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Dialectical behavior therapy versus comprehensive validation therapy plus 12-step for the treatment of opioid dependent women meeting criteria for borderline personality disorder

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Abstract

We conducted a randomized controlled trial to evaluate whether dialectical behavior therapy (DBT), a treatment that synthesizes behavioral change with radical acceptance strategies, would be more effective for heroin-dependent women with borderline personality disorder ($N = 23$) than Comprehensive Validation Therapy with 12-Step (CVT + 12S), a manualized approach that provided the major acceptance-based strategies used in DBT in combination with participation in 12-Step programs. In addition to psychosocial treatment, subjects also received concurrent opiate agonist therapy with adequate doses of LAAM (thrice weekly; modal dose 90/90/130 mg). Treatment lasted for 12 months. Drug use outcomes were measured via thrice-weekly urinalyses and self-report. Three major findings emerged. First, results of urinalyses indicated that both treatment conditions were effective in reducing opiate use relative to baseline. At 16 months post-randomization (4 months post-treatment), all participants had a low proportion of opiate-positive urinalyses (27% in DBT; 33% in CVT + 12S). With regard to between-condition differences, participants assigned to DBT maintained reductions in mean opiate use through 12 months of active treatment while those assigned to CVT + 12S significantly increased opiate use during the last 4 months of treatment. Second, CVT + 12S retained all 12 participants for the entire year of treatment, compared to a 64% retention rate in DBT. Third, at both post-treatment and at the 16-month follow-up assessment, subjects in both treatment conditions showed significant overall reductions in level of psychopathology relative to baseline. A noteworthy secondary finding was that DBT participants were significantly more accurate in their self-report of opiate use than were those assigned to CVT + 12S.

Keywords: Dialectical behavior therapy; Borderline personality disorder; Heroin; Co-morbidity; Psychotherapy; Women

1. Introduction

Substance use disorders (SUDS), particularly opiate dependence, often co-exist with borderline personality disorder (BPD) (Trull et al., 2000). Prevalence of current SUDS among clients receiving treatment for BPD range from approximately 25 (Miller et al., 1993) to 57% when substance abuse was not used as a criterion for BPD (Dulit et al., 1990). Prevalence of current BPD among individuals receiving treatment for SUDS range from 5.2 (Brooner et al., 1997) to 17% (DeJong et al., 1993). Co-morbidity between BPD and SUDS is associated with greater severity than is found in either diagnostic group alone (Cacciola et al., 2001; Kosten et al., 1989; Skodol et al., 1999). For example, rates of suicide and suicide attempts, already high among both BPD individuals (Frances et al., 1986; Stone et al., 1987) and

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substance abusers (Beautrais et al., 1999; Rossow and Lauritzen, 1999; Farrell et al., 1996) are even higher for individuals with both disorders (Links et al., 1995).

Opiate addicts with Axis II disorders have poor treatment outcome (Hien et al., 2000; Rutherford et al., 1994; Kosten et al., 1989). These individuals are more likely to have higher rates of illicit drug use during treatment and are more likely to drop out of treatment or be administratively discharged because of ongoing behavioral problems. As such, specialized psychosocial treatment programs for severely personality-disordered opiate-addicted clients have been recommended (NIH Consensus Conference, 1998; Kosten et al., 1989). Relatively few studies have evaluated specialized treatments for personality-disordered, opiate dependent clients participating in concurrent opiate agonist treatment. The most consistent finding of the existing studies is that psychotherapy, when added to standard drug treatment for opiate addicts, improves outcomes on drug use and other measures of psychosocial functioning (Kidorf et al., 1998; McLellan et al., 1993; Rounsaville et al., 1983; Woody et al., 1983, 1985). BPD *without* opiate dependence is also typically characterized by poor treatment outcomes, including high treatment drop-out and rates of non-compliance (Kelly et al., 1992; Soloff, 1994; Waldinger and Frank, 1989).

Dialectical behavior therapy is a cognitive-behavioral treatment approach originally developed to treat chronically suicidal clients (Linehan et al., 1991; Linehan, 1993a,b) and subsequently adapted for substance abusers. As a whole, DBT attends to five functions of comprehensive treatment: capability enhancement (skills training), motivational enhancement (individual behavioral treatment plans), generalization (in vivo assignments, phone consultation), structuring of the environment (programmatic emphasis on reinforcement of sobriety and adaptive behaviors), and capability and motivational enhancement of therapists (therapist team consultation group). The treatment has two major characteristics: a behavioral, problem-solving focus blended with acceptance-based strategies, and an emphasis on dialectical processes. The term dialectical is meant to convey both the co-existing multiple tensions that must be dealt with in treating the multi-disordered patients, as well as the thought processes and behavioral styles employed and targeted in the treatment strategies. DBT is defined by its emphasis on behaviorally explicit targets and treatment strategy groups. The conduct of the therapist is guided by a detailed manual of procedures (Linehan 1993a; Linehan et al., 1997).

Data suggest that in the treatment of suicidal women with BPD, DBT is more effective than treatment-as-usual (TAU) for reducing the frequency and medical severity of suicide attempts and self-injury, the frequency and duration of inpatient psychiatric days, treatment drop-out, social adjustment ratings, and self-reported anger (see Koerner and Linehan, 2000 for a review). Similarly, in a randomized controlled trial conducted by Linehan et al. (1999), women meeting criteria for BPD and polysubstance use disorder or substance use disorder for amphetamines, anxiolytics, cocaine, cannabis, hypnotics, opiates, or sedatives had significantly greater reductions in drug use throughout the treatment year and at follow up than did TAU subjects. Further, those assigned to DBT had significantly better treatment retention (64% retention in DBT; 27% retention in TAU). In social and global adjustment, there were no significant between-group differences during treatment or at 12-month follow-up, but DBT subjects did show significantly greater gains on these variables at the 16-month follow-up. These results are encouraging, but the TAU comparison design provides insufficient experimental control to draw firm conclusions. That is, whether the treatment gains were due to DBT per se, or simply the provision of a well-organized psychotherapy remains unclear.

The present study had two primary goals: first, to increase internal validity by evaluating the efficacy of DBT for substance abusers against a more rigorous control condition; second, to determine whether the findings of Linehan et al. (1999) generalize to a sample of opiate-addicted women with BPD. All participants received 1 year of treatment that included opiate agonist treatment and their randomly assigned psychotherapy condition. Opiate agonist therapy was provided to all subjects because the support for such a regime in treating heroin addicts is overwhelming (NIH Consensus Conference, 1998).

Given the absence of another data-based psychosocial intervention for the treatment of substance abusers with BPD, we used a constructive approach to treatment evaluation to develop a suitable control condition (Borkovec, 1990, 1993). The control condition, Comprehensive Validation Therapy with 12-Step (CVT+12S), is a manualized approach that provides the major acceptance-based strategies employed in DBT (such as therapeutic warmth, responsiveness, and empathy) in combination with participation in 12-Step programs. This design will maximize internal validity by holding the following factors constant across treatment condition: use of a manualized psychotherapy, access to treatment (including individual psychotherapy and crisis intervention), academic treatment setting, therapist experience and commitment, and general treatment factors common to standard non-behavioral treatments for opiate addicts. The provision of opiate agonist treatment is also held constant across condition. The primary hypothesis examined in this study was that DBT would be superior to CVT+12S in reducing behaviors targeted for reduction in DBT, including drug use and treatment drop-out. We further hypothe-

sized DBT would be superior to CVT+12S in maintaining treatment effects over a 4-month follow-up.

2. Method

2.1. Subjects

Individuals were recruited from mental health clinics, needle exchange programs, substance abuse clinics, methadone maintenance clinics, and non-profit HIV/AIDS prevention organizations treating under-served minority populations. For inclusion in the study, subjects were required to be females between the ages of 18 and 45 who met the following criteria: (1) diagnosis of BPD according to two structured interviews: the Personality Disorders Exam (PDE; Loranger, 1988) and the Structured Clinical Interview II for DSM-IV (SCID-II; First et al., 1996); (2) diagnosis of current opiate dependence according to the SCID-I (First et al., 1995a); (3) absence of the following diagnoses: bipolar disorder, psychosis, seizure disorder, or mental retardation; (4) absence of pregnancy or any medical condition in which the use of opiate-replacement medication was contraindicated; and (5) absence of indications of treatment coercion (e.g. court-ordered/agency-ordered to retain housing). All participants provided informed consent using protocols approved by the University of Washington Human Subjects Division.

Of 64 in-person screening interviews, 24 (37.5%) were accepted into the study, with the remaining deemed ineligible for one of the following reasons: (1) did not meet criteria for BPD ($n = 34$); met criteria for Bipolar Mood Disorder ($n = 4$); was pregnant ($n = 1$); did not complete pre-treatment and/or medical evaluation ($n = 1$). A minimization random assignment procedure was used to assign subjects to treatment condition by matching on four variables: (1) severity of DSM-IV drug dependence; (2) presence/absence of current cocaine abuse or dependence; (3) presence/absence of DSM-IV antisocial personality disorder; (4) global assessment of functioning (DSM-IV Axis V). This method has been shown to be superior to both simple and stratified randomization in producing balance for separate prognostic variables, particularly when the number of strata is large in comparison to the number of participants (White and Freedman, 1978; Linehan, 1993b). The initial sample of 24 subjects was randomly assigned to treatment, with 12 in each condition. However, immediately following assignment, we discovered that one subject assigned to DBT did not meet the study inclusion criteria. She was therefore dropped from the study, yielding a final sample of 23 (DBT = 11; CVT+12S = 12).

2.2. Psychotherapy conditions

All subjects were provided a comprehensive psychosocial intervention plus an opiate agonist medication for approximately 1 year (48–56 weeks). The psychosocial treatments were either DBT (Linehan, 1993aLinehan, 1993b; Linehan et al., 1997) or Comprehensive Validation Therapy+12-Step (CVT+12S; Linehan et al., 1996). Table 1 summarizes the common and unique components of the treatment protocols.

2.2.1. Dialectical behavior therapy for substance abusers

DBT was applied according to treatment manuals developed by Linehan (1993a,b) and adapted subsequently for substance abusers (Linehan et al., 1997). DBT applies directive, problem-oriented techniques that are balanced with supportive techniques, such as reflection, empathy, acceptance and emphasis on the client's inherent ability to access an internal 'wise mind.' In addition, dialectical strategies are employed, including balancing acceptance with change, alternating validation with problem solving and using paradox and metaphor. Individual DBT targeted dysfunctional behaviors in hierarchical order (suicidal, therapy-interfering, substance use, and quality-of-life interfering behaviors) and replacing those behaviors with skillful behaviors learned in a psycho-educational skills group.

When the client engages in dysfunctional behavior, the therapist elicits a description of the moment-to-moment chain of environmental and behavioral events preceding the problematic response, explores alternate skilled responses, identifies behavioral deficits as well as factors interfering with more adaptive responses, and employs remedial procedures as necessary. Both within and between sessions, the individual therapist actively reinforces adaptive behaviors and withholds reinforcement or provides aversive consequences for behaviors targeted for change. The emphasis is on teaching clients how to manage emotional trauma, rather than reducing negative emotions or taking clients out of crises. Skills taught in group training included mindfulness, interpersonal effectiveness, distress tolerance, and emotion regulation. Individual skills coaching focused primarily on skills strengthening and generalization (i.e. homework review, role plays, etc.).

The overriding dialectic in DBT is its synthesis of both validation and acceptance of the client, on the one hand, with persistent attention to behavioral change on the other. A unique application of dialectics in DBT is the notion of 'Dialectical Abstinence:' a concept which provides a synthesis of two common approaches to the treatment of addictive behaviors-abstinence and harm-reduction (Marlatt, 1998; Marlatt and Gordon, 1985). That is, the therapist promotes absolute abstinence before any illicit drug use has occurred (i.e. the change pole of the dialectic), while simultaneously applying a

