Does the Therapy Manual or the Therapist Matter Most in Treatment of Obsessive-Compulsive Disorder? A Randomized Controlled Trial of Exposure With Response or Ritual Prevention in 118 Patients

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Background: The importance of the therapist's education and experience for the successful behavior treatment of obsessive-compulsive disorder (OCD) has not been investigated. Data on the relative effectiveness of self-controlled versus therapist-controlled in vivo exposure with response or ritual prevention (ERP) have yielded conflicting results. The present study compared the effectiveness of 4 different modes of delivery of ERP in a referred sample of OCD patients.

Method: Of the 146 eligible OCD outpatients, 118 patients enrolled in this randomized controlled trial and were randomly assigned to (1) therapist-controlled ERP performed by experienced behavior therapists; (2) therapist-controlled ERP performed by master's students of clinical psychology; (3) self-controlled ERP performed by experienced behavior therapists; and (4) self-controlled ERP performed by master's students of clinical psychology. This trial was performed from January 1999 to January 2005.

Results: Our analyses revealed no significant differences in clinical outcome between any of the different modes of delivery of ERP at posttreatment. The different ERP modes of delivery were associated with significant pretreatment to posttreatment improvement on all measurements, with large effect sizes on the primary outcome measure, the Yale-Brown Obsessive Compulsive Scale.

Conclusions: Our results indicate that clinically inexperienced master's students with no postgraduate training can be as capable as experienced and certified behavior therapists in treating OCD patients, as long as therapists adhere to a standardized treatment manual and adequate training and supervision is provided. In contrast to other studies, we did not find a supposed benefit of therapist-controlled ERP versus self-controlled ERP in patients with OCD.

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Until 2 decades ago, obsessive-compulsive disorder (OCD) was thought to be one of the most difficult neurotic disorders to treat.[1] Treatment studies carried out in recent years have produced some important insights, and considerable progress has been made in the study of effective treatments in OCD. Exposure with response or ritual prevention (ERP) is generally considered the treatment of choice for OCD.[2] Research has shown that approximately 75%–85% of OCD patients experience a considerable reduction in obsessive-compulsive symptoms[3–6] after treatment with ERP. Several meta-analyses have supported the effectiveness of in vivo ERP and demonstrated that this form of behavior therapy was associated with large effect sizes (ESs) for obsessive-compulsive symptoms.[7–9]

Increasing mental health care costs and extensive waiting lists for mental health care centers have given rise to a discussion on the possibilities of cheaper and more accessible modes of delivery of psychological treatment. One possibility that has been the subject of debate in recent years is the delivery of well-established treatment methods such as ERP by an inexperienced therapist or master's student therapist.

Until fairly recently, clinicians and researchers alike have tended to agree that the effectiveness of psychotherapy relies heavily on experience and graduate training in psychotherapy. However, few studies have actually examined the impact of therapist experience and specialty certification status on the outcome of clinical care for patients with mental disorders.[10–13] The available studies suggest that the amount of experience and education on the therapist's part has little effect on the outcome of psychotherapy, when the treatment is adequately supervised and delivered following a standardized treatment manual.[11] Others have suggested that these studies suffered from methodological shortcomings that might mask the effect of training and experience on the outcome of treatment.[10] Recently, a review demonstrated the effectiveness of psychological treatment conducted by paraprofessionals for anxiety and depressive disorders, but the low number of studies included in this review did not allow firm conclusions about the effect of paraprofessionals compared to professionals.[14] Until now, the importance of the therapist's education and experience for the successful behavior treatment of OCD has not been investigated.

On a different note, ERP for OCD is generally delivered in 1 of 2 different ways: ERP sessions in which the response

prevention is coached by the therapist, usually in the patient's own home (therapist-controlled ERP) and exposure sessions that are carried out as homework assignments in between therapy-sessions (self-controlled ERP). Data on the relative effectiveness of self-controlled versus therapist controlled exposure have yielded conflicting results. Two studies suggest that self-controlled ERP is just as effective as therapist-controlled ERP.[15,16] These studies were performed in the late seventies and eighties. In contrast, a meta-analysis[9] reported larger ESs for therapist-controlled exposure.

The present article reports the first randomized controlled trial comparing the differential effectiveness of 4 different modes of treatment delivery of ERP: (1) therapist-controlled ERP performed by experienced behavior therapists; (2) therapist-controlled ERP performed by master's students of clinical psychology; (3) self-controlled ERP performed by experienced behavior therapists; and (4) self-controlled ERP performed by master's students of clinical psychology. We tested 3 hypotheses: (1) that ERP performed by experienced behavior therapists would be more effective than ERP performed by master's clinical psychology students, (2) that therapist-controlled ERP would be more effective than self-controlled ERP, and (3) that ERP performed by experienced behavior therapists would result in lower dropout rates than ERP performed by master's clinical psychology students.

METHOD

Participants

This study was conducted at the academic outpatient clinic of a mental health institute specializing in the treatment of anxiety disorders in Amsterdam, between January 1999 and January 2005. The study was approved by the VU-University Medical Centre's Ethical Review Committee, Amsterdam.

