

# COTAP: COgnitive Test for ADHD Profiling

Published: 25-02-2015

Last updated: 21-04-2024

Developing a short (+/- 30-40 minutes) computerised test which can measure a large amount of cognitive characteristics of ADHD, and as such can identify a profile of cognitive strengths and weaknesses. The identification of such a subtype serves:•...

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

## Summary

### ID

NL-OMON41008

### Source

ToetsingOnline

### Brief title

COTAP

### Condition

- Cognitive and attention disorders and disturbances

### Synonym

ADHD

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Boom testuitgevers

**Source(s) of monetary or material Support:** Boom testuitgevers

### Intervention

**Keyword:** ADHD, children, cognition, test

## Outcome measures

### Primary outcome

- 1) Accuracy and speed when less alert.
- 2) The ability to suppress the location of a stimulus and give an opposite response.
- 3) Working memory.
- 4) The influence of the reward mechanism on speed, variability and accuracy of response.
- 5) Waiting time tolerance.
- 6) Sustained attention.

### Secondary outcome

None.

## Study description

### Background summary

It has been consistently proven that not just one cognitive deficit underlies ADHD (Fair et al., 2012; Nigg et al., 2005; Sonuga-Barke et al., 2010; de Zeeuw et al., 2012). Just like in the normal population, ADHD patients show relative weakness of one or more cognitive functions in combination with normal cognitive functions in other domains. This means that in clinical practice, only a part of the patients with ADHD will show deficits on the most classical ADHD-related disfunctions, such as sustained attention or inhibition (Nigg et al., 2005). For a test that contributes to the diagnostic process of ADHD it is essential to measure an amount as big as possible of cognitive processes on which children with ADHD can show deficits. Due to the integration of all these functions we can sketch a cognitive profile (subtypes) of the patient, in which relative strengths and weaknesses can be shown. Cognitive weaknesses can contribute to clinical seriousness, but are not necessarily needed to diagnose. As such, cognitive diagnostics won't replace current diagnostic methods but she is an addition. Generally, there is an assumption that cognitive subtypes differ from one another in causal factors (for example genetic)

predisposition), the natural course from childhood to adulthood, and also the sensitivity to certain treatment. As such, a test like the COTAP can bring keystones in the future for prognosis and choosing the course of treatment.

## **Study objective**

Developing a short (+/- 30-40 minutes) computerised test which can measure a large amount of cognitive characteristics of ADHD, and as such can identify a profile of cognitive strengths and weaknesses. The identification of such a subtype serves:

- For the support of explanatory diagnostics of ADHD
- For the support of giving a more focused treatment advice
- For the support of neuroscientific and genetical research to the causes of ADHD (endophenotype).

## **Study design**

Observational study.

Children newly diagnosed with ADHD (still off medication) are asked to participate. Task administration is performed only once for N=500 children. N=100 children are asked to participate twice, for test-retest reliability. This does not interfere with routine clinical practice: it normally takes several months before medication treatment is initiated.

Control children are tested once, except for N=150 children who are asked to participate twice to establish test retest reliability.

## **Study burden and risks**

There are no risks. The burden is minimal because of the short duration and the form of the task, which is presented as a game. Children normally like participating in this kind of research. Furthermore they will receive a small present afterwards and parents could if wanted get a short report about the results of their child.

## **Contacts**

### **Public**

Boom testuitgevers

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## Scientific

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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

ADHD group: ADHD, 6-12 years, no medication during testing.

Controlgroup: 6-12 years

### Exclusion criteria

Neurological disorders, epilepsy

## 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:	Diagnostic

## Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	12-09-2015
Enrollment:	1800
Type:	Actual

## Ethics review

Approved WMO	
Date:	25-02-2015
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO	
Date:	10-08-2015
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO	
Date:	02-11-2015
Application type:	Amendment
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

CCMO

### ID

NL49249.091.14