Randomized Controlled Trial of Yogic Meditation Techniques for Patients With Obsessive-Compulsive Disorder

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ABSTRACT

The objective of this study was to compare efficacy of two meditation protocols for treating patients with obsessive-compulsive disorder (OCD). Patients were randomized to two groups—matched for sex, age, and medication status—and blinded to the comparison protocol. They were told the trial would last for 12 months, unless one protocol proved to be more efficacious. If so, groups would merge, and the group that received the less efficacious treatment would also be afforded 12 months of the more effective one. The study was conducted at Children's Hospital, San Diego, Calif. Patients were selected according to Diagnostic and Statistical Manual of Mental Disorders, *Third Edition-Revised* (DSM-III-R) *criteria and recruited by advertisements and referral. At baseline, Group 1 included 11 adults and 1 adolescent, and Group 2 included 10 adults. Group 1 employed a kundalini yoga meditation protocol and Group 2 employed the Relaxation Response plus Mindfulness Meditation technique. Baseline and 3-month interval testing was conducted using the Yale-Brown Obsessive Compulsive Scale (Y-BOCS), Symptoms Checklist-90-Revised Obsessive Compulsive (SCL-90-R OC) and Global Severity Index (SCL-90-R GSI) scales, Profile of Moods scale (POMS), Perceived Stress Scale (PSS), and Purpose in Life (PIL) test. Seven adults in each group completed 3 months of therapy. At 3 months, Group 1 demonstrated greater improvements (Student's independent group t-test) on the Y-BOCS, SCL-90-R OC and GSI scales, and POMS, and greater but nonsignificant improvements on the PSS and PIL test. An intent-to-treat analysis (Y-BOCS) for the baseline and 3-month tests showed that only Group 1 improved. Within-group statistics (Student's paired t-test) showed that Group 1 significantly improved on all six scales but Group 2 had no improvements. Groups were merged for an additional year using Group 1 techniques. At 15 months the final group (N=11) improved 71%, 62%, 66%, 74%, 39%, and 23%, respectively, on the Y-BOCS, SCL-90-R OC, SCL-90-R GSI, POMS, PSS, and PIL; P<0.003 (analysis of variance). This study demonstrates that kundalini yoga techniques are effective in the treatment of OCD.*

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INTRODUCTION

Obsessive-compulsive disorder (OCD) is one of the most disabling of the anxiety disorders.[1] A condition with a life-long course, OCD is estimated to be the fourth most common psychiatric disorder following phobias, substance abuse disorders, and the major depressive disorders, and is twice as common as schizophrenia and panic disorder.[2] OCD often begins during childhood or adolescence, has a lifetime prevalence rate of 2.5% to 5.0%

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Contributors: David Shannahoff-Khalsa is the guarantor and had the original idea for the study, obtained grant funding with Dr. Levine, and acted as the principal investigator. The experiment was designed by David Shannahoff-Khalsa, Dr. Levine, Ms. Ray, Dr. Gallen, Dr. Schwartz, and Dr. Sidorowich. David Shannahoff-Khalsa designed the group 1 protocol and David Shannahoff-Khalsa and Ms. Ray designed the group 2 protocol. Data analyses were carried out by David Shannahoff-Khalsa and Ms. Ray, with advice from Drs. Gallen, Levine, Schwartz, and Sidorowich. All authors contributed to the discussion of core ideas. David Shannahoff-Khalsa had responsibility for writing the paper with contributions from all other authors.

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and has proven to be refractory to traditional insight-oriented psychotherapy.[3]

Pharmacologic management and behavior therapy (BT) consisting of exposure and response prevention are used in treatment. However, it has been reported that 40% to 60% of patients show only minimal improvement or no change with the use of serotonin-reuptake inhibitors alone,[4] and that up to one third of patients remain unimproved after apparently adequate drug treatment.[4] These patients have been called drug treatment resistant.[4] In responders, medication produces a symptom reduction of 30% to 60% at best, and patients tend to remain chronically symptomatic to some degree despite use of the most effective pharmacologic interventions.[5] Although a decrease of 20% to 35% in the mean Yale-Brown Obsessive-Compulsive Scale (Y-BOCS)[6] scores may represent a clinically meaningful change in symptom severity, there is clearly room for improvement.[7]

Discontinuation of pharmacologic treatment is almost always associated with complete relapse.[8-10] In addition, Kobak et al[11] recently conducted a meta-analysis to compare BT with pharmacologic therapy that consisted of serotonin reuptake inhibitors, concluding that the two treatments were comparable. The sizeable percentage of treatment-refractory patients, the limited short- and long-term success and adverse effects of medication, and the fact that improvement in ritualizing with BT often fails to bring about a significant reduction in generalized anxiety[12] or depression[13] all suggest a need to investigate alternative treatment modalities.

Recently, a small uncontrolled trial demonstrated that kundalini yoga (KY) techniques are successful in improving OCD symptoms.[14] Five of eight patients completed this 12-month investigation, showing a mean Y-BOCS improvement of 54%. The completers also achieved improvements of 53.33% and 52.69%, respectively, on the Symptom Checklist-90-Revised Obsessive-Compulsive (SCL-90-R OC)[15] and Global Severity Index (GSI) subscales. In these five participants, OCD was previously stabilized with fluoxetine for more than 3 months prior to the start of the study. Of the five, three were completely free of medication for at least 5 months prior to study end, and the need for medication in the remaining two was significantly reduced. One year later, four of the five patients had remained off medication for periods ranging between 9 and 19 months, with lasting improvement.

The above findings of sustained and clinically significant improvement were obtained in an uncontrolled trial. Here, we report results after comparing the protocol from the uncontrolled trial,[13] which included a yogic breathing technique claimed to be specific for treating OCD, with a very different meditation protocol. The hypothesis tested here is that this disorder-specific technique would be required for efficacy and that meditation techniques in general may not be effective. Preliminary results (at month 9 of this 15-month trial) from one of the six scales reported here (Y-BOCS) were published earlier.[16]

"The hypothesis tested here is that this disorder specific technique would be required for efficacy and that meditation techniques in general may not be effective."

METHODS

Protocol

Patients with OCD were recruited through a television news commentary, newspaper advertisement, and physician referral. All but one patient had a previous principal diagnosis of OCD.

Inclusion Criteria

All diagnoses were confirmed in a semi-structured interview for suitability using *Diagnostic and Statistical Manual of Mental Disorders,* Third Edition-Revised[17] (*DSM-III-R*) criteria for OCD (300.30), which requires symptoms to be present for a minimum of 6 months before declaring a diagnosis of OCD. A minimum score of 15 on the Y-BOCS for the 10-item total was required for adults. If the patients were taking medication, they had to be dose-stabilized for at least 3 months prior to entry. The minimum age for inclusion was 14 years.

Exclusion Criteria

Patients were excluded if they smoked, had a substance abuse disorder, or had spinal or other physically limiting problems that could interfere with the meditation practice. These problems included being excessively overweight, seizure disorders, pulmonary disorders (eg, severe asthma or emphysema), hypertension (since the KY protocol includes two techniques for holding the breath and tensing muscles), and other cardiovascular problems. Also excluded were patients with the following *DSM-III-R* psychiatric conditions as their primary disorder: schizophrenia, major depressive disorder, bipolar disorder, mental retardation, anorexia nervosa, and bulimia

nervosa. Patients with Tourette syndrome, trichotillomania, or nail biting as their only compulsion were also excluded, as were patients without regular transportation to the study site.

Informed Consent

Prior to enrollment, all patients were informed that this would be a controlled study comparing two meditation protocols with testing at 3-month intervals to determine if one protocol was superior. If one protocol proved to be superior, the groups would be combined. Those who had used the less efficacious protocol initially would also receive 12 months of the more efficacious protocol—allowing for two possible study phases. Patients were informed that they could not begin new medications for any psychiatric disorders during the study if they wished to remain enrolled. They were also told that they were not allowed to participate in other forms of therapy for OCD while participating in the study. They would, however, be allowed to reduce or eliminate their established medication(s).

After describing the study and the possible adverse effects (ie, temporary muscle soreness), we obtained written informed consent from all participants. The study was conducted in compliance with the Code of Ethics of the World Medical Association, Declaration of Helsinki.

"The KY protocol showed significantly greater improvement on the Y-BOCS, both SCL-90-R scales, and the POMS, and greater but nonsignificant improvement on the PSS and PIL scales."

Interventions

Weekly meetings were held on Wednesday evenings from 6:00 to 8:00 PM. Group 1 was instructed by D.S.S.-K., an expert with 20 years of personal and teaching experience in KY therapy, but no formal training as a psychotherapist. Group 1 employed the KY protocol, which required approximately 1 hour to complete. All patients were instructed to practice their respective protocols on a daily basis to the best of their abilities on all subsequent days.

A complete description of the KY protocol was published previously by Shannahoff-Khalsa.[16] It includes eight primary techniques (including a yogic breathing technique for treating OCD) and three nonmandatory techniques.[16] The specific yogic technique for treating OCD[13,16,18] requires blocking the right nostril (a thumb tip or secure plug can be used), with slow deep inspiration through the left nostril, breath retention, and slow complete expiration through the left nostril, followed by a long breath-holding out period. This pattern is continued for a maximum of 31 minutes. The patient is instructed to make every effort to maximize the four phases of the breath cycle until the complete breath cycle equals 1 minute, with the four respective phases each lasting 15 seconds, thus perfecting the technique.

This purportedly OCD-specific technique is one of many meditation techniques in the KY system taught by Yogi Bhajan that are claimed to be useful for treating specific psychiatric disorders.[18] Some of the other techniques in this protocol are also claimed to be useful for treating anxiety disorders, as well as anger and fear.[16] The actual dates of discovery of these techniques are unknown. D.S.S.-K. learned the OCD-specific KY technique in 1975 during his early years of training with this yogic system. He first tested it with the remainder of the protocol in an uncontrolled trial.[13]

Group 2 was instructed by L.E.R., a licensed therapist with 12 years of personal and clinical experience with the popular Relaxation Response (RR)[19] and Mindfulness Meditation (MM) techniques.[20,21] Group 2 used each of these techniques for 30 minutes. Briefly described, RR and MM are relatively passive techniques. RR requires a constant mental focus and repetition of a self-selected special word or phrase. MM requires the conscious observation of thoughts while the individual passively observes the inspiration and expiration of the breath cycle.

Assessments

Various psychological tests were administered as self-rating measures. The Y-BOCS measures both obsessions and compulsions and also yields a combined or total score. The Y-BOCS, which is usually administered in a semistructured interview, was given here in a group format with explanation after the Y-BOCS symptoms checklist. In a recent review of studies,[22] employment of the Y-BOCS as a computer-administered clinician rating scale and a talking-computer telephone-administered version were compared with the standard clinician-administered version. Results showed no significant difference in the modes of administration.

The SCL-90-R includes a scale for obsessions and compulsions (OC) as well as the composite that reflects nine scales: obsessions/compulsions, anxiety, depression, paranoid ideation, somatization, interpersonal sensitivity, hostility, phobic anxiety, and psychoticism. The Profile of Mood States (POMS)[23] measures six variables (ten-

depression, anxiety, vigor, fatigue, and confusion) that are represented by the Total Mood Disorder (TMD) index. The Perceived Stress Scale (PSS)[24] measures the level of stress that the patient perceives. Finally, the Purpose in Life (PIL)[25] test measures how much purpose and meaning the patient perceives in his or her life. Both the Y-BOCS and SCL-90-R OC have been shown to be internally consistent and sensitive to changes with behavioral measures.[26,27]

All tests were administered to all patients as one group at baseline prior to their knowing their group assignments (2 weeks prior to therapy). The first 3-month tests were also administered to the two groups together.