All patients were recruited from referrals by general practitioners and mental health agencies. All participants were given a written description of the trial and gave informed consent in writing prior to enrollment in the study. The initial intake procedure yielded 146 eligible patients. The primary eligibility criteria were a minimum age of 17 years and a main diagnosis of OCD according to the *Diagnostic and Statistical Manual of Mental Disorders*, Fourth Edition (*DSM-IV*)[17] with at least a 1-year duration at intake. Patients with obsessions only, suicidal intent, organic brain disease, past or present psychosis, psychoactive substance use disorder, or severe borderline or antisocial personality disorders were excluded. All *DSM-IV* Axis I disorders were determined by the administration of a Dutch version of the Structured Clinical Interview for *DSM-IV* Axis I Disorders (SCID-I).[18] In the event that indications for severe borderline or antisocial personality disorders were detected during administration of SCID-I, the Structured Clinical Interview for *DSM-IV* Axis II disorders (SCID-II) was used to assess the presence of these preselected personality

disorders.[19] This diagnostic interview was conducted by 2 of the current authors (P.v.O and A.V.B.), who were both extensively trained and experienced in the administration of this instrument. Other exclusion criteria were currently receiving treatment elsewhere; treatment with either behavior therapy or cognitive therapy in the 6 months preceding baseline, and the use of benzodiazepines in a dose of more than (the equivalent of) 15 mg/d of diazepam. Patients taking antipsychotics, mood stabilizers, and antidepressants were included if they were willing and able to discontinue the use of medication at least 4 weeks before baseline measure. Of the 146 patients who met inclusion criteria, 118 (81%) were randomly assigned to treatment. Of the remainder, 18 (12%) met study exclusion criteria, and 10 (7%) withdrew their consent prior to randomization. The flow of the patients from initial recruitment though final analysis is presented in Figure 1.

As indicated in Figure 1, 101 of the 118 patients (86%) who were initially included attended at least 8 sessions of ERP treatment and were classified as completers for the purpose of data analysis, whereas 17 (14%) did not and were classified as dropouts. The majority of dropouts did not respond to numerous attempts at contact, which made it impossible to determine the reason for dropping out. One patient dropped out on account of a diagnosis of cancer. Posttreatment data were obtained for 7 dropouts; for the other 10 dropouts, pretreatment data were used in the intent-to-treat (ITT) analyses. Completers were compared with dropouts on all relevant demographic and clinical variables measured at pretreatment. Dropouts had significantly higher pretreatment total Yale-Brown Obsessive Compulsive Scale (YBOCS) scores, indicating more severe OCD symptoms at baseline, than completers of the trial. No differences were found with respect to sex, married/cohabiting status, education level, comorbidity with anxiety or depressive disorders, previous treatment, or age at onset ($P > .30$).

Procedure

Once eligibility was determined, participants were randomly assigned with equal probability to one of the aforementioned conditions: (1) therapist-controlled ERP performed by experienced behavior therapists; (2) therapist-controlled ERP performed by master's students of clinical psychology; (3) self-controlled ERP performed by experienced behavior therapists; (4) self-controlled ERP performed by master's students of clinical psychology. Participants were assigned to specific therapists within a given condition based on therapist availability.

Participants completed standard comprehensive outcome assessments at pretreatment and posttreatment. All assessments were administered by psychologists who were blind to treatment assignment.

Therapists

Six experienced behavior therapists (4 women, 2 men) and 13 master's clinical psychology students (10 women, 3 men) were recruited to participate as therapists. All therapists

Figure 1. Flow Diagram of Participants From Initial Recruitment Through Final Analysis
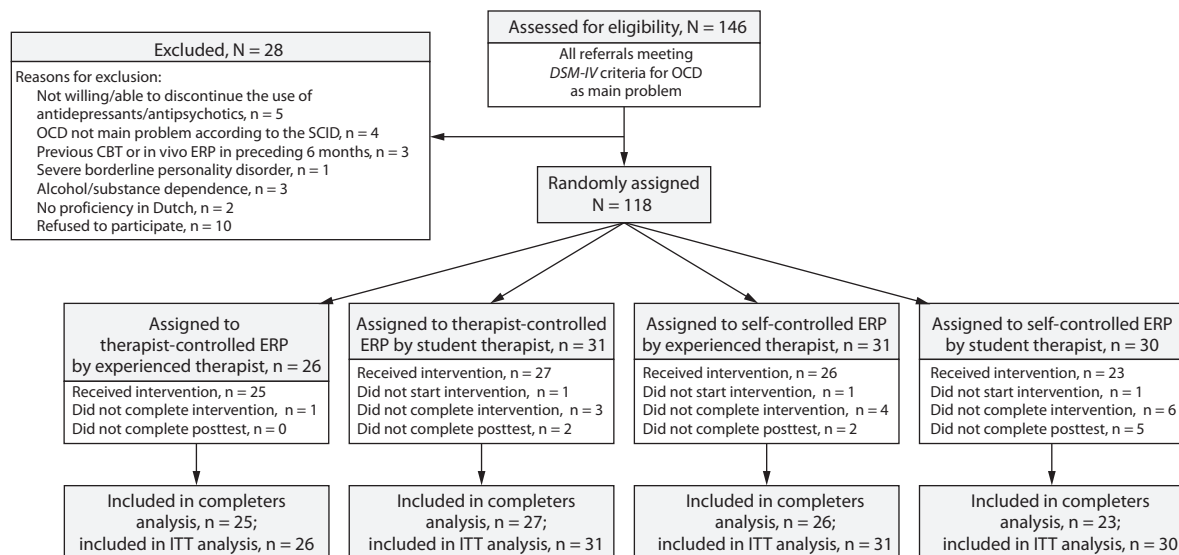
Abbreviations: CBT = cognitive-behavioral therapy; *DSM-IV = Diagnostic and Statistical Manual of Mental Disorders*, Fourth Edition[17]; ERP = exposure with response or ritual prevention; ITT=intent-to-treat; OCD=obsessive-compulsive disorder; SCID=Structured Clinical Interview for *DSM-IV*.

were required to study the ERP manuals and to attend weekly supervision by 1 of the authors (P.E. or P.v.O.), to check adherence to the treatment manual, and to provide assistance in planning the future sessions.