Table 1
Unique and common treatment components of DBT and CVT+12S

DBT	CVT+12S
Etiology	
Both BPD and co-morbid drug abuse are consequences of emotional dysregulation	Both BPD and co-morbid drug abuse are inevitable consequences of inability to self-validate
Treatment rationale	
BPD and drug abuse are viewed as attempts to regulate aversive emotions. Treatment requires a synthesis of *validation* to strengthen self-trustvalidation, reduce fear of self-generated (intrinsically motivated) response patterns, and maintain working alliance, *behavior therapy* to teach emotional regulation, self-validation, and skillful responses to problems in living and to extinguish or punish BPD behaviors (including illicit drug use), and *dialectics* to counteract rigid and extreme response patterns	BPD and drug abuse are viewed as functioning to reduce aversive emotions, increase sense of control, and maintain community that validates negative self-view. Treatment requires a synthesis of *validation* to strengthen self-trust, reduce fear of self-generated (intrinsically motivated) response patterns, decrease arousal, increase the experience of control, and maintain working alliance, *fellowship of similar community such as 12-Step* to validate both sense of self as well as recovery efforts
Allegiance to treatment model	
DBT has been demonstrated effective in our clinic suggesting that the combination of validation, behavior therapy, and dialectics may be uniquely effective	Efforts to get behavior therapy to work with BPD in our clinic were not effective until comprehensive validation was added to the treatment, suggesting that validation may be the key treatment factor
Modes	
Individual DBT (40–90 min/week)	Individual CVT+12S (40–90 min/week)
Group skills training (150 min/week)	'12-and-12' NA group (120 min/week)
Individual skills coaching (30 min/week recommended)	12-Step sponsor meeting (recommended)
12-Step (AA/NA/CA) or other support group meetings (recommended)	12-Step (AA/NA/CA) meetings (recommended)
DBT case management (as needed)	CVT+12S case management (as needed)
Phone consultation and crisis intervention (standard DBT)	Phone consultation and standard crisis intervention; after-hours use of local crisis line
Diary cards including drug use self-monitoring and discussion in sessions	No drug use self-monitoring, but asked by therapist at each session
Common components	
Thrice-weekly urinalysis plus immediate feedback of opiate use to primary therapist	
Thrice-weekly urinalysis of opiate and other drug use	
Opiate agonist therapy with LAAM+clinical management	
Optional psychotropic medications+clinical management	
Optional brief trazadone (for severe sleep disorder)	
Optional brief perphenazine (for psychotic episodes)	
Optional brief PTSD exposure manualized treatment (if assaulted while in treatment)	

cognitive-behavioral relapse prevention approach following relapse (the acceptance pole of the dialectic).

2.2.2. Comprehensive validation therapy for substance abusers (CVT+12S)

Modes and amount of treatment in CVT+12S are also outlined in Table 1. CVT+12S was applied according to a treatment manual developed specifically for this program of research (Linehan et al., 1996) and was designed to control for the provision of support, validation and general therapeutic acceptance and other components of treatment not specific to DBT (e.g. opiate agonist therapy, psychotropic medications, urinalyses, and crisis intervention weekly self-monitoring) and the effects of time, regression to the mean, expectancies for improvement (by therapists and clients), and therapist allegiance, provision of group supervision and regular monitoring of adherence to a manual. Specifically, the treatment included all of the DBT acceptance-based strategies, including validation, reciprocal communication (e.g. warmth, self-disclosure, responsiveness, and genuineness), and environmental intervention when requested (e.g. case management). In contrast to DBT, individual therapists in CVT+12S were, with the limited exceptions noted below, non-directive. The treatment proscribed use of cognitive-behavioral change techniques or any overt suggestion of new behaviors or advice about what to do. The agenda was determined by the client, with the exception that the topic of drug use had to be raised at least once, though no systematic self-monitoring was involved. Problem solving was carefully limited to reducing imminent suicide risk, ensuring treatment attendance and medication compliance.

CVT+12S focused on validating the client and her experience in a warm and supportive atmosphere that encouraged clients to develop their confidence in themselves as capable individuals worthy of the therapist's respect, and reinforcing self-verification even when the environment is invalidating (emphasizing, as in DBT, the client's inherent ability to access an internal 'wise mind'). Importantly, validation of public and

private behaviors only occurred when the behavior was in fact valid (e.g. was effective in terms of the client's long-term goals, was logically consistent with actual data, or was an instance of normative behavior, see Linehan, 1997, for a discussion of key points of validation).

CVT+12S clients attended a 120-min women's Narcotics Anonymous (NA) meeting that was conducted in accordance with NA policy for '12 and 12' meetings. These meetings were advertised as open to the public, but functionally, very few non-research participants ever attended. They were held in our research facility and the CVT+12S therapists attended the meetings, but did not serve as group leader or facilitate the meeting. In short, the majority of meetings included only our CVT+12S clients and therapists. In addition, all CVT+12S clients were strongly encouraged to meet weekly with a 12-Step sponsor of their choice, and to attend as many AA meetings as possible.

2.2.3. Therapists

The five psychotherapists (one male, four female; three DBT and two CVT+12S) who delivered the experimental treatments were experienced in the treatments they delivered as well as committed to the respective treatment models. Two doctoral-level and one masters level behavior therapists delivered DBT, and two master's level therapists with chemical dependency certification and 12-step experience delivered CVT+12S. Therapists each had a minimum of 8 months training, and had supervised training clients in their respective modalities prior to seeing their first research client in this study. To promote adherence to treatment manuals, therapists in each condition met weekly with supervisors to discuss case material and review session videotapes.

2.3. Opiate-replacement medication

Although methadone is the most widely used medication, the need for daily visits to a clinic poses a significant challenge in treating these particular clients given high rates of treatment non-compliance and potential for diversion of take-home medication. An attractive alternative, therefore, was levomethadyl acetate hydrochloride which is as effective as methadone (see Rawson et al., 1998) and requires only three visits per week for dosing. In addition, because there can be no take-homes, there is lower diversion risk.

A psychiatrist acted as the pharmacotherapist throughout the study. At treatment start, all subjects were prescribed an initial dose of 40 mg of levomethadyl acetate hydrochloride oral solution (ORLAAM). During the first 2 weeks of treatment, the dose was increased in 5–10 mg increments per dose every 48 h until reaching a maintenance dose. We decided to use a high maintenance dose given the treatment outcome literature suggesting superior outcomes with use of high doses as compared with low-to-moderate doses (Gossop et al., 2001). During treatment, dosage adjustments were made as necessary in response to side effects or report of ongoing withdrawal symptoms. Clients received their LAAM prior to or immediately following their other clinic appointments on Monday, Wednesday, and Friday. Dose was not contingent on results of urinalyses. No take-home doses were provided; however, doses were delivered directly to participants who were hospitalized or incarcerated. If a dose was missed, clients received their medications the following day and were placed on a 48-h dosing schedule (Thursday, Saturday, Monday) until resuming their usual schedule. Medication clinic staff carefully monitored ORLAAM ingestion.

For all participants, modal dosing of LAAM throughout the trial was 90/90/130 mg; the maximum LAAM schedule was 110/110/180 mg. There were no between-condition differences in dosages. Two subjects (one in each condition) were switched from LAAM to methadone during the trial after becoming pregnant; in one of these cases, the subject resumed use of LAAM following a miscarriage. Another subject was switched to methadone due to an inability to tolerate LAAM. In each case, the methadone dosage was equivalent to their LAAM dosage. At the close of 12 months, all participants were offered immediate treatment in one of several area outpatient clinics that offered opiate-replacement medication, and we had no further therapeutic contact with them. (Those who dropped treatment prematurely were also given referrals, although not assured an immediate opening.)

2.4. Assessment procedure

2.4.1. Urinalyses

The principle outcome measure in this study was the proportion of positive urinalyses tests for opiates. Throughout the treatment year, urine samples were collected three times weekly; that is, prior to each treatment session and/or when the subjects received ORLAAM. Urine specimens were tested in the following two ways: (1) immediately following urine collection, every specimen was tested for the presence of opiates; (2) *One* of the three weekly urine specimens was randomly selected for analysis of the following additional drugs, methadone, benzodiazepines, cocaine, amphetamines, and barbiturates. In sum, for each treatment week, each subject had three urine tests for opiates and one for the full drug panel. Finally, at the 16-month assessment appointment a urine sample was collected immediately prior to the beginning of the assessment and was analyzed for all drugs including opiates. All specimens were collected under the supervision and observation of

a female urinalysis technician, and urinalyses were conducted using on-site enzyme multiplied immunoassay technique (EMIT) analysis. EMIT has a low false positive rate ($<3\%$) but a higher false negative rate (18% for opiates, 23% for cocaine; Visher and McFadden, 1991).

Specimens were defined as positive if results for any illicit drug (other than prescribed ORLAAM or methadone) were positive, or if the subject refused or missed a urine test except in the following cases: subject did not provide a urine specimen due to hospitalization, incarceration, planned vacation, technician error, or if the subject dropped out of the treatment and did not take an alternate treatment referral where urinalysis tests were possible. These cases were coded as 'missing.' A 'percent dirty' score was calculated for each subject as the ratio of positive urine specimens to total collected urine specimens for each assessment period. This ratio was calculated for each drug separately.

2.4.2. Interviews and self-report measures

Independent clinical interviewers, blind to the subjects' treatment conditions, conducted assessments at pre-treatment, 4, 8, 12, and 16 months. Diagnostic assessments (for disorders not used in screening and matching) were conducted using the SCID-I (First et al., 1995b) 8 weeks into treatment after participants were stabilized in treatment and on a maintenance dose of ORLAAM. For subjects who received DBT, the periodic 4-month assessment appointments were timed from the date they began group therapy. Timing of CVT+12S subjects' assessments was determined by yoking each CVT+12S subject with the previously accepted subject assigned to DBT. Post-treatment assessments (12-month appointments) were scheduled to immediately follow the termination of treatment. Average number of days between assessments did not differ between the two conditions ($M=133.6\pm12.6$ for DBT; $M=135.5\pm21.9$ for CVT+12S).

During each periodic 4-month assessment, client report of illicit drug use was measured using the timeline follow-back (TLFB) assessment method (Sobell et al., 1986). The TLFB method was developed to collect information about subjects' drinking histories during a specific time period and was modified to include drugs as well as alcohol. It provides information about quantity, frequency and quantity × frequency of alcohol consumption. This method has demonstrated high reliability when administered to drinking populations. The proportion of drug use days was examined separately for opiates and other drugs by calculating the ratio of the number of drug use days since last assessment to the total number of days since last assessment.

Parasuicidal behaviors were measured using the Parasuicide History Interview (Linehan et al., 1989, 1990) a comprehensive semi-structured interview that assesses the nature and frequency of parasuicidal behavior since the client's last assessment point. The Social History Interview (Linehan and Heard, 1994), an adaptation of both the psychosocial functioning portion of the Social Adjustment Scale and the Longitudinal Interview Follow-up Evaluation base schedule (Keller et al., 1987), allowed interviewers to make two ratings of psychosocial adjustment: the global adjustment scale (GAS; overall level of impairment using a 0–100 scale) and the global social adjustment scale, which is more specifically related to social functioning (GSA; ratings are on a 1–5 scale). At each assessment, interviewers made GAS and GSA ratings for the worst week of the last month of the assessment period and for the best week overall. Also, the DSM-IV Global Assessment of Functioning (GAF) scale was used at pre-treatment. At each assessment, all participants completed the Brief Symptom Inventory (BSI; Derogatis and Melisaratos, 1983), a self-report measure that assesses general psychiatric symptomatology.

3. Results

3.1. Data analysis

All analyses were two-tailed and were conducted on the modified intent-to-treat sample of 23. Baseline characteristics of the DBT and CVT+12S subjects were compared using t-tests for continuous measurements and Pearson's chi-square test or Fisher's exact test as appropriate for categorical measurements. Weekly urinalysis results were analyzed using hierarchical logistic regression models that allowed random subject-specific intercepts and subject-specific time slopes (Diggle et al., 1996). Maximum likelihood estimation for these models was obtained using the SAS procedure NLMIXED.

Similarly, self-reported drug use gathered via TLFB methods was analyzed using longitudinal methods for a scaled response allowing random intercepts and slopes for each participant. Estimates were obtained using the SAS procedure MIXED. We analyzed measures of psychopathology using simple two group comparisons of change since baseline and tested for significant differences using the Wilcoxon rank sum test. We also computed the longest time period that a subject was negative for opiate use and conservatively treated any missing values as positive, effectively terminating a sequence of negative urinalyses either due to a missed test or a positive test.

3.2. Sample description

Of the 23 subjects in the sample, the majority (83%) reported that they had at least one previous trial in a standard methadone maintenance program. Approximately a third of subjects (35%) reported previous involvement in three or more trials of methadone maintenance (36% of DBT subjects and 33% of CVT+12S). Only two subjects (9% of total sample, with one in each treatment condition) had *no* history of methadone maintenance treatment.

Mean age of subjects was 36.1±7.3 years. The majority of subjects were Caucasian (66%), 26% were African–American and one (4%) identified her as mixed ethnicity (Asian and Hispanic American). Slightly over half the sample was divorced (52%), one subject was currently married (4%), and the remainder had never been married (44%). All but one of the subjects completed high school or obtained a GED (96%). Further, 11 (48%) had completed business/technical school or some college, one (4%) had graduated college, and four (18%) had some graduate or professional school without graduating. Half of the subjects were employed (52%).

