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The Effectiveness of Dialectical Behavior Therapy Compared to Schema Therapy for Borderline Personality Disorder: A Randomized Clinical Trial

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Keywords

Borderline personality disorder · Randomized clinical trials · Effectiveness · Psychotherapy research · Treatment outcome

Abstract

Introduction: In the treatment of borderline personality disorder (BPD), there is empirical support for both dialectical behavior therapy (DBT) and schema therapy (ST); these treatments have never been compared directly. This study examines whether either of them is more effective than the other in treating patients with BPD. **Methods:** In this randomized, parallel-group, rater-blind clinical trial, outpatients aged between 18 and 65 years with a primary diagnosis of BPD were recruited in a tertiary outpatient treatment center (Lübeck, Germany). Participants were randomized to DBT or ST with one individual and one group session per week over 1.5 years. The primary outcome was the BPD symptom severity assessed with the mean score of the Borderline

Personality Disorder Severity Index at 1-year naturalistic follow-up. **Results:** Between November 26, 2014, and December 14, 2018, we enrolled 164 patients (mean age = 33.7 [$SD = 10.61$] years). Of these, 81 (49.4%) were treated with ST and 83 (50.6%) with DBT, overall, 130 (79.3%) were female. Intention-to-treat analysis with generalized linear mixed models did not show a significant difference at 1-year naturalistic follow-up between DBT and ST for the BPDSI total score (mean difference 3.32 [95% CI: $-0.58-7.22$], $p = 0.094$, $d = -24 [-0.69; 0.20]$) with lower scores for DBT. Pre-to-follow-up effect sizes were large in both groups (DBT: $d = 2.45 [1.88-3.02]$, ST: $d = 1.78 [1.26-2.29]$). **Conclusion:** Patients in both treatment groups showed substantial improvements indicating that even severely affected patients with BPD and various comorbid disorders can be treated successfully with DBT and ST. An additional non-inferiority trial is needed to show if both treatments are equally

Nele Assmann and Anja Schaich share first authorship.

effective. The trial was retrospectively registered on the German Clinical Trials Register, DRKS00011534 without protocol changes.

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Introduction

Several psychotherapy methods are available for treating borderline personality disorder (BPD) with good empirical evidence [1–3], and international guidelines highly recommend disorder-specific psychotherapy for patients suffering from BPD [4–6]. Two of the most established treatments include dialectical behavior therapy (DBT) [7, 8] and schema therapy (ST) [9, 10]. DBT is the most frequently studied treatment for BPD, and its effectiveness has been demonstrated in several randomized controlled trials (RCTs) [2, 3]. Even though ST is less often studied so far, there are promising results from two large [11, 12] and one small randomized trial [13] as well as studies in routine care [14–16].

DBT and ST have never been compared in a randomized trial so far. Overall, there is a need for comparative clinical trials. Comparing the effectiveness of BPD treatments may improve patients' informed choices and guide decision-making about which treatments to prioritize in health care systems [17].

The programs for BPD (PRO*BPD) study is the first randomized trial to compare the effectiveness of ST and DBT in patients with BPD [18]. It was implemented into a routine tertiary care setting of an outpatient clinic affiliated with inpatient services. This outpatient service was explicitly set up to treat severely affected patients with BPD who are repeatedly seen in emergency rooms or would otherwise be treated in inpatient settings. Research in this population is fundamental considering that BPD is associated with high societal costs [19–22], primarily caused by inpatient treatment.

The primary hypothesis was that BPD associated symptoms differ between DBT and ST at the 1-year naturalistic follow-up. Since information from literature does not allow predictions on the directionality of the difference, a two-sided hypothesis was chosen. Secondary outcomes included treatment retention, general symptom severity, depression, dissociation, quality of life, psychosocial functioning, and participation. In addition, based on former research and theoretical considerations regarding DBT and ST, secondary hypotheses were formulated regarding differential effects in the secondary outcomes: We hypothesized that DBT reduces suicidality,

self-harm, and dissociation better and faster than ST. At the same time, ST would be better in improving the quality of life and reducing general symptom severity and depressive symptomatology (see study protocol for a detailed explanation [18]).

Materials and Methods

Study Design

The PRO*BPD study design is a single-center randomized clinical trial. The recruitment of participants took place in a tertiary outpatient treatment center of a university clinic affiliated with inpatient treatment in Lübeck, Germany, mainly treating severely affected patients who cannot receive treatment elsewhere or cannot sufficiently be treated by practitioners in private practices. The PRO*BPD study was designed in adherence to the Consolidated Standards of Reporting Trials (CONSORT) guidelines and methodology [23] and follows methodological recommendations for trials of psychological interventions [24] (summarized in online suppl. Table S1; for all online suppl. material, see <https://doi.org/10.1159/000538404>). The planned sample size was $N = 160$ based on a power analysis (power 80%; medium effect size, $\alpha = 0.05$, $n = 128$) and taking attrition (20%, $n = 32$) into account [25]. Details about the study design are published in the study protocol [18].

Participants

Patients were eligible when they (1) were between 18 and 65 years of age, (2) had a primary diagnosis of BPD (diagnosed with the Structural Clinical Interview for DSM-IV for Axis II; SCID-II-Interview) [26], (3) had a BPD severity score >20 points on the Borderline Personality Disorder Severity Index (BPDSI), Version 4 [27], (4) gave informed consent, and (5) were able and willing to participate reliably in therapy and assessment procedures. Exclusion criteria were (1) a lifetime diagnosis of a psychotic disorder, (2) intellectual deficits (IQ <85), (3) poor German language skills, and (4) acute substance use disorder that required detoxification treatment. Participation was possible after completing detoxification treatment and 4 weeks of abstinence. Participants with cannabis dependence could participate if they committed to working on abstinence during treatment.

Randomization and Masking

Randomization was conducted by Prof. Michael Hüppe, who was not involved in the data collection and therapy using the program BiaS (11.02) [28]. After completing the baseline assessment, participants were randomized to the two conditions (ST or DBT). Randomization was stratified by sex to avoid biases due to unbalanced sex distribution. The allocation sequence was concealed from both participants and researchers. Raters were blind to the assignment; participants were informed about their condition during the first therapy session.

Procedure

Participants completed assessments at baseline, 0.5 years after the start of treatment, one year after the start of treatment, posttreatment (1.5 years), and two naturalistic follow-up

assessments (0.5 years and one year). In the following, the 1-year follow-up assessment will be referred to as follow-up (primary outcome). Assessments included self-report measures and interviews (conducted by blind and independent raters trained in the interviews). Due to a wide range of measures, the baseline assessment consisted of three to four appointments with the patients and was scheduled within 3 months before the start of treatment. In case, there were more than 3 months between assessment of the primary outcome and start of treatment (due to availability of treatment slots and missed appointments), the interview of the primary outcome was repeated.

Outcomes

The primary outcome was the severity of BPD assessed by the total score of the BPDSI-IV at 1-year naturalistic follow-up. The BPDSI is a semi-structured interview including 70 items rating the frequency and severity of the nine BPD traits described in the DSM-IV over the prior 3 months. The BPDSI is a reliable instrument with good psychometric qualities [29, 30]. In the present study, the assessed interrater reliability was excellent (all intra-class correlation coefficients >0.997 [ICC], online suppl. material). In addition, suicidality and the number of suicide attempts were identified using BPDSI data. An increase of 11.70 or more in the BPDSI total score compared to the baseline assessment was defined as deterioration [11].

