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Naturalistic Outcome of Case Formulation-driven
Cognitive-behavior Therapy for Anxious Depressed Outpatients

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Abstract

This article describes a case formulation-driven approach to the treatment of anxious depressed outpatients and presents naturalistic outcome data evaluating its effectiveness. Fifty-eight patients who received case formulation-driven cognitive-behavior therapy (CBT) in a private practice setting were studied. All received individual cognitive-behavior therapy guided by a case formulation and weekly outcome monitoring; in addition, 40 patients received adjunct therapies, including pharmacotherapy, which were added as indicated by the case formulation and the results of weekly outcome monitoring. Patients treated with case formulation-driven CBT showed statistically and clinically significant changes in anxiety and depression that were generally comparable to those reported in published randomized controlled trials of ESTs for single mood and anxiety disorders. Findings support the proposal that anxious depressed patients who have multiple comorbidities and require multiple therapies can benefit from empirically-supported treatments guided by a case formulation and weekly outcome monitoring.

Naturalistic Outcome of Case Formulation-driven
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A major challenge confronting our field is that large numbers of mental health professionals do not use empirically-supported therapies in their work (Barlow, Levitt, & Bufka, 1999). This phenomenon is particularly disturbing in view of the development of empirically-supported therapies (ESTs) for many disorders and the ready availability of the published protocols for many of these ESTs.

Despite the advances our field has made in developing empirically-supported treatments (ESTs), several barriers impede clinicians from using them in their day-to-day clinical work. One set of barriers to the use of ESTs arises from the fact that most of the currently-available protocols target single disorders (cf. Beck, Rush, Shaw, & Emery, 1979; Craske, Antony, & Barlow, 1997; Foa & Rothbaum, 1998; Steketee, 1993), whereas most patients seen in routine clinical practice have multiple disorders. This obstacle is particularly salient in the context of the mood and anxiety disorders, which are more often comorbid than not (Sanderson, DiNardo, Rapee, & Barlow, 1990) and which make up a large proportion of the cases seen in routine clinical practice. The clinician who is using single-disorder protocols to treat a multiple-disorder patient certainly has the option to treat the multiple disorders in sequence (Wilson, 1997). However, this approach is cumbersome and inefficient. Moreover, the single-disorder protocols do not provide the clinician with any guidance about which disorder of the multiple-disorder patient to target first.

Another barrier resulting, ironically, from the large number of available EST protocols is that the clinician who is treating patients who have mood and anxiety disorders is faced with the need to read more than a dozen substantial tomes. This workload is particularly burdensome in view of the substantial overlap among the protocols as a result of the fact that most of them share common theoretical underpinnings (Beck's cognitive theory and conditioning theories) and interventions (e.g., cognitive restructuring and exposure to fear-evoking stimuli).

Another challenge arising from the existence of multiple ESTs is the need for the clinician to choose from among several ESTs the one most likely to be helpful to his patient. For example, several ESTs are currently available for unipolar depression. Cognitive-behavioral ESTs include Beck's cognitive therapy, Lewinsohn's behavior therapy, behavioral activation (Martell, Addis, & Jacobson, 2001), behavioral marital therapy (Baucom, Shoham, Mueser, Daiuto, & Stickle, 1998) and, most

recently, to prevent relapse, mindfulness-based cognitive therapy (Segal, Williams, & Teasdale, 2002). The protocols themselves do not help the clinician choose which one to use for any particular patient.

Another obstacle to the use of ESTs in routine clinical practice arises from the fact that the protocols typically entail 12 to 20 weeks of treatment. For example, the protocol for Beck's cognitive therapy for depression calls for 18 to 20 sessions (Beck et al., 1979). However, evidence that depressed patients who do not show a substantial response to cognitive therapy after three to four sessions are unlikely to respond at all (Ilardi & Craighead, 1994) indicates that providing the full 20-session treatment to a patient who shows an initial poor response is probably a waste of time. Clinicians who treat patients with mood and anxiety disorders need methods that allow them to make prompt changes in their treatment plans when the patient's symptoms do not respond to the therapist's initial efforts. No currently-available EST protocol provides this degree of clinical flexibility.

The single-disorder protocols also do not provide the clinician with any guidance about combining therapies. Many patients treated in clinical practice receive multiple therapies, including pharmacotherapy as well as other psychosocial therapies (e.g., couple therapy, a twelve-step group, or a meditation class). The therapist needs a systematic way of evaluating whether a patient's multiple therapies constitute a coherent treatment plan.

Thus, even though--and to some degree *because*--many protocols for empirically-supported treatments are available, the practitioner can find it challenging to use these protocols to treat multiple-problem patients in a systematic, evidence-based, and efficient way (Sackett, Haynes, Guyatt, & Tugwell, 1991). Another way of describing the problem is to say that the clinician faces the challenge of using *nomothetic* data to answer *idiographic* questions (Howard, Moras, Brill, Martinovich, & Lutz, 1996). The EST answers a *nomothetic* question about the *average patient's* response to the treatments being studied. However, the clinician typically seeks the answer to *idiographic* questions, such as "What intervention is likely to be most helpful to this *particular* patient at this time?"

To address all of these obstacles to the use of the EST protocols in clinical practice, the therapist needs a framework for clinical decision-making that subsumes the ESTs themselves. To obtain such a framework, we borrowed from multiple sources, especially behavioral assessment (Haynes & O'Brien, 2000), to develop a case formulation-driven approach to treatment.

Case Formulation-driven Cognitive-behavior Therapy

In a case formulation-driven approach to cognitive-behavior therapy, the therapist develops an individualized case formulation and uses it to select and adapt interventions from empirically-supported cognitive-behavioral protocols to fit the case at hand. The therapist also relies on a hypothesis-testing approach to treatment in which the patient and therapist set measurable treatment goals, monitor the process and outcome of treatment at each session, and make adjustments as indicated by the results of monitoring.

Overview of the Present Study

This study describes a case formulation-driven approach to CBT and reports on results of an uncontrolled trial of 58 private practice patients that was carried out to provide an initial test of the hypothesis that it can provide effective treatment for anxious and depressed outpatients in private practice. We tested the hypotheses that case formulation-driven CBT produces *statistically significant* and *clinically significant* change in anxious depressed outpatients.

To address *statistically significant change*, we tested the hypotheses that patients treated with formulation-guided treatment would show statistically significant and large changes in symptoms of anxiety and depression that would be comparable to changes in anxiety and depression reported in published studies of ESTs for single mood or anxiety disorders. In the comparison studies of the ESTs, patients received treatment that was guided by a protocol for one therapy (e.g., cognitive therapy [CT]) or a combined therapy (CT plus pharmacotherapy) that was specified in advance and that targeted one disorder.

To address *clinical significance*, we tested the hypotheses that large numbers of patients receiving formulation-guided treatment would show *improvement* and *recover* from their symptoms of anxiety, depression, and panic, and that rates of improvement and recovery in formulation-guided treatment would be comparable to those seen in published studies of the ESTs for pre-specified treatments for single disorders. To establish normative scores on our measures of anxiety and depression, we obtained comparison data on these measures from a community (student) sample.

Method

Participants

Selection criteria for patients. Fifty-eight patients who received treatment at the San Francisco Bay Area Center for Cognitive Therapy provided data for this study.¹ To select these patients, approximately 439 charts were screened; this was the complete set of closed cases treated by the first author (J. B. P.) and the therapists she supervised at the San Francisco Bay Area Center for Cognitive Therapy. Patients were selected for

the study if they met the following criteria: (1) symptoms of depression and anxiety had been monitored weekly using objective measures (patients were asked by their therapist to complete the measures if the patient suffered from clinically-significant symptoms that were the focus of treatment); (2) at least four sessions of data were available for measures of both anxiety and depression; (3) treatment was individual (i.e., not couple or group), and (4) the patient was aged 19 - 75 years. The most common reasons for excluding a case from study were that fewer than four measures of anxiety and depression were available, the patient sought treatment for problems other than depression or anxiety, or the patient completed only anxiety or depression scales but not both. Two patients whose diagnoses differed markedly from those of the remainder of the sample (schizoaffective disorder and multiple personality disorder) were also excluded.

Patient characteristics. The 58 patients (35 female) had a mean age of 36.4 years ($SD = 12.7$) and had completed an average of 14.3 years of education ($SD = 7.2$). Fifty-one were Caucasian, 2 were Asian, 2 were African American, 2 were Hispanic, and 1 was of mixed race. Twenty-eight were single (never married), 26 were married, 1 was separated, and 3 were divorced.

Psychiatric diagnoses were made at the beginning of treatment on the basis of a psychiatric interview by the clinician, who used the most current version of the *Diagnostic and Statistical Manual of Mental Disorders* (American Psychiatric Association, 1987, 1994) available at the time the patient was treated. All patients received a primary diagnosis of a non-psychotic mood disorder, an anxiety disorder, or both, and endorsed symptoms of both anxiety and depression on self-report inventories (Beck Depression Inventory and Burns Anxiety Inventory).

Forty patients had at least one mood disorder and at least one anxiety disorder, 10 patients had one or more mood disorders, and eight had one or more anxiety disorders. Of those who had mood disorders, 28 had major depressive disorder, 10 had dysthymia, 10 had major depressive disorder and dysthymia, one had depressive disorder-not otherwise specified, and one had cyclothymia. Of those who had anxiety disorders, 14 had generalized anxiety disorder (GAD), 10 had social phobia, seven had panic disorder with agoraphobia, four had obsessive compulsive disorder (OCD), three had panic disorder without agoraphobia, one had post traumatic stress disorder (PTSD), two had GAD and social phobia, two had OCD and social phobia, one had OCD and panic with agoraphobia, one had OCD and panic without agoraphobia, one had PTSD and panic with agoraphobia, one had PTSD and panic without agoraphobia, and one had social

phobia and panic with agoraphobia. Six patients had comorbid somatoform disorders and 22 had Axis II disorders.

Community control sample. To obtain normative data on the Burns Anxiety Inventory and the Beck Depression Inventory against which patient data could be compared, these measures were administered to 132 college students. Students were University of California at Berkeley undergraduates who completed the Psychology Department's Research Participation Pool prescreening packet for class credit. The 132 students had a mean age of 22.0 years ($SD = 4.2$), was 77.9% female, and 38.3% Caucasian, 42.2% Asian and Asian-American, and 19.5% other ethnicities.

Measures

Symptoms of depression. Symptoms of depression were assessed with the Beck Depression Inventory (BDI; Beck et al., 1979), a widely-used, 21-item self-report measure that has been shown to be a reliable and valid tool to assess severity of depressive symptoms in psychiatric patients (Beck, Steer, & Garbin, 1988).

Symptoms of anxiety. Symptoms of anxiety were assessed with the Burns Anxiety Inventory (BURNS AI), a 33-item self-report inventory measuring 6 anxious feelings (e.g., anxiety, nervousness, worry), 11 anxious thoughts (e.g., feeling that you're on the verge of losing control) and 16 physical symptoms (e.g., a lump in the throat) (Burns, 1998). Each symptom was rated on a 0 to 3 scale ranging from 0 (not at all) to 3 (a lot). This measure has been demonstrated to have high internal consistency and convergent validity (Burns & Eidelson, 1998). We used the Burns Anxiety Inventory because we find its classification of anxiety symptoms as feelings, thoughts, or physical symptoms to be clinically helpful, it covers the full range of anxious symptoms we observe in our patients, and it is sensitive to change.

Panic attacks. The number of panic attacks occurring in the two weeks prior to beginning treatment and in the two weeks prior to ending treatment (as was done by Barlow, Craske, Cerny, & Klosko, 1989) was tabulated for patients who received a diagnosis of panic disorder with or without agoraphobia.

Treatment

Patients were treated using case formulation-driven cognitive-behavior therapy (Persons, 1989, 2005). All patients received individual cognitive-behavior therapy (CBT), and many also received other therapies (e.g., pharmacotherapy, twelve-step groups, couple therapy). Treatment was guided by a cognitive-behavioral case formulation and the results of weekly progress monitoring.

An individualized cognitive-behavioral case formulation was developed for each patient (for details, see Persons & Tompkins, 1997). The case formulation included a list of all of the patient's problems and disorders and a hypothesis about the mechanisms causing and maintaining the problems and disorders and accounting for the relationships among them. The therapist's first-line working hypotheses were based on the empirically-supported formulations (e.g., Beck's cognitive theory of depression) that underpin the empirically-supported therapies.

Treatment plans were based on evidence-based cognitive-behavioral theories and protocols, including (Beck, Emery, & Greenberg, 1985; Beck, Freeman, & Associates, 1990; Beck et al., 1979; Foa & Rothbaum, 1998; Heimberg & Becker, 2001; Lewinsohn, Hoberman, & Hautzinger, 1985; Linehan, 1993; Seligman & Johnston, 1973; Steketee, 1993). Typical interventions included self-monitoring, activity scheduling, cognitive restructuring, contingency management, social skills training, and exposure. Interventions were provided in the context of a structured therapy session and patients were expected to complete homework between sessions.

