Obsessive compulsive symptoms in psychosis: Insight into dynamic interaction and symptom variability

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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-OMON38485

Source
ToetsingOnline

Brief title
Obsessive compulsive symptoms in psychosis

Condition

- Schizophrenia and other psychotic disorders

Synonym
psychotic disorders, schizophrenia

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Postdocbeurs (Deutsche Akademische Austauschdienst (DAAD))

Intervention

Keyword: comorbidity, compulsive, obsessive, psychosis

Outcome measures

Primary outcome

Web-based assessments with monthly assessment intervals over 12 months

including psychopathology (psychosis, OCS and affective symptoms),

environmental and individual factors (such as life events and coping

strategies).

Secondary outcome

Subsequent use of the experience sampling method (ESM) over a period of 6 days

in a subgroup of patients with a non-affective psychosis, who recently reported

changes in OCS severity.

Study description

Background summary

A frequent co-morbidity in schizophrenia are obsessive-compulsive symptoms (OCS), which are reported by more than 20% of patients and are associated with additional impairments, more severe depressive symptoms, and poor social outcome (Fenton and McGlashan, 1986;de Haan et al., 2012). Recently, results of prospective studies revealed a high variability of OCS severity in patients with non-affective psychosis over time. In addition associations between symptom changes in OCS, psychotic and affective symptoms were found (de Haan et al., 2012;Schirmbeck et al., 2013). Findings are however limited by long intervals between assessments, allowing no statements on causal interactions and leaving the pathogenic understanding of this co-occurence unresolved.

Study objective

With this research project we aim to investigate the time course and relationship between psychotic, obsessive-compulsive and depressive symptoms and the influence of environmental and individual factors on the course of

symptom severity and interactions.
In more detail the following aims have been formulated:
1. Understanding the interplay between symptoms: As the primary endpoint, we want to elucidate the course and interaction of psychotic, obsessive-compulsive and affective symptoms over time.
2. Identifying the effect of environmental factors and psychological mechanisms on symptom severity and interaction: As secondary endpoints we want to evaluate reactivity to environmental factors (daily hassles, life events, medication) and the influence of individual mechanisms (metacognitive believes and coping strategies) on symptom fluctuation and interaction.

Study design

Two complementary assessment approaches will be conducted within an observational prospective design.

Study burden and risks

The web-based investigation will take approximately one hour to complete at each assessment time. In addition, patients who take part in the subsequent experience sampling method will invest another 2.5 hours of total assessment time. Neither risks nor benefits 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) former GROUP participants, who have given informed consent to be contacted for future studies
2) Age range of 18 to 60 years
3) Diagnosis of non-affective psychotic disorder according to the Diagnostic and Statistical Manual of Mental Disorders
4) Previously reported co-morbid obsessive-compulsive symptoms
5) Good command of the Dutch language
6) Able and willing to give written informed consent
7) Internet access.
Additional Inclusion criterion for the experience sampling approach will be the change in OCS severity during the previous month. Significant change is defined as a delta Y-BOCS score of 5 or more.

Exclusion criteria

1) IQ<60
2) Evidence of psychotic symptoms precipitated by an organic cause
3) Psychotic symptoms resulting from alcohol or drug dependence

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-05-2014
Enrollment:	220
Type:	Actual

Ethics review

Approved WMO

Date:	11-11-2013
Application type:	First submission
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	NL46405.018.13