Intensification of treatment in people with an obsessive compulsive disorder who do not recover sufficiently from regular ERP treatment: a stepped care approach

Published: 22-04-2024
Last updated: 18-11-2024

The aim of the current study is to 1) investigate what the effects are of a condensed, intensive outpatient exposure treatment in patients with OCD who are not sufficiently improved from standard CBT (ERP) and 2) to map early indicators regarding…

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

Summary

ID

NL-OMON56782

Source
ToetsingOnline

Brief title
FOCUS after regular CBT for OCD

Condition

- Anxiety disorders and symptoms

Synonym
Obsessive compulsive disorder

Research involving
Human

Sponsors and support

Primary sponsor: HSK Groep
Source(s) of monetary or material Support: HSK Groep

Intervention

Keyword: CBT, Intensification, OCD, Stepped care

Outcome measures

Primary outcome

The primary objective of this study is to investigate the effects of condensed, intensive ambulatory exposure treatment in patients with OCD, as step 2 in the treatment process, who have not improved sufficiently with standard, protocolled CBT (ERP) as step 1. It is hypothesized that patients with insufficient response after standard treatment will benefit from intensification of treatment (Y-BOCS-SR < 12 and/or improvement percentage Y-BOCS-SR > 35%).

Secondary outcome

A second objective of this study is to map early indicators of treatment outcome. The hypothesis is that early indicators of insufficient response during standard CBT treatment can be identified. Early indicators to consider are: difficulty performing the exposure tasks, sleep problems, depressed mood, and excessive worrying

Study description

Background summary

The obsessive compulsive disorder is an invalidating disorder that can disrupt

the quality of life severely. If the disorder stays untreated, it can take a chronic nature. According to the multidisciplinary guidelines, cognitive behavioural therapy (CBT) with exposure and responseprevention is the first choice of therapy. Nevertheless, only 50% of people receiving this treatment benefit from it at end of treatment or follow up. There has been experimented with intensification of treatment internationally with a positive effect. However, in these studies it is not clear what kind of treatment the clients actually had prior to the study. This is mainly based on a description of the client. The current study aims to follow the state of the art CBT and, when there is not a significant response, to insert a intensive treatment as a stepped care method. Another aim is to try to map early indicators of non response during the first treatment proces and to improve the stepped care.

Study objective

The aim of the current study is to 1) investigate what the effects are of a condensed, intensive outpatient exposure treatment in patients with OCD who are not sufficiently improved from standard CBT (ERP) and 2) to map early indicators regarding treatment outcome. De power of this study lies in the process of following both treatment phases from beginning tot end instead of relying on a description of the client.

Study design

In this study two treatment methods are used as a stepped care model and the study investigates if non response after step 1 standard CBT will significantly improve after intensive treatment. The design of this study will be a single case series design A-B-C-D.
Phase A: Baseline (phase A) will be a period of two weeks prior to start of treatment.
Phase B: After baseline the participant will start with standard CBT at HSK Groep where they will receive 20 sessions.
Phase C: If the patient will not improve significantly, they will be referred to the intensive FOCUS treatment at Overwaal, Pro Persona.
Phase D: After end of treatment there will be a 3 month follow up.

All participants will receive the same intervention. By measuring the symptoms over time on a daily and weekly base, the causal relationship between the intervention and treatment result can be defined. The duration of this study will be 31 weeks plus a follow up 3 months later.

The Y-BOCS-SR will be send to the participant on a weekly base to fill in. This questionnaire will be filled in during phase A to C. During follow up this questionnaire will be filled in once.
In addition, during phase A to C participants will fill in a daily questionnaire of 2-3 minutes. The Experience Sampling Method will be used. This

questionnaire aims to measure the daily symptoms and to analyze if there are signs of early indicators that can predict non response in phase B.
There will be nine moments during the study where additional questionnaires will be filled in, namely the SQ-48 en QIDS-SR. At T8, the evaluation questionnaire will be sent as a standard part after completion of the treatment.

Intervention

The intervention will consist of 20 standard CBT sessions in an outpatient setting at HSK Groep where, if the response is insufficient, the treatment will be followed by an intensive FOCUS treatment at Overwaal, Pro Persona.
The treatment at HSK Groep follows the CBT protocol of Verbraak et al. (2017) with an emphasis on ERP. In the treatment phase, clients are seen weekly and family members are preferably involved in the treatment.
The FOCUS treatment takes place in an outpatient setting at Overwaal, Pro Persona. The treatment there lasts a total of 11 weeks, with an initial consultation taking place. The client is then invited for a preparation day. The program will start two weeks after this day. The first two weeks of the program consist of eight full days of treatment with half days at the facility and half days at home or in other contexts from the clients life. This is followed by four 90-minute booster sessions that take place once a week. A week later, the program ends with an evaluation session. At least one family member or close friend is expected to attend two 90-minute morning blocks during the eight intensive days. They receive psycho-education about the OCD, how they can possibly facilitate this OCD and how they can stop it. In addition, they are invited to a booster session. The client is also asked to bring a coach with them during the booster sessions with whom they can sit together after the treatment to see how they can persevere. This coach can be someone from their environment, but not the partner or parent.

Study burden and risks

The load consists of completing questionnaires on a daily and weekly basis. The sessions will take place weekly in phase B and in phase C the treatment will contain an intensive part of two weeks during which one must be available for eight full days.

Contacts

Public
HSK Groep

Polanerbaan 3

Woerden 3447GN
NL
Scientific
HSK Groep

Polanerbaan 3
Woerden 3447GN
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Participants have a current primary classification of obsessive compulsive disorderd according to the DSM-5, assessed with the DSI.
Participants have a Y-BOCS score of 16 or higher
Participants have a SQ-48 score higher than 37
Participants have an age between 18-64 years
Participants are able to speak the Dutch language on a sufficient level

Exclusion criteria

- Presence of severe developmental disorders
- Severe suicidality
- Presence of a acute psychotic disorder
- Presence of a disorder that interferes with OCD
- Personalitytraits or disorders that need treatment first

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	31-07-2024
Enrollment:	35
Type:	Actual

Ethics review

Approved WMO Date:	22-04-2024
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	13-06-2024
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

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
CCMO	NL84925.091.23