Across Study

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON26462

Source
Nationaal Trial Register

Brief title
TBA

Health condition

Psychiatric disorders

Sponsors and support

Primary sponsor: Amsterdam University Medical Center, AMC
Source(s) of monetary or material Support: None

Intervention

Outcome measures

Primary outcome

The primary outcome measure is cognitive functioning as assessed by the Cambridge Neuropsychological Test Automated Battery (CANTAB).

Secondary outcome

The secondary outcome measures include the clinical symptoms, electro-encephalogram, genetic- and blood markers, hair cortisol.

Study description

Background summary

Background: Patients with psychiatric disorders, such as major depressive disorder, schizophrenia or obsessive-compulsive disorder, often suffer from cognitive dysfunction. The nature of these dysfunctions and their relation with clinical symptoms and biological parameters is not yet clear. Traditionally, cognitive dysfunction is studied in patients with specific psychiatric disorders, disregarding the fact that cognitive deficits are shared across disorders. The Across study aims to investigate cognitive functioning and its relation with psychiatric symptoms and biological parameters transdiagnostically and longitudinally.

Methods: The study recruits patients diagnosed with a variety of psychiatric disorders and has a longitudinal cohort design with an assessment at baseline and at one-year follow-up. The primary outcome measure is cognitive functioning. The secondary outcome measures include clinical symptoms, electroencephalographic, genetic and blood markers (e.g., fatty acids), and hair cortisol concentration levels.

Discussion: The Across study provides an opportunity for a transdiagnostic, bottom-up, data-driven approach of investigating cognition in relation to symptoms and biological parameters longitudinally in patients with psychiatric disorders. The study may help to find new clusters of symptoms, biological markers, and cognitive dysfunctions that have better prognostic value than the current diagnostic categories. Furthermore, increased insight into the relationship among cognitive deficits, biological parameters, and psychiatric symptoms can lead to new treatment possibilities.

Study objective

Some hypotheses to be tested include: 1) executive functioning will be impaired in psychiatric patients, 2) cortisol levels will be associated with memory functioning, 3) lower concentrations of omega-3 PUFAs are associated with poorer cognitive functioning, and 4) verbal memory dysfunction will persist despite improvements in psychiatric symptoms. Other research questions are possible to investigate with the acquired data.

Study design

During the baseline session, clinical symptoms and cognitive functioning are assessed, electroencephalography activity is recorded, and hair and blood samples are collected. Durin the one-year follow-up, clinical symptoms and cognitive functioning are assessed, electroencephalography activity is recorded, and a hair sample is collected.

Contacts

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Eligibility criteria

Inclusion criteria

1. Ability to give informed consent
2. DSM-IV-TR axis I or DSM-5 diagnosis
3. Aged 14 – 75 years at intake
4. For under-aged participants, consent will also be obtained from the participant's parents in addition to the participant's consent
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
Intervention model:	Other

Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-02-2016
Enrollment:	2184
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	19-11-2019
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 43512
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL8170
CCMO	NL55751.018.15

Register	ID
OMON	NL-OMON43512

Study results