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

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Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23107

Bron
Nationaal Trial Register

Verkorte titel
OCD-TBM

Aandoening

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

Ondersteuning

Primaire sponsor: Academic Medical Center
Overige ondersteuning: ZonMW

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

Before treatment and 16 weeks after treatment.

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

Anouk van der Straten
Meibergdreef 5

Amsterdam 1105 AZ
The Netherlands
+31 20 8913661

Wetenschappelijk

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Meibergdreef 5

Amsterdam 1105 AZ
The Netherlands
+31 20 8913661

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	28-11-2016
Aantal proefpersonen:	120
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	08-02-2017
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 45849
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten