

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

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Cognitive and attention disorders and disturbances
Study type	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

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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: NTR

Title:

In other registers

Register	ID
CCMO	NL55751.018.15
OMON	NL-OMON26462