bögels, & Perrin, 2011). In addition, anxiety disorders are among the most common in typically developing children, with prevalence rates up to 27% (Costello, Egger & Angold, 2005). DSM-IV distinguishes the following anxiety disorders: separation anxiety disorder (SAD), social anxiety disorder, specific phobia, agoraphobia, panic disorder, generalized anxiety disorder (GAD), and post-traumatic stress disorder (PTSD). Treating anxiety disorders with Cognitive Behavioral Therapy (CBT) is highly effective (e.g. Bodden et al., 2008), however, its effectiveness for children with ASD is not yet established.

## Sponsors and support

**Primary sponsor:** University of Amsterdam

Participants are recruited by several mental health centers across the Netherlands

**Source(s) of monetary or material Support:** ZonMW

## Intervention

## Outcome measures

### Primary outcome

1. Diagnostic status: whether the child still meets criteria for its (primary) anxiety disorder (ADIS);
2. Anxiety symptomatology (SCARED);
3. Quality of Life (QoL; EQ-5D);
4. Costs (measured by a retrospective costs-questionnaire).

### Secondary outcome

1. General psychopathology (CBCL);
2. ASD-related symptoms (CSBQ);
3. Family Functioning (FFS & FAST);
4. Parental rearing behavior (CDQ);
5. Parental anxiety (SCARED);
6. Parental quality of life (EuroQol);
7. Attachment (AQ).

## Study description

### Background summary

N/A

### Study objective

The aims of the study are:

1. To compare the effectiveness of Cognitive Behavioral Therapy (CBT) for anxiety disorders between children with ASD and children without ASD;
2. To compare the (cost-) effectiveness of CBT to Treatment As Usual (TAU) for anxiety disorders in children with ASD.

No hypotheses are prepared (hypotheses are exploratory).

## **Study design**

For all participants at least three assessments are conducted: At pre- and post treatment, and three months after treatment (follow up 1). For the participants in the CBT-condition, a follow up one year after treatment (follow up 2) and a follow up two years after treatment (follow up 3) are conducted.

## **Intervention**

The study has two arms. The first arm of the study consists of a comparison between children with anxiety disorders, with and without ASD. These children receive the same intervention (CBT). The second arm of the study consists of a comparison between CBT and Treatment As Usual (TAU) for anxiety disorders in children with ASD. For an outline of the interventions, see below.

### **Cognitive Behavioral Therapy (CBT):**

The individual, standardized CBT (Denken + Doen = Durven; Bögels, 2008) consists of 15 sessions within approximately 3 months. There are 12 child sessions and three parent sessions. Its main ingredients are: psycho-education about anxiety, challenging anxious thoughts, exposure with a reward system, behavior experiments, and prevention of relapse. The intervention is delivered by trained therapists, who receive within- and across center training.

### **Treatment as Usual (TAU):**

Interventions that fall under the umbrella of TAU are: psycho-education, parent guidance, school guidance, social skills training, group trainings, family counseling, behavior therapy, individual therapy (not being CBT), and medication.

## Contacts

### **Public**

University of Amsterdam<br>  
Nieuwe Prinsengracht 130  
Bonny Steensel, van  
Amsterdam 1018 VZ  
The Netherlands  
+31 (0)20 5251316

### **Scientific**

University of Amsterdam<br>  
Nieuwe Prinsengracht 130  
Bonny Steensel, van  
Amsterdam 1018 VZ  
The Netherlands  
+31 (0)20 5251316

## Eligibility criteria

### **Inclusion criteria**

1. Children, aged 7-18, must have at least one anxiety disorder (all anxiety disorder are included), according to parent and/or child report;
2. At least one parent is willing to participate in treatment and research.

### **Exclusion criteria**

1. Acute suicidal behavior;
2. Untreated psychotic disorder;
3. IQ below 70;
4. DSM-IV V-code of current sexual or physical abuse;
5. Having had CBT for anxiety disorders in the past year.

## Study design

### Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	03-02-2006
Enrollment:	200
Type:	Actual

## Ethics review

Positive opinion	
Date:	25-05-2011
Application type:	First submission

## 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
NTR-new	NL2776
NTR-old	NTR2916
Other	AZM / ZonMW : P05.1639L/MEC 05-147 / 170881006;
ISRCTN	ISRCTN wordt niet meer aangevraagd.

## Study results

### Summary results

N/A