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

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- 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...

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25957

Bron
Nationaal Trial Register

Verkorte titel
Effectiveness of VSDT

Aandoening

Post-traumatic stress disorder (PTSD)

Ondersteuning

Primaire sponsor: Not applicable
Overige ondersteuning: Not applicable

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

- 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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

- Visual Schema Displacement Therapy
- Eye Movement Desensitization and Reprocessing

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-09-2019
Aantal proefpersonen:	57
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	26-06-2019
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 48388
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten