Prediction of illness course and outcome in patients with a first episode of psychosis

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Schizophrenia and other psychotic disorders
Study type	Observational invasive

Summary

ID

NL-OMON47512

Source
ToetsingOnline

Brief title
Prediction of prognosis after a first psychotic episode

Condition

- Schizophrenia and other psychotic disorders

Synonym
first episode of psychosis; schizophrenia

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Europese Commissie

Intervention

Keyword: first episode of psychosis, illness course, outcome, prediction

Outcome measures

Primary outcome

Psychopathology will repeatedly be examined using semi-structured interviews and questionnaires including the Positive and Negative Syndrome Scale (PANSS), Clinical Global Impression Scale (CGI), Hamilton Depression Rating Scale (HAM-D), Young Mania Rating Scale (YMRS). Psychosocial function is assessed with the Global Assessment of Functioning scale (GAF). The PANSS will also be used to assess illness severity and symptomatic remission. Brain structure and function are measured in two Magnetic Resonance Imaging (MRI) sessions, consisting of structural MRI, resting state functional MRI and Diffusion Tensor Imaging (DTI). Cognition will be assessed using a computerised battery of neuropsychological tests that capture key deficits associated with psychosis, such as attention, memory, emotion recognition and executive function. Blood samples will be drawn to assess levels of genetic, proteomic, metabolomic and immune parameters. One hair sample will be taken for keratinocyte biomarker analyses.

Secondary outcome

Other study parameters include sociodemographics, medical history, physical health, current medication use, recent psychiatric history, psychiatric disorders in first-degree relatives, hospitalisations, and use of drugs of abuse. Handedness (Edinburgh Handedness Inventory), childhood maltreatment (Childhood Trauma Questionnaire) and resilience (Resilience Scale for Adults)

will be assessed with self-report questionnaires. Premorbid function is determined using the Premorbid Adjustment Scale (PAS), health and social needs are assessed with the Camberwell Assessment of Need Short Appraisal Schedule (CANSAS-P) and IQ is assessed using the Wechsler's Adult Intelligence Scale (WAIS).

Current and past episodes of psychopathology will be determined using the Structured Clinical Interview for DSM Disorders (SCID).

Study description

Background summary

Psychotic disorders are relatively common and severely disabling, although both the illness course and outcome vary greatly among patients. Following a first episode of acute psychosis, some patients make a good recovery, whereas others have series of relapses and remissions, or have an unremitting course of the illness. To date, however, we are not able to reliably predict the course and outcome of psychosis at an individual level. As such, there is a pressing need to assist clinical decision-making by developing objective methods to predict psychotic episodes and outcomes in order to tailor psychiatric care to the needs of each patient * i.e. to provide personalised care. Through the current study, we aim to predict illness course and outcome in patients with a first episode of psychosis on the basis of measures of psychopathology, brain structure and function, cognition, and biological markers in blood. These data will be used to develop and validate a quantitative and objective tool that will enable healthcare professionals to tailor psychiatric care to the particular needs of each patient.

Study objective

Primary objective of the current study is to develop and validate a prediction tool focusing on illness course and outcome at an individual level after patients have experienced a first episode of psychosis. This will be achieved by combining the predictive values of measures of psychopathology, clinical characteristics, brain structure and function, cognition, psychosocial functioning and biological markers in blood.

Study design

An international, multicentre, naturalistic follow-up study.

Study burden and risks

This study includes four visits (see for details Table 1 of the protocol). Visit 1 consists of collection of demographic and medical information, assessment of IQ, handedness, childhood trauma, resilience and premorbid function, and administration of a diagnostic interview. In addition, baseline examination of psychopathology, psychosocial functioning, health and social needs, drug use, and cognition is performed, and subjects will undergo a baseline MRI session of at maximum sixty minutes. A blood sample is drawn to assess genetic, proteomic, metabolomic and immune parameters. Both MRI and blood sampling are safe procedures, and standard procedures will be followed to minimise any risks. Visits 2, 3 and 4 are 2 months, 6 months and 1 year after inclusion in the study, respectively. During all these visits, psychopathology and psychosocial functioning will be examined. Visits 3 and 4 additionally include measures of health and social needs, drug use, and cognition. Visit 4 also entails a follow-up MRI session and blood sampling. Individuals younger than eighteen years of age (*16) can be included in this study, as a first episode of psychosis typically emerges in adolescence or young adulthood. Potential individual benefits are those associated with the close monitoring and extensive examination of patients. Since the current study entails a naturalistic design, and assessments (with the exception of drawing blood) are essentially non-invasive, associated risks are deemed negligible. Although there are a substantial number of assessments, it is allowed to complete assessments of each visit in multiple days and participants will be offered frequent breaks. Hence, the burden associated with participation is deemed minimal.

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

*16-40 years old
*Written informed consent of subjects aged 18 to 40 years
*Written informed consent of parents and/or legal guardians for subjects aged 16 or 17, in addition to assent from the minor subject, following local laws and regualtions.
*First episode of psychosis as defined by a DSM-IV diagnosis of schizophrenia or schizophreniform disorder or schizoaffective disorder (depressive type) on the basis of the Structured Clinical Interview for DSM-IV (SCID-I) (First et al., 2002).

Exclusion criteria

*A time interval between the onset of psychosis and study entry exceeding three years. Onset of psychosis is defined as the first contact with a healthcare professional during which the diagnosis *psychotic disorder* is set.
*Any previous neurosurgery or neurological disorder, including epilepsy
*History of head injury resulting in unconsciousness lasting at least 1 hour
*Pregnancy
*Any contraindications for MRI
*Refusing to have their blood drawn and/or their MRI performed
*Incompetency to fully comprehend the purpose of the study or to make a rational decision whether or not to participate

Study design

Design

Study type:	Observational 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):	24-10-2016
Enrollment:	86
Type:	Actual

Ethics review

Approved WMO Date:	30-03-2016
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	29-09-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	27-10-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	12-04-2017
Application type:	Amendment

Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	01-06-2017
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	01-02-2018
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	15-08-2018
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	24-04-2019
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	03-06-2020
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL53930.041.15