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Results of randomized controlled trials of cognitive therapy for depression generalize to private practice

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Running head: RESULTS OF RANDOMIZED CONTROLLED TRIALS

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Abstract

We compared outcomes of 45 depressed patients treated in private practice with cognitive therapy or with cognitive therapy plus pharmacotherapy to outcomes of patients receiving those treatments in two randomized controlled trials. Private practice and research samples differed considerably, with private practice patients having more psychiatric and medical comorbidities and a greater range of initial depression severity. Treatment in private practice and research settings also differed, with private practice treatment conducted in a more flexible manner using an idiographic, formulation-driven approach. As predicted, private practice patients showed statistically significant reductions in depressive symptomatology over the course of treatment, and at post-treatment, Beck Depression Inventory (BDI) scores of patients treated in

private practice and research settings were not statistically significantly different. Clinical significance of outcomes was also comparable in the clinical and research samples. Of the variables measuring demographic, illness and treatment factors, only pre-treatment BDI score predicted post-treatment BDI score in the private practice sample.

key words: effectiveness study; randomized controlled trials, cognitive therapy for depression

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Several psychotherapies, including cognitive therapy for depression, have been shown to be effective in randomized controlled clinical trials conducted in research settings with homogeneous, highly selected samples of patients (see reviews by Agency for Health Care Policy and Research (1993) and DeRubeis & Crits-Christoph (1998)). However, the clinical utility of these new treatments is limited unless they can be shown to be effective when they are used in routine clinical practice to treat heterogeneous samples of patients. Therefore, scientists, clinicians, writers of practice guidelines, health policymakers, insurance companies, and patients and their families would like to know the answer to the question: do results of randomized controlled trials generalize to routine clinical practice?

The present study tests the hypothesis that results of randomized controlled trials (RCTs) of cognitive therapy for depression generalize to routine clinical practice. To test this hypothesis, we compared the outcome of depressed patients in the first author's private practice who received cognitive therapy (CT) or CT plus pharmacotherapy to the outcome of patients who received those treatments in the randomized controlled trial conducted by Murphy, Simons, Wetzel and Lustman (1984). We selected the Murphy et al. trial as a comparison sample because it is a fairly large trial that examined outcome of both CT and CT plus pharmacotherapy, and because uncorrected pre- and post-treatment Beck Depression Inventory scores (the dependent measure we used) appear in the published report of the study.

In the comparison of the private practice and the Murphy et al. samples, we examine the mean post-treatment Beck Depression Inventory score of the two samples. However, as Jacobson and colleagues (Jacobson & Truax, 1991) have pointed out, a treatment that produces a low average BDI score for the sample may or may not have clinically significant effects for individual patients. To address this issue, we use the measure of clinical significance developed by Jacobson and Truax (1991) to compare the clinical significance of outcomes of patients treated in our private practice to patients treated in another important RCT, the Treatment of Depression Collaborative Research Program (TDCRP; Elkin et al., 1989). We chose the TDCRP as a comparison sample because data on the clinical significance of outcomes of patients treated in the TDCRP have been published (Ogles, Lambert, & Sawyer, 1995).

Clinicians (cf. Silberschatz in Persons & Silberschatz, 1998) and researchers (Frances, Kahn, Carpenter, Frances, & Docherty, in press; Seligman, 1996) have argued that results of RCTs are of limited utility in routine clinical practice because the patients treated in the RCTs are a homogeneous, highly selected sample, whereas patients treated in routine clinical practice are quite heterogeneous; often these patients have multiple medical and psychiatric comorbid conditions. Whether comorbidities or other sources of heterogeneity limit generalizability of the findings from the RCTs is an empirical question that we address here by comparing outcomes of a heterogeneous clinical sample to outcomes in a homogeneous research sample. To examine the contribution to outcome of some of the demographic (e.g., years of education), illness (e.g., presence of comorbidities) and treatment (e.g., number of therapy sessions) variables that differed between the clinical and research samples, a multiple regression analysis was conducted to test the hypothesis that these variables do not contribute to outcome in the clinical sample.

The main goal of the present study is to examine the generalizability to clinical practice of Beck's cognitive therapy for depression, as described in Beck, Rush, Shaw, and Emery (1979). However, we found that when we attempted to utilize the Beck et al. (1979) protocol in a clinical setting, it required modification. Modifications were often required because private practice patients had multiple comorbid difficulties (e.g., panic attacks, substance abuse, or poorly controlled diabetes) that are not addressed in the standard protocol. In private practice, interventions were provided more flexibly; the order of administration of interventions was often changed, and some interventions received more or less emphasis than in the research protocol. In private practice, decisions about adjunct therapies, including pharmacotherapy, were made collaboratively by patient and therapist, whereas in the RCTs the decision about whether to provide CT alone or CT plus pharmacotherapy is randomly determined, and other adjunct therapies (e.g., couples therapy) are proscribed. In private practice, treatment was open-ended, whereas in the RCTs, treatment has a maximum length of 20 sessions.

In order to make protocol modifications in a thoughtful, systematic way, the therapist based her interventions on an individualized case formulation. The formulation was an idiographic (individualized) account of how Beck's cognitive model accounted for the patient's depressive and other symptoms; this individualized, formulation-driven approach to cognitive therapy is described in Persons (1989).

In summary, we tested the hypotheses that results of controlled trials studying cognitive therapy and cognitive therapy plus pharmacotherapy for depression generalize to routine clinical practice. We studied the outcome of idiographic CT and CT plus pharmacotherapy in depressed patients treated in private practice, and we compared outcomes for these patients to outcomes for patients receiving these treatments in two RCTs. To determine the role of comorbidities and other differences between the research and private practice samples, we conducted a multiple regression examining the relationship between variables measuring several of these factors and outcome in the clinical sample.

Method

Participants

Subjects were adult outpatients treated in the first author's private practice. Patients were selected for study if they met the following criteria: (1) clinically significant levels of depressive symptoms as reflected by an initial Beck Depression Inventory score of 14 or greater; (2) a systematic, formulation-driven cognitive-behavioral approach to treatment was used, as reflected by a written cognitive-behavioral case formulation in the clinical record; this meant that patients selected for study began treatment after February 1987, when the therapist began using this method; (3) a minimum of three BDI scores was recorded in the clinical chart (this was needed in order to assess change in BDI over the course of treatment); (4) therapy consisted of individual, not couples therapy; (5) treatment was completed at the time data were collected for the study (April 1994). Forty-five patients met these criteria and were selected for study; 27 of these patients received cognitive therapy and 18 received cognitive therapy plus pharmacotherapy.

Measures

The therapist obtained information about the patient's demographics and past psychiatric history in the clinical interview in the initial history-taking sessions. The remaining variables were assessed as follows:

Depressive symptoms. The Beck Depression Inventory (BDI; Beck et al., 1979) was used to assess depressive symptomatology. The BDI is a widely-used 21-item self-report inventory that has been shown to be a reliable and valid measure of depressive symptomatology in psychiatric patients (Beck, Steer, & Garbin, 1988).

Psychiatric diagnoses. The therapist assigned psychiatric diagnoses based on findings from her first several sessions with the patient; diagnoses were based on DSM-IIIR criteria (APA, 1987).

Serious medical problem. Patients were rated as having a serious medical problem if they had a medical problem that interfered significantly with day-to-day functioning.

Current substance abuse. All cases were rated by the therapist, retrospectively, based on the clinical chart, using the scale 0 = no substance abuse at time of treatment, 1 = possible substance abuse, and 2 = definite substance abuse at time of treatment. For purposes of the data analysis, patients were coded 0 on this variable if they had no substance abuse; they were coded 1 if they had possible or definite substance abuse.

Concurrent additional treatment. This variable was coded retrospectively by the therapist on the basis of a review of the clinical chart. Separate codings indicated the presence of the following types of adjunct treatment occuring at the same time the patient received cognitive therapy: pharmacotherapy, couples therapy, psychiatric hospitalization, 12-step programs, self-help groups, family therapy, group therapy, or other.

Procedure

Assessment. Most of the variables listed above were assessed by the therapist in the clinical interview in early therapy sessions. Patients were asked in an early therapy session (generally the first or second) to complete the Beck Depression Inventory and bring it to the next session and to complete the BDI thereafter on a weekly basis.

Treatment. All patients received individual cognitive-behavior therapy from the first author, a Ph.D. psychologist with about 10 years of clinical experience, extensive specialized training in cognitive-behavior therapy, and considerable experience teaching and supervising trainees in cognitive-behavior therapy. To accomodate the need for flexibility while retaining a systematic approach to treatment, the therapist (J. B. P.) developed a systematic approach to individualizing the therapy (described in Persons, 1989; Persons & Tompkins, 1997). In this approach to cognitive-behavior therapy, the therapist utilizes standard cognitive-behavioral interventions. However, instead of carrying out interventions in the standardized order prescribed by Beck et al. (1979), the therapist chose interventions based on an individualized cognitive-behavioral case formulation. In addition, because many patients had significant comorbid problems, many therapist sessions focused on clinical problems other than depression when these appeared to have higher priority. Treatment decisions were made collaboratively by patient and therapist, and the therapist used a systematic, formulation-driven approach to making treatment decisions. Therapy sessions were generally held weekly and lasted approximately 50 minutes. Treatment was open-

ended. Several patients received concurrent treatment of various sorts, including one patient who was hospitalized. Private practice patients paid for treatment.

Pharmacotherapy was provided by a physician in the community; this was either a psychiatrist to whom the therapist referred the patient or a psychiatrist or (occasionally) internist selected by the patient. The therapist generally attempted to establish a collaborative relationship with the pharmacotherapist. Decisions about whether to employ pharmacotherapy in addition to cognitive therapy were made in several ways. At times, patients were already receiving pharmacotherapy when they began cognitive-behavior therapy. At times, the cognitive-behavior therapist recommended pharmacotherapy be added to the cognitive-behavior therapy, usually because the patient was not showing a complete response to cognitive-behavior therapy.

Results

Demographic, illness, and treatment characteristics of private practice and research samples

We first compared the illness and demographic characteristics of the private practice and research samples as well as the characteristics of the treatment provided in the private practice and research settings. As Table 1 shows, the private practice and research samples differ considerably in their illness characteristics. As expected, the private practice sample is more heterogeneous than the research samples. Whereas all the research patients meet criteria for Major Depression and none meet criteria for Bipolar Disorder, only 69% of the private practice patients meet criteria for Major Depression; some private practice patients are more severely ill than research sample patients (seven percent of private practice patients meet criteria for Bipolar Disorder), whereas others are less severely depressed, reporting a 14 or greater on the BDI but not meeting criteria for Major Depression. Sixteen percent of private practice patients have major medical problems; in contrast, patients were screened out of the Murphy et al. trial if they had medical disease requiring medication other than a diuretic and they were screened out of the TDCRP if they had any medical contraindication for treatment with imipramine. Thirteen per cent of private practice patients have panic disorder; in contrast, patients were screened out of the TDCRP if they had concurrent panic disorder. With regard to demographics, the samples are similar in age, but the research sample patient is more likely to be female, less likely to be married or cohabiting, less likely to be white, and less highly educated than the private practice patients.

Insert Table 1 about here

The samples also differ in the treatment patients received. In the private practice sample, 22% of patients received adjunct treatment of some sort, whereas none of the research patients did. Private practice patients received, on average, 34.8 sessions of treatment, whereas research patients received a maximum of 20 sessions of treatment. Cognitive therapy sessions of private practice patients and patients in the TDCRP were 50 minutes in length; sessions for patients in the Murphy et al. (1984) study lasted 50 minutes for CT patients and 60 minutes for CT plus pharmacotherapy patients.

Comparison of treatment outcome for private practice and research samples

To test the hypothesis that outcome findings generalize from the research samples to the private practice sample, we carried out several analyses. First, to show that patients in the private practice sample show changes in depressive symptomatology over the course of treatment, we conducted a paired *t* test examining changes in BDI score across treatment. Second, we compared pre- and post-treatment BDI scores for the private practice and Murphy et al. samples, and third, we compared the clinical significance of outcomes in the private practice and TDCRP samples.

Changes during treatment. Paired *t* tests showed that BDI scores decreased significantly over the course of treatment in the private practice sample (t (44) = 9.37, $p < 0.0001$.

Comparison of pre-and post-treatment mean BDI scores. We present, in Table 2, pre- and post-treatment BDI scores for patients treated with cognitive therapy (CT) and with CT plus pharmacotherapy in the private practice and the Murphy et al. samples. We present outcome data for each sample for all patients in the sample, including both treatment completers and dropouts; these are "intention to treat" samples.

