No Man is an Island Deconstructing social withdrawal across the early psychosis spectrum

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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-OMON42144

Source
ToetsingOnline

Brief title
No Man is an Island

Condition

- Schizophrenia and other psychotic disorders

Synonym
psychosis, schizophrenia

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: Mechanisms, Recent onset schizophrenia, Social Withdrawal, Ultrahigh Risk

Outcome measures

Primary outcome

Cohort clusters associated with social withdrawal behavior, based on disease

characteristics, cognitive and biological measures.

Secondary outcome

Persistency of, and fluctuations in withdrawal behavior as assessed with the

Experiences Sampling method.

Study description

Background summary

Although social withdrawal is relatively common in the general population, in young people prone to develop schizophrenia its negative consequences are far-reaching. No study thus far has disentangled the various mechanisms driving social withdrawal in this vulnerable group of adolescents and young adults. Given the large heterogeneity in clinical profiles it is likely that risk factors for withdrawal differ greatly between subjects, requiring tailored treatment strategies.

Study objective

In the current project we will investigate multiple risk factors and their interaction in a single study design, aiming to identify different profiles associated with social withdrawal behaviour in an Ultrahigh Risk and First Episode Psychosis sample. By asking about social behavior after six months, we will subsequently explore the stability of withdrawal over time and evaluate whether the profiles derived from initial assessment are predictive for withdrawal at 6 months follow-up.

Hypotheses:
We expect to find at least two distinct subgroups:
1. one in which social withdrawal is primarily related to deficits, such as social cognitive-, and neurocognitive deficits, accompanied by disturbances

mental coherence and/or lower levels of Oxytocin, and:
2. one in which social withdrawal is primarily a reaction to clinical symptoms (e.g. anxiety, paranoia, and/or depression).
In addition, we expect demoralization/-decreased self-esteem to moderate both pathways

Study design

Six-month follow-up study with a naturalistic design.

Additionally, we will approach the first 20 participants of the study with the question whether they (in addition to the original protocol , see Appendix page 16 of the custom protocol) are willing to attend a 1 hour group session, accompanied by professionals (researchers, health care) , to brainstorm about their own reasons for social withdrawal .

Study burden and risks

All participants will be assessed using a number of clinical scales/interviews, a computergame (virtual reality), a smartphone application (ESM) that beeps for six days at 10 random times throughout the day and neuropsychological tests. In addition, 4 blood tubes will be drawn for Oxytocin purposes. The first 20 participants will also participate in a 1 hour -long brainstorming session. No risks are attached to this study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Aged 18 to 35.
2. Adequate command of the Dutch language to complete the assessment.;3. Meeting the criteria for:
- An At Risk Mental State for psychosis as defined by the Personal Assessment and Crisis Evaluation Clinic (PACE) (Yung et al 1998; Yung et al 2003) (for details see page 12 protocol), OR,
- A first-episode psychosis <3 year prior to first interview.
4. Having social withdrawal symptoms (at least moderate severity (3) on item 5.1 (social isolation) of the CAARMS for the ARMS group or (3) on item N4 of the PANSS for the recent-episode group.
5. Able and willing to give informed consent.

Exclusion criteria

- IQ< 70
- Symptoms relevant for inclusion are explained by a medical disorder or drugs or alcohol dependency
- Florid psychotic symptoms interfering with feasibility of conducting baseline assessment

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-06-2015
Enrollment:	150
Type:	Actual

Ethics review

Approved WMO Date:	26-01-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	08-05-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	22-07-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	15-12-2015
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

No registrations found.

In other registers

Register	ID
CCMO	NL51493.018.14