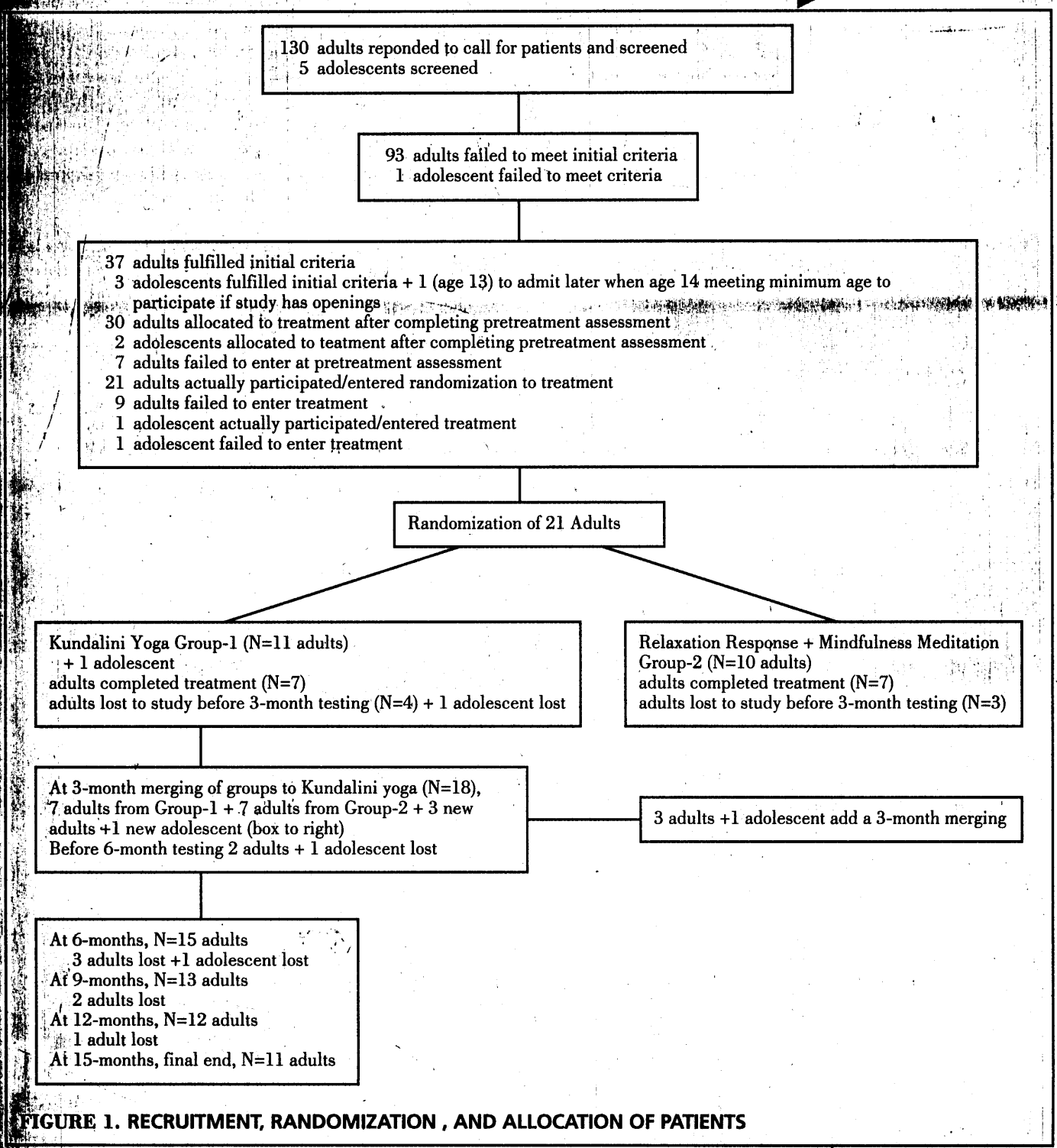

FIGURE 1. RECRUITMENT, RANDOMIZATION , AND ALLOCATION OF PATIENTS

Masking and Randomization

On the same evening immediately after baseline testing, patients were matched for age, sex, and medication status. After forming matched groups, group-to-therapy pairings were determined by a coin toss. Participants had no knowledge of the meditation protocol contents prior to group assignments, or of the content of the other protocol after randomization. D.S.S.-K. knew the contents of both protocols. L.E.R. was not informed about the protocol content for group 1.

Treatment Groups

The flow chart (Figure 1) describes the recruitment, randomization, and allocation of patients. Table 1 describes demographics of the patients in groups 1 and 2 in phase 1 (the first 3-month period) and phase 2 (following merger of the groups at 3 months). Twenty-one adults (14 women, seven men) and one adolescent girl (patient 24, aged 14 years) enrolled in phase 1. In phase 2, two adult women (patient 22 and 23) and one adolescent boy (patient 25, aged 14 years) entered the protocol, along with one woman (patient 21) who had dropped out after 2 weeks with group 2.

