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A pilot randomized controlled trial of Dialectical Behavior Therapy with and without the Dialectical Behavior Therapy Prolonged Exposure protocol for suicidal and self-injuring women with borderline personality disorder and PTSD

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Abstract

Objective—This study evaluates the efficacy of integrating PTSD treatment into Dialectical Behavior Therapy (DBT) for women with borderline personality disorder, PTSD, and intentional self-injury.

Methods—Participants were randomized to DBT (*n*=9) or DBT with the DBT Prolonged Exposure (DBT PE) protocol (*n*=17) and assessed at 4-month intervals during the treatment year and 3-months post-treatment.

Results—Treatment expectancies, satisfaction, and completion did not differ by condition. In DBT + DBT PE, the DBT PE protocol was feasible to implement for a majority of treatment completers. Compared to DBT, DBT + DBT PE led to larger and more stable improvements in PTSD and doubled the remission rate among treatment completers (80% vs. 40%). Patients who completed the DBT PE protocol were 2.4 times less likely to attempt suicide and 1.5 times less likely to self-injure than those in DBT. Among treatment completers, moderate to large effect sizes favored DBT + DBT PE for dissociation, trauma-related guilt cognitions, shame, anxiety, depression, and global functioning.

Conclusions—DBT with the DBT PE protocol is feasible, acceptable, and safe to administer, and may lead to larger improvements in PTSD, intentional self-injury, and other outcomes than DBT alone. The findings require replication in a larger sample.

Keywords

Borderline personality disorder; posttraumatic stress disorder; suicide; self-injury

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Borderline personality disorder (BPD), posttraumatic stress disorder (PTSD), and suicidal and non-suicidal self-injury (NSSI) are commonly co-occurring problems. Among individuals with BPD, the rate of co-occurring PTSD is approximately 30% in community samples (Grant et al., 2008; Pagura et al., 2010) and 50% in clinical samples (Harned, Rizvi, & Linehan, 2010; Zanarini, Frankenburg, Hennen, Reich, & Silk, 2004). More than 70% of BPD patients report a history of multiple episodes and methods of NSSI and 60% report multiple suicide attempts (Zanarini et al., 2008). Individuals with both BPD and PTSD are a particularly high risk group, with rates of suicide attempts two and five times higher than individuals with BPD or PTSD alone (Pagura et al., 2010). In addition, the presence of PTSD more than doubles the frequency of NSSI among suicidal and self-injuring BPD patients (Harned et al., 2010).

Both causal and maintaining relationships exist between BPD, PTSD, and intentional self-injury (i.e., suicide attempts and NSSI) that likely account for the high degree of overlap between these complex problems. Early childhood trauma has been implicated in the development of BPD (e.g., Battle et al., 2004; Widom, Czaja, & Paris, 2009) and increases the risk of adult trauma among individuals with BPD (Zanarini et al., 1999). PTSD has been found to maintain or exacerbate intentional self-injury in BPD, as these behaviors are often precipitated by PTSD symptoms (e.g., flashbacks, nightmares) and exposure to trauma-related cues (Harned et al., 2010). More generally, intentional self-injury most often functions to alleviate negative affect among individuals with BPD (Brown, Comtois, & Linehan, 2002; Kleindienst et al., 2008), and PTSD has been found to increase negative affect and emotion dysregulation in BPD patients (Harned et al., 2010; Marshall-Berenz, Morrison, Schumacher, & Coffey, 2011). Taken together, this constellation of co-occurring problems appears to be particularly intractable, with PTSD predicting a lower likelihood of remitting from BPD and a higher likelihood of attempting suicide among individuals with BPD across 10 to 16 years of naturalistic follow-up (Zanarini, Frankenburg, Hennen, Reich, & Silk, 2006; Wedig et al., 2012).

The emerging consensus in the field is that comorbid conditions are best treated using an integrated approach that allows for targeting of multiple problems in the same treatment with a focus on the relationships between them (Najavits et al., 2009; National Institute of Drug Abuse, 2010; Rizvi & Harned, 2013). However, existing treatments have generally targeted either PTSD alone or BPD with intentional self-injury, but not all three problems in combination. PTSD treatment guidelines uniformly state that such treatment is not appropriate for acutely suicidal patients (e.g., Foa, Keane, Friedman, & Cohen, 2009; National Institute for Clinical Excellence, 2005) and PTSD treatment studies routinely exclude patients with serious suicidality and/or recent NSSI (Bradley, Greene, Russ, Dutra, & Westen, 2005). When acutely suicidal and self-injuring patients are excluded, individuals with and without BPD characteristics show comparable rates of improvement in PTSD during cognitive behavioral treatment (Clarke, Rizvi, & Resick, 2008; Feeny, Zoellner, & Foa, 2002), but are less likely to achieve overall good end-state functioning (Feeny et al., 2002). However, the efficacy of existing PTSD treatments for suicidal and self-injuring patients, as well as individuals meeting full diagnostic criteria for BPD, is unknown. Of note, several characteristics common in this patient population have been found to predict worse response to cognitive behavioral PTSD treatment, such as a history of suicide

planning or attempts (Tarrier, Sommerfield, Pilgrim, & Faragher, 2000) and childhood trauma (Hembree, Street, Riggs, & Foa, 2004), suggesting that existing treatments may be particularly challenging if not ineffective among severe BPD patients.

Consistent with PTSD treatment guidelines, patients with BPD, PTSD, and intentional self-injury are commonly referred to BPD treatments for 'stabilization' prior to or instead of providing treatment focused on PTSD. A number of evidence-based BPD treatments exist (see Stoffers et al., 2012 for a review), and these treatments typically use a here-and-now approach to address problems, rather than focusing on the past, including past trauma. Of these treatments, only Dialectical Behavior Therapy (DBT; Linehan, 1993a) has been evaluated in terms of its impact on comorbid PTSD. DBT prioritizes targeting of intentional self-injury and other forms of behavioral dyscontrol, and does not routinely target PTSD. Accordingly, among suicidal and self-injuring BPD women, the rate of remission from PTSD is relatively low during one year of DBT and one year of follow-up (35%; Harned et al., 2008). In addition, PTSD predicts less reduction in intentional self-injury and BPD symptoms during one year of DBT (Barnicot & Priebe, 2013). Taken together, these findings indicate that the impact of BPD treatments on PTSD is either limited or unknown and, when not addressed, PTSD may negatively impact treatment response.

Increasing awareness of the limitations of existing treatment approaches has led to the recent development and evaluation of several interventions for this multi-problem patient population. Pabst and colleagues (2012) conducted a feasibility trial of Narrative Exposure Therapy for PTSD among patients with comorbid BPD (n=10). Treatment lasted an average of 14 sessions, primarily took place in an inpatient setting, and included patients engaging in NSSI, but excluded those with acute suicidality, a suicide attempt in the past 8 weeks, and other severe comorbidities (e.g., drug abuse). Results indicated a large pre-post reduction in PTSD (g = 0.92). Bohus and colleagues have developed a 12-week intensive residential treatment for women with PTSD related to childhood sexual abuse that includes, but is not limited to, women with comorbid BPD. This intervention, called DBT-PTSD, combines modified DBT with trauma-focused cognitive behavioral treatment strategies. A randomized controlled trial (n=74, 45% BPD) comparing DBT-PTSD to a Treatment as Usual-Waitlist control (TAU-WL) included women engaging in NSSI, but excluded those who had engaged in a life-threatening behavior (including a suicide attempt) in the past 4 months or were currently substance dependent (Bohus et al., 2013). Results indicated that DBT-PTSD was superior to TAU-WL in improving PTSD, depression, and global functioning, but not BPD severity or dissociation, and results did not differ between patients with and without BPD (Bohus et al., 2013). Although both of these treatments reflect advances toward developing more inclusive interventions to treat PTSD in BPD patients engaging in NSSI, limitations include the exclusion of patients with acute suicidality or recent serious suicide attempts, the use of more restrictive treatment settings (residential and inpatient), and the focus on targeting a single disorder (PTSD).

