The effectiveness of Visual Schema Displacement Therapy in treating patients with PTSD.

Published: 15-05-2019
Last updated: 15-05-2024

Determine if VSDT is effective in reducing PTSD symptoms, both directly and at 1- and 3-month follow-up. This will be investigated in a Randomized Controlled Trial (RCT).

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Anxiety disorders and symptoms
Study type	Interventional

Summary

ID

NL-OMON48388

Source
ToetsingOnline

Brief title
Effectiveness of VSDT

Condition

- Anxiety disorders and symptoms

Synonym
PTSD; Post-traumatic Stress Disorder; Trauma disorder; trauma

Research involving
Human

Sponsors and support

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

Intervention

Keyword: EMDR, PTSD, Trauma, VSDT

Outcome measures

Primary outcome

The dependent variables are the presence of PTSD and the severity of the PTSD symptoms, respectively measured with the CAPS-5 and the PCL-5. Secondary outcome measures are depressive symptoms and general psychiatric symptoms, measured with the Beck Depression Inventory (BDI-II) and the Brief Symptom Inventory (BSI) respectively. The CAPS-5 will be conducted at the screening and at follow-up after one and three months. The PCL-5, BDI-II and the BSI will be measured weekly throughout the study.

Secondary outcome

Secondary outcome measures are depressive symptoms and general psychiatric symptoms, measured with the Beck Depression Inventory (BDI-II) and the Brief Symptom Inventory (BSI) respectively. These will be weekly conducted throughout the study.

Study description

Background summary

Eye Movement Desensitization and Reprocessing (EMDR) is an evidence based therapy often indicated for patients suffering from post traumatic stress disorder (PTSD). A new therapy that shows resemblence with EMDR therapy is Visual Schema Displacement Therapy. Results from two recent studies among healthy participants comparing the two treatments showed that VSDT was more effective in reducing the emotional intensity of emotional memories. The question remains if and to what extent VSDT is effective in reducing PTSD

symptoms in patients who are diagnosed with PTSD.

Study objective

Determine if VSDT is effective in reducing PTSD symptoms, both directly and at 1- and 3-month follow-up. This will be investigated in a Randomized Controlled Trial (RCT).

Study design

The study employs a mixed design with both within and between subjects factors. 57 PTSD patients will be randomly assigned to one of three conditions (EMDR, VSDT, waiting list). Both the VSDT and the EMDR condition include 6 sessions of 90 minutes each. PTSD symptoms will be monitored weekly using the Psychotrauma Checklist for DSM-5 (PCL-5), during and following the intervention until the last follow-up measurement after 3 months. A clinical interview for PTSD (Clinician-administered PTSD Scale for DSM-5; CAPS-5) will be conducted upon inclusion, after one month, and after three months after the treatment sessions.

Intervention

The study has three conditions: EMDR, VSDT and a Waitlist control condition (WL). All patients will be randomly assigned to one of the three conditions. Both active interventions conist of six weekly sessions of 90 minutes. The waiting list conditions consists of 6 weeks of no intervention. All conditions are followed by a 12-week period, during which self-report measures are conducted. Follow-up measurements using the CAPS-5 will be conducted four and twelve weeks after the treament period.

Study burden and risks

Patiens might find it difficult to recollect an emotionally loaded memory of a traumatic event, or might be overwhelmed by it; the memory refers to the traumatic event. This might happen in every form of trauma treatment. The participating therapists are used to deal with these situations. It should be realised that patients suffering from PTSD are used to the activation of the emotional memory by all kinds of triggers in daily life. Usually, PTSD patients recover quickly. There are few contro-indications known for traumafocused treatment with EMDR therapy. On grounds of niether theoretical considerations and practical experience should it be expected to be different for VSDT. That is why we deem the burden and risks placed upon participants justified. Nevertheless, we will first complete Study I with the aim of testing the safety of the therapy and its effect on PTSD symptoms, before we start Study II. Because of this study, patients will receive treatment a few months earlier than patients who are on the regular waiting list. Moreover, patients in the

study are offered traumafocused therapy upon completion of the study when they still experience residual complaints.

Contacts

Public
Universiteit Utrecht

Heidelberglaan 1
Utrecht 3584 CS
NL
Scientific
Universiteit Utrecht

Heidelberglaan 1
Utrecht 3584 CS
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- IQ > 80 (estimation)
- PTSD diagnosis according tot he DSM-5 with one or more traumatic events.
- Age: from 18 years
- Sufficient command of the Dutch language

Exclusion criteria

- Acutely suicidal patients
- PTSD diagnosis not the primary diagnosis
- Changes in medication prescription during, or 3 months 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)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-09-2019
Enrollment:	57
Type:	Actual

Ethics review

Approved WMO

Date:	15-05-2019
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 25957
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL68921.041.19
OMON	NL-OMON25957