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# Does Adding the Dialectical Behavior Therapy Prolonged Exposure (DBT PE) Protocol for PTSD to DBT Improve Outcomes in Public Mental Health Settings? A Pilot Nonrandomized Effectiveness Trial with Benchmarking

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## Abstract

The Dialectical Behavior Therapy Prolonged Exposure (DBT PE) protocol improves DBT's effects on PTSD in research settings, but its effectiveness in community settings is largely unknown. This pilot nonrandomized controlled trial examined DBT with and without DBT PE in four public mental health agencies. Patients ($N$ = 35, 12–56 years old, 80.0% female, 64.7% racial/ethnic minorities, 44.1% sexual minorities) had PTSD, were receiving DBT, and completed assessments every four months over one year. Sixteen patients (45.7%) initiated DBT PE, 19 (54.3%) did not, and dropout did not differ between groups (31.3% vs. 26.3%). The primary barrier to initiating DBT PE was clinician turnover (57.9% of non-initiators). After adjusting for confounds, DBT PE initiators ($g$ = 1.1) and completers ($g$ = 1.4) showed a greater reduction in PTSD than patients who received DBT only ($g$ = 0.5; $p$'s < .05). Rates of reliable improvement in PTSD were 71.4% (DBT PE completers), 53.8% (DBT PE initiators), and 31.3% (DBT). Similar patterns were observed for posttraumatic cognitions, emotion dysregulation, general psychological distress, and limited activity days. There was no worsening of self-injurious behavior or crisis service use among patients who received DBT PE. Benchmarking analyses indicated comparable feasibility, acceptability, and safety, but a smaller magnitude of clinical change, than in efficacy studies. Results require replication in a randomized trial but suggest that DBT PE can be transported effectively to community settings.

### Keywords

Posttraumatic stress disorder; suicide; self-injury; Dialectical Behavior Therapy; Prolonged Exposure; public mental health

Dialectical Behavior Therapy (DBT; Linehan, 1993) was originally developed to treat individuals at high risk for suicide with multiple mental health disorders and pervasive emotion dysregulation. DBT has been shown in both efficacy and effectiveness research to reduce self-injurious behavior (SIB), crisis service use, and a wide variety of mental health problems in diverse clinical populations and treatment settings (for reviews see Miga et al., 2019 and Walton & Comtois, 2019). While DBT has been shown to be beneficial for many problems, its effect on posttraumatic stress disorder (PTSD) has typically been limited. Among individuals receiving DBT in routine practice settings, the estimated rate of PTSD ranges from 57–73% (Barnicot & Priebe, 2013; Barnicot & Crawford, 2018). Despite its prevalence, PTSD has historically not been targeted in DBT, resulting in relatively low rates of diagnostic remission of PTSD after one year of DBT (33–35%; Harned et al., 2008; Harned, Korslund, & Linehan, 2014). Furthermore, greater PTSD severity at baseline and lack of improvement in PTSD during DBT predict poorer outcomes in other domains, including a lower likelihood of eliminating SIB and acute suicide risk as well as greater borderline personality disorder (BPD) severity (Barnicot & Priebe, 2013; Barnicot & Crawford, 2018; Harned, Jackson, Comtois, & Linehan, 2010).

The DBT Prolonged Exposure (DBT PE) protocol was developed over the past decade with the goal of improving DBT's effects on PTSD. The DBT PE protocol is based on Prolonged Exposure (PE; Foa, Hembree, Rothbaum & Rauch, 2019), a front-line evidence-based psychotherapy (EBP) for PTSD, and includes adaptations to address the needs of the target population; namely, patients with SIB and other severe problems that require treatment prior to initiating PE (Foa et al., 2019). The integrated DBT + DBT PE treatment begins with standard DBT to reduce behavioral dyscontrol and increase coping skills before progressing to a second stage in which DBT PE is delivered concurrently with ongoing DBT. After DBT PE is complete, standard DBT is used in a third stage of treatment to target any residual problems and improve functioning. This type of integrated treatment approach is recommended for patients who have severe comorbid problems in addition to PTSD (Foa, Keane, Friedman, & Cohen, 2009).

Two efficacy studies conducted in an academic research clinic have evaluated DBT + DBT PE as a one-year outpatient treatment in an open trial ($n$ = 13; Harned, Korslund, Foa, & Linehan, 2012) and a randomized controlled trial (RCT) comparing DBT with and without the DBT PE protocol ($n$ = 26; Harned et al., 2014). Both studies included adult women with PTSD, recent and repeated SIB, and BPD, and excluded patients with bipolar and psychotic disorders or IQ < 70. In these studies, 46–77% of patients initiated the DBT PE protocol and, of these, 70–75% completed it. At post-treatment, 71–80% of DBT PE completers no longer met diagnostic criteria for PTSD compared to 40% of patients who completed DBT alone. In the RCT, DBT PE completers were 2.4 times less likely to attempt suicide (17% vs. 40%) and 1.5 times less likely to engage in any non-suicidal self-injury (NSSI; 67% vs. 100%) than those who completed DBT alone. In addition, both studies found large pre-post improvements in dissociation, depression, anxiety, general psychological distress, and psychosocial functioning and, in the RCT, these improvements were larger in DBT + DBT PE than in DBT alone.

Although these studies suggest that adding the DBT PE protocol to DBT is feasible, safe, and likely to improve PTSD and other outcomes, the generalizability of these findings to usual care conditions is largely unknown. In particular, these efficacy studies were conducted in tightly controlled research settings, treatment was delivered by researcher-employed clinicians who were required to demonstrate and maintain adherence, and patients had to meet multiple eligibility criteria in addition to PTSD. In contrast, DBT is usually delivered in community settings, by agency-employed clinicians with varying levels of adherence, and to adolescent and adult patients with diverse clinical presentations. To date, one open trial of DBT + DBT PE has been conducted in a community setting that evaluated a 12-week intensive outpatient program at a VA medical center (Meyers et al., 2017). The sample included 33 Veterans (51% male) with PTSD and BPD symptoms that had interfered with prior attempts to complete trauma-focused therapy. Most patients (67%) completed treatment and there were no adverse events. Among treatment completers, 91% exhibited a reliable reduction in PTSD, 64% scored below a cutoff for PTSD at post-treatment, and there were significant improvements in suicidal ideation and coping.

The present pilot study aims to evaluate the generalizability of efficacy studies of DBT + DBT PE to usual care settings. Additionally, this study expands on the prior effectiveness study by using a comparison condition, evaluating the treatment in multiple agencies, and including adolescent and adult patients with heterogeneous clinical presentations. To maximize the applicability of the findings, the study was designed to be highly pragmatic according to the PRECIS-2 framework (Loudon et al., 2015), including: (1) recruiting patients after they naturally present for DBT at diverse agencies, (2) including all patients with PTSD without imposing any exclusion criteria, (3) not changing how DBT is being implemented in these agencies, (4) allowing flexibility in the delivery of DBT PE, and (5) including all clinicians regardless of their level of adherence to DBT or DBT PE. Results will also be benchmarked to the prior efficacy studies (Harned et al., 2012; Harned et al., 2014) to evaluate whether the feasibility, acceptability, safety, and effectiveness of DBT + DBT PE differs in research versus community settings.

## Method

### Study Design

This study occurred within the context of a hybrid type two effectiveness-implementation trial (Curran, Bauer, Mittman, Pyne, Stetler, 2012). The present manuscript reports on the effectiveness portion of the trial that used a quasi-experimental, controlled design to evaluate DBT with and without the DBT PE protocol in four public mental health agencies. Participants were not randomly assigned to treatment groups. Instead, to replicate usual care, the decision about whether to provide the DBT PE protocol was determined by clinicians during routine delivery of DBT. This resulted in a non-equivalent groups design with two treatment groups: (1) DBT ($n$ =19; i.e., patients who received only DBT), and (2) DBT + DBT PE ($n$ =16; i.e., patients who received DBT and initiated the DBT PE protocol). Patients were assessed at baseline (i.e., the point of enrollment into the study) and 4, 8, and 12 months post-baseline by independent assessors who were blind to treatment condition. Assessments occurred in-person at a private location of the patient's choosing or via phone.

Clinicians completed online surveys at each patient's baseline and post-treatment or 12 months, whichever came first. Patient enrollment began in April 2016 and the final follow-up assessment occurred in March 2019. Study procedures were approved by the University of Washington Institutional Review Board (IRB) and the City of Philadelphia Department of Public Health IRB and the trial was registered at clinicaltrials.gov (NCT02615197).

## Setting

Philadelphia, Pennsylvania is a large, diverse city of over 1.5 million residents of which nearly 400,000 live below the poverty line (PEW, 2019). Philadelphia's residents are 41.5% African-American, 39.4% White, 7.4% Asian-American, and 8.0% other races. In addition, 15.2% are of Hispanic or Latino ethnicity (U.S. Census Bureau, 2018). Public behavioral health services are overseen by the City of Philadelphia's Department of Behavioral Health and Intellectual disAbility Services (DBHIDS) that serves more than 118,000 Medicaid recipients annually through contracts with approximately 175 provider agencies. Since 2007, DBHIDS has funded initiatives to support the implementation of EBPs in the public mental health system, including DBT, PE, and multiple other treatments. The DBT initiative began in 2011 with training and consultation provided by the DBT treatment developer and her colleagues to seven agencies. Of this original cohort of agencies, six had active DBT programs at the time the present project started and four were invited to participate based on DBHIDS evaluation as having the greatest perceived capacity to successfully implement DBT PE. None of the agencies had participated in the prior PE initiative, nor were they using PE in their DBT programs.

Of the four agencies targeted for recruitment, all four applied to participate in the project and met the eligibility criteria, including: (1) currently providing all four modes of comprehensive DBT (i.e., individual therapy, group skills training, between-session coaching, and therapist consultation team), (2) able to audio- or video-record therapy sessions, and (3) agency leadership supported the implementation of DBT PE and the participation of clinicians and patients in the study. The four agencies included one adult outpatient DBT program, two residential DBT programs (one for adults, one for adolescents), and one DBT program embedded within an Assertive Community Treatment (ACT) program for adults with severe mental illness. The average length of DBT provided in these agencies was 17.2 months ($SD$ = 7.9, range = 9–24). Training was provided at no cost and included a 4-day workshop on the DBT PE protocol followed by 16 months of ongoing support (April 2016 – July 2017), including bi-monthly team consultation (up to 32 hours) with an expert and review of recorded sessions with adherence feedback.

## Participants

Potential patient participants were given information about the study by their DBT clinician. Interested patients or their guardians signed a permission to contact form and were contacted to schedule a screening assessment. Inclusion criteria were: (1) age 12+, (2) meets diagnostic criteria for PTSD, and (3) engaged in DBT with a study-enrolled clinician. There were no exclusion criteria. In addition, patients were eligible to participate regardless of how long they had been engaged in DBT prior to their enrollment in the study. A total of 46 patients were referred to the study, 40 were screened, and 5 were rejected due to not meeting

criteria for PTSD. The remaining 35 patients were enrolled in the study (range = 5–14 per agency) and constitute the intent-to-treat (ITT) sample.

## Treatment

**DBT as usual (DBT).—**All patients were receiving all four modes of DBT. DBT targets, in hierarchical order, life-threatening behaviors (e.g., suicide attempts, NSSI), therapy-interfering behaviors (e.g., noncompliance), and quality of life interfering behaviors (e.g., mental health disorders, including PTSD, functional impairment) using a combination of cognitive-behavioral and acceptance-focused strategies. Given the pragmatic nature of the trial, clinician adherence to DBT, the frequency and length of DBT treatment modes, the overall duration of treatment, and the use of ancillary treatments were not controlled and instead reflected the usual practices of the agencies in which treatment occurred.

**DBT with the DBT PE protocol (DBT + DBT PE).—**In addition to DBT, patients could receive the DBT PE protocol if/when they were deemed ready by their clinician, but they were not required to do so. The standard criteria for determining readiness to begin the DBT PE protocol include: (1) no imminent risk of suicide, (2) no SIB for two months (outpatient) or one month (residential), (3) able to control SIB urges when in the presence of cues, (4) no serious therapy-interfering behavior, (5) PTSD is the highest priority target, and (6) able and willing to experience intense emotions without escaping. As in usual clinical practice, all decisions pertaining to implementing DBT PE, including whether and when to initiate it with specific patients as well as the frequency, length, and number of sessions to provide were made by the clinician, the patient, and/or the treatment team. Although expert consultants encouraged clinicians to use DBT PE with appropriate patients and provided consultation about how to do so, clinicians were free to decide whether to implement DBT PE or follow the guidance of consultants.

**Treatment adherence rating.—**The DBT Adherence Coding Scale (DBT ACS; Linehan & Korslund, 2003) was used to code observer-rated adherence to DBT individual therapy sessions. The sampling goal was to code 3 randomly selected sessions per dyad. However, some clinicians submitted fewer than 3 sessions and in these cases all available sessions were coded. A total of 58 sessions from 29 dyads were coded ($M$ = 2.0 sessions per dyad). The DBT ACS results in a global score ranging from 1 to 5 with scores of 4 and higher indicating adherence. The observer-rated DBT PE adherence measure (Harned & Schmidt, 2016) was modified from the PE adherence measure (Foa, Kushner, Capaldi, & Yadin, 2010) and results in a global score ranging from 0 (Very Poor) to 3 (Excellent) where scores of 2 (Good) or higher meet the criterion for adherence. All DBT PE sessions sent to the research team for review were coded for a total of 48 sessions from 13 dyads ($M$ = 3.7 sessions per dyad, range = 1–9). All coders were trained to reliability by approved coders of each instrument and 10% of sessions were randomly checked for reliability. On average, clinicians delivered DBT below adherence ($M$ = 3.9, $SD$ = 0.2, ICC = 0.8). Of the 58 coded DBT sessions, 28 (48.3%) were below adherence and 30 (51.7%) were adherent. On average, DBT PE sessions were delivered with ‘Good’ to ‘Excellent’ adherence ($M$ = 2.7, $SD$ = 0.6, ICC = 1.0). Of the 48 coded DBT PE sessions, 46 (95.8%) were adherent.

## Clinicians

A total of 28 clinicians were trained in DBT PE, 21 referred patients to the study, and 17 had patients enroll in the study (range = 1–6 per clinician). Clinicians ($n$ = 17) with study-enrolled patients were an average of 35.8 years old ($SD$ = 9.5), primarily female ($n$ = 10, 58.8%) and identified as White ($n$ = 13, 76.5%), African-American ($n$ = 3, 17.6%) and multi-racial ($n$ = 1, 5.9%). Eleven clinicians (64.7%) were Master's level counselors, 4 (23.5%) were Master's level social workers, and 2 (11.8%) were doctoral level psychologists. About half ($n$ = 9, 52.9%) were licensed and most worked full-time ($n$ = 16, 94.1%) as salaried employees ($n$ = 15, 88.2%). On average, they had attended 12.5 days of workshop training in DBT ($SD$ = 8.4), had provided DBT at their agency for more than a year ($M$ = 15.5 months, $SD$ = 14.6), and had 3.7 DBT patients on their caseload ($SD$ = 3.3, range = 0–13). Three clinicians (17.6%) had previously attended a DBT PE or PE workshop and had used these treatments with up to two patients.

## Measures

### Sample characteristics

**Demographic and clinical characteristics.:** A demographic questionnaire assessed patients' self-reported age, gender, racial/ethnic background, sexual orientation, education, and income. Clinicians provided information about patients' current psychiatric diagnoses, Global Assessment of Functioning (GAF) score, and number of months engaged in DBT at the time of study enrollment.

**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 child sexual abuse. To prevent overlap, the TLEQ item assessing child sexual abuse was removed. Participants reported the frequency of each type of traumatic event on a scale ranging from 0 (never) to 6 (more than 5 times) and data from both instruments were combined to calculate the number of lifetime trauma types (range = 0–25).

**Treatment history.:** The Treatment History Interview (Linehan & Heard, 1987) was used to assess patient's use of crisis services in the past year and current psychotropic medications at baseline, and since the last assessment at subsequent time points.

**Treatment feasibility.:** Feasibility of treatment was assessed via rates of treatment dropout as well as DBT PE initiation and completion. Treatment dropout was defined as the patient ending DBT prematurely (i.e., prior to expected program discharge) in the 12 months post-baseline and was determined by clinician report on the post-treatment survey or by team member report if the treating clinician could not be reached. Patients were not considered to have dropped out of treatment if: (1) they completed treatment and were discharged sooner than 12 months post-baseline, (2) they were still actively receiving treatment at 12 months post-baseline, or (3) treatment ended prematurely for reasons other than patient dropout (e.g., their clinician left the agency). Consistent with prior studies (Harned et al., 2014), patients were considered DBT PE initiators if they completed at least one session and DBT PE completers if they received at least eight sessions of which six involved imaginal

exposure. Patients were also considered DBT PE completers if they received fewer than six sessions of imaginal exposure but achieved diagnostic remission from PTSD (i.e., additional sessions were not needed).

**Treatment acceptability.:** Participants' treatment preferences were assessed at baseline using an adapted version of Zoellner and colleagues (2003) treatment choice measure that has been used in previous DBT PE research (e.g., Harned, Tkachuck, & Youngberg, 2013). After reading a brief written description of PE and DBT, participants responded to a single forced choice item asking whether they preferred to receive DBT alone, PE alone, or a combined DBT and PE treatment. A 2-item adapted version of the Expectancies Questionnaire (EQ; Shaw et al., 1999) was assessed patient and clinician expectations of improvement and helpfulness of treatment at baseline. Items were rated on a 1–7 scale with higher scores indicating more positive treatment expectancies. The 8-item Client Satisfaction Questionnaire (Larsen, Attkisson, Hargreaves, & Nguyen, 1979) measured patients' treatment satisfaction after treatment was complete. Items were rated on a 1–4 scale and summed to create a total score.

