

# Dialectical Behavior Therapy for Posttraumatic Stress Disorder (DBT-PTSD) Compared With Cognitive Processing Therapy (CPT) in Complex Presentations of PTSD in Women Survivors of Childhood Abuse

## A Randomized Clinical Trial

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**IMPORTANCE** Childhood abuse significantly increases the risk of developing posttraumatic stress disorder (PTSD), often accompanied by symptoms of borderline personality disorder (BPD) and other co-occurring mental disorders. Despite the high prevalence, systematic evaluations of evidence-based treatments for PTSD after childhood abuse are sparse.

**OBJECTIVE** To compare the efficacy of dialectical behavior therapy for PTSD (DBT-PTSD), a new, specifically designed, phase-based treatment program, against that of cognitive processing therapy (CPT), one of the best empirically supported treatments for PTSD.

**DESIGN, SETTING, AND PARTICIPANTS** From January 2014 to October 2016, women who sought treatment were included in a multicenter randomized clinical trial with blinded outcome assessments at 3 German university outpatient clinics. The participants were prospectively observed for 15 months. Women with childhood abuse-associated PTSD who additionally met 3 or more *DSM-5* criteria for BPD, including affective instability, were included. Data analysis took place from October 2018 to December 2019.

**INTERVENTIONS** Participants received equal dosages and frequencies of DBT-PTSD or CPT, up to 45 individual sessions within 1 year and 3 additional sessions during the following 3 months.

**MAIN OUTCOMES AND MEASURES** The predefined primary outcome was the course of the Clinician-Administered PTSD Scale for *DSM-5* (CAPS-5) score from randomization to month 15. Intent-to-treat analyses based on dimensional CAPS-5 scores were complemented by categorical outcome measures assessing symptomatic remission, reliable improvement, and reliable recovery.

**RESULTS** Of 955 consecutive individuals assessed for eligibility, 193 were randomized (DBT-PTSD, 98; CPT, 95; mean [SD] age, 36.3 [11.1] years) and included in the intent-to-treat analyses. Analysis revealed significantly improved CAPS-5 scores in both groups (effect sizes: DBT-PTSD:  $d$ , 1.35; CPT:  $d$ , 0.98) and a small but statistically significant superiority of DBT-PTSD (group difference: 4.82 [95% CI, 0.67-8.96];  $P$  = .02;  $d$ , 0.33). Compared with the CPT group, participants in the DBT-PTSD group were less likely to drop out early (37 [39.0%] vs 25 [25.5%];  $P$  = .046) and had higher rates of symptomatic remission (35 [40.7%] vs 52 [58.4%];  $P$  = .02), reliable improvement (53 [55.8%] vs 73 [74.5%];  $P$  = .006), and reliable recovery (34 [38.6%] vs 52 [57.1%];  $P$  = .01).

**CONCLUSIONS AND RELEVANCE** These findings support the efficacy of DBT-PTSD and CPT in the treatment of women with childhood abuse-associated complex PTSD. Results pertaining to the primary outcomes favored DBT-PTSD. The study shows that even severe childhood abuse-associated PTSD with emotion dysregulation can be treated efficaciously.

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The experience of childhood abuse (CA), whether sexual and/or physical, increases the likelihood of mental disorders later in life, particularly posttraumatic stress disorder (PTSD) and borderline personality disorder (BPD).<sup>1-6</sup> Cooccurrence of these 2 disorders is frequent: in epidemiological studies, 15% to 29% of individuals with PTSD also met criteria for BPD, while 17% to 53% of individuals with BPD reported PTSD.<sup>7-10</sup> In clinical samples, BPD-PTSD comorbidity often exceeds 50%.<sup>11-13</sup> Recent studies suggest that the experience of CA in particular results in complex presentations of PTSD, with high cooccurrence of these disorders.<sup>8,14</sup>

A recent meta-regression involving 51 randomized clinical trials found that patients with a history of CA and complex PTSD symptoms responded poorly to psychotherapy for PTSD.<sup>15</sup> This might be because of trauma-associated morphological alterations of the central nervous system,<sup>16,17</sup> increased dissociative features,<sup>18</sup> or severe self-criticism,<sup>19</sup> which might impede neural plasticity, emotional learning, and treatment motivation. The empirical base for a negative outcome of co-occurring BPD on treatment response is sparse. One study that investigated efficacy of cognitive behavioral therapy for survivors of childhood sexual abuse found that all the patients with co-occurring BPD dropped out of the cognitive behavioral therapy arm.<sup>20</sup> Five studies<sup>21-25</sup> documented no significant associations of BPD with treatment outcome; however, 3 of these studies<sup>21-23</sup> had excluded patients with current self-injurious behavior. This exclusion corresponds to the frequent exclusion from PTSD trials of patients with severe psychopathology, such as suicidality, ongoing self-harm, and substance abuse.<sup>26,27</sup>

Conversely, a study<sup>28</sup> showed that dialectical behavior therapy (DBT), one of the currently best-established treatments for BPD, did not significantly improve co-occurring PTSD. An attempt to address this problem has been made by adding prolonged exposure therapy to the standard DBT procedure.<sup>29</sup> However, the dropout rates were high, and the data are limited.

Currently, treatment of CA-associated PTSD mostly relies on established treatments that were developed for survivors of adult-onset trauma. Most treatment guidelines recommend prolonged exposure, cognitive processing therapy (CPT), or trauma-focused cognitive behavioral therapy,<sup>30-32</sup> but there is debate on whether these treatments are sufficient for patients with CA-associated PTSD.<sup>33,34</sup> Some authors favor phase-based treatments, focusing on emotion regulation before addressing traumatic memories,<sup>35-39</sup> while others maintain that standard trauma-focused programs without additional components are sufficient.<sup>40,41</sup> To date, no direct comparison has been carried out between standard PTSD therapies and specifically designed phase-based therapies.

Dialectical behavior therapy for PTSD (DBT-PTSD) is a prototypic phase-based treatment that is designed to meet the needs of survivors of CA with highly complex presentations of PTSD, including features of BPD. The first evaluation of this treatment supported its efficacy under residential treatment conditions.<sup>42,43</sup> The present study aimed at testing the superiority of DBT-PTSD compared with CPT in outpatients. We chose CPT as the comparator treatment because it is a highly

## Key Points

**Question** Is dialectical behavior therapy for posttraumatic stress disorder (DBT-PTSD) superior to cognitive processing therapy (CPT) in reducing the severity of complex presentations of posttraumatic stress disorder associated with childhood abuse?

**Findings** In this randomized clinical trial, treatments with DBT-PTSD and CPT both created large and significant improvements in PTSD severity, with improvement more pronounced under DBT-PTSD. The proportions achieving symptomatic remission were 58% in DBT-PTSD vs 41% in CPT, a significant difference.

**Meaning** In this trial, patients with severe childhood abuse-associated complex posttraumatic stress disorder highly improved under both DBT-PTSD and CPT, with DBT-PTSD being superior to CPT.

efficacious,<sup>41,44-46</sup> non-phase-based, well-established therapy for PTSD that has been shown to be efficacious in treating CA-associated PTSD.<sup>44</sup>

## Methods

### Trial Design and Participants

The study was conducted at 3 sites in Germany. Approval was obtained from the applicable ethics committees (Medical Faculty Mannheim at Heidelberg University in Mannheim, Goethe University in Frankfurt, and Humboldt University in Berlin). Before randomization, participants provided written informed consent. Safety and data quality were independently monitored by the Coordination Centre for Clinical Trials, Heidelberg. The study protocol has been published elsewhere<sup>47</sup> and is available in [Supplement 2](#).

Inclusion criteria included female sex and gender identity; an age of 18 to 65 years; a diagnosis of PTSD (according to the *DSM-5*) following sexual or physical abuse before age 18 years; meeting 3 or more BPD criteria, including criterion 6 (affective instability); and availability for 1 year of outpatient treatment. Exclusion criteria included lifetime diagnoses of schizophrenia, bipolar I disorder, mental retardation, or severe psychopathology requiring immediate treatment in a different setting (eg, a body mass index <16.5); life-threatening suicide attempts within the last 2 months; current substance dependence (any usage within the last 2 months); medical conditions contradicting exposure protocol (eg, pregnancy); a highly unstable life situation (eg, homelessness); scheduled residential treatment; and receipt of either CPT or DBT-PTSD treatment during the last year. Patients with ongoing self-harm, suicidality, or high-risk behaviors were not excluded.

Participants were recruited from waiting lists of outpatient clinics in Mannheim, Frankfurt, and Berlin, Germany; through advertisements; and from therapists who had been informed about the study. Recruitment occurred from January 2014 to October 2016. Data analysis took place from October 2018 to December 2019.

### Randomization and Masking

Web-based randomization software (<http://randomizer.at>) was used to assign participants in a 1:1 ratio to DBT-PTSD or CPT. Assessments were conducted by trained and experienced clinicians who were blinded to assignments.

### Interventions

Detailed descriptions of the interventions were published elsewhere and are provided in the supplementary material (eAppendix in Supplement 1).<sup>41,42,47,48</sup> Briefly, DBT-PTSD is a multicomponent phase-based program based on the principles, modes, and functions of standard DBT<sup>49</sup> but supplemented by trauma-focused cognitive-behavioral interventions<sup>40,50</sup> and specific techniques from compassion-focused therapy<sup>51</sup> and acceptance and commitment therapy.<sup>52</sup> Cognitive processing therapy is an established trauma-focused cognitive therapy aiming at challenging dysfunctional trauma-associated cognitions and emotions. Treatment, modified for this study, followed a session-by-session protocol. The first 4 sessions aimed at elaborating a case history, the patient's specific problem behaviors, and emergency plans; the next 12 sessions encompassed the original 12 CPT core sessions; and the content of the remainder was derived from the patient's individual stuck-point log.

To achieve structural equality of the arms, both treatments included individual therapy, plus homework and telephone consultation as needed. All patients received up to 45 weekly sessions over a year, followed by a booster phase of 3 monthly sessions. Participants who missed 6 consecutive weekly sessions or had psychiatric hospitalizations of 2 weeks or longer were considered dropouts, unless they had achieved early remission. Early remission was achieved under predefined conditions, all of which had to be fulfilled: (1) the patient claimed recovery prior to session 45; (2) the therapist agreed; (3) the therapist's supervisor agreed; and (4) a blinded rater assessed that the patient no longer met the PTSD diagnosis (Clinician-Administered PTSD Scale [CAPS-5] score).<sup>53</sup>

To ensure integrity of the treatments, prior to the study, participating therapists were trained in either DBT-PTSD or CPT in 4-day workshops led by the respective treatment developers. All therapists had regular team consultations. The arms were balanced with respect to therapists' experience, age, and structural characteristics, such as the number of patients (eTable 1 in Supplement 1). Therapist adherence and competence were assessed by 2 independent raters (M.M.-E. and 1 nonauthor) who had received intensive training in both treatments and the rating procedure. They viewed a total of 258 videotapes (2 sessions from each patient who completed the study) and rated the therapists using scales that had been specifically developed to assess these characteristics in both arms. Interrater reliability for all scales yielded good to excellent results (intraclass correlations, 0.67-0.97).<sup>54,55</sup>

### Diagnostic Procedures

Diagnoses of PTSD were established with the CAPS-5, co-occurring Axis I disorders with the Structured Clinical Interview for DSM-IV Axis I disorders,<sup>56</sup> and BPD with the

International Personality Disorder Examination.<sup>57</sup> The concordance between the diagnoses of PTSD according to the CAPS-5 vs the Structured Clinical Interview was 100%. Interrater reliability for the diagnosis established with the CAPS-5 in the present sample was high (intraclass correlations, 0.81-0.89).<sup>58</sup>

### Outcome Measures

The predefined primary outcome was the CAPS-5 score at 15 months, for which internal consistency (Cronbach  $\alpha$ ) was 0.93 in our sample.<sup>58</sup> Secondary outcomes included all psychopathology scales assessed at all major assessments and the Global Assessment of Functioning.<sup>59</sup> Rating scales included the PTSD Checklist for DSM-5,<sup>60</sup> the Borderline Symptom List (short version [BSL-23]),<sup>61</sup> the behavioral items of the BSL,<sup>62</sup> the Beck Depression Inventory-II,<sup>63</sup> and the Dissociation Tension Scale covering the last week<sup>64</sup> with the subscales for duration and intensity.

### Assessments and Missing Data

Full assessments were conducted before the start of therapy and after 3, 6, 9, 12, and 15 months. The primary analyses were conducted on the intent-to-treat (ITT) population, which included all participants who were randomized and fulfilled the criteria for participating. Missing items ( $\leq 10\%$ ) were imputed using stochastic regression imputation based on all other items from the respective scale.<sup>65,66</sup> If more than 10% of the items were missing, multiple imputation on the scale level was applied. Given a nonmonotone missing pattern, the Markov chain Monte Carlo method was used for this purpose.<sup>67</sup> Multiple imputation was based on the SAS procedures MI (1000 runs) and MIANALYZE. The ITT analyses were supplemented with analyses according to protocol. Details regarding missing data for the primary outcome are provided in eTable 2 in Supplement 1.

### Statistical Analysis

The planned sample size was determined a priori from a power analysis. As described by Bohus et al,<sup>47</sup> an N of 180 or more would detect a medium-size superiority of DBT-PTSD over CPT with a statistical power of 0.80 or more. Mixed linear models were the predefined primary strategy for analyzing changes. Variables that were in line with the assumption of normality were modeled by the following mixed linear model (Equation 1) based on the unstructured covariance matrix:

Level 1:  $Y_{ij} = \pi_{0j} + \pi_{1j} \text{Time}_{ij} + r_{ij}$ , where  $r_{ij} \sim N(0, \sigma^2)$

Level 2:  $\pi_{0j} = \beta_{00} + \beta_{01} \text{Group}_j + u_{0j}$ ,  $\pi_{1j} = \beta_{10} + \beta_{11} \text{Group}_j + u_{1j}$

where  $\begin{pmatrix} u_{0j} \\ u_{1j} \end{pmatrix} \sim N \left[ \begin{pmatrix} 0 \\ 0 \end{pmatrix}, \begin{pmatrix} \tau_{00} & \tau_{01} \\ \tau_{01} & \tau_{11} \end{pmatrix} \right]$ ,

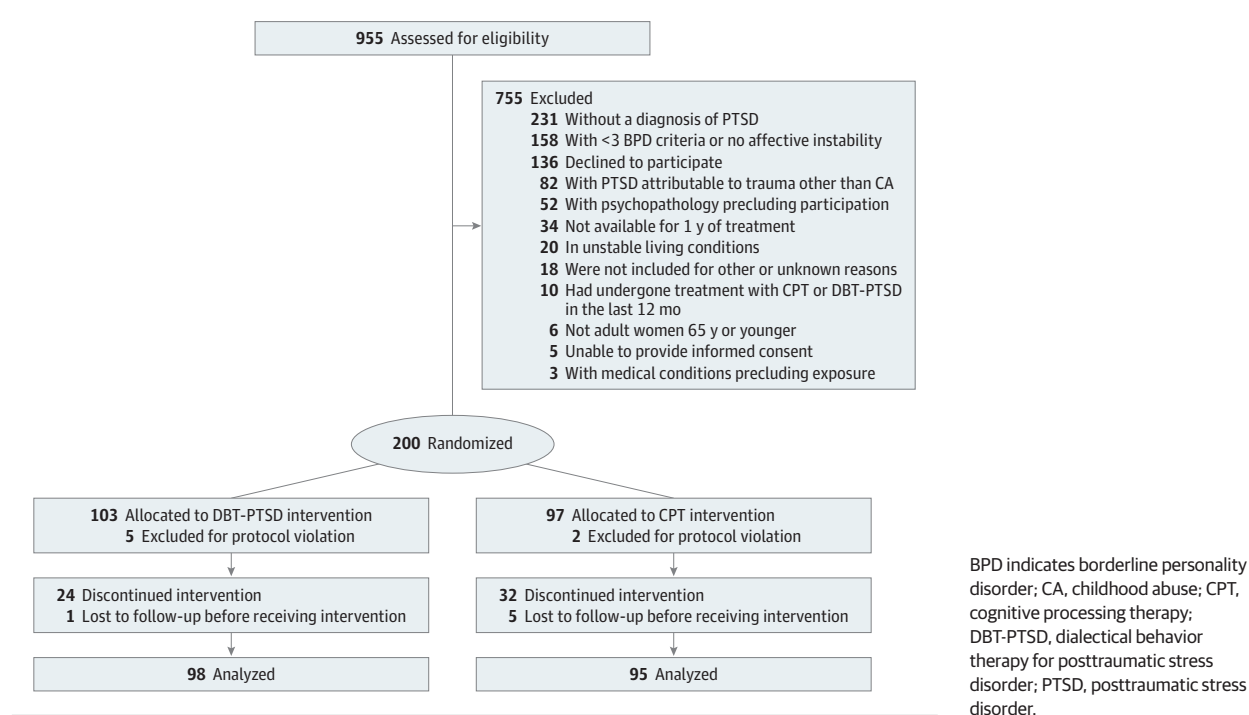
with  $\text{Group} = \begin{cases} 1, & \text{for DBT-PTSD} \\ 2, & \text{for CPT} \end{cases}$ ,

with  $\text{Time} = 1, \dots, 6$ .

