Short and long term effects of clinical DBT-PE for patients with severe posttraumatic stress disorder and co-morbid psychopathology

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The current study aims to determine the effect of a 12-week residential DBT-PE program on a range of different outcomes, including the severity of PTSD, dissociation, personality disorders, and social functioning; The study also aims to predict...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Anxiety disorders and symptoms
Study type	Observational non invasive

Summary

ID

NL-OMON46167

Source
ToetsingOnline

Brief title
Effect of DBT-PE treatment for patients with severe PTSS

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: PPO Research fonds en GGZ Friesland

Intervention

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

Outcome measures

Primary outcome

The primary outcome measure is presence and severity of PTSD.

Secondary outcome

Secondary outcome measures are: severity of borderline personality disorder

symptoms, dissociative symptoms, non-suicidal selfharm, suicidal ideation,

social functioning, quality of life, care consumption.

Study description

Background summary

Until only a few years ago, we had little to offer in terms of evidence-based treatment to those suffering from severe posttraumatic stress disorder (PTSD) and co-morbid conditions such as personality disorders or substance use disorder. There was a trend to stabilize these patients before giving them trauma-focused treatment and a period of five years of ambulatory treatment was not uncommon. In 2012 the Complex Trauma Task Force of the International Society of Traumatic Stress Studies (ISTSS) proposed a stepped model with three treatment phases in the Expert Consensus Guidelines for Complex PTSD (Cloitre, et al., 2012): 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. Bicanic, De Jongh and Ten Broeke (2015), for example, argue that there is no convincing empirical evidence justifying the stabilization phase

prior to an evidence-based trauma treatment (EMDR or Trauma-focused cognitive behavioral therapy). In the Netherlands, a number of experts (Van Minnen, 2009; Jongh, et al., 2016) have also suggested that trauma-focussed therapy without prior stabilization is feasible and clinically beneficial for patients with severe PTSD. In an intensive, residential treatment program of 2 x 4 successive days consisting of a combination of exposure and Eye Movement Desensitisation and Reprocessing (EMDR), Wagenmans, Van Minnen, Sleijpen and De Jongh (2018) show that patients with severe PTSD benefit from treatment without a stabilization phase. Additionally, differentiating in type of trauma showed that this treatment was also beneficial for patients with a history of childhood sexual abuse. Another study of the group proved that treatment was effective for patients with the dissociative subtype of PTSD as well (Zoet, Wagenmans, Van Minnen and De Jongh, 2018). Clearly, patients with severe PTSD and dissociation benefit from trauma-focused treatment without a stabilization phase.

In some patients, especially those with personality disorders and profound emotional instability, deliberate self-harm and suicidal behaviour, 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 PTSD and personality disorders complicating and frustrating each other's treatment, therapists of these patients had the least to offer to those patients who needed it most, that is, until recently.

In 2013, 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 Borderline Personality Disorder (BPD). The program combines dialectical behavioural therapy (DBT), one of the best documented interventions for BPD, with prolonged exposure (PE) to trauma memories (Steil, 2011). Bohus et al. (2013) compared their intervention to a waiting list condition in a single blind randomized design. The results of the Mannheim residential program were 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.

The research group of Marsha M. Linehan, founder of the DBT method, published the results of a similar combined DBT-PE outpatient treatment program. However, with a more linear design than the Mannheim program and a treatment duration of 12 months instead of 12 weeks (Harned, Korslund, Foa & Linehan, 2012; Harned, Korslund & Linehan, 2014; Harned, Wilks, Schmidt & Coyle, 2018). 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. Patients reported significant reductions in PTSD severity

after treatment and there was no evidence of exacerbations of deliberate self-harm (Harned, et al., 2012; Harned, et al., 2014). In addition, compared to DBT alone, DBT-PE was more effective in improving health-related quality of live and global (social) functioning (Harned et al., 2018)

In contrast to this linear model, in the Mannheim protocol exposure starts regardless of the presence or absence of deliberate self-harm. This seems more in line with recent insights about offering trauma-focussed treatment without a long stabilization phase. 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. Results of Routine Outcome Measurements data of the residential DBT-PE program show that patients improved significantly on PTSD symptoms after treatment (effect size: $d=.73$, $p<0.001$).

