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

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PROTOCOL TITLE '<Imagery Rescripting for Obsessive Compulsive Disorder and Body Dysmorphic Disorder: a Multiple-Baseline Single-Case Experimental Design.>'

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Short title	**Treatment of adverse (childhood) experiences in OCD and BDD**
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Subsidising party	***n.a.***
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Laboratory sites <*if applicable*>	***All procedures will be performed at the AMC***

PROTOCOL SIGNATURE SHEET

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LIST OF ABBREVIATIONS AND RELEVANT DEFINITIONS

ABR	**General Assessment and Registration form (ABR form), the application form that is required for submission to the accredited Ethics Committee; in Dutch: Algemeen Beoordelings- en Registratieformulier (ABR-formulier)**
AE	**Adverse Event**
AR	**Adverse Reaction**
CA	**Competent Authority**
CCMO	**Central Committee on Research Involving Human Subjects; in Dutch: Centrale Commissie Mensgebonden Onderzoek**
CV	**Curriculum Vitae**
DSMB	**Data Safety Monitoring Board**
EU	**European Union**
EudraCT	**European drug regulatory affairs Clinical Trials**
GCP	**Good Clinical Practice**
GDPR	**General Data Protection Regulation; in Dutch: Algemene Verordening Gegevensbescherming (AVG)**
IB	**Investigator's Brochure**
IC	**Informed Consent**
IMP	**Investigational Medicinal Product**
IMPD	**Investigational Medicinal Product Dossier**
METC	**Medical research ethics committee (MREC); in Dutch: medisch-ethische toetsingscommissie (METC)**
(S)AE	**(Serious) Adverse Event**
SPC	**Summary of Product Characteristics; in Dutch: officiële productinformatie IB1-tekst**
Sponsor	**The sponsor is the party that commissions the organisation or performance of the research, for example a pharmaceutical company, academic hospital, scientific organisation or investigator. A party that provides funding for a study but does not commission it is not regarded as the sponsor, but referred to as a subsidising party.**
SUSAR	**Suspected Unexpected Serious Adverse Reaction**
UAVG	**Dutch Act on Implementation of the General Data Protection Regulation; in Dutch: Uitvoeringswet AVG**
WMO	**Medical Research Involving Human Subjects Act; in Dutch: Wet Medisch-wetenschappelijk Onderzoek met Mensen**

SUMMARY

Rationale:
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 50% 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 suggests 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.

We hypothesize that a treatment based on targeting the ACE's (manifested in schema or core beliefs) will change underlying mechanisms related to schemas or core beliefs and a change in symptom level for OCD and BDD.

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

Secondary objective:
The change in OCD and BDD symptoms (full questionnaire), schemata and modes, core emotions, mood, affect and obtrusiveness of intrusion.

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:
For this study, a multiple-baseline single-case experimental design (SCED) is used testing different outcome variables in 18 OCD patients and 18 BDD patients.

Study population:
Patients will be recruited at the Amsterdam UMC, location AMC, department of psychiatry in the unit 'anxiety disorders' where OCD and BDD are treated. The study is primarily focused on patients who have experienced relapse or have not responded adequately to standard treatment. However, we also assess individuals for adverse (childhood) experiences, and if such experiences are present, they may be eligible for participation in the treatment. After intake, patients are referred by the psychiatrist and receive an assessment for this intervention in which severity of symptoms, treatment history, and indications for ACE and schemata are measured. Eligible participants will have an age of 18 years and beyond, a diagnosis of OCD or BDD and a Y-BOCS cut-off score of 20.

Inclusion:

- Meet the criteria for OCD or BDD, 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
- No change in medication. Stable dose at least 6 weeks prior to study.

Exclusion criteria are:

- Current (hypo)mania
- Active suicidal plans
- Current psychosis (excluding delusional symptoms related to disorder)
- Alcohol or drugs abuse as diagnosed by DSM-5
- Electroconvulsive therapy in last 6 months
- Neurological disorder or IQ< 80

Intervention (if applicable):

The intervention consists of imagery rescripting, which is an effective treatment for aversive or traumatic experiences based on the protocol of Arntz and Weertman (1999). The intervention is offered after regular intake with a variable baseline period up to a maximum of 10 weeks (waiting time). Subjects form their own control condition. Prior to the intervention patients receive 1-3 sessions consisting of a 'case conceptualization'. This is followed by the intervention in which they receive a 60–90-minute session of ImRs twice a week for the duration of six weeks. Follow-up consist of two sessions with evaluation and a qualitative interview. There is also a follow-up for measurement of outcome variables after 6-8 weeks.

Main study parameters/endpoints:

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)

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.
- For BDD: 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 intrusions.
- Qualitative interview and questionnaire: Imagery rescripting working mechanisms, therapeutic alliance, experiential avoidance, changes in cognition

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

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. The practitioner is highly familiar with the heightened emotional experiences that may arise, having received comprehensive training on managing emotions through the ImRs course, which is mandatory for all practitioners. Additionally, practitioners engage in intervision sessions and receive supervision from a clinical psychologist specialized in this treatment. In the very unlikely event of a severe emotional response, consultation and treatment are available from a psychiatrist within the department.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. Further risk is negligible and there is no risk associated with the treatment.

1. INTRODUCTION AND RATIONALE

Anxiety disorders have a lifetime prevalence of 28.8%, with obsessive compulsive disorder (OCD) a prevalence of 2-3% and body dysmorphic disorder (BDD) a weighted prevalence of 1.9% (varies between 0.7 and 12.7%) (Peeters, 2021; Vulink, 2021). 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 like cognitive behavioural therapy (CBT). This first-line treatment addresses dysfunctional assumptions with cognitive restructuring and exposure and response prevention (ERP). This form of cognitive behavioural therapy has been extensively researched and, in combination with medication, 50-60% of the patients improve. It is proven well in different studies and also in a meta-analysis (Eddy et al., 2004).