Secondary outcome measures included a self-rating questionnaire of the burden experienced by BPD manifestations (BPD checklist) [31], the severity of depression (Quick Inventory of Depressive Symptoms, QIDS-SR) [32], global symptom severity (Brief Symptom Inventory, BSI) [33], dissociation (Dissociation Tension Scale, DSS) [34], psychosocial functioning and participation (World Health Organization Disability Assessment Schedule 2.0, WHODAS 2.0 [35] and Work and Social Adjustment Scale, WSAS [36]) and quality of life (World Health Organization Quality of Life questionnaire, WHOQOL) [37]. Comorbid mental disorders were assessed using the German version of the SCID-I and II-Interview [38, 39]. For further information on secondary outcomes, see online supplementary material. Psychopharmacological treatment and demographic parameters were also assessed. Treatment retention was also analyzed as a secondary outcome. To register also unwanted iatrogenic effects of psychotherapy, we recorded adverse events (inpatient treatment, suicide attempts, cases of death) and analyzed deterioration in the BPDSI.

Treatment

Patients were randomized to DBT or ST; both included one individual session (60 min) and one group session (120 min) per week and followed a written protocol [7, 8, 10, 40]. Groups consisted of up to 10 BPD patients and two therapists and were offered in a semi-open format. The start of the individual therapy was planned four to 10 weeks before the beginning of group therapy. Eligible patients who could not attend group sessions due to family, professional, or educational duties were provided weekly individual therapy only. The treatment duration was 1.5 years. Patients could stop the treatment program prematurely and were considered as an “early success” if their BPDSI score was less than 15 and the therapist team agreed that the patient should stop the program due to re-

mission. Patients could also be “pushed out” of the treatment program based on a decision of the therapist team and the local supervisor [18]. We decided not to define explicit rules for a patient to be “pushed out” of both conditions. It should be noted that this is a difference from the standard DBT protocol [22]. In the PRO*BPD trial, a “push out” was always decided by the therapist team and the local supervisors and was consistent with the respective treatment manual except for the deviation mentioned above. After the end of study treatment, no further treatment was recommended. As it was a naturalistic follow-up, further treatment was not prohibited but registered at follow-up assessments. If needed, patients had the opportunity to see their former therapist monthly or less frequently. We had some deviations from our original protocol due to the COVID-19 pandemic and therefore conducted a sensitivity analysis excluding all participants affected by the pandemic (online suppl. material).

Therapists

Therapists were advanced DBT and ST therapists and therapists who were new to ST or DBT but were experienced in CBT, with training before administering the treatment and learning the method under close supervision. Local and external certified specialists trained therapists for the specific method in several workshops. They participated in weekly supervision sessions under the direction of the locally approved supervisors (DBT: VS, US, ST: EF) and team meetings.

Treatment Integrity

All individual and group sessions were videotaped, and adherence and competence were rated in a random selection of session tapes from different treatment stages (each treatment stage 6 months) by trained raters. The videos of the sessions were rated altogether after the end of the study treatment. Individual sessions were rated using an adapted version (May 2014) of the Therapy Adherence and Competence Scale for therapy of BPD by Young et al. [41] which was also used in Giesen-Bloo et al. [11] and the Dialectical Behavior Therapy Adherence Checklist – Individual Therapy (DBT AC-I) observer-rated version [42]. The latter was chosen because ratings with the originally planned DBT adherence manual [43] were only possible by DBT-specialists certified for this and were not covered by the funding of our study. Adherence to ST group sessions was rated using a scale combining the Schema Therapist Competency Scale for individual therapy sessions (STCS-I-1) [44] and the Group Schema Therapy Rating Scale (GSTRS) and its revised version (GSTRS-R) [45]. Each item of the scales was code 0/1 for adherence and 1–6 for competence. For the DBT group sessions, there was no freely available rating scale. Ratings of DBT group sessions would have been available from certified raters who did not participate in this study. Unfortunately, funding was not available for these ratings. Ten videos of DBT group sessions were rated using the ST scale to ensure discrimination. Details on the rater training can be found in the online supplementary material.

Statistical Analysis

Originally, the hypothesis that there is a difference between patients treated with DBT and ST regarding the reduction of BPD symptoms was operationalized as a difference between the slopes over time (baseline to 1-year naturalistic follow-up) [18].

Due to unexpected baseline differences between DBT and ST (especially self-rated BPD symptoms and depression, see online suppl. Table S2), we had to adapt our analysis plan and had to control for the baseline scores (see below and online suppl. material). Moreover, controlling for baseline scores is recommended independently from baseline differences [46]. As a consequence, we had to change the operationalization of the primary hypothesis and tested the difference at 1-year naturalistic follow-up.

The statistical analyses were performed with SPSS, version 28. Data analyses followed the intention-to-treat (ITT) principle and used all available data. Patients were included in the ITT sample if they were randomized and attended at least one individual session where they were informed about treatment condition. Missing values were not imputed as generalized linear mixed models (GLMMs) can validly estimate effects under the same assumptions as multiple imputation.

A step-by-step report of the statistical analyses can be found in the online supplementary material. Given skewed distributions, continuous outcome variables were analyzed with GLMM gamma regression. As gamma regression cannot handle zeros, a small value (0.01) was added to all scores, if zeros existed. Where estimation allowed, we included a random effect of the treatment cohort to account for the fact that cohorts of patients participated in group therapy together. Time was modeled according to the best model fit, e.g., linear, logarithmic, or segmented development of scores over time. We used a piece-wise regression model if the primary inspection of the data indicated that change during treatment had a different slope than change during the naturalistic follow-up period, and a comparison of model fit confirmed this impression. For piece-wise coded regression, we defined all assessments of the treatment phase as one section and the follow-up assessments separately. As predefined in the study protocol, we included the use of psychotropic medication as a running covariate coding the use for every assessment point. Since this can be discussed controversially, we conducted a sensitivity analyses without the medication covariate. The covariance structure for the repeated part and time was modeled according to the best model fit.

Additional covariates were included as we observed systematic baseline differences between ST and DBT in almost all outcome variables with higher scores for DBT patients (online suppl. Table S2). We included a centered baseline global severity score based on principal component analysis, including all outcome variables at baseline and the number of comorbidities on axis I and II as well as the centered baseline variable as a covariate and excluded the baseline assessment in the dependent time variable for all outcomes [46]. Therefore, the main effect of treatment after 1-year naturalistic follow-up was the primary test of treatment differences. Thus, the fixed effects in the GLMM included time, medication, treatment, and their interaction, as well as global severity, and the particular baseline score was also included in the fixed part. A further fixed effect of time piece-wise and its interaction with treatment and medication were included if a piece-wise regression model was used. The exact configuration of the GLMM for each outcome variable is specified in online supplementary Table S3 and a definition of all variables included in the model can be found in online suppl. Table S4. For a detailed step-by-step description of the statistical analyses, refer to online supplementary material.

The number of suicide attempts during the last 3 months was analyzed using generalized estimating equations with a Tweedie distribution (because of many zero counts) with a log link and first-order autoregression for the repeated part. Treatment retention was analyzed using GLMM survival analysis.

Effect sizes were expressed as r for the fixed effects in the GLMM analyses and Cohen's d as conventional within- and between-groups effect size. For a description of effect sizes, see online supplementary material.