$i = \text{Time} (1, \dots, 6), j = \text{Individual} (1, \dots, 193)$ .

Parameter estimation was based on restricted maximum likelihood estimates in SAS version 9.4 (SAS Institute) PROC

Figure 1. Patient Flow



MIXED. Potential misspecifications were checked by plotting marginal residuals against predicted means and using Q-Q plots. Mixed models were complemented with the following clinically meaningful measures: symptomatic remission, defined as no longer meeting the diagnostic criteria of PTSD according to *DSM-5* vs not achieving this goal (ie, not experiencing remission or dropping out without having experienced remission); reliable improvement (on the CAPS-5), requiring that the improvement exceeds a threshold (calculated as  $SD[CAPS_{pre}] \times \sqrt{2} \times \sqrt{1 - \text{reliability}[CAPS]} \times 1.96 = 7.29$ ) compatible with chance variation and unreliability<sup>68</sup>; or reliable recovery, defined as reliable improvement plus symptomatic remission.<sup>69</sup>

Changes in percentages over time were evaluated using the McNemar test. Categorical data were compared using  $\chi^2$  tests. All *P* values  $\leq .05$  (2-tailed) were considered statistically significant. Effect sizes for comparisons of continuous data before and after the intervention were calculated per Equation 2:

$$d = \left| \frac{Mean_{post} - Mean_{pre}}{\sqrt{Var_{post} + Var_{pre} - 2Cov_{post,pre}}} \right|.$$

## Results

### Patient Flow

Of 955 patients assessed for eligibility, 619 did not meet the inclusion criteria or met exclusion criteria, and 136 declined to participate (Figure 1). Of the 200 who were randomized,

7 were later excluded after they were found to be in violation of inclusion or exclusion criteria, in that they had no diagnosis of PTSD (*n* = 3), were pregnant at the time of randomization, had a brain tumor, had an established diagnosis of schizophrenia at the time of randomization, or did not have a female gender identity and sex. The final sample thus consisted of 193 participants (DBT-PTSD, 98; CPT, 95).

Overall, 62 of the 193 participants (32.1%) withdrew, with significantly more dropouts in the CPT than the DBT-PTSD group (37 [39.0%] vs 25 [25.5%]; *P* = .046). In 10 individuals (CPT, 8; DBT-PTSD, 2; *P* = .06), the reason was psychiatric hospitalization of 2 weeks or more. The numbers of dropouts in CPT vs DBT-PTSD were 20 vs 11 individuals from the start of therapy to 3 months, 6 vs 6 individuals from 3 months to 6 months, 8 vs 5 individuals from 6 months to 9 months, 3 vs 3 individuals from 9 months to 12 months, and 0 vs 0 individuals from 12 months to 15 months.

### Patient Characteristics

Sociodemographic and clinical characteristics of participants are provided in Table 1. Briefly, mean (SD) age was 36.3 (11.1) years. The mean (SD) age at first abuse was 7.7 (4.2) years, and the mean (SD) duration of the abuse was 6.9 (6.0) years. Psychotropic medication was prospectively monitored. By the end of the treatment, prescription rates in the 2 groups were similar for all medication classes except for neuroleptics (DBT-PTSD, 7 [8.0%]; CPT, 17 [21.8%]; uncorrected *P* = .02); however, this was nonsignificant after Bonferroni correction. Pre-to-post changes in psychotropic medication were uncorrelated with pre-to-post changes in the primary and secondary

