

## **THE PERSONALITY DISORDERS INSTITUTE/BORDERLINE PERSONALITY DISORDER RESEARCH FOUNDATION RANDOMIZED CONTROL TRIAL FOR BORDERLINE PERSONALITY DISORDER: RATIONALE, METHODS, AND PATIENT CHARACTERISTICS**

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The Personality Disorder Institute/Borderline Personality Disorder Research Foundation randomized control trial (PDI/BPDRF RCT) is a controlled outcome study for borderline personality disorder (BPD), in which 90 participants were randomized to one of three manualized and monitored, active psychosocial treatment conditions. These treatments are: (a) Transference-Focused Psychotherapy (TFP; Clarkin, Yeomans, & Kernberg, 1999), a treatment for BPD based on object-relational and psychoanalytic principles first applied to BPD by Kernberg (1996), notable for its particular emphasis on interpretation of object relations activated in the ongoing therapeutic relationship; (b) Dialectical Behavior Therapy (DBT; Linehan, 1993), a popular treatment for BPD, with evidence of efficacy (Linehan, Armstrong, Suarez, Allmon, & Heard, 1991) that emphasizes a balance between acceptance and change in its combination of cognitive-behavioral and Zen principles; and (c) supportive psychotherapy (Rockland, 1992), another object-relational and psychoanalytically based treatment for BPD which, in contrast to TFP, eschews transference interpretation and places primary emphasis on development of a collabo-

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rative engagement with the patient to foster identity development. Patients received medication, if clearly indicated, according to the treatment algorithm developed by Soloff (2000). This article describes the significance and rationale of the study and the overall design, methods, plan of analysis, and demographic characteristics of the recruited sample of patients.

Borderline personality disorder (BPD) constitutes one of the most important sources of long-term impairment in both treated and untreated populations (Widiger & Weissman, 1991). BPD is a prevalent, chronic, and debilitating syndrome associated with high rates of medical and psychiatric use of services (Lenzenweger, Loranger, Korfine, & Neft 1997; Torgersen, Kriglen, & Cramer, 2001; Skodol, Gunderson, Pfohl, Widiger, Livesley, & Siever, 2002). Approximately 11% of psychiatric outpatients and 19% of inpatients met the Diagnostic and Statistical Manual (4th ed.) criteria for BPD (Kass, Skodol, Charles, Spitzer, & Williams, 1985), the majority of whom are women.

Suicidal and self-injurious behavior is particularly prevalent with BPD patients, with rates ranging from 69% to 75% (McGlashan, 1986; Stone, 1993; Cowdry, Pickar, & Davies, 1985; Clarkin, Widiger, Frances, Hurt, & Gilmore, 1983). BPD is substantially comorbid with other personality disorders (Nurnberg et al., 1991; Zimmerman & Coryell, 1990) and with Axis I disorders (Fyer, Frances, Sullivan, Hurt, & Clarkin, 1988). BPD negatively affects the treatment efficacy for a number of Axis I disorders (see Clarkin, 1996), and is less responsive to pharmacotherapy (Soloff, 2000).

#### **PREVIOUS PSYCHOTHERAPY RESEARCH ON BPD**

Psychotherapy is the most widely practiced technique for treating borderline patients and a recent meta-analysis by Perry, Banon, and Ianni (1999) suggests that psychotherapy is an effective treatment for personality disorder and may be associated with up to a sevenfold faster rate of recovery in comparison with the natural history of disorders. Although psychotherapy is the recommended primary technique for treating borderline patients (Oldham et al., 2001) and findings like Perry and colleagues' are encouraging, few studies have actually examined the effectiveness of particular treatments for borderline patients (Bateman & Fonagy, 1999; Blum, Pfohl, St. John, Monahan, & Black, 2002; Clarkin, Foelsch, Levy, Hull, Delaney, & Kernberg, 2001; Cookson, Espie, & Yates, 2001; Linehan et al., 1991; Linehan et al., 1999; Ryle & Golyukina, 2000; Stevenson & Meares, 1992). In our review we found only five published randomized controlled trials (Bateman & Fonagy, 1999; Koons et al., 2001; Linehan et al., 1991; Linehan et al., 1999; Munroe-Blum & Marziali, 1995), with only two treatments—a psychodynamic day hospital program and dialectical-behavioral therapy (DBT)—having shown

acute efficacy for treating BPD (Bateman & Fonagy, 1999; Koons et al., 2001; Linehan et al., 1991; 1999).<sup>1</sup>

Linehan and colleagues (Linehan et al., 1991) compared DBT (Linehan, 1993) with community treatment as usual (TAU). They showed that DBT was generally effective. Compared with TAU, DBT led to a reduction in the number and severity of suicide attempts and a decrease in the length of inpatient admissions. In a more recent study (Linehan et al., 1999), DBT was used to treat drug-dependent women who also have BPD as compared with TAU. DBT patients had more treatment than the TAU patients and they had significantly greater reductions in drug abuse and gains in social adjustment. However, in her initial study, there were no between-group differences in the number of hospitalizations or in terms of depression, hopelessness, or reasons for living. Additionally, there were no differences between groups in the number of days hospitalized at 6-month follow up or in self-destructive acts at the end of a 1-year follow up, despite the fact that the patients in the DBT group were still receiving DBT therapy, whereas approximately one-half of the TAU group was not in any therapy (Linehan, Heard, & Armstrong, 1993). Whereas the overall results of Linehan's study are suggestive of the value of DBT, results from her naturalistic follow up of patients in DBT showed variable maintenance of treatment effects, and ongoing impairment in functioning in patients who initially experienced symptom relief. Although there is understandable enthusiasm for the clinical usefulness of DBT, more information is needed on the mechanisms and durability of change effected by DBT (Scheel, 2000; Westen, 2000) and other treatments for BPD.

In a controlled randomized trial, Bateman and Fonagy (1999) compared the effectiveness of 18 months of a psychoanalytically-oriented day hospitalization program with routine general psychiatric care for patients with BPD. Patients randomly assigned to the day hospital program showed a statistically significant improvement in depressive symptoms and better social and interpersonal functioning, in addition to a significant decrease in suicidal and self-mutilatory acts and the number of inpatient days. Although Bateman & Fonagy (2000) showed impressive maintenance of treatment effects in an 18-month follow up, this study lacked a treatment manual and therapists' adherence ratings.

### **LIMITATIONS OF TREATMENT STUDIES**

Treatment studies of BPD are few in number, the total number of patients investigated is small, and power is low in each of these studies. Therefore, any generalizations from these studies must be quite tentative in terms of relative efficacy of different treatments in relationship to a few domains of outcome that have been measured. The outcome domains have been limited

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1. Other controlled studies reported in the literature are difficult to interpret because of small patient group sizes or because the studies focused on either suicidal behavior or mixed types of personality disorders without specifying borderline cohorts (Evans et al., 1999; Guthrie et al., 2001; Liberman & Eckman, 1981; Piper, Joyce, McCallum, & Azim, 1998; Salkovskis, Atha, & Storer, 1990).

and focused mainly on symptoms. The mechanisms of change (mediators of change) have rarely been tested, so the evidence for the specific factors in the treatments that have been investigated is lacking. In addition, both the Linehan et al. (1991) and Bateman and Fonagy (1999) studies did not assess adherence and competence, nor did these studies compare their treatment against another active treatment.

Borderline patients are being identified for treatment studies by the mixture of symptoms, attitudes, and behaviors listed as criteria for the disorder in DSM-III and its successors. There are at least two major problems with the current practice of using DSM-IV diagnoses to select presumed homogeneous patient groups for treatment intervention: (a) the polythetic diagnostic system allows for extensive heterogeneity at the symptom level represented in the diagnostic criteria; and (b) the diagnostic criteria are not stable across time. These surface criteria are variable over time, as some individuals at this level of analysis have the diagnosis at one point in time and not at another (Zanarini et al., 2003). What remains stable is their relative rank among the group, and their work and social functioning. Further, the symptom criteria in DSM-IV have an unknown relationship to cognitive, neurocognitive, and affiliative functions of these patients that is likely to guide treatment planning in the future. At the latter, more basic level of description and understanding, borderline patients are characterized by preponderance of negative affect, defective control of affect expression, and confused and conflicted representation of self and others. It is quite possible that the brain functions, neurochemistry, and neurocognitive functioning of these patients will provide more important ways to classify these patients, and to identify both targets for treatment and subgroups of patients for more specific treatments.

As long as the DSM-IV criteria are used to select patient groups for empirical treatment research without supplemental descriptions of the patients, the efforts to find a clear relationship between a defined intervention and its effects on a homogeneous group of patients with clear goals for treatment will be compromised, if not totally obscured. A central question is which of the constructs that are heterogeneous among these patients is crucial to treatment elements and long-term effects.

In summary, psychotherapy research focused entirely on group mean scores before and after a specified treatment yield little information. Psychotherapy research can be a method of empirically examining and teasing out the various elements and aspects of a particular disorder. In turn, by separating out the elements of a disorder, treatment can be developed to target the various domains of the disorder that may respond differentially to different treatments. In reviewing existing treatment research on personality disorders, Crits-Christoph, Cooper, and Luborsky (1998) stated that future research must match the focus of the treatment to the nature of the disorder, and provide measures of change across time. The form and content of psychotherapy for individuals with personality disorders in general and with BPD more specifically is in a state of treatment development rather than consolidation.

### **WORKING MODEL OF BPD**

Central to Kernberg's conceptualization of borderline personality organization (TFP model of treatment) are mental representations that are derived through the internalization of attachment relationships with caregivers. The degree of differentiation and integration of these representations of self and other, along with their affective valence constitutes personality organization (Kernberg, 1984). Borderline personality can be thought of as a severely disturbed level of personality organization, characterized by the use of primitive defenses (e.g., splitting, projective identification, dissociation), identity diffusion (e.g., inconsistent view of self and others), and deficits in reality testing (e.g., poor conception of one's own social stimulus value).

Our current working model of BPD is an incorporation of the psychodynamic conceptualization of Kernberg concerning identity diffusion, and the more empirically grounded conceptions of negative affect, self-regulation (constraint and effortful control), and affiliative bonding (Clarkin & Posner, in press; Posner et al, 2003; Depue & Lenzenweger, 2001). This conceptualization of the disorder and its major components informs baseline data collection and areas of assessed change in treatment.

