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

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The purpose of this study is to determine whether there is a superiority in efficacy of the sequential combined treatment Traumafocused Therapy preceded by Well Being Therapy versus the control group. The control group receives interventions focused...

Ethische beoordeling	Niet van toepassing
Status	Werving tijdelijk gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON29633

Bron
Nationaal Trial Register

Aandoening

Well-Being
Traumafocused Treatment
PTSD

Ondersteuning

Primaire sponsor: GGZ Mediant
University of Twente
Overige ondersteuning: GGZ Mediant

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Reduced severity of PTSD symptoms as determined by the PTSD Symptom Scale (eg. PSS Foa 1993)

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: 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 utilisation. In the Mental Health Care Institutions in The Netherlands, the overall focus for treating PTSD is on reducing symptoms of PTSD as recommended in the Clinical Practice Guideline (2017) for Psychotrauma and Stress-related Disorders and subscribed by the newest Health Care Standard for Psychotrauma and Stress-related Disorders (in press, Klaassen, et.al.). During those trauma-focused treatments (TFT) less attention is given to increasing 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 behaviours. 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 neither 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 individualised 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 wherein researchers combined WBT with cognitive behaviour therapies with result. A 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 right at the start.

Objective: The current study aims to assess the effectiveness of adding 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 hypothesised 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.
Study population: Eligible participants need to be between 18 and 65 years of age and meet the criteria for the diagnosis PTSD (according to the DSM-5) in the specialised Mental Health Care Organisation, Mediant. Patients received a standard intake procedure. The study will take place at Mediant, Centre for Psychotrauma, in Enschede, the Netherlands. Participants are included when they have a higher score than 33 (cut-off) on the PTSD Checklist for the DSM-5 (PCL-5).

Intervention (if applicable): 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 as usual (CAU): 12 individual TFT sessions (45 minutes).

Main study parameters/endpoints: The primary outcome of the study is the mental well-being as measured with the Mental Health Continuum-Short Form. Other parameters are the level of PTSD symptoms (PCL-5), the level of anxiety symptoms (The Hospital Anxiety Depression Scale), the level of depression symptoms (The Hospital Anxiety Depression Scale), drop-out (observation and the diary filled out by therapists) and psychological well-being (Positieve Geestelijke Gezondheidsschaal).

Nature and extent of the burden and risks associated with participation, benefit and group relatedness

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. In those weeks, they will spend approximately 10 minutes a day exercising at home, during the 6 months. The therapists will be asked to fill out a logbook each session to control the integrity

of the therapists and to write down when people drop-out. We expect no risks associated with participation because of the aim to increase the well-being. 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.

Doel van het onderzoek

The purpose of this study is to determine whether there is a superiority in efficacy of the sequential combined treatment Traumafocused Therapy preceded by Well Being Therapy versus the control group. The control group receives interventions focused on reducing symptoms: a structured program with 6 sessions with interventions focused on the present reducing symptoms, followed by traumafocused therapy.

The first aim is to test the hypothesis that the combined treatment (WBT/ Traumafocused therapy) has a greater value in increasing well-being (psychological, emotional and social well-being) compared to the control group. The second aim is to determine whether there is a significantly lower drop-out rate, a decrease of PTSD symptoms and co morbid symptoms due to the combined treatment (WBT/Traumafocused therapy) compared to the control group.

Onderzoeksopzet

T0 baseline

T1 after 6 sessions WBT

T2 after 8 sessions Traumafocused Therapy

Onderzoeksproduct en/of interventie

The present study will be the first study to utilize the combination traumafocused therapy with well-being therapy for patients with PTSD. The participants will get TFT (12 sessions) combined with 6 sessions of WBT. The WBT consists of 6 structured individual sessions (45 minutes each; during the 6 months) of the structured protocol (WBT; Bolhmeijer, Christenhusz & Meulenbeek, 2013) and following the selfhelpbook ‘Dit is jouw leven’.The participants of the controlgroup will receive care at usual (CAU), 12 individual TFT sessions, face to face.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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. Participants are included when they have a higher score than 20 on the PTSD Symptom Scale (Foa, 1993).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

A potential subject who meets any of the following criteria will be excluded from participation in this study: (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 psychological interventions (for instance medication) or other behavioural/ psychological interventions; (4) subjects who don’t speak Dutch.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving tijdelijk gestopt
(Verwachte) startdatum:	01-09-2018
Aantal proefpersonen:	0
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 48682
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7269
NTR-old	NTR7467
CCMO	NL66400.044.18
OMON	NL-OMON48682

Resultaten