Table 1. Patient Characteristics and Psychotropic Medication

Characteristic	Participants, No. (%)		
	Entire sample	DBT-PTSD	CPT
Age, mean (SD), y	36.3 (11.1)	37.0 (10.7)	35.5 (11.4)
Education <sup>a</sup>			
No graduation or still at school	11 (5.8)	7 (7.2)	4 (4.3)
Lower secondary school (Hauptschule)	30 (15.8)	16 (16.5)	14 (15.1)
Intermediate secondary school (Mittlere Reife)	67 (35.3)	33 (34.0)	34 (36.6)
High school graduation (Abitur)	75 (39.5)	37 (38.1)	38 (40.9)
Other	7 (3.7)	4 (4.1)	3 (3.2)
Marital status <sup>b</sup>			
Single	95 (49.7)	44 (45.8)	51 (53.7)
Married or similar relationship	49 (25.7)	25 (26.0)	24 (25.3)
Separated, divorced, or widowed	47 (24.6)	27 (28.1)	20 (21.1)
No. of Axis I disorders, mean (SD)			
Current	3.25 (1.43)	3.06 (1.31)	3.44 (1.53)
Lifetime	4.21 (1.54)	4.07 (1.45)	4.35 (1.62)
Co-occurring BPD	93 (48.2)	43 (43.9)	50 (53.6)
BPD criteria, mean (SD), No.	4.80 (1.64)	4.68 (1.63)	4.92 (1.65)
≥1 Suicide attempt, lifetime <sup>c</sup>	107 (57.5)	58 (63.0)	49 (52.1)
Nonsuicidal self-injury at least once in the last mo <sup>d</sup>	75 (39.1)	40 (40.8)	35 (37.2)
Index trauma			
Sexual abuse or sexual and physical abuse	144 (74.6)	75 (76.5)	69 (72.6)
Exclusively physical abuse	49 (25.4)	23 (23.5)	26 (27.4)
Repeated abuse <sup>d</sup>	174 (90.6)	86 (88.7)	88 (92.6)
Age at first abuse, mean (SD), y	7.69 (4.21)	7.67 (4.28)	7.71 (4.16)
Duration of abuse, mean (SD), y	6.90 (6.00)	6.36 (5.16)	7.44 (6.69)
Perpetrator known to the patient	182 (94.3)	94 (95.9)	88 (92.6)
Additional sexual or physical abuse in adulthood <sup>e</sup>	124 (67.8)	66 (71.7)	58 (63.7)
Prior psychotherapeutic or psychiatric treatment	172 (89.1)	85 (91.6)	87 (86.7)
Psychotropic medication at baseline <sup>f</sup>			
Any psychotropic medication	133 (69.3)	68 (69.4)	65 (69.2)
Antidepressants	103 (53.7)	52 (53.1)	51 (54.3)
Neuroleptics	55 (28.7)	24 (24.5)	31 (33.0)
Mood stabilizers <sup>g</sup>	4 (2.1)	1 (1.0)	3 (3.2)
Benzodiazepines	14 (7.3)	7 (7.1)	7 (7.5)
Other psychotropic medication	19 (9.9)	7 (7.1)	12 (12.8)
Psychotropic medication at postassessment			
Any psychotropic medication	84 (50.6)	42 (47.7)	42 (53.9)
Antidepressants	64 (38.6)	33 (37.5)	31 (39.7)
Neuroleptics	24 (14.5)	7 (8.0)	17 (21.8)
Mood stabilizers <sup>g</sup>	1 (0.6)	0 (0.0)	1 (1.3)
Benzodiazepines	8 (4.8)	4 (4.6)	4 (5.1)
Other psychotropic medication	10 (6.0)	5 (5.7)	5 (6.4)
Change in psychotropic medication from before therapy to postassessment	87 (52.4)	45 (51.4)	42 (53.9)

Abbreviations: BPD, borderline personality disorder; CPT, cognitive processing therapy; DBT-PTSD, dialectical behavior therapy for posttraumatic stress disorder.

<sup>a</sup> Data regarding education were available for 190 participants.

<sup>b</sup> Marital status was available for 191 participants.

<sup>c</sup> Data regarding suicide attempts (lifetime) were available for 186 participants.

<sup>d</sup> Data regarding nonsuicidal self-injury and repeated abuse were available for 192 participants.

<sup>e</sup> Data regarding additional sexual physical or sexual abuse in adulthood were available for 180 participants.

<sup>f</sup> Data regarding psychotropic medication at pretherapy assessment were available for 192 participants; psychotropic medication at 15 months and change in psychotropic medication data were available for 166 participants.

<sup>g</sup> Lithium, lamotrigine, carbamazepine, or valproate; atypical neuroleptics that are currently being used as mood stabilizers (ie, olanzapine, quetiapine, aripiprazole, risperidone, ziprasidone, asenapine, paliperidone, and lurasidone) have been subsumed under neuroleptics.

outcomes and not significantly associated with either symptomatic remission or dropout rates.

### Treatment Integrity

Mean (SD) adherence to the respective manuals was good in both groups (DBT-PTSD, 4.1 [1.2] points; CPT, 3.9 [1.3] points). Mean (SD) therapeutic competence was likewise good (DBT-PTSD, 4.0 [0.9] points; CPT, 4.0 [0.9] points).

### Primary Outcome

For both therapies, mean changes on the CAPS-5 score were significant, with unadjusted mean (SD) improvements of 19.4 (14.4) points ( $P < .001$ ) in the DBT-PTSD group and 14.6 (14.8) points ( $P < .001$ ) in the CPT group. These reductions correspond to large pre-to-post effect sizes ( $d$ , 1.35 and  $d$ , 0.98, respectively; Table 2). Comparisons of individual CAPS-5 scores before and after therapy (Figure 2) indicated that most