## Clinical effectiveness

**PTSD.:** The adult and adolescent versions of the PTSD Symptom Scale-Interview (PSS-I; Foa, Riggs, Dancu, & Rothbaum, 1993) were used to assess the presence and severity of PTSD during the past two weeks. To enable benchmarking to the original efficacy trials, the DSM-IV version of the PSS-I was used. At baseline, an index trauma was selected by the patient and PTSD was assessed in relation to this index event. At subsequent timepoints, PTSD was first assessed in relation to the index trauma identified at baseline and, if patients no longer met criteria for PTSD in relation to the index trauma, PTSD was re-assessed in relation to the trauma that was currently most distressing. This was done because DBT PE is designed to treat multiple traumas rather than a single index trauma. Patients were considered to meet criteria for PTSD if they reported the minimum number of criteria required in each of three DSM-IV symptom clusters with a score of at least one. PTSD remission was defined as no longer meeting criteria for PTSD in relation to any traumatic event. Inter-rater reliability for the PTSD diagnosis ($\kappa$ = .91) and overall severity ($r$ = .97) are excellent (Foa et al., 1993).

**Secondary outcomes.:** The psychometrically sound Suicide Attempt Self-Injury Interview (Linehan, Comtois, Brown, Heard, & Wagner, 2006) was used to assess the frequency of suicide attempts and NSSI in the past year at baseline and since the last assessment at subsequent time points. Five self-report measures were used to assess pathological dissociation (Dissociative Experience Scale – Taxon; Waller & Ross, 1997), emotion dysregulation (Difficulties in Emotion Regulation Scale, 16-item version; Bjureberg et al., 2016), posttraumatic cognitions (Posttraumatic Cognitions Inventory; Foa et al., 1999), and general psychological distress (Global Severity Index from the Brief Symptom Inventory; Derogatis, 1993). All self-report measures had high internal consistency ($\alpha$'s = 0.90–0.98). In addition, a single item from the CDC Health-Related Quality of Life Healthy Days Core Module (Moriarty, Zack, & Kobau, 2003) was used that has been shown to satisfactorily

quantify disability (i.e., the number of days in the past 30 that poor physical or mental health limited activities; Clark, Bond, Prior, & Cotton 2004).

## Statistical Methods

We conducted four sets of analyses. First, we used descriptive data to evaluate treatment feasibility, acceptability, and safety. Second, we estimated the effectiveness of DBT with and without DBT PE from baseline to post-treatment. Due to the variable length of treatment, post-treatment was defined as the assessment point closest to the actual treatment end date or the 12-month assessment, whichever came first. The assessment points that were coded as post-treatment occurred at month 4 ($n$ = 6, 17.1%), month 8 ($n$ = 4, 11.4%), and month 12 ($n$ = 22, 62.9%). Three patients (8.6%) did not complete assessments after baseline and therefore do not have post-treatment data. The timing of the post-treatment assessment did not differ between patients who did versus did not initiate DBT PE ($\chi^2(3) = 1.8$, $p = .61$). Given the limited sample size, emphasis was placed on evaluating indices of clinical significance. Between- and within-group Hedge's $g$ effect sizes with 95% confidence intervals were used to evaluate the magnitude of treatment effects. Reliable change indices (RCI) were calculated as $RCI = (x_2 - x_1)/S_{diff}$ (Jacobson & Truax, 1991). The RCI values were: PSS-I (±10.1), PTCI (±45.1), and GSI (±0.6). RCI depends on approximate normality of the outcome and therefore could not be calculated for suicide attempts, NSSI, DES-T, and limited activity days due to the highly skewed nature of these outcomes.

Third, we used mixed-effects models to describe the rate of change of the outcomes in the ITT sample across time as well as to evaluate whether outcomes differed between patients who did versus did not initiate or complete DBT PE. With a sample size of 35, an observed attrition from assessments of 29%, and an average within-subject correlation across measures of $\rho = 0.57$, these models had power of 54.4% to detect a large between-group effect ($g$ = 0.8) and power of 22.0% to detect a medium between-group effect ($g$ = 0.5). Given the low power, the focus of these analyses was to identify any apparent trends over time based on DBT PE initiation and completion status. Hierarchical linear models (HLM) were used for continuous outcomes and hierarchical generalized linear models (HGLM) with a negative binomial distribution were used for count outcomes. Predictors in these models were Time (all assessment points from baseline to post-treatment, which varied across subjects), DBT PE initiation status (0 = did not initiate, 1 = initiated), DBT PE completion status (0 = did not complete, 1 = completed), and the twoway interactions of Time*DBT PE initiation and Time*DBT PE completion. Model-based effect sizes were calculated for the two interactions terms that reflect the magnitude of the between-group difference in the rate of change over time. Given the lack of randomization and the variable length of treatment, key demographic and treatment variables were examined as potential confounders in the models, including age, gender, racial/ethnic minority, sexual minority, treatment site, months of DBT prior to baseline, and months between baseline and post-treatment. Confounding variables found to be significantly related to the outcome as either main effects or interacting with time were retained as covariates in the final models. All dependent variables met normality assumptions except for the DES-T that was highly skewed. To address this, four subjects with extreme outlying values were capped at the 95$^{th}$

percentile through winsorization and the DES-T score was square root-transformed for all analyses.

Fourth, benchmarking analyses were conducted to compare the results of the present study to those obtained in two prior efficacy studies (Harned et al., 2012; Harned et al., 2014). For benchmarking purposes, all 13 ITT patients in the Harned et al. (2012) open trial were included, whereas only data from the 17 ITT patients randomized to DBT + DBT PE were used from the Harned et al. (2014) RCT. To compare patient characteristics and outcomes across studies, t-tests and chi-squares were used and effect sizes (Hedge's $g$ for continuous variables and Cohen's $w$ for categorical variables) were calculated.

## Results

### Sample Characteristics

Patients ($N$ = 35) were an average age of 29.9 years old ($SD$ = 13.2, range = 12–56) and included 30 adults (age 18+) and five adolescents (ages 12–17). The sample included 28 females (80.0%), six males (17.1%), and one transgender person (2.9%). Nearly two-thirds (n = 22, 64.7%) identified as a racial or ethnic minority. Racial backgrounds included White ($n$ = 16, 47.1%), African-American ($n$ = 14, 41.2%), and multi-racial ($n$ = 4, 11.8%). Nine patients (26.5%) were of Latinx ethnicity. Almost half of the sample ($n$ = 15, 44.1%) identified as a sexual minority (i.e., lesbian, gay, bisexual, or other non-heterosexual orientation) and most ($n$ = 27, 79.4%) were single and had never been married. A majority of patients had a high school diploma/GED or less ($n$ = 33, 94.3%), were not employed or in school ($n$ = 21, 60.0%), earned less than $5,000 per year ($n$ = 28, 84.8%), and were receiving state or federal financial assistance or benefits ($n$ = 29, 85.3%). At baseline, 16 patients (45.7%) were within the first month of starting DBT, 8 (22.9%) had received 2–5 months of DBT, 5 (14.3%) had received 6–12 months of DBT, and 8 (22.8%) had received more than one year of DBT ($M$ = 7.3 ± 10.8 months, range = 0–43). Patients were receiving DBT in outpatient ($n$ = 10, 28.6%), residential ($n$ = 19, 54.3%) and ACT ($n$ = 6, 17.1%) programs. Baseline clinical characteristics are shown in Table 1.

### Treatment Feasibility

**DBT PE protocol implementation.—**Of the 35 ITT patients, 16 (45.7%) initiated DBT PE in the year after enrolling in the study and 19 (54.3%) did not. For the 19 non-initiating patients, clinicians reported that the most influential reasons for not using DBT PE included: clinician left their job ($n$ = 11, 57.9%), patient dropped out of treatment ($n$ = 5, 26.3%), patient was not interested in DBT PE ($n$ = 4, 21.1%), patient was not appropriate for DBT PE ($n$ = 3, 15.8%), clinician was concerned the patient would decompensate ($n$ = 3, 15.8%), patient was discharged from the program ($n$ = 2, 10.5%), and patient had logistical barriers ($n$ = 1, 5.3%). Totals equal more than 100% because clinicians could select more than one factor as equally influential. The 16 patients who initiated DBT PE did so 10.6 weeks post-baseline on average (SD = 14.7, range = −5–50). Of these, 9 (56.3%) completed DBT PE in the year post-baseline, 2 (12.5%) were actively engaged in DBT PE at the 12-month point, and 5 (31.2%) stopped DBT PE prematurely. DBT PE completers received an average of 9.8 sessions (SD = 4.2, range = 4–16) and two patients (25%) targeted multiple trauma

memories. There were no significant differences in the rate of DBT PE initiation or the number of DBT PE sessions completed based on gender ($p$'s = .26 – .58), racial/ethnic minority identity ($p$'s = .24 – .75), or sexual minority identity ($p$'s = .10 – .72).

