Interactive Multi-sensory Memory Exposure & Rehabilitation Sessions

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

Summary

ID

NL-OMON53549

Source
ToetsingOnline

Brief title
IMMERSE

Condition

- Anxiety disorders and symptoms

Synonym
trauma related disorders

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van Defensie en beurs (¤548.922) van de militaire zorgverzekeraar SZVK voor het ontwikkelen en valideren van een op VR gebaseerde PTSS behandeling.

Intervention

Keyword: Exposure, Immersive, trauma, Virtual Reality

Outcome measures

Primary outcome

The primary outcome is the acceptability and feasibility of the VR intervention, measured with a self-report questionnaire for evaluation one week after the final therapy session. Additionally, to test acceptability, a questionnaire for VR related physical complaints will be used as well as drop out rate and adverse events.

Secondary outcome

The secondary parameters (PTSD and depression symptoms and well-being) will be measured before and after the intervention and during a 3 month follow up.

Study description

Background summary

Posttraumatic stress disorder (PTSD) is a mental disorder that can occur following a traumatic event. Current treatments for posttraumatic stress disorder (PTSD) focus on repeated exposure to the traumatic memory until extinction of the fear response occurs. Especially in military personnel and veterans, current treatments are not effective enough in reducing symptoms, for instance due to high levels of avoidance of the traumatic memory. Virtual reality (VR) is a promising new treatment strategy due to its immersive character and quick manipulation of session intensity.

Study objective

The primary objective of the proposed study is to examine the feasibility and acceptability of VR-delivered exposure sessions in a therapy protocol for PTSD. The secondary objective is to test how effective the intervention is in reducing symptoms of PTSD, depression and increasing well-being.

Study design

An open-label uncontrolled feasibility pilot.

Intervention

VR-delivered exposure sessions will be included in the psycho-therapy treatment protocol for PTSD. During a session, participants will be asked to put on a head mounted display (HMD) and work through a series of photographs in a relaxing virtual environment, while in constant contact with their therapist.

Study burden and risks

Participants with PTSD will receive VR exposure therapy. Possible risks could include VR induced headache or nausea. Increased stress or emotional discomfort might occur due to exposure to a psychological trauma. However, this is the case for all trauma-focused therapies. A therapist is always present with the patient to guide the sessions. Besides the therapy sessions, participants will complete three assessments which will take 60-90 minutes.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- Active military personnel or veteran of the Dutch Ministry of Defence.
- Age 18 and up.
- Master the Dutch language
- should have an indication for trauma treatment
- Provide written informed consent.

Exclusion criteria

- Alcohol or substance use disorder.
- Acute psychosis.
- Acute suicidality.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	29-06-2022
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO Date:	29-04-2022
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	01-09-2023
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	NL80057.041.21