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Dialectical Behaviour Therapy for Post-traumatic Stress Disorder after Childhood Sexual Abuse in Patients with and without Borderline Personality Disorder: A Randomised Controlled Trial

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Key Words

Post-traumatic stress disorder · Borderline personality disorder · Childhood sexual abuse · Trauma · Dialectical behaviour therapy · Cognitive behaviour therapy · Modular treatment · Psychotherapy outcome research · Randomised controlled trial

Abstract

Background: Post-traumatic stress disorder (PTSD) with co-occurring severe psychopathology such as borderline personality disorder (BPD) is a frequent sequel of childhood sexual abuse (CSA). CSA-related PTSD has been effectively treated through cognitive-behavioural treatments, but it remains unclear whether success can be achieved in patients with co-occurring BPD. The aim of the present study was to determine the efficacy of a newly developed modular treatment programme (DBT-PTSD) that combines principles of dialectical behaviour therapy (DBT) and trauma-focused interventions. **Methods:** Female patients (n = 74) with CSA-related PTSD were randomised to either a 12-week residential DBT-PTSD programme or a treatment-as-usual wait list. About half of the participants met the criteria

for co-occurring BPD. Individuals with ongoing self-harm were not excluded. The primary outcomes were reduction of PTSD symptoms as assessed by the Clinician-Administered PTSD Scale (CAPS) and by the Posttraumatic Stress Diagnostic Scale (PDS). Hierarchical linear models were used to compare improvements across treatment groups. Assessments were carried out by blinded raters at admission, at end of treatment, and at 6 and 12 weeks post-treatment. **Results:** Under DBT-PTSD the mean change was significantly greater than in the control group on both the CAPS (33.16 vs. 2.08) and the PDS (0.70 vs. 0.14). Between-group effect sizes were large and highly significant. Neither a diagnosis of BPD nor the severity or the number of BPD symptoms was significantly related to treatment outcome. Safety analyses indicated no increase in dysfunctional behaviours during the trial. **Conclusion:** DBT-PTSD is an efficacious treatment of CSA-related PTSD, even in the presence of severe co-occurring psychopathology such as BPD.

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Introduction

Experience of childhood sexual abuse (CSA) is powerfully associated with the occurrence of mental disorders throughout the course of life [1]. In females, the highest odds ratios (ORs) are seen for the DSM-IV Axis I and Axis II disorders of alcohol and drug abuse (OR = 8.9), borderline personality disorder (BPD; OR = 7.6) and post-traumatic stress disorder (PTSD; OR = 7.25) [2]. The latter two disorders frequently co-occur, and often result in complex conditions with severe psychopathology, pervasive problems in emotion regulation, frequent non-suicidal self-injury (NSSI) and low remission rates [3–5]. Despite the frequent co-occurrence of PTSD and BPD, there is no established treatment approach for these patients. So far, there have been only three uncontrolled open-trial studies that have specifically focused on this group of patients [6–8]. Currently, dialectical behaviour therapy (DBT) is one of the best empirically supported treatments for BPD. DBT has been examined in more than a dozen randomised controlled trials (RCTs), and has been found to be superior to control conditions in reducing the primary problems it is designed to treat such as suicidal and NSSI behaviours, psychiatric hospitalisations, and emergency room visits [9]. However, standard DBT does not specifically target trauma-related features or symptoms, and has only limited effects on PTSD in patients with BPD [10, 11].

The authors of meta-analyses [12, 13] and international treatment guidelines [14–17] consistently recommend trauma-focused cognitive-behavioural therapy (CBT) for the treatment of PTSD. Specifically, exposure therapy is seen as the treatment with the strongest empirical support [14, 15]. However, patients with borderline-typical behaviours such as suicidal and NSSI behaviours are usually excluded from treatments for PTSD in general and for CSA-related PTSD in particular [12]. Accordingly, several PTSD treatment guidelines and researchers question the generalisability of results for patients with Axis II disorders, and call for more research [15–18].

CBT, in which treatments are conducted with a predefined sequence of sessions, has been shown to be efficacious in patients with CSA-related PTSD [19]. To date, there have been three RCTs that have focused exclusively on patients suffering from CSA-related PTSD [20–22], and another five in which at least half the participants reported a history of CSA [23–27]. However, six of these studies either excluded patients with co-occurring BPD [23] or did not report on treatment outcome for this subgroup [20, 22, 24, 26, 27]. In the two studies that provided details on patients with CSA-related PTSD and co-occurring BPD, one

found that all these patients dropped out of an exposure-based treatment [21], whereas the other reported that BPD was associated with an increased completion of a cognitive-behavioural stabilising group treatment [25].

For patients with borderline-typical behaviour, several PTSD treatment guidelines [16, 17] have recommended that management of suicidal and NSSI behaviours take place before trauma-focused treatment is begun. However, the exclusion of patients with current NSSI behaviours seems problematic, as many PTSD patients with co-occurring BPD exhibit NSSI behaviours in order to reduce their suffering from intrusions or dissociative states [28, 29]. Since both the manual on prolonged exposure and the standard DBT manual require the termination of NSSI behaviours before starting trauma-focused interventions [6, 30, 31], such patients would be excluded from receiving the trauma-focused treatment. A modular treatment approach should remove this exclusion criterion and allow for trauma-specific treatment to be provided to highly impaired patients as well. In contrast to a predetermined sequence of session contents, the modular approach includes different treatment modules and allows their flexible use to address the current needs of each individual patient. This is in line with the results of a recently published expert survey on the treatment of complex PTSD [32]. The experts have recommended a multi-component therapy with a set of interventions specifically tailored to specific symptoms. The training in emotion regulation and exposure interventions were judged to be the most effective components.

There are three major challenges in the treatment of PTSD and co-occurring BPD that might interfere with established treatment protocols:

(1) High levels of distress and dissociation. Patients with BPD are prone to exhibit emotional over-engagement or severe dissociative symptoms during exposure, which might inhibit emotional learning and increase dysfunctional behaviour [33–35]. Teaching and applying distress tolerance and anti-dissociative skills not only prior to but also during exposure might attenuate these problems and produce superior results compared to phase-based treatments. Attempts have already been made to merge the merits of emotion regulation and trauma-focused approaches. In a study in patients whose PTSD resulted from childhood abuse, Cloitre et al. demonstrated the superiority of additional DBT-adapted skills training over pure exposure-based trauma therapy [24]. In this study, 24% of the participants met BPD criteria; however, outcome data on the BPD subgroup were not reported. In an open-trial study by Harned et al. [6], 13 BPD patients with PTSD re-

ceived a trauma-focused exposure-based treatment in addition to an ongoing standard outpatient DBT once they had achieved control over so-called stage I treatment targets, e.g. suicidal and NSSI behaviours. Intent-to-treat analyses revealed significant improvement in post-traumatic symptoms and in most secondary outcomes, with medium to large pre-post effect sizes.