**Treatment retention.—**Ten patients (28.6%) dropped out of DBT prematurely in the year post-baseline, including five (31.3%) who initiated DBT PE and five (26.3%) who did not ($\chi^2(1) = 0.10$, $p = .75$). An additional nine patients (25.7%) received less than one year of DBT post-baseline from a study clinician due to clinician turnover ($n = 7$, 20.0%) and discharge from the program ($n = 2$, 5.7%). In total, 16 patients (45.7%) completed one year of DBT with a study clinician after baseline, including seven (43.8%) of patients who initiated DBT PE and 9 (47.4%) of patients who did not ($\chi^2(1) = 0.05$, $p = .83$).

## Treatment Acceptability

At baseline, 29 patients (82.9%) indicated a preference for a combined DBT and PE treatment, four (11.4%) preferred DBT alone, and two (5.7%) preferred PE alone. Patients who did and did not initiate DBT PE did not significantly differ in their preference for a combined DBT and PE treatment (87.5% vs. 78.9%; $\chi^2(2) = 0.78$, $p = .68$). At baseline, patients ($M = 6.4$, $SD = 0.6$) and clinicians ($M = 6.2$, $SD = 0.6$) reported positive treatment expectancies that did not differ between those who did versus did not subsequently initiate DBT PE (patients: $t(33) = 2.6$, $p = .53$; clinicians: $t(33) = 0.3$, $p = .75$). At post-treatment, there was a medium but non-significant effect indicating higher treatment satisfaction among patients who initiated DBT PE ($M = 27.2$, $SD = 3.2$) compared to those who received DBT only ($M = 24.2$, $SD = 7.0$; $t(22) = 1.2$, $p = .24$, $g = 0.5$).

## Treatment Safety

No patients died by suicide and there were no adverse events. Compared to the year prior to baseline, few patients reported a numerical increase in NSSI acts during the year post-baseline and this did not differ between patients who initiated DBT PE (13.3%) and those who did not (17.6%; $\chi^2(1) = 0.11$, $p = .74$). One patient, a DBT PE non-initiator, exhibited an increase in suicide attempts during the year post-baseline. Among the 15 DBT PE initiators with post-baseline data, 3 (20.0%) engaged in SIB during the DBT PE protocol portion of the treatment (suicide attempt and NSSI ($n = 1$), suicide attempt only ($n = 1$), NSSI only ($n = 1$)). Compared to the year prior to baseline, few patients reported a numerical increase in crisis service use during the year post-baseline and this did not differ between patients who did versus did not initiate DBT PE for either psychiatric hospitalizations (20.0% vs. 23.5%; $\chi^2(1) = 0.06$, $p = .81$) or ER visits for psychological reasons 6.7% vs. 23.5%; $\chi^2(1) = 1.72$, $p = .19$).

## Clinical Effectiveness

For all outcomes, descriptive data and pre-post Hedge's $g$ effect sizes are shown in Table 3 and results of mixed-effects models are shown in Table 4.

**Baseline comparisons.—**Patients who initiated DBT PE had more severe dissociation at baseline ($M = 42.8$, $SD = 25.0$) than those who did not ($M = 26.4$, $SD = 17.3$; $t(29) = 2.2$, $p = .04$, $g = 0.8$). This baseline difference was no longer present after winsorizing and square

root-transforming the DES-T score. There were no other differences at baseline between DBT PE initiators and non-initiators on any outcome variable ($p$'s = .33–.68; $g$'s = 0.1–0.4).

**PTSD.—**At baseline, no clinicians reported having previously delivered a formal PTSD treatment to a study-enrolled patient. Clinicians reported that their patient's PTSD had much improved ($n$ = 1, 2.9%), minimally improved ($n$ = 9, 25.7%), not changed ($n$ = 20, 57.1%), minimally worsened ($n$ = 4, 11.4%), or very much worsened ($n$ = 1, 2.9%) during the course of DBT delivered prior to study enrollment. At baseline, patients had severe PTSD on average (PSS-I total score: $M$ = 32.3, $SD$ = 8.1).

From baseline to post-treatment, there was a large reduction in PTSD severity in the ITT sample ($M_\Delta$ = −7.6, $SD$ = 10.9; $g$ = 0.8). Reductions in PTSD severity were medium among patients who did not initiate DBT PE ($M_\Delta$ = −4.9, $SD$ = 11.3; $g$ = 0.5) and very large among patients who initiated DBT PE ($M_\Delta$ = −10.9, $SD$ = 0.7; $g$ = 1.1) and completed DBT PE ($M_\Delta$ = −13.1, $SD$ = 9.3; $g$ = 1.4). Between-group effect sizes at post-treatment were medium between DBT PE non-initiators and initiators ($g$ = 0.5) and large between DBT PE non-initiators and completers ($g$ = 0.8). At post-treatment, 41.4% of the ITT sample had experienced a reliable improvement in PTSD severity. A majority of patients who initiated (53.8%) or completed (71.4%) DBT PE exhibited reliable improvements in PTSD severity compared to 31.3% of patients who did not initiate DBT PE. PTSD reliably worsened for 6.3% of patients who did not initiate DBT PE and 0% of those who did. At post-treatment, 31.3% of the ITT sample no longer met criteria for PTSD, including 23.5% of DBT PE non-initiators, 40.0% of DBT PE initiators, and 44.4% of DBT PE completers. Finally, HLM found a significant reduction in PTSD severity over time in the ITT sample. However, the interactions of Time × DBT PE Initiation and Time ×DBT PE Completion were each significant, indicating that patients who initiated or completed DBT PE exhibited larger improvements in PTSD severity than patients who received DBT only. Significant covariates in this model indicated that sexual minority patients had more severe PTSD on average, whereas racial/ethnic minority patients had less severe PTSD on average and exhibited less improvement in PTSD during treatment. Contrast analyses indicated that racial/ethnic minority and non-minority patients who initiated DBT PE showed comparable improvements in PTSD severity (B = 3.7, SE = 7.04; $t$ (69) = 0.5, $p$ = .60). Among patients who received DBT only, PTSD severity significantly improved among non-minorities (B = −9.7, SE = 3.6, $t$(69) = −2.7, $p$ < .01) but not among racial/ethnic minorities (B = −2.0, SE = 3.3, $t$(69) = −0.6, $p$ =.56).

## Secondary outcomes

**Self-injurious behavior.:** In the ITT sample, 25.0% of patients attempted suicide between baseline and post-treatment, including 35.3% of DBT PE non-initiators, 13.3% of DBT PE initiators, and 0% of DBT PE completers. From baseline to post-treatment, there was a small reduction in the number of suicide attempts in the ITT sample ($g$ = 0.2) compared to the year prior to baseline. Reductions in suicide attempts were large among patients who initiated and completed DBT PE ($g$'s = 1.0) and small among patients who did not initiate DBT PE ($g$ = 0.3). Between-group effect sizes for the number of suicide attempts during treatment were medium in favor of patients who initiated or completed DBT PE ($g$'s = 0.5) compared to

patients who received DBT only. In the ITT sample, 43.8% of patients engaged in NSSI between baseline and post-treatment, including 64.7% of DBT PE non-initiators, 20.0% of DBT PE initiators, and 11.1% of DBT PE completers. Reductions in NSSI acts compared to the year prior to baseline were medium in the ITT sample and all patient subgroups ($g$'s = 0.5–0.6). At post-treatment, between-group effect sizes for NSSI acts during treatment were small between DBT PE non-initiators and initiators ($g$ = 0.2) and large between DBT PE non-initiators and completers ($g$ = 1.0). Overall, the rate of any SIB from pre- to post-treatment was significantly lower among patients who initiated DBT PE than those who received DBT only (26.7% vs. 64.7%, $\chi^2$ (1) = 4.6, $p$ < .04). Mixed-effects models could not be estimated for SIB outcomes due to the small sample size and high between-subject variability.

**Self-report measures.:** In the ITT sample, reductions in dissociation, posttraumatic cognitions, emotion dysregulation, general psychological distress, and limited activity days from pre- to post-treatment were small to medium (average $g$ = 0.4, range = 0.2–0.6). Reductions in these secondary outcomes were generally medium to large among DBT PE initiators (average $g$ = 0.6, range = 0.4–0.8) and completers (average $g$ = 0.6, range = 0.4–0.9), and small among patients who received DBT only (average $g$ = 0.2, range = −0.1–0.4). Posttraumatic cognitions reliably improved for 58.3% of DBT PE initiators and 50.0% of completers compared to 25.0% of patients who received DBT only. Similarly, reliable improvement in general psychological distress was highest for DBT PE initiators (38.5%) followed by DBT PE completers (28.6%) and patients who received DBT only (23.1%). Rates of reliable worsening were 6.3% for posttraumatic cognitions and 15.4% for general psychological distress among patients who received DBT only compared to 0% of DBT PE initiators and completers.

