

The efficacy of the Inference Based Approach, a new cognitive therapy for patients with the Obsessive Compulsive Disorder with poor insight.

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The objective of this study is to improve the prognosis of patients with the Obsessive Compulsive Disorder (OCD), with poor insight. A psychological treatment, the Inference Based Approach (IBA), which is developed and has been proven effective in...

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

Summary

ID

NL-OMON31984

Source

ToetsingOnline

Brief title

The efficacy of the Inference Based Approach.

Condition

- Anxiety disorders and symptoms

Synonym

obsessive neurosis, OCD

Research involving

Human

Sponsors and support

Primary sponsor: Meerkanten GGZ (Ermelo)

Source(s) of monetary or material Support: ZONMW praktijkzorgproject 100000 euro, mogelijke bijdrage van het Fonds psychische gezondheid

Intervention

Keyword: Inference Based Approach, Obsessive-compulsive disorder, Poor Insight, Treatment

Outcome measures

Primary outcome

The primary study outcome is the level of OCD complaints, measured with the Y-BOCS.

Secondary outcome

The secondary outcomes of the study are amongst more general psychopathology, the level of insight and the proportion drop outs.

Study description

Background summary

Obsessive-Compulsive Disorder (OCD) is a severe, often chronic disorder which is diagnosed when either obsessions or compulsions are present and when these symptoms cause marked distress and interfere with work or social functioning. OCD is a severe chronic psychiatric disorder, which affects 1-3% of the adult population and belongs to the 10 most invalidating medical conditions in the industrialized world (Bebbington 1998, Eisen et al. 2006, Karno et al. 1988, Kessler et al. 2005).

Evidence-based treatments for OCD consist of cognitive-behavioral therapy and antidepressants. Of patients with OCD who start with these treatments and are able to complete them, only 25-50% reaches complete recovery of the disorder (Fischer and Wells 2005; van Oppen et al, 2005). Another major clinical problem is that about 40% of the patients prematurely drop out from treatment or refuse treatment beforehand (Stetekee, 1993). One of the clinical most important predictors of poor outcome is the subgroup of patients with OCD with 'poor insight' (Himle et al, 2006, Tolin et al 2004, 2001, Kishore et al, 2003, Tot et al 2003, Erzegovesi et al 2001).

Study objective

The objective of this study is to improve the prognosis of patients with the Obsessive Compulsive Disorder (OCD), with poor insight. A psychological treatment, the Inference Based Approach (IBA), which is developed and has been proven effective in Canada, will be introduced and evaluated in the Netherlands. In this project IBA will be implemented at the outpatient treatment centres of the Marina de Wolf institute of Meerkanten GGZ and of the stichting Buitenamstel de Geestgronden.

The main question to be answered is: do patients with OCD with poor insight improve more from IBA than from cognitive behavioral therapy?

Study design

The study design is a randomized controlled effectiveness study (RCT) of 20 weeks with patients with OCD with poor insight. In this study the effectiveness of IBA will be compared with a control condition in which patients will be treated with cognitive behavioral therapy.

Intervention

After screening the participants will be randomly allocated to a treatment with IBA or the control condition which contains of cognitive behavioral therapy. IBA differs from the standard treatment because within this model specific attention is given to the credibility of the obsession and not only to the appraisal of it. The central idea of this new treatment form is that OCD patients with poor insight perform poor on reality testing (when they are obsessing) and that they treat imagined dangers as real instead of imagined dangers. The treatment teaches the patients to differentiate that imagination always precedes their compulsions. The learn how to distinguish imagination and reality better.

The control treatment consists of cognitive behavioral therapy.

The therapists are trained in a 5-day workshop by the team of O'Connor, the founder of IBA, and will be supervised by them. The IBA-protocol (O'Connor, Aardema & Pelissier, 2005) will be translated for this study. The therapists did participate in a pilot study and will be supervised weekly.

Study burden and risks

There is no risk associated with participating in the study, except time investment. This is, including measurement at follow up 4 hours per patient.

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

Adult patiënts (18 and older) with Obsessive Compulsive Disorder (DSM-IV criteria, assessed on basis of the SCID) with poor insight (assessed on basis of the OVIS, OVIS score is at least 5), OCS is the main diagnosis.

Exclusion criteria

Psychotic Disorder, drugs and or alcohol dependency or abuse

Study design

Design

Study phase: 3

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

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-09-2008
Enrollment:	40
Type:	Anticipated

Medical products/devices used

Registration:	No
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Ethics review

Approved WMO	
Application type:	First submission
Review commission:	METIGG: Medisch Ethische Toetsingscommissie Instellingen Geestelijke Gezondheidszorg (Utrecht)

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

CCMO

ID

NL23521.097.08