(2) Diversity of trauma-related emotions and cognitions. According to recent research, emotions such as unjustified guilt, shame, disgust and self-contempt are common features in PTSD after CSA [36–39]. However, high inter-individual diversity requires individualised specific interventions. For example, irrational guilt often requires cognitive restructuring before the patient can focus on the experience of helplessness during the traumatic event; disgust and the feeling of being contaminated require completely different interventions such as discrimination training [38, 39], and proneness to shame requires specific DBT strategies such as opposite action. A modular treatment approach, based on behavioural analyses, enables the therapist to specifically target those emotions that are sustaining the PTSD symptoms.

(3) Complexity of multiple daily life problems. Almost all traumatised patients with BPD are challenged by rapidly fluctuating daily life hassles and pervasive dysfunctional social interactions. Balancing trauma-focused interventions with the solving of daily life problems seems to be appropriate to address BPD-typical difficulties. Thus, keeping track of a session-by-session organised treatment programme often seems to be inadequate and leads to high dropout rates [21]. Principle-driven modular treatment approaches such as DBT provide decision flow charts that guide module selection and sequencing according to the current needs of patients with severe and complex clinical conditions. Results of a recent RCT in youth with multiple psychiatric disorders found that a modular treatment approach outperformed both treatment-as-usual and established treatments with a manualised sequence of sessions, thereby providing the first evidence for the usefulness of this approach [40].

Based on the encouraging results of the previous studies combining DBT and exposure [6, 23, 24], and in close cooperation with M. Linehan (Director, Behavioral Research and Therapy Clinics, University of Washington, Seattle, Wash., USA), we developed DBT-PTSD, a modification of DBT as a modular therapy approach for PTSD after CSA [8]. DBT-PTSD is specifically tailored to the needs of patients with CSA-related PTSD plus severe emotion regulation difficulties such as BPD. It is a highly structured but flexible multi-component, 12-week resi-

dential programme that is based on the principles and methods of the established and successfully evaluated standard DBT residential programme [41], and integrates trauma-focused cognitive and exposure-based interventions as described by Foa et al. [30] and Ehlers and Clark [42]. Preliminary data suggest that more intensive forms and settings may be valuable for patients with either personality disorders [43–46] or PTSD [47, 48]. The residential setting and the modular approach in DBT-PTSD permits the inclusion of patients who are still exhibiting suicidal ideation, ongoing frequent self-harm, and/or severe dissociative features. Within the DBT-PTSD programme, these high-priority problems are monitored on a regular basis and are addressed by the respective modules following the DBT hierarchy of treatment targets [31]. To maximise the efficacy, safety and acceptability of exposure-based treatment strategies, DBT-PTSD integrates the application of skills into the exposure interventions to deal with typical BPD problems such as emotional over-engagement and dissociation. The exposure protocol allows patients to control the intensity of memory activation by using previously learned skills during sessions and homework assignments (skills-assisted exposure). Finally, the treatment focuses on improvement of relevant psychosocial aspects. The results of a pilot study on the effectiveness of this residential DBT-PTSD programme were recently published [8]. This study, which looked at 29 consecutively admitted women suffering from PTSD related to CSA, revealed a large effect size in self-reported PTSD symptomatology (Cohen's $d = 1.22$) and excellent tolerability, with all patients completing the treatment.

Our aims in the current study were to assess the effect of the DBT-PTSD programme on PTSD symptoms in subjects suffering from CSA-related PTSD with or without co-occurring BPD, to test the impact of BPD severity on the therapeutic outcome, and to test the hypothesis that this treatment is superior to a treatment-as-usual wait-list (TAU-WL) condition (trial registration: ClinicalTrials.gov, number NCT00481000).

Methods

Participants

All participants in this study had been referred by their local psychiatrists for residential treatment at the Department of Psychosomatic Medicine and Psychotherapy at the Central Institute for Mental Health, Mannheim, due to treatment-resistant PTSD. Enrolment was restricted to women. Other inclusion criteria included being aged 17–65 years and meeting a DSM-IV-defined diagnosis of PTSD that was related to CSA. CSA had to be the index trauma leading to PTSD and was defined as a sexual assault that had to occur

under the age of 18 and had to fulfil the PTSD A criterion [49]. Additionally, participants had to meet at least one of the following conditions: current eating disorder, current major depressive disorder, current substance abuse, or meeting ≥ 4 DSM-IV criteria for BPD. Based on our previous studies, we estimated that about 50% of the referred population would meet the full DSM-IV criteria for BPD.

Exclusion criteria included a lifetime diagnosis of schizophrenia, current substance dependence, body mass index < 16.5 , intellectual disability, and medical conditions contradicting the exposure protocol (e.g. severe cardiovascular disorders). For safety reasons, we also excluded individuals who had evidenced a life-threatening behaviour within the last 4 months as assessed by the Severe Behaviour Dyscontrol Interview (SBD-I) [50]. Those individuals were referred to standard DBT treatment. Individuals with ongoing self-harm or other high-risk behaviours were not excluded.

All participants provided written informed consent. Approval was obtained from the independent Ethics Committee of the Medical Faculty Mannheim at Heidelberg University.

Assessments

The Structured Clinical Interview for DSM-IV Axis I Disorders (SCID-I) and the International Personality Disorder Examination (IPDE) were administered by clinician raters to diagnose Axis I and II disorders [49, 51]. Inter-rater reliability was satisfactory (SCID-I: kappa 0.76; IPDE Borderline section: kappa 0.75). The Wechsler Adult Intelligence Scale was used to rule out intellectual disability [52].

The primary outcome measures were scores on the Clinician-Administered PTSD Scale (CAPS) and the self-rating Posttraumatic Stress Diagnostic Scale (PDS) [53, 54]. Both scales were assessed with regard to the CSA event that was currently causing the highest distress (index trauma).

