

# Effectiveness and efficiency on quality of life of an awarenessprogram on sensory processing Issues for adolescents and adults with autism spectrum disorders and a normal or high IQ.

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<b>Ethical review</b>	Not approved
<b>Status</b>	Will not start
<b>Health condition type</b>	Psychiatric disorders NEC
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON37188

### Source

ToetsingOnline

### Brief title

Evaluation of a program on sensory processing for ASS.

### Condition

- Psychiatric disorders NEC

### Synonym

Autism, Autism Spectrum Disorder

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Groningen

**Source(s) of monetary or material Support:** Universitair Medisch Centrum Groningen

## Intervention

**Keyword:** Autism, Quality of life, Sensory processing, Treatment

## Outcome measures

### Primary outcome

Primary outcome is quality of life. This is defined as: 'the functioning of individuals on physical, psychological and social domain as the experience it themselves' and is seen as a generic outcome measure.

### Secondary outcome

Secondary outcome:

- 1) physical and psychological complaints;
- 2) degree of sensory problems;
- 3) psychosocial functioning;
- 4) social participation (dependancy, living situation, work);
- 5) social costs.

## Study description

### Background summary

The past decade has seen reports citing an increase in the prevalence of Autism Spectrum Disorders (ASD). Sensory modulation symptoms are common in persons with ASD, with a heterogenous presentation. Studies indicate however a significant high difference between ASD and typical groups in the presence and frequency of sensory symptoms. The ability of a person to respond to unexpected

stimuli in their environment is a fundamental characteristic of human beings and necessary for functional performance. So there is a link to be expected between sensory processing problems that a person with ASD experiences, difficulties in managing daily life, wellbeing and quality of life. In this research the effectiveness and efficiency of an awarenessprogram on sensory processing Issues is investigated. The expected result of this intervention is better copingmechanisms with sensory processing problems. The interventionmethod consists of four sessions of one hour and information on paper and is offered besides the Care As Usual.

## **Study objective**

The objective of this study is evaluation of an awarenessprogram on sensory processing Issues on effectiveness and efficiency with regard to quality of life.

The central researchquestion is: what are the effects on experienced quality of life of the awarenessprogram on sensory processing Issues as offered by R95 on individuals with ASD (18 years and older with a normal or high IQ), besides Care As Usual?

Primary outcome is quality of life. Secondary outcome:

- 1) physical and psychological complaints;
- 2) degree of sensory problems;
- 3) psychosocial functioning, including;
- 4) social participation (dependancy, living situation, work);
- 5) social costs.

Extra points of attention during the proces in this study are:

- 1) Is this intervention an efficient treatment for individuals with ASDin comparison with CAU?.
- 2) Which recomendations are to be made for improvement of this intervention?
- 3) What are the possibilities for further implementation?
- 4) What theoretical model fits the best with these problems and this intervention?

## **Study design**

This pilot study is a randomised controled trial in one centre with a intervention- and a controlgroup. Patients who want to participate will ne randomised in two groups. The controlgroup gets Care As Usual (CAU) and the experimental group gets CAU plus the new intervention. Both groups will be asked to fill in a baseline questionnaire (T0). After the intervention (two months after) both groups fill in the second questionnaire (T1) en six months later the third.

## **Intervention**

The awarenessprogram on sensory processing Issues consists on five sessions with a participant, is conducted before CAU and spread on a period of two months. The intervention is aimed at prevention of sensory processing problems (problem focused coping) and on learning what to do when sensory problems arise (emotion focused coping). Furthermore the specific sensory processing issues of the individual are systematically evaluated and the participants get information about these problems on paper.

### **Study burden and risks**

Not applicable.

## **Contacts**

### **Public**

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## **Trial sites**

### **Listed location countries**

Netherlands

## **Eligibility criteria**

### **Age**

Adults (18-64 years)  
Elderly (65 years and older)

## Inclusion criteria

Diagnosed with ASS by an medical expert  
18 years of age and older  
IQ higher than 75

## Exclusion criteria

Non-Dutch speaking  
Not allowed to give informed consent  
Not motivated for social participation

## Study design

### Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Health services research

### Recruitment

NL	
Recruitment status:	Will not start
Enrollment:	40
Type:	Anticipated

## Ethics review

Not approved	
Date:	22-02-2013
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	NL41534.042.12