

# Cognitive dysfunctions transcending diagnostic categories: towards biological mechanisms underlying psychiatric symptom-dimensions

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

## Summary

### ID

NL-OMON43512

### Source

ToetsingOnline

### Brief title

AMC psychiatry and cognition study

### Condition

- Cognitive and attention disorders and disturbances

### Synonym

cognitive deficits, psychiatric disorders

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Academisch Medisch Centrum

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** Cognitive deficits, Psychiatric disorders

## Outcome measures

### Primary outcome

Cognitive functioning

### Secondary outcome

- Self-report questionnaires
- Blood markers
- Electro-encephalogram (EEG)
- Hair cortisol analysis

## Study description

### Background summary

The majority of patients with a psychiatric disorder such as major depressive disorder, schizophrenia or obsessive-compulsive disorder, suffers from cognitive dysfunction (e.g. in attention, memory, and planning ability). Cognitive dysfunction can play a major role in functional capacity and independence in everyday activities. Cognitive dysfunction is, therefore, a poorly controlled and highly relevant dimension of psychiatric disorders that cuts across traditional diagnostic boundaries, and improved treatment should be a major goal in efforts to enhance quality of life for patients.

### Study objective

The objective of this protocol is threefold.

1. To investigate transdiagnostic cognitive deficits across a diversity of different psychiatric disorders.
2. To link cognitive deficits with symptom-dimensions, EEG, cortisol, genetic and other blood marker variations in psychiatric patients.

3. To investigate the longitudinal course of cognitive deficits in psychiatric patients in relationship to symptom-dimensions and biological parameters.

### **Study design**

Longitudinal cohort study

### **Study burden and risks**

There are minimal risks associated with participation. Extent of the burden is an assessment of 3 hours at baseline and 1 year follow up. Benefits are that the treating physician and patient can receive a report of the results of the cognitive testbattery and clinical questionnaires, that could be used in the treatment plan.

## **Contacts**

### **Public**

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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)  
Elderly (65 years and older)

## Inclusion criteria

1. Ability to give informed consent
2. Where participants are of legal childhood age, consent will also be obtained from one of the participant\*s parents. Both the parent and participant will be required to sign the consent form in such a case. It will be the investigator\*s responsibility to determine whether a participant of legal childhood age has the capacity to consent to the study.
3. Age 14 - 75 years.
4. DSM-IV-TR diagnosis on Axis I.
5. Fluent in Dutch.
6. Clinically stable

## Exclusion criteria

1. High risk of suicide
2. Unstable medical disorder
3. Premorbid IQ < 70
4. History of a clinically significant abnormality of the neurological system (including dementia and other cognitive disorders or significant head injury) or any history of seizure (excluding febrile seizure).

## Study design

### Design

**Study type:** Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Basic science

### Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated): 14-02-2017

Enrollment: 5000

Type: Actual

## Ethics review

Approved WMO	
Date:	29-04-2016
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	25-01-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

### Other (possibly less up-to-date) registrations in this register

ID: 26462  
Source: Nationaal Trial Register  
Title:

### In other registers

Register	ID
CCMO	NL55751.018.15
OMON	NL-OMON26462