Inference Based Approach (IBA): towards personalized care for OCD patients ;A randomized non-inferiority controlled trial into the effectiveness and working mechanisms of IBA in comparison to CBT.

Published: 20-03-2019
Last updated: 19-08-2024

Primary Objectives: - Is IBA non-inferior to CBT in treating patients with OCD?Secondary Objectives:-* Does treatment modality predict pre- to posttreatment changes in neural networks, and is this related to symptom reduction and changes in...

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

Summary

ID

NL-OMON49344

Source
ToetsingOnline

Brief title
arrIBA

Condition

- Anxiety disorders and symptoms

Synonym
Obsessive Compulsive Disorder, OCD

Research involving
Human

Sponsors and support

Primary sponsor: GGZ Centraal (Amersfoort)
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: Inference Based Approache (IBA), Neurobiological working mechanisms, Non-inferiority, Obsessive Compulsive Disorder (OCD)

Outcome measures

Primary outcome

- Severity of OCD symptoms (Yale-Brown Obsessive Compulsive Scale (YBOCS))

o Responder status (decline on the YBOCS score of >= 35%) (yes/no)

o Remission status (YBOCS <= 8) (yes/no)

Secondary outcome

- T-1 weighted MRI, DTI, rs-fMRI and fMRI during symptom provocation

(watching OCD related pictures)

- Treatment history (Treatment Adherence Survey Patient version (TAS-P))

- Presence of tic disease (Tic symptom screening, optional: Yale Global Tic

Severity Scale (YGTSS))

- Medication use (questionnaire regarding medication use)

- Demographics (age, gender, marital status, level of education, occupation

etc)

- OCD subtype (YBOCS checklist)

- Insight in OCD symptoms (Overvalued Ideas Scale (OVIS) and OVIS self rating

(OVIS-SR))

- Severity of OCD symptoms (Yale-Brown Obsessive Compulsive Scale (YBOCS) and

YBOCS self rating (YBOCS-SR)

- Comorbidity (SCID 5, Becks Depression Inventory (BDI), Becks Anxiety Inventory (BAI), Autism Spectrum Quotient (AQ)
- Quality of life (EuroQol)
- Disability/impairment in work, social life or leisure activities and home life or family responsibilities (Sheehan disability scale (SDS))
- Relationship satisfaction (Relationship Satisfaction Scale (RSS))
- Treatment tolerability (Treatment Acceptability/Adherence Scale (TAAS))
- Treatment expectancy (Credibility and Expectancy Questionnaire (CEQ))
- Work alliance (Work Alliance Inventory Short Form client and therapist version (WAV))
- Treatment compliance (therapist will score their impression of patients compliance to treatment and homework assignments after two sessions on a visual analogue scale (VAS-scale)
- Questionnaire regarding treatment after study participation
- MRI eligibility screening
- PhenX toolkit Handedness
- Wechsler Abbreviated Scale of Intelligence IV- Short Form (WAIS-SF) (including block design, matrix reasoning, vocabulary, similarities)
- Visual Spatial N-back: measures executive functioning (updating), probing the dorsal cognitive CSTC circuit.
- Tower of London Task (ToL): measures executive functioning (planning), probing the dorsal cognitive CSTC circuit.
- Stop-Signal Task (SST); probing the ventral cognitive CSTC circuit.
- Confidence Accuracy Task: measures the accuracy of the confidences in one*s

own performance on a visual perception task.

Study description

Background summary

Obsessive-Compulsive Disorder (OCD) is one of the most disabling psychiatric disorders. However, the standard psychotherapeutic treatment Cognitive Behavioral Therapy (CBT) is unable to redeem about half of all patients and is rejected by many because of its anxiety provoking methods. A promising alternative is the Inference Based Approach (IBA), which appears to be as effective as CBT, and possible more effective for patients with limited insight. The current study will investigate the proposed IBA non-inferiority to CBT, in order to offer patients this much needed alternative. Furthermore, we will investigate the neurobiological working mechanisms of both treatments. Both treatment modalities are expected to alter the connectivity within and between different functional networks. In order to lead the way towards personalized care for OCD sufferers, we will search for clinical and neurobiological predictors of response to both treatment modalities. By predicting on forehand whether an individual patient will respond better to IBA or CBT, we aim to prevent the demoralizing effect of undergoing ineffective treatment.

Study objective

Primary Objectives:
- Is IBA non-inferior to CBT in treating patients with OCD?

Secondary Objectives:
-* Does treatment modality predict pre- to posttreatment changes in neural networks, and is this related to symptom reduction and changes in cognitive performance?
- Do pre-treatment neural network patterns have predictive value for treatment response?
- Is IBA superior to CBT in treating patients with poor insight?
- Is IBA more tolerable than CBT for patients with OCD?
- What are clinical and demographic predictors of treatment outcome?
- Does insight improve more or earlier in patients who underwent IBA, compared to those who underwent CBT? Is change in insight related to symptom reduction?

