# Is clinical DBT-PE the revolution we have all been waiting for in the treatment of victims of childhood sexual abuse?

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The current study aims to replicate the Bohus study published in 2013, comparing the effect of a 12-week residential DBT-PE program on the severity of PTSD to that of a waiting list condition in patients who suffer from CSA related PTSD and from one...

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| **Ethical review** | Not approved |
| **Status** | Will not start |
| **Health condition type** | Anxiety disorders and symptoms |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON44448

**Source**
ToetsingOnline

**Brief title**
Effect of DBT-PE treatment for victims of childhood sexual abuse

### Condition

- Anxiety disorders and symptoms

**Synonym**
posttraumatic stress disorder, PTSD

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** GGZ Friesland (Leeuwarden)
**Source(s) of monetary or material Support:** Het PostMaster Psychologie Opleidingen (PPO) Research Fonds;co-finaciering door GGZ Friesland

## Intervention

**Keyword:** borderline personality disorder, dialectical behavioral therapy, posttraumatic stress disorder, trauma treatment

## Outcome measures

### Primary outcome

KIP * Klinisch Interview PTSS/ CAPS - Clinical Administered PTSD Scale

We will use the Dutch version of the CAPS to measure the presence and severity of PTSD. The CAPS is a semi-structured interview and consists of 30 items concerning the frequency and severity of the PTSD Symptoms, associated features and information about the onset and duration of the symptoms. The Dutch version of de CAPS is called the KIP: Clinical Interview for PTSD. The KIP has a good validity and a high interrater reliability, and is considered to be the gold standard diagnosing PTSD. The KIP will be administered at T0, T1 and T2. It will take about 90 minutes for the interview.

DTS - Davidson Trauma Scale

The Dutch version of the Davidson Trauma Scale will also be used to measure the presence and severity of PTSD. It is a 17-item self-report measure that assesses the 17 DSM IV symptoms of PTSD. Items are rated on a 5-point frequency (not at all - every day) and severity scale (not at all distressing - extremely stressing). Scores can also be calculated for each of the 3 PTSD symptom clusters (National Center for PTSD). The scale demonstrated good test*retest reliability and internal consistency. Concurrent validity was obtained against the SCID. Good convergent and divergent validity was obtained. The DTS showed

predictive validity for response to treatment, as well as being sensitive to treatment effects The DTS will be administered at T0, T1 and T2. It takes about 10 minutes filling in the questionnaire at a computer.

**Secondary outcome**

SCID I * Structured Clinical Interview for DSM-IV Axis I Disorders

The SCID I will be used to diagnose axis I disorders. It is a semi structured interview existing of 10 modules, representing axis I disorders, of which each symptom can be scored with 1 till 3, or a *?* if it is unclear whether the symptom is present. The interrater reliability is satisfying, provided that the interviewers are trained. The SCID I will be administered at T0. The interview takes about 60-90 minutes.

SCID-II - Structured Clinical Interview for DSM-IV axis II Personality Disorders

Part of the SCID-II will be used to diagnose borderline personality disorder (BPD). The SCID-II is a semi-structured DSM IV-based interview, examining the presence of personality disorders. We will only use the part concerning BPD. The SCID-II will be administered at T0 to differentiate between patients with or without BPD. It will take about 10-30 minutes, depending on the presence of BPD-criteria.

BPDSI * Borderline Personality Disorder Severity Interview

Bohus et al. (2013) used the Borderline Symptom List in their study, a self-report measuring borderline symptoms. There is no Dutch version and no

comparable questionnaire with good psychometric data available in Netherlands. Therefore we choose to use the BPDSI, a tool to determine the severity of borderline personality disorder. The dimensional total score gives an indication of the frequency and nature of the borderline symptoms during a defined period. The reliability (0.93), and internal consistency (Cronbach's alpha = 0.85) are good, concurrent and construct validity are excellent. The BPDSI will be administered at T0, T1 and T2 only in the group that scored positive with the SCID-II in the presence of BPD. The interview takes about 90 minutes. This interview is suitable to measure changes in borderline symptomatology. Because the internal consistency of the subscales is good, we can use the subscale *parasuicidal* to score non-suicidal self-injury (NSSI) with this instrument.