Dropout was relatively scarce (23/241, 9.5%). This data is limited for several reasons. It is retrospective data, with a lot of missing values. Our database contained only 55 valid pre-post assessments of disease severity (DTS) in 241 patients. Of all patients that entered the program since 2014 only a small group filled in the questionnaires regularly because of administrative changes at the treatment centre.

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.

Furthermore, the cost-effectiveness of clinical DBT-PE has not been investigated before. Clinical DBT-PE is a costly intervention, as it consists of 12 weeks intensive residential care, including trauma therapy delivered by highly skilled psychotherapists. This is a costly type of care; on the other hand: this integrated treatment program may still prove less costly compared to other strategies. For example, traditional outpatient treatment (treatment as usual) with long periods of stabilization an numerous treatment sessions spread over a couple of years may in the end not be cheaper after all. The same goes for a hypothetical do-nothing strategy, where patients do not receive a disease specific treatment, but nevertheless make healthcare costs that are related to

the disease, such as hospital admissions in times of crisis etcetera.

Study objective

The current study aims to determine the effect of a 12-week residential DBT-PE program on a range of different outcomes, including the severity of PTSD, dissociation, personality disorders, and social functioning; The study also aims to predict which patients benefit most from the program and to explore cost-effectiveness of the program as compared to other strategies, including treatment as usual and a do-nothing strategy.

We differentiate between short and long term effects; short term effects are defined as the change in symptoms over the 12 weeks that the treatment program lasts, whereas long term effects are the changes at 6 and 12 months respectively. Unless specified otherwise, we look at both short and long term effects.

The short term pre vs. post changes will be compared to changes that may be seen during the waiting list period; thus participants of the study may serve as their own controls.

The main questions of the study are:
1) What is the effect of clinical DBT-PE on the severity of PTSD?
2) Which patient characteristics predict the effect of clinical DBT-PE? Possible predictors include: severity of PTSD symptoms at T0, degree of dissociation, type of trauma, borderline personality disorder, cluster C personality disorder.

Secondary questions are:
3) What is the effect of clinical DBT-PE on PTSS related phenomena like dissociation and 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 co-morbid disorders including: borderline and cluster C personality disorders?

5) How stable are the effects of clinical DBT-PE after the clinical treatment program has stopped (i.e. comparing results at 12 weeks with those at 6 and 12 months posttreatment)?

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

7) What is the incremental cost-effectiveness of clinical DBT-PE as compared to other treatment strategies including outpatient treatment as usual and a hypothetical do-nothing strategy? We will use standard cost-effectiveness simulation techniques, such as Markov modelling integrating data collected in this study with literature data and date from other sources, to answer this

question. See statistical methods for details.

Study design

We propose a pre- to posttreatment observational study, in which patients are additionally assessed at the start of the regular waiting list period. To examine the short term effects of the treatment program, we have three measurements: before waiting list period (at intake), immediately pretreatment and posttreatment (12 weeks after start of treatment). Thus, we can compare the changes during the program with the propensity of the outcomes to change over time in the absence of a disease specific intervention (i.e., waiting list). We plan additional follow up measurements at 6 and 12 months posttreatment to study long term effects. For two of the variables, we propose a more frequent sampling during the 12 week program, to be able to study the changes associated with the treatment program in more detail: The Davidson Trauma Scale (DTS) is a weekly self-report PTSD severity. Participants also use daily diary reports on non-suicidal self-injury and suicidal ideation (DBT diary). Both measures are already part of the current routine of the treatment program.