Additionally, we conducted a completer analysis of the primary outcome, including all patients that completed treatment after 1.5 years or left the program earlier after remission. Further, we conducted a sensitivity analysis including only those patients who received the combination of group and individual therapy. We also conducted a sensitivity analysis following the original analytic plan including all assessment points and not controlling for baseline differences. Lastly, we conducted a sensitivity analysis excluding the medication covariate.

Results

Patient Flow and Sample Characteristics

Between November 26, 2014, and December 14, 2018, 255 patients were screened for eligibility, and 164 were included in the PRO*BPD trial's ITT sample of the PRO*BPD trial. The last follow-up assessment was conducted on January 20, 2022. The CONSORT flow diagram of participant recruitment is presented in Figure 1. Table 1 displays the demographic and clinical characteristics of the ITT sample. The mean number of sessions before the start of group therapy was $M = 4.3$ (DBT and ST), and the average number of individual sessions was $M = 44.48$ (DBT) and $M = 46.7$ (ST) for the intent-to-treat sample and $M = 52.4$ (DBT) and $M = 52.1$ (ST) for the completer sample.

Treatment Integrity

Overall, 500 videos out of 7,475 individual sessions and 43 videos out of 436 group sessions were rated by trained raters. The interrater reliability was assessed for 20 ratings of individual sessions (ten ST and ten DBT) and 19 ratings of group sessions (ten ST and nine DBT). Interrater reliability showed to be very good both for the ratings of the individual sessions (ICC between 0.88 and 0.961) and for the ST ratings of the group sessions (ICCs between 0.991 and 0.992). There was significant discrimination between ST and DBT at the ST, respectively, DBT adherence and competence scales (all $p < 0.009$). ST group adherence and competence ratings also indicated a good differentiation between the conditions (all $p < 0.001$).

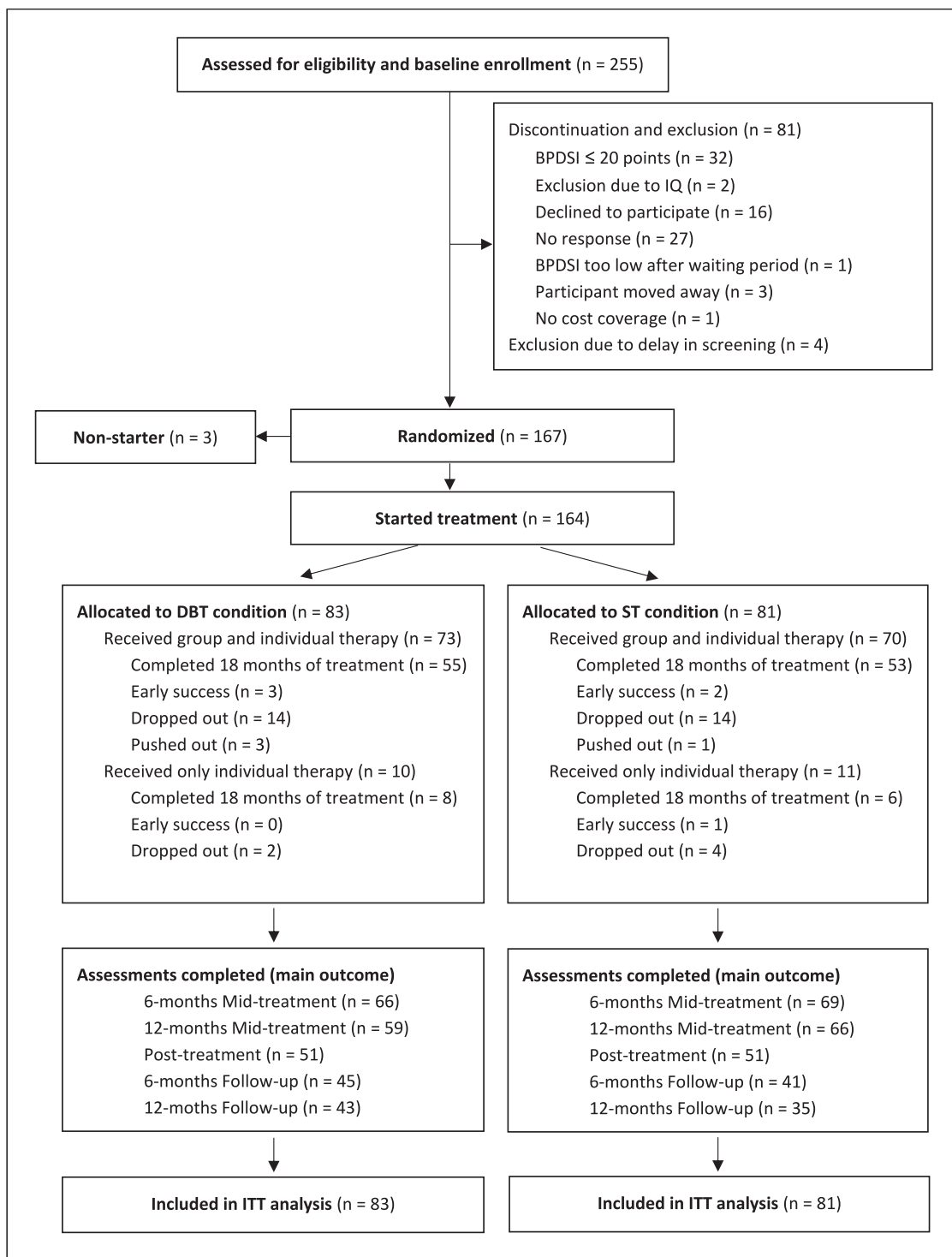


Fig. 1. CONSORT diagram of participant flow.

Mean adherence to the respective manuals was 93.33% in ST and 99.18% in DBT individual therapy. Mean therapeutic competence was 5.27 for ST and

4.99 for DBT. Mean adherence in ST group therapy was 98.10%, and mean therapeutic competence was 5.41.

