Metacognitive therapy vs. exposure and response prevention for obsessive-compulsive disorder: A randomized clinical trial

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22167

Source
Nationaal Trial Register

Health condition

obsessive-compulsive disorder

obssessief compulsieve stoornis

Sponsors and support

Primary sponsor: not applicable
Source(s) of monetary or material Support: initiator = sponsor

Intervention

Outcome measures

Primary outcome

Treatment outcome will be evaluated by means of the Dutch versions of both a standardized self-report scale (Padua Inventory; Burns et al., 1996) and a semi-structured interview (Yale-

Brown Obsessive Compulsive Scale [Y-BOCS]; Goodman et al., 1989) for measuring the core symptoms of OCD (primary outcomes). Additionally, we will do a SCID-I screening.

To study changes in both belief domains that have been proposed to be important in the etiology of OCD and metacognitive beliefs about the meaning, significance, and danger of intrusive thoughts, the Obsessive Beliefs Questionnaire-44 (OBQ-44; OCCWG, 2005), the Thought Fusion Instrument (TFI; Wells et al., 2001) and the Beliefs About Rituals Inventory (BARI; Adrian Wells & Kirsten McNicol, 2012) will be employed.

Secondary outcome

In addition of the primary study parameters, questionnaires of general psychopathology (Symptom Checklist [SCL-90];
Derogatis, 1983), depression (Beck Depression Inventory, 2nd version [BDI-II]; Beck et al., 1996), and quality of life
(WHOQOL-Bref; WHO, 2004) will be administered to assess comorbid symptoms and degree of perceived well-being
(secondary outcomes).

At entry also three additional measurements will be employed in order to describe the participants characteristics at
baseline (intolerance of uncertainty scale [IUS]; Freeston, Rheaume, Letarte, Dugas, & Ladouceur, 1994; NEO Five
Factor Index [NEO-FFI]; Costa & mcCrae, 1992; Anxiety Sensitivity Index [ASI]; Reiss, Peterson, Gursky, & McNally,
1986).

Additionally, on both follow-up assessments, participants will be called by a member of the research team, who will ask
them to provide responses for the Treatment Change Recording Form (TCRF; Tolin et al., 2004), which will be used to
assess the initiation, termination, or change of any form of therapy, hospital services, support group, self-help program, or medication utilized by the participant since posttreatment.

Study description

Background summary

Obsessive-compulsive disorder (OCD) is characterized by recurrent obsessions and/or compulsions that cause marked
distress and interfere with daily functioning. Exposure with responsprevention is the current treatment of choice for OCD.
However, ERP for OCD is a good example of the discrepancy between statistically and

clinically significant change.
Although several studies and meta-analyses have shown ERP to lead to statistically significant improvements and large
effect sizes, only about 60% of treatment completers achieve recovery. These data show that there is room for
improvement and a need for augmentation of current CBT strategies. It has been suggested that progress might be made
by basing treatments on key cognitive processes involved in the development and maintenance of the disorder, such as
metacognition. So far, two studies have provided support for the efficacy of MCT for OCD.

The present trial is initiated to compare the effectiveness of MCT with ERP, the current treatment of choice for OCD, in an
outpatient clinical sample of patients with OCD. The following hypothesis is formulated: MCT is more effective than ERP,
both statistically significant and clinically relevant.

Study objective

MCT is more effective than ERP, both statistically significant and clinically relevant.

Study design

We will conduct a randomized controlled trial (RCT) with a pretest-posttest-6-month-30-month-follow-up-design.

Estimated time to fill in the questionnaires will take about 360 minutes per participant at max. (4 times 90 minutes)

Participation at the telephonic interview will take 20 minutes per participant at max. (2 times 10 minutes).

Their are no risks for the participants.

Intervention

Patients will be randomly assigned to
metacognitive therapy or exposure and responsprevention. The interventions will be offered at the Anxiety Disorders Department of PsyQ (Rotterdam and Spijkenisse). Both manual-driven treatments consist of 15 weekly sessions of 45 minutes duration.

Exposure with responsprevention consists of (1) exposure to the anxiety provoking stimuli and (2) prevention of
neutralizing responses that reduce anxiety.

Metacognition refers to knowledge or beliefs about thinking and strategies used to regulate and control thinking
processes.

The metacognitive model of OCD specifies two subcategories of beliefs that are fundamental to the
maintenance of the disorder; (1) metacognitive beliefs about the meaning and consequences of intrusive thoughts and
feelings, and (2) beliefs about the necessity of performing rituals and the negative consequences of failing to do so.

Resulting from the metacognitive model, treatment focuses on modifying patients' beliefs about thoughts and thought
processes, with the aim to alter the patients' relationship with their thoughts as opposed to challenging the actual content
of thoughts (as is done in CT).

Contacts

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Eligibility criteria

Inclusion criteria

Inclusion criteria are:

1) primary diagnosis of OCD

2) age 18-65.

Exclusion criteria

Patients are only excluded if they currently:

1) meet DSM-IV-TR criteria for severe major depressive disorder that requires immediate treatment, psychotic disorder, or bipolar disorder,

2) have substance abuse requiring specialist treatment, or

3) have a change in psychiatric medication type or dose in the six weeks before assessment or during treatment.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2014

Enrollment:	100
Type:	Anticipated

Ethics review

Not applicable
Application type: Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 42263
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL4601
NTR-old	NTR4855
CCMO	NL50201.058.14
OMON	NL-OMON42263

Study results