In addition to current opiate dependence, 52% of subjects also met criteria for dependence on cocaine, 13% on sedatives, 8.7% on cannabis, and 26% on alcohol. No significant between-group differences were detected for diagnoses, level of general functioning (GAF ratings) or parasuicide acts prior to treatment. As a group, subjects met criteria for an average of 2.4 (S.D. = 1.3) co-morbid Axis I diagnoses, with 39% meeting criteria for Major Depressive Disorder or dysthymia, 52% for a current anxiety disorder, and 18% for an eating disorder. On Axis II, only ASPD was assessed in addition to BPD: 44% met ASPD criteria, with 5 in each treatment condition. The average global assessment of functioning score (GAF) was 43.2 (S.D. = 8.36). The majority of the sample (65%) reported a history of at least one suicide attempt or intentional self-injury.

3.3. Treatment initiation, exposure, and retention

Treatment 'dropout' was defined as four consecutive missed sessions of a required component of treatment. For DBT this included both individual therapy and group skills, for CVT+12S this included individual therapy only. Three (27%) DBT subjects dropped out of study treatment, one after six individual sessions, one by week 12 (12 individual sessions) and one by week 35 (25 individual sessions). A fourth subject switched DBT therapists at week 41 and then completed treatment. This switch was reportedly due to an argument with the therapist and the client's ongoing perception that she was misunderstood by the therapist. In contrast, there were no treatment dropouts or therapist changes in the CVT+12S condition. Counting all four (36%) DBT subjects as dropouts, there was a significantly greater dropout rate in DBT than in CVT-12S (Fisher's exact $P < 0.04$). Notably, three of the four dropouts (including the client who switched at week 41) were clients of the only male therapist. Supervisor comments suggested that this was likely due to the therapist's difficulty understanding, accepting, and validating the perspective of the client.

As outlined in Table 1, each condition had three primary treatment modes: (1) an individual therapy component that was DBT versus CVT; (2) a group treatment component that was the skills training group in DBT versus the 12-Step group meeting ('12-Steps and 12-Traditions') in the CVT+12S condition; and (3) an additional individual session with the participant's skills coach in DBT versus a 12-Step sponsor in CVT+12S. There was no significant difference in the mean number of individual sessions received (DBT: $M = 33.2 \pm 20.4$; CVT+12S: $M = 33.00 \pm$ S.D. $= 9.6$) across the treatment year. However, participants in the DBT condition attended a significantly greater number of skills group sessions ($M = 26.6 \pm 15.9$) as compared with attendance of the CVT+12S participants in the 12-Step group meetings ($M = 10.8 \pm 12.8$; $t[21] = 2.62$, $P < 0.05$). Likewise, those in the DBT condition attended a significantly greater number of individual coaching sessions ($M = 17.6 \pm 9.9$) when compared to the number of 12-step sponsor sessions attended by those in the CVT+12S condition ($M = 6.7 \pm 2.5$; $t[21] = 2.30$, $P < 0.05$).

At the 16-month assessment point, 19 of the 23 subjects (83%) reported that they had remained in ongoing treatment (nine in DBT and ten in CVT+12S), with 15 receiving ongoing opiate agonist treatment (typically methadone maintenance in an outpatient setting) in the 4 months preceding the 16-month assessment point (seven in DBT and eight in CVT+12S). There were no between-condition differences in type of treatment or likelihood of remaining in treatment.

3.4. Drug use outcomes

3.4.1. Percentage of positive urine specimens

As described, urinalyses data were examined separately for opiates and for other illicit drugs to yield a percent opiate-positive urinalyses and a percent other drug-positive urinalyses. To test for between-condition differences, analyses were conducted using time measured in weeks and allowing for differences in slopes across the entire treatment year, and also converting time into three 'trimesters' of treatment that corresponded with the major assessment points in the study (1–4, 4–8, 8–12 month).

When opiate urinalyses were examined, modified intent-to-treat analysis of temporal trends using logistic mixed models indicated significant reductions over time ($t = -7.51$, $P < 0.0001$), with no between-condition differences in slope between pre-treatment and the 4-month point (0–16 weeks) or 4-month and the 8-month point (17–32 weeks). However, the slopes showed significant divergence following the 8-month point ($t = 2.07$, $P < 0.04$) such that CVT+12S subjects were estimated to have significantly increasing use of opiates ($t = 4.17$, $P < 0.001$), while the DBT subjects showed no significant changes in their percent of opiate-positive urine specimens. This course continued until treatment week 52 (i.e. treatment end at 12 months), when DBT subjects had a significantly lower percentage of opiate-positive urinalyses than the CVT+12S subjects ($t = 2.32$, $P < 0.02$). These results are displayed graphically in Fig. 1. In sum, subjects in both groups showed a similar course of declining opiate use up until the 8-month point, at which time the CVT+12S subjects showed a course of increasing opiate use while the DBT subjects maintained treatment gains. The single urinalysis at the 16-month assessment showed no significant between-condition difference, with a low percentage of positive urinalyses in both conditions (DBT = 27%; CVT+12S = 33%).

When the percentage of positive non-opiate urinalyses were examined (see Fig. 2), there was no estimated reduction in use of non-opiate drugs across the treatment year for the modified intent-to-treat sample, nor did significant between-condition differences emerge. During treatment, 57% of weekly urinalyses (calculated for those in treatment only) were positive for at least one non-opiate illicit drug. The majority of these were cocaine (55% positive in once weekly urinalyses). When number of positive tests for opiates were combined with positive tests for other drugs, however, a significant reduction in positive urinalyses over the entire year was estimated ($t = 3.75$, $P < 0.001$) for the modified intent-to-treat sample of 23. This suggests that the reduction in use of opiates was not compensated for by a corresponding increase in use of other illicit drugs.

