

Two-Year Randomized Controlled Trial and Follow-up of Dialectical Behavior Therapy vs Therapy by Experts for Suicidal Behaviors and Borderline Personality Disorder

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Context: Dialectical behavior therapy (DBT) is a treatment for suicidal behavior and borderline personality disorder with well-documented efficacy.

Objective: To evaluate the hypothesis that unique aspects of DBT are more efficacious compared with treatment offered by non-behavioral psychotherapy experts.

Design: One-year randomized controlled trial, plus 1 year of posttreatment follow-up.

Setting: University outpatient clinic and community practice.

Participants: One hundred one clinically referred women with recent suicidal and self-injurious behaviors meeting *DSM-IV* criteria, matched to condition on age, suicide attempt history, negative prognostic indication, and number of lifetime intentional self-injuries and psychiatric hospitalizations.

Intervention: One year of DBT or 1 year of community treatment by experts (developed to maximize internal validity by controlling for therapist sex, availability, expertise, allegiance, training and experience, consultation availability, and institutional prestige).

Main Outcome Measures: Trimester assessments of suicidal behaviors, emergency services use, and general psychological functioning. Measures were selected based on previous outcome studies of DBT. Outcome variables were evaluated by blinded assessors.

Results: Dialectical behavior therapy was associated with better outcomes in the intent-to-treat analysis than community treatment by experts in most target areas during the 2-year treatment and follow-up period. Subjects receiving DBT were half as likely to make a suicide attempt (hazard ratio, 2.66; $P = .005$), required less hospitalization for suicide ideation ($F_{1,92} = 7.3$; $P = .004$), and had lower medical risk ($F_{1,50} = 3.2$; $P = .04$) across all suicide attempts and self-injurious acts combined. Subjects receiving DBT were less likely to drop out of treatment (hazard ratio, 3.2; $P < .001$) and had fewer psychiatric hospitalizations ($F_{1,92} = 6.0$; $P = .007$) and psychiatric emergency department visits ($F_{1,92} = 2.9$; $P = .04$).

Conclusions: Our findings replicate those of previous studies of DBT and suggest that the effectiveness of DBT cannot reasonably be attributed to general factors associated with expert psychotherapy. Dialectical behavior therapy appears to be uniquely effective in reducing suicide attempts.

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SUICIDAL BEHAVIOR IS A BROAD term that includes death by suicide and intentional, non-fatal, self-injurious acts committed with or without intent to die. It is associated with several mental disorders, including depression, substance dependence, and schizophrenia. Borderline personality disorder (BPD) is 1 of only 2 *DSM-IV* diagnoses for which suicidal behavior is a criterion.¹ Borderline personality disorder is a severe and persistent mental disorder experience of severe emotional distress and behavioral dyscontrol.¹⁻³ Among patients with BPD, 69% to 80% engage in suicidal behav-

ior,⁴⁻⁹ with a suicide rate of up to 9%.¹⁰ Forty percent of the highest users of inpatient psychiatric services receive a diagnosis of BPD.^{11,12} Patients with BPD use more services than those with major depression¹³ and other personality disorders.¹⁴ Among patients with BPD seen for treatment, 72% have had at least 1 psychiatric hospitalization and 97% have received outpatient treatment from a mean of 6.1 previous therapists.^{15,16} Despite this high-use pattern, patients with BPD have high rates of treatment failure.^{17,18}

Outpatient dialectical behavior therapy (DBT)^{20,21} and mentalization-based treatment provided in a partial hospital pro-

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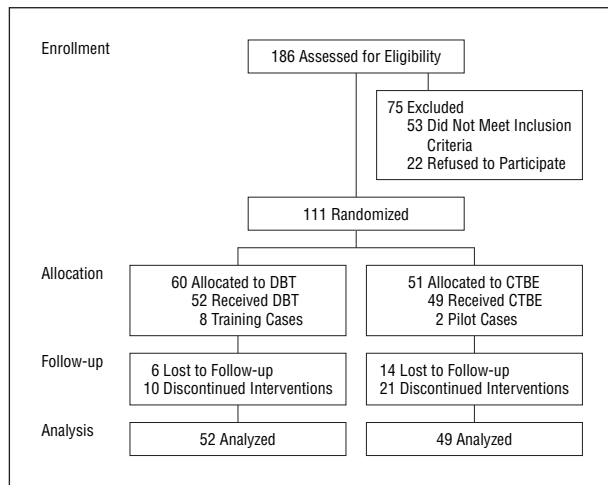


Figure 1. Subject flowchart. CTBE indicates community treatment by experts; DBT, dialectical behavior therapy. Those in DBT lost to follow-up and discontinued interventions were not subtracted from the allocation total in the DBT treatment arm.

gram^{22,23} are the only 2 treatments (to our knowledge) for which randomized controlled trials have been published that demonstrate significantly better results than treatment as usual (TAU) for patients with BPD.²⁴ Of the 2 treatments, DBT has the most empirical support, having been evaluated initially in a 1991 randomized trial²⁵ and follow-up^{19,26,27} and assessed subsequently in 4 published randomized controlled trials²⁸⁻³¹ across 3 separate research centers and in 1 additional randomized controlled trial of a DBT-oriented treatment.³² Evidence from these studies has shown DBT to be an efficacious treatment for BPD. However, as noted in the American Psychiatric Association Practice Guidelines, “[I]t is difficult to ascertain whether the improvement reported for patients receiving dialectical behavior therapy derived from specific ingredients of dialectical behavior therapy.”^{33(p32)} The present study is the first in a program of research systematically examining DBT with the objective of identifying the specific elements of treatment that are necessary and sufficient for an efficacious outcome among individuals with BPD. As such, this is not a “horse race” study pitting one complex active treatment against another. Rather, it is a dismantling study designed to begin answering questions as to the unique effects of DBT.

