Multi-modular Motion-assisted Memory Desensitization and Reconsolidation (3MDR) as treatment for Posttraumatic Stress Disorder

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

Summary

ID

NL-OMON44897

Source
ToetsingOnline

Brief title
3MDR

Condition

- Anxiety disorders and symptoms

Synonym
Posttraumatic Stress Disorder, PTSD

Research involving
Human

Sponsors and support

Primary sponsor: Stichting Centrum '45

Source(s) of monetary or material Support: Vanuit Arq Psychotrauma Expert Groep.

Intervention

Keyword: Posttraumatic Stress Disorders, Treatment Outcome, Treatment resistance, Veterans

Outcome measures

Primary outcome

Main study parameter is the difference between the two groups in change in PTSD

symptom severity between start of the intervention and end of the study.

Secondary outcome

Other areas in which improvement is expected are perceived social support,

anxiety in general, depressive symptoms, avoidance of thoughts and behaviors,

and neuropsychological functioning (memory and attention).

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 draw full benefit from these treatments, or drop out from treatment, which is especially true for the population of 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. In this combination, veterans are challenged to optimally approach their traumatic memories for exposure and working memory is taxed more appropriately than with the standard EMDR procedure. The expectation is that this approach will significantly decrease PTSD symptom severity in comparison to a control group receiving treatment as usual

Study objective

This study 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. The study further assesses perceived social support, anxiety in general, depressive symptoms, avoidance of thoughts and behaviours, and neuropsychological functioning (memory and attention), aimed at assessing changes in these domains.

Study design

This study is a randomized controlled trial (RCT) in a parallel design with one experimental group (N=20) receiving 6 sessions of 3MDR and one control group (N=20) who will receive TAU. Both groups will be followed-up after an additional 6 and 10 weeks of TAU. Furthermore, patients in the intervention group will be asked to participate in a qualitative interview on their experiences with the 3MDR. This study will be performed at Stichting Centrum *45 in Oestgeest or at GGZ Drenthe in Beilen.

Intervention

Participants will either receive six 3MDR treatment sessions followed by ten weeks of TAU or will receive sixteen weeks of TAU, other than a trauma-focused psychotherapy. TAU interventions may for instance include group therapy, creative therapy or psychopharmacological therapy.

Study burden and risks

Subjects in the 3MDR group will receive six weekly 3MDR treatment sessions instead of their treatment as usual. Before and after each sessions cortisol will be measured in the saliva of participants to assess their stress response during the session. Five assessments will take place which consist of structured interviews, questionnaires and neuropsychological tests. None of the procedures are invasive. The 3MDR-protocol includes elements from treatments as Eye-Movement Desensitization and Reprocessing therapy and imaginal exposure based treatments, to which most patients have been exposed before. Therefore it is not likely that this therapy will be counterproductive and we consider the burden of the study reasonable. In a proof of concept and first trial with a total of 12 patients we noticed that those that received the 3MDR treatment did well and improved on PTSD symptom severity and that lasting worsening of symptoms did not occur.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

-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 two-weekly session of at least 90 minutes.

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. In agreement with clinical guidelines patients were allowed to stop anxiolytic medication to better engage in trauma processing.

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

Ethics review

Approved WMO

Date:	01-04-2015
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	07-05-2015
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)

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Approved WMO Date:	26-04-2017
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	01-12-2017
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL51585.058.14