Trauma-focused treatment for PTSD patients with a comorbid borderline personality disorder: a feasibility study of Prolonged Exposure (PE) in an intensive format.

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The main objectives of the present study are to examine the feasibility, efficacy and safety of intensive PE treatment within DBT for patients who have PTSD and a comorbid BPD.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Anxiety disorders and symptoms
Study type	Interventional

Summary

ID

NL-OMON38775

Source
ToetsingOnline

Brief title
Treatment of PTSD in Patients with a comorbid BPD

Condition

- Anxiety disorders and symptoms

Synonym
posttraumatic stress disorder (PTSD) and "trauma"

Research involving
Human

Sponsors and support

Primary sponsor: ProPersona (Nijmegen)
Source(s) of monetary or material Support: Pro Persona - the sponsor

Intervention

Keyword: Borderline personality disorder (BPD), Feasibility study, Intensive Prolonged exposure, Posttraumatic stress disorder (PTSD)

Outcome measures

Primary outcome

- PTSD symptoms measured by the Posttraumatic Stress Symptom Scale, Self Report

- Safety measured by adverse events like suicidal attempts, non-suicidal

self-injury (NSSI), and crisis service use.

- For treatment compliance issues, cancelled treatment appointments will be

recorded throughout the DBT and PE programs, as is dropout of treatment.

- PTSD symptom severity is measured with a clinician rated instrument: the

Clinician-Administered PTSD Scale (CAPS-1)

- Subjective ratings of improvement will be assessed with the Global Severity

index (GSI)

Secondary outcome

- Severity of Borderline Personality Disorder will be assessed with the

Borderline Personality Disorder Severity Index (BPDSI)

- Depression will be measured with the Beck Depression Inventory-II (BDI-II)

- Dissociation will be measured with the Dissociative Experiences Scale -

revised version (DES-II)

- Posttraumatic cognitions will be measured by the Dutch version of the

Posttraumatic Cognitions Inventory (PTCI)

Study description

Background summary

After experiencing a traumatic event, people are at risk for developing a posttraumatic stress disorder (PTSD). Patients suffering from PTSD, classified in the DSM-IV as an anxiety disorder, typically re-experience the traumatic event again and again in flashbacks and nightmares. These re-experiences are highly fearful to patients. Therefore, they avoid thoughts about the traumatic event, and situations that may trigger such memories. In addition, they are continuously alert for possible threats, leading to severe sleeping and concentration problems. A high comorbidity is shown between PTSD and borderline personality disorder (BPD). Though effective treatments for PTSD like Prolonged Exposure (PE) are available, patients with BPD are typically excluded from clinical trials based on the belief that BPD patients are unable to tolerate trauma-focused treatment, and may even get worse. However, recent studies examining modified PE treatments, delivered as stand alone treatment or in combination with Dialectical Behavior Therapy (DBT), have shown promising results among BPD patients. We developed a short, intensive PE treatment for PTSD patients with severe comorbidity like BPD. Preventing dropout, a major problem in the BPD population, could be an important advantage of this short treatment program. The present study aims to examine the feasibility, efficacy and safety of PE in an intensive format for PTSD patients with a comorbid BPD.

Study objective

The main objectives of the present study are to examine the feasibility, efficacy and safety of intensive PE treatment within DBT for patients who have PTSD and a comorbid BPD.

Study design

The study has a multiple baseline design whereby patients are randomly allocated to three different baseline length variations.

Intervention

Patients will receive DBT that is augmented by PE in an intensive format once the patient achieves sufficient control over (non-)suicidal self-injurious behaviour.

Study burden and risks

The burden and risks of the current study are limited. The intensive PE therapy is expected to be an effective and safe form of treatment.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

General inclusion criteria of the study:
- Age between 18 and 65 years
- Current DSM-IV diagnosis of PTSD established with a structured diagnostic interview (CAPS-1), and a severity score of CAPS > 50.
- Current DSM-IV diagnosis of BPD established with a standardized, semi structured,

diagnostic interview (SCID-II),
- Recent and/or imminent suicidal behavior or serious non-suicidal self-injury;Inclusion criteria to start Prolonged exposure
- Not at imminent risk of suicide
- No recent suicide attempts or serious non-suicidal self-injury
- PTSD is the highest priority target for the patient

Exclusion criteria

- Psychosis or delusion disorders (current or in the past)
- Bipolar disorder
- Substance abuse or dependence, or alcohol abuse or dependence
- Mental retardation.
- Insufficient ability to speak and write Dutch

Study design

Design

Study type:	Interventional
Intervention model:	Other
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-10-2014
Enrollment:	5
Type:	Actual

Ethics review

Approved WMO

Date:	15-11-2013

Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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
CCMO	NL45770.091.13

Study results

Date completed:	01-10-2014
Actual enrolment:	0