Walk&Talk; 3MDR as a high intensive exposure treatment for PTSD compared to treatment as usual.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24164

Source
NTR

Brief title
WATA

Health condition

Posttraumatische Stressstoornis
Posttraumatic Stress Disorder

Sponsors and support

Primary sponsor: Arq Psychotrauma Expert Groep
Source(s) of monetary or material Support: ZonMW, doelmatigheidsonderzoek
Arq Psychotrauma Expert Groep
GGZ Drenthe

Intervention

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.

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

Uit eerder onderzoek blijkt dat een deel van de patiënten met een posttraumatische stressstoornis (PTSS) onvoldoende profiteert van het huidige evidence-based behandelaanbod. Een mogelijke verklaring voor deze stagnatie is vermijding, zowel cognitief als emotioneel. Om deze vermijding te doorbreken is bij het Militair Revalidatie Centrum in Doorn de basis gelegd voor een revolutionaire psychotherapie. 3MDR staat voor Multi-modular Motion-assisted Memory Desensitisation and Reprocessing en maakt gebruik van de elementen beweging, virtual reality, muziek en foto’s ter ondersteuning van de exposure.

Het huidige onderzoek is een randomised controlled trial (RCT) gericht op het vergelijken van de 3MDR behandeling met de meer conventionele evidence-based behandelingen: traumagerichte CGT, EMDR, BEPP en NET, waarbij we kijken naar de klinische- en kosteneffectiviteit. Hiervoor nodigen wij patiënten uit die vanwege hun werk een PTSS hebben opgelopen en nog niet eerder traumagerichte behandeling hebben ontvangen.

Het onderzoek wordt uitgevoerd bij Stichting Centrum '45 in Oegstgeest en bij de GGZ Drenthe, locatie Beilen.

Study objective

We hypothesize that 3MDR is superior in clinical and cost-effectiveness compared to care as usual.

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). Both groups will undergo six assessments which will take place at baseline, at eight weeks, at 11 weeks for the control condition, at 17 weeks for the experimental condition, directly after treatment, and with a 12 week interval twice for follow-up.

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 virtual 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).

Contacts

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Eligibility criteria

Inclusion criteria

Work-related PTSD

Naive to trauma treatment or never finished a trauma treatment protocol

18 years and older

Exclusion criteria

Acute psychotic symptoms

Acute substance use disorder

Acute suicidality

Inability to walk

Inability to understand and speak Dutch

No medication or medication should be a consistent dosage for 4 weeks prior to the trial and be held consistent during the entire trail.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-02-2018
Enrollment:	134
Type:	Anticipated

Ethics review

Positive opinion

Date:	09-02-2018
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 55588
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL6837
NTR-old	NTR7074
CCMO	NL60406.058.17
OMON	NL-OMON55588

Study results

Summary results
Vermetten, E., Meijer, L., van der Wurff, P., & Mert, A. (2013). The effect of Military Motion-assisted Memory Desensitization and Reprocessing Treatment on the symptoms of combat-related Posttraumatic Stress Disorder: First preliminary results. Annual Review of

Cybertherapy and Telemedicine, 125-127.