

# Treatment of Complex PTSD

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<b>Ethische beoordeling</b>	Positief advies
<b>Status</b>	Werving nog niet gestart
<b>Type aandoening</b>	-
<b>Onderzoekstype</b>	Interventie onderzoek

## Samenvatting

### ID

NL-OMON22074

### Bron

Nationaal Trial Register

### 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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Pikeursbaan 3

Noortje van Vliet  
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The Netherlands  
0570-604000

## 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
Blindering:	Enkelblind
Controle:	Actieve controle groep

### 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.<br>

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.<br>

3. Article about cost-effectiveness of both treatments.<br>

4. Article about predictors and moderators in the treatment of Complex PTSD.<br>
5. Article about possible predictors of worse outcome and drop-out in the treatment of Complex PTSD.