Mixed effects models found significant reductions across time in the ITT sample for all self-report measures. Significant Time × DBT PE Initiation effects were found for posttraumatic cognitions and limited activity days, indicating that patients who initiated DBT PE showed significantly greater improvements in these outcomes than DBT PE non-initiators. In addition, simple slopes analyses indicated significant improvements in emotion dysregulation among DBT PE initiators (β = −0.9, SE = 0.2; $t$(62) = 3.9, $p$ <.001) and completers (β = −0.9, SE = 0.3; $t$(62) = 2.7, $p$ <.02), but not among patients who received DBT only (β = −0.3, SE = 0.2; $t$(62) = 1.6, $p$ = .11). Similarly, general psychological distress decreased significantly among DBT PE initiators (β = −0.5, SE = 0.3; $t$(66) = 2.1, $p$<.04), but not among those who received DBT only (β = −0.2, SE = 0.2; $t$(66) = 0.8, $p$ = .44).

## Benchmarking Analyses

**Comparison of sample demographics.—**As shown in Table 4, 80% of patients in this effectiveness study were female compared to 100% in the two efficacy studies. In addition, patients in this effectiveness study were significantly more likely to be racial/ethnic minorities and to earn less than $5,000 per year compared to patients in the two efficacy studies. Finally, patients in the current study were significantly younger than those in the Harned et al. (2012) study and significantly less likely to have received education beyond

high school and more likely to be a sexual minority than those in the Harned et al. (2014) study.

**Comparison of treatment feasibility, safety, acceptability, and adherence.—**As shown in Table 4, rates of treatment dropout did not significantly differ in this study (28.6%) compared to the two prior efficacy studies (23.1–41.2%). However, patients receiving care in public mental health settings were significantly more likely to have treatment end for reasons other than dropout (e.g., clinician turnover, program discharge; 25.7% vs. 0%) and, as a result, they were significantly less likely to receive a full year of treatment than patients in the Harned et al. (2012) study (45.7% vs. 76.9%). No statistically significant differences were observed in the rates of initiation or completion of DBT PE, the number of DBT PE sessions received, or rates of any SIB during DBT PE. However, there were medium effects indicating patients in the current study were less likely than those in the Harned et al. (2012) study to initiate DBT PE (45.7% vs. 76.9%, $w = -0.3$) and DBT PE completers received fewer sessions of DBT PE in the current study ($M = 9.8$) than in both efficacy studies ($M$'s = 12.7–13.0; $g$'s = −0.7). There were no statistically significant between-study differences in treatment preferences, expectancies, or satisfaction. However, there was a large effect ($g = -0.8$) indicating that patients in the Harned et al. (2012) study reported higher treatment satisfaction than those in the current study. Compared to research clinicians in the Harned et al. (2014) study, community clinicians in the current study delivered DBT PE with comparable adherence but were significantly less adherent to DBT.

**Comparison of clinical outcomes.—**Clinical outcomes for each study were compared in the ITT samples and among DBT PE completers (see Table 5). At baseline, patients receiving care in public mental health were similar to patients in the two efficacy studies in terms of PTSD severity and general psychological distress. Given that recent and repeated SIB were inclusion criteria in the two efficacy studies but not in the current study, patients in the current study generally had fewer recent suicide attempts and NSSI acts at baseline. Patients in all studies achieved large improvements in PTSD severity from pre- to post-treatment. However, the magnitude of these changes were significantly smaller among patients in the current study ($g$'s = 0.8–1.4) than in the two efficacy studies ($g$'s = 1.6–2.9). In addition, there were medium but non-significant effects indicating that patients in the current study were less likely to achieve remission from PTSD (31.3–44.4%) than those treated in research settings (58.3–80.0%). Patients in all studies showed similar reductions in suicide attempts and nearly all patients (90.6–100%) were abstinent from suicidal behavior in the last four months of treatment. Due to the higher frequency of NSSI at baseline in the efficacy studies, patients in those studies showed larger decreases in NSSI acts during treatment. There were no differences between studies in the percentage of patients who were free from NSSI in the last 4 months of treatment (65.6–88.9%). Finally, improvements in general psychological distress were small to medium among patients in the current study ($g$'s = 0.4–0.5) and very large among patients in the two efficacy studies ($g$'s = 1.3–3.3). In addition, patients in the current study were less likely to reach normative levels of general psychological distress by post-treatment (11.5–14.3%) than those in the Harned et al. (2014) study (41.7–80.0%).

## Discussion

The ultimate goal of developing the DBT PE protocol is for it to be broadly used with high-risk and multi-diagnostic patients with PTSD who are receiving DBT in routine practice settings. Before large-scale efforts to disseminate the DBT PE protocol are undertaken, it is important to evaluate whether and how well the effects found in research settings generalize to usual practice conditions. The present pilot nonrandomized effectiveness trial provides a preliminary test of the transportability of this intervention by evaluating the effect of adding the DBT PE protocol to standard DBT as usual in four public mental health agencies across multiple levels of care. This highly pragmatic trial included any patient with PTSD receiving DBT in these settings, resulting in a sample that was significantly more demographically and clinically diverse than those in prior efficacy studies.

The DBT PE protocol was highly acceptable to both clinicians and patients in these public mental health settings in terms of treatment expectancies, preferences, and satisfaction. This is consistent with prior qualitative studies finding that DBT patients in research and community settings have a strong preference for the combined DBT + DBT PE treatment due to a perceived need for PTSD treatment, beliefs about the treatment's efficacy, and the stage-based approach (Harned et al., 2013; Harned & Schmidt, 2019). The rate of patient dropout (28.6%) was relatively low, did not differ between patients who did versus did not initiate DBT PE, and was comparable to the dropout rate found in a meta-analysis of DBT clinical trials (27.3%; Kliem et al., 2010). Benchmarking analyses indicated no differences in these indices of treatment acceptability across treatment settings.

Consistent with usual clinical practice, patients and clinicians were free to decide whether to initiate the DBT PE protocol and 45.7% of dyads elected to do so. This initiation rate compares favorably to those found in other studies conducted in the Philadelphia public mental health system as well as the VA system where about 20% of patients with PTSD are estimated to initiate available EBPs for PTSD (Beidas et al., 2016; Maguen et al., 2018). The initiation rate of DBT PE in the present study is particularly notable given that patients had many characteristics such as recent SIB, frequent use of crisis services, and severe comorbid disorders that are often used as exclusion criteria in PTSD treatment trials (Ronconi et al., 2014) and cited by clinicians as reasons not to deliver EBPs for PTSD (e.g., Becker, Zayfert, & Anderson, 2004; Osei-Bonsu et al., 2017). Moreover, patients who did and did not initiate DBT PE were comparable in terms of baseline demographic and clinical characteristics, suggesting that decisions about whether to deliver DBT PE may largely be driven by other factors in these settings. Indeed, clinicians reported that the primary reason for not initiating DBT PE was that they had left or changed their jobs, which is consistent with research indicating that the high rate of workforce turnover in community mental health settings is likely to disrupt patient care and hinder EBP implementation efforts (Brabson, Harris, Lindhiem, & Herschell, 2020). Benchmarking analyses found no differences in DBT PE initiation, completion, or adherence, suggesting it is comparably feasible to implement in research and community settings even though the barriers encountered in these settings may differ.

In contrast, clinician adherence to DBT was significantly lower among community therapists in the present study compared to research therapists in the prior efficacy trials. This is consistent with other pragmatic trials of DBT in which community clinicians have been found to deliver a substantial proportion of sessions below adherence (Priebe et al., 2012). The relatively lower adherence to DBT compared to DBT PE is likely due to the differing characteristics of these treatments and their respective adherence measures. DBT PE is a structured protocol with pre-determined session elements, whereas DBT is a principle-driven treatment in which the strategies that are needed vary depending on the patient's behaviors in and out of session. As such, the DBT adherence measure includes items (strategies) that are coded on a continuous scale indicating the degree to which they were needed and sufficiently applied given the context of the session, whereas the DBT PE adherence measure is a more straightforward checklist indicating the presence/absence of required session elements. Overall, these findings suggest that DBT is a more challenging treatment for clinicians to learn and deliver with adherence than DBT PE.