The present study is part of a program of research focused on developing and evaluating an integrated treatment that can safely and effectively address the multiple problems of suicidal and self-injuring BPD patients with PTSD. The treatment consists of one year of standard outpatient DBT with the DBT Prolonged Exposure (DBT PE) protocol integrated into DBT

to target PTSD. The DBT PE protocol is based on Prolonged Exposure therapy for PTSD (Foa, Hembree, & Rothbaum, 2007) and incorporates DBT strategies and procedures to address the specific characteristics of this patient population (Harned, 2013). To date, case studies (Harned & Linehan, 2008) and an open trial (Harned, Korslund, Foa, & Linehan, 2012) have been completed. The open trial included 13 women with BPD, PTSD, and recent and/or imminent intentional self-injury. The treatment was found to be highly acceptable and feasible to implement for a majority of patients, with 100% of treatment completers achieving sufficient stability to start the DBT PE protocol and 70% completing the full protocol. The treatment was also safe to administer, with no evidence of increased intentional self-injury urges or behaviors and an overall low rate of suicide attempts (9.1%) and NSSI (27.3%) during the study. Very large improvements in PTSD were found from pre- to post-treatment in both the intent-to-treat sample (d=1.4, remission = 60.0%) and among treatment completers (d=1.7, remission = 71.4%) that were maintained in the three months following treatment. In addition, patients showed large improvements in dissociation, trauma-related guilt cognitions, shame, depression, anxiety, and social adjustment.

The present study extends this research by conducting a pilot randomized controlled trial (RCT) comparing DBT with and without the DBT PE protocol. The specific aims of the pilot RCT are: (1) to evaluate the feasibility and acceptability of DBT + DBT PE relative to DBT, (2) to evaluate the safety of DBT + DBT PE relative to DBT, and (3) to provide a preliminary estimate of the degree of change in DBT + DBT PE relative to DBT on the primary outcomes of intentional self-injury and PTSD as well as a number of secondary outcomes.

Methods

Study Design

A pilot RCT comparing one year of standard DBT with and without the DBT PE protocol was conducted. Using a 2:1 allocation ratio, participants were randomized to DBT + DBT PE (n=17) or DBT (n=9). Twice as many participants were assigned to the experimental condition (DBT + DBT PE) to maximize the number of clients who received this intervention while still allowing for comparisons with a control condition and random assignment. A minimization randomization procedure (White & Freedman, 1978) was used to match participants on five primary prognostic variables: (1) number of suicide attempts in the last year, (2) number of NSSI episodes in the last year, (3) PTSD severity, (4) dissociation severity, and (5) current use of SSRI medication. Participants were assessed at pre-treatment, at 4-month intervals during the treatment year, and after a 3-month follow-up period. All assessments were conducted by independent clinical assessors who were blind to treatment condition. The periods of enrollment and follow-up ran from June 2010 through May 2013 and Figure 1 summarizes the flow of participants through the study. All study procedures were conducted in accord with IRB approved procedures.

Participants

We recruited participants from individuals seeking treatment at our clinic, as well as via flyers and outreach to area treatment providers. Participants (*n*=26) were consecutively enrolled into the study and inclusion criteria were: (1) female, (2) age 18–60, (3) meets criteria for BPD, (4) meets criteria for PTSD, (5) can remember at least some part of the index trauma, (6) recent and recurrent intentional self-injury (defined as at least two suicide attempts or NSSI episodes in the last 5 years, with at least one episode in the past 8 weeks), and (7) lives within commuting distance of the clinic. Participants were excluded if they: (1) met criteria for a psychotic disorder, bipolar disorder, or mental retardation, (2) were legally mandated to treatment, or (3) required primary treatment for another debilitating condition (e.g., life-threatening anorexia nervosa).

Therapists

Therapists (*n*=19) were primarily female (84.2%), held a master's degree (66.7%), and had a median of 2.0 years of clinical experience since their last degree at the time they were hired (range=0–39, SD=9.2). A majority of therapists were doctoral students in training (52.6%), followed by licensed professionals (36.8%), and postdoctoral fellows (10.5%). All therapists had been intensively trained in DBT and two were certified PE therapists and supervisors. Therapists not certified in PE attended a 1-day workshop on the DBT PE protocol and received supervision from a certified PE supervisor during the administration of the DBT PE protocol with their first patient. Doctoral students and postdoctoral fellows received individual DBT supervision from a licensed professional throughout their study participation.

Treatment

Standard DBT (DBT)—Participants in this condition received one year of standard DBT (Linehan, 1993a,b). DBT consists of (1) weekly individual psychotherapy (1 hr/wk), (2) group skills training (2.5 hr/wk), (3) phone consultation (as needed), and (4) weekly therapist consultation team meeting. DBT targets, in hierarchical order, life threatening behaviors (e.g., suicide attempts and NSSI), behaviors that interfere with treatment delivery (e.g., noncompliance), and severe quality of life interfering behaviors (e.g., severe Axis I disorders, including PTSD). Consistent with standard clinical practice of DBT, therapists were instructed to address PTSD (when relevant) by using DBT skills to manage anxiety (e.g., self-soothing), challenge trauma-related beliefs (e.g., check the facts), and reduce avoidance (e.g., opposite to emotion action). Direct or structured targeting of PTSD via trauma processing or formal exposure procedures was prohibited.

Standard DBT with the DBT PE protocol (DBT + DBT PE)—In addition to receiving one year of standard DBT, participants in this condition could also receive the DBT PE protocol if/when they achieved sufficient control over higher-priority targets. Specifically, the criteria for determining readiness to begin the DBT PE protocol included: (1) not at imminent risk of suicide, (2) no recent (past 2 months) suicide attempts or NSSI, (3) able to control intentional self-injury when in the presence of cues for those behaviors, (4) no serious therapy-interfering behaviors, (5) PTSD was the highest priority target as determined

by the patient, and (6) able and willing to experience intense emotions without escaping. Once these criteria were met, the DBT PE protocol was implemented concurrently with DBT such that patients received either one combined individual therapy session per week (90 minutes of the DBT PE protocol and 30 minutes of DBT) or two individual therapy sessions per week delivered by the same therapist (one DBT PE protocol session (90 minutes) and one DBT session (1 hour)) as well as group DBT skills training and as needed phone consultation. The choice of one or two individual sessions was at the discretion of the patient and therapist, and was typically determined by the number and severity of additional (non-PTSD) treatment targets as well as logistical considerations. The duration of the DBT PE protocol was based on continuous assessment of the patient's PTSD and treatment goals.

As in standard PE (Foa et al., 2007), the DBT PE protocol utilizes in vivo exposure and imaginal exposure followed by processing of the exposure experience as the central treatment components. DBT strategies and procedures were incorporated into PE to: (1) monitor potential negative reactions to exposure (e.g., pre-post exposure ratings of urges to commit suicide and self-injure), (2) target problems that may occur during or as a result of exposure (e.g., dissociation, increased suicide urges), and (3) utilize therapist strategies (e.g., dialectics, irreverence, self-disclosure, validation) that address the particular characteristics of severe BPD patients. In addition, structured procedures for managing common complexities that arise during PTSD treatment with this population were used, including strategies to: (1) address multiple traumas, including experiences that do not meet the DSM-IV definition of trauma (e.g., severe verbal abuse), (2) conduct imaginal exposure with fragmented trauma memories, and (3) target unjustified trauma-related shame. In addition, the DBT PE protocol includes a requirement that the protocol be stopped (ideally temporarily) if any form of intentional self-injury recurs.

Pharmacotherapy protocol—The standard DBT pharmacotherapy protocol, which makes tapering off psychotropic medications a treatment goal (but not a requirement), was used for all medications except SSRIs. Given that SSRIs are an empirically supported treatment for PTSD, patients on SSRIs were asked to either taper off the medication before starting the DBT PE protocol or remain at a constant dose during the DBT PE protocol portion of the treatment. Psychotropic medications were prescribed by community (non-study) providers.