Secondary outcomes were scores on standard self-report measures of psychopathology and social functioning: the Borderline Symptom List (BSL), the short version of the Dissociative Experiences Scale (DES; German version FDS-20), the Beck Depression Inventory-II (BDI-II), the Global Assessment of Functioning (GAF) and the Symptom Checklist-90 – Revised (SCL-90R) [55–59].

Procedures

The trial was conducted at a single centre. Data were collected at admission (t1), and at 12 weeks (t2), 18 weeks (t3) and 24 weeks (t4), which corresponded to the time points of discharge, 6 weeks post-discharge and 12 weeks post-discharge for the DBT-PTSD group.

After completion of assessment procedures, eligible participants were randomly assigned in a 1:1 ratio to either the DBT-PTSD arm or the TAU-WL arm. Participants and all persons involved in the study were blinded to treatment assignment until written informed consent had been obtained, and the clinicians who conducted the post-treatment assessments remained blinded to treatment assignment throughout the study.

Participants assigned to the DBT-PTSD arm were admitted to residential care as soon as possible after enrolment (mean = 22.92 days, SD = 13.44). Those assigned to the TAU-WL arm received any treatment they chose except for DBT-PTSD.

Interventions

DBT-PTSD. The treatment followed the protocol described in the pilot study [8]. DBT-PTSD is a multi-component modular treatment programme. It is conducted as a 12-week residential pro-

gramme. Its goals are to help patients achieve the following: (1) reduce their fear of trauma-associated primary emotions such as fear, disgust and powerlessness, (2) question non-justified secondary emotions such as guilt, shame and self-contempt and (3) radically accept trauma-related biographic facts. Exposure-based techniques are applied to reduce fear of trauma-associated emotions. DBT-PTSD is composed of three treatment phases, which are based on one another and ideally are applied in the following order: (1) from week 1 to week 4, patients learn to identify their typical cognitive, emotional and behavioural escape strategies. Based on these individualised behavioural analyses, they learn to use specific DBT skills to control these behaviours, and they receive psychoeducation; (2) the period from week 5 to week 10 comprises trauma-focused cognitive and exposure-based interventions. If patients exhibit strong dissociative features, they are trained to use specific skills in order to balance the memory activation and the awareness of being in the present (skills-assisted exposure), and (3) weeks 11 and 12 focus on radical acceptance of trauma-related facts and on psychosocial aspects.

Each of these phases includes a set of different modules. For example, there is one module for reducing dissociative symptoms, one for modifying guilt and one for treating nightmares. The composition of the modules within these phases follows decision flow charts, based on individual behavioural analyses. These decision flow charts mainly build on the hierarchy of treatment targets of Linehan [31], in which life-threatening behaviours are always prioritised, followed by treatment-interfering behaviours and then by quality-of-life-interfering behaviours. In close cooperation with Linehan, we tailored this hierarchy specifically for patients with PTSD. It is based on the principle that only those problems that either jeopardise the life or health of the patient (e.g. strong suicidal ideation, severe NSSI, severe high-risk behaviour) or impair the efficacy of exposure techniques (e.g. dissociation, severe depressive symptoms, motivational problems, severe shame) will be attended prior to using exposure techniques. Accordingly, suicidal and NSSI urges are monitored by the patients on a daily basis. Whenever severe dysfunctional behaviour or strong suicidal urges appear, treatment targets are reorganised, prioritising life-threatening or therapy-interfering behaviour.

Participants received twice-weekly 45-min sessions of individual treatment (a total of 23 sessions over the 12 weeks) plus the following weekly group treatments: 90 min of skills training (11 sessions in total), 60 min of group intervention focusing on self-esteem (8 sessions in total), three 25-min mindfulness sessions (35 sessions in total) and 60 min of PTSD-specific psychoeducation (11 sessions in total). They additionally attended three 90-min non-specific weekly group interventions (music therapy, art therapy). The individual treatment sessions were delivered by four clinical psychologists. Therapists were graduate and post-graduate psychologists who had been trained in DBT by a senior DBT trainer (M.B.) and in trauma-focused CBT by a senior trainer of the German Association of Psychotraumatology (R.S.). All therapists were involved in the treatment development and had each conducted at least four training cases. All individual sessions were videotaped. Video-based live online supervision was provided weekly by M.B. and R.S. to ensure therapists' adherence and competence.

TAU-Wait List. Participants randomised to the TAU-WL group received 6 months of any treatment of their choice except for DBT-PTSD. They were allowed to contact study management for supportive counselling. At the end of the study period, they were offered DBT-PTSD treatment.

Medication

Since there is no established psychotropic medication procedure for PTSD, psychiatrists in both treatment arms were free to follow their clinical experience. Psychotropic medication was carefully monitored (online suppl. table 1; for all online suppl. material, see www.karger.com/doi/10.1159/000348451).

In the DBT-PTSD group, sleep disorders were treated with antidepressants or prazosin, and major depressive episodes were treated with selective serotonin reuptake inhibitors. No patients were treated with benzodiazepines.

Statistical Analysis

Mixed-effect models were chosen as the primary strategy for analysing repeated-measures data. For continuous outcome data, hierarchical linear models with random slopes and intercepts were used to test whether the decline over time was more pronounced under DBT-PTSD compared to the TAU-WL group (group \times time interaction). Besides the interaction term, all models included the main effects of time (in weeks) and group (coded as 1 = DBT-PTSD, 0 = TAU-WL). For analyses of count data such as the number of BPD criteria, generalised mixed models were used. The estimations in the mixed effects models were carried out using SASTM (v.9.2) PROC MIXED. *p* values ≤ 0.05 (two-tailed) were considered statistically significant.

On an exploratory level, we further tested whether a diagnosis of BPD and BPD symptom severity was related to treatment response. We also investigated whether the severity of BPD symptoms was related to improvement in severity of PTSD over time by introducing the BSL total score at study entry as an additional independent variable. To further explore a possible relation between severity of BPD and treatment outcome, an alternative model was set up that included the number of BPD criteria (as assessed by the IPDE) instead of the BSL total score. In addition, we tested for a possible relation between severity of BPD and treatment outcome under DBT-PTSD by restricting these analyses to the active treatment group.

