A combination treatment of Well-being Therapy and Trauma-Focused Therapy for patients with PTSD

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON48682

Source
ToetsingOnline

Brief title
Well-being Therapy combined with Trauma-Focused Therapy

Condition

- Other condition
- Anxiety disorders and symptoms

Synonym
posttraumatic stress

Health condition

posttraumatische en stressgerelateerde stoornissen

Research involving
Human

Sponsors and support

Primary sponsor: Mediant (Enschede)
Source(s) of monetary or material Support: Mediant GGZ in het kader van opleiding tot klinisch psycholoog.

Intervention

Keyword: PTSD, traumafocused treatment, well-being

Outcome measures

Primary outcome

The primary outcome of the study is the mental well-being as measured with the

Mental Health Continuum-Short Form.

Secondary outcome

Other parameters are the level of PTSD symptoms (PCL-5),

drop out (observation and the diary filled out by therapists)

the level of anxiety symptoms (The Hospital Anxiety Depression Scale),

the level of depression symptoms (The Hospital Anxiety Depression Scale),

psychological well-being (Positieve Geestelijke Gezondheidsschaal).

Study description

Background summary

The lifetime prevalence of post-traumatic stress disorder (PTSD) in the Netherlands has been estimated on 7.4%. Treatment for PTSD is necessary because left untreated, PTSD can become a chronic condition that engenders long-term social and functional impairment. From a societal perspective, mental illness is costly, often resulting in diminished productivity and increased rates of service utilization. In the Mental Health Care Institutions in The Netherlands, the overall focus for treating PTSD is to reduce symptoms of PTSD as recommended in the Clinical Practice Guideline (2017) for Psychotrauma and Stressrelated Disorders and subscribed by the newest Health Care Standard for Psychotrauma and Stressrelated Disorders (in press, Klaassen, et.al.). During

those trauma-focused treatments (TFT), less attention is given to increase the mental well-being of people with PTSD right at the beginning of the treatment. According to the World Health Organization (WHO, 2001), health cannot be defined as the absence of disease or infirmity but needs to be defined as a state of complete physical, mental and social well-being. There is a growing interest for positive psychology interventions (PPIs) in clinical settings, wherein the focus is on eliciting positive feelings, cognitions or behaviors. A recent review shows that PPIs in clinical settings not only have the potential to improve well-being, but can also reduce distress in populations with clinical disorders. Another important issue in relation to TFT is the level of drop out. Although TFTs have been shown to be effective for PTSD, 36% of individuals with PTSD drop out of these exposure-based treatments. In the clinical practice patients with PTSD are treated as subscribed by the Clinical Practice Guideline and Health Care Standard mainly focused on reducing symptoms right at the beginning of the treatment but not on (1)strengthening the mental well-being nor on (2) decreasing the drop out rates. Well-being therapy (WBT) is a novel psychotherapeutic intervention with the aim to improve a healthy and individualized path to positive mental health. This therapy can have a superior effect on both, the well-being and the drop out rate when offered at the beginning. WBT has been employed in several clinical studies where-in researchers combined WBT with cognitive behavior therapies with result. One recent study in the Netherlands added WBT to the end of the treatment for patients with PTSD, when PTSD symptoms have already been decreased. Yet, no studies have investigated the combination of WBT with TFT right at the beginning of the treatment, with the aim of strengthening the well-being and reducing symptoms.

Study objective

The current study aims to assess the effectiveness of added WBT to TFT (combined sessions of individual WBT and individual TFT during the first 6 months) at the beginning of the treatment for people with PTSD on mental well-being compared to care as usual (CAU), which is individual TFT. It is hypothesized that the combination treatment WBT+TFT at the beginning is superior compared to CAU on the mental well-being, the severity of PTSD symptoms, the rates for drop out for any reason, psychological well-being and severity of depressive and anxiety symptoms.

Study design

A randomised, controlled intervention study with two conditions. Measurements take place at baseline, at mid treatment and after treatment.

Intervention

The present study will be the first study to examine the combination of

individual TFT with WBT for patients with PTSD. The participants will get combined sessions of WBT and TFT during the first 6 months. The participants will get the same 12 individual TFT interventions (12 individual sessions, 45 minutes) as in the CAU but combined with 6 individual sessions of WBT (45 minutes every two weeks). The WBT consists of 6 individual sessions of 45 minutes each using a structured protocol which are given in-between TFT sessions. The participants of the control group will receive care at usual (CAU): 12 individual TFT sessions (45 minutes).

Study burden and risks

The duration of the study will be around 6 months for each individual from baseline to completion of the treatment. During this study, participants complete three assessments of approximately 30 minutes each. Additionally, the experimental group will have 6 added WBT sessions (45 minutes each) to TFT compared to CAU. Every 2 weeks they will have a combined WBT +TFT session, which implies 45 minutes extra to the TFT session. Participants in the experimental group will spend approximately 5-10 additional minutes a day exercising at home in these 6 months, during the 6 weeks wherein they receive the combination treatment WBT +TFT (6 weeks * 10 minutes a day = 420 minutes in total for additional homework)' Participants are free to participate in the study. Subjects can leave the study at any time for any reason if they wish to do so without any consequences. The therapists can decide to withdraw a subject from the study for urgent medical reasons. All therapists are well trained in both treatments and will participate in intervision sessions during the study.

Contacts

Public
Mediant (Enschede)

Raiffeissenstraat 44
Enschede 7514 AM
NL
Scientific
Mediant (Enschede)

Raiffeissenstraat 44
Enschede 7514 AM
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, a subject must meet all of the following criteria: participants are between 18-65 years old and participants have been diagnosed with PTSD (according to DSM-5). Participants are included when they have a higher score than 33 (cutt-off) on the PTSD Checklist for the DSM- 5(PCL-5).

Exclusion criteria

1) participants diagnosed with PTSD that can be treated in the general Mental Health Care and have a score lower than 20 on the PTSD Symptom Scale (cutt off for PTSD: 15, 86%) , (2) subjects who need immediately and high intensive (clinical) care and are at a suicidal condition assessed by the Chronological Assessment of Suïcide Events (conform the Dutch Multiple Discipline Guideline for Suicidal risk, van Hemert et.al, 2012), (3) subjects who immediately need other medical interventions (for instance medication) or other behavioural/ psychological interventions; (4) subjects who don*t speak Dutch, (5) when the team has serious doubts about the competences of the patient,

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):	01-02-2019
Enrollment:	38
Type:	Actual

Ethics review

Approved WMO

Date:	20-11-2018
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO

Date:	27-03-2019
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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: 29633
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL66400.044.18
OMON	NL-OMON29633