Insert Table 2 about here

We first examine results for patients who received CT alone. As shown in Table 2, private practice patients report pre-treatment BDI scores that are statistically significantly lower than those reported by the Murphy et al. sample ($t(49) = 4.96$, $p < 0.0001$); this is because patients were not admitted to the research protocol unless they reported a score of 20 or greater on the BDI and 14 or greater on the Hamilton Rating Scale for Depression and met criteria for Major Depression, whereas patients were treated in private practice if they scored 14 or greater on the BDI. Private

practice patients do not differ from the research samples in post-treatment BDI scores ($t(49) = 0.35$, $p = 0.73$).

We next examine results for patients who received CT plus pharmacotherapy. As shown in Table 2, results are essentially the same as results for CT alone. Private practice patients report pre-treatment BDI scores that are statistically significantly lower than those reported by the Murphy et al. sample ($t(38) = 2.45$, $p = 0.019$). The samples do not differ in post-treatment BDI scores ($t(38) = 0.64$, $p = 0.53$).

In summary, private practice patients constitute a more heterogeneous sample than patients in the Murphy et al. randomized trial. Despite this, the samples do not differ in post-treatment Beck Depression Inventory score.

Comparison of clinically significant changes. To examine the clinical significance of changes in our private practice sample and to compare the clinical significance of changes in private practice and research samples, we used the method for measuring clinically significant change published by Jacobson and Truax (1991), and we compared results in the private practice sample to the results for the TDCRP published by Ogles et al. (1995).

Jacobson and Truax use two criteria to define clinical significance. First, they ask: Does the treatment move the patient from a dysfunctional to a functional or an asymptomatic population? To answer this question, a cutoff score is established on the measure of pathology being investigated; if the patient's score falls within one or two standard deviations of the general population mean for the functional or asymptomatic population, the patient is considered to fall in that population. Second, they ask: Is the change resulting from treatment reliable? That is, is the change resulting from treatment large enough that it probably did not occur by chance? To determine reliability, a Reliable Change Index (RCI) is calculated, where RCI = post-treatment mean minus pre-treatment mean divided by the standard error of the difference between the two scores. An RCI of greater than 1.96 is unlikely to occur ($p < .05$) unless true change has occurred.

Following Jacobson and Truax (1991), we set two cutoff scores, one defining whether the patient has entered the population of functional individuals and one defining whether the patient has entered the population of asymptomatic individuals. We set the cutoff for entering the functional population distribution at 13.46, and the cutoff for entering the asymptomatic population at 4.69; these are the cutoff scores set by Ogles et al. (1995), based on normative data, in their study of the TDCRP.

Speer (1992, 1993) suggested that before calculating the reliable change index, a correction be made for regression to the

mean associated with measurement error if it exists. We looked for regression to the mean in our sample by examining the correlation of the pretreatment BDI and change in BDI (where change is post-treatment - pre-treatment). This correlation is -0.435, suggesting we have regression to the mean, so we corrected the initial BDI scores for regression to the mean using Speer's (1992) formula for doing this.

Results of these calculations for our sample and the TDCRP sample appear in Table 3 and Figure 1. Because Ogles et al. (1995) presented only Completers for the TDCRP, we present completers of our sample as well. Completers in the TDCRP completed at least 12 weeks and 15 sessions of treatment. Completers in the private practice sample terminated treatment at an appropriate (in the therapist's judgment) time and in a collaborative manner.

Insert Table 3 and Figure 1 about here

Results show that the proportions of patients showing clinically significant change are quite comparable for the two samples, with 57% of private practice patients and 50% of TDCRP patients showing reliable change and moving into the distribution of functional individuals. Somewhat fewer private practice patients than TDCRP patients showed reliable change and moved into the distribution of asymptomatic individuals (17% and 28% for the two samples, respectively). One TDCRP patient deteriorated, and no private practice patients did.

In Figure 1, the X axis is the Adjusted Pretreatment BDI score (using the Speer correction) and the Y axis is the post-treatment BDI score. The solid diagonal line is X = Y; patients who fall on this line showed no change in BDI over the course of treatment. The area between the X = Y line and the dotted line below it represents the region of non-reliable improvement; the area below that dotted line represents the area of reliable improvement. The area between the X = Y line and the dotted line above it represents the region of non-reliable deterioration; the area above that dotted line represents the area of reliable deterioration. The horizonal dashed line was drawn at 13.46 to define the boundary of the functional population; patients with post-treatment BDI scores of less than 13.46 were defined as having moved into the population of functional individuals.