To rule out factors commonly believed to be effective across a variety of disorders, the control condition, community treatment by experts (CTBE), was specifically designed to maximize internal validity by controlling for the following: (1) availability of treatment; (2) assistance finding and getting to a first appointment with a therapist; (3) hours of individual psychotherapy offered; (4) therapist sex, training, clinical experience, and expertise; (5) availability of group clinical consultation; (6) allegiance to treatment approach; (7) institutional prestige associated with treatment; and (8) general factors associated with receiving any psychotherapy. This study was designed as a replication of the 1991 study²⁵ comparing DBT with TAU. We predicted that we would find identical outcomes, namely, that DBT would perform significantly better than CTBE in reducing suicidal (suicide attempts and nonsuicidal self-injury) and therapy-

interfering (dropout from treatment) behaviors and in promoting quality-of-life behaviors (use of hospital services for suicidal behaviors and psychological issues).

METHODS

PARTICIPANTS AND ASSESSMENTS

Participants were women between the ages of 18 and 45 years who met criteria for BPD and for current and past suicidal behavior as defined by at least 2 suicide attempts or self-injuries in the past 5 years, with at least 1 in the past 8 weeks. Individuals were excluded if they had (1) a lifetime diagnosis of schizophrenia, schizoaffective disorder, bipolar disorder, psychotic disorder not otherwise specified, or mental retardation; (2) a seizure disorder requiring medication; (3) a mandate to treatment; or (4) the need for primary treatment for another debilitating condition. All participants provided informed consent using protocols approved by the University of Washington Human Subjects Division.

Using a computerized adaptive minimization randomization procedure, eligible subjects were matched to treatment condition on 5 primary prognostic variables: (1 and 2) the number of lifetime suicide attempts or nonsuicidal self-injuries combined and psychiatric hospitalizations; (3) a history of only suicide attempts, only nonsuicidal self-injury, or both; (4) age; and (5) a negative prognostic indicator of a Beck Depression Inventory³⁴ score higher than 30 or a Global Assessment of Functioning³⁵ score lower than 45 for a comorbid condition. This matching method has been shown to be superior to simple and stratified randomization in producing balance for separate prognostic variables, particularly when the number of strata is large compared with the number of subjects.³⁶ Based on 0.8 power to detect significant differences between conditions ($P = .05$, 1-sided), this procedure was used to randomize 101 subjects to DBT ($n = 52$) or to CTBE ($n = 49$). The flow of subjects through the study is shown in **Figure 1**.

Initial assessments were done before informing subjects of treatment assignment and at 4-month intervals during the treatment and follow-up periods. Outcome assessments were yoked across conditions by screening date. Assessments were conducted by blinded independent clinical assessors with master's or doctoral degrees. Lead assessors (K.A.C. and A.M.M.) were trained on interview measures by the instrument developers or by an approved trainer, and then trained, supervised, and evaluated for reliability across assessors (κ statistic or intraclass correlation coefficient for all ratings ranged from 0.74 to 1.00). The participant coordinator, who was not blinded to treatment condition, executed the randomization program and collected all the data related to treatment.

Diagnostic Interviews

The structured clinical interviews for Axis I and Axis II DSM-IV^{36,37} and the International Personality Disorder Examination³⁸ were used as screening and diagnostic instruments. The Peabody Picture Vocabulary Test-Revised³⁹ was used to rule out mental retardation.

Outcome Measures

The Suicide Attempt Self-Injury Interview⁴⁰ measured the topography, suicide intent, and medical severity of each suicide attempt and nonsuicidal self-injury. Interrater reliabilities were 0.88 for medical risk and 0.94 for suicide intent. The Suicidal Behaviors Questionnaire (M.M.L., unpublished work, 1981) was

Table 1. Characteristics of Therapists for the Dialectical Behavior Therapy (DBT) and Community Treatment by Experts (CTBE) Groups*

| Characteristic | DBT Therapists (n = 16) | CTBE Therapists (n = 25) | χ^2 or z | P Value |
|---|----------------------------|-----------------------------|---------------|---------|
| Male sex | 5 (31.3) | 9 (36.0) | -0.31 | .75 |
| >10 y Clinical experience since terminal degree | 4 (25.0) | 14 (56.0) | Fisher exact | .06 |
| Doctoral degree | 12 (75.0) | 14 (56.0) | Fisher exact | .32 |
| No. of study clients, mean \pm SD | 3.6 \pm 2.9 | 2.5 \pm 1.7 | -1.33 | .18 |
| Subjects in group clinical consultation† | 52 (100.0) | 28 (57.1) | Fisher exact | <.001 |

*Data are given as number (percentage) unless otherwise indicated.

†Percentage of clients whose therapist had group clinical consultation for that client. The expert consultant for the CTBE condition attended the group clinical consultation, but the expert consultant for the DBT condition (M.M.L.) did not.

used to assess suicide ideation. The Reasons for Living Inventory⁴¹ assessed the importance of reasons for living. The Treatment History Interview (M.M.L., unpublished work, 1987) measured subjects' experience with professional psychotherapy, comprehensive treatment programs, case management, inpatient units, emergency treatment and other crisis services, and medication use. The Hamilton Rating Scale for Depression-17-Item⁴² was used to evaluate the severity of depressive symptoms. All outcome domains are identical to those reported by Linehan et al²⁵ in 1991.

STUDY TREATMENTS

Therapists

There were 41 therapists in the study (16 DBT therapists and 25 CTBE therapists). Characteristics of the therapists are given in **Table 1**.

Dialectical Behavior Therapy

Dialectical behavior therapy is a cognitive behavioral treatment program developed to treat suicidal clients meeting criteria for BPD.^{20,21} It directly targets (1) suicidal behavior, (2) behaviors that interfere with treatment delivery, and (3) other dangerous, severe, or destabilizing behaviors.

Standard DBT addresses the following 5 functions: (1) increasing behavioral capabilities, (2) improving motivation for skillful behavior (through contingency management and reduction of interfering emotions and cognitions), (3) assuring generalization of gains to the natural environment, (4) structuring the treatment environment so that it reinforces functional rather than dysfunctional behaviors, and (5) enhancing therapist capabilities and motivation to treat patients effectively. These functions are divided among the following 4 modes of service delivery: (1) weekly individual psychotherapy (1 h/wk), (2) group skills training (2½ h/wk), (3) telephone consultation (as needed within the therapist's limits to ensure generalization), and (4) weekly therapist consultation team meetings (to enhance therapist motivation and skills and to provide therapy for the therapists).

Recruitment, Training, and Adherence of DBT Therapists

Psychotherapists recommended by colleagues as potentially good DBT therapists were recruited for the study; 8 had no previous DBT exposure and 8 had experience that ranged from workshop attendance to applied practice. The sample included 3 graduate students and 2 postdoctoral trainees. Training consisted of a 45-hour DBT seminar followed by supervised prac-

tice. The treatment developer (M.M.L.) was not a study therapist and did not attend the weekly DBT team meetings.

Individual therapists were hired once 6 of 8 consecutive training case sessions were rated as adherent to DBT. During the study, adherence was assessed by coding a random selection of sessions on the DBT Global Rating Scale (M.M.L., unpublished work, 2003), which codes DBT adherence on a 5-point scale (to 1 decimal point), with a score of 4.0 or higher denoting adherence. Therapists were blinded to which sessions were rated. Coders were trained to reliability with the treatment developer.

Community Treatment by Experts

The CTBE condition was developed specifically for this study to control for factors previously uncontrolled for in DBT studies. Similar to a TAU (treatment as usual) condition, the treatment provided was uncontrolled by the research team, an essential component of TAU conditions. It differs from TAU conditions in that characteristics of CTBE therapists are controlled by the study via selection of therapists and supervisory arrangements.

Expertise. The CTBE therapists were nominated by community mental health leaders. These included heads of inpatient psychiatric units and clinical directors of mental health agencies, who nominated therapists whom they considered experts in treating difficult clients.

Allegiance to Treatment Provided. The content of the treatment provided by the CTBE therapists was not prescribed by the research study or interfered with in any way. Therapists were asked to provide the type and dose of therapy that they believed was most suited to the patient, with a minimum of 1 scheduled individual session per week. Ancillary treatment could be prescribed as needed.

Availability of Clinical Supervision Group. The CTBE therapists were paid at the same rate as that paid to DBT therapists. The CTBE therapists were not required to attend a weekly clinical supervision group.

Institutional Prestige. The CTBE clinical supervision group met at the Seattle Psychoanalytic Society and Institute and was led by its training director. The institute's prestige outside the field of behavior therapy in Seattle rivals that of the University of Washington within the field of behavior therapy.

General Factors and Assistance Finding a Therapist. The participant coordinator established an independent relationship with subjects in both conditions. The participant coordinator also provided assistance in contacting the therapist and in getting the subject to the first session.

Availability of Affordable and Sufficient Treatment Hours. The study paid for CTBE at the same rate as for DBT. All participants paid a small sliding fee for therapy as determined by the assessment team before condition assignment. No participants were dropped because of failure to pay.

Sex, Training, and Clinical Experience. The randomization program assigned clients to DBT and CTBE therapists, matching on sex, doctoral vs master's training, and years of clinical experience. Results indicated that therapists' sex and training did not differ in the 2 conditions. The CTBE therapists, however, had more clinical experience, which was expected because they were selected for their expertise (Table 1).

Recruiting of CTBE Therapists

Ninety-four potential therapists were recruited. Based on their descriptions of the treatment that they usually provide to patients with BPD, therapists were categorized into 6 groups anchored by "behavior therapist" on one end and "very nonbehavioral" on the other end. The CTBE therapist pool consisted of 38 therapists self-described as "eclectic but nonbehavioral" or "mostly psychodynamic." No cognitive behavior therapists were selected for the CTBE condition. Of the potential 38 CTBE therapists, 25 were assigned patients (the remaining 13 potential therapists declined to accept a patient when one was assigned).

STATISTICAL ANALYSIS

Our primary method for analyzing repeated-measures data (pretreatment through the 24-month assessment) was mixed-effects models.⁴³ Two versions of mixed-effects models were implemented: (1) random regression modeling (RRM), also known as hierarchical linear models and multilevel linear models,^{44,45} and (2) mixed-model analysis of variance (MMANOVA).⁴⁶ Differences in rates of change (ie, slopes) were compared for the 2 treatment groups. Outcome variables with nonnormal distributions were recoded into discrete ordinal levels and were analyzed using RRM for ordinal data (eg, total nonsuicidal self-injurious acts were recoded into 5 ordinal levels).^{47,48}

Outcomes that were infrequent (and highly skewed) were analyzed by means of a generalized MMANOVA using all clients with any outcome data ($n=97$), with the pretreatment values as a covariate. The MMANOVA required that suicide attempts, emergency department visits, and inpatient admissions be recoded into binary variables (none vs any) per assessment period; therefore, absolute frequency of these outcomes could not be statistically compared.⁴⁹

Cox proportional hazards regression model survival analysis tested the time to first suicide attempt.⁵⁰ For simple cross-sectional comparisons (eg, pretreatment differences and manipulation checks), t tests were used for normally distributed variables, Mann-Whitney tests for nonnormal variables, and χ^2 tests for binary variables.

To assess the potential effect of missing data (ie, ignorable vs informative missing data), a pattern-mixture analysis was implemented using 2-tailed tests.⁵¹ We defined patterns using a binary completer status variable, which was entered as a predictor in the RRM and MMANOVA. To determine if the slope differences depend on completer status, a 3-way interaction of completer status \times treatment group \times time was included in the hierarchical linear models. To determine if the mean difference between groups depends on completer status, a 2-way interaction of completer status \times treatment group was included in the MMANOVA. The same analyses were conducted for treatment dropout status.

With mixed-effects models, appropriate covariance structures were analytically determined. Determination of the appropriate covariance structure was based on a mixture of χ^2 tests in comparing nested models.⁵²

RESULTS

SAMPLE CHARACTERISTICS AND BASELINE DIFFERENCES

The treatment groups did not significantly differ on demographic characteristics, diagnoses, or pretreatment number of suicide attempts or nonsuicidal self-injuries. These results are summarized in **Table 2**.

