Journal of Consulting and Clinical Psychology
2000, Vol. 68, No. 4, 594–602

0022-006X/00/$5.00 DOI: 10.1037//0022-006X.68.4.594

Effectiveness of Exposure and Ritual Prevention for Obsessive–Compulsive Disorder: Randomized Compared With Nonrandomized Samples

Martin E. Franklin and Jonathan S. Abramowitz
University of Pennsylvania School of Medicine

Michael J. Kozak
Medical College of Pennsylvania–Hahnemann University

Jill T. Levitt
Boston University

Edna B. Foa
University of Pennsylvania School of Medicine

The efficacy of exposure and ritual prevention (EX/RP) for reducing symptoms of obsessive–compulsive disorder (OCD) has been demonstrated in several randomized controlled trials (RCTs). However, procedures used in these studies to maximize experimental control may have limited their generalizability to typical clinical practice. Treatment outcome data from 110 clinical patients receiving EX/RP on an outpatient fee-for-service basis were compared with findings from 4 RCTs of EX/RP. Adult patients in the clinical sample were not excluded because of treatment history, concomitant pharmacotherapy, psychiatric comorbidity, age, or OCD severity. Clinical patients achieved substantial and clinically meaningful reductions in their OCD and depressive symptoms following EX/RP, which were comparable with those reported in the RCTs. Findings indicate that EX/RP is a potent treatment for OCD, and its benefits are not limited to select patient samples.

The lifetime prevalence of obsessive–compulsive disorder (OCD) in the United States is approximately 2.5% (Karno, Golding, Sorenson, & Burnam, 1988), which is largely consistent with transcultural estimates (Angst, 1994). Individuals with OCD typically report substantial social and work dysfunction; indeed, a recent study found that OCD outpatients were almost four times more likely to be unemployed than were people in the general population (Koran, Thienemann, & Davenport, 1996). OCD sufferers are also at increased risk for social phobia, panic disorder, and simple phobia (Rasmussen & Tsuang, 1986), as well as major depression (Karno et al., 1988). Clearly, OCD is a serious public health concern that warrants the attention of both mental health service providers and the clinical research community.

Martin E. Franklin, Jonathan S. Abramowitz, and Edna B. Foa, Center for the Treatment and Study of Anxiety (CTSA), Department of Psychiatry, University of Pennsylvania School of Medicine; Michael J. Kozak, Department of Psychiatry, Medical College of Pennsylvania–Hahnemann University; Jill T. Levitt, Department of Psychiatry, Boston University.

Michael J. Kozak is now at the Center for Scientific Review, National Institutes of Health (NIH), Bethesda, Maryland.

This research was supported in part by NIH Grant R01-MH45436.

Portions of this research were presented at the 32nd Annual Meeting of the Association for Advancement of Behavior Therapy, Washington, DC, November 1998.

We thank James E. McCusker and Lori A. Zoellner for their editorial comments on an earlier version of this article.

Correspondence concerning this article should be addressed to Martin E. Franklin, CTSA, Department of Psychiatry, University of Pennsylvania School of Medicine, 3535 Market Street, 6th Floor, Philadelphia, Pennsylvania 19104-3309. Electronic mail may be sent to marty@mail.med.upenn.edu.

The efficacy of two forms of treatment for OCD has already been established: serotonergic medications and cognitive–behavioral therapy (CBT) involving exposure and ritual prevention (EX/RP). Meta-analysis of multiple randomized controlled trials (RCTs) has indicated that serotonergic medications (e.g., fluvoxamine [FLX]) are superior to placebo (Abramowitz, 1997). RCTs have also found CBT involving EX/RP to be superior to various control conditions (e.g., Fals-Stewart, Marks, & Schafer, 1993; Kozak, Liebowitz, & Foa, 2000; Lindsay, Crino, & Andrews, 1997; Marks, Hodgson, & Rachman, 1975; Rachman et al., 1979; van Balkom et al., 1998). These studies have placed strong emphasis on internal validity and thus allow for confident conclusions regarding the efficacy of the active treatments in comparison with control conditions.

Critics have argued that the very procedures used to maximize experimental control in RCTs seriously compromise their external validity. For example, large numbers of patients with comorbid disorders are often excluded in order to achieve homogeneous diagnostic samples. It has been suggested that these highly selected groups are not representative of the typical treatment-referred outpatient who presents with multiple problems (Silberschatz as cited in Persons & Silberschatz, 1998). Additionally, many otherwise eligible patients refuse to accept randomization to avoid assignment to placebo treatments or wait-list conditions. Because of possible differences between individuals who enter RCTs and those who refuse participation, this patient self-selection may further compromise generalizability. Adherence to manualized treatments is yet another way in which RCTs do not resemble typical clinical practice (Seligman, 1995).

Whether or not one agrees that the aforementioned criticisms are valid (for responses, see Kendall, Chu, Gifford, Hayes, & Nauta,

1998, and Persons as cited in Persons & Silberschatz, 1998), one implication is that many practicing clinicians may be unconvinced that RCT findings are applicable to their less rarefied clientele. To bridge the growing chasm between controlled treatment outcome research and clinical practice, it is imperative to conduct effectiveness studies using broad clinical samples of patients who choose their treatments. If outcome for these patients is comparable with that of RCT participants, results of RCTs must then be viewed as credible and applicable to "unselected" patient samples. In the present study, we examined this issue using data collected from patients who received fee-for-service EX/RP treatment in our outpatient OCD clinic.

The Center for the Treatment and Study of Anxiety (CTSA) is a clinical research facility in which OCD patients can be randomized to EX/RP as part of an ongoing National Institute of Mental Health–funded RCT, or if they are ineligible for or uninterested in RCT participation, they can receive EX/RP on a fee-for-service basis. Notably, the EX/RP programs delivered in both of these contexts are very similar. In comparison with typical RCT samples, our fee-for-service patients are more representative of the broader population of patients with OCD in that they also suffer from comorbid conditions (e.g., current major depression), are unwilling to discontinue ongoing pharmacotherapy or to risk randomization to inactive treatment, and choose their own therapy. Moreover, as was the case in other generalizability studies of anxiety disorder treatments (e.g., Wade, Treat, & Stuart, 1998), no adult patient was excluded from participation in the present investigation because of age, secondary comorbid diagnoses, medical problems, treatment history, use of concomitant medication, or Axis II disorders. By comparing EX/RP outcome in our fee-for service OCD outpatients with results from RCTs, we can examine the generalizability of these RCT findings.

