Research into EMDR for Military Personnel and Veterans with Psychological Trauma

Published: 07-02-2023 Last updated: 21-12-2024

The primary objective is to study the effectiveness of EMDR in comparison to PE for treating military personnel and veterans with psychological trauma. Secondary objectives are:1. to investigate if working memory capacity is a predictor of EMDR...

Ethical review Approved WMO

Status Pending

Health condition type Anxiety disorders and symptoms

Study type Interventional

Summary

ID

NL-OMON56051

Source

ToetsingOnline

Brief title

REMIND

Condition

Anxiety disorders and symptoms

Synonym

other trauma- and stressor-disorder, posttraumatic stress disorder; other specified traumaand stressor-related disorder, PTSD

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht

Source(s) of monetary or material Support: Ministerie van Defensie

Intervention

Keyword: EMDR, Psychological trauma, RCT, Working memory

Outcome measures

Primary outcome

The main outcome measure is the change in psychological trauma symptoms from before to after the treatment, measured by a self-report questionnaire and a clinical interview.

Secondary outcome

For the secondary outcomes, we will test performance on a (working) memory task. Task performance will be investigated as potential predictor of treatment succes.

Study description

Background summary

Posttraumatic stress disorder (PTSD) and 'Other Specified Trauma- and Stressor-Related Disorder' are mental disorders that can occur following a traumatic event. Psychological trauma in military personnel may differ from civilian psychological trauma for example due to the nature of the trauma, or extensive military training. Eye movement desensitisation and reprocessing (EMDR) and prolonged exposure (PE) are trauma-focused therapies that have been shown to be effective at reducing trauma symptoms in civilians. PE has also been shown to be effective at treating military personnel with trauma. In contrast, the effectiveness of EMDR for military personnel and veterans is currently under debate, because a recent meta-analysis showed that it might not be effective in this population. Despite this, EMDR is often used at military mental health services to treat psychological trauma. In conclusion, there is a need to investigate the effectiveness of EMDR for treating military personnel and veterans with psychological trauma. Furthermore, the mechanism underlying EMDR is unknown. Gaining mechanistic insight into EMDR neuropsychology could contribute to identifying predictors for treatment success.

Study objective

The primary objective is to study the effectiveness of EMDR in comparison to PE for treating military personnel and veterans with psychological trauma.

Secondary objectives are:

1. to investigate if working memory capacity is a predictor of EMDR treatment success

Study design

The proposed study is a single-blind randomised controlled between-subjects non-inferiority trial.

Intervention

Patients will be randomly assigned to EMDR or PE. Both therapies are validated trauma-focused therapies that are recommended by the Dutch guidelines for the treatment of psychological trauma. Patients will receive 10 90-minute treatment sessions during a period of 12 weeks.

Study burden and risks

Patients will receive standard treatment for psychological trauma. Increased stress or emotional discomfort might occur due to exposure to a psychological trauma. However, this is the case for all trauma-focused therapies and therefore we consider this risk acceptable. Following each session, patients will fill in a brief questionnaire. Besides the therapy sessions, patients will complete four main assessments. The first assessment takes about 3 hours, the second 90 minutes, and the third and fourth one take 20 minutes. We consider this an acceptable burden since these assessments are spread out over a period of several months: one before treatment, one immediately following treatment, after 26 and 52 weeks.

Contacts

Public

Universitair Medisch Centrum Utrecht

Lundlaan 1 Utrecht 3584EZ NL

Scientific

Universitair Medisch Centrum Utrecht

Lundlaan 1

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Inclusion criteria

- Military personnel of the Dutch Defence organisation or veterans who served for the Kingdom of the Netherlands
- PTSD or 'other specified trauma and stressor-related disorder' diagnosis by therapist.
- Master the Dutch language
- Assigned to a PTSD psychotherapy treatment
- Aged 18-64 year

Exclusion criteria

_

Study design

Design

Study type: Interventional

Intervention model: Parallel

Allocation: Randomized controlled trial

Masking: Single blinded (masking used)

Control: Active

Primary purpose: Treatment

Recruitment

NL

Recruitment status: Pending

Start date (anticipated): 01-03-2023

Enrollment: 72

Type: Anticipated

Ethics review

Approved WMO

Date: 07-02-2023

Application type: First submission

Review commission: METC NedMec

Approved WMO

Date: 20-06-2023

Application type: Amendment

Review commission: METC NedMec

Approved WMO

Date: 15-09-2023

Application type: Amendment

Review commission: METC NedMec

Approved WMO

Date: 30-04-2024

Application type: Amendment

Review commission: METC NedMec

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 NL81607.041.22