Imagery Rescripting for Obsessive Compulsive Disorder, Body Dysmorphic Disorder and Early Psychosis: a Multiple-Baseline Single-Case Experimental Design.

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Primary Objective: To investigate the effectiveness of imagery rescripting on factors presumed to underlie the disorder, according to schema theory, and on OCD and BDD symptoms and psychosis. Primary objective is the course of schema or core beliefs...

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

Summary

ID

NL-OMON53763

Source
ToetsingOnline

Brief title
The ImRs study for OCD, BDD and early psychosis.

Condition

- Anxiety disorders and symptoms

Synonym
Obsessive Compulsive Disorder AND Body Dysmorphic Disorder AND Psychosis

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Body Dysmorphic Disorder, Imagery Rescripting, Obsessive Compulsive Disorder, Schematherapy, Vroege Psychosis

Outcome measures

Primary outcome

Primary outcomes

- Schema or core beliefs, as measured by VAS scales.

- OCD and BDD core symptoms (based on the Y-BOCS, as measured by VAS scales)

- Well-being (MHQoL) and self-esteem (RSES) (Psychosis)

Secondary outcome

Secondary outcomes

- Y-BOCS(-BDD), which is a semi structured interview (5 items about obsession

and 5 items about compulsions). Measure: OCD and BDD symptoms. Frequency: 4

times.

- Brown Assessment of Beliefs Scale (BABS), a 7-item semi-structured,

rater-administered scale. Measure: Insight/delusions. Frequency: pre-post-FU

- Young Schema Questionnaire (YSQ-S3) and Schema Mode Inventory (SMI), a

self-report questionnaire of respectively 90 and 118 items. Measure: Schemata

and modes. Frequency: pre-post-FU

- Hamilton Rating Scale for Depression (HRSD), a 17-item semi-structured

interview. Measure: Mood. Frequency: 4 times

- VAS scales measuring core emotions (shame, guilt, anxiety, sadness, anger,

disgust, repugnance).

- VAS scale measuring affect strength.

- VAS scale measuring obtrusiveness of imagination.

- Qualitative interview and questionnaire: Imagery rescripting working

mechanisms, therapeutic alliance, experiential avoidance, changes in cognition

- Psychosis: PSYRATS (psychotic symptoms), trauma (PCL-5)

Study description

Background summary

Obsessive Compulsive Disorder (OCD) and Body Dysmorphic Disorder (BDD) are in the top 10 disorders with a reduced quality of life. Fortunately, effective treatments have been developed in recent decades with exposure and response prevention (ERP) as the first-line treatment. This form of cognitive behavioural therapy has been extensively researched and in combination with medication 53% of patients improve and experience remission (Springer et al., 2018). However, almost 47% of patients still have symptoms and don*t or only partial remit.

This non-or partial response may have a relationship with adverse childhood experiences (ACEs), without a mandatory diagnosis of PTSD, that are believed to contribute to the development of schemas and personality traits that interfere with therapy. In OCD 81% of patients report intrusive memories. Preliminary evidence suggest a relationship between ACEs and OCD and BDD symptoms and suggests an improvement of symptoms after treatment of these adverse experiences. This new transdiagnostically perspective on symptoms could help in developing new treatment options, especially for patients who do not respond sufficiently but maybe also as a stand-alone treatment. A technique like imagery rescripting, an old technique from gestalt therapy and used in schema therapy, seems promising in treating ACEs. Some research had been.

Related to OCD and BDD, there is growing body of studies emphasizing the role of ACE*s in symptom development and the potential of treatments like schema therapy or ImRs as a stand-alone treatment. A few studies have been carried out with ImRs and the application of schema therapy elements in CBT in OCD (Basile et al., 2018; Tenore et al., 2020; Thiel et al., 2016; Veale et al., 2015). A limited number of studies have been carried out on BDD (Ritter & Stangier, 2016; Willson et al., 2016), in which research has been done on ImRs as a

stand-alone treatment in patients with intrusions. These studies demonstrated significant effects of ImRs on symptom level. However, these studies are based on a limited number of sessions (max 1-2 sessions), offered in addition to CBT treatment, with only a focus on past aversive events and did not investigate the working mechanisms of ImRs.There are also some studies of trauma in psychosis. There is not yet sufficient consensus about the A-criterion, but various studies indicate that the fears that people with psychosis experience are so realthat they should therefore count as A criterion traumata (Morrison, Frame & Larkin, 2003. Mueser et al, 2010). Without A-criterion, 66% appear to meet PTSD and of this 39% remain if A-criterion was strictly adhered to (Kilpatrick et al. 1989). This shows that experiencing a psychosis can be traumatic with a high chance of developing PTSD complaints, which can influence identity, relationships and view of the world. Some studies have now investigated the application of ImRs in psychosis with an effect on voice hearing (Paulik et al. 2019), PTSD symptoms (Morrison, 2014) and delusions (Taylor et al, 2020). The conclusion is that this treatment can be applied safely without an increase in dropout or worsening of psychotic complaints. However, this has not yet been investigated focusing on events surrounding the development of a psychosis.

