Treatment of Obsessive compulsive symptoms in Psychotic disorders: Cognitive Behavioural Therapy

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Anxiety disorders and symptoms
Study type	Interventional

Summary

ID

NL-OMON42610

Source
ToetsingOnline

Brief title
TOP_CBT

Condition

- Anxiety disorders and symptoms

Synonym
obsessive-compulsive disorder, OCD in psychosis

Research involving
Human

Sponsors and support

Primary sponsor: Psychiatrie
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: CBT, obsessive-compulsive, psychosis, treatment

Outcome measures

Primary outcome

The primary endpoint is the change in OCS severity as assessed by the Yale-Brown-Obsessive-Compulsive Scale (YBOCS) compared to the waiting list condition.

Secondary outcome

Secondary endpoints are changes in symptoms of psychosis and depression, social functioning, and quality of life.

Study description

Background summary

Patients with psychotic disorders frequently report co-occurring obsessive-compulsive symptoms (OCS), with 12% fulfilling the criteria for an obsessive-compulsive disorder (OCD). Comorbid OCS are associated with additional impairments, lower quality of life and a less favourable prognosis. Although cognitive behavioural therapy (CBT) is considered treatment of first choice in primary OCD, evidence concerning treatment options of comorbid OCS in patients with a psychotic disorder is largely lacking and most patients remain untreated.

Study objective

We aim to evaluate the efficacy and applicability of a CBT intervention for relevant persistent comorbid OCS in patients with a psychotic disorder.
We hypothesize that 1) CBT of comorbid OCS will result in a clinical relevant reduction in severity of OCS. 2) We further expect that CBT will lead to an improvement in overall psychopathology, increased quality of life and overall functioning

Study design

Monocentric single blind randomized controlled trial with 3 month-follow up.

Intervention

Manualized CBT will be applied over a period of 12 weeks.

Study burden and risks

Burden: Patients will undergo a 1-hour structured interview during baseline assessment and will be asked to fill in additional questionnaires via an online platform, which will take another 30 min. These assessments will be repeated pre-treatment, post-treatment and at 3-month follow-up. Risks: In general, no risks, side effects or adverse effects have been described with respect to CBT. Benefits: In the vast majority of published cases the application of CBT for comorbid OCS resulted in significant decrease of symptom severity and stable remitted psychosis or even improvement of psychotic symptoms during treatment. With this intervention we hope to diminish OCS and to thereby improve the quality of life and functional outcome of participants.

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) Obsessive-compulsive symptoms (YBOCS * 12 for at least 2 months)
2) Age range of 18 to 50 years
3) Diagnosis of a schizophrenia spectrum disorder according to the Diagnostic and Statistical Manual of Mental Disorders 5
5) Good command of the Dutch language
6) Able and willing to give written informed consent

Exclusion criteria

1) Rumination or repetitive behaviour solely related to psychotic symptoms. Positive symptoms as such are not an exclusion criterion; only when they are considered to be the primary cause of OCS-like symptoms or when they are so severe that primary treatment focused on positive symptoms is called for (more than one PANSS item of the positive subscale has a score of 5 or when one PANSS item of the positive subscale has a score of 6 or more).
2) Sever intellectual impairment, defined as an estimated IQ<70
3) Psychopathology precipitated by an organic cause
4) High suicidality, operationalized as having a high suicidality score on the M.I.N.I. with the last suicide attempt within the past six months.
5) Changes in medication (mood regulators, antipsychotics) within one months prior to the inclusion of the study
6) Not being able to travel
7) Participant is in seclusion or admitted to a closed ward.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial

Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-01-2016
Enrollment:	88
Type:	Actual

Ethics review

Approved WMO

Date:	19-10-2015
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	NL54107.018.15