In conducting this effectiveness study, we employed the benchmarking research strategy utilized by Wade et al. (1998), who used RCT findings as a gold standard in evaluating the effectiveness of CBT for panic disorder delivered in a community mental health setting. In the present study, we used the percentages of symptom reduction found in several RCTs as benchmarks for evaluating the effectiveness of EX/RP for our fee-for-service patients. RCTs were selected for benchmarking if they (a) included adult patients with a primary diagnosis of OCD according to *Diagnostic and Statistical Manual of Mental Disorders* (3rd ed., rev.; *DSM–III–R*; American Psychiatric Association, 1987) or *DSM* (4th ed.; *DSM–IV*; American Psychiatric Association, 1994) criteria, (b) included random assignment to EX/RP or a control condition, (c) used the Yale–Brown Obsessive–Compulsive Scale (Y-BOCS; Goodman, Price, Rasmussen, Mazure, Delgado, et al., 1989a; Goodman, Price, Rasmussen, Mazure, Fleischmann, et al., 1989b) as the primary outcome measure, and (d) used a manualized EX/RP treatment. Four EX/RP studies, including an ongoing RCT being conducted in part at our center, met these inclusion criteria and are described below.

Fals-Stewart et al. (1993) examined the relative efficacy of group EX/RP, individual EX/RP, and relaxation control. Because all of our patients received individual treatment, we used Fals-Stewart et al.'s individual EX/RP condition as a benchmark for our study. Exclusion criteria for Fals-Stewart et al.'s RCT were (a) any concurrent Axis II diagnosis and (b) concurrent Axis I diagnosis of major depression and a Beck Depression Inventory (BDI; Beck, Ward, Mendelsohn, Mock, & Erlbaugh, 1961) score greater than 22. Treatment sessions occurred twice weekly for 12 weeks. Although active treatments were superior to the control condition, there were no differences between group and individual EX/RP. Notably, no participants in Fals-Stewart et al.'s RCT reported that they had received any previous treatment for OCD.

Kozak et al. (2000) reported preliminary findings from an ongoing multicenter RCT examining the relative efficacy of intensive EX/RP, clomipramine (CMI), combined treatment (EX/RP + CMI), and pill placebo. For the purpose of the present investigation, we have included only the preliminary outcome data reported for the EX/RP condition. Exclusion criteria for the study were (a) comorbidity with major depression, substance abuse, schizotypal personality disorder, or borderline personality disorder; (b) prominent suicidal ideation; (c) pregnancy or lactation; (d) subclinical OCD (Y-BOCS $\leq$ 18); (e) previous adequate trials of EX/RP or CMI; or (f) concurrent pharmacotherapy. The EX/RP program used in the Kozak et al. study is similar to the regimen used in our outpatient clinic.

Lindsay et al. (1997) randomly assigned patients to EX/RP or anxiety management training (AMT) to examine the efficacy of intensive EX/RP in comparison with a credible psychosocial placebo. Study exclusion criteria were not specified. Intensity of EX/RP was similar to that conducted by Kozak et al. (2000) in that each program involved 15 daily sessions conducted over a 3-week period. The clear superiority of EX/RP versus AMT found in the Lindsay et al. study could not be attributed to differences in therapist–client relationship quality because both groups rated their therapists as highly supportive and understanding.

Finally, van Balkom et al. (1998) examined the relative efficacy of the following five treatments: (a) EX/RP, (b) cognitive therapy, (c) EX/RP + FLX, (d) cognitive therapy + FLX, and (e) wait list. In each of the four active treatments, therapists met with patients 16 times over 16 weeks. We compared CTSA outcomes with van Balkom et al.'s EX/RP results. Patients with obsessions only, organic mental disorders, psychotic disorders, and mental retardation and those unwilling to stop psychotropic medication use were excluded from this RCT. Exposure was not practiced with the therapist during treatment sessions but was assigned only for homework. Moreover, to test hypotheses about the role of cognitive interventions, expectations of disastrous consequences were not discussed during the first 8 weeks of EX/RP.

Method

Participants

Participants were 110 adult outpatients (58 men, 52 women) treated on a fee-for-service basis at the Medical College of Pennsylvania–Hahnemann University's CTSA. Most participants were either referred by a mental health practitioner, responded to media advertisements of our clinical and research programs, or were referred by patient advocacy groups such as the OC Foundation. Patients in the present sample either refused entry (21%) or were deemed ineligible for participation (79%) in RCTs being conducted at the CTSA. Reasons for ineligibility included a Y-BOCS score less than or equal to 18 (4%), comorbid Axis I diagnosis (47%), previous EX/RP (7%), previous adequate trial of CMI (24%), and out-of-town residence (13%). Of the 20 patients who refused participation in RCTs, 6 (30%) did so specifically because they did not wish to receive placebo or medication.

Participants were treated between 1992 and 1998; 20 additional patients who also received open EX/RP treatment at our clinic during this period were excluded from the present study because of missing essential data (e.g., pretreatment Y-BOCS). Written informed consent was obtained from all of the patients after a complete description of the EX/RP treatment program was provided. No adult patient was excluded from participation because of age, secondary comorbid Axis I diagnoses, medical problems, treatment history, use of concomitant medication, or Axis II disorders.

The 110 patients who entered the EX/RP open treatment program ranged in age from 18 to 74 years (M = 34.2, SD = 13.1); 98% were Caucasian, 1% were African American, and 1% were Asian. Forty-six percent of the sample held a 4-year undergraduate or graduate degree. Marital status was 31% married; 57% never married; and 13% divorced, separated, or widowed. With respect to employment status, 39% were employed at least part-time, 32% were unemployed, 23% were students, and 5% described themselves as full-time homemakers. More than half of our sample (54%) met the criteria for comorbid psychiatric diagnoses. Frequencies of each comorbid condition are listed in Table 1.

Concurrent Treatment

Forty-four of the 110 EX/RP entrants (40%) were not taking any psychotropic medications at intake. However, most of these patients reported previous treatment with a serotonergic medication of documented efficacy for OCD. Twenty-eight of our patients (26%) were currently taking either CMI or a selective serotonergic medication (e.g., sertraline); 4 (4%) were taking one anxiolytic medication (e.g., buspirone); 15 (14%) were taking either CMI or a selective serotonergic medication plus an anxiolytic; and 19 (17%) were taking several medications, including CMI, selective serotonergic compounds, and anxiolytic medications. Of the 62 patients (56%) using at least one antidepressant medication of documented efficacy for OCD, 31 were taking CMI, 20 were taking fluoxetine, 9 were taking sertraline, 7 were taking FLX, and 4 were taking paroxetine. Patients on medication at intake continued to take their medication throughout EX/RP treatment.