Table 1. Descriptive statistics at baseline

	Treatment condition		
	all (<i>N</i> = 164)	DBT (<i>n</i> = 83)	ST (<i>n</i> = 81)
Characteristic			
Age, years, <i>M</i> (<i>SD</i>)	33.71 (10.61)	34.54 (11.15)	32.85 (10.01)
Gender, <i>n</i> (%)			
Male	33 (20.1)	17 (20.5)	16 (19.8)
Female	130 (79.3)	66 (79.5)	64 (79.0)
Non-binary	1 (0.6)	–	1 (1.2)
Relationship status, <i>n</i> (%)			
Partner	82 (50.0)	41 (49.4)	41 (50.6)
No partner	82 (50.0)	42 (50.6)	40 (49.4)
Education level, <i>n</i> (%)			
No/primary education	9 (5.5)	5 (6.0)	4 (4.9)
Lower secondary education	92 (56.1)	46 (55.4)	46 (56.8)
Upper secondary education	49 (29.9)	26 (31.3)	23 (28.4)
Tertiary education	14 (8.5)	6 (7.2)	8 (9.9)
Ethnic background, <i>n</i> (%)			
German	151 (92.1)	78 (94.0)	74 (91.4)
Different	12 (7.3)	5 (6.0)	7 (8.6)
Work status, <i>n</i> (%)			
Working	20 (12.2)	7 (8.4)	13 (16.0)
Studying	17 (10.4)	7 (8.4)	10 (12.3)
Homemaker	12 (7.3)	6 (7.2)	6 (7.4)
Disability pension	41 (25.0)	22 (26.5)	19 (23.5)
Unable to work due to sick leave	44 (26.8)	25 (30.1)	19 (23.5)
Unemployed	15 (9.1)	8 (9.6)	7 (8.6)
Retirement pension	3 (1.8)	3 (3.6)	–
Other	12 (7.3)	5 (6.0)	7 (8.6)
BPD severity			
BPDSI at baseline, <i>M</i> (<i>SD</i>)	32.80 (8.71)	33.19 (9.38)	32.39 (8.01)
Number of BPD criteria (SKID-II)	7.26 (1.26)	7.23 (1.32)	7.30 (1.21)
Comorbid Disorders			
Number of comorbid SCID-I diagnoses, <i>M</i> (<i>SD</i>)	3.99 (1.95)	4.12 (1.88)	3.85 (2.03)
Number of comorbid SCID-II diagnoses (excl. BPD), <i>M</i> (<i>SD</i>)	1.35 (1.12)	1.37 (1.06)	1.32 (1.18)
Comorbid personality disorders, <i>n</i> (%)			
Paranoid personality disorder	37 (22.6)	17 (20.5)	20 (24.7)
Schizoid personality disorder	1 (0.6)	–	1 (1.2)
Schizotypal personality disorder	6 (3.7)	3 (3.6)	3 (3.7)
Antisocial personality disorder	3 (1.8)	1 (1.2)	2 (2.5)
Histrionic personality disorder	12 (7.3)	9 (10.8)	3 (3.7)
Narcissistic personality disorder	13 (7.9)	4 (4.8)	9 (11.1)
Avoidant personality disorder	69 (42.1)	39 (47.0)	30 (37.0)
Dependent personality disorder	21 (12.8)	14 (16.9)	7 (8.6)
Obsessive-compulsive personality disorder	59 (36.0)	27 (32.5)	32 (39.5)
Comorbid disorders axis I, <i>n</i> (%)			
Any comorbid axis I diagnosis	161 (98.2)	82 (98.8)	79 (97.5)
Affective disorders	108 (65.9)	59 (71.1)	49 (60.5)
Anxiety disorders	144 (87.8)	74 (89.2)	70 (86.4)
Somatic symptom disorder	21 (12.8)	11 (13.3)	10 (12.3)
Substance use disorder	51 (31.1)	24 (28.9)	27 (33.3)
Eating disorders	76 (46.3)	41 (49.4)	35 (43.2)

Table 1 (continued)

	Treatment condition		
	all (<i>N</i> = 164)	DBT (<i>n</i> = 83)	ST (<i>n</i> = 81)
Psychiatric medication ¹ , <i>n</i> (%)	126 (76.8)	64 (77.1)	62 (76.5)
Previous treatment, <i>n</i> (%)	154 (93.9)	82 (98.8)	72 (88.9)
Previous psychotherapeutic treatment, <i>n</i> (%)	151 (92.1)	80 (96.4)	71 (87.7)

¹Including medication irregularly taken as needed.

Main Outcome

The GLMM showed a significant reduction of BPD severity measured by the BPDSI-IV total score over time (0.5 years to 1-year naturalistic follow-up) with large effect sizes (pre-post and pre-follow-up) for both conditions (Table 2; Fig. 2a). However, treatment had no significant effect at 1-year naturalistic follow-up ($t_{131} = 1.69, p = 0.94, d = -0.24 [-0.69; 0.20]$). See online supplementary Table S5 for the effects of GLMM covariates on all outcomes. The completer and sensitivity analyses did not show different results (see online suppl. material).

Secondary Outcomes

BPDSI-Based Secondary Outcomes

All BPDSI subscales except for (para)suicide showed a significant reduction over time (0.5 years to 1-year naturalistic follow-up) (online suppl. Table S6). For this subscale, the within-group pre-follow-up effect sizes were also large in both conditions indicating a substantial improvement between baseline and 0.5 years which was not included in the GLMM. The within-group pre-follow-up effect sizes for all other subscales were large; only in the subscale anger the effect size in the ST condition was medium. This subscale was the only one with a significant treatment effect at 1-year naturalistic follow-up: patients in the DBT condition had significantly lower scores at this time point.

The suicidality score showed no significant effects, and the within-group pre-post effect sizes were medium in both conditions (online suppl. Table S6). For the number of suicide attempts in the last 3 months, there were also no significant effects. The within-group pre-follow-up effect sizes were small to medium.

Other Secondary Outcomes

All GLMM of secondary outcomes showed a significant time effect (0.5 years to 1-year naturalistic follow-up), indicating improvement, but no effect of treatment at

1-year naturalistic follow-up (Table 2). The within-group pre-follow-up effect sizes were large for the BPD Checklist, BSI, QIDS-SR, WSAS, and WHODAS and small to large for the DSS (Table 2) and the WHOQOL subscales (online suppl. Table S7).

Treatment Retention

Figure 2b shows treatment retention during the 1.5 years treatment period. Deviation contrasts of the GLMM survival analysis showed that in the second quarter, significantly more patients dropped out from DBT, $t_{870} = -2.79, p = 0.005$ (ST: 0% vs. DBT: 7.2%), whereas in the fifth quarter, significantly more patients dropped out from ST $t_{870} = -2.21, p = 0.028$ (ST: 4.9% vs. DBT 0%). The overall dropout rate was 22.9% for DBT and 23.5% for ST also including few “push-outs” (3.6% DBT; 1.2% ST). Details on reasons for drop out can be found in online supplementary Table S8.

Deterioration and Adverse Events

Deterioration was found in <1% of all assessments (0.74% DBT, 0.76% ST). For an overview of adverse events during the study period, see online supplementary material.

Effects of Psychotropic Medication

The proportion of patients taking psychotropic medication is described in online supplementary Table S9 separately for each assessment point and different medication categories. The main effects and interactions involving psychotropic medication in the GLMMs are reported in online supplementary Table S5 and interpreted in the online supplementary results.

Treatment during the Naturalistic Follow-Up Phase

An overview of the treatments received during the naturalistic follow-up period can be found in online supplementary Table S8. Briefly, 3.0% (0.5 years) and

Table 2. Estimated means, 95% CIs, and effect sizes for the primary and secondary outcomes and effects (time, time piece-wise, and treatment) of the GLMM