Treatment response was defined as a reduction of at least 30 points in the CAPS score [60]. For a categorical diagnosis of PTSD, a symptom was considered present if the frequency score was at least 1 (meaning one or two occurrences in the last month) and the intensity score was at least 2 (meaning moderate intensity) [53]. Remission was defined as not meeting DSM-IV PTSD criteria any longer according to the CAPS. Dichotomous data such as the treatment response and remission were compared across treatment groups using Fisher's exact test. For quantification of between-group differences in improvement over time, Hedges' *g* effect sizes were calculated. Hedges' *g* is asymptotically equivalent to Cohen's *d* but provides a more accurate estimate.

Several strategies were used to address potential effects of missing data. We followed the recommendation on the analysis of missing data in studies of PTSD issued by the Institute of Medicine to use a modern approach such as hierarchical regression models to minimise bias which might arise from missing data [15]. We chose mixed models as the primary method of data analysis as these models allow for including all cases, even if some data are missing. We further tested whether missing data were informative versus ignorable by applying a pattern-mixture approach as described by Hedecker and Gibbons [61]. Accordingly, we tested whether the addition of (1) the completer status, (2) the completer status \times time interaction, and (3) the 3-way interaction between completer status, time and group would significantly contribute to the core mod-

el. On the level of effect sizes, we calculated the effect both for just those patients who completed the study according to protocol and for the intention-to-treat population, which included all patients. For the intention-to-treat effect sizes, we chose a conservative approach (last observation carried forward). In a context where the improvement is more pronounced in the active treatment group than in the control group, these effect sizes give a conservative estimate of the between-group effect. Furthermore, they facilitate comparisons with previous studies – as pointed out by the Institute of Medicine, the last observation carried forward approach is the most common way in which missing values have been handled in the literature on treatment of PTSD [15]. The sample size of 82 patients was chosen to achieve adequate statistical power ($1 - \beta = 0.8$) for detecting a large effect ($f = 0.4$) for the group \times time interaction with a dropout rate of about 10–15%. The assumptions were based on our pilot data [8]. The power analysis was carried out using the O'Brien-Shieh algorithm implemented in GPowerTM (v.3.1.2) [62].

Results

Patient Flow, Missing Analysis

Of 176 patients who were referred for residential treatment within the recruitment period (April 2007 to December 2009), 82 were found to be eligible for participation in the study and were randomly assigned to either DBT-PTSD (*n* = 43) or TAU-WL (*n* = 39) (online suppl. fig. 1). Of the 94 patients who were not included in the study, 13 did not complete the assessment, 30 did not meet all inclusion criteria (14 did not meet criteria for PTSD related to CSA, and 16 did not meet at least 1 of the co-occurring conditions), 18 met at least 1 exclusion criterion (11 had had a life-threatening behaviour within the last 4 months, and 7 met other exclusion criteria), and 33 chose not to participate.

Of the 82 patients who were randomised, 5 patients (DBT-PTSD, *n* = 4; TAU-WL, *n* = 1) decided within 3 days after randomisation to not begin treatment, and were defined as non-starters and not included in the analyses. An additional 3 patients were excluded from the study within the first 3 days due to protocol violations: 1 suffered from a severe cardiovascular disorder, 1 was found to not fulfil the DSM-IV PTSD criteria, and 1 refused to complete any questionnaires. A total of 74 participants (DBT-PTSD, *n* = 36; TAU-WL, *n* = 38) started the allocated intervention (intention-to-treat sample). Two individuals randomised to the DBT-PTSD arm dropped out before exposure started, and 3 randomised to the TAU-WL arm dropped out of treatment and refused further assessment.

The addition of (1) completer status, (2) completer status \times time interaction and (3) the 3-way interaction between completer status, time and group was not statistically significant for either the primary or secondary out-

Table 1. Baseline characteristics

	Whole sample (n = 74)		≥5 BPD criteria (n = 33)		<5 BPD criteria (n = 41)	
	DBT-PTSD (n = 36)	TAU-WL (n = 38)	DBT-PTSD (n = 17)	TAU-WL (n = 16)	DBT-PTSD (n = 19)	TAU-WL (n = 22)
Age, years	35.14 (10.60)	36.71 (9.84)	31.76 (9.51)	33.06 (6.98)	38.16 (10.85)	39.36 (10.88)
p values		0.47 ^a		0.37 ^a		0.70 ^a
Years of education	12.69 (2.65)	12.18 (2.18)	13.18 (2.86)	12.25 (2.02)	12.26 (2.45)	12.14 (2.34)
p values		0.46 ^a		0.45 ^a		0.80 ^a
Number of Axis I disorders – current	3.03 (1.03)	3.00 (1.16)	2.94 (1.03)	2.81 (1.17)	3.11 (1.05)	3.14 (1.17)
p values		0.90 ^a		0.82 ^a		1.00 ^a
Number of BPD criteria	4.18 (1.66)	3.94 (2.07)	5.56 (0.84)	6.07 (1.07)	2.94 (1.16)	2.59 (1.22)
p values		0.93 ^a		0.85 ^a		0.95 ^a
Age at first sexual abuse, years	7.56 (4.0)	7.59 (4.1)	5.50 (2.59)	7.33 (4.05)	9.17 (4.37)	7.79 (4.24)
p values		1.00 ^a		0.23 ^a		0.34 ^a
<i>Duration of childhood sexual abuse</i>						
Singular incident, %	12.9	14.7	7.1	13.3	17.6	15.8
Up to 5 years, %	38.8	41.1	21.4	46.7	53.0	53.0
Longer than 5 years, %	48.4	44.1	71.4	40.0	29.4	47.4
p values		1.00 ^b		0.51 ^b		0.99 ^b
<i>Further characteristics of childhood sexual abuse</i>						
Relative as an abuser, %	85.3	74.3	88.2	75.0	82.3	73.7
p values		0.37 ^c		0.40 ^c		0.70 ^c
Sexual stimulation with penetration, %	74.3	77.8	68.8	68.8	78.9	85.0
p values		0.79 ^c		0.65 ^c		0.70 ^c

Data are expressed as mean (SD), or as number (%).

^a Mann-Whitney U test. ^b Kolmogorov-Smirnov test. ^c Fisher's exact test.

comes (all p values > 0.1). Accordingly, there was no evidence that missing data might have biased the results from our mixed model analyses.