However, many patients show no or only partial recovery and there is a high relapse rate: about 40-50% of patients respond insufficiently to first-line treatment and significantly experience symptoms after treatment (Maloney et al., 2019; Peeters, Stappenbelt, et al., 2021).

Research shows that beneath the symptoms of these disorders may be, among other factors, adverse childhood experiences (ACEs) and aversive memories, that according to schema theory are believed to contribute to the development of schemas (negative core believes about oneself, others and the world) and personality traits that interfere with therapy, even without a diagnosis of PTSD (Arntz, 2012; Maloney et al., 2019; Speckens et al., 2007; Willson et al., 2016). These negative adverse events are supposedly a predictor of an unfavourable course of illness and treatment outcome (Nanni et al., 2012). Data from several studies suggest that adverse (childhood) experiences increases the risk of developing obsessive compulsive related disorders (OCRDs) such as OCD (Thiel et al., 2014;) and BDD (Valderrama et al., 2020) and predict a worse outcome (Tibi et al., 2020). Speckens study concluded that in OCD, 81% of the patients report intrusive memories (Speckens et al., 2007). A meta-analysis of Longobardi et al. identified several negative childhood experiences or bullying experiences related to appearance in BDD patients; between 28% and 68% of patients with BDD report childhood physical abuse or neglect, including appearance-related teasing, and 22-35% report experiences of sexual abuse (Longobardi et al., 2022). Overall, these studies indicate a relationship between ACEs and symptom development in OCD and BDD and highlight the need for new treatment options.

Schema therapy seems promising in addressing adverse childhood experiences and especially the experiential techniques (Morina et al., 2017). A technique from Gestalt therapy and used in schema therapy addressing adverse childhood experiences, or negative experiences related to the symptoms, is imagery rescripting (ImRs). A technique with a focus on past experiences but also suitable for future oriented situations and images like intrusions (Kadriu et al., 2021).

ImRs intervenes by modifying mental self-representations induced by negative experiences in the past and has proven to be effective for emotional symptoms related to aversive emotional memories (Morina et al., 2017). In ImRs, aversive memories are activated and emotional and cognitive properties of the mental representation of aversive stimuli are altered and potentially reconsolidated. It is believed that ImRs directly devalues or revalues the interpretation coupled to stimuli related to the aversive memory and reduces the emotional charge and salience of autobiographical memories and associated negative core beliefs. For example, a comment from a manager that reminds you of a bullying experience in the past in which you were left out can cause the activation of the underlying schema 'I am not likeable and people will reject me'. ImRs can alter the managers' comment into a less emotionally charged memory by changing the emotional meaning of the bullying experience. This technique appears not to be useful exclusively for intrusive images or related memories, but is more widely applicable for disorders in which aversive experiences are prevalent (Arntz, 2012; Hagenaars & Arntz, 2012).

The precise working mechanisms of this technique are not yet fully understood.
The existing body of research on ImRs has highlighted several explanations for the alterations in episodic memory. Brewin's research suggests that after ImRs a new alternative memory is created which competes with the old memory but is retrieved more easily, the so-called retrieval competition theory (Brewin et al., 2009; Wheatley & Hackmann, 2011). A growing body of research suggest ImRs affects the episodic memory by producing a different meaning by reattribution and providing in basic needs, providing a different meaning at the child level and expression of inhibited responses and a more positive, less toxic representation that decreases the emotional charge (Arntz, 2012; Dibbets & Arntz, 2016). Others suggest that ImRs provides the integration of a sense of self (Çili et al., 2017) or a sense of 'mastery', which is a feeling of control about the image/situation (Strohm et al., 2019). A small amount of literature has been published about obsessive-compulsive related disorders (OCRDs) and suggests ImRs is causing a change in the strength of the encapsulated negative believes (Lee & Kwon, 2013) or a change in the valence of the

associated memory (Dibbets & Arntz, 2016) related to the symptoms and therefore highlights it relevance for these disorders (Basile et al., 2018).

Taken together, these studies support the notion that the working mechanisms of ImRs are based on a change is the episodic memory. However, from the literature there is not yet consensus about what exactly causes this change. Is it a change in the actual content or is it mere a change in encapsulated beliefs and associated emotions related to the memory?

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.

In view of all that has been mentioned so far, which is the growing body of literature about OCD and BDD mentioning the contribution of ACEs in symptom development, the potential of a powerful technique like ImRs in addressing ACEs and thereby influence symptoms, but also the limited number of studies and the lack of knowledge about the precise working mechanisms of ImRs, one may conclude more research is needed into the efficacy and working mechanisms of ImRs as a stand-alone treatment for OCD and BDD.

In this study, therefore, we will investigate the potential of a more elaborate protocol of 12 sessions of ImRs focusing on past experiences as well as future potential harmful experiences (in combination with a more profound case conceptualization). Additionally, this study will investigate the working mechanisms of ImRs.

2. OBJECTIVES

OBJECTIVES

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

Primary objective is the course of schema or core beliefs and change in OCD and BDD.

Hypothesis 1: Patients with OCD and BDD who receive a treatment with ImRs will show a decrease in strength of dysfunctional schema / core beliefs

Hypothesis 2: Patients with OCD and BDD who receive a treatment with ImRs will show a reduction in primary (OCD or BDD) symptoms.

Secondary objective:
The course of OCD and BDD symptoms (full questionnaire), schemata and modes, core emotions, mood, affect and obtrusiveness of image.

Hypothesis 1: Patients who receive a treatment with ImRs will improve on OCD and BDD symptoms.

Hypothesis 2: Patient with OCD and BDD who receive a treatment with ImRs will show a reduction in schemata and modes scores. For OCD a positive effect is hypothesized in the schemata emotional inhibition, failure, unrelenting standards, social isolation, mistrust/abuse, defectiveness/shame and in the dysfunctional parent modes (especially demanding parent).

Hypothesis 3: A treatment with ImRs will at first increase emotional symptoms like anger and sadness followed by a decrease in these symptoms and especially the emotion guilt for OCD and shame for BDD.

Hypothesis 4: Depressed mood will reduce after treatment with ImRs

Hypothesis 5: Strength of affect and obtrusiveness of intrusions will decrease over the course of the treatment

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

3. STUDY DESIGN

For this study, a multiple baseline case-series design (MBCD) is used. The justification for this design is that it allows to draw inference about the intervention based on a small number of participants and without a control group because participants form their own control (which is the variable baseline condition). For a visual impression see figure 1 and 2 on page 16)

Our research aims to assess the efficacy of ImRs (up to 12 sessions) as an additional intervention prior to standard treatment. It can be utilized as a standalone treatment if there is sufficient response or incorporated into the standard treatment protocol if the response is insufficient, followed by CBT.After the regular intake patients are seen by researchers for indication (T0) for the ImRs study followed by a variable baseline period with a maximum of 10 weeks (T1) and an assessment (T2) with 'case conceptualization' (charting current symptoms, schemata/modes, coping, early experiences with important caregivers, schema or core beliefs) and administration of measuring instruments. After case conceptualization starts the intervention (T3) with ImRs with approximately nine sessions of ImRs and three sessions of 'future imagery rescripting' (number of sessions is depending on individual case conceptualization and therefore can differ). Measurement of outcome variables will take place after the intervention phase (T4) and at follow-up (T5). Total duration of the intervention is six to seven weeks.
In case of insufficient response (Y-BOCS>12) participants can enter treatment as usual (CBT treatment) at the department of psychiatry, with a duration of 16 weeks or will be referred for further treatment elsewhere.
Measurements at T0 are syndromal screening (SCID-5-S) and measurement of symptoms, depression and schema- of core beliefs. At T3 is the measurement of ACEs and further case conceptualization. At T0, T2, T4 and T5 OCD and BDD symptoms, mood and beliefs. Schemata and modes will be measured at T0 and T5. The measurement of primary outcomes (T1-T5) is operationalized by VAS scales which will be administrated daily. Post treatment follows a qualitative interview.

Duration of the whole study is approximately 12-18 months, this is based on the availability of patients at the unit anxiety disorders, which can vary over time. The setting of the study is the unit anxiety disorders at the department psychiatry where mainly OCD and BDD are treated.

