ISRCTN00874587 https://doi.org/10.1186/ISRCTN00874587

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	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 28/04/2006	**Overall study status** Completed	
Last Edited 11/01/2021	**Condition category** Mental and Behavioural Disorders	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number

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

Study type(s)
Treatment

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(s)
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)

Key secondary outcome(s))
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)

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

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

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)

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

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