Treating Adults With a Dual Diagnosis of Borderline Personality Disorder and Posttraumatic Stress Disorder Related to Childhood Abuse: Results From a Randomized Clinical Trial

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Author note:

NK and MBi have no known conflict to declare. DBT-PTSD will be published as a manual and is distributed by workshops for which MBo, RS, KP, and MME receive income.

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Public health significance statement

The results of this randomized clinical trial will have an immediate impact for adults with a dual diagnosis of BPD and PTSD as defined in the DSM-5, because they show that the full symptomatic spectrum of both conditions can be efficaciously treated through a psychotherapeutic treatment.

Abstract

Objective: About half of individuals seeking treatment for borderline personality disorder (BPD) present with co-occurring posttraumatic stress disorder (PTSD). However, therapies that have been proven efficacious for simultaneously treating the full spectrum of core symptoms in patients with a dual diagnosis of BPD+PTSD are lacking.

Methods: This is a subgroup analysis from a randomized controlled trial (registration number DRKS00005578) which compared the efficacy of two treatment programs, Dialectical Behavior Therapy for PTSD (DBT-PTSD) versus Cognitive Processing Therapy (CPT). Specifically, the present analysis was carried out in 93 women with a dual diagnosis of BPD+PTSD (DSM-5). Outcome evaluations included the Clinician-Administered PTSD Scale, the Borderline Symptom List, and validated scales assessing dissociation, depression, and global functioning. The primary analysis was based on the intent-to-treat population, using mixed models.

Results: Both PTSD and BPD symptoms significantly decreased in both treatment groups. For PTSD symptoms, pre-post effect sizes were d=1.20 (95%-CI: 0.80-1.58) in the DBT-PTSD group and d=0.90 (95%-CI: 0.57-1.22) in the CPT group; for BPD symptoms, they were d=1.17 (95%-CI: 0.77-1.55) and d=0.50 (95%-CI: 0.20-0.79), respectively. Between-group comparisons significantly favored DBT-PTSD for improvement in symptoms of PTSD, BPD, and dissociation. Between-group differences regarding depression and global functioning were not significant.

Conclusion: Both DBT-PTSD and CPT emerged as promising treatment options for simultaneously addressing the full spectrum of core symptoms in patients diagnosed with BPD+PTSD. Differential efficacy was in favor of DBT-PTSD because participants randomized to the DBT-PTSD arm improved more with respect to both their BPD and PTSD symptoms.

Introduction

Prevalence and clinical significance of a dual diagnosis of BPD+PTSD

Epidemiological studies indicate that about one in three individuals with a diagnosis of borderline personality disorder (BPD) also meets the diagnostic criteria for posttraumatic stress disorder (PTSD) (Pagura et al., 2010). Among patients who seek treatment for BPD, the percentage of those with co-occurring PTSD is even higher, exceeding 50% in several clinical samples (Cackowski et al., 2016; Harned et al., 2008; Harned et al., 2010; McGlashan et al., 2000; Sack et al., 2013; Zanarini et al., 1998). A dual diagnosis of BPD+PTSD is particularly prevalent in survivors of child abuse (CA), which is here defined as having been subjected to sexual or physical abuse before the age of 18 (Scheiderer et al., 2015).

Individuals with a dual diagnosis of BPD+PTSD have a high need of treatment. At a minimum, they require therapy that addresses the symptoms of both disorders. Furthermore, they may exhibit very high levels of problematic clinical features, including emotion dysregulation, self-harming behaviors, interpersonal difficulties, and dissociation (Cackowski et al., 2016; Harned et al., 2010; Heffernan et al., 2000; Krause-Utz, 2021; Marshall-Berenz et al., 2011), and are at a high risk for suicide attempts (Yen et al., 2021). However, there is a lack of treatment programs that proved efficacious for both aspects of the dual diagnosis within a randomized controlled trial (RCT). Given this lack, one approach has been to apply therapies that are efficacious for treating either BPD or PTSD: i.e., to focus on one of the two aspects of the dual diagnosis at least as an initial step of treatment. Some of these approaches are reviewed below.

BPD-specific treatments used for patients with a dual diagnosis of BPD+PTSD

Harned et al. (2008) assessed the efficacy of dialectical behavior therapy (DBT), a treatment mostly used for BPD, in treating BPD patients with comorbidities including PTSD. They

found that after one year of DBT treatment, the remission rate for PTSD was lower than that for the other comorbidities looked at in this study, and was not significantly different from patients who were treated in the community (34.8% vs. 23.5%). This suggested approaches in which DBT could be complemented by components specifically addressing PTSD.

There is some controversy over whether the efficacy of BPD-tailored psychotherapies in treating BPD symptoms is impacted when there is a co-occurring diagnosis of PTSD. Several clinical studies and meta-analyses summarizing evidence-based treatment programs for BPD, including DBT and mentalization-based therapy (MBT), found a negative relation between co-occurring PTSD and successful treatment of BPD symptoms (e.g., Barnicot & Crawford, 2018, Barnicot & Priebe, 2013, Harned et al., 2010). However, others did not find this relation (e.g., Gratz et al., 2020).

In summary, current knowledge does not conclude that evidence-based BPD-specific standard treatments are sufficient for addressing the full symptomatic spectrum in patients with a dual diagnosis of BPD+PTSD. A review of psychotherapy for BPD has identified the extension of "therapies beyond the current evidence, e.g., for patients with BPD and comorbid PTSD" as one of the highest priorities to be addressed in future research (Links et al., 2017, p. 1-2).

PTSD-specific treatments used for patients with a dual diagnosis of BPD+PTSD

A recent meta-analysis found that psychotherapy for PTSD is feasible for BPD patients as well, and can be efficacious in reducing PTSD symptoms in patients with a dual diagnosis (Slotema et al., 2020). In particular, among such patients, PTSD symptoms improved more in those who received CBT for PTSD compared to those who received treatment as usual (TAU) (Kredlow et al., 2017). In a study of female veterans suffering from PTSD with or without co-occurring BPD, Holder et al. (2017) found that after treatment with cognitive processing therapy (CPT; Resick & Schnicke, 1992), PTSD symptoms lessened regardless of whether co-occurring BPD was present. However, the body of evidence remains limited, since patients

with BPD, or with features of BPD such as ongoing non-suicidal self-injury (NSSI), have frequently been excluded from trials investigating the efficacy of PTSD treatments (e.g., Ronconi et al., 2014).