We are aware of the fact that an observational study to assess the effects of the DBT-PE program has some methodological disadvantages as compared to a randomized controlled trial (RCT). We seriously considered a RCT design and a wide range of different possible comparators. A RCT, however, has its own disadvantages and possible sources of bias, especially if the participants cannot be blinded to the condition and if intervention that is studied requires commitment of the participant, which is the case in our study. If less than 100% of potential candidates are willing to participate and many participants have strong opinions about the treatment alternatives, the results of a classical RCT may be severely biased or not representative for the target population. In a pilot study we asked 14 patients on the waiting list or during the DBT-PE treatment program whether they would have been willing to be randomized to a different treatment center with a short, intensive, clinical program purely focused on PTSD treatment (PsyTrec, Bilthoven). Only two of these patients expressed their willingness to participate in such a design. We concluded that an RCT would not be feasible on the basis of recruitment problems alone, apart from the methodological and logistical problems that we would face.

Intervention

The intervention consists of a 12-week residential program of trauma-focused treatment, in which patients are offered dialectical behavioural therapy combined with prolonged exposure (DBT-PE). DBT is developed by Linehan (Harned, 2010), specifically for people with a borderline personality disorder (BPD). The main goal of the therapy is to increase emotional and cognitive regulation by increased insight in triggers that lead (undesired) reactions and applying

appropriate coping skills. DBT has been found effective in patients with BPS (Kliem, 2010) and, among others, in survivors of childhood sexual abuse (Decker, 2010).

The other important component of the trauma therapy is prolonged exposure, which is specifically targeted at decreasing PTSD-burden. The therapy mainly consists of imaginary exposure, which is a specific type of cognitive behavioural therapy developed for the treatment of PTSD. During the imaginary exposure, the traumatic experience is repeatedly described and re-experienced. By being confronted with the traumatic experience in this way, rather that avoiding feelings and thoughts about it, emotions are weakened and patients can start to process the traumatic experience. Prolonged exposure is a very effective treatment for chronic and severe PTSD.

The 12-week residential program is 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 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 optional. 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.

Medication
Since there is no established farmacotherapeutic treatment for PTSD, nor for BPD, psychiatrists are free to follow their clinical experience. However, benzodiazepines should be avoided, because of their negative influence on cognitive functioning like memory, attendance and information processing (see for instance Hendriks 2012).

Study burden and risks

The burden associated with participation consists of in total 13,5 hours of interview time (T0: 5 hours, T1: 1 hours, T2: 0,5, T3 and T4: 3,5 hours each). We are aware this may be considered burdensome for participants. However, the questionnaires can be filled in at home on the computer in participants* own time and schedule. To furthermore decrease the burden, we will split up the interviews in multiple sessions, and the follow-up interviews will be done by telephone. Earlier studies with extensive interview time, such as the Frysian Trauma Study (Swart et al, 2017), encountered hardly any problems even though they had 8 hours of interview time per measurement.
We expect no risk of participation, as an earlier study into the effectiveness of this therapy showed no increase in self-harming behaviour or in suicidal behaviour. DBT-PE is a highly promising intervention of which participants are likely to benefit, in a much faster pace compared to care as usual.
Furthermore, most questionnaires applied in this study are part of regular diagnostics or Routine Outcome Monitoring procedures, albeit we carry out additional measurements, i.e. before the waiting list period and 6 and 12 months posttreatment.

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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 ; (3) meeting the diagnostic criteria for at least one comorbid psychiatric disorder

Exclusion criteria

Exclusion criteria for this research are current psychosis, substance dependence, a body-mass-index < 17, antisocial personality disorder, possible intellectual disability defined as a score on the screening instrument SCIL<20 (see 8.3), medical conditions contradicting the exposure protocol (their family doctor or medical specialist will be consulted whether it is safe to carry out the exposure protocol) and war veterans. For safety reasons, patients with a recent suicide attempt (in the last three months) will not be included. Because of their negative influence on cognitive functioning like memory, attendance and information processing, patients (frequently) using benzodiazepines are excluded from study participation.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	16-01-2019

Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	01-10-2018
Application type:	First submission
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)
Approved WMO Date:	05-12-2022
Application type:	Amendment
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

ID: 27279
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL66906.099.18