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

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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...

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

Summary

ID

NL-OMON42263

Source
ToetsingOnline

Brief title
metacognitive therapy vs. exposure and respons prevention for OCD.

Condition

- Anxiety disorders and symptoms

Synonym
obsessional problems, obsessive disorder, OCD

Research involving
Human

Sponsors and support

Primary sponsor: PsyQ Rijnmond, onderdeel van parnassia bavo groep

Source(s) of monetary or material Support: PsyQ Rijnmond

Intervention

Keyword: exposure and response prevention, metacognitive therapy, obsessive-compulsive disorder, randomized clinical trial

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) and the Thought Fusion Instrument (TFI; Wells et al., 2001) 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.

Study objective

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 design

We will conduct a randomized controlled trial (RCT) with a pretest-posttest-6-month-30-month-follow-up-design, with two treatment conditions. Both manual-driven treatments consist of 15 weekly sessions. To achieve a power of 0.80 ($\alpha = 0.05$) to detect a medium difference (effect size 0.5) the minimum sample size necessary in each condition is 45.

Intervention

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).

Study burden and risks

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.

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

Primary diagnosis of obsessive-compulsive disorder, age between 18-65

Exclusion criteria

To enhance the clinical representativeness of the sample, exclusion criteria will be kept to a minimum. Patients are only excluded if they currently:
1) meet DSM-V criteria for severe major depressive disorder that requires immediate treatment, psychotic disorder, or bipolar disorder
2) have mental impairment or evidence of organic brain disorder
3) have substance abuse requiring specialist treatment
4) have a change in medication type or dose in the six weeks before assessment or during treatment.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	01-04-2015
Enrollment:	90
Type:	Actual

Ethics review

Approved WMO

Date:	10-03-2015
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 22167
Source: NTR

Title:

In other registers

Register	ID
CCMO	NL50201.058.14
OMON	NL-OMON22167