Of the 25 patients, 23 had received one or more prior forms of therapy (medication, BT, and/or psychotherapy) for OCD, and all but three began experiencing symptoms during early childhood or adolescence. The patient population had a characteristic array of OC symptoms and severities—all presented with multiple obsessions and compulsions. (See Shannahoff-Khalsa[16] for a complete description of these Y-BOCS obsessions and compulsions). Four patients (2, 9, 13, and 1 also had trichotillomania.

At the beginning of phase 1, group 1 consisted of 12 participants, including eight women and the adolescent girl (Table 1, patients 1–11 and 24). Subsequently, prior to three months one patient (patient 6, aged

TABLE 1. PATIENT DEMOGRAPHICS

Patient No.	Sex	Age (Years)*	Age at Onset (Years)	History† BT	Meds	Psych	Employed	Marital Status	Psychiatric History	Physical Disease	Relatives With OCD
1	F	37	3	+	+	+		m	Dep	BP	+
2	F	38	7	+	+	+	PT	D			+
3	F	25	13			+	ST	S		BP	
4	M	36	13		+	+	FT	S			
5	F	22	Ch		+	+	ST	S	Dep/Anr/Bul		
6	F	62	30s		+	+		m			
7	M	24	8		+	+	ST	S			+
8	F	38	18	+	+	+	FT	m			
9	F	36	5	+		+	FT	m		BP	
10	M	46	11	+	+	+		S	SP/Dep/ADD	CFS	?
11	F	60	24		+	+	PT	D			
12	F	40	14		+	+	FT	m	Dep	BP	?
13	M	67	?		+	+	PT	D	BD		
14	F	49	Teens		+	+		m	SD		
15	M	29	8		+	+	FT	S			
16	M	30	19	+	+	+	FT	m			+
17	F	46	20			+	FT	m	Dep		
18	M	29	5		+	+	FT	m	Dep		+
19	F	28	Ch		+	+	ST	S	Dep		+
20	F	57	Ch					D			
21	F	26	19		+	+		S	Anr/Bul		
22	F	30	Ch		+	+	ST	S	Dep		
23	F	66	16				PT	m			+
24	F	14	Ch		+	+	ST	S	Dep/ADHD		
25	M	14	11		+	+	ST	S	ADHD/Dep/TS		

BT=behavioral therapy; Meds=previous treatment with medication; Psych=previous psychotherapy; F=female; M=male; ch=childhood onset; FT=full-time; PT=part-time; ST=student; m=married; D=divorced; S=single; Dep=depression; Anr=anorexia; Bul=bulimia; SP=social phobia; ADD=attention deficit disorder; BD=bipolar disorder; SD=sleep disorder; ADHD=attention deficit/hyperactivity disorder; TS=Tourette's syndrome; BP=back pain; CFS=chronic fatigue syndrome.

*The mean age of the participants was 37.96 years (SD=15.29); the mean age of OCD onset when known was 13.55 years (SD=7.20)..

†Overall, 24% of participants had previously been treated with BT, 80% had received medication, and 92% had tried some form of individually based psychotherapy. In addition, 76% were either employed or students, 40% were married, 44% were single, and 16% were currently divorced. Fifty-two percent had a history of a psychiatric disorder other than OCD; 20% had a current physical disorder; and 28% had a relative with OCD.

12 years) was eliminated from the study due to an apparent need to increase her dose of a benzodiazepine. Group 2 (patients 12–21) included 10 adults (six women). The mean age was 38.55 years (standard deviation [SD]=13.25; n=11, range, 22–62) for the group 1 adults and 40.00 years (SD=14.3; n=10; range, 21–67) for the group 2 adults. Each group initially had six adults treated pharmacologically for OCD.[16]

Statistical Analysis

We chose the Y-BOCS as the primary outcome measure for hypothesis testing at the 5% level of significance (two-tailed Student's *t*-test). We based our power analysis for group sizes on our previous pilot study[13] and found that a sample size of eight subjects would allow us to test our hypothesis with α=0.05 and a power=0.80 or greater. Statistical analyses were performed using two-tailed Student's *t*-tests with PC!INFO 4.0 time-oriented data management/analysis system software (Retriever Data Systems, Seattle, Wash) and Biomedical Data Package Statistical Software (University of California Press).