Assessment

Diagnosis of OCD according to *DSM–III–R* (American Psychiatric Association, 1987) or, if during or after 1994, *DSM–IV* (American Psychiatric Association, 1994) criteria was established in a two-stage intake process in which each patient was interviewed separately by two assessors. First, each patient was interviewed for 2 hr by a doctoral-level clinical psychologist experienced and trained extensively in diagnosing OCD. The interview began with general inquiry into the current symptoms, review of treatments for OCD and related problems, and an unstructured assessment of current comorbid Axis I conditions. The interview was then guided by the use of the Y-BOCS checklist, a comprehensive list of typical obsessions and compulsions, and the Y-BOCS Symptom Severity scale (see description in the *Measures* section). In addition, inquiry was made about current cognitive and vegetative symptoms of depression (see description of the Hamilton Rating Scale for Depression [HRSD; Hamilton, 1960] in the *Measures* section). On completion of this intake, the first assessor presented the interview data to a senior psychologist (Edna B. Foa, Michael J. Kozak, or Martin E. Franklin) who confirmed the OCD diagnosis and discussed treatment options with the patient and their family. All of the patients in the present study were diagnosed as having primary OCD by both interviewers (100% interrater agreement) and agreed to enter the fee-for-service treatment program. Symptom severity was assessed at pre- and posttreatment by evaluators not otherwise involved in the patient's therapy.

Table 1
Comorbid Psychiatric Diagnoses in CTSA Sample

Comorbid diagnosis	*n*	%
None	53	54
Major depressive disorder	25	26
Axis II disorder	17	17
Other anxiety disorder	12	12
Other Axis I disorder	7	7
Bipolar disorder	3	3
Psychotic disorder	1	1

Note. Some patients had multiple comorbid diagnoses. Data were missing for 12 patients. CTSA = Center for the Treatment and Study of Anxiety.

Measures

Y-BOCS (Goodman, Price, Rasmussen, Mazure, Delgado, et al., 1989a; Goodman, Price, Rasmussen, Mazure, Fleischmann, et al., 1989b). OCD symptoms were assessed using the Y-BOCS, a semistructured clinical interview that includes a 10-item Symptom Severity scale. Obsessions and compulsions are rated separately, yielding two subscores (range = 0–20) that are added to produce a total severity score (range = 0–40). Symptoms are rated on a 5-point Likert scale ranging from 0 (*no symptoms*) to 4 (*severe symptoms*). Items are as follows: time spent on symptoms, interference, distress, resistance, and control. The instrument also contains a checklist of obsessions and compulsions. The Y-BOCS has satisfactory psychometric properties and has been found sensitive to treatment effects (e.g., Hiss, Foa, & Kozak, 1994).

HRSD (Hamilton, 1960). Depressive symptoms were assessed using the 17-item HRSD, a widely used clinician rating scale for vegetative symptoms of depression. Scores on this version of the HRSD range from 0 (*no symptoms*) to 50 (*very severe symptoms*). The sound psychometric properties of the scale are supported by an extensive literature (Hedlund & Vieweg, 1979).

BDI (Beck et al., 1961). The BDI is a 21-item self-report scale that assesses the severity of affective, cognitive, motivational, vegetative, and psychomotor components of depression. Scores of 10 or less are considered normal; scores of 20 or greater suggest the presence of clinical depression. The BDI has been shown to have excellent reliability and validity (Beck, Steer, & Garbin, 1988) and is widely used in treatment outcome research.

Treatment

All of the CTSA patients received intensive CBT for OCD, typically involving 3 treatment planning sessions followed by 15 EX/RP sessions. Sessions lasted for 2 hr each, and treatment was conducted over the course of approximately 4 weeks. Treatment was manualized but formal treatment fidelity data were not gathered. Treatment planning sessions were devoted to information gathering about the nature of the OCD symptoms, development of an exposure hierarchy, education about OCD, and the rationale for EX/RP. Patients were told that adequate exposure to feared situations and objects ultimately reduces obsessional distress, and adequate exposure requires refraining from rituals and avoidance. Following the planning sessions, EX/RP sessions began. Each session consisted of EX/RP and a review of homework assignments that patients had been asked to complete between sessions. Degree of involvement of support persons and family was determined by clinical judgment.

Exposure exercises. These were designed to trigger the patient's specific obsessional concerns. Patients were encouraged to persist with each exposure until the distress decreased noticeably. Exposure exercises were arranged hierarchically, beginning with moderately distressing ones. Exposure exercises gradually progressed toward the most distressing situation or object, which was typically confronted during exposure Session 6. In addition to practicing during the session, patients were assigned approxi-

mately 2 hr of exposure and ritual prevention homework tasks to complete between each daily session.

Ritual prevention. Patients were instructed to refrain from rituals throughout the entire treatment period. The rationale for ritual prevention was introduced at the first session and emphasized before and throughout treatment. Self-monitoring was used throughout treatment to enhance awareness of situations that triggered patients' urges to ritualize. When violations of ritual prevention occurred, therapists reviewed strategies of how to cope more effectively with compulsive urges. To improve compliance, therapists encouraged patients to seek assistance from their designated support person or call the therapist instead of engaging in compulsions. Toward the latter part of the program, the therapist introduced relapse-prevention techniques that have been found effective with OCD (Hiss et al., 1994).

Therapists, Therapist Assignment, and Supervision

Treatment was conducted by clinical psychologists and clinical psychology interns who had received training in EX/RP treatment for OCD at the CTSA. There was a broad range of general clinical experience and OCD expertise among these therapists. Amount of experience ranged from no postdoctoral training to 16 years postdoctoral experience and expertise with OCD. Therapist training consisted of reading the treatment manual, sitting in while a patient received intensive treatment and assisting the primary therapist with exposure exercises, and then serving as the primary therapist on the next case. Cases were assigned to therapists nonrandomly and on the basis of clinical factors (e.g., case complexity), patient variables (e.g., preference for female therapist), and practical matters (e.g., therapist availability). Senior clinical psychologists with expertise in these procedures (Edna B. Foa, Michael J. Kozak, and Martin E. Franklin) provided individual supervision for nonlicensed therapists. Supervision for less experienced therapists (e.g., interns) typically consisted of daily individual contact for approximately 30 min; more experienced therapists met less frequently (e.g., twice weekly) with their supervisors. All cases were also discussed in weekly group supervision meetings.

