A feasibility study on applying Virtual Reality EMDR as an add-on to regular trauma focused treatment in veterans with posttraumatic stress disorder

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Feasibility is assessed after every VR-EMDR session and after treatment completion. PTSD symptoms, quality of life and self-empowerment are assessed before and after treatment.

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

Summary

ID

NL-OMON53982

Source
ToetsingOnline

Brief title
VR-EMDR

Condition

- Anxiety disorders and symptoms

Synonym
post traumatic stress disorder, PTSD

Research involving
Human

Sponsors and support

Primary sponsor: Reinier van Arkelgroep (Den Bosch)
Source(s) of monetary or material Support: Nederlands Veteranen Instituut

Intervention

Keyword: Eye Movement Desensitisation and Reprocessing (EMDR), Posttraumatic Stress Disorder (PTSD), Virtual Reality (VR)

Outcome measures

Primary outcome

The main study parameter is the feasibility and the safety of the application of VR as an add-on to treatment as usual. This is measured using Visual Analogue Scales (VAS) after every VR session and a semi-structured interview after treatment is completed.

Secondary outcome

Severity of PTSD symptoms, quality of life and empowerment are all examined using short questionnaires. These are administered before the start of treatment and after treatment completion. In addition, de questionnaire on PTSD symptom severity is administered before every VR-EMDR session.

Study description

Background summary

Despite the existence of effective trauma-focused treatment for PTSD, such as Eye Movement Desensitization and Reprocessing (EMDR), not all veterans with PTSD seem to benefit from this sufficiently. The application of Virtual Reality (VR) and high intensity treatment are relatively new interventions that look promising. In addition, it seems that home interventions, such as eHealth, are effective in PTSD treatment. Virtual Reality EMDR (VR-EMDR) combines those elements creating a treatment approach in which individuals intensify their treatment by performing VR-EMDR in the home environment using VR technology. There is currently no empirical evidence that supports the use of VR-EMDR in PTSD patients.

Study objective

Feasibility is assessed after every VR-EMDR session and after treatment completion. PTSD symptoms, quality of life and self-empowerment are assessed before and after treatment.

Study design

Feasibility is assessed after every VR-EMDR session and after treatment completion. PTSD symptoms, quality of life and self-empowerment are assessed before and after treatment.

Intervention

Veterans get access to VR technology to do VR-EMDR treatment at home on top of treatment as usual in addition to their regular, weekly EMDR treatment provided by their therapist.

Study burden and risks

Veterans are receiving treatment for PTSD regardless of their participation in the study. Extra burden associated with participation in this study is to carry out VR-EMDR sessions at home. A possible risk is that the veteran experiences state PTSD symptoms aggravation during the VR session when their therapist is not readily available to assist. This risk is aimed to be reduced through a safety protocol and the possibility of having the therapist available through a video connection during the first VR-EMDR session. Benefits are that VR-EMDR could improve self-efficacy and willingness to fully engage in trauma exposure, thus improving PTSD symptoms. This is important because veterans show less reduction in PTSD symptoms in trauma-focused treatment compared to other PTSD populations, such as civilians

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Participants are eligible to participate if they:
Have a formal PTSD diagnosis;
Are veteran;
Are 18 years or older;
Have sufficient master of the Dutch language to perform assessments;
Are able to verbally express their traumatic memory;
Motivation to engage in a trauma-focused treatment

Exclusion criteria

Participants cannot take part in this trial if they:
Have an acute high risk for suicide;
Show acute, positive psychotic symptoms (for instance hallucinations or delusions);
Suffer from severe impulse control issues or addiction which prevent them from making safety agreements with their therapist;
Have an unsafe home environment or there is a lack of reliable information regarding the home environment to assess the safety.

Study design

Design

Study type: Interventional
Masking: Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-02-2023
Enrollment:	16
Type:	Actual

Medical products/devices used

Generic name:	EMDR-VR
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	11-08-2022
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL80886.068.22