

STUDY PROTOCOL

Title:

Imagery rescripting as a stand-alone treatment for depression: a pilot study.

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1. INTRODUCTION AND RATIONALE

“Just to hold an image in mind is a more emotionally charged experience than verbal processing of the same material (Holmes et al., 2007)”

In light of this quote it comes as no surprise that Imagery Rescripting (ImRs) is becoming an increasingly popular therapeutic intervention in clinical practice.

It is a technique that aims to reduce the distress associated with memories of past events by modifying the content of pre-existing unpleasant memories into more benign images (Holmes et al., 2007). Patients are instructed to retrieve a painful memory and imagine it as vividly as possible -as if it were happening in the here and now. Next, either the patient or (in case of higher degrees of severity and complexity) the therapist continues to “rescript” the imagined event by imagining intervening and thus creating a different (more favorable) turn of events.

The aim is to modify related dysfunctional core beliefs and fulfill unmet (childhood) needs that are associated with the image, ideally resulting in processing psychological traumas, so that they are of less influence on the patient’s functioning, and in an improved sense of connection to one’s emotional needs in the here and now and being better equipped to (adequately) connect action to emotions.

Originally embedded in a comprehensive treatment, such as cognitive behavior therapy or schema therapy, a growing amount of research also shows promising results of ImRs as a stand-alone treatment. It has proved to be successful in reducing symptoms and complaints in a relatively short amount of time (on average 4.5 sessions) (Morina et al., 2017). Since negative mental images are a transdiagnostic feature of a number of mental conditions it is not surprising that ImRs can successfully be applied to a wide range of disorders among which: posttraumatic stress disorder, social anxiety disorder, body dysmorphic disorder, bulimia nervosa, obsessive-compulsive disorder, and depression (Morina et al., 2017). It must be noted however, that the use of ImRs is not solely restricted to visual intrusions or memories that are associated to intrusions. It also addresses negative core beliefs and (childhood) memories underlying current problems (Arntz, 2012).

Taking a closer look at depression, we find that working with imagery seems to have been relatively neglected in standard evidence-based screening and treatment, such as Cognitive Behavior Therapy (CBT) which appears to be more verbally based and oriented. This is somewhat remarkable considering depressive symptoms are frequently accompanied by intrusive images (almost as often as in Post-Traumatic Stress Disorder), which are also believed to be an important perpetuating factor (Holmes et al., 2016). These negative intrusive images are reported in 44%-96% of depressed patients and commonly manifest themselves as imagery of past negative events or so-called flash forwards of suicide or self-harm (van der Wijngaart, 2020). The content is often linked to critical life events or traumas and typically involves topics such as illness, death, or interpersonal problems; causing feelings of sadness, anger, guilt or hopelessness (Weßlau & Steil, 2014). This kind of mental imagery is of great significance in the pathogenesis of depression and is often associated with experiential avoidance, typically involving ineffective coping styles like rumination and worry (Yuen-ting, 2017). In addition to

this, negative core beliefs or cognitive schemas (as a result of the aforementioned unmet core emotional needs) represent key vulnerability factors to depression (Malogiannis et al., 2014) and adverse childhood experiences have been found to be an important factor predicting relapse (Nanni et al., 2012). In sum, we see that multiple studies support both the significance of mental imagery, negative core beliefs and adverse childhood experiences in the etiology and the manifestations of depression; as well as the therapeutic potential of ImRs when targeting these areas.

Available research on the application of ImRs in the specific area of depression is still limited, but promising. Wheatley et al. (2007) and Brewin et al. (2009) offered ImRs as a brief stand-alone treatment to 10 depressed patients in an exploratory study and found a significant reduction of symptoms in an average of 8.1 sessions with treatment effects well maintained at one year follow-up. Both studies were aimed specifically at patients reporting intrusive memories. An extensive meta-analysis conducted by Morina et al. (2017) showed large effects of ImRs on co-morbid depression. To our knowledge Yuen-ting (2017) conducted the first RCT comparing ImRs with another renowned intervention (cognitive restructuring (CR)); randomly assigning 41 patients to either one of the two treatment conditions. ImRs proofed to be superior in even as few as three sessions. Although CR was comparable in reducing depressive symptoms, ImRs led to a greater magnitude of change and yielded continuous treatment effects at 2 month follow-up, contrary to CR. Lastly Moritz et al. (2018) showed that ImRs can also be successfully applied as a self-help intervention, as long as the use-at-home treatment manual is not too brief and allows for enough repetition and redundancy. In their RCT 127 participants were randomly allocated to either two intervention subgroups (brief vs long version of the treatment manual), or to a wait-list control group (equal chance). The long version manual proofed superior to both the brief version and the wait-list control group and was successful in reducing depressive symptoms and improving self-esteem and quality of life. Unfortunately no follow-up measurements were included in this study, thus preventing insight in the sustainability of the effects.

Globally the total number of people with depression was estimated to exceed 300 million in 2015, equivalent to 4.4% of the world's population (World Health Organization; 2017). Shifting the focus to a more local angle shows us that depression is the most common mental disorder among patients in the Netherlands. About 797.000 people (including youth from the age of 13 and the elderly) suffer from depression each year (GGZ Standaarden, 2018). Approximately 50% of patients with depression do not respond to treatment and about half of the patients reporting a first depressive episode will experience relapse within 2 years after initial recovery reached in psychological therapy (Holmes et al., 2016).

These numbers create a certain sense of urgency and underline the strong need for treatment innovations of all sorts that can be easily implemented as well as help to prevent relapse after treatment. As explained earlier, ImRs appears to be an obvious candidate for this since it can intervene on important underlying mechanisms (negative mental imagery, unmet emotional needs, dysfunctional core beliefs) which seem to be addressed notably less in the prevailing treatments - generally based on a more complaint/symptom-oriented approach.

Based on the presented findings the idea of the current study is to further explore the efficacy of ImRs as a brief stand-alone treatment for patients suffering from depression. A clear treatment manual is to be formulated ensuring that the patients feelings, thoughts and needs are addressed. A protocol that meets these criteria has been described by Arntz & Weertman (1999)

2. OBJECTIVES

The primary aim of the study is to examine the effects of ImRs as a stand-alone treatment for patients with depression (Major Depressive Disorder (MDD), according to DSM-5 criteria) on the decrease of dysfunctional core beliefs and depressive symptoms.

Hypotheses:

1. The slopes of improvement as expressed in a decrease in dysfunctional core beliefs measured with the VAS for beliefs) are significantly stronger during ImRs than during control conditions (pre- & post-baseline; post-preparation; post-treatment and at follow-up).
2. The slopes of improvement as expressed in a decrease in depressive symptoms (measured with the PHQ-2) are significantly stronger during ImRs than during control conditions (pre- & post- baseline; post-preparation; post-treatment and at follow-up).

The secondary aim of this study is to examine the effects of ImRs as a stand-alone treatment on two areas that represent key factors in the pathogenesis of MDD: rumination and worrying.

Hypotheses:

3. A significant reduction of Rumination (compared to baseline) is expected at post-treatment and at follow-up. No significant changes (compared to baseline) are expected post-wait and post-preparation.
4. A significant reduction of Worrying (compared to baseline) is expected at post-treatment and at follow-up. No significant changes (compared to baseline) are expected post-wait and post-preparation.

Lastly, the final aim of the study is to gain insight into the patients' experience and qualitative evaluation of this treatment. At post-treatment a brief qualitative interview will be conducted among participants to gain insight in their experience.

Questions / topics to be included:

How would patients evaluate their experience of undergoing the treatment? What aspects in particular did they appreciate? What aspects in particular did they disapprove? What aspects do they believe to contribute to the outcome? Do they feel the treatment continued to have effects outside of the treatment sessions? If so: in what way? In case they have undergone psychological treatment for depressive symptoms prior to the current treatment; what treatment was that? If compared to the current treatment, do they hold a preference of one over the other and if so: why?

3. STUDY DESIGN

The study design is a non-concurrent multiple baseline case series design with N=10 patients reporting levels of depression as well as ratings of dysfunctional core beliefs on a weekly basis. Patients will be randomized over five conditions of baseline length (6, 7, 8, 9, 10 weeks; 2 patients per condition), thus isolating time from the consecutive condition so that the effects of treatment can be distinguished from that of time per se. After baseline, 5 preparatory sessions will take place followed by 8 to 12 sessions of ImRs (according to clinical need). This brings the total amount of sessions to a minimum of 13 and a maximum of 17 (5 prep + 8 – 12 IMRS). In addition to the weekly measurements, there will be 6 moments of assessment: start of baseline, pre-preparation, pre-treatment, post-treatment and two follow-ups to assess the stability of the effects (6 and 12 months post-treatment).

4. STUDY POPULATION

4.1 Population

Patients with a main diagnosis of MDD will be recruited at the Academic Center for Trauma and Personality (ACTP) at Amsterdam, the Netherlands. This institute provides state-of-the-art, professional treatment for trauma and personality related mental health problems. Male and female patients within the age range of 18-65 will be included if they meet the criteria of MDD based on the DSM-5 criteria as their primary diagnosis, assessed with the SCID-5-S.

4.2 Inclusion criteria

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

- Primary diagnosis of MDD as assessed with the SCID-5-S
- Total score of 20* or above on the BDI-II (cut-off score for moderate depression) (Beck et al., 1996). (*Based on previous research by Brewin et al. (2009) & Yuen-tin (2017) demonstrating averages of BDI-II: 34-35, in their population.)
- Age 18-65
- Dutch or English as a first language (or estimated as sufficient to receive treatment in either of these languages without interpreter)
- Willingness to participate in the study (signed informed consent)

4.3 Exclusion criteria

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

- DSM-5 Bipolar disorder, type 1 (current or past); if there has been no manic episode the last year patients will be included
- Psychotic disorders (though psychotic features alongside depression will be allowed)
- Organic brain disease

- IQ < 80
- High risk of self-harm or suicide
- Current substance abuse
- Start of new medication within 2 months before beginning the study (medication used for longer periods can be continued; patients are requested to keep medication stable during the course of the study)
- Having received ImRs (either as a stand-alone or embedded in a greater treatment such as CBT or schema therapy) within the last year
- No other evidence-based treatment of MDD is allowed during the study.
- Not able to plan enough time for weekly therapy sessions (45-60 minutes); weekly measurements (estimate of 5 minutes) and other measurements (estimate of 20 minutes); and the qualitative post-treatment interview (estimate of 60 minutes) during the treatment period.

4.4 Sample size calculation

No simple way to perform power analysis for this type of mixed regression is known to the authors. As an approximation we power the study at 80% to detect a large effect size of Cohen's $d = 1$ for the change from baseline to post treatment at a significance level of .05 (two-tailed)), ten participants are necessary for this. Given the effect size $d=1.92$ reported by Brewin et al (2009), $d=1$ is a conservative estimate of the to be expected effect size.

5. TREATMENT

5.1 Investigational treatment

Eight to 12 sessions (45-60 minutes) of ImRs will be offered to participating patients. The stand-alone ImRs treatment will be based upon the protocol described by Arntz & Weertman (1999). (This protocol can be modified to tailor the needs of this study more specifically. Possible adaptations shall be based upon the manual developed by Brewin and colleagues (2009) for their study of applying ImRs to depression.)

Before patients start the ImRs sessions, they will receive 5 preparatory sessions. During these sessions the rationale of ImRs will be explained in more detail and a list of painful (childhood) memories to be addressed with ImRs is to be compiled, based on any further input from the patient. During the course of treatment other memories that come up during or in between sessions can also be added. There is no specific order / hierarchy in which the memories have to be addressed during the sessions, nor do they all have to be discussed.

Patients are allowed to finish treatment before 8 sessions if the patient, therapist, and site coordinator agrees that treatment is no longer necessary. In these cases assessments will still be conducted at the originally planned time points. Participating therapists are licensed psychologists, psychotherapists, or clinical psychologists that have undergone basic training in either cognitive-behavioral therapy or schema therapy. An additional 2-day training in ImRs according to the model of Arntz (2011, 2015) is required. Therapists will be provided with ongoing peer supervision throughout the study.

5.2 Use of co-intervention

Patients may continue taking medication during the course of the study. Start of new medication within 2 months before beginning the study is listed as an exclusion criterium. Patients are requested to keep medication stable during the course of the study. No other psychological therapy is allowed during treatment (crisis interventions excluded).

5.3 Escape medication / treatment

Patients might start taking medication or another form of treatment/therapy in case of acute crisis during the study. The use of these medications or crisis intervention during the study as co-intervention will not lead to exclusion from the study, but will be monitored, documented, and reported.

5.4 Further treatment

Participation in this study will not affect patients' access to standard psychological treatment. However, they will be asked and advised to withhold such treatment at least until the first follow-up measurement has been completed (6 months post-treatment). In the case of patients requesting help during the follow-up period, an evaluation is required whether the necessity of the request for help should overrule the planned treatment-free period.

6. METHOD

6.1 Main study parameter / endpoint

The primary outcome measure is a change in the manifestation and the severity of dysfunctional core beliefs and depressive symptoms. These will be measured on a weekly basis with the following instruments:

1. The Patient Health Questionnaire (Kroenke et al., 2003). The PHQ-2 consists of the first two items of the PHQ-9 and has strong psychometric properties. (Staples et al. (2019) reported an effect size of 1.38 (0.95-1.79) and a good internal consistency ($\alpha = 0.83$)).
2. The idiosyncratic dysfunctional core beliefs formulated by the patients -> belief ratings will be expressed on a Visual Analogue Scale (VAS) ranging from 1 – 100.

6.2 Secondary study parameters

The secondary outcome measures consist of the following 3 instruments applied at 6 consecutive time-intervals* (pre-baseline; post-baseline, post-preparation; post-treatment; follow-up 1 and follow-up 2):

(*See 6.4.2; table 1 for an overview of the assessment moments)

1. The Beck Depression Inventory-II (Beck et al., 1996). The BDI-II is a 21-item self-report measure of depressive symptoms that possesses strong psychometric properties. Items are rated based on selecting the best-fitting statement that reflects one's mood state, with each item ranging from 0 to 3 in regards to increasing levels of severity of that symptom.
2. The Ruminative Response Scale; "Brooding" subscale (Nolen-Hoeksema & Morrow, 1991). The RRS is a 22-item scale that assesses individuals' tendency to ruminate in response to depressed mood.

Items are rated based on a 4-point Likert scale ranging from 1 (“almost never”) to 4 (“almost always”). Instead of using the total score (22 items); it has become common practice to focus on a subset of 10 items (divided into 2 subscales: Reflection & Brooding). For purposes of the current study, only the 5-item “Brooding” subscale will be used since these seem to reflect the most maladaptive aspect of rumination (Treyner et al., 2003; as cited in Raes & Bijttebier, 2012).

3. The Penn State Worry Questionnaire (Meyer et al., 1990). The PSWQ is a 16-item self-report measure of worry phenomena. Items are rated on a 5-point Likert scale ranging from 1 (“not at all typical of me”) to 5 (“very typical of me”).
4. An evaluation of treatment experience. Insight in the way patients will have experienced and how they evaluate the treatment will be gathered by means of a brief qualitative interview at post treatment. Topics to be included: *How would patients evaluate their experience of undergoing the treatment? What aspects in particular did they appreciate? What aspects in particular did they disparage? What aspects do they believe to contribute to the outcome? Do they feel the treatment continued to have effects outside of the treatment sessions? If so: in what way? In case they have undergone psychological treatment for depressive symptoms prior to the current treatment; what treatment was that? If compared to the current treatment, do they hold a preference of one over the other and if so: why?*

6.3 Other study parameters (diagnostic & baseline assessments)

The Dutch DSM-5 version of the SCID-5-S will be used to assess syndromic disorders during screening.. A checklist will be used to assess inclusion and exclusion criteria.

6.4 Study procedures

6.4.1 Screening procedures

During the screening procedure, the eligibility will be determined according to the aforementioned in- and exclusion criteria. The SCID-5-S will be used to assess syndromic disorders. The BDI-II will be used to assess the severity of the depression. All participating patients will be asked for their consent, which will be documented by a signed consent-form.

In a (separate) pre-interview conducted by the primary researcher or an assigned research assistant, a list of idiosyncratic dysfunctional core beliefs (min.3; max. 5) patients wish to work on will be assembled. These can either be a direct appraisal of certain intrusive memories or they can be of a more general / diffuse nature.

6.4.2 Study Assessment Moments

The primary outcome measures will take place on a *weekly* basis during the entire course of baseline; the preparation sessions and the ImRs sessions; followed up with 5 weekly measures during week 1-5 post-treatment.

The secondary measures will take place at *6 allocated time intervals*:

- 1) Pre-baseline (prior to the allocated waiting time; counted as 0 weeks)
- 2) Post-baseline (6 – 10 weeks, depending on the allocated waiting time)

- 3) Post-preparation (waiting time + 5 prep. sessions)
- 4) Post-treatment (min. week 19 – max. week 27: depending on baseline and ImRs duration)
- 5) Follow-up 1 (6 months)
- 6) Follow-up 2 (12 months)

Table 1 Overview in time of the study assessment moments

Instrument/Action	Screening	Weekly (Start: pre- baseline End: 5 weeks > post-treatment)	Pre- Baseline	Post- Baseline	Post-Prep.	Post-treatment: (>5 weeks after finishing ImRs)	Follow-up 1: 6 months > Post-treatment	Follow-up 2: 12 months > Post- treatment
Diagnostic / baseline assessments								
SCID-5-S	•							
Inclusion / exclusion criteria	•							
BDI-II	•							
Primary outcomes / weekly measures								
VAS (dysf. core beliefs)		•					•	•
PHQ-2		•					•	•
Secondary outcomes / repeated measures								
BDI-II			•	•	•	•	•	•
RRS (5-item "Brooding" subscale			•	•	•	•	•	•
PSWQ			•	•	•	•	•	•
Secondary outcome / single measure								
Qualitative interview on exp./eval.						•		

6.4.3 Assessment Procedures

All quantitative measurements as well as the qualitative interview at post-treatment will be conducted by either the primary researcher or an assigned research assistant.

Self-report instruments will be filled out by patients themselves, either at home or at the research site; digitally or in paper. This applies to all instruments that are used, with the exception of: the Scid-5-S, the list of in- and exclusion criteria and the qualitative interview at post-treatment.

To assess treatment integrity, all ImRs sessions will be recorded (audio or video) and a random sample will be drawn to be rated by independent trained judges for treatment adherence. The recordings may also be used to study other issues that might arise during the course of treatment and can be discussed in the peer supervision for this purpose. Recordings will be destroyed 5 years after publication of the main findings.

The results of the screening assessment will be given to the assigned therapist to help them focusing the ImRs; e.g. a list of the idiosyncratic dysfunctional core beliefs.

6.4.4 Withdrawal of individual subjects

Patients can leave the study at any time for any reason if they wish to do so without any consequences. Their right for treatment at the participating centre will remain intact. Patients may provide their reasons(s) for leaving the study, but this is not required. The responsible clinician can decide to withdraw a patient due to urgent clinical reasons, after consultation with the primary investigator.

7. STATISTICAL ANALYSIS

7.1 Primary study parameter(s)

There will be two primary outcomes: (1) the idiosyncratic negative beliefs and (2) the PHQ-2. (2). Total scores will be used for the PHQ-2, and the mean score of the idiosyncratic belief ratings. These scores will be analyzed by mixed regression (Arntz et al., 2013; Videler et al., 2018). Either AR1 or ARMA11 will be chosen for the repeated part, depending on what covariance structure has the best fit. For the fixed part, condition (baseline, preparation, treatment, post-treatment, FU1 and FU2), as well as centered time per condition (except for FU1 and FU2, which are single assessments) will be included, with baseline as reference. Nonsignificant time-within-condition effects will be stepwise deleted from the model. It is expected that the change in the primary outcomes stronger is during treatment than during baseline, and that preparation does not lead to a stronger change than baseline. Furthermore, it is expected that during post-treatment and follow-up results are maintained, or show further improvement. The final model will be compared to a model with only time as fixed effect by a fit test, to test whether the hypothesized model (treatment being responsible for the changes) explains the data better than an effect of time only. If the data are not normally distributed, appropriate other distributions will be chosen for analysis with generalized linear mixed models (GLMM) (e.g. negative binomial or gamma regression with log-link in case of skewed distribution).

7.2 Secondary study parameter(s)

There will be three secondary outcomes: the BDI-II; the RRS 5-item "Brooding" subscale and the PSWQ. Total scores will be used for analysis by mixed regression or GLMM (Arntz et al., 2013;

Videler et al., 2018). The approach is the same as with the primary outcome, except that no time-within-condition are part of the model.

The brief qualitative interview conducted post-treatment will not be statistically, but qualitatively, analyzed. Answers will solely be used to gain insight in patients' experience and as helpful tool to give direction to possible further research and / or development of treatment. Answers will not be used to draw conclusions from, nor will they be presented as proof to confirm or discard any of the aims of this study.

8. Dissemination, Implementation, Future Studies

The results of the study will be disseminated in the scientific community by publication of an article in a scientific journal and presentation(s) at (a) scientific conference(s). Clinicians will be informed by presentations at conferences attended by clinicians (e.g., the national and international conferences). Trainings in ImRs for colleague clinicians will be organised, as well as supervision possibilities. Among participating therapists are teachers (e.g., courses in ST) and supervisors, which will facilitate dissemination. Implementation will be stimulated by offering in-company training and supervision. As this study is a pilot, evidence in favour for the effectiveness of ImRs as a stand-alone treatment for depression can be seen as an invitation for further research on the subject.

9. Time schedule

August 2023: start of recruitment of patients, assessment of in/exclusion criteria, first assessments.

Autumn 2023: start of first treatments, data are centrally stored, checked and prepared for analysis

Summer 2026: last treatment and post-treatment assessments completed

Summer 2027: last 1 year follow-up assessments completed; analyses of outcome data, reports of results (article, conference(s)). Start of dissemination & implementation activities.

10. Participating Sites

At this moment the following site committed to participate:

ACTP Amsterdam (website: <https://actp.nl>)

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