The effectiveness of a 12-week clinical trauma therapy program for victims suffering from post-traumatic stress disorder after childhood sexual abuse.

Published: 04-09-2017
Last updated: 05-10-2024

A 12-week clinical dialectical behavioral therapy with prolonged exposure (DBT-PE) will decrease severity of post traumatic stress disorder (PTSD) symptoms, that are a consequence of experiencing childhood sexual abuse.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	-

Summary

ID

NL-OMON27279

Source
Nationaal Trial Register

Health condition

PTSD, borderline personality disorder, childhood sexual abuse, non-suicidal self-injury (NSSI).

Sponsors and support

Primary sponsor: GGZ Friesland
Source(s) of monetary or material Support: GGZ Friesland
PPO Research Fonds (Groningen)

Intervention

Outcome measures

Primary outcome

Presence and severity of PTSD

Secondary outcome

Presence and severity of borderline and other personality disorders (including non-suicidal self-injury and suicidal ideation), presence of comorbid axis 1 disorders, dissociative symptoms, general psychopathology.

Study description

Background summary

A few years ago, promising results were published of a clinical treatment program of dialectical behavioral therapy (DBT) and prolonged exposure (PE) for those who suffer from the most severe consequences of childhood sexual abuse (CSA), a combination of a posttraumatic stress disorder (PTSD) and co-morbid conditions such as a borderline personality disorder (BPD). To solidify the evidence base of this promising new method, replication studies in another centre, without the developer involved, are necessary. The objective of this trial is to examine the effectiveness of clinical DBT-PE on symptoms of Post Traumatic Stress Disorder in persons with a history of CSA. The research questions are: 1) What is the effect of clinical DBT-PE on the severity of PTSD at 12 weeks from the start of the program? 2) Does the effect of clinical DBT-PE depend on the presence or absence, or the severity of symptoms of a co-morbid borderline personality disorder? 3) What is the effect of clinical DBT-PE on the frequency of and urge for non-suicidal self-injury (NSSI) and suicidal ideation? 4) What is the effect of clinical DBT-PE on the severity of the symptoms of borderline personality disorder? Question 5) How stable are the effects of clinical DBT-PE after the clinical treatment program has stopped? We will carry out a single-blind randomised controlled clinical trial in persons (men and women) aged 18-65 years, referred to the Trauma clinic for the treatment of PTSD related to childhood abuse before the age of 18, with at least one of the following comorbid conditions: eating disorder, major depressive disorder, substance abuse, or meeting ≥4 DSM-IV criteria for borderline personality disorder. The intervention consists of 12 weeks of DBT-PE, the control condition is 12 weeks waiting list, in which patients continue current therapy and/or start stabilisation treatment; all care as usual in the waiting list condition is possible except for trauma therapy.
Main study parameters/endpoints are presence and severity of PTSD, measured by the Dutch version of the Clinical Administered PTSD Scale and the Davidson Trauma Scale. Secondary outcome measures are presence and severity of borderline and other personality disorders, dissociative experiences and psychiatric symptoms (SCL-90). We will measure participants at baseline, after 12 weeks of treatment and again after 12 weeks follow up (i.e. 24 weeks after baseline).

Study objective

A 12-week clinical dialectical behavioral therapy with prolonged exposure (DBT-PE) will

decrease severity of post traumatic stress disorder (PTSD) symptoms, that are a consequence of experiencing childhood sexual abuse.

Study design

Baseline measurement (T0), posttreatment measurement after 12 weeks DBT-PE (T1) and follow-up measurement 24 weeks after baseline (T2).

Intervention

Dialectical behavioural therapy + prolonged exposure (DBT-PE). The DBT-PE is a 12-week residential program with an intensive modular therapy program that is specifically tailored to the individual patient. It consists of individual treatment within a group setting; in addition to individual trauma therapy there are numerous group modules that are targeted at increasing the general coping skills of the participants. The program allows for a total of 25 individual psychotherapy sessions, lasting 60 minutes each.

There is a strong holding environment for the patient thanks to the 24-hour care. The treatment entails three different phases. The first phase covers the first three weeks during which patients prepare themselves for trauma therapy by determining their individual goals during their therapy and learning skills to regulate their arousal. During the second phase, from week 4 until week 9, the focus is on skills-based prolonged exposure. Skills-based prolonged exposure implies that patients use their skills to regulate their arousal during the trauma therapy, allowing the patient to process his trauma. In the last three weeks, the aim is to finalize processing of the trauma through radical acceptance of the trauma as part of history with its consequences for the future and the main focus will be resocialization in order to prepare to return home.

In each phase there is a variety of treatment modules to suit the purpose of the relevant phase. Some modules are standard, others are facultative (Table 1). From this complete set of treatment modules, a subset is selected that is tailored to the specific needs of the participant. This individual program can be adjusted during the course of the therapy.

Contacts

Public
GGZ Friesland
Postbus 932
Frederike Jörg
Leeuwarden 8901 BS
The Netherlands
+31 (0)58 2848985
Scientific
GGZ Friesland

Postbus 932
Frederike Jörg
Leeuwarden 8901 BS
The Netherlands
+31 (0)58 2848985

Eligibility criteria

Inclusion criteria

Inclusion criteria are: (1) age 18-65 years old; (2) meeting the DSM-IV-defined diagnosis criteria of PTSD related to childhood abuse before the age of 18; (3) meeting the diagnostic criteria for at least one of the following conditions: eating disorder, major depressive disorder, substance abuse, or meeting ≥4 DSM-IV criteria for borderline personality disorder.

Exclusion criteria

Exclusion criteria for this research are a lifetime diagnosis of schizophrenia, the presence of psychotic symptoms, substance dependence, a body-mass-index ≤ 17, antisocial personality disorder, intellectual disability defined by an IQ<70, medical conditions contradicting the exposure protocol (e.g. severe cardiovascular disorders). Individuals with ongoing self-harm or other high-risk behaviour are not excluded. However, for safety reasons, patients with a recent suicide attempt (in the last four months) will not be included.

Study design

Design

Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL
Recruitment status: Pending

Start date (anticipated):	01-01-2018
Enrollment:	92
Type:	Anticipated

Ethics review

Not applicable
Application type: Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 46167
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL6491
NTR-old	NTR6678
Other	PPO Research Fonds : PPO-RF-21CM
CCMO	NL66906.099.18
OMON	NL-OMON46167

Study results