Experienced behavior therapists. The experienced behavior therapists had a master's degree in clinical psychology and were certified as members of the National Association of Behavior Therapy and Cognitive Therapy (NABTCT) in The Netherlands. All experienced therapists had completed an extensive certified postgraduate cognitive-behavioral treatment (CBT) training to ensure that they had the proficiency to apply CBT principles. Four experienced behavior therapists were certified as behavior therapy supervisors by the NABTCT at the start of the treatment, and 2 were certified as supervisors during the study; they had been providing psychological treatment in clinical practice for a mean duration of approximately 15 years.

Master's clinical psychology students. All students were in their final year of completing their master's degree in clinical psychology. None of them had any experience in providing behavior therapy, and they were allowed to participate as therapists for a maximum period of 1 year. All students were trained in a 2-day ERP workshop using appropriate training and treatment manuals that were developed by one of the authors (P.E.).

Treatment Conditions

Standardized treatment manuals were used for all conditions. In order to ensure treatment integrity, the first 2 therapy sessions were audiotaped, and a random sample of these tapes was reviewed by one of the authors (P.E. or P.v.O.). Since, in the therapist-controlled ERP condition the exposure sessions were performed in the natural environment, it was impossible to audiotape the sessions after session 2.

In supervision, the supervisors judged that all therapists adhered strictly to the treatment manual. All treatments consisted of 12 weekly sessions except when therapist and patient agreed that full recovery was achieved before the 12 sessions were completed. The completers of the trial had a mean number of 11.6 (SD = 0.99) treatment sessions and at least 8 treatment sessions. In the first treatment session, information was given about the ERP treatment rationale. At the end of this session, all patients were asked to write down the rationale of ERP in their own words as a homework assignment.

Furthermore, in the first 2 sessions (both sessions lasted 45 minutes) of all treatment conditions, an extensive inventory was drawn up of the different compulsions and of the stimuli that might trigger compulsive rituals. On the basis of this inventory, a hierarchy was constructed. The extent of exposure and the extent of response or ritual prevention were structured into 1 hierarchy with the help of a "fear thermometer."

Therapist-controlled ERP. In therapist-controlled ERP, after the hierarchy was constructed in the first 2 sessions, the natural environment in which the rituals were most frequently performed was chosen as the location for the next 10 treatment sessions. In most cases, this choice implied that the intervention took place within the participant's own home, although some sessions were conducted in parks, public places or the street. Each session lasted for 90 minutes. Family members were instructed to be absent during the treatment sessions. ERP sessions consisted of gradual (in vivo) exposure to the items in the hierarchy, combined with explicit instructions to refrain from performing any type of compulsive behavior. The therapist was present during all the exercises. As a rule, the patients determined the speed at which they worked through the hierarchy. If a participant

tried to avoid anxiety by not choosing a new item for practice when the previous ERP exercise no longer elicited any substantial discomfort, the therapist encouraged the patient to choose a new item for practice. If the whole hierarchy of items had been worked through before the 12 sessions were completed, the remaining sessions were spent on repeating the most difficult exercises in the hierarchy. The gradual (in vivo) exposure in the session was followed by homework assignments in which the patient was instructed to practice the same ERP exercise on his or her own at least twice within the following week, for at least 1 hour at a time.

Self-controlled ERP. In this condition, after the hierarchy was constructed in the first 2 sessions, all patients were treated at the psychiatric outpatient clinic that specialized in the treatment of anxiety disorders in Amsterdam. The last 10 sessions lasted 30 minutes. In each session, the participant was given a number of ERP tasks (items from the hierarchy) which were to be performed by her or him in the natural environment. These homework assignments consisted of gradual (in vivo) exposure to the items in the hierarchy, combined with explicit instructions to refrain from performing any type of compulsive behavior. These tasks were described clearly, written down and discussed with the patient at length, at least 3 times within the following week, for at least one hour at a time. At the beginning of each new session, the completion of homework ERP assignments was discussed. As in the therapist-controlled condition, the participant worked through the hierarchy at his or her own pace, but the therapist would encourage the patient to choose a new item in the hierarchy if he or she was reluctant to do so when the previous exercise no longer elicited any substantial discomfort. At the end of the session, homework assignments were given to practice the selected ERP task(s) at least 3 times during the following week, for at least 1 hour at a time.

Measures

Participants completed both standardized clinical interview and self-report measures. All measures were administered at pretreatment and posttreatment. All interviewers were trained, certified, and monitored in the assessment techniques by senior project personnel. Interviewers were blind to participants' treatment condition and were supervised weekly.

