# ADHD, from behaviour to biology

Published: 12-02-2013
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Objective: Our general objective is to investigate the neurobiological substrates of a broader ADHD phenotype.

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Developmental disorders NEC |
| **Study type** | Observational invasive |

## Summary

### ID

NL-OMON39334

**Source**
ToetsingOnline

**Brief title**
ADHD, from behaviour to biology

### Condition

- Developmental disorders NEC

**Synonym**
ADHD, Attention Deficit Hyperactivity Disorder

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Utrecht
**Source(s) of monetary or material Support:** NWO VICI

### Intervention

**Keyword:** ADHD, fMRI, Neuropsychology

## Outcome measures

### Primary outcome

Main study parameter/endpoint

(1) Task related brain activity (BOLD-signal change) and connectivity measures

from fMRI

(2) Neuropsychological performance measures collected with computerized tasks

### Secondary outcome

Secondary study parameters/endpoints

(1) Resting-state functional connectivity, assessed with resting-state fMRI

(2) Symptoms of ADHD from symptom rating scales (CBCL/TRF/SWAN)

(3) White matter integrity, assessed using tract-based FA (Fractional

Anisotropy) measures from DTI (Diffusion Tensor Imaging)

(4) Genotype on risk genes for ADHD

# Study description

### Background summary

Rationale: Recent studies point toward a more heterogeneous aetiology of Attention Deficit Hyperactivity Disorder (ADHD), considering multiple pathways that might separately lead to the disorder. In this protocol we propose to investigate several cognitive domains that are implied in ADHD on both a neuropsychological and a functional Magnetic Resonance Imaging (fMRI) level. An important aspect of this project is the inclusions of a third group of children (aside from children with ADHD and typically developing controls) with symptoms of ADHD, but without a diagnosis of ADHD.

### Study objective

Objective: Our general objective is to investigate the neurobiological substrates of a broader ADHD phenotype.

### Study design

Study design: We propose to conduct a cross-sectional combined neuropsychological and MRI-study to investigate brain activity and connectivity in ADHD.

### Study burden and risks

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Participants will be asked to perform neuropsychological tasks and to undergo an MRI-scan lasting approximately 60 minutes. Subjects will be prepared for MR-scanning using an MR-simulation procedure. Incidental findings of structural cerebral pathology requiring medical treatment may occur. If this happens, the subject and his/her parents will be notified. No immediate benefits for subjects are to be expected from participation in this study. In the long run, increased understanding of the aetiology and pathophysiology of ADHD may contribute to refined diagnosis and an improved specificity of treatment options.

## Contacts

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## Trial sites

### Listed location countries

Netherlands

# Eligibility criteria

**Age**
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

## Inclusion criteria

Inclusion criteria for parents:
• No additional criteria if a child meets all of the inclusion criteria;General inclusion criteria for all subject groups (excluding parents):
• Aged 6 through 18 years at first scan
• Ability to speak and comprehend Dutch;Inclusion criteria for subjects with ADHD
• Clinical DSM-IV diagnosis of ADHD, supported by the Diagnostic Interview Schedule for Children (DISC) ;Inclusion criteria for control subjects
• No DSM-IV diagnosis, according to the DISC
• No scores in the clinical range on any scale of the Child Behavior Checklist (CBCL) as reported by one of the parents.;Inclusion criteria for subjects with a psychiatric diagnosis but no diagnosis of ADHD
• Any clinical DSM-IV diagnosis except ADHD, supported by the DISC interview
• A score in the subclinical or clinical range of the CBCL subscale of Attention Problems as reported by one of the parents.

## Exclusion criteria

Mental retardation (IQ < 70)
Major illness of the cardiovascular, endocrine, pulmonal or the gastrointestinal system
Presence of interfering metal objects in or around the body (eg. pacemaker)
History of or present neurological disorder. A neurological disorder is defined as any disorder that requires care from a neurologist.

# Study design

## Design

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| Study type: | Observational invasive |
| Intervention model: | Other |

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| Allocation: | Non-randomized controlled trial |
| Masking: | Open (masking not used) |

**Primary purpose:** Basic science

### Recruitment

NL

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|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 08-04-2013 |
| Enrollment: | 450 |
| Type: | Actual |

## Ethics review

Approved WMO

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| Date: | 12-02-2013 |
| Application type: | First submission |
| Review commission: | METC Universitair Medisch Centrum Utrecht (Utrecht) |

## 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 | NL40444.041.12 |