STUDY IMPLEMENTATION

Dialectical behavior therapy adherence was rated for 51 client-therapist dyads across 571 therapy sessions. Adherence scores ranged from 2.5 to 4.8, with a mean \pm SD score of 4.0 ± 0.2 .

Compared with the CTBE group, the DBT group received significantly more therapy from study therapists, primarily because of their weekly group sessions and their greater treatment retention (**Table 3**). There were no significant differences in total hours of therapy, however, when all study-provided and non-study-provided treatment hours (group, individual, case management, day treatment, and inpatient treatment) were summed. There were no differences between conditions in the use or the types of psychotropic medications at pretreatment. During the treatment year, the use of psychotropic medications decreased significantly more in the DBT group than in the CTBE group ($t_1=2.6$, $P<.01$, RRM). There were no significant differences between conditions during the follow-up year (**Figure 2**). At the pretreatment and 4-month assessments, the DBT and CTBE groups did not significantly differ in their expectations of receiving help from the study therapy. The mean \pm SD expectancy ratings were 5.52 ± 0.95 and 5.42 ± 1.02 at the pretreatment assessment and 5.46 ± 0.98 and 5.29 ± 1.37 at the 4-month assessment, for the DBT and CTBE groups, respectively.

ANALYSIS OF THE EFFECT OF MISSING DATA PATTERNS

Eight episodes were not included in the analyses of suicide attempts and nonsuicidal self-injury because the subjects did not provide enough information in the interviews to make that classification. The information was missing because the subjects refused to answer the question or said they could not remember, or the interviewer skipped needed questions because the subject was too emotionally distraught.

Compared with subjects assigned to the DBT condition, subjects assigned to the CTBE condition were significantly more likely to drop out of study assessments during the treatment year (3.8% vs 20.4%, $P=.01$, Fisher exact test) and during the overall study (11.5% vs 28.6%, $P=.03$, Fisher exact test). We examined the effects of differential missing data and treatment dropout on each of our major outcome variables and found no evidence that the findings were biased by these differences.

Table 2. Pretreatment Demographic, Suicide Attempt, Nonsuicidal Self-injury, and Diagnostic Data for the Dialectical Behavior Therapy (DBT) and Community Treatment by Experts (CTBE) Groups*

| Variable | DBT Group (n = 52) | CTBE Group (n = 49) | Total |
|--|-----------------------|------------------------|-----------------|
| Demographic Characteristics | | | |
| Age, mean ± SD, y | 29.0 ± 7.3 | 29.6 ± 7.8 | 29.3 ± 7.5 |
| Race | | | |
| African American | 3.8 | 4.1 | 4.0 |
| Asian American | 1.9 | 2.0 | 2.0 |
| Native American or Alaskan Native | 1.9 | 0 | 1.0 |
| Other | 5.8 | 6.1 | 5.0 |
| White | 86.5 | 87.8 | 87 |
| Single, divorced, or separated | 88.4 | 85.7 | 87.2 |
| Education | | | |
| <High school | 9.6 | 6.1 | 7.9 |
| High school graduate or general equivalency diploma | 15.4 | 18.4 | 16.8 |
| Some college or technical school | 50.0 | 53.1 | 51.5 |
| College graduate | 25.0 | 22.4 | 23.8 |
| Annual income, \$ | | | |
| <15 000 | 75.0 | 75.5 | 75.2 |
| 15 000-30 000 | 13.4 | 8.2 | 10.9 |
| >30 000-50 000 | 9.6 | 10.2 | 9.9 |
| Suicide Attempt and Nonsuicidal Self-injury, Median (Interquartile Range) | | | |
| Suicide attempt | 1.0 (0.0-3.0) | 2.0 (1.0-4.0) | 1.0 (0.5-4.0) |
| Nonsuicidal self-injury | 11.0 (2.3-51.5) | 7.0 (2.0-34.0) | 10.0 (2.0-47.0) |
| Diagnostic Data | | | |
| Lifetime psychiatric diagnoses meeting <i>DSM-IV</i> criteria† | | | |
| Major depressive disorder | 94.2 | 98.0 | 96.0 |
| Panic disorder | 48.1 | 55.1 | 51.5 |
| Posttraumatic stress disorder | 59.6 | 51.0 | 55.4 |
| Any anxiety disorder | 90.4 | 83.7 | 87.1 |
| Any substance use disorder | 78.8 | 67.3 | 73.3 |
| Any eating disorder | 44.2 | 34.7 | 39.6 |
| Current psychiatric diagnoses meeting <i>DSM-IV</i> criteria† | | | |
| Major depressive disorder | 71.2 | 73.5 | 72.3 |
| Panic disorder | 42.3 | 38.8 | 40.6 |
| Posttraumatic stress disorder | 50.0 | 49.0 | 49.5 |
| Any anxiety disorder | 82.7 | 73.5 | 78.2 |
| Any substance use disorder | 23.0 | 36.7 | 29.7 |
| Any eating disorder | 25.0 | 22.4 | 23.8 |
| Axis II | | | |
| Cluster A | 1.9 | 4.1 | 3.0 |
| Cluster B other than borderline personality disorder | 11.5 | 10.2 | 10.9 |
| Cluster C | 25.0 | 26.5 | 25.7 |
| Paranoid | 1.9 | 4.1 | 3.0 |
| Schizoid | 0.0 | 0.0 | 0.0 |
| Schizotypal | 0.0 | 0.0 | 0.0 |
| Antisocial | 11.5 | 10.2 | 10.9 |
| Histrionic | 1.9 | 2.0 | 2.0 |
| Narcissistic | 0.0 | 0.0 | 0.0 |
| Avoidant | 17.3 | 24.5 | 20.8 |
| Dependent | 3.8 | 8.2 | 5.9 |
| Obsessive compulsive | 7.7 | 8.2 | 7.9 |
| Psychiatric disorder not otherwise specified | 94.2 | 83.7 | 89.1 |

*Data are given as percentages unless otherwise indicated. No values were statistically significant. Analyses were conducted using the *t* test, Mann-Whitney test, and χ^2 test as appropriate.