Another limitation of the studies investigating PTSD treatments in dual-diagnosis patients is that they did not systematically evaluate whether improvements in PTSD symptoms translated into improvements in BPD symptoms. Furthermore, in some trials that evaluated standard PTSD treatments in these patients, the rates of incomplete compliance or dropout were as high as 40% to 100% (e.g., Heffernan et al., 2000; McDonagh et al., 2005), which exceed the pooled dropout rates of 16% and 28% reported in recent meta-analyses for PTSD and BPD trials, respectively (Lewis et al., 2020; Dixon et al., 2020). One exception to these limitations was a study by Pabst et al. (2014), who reported large effect sizes in dual-diagnosis patients with respect to both their PTSD and BPD symptoms. However, that study was not fully conclusive because it enrolled only 11 patients and because the results regarding BPD and PTSD symptomatology did not differ from those observed in matched controls who had received treatment from experts.

Several other PTSD studies that included individuals with BPD characteristics remained inconclusive because they did not establish BPD diagnoses (e.g., De Jongh et al., 2020, Clarke et al., 2008; Feeny et al., 2002). The study by De Jongh et al. (2020) involved a brief intensive trauma-focused treatment that included both prolonged exposure (PE) and Eye Movement and Desensitization and Reprocessing (EMDR) therapy. Setting aside the important limitation described above, the authors reported promising results with respect to feasibility, patient compliance, safety, and efficacy, with clinically relevant improvements not limited to symptoms of PTSD but seen for symptoms of BPD as well.

Overall, the current evidence supports the use of standard trauma-focused treatments in patients with BPD+PTSD, but there is a need for the development and evaluation of more

comprehensive interventions designed to address symptoms of both disorders. It remains unclear whether standard treatments for PTSD (i.e., treatments that do not include interventions addressing the complexity typically seen in individuals with a dual diagnosis) are optimal for treating this group of patients, or whether modifications are required (Cook et al., 2004; Resick et al., 2003).

Therapeutic approaches for treating patients with a dual diagnosis of BPD+PTSD

During the last decade, treatment concepts for individuals with a dual diagnosis of BPD+PTSD have been developed. An earlier survey of psychologists' attitudes regarding exposure-based trauma treatments found that many practitioners considered symptoms of severe dissociation, as well as suicidal and NSSI behaviors, to be obstacles for starting such treatment (Becker et al., 2004). Currently, however, there is a line of research that postulates that although exposure treatment should not be done immediately in individuals with a dual diagnosis, it is feasible once the patient has achieved control over particular dysfunctional behaviors (Cloitre et al., 2011).

Systematic studies by Harned et al. have shown the potential of DBT to reduce these dysfunctional behaviors. In a seminal work (Harned et al. 2010a), participants with BPD+PTSD started with DBT treatment, and those who achieved sufficient control over their dysfunctional behaviors (defined as no imminent risk of suicide, no suicide attempts or NSSI during the last two months, no serious therapy-interfering behaviors, ability to control NSSI even in the presence of triggers, and ability to stand intense emotions without escaping) were eligible to enter a prolonged exposure (PE) phase. That treatment, titled DBT PE, included exposure for treating PTSD symptoms such as intrusive re-experiencing, hypervigilance, and avoidance. Following an uncontrolled trial (Harned et al., 2012), the researchers carried out a pilot RCT (Harned et al., 2014, 2020) that compared standard DBT treatment (N=9) against DBT followed by DBT PE (N=17). For the DBT + DBT PE arm, large pre-post effect sizes

were observed for global PTSD severity, and medium to large pre-post effect sizes were seen for aspects of BPD severity (suicide attempts, NSSI, and dissociation). However, the results are not fully conclusive because the comparisons between the arms on these measures were not statistically significant. This could be due to the limited sample sizes, to the active control condition, and to the fact that 47.1% (8/17) of the patients who entered the initial DBT phase either did not achieve sufficient stability to enter the DBT PE phase or dropped out after they did.

Some other multi-component approaches to BPD+PTSD were explored in two small pilot studies. Steuwe et al. (2016) investigated the potential of Narrative Exposure Therapy (NET; Schauer et al., 2011) combined with a standard inpatient care program, and found medium to large effect sizes with respect to symptoms of PTSD, BPD, depressivity, and dissociation. Slotema et al. (2019) investigated Eye Movement Desensitization and Reprocessing (EMDR) combined with an outpatient treatment-as-usual program for patients with personality disorders including BPD, and reported significant pre-post comparisons for symptoms of PTSD and dissociation. Neither of these studies assessed overall severity of BPD. Although the results show potential for both NET and EMDR in the treatment of BPD+PTSD when combined with treatment modules addressing BPD, these studies were small (N=11 and N=22, respectively) and lacked control groups.

Another approach is DBT-PTSD, a multi-component modular treatment for adult survivors of CA presenting with PTSD or complex PTSD, with or without comorbid BPD (Bohus et al., 2013, 2019). In addition to trauma-focused interventions, DBT-PTSD includes DBT skills training. Skills are used for reducing BPD-specific dysfunctional behavioral patterns such as NSSI or aggressive outbursts, which could be aggravated by the trauma-focused component of the therapy, as well as for the mitigation of dissociation and emotional avoidance, which could interfere with the successful treatment of PTSD (Harned et al., 2020; Kleindienst et al.,

2016). Two pilot studies (Steil et al., 2011, 2018) were followed by two RCTs (Bohus et al., 2013, 2020). The first RCT investigated the efficacy of residential DBT-PTSD and compared it to a treatment-as-usual waitlist (TAU-WL). All participants (N=74) had severe presentations of complex PTSD following child sexual abuse, and a subset of 33 participants had a dual diagnosis of BPD+PTSD. An analysis conducted on this subset revealed a large between-group effect size in PTSD-specific symptomatology (ITT-based g = 1.50; remission rates 38.9% vs. 2.6%). However, it did not establish superiority of DBT-PTSD to TAU with respect to BPD-specific symptomatology and dissociation (Bohus et al., 2013).

More recently, Bohus et al. (2020) conducted a large outpatient RCT that evaluated the comparative efficacy of two specialized treatments for patients with PTSD related to childhood abuse. The therapies being compared were DBT-PTSD and CPT. The latter is a highly recommended first-line treatment for PTSD in general (e.g., American Psychological Association, 2017) and has been found to be efficacious in women with PTSD related to CA (Chard, 2005). However, CPT does not provide BPD-specific interventions.