Study design

The current study is a multicenter, randomized controlled non-inferiority trial. During 130 weeks, we will recruit 203 OCD patients fulfillling in- and exclusion criteria. During intake for treatment at one of the participating specilized clinical care units, patients will be informed about the study and, if interested, receive the patient information letter. They will be contacted at least one week later by the local study coordinator, providing sufficient time to consider participation. If they are willing to participate, they will be invited for a baseline visit, during which the in- and exclusion criteria will be assessed. The patient will subsequently be randomized to either 20 sessions IBA or 20 sessions CBT. The randomization ratio is 1:1, stratified by site. OCD symptom severity will be assessed by a blind assessor during baseline, after 10 sessions, after all 20 sessions, and during two follow-up visits (6 and 12 months after posttest). Patients will rate the severity of OCD and insight in OCD with weekly questionnaires.

In order to explore working mechanisms of both treatment modalities, 43 patients of each treatment arm will receive pre- and posttreatment brain imaging and neuropsychological assessment at the VU medical center in Amsterdam. After randomization, interested patients are screened for MRI eligibility, until we have reached the sufficient amount of participants. Additionally, 43 healthy controls will receive a single brain imaging and neuropsychological testing session to allow for comparison with OCD patients.

Intervention

The IBA treatment, a focused form of psychotherapy consists of twenty 45-minutes sessions, delivered weekly and carried out as specified in a session-by-session IBA protocol, containing standardized forms for exercises and homework assignments that was translated into Dutch. Each session has a standard format, starting with agenda setting and evaluating homework assignments, followed by determining and executing a new exercise and determining new homework. The IBA model is based on the assumption that patients with OCD feel the need to perform compulsive acts because they misjudge the actual state of affairs. It is assumed that certain reasoning processes lead to these erroneous conclusions and distract the patient*s attention from observable reality.

The IBA treatment teaches patients how to defend themselves against the absorbing and confusing effect of obsessive reasoning processes and how to stay in touch with reality by actively relying on the sensory information of the very moment. As a consequence, the patient realizes that any compulsive act is superfluous and feels able to omit it.

Study burden and risks

No negative side effects of undergoing CBT, IBA and MRI scanning are known. The

burden of participating will mainly consist of an extra time investment.

Anticipated risk factors:
1. Distress from receiving IBA treatment
Subjects may experience distress, anxiety or fatigue during IBA treatment, which can be expected by undergoing any form of psychotherapy. However, we expect no additional risk factors when compared to CBT, the standard clinical care. In fact, we expect IBA to be more tolerable than CBT, because it does not use anxiety provoking methods.
2. Distress from study assessments
Before, during and after treatment, an independent assessor will discuss emotional symptoms with the participant. This may be confronting and could cause distress. However, this does not exceed treatment as usual procedures.
3. Risks associated with Magnetic Resonance Imaging
MRI Scanning on 3Tesla MRI Scanners can be classified as a non-significant risk.

Procedures to minimize risks:
1. Distress from receiving IBA treatment
IBA treatment will be performed by experienced clinicians, who are well trained in recognizing and handling distress, anxiety and fatigue. Additionally, clinicians will participate in an intensive 4-day during IBA training, to ensure proper conducting of the treatment. Participants are carefully monitored during every study phase and encouraged to report any discomfort.
2. Distress from study assessments
All assessors will be extensively trained to recognize signs of distress. To minimize any potential distress from discussing emotional symptoms, participants are told they may move to the next question, if any makes him/her uncomfortable. Breaks will be offered in between measurements to reduce fatigue.
3. Risks associated with Magnetic Resonance Imaging
A thorough safety screening (e.g. metal screening) will be performed before entering the MRI room. No other precautions are necessary, given the classification as a non-significant risk.

Contacts

Public
GGZ Centraal (Amersfoort)

Landgoed Veldwijk 1117
Ermelo 3853LC
NL
Scientific

GGZ Centraal (Amersfoort)

Landgoed Veldwijk 1117
Ermelo 3853LC
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Referred to one of the participating sites for OCD treatment
- Age 18 or above
- Primary DSM-5 diagnosis of OCD (established by the SCID-I)
- Moderate to severe OCD symptoms (expressed as a minimum score of 16 on the Yale Brown Obsessive Compulsive Scale (YBOCS)
- Not currently using psychotropic medication, or on a stable dose for at least 12 weeks prior to randomisation with no plans to change the dose during the course of the study (this will be monitored during the study)
- If CBT already has been received, treatment has ended at least 26 weeks before study participation.

Exclusion criteria

- Suffering from a current psychotic disorder, organic mental disorder, substance use disorder or mental retardation.
- No sufficient command of the Dutch language

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-05-2019
Enrollment:	246
Type:	Actual

Ethics review

Approved WMO Date:	20-03-2019
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	05-03-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	03-03-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	03-01-2022
Application type:	Amendment

Review commission: METC Amsterdam UMC

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	ID
ClinicalTrials.gov	NCT03929081
CCMO	NL66299.029.18