Psychotic disorder: positive, negative and cognitive symptoms in daily life

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

Summary

ID

NL-OMON41303

Source
ToetsingOnline

Brief title
CogHyg

Condition

- Schizophrenia and other psychotic disorders

Synonym
psychosis, schizophrenia

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Janssen-Cilag

Intervention

Keyword: cognition, daily life, negative symptoms, psychosis

Outcome measures

Primary outcome

Cognition assessed in daily life

Social cognition assessed in daily life

Negative symptoms assessed in daily life

Positive symptoms assessed in daily life

Fluctuations in both cognition and social cognition in daily life and

the influence of these fluctuations on positive and negative symptoms

Secondary outcome

Saliva samples will be collected for the purpose of molecular genetic studies.

These studies aim at selecting SNPs (parts of the DNA where one nucleotide is

different from one person to another) that contribute to the psychosis

phenotype.

Study description

Background summary

Individuals with psychosis often have cognitive complaints, such as difficulties with concentration or memory complaints. It is known that cognitive problems are related with the negative symptoms of psychosis like lack of motivation or anhedonia. Additionally, negative symptoms have a large influence on quality of life and daily functioning. The current study focuses on the cognitive problems that individuals with psychosis or a subclinical psychosis encounter in daily life.
The main goals are to examine fluctuations in cognition (concentration, attention, planning skills) in daily life, and to examine the diagnostic value of cognition in daily life for subclinical psychosis. Another aim is to study

the fluctuation of negative and positive symptoms in daily life, and their association with social and cognitive functioning.

Study objective

The primary goal of the study is to examine whether fluctuations in cognitive functioning can be measured in daily life. Another goal is to study which factors influence cognitive functioning in daily life. Finally, it will be examined whether fluctuations in cognitive functioning are related to specific psychological complaints.

Study design

This is an observational study which consists of 4 appointments and 6 days of measuring symptoms in daily life with the aid of an electronic device (PsyMate). During the first appointment the participant will receive information about the study, and has the opportunity to ask questions.
During the second appointment the participant signs informed consent, and during the second and third appointment several questionnaires and neurological tasks will be done. Additionally, the participant receives information about the PsyMate. The PsyMate is a small device which the participant will carry for 6 consecutive days. The PsyMate beeps at random moments during the day, after wich the participant will fill out a short questionnaire and will do a short (social) cognition task. The PsyMate enables the measurement of cognition and fluctuation thereof in daily life. During the second meeting the participant will also be asked to provide a saliva sample for the study of DNA.
During the fourth meeting, the participant is asked about the experiences during the PsyMate week, and will complete several computertasks that asses neuropsychological (attention, speed, processing of information, etc.) functioning.

Study burden and risks

The total time of participation in this study is 6 hours per participant, for which participants receive a reinbursement which is in proportion with respect to the invested time (by the participant). Given the fact that none of the tasks in the study (filling in questionnaires, doing (computerised) tasks, carrying the PsyMate and providing a saliva sample) has any risk, the participation is without risk for the participants.
The inclusion of under aged subjects (aged 15 years or older) is based on this minimal risk, and the fact that subclinical psychosis typically develops during adolescence, which would lead to non sufficient sample sizes if only adults were included in this study.

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

Inclusion criteria for the early psychosis group are: (i) the presence of attenuated psychotic symptoms, brief limited intermittent psychotic symptoms, genetic risk or the occurrence of a psychotic episode according to DSM-IV criteria, , (ii) age 15-35 years, (iii) sufficient knowledge of the Dutch language.;Inclusion criteria for the chronic psychosis group are: (i) life time occurrence of a psychotic episode according to DSM-IV criteria, (ii) illness onset > 6 years, (iii) age 25-55 years, (iv) sufficient knowledge of the Dutch language.

Exclusion criteria

Exclusion criteria for the early psychosis group are: (i) onset of symptoms >2 years, (ii) frequent drug use (>2 times a week), (iii) Mental Retardation (IQ score <70), (iiii) psychosis with organic cause. ;Exclusion criteria for the chronic psychosis group are: (i) illness onset <6 years, (ii) frequent drug use (>2 times a week), (iii) Mental Retardation (IQ score <70), (iiii) psychosis with organic cause.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-08-2011
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO

Date:	20-06-2011
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL35154.068.11