EMDR and Imagery Rescripting as a Treatment for Trauma-Related Intrusive Images

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Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON56857

Source
ToetsingOnline

Brief title
EMDR and Imagery Rescripting for Trauma-Related Intrusions

Condition

- Other condition
- Mood disorders and disturbances NEC

Synonym
depression, PTSD

Health condition

PTSS

Research involving
Human

Sponsors and support

Primary sponsor: GGZ Eindhoven (Eindhoven)
Source(s) of monetary or material Support: Ministerie van OC&W,GGzE en Stichting tot Steun

Intervention

Keyword: EMDR, Imagery Rescripting, Intrusions, Personalised treatment

Outcome measures

Primary outcome

The primary outcome is a brief measure of characteristics of intrusions (specifically, the frequency, uncontrollability, and degree of interference with daily life), which will be assessed twice daily via an online link. Additionally, process measures indexing possible mediators concern brief questionnaires on emotion regulation, self-compassion, rumination, positive affect, and the vividness, distress, and related meaning of intrusions, which also serve as our primary outcome measures. These questionnaires will be assessed daily. All primary outcome measures will be administered during the baseline, experimental, and withdrawal phase.

Secondary outcome

Secondary outcome measures concern questionnaires on quality of life, depression symptoms, and PTSD symptoms which are endorsed at baseline, post-treatment (i.e., 4 weeks after the last intervention session, at the end of the withdrawal phase), and at 6-month follow-up. A questionnaire about outcome expectancies will be administered at baseline, and weekly during the treatment phase.

Study description

Background summary

Patients with post-traumatic stress disorder (PTSD) experience highly frequent and distressing intrusive images depicting earlier aversive experiences. Not only patients with PTSD experience these intrusions; they are also very common in depression. Therefore, trauma treatments that target these intrusions may also benefit patients with depression.
Additionally, comorbid depression in patients with PTSD reduces the effects of trauma treatment. It is currently unknown which treatment for traumatic intrusions is most effective for patients who meet criteria for PTSD, depression, or both, and treatment selection is often a process of trial and error. The mechanisms of action of trauma treatments may inform us how to select the most appropriate treatment for a particular individual.

Study objective

Our primary objective is to investigate whether EMDR and Imagery Rescripting are effective for individual patients who experience intrusions: patients with PTSD, patients with depression, and patients with PTSD and a comorbid depression. To this end, we will examine the patterns of the reduction in the severity of intrusions (i.e., frequency, uncontrollability, and degree of interference with daily life) within each individual and within each of the six groups (i.e., three patient groups and two interventions). In this way, we want to gain more insight into the mechanisms of action of both treatments. We will specifically investigate the potential mediating roles of self-compassion, emotion regulation, positive affect, rumination, the vividness and distress of intrusions, and intrusion-related beliefs about oneself.

Our second objective is to investigate the effect of EMDR and IR on quality of life, PTSD and depression symptoms in each individual and within each group.
Our third objective is to explore the patients* and therapists* perspectives on deciding factors in treatment selection, by asking them about preferences and expectations concerning EMDR and IR.

Study design

The present study uses a single-case experimental design with a baseline phase, an experimental or treatment phase, and a withdrawal of treatment phase, as well as a 6-month follow-up.

Intervention

Patients will be randomly assigned to EMDR or IR. In each condition, patients

will receive two 75-minute sessions of EMDR or IR each week, as well as an additional coaching session each week. Treatment length depends on patients* needs and varies between 2.5 and 6 weeks.

Study burden and risks

There is a regular procedure for patients who are referred to the *Kortdurende Intensieve Trauma Traject* (KITT) of GGzE, which involves assessment as well as treatment (EMDR or IR). Participation in the study requires completing additional questionnaires for research purposes at baseline, post-treatment, and follow-up (18 min each time), as well as daily measures during the baseline, treatment, and withdrawal phases. There are two daily measures. Once every week, questions about Outcome Expectancies will be added, which will take an additional 2 minutes to complete. One of the daily measures indexes intrusions only and will take 2 minutes to complete. The second daily measure assesses intrusions as well as the potential mediators and will take 7 minutes to complete. There are no known risks associated with the completion of the questionnaires for the study. The total study duration (baseline up to and including the withdrawal phase but excluding the 6-month follow-up) is a minimum of 8.5 weeks and a maximum of 12 weeks, depending on the number of intervention sessions patients receive. In addition to the time required for the study, a potential burden for patients is the fact that they are randomized to one of two interventions and, therefore, cannot choose their preferred treatment. The benefits of the study include a better understanding of the effectiveness of EMDR and IR for different patient groups, and the mechanisms underlying the treatment effects. In addition, patients may benefit from self-monitoring through completion of questionnaires throughout the study period. Patients who have completed the study will be offered a feedback session on their questionnaires and changes in scores after the 6-month follow-up, which may help to guide any further treatment of the patients. Patients will receive a financial compensation varying from ¤60 to ¤80 in VVV-vouchers, depending on their time investment in the study.

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

- Age between 18 and 70 years;
- Experiencing intrusions and/or nightmares;
- Meet criteria for unipolar depressive disorder, PTSD, or both disorders;
- Past aversive events still cause considerable distress;
- Be available for trauma treatment twice a week, with an additional coaching session each week;
- Be proficient in the Dutch language.

Exclusion criteria

- A dissociative identity disorder;
- Acute suicide risk;
- Acute psychosis;
- Substance use disorder;
- Bipolar disorder type 1 and 2.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	16-12-2024
Enrollment:	42
Type:	Anticipated

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Date:	27-06-2024
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO

Date:	17-01-2025
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL85848.068.23