

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.

Submission date 28/04/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 28/04/2006	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 11/01/2021	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof A.J.L.M. Balkom, van

Contact details
VU University Medical Center
Department of Psychiatry/GGZ Buitenamstel
Ernststraat 887
Amsterdam
Netherlands
1081 HL
+31 (0)20 7884502 or +31 (0)20 7885630
vanbalkom@ggzba.nl

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

NL575, NTR631

Study information

Scientific Title

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.

Study objectives

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

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the local medical ethics committee

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Post Traumatic Stress Disorder (PTSD)

Interventions

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

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

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 self-destructiveness)
4. Dissociative Experiences Scale (DES)

Secondary outcome measures

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

Overall study start date

20/03/2006

Completion date

20/03/2009

Eligibility**Key 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).

Participant type(s)

Patient

Age group

Adult

Sex

Female

Target number of participants

72

Total final enrolment

71

Key exclusion criteria

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

Date of first enrolment

20/03/2006

Date of final enrolment

20/03/2009

Locations

Countries of recruitment

Netherlands

Study participating centre

VU University Medical Center

Amsterdam

Netherlands

1081 HL

Sponsor information

Organisation

VU University Medical Center, Department of Psychiatry and GGZ Buitenamstel (The Netherlands)

Sponsor details

A.J. Ernststraat 887

Amsterdam

Netherlands

1081 HL

Sponsor type

University/education

ROR

<https://ror.org/00q6h8f30>

Funder(s)

Funder type

Research organisation

Funder Name

Netherlands Organisation for Health Research and Development (ZonMw)

Alternative Name(s)

Netherlands Organisation for Health Research and Development

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

Netherlands

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2012	11/01/2021	Yes	No