

Treatment of Complex PTSD

No registrations found.

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

Summary

ID

NL-OMON22074

Source

Nationaal Trial Register

Brief title

ToPrepareOrNot (TOPRON)

Health condition

Complex PTSD
Phase-based treatment
Trauma-focused
EMDR
STAIR
Complexe PTSS
Traumagericht
Gefaseerde behandeling

Sponsors and support

Primary sponsor: University of Amsterdam UvA

University of Groningen RuG

Source(s) of monetary or material Support: Dimence GGZ

Funding (NGO's)

Intervention

Outcome measures

Primary outcome

Severity of PTSD symptoms

Secondary outcome

Secondary parameters include the presence of a PTSD diagnosis, severity of Complex PTSD symptoms and 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 in 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, patients' positive self-concept, and interpersonal skills. However, superiority of a phase-based approach starting with a stabilization phase is yet to be established.

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 (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 objective

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, patients' positive self-concept, and interpersonal skills.

In accordance with the ISTSS guidelines, it would be expected that a phase-based treatment (EMDR preceded by STAIR) is significantly more effective with regard to PTSD (PTSD severity), would lead to a significantly better outcome in terms of comorbid symptom decrease, a lower drop-out rate, and increased quality of life, than when the direct trauma-focused treatment (EMDR alone) is applied.

Study design

Patients will be subjected to a series of measures before, during and after treatment and at 3 and 6 months follow-up.

Intervention

EMDR alone (16 sessions) versus EMDR (16 sessions) preceded by STAIR (stabilization program)

Contacts

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Eligibility criteria

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

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	08-09-2016
Enrollment:	122
Type:	Anticipated

Ethics review

Positive opinion

Date: 23-08-2016

Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 47004

Bron: ToetsingOnline

Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL5836
NTR-old	NTR5991
CCMO	NL56641.044.16
OMON	NL-OMON47004

Study results

Summary results

1. Study protocol.

2. Article about the results of the RCT in which phase-based treatment versus directe trauma-focused treatment are compared in patients with Complex PTSD.

3. Article about cost-effectiveness of both treatments.

4. Article about predictors and moderators in the treatment of Complex PTSD.

5. Article about possible predictors of worse outcome and drop-out in the treatment of

Complex PTSD.