Obsessive compulsive measures. The YBOCS-severity scale is the most commonly used clinician-rated measure of obsessive-compulsive symptom severity, with documented reliability and validity.[20,21] In the OCD literature, the YBOCS-severity scale is frequently regarded as the instrument of choice for assessing OCD severity and treatment change.[22,23] This measure has a total of 10 items, with a range of scores from 0 to 40. Additionally, the Padua Inventory-Revised (PI-R) was used to assess both the overall severity of OCD symptoms and the presence and severity of specific OCD subtypes.[24,25] This self-report questionnaire has been proven to have a robust factor structure across samples. The PI-R consists of 41 self-rated items, which are rated on a 5-point scale from 0 (not at all) to 4 (very much). The total score ranges from 0 to 164. The reliability and validity of the PI-R are well-established.[25,26] Finally, the Anxiety Discomfort Scale (ADS) was completed by the independent interviewer. The ADS used in this study is an adapted version of Watson and Marks.[27] The scale consists of 5 idiosyncratic situations that are scored on a 9-point scale measuring the level of anxiety and discomfort in these specific OCD situations. Previous studies have found this scale to be more sensitive with regard to the detection of differences in treatment results than other common OCD measures.[26,28]

Depression severity measure. The severity of depressive symptoms was assessed by the Beck Depression Inventory (BDI). The BDI is a widely used self-report measure that consists of 21 items. The total score ranges from 0 to 63. Numerous studies have supported the psychometric status of the BDI.[29,30] The validity of this instrument has been found to be satisfactory in a Dutch population.[31]

Statistical Analyses

We set out to include 118 participants. Sample sizes were based on a power of .80 and an α of .05 to detect a moderate ES (approximately 0.40) on the YBOCS between therapist-controlled versus self-controlled or between experienced versus inexperienced therapists. Nonparametric and parametric tests were used to assess differences between the 4 conditions with regard to baseline assessment of all relevant demographic and clinical variables.

Main group (therapist-controlled versus self-controlled and experienced versus inexperienced) and interaction effects of the 4 conditions were analyzed using multivariate analysis of covariance (MANCOVA), with the pretest scores as covariates. Both completer analyses and ITT analyses were carried out. A conservative last-observation-carried-forward method, in which the available pretreatment score was used as the subsequent posttreatment score, was used to account for missing data in patients who dropped out of therapy without completing posttreatment assessments. Paired *t* tests were used to assess the changes within each treatment condition between pretreatment and posttreatment.

To evaluate the clinical significance of the impact of treatments on outcome, ESs were calculated within the treatment conditions using Cohen's formula.[32] Effect sizes were calculated as $X_1 - X_2 / SD_{pooled}$, where X_1 represents the pretreatment scores, X_2 the posttreatment scores, and SD_{pooled} represents the pooled standard deviations of the pre- and posttreatment scores.

The standardized method of Jacobson and Truax[33] was used to determine statistically reliable change. This calculation yielded a Reliable Change Index (RCI) of patient improvement as assessed on the YBOCS. If the RCI is higher than 1.96, the probability that the mean difference in treatment outcome occurred by chance is less than .05. According to Jacobson and Truax, subjects are "recovered" when they meet the following 2 criteria: (1) RCI and (2) end-state functioning within the nonpatient distribution

Table 1. Baseline Characteristics of Obsessive Compulsive Disorder (OCD) Patients Receiving Therapist-Controlled Exposure Performed by Experienced Behavior Therapists (THCONEXP), Therapist-Controlled Exposure Performed by Students (THCONSTUD), Self-Controlled Exposure Performed by Experienced Behavior Therapists (PATCONEXP), or Self-Controlled Exposure Performed by Students (PATCONSTUD)

Characteristic	THCONEXP n = 26	THCONSTUD n = 31[a]	PATCONEXP n = 31[b]	PATCONSTUD n = 30[c]	Statistic	P Value	Total n = 118[d]
Sex, male, %	31	52	42	33	$\chi^2_3 = 3.27$	$P > .35$	40
Age, mean (SD), y	34 (10)	35 (14)	37 (8)	34 (11)	$F_3 = 0.48$	$P > .69$	35 (11)
Ethnicity, %							
White	89	94	90	93			91
African	11	3	7	7			7
Asian	0	3	3	0			2
Married, %	23	26	23	37	$\chi^2_3 = 1.95$	$P > .58$	27
Education, %					$\chi^2_6 = 3.37$	$P > .76$	
Low	38	30	42	28			34
Medium	39	53	48	55			49
High	23	17	10	17			17
Working status, %					$\chi^2_6 = 0.09$	$P = 1.0$	
Works < 15 hours	31	32	29	30			31
Works > 15 hours	50	48	52	50			50
Officially sick	19	19	19	20			19
Antidepressant use before entering the trial, %[e]	12	16	0	14	$\chi^2 = 6.01$	$P > .10$	10
Axis I diagnosis, %[f]							
OCD only	42	39	48	43	$\chi^2_3 = 0.60$	$P > .89$	43
Anxiety disorder	27	42	36	27	$\chi^2_3 = 2.18$	$P > .53$	33
Depressive disorder	35	42	26	23	$\chi^2_3 = 3.08$	$P > .37$	31
Previous treatment	69	84	68	70	$\chi^2_3 = 2.61$	$P > .45$	73
Total YBOCS score, mean (SD)	25 (5)	26 (5)	27 (7)	26 (5)	$F = 0.48$	$P > .69$	26 (6)
Duration of OCD, mean (SD), y	18 (12)	20 (14)	14 (9)	16 (11)	$F = 1.24$	$P > .29$	17 (12)

