Neural correlates of cognitive subtypes in Attention Deficit Hyperactivity Disorder

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cognitive and attention disorders and disturbances
Study type	Observational non invasive

Summary

ID

NL-OMON32162

Source
ToetsingOnline

Brief title
Cognitive Subtypes in ADHD

Condition

- Cognitive and attention disorders and disturbances

Synonym
attention deficit disorder, hyperactivity

Research involving
Human

Sponsors and support

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

Intervention

Keyword: ADHD, fMRI, genes, subtypes

Outcome measures

Primary outcome

The primary outcome measures will be the intensity and location of neural activation during the behavioural tasks in the MRI scanner, and the genotype on ADHD risk genes.

Secondary outcome

Secondary outcome measures will be the results from the questionnaires, the interview and the results on neurpsychological tasks.

Study description

Background summary

Attention Deficit Hyperactivity Disorder is a neuropsychiatric disorder that affects 7-10 percent of children between the age of 8-15, making it the most prevalent childhood disorder. It places a large burden on mental health services both directly and indirectly, as there is a range of problems associated with ADHD such as learning disabilities, conduct disorders, personality disorders, substance disorders and a higher rate of mood and anxiety disorders.
However, ADHD is a heterogeneous disorder. Individuals with ADHD diverge greatly in their performance on behavioural tasks, and the neural activation patterns associated with these tasks are also highly variable between individuals. We hypothesize that these large individual differences reflect differences in the neurobiological basis of ADHD in different individuals.

Study objective

By restricting the inclusion on the fMRI studies to participants with deficits on a specific domain we hope to examine the unique neural mechanisms contributing to specific impairments. This will allow us to address the

question whether neuropsychological subtypes of ADHD are rected in individual differences in the neurobiological background of ADHD.

Study design

All subject will be at least 6 years of age. Subjects will be asked to participate in a neurpsychological assessment (maximum duration 2.5 hrs, an abbreviated 1 hr version will be used whenever possible), and subjects (or their parents) will be asked to participate in a structured interwiew(1.5 hrs.) as well as fill in some questionnaires (45 min.). For school age subjects, they will also be asked to approache a teacher to fill out a questionnaire (20 min.). Subjects (and their parents) will be asked to provide a DNA sample for genetic analysis, by means of saliva or cheekswabs.
A selected group of participants will be asked to participate in a fMRI scanning session (1hr). Prior to the MRI scan, all child subjects (6-12 yrs) will participate in a protocolized practice session using a MRI simulator to desensitize them to the scanner environment, and prevent any anxiousness or nervousness. Only after acclimating the subject to the scanner environment, so that both subjects and parents are comportable with the procedure, will the subject be taken to the actual scanner. As much time will be taken as needed, but actual practice sessions usually take up to 30 minutes. If the subject or the parent is uncomfortable with any aspect of the procedure the study will be cancelled.The same procedure can be used with older subjects if the reseacher or subject feels this is advisable.

Study burden and risks

There are no known risks associated with MRI acquisition, or any of the proposed methodologies, and we believe the impact on the subjects will be minimal. Research into the neurbiological background of ADHD will improve our insight into the pathofysiology of this disorder, and will facilitate the future design of new and effective ways to treat this disorder.

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

General inclusion criteria:
1) aged 6-24 years
2) ability to comprehend and speak dutch;Inclusion criteria for subjects with ADHD:
1)DSM-IV (APA, 1994) diagnosis of ADHD
2) scores in the clinical range on the Child Behavior Checklist (CBCL) and Teacher Rating Form(TRF).
3) IQ > 70.;Inclusion criteria for controls:
1) no DSM-IV (APA, 1994) diagnosis
2) no scores in the clinical range on the Child Behavior Checklist (CBCL) and Teacher Rating Form(TRF).
3) IQ > 70.

Exclusion criteria

1)mental retardation (IQ < 70)
2)major illness of the cardiovascular, the endocrine, the pulmonal or the gastrointestinal system
3)presence of metal objects in or around the body (pacemaker, dental braces)
4)history of or present neurological disorder
5)for individuals over 12 years of age: legal incompetence, defined as the obvious inability to

comprehend the information that is presented by the investigator and is outlined in the Information letter and on which the decision to participate in the study is to be based

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-09-2008
Enrollment:	6000
Type:	Actual

Ethics review

Approved WMO

Date:	24-06-2008
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	NL21976.041.08