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

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25957

Source
Nationaal Trial Register

Brief title
Effectiveness of VSDT

Health condition

Post-traumatic stress disorder (PTSD)

Sponsors and support

Primary sponsor: Not applicable
Source(s) of monetary or material Support: Not applicable

Intervention

Outcome measures

Primary outcome

- PTSD symptoms (CAPS-5; PCL-5)

Secondary outcome

- Depressive symptoms (BDI-II)
- General symptoms of psychopathology (BSI)

Study description

Background summary

Background of the study:
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.

Objective of the study:
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.

Study objective

- We expect VSDT to be a safe, meaning no Serious Adverse Events will take place during the study.
- We expect the VSDT and EMDR conditions to reduce PTSD symptoms from pre to post measurement.
- We expect the VSDT and EMDR conditions to reduce PTSD symptoms from pre to follow-up 1 measurement.
- We expect the VSDT and EMDR conditions to reduce PTSD symptoms from pre to follow-up 2 measurement.

Study design

CAPS-5: Pre, Follow-up 1 (4 weeks after treatment completion), Follow-up 2 (12 weeks after treatment completion).

Intervention

- Visual Schema Displacement Therapy
- Eye Movement Desensitization and Reprocessing

Contacts

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Eligibility criteria

Inclusion criteria

- IQ greater than 80 (estimation)
- PTSD diagnosis according to the DSM-5
- Age: 18 years and older
- Sufficient command of the Dutch language

Exclusion criteria

- Acute suicidality
- PTSD is not the primary diagnosis
- Changes in medication 3 months prior or during the study.
- Use of sedating medication

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2019
Enrollment:	57
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	26-06-2019
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 48388
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL7834
CCMO	NL68921.041.19
OMON	NL-OMON48388

Study results