Imagery rescripting for patients with obsessieve compulsive disorder not responding to outpatient cognitive behavioral therapy (CBT).

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

Summary

ID

NL-OMON54155

Source
ToetsingOnline

Brief title
ImRs and OCD after CBT

Condition

- Anxiety disorders and symptoms

Synonym
Obsessive compulsive disorder

Research involving
Human

Sponsors and support

Primary sponsor: ProPersona (Nijmegen)

Source(s) of monetary or material Support: Financiering door Pro Persona

Intervention

Keyword: Imagery rescripting, Obsessive compulsive disorder

Outcome measures

Primary outcome

The primary objective is to investigate whether ImRs lead to symptom reduction in patients with OCS who have not sufficiently benefited from previous outpatient ERP treatment.

Secondary outcome

Secondary Objectives:

To investigate whether Mastery and believability of core cognitions (related to the memories processed in ImRs) change in a positive way to indicate the possible mechanism of action of ImRs in OCD. In addition, to investigate whether using ImRs leads to change in the areas of dysfunctional schemas, depressive symptoms, quality of life and the emotions guilt, shame, anger, sadness, fear and disgust.

It is hypothesized that an increase in Mastery leads to a decrease in OCS symptoms.

It is hypothesized that a decrease in the believability of the Core Cognitions leads to a decrease in OCS symptoms.

The hypothesis is that the practice of ImRs will lead to a decrease in dysfunctional schemas.

The hypothesis is that practicing ImRs will lead to a decrease in depressive

symptoms.

The hypothesis is that practicing ImRs will lead to an increase in quality of

life.

It is hypothesized that the practice of ImRs will lead to a decrease in the

emotions guilt, shame, anger, sadness, fear, and disgust.

Study description

Background summary

Obsessive-compulsive disorder (OCD) is a severe disorder that causes limitations for patients in multiple areas of life. When not treated, this disorder takes on a chronic nature. Effective forms of treatment for OCS include Exposure and Response Prevention (ERP) and Cognitive Therapy (CT). However, research shows that 40% of patients do not benefit sufficiently from these first choice treatments. Scaling up therapy to clinical treatment is drastic for the patient and his/her environment and is socially costly. There is a need to explore alternative forms of treatment for OCS that act on other working mechanisms than exposure in vivo (which includes ERP) to increase the response to psychological treatments. One of these alternative treatments is Imaginary Rescripting (ImRs). ImRs is a technique by which past memories are edited through mental imagination, creating different meaning. Research shows that past events may be related to the onset and severity of OCS symptoms. It also appears that 80% of patients with OCS have mental images of a direct or associated memory of aversive past events. When these negative events are worked on, a decrease in compulsive symptoms may be possible. Meanwhile, some small studies have been done in patients with OCS and a (partial) treatment with ImRs and the results are encouraging.

Study objective

The purpose of this study is to expand the so far limited research on the effectiveness of ImRs in the treatment of OCS. The primary objective is to investigate whether the application of ImRs, after previous outpatient ERP treatment, leads to symptom reduction in patients who have not benefited, or have benefited too little, from ERP treatment (Y-bocs score of 16 or higher). If positive results are obtained, another study may be conducted in the form of an RCT, which will provide more insight into the effectiveness of this treatment intervention in OCS. Also, two process measures will be included in the study (Mastery and Core Cognitions) to gain more insight into the working

mechanisms of ImRs in OCD.

Study design

This is an efficacy study in the form of a randomized single case design with repeated measurements (within-subject time-series design). This study is an experimental study that is suitable for research into the effects of treatment in which the chance of spontaneous recovery is small. This is the case with non-responders to previous outpatient CBT for OCS.
Patients all receive the same intervention, but are randomly assigned to different time periods before and after treatment, during which symptoms are monitored 2-weekly. By measuring the change in symptoms over time weekly, the causal relationship between intervention and treatment outcome can be established. The 11-week study period will be divided into four phases:

T0: Screening
T1: Baseline 2.5-5.5 weeks
T2: Active intervention (3 weeks, pretreatment session + 2x ImRs per week)
T3: Post-treatment phase 2.5-5.5
T4: Follow-up (after 3 months)

Intervention

The intervention used is ImRs. ImRs is a technique from schema therapy that rewrites images and changes events in a more desirable direction. The aversive memories from childhood are rewritten, therefore changing the meaning of the original memory or forming an alternative, more competitive memory. ImRs is an effective therapeutic technique that is becoming more widely used and increasingly researched. A recent meta-analysis shows that ImRs is effective for treating negative memories in various mental disorders such as depressive disorder, post-traumatic stress disorder, social phobia and also OCS.

Patients in this study will receive a preteratment session and six sessions of ImRs (two sessions per week). The affect bridge will be used to select the memory that will be worked on with ImRs. A recent situation related to the obsessive-compulsive disorder will serve as a gateway to original meaningful experiences.

In the first two ImRs sessions, the therapist will rescript the situation. In the following sessions, the patient will step into the picture as an adult and rescript the situation. If necessary, the therapist can assist or possibly rescript himself again (if the patient's capabilities do not allow it).

In this study, the ImRs is described as a stand-alone intervention, without the addition of other treatment methods such as cognitive restructuring.

The therapists conducting the ImRs sessions have already been trained in the application of ImRs and will also receive supervision. Also, the ImRs sessions will be recorded (audio) and scored using a compliance checklist.

Study burden and risks

The burden will consist of the completion of questionnaires and the administration of interviews. Interviews will be conducted twice a week with an average duration of 15-30 minutes. Also, four measurement moments will take place throughout the study and a measurement will last approximately 60-90 minutes.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- Patients have a current DSM-5 diagnosis of obsessive-compulsive disorder as classified with the MINI--S.
- The main compulsive symptoms come from the domains of "worry about/anxiety about bacteria and contamination" and "fear of being responsible for calamity/misfortune, injury or misfortune" as measured with the DOCS.
- Patients possess imaginary ability.
- Patients have a Y-BOCS score of 16 or higher.
- Patients have an age between 18 and 64 years.
- Patients had previously an adequate CBT for the OCD with insufficiently treatment effect (Y-BOCS 16 or higher).

Exclusion criteria

-Patients are diagnosed with a severe depressive disorder for which they need immediate treatment.
-Acute suicidality or high risk of suicide
-Patients are diagnosed with a psychosis for which they need immediate treatment.
-Intellectual disability (IQ below 70) or severe cognitive function disorders.
-Substance abuse or dependance or alcohol abuse or dependence which requires treatment.
-Psychofarmacology is changed in the last 8 weeks
-Having an additional treatment for the OCD
-Inability to fill in questionary due to lack of the Dutch language
-Other comorbid psychiatric disorders are not an exclusion criteria

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	20-04-2023
Enrollment:	7
Type:	Actual

Ethics review

Approved WMO Date:	22-09-2022
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	07-03-2023
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL78486.091.22