Table 2. Primary and Secondary Outcome Data Before Therapy vs Postassessment

	Mean (SD)		Effect size, Cohen <i>d</i>				Mixed linear models, $\beta$ (SE)	Term	<i>P</i> value
Measure	Pretherapy	Postassessment	Intent-to-treat population <sup>a</sup>		Population according to protocol <sup>b</sup>				
			<i>P</i> value		<i>P</i> value				
Clinician Administered PTSD Scale									
DBT-PTSD	39.93 (10.84)	20.56 (15.81)	1.35	NA	1.66	NA	$\beta_{10} = -4.84$ (0.73)	Time	<.001
CPT	40.96 (8.95)	26.41 (16.04)	0.98	NA	1.25	NA	$\beta_{01} = -0.30$ (1.54)	Group	.85
Comparison	NA	NA	0.33	.02	0.21	.26	$\beta_{11} = 0.93$ (0.47)	Group $\times$ time	.047
Posttraumatic Stress Disorder Checklist for DSM-5									
DBT-PTSD	49.39 (11.46)	23.82 (17.86)	1.55	NA	2.34	NA	$\beta_{10} = -6.98$ (0.89)	Time	<.001
CPT	49.54 (11.04)	33.74 (19.60)	0.90	NA	1.34	NA	$\beta_{01} = -1.24$ (1.82)	Group	.50
Between	NA	NA	0.57	<.001	0.46	.04	$\beta_{11} = 1.86$ (0.57)	Group $\times$ time	.001
Dissociation Tension Scale-duration									
DBT-PTSD	24.13 (16.88)	14.04 (14.58)	0.79	NA	1.23	NA	$\beta_{10} = -3.13$ (0.74)	Time	<.001
CPT	23.96 (14.81)	20.87 (18.08)	0.20	NA	0.31	NA	$\beta_{01} = -0.57$ (2.45)	Group	.82
Comparison	NA	NA	0.50	<.001	0.30	.20	$\beta_{11} = 1.17$ (0.48)	Group $\times$ time	.02
Dissociation Tension Scale-intensity									
DBT-PTSD	2.82 (1.70)	1.77 (1.70)	0.82	NA	1.22	NA	$\beta_{10} = -0.30$ (0.08)	Time	<.001
CPT	3.12 (1.62)	2.61 (1.88)	0.33	NA	0.55	NA	$\beta_{01} = 0.28$ (0.27)	Group	.32
Comparison	NA	NA	0.39	.007	0.20	0.41	$\beta_{11} = 0.09$ (0.05)	Group $\times$ time	.09
Borderline Symptom List-23									
DBT-PTSD	2.01 (0.82)	1.14 (0.86)	1.11	NA	1.4	NA	$\beta_{10} = -0.25$ (0.04)	Time	<.001
CPT	2.04 (0.80)	1.63 (0.95)	0.47	NA	0.72	NA	$\beta_{01} = -0.001$ (0.12)	Group	.99
Comparison	NA	NA	0.55	<.001	0.27	.22	$\beta_{11} = 0.08$ (0.03)	Group $\times$ time	.003
Borderline Symptom List-behavioral items									
DBT-PTSD	0.34 (0.33)	0.18 (0.18)	0.54	NA	0.76	NA	NA <sup>c</sup>	NA <sup>c</sup>	NA <sup>c</sup>
CPT	0.31 (0.28)	0.29 (0.25)	0.08	NA	0.34	NA			
Comparison	NA	NA	0.50	<.001	0.39	.06			
Beck Depression Inventory-II									
DBT-PTSD	33.24 (11.20)	21.57 (14.04)	0.98	NA	1.37	NA	$\beta_{10} = -3.20$ (0.78)	Time	<.001
CPT	34.10 (10.81)	26.99 (15.09)	0.48	NA	0.76	NA	$\beta_{01} = 0.33$ (1.93)	Group	.86
Comparison	NA	NA	0.32	.02	0.17	.45	$\beta_{11} = 0.86$ (0.49)	Group $\times$ time	.09
Global Assessment of Functioning									
DBT-PTSD	50.75 (9.14)	60.13 (13.95)	0.67	NA	1.12	NA	$\beta_{10} = 2.38$ (0.62)	Time	<.001
CPT	49.19 (7.69)	55.25 (12.55)	0.51	NA	0.87	NA	$\beta_{01} = -0.71$ (1.39)	Group	.61
Comparison	NA	NA	0.26	.08	0.27	.16	$\beta_{11} = -0.52$ (0.40)	Group $\times$ time	.20

Abbreviations: CPT, cognitive processing therapy; DBT-PTSD, dialectical behavior therapy for posttraumatic stress disorder; NA, not applicable; PTSD, posttraumatic stress disorder.

<sup>a</sup> Intent-to-treat:  $n = 98$  (DBT-PTSD), and  $n = 95$  (CPT), respectively; besides the Dissociation Tension Scale-duration under CPT and the Borderline Symptom List-behavioral items under CPT all pre-to-post effect sizes  $d$  were statistically different from 0.

<sup>b</sup> According to protocol:  $n = 73$  (DBT-PTSD), and  $n = 58$  (CPT), respectively; besides the Dissociation Tension Scale-duration under CPT, all pre-to-post effect sizes  $d$  were statistically different from 0.

<sup>c</sup> Mixed linear models for the Borderline Symptom List-behavioral items are not reported because the assumption of linearity was not met and the Newton-Raphson algorithms used in generalized linear models did not consistently converge during the procedure of multiple imputation.

participants in both groups showed improvement with respect to the primary outcome, and none showed reliable worsening.

Between-group comparison of the predefined primary outcome favored DBT-PTSD. For the ITT population, the mean change on the CAPS-5 scores was larger for DBT-PTSD than CPT,

albeit with a small effect size ( $d$ , 0.33;  $P = .02$ ). Similarly, the mixed linear model indicated a steeper slope of linear improvements for DBT-PTSD ( $\beta_{11}$ ,  $0.93 \pm 0.47$ ;  $P = .047$ ; Table 2 and Figure 3). The more pronounced decline of CAPS-5 scores in the DBT-PTSD group was mirrored by a higher percentage of participants achieving symptomatic remission (52 of 89