†The first 8 subjects entering the study met criteria using the *DSM-III-R*.

SUICIDAL BEHAVIORS

There were no documented suicides in either condition during the 2-year study. The DBT group had half the rate of suicide attempts compared with the CTBE group (23.1% vs 46%, $\chi^2=5.98$, $P=.01$; hazard ratio, 2.66, $P=.005$; and number needed to treat [NNT], 4.24 [95% confidence in-

terval {CI}, 2.40-18.07]) (**Figure 3**). The NNT of 4.24 indicates that, during 2 years of treatment plus follow-up, 4 patients would need to be treated with DBT to prevent 1 patient from attempting suicide. Similarly, half as many subjects in the DBT group made nonambivalent suicide attempts (5.8% vs 13.3%, $P=.18$, Fisher exact test and NNT, 13.3 [95% CI, 5.28-25.41]). There were significantly fewer suicide at-

Table 3. Treatment Implementation and Treatment Dropouts for the Dialectical Behavior Therapy (DBT) and Community Treatment by Experts (CTBE) Groups*

| Variable | DBT Group (n = 52) | CTBE Group (n = 49) |
|--|-----------------------|------------------------|
| Treatment Implementation | | |
| First year | | |
| No. of individual study therapy sessions, study† | 42.5 (33.3-51.5) | 33.0 (14.0-46.0)‡ |
| No. of all individual therapy sessions§ | 51.0 (42.5-57.0) | 45.0 (21.0-62.5) |
| No. of group therapy sessions, study† | 38.0 (25.3-45.3) | 0.0 (0.0-0.0) |
| No. of all group therapy session§ | 38.0 (26.0-45.3) | 0.0 (0.0-0.0) |
| Total No. of treatment hours¶ | 64.7 (56.0-73.7) | 56.0 (21.0-86.9) |
| No. of weeks in study treatment# | 52.5 (50.0-73.7) | 50.9 (20.8-53.0) |
| Second year | | |
| Any outpatient therapy, % | 71.2 | 67.6 |
| Individual therapy, % | 63.0 | 67.6 |
| No. of individual therapy sessions | 6.5 (0.0-28.0) | 9.0 (0.0-37.5) |
| Total No. of treatment hours | 16.8 (0.0-42.0) | 17.0 (0.0-64.0) |
| Treatment Dropouts | | |
| Dropped first study therapist, No. (%) | 13 (25.0) | 29 (59.2) |
| No. of weeks before dropped first therapist | 16.9 (7.0-31.4) | 9.7 (2.4-26.3) |
| No. who saw 2 therapists, No. (%) | 5 (9.6) | 12 (24.5) ‡ |
| No. who saw 3 therapists, No. (%) | 0 | 2 (4.1) |

*Data are given as median (interquartile range) unless otherwise indicated. Proportions were compared using χ^2 tests, and continuous variables were compared using the Mann-Whitney test. *P* values are 2-tailed.

†Individual therapy sessions by study therapists during the treatment year.

‡*P* < .05.

§Any therapy sessions during the year, including sessions outside the study.

|| *P* < .001.

¶Total inpatient and outpatient treatment time. Each session of individual therapy, family therapy, and vocational counseling was counted as 1 hour of therapy; each group therapy session was counted as 20 minutes of therapy; each day of day treatment was counted as 30 minutes of therapy; and each psychiatric inpatient day was counted as 3½ hours of therapy.

#Total number of weeks clients saw any study therapist, including time after dropping first therapist.

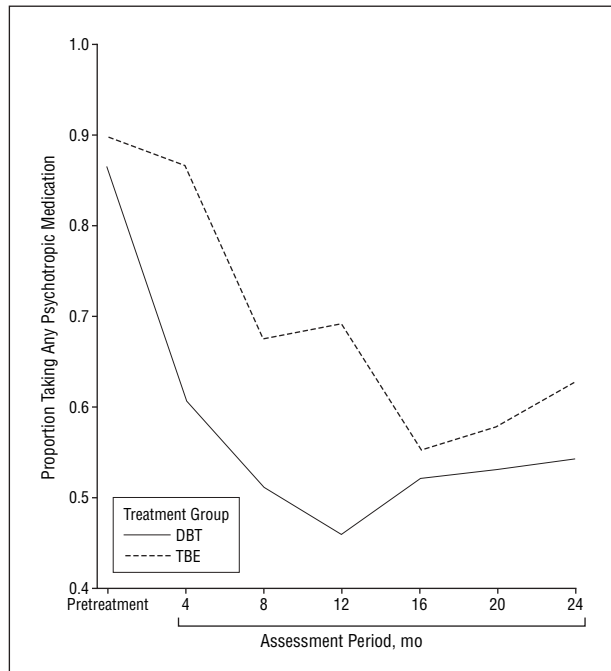


Figure 2. Proportion of subjects taking any psychotropic medication in the past 2 months. The treatment period ended at 12 months, and the follow-up period ended at 24 months. CTBE indicates community treatment by experts; DBT, dialectical behavior therapy.

tempts per period in the DBT group across the 2 years when controlling for the number of suicide attempts during the

pretreatment year ($F_{1,94} = 3.20, P = .04$, MMANOVA). The mean proportions of suicide attempters per treatment group per period were 6.2% (95% CI, 3.1%-11.7%) and 12.2% (95% CI, 7.1%-20.3%) for the DBT and CTBE groups, respectively. Across the 2 years, the median number of suicide attempts was 0 for the DBT group and for the CTBE group. The interquartile range for suicide attempts during the 2 years was 0 to 0 for the DBT group and 0 to 1 for the CTBE group. Similarly, both treatments were effective in reducing the number of nonsuicidal self-injuries ($\chi^2 = 120.6, P < .001$, ordinal RRM), but the difference in the rates of change was not significant ($F_{1,99} = 1.1, P = .15$ [standardized effect size, 0.47]) (**Figure 4**). The median number of nonsuicidal acts for the 2 years was 3.0 (interquartile range, 1.0-7.8) for the DBT group and 3.0 (interquartile range, 0.0-8.0) for the CTBE group.