Results

Overview

Our approach to data analysis and benchmarking included five steps. First, demographic characteristics of the CTSA sample were compared with samples that received EX/RP in the selected RCTs. Second, features of EX/RP treatment programs (e.g., session frequency) were compared across studies. Third, treatment completers in our sample were compared with patients who discontinued treatment. Fourth, pre–post changes in OCD and depressive symptoms in the CTSA sample were examined and then contrasted with results from the selected RCTs. Finally, we examined predictors of treatment outcome in the CTSA sample.

Demographic Characteristics

Descriptive statistics from the CTSA clinical sample and the Fals-Stewart et al. (1993), Kozak et al. (2000), Lindsay et al. (1997), and van Balkom et al. (1998) samples appear in Table 2. As can be seen, mean ages and the male:female ratio of each sample were similar. The Kozak et al. sample had fewer years of schooling than the CTSA or Lindsay et al. sample; data on educational status were not reported by Fals-Stewart et al. or van Balkom et al.

Comparison of EX/RP Features Across Samples

Procedures for EX/RP treatment can vary along the following dimensions: (a) length of individual exposure sessions, (b) number of sessions per week, (c) number of weeks in treatment, (d) exposure medium (in vivo and/or imaginal), (e) control of exposure (therapist and/or patient), (f) exposure strategy (graded or flooding), (g) inclusion of exposure homework assignments, and (h) degree of ritual prevention. Table 3 summarizes characteristics of the EX/RP programs used in the CTSA sample and in the selected RCTs.

The intensive EX/RP programs used in the CTSA and Kozak et al. (2000) samples were highly similar to those used by Lindsay et al. (1997), with the exception of session length. In contrast to these studies, Fals-Stewart et al. (1993) and van Balkom et al. (1998) used less intensive programs. Additionally, ritual prevention instructions were more lenient in the Fals-Stewart et al. and van Balkom et al. studies. With respect to control of exposure exer-

Table 2
Descriptive Characteristics of Treatment Completers in the CTSA and Randomized Controlled Trial Samples

		Randomized controlled trial			
Variable	CTSA[a]	Kozak et al. (2000)	van Balkom et al. (1998)	Fals-Stewart et al. (1993)	Lindsay et al. (1997)
Completer sample size	100	13	19	31	9
Mean age (years)	34.2	34.8	33.8	30.5	31.6
Gender (% female)	47	46	53	55	56
% married	28				44
% with undergraduate or graduate degree	45	34			44
% employed full-time	39				
% White/Caucasian	98	84			
% using SRIs	61	0	0	0	56
% with comorbid diagnosis	46				

Note. CTSA = Center for the Treatment and Study of Anxiety, SRIs = serotonin reuptake inhibitors.
[a] Data were missing for some patients on some measures.

Table 3
Exposure and Ritual Prevention Procedures Used to Treat the CTSA and Randomized Controlled Trial Samples

Treatment variable	CTSA and Kozak et al. (2000)	Fals-Stewart et al. (1993)	Lindsay et al. (1997)	van Balkom et al. (1998)
Length of session	1.5 hr	1.5 hr	1–2 hr	45 min
No. of sessions per week	5	2	5	1–2
No. of weeks in treatment	3	12	3	16
Exposure medium	in vivo and imaginal	in vivo and imaginal		in vivo only
Control of exposure	therapist and patient	therapist and patient	therapist and patient	patient only
Exposure strategy	graded	graded	graded	graded
Use of in-session exposure	yes	yes	yes	no
Use of homework exposure	yes	yes	yes	yes
Ritual prevention instructions	no ritualizing at all	no ritualizing for 1 hr after exposure	no ritualizing at all	gradual

Note. CTSA = Center for the Treatment and Study of Anxiety.

cises, only in van Balkom et al.'s study were such exercises never conducted in face-to-face sessions with the therapist.

Comparison of Completers and Noncompleters in the CTSA Sample

Of the 110 patients who began treatment at the CTSA, 10 (9%) discontinued treatment prior to completing the EX/RP program. This attrition rate is almost identical to that reported in Fals-Stewart et al.'s (1993) individual EX/RP condition (9%) and lower than that reported for EX/RP in the van Balkom et al. (1998) and Kozak et al. (2000) studies (15% and 28%, respectively). Lindsay et al. (1997) reported no discontinuation among the 9 patients who received EX/RP in their study.

Mean age of noncompleters in our sample was 38.5 years (SD = 11.7). Thirty percent of these patients were married, 50% held a 4-year undergraduate or postgraduate degree, 75% were employed full-time, all were Caucasian, and 50% were using psychotropic medication. Chi-square and t tests used to compare noncompleters with CTSA treatment completers (see Table 1) revealed no significant differences between groups (all $ps \geq .10$). Pretreatment Y-BOCS total scores for the 100 completers (M = 26.64, SD = 4.94) and 10 noncompleters (M = 28.30, SD = 4.35) were not significantly different, $t(108) = 1.02$, $p = .31$. Similarly, pretreatment BDI scores for completers (M = 18.70, SD = 8.43) and noncompleters (M = 17.14, SD = 8.51) were not significantly different, $t(92) = 0.37$, $p = .71$. Thus, treatment dropouts and completers did not appear to differ with respect to demographics or severity of their pretreatment OCD and depressive symptoms.

Treatment Outcome in the CTSA Sample and Benchmarking to RCTs

Main outcome. Pre- and posttreatment means and standard deviations on the Y-BOCS, the HRSD, and the BDI for intent-to-treat and the completer sample in the CTSA are presented in Table 3. Patients who dropped out of treatment (n = 10) were retained in the intent-to-treat analysis by substituting their pretreatment scores for the missing posttreatment scores. This analysis, therefore, is a more conservative test of the effectiveness of treatment. To determine whether significant reduction in symptoms occurred following treatment, we conducted a repeated measures multivariate analysis of variance using the Y-BOCS, HRSD, and BDI scores. This analysis revealed that changes from pre- to posttreatment were highly significant for the intent-to-treat, $F(3, 85) = 208.74$, $p < .001$, and completer samples, $F(3, 75) = 201.55$, $p < .001$. Given the significant multivariate findings, we computed follow-up paired t tests separately for each of the three dependent measures. As can be seen in Table 4, all of the pre- versus posttreatment contrasts were highly significant: Patients in the CTSA sample improved significantly on all three measures of psychopathology.