While the study by Bohus et al. (2020) found that DBT-PTSD was overall superior to CPT in treating PTSD, it did not report the results for patients with a dual diagnosis of BPD+PTSD. Accordingly, simultaneous efficacy in treating both conditions in those patients remains to be established.

Research question

The current report presents the findings of an analysis that specifically looked at the participants in the RCT by Bohus et al. (2020) who had a dual diagnosis of BPD+PTSD, in order to evaluate the ability of the treatments to simultaneously reduce the severity of both PTSD-specific and BPD-specific symptoms in this patient population. The null hypothesis tested was that there would be no difference between the treatments. Given the symptomatic complexity in this population, the evaluation was designed to be multivariate, including (i)

severity of PTSD, (ii) severity of BPD, (iii) maladaptive behaviors frequently encountered in BPD such as NSSI, high-risk behaviors, and suicide attempts, (iv) dissociation, (v) severity of depressive symptoms, and (vi) global assessment of functioning (GAF).

Methods

Trial design, inclusion and exclusion criteria, randomization

The data of the present study stem from a multicenter RCT (Bohus et al., 2019, 2020) comparing DBT-PTSD or CPT in cisgender women with a diagnosis of CA-related PTSD and severe emotion dysregulation who were available for one year of outpatient treatment. The current study presents the findings of an analysis that was carried out on the subgroup of participants in this study with a dual diagnosis of BPD+PTSD according to DSM-5 (N=93). Exclusion criteria were (i) diagnosis of schizophrenia, bipolar I disorder, or mental retardation, (ii) severe psychopathology necessitating immediate treatment in a different setting (e.g., body mass index < 16.5), (iii) suicide attempts within the last 2 months that entailed a "very high" (e.g., attempted drowning) or "extremely high" (e.g., shooting herself in the head) risk of success. (Attempts whose risk was rated as "high" (e.g., running into heavy traffic) and ongoing NSSI behaviors were not exclusionary), (iv) current substance dependence, (v) medical conditions contradicting exposure (e.g., pregnancy), (vi) a highly unstable life situation (e.g., homelessness), (vii) scheduled residential treatment, and (viii) receipt of either CPT or DBT-PTSD during the last year. Randomization was concealed, and both diagnosticians and raters were blinded. The study was approved by the pertinent institutional ethics boards, and written informed consent was obtained from all participants prior to randomization. Power analyses (based on $\alpha = 0.05$, $\beta = 0.20$, N=93) indicated that there was adequate power to detect medium to large between-group effect sizes (of $d \geq 0.59$)

in the intent-to-treat (ITT) population and large between-group effect sizes (of $d \geq 0.78$) in the subset of patients who completed the study according to protocol (ATP).

Interventions

The interventions of DBT-PTSD and CPT have been described in detail elsewhere (Bohus et al., 2019; Resick et al., 2008). Briefly, DBT-PTSD was designed to treat psychosocial sequelae of CA in adult patients with PTSD, and offers a dual approach to treating both PTSD and BPD. It has adopted the principles of standard DBT, such as the hierarchy of treatment focuses, as well as several of its components, such as skills training and consultation teams. Skills have been adapted for PTSD (e.g., by including anti-dissociative skills). Furthermore, DBT-PTSD includes trauma-focused cognitive-behavioral interventions (Ehlers & Clark, 2000) and components from both acceptance and commitment therapy (Hayes, 2004) as well as compassion-focused therapy (Gilbert, 2010).

CPT is an established trauma-focused cognitive therapy that mainly aims to identify and challenge dysfunctional trauma-related cognitions and subsequent emotions. The original CPT protocol comprises 12 sessions, but for this RCT, which was adapted for patients with CA and emotion dysregulation, four sessions were added at the start and 29 more sessions were added at the end. The first four sessions included recording of the case history, building a therapeutic relationship, and elaborating emergency plans for crises (e.g., suicidal situations). In particular, situations that might engender problematic behaviors (e.g., self-injury or substance abuse) were identified and analyzed, and alternative strategies such as going jogging or calling a friend, were identified before trauma-focused treatment was begun. In contrast to DBT-PTSD, these sessions did not include explicit skills teaching. The next 12 sessions followed the original CPT protocol, and included psychoeducation as well as an "impact statement" (a written statement by the participant on the impact that CA had had on her life), followed by cognitive restructuring with regard to denial and guilt. Worksheets were introduced step-by-step to

support identifying and restructuring further dysfunctional trauma-related beliefs ("stuck-points"); e.g., regarding safety, trust, intimacy, and self-esteem. From session 17 on, the choice of topics was guided by the patient's individual "stuck point" log. In particular, issues that were still open from the previous 12 sessions were addressed. After working on the index trauma, other traumatic events could become the focus. These sessions were based on the same treatment materials as the previous ones. Finally, questions of life choices (e.g., social relations, career prospects, etc.) could be addressed.

In the RCT, both DBT-PTSD and CPT treatments comprised individual sessions, homework, and telephone consultation as required. In both groups, 45 weekly therapeutic sessions during the first 12 months were followed by a booster phase with three additional sessions during the following three months. The study protocol included the possibility of terminating the study early if all the following predefined conditions were fulfilled: 1) the treatment goals were achieved in the participant's view and she asked for early termination; 2) both the therapist and the supervisor agreed that the treatment goals had been achieved; and 3) a blinded assessor determined symptomatic remission from the diagnosis of PTSD. If all of these criteria were fulfilled, then the patients were considered to be remitted according to protocol ("early remission"). Patients achieving early remission were not considered dropout patients.

Several measures were taken to assure treatment integrity. Prior to the study, therapists were trained in either DBT-PTSD or CPT via workshops. During the study, therapists were routinely supervised and had regular team consultations. The two treatments were never provided by the same therapist, to prevent cross-contamination. To avoid bias in favor of either group, therapeutic training and therapists' experience were balanced across treatment groups. These measures were supplemented by assessments of adherence and competence, which were based on manual-based adherence and competence scales for both DBT-PTSD and for CPT as used in this RCT. Adherence and competence were assessed by two independent raters, based on two

videotaped sessions per patient. Global adherence was rated on a Likert scale ranging from 0 to 6, with the following anchors: 0 = not adherent; 2 = large deviations, 4 = minor deviations, 6 = very adherent to the manual (Bohus et al., 2020; Dittmann et al., 2017a,b). Global competence was also rated on a Likert scale ranging from 0 to 6, with the following anchors: 0 = poor; 2 = average, 4 = good, 6 = very good competence. Intraclass correlations calculated for assessing inter-rater reliabilities for these scales ranged from 0.67 to 0.97, indicating good to excellent reliability.