Treatment adherence rating—The DBT adherence measure (Linehan & Korslund, 2003) was used to code a random selection of 10% of all DBT sessions for adherence. The DBT adherence measure results in a global score ranging from 0 to 5 with scores of 4 and higher indicating adherence. The PE adherence measure (Foa, Kushner, Capaldi, & Yadin, 2010) was modified to reflect changes to the standard PE therapy elements and results in a global score ranging from 0 (Very Poor) to 3 (Excellent). Two DBT PE protocol sessions were coded per dyad, including one randomly selected session from the pre-exposure sessions (Sessions 1–3) and one randomly selected session from the imaginal exposure sessions (Sessions 4+). Overall, 17.4% of DBT PE sessions were coded. All coders were trained to reliability by approved coders of each instrument and reliability checks were conducted on a random selection of 10% of all coded sessions. Results indicate that on

average therapists in both conditions delivered adherent DBT (*M*'s=4.1, SD's=0.2, ICC=0.99) and adherence ratings did not differ by condition ($t(93)=0.3$, $p=.80$). DBT PE sessions were also delivered with 'Excellent' adherence to the protocol (*M* =2.9, SD=0.2, ICC=1.0).

Measures

Sample characteristics

Demographics: A demographic questionnaire assessed participants' self-reported age, racial/ethnic background, education, and income.

Diagnostic interviews: The International Personality Disorder Examination (IPDE; Loranger, 1995) was used to diagnose BPD and all other Axis II diagnoses using DSM-IV criteria. The PTSD Symptom Scale-Interview (PSS-I; Foa, Riggs, Dancu, & Rothbaum, 1993) was used to diagnose PTSD. The PSS-I consists of 17 items corresponding to the DSM-IV PTSD diagnostic criteria and items are rated on 0–3 scales for combined frequency and intensity in the past two weeks. At baseline, an index (i.e., most distressing) trauma was established and all PTSD symptoms were assessed in relation to this specific index event. Patients are considered to meet DSM-IV criteria for PTSD if they report the minimum number of symptoms in each symptom cluster with a score of at least 1. Inter-rater reliability for the PTSD diagnosis ($\kappa = .91$) and overall severity ($r = .97$) are excellent (Foa et al., 1993). The Structured Clinical Interview for DSM-IV, Axis I (SCID-I; First, Spitzer, Gibbon, & Williams, 1995) was used to diagnose mood, anxiety (excluding PTSD), eating, substance use, and psychotic disorders.

Trauma history: The Traumatic Life Events Questionnaire (TLEQ; Kubany et al., 2000) assessed self-reported lifetime history of 22 types of traumatic events. The 3-item Childhood Experiences Questionnaire (Wagner & Linehan, 1994) assessed self-reported history of three types of childhood sexual abuse. To prevent overlap across instruments, the TLEQ item that assessed childhood sexual abuse was removed. For both instruments, participants reported the frequency of each type of traumatic event on a scale ranging from 0 (never) to 6 (more than 5 times) and, when relevant, the age of onset. Data from both instruments were combined to calculate the number of trauma types experienced (range = 0–25) and the age of onset of the earliest traumatic event.

Treatment feasibility—Feasibility of treatment was assessed via rates of treatment retention, attendance, and completion. Consistent with prior DBT studies (e.g., Linehan et al., 2006b), completing standard DBT was defined as attending one year of treatment without missing four consecutive weeks of either individual DBT therapy or group DBT skills training. Completing the DBT PE Protocol was defined as completing at least 8 sessions of the protocol, at least 6 of which included imaginal exposure (i.e., the active in-session treatment component). This is consistent with definitions of treatment completion used in prior studies of PE (Foa et al., 2005). Patients that dropped out of treatment completed a 19-item Reasons for Termination-Client scale adapted from a measure developed by Hunsley et al. (1999). The original measure assessed client-focused reasons for termination (e.g., dissatisfaction with treatment, felt problems had improved) and items

were added to assess client-related practical barriers (e.g., moved from area, medical problems interfered with treatment) as well as therapist-focused reasons (e.g., therapist terminated treatment because he/she was burned out).

Treatment acceptability—The acceptability of treatment was measured in terms of treatment preferences, expectancies, and satisfaction. Participants' treatment preferences were assessed at intake using an adapted version of Zoellner and colleagues (2003) treatment choice measure. This measure includes a written description of PE and was adapted to include a written description of DBT. After reading both descriptions, participants responded to a single item asking whether they preferred to receive DBT alone, PE alone, or a combined DBT and PE treatment. Two items adapted from Sotsky et al. (1991) assessed patient and therapist expectations of improvement and helpfulness of the treatment on a scale from 1 (very much worse/harmful) to 7 (very much improved/helpful). Patient treatment expectancies were assessed at baseline, after the first therapy session, and at all outcome assessments (Cronbach's alphas = 0.85–0.90), whereas therapist treatment expectancies were assessed after the first therapy session, at 4-months, 8-months, and post-treatment (Cronbach's alpha = 0.93). Items were rated on a 1–7 scale with higher scores indicating more positive treatment expectancies. The 8-item Client Satisfaction Questionnaire (CSQ; Larsen, Attkisson, Hargreaves, & Nguyen, 1979) was used to measure patients' treatment satisfaction at the post-treatment assessment. Items were rated on a 1–4 scale and summed to create a total score.

Treatment safety—Potential adverse reactions were measured in terms of increases in suicidal and self-injurious urges and behaviors. Urges to commit suicide and self-injure were assessed immediately before and after each individual therapy session, as well as before and after each imaginal and in vivo exposure task (both in-session and homework tasks). Urges were rated on a scale ranging from 0 (not at all) to 5 (extremely). The occurrence of suicide attempts and NSSI was assessed via the Suicide Attempt Self-Injury Interview (SASII; Linehan, Comtois, Brown, Heard, & Wagner, 2006a).

Primary clinical outcomes

PTSD: The PSS-I (Foa et al., 1993) was used to assess the presence and severity of PTSD during the past two weeks at each outcome assessment. PTSD remission was defined as no longer meeting DSM-IV criteria for PTSD in relation to any traumatic event. A PTSD severity score was also computed by summing the 17 PSS-I items (range= 0–51). Cronbach's alpha was 0.90.

Intentional self-injury: The SASII (Linehan et al., 2006a) is a psychometrically sound interview that assessed the frequency of suicide attempts and NSSI since the last assessment.

Secondary clinical outcomes—Four self-report measures were used to assess pathological dissociation (Dissociative Experiences Scale – Taxon (DES-T); Waller & Ross, 1997), trauma-related guilt cognitions (Trauma Related Guilt Inventory (TRGI); Kubany et al., 1996), shame (Experience of Shame Scale (ESS); Andrews, Qian, & Valentine, 2002), and general psychological well-being (Global Severity Index (GSI) from the Brief Symptom

Inventory; Derogatis, 1993). The ESS and GSI assess symptoms over the past month, whereas the TRGI and DES-T are trait measures (no specific time frame). Interviewer-rated depression (past two weeks) and general anxiety (past week) were assessed via the Hamilton Rating Scale for Depression (HRSD; Hamilton, 1960) and Hamilton Rating Scale for Anxiety (HRSA; Hamilton, 1959). All measures demonstrated high internal consistency (Cronbach's alphas = 0.85–0.98).