DES * Dissociative Experience Scale

The Dutch version of the DES will be used to screen for dissociative experiences. It consists of 28 questions which are scored on a Likert-scale varying from 0% (never) till 100% (all the time). The reliability and validity have been confirmed in several studies. The DES will be administered at T0, T1 and T2. It takes about 10 minutes to fill in the scale.

SCL *90 * Symptom Checklist 90

The Symptom Checklist 90 will be used to obtain information regarding symptom severity on nine different subscales. The 90 items of the questionnaire are scored on a five-point Likert scale, indicating the rate of occurrence of the

symptoms during the time reference. Internal consistencies have been good and test-retest reliability has been adequate. The validity of the instrument is controversial: some studies claim convergence to theoretically similar constructs, most report a lack of sufficient discriminant validity. There is strong support for the validity of the SCL *90 as a measure of general symptom severity. The SCL*90 will be administered at T0, T1 and T2 and takes about 15 minutes to complete.

WSAS - Work and Social Adjustment Scale

The WSAS is a simple, reliable and valid measure of impaired functioning. It contains of five items, inquiring into the level of impairment, due to the disorder, on the domains of work, home management, social leisure activities (visiting clubs, bars, parties, sports clubs), private leisure activities (reading, gardening, listening to music) and maintaining close relationships. Cronbach's * ranged from 0.70 to 0.94 and the test-retest reliability was 0.73. The WSAS is sensitive to different levels of severity and to treatment-related change (Mundt, 2002).

Tic-P

The questionnaire on healthcare consumption and productivity losses for patients with a Psychiatric disorder (TiC-P) is a questionnaire focused on establishing direct medical costs and productivity costs due to absence from work and is widely used in the Netherlands for economic evaluations in mental health (Bouwmans, 2013). The questionnaire has been shown to be a feasible and

reliable instrument to assess costs associated with care consumption and work absence in patients with psychiatric disorders (Bouwmans, 2013).

EQ-5D

EQ-5D is a standardized instrument developed by the EuroQol Group as a measure of health-related quality of life that can be used in a wide range of health conditions and treatments. The descriptive system comprises five dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each dimension can be rated at three levels: no problems, some problems and major problems (Euroquol Group, 1990).

WAIS-IV

The WAIS-IV (Wechsler Adult Intelligence Scale * IV, Dutch version, Wechsler, 2009) is an instrument for clinical use to investigate cognitive performance in adults (age 16+). The WAIS IV will be administered to all eligible patients interested in participating in this trial. Patients with an IQ <70 as measured by the WAIS IV, will be excluded from this trial, as intellectual disability is one of the exclusion criteria. For psychometric properties, see James et al. (James 2011).

REFERENCES

see the comprehensive study outline that is added as an Appendix

# Study description

**Background summary**

BACKGROUND

Until only a few years ago, we had little to offer in terms of evidence based treatment to 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) or substance use disorder.

A history CSA is strongly associated with a substantial increase in the life time risk of a variety of psychiatric disorders, including not only PTSD, but also mood- and anxiety disorders, somatoform disorders, attention deficit disorder, psychosis and schizophrenia, substance use disorders, suicidal behaviour, deliberate self-harm and personality disorders.

Traditionally, treatment programs for patients with PTSD include stabilizing interventions that are used to prepare patients with more severe forms of PTSD for what is considered to be essential in the recovery from PTSD: exposure in some form to trauma memories. For example, the ISTSS Expert Consensus Guidelines for Complex PTSD propose a stepped model with three treatment phases: 1. Stabilization and strengthening: patient safety, strengthening one*s capacities for emotional awareness and expression, increasing positive self-concept, addressing feelings of guilt and shame, and increase interpersonal and social competencies. 2. Review and reappraisal of trauma memories: re-experiencing traumatic events in the context of an actual and subjectively experienced safe environment. 3. Consolidation of the gains of the treatment so far.