Participant Characteristics

With respect to participant characteristics, there were no significant differences between the DBT-PTSD group and the TAU-WL groups or between treatment completers and non-completers. On average, participants met 4.18 (SD = 1.66) BPD criteria. A diagnosis of BPD, defined as meeting at least 5 of the 9 DSM-IV BPD criteria, was fulfilled by 33 (44.6%) of the 74 evaluable participants: 17 in the DBT-PTSD arm and 16 in the TAU-WL arm. The average number of current Axis I disorders was 3.01 (SD = 1.09), with 59 participants (79.7%) meeting the diagnostic criteria for major depressive disorder.

The mean reported age at the time of the first sexual abuse was 7.6 years, with a range of 2–17 years, and in many cases the abuse had lasted longer than 5 years (46%), included penetration (76%), and was inflicted by a relative (80%).

A history of one or more events of NSSI behaviours during the 18 weeks prior to randomisation was reported

by a total of 70% of participants (median 6.0, range 1–120), with a rate of 75% (median 6.5, range 1–120) in the DBT-PTSD group and of 64.6% (median 4.0, range 1–90) in the TAU-WL group. Further baseline clinical and sociodemographic data are shown in table 1.

Treatment Delivery

Patients in the DBT-PTSD group received on average 12.5 weeks of residential treatment, with a mean number of 25.0 individual treatment sessions. Approximately one quarter of the individual sessions were dedicated to exposure techniques.

Of the 38 TAU-WL participants, 94.7% (n = 36) received psychosocial and/or pharmacological treatments (outpatient psychological treatment 52.6%, n = 20; residential treatment 23.7%, n = 9; pharmacological treatment 89.5%, n = 34).

Treatment Effects

The mean change on the CAPS scores was greater in the DBT-PTSD group than in the TAU-WL group (33.16 vs. 2.08; table 2). Accordingly, the slope of linear im-

Table 2. Treatment results: primary outcome data

Measurement	Available data		ITT data	
	DBT-PTSD (n = 29)	TAU-WL (n = 29)	DBT-PTSD (n = 36)	TAU-WL (n = 38)
<i>Whole sample (n = 74)</i>				
CAPS				
Pre-treatment	87.92 (14.20)	82.63 (18.20)	87.92 (14.20)	82.63 (18.20)
12 weeks (discharge)	57.24 (25.49)	82.73 (17.19)	60.31 (26.79)	83.53 (16.50)
18 weeks (follow-up)	53.07 (21.44)	79.03 (22.98)	57.47 (25.66)	79.74 (21.67)
24 weeks (follow-up)	54.76 (24.05)	80.55 (19.89)	58.50 (24.20)	80.21 (19.21)
Hedges' g (between groups; t1–t4)		1.60		1.35
PDS				
Pre-treatment	2.22 (0.44)	2.09 (0.45)	2.22 (0.44)	2.09 (0.45)
12 weeks (discharge)	1.61 (0.67)	2.02 (0.47)	1.61 (0.64)	2.09 (0.46)
18 weeks (follow-up)	1.52 (0.49)	2.00 (0.48)	1.53 (0.55)	2.05 (0.47)
24 weeks (follow-up)	1.52 (0.67)	1.95 (0.43)	1.53 (0.65)	2.00 (0.42)
Hedges' g (between groups; t1–t4)		0.98		1.00
≥ 5 BPD criteria (n = 33)	(n = 14)	(n = 13)	(n = 17)	(n = 16)
CAPS				
Pre-treatment	85.06 (15.61)	86.44 (16.04)	85.06 (15.61)	86.44 (16.04)
12 weeks (discharge)	61.44 (25.92)	82.77 (17.55)	63.29 (26.23)	85.19 (16.70)
18 weeks (follow-up)	57.15 (23.49)	84.69 (19.89)	54.53 (25.66)	84.56 (19.16)
24 weeks (follow-up)	49.64 (24.89)	88.46 (13.91)	54.06 (25.80)	85.75 (14.81)
Hedges' g (between groups; t1–t4)		1.86		1.50
PDS				
Pre-treatment	2.23 (0.44)	2.22 (0.44)	2.23 (0.44)	2.22 (0.44)
12 weeks (discharge)	1.69 (0.72)	2.12 (0.50)	1.71 (0.70)	2.12 (0.49)
18 weeks (follow-up)	1.54 (0.62)	2.05 (0.47)	1.48 (0.60)	2.11 (0.45)
24 weeks (follow-up)	1.50 (0.70)	2.01 (0.42)	1.52 (0.69)	2.05 (0.41)
Hedges' g (between groups; t1–t4)		0.87		0.85
< 5 BPD criteria (n = 41)	(n = 15)	(n = 20)	(n = 19)	(n = 22)
CAPS				
Pre-treatment	90.53 (12.62)	80.14 (19.73)	90.47 (12.67)	79.86 (19.51)
12 weeks (discharge)	53.29 (25.21)	82.70 (17.41)	57.63 (27.71)	82.32 (16.63)
18 weeks (follow-up)	50.14 (19.59)	75.58 (24.88)	60.11 (26.07)	76.23 (23.12)
24 weeks (follow-up)	60.07 (22.87)	75.40 (21.76)	62.47 (22.63)	76.18 (21.00)
Hedges' g (between groups; t1–t4)		1.34		1.17
PDS				
Pre-treatment	2.22 (0.46)	2.00 (0.43)	2.22 (0.46)	2.00 (0.43)
12 weeks (discharge)	1.54 (0.63)	2.03 (0.46)	1.53 (0.59)	2.07 (0.45)
18 weeks (follow-up)	1.51 (0.35)	1.97 (0.50)	1.58 (0.51)	2.00 (0.49)
24 weeks (follow-up)	1.57 (0.67)	1.90 (0.44)	1.54 (0.64)	1.97 (0.44)
Hedges' g (between groups; t1–t4)		1.01		1.08
Data are expressed as mean (SD). ITT = Intent-to-treat.				

provement was significantly steeper in patients who had been randomised to DBT-PTSD compared to those randomised to TAU-WL. The hierarchical linear model indicated an average differential weekly decline of -1.138 ± 0.195 points on the CAPS in favour of DBT-PTSD ($p <$

0.001; online suppl. table 2). Both subgroups in the DBT-PTSD arm (i.e. meeting either ≥ 5 or < 5 BPD criteria) showed significantly better weekly improvement in comparison to the control group (-1.510 ± 0.249 , $p < 0.001$ and -0.496 ± 0.234 , $p = 0.038$, respectively). Anal-

Table 3. Treatment results: secondary outcome data (ITT)