Diagnostic procedures and outcome measures

Both BPD and PTSD were diagnosed according to DSM-5 criteria by experienced clinical psychologists who were blinded to treatment assignment. BPD diagnoses were based on the International Personality Disorder Examination (IPDE, Loranger et al., 1994). PTSD diagnoses were assessed from the Clinician-Administered PTSD Scale (CAPS-5, Weathers et al., 2018). Symptomatic remission was defined as either achieving early remission as defined above, or no longer meeting the diagnostic criteria of PTSD at post assessment. Further Axis I diagnoses were diagnosed with the Structured Clinical Interview (SCID-I; First et al., 1997). The Life Events Checklist (Gray et al., 2004) was used for defining the index trauma. All participants with a diagnosis of PTSD as assessed with the CAPS-5 also met the diagnostic criteria for PTSD as assessed with the SCID-I. The dimensional assessment of PTSD included both an observer-based rating (CAPS-5; Weathers et al., 2018) and a standardized self-rating (Posttraumatic Stress Disorder Checklist for DSM-5, PCL-5; Blevins et al., 2015). The dimensional assessment of BPD severity included the Borderline Symptom List (BSL-23; Bohus et al., 2009), and the behavioral items (BI) of the BSL-23 (Bohus et al., 2001) assessing maladaptive behaviors such as suicidal behaviors, non-suicidal self-harming behaviors (e.g., cutting or taking non-prescribed medication), and high-risk behaviors (e.g., balancing on bridge railings). Dissociation was assessed via the Dissociation Tension Scale

(DSS-7; Stiglmayr et al., 2010), which assesses both the duration and the intensity of dissociative experiences such as depersonalization and derealization over the last week. Depressive symptomatology was assessed from the Beck Depression Inventory-II (BDI-II; Beck et al., 1996), and the global assessment of functioning was assessed via the GAF (Endicott et al., 1976).

Assessments and missing data

The major assessments were conducted at the start of therapy (T1) and after 3 months (T2), 6 months (T3), 9 months (T4), 12 months (T5; end of high frequency phase), and 15 months (T6, post assessment). (For details see Bohus et al., 2020.) To minimize bias and loss of efficiency, intent-to-treat (ITT) analyses based on a two-step procedure for imputing missing values were used as the predefined analytical strategy. Item-level imputation was found to be more efficient than scale-level imputation (Gottschall et al., 2012), but this was not always feasible (e.g., when entire assessments were missing). Thus, we started with stochastic regression imputation (SRI) on the item level if the percentage of items from an incompletely assessed scale was less than 10%. Second, multiple imputation (MI) was applied on the scale level to impute missing assessments. Because the missing pattern was non-monotone, we applied the Markov chain Monte Carlo method for MI (Schafer, 1997) based on the SAS™ procedures MI (1000 runs) and MIANALYZE. ITT analyses were supplemented with per protocol analyses that were based on the subsample of those participants who had completed the study according to protocol (ATP). Categorical data such as symptomatic remission were not imputed.

Statistical analysis

As per the study protocol, mixed linear models were used as the predefined primary strategy to analyze and compare changes in the two groups. Continuous variables were modelled by time, group, and the time*group interaction within random slope and intercept models, with

no restrictions set to the covariance matrix (Bohus et al., 2020) using SAS™ v.9.4 PROC MIXED. Besides checking the assumption of linearity, marginal residuals were plotted against the predicted means, and Q-Q plots were used to check for normality of the marginal residuals. The diagnostic procedure indicated a misspecification for the behavioral item score of the BSL (BSL-BI) which showed a markedly non-linear course. Accordingly, the BSL-BI was not analyzed with mixed linear models. Categorical data were compared using χ^2-tests and Fisher's exact test (if ≥ 1 expected frequencies were < 5). Effect sizes for pre-post comparisons of continuous data (gain scores) were standardized at the standard deviations of the gain scores. Between-group effect sizes of gain scores were based on pooled standard deviations.

To avoid bias that might emerge from selective reporting, this study included all psychopathology scales that had been assessed at all major assessments. Besides assessing dimensional outcomes, we determined the percentage of participants who reliably improved with respect to both the CAPS-5 and the BSL-23. Reliable improvement requires pre-post-changes to exceed a threshold compatible with the unreliability of the respective measurement (Clark et al., 2018). Reliable improvement with respect to the CAPS-5 and the BSL-23 requires participants to improve by $SD(CAPS_{pre}) * \sqrt{2} * \sqrt{1 - reliability(CAPS)} * 1.96 = 7.50$ points on the CAPS-5 as well as by $SD(\text{BSL23}_{pre}) * \sqrt{2} * \sqrt{1 - reliability(BSL23)} * 1.96 = 0.60$ points on the BSL-23. The criterion required for establishing efficacy of a treatment with respect to a specific facet of psychopathology was a significant ($p \leq 0.05$) superiority versus the other group. This criterion was applied to both the evaluation of our own data and for evaluating previously reported results.

Results

A detailed patient flow starting with the 955 individuals who were assessed for eligibility is provided in Figure S1 of the supplement. The final sample included 93 participants who had a combined diagnosis of BPD+PTSD, of whom 43 were randomized to the DBT-PTSD arm and 50 to the CPT arm. Within this subgroup, 39 (41.9%) participants dropped out. The dropout rate in the DBT-PTSD group was numerically lower than in the CPT group (32.6% vs. 50.0%), but the difference was not statistically significant ($p = 0.089$).

