3MDR as treatment for Posttraumatic Stress Disorder

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22172

Source
Nationaal Trial Register

Brief title
3MDR for PTSD

Health condition

Posttraumatic Stress Disorder
Posttraumatische Stress Stoornis

Sponsors and support

Primary sponsor: Stichting Centrum '45 partner in Arq Psychotrauma Expert Group, Oegstgeest, the Netherlands
Source(s) of monetary or material Support: Stichting Centrum '45 partner in Arq Psychotrauma Expert Group, Oegstgeest, the Netherlands

Intervention

Outcome measures

Primary outcome

PTSD symptom severity as measured with the Dutch version of the Clinician Administered PTSD Scale for DSM-5 (CAPS-5).

Secondary outcome

Secondary outcomes are self-reported PTSD symptoms (PCL-5), anxiety and depression symptoms (HADS), comorbid psychopathology (MINI), quality of life (Cantrill Ladder of Life), cognitive and behavioral avoidance (PABQ), interpersonal support (ISEL) and 3MDR experiences (3MDR-Q). Tertiary outcomes are neuropsychological functioning (verbal memory, visual memory, working memory and attention) and the stress response measured with cortisol in saliva and heart rate during sessions.

Study description

Background summary

Several exposure-based therapies for treatment of Posttraumatic Stress Disorder (PTSD) have been proven successful, in which (imaginal) exposure takes a central role. Not all patients fully benefit from these treatments, or drop out from treatment, especially veterans with combat-related PTSD (cr-PTSD). For these patients the Multi-modular Motion-assisted Memory Desensitization Reconsolidation (3MDR)-protocol may have additional value. It incorporates elements from Virtual Reality Exposure therapy (VREt) and Eye Movement Desensitization and Reprocessing (EMDR), while adding a motion-based component.

This randomized controlled trial is aimed at assessing the effect of 3MDR treatment as compared to treatment as usual (TAU) on PTSD symptom severity in treatment resistant veterans with chronic cr-PTSD. It is expected that 3MDR will give a boosting effect to TAU following 3MDR and will lead to a PTSD symptom decrease in the intervention group. The study further assesses general anxiety, depressive symptoms, cognitive and behavioral avoidance, interpersonal support, neuropsychological functioning (memory and attention), and the physiological stress response during sessions.

Study objective

In line with a previous pilot study we hypothesize that 3MDR will significantly decrease PTSD symptom severity in treatment resistant veterans with chronic PTSD in comparison with treatment as usual.

Study design

Patients are assessed at four time points:

1. Before treatment (baseline)

2. First post-assessment after the 3MDR sessions: 6 weeks after baseline assessment.

3. Second post-assessment at 12 weeks after baseline assessment.

4. Third post-assessment at 16 weeks after baseline assessment.

Intervention

3MDR incorporates elements from Virtual Reality Exposure therapy (VREt) and Eye Movement Desensitization and Reprocessing (EMDR), while adding a motion-based component. In this combination, veterans are challenged to optimally approach their traumatic memories for exposure and to overcome their avoidance. Patients select pictures that remind them of their traumatic experiences. These are used during the session. Also, music is selected by the patients and played during the session. Patients are asked to walk in a virtual environment will interacting with their chosen images followed by a distracting dual task. A single session lasts 60 minutes.

In the intervention group patients receive 6 sessions of 3MDR followed by a period of 10 weeks treatment as usual.

Patients in the control group receive care as usual other than individual trauma-focused psychotherapy, e.g. group therapy, creative therapy and/or medication.

Contacts

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Eligibility criteria

Inclusion criteria

- Between 18 and 70 years old.

- Current chronic combat-related Posttraumatic Stress Disorder (Clinician Administered PTSD scale (CAPS) score > 50, for at least 3 months).

- Being treatment resistant for trauma-focused psychotherapeutic interventions, which means having been treated for PTSD for a minimum of 6 consecutive months, of which 3 months with trauma-focused therapy, for instance Eye-Movement Desensitization Reprocessing (EMDR), Brief Eclectic Psychotherapy (BEP), Narrative Exposure Therapy (NET) or Prolonged Exposure (PE) with weekly sessions of at least 45 minutes or twoweekly session of at least 90 minutes. Or having started trauma-focused therapy at least twice and failing to engage in treatment.

Exclusion criteria

- Acute suicidality

- Difficulties walking, especially on a treadmill

- Current severe alcohol and/or substance dependence according to DSM-IV (patients are allowed to enter after initial treatment of this disorder).

- Acute psychosis.

- Patients must be stable on their current psychotropic medication for a period of 4 weeks before entering the trial and agree to not make changes in dosages or add any new medications during the course of the 3MDR treatment.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	27-05-2015
Enrollment:	40
Type:	Actual

Ethics review

Positive opinion

Date:	19-06-2015
Application type:	First submission

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
NTR-new	NL5126
NTR-old	NTR5258
Other	Commissie Medische Ethiek (CME) Leiden University Medical Center : P14.325

Study results

Summary results

Vermetten, E., Meijer, L., van der Wurff, P., & Mert, A. (2013). The effect of Military Motion-

assisted Memory Desensitization and Reprocessing Treatment on the symptoms of combat-related Posttraumatic Stress Disorder: First preliminary results. Annual Review of Cybertherapy and Telemedicine, 125-127.