TEMPO trial: Trauma-focused Exposure with Motion for Posttraumatic stress disorder

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

Summary

ID

NL-OMON53394

Source
ToetsingOnline

Brief title
TEMPO trial

Condition

- Anxiety disorders and symptoms

Synonym
Posttraumatic Stress Disorder, PTSD

Research involving
Human

Sponsors and support

Primary sponsor: GGZ Drenthe (Assen)
Source(s) of monetary or material Support: Espria Investeringsfonds

Intervention

Keyword: Avoidance, Motion, Posttraumatic Stress Disorder, Virtual Reality Exposure Therapy

Outcome measures

Primary outcome

The primary outcome parameter is PTSD severity over time, measured with

Clinical-Administered PTSD Scale for DSM-5 (CAPS-5).

Secondary outcome

Secondary outcome parameters are trauma-related avoidance and general avoidance

tendencies. Moreover, self-reported PTSD symptoms, depressive- and dissociative

symptoms, treatment expectancy and engagement, and heart and respiration rate

during VR exposure sessions will be measured.

Study description

Background summary

A new innovative Virtual Reality (VR) exposure treatment, 3MDR aims to improve treatment outcome for patients with posttraumatic stress disorder (PTSD). This trauma-focused treatment is delivered in a VR environment while patients walk on a treadmill to trauma-related pictures, and aims to address avoidance during treatment more effectively. Although previous randomised controlled trials found 3MDR to be effective in veterans with treatment-resistant PTSD, it is currently unknown if there is an added value of walking on a treadmill during this treatment. Moreover, it remains unclear whether preventing avoidance during treatment will indeed lead to enhanced PTSD symptom reduction, as this is the hypothesized working mechanism of this novel VR treatment.

Study objective

This study primarily aims to test the additional effect of walking during a Virtual Reality exposure treatment (3MDR) for patients with PTSD. Next, this study aims to investigate whether addressing trauma-related avoidance during

3MDR treatment is related to treatment outcome. Other objectives are to gain insight into the association of both general avoidance tendencies and trauma-related avoidance in relation to treatment outcome, and to test the effectiveness of the 3MDR treatment in a general population of PTSD patients.

Study design

This study is a single blind randomized controlled trial in which PTSD patients receive either VR exposure treatment or motion-assisted VR exposure treatment. Assessments will be conducted at baseline (T0), before the start of the treatment (T1), after the 6th VR exposure session (T2), after six additional VR exposure sessions or six weeks post treatment (T3), and at 3-, 6-, 12- and 18-months follow-up.

Intervention

Participants in both VR exposure conditions receive at least 9 weekly treatment sessions, including two preparatory treatment sessions, six VR exposure sessions, and one concluding session. Based on residual symptom severity after the first six VR exposure sessions, participants either continue with six additional VR exposure sessions or complete treatment with a concluding treatment session. Therefore, treatment duration will be nine or fifteen weeks. The VR exposure treatment in both conditions use the exact same treatment protocol, and only differ in whether the treatment is delivered while the participant is walking or is in a stationary position.

Study burden and risks

All participants will receive an appropriate trauma-focused treatment which is expected to be effective for patients with PTSD. Participants might experience PTSD symptom exacerbation, and emotional discomfort during treatment. This is inherent to receiving any trauma-focused treatment. For participants who receive motion-assisted VR exposure treatment (3MDR), there is a risk of falling on the treadmill, but many safety measures are in place to prevent them from injuries (i.e., safety harness, safety handrails and emergency stops). Besides the expected positive effect of this VR exposure treatment in reducing PTSD symptoms, participants get the opportunity to choose for a different treatment option (VR exposure) instead of traditional trauma-focused treatments. Lastly, participants have to invest personal time for conducting eight assessments, which is considered to be an acceptable burden given the two-year study duration.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

1) PTSD diagnosis established by the Clinician-Administered PTSD scale for DSM-5 (CAPS-5)
2) age 18 years or older
3) sufficient mastery of the Dutch language to perform the assessments
4) be able to keep a stable dose of psychotropic medication between four weeks before entering the trial and until the first follow-up assessment, three months post treatment (F4).

Exclusion criteria

1) unable to walk for approximately one hour
2) a high acute risk of suicidality

3) hospitalized in the past three months due to severe psychiatric conditions (e.g., severe self-injury, acute florid psychotic symptoms or severe eating disorder
4) report high levels of acute dissociative amnesia (memory gaps) which might prevent them to store new, corrective information from the trauma-focused treatment session
5) severe substance use disorder which needs specialized treatment
6) uses substances and cannot adhere to the agreement of not being under the influence of addictive substances during treatment.

Study design

Design

Study type: Interventional

Masking:	Single blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	27-11-2023
Enrollment:	182
Type:	Actual

Medical products/devices used

Generic name:	3MDR
Registration:	No

Ethics review

Approved WMO

Date:	30-08-2023
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL83110.042.22