Table 4
Means and Standard Deviations on Outcome Variables at Pre- and Posttreatment for CTSA Entrants (Intention to Treat) and CTSA Completers

	Pretreatment		Posttreatment			
Measure	M	SD	M	SD	df	t
Intention to treat (n = 110)						
Y-BOCS	26.79	4.89	11.81	7.30	109	20.90*
BDI	18.44	8.47	8.16	7.75	90	12.16*
HRSD	12.96	5.84	6.51	5.33	90	11.38*
Completers (n = 100)						
Y-BOCS	26.64	4.94	10.54	5.94	99	24.70*
BDI	18.70	8.43	8.08	7.42	86	11.94*
HRSD	12.54	5.91	6.46	5.38	88	11.74*

Note. Sample sizes varied because of missing data. CTSA = Center for the Treatment and Study of Anxiety; Y-BOCS = Yale–Brown Obsessive–Compulsive Scale; BDI = Beck Depression Inventory; HRSD = Hamilton Rating Scale for Depression.
* $p < .01$, improvement from pre- to posttreatment.

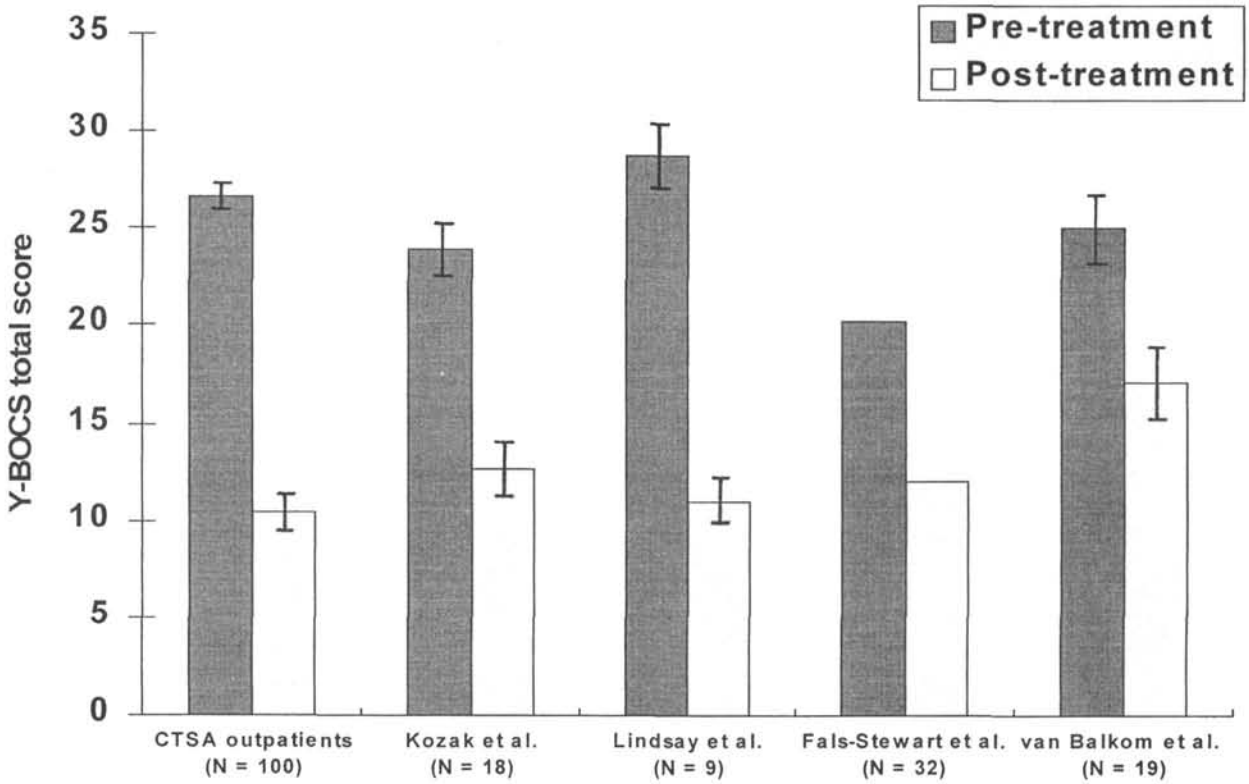

Figure 1. Pre- and posttreatment Y-BOCS scores ($\pm SD$) for CTSA outpatients and the Kozak et al. (2000), Lindsay et al. (1997), Fals-Stewart et al. (1993), and van Balkom et al. (1998) samples in randomized controlled trials. CTSA = Center for the Treatment and Study of Anxiety; Y-BOCS = Yale–Brown Obsessive–Compulsive Scale.

Benchmarking comparisons. The Y-BOCS was used to make benchmarking comparisons for OCD symptoms, and the BDI was used to make benchmarking comparisons of depressive symptoms. The BDI was chosen for benchmarking because it was reported more frequently in the selected RCTs than was the HRSD. Pre- and posttreatment Y-BOCS and BDI results for the CTSA treatment completers and RCT samples are presented in Figures 1 and 2.

Pretreatment OCD severity of the CTSA clinical sample was comparable with that of the Kozak et al. (2000), Lindsay et al. (1997), and van Balkom et al. (1998) samples and somewhat greater than that of the Fals-Stewart et al. (1993) sample. Mean Y-BOCS reduction at posttreatment for the CTSA group was 60%, which was comparable with that reported by Lindsay et al. (62%) and Kozak et al. (54%) yet apparently larger than that found by Fals-Stewart et al. (40%) and van Balkom et al. (32%).

Mean reduction in the BDI at posttreatment for the CTSA patients was 57%. This was somewhat larger than the 39% reduction reported by Lindsay et al. (1997) and the 43% reduction observed by Fals-Stewart et al. (1993). In the van Balkom et al. (1998) study, patients in the EX/RP condition evidenced a slight increase (15%) in depressive symptoms as measured by the BDI. BDI data were not available for the Kozak et al. (2000) sample.

To further examine the effects of treatment in each sample, we computed effect sizes by dividing the mean pre–post difference in the dependent measure by the pretreatment standard deviation. Because standard deviations were not reported in the Fals-Stewart et al. (1993) investigation, effect sizes from this study were calculated from statistical tests using the procedures outlined by Ray and Shadish (1996, p. 1324). Effect sizes for the Y-BOCS and BDI are reported in Table 4. Cohen (1977) asserted that effect sizes of 0.2, 0.5, and 0.8 correspond to small, medium, and large effects. As is evident from Table 5, large effects emerged for EX/RP in each study on OCD symptoms. Effects of EX/RP on depressive symptoms were also large, with the exception of the van Balkom et al. (1998) study.