We do not assume that a temperamental disposition of negative affect and poor effortful control will result in BPD. Rather, it is assumed that these temperamental dispositions in the context of an environment involving early separations, physical or sexual abuse, and parental neglect can lead to identity diffusion and impulsive, self-destructive behavior. Other neurobehavioral systems could also interact with the basic high negative affect/low control (constraint) to potentiate the expression of a BPD-prone temperament (Depue & Lenzenweger, 2001).

### **AFFECT**

Negative affect, especially hostility and aggression, with relatively minimal positive affect is an essential aspect in understanding the individual with BPD (Kernberg, 1984; Depue & Lenzenweger, 2001). Negative affect invades the information processing of the individual (Silbersweig et al., 2001) and the organization of the individual's interpersonal and personal experience.

### **SELF-REGULATION**

A second central feature of borderline pathology is poor self-regulation. This relative inability to self-regulate is manifested in impulsive behaviors, including impulsive self-destructive behaviors, and difficulties in regulating affect. The construct of impulsivity has been defined differently in a variety of studies, involving the following elements: (a) rapid, unplanned reactions to stimuli; (b) decreased sensitivity to negative consequences of behavior; and (c) lack of regard for long-term consequences of behavior (Moeller, Barratt, Dougherty, Schmitz, & Swann, 2001).

Impulsivity or impulsive aggression are considered to be underlying dimensions in BPD (Siever & Davis, 1991; Zanarini, 1993; Links, Heslegrave, & van Reekum, 1999). In a stepwise, multiple-regression model, the impulse action score from the Diagnostic Interview for Borderline Personality

Disorder (DIB) best predicted borderline psychopathology at follow up (Links et al., 1999). Impulsivity combined with other factors has been related to suicidal behavior in BPD patients. For example, Soloff, Lynch, and Kelly (2002) found impulsive actions, comorbid antisocial personality disorder, and depression related to a history of suicidal behavior in BPD patients. In a diagnostically mixed group of patients, aggression and impulsivity were higher in suicide attempters, compared with those without suicide attempts (Mann, Waternaux, Haas, & Malone, 1999).

There is evidence of the link between impulsivity and underlying biological systems (Depue & Lenzenweger, 2001). Both impulsive aggression and affective instability show a stronger familial relationship than the diagnosis of BPD itself (Silverman et al., 1991). In twins, impulsivity and affective instability are heritable (Torgersen, 1984; Torgersen et al., 2000). Biological, neuroendocrine, and imaging studies provide evidence for the involvement of serotonergic activity in impulsive aggression (Coccaro et al., 1989; Siever & Trestman, 1993; Gurvits et al., 2000).

Affect dysregulation or emotional instability has been described as involving unpredictability of responses to stimuli, increased lability of baseline, unusual intensity of responses, and unusual responses (Spoont, 1996), all characteristics of a poorly constrained biobehavioral regulatory system (Mandell, Knapp, Ehlers, & Russo, 1984; Spoont, 1992). Patients with affective disorders display dysregulation of positive affectivity (Depue & Spoont, 1986; Spoont, 1992), whereas BPD patients have explicit dysregulation of negative affect (Spoont, 1996). It is hypothesized that BPD patients have elevated levels of negative affect in conjunction with a nonaffective constraint system that is less effective (Depue & Lenzenweger, 2001; Spoont, 1996).

The evolution of self-regulation in the developing child is central to understanding both the development of normal personality and its organization and personality pathology (Posner & Rothbart, 2000). Studies suggest that effortful control has a developmental course in which some children by age 3 years are capable of using executive control systems to efficiently make choices in conflict situations, especially those involving the suppression of dominant response modes. Effortful control is related to approach of situations that involve aversive stimuli and avoidance of situations that may give immediate reward. This capacity of inhibiting a predominant response in favor of a subdominant one is considered a form of behavioral self-control, and, therefore, a mechanism of self-regulation, in that the individual has the ability to control arousal and response.

The constructs of arousal, affect, and self-regulation are central to a number of conceptualizations of human psychological development (Derryberry & Rothbart, 1988). Both motivational systems (including appetitive and approach behavior, fearful behavior, frustrative and aggressive behavior, and affiliative and nurturing behavior) and attentional systems are seen as contributors to the psychological development of the individual. For example, the shifting of attention from a negative to a positive stimulus can help soothe a distressed child (Derryberry & Rothbart, 1988). The critical role of effortful control in socialization is reflected in research showing that effortful control is positively related to conscience development (Kochanska,

1995; Kochanska, Murray & Coy, 1997) and negatively related to the expression of aggression (Rothbart, Ahadi, & Hershey, 1994).

#### EVOLVING CONCEPTUALIZATION OF SELF AND OTHERS

Many (Bowlby, 1969, 1973, 1980; Kernberg, 1996) have postulated that the developing child evolves a working conceptualization of self and others, especially under the influence of affectively charged interactions with others that are comforting and pleasurable or aversive and dangerous. It is from these early interactions that the developing individual builds an internal model of self and others that subsequently provides expectations in later interactions with others.

