

# **What is the effect of a stabilising group treatment in complex PTSD patients? A Multicenter Randomised Clinical Trial for women with Child Abuse related Post Traumatic Stress Disorder with Associated Features.**

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The effectiveness of a 20-week stabilising group therapy in patients with complex PTSD is superior to treatment as usual.

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

## **Samenvatting**

### **ID**

NL-OMON27986

### **Bron**

NTR

### **Verkorte titel**

N/A

### **Aandoening**

Stabilising group therapy vs treatment as usual

### **Ondersteuning**

**Overige ondersteuning:** ZON-MW programme OOG 100-002-024

### **Onderzoeksproduct en/of interventie**

## **Uitkomstmaten**

### **Primaire uitkomstmaten**

1. CAPS and Davidson Trauma Scale (severity of PTSD symptoms);
2. SCID-DSNOS (overall severity of complex PTSD symptoms);
3. Borderline Personality Disorder Severity Index (BPDSI) (severity of affect-dysregulation and selfdestructiveness);
4. Dissociative Experiences Scale (DES).

## **Toelichting onderzoek**

### **Achtergrond van het onderzoek**

The aim of this randomised controlled trial is to improve and implement outpatient treatment for severely traumatized women with 'PTSD with associated features' in terms of DSM-IV-TR. Especially after interpersonal traumatization in childhood PTSD - re-experiencing, numbing and hyper arousal - is complicated by personality changes such as affect dysregulation, memory disturbances, dissociation, disturbances of self-image, somatization and relational problems. This chronic syndrome is called 'PTSD with enduring personality change' in ICD-10, 'complex PTSD' or 'disorders of extreme stress NOS'. It is associated with severe psychiatric symptoms, high morbidity, social maladjustment and tends to run a chronic course in spite of considerable use of medical and psychiatric services. Regular PTSD exposure treatment does not lead to improvement and recent Dutch research shows a lack of adequate treatment. There is some evidence that stabilising group therapy is the most effective treatment with psycho-education and a cognitive behavioural training as techniques.

In this multicenter trial the first aim is to study the effectiveness of a 20 weekly stabilising group therapy based on Zlotnick as supplement to treatment as usual compared to TAU alone. Criteria (core symptoms) will be symptoms of C-PTSD (see above). The second aim is to identify prognostic variables: hypothesis is that the severity of dissociative symptoms (interfering with attention) and the severity of borderline symptoms (interfering with compliance) will affect success. Four centres of outpatient mental health care will participate. Assessments and treatment protocol have been successfully tested in a pilot study.

### **Doel van het onderzoek**

The effectiveness of a 20-week stabilising group therapy in patients with complex PTSD is superior to treatment as usual.

### **Onderzoeksproduct en/of interventie**

20-week group stabilising treatment for complex PTSD plus TAU vs TAU alone.

# Contactpersonen

## Publiek

VU University Medical Center<br>Department of Psychiatry / GGZ Buitenamstel <br>

A.J.L.M. Balkom, van  
A.J. Ernststraat 887

Amsterdam 1081 HL  
The Netherlands  
+31 (0)20 7884549

## Wetenschappelijk

VU University Medical Center<br>Department of Psychiatry / GGZ Buitenamstel <br>

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A.J. Ernststraat 887

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The Netherlands  
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# Deelname eisen

## Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Females diagnosed with Complex PTSD according to SCID-DESNOS with or without comorbid axis I or axis II disorders (see also exclusion criteria).

## Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Comorbid psychotic disorders, substance dependence; antisocial personality disorder or dissociative identity disorder, all diagnosed with SCID-I, SCID-D or SCID-II.

# Onderzoeksopzet

## Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Blindering:	Enkelblind
Controle:	Geneesmiddel

## Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	20-03-2006
Aantal proefpersonen:	72
Type:	Verwachte startdatum

## Ethische beoordeling

Positief advies	
Datum:	17-03-2006
Soort:	Eerste indiening

## Registraties

### Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

### Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

## In overige registers

Register	ID
NTR-new	NL575
NTR-old	NTR631
Ander register	: N/A
ISRCTN	ISRCTN00874587

## Resultaten

### Samenvatting resultaten

Dorrepaal, E., Thomaes, K., Draijer, P.J. (2006). Stabilisation therapy as an answer to complex post-traumatic stress disorder. Complex post-traumatic stress disorder in woman abused in childhood: progress in diagnostics, treatment and research. Tijdschrift voor Psychiatrie, 3: 217-222.