Presented in Table 2 are the probabilities of producing a positive urinalysis test for opiates and non-opiates. The probabilities were derived from the logistic regression model used to fit the urinalysis data, and they provide a clinically meaningful index of drug use in each treatment condition within each treatment trimester. Parallel with the graphical representation of the opiate urinalyses results in Fig. 1, it is clear that the entire sample showed a notable reduction in drug use across the treatment year. With regard to non-opiate drugs, it

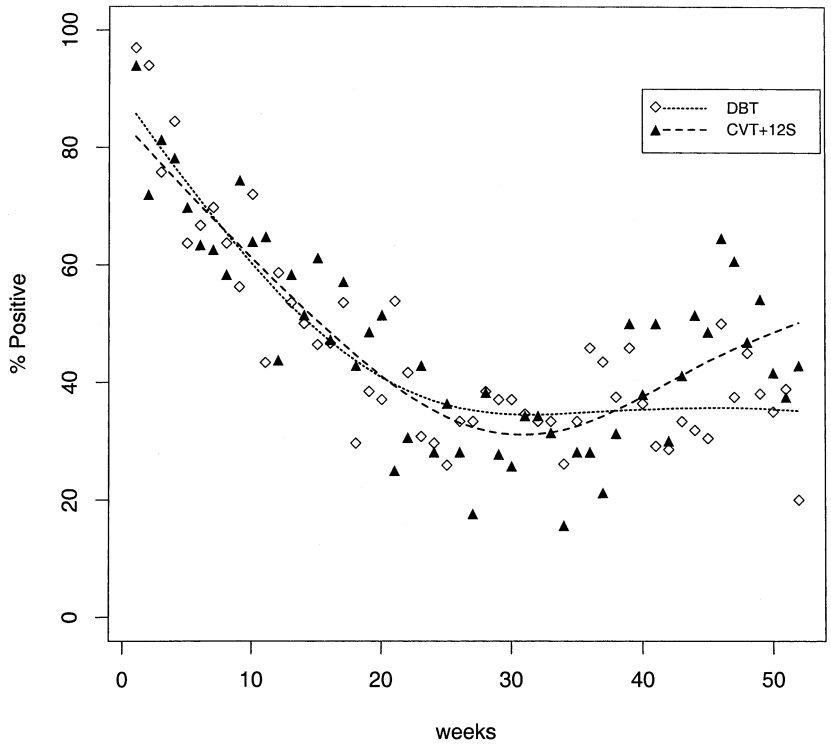

Fig. 1. Opiate use across the treatment year. Each point represents the crude rate of opiate-positive tests defined as the ratio of the total number of opiate-positive tests divided by the total number of available tests (summing over the 3 measurements per subject and summing over subjects) for each treatment condition. These ratios were then converted to percentages. The temporal trend for each group is characterized using a smoothing spline with 4 degrees of freedom.

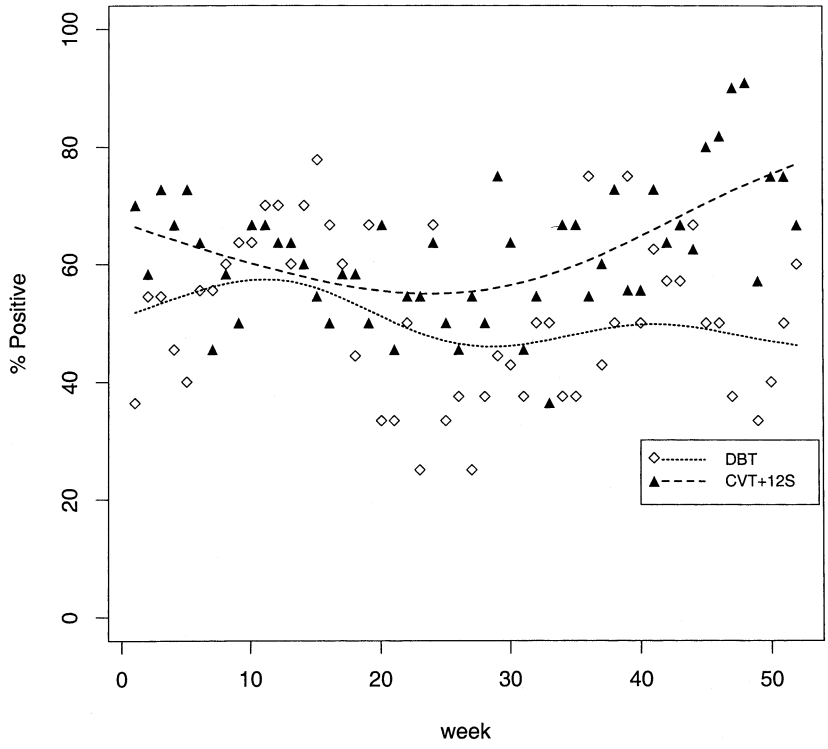

Fig. 2. Other drug use across the treatment year. Each point represents the crude rate of non-opioid positive tests defined as the ratio of the total number of positive tests for non-opioid drugs divided by the total number of available tests (summing over subjects) for each treatment condition. These ratios were then converted to percentages. The temporal trend for each group is characterized using a smoothing spline with 4 degrees of freedom.

is remarkable that by the end of the treatment year, level of drug use in both treatment conditions ended up where they started.

3.4.2. Longest duration of opiate-negative urine specimens

To examine the longest period of consecutive weeks of opiate abstinence, we collapsed the thrice-weekly urinalysis outcomes into a single composite score for each week. Our definition of an 'opiate-negative week' was conservative in that all specimens had to be opiate-negative and present. When conditions were combined, the median longest duration of opiate abstinence was 7.6 weeks (range = 0–37). There were no between-condition differences, with a median of 5 weeks as the longest duration of opiate abstinence in each condition.

3.4.3. Self-reported drug use

The Wilcoxon rank sum test indicated that a significant number of participants in both treatment conditions reported fewer drug use days at 16-month follow-up than at baseline (see Table 3). This was true both for opiate use ($z = 1.96$, $P < 0.05$ and $z = 2.71$, $P = 0.007$ for DBT and CVT+12S, respectively) and for use of other drugs including alcohol ($z = 2.09$, $P < 0.04$ and $z = 2.85$, $P = 0.004$ for DBT and CVT+12S, respec-

Table 2
Probability of opiate-positive and other-drug positive urinalysis by treatment condition and trimester of treatment

Trimester (months)	DBT		CVT+12S	
	Probability	Confidence interval	Probability	Confidence interval
Opiate urinalyses				
0–4	0.68	[0.61–0.74]	0.65	[0.59–0.71]
4–8	0.40	[0.30–0.44]	0.36	[0.31–0.42]
8–12	0.35	[0.29–0.42]	0.42	[0.36–0.47]
Other drug urinalyses				
0–4	0.55	[0.33–0.77]	0.64	[0.41–0.82]
4–8	0.44	[0.23–0.68]	0.60	[0.37–0.80]
8–12	0.55	[0.31–0.78]	0.64	[0.41–0.83]

Table 3
Mean percentage of self-report abstinent days vs. mean percentage of clean urinalyses by condition: pre-treatment to 12-month assessment point

Year total	DBT		CVT+12S	
	Mean (%)	S.D.	Mean (%)	S.D.
Self-report				
Heroin	66.26	67.01	91.14	91.86
Cocaine	83.12	80.93	78.90	72.08
Amphetamines	99.97	99.92	100.00	100.00
Barbiturates	99.97	99.92	99.92	99.84
Sedatives	99.82	99.39	99.83	99.48
Urinalyses				
Heroin	46.43	68.34	53.30	83.40
Cocaine	70.86	80.66	72.27	78.58
Amphetamines	88.07	89.87	91.72	88.68
Barbiturates	88.46	90.11	92.45	88.14
Sedatives	86.36	89.24	90.92	88.22

tively). Similar patterns were observed for reduced non-opiate use from pre-treatment to the 12-month assessment point, however, within the DBT condition, self-reports of opiate use did not differ.