Measurable treatment goals were set and progress was monitored at every therapy session. Treatment goals for all patients were to reduce symptoms of anxiety and depression and also included other idiographic goals, such as improving interpersonal relationships or completing a dissertation.

The case formulation and the results of weekly progress monitoring helped the therapist make decisions about the order in which to target problems and disorders (Haynes & O'Brien, 2000), select treatment targets and interventions, and guide clinical decision-making generally. Weekly symptom monitoring helped the therapist identify poor treatment response promptly. If outcome was poor, the therapist attempted to revise the formulation of the case to generate some new intervention ideas, monitoring outcome continuously to determine if the change in treatment strategy was having the desired effect.

Patients received an average of 18 sessions of treatment, ranging from four to 54 sessions. Forty-nine patients were treated by the first author, a Ph.D. psychologist with nearly 20 years of experience. Nine patients were treated by three therapists with two to six years of experience and who had been trained and were supervised by the first author as they provided the treatment reported here. Thirty-eight patients (66%) received adjunct pharmacotherapy, and 11 (19%) also received another psychosocial treatment, which typically consisted of couple therapy, 12-step group treatment, or occasionally an insight-oriented individual psychotherapy.

Procedure

Clinicians wrote an individualized case formulation and treatment plan in the clinical record of each patient, typically after three to four sessions. Patients completed the Beck Depression Inventory (BDI) and the Burns Anxiety Inventory (Burns AI) in the waiting room before the therapy session; the therapist reviewed the scales and plotted the patient's scores on a graph at the beginning of the therapy session.

Patient data were culled from the clinical record by the first author after treatment was completed. Upon beginning treatment, patients gave written permission for their chart data to be used in a retrospective study that did not report any identifying information.

Results

Overview

This study tested the hypothesis that cognitive-behavior therapy (often in combination with adjunct therapies) guided by an individualized cognitive-behavioral case formulation and weekly symptom monitoring provides effective treatment for anxious depressed patients in routine clinical practice. More specifically, we tested the hypotheses that case formulation-driven CBT produces *statistically* and *clinically* significant change in anxious depressed patients treated in routine clinical practice and that these changes are comparable to changes produced by ESTs for single mood and anxiety disorders. We used the meta-analyses reported by Westen & Morrison (2001) and the review paper by Barlow & Lehman (1996) as our major sources of comparison data because they reviewed outcomes of ESTs for both mood and anxiety disorders and reported them in a way that facilitated comparisons with the private practice sample studied here.

In the evaluation of *clinically-significant change*, we examined both *improvement* and *recovery*, because a patient could improve but still be ill at the end of treatment (Beutler & Moleiro, 2001). To determine whether patients *recovered*, we compared their post-treatment outcomes with published reports of post-treatment outcomes of patients treated for depression in the ESTs and with scores on measures of anxiety and depression provided by a community sample of students.

We collected data from a student sample in order to obtain normative data on our anxiety measure (the Burns Anxiety Inventory; Burns AI). We selected students for the sake of convenience. To aid the interpretation of results on the Burns AI, we also collected the Beck Depression Inventory (BDI), for which extensive normative data are available, from the student sample.

In the analyses of change in symptoms of depression for the patients receiving formulation-guided treatment, we omitted 20 patients whose outcomes on the BDI were previously reported in Persons, Bostrom, and Bertagnolli (1999). In the analyses of changes in symptoms of anxiety we omitted two patients who were missing BURNS AI data (but who had completed the BDI). This left a sample size of 38 for the BDI and 56 for the BURNS AI.

Statistically Significant Change

Comparison of pre- and post-treatment scores. Patients who received case formulation-driven CBT showed statistically significant changes in symptoms of depression and anxiety over the course of treatment as measured by the Beck Depression Inventory (BDI) and the Burns Anxiety Inventory (BURNS AI). On the BDI, patients changed from a mean score at pre-treatment of 22.7 ($SD = 7.7$) to a mean score at post-treatment of 11.7 ($SD = 9.9$), $t(37) = 8.51$, $p < 0.001$. On the BURNS AI, patients changed from a mean score at pre-treatment of 38.1 ($SD = 17.8$) to a mean score at post-treatment of 20.7 ($SD = 16.9$), $t(55) = 7.22$, $p < 0.001$.