RESULTS

Participant Flow

The study had two phases. Phase 1 was a 3-month, randomized, controlled trial with only one of the two therapies leading to improvements. In Phase 2, the groups were merged, and the more efficacious protocol from phase 1 was employed for an additional 12 months. Figure 1 describes the recruitment, randomization, and allocation of patients.

Analysis of Phase I

The separate group baseline means, SD, and 95% confidence interval (CI) baseline values for all scales are listed in Table 2. Y-BOCS scores showed that the groups were matched for the severity of OC symptoms. During the first 3-month period, each group had three adults withdraw (not including the woman eliminated from group 1 for increasing her dose of a benzodiazepine). Three patients dropped out of group 1: a 22-year-old woman with a Y-BOCS score of 26, a 25-year-old woman with a Y-BOCS of 18, and a 24-year-old man with a Y-BOCS of 18. Three patients also dropped out of group 2: a 26-year-old woman with a Y-BOCS of 35, a 57-year-old woman with a Y-BOCS of 26, and a 67-year-old man with a Y-BOCS of 23. The group 1 adolescent (14-year-old girl with a Y-BOCS of 14) also withdrew.

Dropouts chose not to retake tests, leaving each group with seven adults. The recalculated mean baseline Y-BOCS scores were 24.57 for the seven adults in group 1 (SD=4.68; 95% CI, 28.89–20.24) and 20.57 for the seven adults in group 2 (SD=3.36; 95% CI, 23.67–17.46). The two new means were tested for statistical differences using a two-tailed independent groups Student's *t*-test; the differences were not significant (t=1.836, P=0.091).

Group differences, pre- vs post-differences, and the group interaction for the first 3 months of therapy were evaluated using the Y-BOCS. The 3-month mean total Y-BOCS scores were 15.14 for group 1 (SD=6.2; N=7, 95% CI, 20.87–9.40) and 17.71 for group 2 (SD=2.98; N=7, 95% CI, 20.46–14.95). Using ▶

TABLE 2. ADULT 0-MONTH BASELINE MEASURES

	Group 1 (n=10)		Group 2 (n=10)	
	Mean (SD)	95% CI	Mean (SD)	95% CI
Y-BOCS*				
Totals (obsessions + compulsions)	22.75 (5.15)	26.02–19.48	22.80 (5.39)	26.66–18.94
Obsessions	11.00 (2.89)	12.84–9.16	11.60 (2.41)	13.32–9.88
Compulsions	11.75 (3.11)	13.73–9.77	11.20 (4.05)	14.10–8.3
SCL-90-R				
OC scale	1.98 (0.84)	2.58–1.38	1.78 (0.459)	2.11–1.45
GSI scale	1.23 (0.68)	1.72–0.74	1.01 (0.45)	1.33–0.69
POMS (TMD score)	55.20 (38.70)	82.89–27.52	67.10 (35.19)	92.27–41.93
PSS	22.20 (5.47)	26.11–18.29	22.30 (6.75)	27.13–17.47
PIL	88.40 (23.63)	105.3–71.5	90.10 (18.25)	103.16–77.05

Y-BOCS=Yale-Brown Obsessive Compulsive Scale; SCL-90-R=Symptom Checklist 90-Revised; OC=obsessive compulsive; GSI=global severity index; POMS=Profile of Moods Scale; MD=Total Mood Disorder index; PSS=Perceived Stress Scale; PIL=Purpose in Life test.

Mean values, standard deviations (SDs), and 95% confidence intervals (CIs) for the Y-BOCS (totals=[obsessions: items 1–5] + [compulsions: items 6–10]), SCL-90-R (raw scores for OC and GSI scales), POMS (total mood disorder raw scores), PSS, and PIL for the 0-month baselines for groups 1 and 2 with the original 10 adult patients in each group before others withdrew. *N=12 in group 1 for the Y-BOCS only (includes the adult woman eliminated due to drug complications, and the adolescent girl). All tests were taken prior to the patients' knowledge of group assignments.

a two-way mixed model analysis of variance, we found that the interaction term reflecting the potential differential effects of each therapy was significant (F[1,12]=4.89, $P<0.0471$), indicating that the change in group 1 was greater than that in group 2. The mean group changes in Y-BOCS totals from baseline to 3 months were 9.43 for group 1 (SD=7.21; 95% CI, 16.09–2.76), and 2.86 for group 2 (SD=3.13; 95% CI, 5.75 to -0.035). A two-tailed paired Student's *t*-test showed a significant improvement of 38.36% (t=3.461, P=0.013) for group 1, and only a positive but nonsignificant improvement of 13.9% for group 2 (t=2.414, P=0.052).