Measurement	Whole sample (n = 74)		≥5 BPD criteria (n = 33)		<5 BPD criteria (n = 41)	
	DBT-PTSD (n = 36)	TAU-WL (n = 38)	DBT-PTSD (n = 17)	TAU-WL (n = 16)	DBT-PTSD (n = 19)	TAU-WL (n = 22)
GAF						
Pre-treatment	41.50 (4.50)	42.79 (7.19)	41.88 (4.34)	39.44 (6.31)	41.16 (4.72)	45.23 (6.91)
12 weeks (discharge)	49.44 (8.40)	43.79 (7.51)	47.88 (7.80)	40.88 (6.64)	50.84 (8.87)	45.91 (7.52)
18 weeks (follow-up)	51.33 (7.88)	42.92 (8.00)	50.12 (7.54)	38.75 (6.06)	52.42 (8.22)	45.82 (8.20)
24 weeks (follow-up)	51.08 (9.89)	42.92 (8.00)	49.94 (11.46)	39.31 (5.58)	52.11 (8.43)	45.55 (8.56)
Hedges' g (between groups; t1–t4)		1.02		0.80		1.21
BSL						
Pre-treatment	2.18 (0.69)	2.27 (0.67)	2.13 (0.69)	2.56 (0.62)	2.22 (0.71)	2.04 (0.63)
12 weeks (discharge)	1.57 (0.75)	2.17 (0.70)	1.74 (0.76)	2.40 (0.71)	1.41 (0.73)	2.00 (0.66)
18 weeks (follow-up)	1.62 (0.75)	2.03 (0.73)	1.68 (0.71)	2.28 (0.80)	1.57 (0.80)	1.86 (0.64)
24 weeks (follow-up)	1.62 (0.77)	2.03 (0.74)	1.73 (0.83)	2.35 (0.56)	1.52 (0.71)	1.80 (0.79)
Hedges' g (between groups; t1–t4)		0.52		0.28		0.65
DES (FDS-20)						
Pre-treatment	31.39 (16.78)	26.90 (17.05)	33.99 (14.98)	34.21 (18.74)	28.92 (18.41)	21.34 (13.60)
12 weeks (discharge)	20.83 (13.44)	26.58 (14.91)	24.35 (14.79)	30.80 (14.68)	17.68 (11.60)	23.51 (14.64)
18 weeks (follow-up)	20.40 (12.55)	25.97 (17.68)	24.38 (14.56)	30.46 (18.94)	16.84 (9.45)	22.71 (16.38)
24 weeks (follow-up)	20.65 (15.55)	24.30 (16.75)	24.65 (17.82)	28.83 (15.43)	17.08 (12.63)	21.01 (17.24)
Hedges' g (between groups; t1–t4)		0.50		0.30		0.62
BDI-II						
Pre-treatment	38.00 (9.75)	39.53 (9.13)	38.74 (8.20)	38.32 (9.48)	38.74 (8.21)	38.32 (9.48)
12 weeks (discharge)	26.81 (11.45)	40.55 (10.59)	25.32 (11.79)	41.75 (9.31)	25.32 (11.79)	39.68 (11.56)
18 weeks (follow-up)	28.56 (10.62)	40.18 (11.10)	28.05 (11.15)	41.75 (11.62)	28.05 (11.15)	39.05 (10.83)
24 weeks (follow-up)	29.47 (12.61)	37.87 (12.62)	28.74 (12.49)	39.38 (12.50)	28.74 (12.48)	36.77 (12.90)
Hedges' g (between groups; t1–t4)		0.70		0.47		0.90
SCL-90 – Revised						
Pre-treatment	1.90 (0.66)	2.01 (0.58)	1.80 (0.66)	2.05 (0.56)	1.99 (0.67)	1.97 (0.59)
12 weeks (discharge)	1.39 (0.63)	1.94 (0.64)	1.45 (0.67)	1.97 (0.66)	1.33 (0.60)	1.92 (0.63)
18 weeks (follow-up)	1.38 (0.63)	1.81 (0.70)	1.34 (0.61)	1.88 (0.81)	1.42 (0.66)	1.76 (0.64)
24 weeks (follow-up)	1.41 (0.63)	1.73 (0.69)	1.44 (0.63)	1.91 (0.59)	1.39 (0.65)	1.61 (0.75)
Hedges' g (between groups; t1–t4)		0.36		0.38		0.39
IPDE-BPD criteria						
Pre-treatment	4.22 (1.64)	4.00 (2.03)	5.59 (0.80)	5.94 (1.06)	3.00 (1.16)	2.59 (1.22)
12 weeks (discharge)	2.67 (1.87)	3.55 (2.06)	3.24 (2.14)	4.62 (1.67)	2.16 (1.46)	2.77 (2.00)
18 weeks (follow-up)	3.00 (1.51)	3.50 (2.31)	3.47 (1.63)	4.75 (1.92)	2.58 (1.31)	2.59 (2.18)
24 weeks (follow-up)	2.61 (1.71)	3.24 (2.14)	2.88 (2.03)	4.62 (2.19)	2.37 (1.38)	2.23 (1.45)
Hedges' g (between groups; t1–t4)		0.43		0.63		0.18

Data are expressed as mean (SD). ITT = Intent-to-treat.

yses that included either the number of BPD criteria or the BSL total score at study entry as independent variables revealed no significant relation between these variables and linear improvement under DBT-PTSD with respect to CAPS scores ($p = 0.92$ and 0.44 , respectively, for the time \times severity interactions). The group \times time interactions remained significant ($p < 0.001$ in both models).

Similarly, the mean change on the PDS was greater in the DBT-PTSD group than in the control group (0.70 vs. 0.14). Accordingly, the group \times time interaction in the hierarchical linear model was also significant for PDS scores, indicating a more pronounced improvement in the treatment group compared to the control group (-0.021 ± 0.006 , $p < 0.001$). Again, this effect was significant within both subgroups of the sample ($-0.026 \pm$

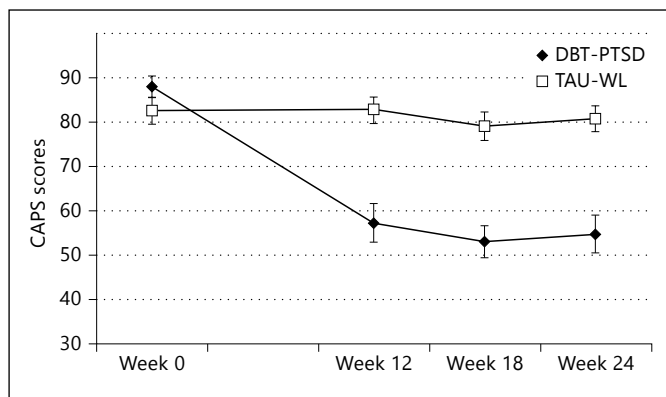


Fig. 1. Change of CAPS scores in DBT-PTSD and TAU-WL. Means and standard errors in the DBT-PTSD and TAU-WL groups at randomisation (Week 0), at 12 weeks (DBT-PTSD: discharge; TAU-WL: 12 weeks after study start), and at the follow-up assessments (weeks 18 and 24).