Statistical Methods

Descriptive data were used to evaluate treatment feasibility, safety, and acceptability. This study was not powered to test hypotheses about potential between-condition differences on primary and secondary outcomes. Given the sample size of 26, an observed attrition from assessments of 31%, and an average within-subject correlation of ρ=0.31, the study had power of 64.1% to detect a large effect (d = 0.8). Given the low power, emphasis was placed on evaluating indices of clinical significance. Between- and within-group Hedge's g effect sizes that correct for small samples were used to evaluate the magnitude of treatment effects. Reliable and clinically significant improvement were calculated according to the criteria suggested by Jacobson and Truax (1991). Specifically, reliable change (RC) was calculated as $RC = x_2 - x_1/S_{diff}$ and clinically significant change (CSC) was defined as reaching a level of functioning after treatment that is closer to the mean of the non-patient population than to the patient population. For measures without non-patient normative data (PSS-I), CSC was defined as reaching a level of functioning that was greater than two standard deviations below the pre-treatment sample mean. Patients achieving both reliable and clinically significant improvement are considered recovered. Normative data were derived from standardized norms or studies using large samples. The RC indices, CSC cut-offs, and sources of normative data were as follows: PSS-I (RC = ±10.5, CSC ≤ 14.9; Foa et al., 2005); TRGI (RC = ±0.9, CSC ≤ 1.5; Kubany et al., 1996); ESS (RC = ±13.2, CSC ≤ 66.3; Doran & Lewis, 2012); HRSA (RC = ±8.7, CSC ≤ 6.4; Huppert, Simpson, Nissenson, Liebowitz, & Foa, 2009; Shear et al., 2001); HRSD (RC = ±5.9, CSC ≤ 9.0; Grundy, Lambert, & Grundy, 1996; Zimmerman, Chelminski, & Posternak, 2004); GSI (RC = ±0.6, CSC ≤ 0.7; Derogatis, 1993). Derivation of RC and CSC depend on approximate normality of the outcome; thus, these are not included for suicide attempts, NSSI, and the DES-T because of the highly skewed nature of these outcomes.

Two types of mixed-effects models were used to preliminarily describe the rate of change of the outcomes in the two groups across time. To allow for the possibility of non-linear change over time, both hierarchical linear models (HLM; Bryk & Raudenbush, 1992) and mixed model analyses of variance (MMANOVA; Khuri, Mathew, & Sinha, 1998) were examined for each outcome and the appropriate variance-covariance structure was analytically determined based on a mixture of chi-squares in comparing nested models (Verbeke, 1997). Predictors in these models were time, condition, treatment completion status, and the two- and three-way interactions of these effects. Treatment completion status was included as a predictor given that this variable is necessary to discriminate between the two conditions. Specifically, only the patients in DBT + DBT PE who completed the DBT PE protocol received a different treatment than those in DBT. Given the small sample size, each model was evaluated for potential influential observations or subjects using Cook's

distance and residual analyses to assess model fit (Martin, 1992). These analyses revealed one influential subject on the DES-T who was excluded from the model; no other influential observations or subjects were found in any model. In general, the focus of these analyses was not statistical significance, but rather to identify any apparent trends over time in the two treatments.

Results

Sample Characteristics

The sample was an average age of 32.6 years (SD=12.0, range=19–55) and was primarily Caucasian (80.8%) followed by biracial (15.4%) and Asian-American (3.8%). A majority of the sample was single, divorced, separated or widowed (84.6%), had less than a college degree (69.2%), and earned $20,000 or less per year (75.0%). Patients in DBT were more likely to be married than those in DBT + DBT PE (44.4% vs. 0%, $\chi^2(1)=8.9$, $p<.01$). There were no other significant between-condition differences on demographic variables. Clinical characteristics of the sample are presented in Table 1.

Treatment Feasibility

Treatment retention—Completion rates for the one year of treatment did not differ between conditions (DBT=55.6%, DBT + DBT PE=58.8%; $\chi^2(1)=0.3$, $p=.87$), but were lower than those typically found in DBT studies (73%; Kliem, Kroger, & Kosfelder, 2010). The lower than average completion rate is accounted for by one therapist who was not adherent to DBT and had a 100% dropout rate. Excluding this therapist's four patients, the treatment completion rates were: DBT=71.4%, DBT + DBT PE=66.7%. In general, patients could choose reassignment to another therapist, and the number of therapists dropped was significantly correlated with lower therapist adherence to DBT ($r= -0.5$, $p<.02$). Premature dropout occurred on average at week 19.3 in DBT (SD=9.7) and 29.3 in DBT + DBT PE (SD=13.4). Reasons for premature dropout from DBT were: committed suicide ($n=1$), not motivated to attend treatment ($n=1$), and unknown ($n=2$). Reasons for premature dropout from DBT + DBT PE were: time problems due to full-time work and/or school and felt problems had improved ($n=2$), out of town for four consecutive weeks ($n=1$), practical problems attending treatment due to move ($n=1$), and unknown ($n=3$).

Treatment attendance—There were moderate, but non-significant effects indicating that patients in DBT + DBT PE attended a greater number of individual therapy sessions than those in DBT in the ITT sample (DBT: $M=28.8$, SD=16.7, DBT + DBT PE: $M=38.6$, SD=18.5; $t(24)=1.3$, $p=.19$, $g=0.5$) and among treatment completers (DBT: $M=41.0$, SD=9.3, DBT + DBT PE: $M=48.5$, SD=11.3; $t(9)=1.2$, $p=.27$, $g=0.7$). The number of skills training groups attended did not differ by condition in the ITT sample (DBT: $M=24.4$, SD=17.8, DBT + DBT PE: $M=28.7$, SD=14.4; $t(24)=0.7$, $p=.51$, $g=0.3$) or among treatment completers (DBT: $M=38.4$, SD=7.9, DBT + DBT PE: $M=35.8$, SD=5.3; $t(9)=0.6$, $p=.56$, $g=0.4$).

DBT PE Protocol implementation—Of the 17 patients in the DBT+DBT PE condition, 8 (47.1%) started the DBT PE protocol and 9 (52.9%) did not. Of the 9 patients that did not

start the DBT PE protocol, reasons for not starting included: dropped out of treatment (*n*=4; 44.4%), PTSD remitted without targeted treatment (*n*=3; 33.3%), and did not achieve sufficient stability (*n*=2; 22.2%). The 8 patients that started the DBT PE protocol did so at week 21.9 of DBT on average (SD=11.6, range=6–37). Of these, 6 (75%) completed the protocol in an average of 12.7 sessions (SD=2.9, range=9–17) during which an average of 3.0 trauma memories were targeted (SD=1.7, range=1–6). Reasons for non-completion included difficulty controlling NSSI (*n*=1) and unwillingness to continue (*n*=1). Among patients who started the DBT PE protocol, 2 (25%) were not taking an SSRI and 6 (75%) remained at a stable dose of an SSRI during this portion of the treatment.

Treatment Acceptability

At intake, the majority of patients indicated a preference for a combined DBT and PE treatment (*n*=19, 73.1%) and the remainder preferred to receive DBT only (*n*=7, 26.9%). No patients reported a preference for PE alone. Treatment preference did not differ between conditions (Fisher's exact *p* =.19). Patients in both conditions reported comparably positive treatment expectancies (DBT: *M*=5.6, SD=1.5, DBT + DBT PE: *M*=5.9, SD=1.0, $t(127)=1.1$, $p=.29$, $g=0.2$) and were highly satisfied with the treatment they received at post-treatment (DBT: *M*=25.3, SD=7.5, DBT + DBT PE: *M*=25.4, SD=6.4, $t(17)=0.04$, $p=.97$, $g=0.02$). In addition, therapist treatment expectancies were very positive and did not differ between conditions (DBT: *M*=5.8, SD=0.9, DBT + DBT PE: *M*=5.9, SD=0.8, $t(82)=0.6$, $p=.55$, $g=0.1$)

Treatment Safety

Pre- and post-session urges to commit suicide and self-injure were higher and more stable among patients in DBT compared to those in DBT + DBT PE (Table 2). Specifically, patients in DBT reported significantly higher pre- and post-session urges to commit suicide (*M*'s=1.8–2.0) and self-injure (*M*'s=1.8–2.0) than those in DBT + DBT PE (*M*'s=1.0–1.3 and 1.1–1.4, respectively). Moreover, there was a significant difference in the pattern of pre-post session change in urges to commit suicide by condition, which was accounted for by the fact that suicide urges were more likely to decrease after sessions in DBT + DBT PE (29.7% vs. 18.2%; $\chi^2(1)=8.0$, $p<.01$) and to remain unchanged after sessions in DBT (76.7% vs. 60.3%, $\chi^2(1)=14.1$, $p<.001$). The pattern of change in pre-post session urges to self-injure did not significantly differ between conditions.

