

# An RCT on the effectiveness of a serious game for patient with a developmental disorder with anxiety symptoms using cognitive bias modification.

Published: 08-02-2016

Last updated: 19-04-2024

The objective of this study is to examine wheter a serious game using cognitive bias modification is effective on anxiety symptoms regarding patients with an autism spectrum disorder.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Will not start
<b>Health condition type</b>	Developmental disorders NEC
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON42588

### Source

ToetsingOnline

### Brief title

Serious game for patients with autisme spectrum disorder.

### Condition

- Developmental disorders NEC

### Synonym

developmental disorder

### Research involving

Human

### Sponsors and support

**Primary sponsor:** GGZ Friesland (Leeuwarden)

**Source(s) of monetary or material Support:** GGZ Friesland, Subsidie van de Friesland Zorgverzekeraar

## Intervention

**Keyword:** anxiety, CBM, developmental disorder, serious game

## Outcome measures

### Primary outcome

Anxiety symptoms measured with LSAS.

### Secondary outcome

Game experience measured with GEQ

## Study description

### Background summary

Autism Spectrum Disorders (ASD) are neuropsychiatric disorders which express in childhood and penetrate deeply into the development of the adulthood. Comorbid mental disorders are widespread along ASD. Social anxiety is a common comorbid disorder in people with ASD. There is no evidence based treatment for social anxiety in people with ASD. Cognitive therapy appears to be effective.

Cognitive Bias Modification interpretation (CBM-I), a new but evidence-based intervention in patients with social anxiety disorder, is for patients with an ASD unknown. Within a recently developed serious game for people with a psychotic disorder, these CBM-I components were used. We hypothesize that playing this game by patients with ASD also has an effect in reducing comorbid social anxiety in this group.

### Study objective

The objective of this study is to examine whether a serious game using cognitive bias modification is effective on anxiety symptoms regarding patients with an autism spectrum disorder.

### Study design

A randomised controlled trial with a cross over design.

## Intervention

The intervention is a serious game using cognitive bias modification designed to reduce anxiety symptoms.

## Study burden and risks

Previous studies on the effect of CBM-I on social anxiety showed no evidence that the intervention in any way can harm the subject. Subjects receive explanation of the procedure and the purpose of the investigation in advance. Subjects are then asked both oral and written informed consent, in accordance with the applicable rules (Polit, Beck, 2012). Subjects receive time to decide whether they would like to participate for one week.

Subjects in the control receive treatment as usual. The burden of the study to the subject is low. There is one assessment of about 60 minutes requested for the T0 measurement. Too much for a patient it can be split up in two measurements. A development history and the DSM5 ASD interview is conducted by default in the diagnosis phase of the developmental clinic and is therefore already available. Follow-up measurements (after 12 and 24 weeks) takes about 15 minutes.

Benefit from participation in the study for subjects hopefully will be the decline of social anxiety.

## Contacts

### Public

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### Scientific

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## Trial sites

## Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

- An Autism Spectrum disorder (ASS).
- Social anxiety symptoms determined with the LSAS (score > 30)
- > 18 years treated at friesland mental health care.
- sufficient understanding of the Dutch language (especially reading comprehension).
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### Exclusion criteria

- suïciderisk

## Study design

### Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

**Primary purpose:** Health services research

### Recruitment

NL	
Recruitment status:	Will not start
Enrollment:	80

Type: Anticipated

## Ethics review

Approved WMO

Date: 08-02-2016

Application type: First submission

Review commission: METC Universitair Medisch Centrum Groningen (Groningen)

## 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	NL54371.042.15