Patients who initiated or completed DBT PE demonstrated statistically and clinically significant improvements in PTSD that were larger than those found among patients who received DBT alone. After controlling for potential confounds, there was a significantly greater rate of change in PTSD severity during treatment among patients who initiated or completed DBT PE than those who did not. DBT PE initiators and completers had very large pre-post improvements in PTSD severity ($g$'s = 1.1–1.4), high rates of reliable improvement of PTSD (53.8–71.4%), and 40.0–44.4% lost their PTSD diagnosis by post-treatment. In contrast, patients who did not initiate DBT PE exhibited moderate improvements in PTSD severity ($g$ = 0.5) and had relatively low rates of reliable improvement (31.3%) or remission (23.5%) of PTSD. A similar pattern of results was found for secondary outcomes with patients who initiated DBT PE showing significant improvements in posttraumatic cognitions, emotion dysregulation, general psychological distress, and limited activity days, whereas patients who received DBT only either did not significantly change or improved less on these outcomes. These findings are consistent with prior studies indicating that PE is likely to lead to improvements in comorbid problems that are maintained or exacerbated by PTSD (van Minnen, Zoellner, Harned, & Mills, 2015). In addition, despite common concerns that exposure therapy for PTSD will increase suicidality (e.g., Becker et al., 2004), there was no evidence that patients who received DBT PE exhibited increases in SIB or crisis service use compared to those who received DBT only. Indeed, rates of SIB during treatment were significantly lower among patients who initiated DBT PE, although this is likely at least partially due to the requirement that patients abstain from SIB for 1–2 months prior to initiating DBT PE. Taken together, these findings provide preliminary evidence that adding DBT PE to DBT as usual in community practice settings may significantly improve PTSD and comorbid problems beyond the effects of DBT alone and without compromising patient safety.

Although this general pattern of findings is highly consistent with prior efficacy trials, benchmarking analyses indicated that the degree of improvement in the present study was smaller. Most notably, although the changes in PTSD severity among patients who received DBT PE in the present study were very large ($g$'s = 1.1–1.4), the magnitude of these effect sizes was significantly smaller than in the original efficacy studies ($g$'s = 1.6–2.9). In

addition, there were moderate but non-significant effects indicating that DBT PE completers had a lower rate of PTSD remission in the present study (44.4%) than in prior efficacy studies (71.4–80.0%). Similar decreases in effectiveness have been found when transporting other research-tested PTSD treatments into community settings. For example, efficacy studies of PE have found very large pre-post improvements in PTSD severity (e.g., *d*'s = 1.5–1.9; Foa et al., 1999), whereas PE delivered in routine VA settings has been shown to have smaller (but still large) effects (*d*'s = 0.9–1.2; Eftekhari et al., 2013). Similarly, a benchmarking study of trauma-focused cognitive-behavioral therapy for youth found significantly reduced effects on PTSD when delivered in Philadelphia's public mental health system (*d* = 0.3) than in efficacy studies (*d* = 1.7; Rudd et al., 2019).

One potential explanation for these attenuated outcomes is that DBT and DBT PE were implemented differently in this study compared to prior efficacy trials. In the present study, patients received both shorter and less adherent DBT on average than in the efficacy trials, which may have contributed to their smaller gains. In addition, patients in the present study who completed DBT PE received an average of 3 fewer sessions than those in the efficacy trials (9.8 vs. 12.7–13.0). Prior research on PE has found that relatively few patients (28%) reach excellent response (at least a 70% reduction in PTSD severity) after 9 sessions and most patients (72%) need up to 3 additional sessions (Zang, Su, McLean, & Foa, 2019). In addition, patients with a history of repeated interpersonal trauma are more likely to only reach partial response after 9 sessions, particularly when PE is delivered by community clinicians compared to expert research therapists (Zang et al., 2019). Thus, the combination of a multiply traumatized sample of patients, clinicians with little to no prior experience with DBT PE, and a smaller dose of treatment may explain the reduced effects on PTSD in the present study, which may in turn have contributed to smaller improvements in general psychological distress.

In addition, the smaller treatment gains in the present study may be due to differences in the patient samples. Patients in the present effectiveness study were primarily ethnoracial and sexual minorities who were living in extreme poverty, whereas patients in the prior efficacy trials were more likely to be White, heterosexual, and less economically disadvantaged. Health inequities are well-documented among ethnoracial and sexual minorities and these inequities may complicate treatment with patients from these marginalized groups and contribute to the reduced treatment gains found in the present study. Encouragingly, the findings indicate that ethnoracial and sexual minorities were equally likely to initiate and show improvement in PTSD during DBT PE, which is consistent with prior studies that have found a lack of ethnoracial differences in PTSD treatment-related outcomes (McClendon, Dean, & Galovski, 2020). However, ethnoracial minorities who received DBT only exhibited less improvement in PTSD than their White counterparts, suggesting that it may be particularly important to provide DBT PE to ethnoracial minorities. It is also important to note that the present study had a more clinically heterogeneous sample that included patients with and without BPD as well as patients with bipolar disorders, psychotic disorders, and intellectual disability who were excluded from the efficacy trials. Additional research is needed to better understand the impact of patient sociodemographic and clinical characteristics as well as other patient factors (e.g., treatment preferences) on outcomes of DBT with and without DBT PE.

This study had several notable strengths including the use of a demographically and clinically diverse sample of patients and the evaluation of the treatment in multiple agencies under usual care conditions. A limitation of this highly pragmatic research design was the lack of randomization, which we attempted to address by controlling for potential baseline confounds in the analyses and benchmarking results to prior randomized and nonrandomized efficacy studies. To facilitate these benchmarking analyses, we had to use DSM-IV diagnostic criteria for PTSD so that the PSS-I scores could be directly compared to the original efficacy studies. In addition, the relatively small sample size limited the power to detect potential group differences. Future adequately powered randomized controlled effectiveness trials of DBT + DBT PE that use DSM-5 diagnostic criteria for PTSD are needed to replicate and extend these findings. Furthermore, future research could examine whether a similar patient population might benefit from PE or another EBP for PTSD without prior and/or concurrent DBT. Finally, training and ongoing support was provided at no cost to the agencies that participated in this study, which may not be available in other public mental health settings. Despite these limitations, this quasi-experimental controlled trial provides preliminary evidence that the DBT PE protocol can be provided safely and effectively by clinicians delivering DBT to high-risk and multi-diagnostic patients in routine practice settings.

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## Highlights

- A nonrandomized trial compared DBT vs. DBT + DBT PE in 35 patients with PTSD.
- Treatment occurred in 4 public mental health agencies under usual care conditions.
- DBT PE was acceptable, feasible, and safe to deliver.
- Adding DBT PE to DBT enhanced PTSD and secondary outcomes.
- The magnitude of clinical change was smaller than in prior efficacy studies.

## Table 1

Clinical Characteristics of the Sample at Baseline

| | Full ITT Sample (*N* = 35) | DBT PE Status | |
|---|---|---|---|
| | | Initiators (*n* = 16) | Non-Initiators (*n* = 19) |
| **Self-Injurious Behavior History** | | | |
| Any suicide attempt, lifetime | 71.4 | 75.0 | 68.4 |
| Any suicide attempt, past year | 45.7 | 56.3 | 36.8 |
| Any non-suicidal self-injury, past year * | 60.0 | 37.5 | 78.9 |
| **Trauma History** | | | |
| Types of lifetime trauma, *M (SD)* | 12.5 (4.7) | 11.7 (3.9) | 13.2 (5.3) |
| Index Traumas | | | |
| Unwanted sexual contact (before age 17) | 37.1 | 25.0 | 47.4 |
| Unwanted sexual contact (age 17+) | 17.1 | 18.8 | 15.8 |
| Sudden death of friend/loved one | 17.1 | 25.0 | 10.5 |
| Childhood physical abuse | 8.6 | 0.0 | 15.8 |
| Intimate partner violence | 5.7 | 6.3 | 5.3 |
| Physically assaulted by acquaintance/stranger | 5.7 | 12.5 | 0.0 |
| Threatened with death/serious harm | 5.7 | 12.5 | 0.0 |
| Witnessed family violence as a child | 2.9 | 0.0 | 5.3 |
| **Current Psychiatric Diagnoses** | | | |
| Posttraumatic stress disorder | 100 | 100 | 100 |
| Borderline personality disorder | 54.3 | 37.5 | 68.4 |
| Bipolar I or II disorder | 34.3 | 31.3 | 36.8 |
| Major depressive disorder | 31.4 | 43.8 | 21.1 |
| Any substance use disorder | 20.0 | 18.8 | 21.1 |
| Any psychotic disorder | 17.1 | 6.3 | 26.3 |
| Any disorder of childhood and adolescence | 14.3 | 25.0 | 5.3 |
| Any anxiety disorder | 11.4 | 6.3 | 15.8 |
| Any eating disorder | 11.4 | 12.5 | 10.5 |
| Total no. current diagnoses, *M (SD)* | 3.9 (1.5) | 2.9 (1.2) | 2.7 (1.2) |
| Global Assessment of Functioning, *M (SD)* | 44.4 (12.8) | 44.7 (11.2) | 44.3 (14.3) |
| **Psychiatric Treatment History** | | | |
| Any inpatient psychiatric admission, past year | 48.6 | 43.8 | 52.6 |
| Any ER visit for psychological reasons, past year | 31.4 | 37.5 | 26.3 |
| Any current psychotropic medication | 97.1 | 94.7 | 100 |

Note: Data are given as percentages and there were no between-group differences unless otherwise indicated. ITT = intent to treat. DBT PE = Dialectical Behavior Therapy Prolonged Exposure protocol.