Some experts have questioned this somewhat conservative approach to trauma treatment. For example, some argue that there is no convincing empirical evidence justifying the stabilization phase prior to an evidence-based trauma treatment (EMDR of Trauma-focused cognitive behavioral therapy). In the Netherlands, a number of experts have also suggested that trauma-focussed therapy without a prior stabilisation phase is feasible and clinically beneficial for patients with PTSD.

Especially in patients with a comorbid BPD, that may be characterized by profound emotional instability, deliberate self-harm and suicidal behavior, stability as a pre-treatment condition may be too much to ask for. Moreover,

often the symptoms and problems associated with the PTSD in turn complicate the treatment of the personality disorder. With the two conditions complicating and frustrating each other's treatment, therapists of victims of CSA had the least to offer to those patients who needed it most, i.e., until recently.

In 2013, Martin Bohus and his co-workers from the Central Institute of Mental Health in Mannheim published the results of a 12-week residential treatment program that was specifically designed for patients with severe PTSD complicated by comorbid conditions such as a BPD (Bohus 2013). The program combines dialectical behavioral therapy (DBT), one of the best documented interventions for BPD, with prolonged exposure (PE) to trauma memories (Steil 2011).

Bohus distinguishes three major challenges in the treatment of PTSD and comorbid BPD that might interfere with the traditional treatment protocols for PTSD. Firstly, patients with BPD are prone to exhibit emotional over-engagement or severe dissociative symptoms during exposure. Secondly, the diversity of trauma-related emotions and cognitions requires individualized, specific interventions. Thirdly, the *complexity of multiple daily life problems* referring to the problems PTSD-BPD patients often have with their daily hassles because of their difficulties in social interaction, and their interference with the therapeutic task. Bohus argues that, for the PTSD-BPD patients, a modular programme that can be tailored to the actual needs of the patients is better suited than a phase-based linear program, that often leads to early dropout in this population.

Bohus et al. compared their intervention to a waiting list condition in a single blind randomized design. The results of the Mannheim residential program are very promising, with significant and clinically relevant changes in the patient group that was randomized to the active condition, a large effect size (a Hedges'g of 1.6), and little dropout. The treatment results on the PTSD severity seem to be independent of severity of the personality disorder; neither a diagnosis of BPD nor the severity of the number of BPD symptoms was significantly related to treatment outcome.

One year earlier, in 2012, the research group of Marsha M. Linehan, founder of DBT method, published the results of a similar combined DBT-PE treatment program, however with a more linear design (Harned 2012). In this program, if DBT leads to a complete disappearance of deliberate self-harm, patients are allowed to start with prolonged exposure, while continuing with the DBT programme. In contrast, in the Mannheim protocol, exposure starts, regardless of the presence or absence of deliberate self-harm. Harned et al. also report significant reductions in PTSD severity after treatment and no evidence for exacerbations of deliberate self-harm.

Inspired by the promising results of the Mannheim program, GGZ Friesland started a similar residential treatment program in Leeuwarden. The complete

staff of our department was trained by Martin Bohus before the first patients were included in March 2014.

To date, there is only one published clinical trial, with less than a total of 80 randomized patients, to substantiate the claim of success of this new intervention (Bohus 2013). It has been shown in numerous studies that the results in first trials of new interventions are not necessarily replicated in follow-up studies. Apart from publication bias that selects trials with positive findings, the relation between effect and protocol adherence, the effects of a particular psychological intervention may also be somewhat dependent of the personal qualities of the founder and his or her team. Implementation of the method by a different group, regardless of protocol adherence, may not be as effective as the original one. To further solidify the evidence base of this promising new method, follow-up studies are absolutely necessary.

REFERENCES

Bohus, M., Dyer, A. S., Priebe, K., Kruger, A., Kleindienst, N., Schmahl, C., et al. (2013). Dialectical behaviour therapy for post-traumatic stress disorder after childhood sexual abuse in patients with and without borderline personality disorder: A randomised controlled trial. Psychotherapy and Psychosomatics, 82(4), 221-233.

Harned, M. S., Korslund, K. E., Foa, E. B., & Linehan, M. M. (2012). Treating PTSD in suicidal and self-injuring women with borderline personality disorder: Development and preliminary evaluation of a dialectical behaviour therapy prolonged exposure protocol. Behaviour Research and Therapy, 50(6), 381-386.

