Social cognition in adolescents with Attention Deficit Hyperactivity Disorder (ADHD)

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON37595

Source
ToetsingOnline

Brief title
Social cognition in adolescents with ADHD

Condition

- Other condition

Synonym
ADHD, Attention Deficit Hyperactivity Disorder

Health condition

psychische stoornissen: aandachtstekortstoornis met hyperactiviteit

Research involving
Human

Sponsors and support

Primary sponsor: Rijksuniversiteit Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: ADHD, adolescents, social cognition, stimulants

Outcome measures

Primary outcome

Performance on tasks for social cognition of the ADHD groups is compared to the healthy control group.

Secondary outcome

The performance on social cognition of patients with ADHD on stimulants is compared to the performance of ADHD patients without stimulant medication (medication-free and stimulants off). Furthermore, the following additional measures will be used to predict the performance on social cognition measures and daily social functioning: 1) task performance on tests for executive functions, and 2) scores on a range of questionnaires on social functioning in daily life.

Study description

Background summary

Social cognition refers to the ability to understand the feelings of other people. It covers basic processes like the perception and recognition of emotion from faces, gestures and verbal intonation (prosody) as well as more complex processes such as the ability to understand other peoples* feelings, thoughts, expectations and beliefs (theory of mind: ToM), empathy and humor. Whereas deficits in social cognition are extensively reported in many populations like in autism, schizophrenia, bipolar disorder or after frontal

lobe brain damage, there is surprisingly little literature about social cognition in patients with attention-deficit/hyperactivity disorder (ADHD), especially in adolescence and adulthood. However, there are good reasons to believe that adolescents and adult patients with ADHD have impairments in social cognition, since observable social impairments are repeatedly reported in patients with ADHD. While social cognition in adults with ADHD is currently investigated by our group (METc2010.357, ABR NL34794.042.11), the focus of the present study lies on the adolescent population. A literature review on the cognitive effects of pharmacological treatment (stimulants) in patients with ADHD, leads to the assumption that possible deficits in social cognition will not be consistently improved by stimulants. Thus, we expect a decreased performance of adolescent patients with ADHD both with and without medication on affective and complex social cognition tasks compared to a healthy control group.

Study objective

The main objective is to determine whether medication-free adolescents with ADHD show impairments in affective and complex social cognition. The secondary objectives are: 1) To determine whether the use of stimulant medication (on and off) affects the performance of adolescents with ADHD on tasks of affective and complex social cognition; 2) To determine whether the performance on the more fundamental executive functioning tasks, in particular inhibition and working memory, predicts social cognitive performance in adolescents with ADHD; 3) To determine whether the performance on social cognition tasks predicts social functioning in daily life in adolescents with ADHD.

Study design

One factorial, between-subject, quasi-experimental design with four cross-sectional groups.

Study burden and risks

The investigator will meet the patient once for assessment and the duration of assessment is approximately 2.5 to 3 hours. The time for filling out the questionnaires is estimated to take 15 minutes for the adolescent and 60 minutes for the parents/caretakers. The behavioral assessment will require a certain amount of concentration from which a patient can recover after short breaks. Patients will be unaware of their level of performance. The risks of this study are negligible and the burden can be considered minimal. Patients will have no direct benefit from the study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)

Inclusion criteria

Inclusion criteria for the healthy control group:
• Age of 12 to 16 years, inclusive 16.
• Intelligence score of IQ >= 80
• Both adolescent and parents/caretakers are willing to sign informed consent;General inclusion criteria for patients diagnosed with ADHD:
• Age of 12 to 16 years, inclusive 16.
• Diagnosed with ADHD according to DSM-IV-TR: all subtypes are allowed
• Intelligence score of IQ >= 80
• Both adolescent and parents/caretakers are willing to sign informed consent;Extra inclusion criteria for the specific medication groups:
Medication-free:
• No psychopharmaca usage during the past year; no psychopharmaca prescribed by

clinician.;On stimulants:
• Regular intake of stimulant medication, as prescribed by the clinician (co-medication with other psychopharmaca is allowed).
• Intake of the regular dose of stimulant medication on the day of the assessment;Off stimulants:
• Regular intake of stimulant medication, as prescribed by the clinician (co-medication with other psychopharmaca is allowed).
• Discontinuation of stimulant medication intake on the day of the assessment
• Willing to delay stimulant medication intake for this study. If not, the participant is excluded.

Exclusion criteria

Healthy controls:
• Attendance of primary school. All participants should have made the transition from primary to secondary school because this is a major life event for adolescents that impacts on various aspects of their lives, including their social life, which is important for the development of social-cognitive functions.
• Psychiatric diagnosis confirmed by clinician
• Signs of clinical psychopathology as assessed with the Child Behavioural Checklist (see section 4.3 Study procedures)
• Signs of clinical ADHD, as assessed with the Conners* Parent Rating Scale (see section 4.3 Study procedures)
• Signs of clinical autistic spectrum disorder (ASD) as screened with the Social Communication Scale (see section 4.3 Study procedures).;ADHD groups:
• The ADHD-diagnosis is not confirmed by the semi-structured Parent Interview Schedule for Child symptoms (PICS-5: Schachar, Ickowicz, Sugarman, 2008) and the Teacher Telephone Interview (TTI) administered by the researchers. If recent scores (<2 years old) are available, these scores are requested from the patient file.
• Attendance of primary school. All participants should have made the transition from primary to secondary school because this is a major life event for adolescents that impacts on various aspects of their lives, including their social life, which is important for the development of social-cognitive functions.
• Clinical diagnosis of ASD. If scores of the Autism Diagnostic Observation Scale (ADOS) and/or Autism Diagnostic Interview (ADI) are available from the patient record, these scores will be leading in the decision for exclusion.
• Signs of clinical ASD, as screened with the Social Communication Scale (see section 4.3 Study procedures). Other comorbid psychiatric disorders than ASD are allowed.
• Any cerebral neurological diseases

Study design

Design

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

Primary purpose: Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-01-2013
Enrollment:	144
Type:	Actual

Ethics review

Approved WMO

Date:	15-11-2012
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	NL40031.042.12