[a]n = 30 for education level; data missing for 1 subject.
[b]n = 29 for education level; data missing for 2 subjects.
[c]n = 30 for education level; data missing for 1 subject.
[d]n = 114 for education level; data missing for 4 subjects.
[e]Fisher exact test was used due to several cells with count less than 5.
[f]Assessed using Structured Clinical Interview for *DSM-IV* disorders.[18]
Abbreviation: YBOCS = Yale-Brown Obsessive Compulsive Scale.

of YBOCS scores. Since calculation of change and determination of recovery are complementary procedures, we investigated both the RCI and the end-state functioning. Data from previous psychometric research[34] on the YBOCS were used to calculate the cutoff score for the nonpatient YBOCS distribution (YBOCS ≤ 16). Next, the same nonpatient YBOCS data were used to define a reliable change index. A reliable change on the YBOCS is defined as a decrease of at least 5 points (pre-post change).[34] Finally, non-parametric tests were run to compare the recovery percentages achieved with the various treatments. Data were analyzed using the personal computer 15.0 version of the Statistical Package for the Social Sciences (SPSS Inc, Chicago, Illinois).

RESULTS

Baseline Characteristics and Study Retention

Sixty percent of the 118 participants were female. Mean age was 35.08 years (SD = 10.71), the mean duration of OCD was 16.85 years (SD = 11.83), and more than half of the patients met diagnostic criteria for 1 or more additional Axis I disorders. The baseline characteristics are summarized in Table 1. Pearson χ^2 or likelihood ratio analyses and analyses of variance revealed that demographic and clinical characteristics, including severity of OCD symptoms, and diagnostic characteristics at baseline did not differ significantly across groups (see Table 1).

Duration of time in treatment, a variable that may be associated with treatment outcome, did not differ across treatment groups. Self-controlled ERP had a mean number of 10.7 (SD = 2.8) treatment sessions, therapist-controlled ERP had a mean number of 10.8 (SD = 2.5) treatment sessions, ERP performed by experienced behavior therapists had a mean number of 11.1 (SD = 2.1) treatment sessions, and ERP performed by students of clinical psychology had a mean number of 10.3 (SD = 3.0) treatment sessions.

Seventeen patients (14%) were classified as noncompleters. Dropout rates for patient-controlled versus therapist-controlled ERP were as follows: 12 patients of the self-controlled ERP (20%), 5 patients of the therapist-controlled ERP (9%) ($\chi^2_1 = 2.84$, $P > .07$). Dropout rates for experienced behavior therapists versus student therapists were as follows: 6 patients of the ERP performed by experienced behavior therapist (11%) and 11 patients of the ERP performed by students (18%) ($\chi^2_1 = 1.35$, $P > .18$). Completers of this trial were compared with the dropouts on all relevant demographic and clinical variables measured at pretest. No differences were found with respect to sex, education, duration of OCD, comorbid Axis I disorders, previous treatment, working status, or marital status ($P > .3$). There were also no significant differences on the BDI or the PI-R between completers and dropouts. However, mean ratings of OCD symptoms at baseline, as measured by the YBOCS (mean YBOCS completers = 25.6,

Table 2. Means and Standard Deviations of Pretreatment and Posttreatment Outcome Measures of ERP by Experienced Therapists Versus ERP by Student Therapists

	Intent-To-Treat Analysis										
	ERP by Experienced Therapist, n = 57						ERP by Student Therapist, n = 61				
	Pretreatment		Posttreatment		Effect		Pretreatment		Posttreatment		Effect
Measure	Mean	SD	Mean	SD	Size		Mean	SD	Mean	SD	Size
YBOCS total score	26.3	6.3	17.1	9.2	1.19		26.2	4.7	17.5	8.8	1.29
PI-R total score	63.3	27.7	49.4	30.3	0.48		68.9	24.6	50.4	29.0	0.69
ADS total score	29.5	6.0	17.7	11.5	1.35		30.8	5.6	20.7	10.3	1.27
BDI total score	15.6	10.0	13.1	11.1	0.24		15.0	9.2	10.9	9.5	0.44
	Completers Analysis										
	ERP by Experienced Therapist, n = 51						ERP by Student Therapist, n = 50				
	Pretreatment		Posttreatment		Effect		Pretreatment		Posttreatment		Effect
Measure	Mean	SD	Mean	SD	Size		Mean	SD	Mean	SD	Size
YBOCS total score	25.7	6.2	15.8	8.7	1.33		25.6	4.5	14.9[b]	7.3	1.81
PI-R total score	65.5[a]	28.2	48.9	31.6	0.56		65.7	21.8	43.1[b]	22.9	1.01
ADS total score	29.9	5.8	16.4	11.2	1.59		31.5	4.5	17.2	8.8	2.15
BDI total score	15.8[a]	10.1	12.5	11.0	0.31		13.9	8.7	8.8	8.1	0.61

[a]n = 48; data missing for 3 subjects.
[b]n = 49; data missing for 1 subject.
Abbreviations: ADS = Anxiety Discomfort Scale, BDI = Beck Depression Inventory, ERP = exposure with response or ritual prevention, PI-R = Padua Inventory-Revised, YBOCS = Yale-Brown Obsessive Compulsive Scale.