Influenced by temperamental disposition, environmental (traumatic) events or a combination of both, a secondary level of intrapsychic organization takes place that determines the clinical syndrome of identity diffusion (Kernberg, 1996) that is reflected in the DSM-IV diagnostic criteria for BPD. Identity diffusion is characterized by a lack of integration of the concept of self and the related concept of significant others. These poorly integrated conceptions of self and others are derived from an excessive splitting, often referred to as dichotomous thinking, or primitive dissociation between positive and negative affective investment of self and other representations, leading to the chronic deficiency in the assessment of self and self-motivations. The clinical characteristics of identity diffusion are chronic immaturity in judgments of emotional relationships, difficulties in the commitment to intimate relations and disturbances in sexual and love life, and problems with commitment to work or to a profession.

Recently, clinical researchers and theorists have understood fundamental aspects of BPD such as unstable, intense interpersonal relationships, feelings of emptiness, bursts of rage, chronic fears of abandonment and intolerance for aloneness, as stemming from impairments in the underlying attachment organization (Blatt, 1995; Fonagy et al., 1996; Gunderson, 1996).

#### **TRANSFERENCE-FOCUSED PSYCHOTHERAPY**

Among several other promising treatment approaches to BPD is the object relations approach based on Kernberg's clinical theorizing (Kernberg, 1984; 1996). Kernberg and colleagues call this treatment transference-focused psychotherapy (TFP; Clarkin et al., 1999) because it relies principally on the techniques of clarification, confrontation, and interpretation within the evolving transference relationship between the patient and the therapist. With the assistance of an NIMH treatment development grant (awarded to John Clarkin), we have provided evidence that TFP is effective using patients as their own controls (Clarkin et al., 2001), and in comparison to a TAU BPD group (Levy, Clarkin, Foelsch, & Kernberg, 2003).

The major goals of TFP are better behavioral control, increased affect regulation, more intimate and gratifying relationships and the ability to pursue life goals. This is believed to be accomplished through the development of integrated representations of self and others, the modification of primitive de-

fensive operations and the resolution of identity diffusion that perpetuate the fragmentation of the patient's internal representational world. In this treatment, the analysis of the transference is the primary vehicle for the transformation of primitive (e.g., split, polarized) to advanced (e.g., complex, differentiated, and integrated) object relations.

TFP begins with explicit contract setting that clarifies the conditions of therapy, the method of treatment, and the respective roles of patient and therapist. The primary focus of TFP is on the dominant affect-laden themes that emerge in the relationship between borderline patients and their therapists in the here and now of the transference. During the first year of treatment, TFP focuses on a hierarchy of issues: (a) the containment of suicidal and self-destructive behaviors; (b) the various ways of destroying the treatment; and (c) the identification and recapitulation of dominant object relational patterns, as they are experienced and expressed in the here and now of the transference relationship.

Within psychoanalysis, the TFP approach is closest to the Kleinian school (Steiner, 1993), which also emphasizes a focus on the analysis of the transference. However, TFP can be distinguished from Kleinian psychoanalysis in that in that TFP is practiced twice per week and includes a more highly structured treatment frame by emphasizing the treatment contract and an established set of priorities on which to focus (e.g., suicidality, treatment interfering behaviors, etc.). The role of the treatment contract and the treatment priorities both go beyond that found in more typical psychoanalytic psychotherapy or psychoanalysis, including Kleinian psychoanalysis. In addition, transference interpretations are consistently linked with both extratransference material and, importantly, long-term treatment goals (e.g., better behavioral control). Although TFP adheres more strictly to technical neutrality than many psychodynamic treatments (Buie & Adler, 1982; Waldinger & Gunderson, 1989), in contrast to Kleinian approaches, the TFP approach is a highly engaged, more talkative, and interactive. Additionally, technical neutrality is de-emphasized to the extent required to maintain structure. TFP also differs from other expressive psychodynamic approaches with a persistent focus on the here and now, a focus on the immediate interpretation of the negative transference, and an emphasis on interpretation of the defensive function of idealization, as well as a focus on the patients' aggression and hostility. In contrast, many other psychodynamic approaches view the central task, particularly of the early phase, as primarily supportive and relationship building (Buie & Adler, 1982; Chessick, 1979; Masterson, 1981) and foster idealizing aspects of the transference (Buie & Adler, 1982; Chessick, 1979). Some recent articulations of psychodynamic approaches de-emphasize working in the symbolic realm, noting that the BPD patient's ability to understand and use interpretations varies widely, and instead stress supportive, behavioral, or psycho-educational techniques (Rockland, 1992; Gunderson, Berkowitz, Ruiz-Sancho, 1997; Gunderson & Wheelis, 1999).

In relation to DBT, some of the most salient differences between the two treatments center on the frame. The TFP therapist is considered unavailable between sessions, whereas in DBT the patient is encouraged to phone the individual therapist between sessions. Another difference is the TFP empha-

sis on technical neutrality versus the DBT validation, coaching, and cheer-leading strategies. Despite these differences, both TFP and DBT have in common a firm, explicit contract, a focus on a hierarchy of acting out behaviors, a highly engaged therapeutic relationship, and a structured disciplined approach.