Clinically significant change. As indicated above, treatment gains were highly significant in the CTSA sample, even in the more conservative intent-to-treat analyses. In addition to examining statistical significance, it is important to determine the clinical significance of the obtained changes in OCD symptoms. Accordingly, we used procedures described by Kendall, Marrs-Garcia, Nath, and Sheldrick (1999) to determine whether the CTSA completer sample, at posttreatment, was distinguishable from nonpatients with respect to OCD symptoms. Nonpatient Y-BOCS data reported by Steketee, Frost, and Bogert (1996; $M = 7.2$, $SD = 4.5$) were used to specify the range of clinical equivalence ($\delta_1 = -4.5$, $\delta_2 = \infty$). Whereas the CTSA posttreatment Y-BOCS scores were higher than the nonpatient scores, $t(117) = 2.42$, $p < .01$, the treated sample's mean was within the defined range of clinical equivalence, $t(117) = 2.44$, $p < .01$. Thus, although statistically

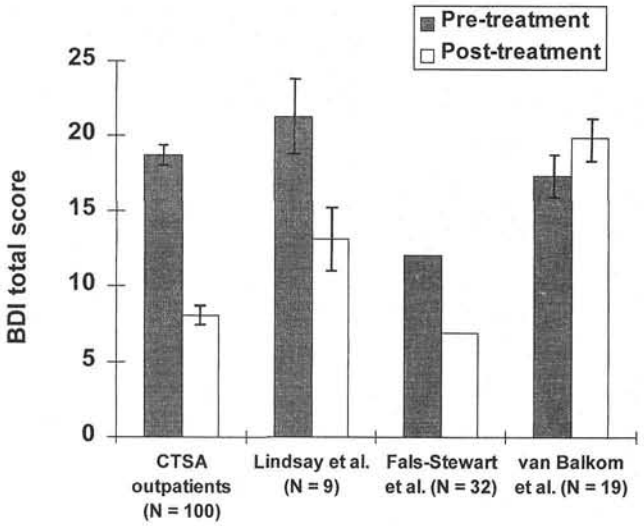

Figure 2. Pre- and posttreatment BDI scores (±*SD*) for CTSA outpatients and the Lindsay et al. (1997), Fals-Stewart et al. (1993), and van Balkom et al. (1998) samples in randomized controlled trials. CTSA = Center for the Treatment and Study of Anxiety; BDI = Beck Depression Inventory.

significant, the difference between treated OCD patients and nonpatients was clinically meaningless.

To determine the number of CTSA patients who achieved (a) end-state functioning within the nonpatient distribution of Y-BOCS scores and (b) reliable change, we used the methods detailed by Jacobson and Truax (1991). The same nonpatient Y-BOCS data were used to calculate the cut score for the nonpatient Y-BOCS distribution (Y-BOCS = 16). Next, the test–retest reliability of the Y-BOCS interview (r = .88; Steketee et al., 1996) was used to calculate a reliable change index (Jacobson & Truax, 1991) that indicated whether each patient's pre–post change was attributable to therapy as opposed to imprecision in the Y-BOCS. Eighty-six percent of the CTSA treatment completers had posttreatment Y-BOCS scores that were lower than the cut score and also evidenced reliable change, providing further evidence of clinically significant improvement.

Predictors of Outcome in the CTSA Sample

A hierarchical multiple regression approach was used to examine the unique associations between posttreatment OCD symptom severity and the following pretreatment patient characteristics: age, highest obtained educational level, use of antiobsessional medication, pretreatment OCD severity, and pretreatment depression severity. The posttreatment Y-BOCS total score was used as the dependent variable. In Step 1, pretreatment depression severity (the HRSD) entered the equation first, accounting for 13% of the variance in posttreatment Y-BOCS scores (β = 0.34), $F(1, 67) = 10.30$, $p < .01$. Pretreatment OCD severity (the Y-BOCS) then added significantly to the model, accounting for an additional 5% of the variance (β = 0.24), $F(2, 66) = 7.53$, $p < .01$. The final model accounted for 18% of the variance in the posttreatment Y-BOCS score; no other predictors added significantly to the model.

Discussion

In the present study, we found that OCD patients receiving outpatient EX/RP on a fee-for-service basis achieved mean OCD and depressive symptom reductions comparable with those observed in several RCTs. Thus, it appears that the encouraging findings for EX/RP from these RCTs cannot be dismissed readily as nonrepresentative of what can be achieved with "real" patients being seen outside research trials. Our findings were especially encouraging in that substantial and clinically significant symptom reductions were evident at posttreatment: 86% of treatment completers surpassed a conservative criterion of clinical improvement. Thus, intensive EX/RP is a robust treatment for OCD that yields substantial symptom reduction, and its immediate benefits are not limited to highly selected patient samples.

Pretreatment depressive symptoms and OCD severity were the only variables found to be predictive of outcome in the CTSA sample; patient age, education level, and use of antiobsessional medication were not predictive of posttreatment OCD severity. The absence of medication status from the final regression equation suggests that patients can benefit substantially from EX/RP whether or not they are receiving concomitant pharmacotherapy. The regression equation accounted for only 18% of the variance in posttreatment Y-BOCS scores, suggesting that additional research is needed for identifying variables that predict treatment response. However, it is important to note that in the present study, the range of posttreatment scores was restricted, thereby reducing the likelihood of detecting predictors of outcome.

Although their pretreatment OCD symptoms were on the whole fairly severe, the CTSA patients probably represent a highly motivated group who entered treatment despite clear discussions at intake of the kinds of EX/RP tasks that would be required for successful outcome. Future study should include predictors of treatment acceptance, as many patients who are offered EX/RP refuse entry into the program for a variety of reasons that may be clinically important.