Table 3. Means and Standard Deviations of Pretreatment and Posttreatment Outcome Measures of Patient-Controlled ERP vs Therapist-Controlled ERP

	Intent-To-Treat Analysis										
	Patient-Controlled ERP, n = 61						Therapist-Controlled ERP, n = 57				
	Pretreatment		Posttreatment		Effect		Pretreatment		Posttreatment		Effect
Measure	Mean	SD	Mean	SD	Size		Mean	SD	Mean	SD	Size
YBOCS total score	26.8	6.0	18.7	9.2	1.09		25.7	5.0	15.8	8.5	1.47
PI-R total score	62.4	27.9	50.6	30.2	0.42		70.3	23.8	49.3	29.0	0.80
ADS total score	30.2	6.2	20.9	10.7	1.14		30.1	5.3	17.5	11.0	1.55
BDI total score	14.2	9.1	12.2	9.8	0.22		16.4	9.9	11.8	11.0	0.44
	Completers Analysis										
	Patient-Controlled ERP, n = 49						Therapist-Controlled ERP, n = 52				
	Pretreatment		Posttreatment		Effect		Pretreatment		Posttreatment		Effect
Measure	Mean	SD	Mean	SD	Size		Mean	SD	Mean	SD	Size
YBOCS total score	26.5	5.9	15.9	7.8	1.55		26.7	5.1	14.8	8.3	1.78
PI-R total score	60.6	26.2	44.0[a]	26.8	0.63		70.3	23.4	47.8[d]	28.4	0.89
ADS total score	30.2	5.8	17.0[b]	8.9	1.80		30.1[d]	5.0	16.6	11.1	1.68
BDI total score	13.2	9.1	10.3[c]	9.2	0.32		16.3	9.6	10.9[d]	10.4	0.54

[a]n = 46; data missing for 3 subjects.
[b]n = 48; data missing for 1 subject.
[c]n = 47; data missing for 2 subjects.
[d]n = 51; data missing for 1 subject.
Abbreviations: ADS = Anxiety Discomfort Scale, BDI = Beck Depression Inventory, ERP = exposure with response or ritual prevention, PI-R = Padua Inventory-Revised, YBOCS = Yale-Brown Obsessive Compulsive Scale.

mean YBOCS dropouts = 29.8; $F_1 = 8.86$, $P < .004$) and the ADS (mean ADS completers = 29.6, mean ADS dropouts = 33.5; $F_1 = 7.07$, $P < .009$) were significantly higher for dropouts than for completers, indicating a higher initial OCD symptom level.

Overall Treatment Effectiveness

Table 2 and Table 3 present pretreatment and posttreatment mean scores, SDs, and ESs for all of our outcome measures for ERP performed by experienced behavior therapists versus ERP performed by students (Table 2) and of patient-controlled ERP versus therapist-controlled ERP (Table 3), for both ITT and completer analyses.

Within-group t tests were used to assess pretreatment to posttreatment change for all outcome measures.

ERP performed by experienced behavior therapists and ERP performed by master's students of clinical psychology were each associated with significant pretreatment to posttreatment improvement on all OCD measures and on the depressive complaints measure (BDI). As follows from Table 2, ESs for the YBOCS and the ADS were large (all ESs ≥ 1.19), ESs for the PI-R were medium to high (ESs ≥ 0.48 and ≤ 1.01, respectively), and ESs were small to moderate for comorbid depressive symptoms in these treatment groups (ESs ≥ 0.24 and ≤ 0.61, respectively). Patient-controlled ERP and therapist-controlled ERP were also associated with significant pretreatment to posttreatment improvement on all outcome measures. As can be seen in Table 3, ESs for the YBOCS and the ADS were large (all ESs ≥ 1.09), ESs for the PI-R were moderate to high

Table 4. Clinically Significant Changes Measured With YBOCS at Posttreatment

	Jacobson Criteria (YBOCS)			P
Treatment	Reliable Change[a]	Clinically Significant Improvement[b]	Statistic	Value
ERP by experienced therapist, % (n = 57)	72	46	$\chi^2_1 = 0.55$	$P > .46$
ERP by student therapist, % (n = 61)	66	53		
Self-controlled ERP, % (n = 61)	66	43	$\chi^2_1 = 2.15$	$P > .14$
Therapist-controlled ERP, % (n = 57)	72	56		

[a]Reliable change = YBOCS difference of ≥ 5.
[b]Clinically significant improvement = posttreatment YBOCS score of ≤ 16.
Abbreviations: ERP = exposure with response or ritual prevention, YBOCS = Yale-Brown Obsessive Compulsive Scale.

(ESs ≥ 0.42 and ≤ 0.89, respectively), and ESs for depressive symptoms were small in both conditions (ESs ≥ 0.22 and ≤ 0.54, respectively).