When only the 30 days prior to assessment were examined, self-reported opiate use in both DBT ($z = 1.96$, $P = 0.05$) and CVT+12S ($z = 2.75$, $P = 0.006$) was reduced from pre-treatment to the 12-month as well as 16-month assessments. Non-significant between-condition differences in self-reported opiate use were observed at the 12-month point: CVT+12S subjects reported fewer days using opiates than DBT subjects when days are summed over the entire year ($z = 1.71$, $P = 0.09$). There were no between-condition differences, however, for proportion opiate use days or total drug and alcohol days between the end of treatment and the 16-month follow-up.

3.4.4. Correlation between drug use via self-report and urine testing

To further examine the discrepancy between urinalyses results and those obtained by self-report, we recalculated both the urinalyses results and the self-reports to reflect the percentage of urinalyses testing negative for opiates, and the corresponding percentage of self-reported days opiate-abstinent during the same time period. Within the entire sample, the Pearson correlation between self-reported opiate use and urinalysis testing was moderate ($r = 0.53$, $P < 0.01$). However, when the treatment conditions were examined separately, a different pattern emerged; the correlation for subjects assigned to DBT was 0.72 ($P < 0.02$), whereas the correlation for subjects assigned to CVT+12S was a non-significant 0.02. To examine whether the discrepancies between self-reports and urinalyses tests were greater in one group than the other, we subtracted the percentage of opiate-negative urinalyses from the self-report days opiate-abstinent. Results indicated significantly greater discrepancy over the entire year for CVT+12S compared to DBT (CVT+12S discrepancy = 37.8; DBT discrepancy = 19.8; $z = -2.63$, $P < 0.008$). One would expect a higher percentage of urinalyses to be positive since opiate can be detected in urine testing for approximately three days after use. Nonetheless, assuming that the relationship of urinalyses data to self-report data is the same across treatment conditions, the larger discrepancy found in the CVT+12S condition would suggest either a greater degree of under-reporting or a lesser degree of over-reporting of actual drug use. Mean percentages of clean urinalyses and self-reported days clean for all drugs are presented in Table 3.

3.5. Psychopathology outcomes

The Wilcoxon rank sum test indicated that in both treatment conditions, scores showed significant improvement across 12 months of treatment on both the BSI ($z = 3.17$, $P < 0.002$; pre-treatment: $M = 1.78 \pm 71$; 12-month: $M = 1.17 \pm 0.60$) and GAS ratings ($z = 3.59$, $P < 0.001$; pre-treatment: $M = 37.6 \pm 5.6$; 12-month: $M = 47.4 \pm 10.7$). At the 16-month follow-up point, BSI scores continued to improve but were not reliably different from the 12-month point ($z = 1.76$, $P < 0.08$; 16-month: $M = 0.98 \pm 0.74$). Global adjustment improvements were maintained but did not improve further. No between-condition differences emerged for either measure nor were any improvements found on social adjustment ratings (GSA). The incidence of parasuicidal behavior during the treatment year was low (17.4% of subjects), and did not significantly differ by treatment condition. The incidence of psychiatric or drug related visits to emergency rooms (three visits over the entire year) and inpatient units (only one subject) were also low over the year, and there were no significant between-condition differences. Sixteen of the 23 clients (70%; eight subjects in each condition) spent at least one night in jail between pre-treatment and the 16-month assessment point. Although this number is high, it should be noted that many of the jail stays were for outstanding warrants issued prior to entry into the study. For those incarcerated, the mean number of nights in jail was 7.7 ± 14.5 for DBT and 18.8 ± 34.4 for CVT+12S, with no statistically significant difference between-conditions.

4. Discussion

This comparison of DBT to Comprehensive Validation Therapy+12-Step among clients receiving opiate agonist medication had three primary results. First, both

treatments when combined with LAAM were effective in reducing opiate use and in maintaining the reduction during the 4-month follow-up period. Participants assigned to DBT, however, showed better maintenance of treatment gains (i.e. reduced opiate use) through 12 months of active treatment while those assigned to CVT+12S increased opiate use significantly during the last 4 months of treatment.

Second, CVT+12S was remarkably effective in maintaining subjects in treatment; 100% stayed for the entire year. Premature dropout rate in DBT was 36%, significantly higher than in CVT+12S. Third, improvements on measures of global adjustment were observed in both treatment approaches with no differences between-conditions. From pre-treatment to both post-treatment and follow-up assessments, subjects reduced their overall level of psychopathology. When between-condition effect sizes were examined on these measures, they were small, arguing against the possibility that low power prevented us from detecting clinically meaningful differences. Finally, a noteworthy secondary result was that subjects assigned to DBT were significantly more accurate in self-reporting opiate use than were those assigned to CVT+12S.

When the present results are compared with those found in the literature, treatment retention rates in both conditions were markedly higher than those typically found in treatment studies of either heroin addicts or BPD patients. At the 6-month-point, the overall drop-out rate was only 8% (18 and 0% for DBT and CVT+12S, respectively) as compared with 6-month drop-out rates of 36–65% reported in other opiate treatment studies (Magura et al., 1994; Schottenfeld et al., 1997; Savage et al., 1976). In our previous study with substance dependent clients (Linehan et al., 1999), the one-year retention rate in DBT was 64%, similar to that obtained in this study at 1 year.