Patient characteristics and psychotropic medication

Mean age of participants was 33.5 years (SD = 10.6, range: 18–58). Apart from the diagnoses of BPD and PTSD, patients currently met the diagnostic criteria of an additional 2.43 ± 1.58 Axis I disorders. The most prevalent diagnoses other than BPD+PTSD were major depressive disorder (60.2%, n = 56), social phobia (33.3%, n = 31), panic disorder (22.6%, n = 21), dysthymia (19.4%, n = 18), obsessive compulsive disorder (17.2%, n = 16), and specific phobias (15.1%, n = 14). On average, the participants met 6.23 BPD criteria (SD = 1.16, range: 5-9). The index trauma was childhood sexual abuse for 76.3% of the patients and childhood physical abuse for 23.7%. Further clinical and socio-demographic data are provided in Supplemental Table S1. With respect to psychotropic medication, the study reflected the current practice applied in outpatient settings by allowing use of medication as considered appropriate by the treating psychiatrists. Systematic monitoring of psychotropic medication revealed no differences between the treatment groups at baseline or post-treatment (all p-values ≥ 0.111; for details, see Supplemental Table S1). Changes in medication were not significantly correlated with any of the dimensional pre-post changes (all p-values ≥ 0.179) or with the risk of dropping out of the study ($p = 0.699$).

Treatment integrity

For both DBT-PTSD and CPT, the mean values of global adherence in the original RCT indicated “good” adherence to the respective manual (DBT-PTSD: M = 4.06, SD = 1.18;

CPT: M = 3.91, SD = 1.27). Similarly, the mean global therapeutic competence was "good" in both groups (DBT-PTSD: M = 3.96, SD = 0.90; CPT: M = 3.97, SD = 0.93).

Comparative efficacy

Figure 1 shows that both PTSD and BPD symptoms decreased substantially from pre- to post-treatment. The overall declines were significant, as indicated by ITT-based mixed linear models applied to the unstandardized scales (CAPS-5: β = -3.301 ± 1.035, p < 0.001; BSL-23: β = -0.233 ± 0.052, p < 0.001), and were more pronounced in the DBT-PTSD group, as indicated by a significant time*group interaction (CAPS-5: β = 1.402 ± 0.640, p = 0.031; BSL-23: β = 0.081 ± 0.032, p = 0.013). For the CAPS-5, ITT-based pre-post effect sizes were large in both groups (DBT-PTSD: d=1.20, 95%-CI: 0.80-1.58; CPT: d = 0.90, 95%-CI: 0.57-1.22), and the between-group effect size was d = 0.48 (95%-CI: 0.06-0.89, p = 0.024). For the BSL-23, these effect sizes were large in the DBT-PTSD group (d = 1.17, 95%-CI: 0.77-1.55) and medium (d = 0.50, 95%-CI: 0.20-0.79) in the CPT group, and the between-group effect size was d = 0.59 (95%-CI: 0.17-1.00, p = 0.006).

--- Insert Figure 1 about here ---

Overall, 43.0% of the participants achieved reliable improvement with regard to both BPD and PTSD symptomatology. This percentage was higher in the DBT-PTSD group than in the CPT group (60.5% vs. 28.0%, p = 0.002). A complete presentation of the unstandardized psychopathology scales is provided in Figure 2, and the means and standard deviations of these scales are provided in Supplemental Table S2. Pre-post improvements in PTSD-specific psychopathology as assessed with the CAPS-5, the PCL-5, the BSL-23, the BDI, and the GAF were statistically significant in both groups. The behavioral items of the BSL (BSL-BI) and dissociation (DSS-I, DSS-D) were statistically significant in the DBT-PTSD but not in the CPT group.

In the DBT-PTSD group, pre-to-post effect sizes (ITT) ranged from d = 0.71 (for the behavioral items of the BSL) to d = 1.39 (for PTSD-specific psychopathology as assessed with the PCL-5). In the CPT group, they ranged from d = 0.19 (for the behavioral items of the BSL) to d = 0.90 (for PTSD-specific psychopathology as assessed with the CAPS-5). All of the pre-post effect-sizes were numerically larger in the DBT-PTSD group (Figure 2), with the difference being statistically significant for both BPD scales (global severity of BPD and the total scores of behavioral items), the PTSD scales (observer-based and self-rating), and for both the intensity and duration of dissociation. The reduction in the BDI-II scores and the increase in the global assessment of functioning (GAF) did not differ significantly across groups. It should be noted that the findings seen for the 100 patients in the parent study who had a diagnosis of PTSD but not BPD (i.e., those not included in the main analyses presented here), were generally in favor of DBT-PTSD. (See Supplemental Figure S3).

Analyses for the subgroup of the dual-diagnosis participants who completed the study according to protocol (ATP) are summarized in Supplemental Table S2. The pre-post effect sizes seen for the ATP sample were numerically larger than those observed for the ITT sample, likely because individuals who completed the study had received the full treatment and were more compliant with treatment. All improvements were numerically more pronounced in the DBT-PTSD group. However, the between-group effect sizes in the ATP analyses were not statistically significant, and were numerically smaller than the respective between-group effect sizes from the ITT sample (for comparison, see Supplemental Table S2). Again, the shrinking of the between-group effect sizes in the ATP sample is likely because the higher dropout rate in the CPT vs. PTSD group (50.0% vs. 32.6%) differentially affected the selection effects in the ATP samples.

--- Insert Figure 2 about here ---

Early remission, remission, hospitalization during treatment and suicidal acts

One patient in each group achieved early remission (DBT-PTSD: 2.2%, CPT: 2.0%, $p > 0.999$). The percentages of patients achieving symptomatic remission with respect to PTSD were 48.7% (18 of 37 observed cases) in the DBT-PTSD group and 32.6% (15 of 46 observed cases) in the CPT group ($p = 0.138$). Psychiatric hospitalizations were assessed for the first year after randomization (high-frequency phase). During that period, 13 (14.0%) participants had a documented inpatient stay in a psychiatric hospital. The percentages of inpatient stays in the treatment groups were not statistically different (DBT-PTSD: 9.3%, CPT: 18.0%, $\chi^2 = 1.454$, $p = 0.229$). One suicide attempt occurred during the observation period of 15 months, in a patient in the CPT group. No patient died by suicide in either group.

Discussion

Aims and major findings of the study

This study is a secondary analysis of a larger RCT evaluating the comparative efficacy of DBT-PTSD and CPT, with the focus here on the group of patients with a dual diagnosis of BPD plus CA-related PTSD. The evaluation comprised the full spectrum of both BPD and PTSD symptoms as defined in the DSM-5. Because patients with a dual diagnosis of BPD+PTSD typically show further aggravating features, including self-harming, other high-risk behaviors, dissociation, and sometimes severe depressive symptoms, the outcome evaluations included analyses of all of these psychopathological facets. These analyses were complemented with a global assessment of functioning (GAF), assessment of treatment retention, rates of psychiatric hospitalization, and suicidal behaviors.