In terms of patient selection, Kernberg (1984) suggests that borderline patients with narcissistic, paranoid, and antisocial personality disorder, termed *malignant narcissism*, would be more difficult to engage in treatment and have a poorer prognosis. Others have suggested that TFP is designed only for those patients with sufficient motivation, intelligence, and psychological mindedness (Swenson, 1989). Further research is needed in understanding patient prognostic factors for TFP. In the current study patients were not assessed for inclusion based on any of these variables or any other signs of good prognosis, nor were patients excluded because of indicators of poor prognosis.

How does TFP relate to the model of BPD with its emphasis on the constructs of negative affect, effortful control and constraint, and conception of self and others? TFP focuses its therapeutic efforts on the relationship between therapist and patient in which the patient demonstrates by words, feelings, and actions his or her conceptualization of the other (therapist) in relationship to conceptualization of self with associated affects. Through the clarification and understanding of the expectations and distortions that the patient brings to that relationship, it is thought that the patient slowly evolves a more integrated sense of self and realization that expectations of others based on prior experiences are often inaccurate. It is hypothesized that through the more coherent conceptualization of self and others, the patient achieves control over affects, especially as they are related to interpersonal interactions.

#### **ORGANIZATION OF OUR RESEARCH EFFORT**

Our psychotherapy study is used as a platform on which we recruit, assess, and provide treatment for patients with BPD. On this basic structure, we have built a procedure that provides data on pathology and neurocognitive functioning. The primary purpose of the study is to examine the efficacy of three standard treatments for BPD of 1-year duration. First, a cognitive-behavioral treatment called DBT (Linehan, 1993), was compared with a psychodynamic treatment called TFP (Clarkin et al., 1999) and with a supportive treatment (Rockland, 1992), used to contrast with these two active treatments as a control for attention and support. Secondary and tertiary purposes were: (a) to create a database of well-characterized patients in order to examine patient personality and neurocognitive variables that predict treatment response as well as the subsequent naturalistic course of the disorder; and (b) to examine the processes and mechanisms of change during the course of psychotherapy.

This treatment study of BPD patients is unique and goes beyond existing treatment studies in a number of ways: (a) this is the first BPD treatment study to include males; (b) this study includes not only borderlines with suicidal behavior, but all participants who meet the diagnosis; (c) this is the

first study to compare two forms of active treatment to a supportive treatment; (d) therapists are not located at a university clinic or hospital but in their private offices in the community; (e) medication is carefully delivered, when needed, by an algorithm; patients with and without medication provide a contrast in the data analysis; and (f) outcome measures involve not only symptom change, but also changes in organization of the personality at the psychological and neurocognitive levels.

## PROCEDURE

Patients were assessed with a number of semistructured interviews and self-report instruments to establish the diagnosis. Diagnostic instruments included the Structured Clinical Interview for DSM-IV Axis I Disorders (SCID-I; First, Gibbon, Spitzer, & Williams, 1996) and the International Personality Disorder Examination (IPDE; Loranger, 1999). Assessment instruments were chosen to reflect important domains that might show change in treatment such as symptoms, behaviors, attention, positive and negative affect, affect regulation, work and social functioning, identity, and identity diffusion.

Patients were also assessed using neurocognitive tasks known to tap executive functioning and attention (e.g., the Attention Network Task, the Wisconsin Card Sort Test, the Continuous Performance Test). A subgroup of patients underwent functional imaging (fMRI) before and after 1 year of treatment. On completing the assessment patients were randomized to one of the three treatment conditions for 1-year outpatient treatment.

*Patients.* The BPD patients were recruited from New York City and adjacent Westchester County, referred by private practitioners, clinics, family members and self-referred. To foster subject retention over the duration of the study, we recruited patients who lived within a 50-mile radius of the study site. Participants were males and females between the ages of 18 and 50 years. Patients with comorbid schizophrenia, schizoaffective disorder, bipolar disorder, delusional disorder, delirium, dementia, amnesic and other cognitive disorders were excluded because of the influence of brain pathology and thought disorder on the ability to provide meaningful self-report data and complicated response to treatment. The exclusion of psychotic patients from a study of personality disorder is a common research standard at many centers and allows for a “cleaner window” on personality pathology. We include patients with other comorbid Axis I disorders, as issues of comorbidity across time with these Axis I disorders is a focus of investigation.

We were clinically referred and interviewed 207 individuals for at least one evaluation session. Of these 207 participants, 109 were eligible for randomization. Most exclusions were due to the absence of five criteria for BPD ( $N = 34$ ). The second most common reason was age ( $N = 30$ ), followed by nine patients who met criteria for current substance dependence, eight patients who met criteria for schizophrenia or a schizophrenic disorder, eight patients who dropped out of the evaluation process, six patients who met criteria for bipolar I disorder, two patients who had IQs lower than 80, and one patient who had a scheduling conflict. Of the 109 patients eligible

for randomization, 90 were randomized to treatment. There were no differences in terms of demographics, diagnostic data, and severity of psychopathology between those patients randomized to treatment and those that were not.