Thirteen patients fall below the bottom dashed line; these are the 13 who showed reliable improvement (see Table 3 and Figure 1). There are 15 dots below the horizontal dashed line, and these are the 15 who, at the end of treatment, fell in the functional distribution. Thirteen patients (57%) showed both reliable change

and ended treatment in the distribution of functional individuals. No patient showed reliable deterioration.

Predictors of outcome in the private practice sample

To examine the contribution to outcome of some of the demographic (e.g., years of education), illness (e.g., presence of comorbidities) and treatment (e.g., number of therapy sessions) variables that differed between the private practice and research samples, we conducted a multiple regression analysis testing the hypothesis that these variables did not make significant contributions to the prediction of post-treatment BDI score in the private practice sample.

The dependent variable was post-treatment BDI score. Predictor variables were Years of education, Initial BDI score, Diagnosis of major depression, Diagnosis of panic disorder, Substance abuse problem, Major medical problem, Number of therapy sessions, and Pharmacotherapy treatment. Simple correlations of these variables show only Initial BDI score (BDI score at the beginning of treatment) to have a statistically significant relationship to post-treatment BDI (r = 0.47, p = 0.002). All other p values were greater than 0.15. A multiple regression analysis with all of these variables as predictors produces an R^2 of 0.322 (p = 0.058). Only Initial BDI was a statistically significant predictor (t = 3.459, p = 0.0014) of post-treatment BDI. The increment in R^2 above the 0.219 that results from just using Initial BDI score as a predictor is 0.103, which is not statistically significant (p = 0.61).

Discussion

As predicted, patients treated with cognitive therapy for depression in private practice showed outcomes comparable to those of patients treated in research settings. Outcomes were comparable for patients receiving cognitive therapy, for those receiving cognitive therapy plus pharmacotherapy, when mean post-treatment BDI scores were calculated, and when proportions of patients moving into the distribution of functional individuals were tallied.

Comparable outcomes occurred in the research and private practice samples despite the fact that the samples differed considerably. The private practice sample was at once both more and less severely pathological than the RCT samples. The private practice sample was more severely pathological in that it included patients with multiple comorbidities and acutely ill (e.g., suicidal) individuals who would be screened out of the RCTs; it was less severely pathological in that private practice patients were, on average, less severely depressed at pre-treatment than research patients. The finding that patients in research and private practice samples differed considerably and yet had comparable

treatment outcomes is consistent with the finding that several variables measuring differences between the samples (diagnosis of major depression, panic disorder, a substance abuse problem, a major medical problem) did not predict outcome of the private practice patients.

The present study replicates earlier studies of patients treated in private practice (Persons, Burns, & Perloff, 1988) and at the Center for Cognitive Therapy at the University of Pennsylvania (Haaga, DeRubeis, Stewart, & Beck, 1991). And Wade, Treat, and Stuart (1998) recently showed that Barlow's panic control treatment is as effective in community mental health center as in a research setting.

However, results of RCTs do not always generalize to clinical practice. Organista, Muñoz, and Gonzalez (1994) reported that a disadvantaged minority patient population with multiple medical, psychiatric, and psychosocial comorbidities did not respond as well to cognitive therapy for depression as patients studied in the RCTs. And Weisz, Donenberg, Han, and Kauneckis (1995) found that children who received psychotherapy in RCTs had better outcome than those treated in clinical settings.

These studies indicate that although results of RCTs generalize to some treatments and some patient populations, they do not generalize to others. Future studies examining the relationship between outcome and psychiatric and medical comorbidities, cultural factors, ethnic differences, socio-economic factors, and other variables, will allow us to pinpoint which are related to generalizability.

The present study has several limitations. Because there is no control group, we cannot be certain that the improvement shown by the private practice patients during the course of treatment is in fact due to the treatment; it might be due to the passage of time or other, unmeasured variables. The fact that outcome was measured with a single, self-report measure (the Beck Depression Inventory) limits what we can learn about the outcome of the clinical sample and about the comparability of the clinical and research samples. However, the utilization of a single outcome measure also reflects the real-life constraints of the naturalistic setting in which these data were collected; it is probably not realistic to expect clinicians to collect more than one measure of depressive symptomatology (though they might well measure more than one set of symptoms).