ER = emergency room.

* DBT PE initiators and non-initiators significantly differed ($p < .05$)

## Table 2

Means, Standard Deviations, and Pre-post Effect Sizes for each Outcome by DBT PE Status

| | Full ITT Sample (*N* = 35) | DBT PE Status | | |
|---|---|---|---|---|
| **Outcome** | | **Non-Initiators (*n* = 19)** | **Initiators (*n* = 16)** | **Completers (*n* = 9)** |
| PTSD | | | | |
| Pre | 32.3 (8.1) [34] | 32.8 (8.5) [19] | 31.6 (7.9) [15] | 30.5 (8.7) [8] |
| Post | 24.3 (11.4) [32] | 27.0 (11.8) [17] | 21.3 (10.7) [15] | 18.1 (8.4) [9] |
| Hedge's *g* (95% CI) | 0.8 (0.2, 1.3) | 0.5 (−0.2, 1.2) | 1.1 (0.3, 1.9) | 1.4 (0.3, 2.5) |
| Suicide attempts | | | | |
| Pre[a] | 2.4 (8.3) [35] | 3.7 (11.2) [19] | 0.9 (1.1) [16] | 0.6 (0.7) [9] |
| Post[b] | 1.0 (3.1) [32] | 1.8 (4.1) [17] | 0.1 (0.4) [15] | 0.0 (0.0) [9] |
| Hedge's *g* (95% CI) | 0.2 (−0.2, 0.7) | 0.2 (−0.4, 0.9) | 0.9 (0.2, 1.7) | 1.0 (0.03, 2.0) |
| NSSI acts | | | | |
| Pre[a] | 23.6 (61.9) [35] | 17.2 (28.4) [19] | 31.2 (87.2) [16] | 36.9 (109.9) [9] |
| Post[b] | 4.2 (7.3) [32] | 5.0 (5.5) [17] | 3.4 (9.1) [15] | 0.4 (1.3) [9] |
| Hedge's *g* (95% CI) | 0.5 (−0.04, 0.9) | 0.6 (−0.1, 1.3) | 0.5 (−0.3, 1.2) | 0.4 (−0.5, 1.4) |
| Dissociation | | | | |
| Pre | 33.3 (22.1) [31] | 26.4 (17.3) [18] | 42.8 (25.0) [13] | 37.9 (24.7) [7] |
| Post | 24.7 (24.4) [29] | 19.9 (21.1) [15] | 29.7 (27.4) [14] | 15.5 (15.5) [8] |
| Hedge's *g* (95% CI) | 0.3 (−0.3, 0.8) | 0.2 (−0.6, 0.9) | 0.4 (−0.4, 1.2) | 0.9 (−0.2, 2.0) |
| Posttraumatic cognitions | | | | |
| Pre | 168.4 (42.0) [35] | 163.8 (33.3) [19] | 173.8 (51.1) [16] | 152.4 (51.6) [9] |
| Post | 145.3 (51.6) [31] | 151.0 (51.4) [17] | 138.4 (52.9) [14] | 133.4 (51.5) [8] |
| Hedge's *g* (95% CI) | 0.6 (0.1, 1.1) | 0.4 (−0.3, 1.1) | 0.8 (0.01, 1.5) | 0.4 (−0.6, 1.4) |
| Emotion dysregulation | | | | |
| Pre | 54.9 (17.5) [34] | 54.2 (17.7) [19] | 55.8 (17.8) [15] | 54.9 (19.1) [8] |
| Post | 44.6 (18.5) [29] | 46.5 (19.3) [15] | 42.6 (18.1) [14] | 42.2 (19.9) [8] |
| Hedge's *g* (95% CI) | 0.5 (0.02, 1.1) | 0.3 (−0.4, 1.0) | 0.8 (0.02, 1.6) | 0.5 (−0.5, 1.6) |
| General psychological distress | | | | |
| Pre | 2.1 (0.9) [35] | 2.1 (0.9) [19] | 2.0 (0.9) [16] | 1.8 (1.0) [9] |
| Post | 1.7 (1.1) [29] | 1.8 (1.1) [15] | 1.6 (1.0) [14] | 1.4 (0.9) [8] |
| Hedge's *g* (95% CI) | 0.4 (−0.1, 0.9) | 0.2 (−0.5, 0.9) | 0.5 (−0.2, 1.3) | 0.5 (−0.5, 1.5) |
| Limited activity days | | | | |
| Pre | 11.5 (10.7) [35] | 10.1 (9.4) [19] | 13.1 (11.5) [16] | 9.9 (10.0) [9] |
| Post | 9.5 (10.2) [30] | 11.1 (11.0) [15] | 7.8 (9.4) [15] | 3.8 (6.4) [9] |
| Hedge's *g* (95% CI) | 0.2 (−0.3, 0.7) | −0.1 (−0.8, 0.6) | 0.5 (−0.2, 1.2) | 0.7 (−0.3, 1.6) |

Note. Pre and post values use all observed data and are presented as M (SD)[n]. Hedge's *g* within-group effect sizes were calculated using data from patients who completed both the pre and post assessment. For Hedge's *g*, small effect = 0.2, medium effect = 0.5, and large effect = 0.8. ITT = intent to treat. DBT PE = Dialectical Behavior Therapy Prolonged Exposure protocol. PTSD = posttraumatic stress disorder. NSSI = non-suicidal self-injury.

[a] Includes the number of episodes in the past year.

[b] Includes the number of episodes from pre- to post-treatment.

**Table 3**

Results of Mixed Effects Models

| | Main Effects | | | Interactions | | | |
|---|---|---|---|---|---|---|---|
| | Time | DBT PE Initiation | DBT PE Completion | Time × DBT PE Initiation | | Time × DBT PE Completion | |
| | B (SE) | B (SE) | B (SE) | B (SE) | g | B (SE) | g |
| PTSD[a] | −11.7 (2.3) *** | −0.8 (2.6) | −1.9 (3.0) | −8.8 (4.0) * | 0.5 | −11.0 (5.0) * | 0.5 |
| Dissociation[b] | −1.1 (0.4) * | 0.6 (0.9) | 0.1 (1.0) | 0.3 (0.5) | 0.2 | −0.7 (1.1) | 0.1 |
| Posttraumatic cognitions[c] | −36.9 (8.0) *** | 16.6 (13.5) | −0.8 (17.0) | −34.1 (14.7) * | 0.6 | −17.6 (18.6) | 0.2 |
| Emotion dysregulation[d] | −16.8 (3.9) *** | 2.1 (5.3) | 5.2 (6.5) | −14.1 (7.1) ^ | 0.5 | −13.6 (9.1) | 0.4 |
| General psychological distress | −0.4 (0.2) * | −0.2 (0.3) | −0.6 (0.4) | −0.4 (0.4) | 0.2 | −0.2 (0.5) | 0.1 |
| Limited activity days | −0.3 (0.1) ** | 0.2 (0.4) | −0.1 (0.5) | −0.9 (0.2) *** | 1.3 | −1.3 (0.2) *** | 1.2 |

Note. HLM was used for all outcomes except limited activity days used HGLM with a negative binomial distribution. Models that included significant covariates are indicated by superscripts. Covariates were coded as follows: racial/ethnic minority (0 = non-Latinx White, 1 = racial/ethnic minority), sexual minority (0 = heterosexual, 1 = lesbian/gay/bisexual), sex (0 = male, 1 = female). Hedge's *g* effect sizes are model-based estimates of between-group differences in the rate of change across time. DBT PE = Dialectical Behavior Therapy Prolonged Exposure protocol. PTSD = posttraumatic stress disorder.

^ $p = .05$

* $p < .05$.

** $p < .01$.

*** $p < .001$.

[a] Includes racial/ethnic minority (B = −6.1, SE = 2.9, $p < .05$), time × racial/ethnic minority (B = −10.5, SE = 4.5, $p < .05$), and sexual minority (B = 7.1, SE = 2.6, $p < .05$) as covariates.

[b] Includes time × treatment site as a covariate ($F(3, 35) = 2.9$, $p < .05$).

[c] Includes sex (B = 44.6, SE = 16.3, $p < .05$) as a covariate.

[d] Includes sexual minority (B = 12.1, SE = 5.8, $p < .05$), sex (B = 17.1, SE = 8.0, $p < .05$), and time ×racial/ethnic minority (B = −15.3, SE = 7.2, $p < .05$) as covariates.