0.009, $p = 0.007$ and -0.016 ± 0.008 , $p = 0.043$, respectively). Both the number of BPD criteria and the BSL total score at study entry were not significantly related to linear improvement in PDS scores under DBT-PTSD ($p = 0.50$ and 0.07 for the time \times severity interactions), while the group \times time interactions remained significant ($p \leq 0.001$ for both the group \times time interactions).

Results for the secondary outcome measures were mixed (table 3 for intent-to-treat data; online suppl. tables 2 and 3 for additional results). With respect to the BDI and the GAF, patients in the DBT-PTSD group showed significantly more improvement than did those in the TAU-WL group; however, they did not show statistically better improvements on the SCL-90-R, the DES, the BSL, and the number of BPD criteria. Between-group effect sizes were large for the primary outcome measures, and ranged from small to large for the secondary outcome measures (fig. 1; tables 2, 3). Results were confirmed for both the BPD and non-BPD subgroups.

Significantly more patients in the DBT-PTSD arm showed a response to treatment in comparison to patients in the TAU-WL arm [38.9% ($n = 14$) vs. 2.6% ($n = 1$), $p < 0.001$]. Within the subgroups of patients with co-occurring BPD, the respective rates were 29.4% ($n = 5$) for DBT-PTSD versus 0.0% for TAU-WL ($p = 0.039$).

At t4 (12 weeks post-DBT-PTSD treatment), significantly more patients in the DBT-PTSD group were remitted compared to the TAU-WL group [38.9% ($n = 14$) vs. 10.5% ($n = 4$), $p = 0.0018$]. Superiority with respect to

remission rates was also found within the subgroups of patients meeting diagnostic criteria of BPD [41.2% ($n = 7$) for DBT-PTSD vs. 0.0% for TAU-WL, $p = 0.0058$].

Adverse Effects

None of the participants in the DBT-PTSD group versus 6 participants in the TAU-WL group showed worsening of PTSD symptoms during the study period (fig. 2). No suicide attempts were observed during the study. At admission to the DBT-PTSD ward, 61.8% ($n = 21$) of the patients reported NSSI behaviours; this rate dropped to 20.6% ($n = 7$) within the first 3 weeks after admission, and remained constant during the exposure treatment. Suicidal ideation did not accelerate during treatment (table 4).

Medication

There were no significant correlations between change of medication and treatment outcome (online suppl. table 4).

Discussion

This study looked at the efficacy of a newly developed modular residential treatment approach for women with CSA-related PTSD, about half of whom had co-occurring BPD. The two primary outcome measures, reduction of PTSD symptoms as assessed by the CAPS and by the PDS, revealed significantly more improvement in the DBT-PTSD group compared with a TAU-WL control, with large between-group effect sizes. Responses to treatment, defined as a reduction of at least 30 points on the CAPS score, were seen in 39% of the DBT-PTSD patients compared to just 3% of the TAU-WL patients, and remission from PTSD as assessed with the CAPS was achieved by 39 versus 11%, respectively.

Regarding the secondary outcome measures, improvements were seen in global social functioning and depression. However, DBT-PTSD treatment was not superior to TAU-WL on other symptomatic measures such as the SCL-90-R, the DES and the BSL. The corresponding between-group effect sizes were mostly small to medium.

Subgroup analyses revealed that significant between-group differences were evident for patients both with and without a diagnosis of BPD, with quite similar effect sizes. According to further analyses, neither the number of BPD criteria nor the severity of borderline symptoms as assessed with the BSL was related to treatment outcome.

For the sake of external validity, we reduced the exclusion criteria of this study to a minimum, resulting in a pop-