Using a benchmarking strategy (Wade, Treat, & Stuart, 1998), in Figure 1 we made point-by-point comparisons of pre- and post-treatment BDI scores for patients receiving formulation-guided treatment and those receiving ESTs in three randomized trials of cognitive therapy and cognitive therapy plus pharmacotherapy for depression (Elkin et al., 1989; Hollon et al., 1992; Jacobson et al., 1996). As Figure 1 shows, the complete sample of patients receiving formulation-guided treatment showed post-treatment BDI scores very similar to those of the patients receiving ESTs in the three randomized trials. However, pre-treatment scores for the patients receiving formulation-guided treatment were lower than for patients receiving ESTs in the randomized trials. This discrepancy reflects the fact that patients who received the ESTs in the randomized trials were required to meet the selection criterion of a pre-treatment BDI score of 20 or greater but of course the patients receiving formulation-guided treatment did not meet this selection criterion. As Figure 1 shows, when patients in the formulation-guided treatment sample who began treatment with a BDI score of 20 or more were selected ($N = 24$), they showed pre- and post-treatment BDI scores comparable to those of patients treated in the randomized controlled trials (RCTs) for Major Depressive Disorder.

Size of change during treatment. To evaluate the size of changes in symptoms of anxiety and depression for the patients who received formulation-guided treatment, we calculated pre-post effect sizes by dividing the mean pre-post difference by the pre-treatment standard deviation. We compared these effect

sizes to those reported in the efficacy studies of ESTs for single mood and anxiety disorders (Westen & Morrison, 2001). This strategy was particularly useful for comparing outcomes on anxiety because in the formulation-guided treatment sample outcomes were based on the Burns Anxiety Inventory, a measure that is clinically-useful but not widely used by researchers.

For patients who received formulation-guided treatment, the pre-post effect size for the BDI was 1.33. Using Cohen's (1988) claim that effect sizes of 0.2, 0.6 and 0.8 correspond to low, medium, and large effect sizes, respectively, this is a large effect size. However, it is a bit smaller than the effect size reported in the meta-analyses reported by Westen and Morrison (2001), who reported an average pre-post effect size on the BDI over eight randomized trials of EST for depression of 2.2 (SD 0.8). One cause of the smaller effect size for the patients who received formulation-guided treatment might be that we did not require patients to score 20 or higher on the BDI at pre-treatment, as did the randomized trials. In support of this hypothesis, we found that the pre-post effect size for patients receiving formulation-guided treatment who began treatment with a BDI of 20 or greater was 2.1.

In patients who received formulation-guided treatment, the pre-post effect size for symptoms of anxiety as measured by the Burns Anxiety Inventory was 0.98. Westen and Morrison (2001) reported a mean pre-post effect size over 14 studies of EST (mostly CBT) for panic of 1.5 ($SD = 1.2$) and over five studies of GAD of 2.1 ($SD = 0.8$). Again, the somewhat smaller effect size for the patients who received formulation-guided treatment may be due in part to the fact that in the randomized trials (but not in private practice), patients are typically required to meet certain minimal illness severity criteria at pre-treatment.

Clinically Significant Change

Analyses of clinically significant change tested the hypotheses that large numbers of patients who received formulation-guided treatment *improved* and *recovered* from their symptoms of anxiety and depression and that changes were comparable to those reported in published studies of patients treated with ESTs for single mood or anxiety disorders.

Improvement. To determine how many patients improved during treatment, we calculated the proportion of patients who showed a reduction of 50% or more in their symptoms. Twenty-one of 38 patients (55.3%) met this criterion on the BDI and 26 of 56 patients (46.4%) met this criterion on the BURNS AI. Nineteen of 56 patients (33.9%) improved 50% or more on both anxiety and depression. These figures are comparable to the improvement rates reported by Westen and Morrison (2001). Their study

examined percent improved because many studies reported this figure (of course, studies differed in their definition of improvement), and reported that the mean percent improved was 36.8% in 7 studies of depression, 53.8% in 14 studies of panic, and 43.5% in 5 studies of GAD.

Recovery. To assess recovery from symptoms of depression, we calculated the percent of patients receiving formulation-driven treatment who ended treatment with a BDI score of nine or less, as this was the cutoff score used in several randomized trials of ESTs for depression. Nineteen of 38 patients (50.0%) who received formulation-driven treatment had a post-treatment BDI score of nine or less. This figure is comparable to those reported in published studies of ESTs, where the percentages of patients ending treatment with a BDI score of nine or less was 49% for the cognitive therapy patients in Elkin et al.(1989), 44% for the cognitive therapy (CT) patients and 48% for the CT plus pharmacotherapy patients in Hollon et al.(1992); the percent ending treatment with a BDI score of less than eight was 56% of patients in a trial by Jacobson et al.(1996).