		Effects of the GLMM ^a											
Estimated means (95% CI), effect size Cohen's <i>d</i>		within-group effect size <i>d</i> ^c [95% CI]					between-group effect size <i>d</i> ^b [95% CI]						
DBT		ST		M [95% CI]		within-group effect size <i>d</i> ^c [95% CI]		observed		estimated			
Outcome and time point	M [95% CI]	within-group effect size <i>d</i> ^c [95% CI]	M [95% CI]	within-group effect size <i>d</i> ^c [95% CI]	M [95% CI]	within-group effect size <i>d</i> ^c [95% CI]	observed	estimated	t	df	p	r	
BPDSI total													
Baseline	25.20 [23.53; 26.99]	1.00 [0.54; 1.45]	M = 32.80 ^e 27.76 [25.98; 29.66]	0.64 [0.19; 1.08]	–	–	–0.24 [–0.58; 0.10]	–0.27 [–0.61; 0.07]	–10.12	244	<0.001	0.54	
0.5 years	21.21 [19.64; 22.91]	1.70 [1.17; 2.17]	23.43 [21.71; 25.28]	1.29 [0.81; 1.77]	–	–	–0.04 [–0.39; 0.31]	–0.21 [–0.56; 0.14]	4.98	260	<0.001	0.29	
1 year	17.85 [16.02; 19.89]	2.33 [1.77; 2.89]	19.77 [17.76; 22.01]	1.94 [1.41; 2.47]	–	–	–0.01 [–0.40; 0.37]	–0.17 [–0.56; 0.22]	1.69	131	0.094	0.15	
1.5 years (post)	17.58 [15.78; 19.59]	2.39 [1.83; 2.95]	20.20 [18.11; 22.53]	1.86 [1.34; 2.38]	–	–	–0.17 [–0.59; 0.26]	–0.19 [–0.61; 0.24]	0.08	245	0.936	<0.01	
0.5 years FU	17.31 [15.03; 19.94]	2.45 [1.88; 3.02]	20.63 [17.79; 23.93]	1.78 [1.26; 2.29]	–	–	–0.15 [–0.60; 0.30]	–0.24 [–0.69; 0.20]	0.49	260	0.628	0.03	
1 year FU					–	–							
BPD checklist^d													
Baseline	61.92 [55.31; 69.33]	0.94 [0.49; 1.39]	M = 84.67 ^e 72.08 [64.39; 80.70]	0.48 [0.04; 0.93]	–	–	–0.03 [–0.39; 0.33]	–0.32 [–0.68; 0.04]	–7.06	291	<0.001	0.38	
0.5 years	54.61 [49.14; 60.70]	1.32 [0.84; 1.79]	64.51 [57.90; 71.87]	0.82 [0.36; 1.27]	–	–	–0.09 [–0.47; 0.28]	–0.26 [–0.63; 0.12]	1.65	86	0.102	0.18	
1 year	48.17 [42.89; 54.10]	1.69 [1.19; 2.19]	57.73 [51.22; 65.08]	1.15 [0.68; 1.62]	–	–	–0.02 [–0.46; 0.42]	–0.20 [–0.64; 0.24]	0.436	291	0.663	0.03	
1.5 years (post)	42.48 [36.87; 48.95]	2.07 [1.54; 2.60]	51.67 [44.66; 59.78]	1.48 [0.99; 1.98]	–	–	–0.19 [–0.66; 0.27]	–0.25 [–0.72; 0.22]					
0.5 years FU	37.47 [31.40; 44.70]	2.45 [1.88; 3.02]	46.24 [38.60; 55.40]	1.82 [1.30; 2.33]	–	–	–0.12 [–0.63; 0.38]	–0.25 [–0.76; 0.25]					
1 year FU					–	–							
DSS													
Baseline	2.12 [1.73; 2.58]	0.45 [0.01; 0.89]	M = 2.90 ^e 2.40 [1.99; 2.90]	0.27 [–0.17; 0.71]	–	–	–0.07 [–0.43; 0.28]	–0.15 [–0.50; 0.21]	–2.76	179	0.006	0.20	
0.5 years	1.82 [1.54; 2.16]	0.67 [0.22; 1.11]	2.06 [1.74; 2.43]	0.49 [0.05; 0.93]	–	–	0.13 [–0.24; 0.50]	–0.15 [–0.52; 0.23]	1.31	246	0.193	0.08	
1 year	1.57 [1.27; 1.93]	0.88 [0.43; 1.33]	1.76 [1.42; 2.18]	0.71 [0.26; 1.16]	–	–	–0.03 [–0.47; 0.42]	–0.11 [–0.56; 0.33]	0.48	178	0.633	0.04	
1.5 years (post)	1.57 [1.30; 1.89]	0.88 [0.43; 1.33]	1.90 [1.57; 2.30]	0.60 [0.16; 1.05]	–	–	–0.09 [–0.57; 0.40]	–0.20 [–0.68; 0.29]					
0.5 years FU	1.57 [1.23; 1.99]	0.88 [0.43; 1.33]	2.05 [1.57; 2.69]	0.49 [0.05; 0.94]	–	–	0.12 [–0.40; 0.63]	–0.26 [–0.78; 0.26]					
1 year FU					–	–							

Table 2 (continued)

		Estimated means (95% CI), effect size Cohen's <i>d</i>				Effects of the GLMM ^a				
		DBT		ST		between-group effect size <i>d</i> ^b				
Outcome and time point	<i>M</i> [95% CI]	within-group effect size <i>d</i> ^c [95% CI]	<i>M</i> [95% CI]	within-group effect size <i>d</i> ^c [95% CI]	observed [95% CI]	estimated	<i>t</i>	<i>df</i>	<i>p</i>	<i>r</i>
BSI										
Baseline			<i>M</i> = 1.94 ^e							
0.5 years	1.64 [1.50; 1.79]	0.44 [0.01; 0.88]	1.77 [1.63; 1.92]	0.24 [-0.19; 0.68]	0.10 [-0.25; 0.46]	-0.16 [-0.52; 0.19]	-5.20	246	<0.001	0.31
1 year	1.49 [1.38; 1.61]	0.69 [0.25; 1.14]	1.64 [1.52; 1.77]	0.44 [-0.00; 0.88]	0.08 [-0.29; 0.45]	-0.19 [-0.56; 0.19]	1.45	147	0.150	0.12
1.5 years (post)	1.35 [1.23; 1.48]	0.95 [0.49; 1.40]	1.53 [1.39; 1.67]	0.63 [0.18; 1.07]	0.10 [-0.34; 0.55]	-0.15 [-0.60; 0.30]	0.71	245	0.481	0.05
0.5 years FU	1.23 [1.09; 1.39]	1.20 [0.73; 1.66]	1.42 [1.25; 1.61]	0.82 [0.37; 1.27]	-0.07 [-0.56; 0.41]	-0.20 [-0.68; 0.29]				
1 year FU	1.11 [0.95; 1.31]	1.45 [0.97; 1.93]	1.32 [1.12; 1.55]	1.01 [0.55; 1.47]	0.05 [-0.47; 0.57]	-0.21 [-0.73; 0.31]				
QIDS-SR										
Baseline			<i>M</i> = 16.26 ^e							
0.5 years	14.27 [13.26; 15.35]	0.42 [0.08; 0.76]	14.30 [13.33; 15.33]	0.42 [0.08; 0.75]	0.20 [-0.16; 0.55]	-0.01 [-0.36; 0.35]	-5.03	202	<0.001	0.33
1 year	13.23 [12.33; 14.64]	0.67 [0.31; 1.02]	13.67 [12.77; 14.64]	0.56 [0.21; 0.90]	0.16 [-0.22; 0.53]	-0.08 [-0.46; 0.29]	1.35	147	0.179	0.11
1.5 years (post)	12.26 [11.30; 13.30]	0.91 [0.52; 1.30]	13.08 [12.04; 14.20]	0.70 [0.30; 1.10]	0.11 [-0.34; 0.55]	-0.08 [-0.53; 0.36]	1.31	203	0.193	0.09
0.5 years FU	11.36 [10.26; 12.59]	1.16 [0.73; 1.57]	12.51 [11.25; 13.90]	0.85 [0.41; 1.27]	-0.07 [-0.55; 0.41]	-0.12 [-0.61; 0.36]				
1 year FU	10.53 [9.27; 11.97]	1.40 [0.96; 1.83]	11.96 [10.46; 13.68]	0.99 [0.51; 1.46]	0.08 [-0.44; 0.60]	-0.18 [-0.7; 0.34]				
WSAS										
Baseline			<i>M</i> = 23.59 ^e							
0.5 years	18.93 [16.69; 21.48]	0.67 [0.23; 1.11]	21.23 [18.75; 24.03]	0.32 [-0.12; 0.76]	0.02 [-0.33; 0.38]	-0.19 [-0.55; 0.16]	-2.39	411	0.018	0.12
1 year	18.45 [16.65; 20.11]	0.75 [0.30; 1.19]	20.04 [18.08; 22.22]	0.50 [0.05; 0.94]	0.10 [-0.27; 0.48]	-0.12 [-0.50; 0.26]	-0.10	273	0.924	0.01
1.5 years (post)	17.97 [16.28; 19.83]	0.83 [0.38; 1.28]	18.93 [17.07; 20.99]	0.67 [0.22; 1.12]	0.19 [-0.26; 0.64]	-0.05 [-0.50; 0.40]	-0.89	412	0.374	0.04
0.5 years FU	17.51 [15.59; 19.66]	0.91 [0.46; 1.36]	17.88 [15.76; 20.25]	0.85 [0.22; 1.12]	0.12 [-0.36; 0.60]	-0.02 [-0.50; 0.45]				
1 year FU	17.06 [14.72; 19.77]	0.99 [0.53; 1.44]	16.88 [14.39; 19.80]	1.02 [0.56; 1.48]	0.24 [-0.28; 0.75]	0.01 [-0.50; 0.53]				

