Is the performance on pretreatment exposure, assessed by the BAT-procedure, related to symptom change after 12 weeks of specialized clinical CBT, in patients with Obsessive-Compulsive Disorder?

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Anxiety disorders and symptoms
Study type	Observational non invasive

Summary

ID

NL-OMON43347

Source
ToetsingOnline

Brief title
Is pretreament exposure related to symptom change in patients with OCD?

Condition

- Anxiety disorders and symptoms

Synonym
obsessive compulsive disorder

Research involving

Human

Sponsors and support

Primary sponsor: GGZ Centraal (Amersfoort)
Source(s) of monetary or material Support: De instelling zelf (GGZ Centraal) en subsidie van Stichting Achmea Gezondheidszorgpostbus 444;2300 AK Leiden; 070-3670287;Kenmerk Z707;Behandeld door: Marjan Boekestijn

Intervention

Keyword: Behavior Approach Test, cognitive behavioral therapy, Obsessive Compulsive DIsorder, Treatment indication

Outcome measures

Primary outcome

Dependent variables:

1/ Difference in score on YBOCS assessed at start of treatment and after 12

weeks (continuous data);

2/ Response to treatment (>=35% OCD symptom reduction) yes/no;

3/ Remission (post-treatment YBOCS score <=8) yes/no.

Secondary outcome

Secondary outcome measures will be

- Difference in score on quality of life, assessed by the Euroquol at start of

treatment and after 12 weeks.

- Proportion of dropouts.

- Outcome at 16 and 40 weeks.

Study description

Background summary

Rationale: Obsessive-compulsive disorder (OCD) is a serious, disabling and often chronic psychiatric disorder, with a severe impact on daily functioning for patients and their families. (Bobes J, González MP et al. 2001; Subramaniam M, Abdin E et al. 2012). First en second step- interventions of the multidisciplinairy treatment guidelines can help, but 40-50% (Farris, McLean et al. 2013; Olatunji, Davis et al. 2013) does not benefit from regular treatment. From these patients 50-60% benefit from a specialized residential or daytime treatment, with Cognitive Behavioral Therapy (CBT) as major component (which we will call specialized clinical CBT in this protocol). 40-50% can be regarded as non-responders (Stewart, Stack et al. 2005). We cannot yet identify these patients on an individual level before we start the treatment. If we could do so, this would save a lot of medical costs and most of all, demoralisation for the patient and give us the possibility to think of alternatives in an earlier stage. In CBT exposure to feared situations is a important intervention. Research and clinical (Keijsers, Minnen et al. 2004; Simpson, Maher et al. 2011; Cammin- Nowak, Helbig-Lang et al. 2013; Glenn, Golinelli et al. 2013) imply that patients who are not willing or able to truly come to exposure to their feared situations during treatment, don*t benefit from the treatment. We want to study whether the extent to which patients truly expose themselves to their feared situations before the start of their treatment, predicts symptom change after specialized clinical CBT.. We want to develop a Behavior Approach Test (BAT) to measure the extent of the exposure before the start of treatment.

Study objective

Is the performance on pretreatment exposure, assessed by the BAT-procedure, related to symptom change after 12 weeks of specialized clinical CBT, in patients with Obsessive-Compulsive Disorder?

Study design

Study design: This study is a longitudinal hypothesis-testing study.

Study burden and risks

A participant is asked to do a pretreatment exposure-session at home under guidance of a nurce, of a duration of about an hour. During the BAT-procedure a participant is likely to experience distress. During the BAT heartrate is assessed. Furthermore the participant is asked to fill in questionnaires during the intake program, after 12 weeks of treatment and at follow up at 18 and 40 weeks after start treatment. Any possible risks are no different from the regular treatment and are considered low.

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

Referred patients (aged >18years), who meet a primary DSM-IV diagnosis of OCD, follow a specialized residential treatment with CBT as main component and give informed consent.

Exclusion criteria

Referred patients suffering from a psychotic disorder, an organic mental disorder, substance dependence, or mental retardation.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2017
Enrollment:	70
Type:	Actual

Ethics review

Approved WMO

Date:	03-01-2017
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	NL57070.029.16