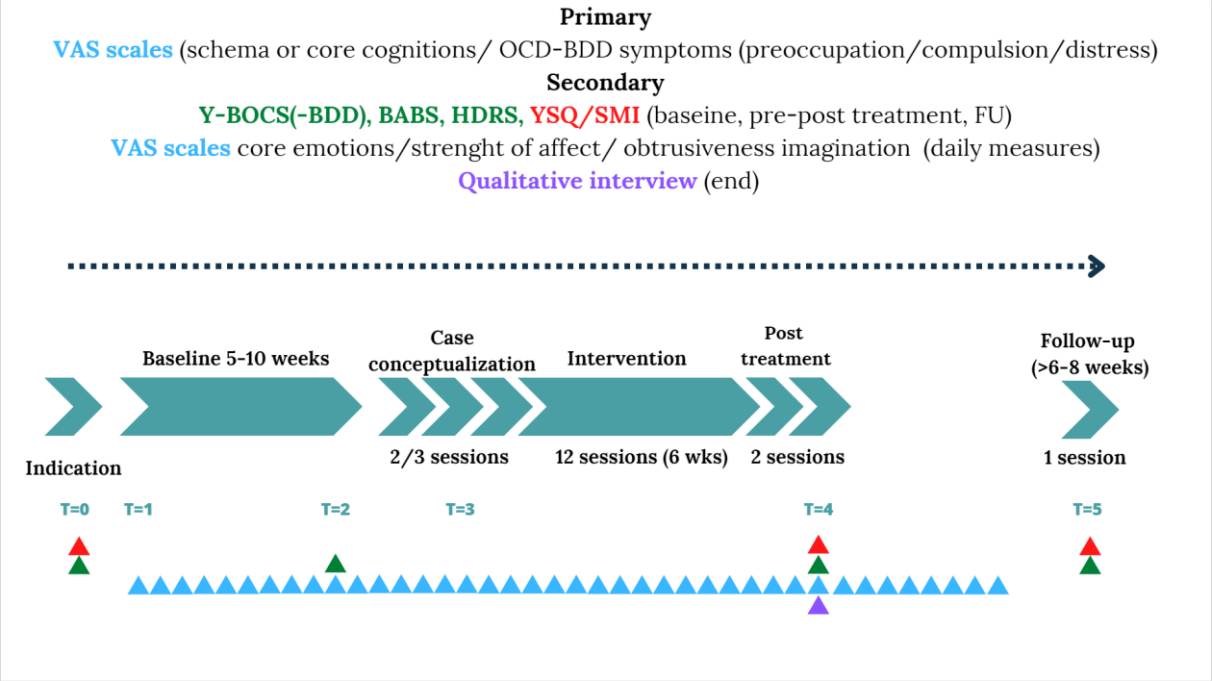

Figure 1 Flowchart research design

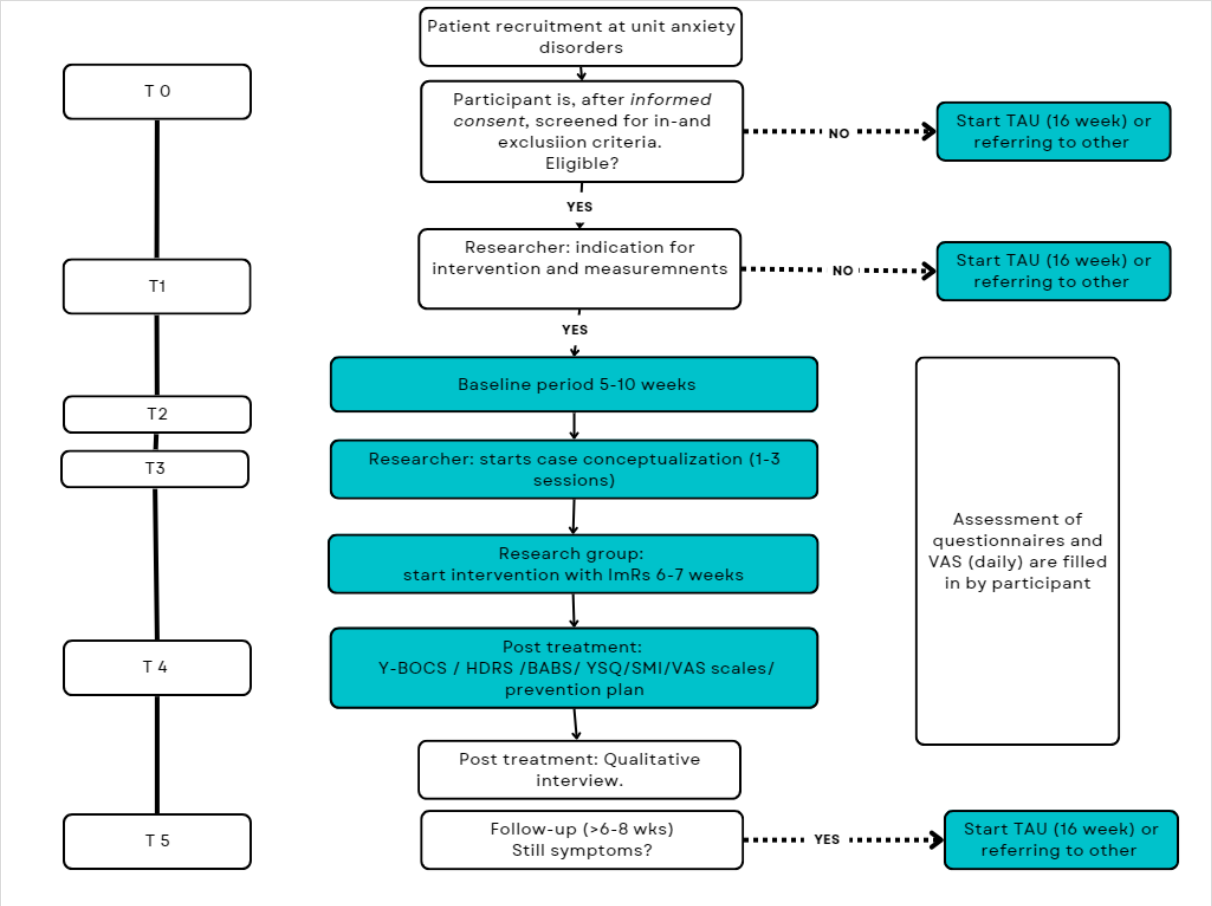

Figure 2 Flowchart of procedure

4. STUDY POPULATION

4.1 Population (base)

Recruitment takes place at the Amsterdam UMC, location AMC, department of psychiatry in the unit 'anxiety disorders' where OCD and BDD are treated. After intake, patients receive an assessment for ImRs based on treatment history, severity of symptoms and indications for ACE and schemata.

It is a within-subject design using parametric and non-parametric testing and visual inspection. Randomization tests and visual inspection of the course of daily measurements will also be used to measure the changes from baseline to intervention (Bouwmeester & Jongerling, 2020). For each participant at least five measurements, but preferably around 20 measurements per treatment phase, is sufficient.

4.2 Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:

Inclusion:

- Meet the criteria for OCD or BDD, 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
- No change in medication. Stable dose at least 6 weeks prior to study.

Exclusion criteria are:

- Current (hypo)mania
- Active suicidal plans
- Current psychosis (excluding delusional symptoms related to disorder)
- Alcohol or drugs abuse as diagnosed by DSM-5
- Electroconvulsive therapy in last 6 months
- Neurological disorder or IQ< 80

4.3 Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:

Exclusion criteria are:

- Current (hypo)mania
- Active suicidal plans
- Current psychosis (excluding delusional symptoms related to disorder)
- Alcohol or drugs abuse as diagnosed by DSM-5
- Electroconvulsive therapy in last 6 months
- Neurological disorder or IQ< 80

4.4 Sample size calculation

The number of participants was calculated based on a power calculation (via G*Power) using paired t-test (two tailed), with a power of 0.8, an alpha of 0.025 (Bonferroni correction) and a desired effect size of 0.8.

The effect size was chosen lower than reported Hedge's g from studies by Veale (2015):1.16, Wilson et al (2016): 1.16 and Ritter & Stangier (2016): 1,312, the reason is that in these studies uncontrolled effect sizes were calculated and therefore the controlled effect size (as in this study) is expected to be lower. Comparable studies with a passive control condition found hedges g effect sizes of around 0,90. We think therefore an effect size of 0.8 is reasonable.

The number of participants for this study will be 18 per group (OCD, BDD) with a total of 36 participants.

5. TREATMENT OF SUBJECTS

5.1 Investigational product/treatment

After informed consent, patients will be allocated into the intervention condition consisting of a variable baseline period (control condition) followed by the ImRs-intervention and a follow-up period. The treatment will be delivered by a trained and licenced psychologist and they will be part of an intervision and supervision by a clinical psychologist specialized in this intervention.