Table 2 (continued)

Outcome and time point	Estimated means (95% CI), effect size Cohen's <i>d</i>				Effects of the GLMM ^a							
	DBT		ST		between-group effect size <i>d</i> ^b							
	<i>M</i> [95% CI]	within-group effect size <i>d</i> ^c [95% CI]	<i>M</i> [95% CI]	within-group effect size <i>d</i> ^c [95% CI]	observed [95% CI]	estimated	<i>t</i>	<i>df</i>	<i>p</i>	<i>r</i>		
WHODAS												
Baseline			<i>M</i> = 41.89 ^e									
0.5 years	32.13 [29.16; 35.41]	0.68 [0.24; 1.13]	34.38 [31.31; 37.75]	0.51 [0.07; 0.95]	0.06 [-0.28; 0.40]	-0.13 [-0.47; 0.21]		-3.39	314	<0.001	0.19	
1 year	30.66 [28.07; 33.49]	0.81 [0.36; 1.25]	31.81 [29.17; 34.69]	0.71 [0.26; 1.16]	0.16 [-0.19; 0.52]	-0.06 [-0.42; 0.29]		-0.41	182	0.682	0.03	
1.5 years (post)	29.25 [26.27; 32.57]	0.93 [0.47; 1.38]	29.43 [26.43; 32.77]	0.91 [0.45; 1.37]	0.21 [-0.22; 0.64]	-0.01 [-0.44; 0.42]		-0.83	314	0.405	0.05	
0.5 years FU	27.91 [24.18; 32.21]	1.05 [0.59; 1.51]	27.23 [23.58; 31.46]	1.11 [0.65; 1.58]	0.02 [-0.41; 0.44]	0.03 [-0.40; 0.46]						
1 year FU	26.63 [22.09; 32.09]	1.17 [0.70; 1.64]	25.20 [20.89; 30.40]	1.31 [0.83; 1.79]	0.05 [-0.42; 0.52]	0.05 [-0.42; 0.52]						

Estimated means are in original scale. Effect sizes *r* are defined as $r = \sqrt{(t^2 / (t^2 + df))}$, these represent the effect size associated with the effect tests in the fixed part of the GLMM. Time was coded in steps of 0.5 years and centered at the last follow-up (2.5 years). Hence, the treatment effect represents the difference between treatments at 2.5 years. BPDSI, Borderline Personality Disorder Severity Index; BPD Checklist, Borderline Personality Disorder Checklist; DSS, Dissociation Tension Scale; BSI, Brief Symptom Inventory; QIDS-SR, Quick Inventory of Depressive Symptoms – Self-Rating; WSAS, Work and Social Adjustment Scale; WHODAS, World Health Organisation Disability Assessment Schedule. FU, follow-up. ^aEffects of global severity, medication and baseline scores are presented in the supplement. ^bStandardized mean differences: difference between means divided by the pooled SD; calculated on observed means (transformed scale) and the pooled SD of the observed means calculated at each time point based on a GLMM gamma regression with only a fixed intercept; respectively, on the estimated means (corrected for baseline) and pooled SD of the observed means divided by the square-root of the baseline variance of a model with no for DBT and negative values higher scores for ST. ^cCalculated as difference between transformed means divided by the square-root of the baseline variance of a model with no random parts and only a fixed intercept. ^dEstimated means are -46.99 points lower than on the original scale. Scores were transformed by subtracting 46.99 to bring the minimum to just greater than 0 to enable gamma regression. ^eBaseline means are overall descriptive means because the baseline score was included as covariate in the GLMM to control for baseline differences.