To assess recovery from symptoms of anxiety, we compared the post-treatment Burns Anxiety Inventory scores of the patients receiving formulation-driven treatment to scores on the Burns Anxiety Inventory (and the BDI) of UC-Berkeley undergraduate students who served as a control sample. The students reported a mean score on the Burns AI of 16.01 (*SD* 14.14) and on the BDI of 7.89 (*SD* 6.57). The mean BDI score of 7.89 is very close to the definition of recovery used by the RCTs. Therefore, we defined recovery in our patient sample as a post-treatment score lower than the mean score of the student sample (that is, lower than 16.01 on the Burns AI and 7.89 on the BDI). Thirty-two of 56 patients (57.1%) met this criterion on the BURNS AI, 18 of 38 patients (47.4%) met this criterion on the BDI, and 21 of 56 patients (37.5%) met both the BDI and Burns AI criteria.

Recovery rates are rarely reported in the randomized trials of the ESTs for anxiety disorders except for studies of panic. To assess recovery from symptoms of panic, we used the method of Barlow et al.(1989), who viewed patients as panic-free if they did not have a panic attack in the two weeks prior to the end of treatment. Using that criterion, eight of the nine (88.9%) private practice patients who were having panic attacks at pre-treatment were panic-free at the end of treatment. This figure is comparable to the figure reported by Barlow, Raffa, and Cohen (2002), who reported that an average of 75% of patients treated in 15 studies of psychosocial treatment (mostly CBT) of panic disorder were panic-free at the end of treatment.

Discussion

Anxious depressed patients who were treated in private practice with cognitive-behavior therapy and adjunct therapies guided by an individualized case formulation and the results of weekly symptom monitoring had good outcomes that were generally comparable to outcomes reported for patients treated with ESTs for single mood and anxiety disorders. The main difference between the outcomes of the patients who received case formulation-driven CBT and those treated in the randomized trials with the ESTs was that pre-post effect sizes of the patients who received case formulation-driven CBT were smaller, a finding that may have resulted from the fact that pre-treatment symptom severity of the private practice sample was less than that of patients in the RCTs. These findings are similar to those obtained in an earlier study of depressed patients (Persons et al., 1999).

Case formulation-driven CBT compared to standard CBT

How does case formulation-driven CBT differ from standard CBT? In general terms, the therapist using case formulation-driven CBT relies more on the case formulation, the results of idiographic assessment data, and on cognitive-behavioral principles, than does the standard CB therapist who relies on the protocol. In specific terms, case formulation-driven and standard CB therapy differ in several ways. One difference between formulation-guided and protocol-guided therapy is that a therapist using case formulation-guided treatment often uses interventions taken from several EST protocols, not just one. So, for example, if a patient responds poorly to traditional cognitive restructuring, the therapist may quickly, even within a single session, turn to mindfulness techniques, shifting from helping the patient identify and defeat distorted thinking to helping him watch negative cognitions float by like clouds. The case formulation-driven CB therapist is also guided more by principles and less by the manual. Thus, the CB therapist who noted that his patient's use of cognitive restructuring exercises seemed to serve an avoidance function abandoned cognitive restructuring in favor of behavioral exposure interventions (Persons, 1990).

The therapist using case formulation-driven treatment is guided more by idiographic outcome data and by new findings in the literature than is the therapist who is following a protocol. Thus, (Ilardi & Craighead, 1994) recently showed that most patients who respond to CBT for depression show a significant response after only 3 to 4 sessions of treatment. Guided by that finding and the observation at, say, session 8, that his patient has not shown any improvement, the therapist using a case formulation-driven approach is likely to begin attempting to develop a new formulation that might lead to some

new intervention ideas for this patient. The therapist following the protocol may continue to follow the protocol.

Another difference between formulation-guided and standard CBT is that in formulation-driven CBT, the therapist is likely to make initial intervention decisions by selecting interventions from the protocol guided by the nomothetic formulation that most closely matches the idiographic formulation of the case (Haynes, Kaholokula, & Nelson, 1999). So, for example, if the patient's depression appears to be due to a loss of reinforcers, the therapist may intervene with pleasant event scheduling (Lewinsohn et al., 1985), whereas if the patient's depression appears to be driven by distorted cognitions, the therapist may elect to do cognitive restructuring. In contrast, the therapist using standard CBT may learn one EST protocol and use it with all her depressed patients.