#### TREATMENT AND THERAPISTS

Patients were randomized to one of the three treatment conditions for 1-year outpatient treatment. Two treatments, a cognitive-behavioral treatment called DBT (Linehan, 1993), and a psychodynamic treatment called TFP (Clarkin et al., 1999), have received preliminary empirical support for their effectiveness. The mechanisms of change in these two treatments are conceived in very different ways. DBT is hypothesized to operate through the learning of emotion regulation skills in the validating environment of the treatment (Linehan, 1993). TFP is hypothesized to operate through the integration of conflicted, affect-laden conceptions of self and others via the understanding of these working models as they are actualized in the here-and-now relationship with the therapist. A third treatment, called supportive treatment (Rockland, 1992), is used in contrast to these two active treatments as a control for attention and support.

Therapists in each of the three treatment conditions were selected based on prior demonstration of competence in the treatment. In order to ensure ongoing therapist adherence and competence, all treatments were supervised on a weekly basis by experts in each treatment. Barbara Stanley, PhD, an acknowledged expert in DBT and NIMH funded researcher in this area, is the supervisor of DBT. Otto Kernberg, a psychoanalyst of international stature, is the supervisor of TFP. Ann Appelbaum, expert therapist, is the supervisor of the supportive treatment.

#### MONITORING OF TFP, DBT, AND SPT

Treatment integrity was monitored in a number of ways. First, each treatment cell leader was responsible for recruiting therapists for their treatment cell. Therapists were known to the treatment cell leaders. Second, therapists in each treatment cell attended weekly group supervisions where treatment cell leaders were able to observe videotaped sessions. Feedback to therapists was provided by treatment cell leaders whenever a therapist fell below an acceptable level of either adherence to the manual or competence. When a therapist's ratings were consistently low for adherence, then ratings were made more frequently (approximately every 4 sessions) for the succeeding 3-month interval, and supervision focused on the difficulties identified by raters. Additional supervision was provided when either adherence or competence fell below acceptable levels. When a therapist fell below acceptable levels, no new cases were assigned to them. Third, we asked treatment cell leaders to rate and rank the therapist on each case. Finally, both expert raters and independent naive raters evaluated videotaped TFP, DBT, and SPT sessions for adherence and competence at regular intervals. Raters assessed therapists for adherence and competence on every 10 sessions, over

two consecutive sessions, beginning with session number 10. Adherence and competence rating were averaged over these sessions.

#### DOMAINS OF OUTCOME

The domains of outcome in a psychotherapy study are determined by the goal of the treatment (e.g., what patient changes does the therapy intend) and the hypothesized mechanisms of change (e.g., predictors, mediators, and moderators). Thus, in our ongoing treatment study we assess the influence of treatment in reference to the central temperamental features of negative affect (i.e., lowered negative affect) and effortful control (i.e., increased effortful control/constraint), in addition to the changes in the BPD Axis II criteria themselves. The advantage of assessing change in these two key temperamental dimensions is their close relationship to underlying neurobehavioral systems of the organism on the one hand, and their obvious impact on everyday functioning on the other. We postulate that decrease in negative affect (or change in the balance of positive and negative affect) and increase in effortful control would be features of any successful treatment of BPD patients. Focus on these variables provides a context in which we can judge the relative success of different types of psychosocial treatment. It also provides us with a unique opportunity to determine if there are specific gains that maintain or accrue with each of the three treatments. For example, there may be notable gains associated with one of the three treatments in one area of psychosocial functioning, which are themselves seen in correlation with changes in negative affect or effortful control. We also assess the third crucial variable of conceptualization of self and others, as it is through the conceptualization of the interpersonal world that the individual controls and modulates affect.

#### **PLANNED STATISTICAL ANALYSES: PRECISION AND SENSITIVITY FOR DETECTING CHANGE**

Most psychotherapy studies are underpowered (especially those that compare one or more active treatments), do not have focused predictions regarding outcome, and use techniques (repeated-measures multivariate analysis of variance [MANOVA]) that are inappropriate for detecting change in multiwave data. Given the limitations of the amount of funding provided by the BPDRF for this initial study of treatments in BPD, we developed a study protocol that would contrast three treatments in 90 patients across time (12 months). Our design, therefore, included the use of multiple data collection points and data-analytic procedures that would maximize the power to detect change in our patients, in relation to the treatment modalities tested.

The variables of primary interest in this psychotherapy outcome study are continuous in nature and each of these variables was assessed at four time points, namely at baseline, 4 months, 8 months, and 12 months (termination of treatment). Thus, each study subject will have been measured on the same variables at roughly the same intervals at four points in time. The data for this study will be analyzed principally from two different perspectives. The first perspective, which represents a more traditional (pre- vs.

posttreatment) approach with the added precision of contrast analysis, will involve the evaluation of treatment gain scores, which will simply be the amount of improvement observed from baseline to the 12-month assessment on a given dimension of interest (e.g., BPD symptoms, negative affect, impulsivity, self-destructive behaviors, etc.). These “gain scores,” which will be adjusted for initial level on the variable of interest at baseline, will then be compared across the three treatment modalities through a series of focused contrast analyses within an analysis of variance (ANOVA) framework (Rosenthal, Rosnow, & Rubin, 2000; Rosenthal & Rosnow, 1991). Our data configuration is ideally suited for the a priori specification of theory-guided contrast analyses. For these one-way ANOVA analyses (with focused contrasts), the patients will be subdivided across a between-subjects (B-S) factor with 3 levels (3 types of treatment). Thus, the one-way ANOVA will turn into what is essentially a single degree of freedom test (in the numerator), tested with the *t*-statistic, and yielding an “effect-size *r*.” It is noted that rather than using a traditional “unfocused” approach to ANOVA, the focused contrast analysis approach reduces the degrees of freedom, which has the net effect of both a more powerful and more precise analysis (Rosenthal & Rosnow, 1991; Rosenthal et al., 2000). Power analyses suggest that, within a contrast analysis framework, the present study should have adequate power (80% or more) to detect modest effects, even with some attrition in the sample.