Among patients in DBT + DBT PE, neither the average intensity nor the pattern of change of pre-post session urges to commit suicide and self-injure differed between DBT and DBT PE protocol sessions (Table 2). Similarly, urges to commit suicide and self-injure were low both before and after completing exposure tasks (*M*'s = 0.3–0.5) and completing an exposure task rarely led to an increase in urges (<12% of tasks). Of the 8 patients who started the DBT PE Protocol, 2 (25.0%) reported a relapse of intentional self-injury during this portion of the treatment (suicide attempt (*n*=1), NSSI (*n*=1)).

Clinical Outcomes

For all outcomes, descriptive data are shown in Table 3, within- and between-group Hedge's *g* effect sizes are shown in Table 4, rates of reliable and clinically significant change are shown in Table 5, and results of mixed-effects models are shown in Table 6.

Primary outcomes

Intentional self-injury: One patient in DBT committed suicide during the study. In the ITT sample, the rate of any suicide attempt during the study was 37.5% in DBT + DBT PE and 50.0% in DBT. Among treatment completers, the rate of any suicide attempt was 16.7% in DBT + DBT PE and 40.0% in DBT. Pre-post changes in the frequency of suicide attempts were moderate to large in DBT + DBT PE (*g*'s=0.6–0.8) and small in DBT (*g*'s=0.0–0.4). At post-treatment, between-group effect sizes were moderate in favor of DBT + DBT PE (*g*'s=0.6–0.7). During the follow-up period, 91.7% of patients in DBT + DBT PE and 100% of patients in DBT were abstinent from suicidal behavior.

A similar pattern of results was found for NSSI. In the ITT sample, the rate of any NSSI during the study was 68.8% in DBT + DBT PE and 87.5% in DBT. Among treatment completers, the rate of any NSSI was 66.7% in DBT + DBT PE and 100% in DBT. Pre-post changes in the frequency of NSSI were very large in DBT + DBT PE (*g*'s=1.0–1.1) and large in DBT (*g*'s=0.8). At post-treatment, between-group effect sizes were small in the ITT sample (*g*=0.0) and moderate in favor of DBT + DBT PE among treatment completers (*g*=0.6). During the follow-up period, 75.0% of patients in DBT + DBT PE and 66.7% of patients in DBT were abstinent from NSSI. Among treatment completers, rates of abstinence from NSSI during follow-up were 80.0% in DBT + DBT PE and 60.0% in DBT. Mixed effects models did not converge for either suicide attempts or NSSI due to the high model complexity and low within-subject variability.

PTSD: There were very large pre-post changes in PTSD severity in both conditions (*g*'s>1.2), with the largest effect found for DBT PE protocol completers (*g*=2.9). At 3-month follow-up, changes in PTSD severity remained very large in DBT + DBT PE (*g*'s=1.4–1.6) and large in DBT (*g*'s=0.9). Between-group effect sizes at post-treatment and follow-up were small in the ITT sample (*g*'s=0.0–0.1) and moderate among treatment completers (*g*'s=0.6–0.7). At post-treatment, a majority of patients in the ITT sample had reliably improved and reached a normal level of functioning (i.e., recovered; DBT + DBT PE=58.3%, DBT=50.0%), and recovery was highest among DBT + DBT PE treatment completers (80%). At 3-month follow-up, the rate of recovery remained unchanged in DBT + DBT PE, but decreased to 0% in DBT. When using the most stringent criterion of diagnostic remission, this pattern of findings was even more pronounced. At post-treatment, rates of PTSD remission were: DBT + DBT PE (ITT = 58.3%, completers = 80.0%) and DBT (ITT = 33.3%, completers = 40.0%). At 3-month follow-up, no patients in DBT (0%) were in remission, whereas remission rates remained high in DBT + DBT PE (ITT = 50.0%, completers = 60.0%). Finally, a MMANOVA found a significant reduction in PTSD severity across time. However, a significant Time x Condition x Completer interaction indicated that completers in DBT + DBT PE showed the largest improvement in PTSD severity.

Secondary outcomes—Within-group effect sizes for dissociation, trauma-related guilt cognitions, shame, anxiety, depression, and global severity were generally very large in DBT + DBT PE (ITT average *g*=1.2, range=0.4–2.1), particularly among DBT PE protocol completers (average *g*=2.0, range=0.6–3.9). In DBT, within-group effect sizes on these secondary outcomes were generally large in both the ITT sample (average *g*=0.9, range=0.3–1.6) and among treatment completers (average *g*=0.8, range=0.2–1.4). At post-treatment, between-group effect sizes in favor of DBT + DBT PE were generally moderate in the ITT sample (average *g*=0.5, range=0.2–1.0) and very large among treatment completers (average *g*=1.1, range=0.7–1.4). At 3-month follow-up, between-group effect sizes were generally small in the ITT sample (average *g*=0.3, range=0.0–0.7) and moderate among treatment completers (average *g*=0.7, range=0.4–1.1). In addition, 60% to 100% of treatment completers in DBT + DBT PE both reliably improved and reached normal levels of functioning (i.e., recovered) for all secondary outcomes at post-treatment and/or follow-up. In contrast, 0% to 20% of treatment completers in DBT recovered on each secondary outcome at post-treatment and follow-up with the exception of shame at follow-up (40%). Mixed effects models found significant reductions across time for all secondary outcomes except trauma-related guilt cognitions. However, significant Time x Completer and Condition x Completer interactions were found for trauma-related guilt cognitions, indicating that completers showed a significantly greater improvement than non-completers across time, and this was particularly true for completers in DBT + DBT PE. In addition, simple slopes analyses indicated that anxiety decreased significantly in DBT + DBT PE (β=−3.0, $t(54)=4.6$, $p<.0001$), but not in DBT (β=−2.0, $t(54)=1.9$, $p=.06$). Similarly, there was a significant reduction in global severity in DBT + DBT PE (β=−0.3, $t(54)=5.1$, $p<.0001$), but only a trend in DBT (β=−0.2, $t(54)=2.0$, $p=.05$).

Discussion

This pilot randomized controlled trial provides a preliminary comparison of DBT with and without the DBT PE protocol in a sample of suicidal and self-injuring women with BPD and PTSD. Both treatments were found to be comparably acceptable and feasible to implement. Specifically, patients in both treatments reported positive treatment expectancies and high satisfaction, and rates of treatment completion did not differ between conditions. In addition, a majority of patients (73.1%) preferred a combined DBT and PE treatment rather than DBT alone (26.9%). These findings stand in contrast to common clinician concerns that exposure therapy for PTSD is likely to be unacceptable to many patients and may increase their desire to drop out of therapy (Becker et al., 2004). Instead, integrating exposure-based PTSD treatment into DBT did not negatively impact treatment acceptability and, in fact, appears to be the preferred treatment approach (Harned, Tkachuck, & Youngberg, 2013).