Because the ITT and the completer analyses yielded similar findings, we focus here on reporting the results of the ITT analyses. A MANCOVA using pretest scores as a covariate was performed to analyze all the outcome measures (YBOCS; PI-R, ADS and BDI). Results of evaluation of assumptions of normality, homogeneity of variance-covariance matrices, linearity, and multicollinearity were satisfactory. No significant differences were found between the experienced and the inexperienced condition ($F_{4,107} = 2.32$, $P > .06$) and between the self-controlled and the therapist-controlled condition ($F_{4,107} = 0.76$, $P > .55$) and no statistically significant interaction effects were found on all measures ($F_{4,107} = 1.00$, $P > .40$). Because the MANCOVA revealed a trend on the interaction effect between the experienced and the inexperienced condition, we further analyzed this trend with analyses of covariance (ANCOVAs). Four ANCOVAs, using pretest scores as covariate, were run, 3 with the obsessive-compulsive measures (YBOCS; PI-R and ADS) and 1 with the depression measure (BDI). On the ITT analyses no statistically significant interaction effects were found on obsessive-compulsive measures (YBOCS: $F_{1,115} = 0.11$, $P > .74$; PI-R: $F_{1,115} = 0.47$, $P > .49$; ADS: $F_{1,115} = 0.73$, $P > .40$). Furthermore, we did not find a significant interaction effect on the depressive measure ($F_{1,115} = 1.59$, $P > .21$). The results thus demonstrated that the treatments did not differ substantially in effectiveness at posttest.

Clinically Significant Changes

We also compared rates of clinically significant improvement of all included patients at follow-up. The YBOCS was used to determine the improvement (according to the RCI) and determine the end-state functioning of all patients. Based on psychometric YBOCS data,[34] the cutoff point for the RCI on the YBOCS was ≥ 5. The cutoff score for determination of recovery as defined by a YBOCS score within the nonpatient distribution[33] was set at 16. Participants were considered to be recovered from their OCD if they had a score of ≤ 16 on the YBOCS, and this score represented an improvement of ≥ 5 compared with pretest (RCI). An overview of RCI and recovery is presented in Table 4.

Seventy-two percent of patients treated with ERP performed by an experienced therapist versus 66% of patients treated with ERP performed by a master's student therapist met the criteria for reliable change. Forty-six percent of patients treated with ERP performed by an experienced therapist versus 53% of patients treated with ERP performed by a student therapist met criteria for recovery. Sixty-six percent of patients treated with self-controlled ERP versus 72% of patients treated with therapist-controlled ERP met the criteria for reliable change. Forty-three percent of patients treated with ERP performed by an experienced therapist versus 56% of patients treated with ERP performed by a student therapist met criteria for recovery. RCI and recovery rates did not differ significantly between the treatment groups.

DISCUSSION

The present study evaluated the effectiveness of different modes of delivery of ERP in a referred sample of OCD patients. None of our 3 hypotheses could be confirmed: (1) ERP performed by experienced behavior therapists was not more effective than ERP performed by clinical psychology master's students; (2) Therapist-controlled ERP was not more effective than self-controlled ERP; and (3) ERP performed by experienced behavior therapists did not lead to a lower dropout rate than ERP performed by students.

To the best of our knowledge, this is the first study to evaluate the differential effectiveness of ERP delivered by highly qualified behavior therapists versus treatment delivered by inexperienced master's student therapists in a sample of severe OCD patients. In this study, specialty certification and higher levels of therapist experience did not result in better outcomes of OCD patients treated with a standardized ERP intervention. Closer inspection of completer data (Table 2) indicates that ESs for the student-therapist group were higher on average than ESs in the experienced condition. In order to investigate substantial differences that may be masked in the ITT analyses, we also performed a completer analysis. Although this analysis failed to show significant difference between student therapists and experienced behavior therapists, the direction of the difference in ESs suggests that lack of power was not responsible for masking greater treatment effectiveness in the experienced condition.

The level of expertise in the delivery of behavior therapy is commonly defined by years of experience and postgraduate training in the delivery of behavior therapy. For example, therapists are often selected to participate in clinical research studies on the basis of years of clinical experience or greater experience with OCD patients, to ensure an optimal treatment delivery. Our results did not support this premise.

Various explanations may be offered for our findings. First, expertise may be determined by various other variables besides years of experience and the level of training received. Second, as has been put forward in other studies, the level of expertise may be less decisive in the establishment of treatment effectiveness when standardized treatment manuals are used, as opposed to an individually tailored behavior therapy. One might even argue that the surprisingly high ESs in our inexperienced condition might be due to youthful enthusiasm, high fidelity to the treatment manual, and/or openness to criticism during supervision. Earlier research has demonstrated that therapist adherence to manual-based treatments was significantly correlated with symptom reduction in depression.[13] In our study, specific training of ERP techniques, treatment manuals, and weekly supervision sessions were used to enhance adequacy of treatment delivery by therapists. This enhancement may have resulted in a higher degree of treatment fidelity in all conditions, which may be quite different from routine clinical practice. The use of a manual might, in effect, cancel out some of the variance that expertise would provide if the therapist weres required to determine the contents of a given therapy without the help of a manual.[11,35] Our results suggest that less-experienced and uncertified behavior therapists are as capable as behavior therapists with longstanding experience and specialty certification in treating OCD patients in the delivery of a standardized ERP treatment, as long as they are adequately trained and supervised.

