

# Functional MRI of cognitive control in autism

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We intend to study the role of fronto-striatal circuitry and cognitive control in the inflexible behaviour that is a defining feature of autism.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Developmental disorders NEC
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON35416

### Source

ToetsingOnline

### Brief title

NeuroImaging of Cognitive control in Autism (NICA)

## Condition

- Developmental disorders NEC

### Synonym

autism

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Utrecht

**Source(s) of monetary or material Support:** subsidie is aangevraagd bij de National Alliance for Autism Research (NAAR). Het onderzoek zal alleen dan van start gaan; als ook daadwerkelijk financiering is verkregen.

## Intervention

**Keyword:** autism, cognition, developmental neuroimaging

## Outcome measures

### Primary outcome

The primary outcome measure in the fMRI studies will be MR signal. This signal represents the activation level (compared to a control condition) and is hypothesized to differ in fronto-striatal regions between children with autism and control children. A second, behavioral outcome measure is performance (reaction times and accuracy) on the cognitive controls tasks. The primary outcome measure for the DTI-scans will be anisotropy (representing the unequal regional diffusion of water), which is a measure of regional white matter regularity. Finally the primary outcome measure of the exploratory genetic studies will also be MR signal, which we hypothesize will differ in fronto-striatal regions between groups with different genetic profiles.

### Secondary outcome

n/a

## Study description

### Background summary

Autism is a heritable and disabling child-psychiatric disorder. Autism is characterized by three clusters of symptoms: 1) social deficits, 2) deficits in communication and 3) repetitive and stereotyped behaviour. The current proposal intends to investigate the neuroanatomical correlates of rigid behaviour in autism. This cluster of symptoms can be conceptualized as cognitive inflexibility and may be related to deficits in cognitive control and associated neural circuitry.

Cognitive control refers to the ability to flexibly adapt behaviour in a continuously changing environment. Fronto-striatal loops are involved in many aspects of controlling behaviour, and recent evidence indicates that a shift from diffuse to more focal activity in fronto-striatal areas supports the development of cognitive control in typically developing children. Animal studies and neuropsychiatric studies in humans have further implicated the basal ganglia in repetitive and stereotyped behaviour. Taken together, this potentially implicates fronto-striatal circuitry in the development of rigid and stereotyped behaviour in autism.

## **Study objective**

We intend to study the role of fronto-striatal circuitry and cognitive control in the inflexible behaviour that is a defining feature of autism.

## **Study design**

We propose a series of three fMRI studies to address the role of the fronto-striatal circuitry in different aspects of cognitive control in autism. The first study involves an implicit learning paradigm to test the capability of the fronto-striatal system to learn patterns present in the environment. By means of a classic Go/Nogo paradigm (second study) and a novel behavioural adaptation paradigm (third study), we will assess fronto-striatal involvement in the ability to flexibly adapt behavior. In addition, we will acquire diffusion tensor imaging (DTI) scans and perform functional connectivity analyses to assess fronto-striatal connectivity in autism. Finally we will perform an exploratory investigation of the influence of candidate-genes involved in brain development on fronto-striatal function in autism.

## **Study burden and risks**

Subjects will take part in IQ-testing, which will last up to 2.5 hrs. Their parents will take part in a standardized interview, as well as fill in questionnaires. Subjects will also take part in a MRI-scanning session lasting up to an hour. As there are no known risks associated with MR-scanning this procedure is considered completely safe. Anxiety will be minimized by means of a practice session in a MR-simulator. In addition subjects will be asked to provide a sample of saliva or a cheekswab. The complete visit will last a maximum of half a day, and will be spread over two days if possible.

## **Contacts**

### **Public**

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## **Trial sites**

### **Listed location countries**

Netherlands

## **Eligibility criteria**

### **Age**

Adolescents (12-15 years)  
Adolescents (16-17 years)  
Children (2-11 years)

### **Inclusion criteria**

General inclusion criteria:

- 6-16 years ;Inclusion criteria for subjects with autism:
- DSM-IV diagnosis of autism, according to diagnostic interview (ADI-R);Inclusion criteria for controls:
- no DSM-IV diagnosis according to diagnostic interview (DISC)
- no scores in the clinical range on the Child Behavior Checklist (CBCL) and Teacher Rating Form (TRF)
- IQ>70

### **Exclusion criteria**

- history or presence of major illness of the cardiovascular, the endocrine, the pulmonal or the gastrointestinal system
- presence of metal objects in or around the body (pacemaker, dental braces)
- history or presence of neurological illness

## Study design

### Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	25-05-2008
Enrollment:	300
Type:	Actual

## Ethics review

Approved WMO	
Date:	19-09-2006
Application type:	First submission
Review commission:	METC NedMec
Approved WMO	
Date:	25-08-2009
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO	
Date:	28-09-2010
Application type:	Amendment
Review commission:	METC NedMec

## 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	NL13107.041.06