The DBT PE protocol was also feasible to implement in this seriously impaired sample. The combined DBT and DBT PE protocol treatment uses a phase-based approach in which DBT is used to achieve stabilization prior to initiating targeted PTSD treatment. Specifically, patients are required to achieve abstinence from suicidal and self-injurious behaviors for at least two months prior to beginning the DBT PE protocol, and to have developed sufficient control over any other behaviors that are either higher-priority or likely to interfere with PTSD treatment (e.g., severe dissociation). Encouragingly, the present results indicate that a

majority of patients (80%) who stay in DBT and continue to meet criteria for PTSD are able to achieve sufficient stability to begin the DBT PE protocol after an average of five months of DBT. In addition, the rate of completion of the DBT PE protocol (75%) was comparable to other exposure-based PTSD treatments (76%; Bradley et al., 2005). These results are consistent with the findings of the prior open trial (Harned et al., 2012) and provide additional evidence that DBT is an effective and reasonably quick stabilizing treatment for the majority of suicidal and self-injuring BPD patients who require PTSD treatment. Indeed, the most common barrier to implementing PTSD treatment in this population appears to be premature dropout from DBT, whereas failure to stabilize was the least common barrier.

Both treatments were also associated with large improvements in PTSD severity. However, patients who completed the DBT PE protocol had significantly greater improvements in PTSD severity over time than those in DBT. At post-treatment, completers in DBT + DBT PE were 1.3 times more likely to report reliable and clinically significant improvement in PTSD (80% vs. 60%) and 2 times more likely to achieve diagnostic remission (80% vs. 40%) than those in DBT. In general, the rate of PTSD remission among patients who did not receive the DBT PE protocol was 33% in both conditions, a rate comparable to that found in a prior study of DBT (35%; Harned et al., 2008). These findings suggest that DBT reduces the severity of PTSD, but targeted PTSD treatment is likely to be necessary to reach the level of diagnostic remission. In addition, the effects achieved in DBT were less stable, as no patients remained in recovery or remission from PTSD three months after treatment ended, whereas these rates remained high in DBT + DBT PE (50–60%). It is possible that the reduction in PTSD severity during DBT may be due to the use of DBT skills to manage anxiety as well as non-specific treatment factors (e.g., therapeutic alliance, the structure of treatment), whereas the DBT PE protocol changes the mechanisms underlying PTSD (e.g., trauma-related cognitions) resulting in more substantial and lasting change. Future research is needed to evaluate the mechanisms of action leading to improvement in PTSD and to determine whether these differ by treatment.

Critically, the larger improvements in PTSD found in DBT + DBT PE were achieved without compromising the safety of patients. Among patients in DBT + DBT PE, urges to commit suicide and self-injure rarely increased immediately after exposure tasks (8–11%) and were no more likely to increase after DBT PE sessions (9–10%) than DBT sessions (10–14%). In addition, pre- and post-session urges to commit suicide and self-injure were significantly higher among patients in DBT compared to those in DBT + DBT PE, suggesting that integrating PTSD treatment into DBT may actually decrease urges to engage in these behaviors across treatment as a whole. Indeed, the suicide attempt rate was 1.4 to 2.4 times lower in DBT + DBT PE (17–37%) than in DBT (40–50%). Similarly, the rate of NSSI was 1.3 to 1.5 times lower in DBT + DBT PE (67–69%) than in DBT (88–100%). These findings indicate that providing PTSD treatment to severe BPD patients does not exacerbate, and may even reduce, suicidal and self-injurious urges and behaviors. This is likely accomplished not only by making PTSD treatment contingent on the resolution of these behaviors (a motivating factor for many patients), but also by reducing the PTSD symptoms that may have previously precipitated intentional self-injury.

More generally, patients in DBT + DBT PE had superior outcomes across a range of domains compared to those in DBT, particularly those who completed the DBT PE protocol. Among treatment completers, between-condition effect sizes at post-treatment were large in favor of DBT + DBT PE for dissociation, trauma-related guilt cognitions, shame, anxiety, depression, and global functioning. In addition, a majority of completers in DBT + DBT PE (60–100%) showed reliable and clinically significant improvement on each of these outcomes at post-treatment and/or follow-up, compared to 0–20% of completers in DBT. These findings suggest that successful treatment of PTSD in this multi-problem population may lead to larger and more sustained improvements in a variety of domains that were either being exacerbated or maintained by PTSD. This is consistent with research showing that changes in PTSD symptoms account for 80% of changes in depression during PE (Aderka, Gillihan, McLean, & Foa, 2013). Further, reductions in these secondary outcomes may be critical for long-term maintenance of gains in intentional self-injury. For example, dissociation and shame each prospectively predict intentional self-injury in BPD (Brown, Linehan, Comtois, Murray, & Chapman, 2009; Wedig et al., 2012). Future research is needed to evaluate the temporal relationships between reductions in PTSD, intentional self-injury, and other outcomes.

This study had several notable strengths, including the selection of a high-risk and highly comorbid sample, the evaluation of a novel intervention, and the use of a rigorous randomized, controlled design with a strong comparison condition. A limitation of the study is that recruiting specifically for individuals with BPD and PTSD may have resulted in a sample of BPD patients that was more motivated to receive PTSD treatment than may be the case among individuals with BPD and PTSD more generally. The primary limitation of this study, however, is the small sample size, which was further complicated by the higher than usual rate of treatment dropout. Given the low power in this study, emphasis was placed on indices of clinical rather than statistical significance. Future research with larger, adequately powered samples is needed.

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Highlights

- A RCT compared DBT with and without the DBT PE protocol in 26 BPD women with PTSD.
- Treatment expectancies, satisfaction, and retention did not differ by treatment.
- The DBT PE protocol was feasible to deliver for a majority of treatment completers.
- Rates of intentional self-injury were 1.3 – 2.4 times lower in DBT+DBT PE than DBT.
- DBT+DBT PE led to larger, more stable gains in PTSD and other outcomes than DBT.

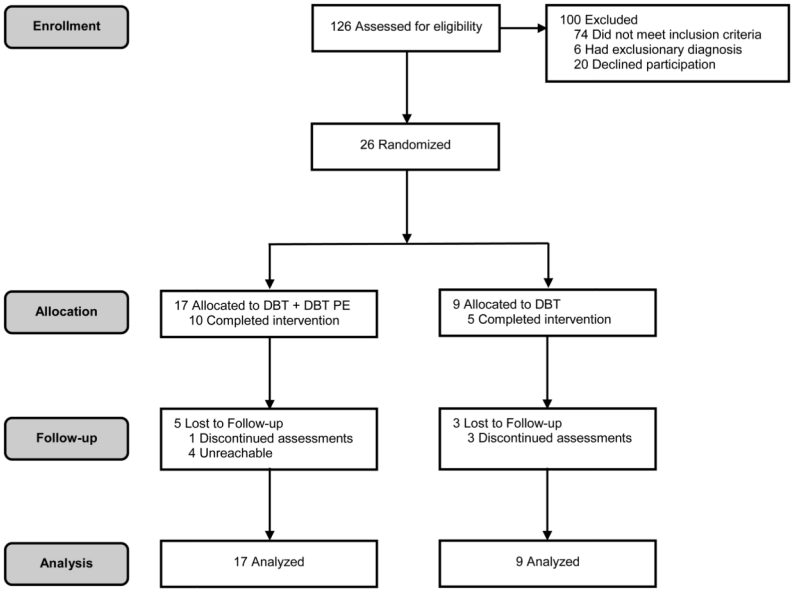

Figure 1.
Subject flow through enrollment and follow-up.