**Table 4**

Benchmarked Sample Characteristics, Treatment Feasibility, Treatment Acceptability, and Adherence Outcomes

| | **Effectiveness Trial *(Current Study)*** | **Efficacy Trial #1 (Harned et al., 2014)** | **Efficacy Trial #2 (Harned et al., 2012)** | **Effectiveness vs. Efficacy #1** | **Effectiveness vs. Efficacy #2** |
|---|---|---|---|---|---|
| | **(*N* = 35)** | **(*n* = 17)** | **(*n* = 13)** | **ES** | **ES** |
| **Sample Demographics** | | | | | |
| Age, *M (SD)* | 29.9 (13.2) | 33.2 (13.1) | 39.4 (11.4) | −0.2 | −0.7* |
| Female | 80.0 | 100.0 | 100.0 | 0.3* | 0.2 |
| Racial/ethnic minority | 64.7 | 23.5 | 30.8 | 0.4** | 0.3* |
| Sexual minority | 44.1 | 12.5 | 53.8 | 0.3* | 0.1 |
| Highest education high school or less | 60.0 | 17.6 | 38.5 | 0.4** | 0.2 |
| Annual income <$5,000 | 84.8 | 31.3 | 36.4 | 0.5*** | 0.5** |
| **Treatment Feasibility and Safety** | | | | | |
| Tx ended due to patient dropout | 28.6 | 41.2 | 23.1 | 0.1 | −0.1 |
| Tx ended for other reasons | 25.7 | 0 | 0 | −0.3* | −0.3* |
| Received one year of treatment | 45.7 | 58.8 | 76.9 | −0.1 | −0.3* |
| Initiated DBT PE | 45.7 | 47.1 | 76.9 | 0.0 | −0.3 |
| Completed DBT PE[a] | 56.3 | 75.0 | 70.0 | −0.2 | −0.1 |
| # of DBT PE sessions[b], *M (SD)* | 9.8 (4.2) | 12.7 (2.9) | 13.0 (4.5) | −0.7 | −0.7 |
| Any SIB during DBT PE[a] | 20.0 | 25.0 | 20.0 | 0.1 | 0.0 |
| **Treatment Acceptability** | | | | | |
| Preference for DBT PE (pre) | 82.9 | 82.4 | 76.9 | 0.0 | 0.1 |
| Patient expectancies (pre), *M (SD)* | 6.4 (0.6) | 6.4 (0.6) | 6.5 (0.4) | 0.0 | −0.1 |
| Clinician expectancies (pre), *M (SD)* | 6.2 (0.6) | 6.2 (0.7) | 6.1 (1.4) | 0.0 | 0.1 |
| Patient satisfaction (post)[a], *M (SD)* | 27.2 (3.2) | 27.0 (6.9) | 29.6 (2.4) | 0.0 | −0.8 |
| **Treatment Adherence** | | | | | |
| DBT adherence, *M (SD)* | 3.9 (0.2) | 4.1 (0.2) | - | −0.9*** | - |
| DBT PE adherence[a], *M (SD)* | 2.7 (0.6) | 2.9 (0.2) | - | −0.4 | - |

Note. Data are given as percentages and are based on the intent-to-treat samples unless otherwise indicated. Between-group effect sizes (ES) are Hedge's *g* for continuous outcomes and Cohen's *w* for categorical outcomes. For Hedge's *g*, small effect = 0.2, medium effect = 0.5, large effect = 0.8. For Cohen's *w*, small effect = 0.1, medium effect = 0.3, large effect = 0.5. Negative between-group effect sizes indicate poorer outcomes in the current effectiveness trial than in the benchmarked efficacy trial and comparisons were conducted using *t*-tests for continuous outcomes and chi-squares for categorical outcomes. DBT PE = Dialectical Behavior Therapy Prolonged Exposure protocol. Tx = treatment. SIB = self-injurious behavior.

[a] Among patients who initiated DBT PE.

[b] Among patients who completed DBT PE.

* $p < .05$,

** $p < .01$,

*** $p < .001$.



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**Table 5**

Benchmarked Outcomes for DBT + DBT PE

| | **Effectiveness Trial *(Current Study)*** | | **Efficacy Trial #1 (Harned et al., 2014)** | | **Efficacy Trial #2 (Harned et al., 2012)** | | **Effectiveness vs. Efficacy #1** | | **Effectiveness vs. Efficacy #2** | |
|---|---|---|---|---|---|---|---|---|---|---|
| | **ITT (*N* = 35)** | **TC (*n* = 9)** | **ITT (*N* = 17)** | **TC (*n* = 6)** | **ITT (*N* = 13)** | **TC (*n* = 7)** | **ITT ES** | **TC ES** | **ITT ES** | **TC ES** |
| PTSD | | | | | | | | | | |
| Pre, M *(SD)* | 32.3 (8.1) | 30.5 (8.7) | 32.8 (8.0) | 30.7 (6.8) | 35.5 (10.1) | 36.6 (8.6) | 0.1 | 0.0 | 0.4 | 0.7 |
| Post, M *(SD)* | 24.3 (11.5) | 18.1 (8.4) | 13.6 (13.2) | 6.2 (8.2) | 15.2 (11.7) | 13.9 (13.3) | −0.9* | −1.3* | −0.8* | −0.4 |
| Hedge's *g* (pre-post) | 0.8 | 1.4 | 1.8 | 2.9 | 1.6 | 1.9 | −1.1** | −1.2* | −0.9* | −0.8 |
| % remission (post) | 31.3 | 44.4 | 58.3 | 80.0 | 60.0 | 71.4 | 0.2 | 0.3 | 0.3 | 0.3 |
| Suicide attempts | | | | | | | | | | |
| Pre, M *(SD)* | 0.4 (0.9) | 0.0 (0.0) | 1.0 (2.2) | 0.2 (0.4) | 0.1 (0.2) | 0.0 (0.0) | 0.4 | 0.8 | −0.4 | 0.0 |
| Post, M *(SD)* | 0.1 (0.4) | 0.0 (0.0) | 0.0 (0.0) | 0.0 (0.0) | 0.0 (0.0) | 0.0 (0.0) | −0.3 | 0.0 | −0.3 | 0.0 |
| Hedge's *g* (pre-post) | 0.4 | - | 0.6 | 0.8 | 0.6 | - | −0.6 | - | 0.2 | - |
| % SA free (post) | 90.6 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 0.2 | 0.0 | 0.2 | 0.0 |
| NSSI acts | | | | | | | | | | |
| Pre, M *(SD)* | 7.3 (23.4) | 0.0 (0.0) | 28.7 (38.5) | 42.0 (49.0) | 12.8 (23.1) | 4.0 (4.3) | 0.7* | 1.3* | 0.2 | 1.4* |
| Post, M *(SD)* | 1.9 (4.6) | 0.4 (1.3) | 0.9 (2.0) | 0.2 (0.4) | 1.0 (2.2) | 0.7 (1.8) | −0.3 | −0.2 | −0.2 | 0.1 |
| Hedge's *g* (pre-post) | 0.3 | −0.4 | 1.0 | 1.1 | 0.8 | 1.0 | −0.8* | −1.4* | −0.3 | −1.0* |
| % NSSI free (post) | 65.6 | 88.9 | 75.0 | 80.0 | 72.7 | 85.7 | 0.1 | 0.1 | 0.1 | 0.0 |
| General psychological distress | | | | | | | | | | |
| Pre, M *(SD)* | 2.1 (0.9) | 1.8 (1.0) | 2.6 (0.6) | 2.6 (0.7) | 2.5 (0.7) | 2.4 (0.7) | 0.6 | 0.8 | 0.5 | 0.6 |
| Post, M *(SD)* | 1.7 (1.1) | 1.4 (0.9) | 1.1 (0.7) | 0.6 (0.4) | 1.5 (0.7) | 1.3 (0.8) | −0.6 | −1.1 | −0.3 | −0.1 |
| Hedge's *g* (pre-post) | 0.4 | 0.5 | 2.1 | 3.3 | 1.3 | 1.4 | −1.2*** | −1.9** | 0.7 | −0.8 |
| % recovered (post) | 11.5 | 14.3 | 41.7 | 80.0 | 9.1 | 14.3 | 0.3* | 0.7* | 0.0 | 0.0 |

*Note*. Between-group effect sizes (ES) are Hedge's *g* for continuous outcomes and Cohen's *w* for categorical outcomes. For Hedge's *g*, small effect = 0.2, medium effect = 0.5, large effect = 0.8. For Cohen's *w*, small effect = 0.1, medium effect = 0.3, large effect = 0.5. Negative between-study effect sizes indicate poorer outcomes in the current effectiveness trial than in the benchmarked efficacy trial and effect sizes with an asterisk indicate statistically significant differences between studies based on *t*-tests or chi-squares. Suicide attempts (SA) and non-suicidal self-injury (NSSI) acts are for the past 4 months at pre and post. ITT = intent-to-treat. TC = treatment completer. DBT PE = Dialectical Behavior Therapy Prolonged Exposure protocol. PTSD = posttraumatic stress disorder.

* $p < .05$,

** $p < .01$,

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