The second approach to the analysis of change in the dimensions of interest for the patients in this study will involve the application of state-of-the-art individual growth curve analysis. Analysis of individual growth curves will be done via a multilevel modeling approach (Goldstein, 1995) (also known by some as hierarchical linear modeling [Raudenbush & Bryk, 2001]). In this powerful statistical framework, which is ideally suited to multiwave data, we will investigate our continuous dependent variables in a model that casts them as Level I variables organized by time (i.e., nested within persons) and Level II variables (between persons) which include the nesting variables, such as treatment group and sex. The individual growth analyses for the data from the patients will proceed in a sequential fashion: (a) estimation of unconditional growth models with intervals between assessments, wherein time is defined from study entry and intervals (months) will be centered on the individuals’ means; (b) estimation of a Level II model that includes age at entry to study in the prediction of initial status (intercept, “elevation”) and change (slope, “change”) values retained from Level I; and (c) estimation of a Level II model that includes age at entry, sex, and treatment group. Additional Level II models will also be estimated after these basic models and they shall typically include baseline measures (e.g., temperament constructs) as time-invariant predictors at Level II. The four assessment points that we will have for each of the dependent variables of interest will allow us to fit not only linear growth models, but also quadratic models. The multilevel modeling approach is statistically superior to a repeated-measures MANOVA (and ANOVA) approach that is now regarded as outmoded by most longitudinal methodologists (Singer & Willett, 2003). The multilevel modeling approach can handle missing data very effectively and does not require that all subjects have complete data at all assessment

waves (unlike MANOVA). The individual growth curve analytic approach has recently been applied to longitudinal data on personality disorders and this analysis yielded insights into the stability and change of PD features over time in a manner that could not have been achieved with repeated measures MANOVA (Lenzenweger, Johnson, & Willett, submitted).

#### PRELIMINARY DATA ON PATIENT CHARACTERISTICS

We review the preliminary data on patient demographics, the crucial areas of negative affect, affect modulation, conception of self and others, and environmental variables. These theoretical crucial patient variables will be important correlates of patient behavior in the randomized treatment study.

The patients were predominantly female (92%), with a mean age of 31 years. They were ethnically diverse and patients were 62% Caucasian, 10% African American, 9% Hispanic, 5% Asian, and 8% other. They had first contact with psychiatric treatment at a mean age of 17 years. The mean Global Assessment of Functioning (GAF) score at the time of admission into the study was 50, indicating a substantial degree of symptoms and disrupted functioning. Whereas all patients met criteria for BPD, they were heterogeneous in terms of co-existing personality disorders and Axis I conditions. In terms of suicidal behavior, 57% manifested prior suicidal behavior, 64% manifested prior parasuicidal behavior, and 17% ( $N = 15$ ) had a history of neither.

#### **CHALLENGES ENCOUNTERED IN THE DESIGN AND EXECUTION OF A THERAPY STUDY OF BPD**

In any empirical study of psychotherapy there are compromises that divert from an ideal design. We think it is helpful to review some of the design issues that we faced, as others could confront them and may profit from our experience.

First, the three treatments were delivered with attention to preserving the integrity of each treatment under investigation (Elkin, Pilkonis, Docherty, & Sotsky, 1988). Thus, the frequency of contact between patient and therapist, the nature of the treatment, and the manner in which the treatment was ended was not strictly equalized across the three treatment conditions, but rather delivered in accordance with the specific definition of each of the three treatments.

We are aware, therefore, that the number of hours of contact between patients and therapists varies between the three treatment conditions. Supportive treatment is one 50-minute contact per week, TFP is two 50-minute contacts per week, and DBT is 1 hour of individual therapy contact and one and one-half hours group treatment contact per week. In addition, the patients in DBT are encouraged to telephone the therapist between sessions. We have tracked the contact time in each treatment condition. However, attempts to equalize the contact time between the three treatment conditions would threaten the integrity of the treatments. We delivered the treatments as designed, and will do a cost analysis of the treatments to compare the cost to the benefit ratio of each.

Second, allegiance effects were a design issue. Those researchers with a passionate interest and dedication to a particular approach to therapy are the likely ones to have the energy and enthusiasm to investigate that treatment in some form of randomized clinical trial. This is both humanly necessary and a problem in the interpretation of the outcome of such studies (Luborsky et al., 1999).

We attempted to control potential allegiance effects by several ways. First, we placed randomization to treatment in the hands of a researcher in our department who was independent of the study and not informed about our study hypotheses. Secondly, patients were not treated within the physical environment of the medical school setting that was the site of assessment and randomization. Rather, patients were treated in the private offices of therapists who were committed to one of the three treatments under study.

