Phase-based treatment versus direct trauma-focused treatment in patients with Complex PTSD.

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Ethical review	Approved WMO
Status	Completed
Health condition type	Anxiety disorders and symptoms
Study type	Observational non invasive

Summary

ID

NL-OMON47004

Source
ToetsingOnline

Brief title
RCT Complex PTSD

Condition

- Anxiety disorders and symptoms

Synonym
posttraumatic stress disorder, trauma

Research involving
Human

Sponsors and support

Primary sponsor: Dimence (Deventer)
Source(s) of monetary or material Support: wordt nog aangevraagd,Beroepsverenigen ;fondsen (wordt nog aangevraagd)

Intervention

Keyword: Phase-based trauma-focused Complex PTSD

Outcome measures

Primary outcome

The primary study parameters include the presence of a PTSD diagnosis, the severity of (Complex) PTSD symptoms, before and after completion of treatment, and at follow-up after 3 and 6 months.

Secondary outcome

Secondary parameters include severity of comorbid symptoms (i.e., anxiety, depression, general psychopathology), dissociation, health-related quality of life and drop out during treatment in both conditions.

Study description

Background summary

Complex Post Traumatic Stress Disorder (Complex PTSD) is a term used to denote a severe form of PTSD following repeated interpersonal traumatization in childhood. This construct comprises symptom clusters reflecting difficulties regulating emotions, disturbances in relational capacities, alterations in attention and consciousness, adversely affected belief systems and somatization. According to the guidelines of the International Society of Traumatic Stress Studies (ISTSS), treatment should be *phase-based*, indicating that patients with Complex PTSD symptoms will profit more from trauma-focused treatment if this phase in treatment is preceded by a stabilization phase aimed at achieving patient safety and improving emotion regulation, clients* positive self-concept, and interpersonal skills. However, superiority of a phase-based approach starting with a stabilization phase is yet to be established.

Study objective

The purpose of the present study is to determine superiority in efficacy of a phase-based treatment (i.e., EMDR therapy preceded by Skills Training in Affective and Interpersonal Regulation, STAIR) versus trauma-focused treatment

alone (i.e., EMDR therapy) to treat individuals suffering from (Complex) PTSD due to a history of repeated sexual and/or physical abuse in childhood (by a caretaker or person in authority, and before the age of 18). Our first aim is to test the hypothesis that a phase-based treatment (EMDR preceded by STAIR) is significantly more effective with regard to PTSD (proportion of lost diagnoses and decrease of PTSD symptoms), would lead to a significantly better outcome in terms of comorbid symptom decrease, lower drop-out rate, and increased quality of life, than when the direct trauma-focused treatment (EMDR alone) is applied. Our second aim is to identify possible predictors of worse outcome and drop-out (e.g. pre-treatment anxiety, depression, and personality disorders).

Study design

A randomized controlled trial, with two conditions (STAIR-EMDR therapy versus EMDR therapy alone). Intervention: Patients in one study arm will receive 8 sessions of 90 minutes STAIR (stabilization component), followed by 16 sessions of 90 minutes EMDR therapy (trauma-focused component). In the second study arm, patients will receive 16 sessions of 90 minutes of EMDR therapy.

Study burden and risks

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Patients will be subjected to a series of measures before, during and after treatment and at 3 and 6 months follow-up. Major adverse effects, different than occurring during treatment as usual, are not expected, because these have not been documented in previous studies.

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

In order to be eligible to participate in this study, a patient must meet all of the following criteria: a) meeting the criteria for PTSD, according to the Clinical-Administered PTSD Scale for DSM-5 (CAPS-5; Weathers et al., 2013), b) having symptoms of Complex PTSD, c) reporting a history of repeated physical and/or sexual abuse by a caretaker or person in authority during childhood (before the age of 18), d) being in the age between 18 and 65 years, e) giving an informed consent for study participation.

Exclusion criteria

A patient who meets any of the following criteria will be excluded from participation in this study: a) insufficient competence in speaking the Dutch language, b) high risk of suicidality assessed by the BDI-II (Beck, Steer, and Brown, 1996), c) currently in treatment for PTSD, d) severe alcohol or drug dependence or abuse, e) IQ under 80, and f) victim of ongoing physical and/or sexual abuse.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	05-09-2016
Enrollment:	122
Type:	Actual

Ethics review

Approved WMO Date:	19-05-2016
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	15-11-2016
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	28-02-2017
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	18-12-2018
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: 22074
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL56641.044.16
OMON	NL-OMON22074

Study results

Date completed:	28-08-2020
Results posted:	22-05-2021
Actual enrolment:	122

First publication
22-05-2021