As summarized in **Table 4**, among subjects with any suicide attempt or intentional self-injury during the treatment year, the highest medical risk was significantly lower for the DBT group than for the CTBE group ($F_{1,156} = 3.2, P = .04$). Both treatment groups made significant improvement in suicide ideation and in reasons for living ($P < .001$ for both), but the slope difference between conditions was not significant.

USE OF CRISIS SERVICES

Based on results of the MMANOVA, the DBT group used crisis services significantly less than the CTBE group through-

out the 2 years of the study (**Table 5**). Fewer DBT subjects went to the emergency department at least once for any psychiatric reason, including drug or alcohol problems (year 1: 43.1% of DBT subjects vs 57.8% of CTBE subjects, and year 2: 23.4% of DBT subjects vs 28.9% of CTBE subjects; $F_{1,92}=2.9$, $P=.04$; NNT, 9.09 [95% CI, 3.30-12.04]), or for suicide ideation specifically (year 1: 15.7% of DBT subjects had at least 1 visit vs 33.3% of CTBE subjects, and year 2: 10.6% of DBT subjects vs 18.4% of CTBE subjects; $F_{1,92}=4.3$, $P=.02$; NNT, 4.42 [95% CI, 2.49-19.76]).

In addition, significantly fewer DBT subjects were admitted to hospitals for any psychiatric reason (year 1: 19.6% of DBT subjects had at least 1 admission vs 48.9% of CTBE subjects, and year 2: 23.4% of DBT subjects vs 23.7% of CTBE subjects; $F_{1,92}=6.0$, $P=.007$; NNT, 3.88 [95% CI, 2.26-13.71]) or for suicide ideation specifically (year 1: 9.8% of DBT subjects had at least 1 admission vs 35.6% of CTBE subjects, and year 2: 14.9% of DBT subjects vs 18.4% of CTBE subjects; $F_{1,92}=7.3$, $P=.004$; NNT, 4.46 [95% CI, 2.53-19.17]).

BEHAVIORS THAT INTERFERE WITH THERAPY

More CTBE than DBT subjects dropped out of the study therapy (Table 3). Subjects could choose reassignment to up to 2 additional therapists for the same condition. Cox proportional hazards regression model survival analysis indicated that the risk of dropping out of therapy was 3 times higher for CTBE subjects for dropping the first therapist (hazard ratio, 3.2, $P<.001$; and NNT, 2.92 [95% CI, 1.91-6.21]) and for dropping therapy entirely (relative risk ratio, 2.7, $P=.01$; and NNT, 4.22 [95% CI, 2.43-16.16]). In all, 29 CTBE subjects (59.2%) and 13 DBT subjects (25.0%) dropped their first study therapist. Twenty-one CTBE subjects (42.9%) and 10 DBT subjects (19.2%) dropped all study therapy ($P=.005$).

BEHAVIORS REFLECTING QUALITY OF LIFE

Both treatment groups had significant reductions in scores on the Hamilton Rating Scale for Depression-17 Item ($P<.001$ for both). However, the slope difference between the treatment groups was not significant (Table 4).

COMMENT

This study compared DBT with a rigorous comparison condition, nonbehavioral CTBE, to address whether the effectiveness of DBT in treating suicidal patients and patients with BPD can be accounted for by treatment factors common to most psychotherapy by experts. Results indicated that DBT was superior to CTBE in preventing suicide attempts, with a hazard ratio suggesting that suicide attempts can be reduced by half with DBT compared with non-behavioral therapy by experts. Dialectical behavior therapy was also more effective in reducing emergency department visits and inpatient psychiatric care for suicide ideation. In addition, DBT was more than twice as effective as non-behavioral therapy by experts in keeping subjects in treatment, as reflected by a 25% dropout rate from the first therapist in DBT compared with 59% in CTBE. The

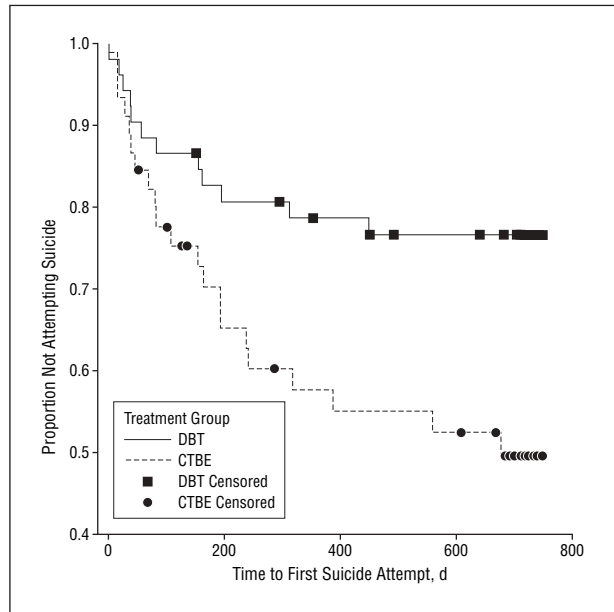


Figure 3. Survival analysis for time to first suicide attempt. The treatment period ended at 365 days, and the follow-up period ended at 730 days. CTBE indicates community treatment by experts; DBT, dialectical behavior therapy.

