Bringing Neuroimaging and Genetics to the Clinic: A case for Attention-Deficit/Hyperactivity Disorder and Autism Spectrum Disorder

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Ethical review	Approved WMO
Status	Will not start
Health condition type	Cognitive and attention disorders and disturbances
Study type	Observational invasive

Summary

ID

NL-OMON44585

Source
ToetsingOnline

Brief title
Clinical Neuroimaging and Genetics of ADHD and ASD

Condition

- Cognitive and attention disorders and disturbances

Synonym
Attention-Deficit/Hyperactivity Disorder; Disorder 2) ASD, Autisme Spectrum Disorder, Disorder 1) ADHD

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Attention-Deficit/Hyperactivity Disorder, Autism Spectrum Disorder, Genetics, Magnetic Resonance Imaging

Outcome measures

Primary outcome

Classifiers, and associated multimodal biomarker profiles, for application of

neuroimaging and genetics in the diagnostic process, prognostics and treatment

selection in ADHD and ASD.

Secondary outcome

N/A

Study description

Background summary

Current diagnostics of Attention-Deficit/Hyperactivity Disorder (ADHD) and Autism Spectrum Disorder (ASD) rely on symptom assessment. Increasingly, child and adolescent psychiatrists are confronted with marked phenotypic heterogeneity within these patient groups which is reflected in heterogeneous symptom profiles, developmental courses and treatment responses. The use of objective biological measures such as genetic and neural architecture biomarkers can potentially improve: 1) diagnostics, 2) subtype definition, 3) prognostics and 4) treatment selection. Although many studies have identified genetic and neural architectural features implicated in ADHD and ASD, results are marked by heterogeneity. This complicates clinical application of such features. Translation of research findings to clinical practice are furthermore limited due to the focus of those studies on ADHD and ASD cases that meet strict inclusion criteria. Therefore the included subjects are not representative of ADHD and ASD cases observed in clinical practice.

Study objective

The proposed study aims to bring neuroimaging and genetics closer to the child/adolescent psychiatric clinic by developing automated classifiers, and obtain associated multimodal biomarker profiles. Such biomarkers are prospected to, aid in clinical decision making by defining more homogeneous subtypes of current psychiatric diagnoses and predicting diagnosis, prognosis or treatment response. To tackle the marked heterogeneity in symptomatology as well as underlying pathologies of both disorders, we will focus on integration of multiple measures across modalities (e.g. genetics and neuroimaging).

Study design

This study has an observational case-control design for which we will recruit a clinical sample of children referred to a psychiatrist for evaluation on ADHD or ASD. The data collected in this design will be subjected to pattern recognition analysis techniques, combining complementary information across different biological measures and focusing on patterns of multiple measures rather than specific measures in isolation.
We will acquire measures in three domains: genetics (DNA analysis), neural architecture (structural MRI, Diffusion Tensor Imaging, resting-state fMRI) and phenotype (symptoms, developmental course and treatment response).

Study burden and risks

The participants will undergo a venapuncture (or donate saliva) to obtain DNA and biomarkers. Furthermore, the participants will undergo a 30-minute MRI-scanning session preceded by a short MRI-simulation session aimed at alleviating the potential stress of scanning. If children report resistance or discomfort the procedure will be stopped immediately. One of the parents will be asked to digitally complete questionnaires at home at time of inclusion and to complete a smaller set of questionnaires every 6 months (for maximally 2 years) in case the participant will follow a clinical trajectory at Karakter Child and Adolescent Psychiatry. The participant is asked to complete two short questionnaires at time of inclusion. The teacher of the participant will be asked to fill in two questionnaires at the time of inclusion. Disadvantages for the participants are therefore mainly time-burden, stress/discomfort during the venapuncture, stress and lying still during the MRI session, potential incidental findings and possibly temporarily putting medical treatment on hold.

Participation on this study does not interfere with the clinical trajectory the participants are undergoing at the department of child/adolescent psychiatry. The participants will not directly benefit from this study.

Contacts

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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

- Referral to Karakter Child and Adolescent Psychiatry, to be evaluated for ADHD or ASD.
- Aged 8 years * 18 years at initial inclusion
- Signed informed consent by parents or legal representative
- Ability to speak and comprehend Dutch

Exclusion criteria

- Contra-indications for MRI assessment, such as the presence of metal objects in or around the body (pacemaker, dental braces)

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	1125
Type:	Anticipated

Ethics review

Approved WMO

Date:	24-05-2016
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL47738.091.15