With regard to the effectiveness of therapist-controlled ERP versus self-controlled ERP, our findings run contrary to the findings of a meta-analysis of the psychological treatment of OCD.[9] We found no evidence for a supposed benefit of therapist-controlled exposure, whereas previous findings do relate treatment effectiveness to the presence of a therapist during the exposure exercises.[9] A possible explanation for this apparent discrepancy might be found in the fact that the intensity of the ERP exercises in our study was equally high in all conditions (at least 150 min in 1 week), whereas most studies involving therapist-controlled exposure tend to spend more time on ERP exercises than studies involving self-controlled ERP. These findings are supported by a meta-analysis and by several controlled outcome studies,[6] which demonstrated that a greater amount of time spent on ERP exercises is related to larger reductions of OCD symptomatology.[9] Furthermore, our findings do corroborate another meta-analysis[7] and the results of 2 RCTs in which these different forms of ERP were directly compared.[15,16]

Recently, benchmarking strategies have been used to estimate the effect of psychotherapy delivered in a natural setting and to compare outcomes from more laboratory-like environments with naturalistic settings for OCD.[36,37] One might wonder about the selection of our sample and argue that the findings from our study cannot be readily applied to clinical practice, since academic studies tend to investigate the relatively "healthy" patients, while excluding those with higher illness severity and comorbidity. However, our study was specifically designed to recruit patients similar to those seen in clinical practice. We recruited all participants from referrals to a psychiatric outpatient clinic specializing in the treatment of anxiety disorders, and our exclusion criteria were minimized. We compared our baseline characteristics with those from a study in which Franklin and colleagues[38] examined the effectiveness of fee-for-service ERP in an "unselected" OCD patient sample of an outpatient OCD clinic. Our sample showed similar (or higher) Axis I comorbidity rates and YBOCS severity ratings.

Effect sizes of ERP in our study were comparable to those found in previous ERP studies.[39–41] The present study demonstrated effectiveness of standardized ERP even though this therapy was applied less intensively than some of the regularly investigated intensive (sometimes even daily) ERP programs.[39,40] Fidelity to treatment manuals, specific training, and weekly supervision sessions concerning the ERP procedures may well have contributed to these results. These findings are relevant for the generalizability of research findings on treatment effectiveness, as 1-hour ERP sessions on a weekly basis represent an adequate reflection of routine clinical practice.

Study Limitations

Some limitations of the present study need to be acknowledged. Potential criticisms involve selective attrition, with about 8% of the eligible OCD patients refusing to participate in this clinical trial, and 14% of the randomized ERP patients never starting or prematurely ending the ERP treatment. Treatment attrition is a well-known problem in both treatment studies and daily clinical practice. Previous research has demonstrated attrition rates of 30% or even higher in an outpatient clinic for anxiety disorders.[38,42] Our attrition percentage is comparable to those found in other ERP studies with OCD patients.[38] A direct comparison between completers and noncompleters revealed that the noncompleters showed higher initial OCD symptom levels, possibly reflecting a higher degree of illness severity. However, since the results of the ITT analysis based on all randomly assigned patients were similar to the results of the completer analysis, and attrition rates were similar across conditions, we expect that potential bias of our results due to selective attrition is unlikely. On the other hand, no data were recorded on those who refused any kind of participation in the RCT, so attrition bias can never be precluded entirely.

Furthermore, it should be mentioned that 91% of our patients were white. The ethnicity characteristics were representative of the region and outpatient clinic in which this study was performed, but they may limit the generalizability of the results to other ethnic groups.

Although we did not find a statistically significant difference with regard to dropout rates between student therapists and the experienced therapists, caution should be exercised in reaching definite conclusions about this topic. Our study was powered to detect a moderate difference in

ESs on the main outcome measure, the YBOCS, but it was probably underpowered to detect significant differences in dropout rates between groups. Despite the absence of statistically significant findings, it is important to observe that dropout rates of ERP performed by students (18%) and self-controlled ERP (20%) were very close to dropout rates of previous RCT studies, while dropout rates in the experienced condition (11%) and the therapist-controlled condition (9%) were rather low in comparison with other OCD studies.[2,6] This finding deserves further research.

The present investigation compared the short-term effectiveness of different forms of standardized ERP; possible differences in long-term effectiveness for OCD patients in adults were not examined. As assessments were limited to pretreatment and posttreatment, we cannot draw any conclusions about possible differences between conditions with regard to long-term effects.

Finally, it should be noted that, although adequate care was taken to ensure treatment integrity by means of treatment manuals, weekly supervision meetings, and the review of audio recordings of the first 2 sessions, formal data on treatment integrity were not collected.

Clinical Implications

In conclusion, our findings indicate that patients with OCD can benefit as much from standardized ERP treatment provided weekly by master's student therapists as from a similar treatment performed by experienced behavior therapists. Our results support the possibility of effective dissemination of standardized ERP by master's student therapists, on the basis of a 2-day training followed by weekly expert group supervision. A challenging task for further research is to investigate whether other psychotherapies are able to communicate their specific treatments techniques in clear instructions in a treatment manual. Furthermore, the use of standardized treatment manuals seems to be an obvious choice in the treatment of OCD with ERP. This finding is highly relevant for clinical practice, since a substantial proportion of OCD patients never receive behavior therapy or are referred to an extensive waiting-list as a result of the shortage of experienced and certified clinicians.

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