Actively working on recovery: The influence of physical activity on PTSD treatment outcome.

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

Summary

ID

NL-OMON49822

Source
ToetsingOnline

Brief title
The influence of physical activity on PTSD treatment outcome.

Condition

- Anxiety disorders and symptoms

Synonym
'Post-traumatic stress disorder' and 'Stress disorder'

Research involving
Human

Sponsors and support

Primary sponsor: PSYTREC
Source(s) of monetary or material Support: PSYTREC

Intervention

Keyword: Intensive trauma-focused treatment, Physical activity, Post-traumatic stress disorder, Randomized Controlled Trial

Outcome measures

Primary outcome

The primary outcome measure is the change in PTSD symptoms from pre- to posttreatment and at 6-month follow-up, measured with the Clinician-Administered PTSD Scale (CAPS-5) and the PTSD Checklist for DSM-5 (PCL-5).

Secondary outcome

The secondary outcome measures are the underlying biological and psychological mediators, measured with the Cortisol Awakening Response (CAR), inflammation levels, DNA methylation, Insomnia Severity Index (ISI), Depressive Symptomatology Self-Report (QIDS-SR), Difficulties in Emotion Regulation Scale (DERS), Dissociative Experiences Scale-II (DES-II), and the Anxiety Sensitivity Index (ASI).

Study description

Background summary

Several empirical studies revealed a positive influence of supplemental physical activity on the treatment of individuals suffering from post-traumatic stress disorder (PTSD). In accordance with the positive results, new intensive trauma-focused treatment (TFT) programmes have been developed for people with PTSD that incorporate physical activity often in combination with evidence-based TFT*s such as prolonged exposure (PE) and eye movement desensitization and reprocessing (EMDR) therapy. However, the unique contribution of physical activity in the treatment of PTSD symptoms has never been investigated in a controlled manner in the context of a brief intensive

TFT programme.

Study objective

To determine the unique contribution of physical activity on PTSD treatment outcome within an intensive TFT programme. In addition, the study aims to investigate the underlying biological and psychological pathways of the effects of physical activity on PTSD symptoms.

Study design

The study is a randomized controlled trial (RCT) with two arms, comparing the change in PTSD symptoms of a physical activity and an active control condition from baseline to posttreatment and at 6-month follow-up.

Intervention

Participants in both conditions will receive the same intensive TFT lasting 8 days within 2 consecutive weeks, in which daily TFT-sessions, PE and EMDR therapy, and psycho-education are combined. The amount of physical activity will differ per condition. The physical activity condition is meant to induce daily physical activity with 60-70% of a person*s maximum heart rate. In the active control condition no physical activity besides TFTs is performed.

Study burden and risks

All patients will receive the same effective evidence-based TFT that consists of PE and EMDR therapy. Although physical activity is not a standard component within first-line evidence-based treatments for PTSD, there are no indications that the addition of physical activity yields any risks for PTSD patients. For example, physical activity is a standard part of the TFT programme at PSYTREC that has proven to be effective for patients undergoing this treatment since 2015 (Van Woudenberg, et al. 2018). Furthermore, there are no additional risks in the administration of the questionnaires as patients with PTSD in general report questionnaire participation as beneficial (Jaffe, et al. 2015). The biological samples are also very safe and easy assessments in which the patients perform the action themselves so that they retain full control.

Contacts

Public
PSYTREC

Professor Bronkhorstlaan 2

Bilthoven 3723 MB
NL
Scientific
PSYTREC

Professor Bronkhorstlaan 2
Bilthoven 3723 MB
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

In order to be eligible to participate in this study, subjects must meet all of the following criteria: (1) a diagnosis of PTSD based on the Clinician-Administered PTSD Scale (CAPS-5), (2) being at least 18 years old (3) sufficient knowledge of the Dutch language to undergo treatment.

Exclusion criteria

Potential subjects who meet any of the following criteria will be excluded from participation in this study: (1) a suicide attempt less than three months prior to treatment, (2) being medically unfit to participate in the physical activity intervention operationalized as not being able to walk for at least 30 minutes (e.g., physical impairments that necessitate the use of wheelchair).

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:	Recruitment stopped
Start date (anticipated):	07-12-2020
Enrollment:	120
Type:	Actual

Ethics review

Approved WMO Date:	15-05-2020
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	14-12-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL70812.029.19