As has been shown with the predefined primary analytic strategy (i.e., mixed linear models), the severity of PTSD symptoms receded over time in both treatment groups. In both groups, the respective pre-post effect sizes were large and statistically significant. Similarly, the

severity of BPD symptoms declined with large (DBT-PTSD) and medium (CPT) pre-post effect sizes, which were significant in both treatments. Differential effects for both PTSD and BPD symptoms were significantly in favor of DBT-PTSD. This finding was supported by analyses of the simultaneous reliable change in the two major psychopathological aspects investigated in this study. Reliable change with respect to both PTSD and BPD symptoms was achieved by 60% of patients in the DBT-PTSD group vs. 28% in the CPT group.

Patients in the DBT-PTSD group also showed significant improvement of maladaptive behaviors and a large and significant drop in both the intensity and duration of dissociative symptoms, effects that were not observed in the CPT group. No statistically significant group differences were observed with respect to the improvement of depressive symptoms or of global functioning. The number of suicidal acts, number of inpatient stays, and dropout rates were not statistically different across treatment groups. Suicidal acts were rare events (just one suicide attempt, in the CPT group, and no completed suicides). The dropout rates were quite high in both groups, especially the CPT group (DBT-PTSD: 32.6%, CPT: 50.0%).

Discussion of the study results in the context of previous findings

Our findings confirm and extend previously published results on the efficacy of psychotherapy in simultaneously treating PTSD and PBD symptoms in patients with a dual diagnosis. In line with earlier RCTs (Bohus et al., 2013; Kredlow et al., 2017; Slotema et al., 2020), the current study verifies that PTSD can be effectively treated even in patients with co-occurring BPD. Further, in comparison to the RCT by Bohus et al. (2013) which was carried out in a residential setting and which used a weak comparator, the current trial was done in outpatients and compared two manualized treatments administered at the same dose, thus yielding stronger evidence. The limitation relating to the comparator also applies to the study by Kredlow et al. (2017), who found CBT for PTSD to be significantly superior to TAU in

reducing PTSD symptoms in BPD+PTSD participants, but TAU was not a strong control group.

Other studies that investigated ways to reduce CA-related PTSD symptoms in samples that included patients with a dual diagnosis do not allow to establish efficacy in patients with a diagnosis of BPD+PTSD as well. The studies by De Jongh et al. (2020) and Steil et al. (2011, 2018) did not include a control group, and Steil et al. did not report separate results for the subset of patients with BPD+PTSD in their studies. The pilot RCT by Harned et al. (2014) comparing DBT vs. DBT + DBT PE did report on participants with BPD+PTSD, but while large pre-post effects were seen in both treatment arms, the results were not entirely conclusive because the between-group comparisons were not significant and only six patients had completed the combination of DBT + DBT PE. Premature treatment termination and a small sample size were also an issue in the study by McDonagh et al. (2005), who reported that all of the participants with a diagnosis of BPD+PTSD (4/4) who had been randomized to cognitive behavioral therapy dropped out. Finally, various limitations apply to the studies that investigated the efficacy of NET-based approaches: lack of a control group and small sample sizes of dual-diagnosis patients in the BPD+PTSD arm (Steuwe et al., 2016; Slotema et al., 2019); small sample size of dual-diagnosis patients in the CPT arm (Holder et al., 2017); and lack of between-group significances (Pabst et al., 2014).

Another major addition to the literature pertains to the reductions in BPD symptoms seen in the CPT group. These findings fully confirm those of De Jongh et al. (2020), who used an intensive trauma-focused treatment to treat dual-diagnosis patients. In both that study and the current one, BPD symptoms were significantly improved even though neither the treatment used by De Jongh et al. nor CPT specifically addresses BPD. (In both treatments, improvements in BPD were less pronounced than those seen in PTSD symptoms.) While the findings regarding PTSD align with previous findings, the evidence for an efficacious

treatment of the BPD facet in individuals with a dual diagnosis of BPD+PTSD extends the current evidence.

The between-group effects in our study were d = 0.59 (95%-CI: 0.17-1.00) for the general BPD symptoms and d = 0.66 (95%-CI: 0.24-1.08) for the behavioral aspects of BPD. Both effect sizes were numerically larger than the aggregated main effect on BPD symptoms of g = 0.31, as reported in the meta-analysis on the efficacy of psychotherapies for BPD by Cristea et al. (2017), and the between-group effect sizes in the previous RCTs comparing BPD symptomatology as assessed with a validated scale in patients with a dual diagnosis of BPD+PTSD. Between-group effect sizes for the general BPD symptoms were g = 0.28 in the DBT-PTSD trial by Bohus et al. (2013) and were slightly negative in the NET trial by Pabst et al. (2014). In other reports, pre-post effect sizes for single symptoms of BPD such as suicide attempts, NSSI, and deliberate self-harm in patients with a dual diagnosis were medium to large in the study of DBT + DBT PE (Harned et al., 2014) and very small in the study of EMDR (Slotema et al., 2019). Between-group effects were not statistically significant in these studies, and the assessment of BPD only included single symptoms. In summary, the finding of a significant between-group effect within the framework of our RCT is a major advancement, because most prior work that reported results for the subgroup with BPD+PTSD did not systematically address this dimension or did not report a statistically significant between-group effect. A further contribution of this RCT relates to the treatment of dissociation in individuals with BPD+PTSD. Previous studies on the treatment of dissociation in this population reported medium to large effects (e.g., Bohus et al., 2013; Harned et al., 2014; Pabst et al., 2014; Slotema et al., 2019). The present RCT adds to these findings by providing evidence for the superiority of DBT-PTSD as compared to CPT with respect to dissociation. Dissociation is an important treatment target because it is particularly high in individuals with a dual diagnosis (Lyssenko et al., 2018) and can present a significant obstacle to successful treatment of both conditions (Kleindienst et al., 2011, 2016). (It should be noted,

however, that a negative impact of dissociation was not supported in a meta-analysis by Hoeboer et al., 2020.) In addition, our results provide initial evidence for the safety of both DBT-PTSD and CPT in this patient group. However, while patients with milder forms of parasuicidal behaviors including ongoing self-harm or high-risk behaviors were admitted for the study, patients with recent suicide attempts bearing a very high risk to die were excluded.