Case formulation-driven treatment also differs from standard CBT in that the therapist uses cognitive-behavioral principles to think about *all* the treatments the patient is receiving, not just the interventions the therapist is providing. Thus, to give a simple example, a therapist using a case formulation-driven approach to treatment will quickly perceive that the panic control treatment (Barlow et al., 1989) she is providing and the prn benzodiazepine therapy the patient is receiving from her primary care physician are incompatible, and she will consider it her responsibility to determine how to work with the patient and the physician to solve the problem.

Limitations

The major limitation of the study results from its design as an uncontrolled open trial. Because patients were not randomly assigned to case formulation-driven CBT and a control condition, it is not possible to assert that the good outcomes seen here result from case formulation-driven CBT. Other factors, such as spontaneous remission, may be responsible for these patients' good outcomes. Nevertheless, an open trial is an appropriate first step to tackle the question of the efficacy of a case formulation-driven approach to treatment for anxious depressed patients. Despite its centrality in the thinking of clinicians, case conceptualization, and especially its contribution to treatment outcome, has rarely been subjected to careful empirical study (Nelson-Gray, 2003).

Another limitation is the fact that most of the patients studied here were treated by one therapist, and, moreover, one who is familiar with many of the EST manuals. Therefore, the degree to which a formulation-driven approach to treatment can help clinicians who are less experienced and less familiar with the EST manuals has not yet been demonstrated. Another

limitation is the study of only one approach to cognitive-behavioral case formulation. Other extant approaches include those developed by Haynes and O'Brien (2000), Nezu, Nezu, Friedman, and Haynes (1997) and Koerner and Linehan (1997). We would expect the results reported here to generalize to these other methods of case formulation, but of course this is an empirical question.

Another limitation is that selection bias may have influenced the findings. One of the selection criteria that excluded the largest number of subjects was the requirement that subjects provide a minimum of four scores on both the measures of anxiety and depression; this criterion was set because we originally collected these data as part of a study of change in anxiety and depression during treatment (Persons, Roberts, & Zalecki, 2003). The fact that only patients who provided four sessions of data on the outcome measures were studied may have biased the study in favor of patients who complied with and persisted in therapy. We would point out, however, that patients treated in the RCTs typically must complete several assessment interviews before treatment begins, so the sample studied here may not differ significantly from the research samples in that regard. Nevertheless, the potential for selection bias means that the results of this study should be viewed with some caution.

Other limitations of the present study are that anxiety and depression were measured using only self-report scales; outcome was assessed with measures of symptoms, not functional status; psychiatric diagnoses were assigned by the treating clinician based on a clinical interview and questionnaire data; no long-term follow-up data were collected; and patients' progress achieving their idiographic treatment goals was not monitored systematically enough to report it here. To address these shortcomings, future studies could use controlled designs of the sort proposed by Nelson-Gray (2003) or extend the naturalistic line of work reported here repeating the study at another site and by assessing functional status, idiographic goal attainment, and long-term follow-up. Some of this study's limitations are inextricably tied to one of its strengths: data were collected in the course of routine work in a real-world clinical setting from patients who had multiple comorbidities and received multiple interventions provided by multiple clinicians.

Importance and Implications

The findings reported here are important for several reasons. First, they provide a strategy that assists in the care of the anxious depressed patient in the clinical setting. These patients are common, and clinicians need help with them, because the currently-available ESTs for treating mood and anxiety

disorders generally target single disorders. We offer a method for adapting the available ESTs to the depressed anxious patient in a systematic, empirical way that answers many questions that clinicians encounter that are not answered by the ESTs themselves (e.g. in what order to treat a patient's multiple disorders) (Persons, 2005).

However, although it helps the therapist determine in what order to treat a patient's multiple disorders, select a protocol when many are available, identify and overcome treatment failure, and plan an effective multiple-component treatment plan, case formulation-driven CBT does not solve the problem that clinicians treating patients with cognitive-behavior therapy for mood and anxiety disorders currently must read many protocols with overlapping conceptual and intervention components. To address that problem, new protocols are needed, and are now beginning to appear. Many (but not all--see (Barlow, Allen, & Choate, 2002)) of these protocols call for the therapist to develop a formulation of the case and use it to select intervention modules (Albano, 2003) and (Chorpita, Taylor, Francis, Moffitt, & Austin, 2004).