Figure 2. Individual Participant Scores

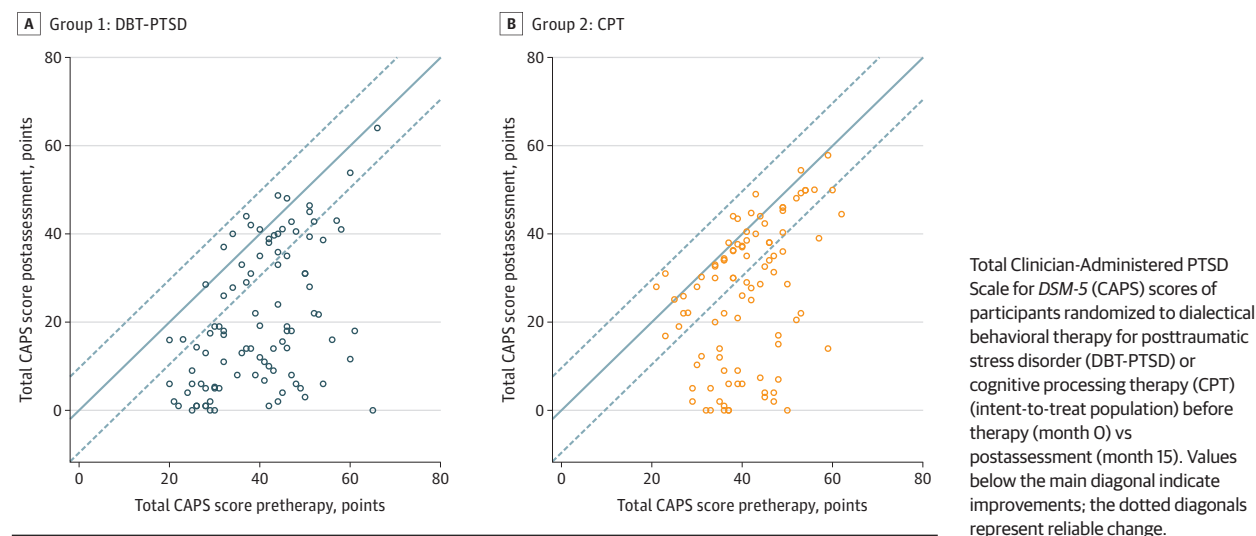
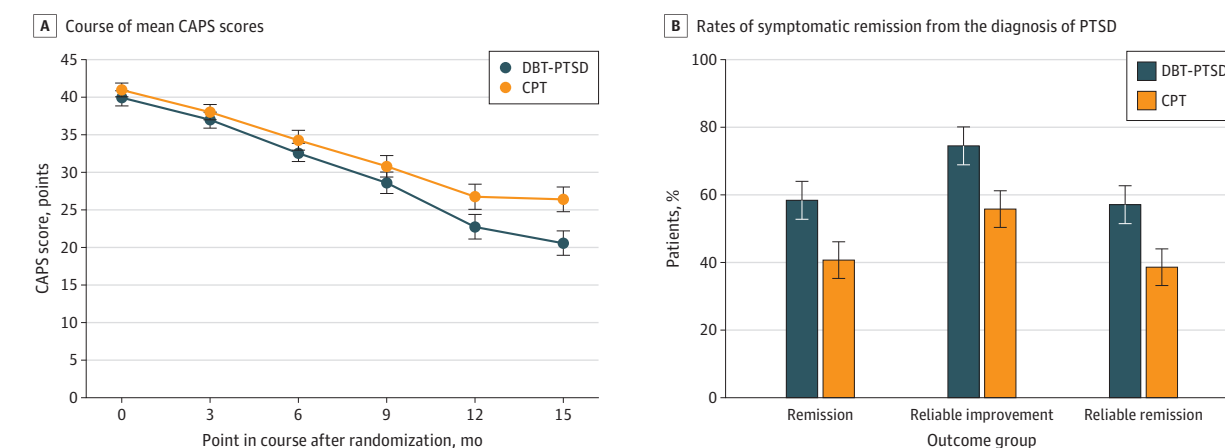


Figure 3. Dimensional and Categorical Treatment Outcomes



Scores and categories are based on Clinician-Administered PTSD Scale for *DSM-5* (CAPS-5) scores for dialectical behavioral therapy for posttraumatic stress disorder (DBT-PTSD; dark color) and cognitive processing therapy (CPT; light color). Error bars indicate standard errors of means. A, Course of mean CAPS scores from before therapy (month 0) to postassessment (month 15). B,

Rates of symptomatic remission from the diagnosis of PTSD (not meeting the full criteria of posttraumatic stress disorder (PTSD) in the CAPS-5) of reliable improvement (improvement from before to after therapy that exceeds a threshold compatible with the unreliability of measurement) and reliable recovery (reliable improvement plus symptomatic remission).

observed cases [58.4%] vs 35 of 86 observed cases [40.7%];  $P = .02$ , reliable improvement (73 [74.5%] vs 53 [55.8%];  $P = .006$ ), and reliable recovery (52 of 91 observed cases [57.1%] vs 34 of 88 observed cases [38.6%];  $P = .01$ ). However, the percentage of participants achieving early remission was higher for CPT than DBT-PTSD (9 [9.5%] vs 2 [2.0%];  $P = .03$ ).

### Secondary Outcomes

Changes in the PTSD Checklist for *DSM-5* were large in both groups. Mean changes in the ITT population were larger for the DBT-PTSD group (DBT-PTSD:  $d$ , 1.55; CPT:  $d$ , 0.90; between-group effect size  $d$ , 0.57;  $P < .001$ ). This finding was supported by the significant group  $\times$  time interaction in the mixed linear model, indicating a more pronounced improvement in

the DBT-PTSD group for self-rated severity of PTSD symptoms ( $\beta_{11}$ ,  $1.86 \pm 0.57$ ;  $P = .001$ ).

Findings regarding dissociation were less homogeneous. While duration of dissociative symptoms (Dissociation Tension Scale) declined in both groups, decline in the intensity of dissociative symptoms was significant only for DBT-PTSD. Mean changes were large for DBT-PTSD ( $d$ , 0.79 and  $d$ , 0.82 for the duration and intensity of dissociation, respectively) and small for CPT ( $d$ , 0.20 and  $d$ , 0.33, respectively). Between-group effect sizes were significant for both duration and intensity of dissociation ( $d$ , 0.50;  $P < .001$ ;  $d$ , 0.39;  $P = .007$ ). Mixed linear models partially supported these findings ( $\beta_{11}$ ,  $0.09 \pm 0.05$ ;  $P = .02$  and  $\beta_{11}$ ,  $1.17 \pm 0.48$ , respectively;  $P = .09$  for the group  $\times$  time interactions; Table 2).

