

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.

No registrations found.

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

Summary

ID

NL-OMON27986

Source

NTR

Brief title

N/A

Health condition

Stabilising group therapy vs treatment as usual

Sponsors and support

Source(s) of monetary or material Support: ZON-MW programme OOG 100-002-024

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

1. SE (Self Esteem measure);
2. SDQ (somatic dissociation);
3. WHO- QoL (Quality of Life);
4. SCL-90 (comorbid psychopathology);
5. BDI (depression);
6. STAI (anxiety).

Study description

Background summary

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.

Study objective

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

Intervention

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

Contacts

Public

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Scientific

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

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

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	20-03-2006
Enrollment:	72
Type:	Anticipated

Ethics review

Positive opinion	
Date:	17-03-2006
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

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

Study results

Summary results

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.