The most significant implications of these findings extend beyond the anxious depressed patient. The use of the case formulation and weekly symptom monitoring for adapting single-disorder ESTs to the treatment of multiple-disorder, multiple-therapy cases is not specific to anxiety and depression nor even to cognitive-behavior therapy, and in fact can be applied to the treatment of complex cases more generally. Several investigators working with complex cases and problems are writing protocols that include features of the case formulation-driven approach to CBT described here, such as frequent individualized assessment (Linehan, 1993), reliance on a case formulation (McCrady & Epstein, 2003), and reliance on principles rather than a list of interventions (Henggeler, Schoenwald, Borduin, Rowland, & Cunningham, 1998).

Finally and perhaps most important, because it addresses obstacles to implementing ESTs in routine clinical practice and because it includes a reliance on idiographic assessment and clinical decision-making that is highly valued by clinicians (Addis & Carpenter, 2000), case formulation-driven CBT has the potential to increase clinicians' willingness to use ESTs in their daily clinical work.

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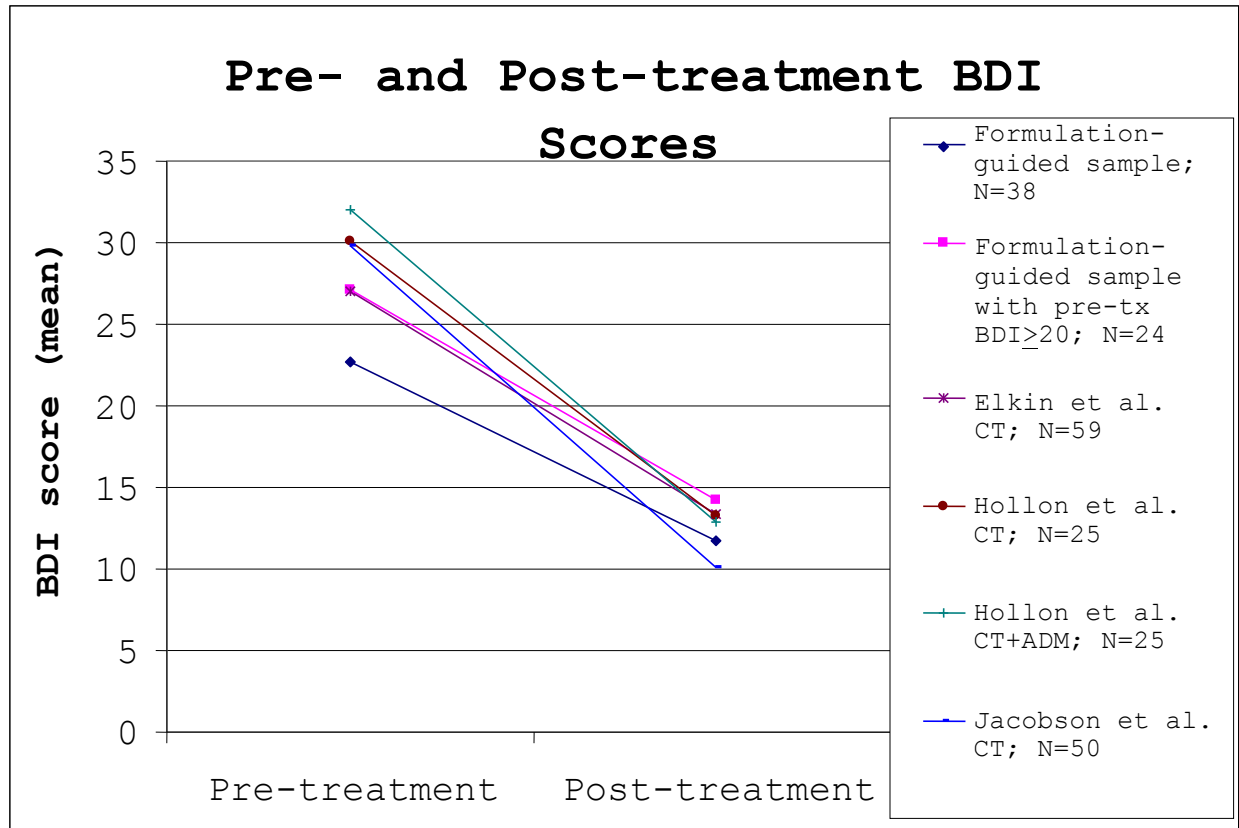
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Figure Caption

Figure 1. Pre- and Post-treatment BDI Scores for Patients Receiving Formulation-guided or Protocol Therapy



Notes. CT = cognitive therapy. ADM = Antidepressant medication.

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