ImRs treatment

All participants receive twice per week a session with ImRs for the duration of six to seven weeks, 60-90 minutes per session. The decision to conduct sessions twice a week is based on several factors. Firstly, it helps minimize the likelihood of patients avoiding emotional experiences while allowing ample time for recovery between sessions. Additionally, there is evidence from the IREM-Freq study indicating that a twice-per-week frequency has shown a more favorable effect (Wibbelink et al, 2021). Moreover, a recent study conducted by Raabe et al. (2022) specifically focused on the effectiveness of ImRs as a standalone treatment with a twice-weekly schedule. Taking these factors into account, we have chosen to offer our patients ImRs twice a week.
Pre-treatment, participants receive 1-3 sessions for the case conceptualization and feedback from the questionnaires. This is followed by a baseline period which is variable in duration up to a maximum of 10 weeks. After baseline the intervention phase starts. After each session participants receive a homework assignment consisting of listening to the recording of the session in combination with daily measures of wellbeing and changes in measure outcomes.

The process of imagery rescripting typically involves several steps:

1. Identification of the target memory: The individual, with the help of a therapist, selects a specific memory or event that causes distress or triggers negative emotions.
2. Imagery activation: The person mentally activates the memory and tries to visualize it as vividly as possible. They focus on the sensory details, emotions, and thoughts associated with the memory.
3. Exploration of negative beliefs: The individual identifies the negative beliefs or self-critical thoughts that are connected to the memory. These beliefs might include feelings of worthlessness, shame, or guilt.
4. Imagery rescripting: Once the negative beliefs and emotions are identified, the person is guided to imagine a different outcome or a more positive scenario related to the

memory. They engage their imagination to create a new version of the event that contradicts the negative beliefs and emotions.

5. Emotional processing: The individual experiences the new version of the memory, paying attention to any changes in emotions, beliefs, or physical sensations. By repeatedly visualizing the rescripted version, they aim to establish a new and more adaptive cognitive and emotional response.

5.2 Use of co-intervention (if applicable)

Psychiatric medication is allowed during the study, if necessary, but alterations in medications are asked to prevent. Furthermore, a treatment with rTMS is not desirable but not prohibited.

6. INVESTIGATIONAL PRODUCT

Not applicable

6.1 Name and description of investigational product(s)

This study is not a pharmaceutical study and therefore information about the investigational object can be found under 5.1.

6.2 Summary of findings from non-clinical studies

Not applicable to this study.

6.3 Summary of findings from clinical studies

The findings from clinical studies are summarized here with first the focus on the relationship between ACEs and symptoms followed by studies investigating ImRs transdiagnostically and specifically OCD and BDD.

In BDD some studies have examined the relationship between ACEs and BDD symptoms. A recent a meta-analysis from Longobardi et al. found in 27 studies a moderate effect for ACEs and large effect on the relationship between bullying and BDD symptoms, but also emotional abuse (Longobardi et al., (2022). They propose their view on BDD as having a mental representation of the self as vulnerable, imperfect and inadequate and feelings of rejection and shame. Due to the cross-sectional nature of the studies no causal relation can be drawn and they note the possibility of fake memories because of heightened risk of paranoid thinking. The relationship between ACEs, shame and BDD symptoms is also found by a study of Stechler & Henton (2022) who collected data form semi-structured interviews of six women with BDD and showed that shame, trauma and dissociation were common along with themes as shame about being seen as a person, disgust and detachment during intimacy and a flawed self. This was confirmed by Weingarden et al. (2018) who found in 83 adults with BDD that shame was significantly higher in BDD patients compared to healthy control and psychiatric outpatient groups. In summary there is a growing body of literature that recognises a relationship between shame, feelings of rejection, the development of early maladaptive schema's (EMS) and BDD symptoms.

These studies show a relationship between ACEs and symptom development. A growing body of literature exists on investigating ImRs as a treatment for several disorders.

Several studies have investigated schema therapy and especially imagery rescripting in a variety of disorders like PTSD, personality disorders, social anxiety disorder and generalized anxiety disorder. Imagery rescripting has been proven as a valid technique in lowering PTSD symptoms (Arntz et al., 2013; de Haan et al., 2017) and in SAD. A meta-analysis of Morina et al. (2017) , based on 19 trials showed that ImRs influences the different outcomes measures on PTSD, social anxiety disorder, body dysmorphic disorder, obsessive compulsive disorder and bulimia nervosa. There is some preliminary evidence for the effectiveness of ImRs in MDD (Brewin et al., 2009), in OCD (Veale et al., 2015) and in BDD (Ritter & Stangier, 2016; Willson et al., 2016). In all studies ImRs was applied as a stand-alone treatment.

In 2017 the studies on OCD and BDD were scarce, two studies on BDD and one study on OCD. The research was operationalized with a case series design in which a small number of participants were frequently measured on primary outcomes like OCD and BDD symptoms and secondary outcomes like mood. Number of sessions were one for OCD and one and two for the BDD studies. The data from these studies show a large pre-post effect for BDD (1,161 (Wilson et al, 2016) and 1,312 (Ritter & Strangier, 2016)) and for OCD as well (1,032 (Veale et al, 2015). Since 2017 the research on ImRs as an adjunct or stand-alone intervention for OCD is extended by two studies. Maloney et al. (2019) studied in a SCED design the effect of 1-6 ImRs sessions as an adjunct intervention for OCD in 13 patients. The results show that a small number of sessions result in a significant reduction in OCD symptoms if past aversive experiences prevailed and if symptoms after ERP were still in the mild-moderate range. The study has some limitations like a selection bias (own psychologist) and variable randomization and therefore the results are preliminary.

A more recent study from Tenore et al. (2020) found in 18 OCD patients that three sessions ImRs, focusing on guilt inducing reproaches in early childhood, reduces OCD symptoms from screening to 90-day follow up. Limitation is solely focussing on guilt which makes it unable to explore other emotion-induced reproaches and not measuring core beliefs and emotions. The effect was however clinically significant, and this is in line with the study of Basile et al. (2018) in which they found more guilt inducing events with parents, more feelings of guilt and need for acceptance and to be seen. Schemata associated with these emotions are social isolation, failure, relentless standards, vulnerability for disease and negativism.