Pre-to-post effect sizes in the BSL-23 were large for DBT-PTSD ( $d$ , 1.11) and medium for CPT ( $d$ , 0.47). The difference between the groups was significant (between-group effect size:  $d$ , 0.55;  $P < .001$ ). While the BSL-behavioral items score involving frequencies of dysfunctional behaviors, such as self-harm, high-risk behaviors, or consumption of drugs, declined in both groups, the decline in the DBT-PTSD group was significant ( $d$ , 0.54;  $P < .001$ ), while that for CPT was not ( $d$ , 0.08;  $P = .42$ ). This decline was more pronounced under DBT-PTSD (between-group effect size:  $d$ , 0.50;  $P < .001$ ).

Improvements of Beck Depression Inventory-II scores were large for DBT-PTSD ( $d$ , 0.98) and medium for CPT ( $d$ , 0.48). This difference of pre-to-post differences was small and significant ( $d$ , 0.32;  $P = .02$ ), but the group  $\times$  time interaction in the mixed linear model was not significant. With respect to the Global Assessment of Functioning, medium improvements were observed (DBT-PTSD:  $d$ , 0.67; CPT:  $d$ , 0.51), but there were no significant between-group effects (Table 2). The means (SDs) for all dimensional scales and assessment points and the length of hospitalization by condition are provided in eTable 3 and 4 in Supplement 1, respectively.

Results pertaining to the analyses according to protocol are summarized in Table 2. No differences in any outcome variables were noted between the 3 sites (eTable 5 in Supplement 1).

No suicides occurred during the observation period. One suicide attempt was noted in the CPT group.

## Discussion

Dialectical behavior therapy for PTSD (DBT-PTSD) is designed as a phase-based treatment specifically for patients with highly symptomatic CA-associated PTSD and complicating conditions, such as emotion dysregulation and other features of BPD. This randomized clinical trial compared the efficacy of DBT-PTSD with that of CPT, which is one of the best available treatments for PTSD but is not specifically designed for this population. Improvements in the primary outcome measure were large and significant for both treatments but more pronounced in the DBT-PTSD group. The same results were seen for other aspects of psychopathology closely associated with a history of CA, such as dissociation, self-harm, and high-risk behaviors. Furthermore, participants in the DBT-PTSD group were more likely to achieve symptomatic remission, reliable improvement, and reliable recovery and were less likely to drop out of treatment.

The large pre-to-post effect sizes in both treatment groups parallel the effect sizes observed in previous studies of both CPT and DBT-PTSD.<sup>41-44,70</sup> Similarly, the low rates of suicidal acts and the absence of significant symptom exacerbations in both groups are in line with previous studies.

Cognitive processing therapy did not perform as well as it has in PTSD studies in general.<sup>41,44</sup> This might be because of the relatively high dropout rate within the first 3 months. It is unclear how sessions 1 to 4, which were added to the CPT protocol for safety reasons, affected treatment dropout. On the other hand, high dropout rates might be explained by clinical

characteristics of the study population (in that all participants met at least 3 BPD criteria, including affective instability, and 48% had co-occurring BPD). These characteristics might require specifically tailored interventions for this population, as provided by DBT-PTSD.

## Strengths

Strengths of this study included measures to control for potentially confounding variables. Both groups received equal dosage and frequency of therapy, the process of therapist training was guided by the treatment developers, training and experience of the therapists were balanced across treatment groups, and structured observer-based scales were used to assess treatment integrity. In line with the updated CONSORT statement, randomization was concealed to all persons involved,<sup>71</sup> and raters were blinded.

We tried to balance developers' bias by including the CPT developer (P.A.R.) as a senior trainer and consultant for CPT supervisors. Therapists in both groups had similar experience and competence and received the same amounts of training and supervision. Assessments of adherence and competence revealed good treatment integrity to both manuals.

## Limitations

Nevertheless, allegiance effects cannot be completely ruled out, and the findings need to be replicated by independent research groups. In the DBT-PTSD arm, the treatment developers were part of the consultation teams, while in the CPT arm, the supervisors were experienced in cognitive behavior therapy but did not have more experience in CPT than the therapists.

We emphasize that the study population consisted of patients whose PTSD was associated with CA and who had severe problems in emotion regulation and features of BPD, so the findings cannot be extended to PTSD in general. It also remains unknown whether our results can be generalized to patients of any age, sex, or gender identity. It is further unclear whether the improvements achieved and the superiority of DBT-PTSD over CPT will persist in the long term. These limitations should be addressed by future research.

Given the dropout rate of 32%, the results may be affected by attrition bias. To minimize potential bias, the primary analysis was based on the ITT sample.

Finally, the observed effects might have been confounded by intercurrent treatments. However, this seems unlikely since, with the exception of inpatient crisis interventions, only CPT and DBT-PTSD were allowed during the study period. Use of medication was unrestricted, but neither hospitalization nor changes in psychotropic medication were significantly associated with the outcome variables.

## Conclusions

The study shows that even severe forms of CA-associated PTSD that include multiple co-occurring mental disorders and emotion dysregulation can be treated efficaciously. Future studies should strive for a better definition of patient groups that might profit from current therapies. In particular, additional



research is required to test whether treatment efficacy might extend beyond adult women, and whether the DBT-PTSD protocol could be condensed to reduce cost burdens and patient burdens and facilitate dissemination.

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