The data analysis used here also has limitations. We concluded that the findings from the Murphy et al. study generalize to clinical practice based on our failure to find differences in post-treatment scores between the Murphy sample and the private

practice sample. However, the failure to find statistically significant differences between the two samples' mean post-treatment BDI scores means only that we fail to reject the null hypothesis; we cannot confirm the null hypothesis. To strengthen our argument that private practice patients responded to treatment in a manner similar to patients treated in the RCTs, we demonstrated that private practice patients showed statistically significant changes in BDI from pre- to post-treatment. The demonstration patients showed reliable changes from pre- to post-treatment provides some evidence countering explanations that are commonly advanced to account for failures to find differences between mean scores (lack of power, and insensitive and unreliable measures).

The data presented here do not provide an unbiased comparison of outcomes of patients receiving CT alone and CT plus pharmacotherapy. That is because patients were not randomly assigned to those groups. In fact, some of the patients in the combined CT plus pharmacotherapy group are in that group as a result of failing to respond to a single therapy, and this could negatively bias the outcome findings for the combined group and positively bias the findings for the CT only group. The implications of this point for our study are mitigated by the fact that we do not focus in this paper on the comparison between CT alone and CT plus pharmacotherapy.

Finally, the generalizability of the present findings is limited to cognitive therapy and CT plus pharmacotherapy for depression, to private practice patients, to the single therapist studied, and to Oakland, California.

Some of the limitations of the present study are, to some degree, inherent to the design of a naturalistic study, which, by definition, can never be as elegant and fully controlled as a RCT. Despite this fact, more naturalistic studies are needed. We must show that results of the RCTs generalize to clinical practice. Unless we do so, the new treatments shown effective in RCTs may not redound to improved patient care in day-to-day clinical practice. And the demonstration that results of RCTs generalize to clinical practice may facilitate the dissemination of new treatments from the ivory tower to the front lines of clinical practice (Chambless, et al., 1993; Persons, 1995; Wilson, 1995).

Another research strategy may also be useful in demonstrating generalizability of findings from homogeneous samples to heterogenous ones--and that is the RCT itself. A common criticism of the RCT is that it studies homogeneous samples of patients who do not resemble the heterogeneous samples seen in routine practice (Seligman, 1995; Silberschatz in Persons & Silberschatz, 1998).

Certainly the distinction (Seligman, 1995) between the controlled study of rarified samples (the "efficacy" study) and the uncontrolled study of real-life clinical samples (the "effectiveness" study) provided an important motivating factor for the present study. However, the study of homogeneous samples is not inherent to the design of the RCT; as Jacobson and Christensen (1996) pointed out, there is no reason that RCTs cannot study heterogeneous samples. We recommend that future RCTs of cognitive therapy of depression (which has been extensively studied in RCTs of homogeneous populations), relax the stringent selection criteria typically used in these RCTs; this strategy would increase the generalizability of the findings of the RCT.

Expanding the populations studied in RCTs of cognitive therapy for depression will, we believe, require some changes in the treatment protocol, as we found was necessary in the present study. The presence of multiple comorbidities leads to the need for a flexible treatment approach that allows the clinician to address multiple problems. Our solution to this problem was to design a treatment approach that might be described a "principle-driven" approach rather than a "procedure-driven" approach (Eifert, Evans, & McKendrick, 1990). Here, treatment is individualized based on a formulation of the case, and both the case formulation and the intervention strategies are guided by the principles of (in this case) cognitive therapy, which is supported by evidence from efficacy studies (for more details, see Persons, 1989). The therapist uses the experimental method in the context of a single case, where the formulation is a hypothesis, outcome data are collected to evaluate the utility of the hypothesis, and the therapist is engaged in an ongoing process of hypothesis-testing and outcome-monitoring, as described by Barlow, Hayes and Nelson (1984). The work of David Sackett and the Evidence-based Medicine Working Group (Sackett, Richardson, Rosenberg, & Haynes, 1997) also makes an important contribution to this approach to clinical work.

A formal efficacy study of formulation-driven treatment could certainly be done (Persons, 1991) and would blur the boundary between efficacy and effectiveness studies. In fact, a recent RCT by Blanchard and colleagues (Greene and Blanchard, 1994) examining effficacy of cognitive-behavior therapy for irritable bowel syndrome utilized a formulation-driven approach to cognitive-behavior therapy.

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