The dropout rates for DBT-PTSD and CPT were 32.6% and 50.0%, respectively, which exceed the pooled rates of 28.0% and 16% reported in the most recent meta-analysis on dropout rates in RCTs of psychological therapies of BPD and PTSD (Dixon et al., 2020; Lewis et al., 2020). Reasons for this might relate to the study population and the long duration of our study. Although the evidence for these assumptions remains limited, they are supported by similar or even higher dropout rates from controlled trials that investigated psychological treatments in patients with a dual diagnosis of BPD and PTSD (McDonagh et al., 2005; Harned et al., 2014; Slotema et al., 2019), and by substantially lower dropout rates in trials with a shorter intervention (De Jongh et al., 2020; Bohus et al., 2013). The relatively high dropout rate may restrict the full potential of the investigated therapies, and thus is an important target for improvement.

Limitations

The present study has both strengths and limitations. On the positive side, an RCT comparing two active treatments statistically controls for unspecific confounding variables, and thus offers a high level of evidence. To avoid selection bias, randomization was concealed to all persons involved. To avoid response bias, all observer-based assessments were carried out by blinded assessors. Furthermore, the study design aimed at equality across the two treatments with respect to the number and frequencies of therapeutic sessions; and the experience and specific training of the therapists, as assessed by validated scales of treatment integrity, were balanced and were found to be essentially equally distributed across the treatment groups.

Limitations mostly relate to the external validity of our findings. Enrollment was restricted to adult cisgender women with an index trauma of sexual or physical child abuse, thereby precluding generalization of the findings to other patient groups with BPD+PTSD. In particular, efficacy needs to be established for adolescents, for individuals of both sexes and all genders, and for patients with other types of trauma. It also remains to be established for patients with very severe conditions, such as recent suicide attempts where the individual was at very high risk of dying, or current substance dependency. However, while the study excluded individuals who met those criteria, it did include those who had recently made suicide attempts that were rated no more than highly dangerous (e.g., running into heavy traffic), or who had survived extremely high-risk suicide attempts but not recently. It should be noted that 69.3% of the patients enrolled had a history of suicide attempts.

Given the high dropout rate, the results may also be affected by attrition bias. As per the study protocol, and to minimize the impact of attrition on the results, analyses were primarily based on the intent-to-treat sample and were complemented with analyses according to protocol. In line with the assumption of an attrition bias, all pre-post effect sizes in both treatment arms were numerically larger in the ATP analyses than in the ITT analyses. Similarly, the between-group effect sizes in the ATP analyses were consistently smaller than those seen in the ITT analyses, and while still numerically in favor of DBT-PTSD, they were no longer statistically significant. In our view, potential reasons for these non-significant results include reduced statistical power related to the substantially smaller ATP samples, and a differential attrition bias favoring CPT related to the numerically higher dropout rate in the CPT group. As mentioned above, the relatively high attrition rates of 50.0% and 32.6% clearly indicate that the risk of dropping out, which seems to be high in this population, needs to be further addressed. Possible approaches might include using the residential setting for the treatment of patients who are at a high risk for dropping out (this is available for DBT-PTSD), going with

a condensed treatment program, and/or continuous monitoring of variables that might indicate an imminent dropout.

Another limitation relates to the non-convergence of the Newton-Raphson algorithm used for modelling the behavioral items of the BSL. Accordingly, the results relating to that outcome measure did not result from the primary analytic strategy. Furthermore, the study did not specifically recruit people with BPD; rather, this was a secondary analysis from a larger trial.

Psychotherapies were strictly controlled to avoid cross-contamination, but prescription of medication was not restricted by the study protocol and might have impacted the results. However, use of psychotropic medication decreased in both groups, and changes in medication were statistically to treatment outcome in either group. Accordingly, it seems unlikely that adaptations in medication, which are common clinical practice in a population with an average of more than three Axis I disorders, might have affected the essence of the findings. Imposing restrictions on the use of medications would have been at the cost of external validity.

When interpreting the results pertaining to CPT, we emphasize that CPT was adapted as being suitable for patients with a high risk for suicide attempts and NSSI, and that treatment dosage was extended beyond the number of individual sessions typically provided for this treatment. In particular, four sessions were added before the start of the usual CPT program, and additional sessions were added to address issues that were still open after its completion. Finally, developers of both DBT-PTSD and CPT were involved in the study. Accordingly, replication by independent research groups is required, and the effectiveness in regions lacking specialized treatment units has yet to be established.

Clinical implications and future directions

Despite the above limitations, the results of this study indicate that patients with a dual diagnosis can be effectively treated for both their PTSD and BPD symptoms. Significant pre-post effects were seen for both of the active manualized treatments, with DBT-PTSD found to be more efficacious than CPT. However, this study is the first RCT to report these outcomes, and its findings need to be replicated by others. Beyond replication, future research should aim to clarify the mechanisms related to both improvement of psychopathology and to the prevention of premature termination. Overall, the results suggest that the addition of trauma-focused elements are beneficial for BPD patients with co-occurring PTSD. This is of high clinical relevance because this large group of patients clearly needs evidence-based treatments that are effective against both symptoms of BPD and PTSD.