Table 1

Clinical Characteristics of the Sample at Pre-Treatment

	DBT (n=7)	DBT+DBT PE (n=19)	Total (*N*=26)
Intentional Self-Injury History			
Suicide attempts, past year			
Any suicide attempt	55.6	58.8	57.7
Total suicide attempts (M ± SD)	1.1 ± 1.2	3.1 ± 6.7	2.4 ± 5.5
Non-suicidal self-injury (NSSI), past year			
Any NSSI	88.9	100.0	96.2
Total NSSI acts (M ± SD)	20.1 ± 29.4	86.2 ± 115.4	63.3 ± 99.1
Trauma History			
Lifetime Trauma History (M ± SD)			
Types of lifetime trauma	10.6 ± 5.8	11.8 ± 4.3	11.4 ± 4.8
Age of trauma onset	7.1 ± 5.5	5.8 ± 4.3	6.2 ± 4.7
Index Traumas			
Childhood sexual abuse	55.5	47.1	50.0
Adult rape	11.1	17.6	15.4
Childhood physical abuse	0.0	17.6	11.5
Intimate partner violence	22.2	5.9	11.5
Threatened with death/serious harm	11.1	5.9	7.7
Sudden death of friend/loved one	0.0	5.9	3.8
Diagnostic Data			
Current Axis I disorders			
Any mood disorder	75.0	87.5	83.3
Any anxiety disorder other than PTSD	87.5	87.5	87.5
Any eating disorder	12.5	12.5	12.5
Any substance use disorder	37.5	43.8	41.7
Total no. Axis I disorders (M ± SD)	4.5 ± 2.4	5.2 ± 2.1	5.0 ± 2.2
Current Axis II Disorders			
Any Axis II disorder other than BPD	50.0	68.8	62.5
Total no. Axis II disorders (M ± SD)	1.9 ± 1.1	2.1 ± 1.0	2.0 ± 1.0
Global Assessment of Functioning (M ± SD)	44.6 ± 3.7	42.3 ± 3.6	43.0 ± 3.7
Psychiatric Treatment History			
Any inpatient psychiatric admission, past year	44.4	52.9	50.0
Any ER visit for psychological reasons, past year	77.8	70.6	73.1
Any psychotropic medication, past year	87.5	88.2	88.0

Note: Data are given as percentages unless otherwise indicated. BPD = borderline personality disorder.

Table 2

Urges to Commit Suicide and Self-Injure Before and After Individual Therapy Sessions and Exposure Tasks

	DBT + DBT PE				DBT	
	Exposure Tasks (*n*=256)	**DBT sessions (*n*=429)**	**DBT PE sessions (*n*=70)**	**Within-group test**	**DBT sessions (*n*=159)**	**Between-group test**
Urges to Commit Suicide						
Intensity of Urges, M ± SD						
Pre	0.3 ± 0.7	1.4 ± 1.6	1.1 ± 1.4	t (560) = 1.5	2.0 ± 2.2	t (736) = 4.2***
Post	0.3 ± 0.9	1.1 ± 1.5	0.9 ± 1.3	t (500) = 1.1	1.8 ± 2.0	t (659) = 5.0***
Change in Urges, n (%)						
Decrease in urges	24 (9.4%)	133 (31.0%)	15 (21.4%)	χ^2 (2) = 3.3	29 (18.2%)	χ^2 (2) = 14.3**
No change in urges	211 (82.4%)	252 (58.7%)	49 (70.0%)		122 (76.7%)	
Increase in urges	21 (8.2%)	44 (10.3%)	6 (8.6%)		8 (5.0%)	
Urges to Self-Injure						
Intensity of Urges, M ± SD						
Pre	0.4 ± 1.0	1.4 ± 1.7	1.1 ± 1.5	t (564) = 1.7	2.0 ± 2.1	t (740) = 4.0***
Post	0.5 ± 1.2	1.1 ± 1.6	0.9 ± 1.3	t (501) = 1.0	1.8 ± 2.0	t (660) = 4.7***
Change in Urges, n (%)						
Decrease in urges	28 (10.9%)	141 (32.6%)	16 (22.9%)	χ^2 (2) = 4.5	41 (25.8%)	χ^2 (2) = 4.5
No change in urges	199 (77.7%)	232 (53.6%)	47 (67.1%)		103 (64.8%)	
Increase in urges	29 (11.3%)	60 (13.9%)	7 (10.0%)		15 (9.4%)	

Note. Urges were rated on a 0 to 5 scale. Within-group tests compared DBT to DBT PE sessions within the DBT + DBT PE condition. Between-group tests compared the two conditions across all sessions.

** $p < .01$.

*** $p < .001$.

Table 3

Descriptive Statistics for Outcome Variables by Condition and Treatment Completer Status

	DBT + DBT PE						DBT					
	Intent to Treat			Treatment Completers			Intent to Treat			Treatment Completers		
Outcome	Pre (*n*=17)	Post (*n*=12)	FU (*n*=12)	Pre (*n*=6)	Post (*n*=5)	FU (*n*=5)	Pre (*n*=9)	Post (*n*=6)	FU (*n*=6)	Pre (*n*=5)	Post (*n*=5)	FU (*n*=5)
	M (SD)	M (SD)	M (SD)	M (SD)	M (SD)	M (SD)	M (SD)	M (SD)	M (SD)	M (SD)	M (SD)	M (SD)
PTSD	32.8 (8.0)	13.6 (13.2)	16.7 (14.1)	30.7 (6.8)	6.2 (8.2)	11.0 (14.3)	30.1 (9.6)	13.8 (9.3)	18.4 (7.7)	30.8 (10.7)	13.8 (10.4)	19.8 (8.2)
Suicide attempts[a]	1.0 (2.2)	0.0 (0.0)	0.1 (0.3)	0.2 (0.4)	0.0 (0.0)	0.2 (0.5)	0.4 (0.4)	0.2 (0.4)	0.0 (0.0)	0.2 (0.3)	0.2 (0.5)	0.0 (0.0)
NSSI acts[a]	28.8 (38.5)	0.9 (2.0)	0.6 (1.2)	42.0 (49.0)	0.2 (0.5)	0.8 (1.8)	6.7 (9.8)	1.0 (2.0)	0.3 (0.5)	6.3 (7.5)	1.2 (2.2)	0.4 (0.5)
Dissociation	22.7 (21.6)	10.0 (16.9)	11.3 (16.7)	23.1 (22.3)	5.8 (3.3)	6.8 (8.7)	21.8 (21.7)	14.6 (12.5)	17.3 (15.3)	21.8 (28.5)	13.8 (13.8)	16.5 (16.9)
Trauma-related guilt cognitions	2.4 (0.8)	1.6 (0.8)	1.7 (0.9)	2.7 (0.6)	1.0 (0.6)	1.2 (0.8)	2.4 (0.9)	2.5 (1.0)	2.4 (1.3)	2.8 (0.5)	2.4 (1.1)	2.2 (1.3)
Shame	87.7 (10.5)	61.8 (16.1)	65.3 (19.6)	90.7 (7.1)	49.6 (10.6)	59.0 (18.8)	84.1 (13.7)	67.7 (15.3)	66.0 (15.2)	84.0 (14.8)	69.4 (16.5)	67.6 (16.5)
Anxiety	25.8 (9.0)	14.2 (10.8)	15.0 (10.6)	27.3 (8.9)	8.4 (6.9)	11.2 (13.6)	27.6 (10.9)	17.8 (8.6)	16.3 (7.0)	25.8 (11.8)	16.8 (9.2)	15.8 (7.7)
Depression	22.9 (5.7)	11.8 (8.0)	12.5 (8.2)	21.2 (3.9)	8.2 (4.9)	9.4 (8.9)	25.6 (6.2)	15.5 (6.5)	16.8 (3.4)	25.0 (6.2)	15.0 (7.2)	17.4 (3.5)
Global severity	2.6 (0.6)	1.1 (0.7)	1.4 (0.9)	2.6 (0.7)	0.6 (0.4)	1.1 (1.0)	2.2 (0.7)	1.2 (0.5)	1.7 (0.8)	2.3 (1.0)	1.3 (0.5)	1.7 (0.8)

Note. In DBT + DBT PE, treatment completion is defined as completing the DBT PE protocol. In DBT, treatment completion is defined as completing one year of DBT. Means, standard deviations and effect sizes were calculated using the observed data. NSSI = nonsuicidal self-injury. FU = 3-month follow-up.

[a] Includes the number of episodes in the past 4 months.