The aforementioned studies suggest that ImRs can be used as a treatment for several mental disorders with significant effect on symptom level and comorbid disorders like depression. The preliminary results show ImRs to influence aversive imagery and assumed incapsulated believes, which would make it transdiagnostically promising because of the prevalence of adverse experiences in many psychiatric disorders. The results also suggests that patients with ACEs have a greater anticipation on events with negative outcomes and vivid imagery about prospective events, a so called flashforward (Morina et al., 2011). Because of that it is surprising that up to now no research has been done on prospective imagery and all the more a combination of retrospective and prospective imagery rescripting. Although ImRs being a promising intervention with a potence for transdiagnostical applicability, the existing literature on this subject is still scarce with a small number of studies, a small number of participants, variability in control group and no prospective imagery.

Based on the secondary objective of this study, research on emotions is described by Strachan et al. (2020) who describe a different mechanism for ImRs other than habituation and extinction. The proposed explanation is that learning theories do not explain for the change in non-fear emotions like self-disgust, self-blame, and helplessness. They propose a clinical study in which self-report measures of schema or core beliefs, assumptions, attributions, and appraisals associated with adverse memories can be administered before and after ImRs. For OCD, Basile et al (2018), as aforementioned, evaluated forty-one imagery exercises and found more blame/reproach memories, more expression of guilt emotion and needs for acceptance. A recent study by Stechler & Henton (2022) found three superordinate themes in semi-structured interviews from six women with BDD: the shame in being seen, disgust and detachment during intimacy, and a flawed self, unworthy of relationships. This is in line with the findings from Weingarden et al. (2018) who followed eight-three adults with BDD treated with an antidepressant and found shame to be significantly higher in BDD, to be correlated with severity, greater suicidal thought and hopelessness.

In summary there is a growing body of literature that recognises a relationship between guilt inducing events, the development of early maladaptive schema’s (EMS) and OCD symptoms and a relationship between shame and BDD symptoms. The results are preliminary and studies still scarce, therefore, more studies are needed that address the emotional content of ACEs and effect of treatment of these ACEs on emotions and schema or core beliefs and OCD and BDD symptoms.

6.4 Summary of known and potential risks and benefits

Not applicable. The trials discussed have not reported any adverse events. We do not anticipate any risk of the intervention except for the potential benefits and risks as described under 11.4.

6.5 Description and justification of route of administration and dosage

Not applicable

6.6 Dosages, dosage modifications and method of administration

Not applicable

6.7 Preparation and labelling of Investigational Medicinal Product

Not applicable

6.8 Drug accountability

Not applicable

7. NON-INVESTIGATIONAL PRODUCT

Not applicable

8. METHODS

8.1 Study parameters/endpoints

8.1.1 Main study parameter/endpoint

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)

8.1.2 Secondary study parameters/endpoints (if applicable)

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.
- For BDD: 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 intrusions.
- Qualitative interview and questionnaire: Imagery rescripting working mechanisms, therapeutic alliance, experiential avoidance, changes in cognition.

8.1.3 Other study parameters (if applicable)

Additional parameters will be collected, namely: age, marital status, gender, ethnicity, level of education, medication use, substance abuse, psychiatric history.

8.2 Randomisation, blinding and treatment allocation

Because all participants receive the same treatment with only a difference in baseline duration no randomisation is necessary.

8.3 Study procedures

Participants will be recruited at the unit anxiety disorders at the department psychiatry of the Amsterdam UMC, location AMC. Participants will be referred by the psychiatrist at the intake and the contact information will be forwarded to the researcher by the coordinator of the OCD and BDD groups. Participants will be asked to give written consent to share personal information and the participants will be contacted by the main investigator.

Initial screening / case conceptualization

Initial screening consists of providing patient information via an infographic and/or patient folder and guaranteeing privacy, anonymity and confidentiality. Further information about the study will be given to the participants and permission to record the intervention. If participants want to participate in the study an informed consent is asked to be signed. They will be given a week to decide whether they want to participate.

Psychiatric assessment

The screening of potential participants will take place. Prior to baseline screening participants will be asked to fill in the screener SCID-5-SV and the schema questionnaires (YSQ and SMI). In the indication session the SCID-5-S for syndromal disorders, the Y-BOCS(-BDD)/BABS for obsessive compulsive symptoms or body dysmorphic symptoms and the HDRS to measure depressive symptoms are measured.

Baseline

Following the psychiatric assessment is the baseline period with a variable duration with a maximum of ten weeks in which daily measures will be taken and no intervention.

Case conceptualization

After baseline we will conduct a case conceptualization of 1-3 sessions in which we integrate the information from the questionnaires and combine this with adverse childhood experiences, schema of core beliefs and modes, core emotions, coping and triggers for schema activation. This information will be integrated into a document (with a conceptualization figure) which will be created together with the participant. If not sufficient clear in the case conceptualization, adverse childhood experiences can be measured by additional questionnaires like the JTV/CTQ/VBE and for core emotions the TRGI and TRSI.

Interventions

The ImRs intervention starts with 2-weekly sessions of 60-90 minutes for the duration of a maximum of six to seven weeks. Participants are asked permission again for recording of the session. Furthermore, participants are asked to fill in the Y-BOCS(-BDD)/BABS pre- and postintervention and daily measures of VAS variables.

End of treatment assessment

After the intervention participants are asked to fill in the schema questionnaires again and a session is planned for the qualitative interview.

Recurring assessments

As follow-up procedure participants are asked to fill in the schema-questionnaires after 6-8 weeks.

Pilot study

Prior to the study a pilot will be conducted at two patients with BDD/OCD to test the abovementioned procedures and assessments. The two pilot patients receive the same procedures and assessment as participants in the study. The practitioner will adhere to the protocol and document any areas of improvement regarding instructions, measurements, and the implementation of the intervention. The primary objective is to evaluate the user-friendliness of the protocol. This will be reported back to the researchers and taken into consideration for improvements in the protocol.

Overview of assessments

The following questionnaires will be administered and this will be assessed using Castor:

Table 1. Assessment of measurements

	Time	Screen-ing	Indi-cation	Baseline	Pre-treatment	Intervention	Post-treatment	FU (>3m)
Demographics	5	·						
SCID-5-SV	20	·						
SCID-5-S	60-90	·						
BSI	10	·		·		·	·	·
ACEs								
YSQ	35		·				·	·
SMI	20		·				·	·
Case Conceptualization	120-180		·		·			
Y-BOCS-(BDD)	20		·	·		·	·	·
BABS	5-10							
HDRS	20-30		·	·		·	·	·
VAS scales (daily)				·		·	·	
Qualitative interview	60--90						·	
Optional:								
JTV/CTQ	10		·					
VBE/PCL-LEC-5	10		·					
TRGI/ TRSI	10		·			·	·	·

SCID Structured Clinical Diagnostic Interview, BSI Brief Symptom Inventory, ACE Adverse Childhood Experiences, YSQ Young Schema Questionnaire, SMI Schema Mode Inventory, Y-BOCS Yale-Brown Obsessive Compulsive Scale (-BDD), BABS Brown Assessment of Beliefs Scale, HDRS Hamilton Depression Rating Scale, Visual Analogue Scale, (CTQ Childhood Trauma Questionnaire , PCL-5 PTSD checklist for the DSM-5, LEC-5 Life Events Checklist, TRGI Trauma-Related Guilt Inventory, TRSI Trauma-Related Shame Inventory

8.4 Withdrawal of individual subjects

Subjects can leave the study at any time for any reason if they wish to do so without any consequences. The investigator can decide to withdraw a subject from the study for urgent medical reasons.

8.4.1 Specific criteria for withdrawal (if applicable)

Not applicable

8.5 Replacement of individual subjects after withdrawal

After withdrawal another participant will be recruited to obtain the number of participants (18 for OCD and 18 for BDD). Replacement will only take place in case of withdrawal after baseline, not after treatment. Based on the literature the drop-out rate is expected to be low.

8.6 Follow-up of subjects withdrawn from treatment

If a participant decides to terminate the treatment, they have the option to remain in the study, allowing their data from the duration of their participation to be included in the analysis, with their agreement. In the event of study termination, participants can choose to continue their treatment without any consequences. While they would no longer be required to participate in additional measurements, they can still opt to receive the ImRs treatment if desired.

8.7 Premature termination of the study

At any stage the safety board may request reconsideration of the trial. In case of an premature ending of the study, the investigator will notify the accredited METC, including the reason for termination. In case of termination participants will be notified and the study will be ended. In collaboration with the safety board it will be defined what the exact consequences are for the study and participants. No criteria are defined for ending.

9. SAFETY REPORTING

9.1 Temporary halt for reasons of subject safety

In accordance to section 10, subsection 4, of the WMO, the sponsor will suspend the study if there is sufficient ground that continuation of the study will jeopardise subject health or safety. The sponsor will notify the accredited METC without undue delay of a temporary halt including the reason for such an action. The study will be suspended pending a further positive decision by the accredited METC. The investigator will take care that all subjects are kept informed.

9.2 AEs, SAEs and SUSARs

9.2.1 Adverse events (AEs)

Adverse events are defined as any undesirable experience occurring to a subject during the study, whether or not considered related to [the investigational product / trial procedure/ the experimental intervention]. All adverse events reported spontaneously by the subject or observed by the investigator or his staff will be recorded.

9.2.2 Serious adverse events (SAEs)

A serious adverse event is any untoward medical occurrence or effect that

- results in death;
- is life threatening (at the time of the event);
- requires hospitalisation or prolongation of existing inpatients' hospitalisation;
- results in persistent or significant disability or incapacity;
- is a congenital anomaly or birth defect; or
- any other important medical event that did not result in any of the outcomes listed above due to medical or surgical intervention but could have been based upon appropriate judgement by the investigator.

An elective hospital admission will not be considered as a serious adverse event.

In case during the study an undiagnosed serious psychiatric illness manifest itself the health care provider or general practitioner will be advised, as will also be the case if suicidality is manifest but also the consultation of a psychiatrist or crisis centre in case of the latter. In case of medical problems the local emergency number will be contacted.

The sponsor will report the SAEs through the web portal '*Toetsing Online'* to the accredited METC that approved the protocol, within 7 days of first knowledge for SAEs that result in death or are life threatening followed by a period of maximum of 8 days to complete the initial preliminary report. All other SAEs will be reported within a period of maximum 15 days after the sponsor has first knowledge of the serious adverse events.

9.3 Follow-up of adverse events

Based on the studies in literature no AES are expected, All AEs will be followed until they have abated, or until a stable situation has been reached. Depending on the event, follow up may require additional tests or medical procedures as indicated, and/or referral to the general physician or a medical specialist.
SAEs need to be reported till end of study within the Netherlands, as defined in the protocol

9.4 [Data Safety Monitoring Board (DSMB) / Safety Committee]

Not applicable due to the nature of this study (negligible risks of the added intervention on top of regular care).

10. STATISTICAL ANALYSIS

General

It is a within-subject design using parametric and non-parametric testing and visual inspection. The number of participants was calculated based on a power calculation (via G*Power) using paired t-test (two tailed), with a power of 0.8, an alpha of 0.025 and a desired effect size of 0.8 (chosen for lower than reported Hedge's g from studies by Veale et al., (2015):1.16, Willson et al., (2016): 1.16 and Ritter & Stangier, (2016): 1,312. The number of participants for this study will be 18 per group (OCD, BDD). In total 36 participants.