Third, the manner in which patients are recruited, and the way they are handled between recruitment and the initiation of the treatment can have significant effects on the results of the study, including dropout rate and the generalizability of the results.

Fourth, it is common in randomized clinical trials of the treatment of symptom disorders to have as the primary outcome measure symptoms that are the target of change. Often, the outcome domains are not extensive and are mainly related to symptoms. Even in the treatment of personality disorders, such as BPD, the main domains of measurement involve symptoms such as suicidal behavior and depression (Linehan et al., 1991). It is customary for statistical reasons to state a few primary areas of change in the design. Whereas this design issue is understandable, we think that the domains of change must be expanded to understand the nature of the pathology in interaction with the nature of the treatment, and to understand long term benefits of the treatments. As described earlier in this article, our model of borderline personality pathology suggests that negative affect, effortful control, and conceptualization of self and others are crucial elements in the pathology, and, therefore, foci for change in treatment. This conceptualization would indicate that these constructs be measured pre and post treatment.

Because different treatments have diverse treatment foci, while at the same time attempting to change the same symptom complex, we thought it would be important to measure constructs seen as mechanisms of change or mediating variables in the treatments, to be measured along with the symptom outcomes. In the context of validation, DBT posits the education of the patient in the use of skills that should lead to the reduction of suicidal behavior, control of affect, and more prosocial behavior. TFP attempts to modify suicidal and self-destructive behavior through the modification of internalized conceptions of self and others that are hypothesized to be polarized and dysfunctional in the borderline patient. In short, we anticipate that different treatments will affect different domains of functioning in these BPD patients; we do not expect all three treatment modalities to affect all aspects of BPD symptomatology, personality functioning, and behavior outcomes comparably.

Fifth, it is often assumed that the type of treatment provides the specific effect, and that therapists delivering a specific type of treatment are adherent

and competent, and thus do not create a variable influencing results. This assumption of therapist uniformity has been questioned and most recently, Wampold (2001) has made extensive use of meta-analysis to demonstrate that therapist effects are more potent than brand of therapy effects.

Our approach was threefold: (a) to control for therapist adherence and competence by training before the initiation of the study; (b) ongoing supervision of all therapists during the study to ensure timely adherence and competence; and (c) sufficient numbers of patients per therapist to examine the data for therapist effects.

Sixth, we discussed in some detail the exact quantification of “one year” of treatment. Because there can be legitimate reasons to “suspend” treatment (e.g., patient or therapist medical illness) during the year following admission to the study, it was decided to define the treatment as 50 weeks of treatment exposure that could take place over a time period of up to 13.5 months. At the end of 1 year of treatment, the treatment (i.e., medication treatment and either supportive, TFP, or DBT) provided free of charge to the patient will end. The controlled part of the study will end at that time, and at that point the naturalistic follow up period will begin.

Seventh, borderline patients are extremely sensitive to issues of attachment and feared abandonment, and this applies to their treatment providers and to significant others in the environment. In order to control for the patients’ mindset regarding the availability of their study therapist, patients in all three treatment conditions were informed of the 1-year duration of treatment financed by the grant and free of charge to the patient. In this way, patients in all treatment conditions were faced with the dilemma of 1 year of predictable attachment to a therapist that would be potentially changed at a known date. In this way, we hope to disentangle the effects of the specific treatments, from the anticipation of duration of attachment to a known therapist.

Because these are very disturbed patients, it is not expected that their treatment will be completed at 1 year. However, the reality of the current health care system is that 1 year of treatment is more than what can usually be obtained. The rationale for follow up is to assess the maintenance of treatment gains. This will be a naturalistic follow up because some patients will continue with the study therapists, others will seek treatment elsewhere, and others will receive no further treatment.

Eighth, because all patients were provided with an evaluation by a psychiatrist and the prescription of medication if deemed appropriate by instruments and guidelines, we have a design in which some patients receive a combination of medication and one of three types of psychosocial treatment, and some patients receive no medication because it is deemed unnecessary. This creates a complicated research situation.

We considered several options. First, we could have included only borderline patients in the study that did not meet indications for medication, and compared three forms of treatment for those selected patients. We thought the price to pay for this design would be lack of external validity. A study of borderline patients limited only to those not in need of medication would not be representative of the majority of borderline patients. Another design alternative would have been to select a subset of borderline patients who

could be adequately treated with one class of medication (e.g., those who could be treated with a particular SSRI). This option, too, would have reduced generalizability of the study results.

### THE NEAR FUTURE: TREATMENT DEVELOPMENT

As the phenomenology and mechanisms of borderline personality pathology become clearer, it provides an opportunity to either modify existing approaches to the specifics of the pathology and/or important subgroups, or to develop new treatments that address the issues. In our on-going randomized clinical trial, we will utilize contrast analyses to explore specific hypotheses concerning the relative efficacy of the three treatments in question, given our current understanding of the outstanding features of the patients' pathology. These findings may provide leads as to which treatments have the most impact on patient subgroups in terms of specific domains of change. All changes that appear after one year of treatment must be assessed for their durability over time in a longer-term follow up.

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