

Treatment of Complex PTSD

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Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22074

Bron

NTR

Verkorte titel

ToPrepareOrNot (TOPRON)

Aandoening

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

Ondersteuning

Primaire sponsor: University of Amsterdam UvA
University of Groningen RuG

Overige ondersteuning: Dimence GGZ
Funding (NGO's)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Severity of PTSD symptoms

Toelichting onderzoek

Achtergrond van het onderzoek

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).

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

Dimence GGZ
Pikeursbaan 3

Noortje van Vliet
Deventer 7411 GT
The Netherlands
0570-604000

Wetenschappelijk

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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 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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	08-09-2016
Aantal proefpersonen:	122

Type:

Verwachte startdatum

Ethische beoordeling

Positief advies

Datum: 23-08-2016

Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 47004

Bron: ToetsingOnline

Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten

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.