

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

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

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22167

Bron

Nationaal Trial Register

Aandoening

obsessive-compulsive disorder

obsessief compulsieve stoornis

Ondersteuning

Primaire sponsor: not applicable

Overige ondersteuning: initiator = sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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).

There are no risks for the participants.

Onderzoeksproduct en/of interventie

Patients will be randomly assigned to metacognitive therapy or exposure and response prevention. 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 response prevention 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).

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Inclusion criteria are:

- 1) primary diagnosis of OCD
- 2) age 18-65.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blinding:	Dubbelblind
Controle:	Actieve controle groep

Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-10-2014
Aantal proefpersonen:	100
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing	
Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 42263

Bron: ToetsingOnline

Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten