Imagery in depression: augmenting cognitive behavioral therapy with imagery reprocessing using EMDR: a pilot randomized controlled trial

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Mood disorders and disturbances NEC
Study type	Interventional

Summary

ID

NL-OMON45560

Source
ToetsingOnline

Brief title
ImaginD

Condition

- Mood disorders and disturbances NEC

Synonym
Depression; major depressive disorder

Research involving
Human

Sponsors and support

Primary sponsor: Parnassia (Den Haag)

Source(s) of monetary or material Support: intern gefinancieerd door Parnassia groep; tevens is een aanvraag gedaan voor subsidie door de Vereniging EMDR

Intervention

Keyword: CBT, Depression, EMDR, Imagery

Outcome measures

Primary outcome

The primary outcome measure is depression severity measured with the Hamilton Depression Rating Scale (HDRS; Hamilton, 1960)

The 17-item HDRS is a clinician rating that consists of depressive symptoms that are recorded using 5- or 3-point scales reflecting presence and severity over the past week.

To enhance the interrater reliability the HDRS will be queried with the structured interview guide for the HDRS (SIGH-D; Williams, 1988). This structured interview has proven to produce uniformly higher item- and summary-scale reliabilities than the unstructured HDRS (Moberg et al., 2002; Allen et al., 2010).

Secondary outcome

Remission from depression, which will be defined as a score of * 6 as administered with the Hamilton Depression Rating Scale (HDRS; Riedel et al., 2010).

To test self-reported depression severity the Inventory of Depressive Symptomatology-Self Report (IDS-SR) will be used. The IDS-SR is a self-report questionnaire (Rush, Gullion, Basco, Jarrett, & Trivedi, 1996) and consists of 30 items (rated zero to three), each describing a depressive symptom in four

levels of severity. The IDS-SR asks for all DSM cores symptom domains including mood, cognitive and psychomotor symptoms, but also covers commonly associated symptoms including anxiety. The IDS-SR has high internal consistency (*=0.92, Rush et al., 2003). Remission is defined as an IDS-SR-30 score of 14 or less.

The Depressive Symptomatology-Self Report (IDS-SR) will also be used as a weekly before sessions measurement of self-reported depressive symptoms to assess speed of recovery. Two visual analogue scales will be used to measure decrease of emotionality and vividness of the most distressing (memory) image (Leer, Engelhard, & Van Den Hout, 2014).

Study description

Background summary

Depression is a common mental disorder. Globally, an estimated 350 million people of all ages suffer from depression. Depression is the leading cause of disability worldwide, and is a major contributor to the overall global burden of disease (World Health Organization [WHO], 2016). Over the past three decades, numerous studies have demonstrated that cognitive behavior therapy (CBT), interpersonal psychotherapy (IPT), and antidepressant medication (ADM) are equally efficacious in the treatment of major depressive disorder (De Maat, Dekker, Schoevers & De Jonghe, 2006; Cuijpers, Andersson, Donker, & van Straten, 2011). However, a substantial proportion of depressed patients fail to receive any benefit from therapy. Psychological treatments were found to be equally effective with a mean effect size of 0.67, which was reduced after adjustment for publication bias to 0.42 (Cuijpers, van Straten, Bohlmeijer, Hollon, & Andersson, 2010). Thus, there remains room for improvement of the existing psychotherapies. Most existing treatments are generic, in that they are applied without regard to the specific pattern of depressive symptoms reported by individual patients. Major depressive disorder (MDD) is a clinical syndrome notable for heterogeneity of its clinical presentation, genetics, neurobiology, clinical course, and treatment responsiveness (Rush, 2006). A possible approach to enhance treatment efficacy, is to target specific symptoms with focused, theoretically-driven interventions, with the aim of achieving more rapid change in defined subgroups of depressed patients (Brewin et al., 2009). This protocol describes a Randomized Controlled Trial (RCT) of cognitive

behavior therapy augmented with imagery reprocessing using eye movement desensitization and reprocessing (EMDR) for a subset of depressed patients with intrusive memories.

Imagery plays a role across a wide range of mental disorders (Pearson, Deeprose, Wallace-Hadrill, Heyes, & Holmes, 2013). We use the term imagery to refer to mental images and the accompanying experience of sensory information without a direct external stimulus. Traditionally, depression has been associated with verbal, rather than imagery based processes, such as negative rumination (Fresco, Frankel, Mennin, Turk, & Heimberg, 2002). However, a role for imagery has more recently become of concern, with up to 90% of depressed patients reporting distressing intrusive memories of past experiences (Birrer, Michael, & Munsch, 2007). Several studies have shown that patients with depression frequently experience high levels of intrusive visual memories (Birrer et al., 2007; Brewin, Hunter, Carroll, & Tata, 1996; Patel et al., 2007; Reynolds, & Brewin, 1999). Patients with depression, like patients with posttraumatic stress disorder, typically have memories of specific autobiographical events that intrude into consciousness at high frequency. Brewin, Reynolds, & Tata (1999) found that the presence of intrusions in clinically depressed patients negatively influences the course of the disorder even when initial symptoms are controlled for, suggesting that they are an important maintaining factor. Experimental research indicates that imagery may elicit stronger emotional responses than corresponding verbal cognitions (Holmes, & Mathews, 2010).

Whereas memories of personal illness, injury, or assault are more common in PTSD, the content of intrusive memories in depression consists mainly of memories of death, illness, injury to family members, and interpersonal problems (Brewin et al., 1996). These memories can be vivid, full of sensory details, distressing, absorbing, and associated with intense negative emotions. The intrusive imagery can also be accompanied by a re-experiencing of emotions and physical sensations associated with the original event, but to a lesser extent by a sense of *nowness* as seen in PTSD. Also, the intrusive imagery was found to be experienced as highly uncontrollable and interfering significantly with patients* everyday lives (Patel et al., 2007). Furthermore, negative, maladaptive appraisals of intrusive memories, (e.g., *having this memory means that I am weak*) have been proposed to maintain the occurrence of intrusive memories, and in turn, depressive symptoms (Starr, & Moulds, 2006;Williams, & Moulds, 2008). As a result, interventions targeting these intrusions in this subgroup of depressed patients could potentially improve treatment outcomes.

The primary aim is to study the effect of augmenting CBT with reprocessing intrusive imagery, by using EMDR. EMDR is a guideline evidence-based treatment for PTSD (Bisson, & Andrew, 2007), but there*s limited evidence for it*s efficacy in other mental health problems such as depression. EMDR is a therapeutic approach oriented to reprocess dysfunctionally stored traumatic memories by reducing the vividness and emotional intensity of mental images (Hornsveld et al., 2010; Leer, Engelhard, & Van Den Hout, 2014; Van den Hout, 2001; Van den Hout, & Engelhard, 2012; Van den Hout, Bartelski, & Engelhard, 2013). The goal of EMDR is to address past, present and future

issues related to traumatic events and reprocess them. We hypothesize that by reprocessing imagery, in a way of reducing the vividness and emotional intensity of the intrusive imagery with EMDR, patients will become more susceptible to CBT.
Although the activation and confrontation of these intrusive imagery may be intense and temporarily distressing, the effect of the reprocessing can be extremely positive and lead to significant cognitive shifts that promotes openness to CBT. Indeed EMDR was found to enhance effects of CBT in a case-control study in which EMDR therapy was added to CBT compared to CBT. The addition of a mean of 7 sessions of EMDR therapy to a mean of 45 sessions of CBT resulted in a significant difference in symptom decline compared to 47 sessions of CBT alone (Hofmann et al., 2014).
This study aims to target a specific group of patients with intrusive imagery associated with negative (traumatic) life event in the onset and/or course of the depressive disorder. To our knowledge, no (pilot) RCT has been published that tested the effects of augmentation of CBT with EMDR in a specific subgroup of patients with intrusive imagery associated with negative (traumatic) life event in the onset and/or course of the depressive disorder.

Study objective

The primary objective is to test whether the augmentation of imagery processing, using EMDR, to CBT, results in greater reductions of clinician rated depression symptoms in participants with a depressive disorder with intrusive imagery associated with negative (traumatic) life event in the onset and/or course of the depressive disorder.

Study design

A single-blind single-centre pilot randomized controlled trial with two arms CBT: EMDR/CBT (ImaginD protocol) versus CBT. The two groups will be compared at baseline (T0), midtreatment (T1), posttreatment (T2) and at 3-month follow-up (T3). Assessment will contain a baseline imagery interview, structured interview of depressive symptoms, a self-report depressive symptom questionnaire, and two visual analogue scales concerning emotionality and vividness of the most distressing image. Similarly, before every treatment session depression symptoms will be assessed via self-report to track course of self-reported depression symptoms during treatment.

Intervention

The patients in the intervention group receive a treatment of 16 sessions EMDR & CBT (maximum of 6 sessions EMDR followed by CBT). Patients in the control group will follow 16 sessions CBT. Randomization will be performed by an external researcher using a computerized random number generator.

Study burden and risks

There are no potential risks for the participants when participating in the study. EMDR is a safe procedure, evidence-based in PTSS. Both treatment options will be offered by skilled and experienced therapists. The measurements take a total of 3 hours and 45 minutes.
The subjects may benefit from the intervention (therapeutic effect). They get a supplement to their evidence-based treatment.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

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

criteria:
* a primary diagnosis of major depressive disorder (MINI)
* presence of disturbing intrusive imagery associated with negative (traumatic) life event in the onset and/or course of the depressive disorder
* able to undergo psychotherapy
* willingness to receive EMDR on stressful memories
* the patient is currently not using antidepressants or the use of antidepressants has been unchanged for at least six weeks and no change in the use of antidepressants is planned

Exclusion criteria

* a primary diagnosis other than major depressive disorder
* estimated IQ below 70
* substance dependence

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-01-2018
Enrollment:	28
Type:	Actual

Ethics review

Approved WMO

Date:	05-09-2017
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL61354.058.17

Study results

Date completed:	24-04-2019
Actual enrolment:	19

Summary results
Trial is onging in other countries