We hypothesize that a treatment with ImRs based on targeting the A(C)E*s and future adverse events will change underlying mechanisms related to schemas or core beliefs and improve symptoms for OCD, BDD and psychosis reduce future intrusions.

Study objective

Primary Objective:
To investigate the effectiveness of imagery rescripting on factors presumed to underlie the disorder, according to schema theory, and on OCD and BDD symptoms and psychosis.

Primary objective is the course of schema or core beliefs and change in OCD and BDD symptoms (1. Obsessive thoughts, 2. obsessive compulsions, 3. distress) and in psychosis well-being and self-esteem

Secondary objective:
The change in OCD and BDD symptoms (full questionnaire), schemata and modes, core emotions, mood, affect and obtrusiveness of image. And for psychosis also the psychotic symptoms.

Other objectives are research into the working mechanisms of imagery rescripting by collecting qualitative data from patients and their practitioner in a qualitative interview.

Study design

This study uses a multiple-baseline single-case experimental design (SCED) to test different outcome variables in 18 OCD patients and 18 BDD patients. Given that it is a within-subject design, fewer patients can be sufficient because sufficient power remains. For psychosis, the aim is to include at least 5 patients.

Intervention

The intervention consists of imaginary rescripting that is offered after regular intake with a variable baseline period of up to 10 weeks (OCD and BDD) and 3 weeks (psychosis) (waiting time). Patients form their own control condition. Prior to the intervention, patients receive 1-3 sessions consisting of a 'case conceptualization' and trauma symptoms will be assessed with the TALE/TSQ and VIBE. This is followed by the intervention in which they receive a 60-90 minute session with ImRs twice a week for six weeks (OCD & BDD) or 3 weeks (psychosis). The follow-up consists of evaluation, a relapse prevention plan and a qualitative interview. There is also a follow-up to measure outcome variables after 6 weeks (OCD & BDD) and 3 weeks (psychosis)

Study burden and risks

For OCD and BDD this short intervention is aimed at reducing factors presumed to underlie the disorder, according to schema theory, and on OCD and BDD symptoms.
By targeting ACEs and improving negative schema or core beliefs and OCD and BDD symptoms patients will have direct clinical benefits and more experiential and emotional processing, supposedly a more durable effect and a shorter treatment compared to treatment as usual, which consists of a 16-week treatment one-day per week. For this effect a requirement is to increase the emotional processing and therefore it is expected that emotions like guilt, shame, sadness and anger first will increase prior to an improvement in emotional processing. Treatment as usual is not withholden, this is an extra intervention which is offered prior to treatment as usual.

There will be some burden, which includes a case conceptualization (1-3 sessions) and different measurement over the course of the treatment. The subjects are asked to complete questionnaires, complete daily short measurements and review the recording of the sessions. Furthermore, we ask patient to come to the AMC twice a week for a session of 60-90 minutes for the duration of the study, which is six/seven weeks. Symptoms and experiencing emotions are expected to increase in the first sessions, this is conform expectation and necessary for further experiential processing.

For psychosis, treatment will take place during the day clinic and will therefore be built into the program. A possible expected risk could be that psychotic complaints could increase. However, in the scientific literature

there is no sign of such an increase and this treatment, like other trauma treatments, can be safely applied without an increase in dropout (it appears to be a lower dropout) and without an increase in psychotic symtpomns and with a lasting effect of the treatment . This is supported by a pilot patient who was treated in the department with a positive effect and positive patient experience.

Further risk is negligible and there is no risk associated with the treatment.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

• Meet the criteria for OCD, BDD or psychosis, a primary diagnosis according to the Diagnostic and Statistical Manual of Mental Disorders (5th ed; American Psychiatric Association, 2013)

• Are aged 18 and beyond
• Dutch literacy
• Cut-off Y-BOCS of 20 (not eligible for psychosis)
• No change in medication. Stable dose at least 6 weeks prior to study (not eligible for psychosis)

Exclusion criteria

• Current (hypo)mania
• Psychotic disorder (excluding delusional symptoms related to disorder) (not eligible for psychose)
• Alcohol or drugs abuse as diagnosed by DSM-5
• Electroconvulsive therapy in last 6 months
• Neurological disorder or IQ< 80

Study design

Design

Study phase:	3
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-08-2023
Enrollment:	41
Type:	Anticipated

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	03-07-2023
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	23-02-2024
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
CCMO	NL83374.018.23