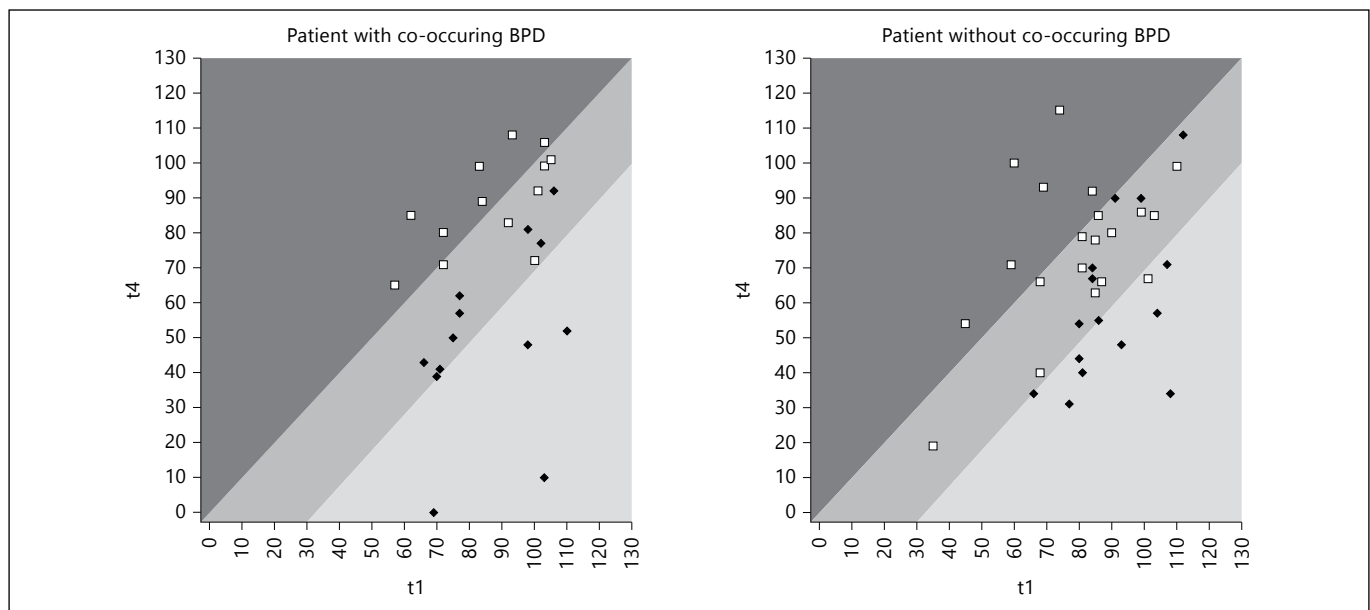


Fig. 2. Change of CAPS scores (at t1-t4) in PTSD patients with and without co-occurring BPD randomised to either DBT-PTSD or TAU-WL. Diamonds = DBT-PTSD; squares = TAU-WL; light grey area = response criterion fulfilled (improvement by at least 30

points on the CAPS); medium grey = numerical improvement without meeting the response criterion; dark grey = numerical deterioration.

Table 4. Rate of NSSI behaviours and intensity of suicidal ideation in completers of DBT-PTSD

	Pre-treatment	Treatment weeks 1–3	Treatment weeks 4–6	Treatment weeks 7–9	Treatment weeks 10–12
NSSI behaviours					
All (n = 34)	21 (61.8)	7 (20.6)	8 (23.5)	7 (20.6)	6 (17.7)
≥5 BPD criteria (n=16)	14 (87.5)	4 (25.0)	5 (31.3)	4 (25.0)	4 (25.0)
<5 BPD criteria (n = 18)	7 (38.9)	3 (16.7)	3 (16.7)	3 (16.7)	2 (11.1)
Suicidal ideation					
All (n = 34)		0.78±1.00	0.70±1.00	0.83±0.92	0.81±0.99
≥5 BPD criteria (n = 16)		0.74±0.92	0.65±0.81	0.72±0.69	0.91±0.88
<5 BPD criteria (n = 18)		0.82±1.12	0.74±1.18	0.93±1.09	0.74±1.08

Data are expressed as number (%), or as mean ± SD. NSSI: Percentage of patients completing treatment who show NSSI. Suicidal ideation is rated on a 6-point Likert scale ranging from 0 to 5 (uncontrollable suicidal ideas). Mean values of patients completing the treatment are shown. For suicidal ideation, we tested whether the numerical changes were significant by applying the Friedman test. All p values were ≥ 0.80.

ulation with high levels of reported traumatic experience, previous treatments, NSSI behaviours and PTSD symptom severity. In the year before randomisation, 67% of participants reported admission to inpatient psychiatric care where they had spent on average 87.31 days. At randomisation, the mean scores of the CAPS and BDI were 85 and 39, respectively, compared to scores of about 65 and 20 in

the other currently published RCTs [20, 24] that looked at CBT treatment for CSA-associated PTSD. These high baseline scores might explain the relatively low remission rate. We wish to emphasise that even though about 50% of the patients showed clinically relevant responses, the majority still needed further psychosocial support. In addition, the contrast between the large improvements in post-

traumatic symptomatology and the small to medium effect sizes on secondary outcomes indicate that this PTSD-specific treatment is only one treatment module for these highly symptomatic patients. This is in line with the findings by Harned et al. [6], who found no significant change in measures of depression and anxiety in BPD patients with PTSD at 3 months post-treatment.

With respect to safety, the data did not reveal an increase in dysfunctional behaviour or suicidal ideation either during or after exposure therapy. Thus, our findings contradict the clinical concern that patients with severe dysfunctional behaviour should not be confronted with exposure-based treatments.

Caution is required regarding interpretation of the results. First, the treatment was designed for and was applied under residential conditions, and the participating staff were highly experienced and well trained, having collectively treated about 120 patients with these diagnoses prior to this study. Such a level of experience should be considered in discussing external validity. Replication of the results by independent research teams is currently being conducted.

The same holds true for the safety issues. As reported, we did not find worsening of PTSD symptoms or acceleration of dysfunctional behaviour, including NSSI behaviours or suicide attempts, during the treatment. This may also be due to the specific modular treatment approach, to residential conditions, or to both. As, to our knowledge, we are the first to systematically apply exposure therapy to patients with such a high level of dysfunctional behaviour, for safety reasons we conducted the study under residential conditions.

We are aware that such residential treatment is cost intensive and that in many countries inpatient treatment is only offered as a short-term crisis intervention. However, this type of residential or day treatment programme is still quite common in Europe, especially in Germany. Long-term analyses of the treatment group will be necessary to answer whether the costs will be exceeded by the possible savings due to reduced hospitalisation and increased employment rate. Bartak et al. [43–45] compared different treatment modalities for patients with personality disorders in a non-experimental study in the Netherlands, and results favoured inpatient treatment over other treatment modalities. The findings suggest that such a high level of care may provide the greatest potential for these highly symptomatic patients. Future studies should address whether the possible benefits of an inpatient treatment compared to other treatment modalities are worth the short-term costs [46].

DBT-PTSD is a comprehensive modular treatment programme that includes a psychoeducation programme, skills training, mindfulness sessions, and exposure-based individual sessions; it remains unclear which of these ingredients are necessary for its success. The same is true for the newly developed component of ‘skills-assisted exposure’, which differs from standard prolonged exposure by either skills-driven enhancement or attenuation of the experienced emotions in order to facilitate context-related revision of biographic traumatic experience. Further dismantling studies will show whether these modifications are needed or not.

Finally, we are aware that the control condition (TAU-WL) is not a strong comparison group, even though almost all patients received standard care. It cannot be ruled out that non-specific variables such as group cohesion, residential care, etc. had a strong effect. However, several studies that compared trauma-specific treatment including psychoeducation and affect regulation training under comparable residential conditions and a wait-list control group revealed only small to medium between-group effect sizes in patients whose PTSD resulted from childhood trauma [63–65].

Considering these limitations, we state that this newly developed modular treatment approach is the first to be shown to be both effective and safe for patients with CSA-related PTSD and co-occurring BPD including current self-harming behaviour. Utilisation of the treatment under outpatient conditions will be the next step.

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Disclosure Statement

DBT-PTSD will be published as a manual and is distributed by workshops for which M.B., R.S., K.P., A.D. and A.K. receive income.

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