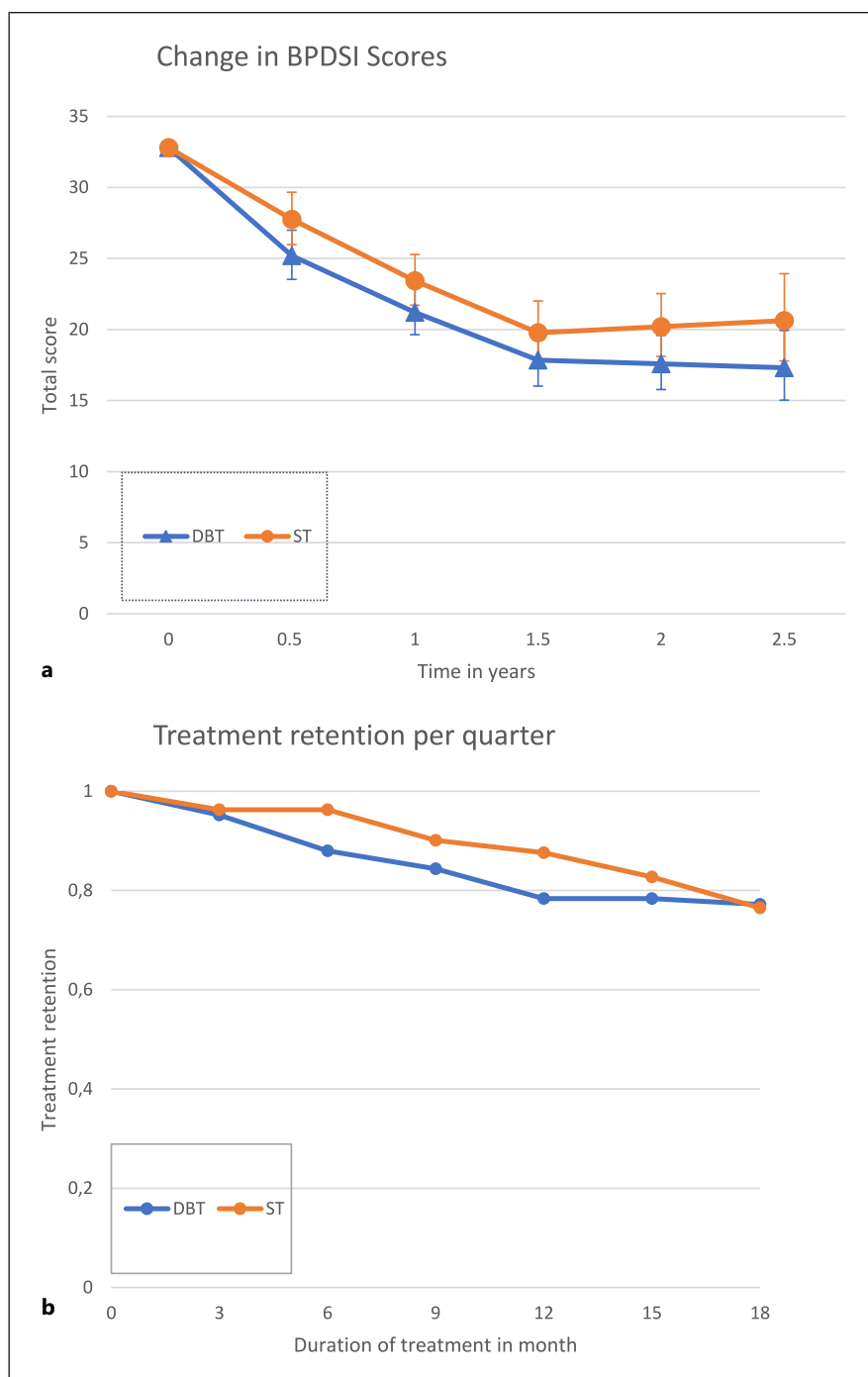


Fig. 2. Treatment outcome. **a** Change in BPDSI scores. The graph shows BPD severity measured by the BPDSI-IV total score over time (0.5 years–2.5 years) for DBT (blue) and ST (orange). Data are expressed as mean \pm SE. **b** Treatment retention per quarter: The graphs shows treatment retention during the 1.5 years treatment period. In the second quarter, significantly more patients dropped out from DBT (blue), whereas in the fifth quarter, significantly more patients dropped out from ST (orange). The overall dropout rate was similar in both treatment groups (22.9% for DBT and 23.5% for ST).

0.6% (1 year) of all patients received inpatient treatment during the follow-up period, but the information was missing for 49.4% (0.5 years) and 54.9 (1 year) of all patients. About one-third of all patients received outpatient treatment during the follow-up period, mainly between one and eight sessions in 0.5 years, but again there was no information for about one half of the sample.

Discussion

This study aimed to compare the effectiveness of DBT and ST for patients with BPD who received treatment in a tertiary outpatient center affiliated with inpatient treatment. Significant reductions in BPD and general symptom severity, as well as improvements in

psychosocial functioning and quality of life, were observed in both treatment conditions. Within-group effect sizes from pre-follow-up were large for most of the outcome variables, pointing out the effectiveness of ST and DBT in this specific outpatient setting. See online supplementary discussion in the online supplementary material for comparing pre-post within-group effect sizes in our studies with previous studies on psychotherapy in BPD.

In contrast to our hypotheses, there were no significant differences between DBT and ST at 1-year naturalistic follow-up in the primary and almost all secondary outcomes. There was a significant effect of treatment at 1-year naturalistic follow-up in favor of DBT in the BPDSI subscale anger. This finding seems to be plausible in that DBT focuses on emotion regulation. However, it has to be stressed that this effect was only found in one subscale. Although retention rates at 1.5 years did not differ between the conditions, DBT patients tended to drop out earlier than ST patients. Overall, dropout rates were low compared to a recent meta-analysis [47] (online suppl. material for detailed discussion).

One possible explanation for the absence of a difference between ST and DBT might be shared factors of ST and DBT (e.g., an explicit treatment framework and coherent explanatory model, an active, supporting, and validating therapist, focus on emotions, the balance of acceptance and change strategies) which are especially relevant for BPD patients and therefore might cause similar symptom reduction in both treatments. However, ST and DBT use very different explanatory models and treatment techniques [48] (e.g., skill training in DBT and experiential techniques in ST) in practice. These different techniques might result in similar outcomes by using different pathways of change. Possibly, there are differential effects for specific subgroups of BPD patients even though there is no significant difference between the two methods for the whole group of patients on average. As a meta-analysis recently supported the heterogeneity of treatment effects for both outcomes (i.e., BPD symptoms and functioning) in BPD [49], maybe one treatment is more suitable than the other for patients with specific characteristics (e.g., different patterns of childhood abuse, comorbid disorders) facilitating a personalized treatment selection. Of course, with two bona fide psychotherapies, differences between the two groups might have been too small to detect with our sample size, being a limitation of the study. The present study is not designed as a non-inferiority trial and, thus, cannot prove that ST is as effective as DBT.

Further limitations include the absence of a waiting list control condition. We felt that such a control condition would have been unethical in our setting due to the high illness severity and the long treatment period, and a no-treatment or treatment-as-usual control group might have enhanced patients' resistance to participate in a randomized trial and thus endangered the representativeness of the study group and the practicability of patient recruitment. Moreover, previous studies have shown that DBT and ST are superior to treatment as usual [3, 12, 13]. Even though missing data due to study dropout are to be expected in BPD patients, the missing assessments might extenuate the validity of our results. The deviations from the standard DBT protocol (a small group of patients without group treatment and individual decisions on "push-out") must also be seen as limitations. Even though the sensitivity analysis excluding patients without group therapy did not show any different results in our trial, a component analysis on DBT points out the importance of skills training groups [50]. For the adherence checks, an alternative to the "gold-standard" has to be chosen because extern ratings were not covered by the funding of the study. The single-site character of our study and the specific focus of our tertiary outpatient treatment center on severely affected patients also limits the external validity. Strengths of the study include the interview-based primary outcome with an excellent ICC and the wide range of secondary outcomes covering a broad array of BPD manifestations and other symptoms. We also recorded adverse events, performed treatment integrity checks, included a 1-year naturalistic follow-up period, and followed CONSORT guidelines and methodology. Most importantly, minimal exclusion criteria were applied so that BPD patients with almost all comorbidities could participate and a broad array of BPD patients is represented.

Conclusion

The Pro*BPD trial was the first to compare the effectiveness of DBT and ST for BPD patients in a large randomized trial. Patients in both treatment groups showed substantial improvements indicating that even severely affected patients with BPD and various comorbid disorders can be treated successfully with DBT and ST. Overall the treatments did not show significant differences, except for anger and treatment retention. An additional equivalence trial is warranted to test whether both treatments are equivalent in effectiveness.

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We dedicate this study and manuscript to Ulrich Schweiger. In the Department of Psychiatry and Psychotherapy in Lübeck, Ulrich Schweiger did not only introduce dialectical behavioral therapy and schema therapy but numerous other modern methods of psychotherapy. He thus laid the foundation for this trial and supported it in all stages. He was involved in the conceptualization of the study, supervision as well as analysis and interpretation of the data. Without him, this study would not have been possible. His untimely death in November 2022 left an irreplaceable gap. However, his passion for modern psychotherapy and his commitment to improving treatment for patients with severe mental disorders will continue to serve as an inspiration and guide. Further, we wish to thank all patients and therapists participating in this trial as well as our research assistants and students for their engagement.

