Walk and Talk: A Randomized Controlled Trial of High Intensive 3MDR Treatment versus Care as Usual 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-OMON55588

Source
ToetsingOnline

Brief title
WATA

Condition

- Anxiety disorders and symptoms

Synonym
Posttraumatic Stress Disorder, PTSD

Research involving
Human

Sponsors and support

Primary sponsor: ARQ Nationaal Psychotrauma Centrum

Source(s) of monetary or material Support: ZonMw,Arq Psychotrauma Expert Groep en GGZ Drenthe

Intervention

Keyword: 3MDR, Cost-effectiveness, Posttraumatic Stress Disorder, Trauma treatment

Outcome measures

Primary outcome

The primary clinical outcome parameter is the difference in PTSD symptom severity measured prior to, during and after treatment. Furthermore, cost-effectiveness will be assessed through health-related quality of life and social costs. Our secondary outcomes include: avoidance behaviour, PTSD severity rated by a spouse, anxiety and depressive symptoms, impairment in daily functioning due to PTSD symptoms, neuropsychological functioning, and for the 3MDR condition physiological responses during sessions.

Secondary outcome

Our secondary outcomes include: avoidance behaviour, PTSD severity rated by a spouse, anxiety and depressive symptoms, impairment in daily functioning due to PTSD symptoms, neuropsychological functioning, and for the 3MDR condition physiological responses during sessions.

Study description

Background summary

Posttraumatic stress disorder (PTSD) is a mental disorder with a major health and economic burden on patients, their relatives and society. National and international guidelines recommend trauma-focused psychotherapies (TF-PT) as first-line treatments. TF-PT have proven to be efficacious and cost-effective, but two thirds of selected PTSD populations do not benefit sufficiently. We

hypothesize that innovative exposure-based psychotherapy that employs personalisation and interactive movement as novel ingredients (called multi-modular motion-assisted memory desensitization and reconsolidation (3MDR)) will augment recovery processes and speed of recovery, will promote compliance and will therefore be superior in cost-effectiveness compared to usual care.

Study objective

The primary objective is to assess the efficacy and cost-effectiveness of 3MDR against conventional TF-PT in the treatment of work-related PTSD. In addition, we will examine whether 3MDR treatment compared to care as usual (CAU) results in a significant difference in depressive symptoms, anxiety symptoms, avoidance, and impairment in daily functioning due to PTSD symptoms. For both groups neuropsychological functioning will be examined and possible predictors for treatment outcome will be explored.

Study design

This study is set up as a single blind parallel group randomized controlled trial in which patients will be randomized to receive 3MDR treatment (10 weekly sessions) or CAU (16 weekly sessions of TF-PT). Measurements for both groups will take place at baseline, at eight weeks , directly after treatment, and with a 12 week interval twice for follow-up. The control condition will undergo a short additional assessment at 11 weeks, the experimental condition at 17 weeks.

Intervention

This study entails two treatment conditions: the experimental 3MDR intervention and conventional TF-PT. The 3MDR intervention is a new type of high intensive exposure treatment, which combines elements of virtual reality exposure therapy (VRET), eye movement desensitisation and reprocessing (EMDR), physical activity and music. During a 3MDR session patients are continuously walking on the treadmill. The protocollized sessions start with music that facilitates reminders of the traumatic period, followed by walking on a vitual path towards prior selected pictures that are highly affect laden. After narrating each picture and labeling current emotions and physical sensations a second neurocognitive task is presented in the form of a oscilating ball with numbers that need to be read. This task is taxing working memory, and is aimed as distractor from the highly affective memories recalled just before. After seven pictures the session finishes by walking back on the path to current time accompanied by contemporary music that facilitates reorientation into the present. The CAU condition can consist of one of four selected evidence-based psychotherapies: trauma-focused cognitive behavioural therapy (TF-CBT), EMDR, narrative exposure therapy (NET) or brief eclectic psychotherapy for PTSD

(BEPP).

Study burden and risks

Subjects in the 3MDR group will receive a different treatment than care as usual. Possible risks from the 3MDR condition are physical harm due to falling on the treatmill. For this the necessary safety precautions have been taken by the use of a safety harnass and emergency protocol. Patients might experience initial emotional discomfort and stress due to exposure to their trauma. However, these risks are comparable to regular trauma treatments. Therefore, these risk are considered acceptable and maintainable. A previous proof of concept and pilot study have shown positive effects for 3MDR in therapy resistant war veterans reported no drop-out or counterproductive effects. In addition, six assessments are planned which will take 20 minutes to three hours each. We consider this an acceptable burden, since these assessments are spread over a period of approximately nine months. None of the procedures are invasive.

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

- Patients with work-related Posttraumatic Stress Disorder
- 18 years or older
- Meet the DSM-5 criteria for Posttraumatic Stress Disorder
- Trauma-focused therapy naive
- Master the Dutch language
- Must be on a stable dose of medication at commencement of the trial for at least four weeks, and will be asked to keep the dosage stable during the trail.

Exclusion criteria

- Inability to walk
- Current severe alcohol or substance use disorder (SUD)
- Acute suicidality
- Acute psychosis

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: Recruiting

Start date (anticipated):	15-02-2018
Enrollment:	134
Type:	Actual

Medical products/devices used

Generic name:	3MDR installation
Registration:	No

Ethics review

Approved WMO Date:	31-01-2018
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	08-10-2018
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	08-02-2021
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

ID: 24164
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL60406.058.17
OMON	NL-OMON24164