Steil, R., Dyer, A., Priebe, K., Kleindienst, N., & Bohus, M. (2011). Dialectical behaviour therapy for posttraumatic stress disorder related to childhood sexual abuse: A pilot study of an intensive residential treatment program. Journal of Traumatic Stress, 24(1), 102-106.

**Study objective**

The current study aims to replicate the Bohus study published in 2013, comparing the effect of a 12-week residential DBT-PE program on the severity of PTSD to that of a waiting list condition in patients who suffer from CSA related PTSD and from one or more comorbid conditions such as BPD.

Question 1) What is the effect of clinical DBT-PE on the severity of PTSD at 12 weeks from the start of the program?

Secondary questions are:

Question 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?

Question 3) What is the effect of clinical DBT-PE on the frequency of and urge for non-suicidal self-injury (NSSI) and suicidal ideation?

Question 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?

Question 6) What is the effect of the clinical DBT-PE on social functioning?

Question 7) What is the incremental cost-effectiveness of clinical DBT-PE as compared to a 5-year traditional ambulatory treatment?

**Study design**

We propose a single-blinded randomized controlled trial (RCT), comparing our 12-week clinical DBT-PE program to a 12-week waiting list condition (WL). In this waiting list condition, participants are allowed to continue their current treatment with the referring therapist, except for trauma therapy. The proposed design and choice of effect parameters deliberately concur with those of the trial published by Bohus et al. (Bohus 2013). It is in many respects a replica, because we want to examine the generalizability of their results to a new treatment centre (i.e., a different team in a different country). It is single blinded in the sense that only the observers of the treatment effect will be blinded for the treatment condition. The proposed duration of our WL condition (12 weeks) accidentally approximates the current average waiting time for our program. Thus, participation with the possibility of being randomized to WL will not pose an extra burden on our patients, as far as waiting for treatment is concerned. For the WL condition we schedule two evaluations, the first (T0) before randomization, the second (T1) at 12 weeks. For the DBT-PE condition, we add a third evaluation (T2) at 24 weeks in order to examine the stability of the treatment effects (study question 5). The follow-up duration for the participants randomized to the WL condition in our study will be limited to 12 weeks, in contrast to the 26 weeks in the Bohus trial. Bohus et al. (2013) demonstrated that the symptom severity among patients in the WL condition remains essentially unchanged during the 26 weeks of follow-up.

Bohus, M., Dyer, A. S., Priebe, K., Kruger, A., Kleindienst, N., Schmahl, C., et al. (2013). Dialectical behaviour therapy for post-traumatic stress disorder after childhood sexual abuse in patients with and without borderline personality disorder: A randomised controlled trial. Psychotherapy and Psychosomatics, 82(4), 221-233.

## Intervention

Dialectical behavioural therapy + prolonged exposure (DBT-PE): our clinical DBT-PE program is very similar to the treatment program in Mannheim. Our team has been fully trained in all details of the interventions by prof. Bohus before we included our first patients. During the first year, our team was supervised on a regular basis by prof. Bohus, to enhance protocol adherence.
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. 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.
There are a few small differences between our program and the Mannheim program. Our program, for example, provides the possibility of family therapy, whereas in Mannheim, the program allows for massages, physiotherapy and therapeutic boxing. In Mannheim it is possible to consult a social worker about resocialization.

Waiting list (WL): the participants randomised to the TAU-WL group, are allowed to continue their current treatment with the referring therapist, except for trauma therapy. For support, they are allowed to contact an independent person who is not involved in the investigation. Participants of this group are offered to start DBT-PE with priority after 12 weeks.

## Study burden and risks

see E9

# 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

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

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| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Single blinded (masking used) |

**Primary purpose:** Treatment

## Recruitment

NL

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|---|---|
| Recruitment status: | Will not start |
| Enrollment: | 92 |
| Type: | Anticipated |

# Ethics review

Not approved

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|---|---|
| Date: | 18-12-2017 |
| Application type: | First submission |
| Review commission: | RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden) |

# 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 | NL62862.099.17 |