Randomization tests and visual inspection of the course of daily measurements will also be used to measure the changes from baseline to intervention (Bouwmeester & Jongerling, 2020). For each participant at least five measurements but preferably around 20 measurements per treatment phase is sufficient.

Missing values

A limited amount of missing values is no problem for the analysis since it is based on the change over time which can still be measured with omissions.

10.1 Primary study parameter(s)

Parameter 1: difference in VAS scales concerning schema or core beliefs, OCD and BDD symptoms as measured by VAS scales

During the intervention we will measure on a daily basis the change in schema or core beliefs and OCD and BDD symptoms based on obsessive thoughts, obsessive compulsions and distress.

The baseline serves as a benchmark for assessing change induced by the experimental condition. Assessing treatment effects will be done by visual inspection in which the pattern of outcomes across the phases is sufficient to identify change if the trend of the data in the baseline phase is different from the pattern in the intervention phase. Also statistical analysis will be performed such as a time-series analysis if a great variability in the data is manifest. With cross-lagged correlations will the coherence (direction and relationship of time) between two variables over time be analysed (Joos et al., 1996). Cross-lagged correlations can be easily be calculated using software developed by Borckardt and colleagues, called Simulation Modelling Analysis (Borckardt et al., 2008).

10.2 Secondary study parameter(s)

Parameter 2: the change in OCD and BDD symptoms (full questionnaire), schemata and modes, core emotions, severity of depression, affect and obtrusiveness of intrusion.

During the intervention we will measure on a daily basis the change in core emotions, affect and obtrusiveness of image.
Assessing treatment effects will be the same as under parameter 1,

During the study we will measure at different moments (see figure 1) the change in schemata and modes, OCD and BDD symptoms (full questionnaire), mood, affect and obtrusiveness of image.
In order to study the effect of secondary study parameters we will perform statistical analysis on scores on the YSQ/SMI, Y-BOCS(-BDD), HDRS, BABS.

10.3 Other study parameters

Qualitative interview: exploratory analysis on working mechanisms of intervention: imagery rescripting working mechanisms, therapeutic alliance, experiential avoidance, changes in cognition

10.4 Interim analysis (if applicable)

Not applicable.

11. ETHICAL CONSIDERATIONS

11.1 Regulation statement

The study will be conducted according to the principles of the Declaration of Helsinki (general Assembly, Fortaleza, Brazil, October 2013) and in accordance with the Medical Research Involving Human Subjects Act (WMO) and other guidelines, regulations and Acts

11.2 Recruitment and consent

Participants are recruited from the unit anxiety disorders from the department psychiatry of the Amsterdam UMC, location AMC. After the intake process, potential participants will be referred by the psychiatrist. The researchers will then reach out to these individuals to arrange an on-site screening session. During this session, the patient folder will be reviewed, informed consent will be provided and any questions will be addressed. Upon agreement, the informed consent form will be signed. Subsequently, an appointment for the start of the study will be scheduled for those patients who choose to participate.

11.3 Objection by minors or incapacitated subjects (if applicable)

Not applicable

11.4 Benefits and risks assessment, group relatedness

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

11.5 Compensation for injury

The sponsor/investigator has a liability insurance which is in accordance with article 7 of the WMO.

The sponsor (also) has an insurance which is in accordance with the legal requirements in the Netherlands (Article 7 WMO).

11.6 Incentives (if applicable)

Not applicable. In case of extra visits we will investigate the option for video calling, but if a visit to the Amsterdam UMC, location AMC, is necessary travel expenses will be compensated.

12. ADMINISTRATIVE ASPECTS, MONITORING AND PUBLICATION

12.1 Handling and storage of data and documents

All study and medical data will be handled confidentially and encrypted in accordance with the EU General Data Protection Regulation and the Dutch Act on Implementation of the General Data Protection Regulation (in Dutch: Uitvoeringswet Algemene Verordening Gegevensbescherming, UAVG). Participant data will be coded with a unique participant number and stored in Castor. A subject identification code list linking these participant numbers to the participant identification data will be created. This subject identification code list will be available to the principal investigators involved in this study only. Only staff members (e.g. clinical interns, clerical personnel) authorized by the principal investigators, monitoring agency of the AMC will be allowed access to the coded participant data. Study data will be recorded coded with a unique study number. A table linking these study numbers to the patients' identification data will be created. This table will only be available to the principal investigators and medical doctors / clinical psychologists that are involved in this study. Original source documents will be archived for a period of 15 years after the report of the study has been finalized. Thereafter, all study-related documents will be destroyed.

12.2 Monitoring and Quality Assurance

Monitoring of the conduct of the study will take place by the CRU, with whom a monitoring plan will be made.

12.3 Amendments

Amendments are changes made to the research after a favourable opinion by the accredited METC has been given. All amendments will be notified to the METC that gave a favourable opinion.

12.4 Annual progress report

The sponsor/investigator will submit a summary of the progress of the trial to the accredited METC once a year. Information will be provided on the date of inclusion of the first subject, numbers of subjects included and numbers of subjects that have completed the trial, serious adverse events/ serious adverse reactions, other problems, and amendments.

12.5 Temporary halt and (prematurely) end of study report

The investigator/sponsor will notify the accredited METC of the end of the study within a period of 8 weeks. The end of the study is defined as the last patient's last visit.

The sponsor will notify the METC immediately of a temporary halt of the study, including the reason of such an action.

In case the study is ended prematurely, the sponsor will notify the accredited METC within 15 days, including the reasons for the premature termination.

Within one year after the end of the study, the investigator/sponsor will submit a final study report with the results of the study, including any publications/abstracts of the study, to the accredited METC.

12.6 Public disclosure and publication policy

The results of the study will be shared with the participating organizations and departments. The results will also be presented at seminars and published in peer-reviewed journals. No personal information will be shared . researchers will disclose research using databases. None of the parties (i.e. sponsor or investigator) have a right of veto.

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