The effectiveness of EMDR vs EMDR 2.0 vs the Flash technique in the treatment of patients with PTSD: A Randomized Controlled Trial

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

Summary

ID

NL-OMON54264

Source
ToetsingOnline

Brief title
Effectiveness of EMDR vs. EMDR 2.0 vs. the Flash technique

Condition

- Other condition
- Anxiety disorders and symptoms

Synonym
PTSD Posttraumatic Stress Disorder, Trauma

Health condition

Traumagerelateerde stoornissen

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: EMDR, EMDR 2.0, Flash, PTSD

Outcome measures

Primary outcome

The primary dependent variables for measuring the effectiveness of the treatment are the presence of the diagnosis PTSD (CAPS-5) and complex PTSD (ITQ) and the severity of PTSD symptoms (PCL-5, CAPS-5, ITQ). The CAPS-5 and ITQ are administered before treatment and four and twelve weeks after termination of treatment.

Secondary outcome

De secondary dependent variables for measuring the effectiveness of treatment are depressive, dissociative and general psychiatric symptoms (BDI, DES and BSI respectively) and experiential avoidance (AAQ-II). The dependent variables for measuring treatment efficiency are amount of treated targets per session and duration of each session. The dependent variables for measuring treatment acceptability are four open questions about treatment acceptability with answer options rated on a 7-point scale. Safety of the intervention will be measured with the amount of serious aversive events (SAEs). The PCL-5, BDI, BSI and AAQ-II will be adminstered weekly during the treatment period and biweekly until 12 weeks after termination of treatment. The treatment acceptability

questionnaire will be adminstered after the first and final treatment session.

Study description

Background summary

Eye Movement Desensitization and Reprocessing (EMDR) therapy is an evidence based treatment for patients suffering from a post-traumatic stress disorder (PTSD). To investigate if EMDR therapy can be applied more effective and efficient, an adapted version of EMDR therapy has been developed, which will be referred to as EMDR 2.0. A recent experimental study with healthy participants suggests that EMDR 2.0 is not more effective than EMDR in decreasing the emotionality and vividness of aversive memories. EMDR 2.0 however seems to be more efficient than EMDR with respect to amount of sets of working memory taxation per session. Another type of treatment that can be applied to prepare for EMDR treatment or as a stand alone PTSD treatment is the Flash technique. A recent experimental study with healthy participants shows that a digital version of Flash is as effective as EMDR in decreasing the emotional load and vividness of aversive memories. Although EMDR 2.0 and the Flash technique show positive results in healthy participants, both treatment have not yet been investigated in a clinical population diagnosed with PTSD. In the current study it will therefore be investigated which of these treatments, EMDR, EMDR 2.0 or the Flash technique, is most effective and efficient in decreasing PTSD symptoms in patients diagnosed with PTSD.

Study objective

The primary objectives of the current study is to investigate if the three treatments, EMDR, EMDR 2.0 or the Flash technique, are effective in decreasing PTSD symptoms and which treatment is most effective in decreasing PTSD symptoms. Another primary objective is to investigate which treatment is most efficient. A secondary objective is to investigate which treatment is most effective in decreasing comorbid depressive, dissociative and general psychiatric symptoms and experiential avoidance. A third objective is to investigate how EMDR, EMDR 2.0 and the Flash technique are experienced in terms of acceptability. A fourth objective is to investigate what moderators of treatment are.

Study design

The design of the current study is an Open Randomized Controlled Trial (RCT) with one between-subjects factor (treatment condition: EMDR vs EMDR 2.0 vs de Flash technique) and one within subjects factor (time).

Intervention

There are three treatment conditions: EMDR, EMDR 2.0 and the Flash technique. Patients are divided at random to one of the three treatment conditions. The treatments consist of six weekly sessions of 60 minutes. After the treatment follows a period of 12 weeks in which self-report questionnaires (PCL-5, BDI, BSI and AAQ-II) will be administered biweekly. After 4 (FU1) and 12 (FU2) weeks the CAPS-5, ITQ and DES will be administered. After the first and the last treatment session, a treatment acceptability questionnaire will be administered.

Study burden and risks

It is possible that a patient finds the recall of a traumatic memory difficult, or overwhelming, because this refers to the traumatic events. This is something that could happen in any treatment for PTSD. The therapists that participate in the current study are used to these kinds of situations. One should realize that PTSD patients are used to the fact that the emotionally loaded memories can be activated in daily life due to triggers of any kind. PTSD patients tend to recover quickly. There are little contraindications known for traumafocused treatment such as EMDR, EMDR 2.0 or the Flash technique. The additional burden that is caused by participation in the study consists of completing additional measurements. These measurements take about 30 minutes, for 18 weeks, what comes down to around 360 minutes or 6 hours. Therefore, we find the burden of patients justified. Patients participating in the current study receive treatment several months sooner than patients that are applied for regular treatment. Moreover, patients in all conditions receive traumafocused treatment after the study if they still experience symptoms.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Estimated IQ > 80
PTSD diagnosis according to the DSM-5
18 years or older
Sufficient understanding of the Dutch language

Exclusion criteria

Acute suicidality
PTSD diagnosis not the primary diagnosis
Changes in medication during, or 6 weeks prior to participation in the research
Use of strongly sedating medication

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2022
Enrollment:	130
Type:	Anticipated

Ethics review

Approved WMO Date:	14-07-2022
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	03-04-2023
Application type:	Amendment
Review commission:	METC NedMec

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	NL79163.041.22