Table 4

Within and Between-Group Hedge's g Effect Sizes

	Within-Group Effect Sizes								Between-Group Effect Sizes			
	DBT + DBT PE				DBT				DBT + DBT PE vs. DBT			
	Pre-Post		Pre-FU		Pre-Post		Pre-FU		Post		FU	
Outcome	**ITT**	**TC**	**ITT**	**TC**	**ITT**	**TC**	**ITT**	**TC**	**ITT**	**TC**	**ITT**	**TC**
PTSD	1.8	2.9	1.4	1.6	1.3	1.5	0.9	0.9	0.0	0.7	0.1	0.6
Suicide attempts	0.6	0.8	0.5	0.1	0.4	0.0	1.0	0.9	0.7	0.6	−0.3	−0.6
Nonsuicidal self-injury acts	1.0	1.1	1.1	1.1	0.8	0.8	0.9	1.0	0.0	0.6	−0.2	−0.3
Dissociation	0.5	0.8	0.4	0.6	0.5	0.3	0.3	0.2	0.3	0.7	0.4	0.7
Trauma-related guilt cognitions	0.9	2.3	0.8	1.8	0.4	0.5	0.4	0.6	1.0	1.4	0.7	0.8
Shame	1.9	3.9	1.4	2.0	1.1	0.8	1.2	1.0	0.4	1.3	0.0	0.4
Anxiety	1.1	2.0	1.1	1.2	0.7	0.8	0.9	0.9	0.3	0.9	0.1	0.4
Depression	1.7	3.0	1.6	1.7	1.4	1.4	1.6	1.4	0.5	1.0	0.6	1.1
Global severity	2.1	3.3	1.4	1.6	1.3	1.2	0.6	0.5	0.2	1.4	0.2	0.6

Note. Within-group effect sizes were calculated using observed data from those patients who completed both of the relevant assessment points: DBT + DBT PE (ITT n=12, TC n=5), DBT (ITT n=6, TC n=5). Positive within-group effect sizes indicate improvements in outcomes, whereas negative within-group effect sizes indicate worsening in outcomes. Positive between-group effect sizes indicate a greater improvement in DBT + DBT PE than in DBT. ITT = Intent to treat, TC = Treatment completers, FU = 3-month follow-up.

Table 5

Reliable and Clinically Significant Improvement

	Intent to Treat						Treatment Completers					
	Reliable Improvement		Normal Functioning		Both Criteria		Reliable Improvement		Normal Functioning		Both Criteria	
	DBT + DBT PE	DBT	DBT + DBT PE	DBT	DBT + DBT PE	DBT	DBT + DBT PE	DBT	DBT + DBT PE	DBT	DBT + DBT PE	DBT
PTSD												
Post-treatment	10 (83.3)	4 (66.7)	7 (58.3)	5 (83.3)	7 (58.3)	3 (50.0)	5 (100.0)	4 (80.0)	4 (80.0)	4 (80.0)	4 (80.0)	3 (60.0)
Follow-up	8 (66.7)	2 (40.0)	7 (58.3)	1 (20.0)	7 (58.3)	0 (0.0)	4 (80.0)	2 (50.0)	4 (80.0)	0 (0.0)	4 (80.0)	0 (0.0)
Trauma-related guilt cognitions												
Post-treatment	4 (33.3)	1 (16.7)	5 (45.5)	1 (16.7)	3 (27.3)	1 (16.7)	3 (60.0)	1 (20.0)	4 (80.0)	1 (20.0)	3 (60.0)	1 (20.0)
Follow-up	3 (25.0)	1 (16.7)	4 (36.4)	1 (16.7)	2 (18.2)	1 (16.7)	3 (60.0)	1 (20.0)	3 (60.0)	1 (20.0)	2 (40.0)	1 (20.0)
Shame												
Post-treatment	9 (75.0)	4 (66.7)	7 (63.6)	3(50.0)	7 (63.6)	2 (33.3)	5 (100.0)	3 (60.0)	5 (100.0)	2 (40.0)	5 (100.0)	1 (20.0)
Follow-up	7 (58.3)	3 (50.0)	6 (54.5)	4 (66.7)	6 (54.5)	3 (50.0)	3 (60.0)	2 (40.0)	3 (60.0)	3 (60.0)	3 (60.0)	2 (40.0)
Anxiety												
Post-treatment	7 (58.3)	4 (66.7)	3 (25.0)	0 (0.0)	3 (25.0)	0 (0.0)	4 (80.0)	4 (80.0)	2 (40.0)	0 (0.0)	2 (40.0)	0 (0.0)
Follow-up	7 (58.3)	3 (50.0)	3 (25.0)	1 (16.7)	3 (25.0)	1 (16.7)	4 (80.0)	3 (60.0)	3 (60.0)	1 (20.0)	3 (60.0)	1 (20.0)
Depression												
Post-treatment	7 (58.3)	4 (66.7)	5 (41.7)	1 (16.7)	5 (41.7)	1 (16.7)	4 (80.0)	4 (80.0)	3 (60.0)	1 (20.0)	3 (60.0)	1 (20.0)
Follow-up	7 (58.3)	4 (66.7)	3 (25.0)	0 (0.0)	3 (25.0)	0 (0.0)	4 (80.0)	3 (60.0)	2 (40.0)	0 (0.0)	2 (40.0)	0 (0.0)
Global severity												
Post-treatment	9 (75.0)	3 (50.0)	5 (41.7)	1 (16.7)	5 (41.7)	0 (0.0)	5 (100.0)	2 (40.0)	4 (80.0)	1 (20.0)	4 (80.0)	0 (0.0)
Follow-up	8 (66.7)	3 (50.0)	3 (25.0)	0 (0.0)	3 (25.0)	0 (0.0)	4 (80.0)	2 (40.0)	2 (40.0)	0 (0.0)	2 (40.0)	0 (0.0)

Note. All data are presented as *n* (%). Only patients who had pre-treatment scores larger than the cut-offs for reliable change and clinically significant change were included in the calculations.

Table 6

Results of Mixed Effects Models

	Main Effects			Interactions			
	Time	**Condition**	**Completer**	**Time x Condition**	**Time x Completer**	**Condition x Completer**	**Time x Condition x Completer**
PTSD[a]	$4.5_{3,42}^{**}$	$0.4_{1,22}$	$0.5_{1,21}$	$0.3_{3,42}$	$2.3_{3,42}^{\wedge}$	$0.6_{1,22}$	$3.4_{3,42}^{*}$
Dissociation[a]	$2.8_{3,41}^{*}$	$0.5_{1,20}$	$0.3_{1,20}$	$0.5_{3,41}$	$0.2_{3,41}$	$1.1_{1,20}$	$0.1_{3,41}$
Trauma-related guilt cognitions	$0.0_{1,19}$	$0.4_{1,87}$	$9.0_{1,87}^{**}$	$1.5_{1,19}$	$6.2_{1,19}^{*}$	$3.9_{1,87}^{*}$	$0.6_{1,19}$
Shame	$21.5_{1,29}^{***}$	$0.1_{1,92}$	$2.0_{1,92}$	$0.0_{1,29}$	$0.3_{1,29}$	$0.1_{1,92}$	$1.6_{1,29}$
Anxiety	$16.5_{1,22}^{**}$	$0.7_{1,22}$	$0.1_{1,22}$	$0.6_{1,22}$	$2.4_{1,22}$	$0.4_{1,22}$	$0.3_{1,22}$
Depression	$11.9_{1,28}^{**}$	$2.5_{1,93}$	$3.2_{1,93}^{\wedge}$	$0.0_{1,28}$	$0.1_{1,28}$	$0.1_{1,93}$	$0.1_{1,28}$
Global severity	$17.9_{1,16}^{**}$	$0.4_{1,23}$	$0.2_{1,23}$	$0.6_{1,16}$	$0.3_{1,16}$	$0.2_{1,23}$	$0.7_{1,16}$

Note. All results are presented as *F*-values ($F_{df1, df2}$). Unless otherwise specified, hierarchical linear models were used.

$^{\wedge}p < .10$

$^{*}p < .05.$

$^{**}p < .01.$

$^{***}p < .001.$

[a]Mixed model analyses of variance were used to account for the non-linearity of the data