Predicting treatment outcome in obsessive-compulsive disorder using neuroimaging biomarkers.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23107

Source
Nationaal Trial Register

Brief title
OCD-TBM

Health condition

Obsessive-compulsive disorder (OCD)
Obsessieve-compulsieve stoornis (OCS)

Sponsors and support

Primary sponsor: Academic Medical Center
Source(s) of monetary or material Support: ZonMW

Intervention

Outcome measures

Primary outcome

Classifier accuracy as the proportion of patients correctly classified as responder (sensitivity) and non-responder (specificity)

Secondary outcome

Differences in the proportion of responders between the randomized (first) and fMRI biomarker allocated (second) cohort

Study description

Background summary

Obsessive-compulsive disorder (OCD) is a severely debilitating psychiatric disorder that is characterized by repetitive behaviour such as washing or cleaning, which may take up the entire day. First-line treatment for OCD consists of pharmacological treatment with selective serotonin reuptake inhibitors (SSRIs) or psychological treatment with cognitive-behavioral therapy (CBT) (van Balkom et al. 2013). Both these treatments are effective, but 40-60% of patients do not benefit sufficiently (Pallanti et al. 2002; Eddy et al. 2004). We recently found that machine learning analysis of resting-state functional MRI obtained prior to treatment can reliably predict treatment outcome in depression (van Waarde et al. 2015).
Here, we aim to apply these methods to OCD to develop a treatment selection biomarker that enables the allocation of patients to the treatment with the largest chance of success. In addition, we aim to determine the common and specific neural mechanisms underlying treatment efficacy. The analysis of CBT and SSRI-related changes at the level of brain areas and circuits will provide more perspective on the pathophysiology of OCD and the response to different treatments. Patients in the first cohort are randomized to SSRI or CBT to develop and validate a treatment selection fMRI biomarker for allocating OCD patients and to determine the divergent longitudinal effects on brain measures of treatment in patients with OCD. In the second cohort, patients will be allocated to SSRI or CBT based on fMRI biomarkers identified in the first cohort.

Study objective

We recently found that machine learning analysis of resting-state functional MRI obtained prior to treatment can reliably predict treatment outcome in depression (van Waarde et al. 2015). Here, we aim to apply these methods to OCD to develop a treatment selection biomarker that enables the allocation of patients to the treatment with the largest chance of success. In addition, we aim to determine the common and specific neural mechanisms underlying treatment efficacy.

Study design

Before treatment and 16 weeks after treatment.

Intervention

The subjects will be randomized to pharmacological treatment or cognitive behavioral therapy (CBT).

Contacts

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Eligibility criteria

Inclusion criteria

Patients:

• Diagnosis of obsessive compulsive disorder (OCD) according to the DSM-IV

• 18-70 years of age

• Willingness and ability to give written informed consent and willingness and ability to understand, to participate and to comply with the study requirements

Exclusion criteria

Patients:

• Bipolar disorder, current or past psychosis, primary alcohol or drug abuse assessed by the MINI

• Contraindication for MRI, such as metal implants, claustrophobia, and pregnancy

• Major head trauma or neurological disease, current or in history

• Adequate treatment of OCD with high dosed SSRI or CBT at the moment of screening or within 4 weeks before screening. Current treatment with tricyclic antidepressant or antipsychotic medication.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	28-11-2016
Enrollment:	120
Type:	Anticipated

Ethics review

Positive opinion

Date:	08-02-2017
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 45849
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL6400
NTR-old	NTR6575
CCMO	NL57808.018.16
OMON	NL-OMON45849

Study results