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Figure

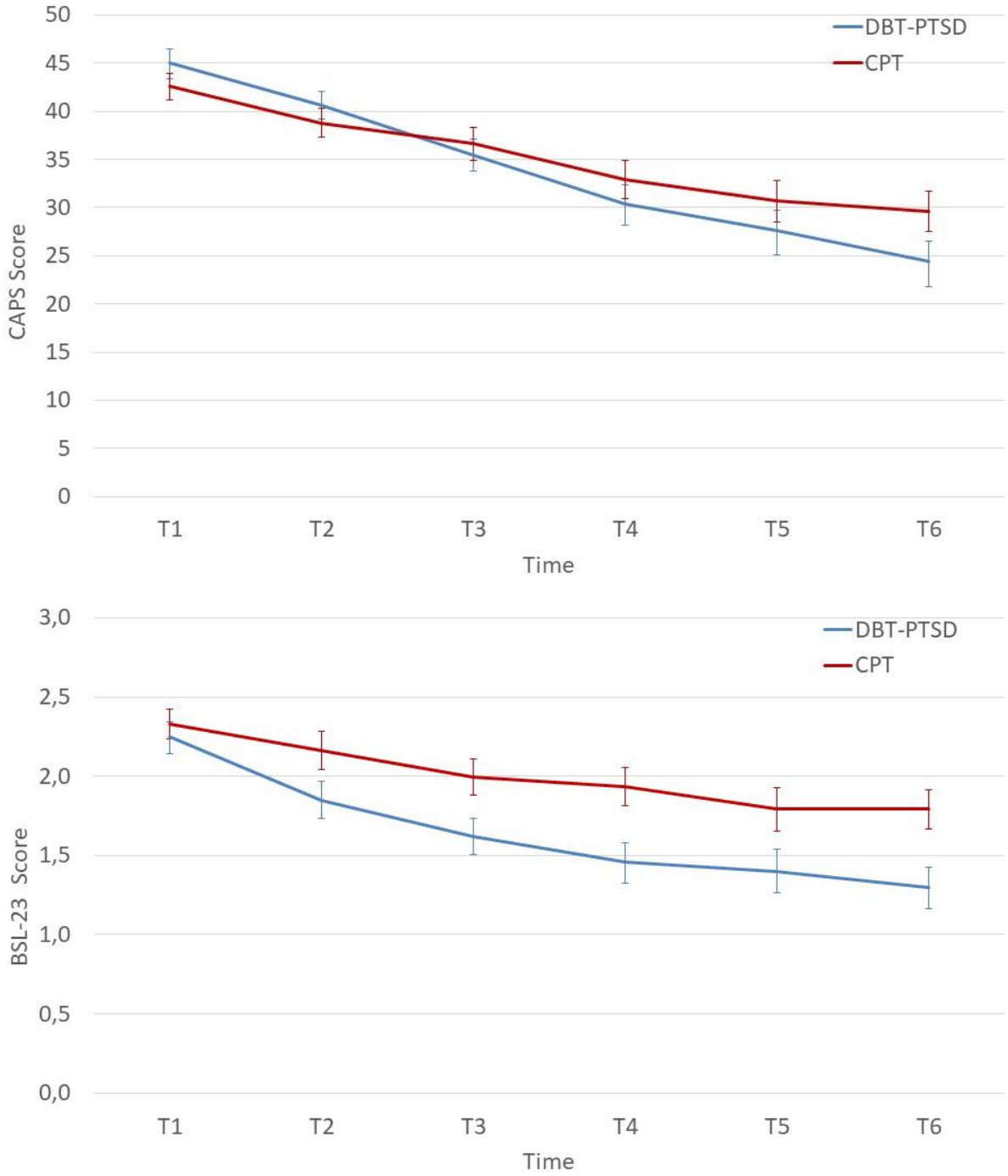

Figure 1. Course of PTSD- and BPD-symptoms at T1 (start of therapy), T2 (after 3 months), T3 (6 months), T4 (9 months), T5 (12 months, end of high frequency phase), T6 (post assessment after 15 months) based on the CAPS-5 total scores (above) and on the BSL-23 mean scores (below). Error bars indicate standard error of means.

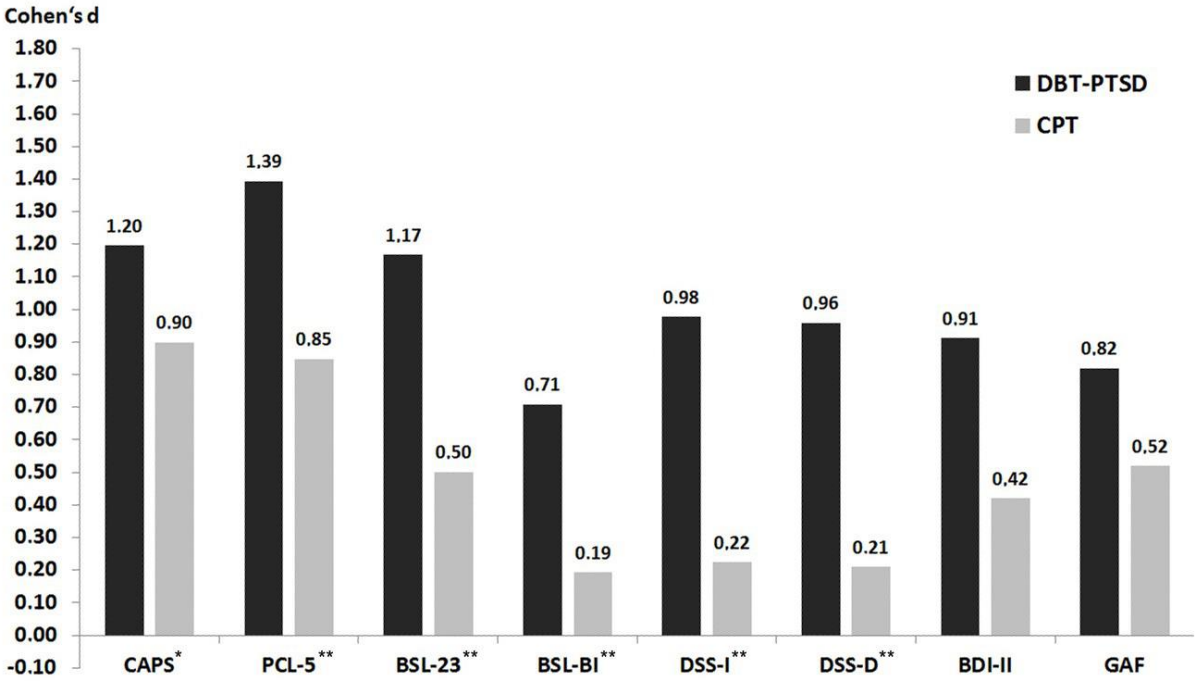

Figure 2. Pre-to-post effect-sizes (Cohen's d) based on the ITT-sample of all patients with a dual diagnosis of BPD+PTSD (n=93). CAPS=Clinician Administered PTSD Scale; PCL-5=Posttraumatic Stress Disorder Checklist for DSM-5; BSL-23=Borderline Symptom List; BSL-BI=behavioral items of the Borderline Symptom List; DSS-I=Dissociation Tension Scale, Intensity; DSS-D=Dissociation Tension Scale, Duration; BDI-II= Beck Depression Inventory-II; GAF=Global Assessment of Functioning. **($p<0.01$) and *($p<0.05$) indicate statistically significant differences between treatment groups. In the DBT-PTSD group all pre-to-post effect-sizes were statistically significant; In the CPT-group all pre-to-post effect-sizes except for the BSL-BI, DSS-I, and DSS-D were statistically significant.