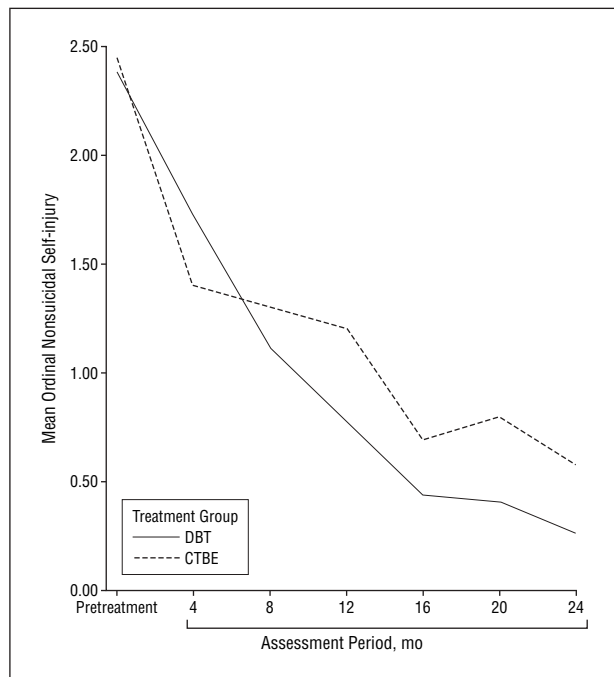


Figure 4. Mean ordinal nonsuicidal self-injury during the 2-year study.¹ The treatment period ended at 12 months, and the follow-up period ended at 24 months. The 5-level ordinal categories per assessment period were 0, 0.01 to 1, 1.01 to 2, 2.01 to 4, and 4.01 and higher. CTBE indicates community treatment by experts; DBT, dialectical behavior therapy.

findings of this study indicate that the efficacy of DBT cannot reasonably be attributed solely to general factors associated with receiving expert psychotherapy.

The hazard ratio for nonambivalent suicide attempts (ie, those with high intent and planning) was 2.2, almost identical to that for suicide attempts overall. (We cannot conclude that this is a statistically significant difference, as the low base rate of serious suicide attempts precludes adequate

Table 4. Longitudinal Outcome Measures for the Dialectical Behavior Therapy (DBT) and Community Treatment by Experts (CTBE) Groups*

| Variable | Pretreatment | | 12-mo Posttreatment | | 24-mo Follow-up | | Δ in Slopes | |
|--|--------------------|---------------------|---------------------|---------------------|--------------------|---------------------|-------------|---------|
| | DBT Group (n = 52) | CTBE Group (n = 49) | DBT Group (n = 50) | CTBE Group (n = 39) | DBT Group (n = 46) | CTBE Group (n = 35) | F | P Value |
| Highest medical risk† | 7.1 ± 4.9 | 8.8 ± 4.9 | 5.0 ± 4.2 | 7.4 ± 5.6 | ... | ... | 3.2 | .04 |
| Suicide ideation | 51.7 ± 20.3 | 59.9 ± 21.6 | 29.8 ± 24.5 | 32.8 ± 26.3 | 24.1 ± 19.8 | 31.92 ± 26.8 | 0.2 | .31 |
| Reasons for Living Inventory | | | | | | | | |
| Mean total item score | 2.8 ± 0.7 | 2.7 ± 0.9 | 3.2 ± 0.9 | 3.0 ± 0.8 | 3.3 ± 0.9 | 3.1 ± 0.8 | 0.9 | .17 |
| Survival and coping | 2.7 ± 0.9 | 2.7 ± 1.0 | 3.4 ± 1.2 | 3.3 ± 1.2 | 3.7 ± 1.0 | 3.3 ± 1.4 | 1.4 | .12 |
| Hamilton Rating Scale for Depression-17 Item | 20.2 ± 5.9 | 21.7 ± 7.3 | 14.0 ± 7.3 | 17.0 ± 8.2 | 12.6 ± 6.8 | 14.4 ± 9.1 | 0.0 | .43 |

*Data are given as mean ± SD unless otherwise indicated. Reported means are estimates of the random regression modeling (RRM). Unless otherwise specified, slope and intercept were included as random effects in standard linear RRM, and RRM was based on all available data (pretreatment, 4-, 8-, 12-, 16-, 20-, and 24-month assessments).

†Analysis of combined suicide attempt and self-injury data aggregated per year includes only subjects with suicide attempt or nonsuicidal self-injury during the treatment year. There were too few acts during the follow-up year for analysis. Random intercept RRM (without slope as a random effect) was used.

Table 5. Emergency Department Visits and Hospital Admissions for the Dialectical Behavior Therapy (DBT) and Community Treatment by Experts (CTBE) Groups*

| Variable | Treatment Year | | | | Follow-up Year | | | | F | P Value |
|------------------------------------|----------------|------------------------------|------------|------------------------------|----------------|------------------------------|------------|------------------------------|-----|---------|
| | DBT Group | | CTBE Group | | DBT Group | | CTBE Group | | | |
| | % | Median (Interquartile Range) | % | Median (Interquartile Range) | % | Median (Interquartile Range) | % | Median (Interquartile Range) | | |
| Emergency Department Visits | | | | | | | | | | |
| For psychiatric reason | 43.1 | 0 (0-1) | 57.8 | 1 (0.0-2.5) | 23.4 | 0 (0-0) | 28.9 | 0 (0.0-1.0) | 2.9 | .04 |
| For suicide ideation | 15.7 | 0 (0-0) | 33.3 | 0 (0.0-1.0) | 10.6 | 0 (0-0) | 18.4 | 0 (0.0-0.0) | 4.3 | .02 |
| Hospital Admissions | | | | | | | | | | |
| For psychiatric reason | 19.6 | 0 (0-0) | 48.9 | 0 (0.0-2.0) | 23.4 | 0 (0-0) | 23.7 | 0 (0.0-0.3) | 6.0 | .007 |
| For suicide ideation | 9.8 | 0 (0-0) | 35.6 | 0 (0.0-1.0) | 14.9 | 0 (0-0) | 18.4 | 0 (0.0-0.0) | 7.3 | .004 |

*Differences were tested by means of mixed-model analysis of variance using data from all assessment periods (pretreatment, 4-, 8-, 12-, 16-, 20-, and 24-month assessments). The highly skewed distribution analysis precluded a statistical comparison of absolute numbers of these events.

power in any single-site clinical trial.) This finding, however, combined with the significantly lower risk for any type of suicide attempt suggests that DBT may be uniquely effective in treating suicidal individuals. Similar to other DBT randomized trials,^{26,28,32,53} there was a low mortality rate during the study. There were no documented suicides (other than 1 death in the CTBE group related to the cumulative effects of previous suicide attempts). The absence of any death by suicide may be due to any number of factors. Subjects were offered not only expert therapy but also extensive contact with an assessment team. They were mailed frequent non-demanding cards throughout the treatment and follow-up years. Such a regimen has been found to reduce completed suicides among individuals treated for suicidality.⁵⁴