Statement of Ethics

The study was reviewed and approved by the Ethics Committee of Lübeck University, reference number 13-005. Furthermore, the patients provided written informed consent to participate in this study.

Conflict of Interest Statement

Dr. Alvarez-Fischer reported receiving consultancy fees and fees for lectures, workshops, and brochures from Takeda Pharma GmbH and Medice Arzneimittel Pütter GmbH & Co KG in the last 12 months. Neither activity represents a conflict of interest. Prof. Arntz reported receiving grants from the Netherlands Organization for Health Research and Development and Netherlands Foundation for Mental Health, and receiving other grants outside the submitted work from Netherlands' Organization for Scientific Research (NWO), Netherlands Organization for Health Research and Development (ZONMW), Stichting Achmea Gezondheidszorg, CZ Fonds, Stichting Volksbond Rotterdam, and Stichting tot Steun VCVGZ; receiving royalties (paid to the university) from Academic Press, American Psychological Association Press, Beltz, Bohn Stafleu van Loghum, Boom Uitgevers, Cambridge University Press, Context Press, Guilford, De Tijdstroom, Oxford University Press, SAGE Publications, Uitgeverij Nieuwezijds, Wiley; providing workshops and lectures on cognitive behavioral therapy, imagery rescripting, personality disorders, schema therapy, and small-scale research in clinical practice (remuneration to the university) for the BABCP, Bulgarian Association for CBT, Clinical Academic Group for Psychotherapy Denmark, Danish Competence Centre for Psychotherapy, EABCT, ECNP, ESSPD, Estonian CBT Association, German Psychosomatic Congress, GGZ InGeest, Greek CBT Association, ICCP, Institut für Schematherapie Frankfurt, ISC International, ISSPD, ISST, Jellinek, Kenniscentrum Persoonlijkheidsstoornissen, Leiden University Medical Center, Lemion, Moroccan Association of CBT, Norwegian Psychological Association, Parnassia/PsyQ, Polish Association for Cognitive and Behavioural Therapies, Portuguese Association of Behaviour Therapy, Psyflix,

SCEM, Scuole APC-SPC-SICC-IGB-AIPC, Tunisian Association of CBT, Turkish Association for Cognitive & Behavioural Psychotherapies, Ukraine Association for CBT, Ukraine Institute for CBT, University of Bordeaux, VGCT, VST, WCBCT; supervising research at the mental health institute PsyQ (remuneration to the University of Amsterdam); and being chair of the board of the PDO foundation, North Holland postgraduate training institute (unpaid). Dr. Assmann provided workshops on ST (Institut für Schematherapie Hamburg, Ausbildungsinstitut für Verhaltenstherapie und Verhaltensmedizin Hannover), received personal fees from supervision in ST and received grants from Lübeck University for an observational study and for open access publication fees (both outside the submitted work). PD Dr. Fassbinder reported receiving grants for the PROBPD study from the Else Kröner-Fresenius-Stiftung and the University of Lübeck, and grants outside the submitted work from Addisca GmbH; receiving royalties from Beltz Verlag and Elsevier Books; receiving personal fees from supervision in ST and group ST and from workshops and presentations on CBT, imagery rescripting, personality disorders, ST, and behavioral activation for Ausbildungsinstitut für Verhaltenstherapie und Verhaltensmedizin Hannover, Arbeitsgemeinschaft Wissenschaftliche Psychotherapie Berlin, the DGPPN, IPAM Marburg, IFT-Nord Institut für Therapie- und Gesundheitsforschung gemeinnützige GmbH Kiel, IPP Halle, Institut für Schematherapie Hamburg, Institut für Schematherapie Köln, Institut für Schematherapie Berlin, Oberberg Kliniken, and the WCBCT; and being co-chair of the Deutscher Fachverband für Verhaltenstherapie eV (unpaid) and member of the board of the Gesellschaft zur Erforschung und Therapie von Persönlichkeitsstörungen (GePs) e.V. Prof. Klein received funding for clinical trials (German Federal Ministry of Health, Servier), payments for presentations on internet interventions (Oberberg, Servier, Stillachhaus), consulting fees from developers and distributors of internet interventions (all about me, Etypharm), payments for workshops and books (Beltz, Elsevier, Hogrefe, and Springer) on psychotherapy for chronic depression and psychiatric emergencies. Dr. Schaich received intramural from University of Lübeck (Habitationsförderung für Wissenschaftlerinnen), personal fees from supervision in ST and imagery rescripting, payments for manuscripts (Thieme) and workshops (ISST Hamburg) on ST, support for attending meetings and/or travel from GePs e.V. Hamburger Fellowship and Verbund Norddeutscher Universitäten (Impulse Forschung) as well as funding of open access publication from Lübeck University. Dr. Schweiger received royalty fees from Beltz, Herder, Hogrefe, Kohlhammer, and Springer; fees for workshops for institutes associated with the Deutsche Fachverband für Verhaltenstherapie on psychotherapy topics; and was Vice President of the Deutsche Fachverband für Verhaltenstherapie (no honorarium). Dr. Sipos reported receiving royalty fees from Beltz, Herder, Hogrefe, Kohlhammer, and Springer; receiving personal fees from supervision in DBT and psychotherapy and fees for workshops on psychotherapy topics for IFT-Nord Institut für Therapie- und Gesundheitsforschung gemeinnützige GmbH Kiel, IPAM Marburg, Leipziger Ausbildungsinstitut für Psychologische Psychotherapie (LAP), Zentrum für Psychologische Psychotherapie der Universität Heidelberg (ZPP Heidelberg), and was a board member of the Dachverband Dialektische Behaviourale Therapie (DBT) e.V. (no honorarium). Dr. Herzog, Prof. Jauch-Chara, Prof. Hüppe, and Dr. Wagner reported that he has no conflict of interest to declare.

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Author Contributions

Dr. Assmann and Dr. Schaich had full access to all the data in the study. They take responsibility for the data's integrity and the data analysis's accuracy. Concept and design: Fassbinder, Arntz, and Schweiger. Acquisition, analysis, or interpretation of data: Schaich, Assmann, Arntz, Fassbinder, Klein, and Schweiger. Drafting of the manuscript: Assmann, Schaich, Fassbinder, Arntz, and Klein. Critical revision of the manuscript for important intellectual content: all authors. Statistical analysis:

Assmann, Schaich, and Arntz. Obtained funding: Fassbinder and Schaich. Administrative, technical, or material support: Schaich, Assmann, Fassbinder, Jauch-Chara, Hüppe, Herzog, Wagner, Alvarez-Fischer, Sipos, and Schweiger. Supervision: Fassbinder, Sipos, and Schweiger. Since Ulrich Schweiger deceased in November 2022, he could not review the final version of the manuscript but contributed to the preparation, execution, analysis and publication of the study in an essential way.

Data Availability Statement

In this study, data of outpatients of a mental health clinic were analyzed. In order to protect the privacy of these patients and ensure the secure storage of their data, we refrain from making the data freely available in a repository. However, the data can be shared with researchers who provide a methodologically sound proposal to Nele Assmann (Nele.Assmann@uksh.de). Proposals may be submitted up to 36 months following the publication of the principal analysis, and the decision will be made by the steering committee. In case of an approval of the proposal data and additional, related documents will be available (study protocol, statistical analysis plan) with a signed data access agreement.

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