Our findings also support an oft-cited (e.g., Kozak & Foa, 1997) clinical observation regarding the superiority of intensive treatment over less intensive regimens, but this observation must be interpreted cautiously. The largest apparent reductions in OCD symptoms were observed in the CTSA, Kozak et al. (2000), and Lindsay et al. (1997) samples, each of which used an intensive treatment program. However, the sample receiving individual EX/RP in Fals-Stewart et al.'s (1993) study began treatment with

Table 5
Treatment Effect Sizes for the CTSA Outpatients and Randomized Controlled Trial Samples

Sample	OCD symptoms (Y-BOCS)	Depressive symptoms (BDI)
CTSA outpatients	3.26	1.26
Kozak et al. (2000)	2.31	
Fals-Stewart et al. (1993)	0.93	0.93
Lindsay et al. (1997)	3.88	0.79
van Balkom et al. (1998)	1.00	−0.33

Note. CTSA = Center for the Treatment and Study of Anxiety; OCD = obsessive–compulsive disorder; Y-BOCS = Yale–Brown Obsessive–Compulsive Scale; BDI = Beck Depression Inventory.

milder OCD and thus had a limited range for symptom reductions. Additionally, patients in that study were instructed to refrain from rituals for 1 hr following exposure exercises rather than continuously, and there is evidence that less strict response prevention instructions are related to poorer outcome (Abramowitz, 1996). Several factors may have limited the benefits of treatment in van Balkom et al.'s (1998) study. First, discussions of disastrous consequences were prohibited throughout the first 6 weeks of EX/RP. These discussions are a routine part of EX/RP treatment as typically conducted (Kozak & Foa, 1997), and therefore outcome may have been attenuated by this omission. In the van Balkom et al. study, therapist-aided exposure was not included, sessions were half the length of those in the other studies, and ritual prevention instructions were more lenient than those used in the CTSA, Kozak et al., and Lindsay et al. studies. Because of the procedural variations in the Fals-Stewart et al. and van Balkom et al. EX/RP treatments, it is difficult to isolate the effects of treatment intensity. A study under way in our center comparing intensive EX/RP with an otherwise identical twice-weekly regimen (e.g., therapist-assisted exposure and strict ritual prevention instructions) will allow for stronger inferences about the effect of treatment intensity than can be gleaned from the present investigation. That study is of particular importance because practical difficulties posed by daily treatment can sometimes be a barrier to its use by clinicians, insurance companies, and patients alike.

The efficacy of EX/RP for OCD having already been established, the present investigation should be considered an important step in demonstrating its effectiveness. Our findings indicate that EX/RP yields substantial and clinically meaningful OCD symptom reduction even for patients with a wide variety of comorbid problems and complex treatment histories, some of whom were receiving concomitant pharmacotherapy. Additionally, there was a greater range of therapist experience in the present investigation than is typical of RCTs: The therapists who conducted EX/RP with CTSA patients ranged from clinical psychology interns to highly experienced EX/RP clinicians. It is important now to determine the degree of training and expert supervision needed to produce comparable results. This approach to the establishment of treatment effectiveness has been advocated by Strosahl, Hayes, Bergan, and Romano (1998) with respect to action and commitment therapy and may be a fruitful direction for OCD effectiveness research.

A meaningful distinction has been made between approaches to therapist supervision in research, as opposed to nonresearch, settings (Kendall & Southam-Gerow, 1995). In the present study, therapists were supervised by the very experts who developed the treatment protocol. Additionally, supervision was often conducted in groups with several therapists who were using the same treatment manual. This context likely fostered increased social support and collective encouragement and may have contributed to the generally favorable outcomes reported here. Whereas the supervision conditions in research-based settings are ripe for influencing the apparent efficacy of a manualized treatment, such conditions are less likely to be present in general clinic settings. Therefore, research addressing the transportability of EX/RP to service settings should be cognizant of the potential effects of supervision. Although not addressed formally in this study, the influence of supervision on treatment outcome may also be examined in future effectiveness studies by manipulating supervision frequency (e.g., weekly group and individual supervision vs. occasional and brief telephone contact).

Our findings are encouraging with regard to the generalizability of EX/RP, but the present study focused more on ecological validity than on experimental control and therefore has limitations attendant to such an approach. Although a treatment manual was used and supervisors met frequently with therapists, formal treatment integrity data were not collected, and thus information about protocol adherence cannot be ascertained. Wade et al.'s (1998) suggestion to use brief rating scales to assess treatment integrity might afford an advance. Also, although patients were not excluded for the presence of comorbid secondary Axis I or Axis II diagnoses, systematic and rigorous assessment of these comorbid diagnoses was not conducted. Thus, although our clinical impression of these patients is that they are on the whole more complex than those we treat in our ongoing RCT, we cannot determine with sufficient accuracy whether or not the present sample is actually more "comorbid" than RCT samples. Future studies might attempt to bridge the gap by using available self-report measures and brief interviews currently available for such purposes. Finally, the present study does not include long-term follow-up data to examine maintenance of gains and medication status over time; a large-scale study of this sort is planned, which we hope will provide additional information about EX/RP's generalizability and residual impairments in treated OCD patients.

The present study was designed specifically to address the question of the generalizability of EX/RP for OCD and suggests that RCT findings of its efficacy are indeed generalizable to clinical practice. The present investigation serves as a first step in this endeavor, as the clinical research context and availability of expert supervisors limits the degree to which our setting is like typical clinical practice. Nevertheless, our findings clearly address the question raised by Silberschatz (as cited in Persons & Silberschatz, 1998) of whether randomized and nonrandomized patients respond similarly to EX/RP, and it appears as if they do. Future studies should focus on dissemination of EX/RP to clinicians who see OCD patients in their practices but have not had the opportunity to achieve competence in EX/RP procedures. In such investigations, degree of therapist training in EX/RP for OCD and availability of ongoing expert supervision may be assessed to examine the impact of these variables on EX/RP treatment outcome, perhaps in comparison with treatment as usual or with naturally occurring wait-list controls. It is incumbent on clinical researchers involved with OCD to extend their efforts to examine transportability of EX/RP to a variety of clinical settings. Otherwise, this potent treatment is likely to remain only scarcely available to patients because of a shortage of clinicians who are skilled with EX/RP.

References

Abramowitz, J. S. (1996). Variants of exposure and response prevention in the treatment of obsessive–compulsive disorder: A meta-analysis. *Behavior Therapy, 27,* 583–600.

Abramowitz, J. S. (1997). Effectiveness of psychological and pharmacological treatments for obsessive–compulsive disorder: A quantitative review. *Journal of Consulting and Clinical Psychology, 65,* 44–52.

American Psychiatric Association. (1987). *Diagnostic and statistical manual of mental disorders* (3rd ed., rev.). Washington, DC: Author.

American Psychiatric Association. (1994). *Diagnostic and statistical manual of mental disorders* (4th ed.). Washington, DC: Author.

Angst, J. (1994). The epidemiology of obsessive compulsive disorder. In E. Hollander, J. Zohar, D. Marazziti, & B. Oliver (Eds.), *Current insight in obsessive compulsive disorder* (pp. 93–104). West Sussex, United Kingdom: Wiley.

Beck, A. T., Steer, R. A., & Garbin, M. G. (1988). Psychometric properties of the Beck Depression Inventory: Twenty-five years of evaluation. *Clinical Psychology Review, 8,* 77–100.

Beck, A. T., Ward, C. H., Mendelsohn, M., Mock, J., & Erlbaugh, J. (1961). An inventory for measuring depression. *Archives of General Psychiatry, 4,* 561–571.

Cohen, J. (1977). *Statistical power analysis for the behavioral sciences* (Rev. ed.). New York: Academic Press.

Fals-Stewart, W., Marks, A. P., & Schafer, J. (1993). A comparison of behavioral group therapy and individual behavior therapy in treating obsessive–compulsive disorder. *Journal of Nervous and Mental Disease, 181,* 189–193.

Goodman, W. K., Price, L. H., Rasmussen, S. A., Mazure, C., Delgado, P., Heninger, G. R., & Charney, D. S. (1989a). The Yale–Brown Obsessive Compulsive Scale: II. Validity. *Archives of General Psychiatry, 46,* 1012–1016.

Goodman, W. K., Price, L. H., Rasmussen, S. A., Mazure, C., Fleischmann, R. L., Hill, C. L., Heninger, G. R., & Charney, D. S. (1989b). The Yale–Brown Obsessive Compulsive Scale: I. Development, use, and reliability. *Archives of General Psychiatry, 46,* 1006–1011.

Hamilton, M. (1960). A rating scale for depression. *Journal of Neurological and Neurosurgical Psychiatry, 18,* 315–319.

Hedlund, J., & Vieweg, B. (1979). The Hamilton Rating Scale for Depression: A comprehensive review. *Journal of Operating Psychiatry, 10,* 149–165.

Hiss, H., Foa, E. B., & Kozak, M. J. (1994). A relapse prevention program for obsessive–compulsive disorder. *Journal of Consulting and Clinical Psychology, 62,* 801–808.

Jacobson, N., & Truax, P. (1991). Clinical significance: A statistical approach to defining meaningful change in psychotherapy research. *Journal of Consulting and Clinical Psychology, 59,* 12–19.

Karno, M., Golding, J. M., Sorenson, S. B., & Burnam, A. (1988). The epidemiology of obsessive–compulsive disorder in five U.S. communities. *Archives of General Psychiatry, 45,* 1094–1099.

Kendall, P. C., Chu, B., Gifford, A., Hayes, C., & Nauta, M. (1998). Breathing life into a manual: Flexibility and creativity with manual-based treatments. *Cognitive and Behavioral Practice, 5,* 177–198.

Kendall, P. C., Marrs-Garcia, A., Nath, S. R., & Sheldrick, R. C. (1999). Normative comparisons for the evaluation of clinical significance. *Journal of Consulting and Clinical Psychology, 67,* 285–299.

Kendall, P. C., & Southam-Gerow, M. A. (1995). Issues in the transportability of treatment: The case of anxiety disorders in youths. *Journal of Consulting and Clinical Psychology, 63,* 702–708.

Koran, L., Thienemann, M., & Davenport, R. (1996). Quality of life for patients with obsessive–compulsive disorder. *British Journal of Psychiatry, 156,* 51–54.

Kozak, M. J., & Foa, E. B. (1997). *Mastery of obsessive–compulsive disorder: A cognitive–behavioral approach.* San Antonio, TX: Psychological Corporation.

Kozak, M. J., Liebowitz, M. R., & Foa, E. B. (2000). Cognitive behavior therapy and pharmacotherapy for OCD: The NIMH-sponsored collaborative study. In W. Goodman, M. Rudorfer, & J. Maser (Eds.), *Obsessive compulsive disorder: Contemporary issues in treatment* (pp. 501–530). Mahwah, NJ: Erlbaum.

Lindsay, M., Crino, R., & Andrews, G. (1997). Controlled trial of exposure and response prevention in obsessive–compulsive disorder. *British Journal of Psychiatry, 171,* 135–139.

Marks, I. M., Hodgson, R., & Rachman, S. (1975). Treatment of chronic obsessive–compulsive neurosis by in vivo exposure. *British Journal of Psychiatry, 127,* 349–364.

Persons, J. B., & Silberschatz, G. (1998). Are results of randomized controlled trials useful to psychotherapists? *Journal of Consulting and Clinical Psychology, 66,* 126–135.

Rachman, S., Cobb, J., Grey, S., McDonald, B., Mawson, D., Sartory, G., & Stern, R. (1979). The behavioural treatment of obsessive–compulsive disorders with and without clomipramine. *Behaviour Research and Therapy, 17,* 467–478.

Rasmussen, S. A., & Tsuang, M. T. (1986). Clinical characteristics and family history in *DSM–III* obsessive–compulsive disorder. *American Journal of Psychiatry, 143,* 317–322.

Ray, J. W., & Shadish, W. R. (1996). How interchangeable are different estimators of effect size? *Journal of Consulting and Clinical Psychology, 64,* 1316–1325.

Seligman, M. E. P. (1995). The effectiveness of psychotherapy: The *Consumer Reports* study. *American Psychologist, 50,* 965–974.

Steketee, G. S., Frost, R. O., & Bogert, K. (1996). The Yale–Brown Obsessive–Compulsive Scale: Interview versus self report. *Behaviour Research and Therapy, 34,* 675–684.

Strosahl, K. D., Hayes, S. C., Bergan, J., & Romano, P. (1998). Assessing the field effectiveness of acceptance and commitment therapy: An example of the manipulated training research method. *Behavior Therapy, 29,* 35–64.

van Balkom, A. J. L. M., de Haan, E., van Oppen, P., Spinhoven, P., Hoogduin, K. A. L., & van Dyk, R. (1998). Cognitive and behavioral therapies alone versus in combination with fluvoxamine in the treatment of obsessive–compulsive disorder. *Journal of Nervous and Mental Disease, 186,* 492–499.

Wade, W. A., Treat, T. A., & Stuart, G. L. (1998). Transporting an empirically supported treatment for panic disorder to a service clinic setting: A benchmarking strategy. *Journal of Consulting and Clinical Psychology, 66,* 231–239.

Received April 26, 1999
Accepted December 16, 1999 ■