A number of factors might account for these strong retention rates. First, we used high LAAM doses, which, when compared to lower doses, are associated with better retention over 12 months (Ling et al., 1996). In addition, both treatment conditions put a high emphasis on validation, which may be a social reinforcer and may have increased the positive valence of treatment. Finally, the treatment took place in a BPD treatment clinic where policies and procedures have been developed specifically to keep this population of clients in the treatment milieu. For example, the clinic coordinator acts as an 'ombudsperson,' maintaining contact with all clients and addressing treatment or assessment difficulties; the clinic sends cards to clients at holidays and for a number of other events; the assessment staff is very experienced in working with BPD clients; there were rarely lines for LAAM dosing; all therapists were extremely flexible in scheduling sessions and highly tolerant of cancellations, late-shows, and no-shows; and clients are not threatened with termination for drug use, misuse of medications or other maladaptive behavioral pattern. The one instance in which a DBT client can be terminated is if she misses four consecutive therapy weeks. However, if a DBT client misses 3 weeks in a row, the entire treatment team goes on 'high alert' to mobilize the individual therapist to do sufficient outreach to get the client back in.

The superiority of CVT+12S in retaining subjects in treatment suggests that validation and use of other DBT acceptance strategies, or conversely the absence of an explicit focus on behavioral change, including an absence of aversive confrontation, are likely important factors in maintaining clients in treatment. The 100% retention rate (12 out of 12 clients) is considerably higher than the 40% retention rate (three of five clients) found in a pilot trial of a 6-month version of CVT+12S that was conducted in our research clinic. The improvement shown in the present results may highlight the importance of extensive training in CVT+12S for therapists who had to overcome their previous reliance on change strategies. Interestingly, in that same pilot trial, DBT retained 83% of the clients for the 6-month treatment, similar to the 82% retention rate found for DBT at 6 months in the present study.

Analyses indicated substantial and comparable reductions in opiate-positive urinalyses in both treatments from pre-treatment to the 8-month point, but a significantly better retention of gains in DBT compared to CVT+12S for the subsequent 4 months of treatment. This finding is similar to results of Carroll et al. (1994) who compared cognitive-behavioral treatment to clinical management. In their randomized trial, both cognitive-behavioral relapse prevention and supportive clinical management were comparable at post-treatment in reducing cocaine use. However, at a 1-year follow-up, subjects assigned to cognitive-behavioral relapse prevention maintained gains better than those assigned to supportive clinical management therapy. This suggests that a treatment that includes a focus on change and on learning new skills may have more lasting effects on drug use than those that focus primarily on providing validation and acceptance. However, the estimates of greater retention of gains in DBT, must be viewed with caution due to the differential dropout rates in the two interventions. Two subjects assigned to DBT had no weekly urinalyses after week 17 and one had no weekly urinalyses after week 31. Thus, the number of missing (and hence statistically estimated) urinalyses results was greater in the DBT condition than in the CVT+12S condition.

The reduction in illicit drug use by subjects in the validation condition is very encouraging since CVT+12S is easier to teach (requiring only training in the DBT validation and acceptance strategies and no training in behavioral strategies), and requires less professional

time. It is not clear, however, whether similar results would have been obtained if subjects had attended community NA meetings instead of an on-site weekly meeting attended by their individual therapists. Nor is it clear what the mechanisms of change are in CVT-12S. From one perspective, CVT+12S can be considered a supportive psychotherapy with an emphasis on values clarification. From another perspective, however, it can be considered a pure reinforcement therapy. The therapist watches for valid responses in session or reports of valid responses out of session and responds with immediate validation. Swann's (Swann, 1984; Swann et al., 1992) research suggests that validation is a powerful reinforcer. Reports of drug use or other maladaptive behaviors were not followed by aversive contingencies in CVT+12S. Rather, the primary emphasis in CVT+12S is on finding the 'kernel of wisdom' in every response and to reflect that wisdom back to the client.

Our findings of reductions in opiate-positive urinalyses from 68 and 65% during the first 4 months of treatment to 35 and 42% (DBT and CVT+12S, respectively) during the last 4 months of treatment are comparable to the rates found in other treatment studies with heroin addicts (Kidorf et al., 1994; Schottenfeld et al., 1997; Woody et al., 1995). Given the high co-morbidity in the sample studied here, this is in itself a noteworthy finding. It is unclear whether the positive outcomes are due primarily to the psychosocial intervention or the LAAM. Given the severity of dysfunction in the population of BPD opiate addicts, it was most likely due to the combination of both.

Results from urinalyses are in marked contrast to those assessed by self-report. Despite the absence of aversive contingencies for reporting use, subjects in both treatment conditions appear to have under-estimated their use of opiates when asked about days clean since the last assessment point. However, the under-estimation among CVT+12S was significantly greater than among DBT subjects. Similarly, whereas self-report and urinalysis results were highly correlated for DBT subjects, there was no correlation among CVT-12S subjects. These results may have important implications. First, use of urinalysis to assess drug use is essential in treatment outcomes studies such as this one, and sole reliance on self-report may actually lead to the opposite conclusion that would be indicated by urinalysis data. This is consistent with findings of Morral et al. (2000) who report substantial under-reporting of drug use among chronic, 'hardcore' drug users. It is possible that the apparently greater accuracy of drug use reporting found in the DBT condition is the result of completing and in-session reviewing of weekly diary cards that required clients to report detailed drug use information.

This study has several limitations. Due to funding constraints, there were relatively few subjects in each treatment condition, which compromised statistical power to find other differences in drug use outcomes that might exist. It remains unclear how our results would generalize to less dysfunctional individuals, to males, or to other impulsive behaviors. Finally, the differences between therapists in the two treatment conditions does not allow us to rule out effects of therapists or therapist characteristics (e.g. gender or personal experience with substance abuse) as important factors in treatment effectiveness (Wampold and Serlin, 2000).

Despite these limitations, this study has a number of strengths. First, this randomized controlled trial used a component analyses design. This allowed us to examine the contribution to outcome of the total package of DBT compared to a treatment that included all of the acceptance-based strategies but far fewer of the DBT change strategies. Second, we made use of a fairly rigorous urinalysis standard in our data analysis procedure-counting all missing urinalyses, except those due to our error, planned absences, or following treatment drop-out as 'dirty.' Finally, with the exception of one subject who was randomized in error (and hence dropped from the study), we used an intent-to-treat approach incorporating all available data.

In summary, while supportive of DBT as a treatment for opioid-dependent women meeting criteria for BPD, this study also clearly suggests that a pure reinforcement and acceptance treatment that avoids the use of behavioral change strategies, such as CVT+12S, holds promise and should be developed further. In a permissive clinic with no automatic rules for terminating clients who continue to use opiates, BPD women not only tolerated LAAM well, but on average they substantially reduced their use of illicit drugs over time.

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