In contrast to previous DBT randomized trials,^{25,28,31,32,54} there were no significant differences between conditions in the incidence or the frequency of nonsuicidal self-injury in our study. An examination of outcomes from the 1991 DBT trial of suicidal women with BPD suggests that non-behavioral CTBE may be more effective than TAU in reducing nonsuicidal self-injury. The mean ± SD number of nonsuicidal acts during the treatment year for subjects assigned to TAU in the 1991 study²⁵ was 32.32 ± 69.97, with half that many

(16.82 ± 60.81) for subjects assigned to CTBE in the present study; in contrast, DBT had outcomes in the present study almost identical to those found in the 1991 study (6.05 ± 11.55 and 6.38 ± 7.41 for the 1991 study and the present study, respectively). The differences between conditions in outcome variability across the 2 studies are remarkably similar, with DBT outcomes being consistently less variable across persons than those of either comparison condition. It is possible that the present study may have been underpowered to detect the 0.49 effect size of DBT vs CTBE.

An alternate explanation of our findings may be that subjects in CTBE underreported habitual self-injury to a greater extent than those in DBT. In a previous study³⁰ among drug abusers, retrospective reports of opiate use at 4-month intervals to a blinded assessor were compared with contemporaneous urinalyses data. The correlation of DBT subjects' self-reports with urinalyses data was 0.71, whereas the correlation in the nonbehavioral control condition was 0.02, despite a lack of any negative consequence for self-reporting drug use. Subjects in DBT self-reported using opiates more frequently even when thrice-weekly urinalyses indicated that they were actually using opiates less frequently.³⁰ Daily diary keeping and weekly discussion of recorded behaviors

most likely enhance memory of targeted behaviors in DBT.

Subjects assigned to CTBE were also much more likely than those assigned to DBT to be hospitalized for suicide ideation, despite no apparent differences over time in suicide ideation for the 2 conditions. An important DBT strategy, at least as a first step, is to encourage outpatient use of behavioral skills over inpatient treatment even when suicidal risk is high. Consequently, we cannot determine from the present data whether the difference in hospitalization is due to a lesser tendency of DBT therapists to recommend inpatient treatment or to differences in actual need for hospitalization. There is no evidence that inpatient hospitalization is an effective treatment for suicidality. Therefore, it may be that inpatient admissions for suicide ideation were actually iatrogenic rather than therapeutic. These questions need to be addressed in future studies.

Depression, suicide ideation, and reasons for living improved significantly in both conditions. The absence of significant differences on these measures is similar to our previous findings²⁵ among severely suicidal patients with BPD and does not appear to be due to inadequate power. In contrast, a clinical trial among patients with less severe BPD found superiority of DBT compared with other treatments in reducing depression and suicide ideation.²⁸ Both findings fit the 2-stage model of DBT that targets out-of-control behaviors first (stage 1 target) among more severe patients (stage 1 DBT target) and targets "quiet desperation" such as depression (stage 2 DBT target) among less severe patients who demonstrate behavioral control.

The overall dropout rate in CTBE was high. In addition, significantly more CTBE subjects were assigned a second or third therapist (24% of the CTBE group) compared with DBT subjects (10% of the DBT group). Because of this reassignment to new therapists and the greater tendency of CTBE subjects to see a therapist outside the study, the overall number of individual sessions was similar between conditions. Not surprisingly, DBT subjects had more group therapy hours. However, there were no significant differences between conditions in the total amount of therapy received when hours of individual, group, day treatment, and inpatient treatment were included. Therefore, the simple amount of therapeutic contact is not a viable explanation for differences in outcome between DBT and CTBE. A previous study²⁰ comparing DBT group "skills training" combined with community psychotherapy vs community psychotherapy without group training skills found no significant benefit of the group component when added to non-DBT psychotherapy. However, we cannot rule out its effects when combined with individual DBT. A component analysis study is under way to tease out the effects of the DBT group component.

Subjects assigned to DBT were less likely to continue taking psychotropic medications, including antidepressant drugs, during the treatment year. The use of psychotropic medications in general (and antidepressants specifically) resumed in the follow-up year, despite no apparent increase in depression or other dysfunctional behaviors. This suggests that medication use in this population may be influenced by psychotherapists' treatment philosophy as much as by symptomatic need for medication.

An innovative characteristic of this research was the development of the CTBE condition to control for nonspecific treatment factors of expert therapy. We could find no

other published randomized trial that demonstrated the effectiveness of any other outpatient treatment for suicidal individuals with BPD. Therefore, there is no "standard" treatment with which to compare DBT. Indeed, with 6 previous randomized trials^{25,28-32,54} (more than any other treatment for suicidal behavior or BPD), DBT can be considered the current standard. Comparing DBT with an alternative, however, would provide little, if any, scientific information. Although knowing that one multicomponent treatment is more effective than another might be of clinical value in deciding which treatment to offer, it does not provide information about mechanisms of treatment and is of little help in developing more effective treatments.

The major limitation of this study is that CTBE subjects dropped out of the entire study more often than DBT subjects, despite our best efforts to keep all participants enrolled. Careful statistical analyses, however, showed that this differential treatment dropout does not explain the differences in outcomes. Nonetheless, future studies must find a way to keep more suicidal patients with BPD enrolled. Although we attempted to control for allegiance and adherence to a coherent model by selecting expert therapists and by asking them to use the treatment that they believed to be most effective, results might be limited by the heterogeneity of the treatments used by the community experts compared with the more homogeneous DBT condition.

Additional dismantling studies of DBT are also needed to clarify which components of DBT are essential and to what degree fidelity to the DBT manual is needed to achieve results comparable to those found herein and in other studies. This research is under way. Finally, further investigation is warranted on community-delivered psychotherapy by experts. Weekly non-behavioral CTBE may have much to recommend it as treatment for BPD. Nonetheless, findings from this study suggest that DBT may indeed be the superior intervention.

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