An intent-to-treat analysis for the Y-BOCS using a paired Student's *t*-test (two-tailed) was performed for group 1 (N=12, 11 adults and 1 adolescent) and group 2 (N=10 adults). The 0-month baseline scores for those leaving the study were carried forward to 3 months. The group 1 0-month mean was 22.75 (SD=5.15; 95% CI, 26.02–19.48), and the 3-month mean was 17.25 (SD=6.11; 95% CI, 21.13–13.36). The group 2 0-month mean was 22.80 (SD=5.39; 95% CI, 26.66–18.94), and the 3-month mean was 20.80 (SD=6.27; 95% CI, 25.28–16.31). Group 1 showed a significant Y-BOCS improvement of 5.5 (t=2.644, P=0.023), and group 2 showed a positive but nonsignificant trend toward improvement of 2.0 (t=2.176, P=0.058).

Table 3 shows the 0-month and 3-month mean scores, SD, and 95% CIs for all scales, as well as the results of a statistical ("completer") analysis for group differences using Student's independent groups *t*-test (two-tailed). It must be noted that Table 3 does not include the results for the three dropouts for each group, explaining the differences in n values compared with Table 2. Lower scores on all scales, except the PIL test, reflect an improved state. The KY protocol showed significantly greater improvement on the Y-BOCS, both SCL-90-R scales, and the POMS, and greater but nonsignificant improvement on the PSS and PIL scales.

A paired Student's *t*-test (two-tailed) was used to compare within-group differences at 0 and 3 months for all six scales. The Y-BOCS, SCL-90-R-OC and -GSI scales, POMS, PSS, and PIL test all showed significance for the group 1 protocol (n=7; P=0.013, 0.01, 0.017, 0.004, 0.034, and 0.004, respectively). The respective improvements were 38.36%, 47.68%, 49.44%, 62.41%, 30.05%, and 10.60%. No scale was significant for group 2 (n=7), with respective changes of

TABLE 3. ADULT 0-MONTH MEAN BASELINE AND 3-MONTH MEASURES

Independent Groups Student's t-Test (Two-Tailed) for Comparing Efficacy of Group 1 vs Group 2

	0-Month (SD) (95% CI)	3-Month (SD) (95% CI)	Mean Difference (SD) (95% CI)	*P* Value
Y-BOCS (Totals)				
Group 1 (n=7)	24.57 (4.68) (28.89–20.24)	15.14 (6.20) (20.87–9.40)	9.43 (7.21) (16.09–2.76)	0.047
Group 2 (n=7)	20.57 (3.36) (23.67–17.46)	17.71 (2.98) (20.46–14.95)	2.86 (3.13) (5.75–0.035)	
SCL-90-R				
OC scale				
Group 1	1.829 (0.850) (2.61–1.04)	0.957 (0.635) (1.54–0.37)	0.871 (0.528) (1.36–0.382)	0.003
Group 2	1.857 (0.500) (2.32–1.39)	1.929 (0.512) (2.40–1.46)	-0.071 (0.399) (0.298–0.44)	
GSI scale				
Group 1	0.983 (0.517) (1.46–0.51)	0.497 (0.328) (0.800–1.93)	0.486 (0.394) (0.850–0.122)	0.035
Group 2	1.113 (0.157) (1.26–0.97)	1.106 (0.390) (1–0.74)	0.007 (0.359) (0.339–0.325)	
POMS				
Group 1	43.71 (37.01) (77.94–9.48)	16.43 (29.71) (43.90–11.05)	27.29 (21.52) (47.19–7.39)	0.046
Group 2	68.42 (21.32) (88.14–48.70)	70.14 (31.47) (99–41.04)	-1.71 (26.91) (23.18–26.60)	
PSS				
Group 1	20.43 (4.93) (24.99–15.87)	14.29 (5.76) (19.62–8.96)	6.14 (5.96) (11.65–0.63)	0.207
Group 2	24.00 (2.94) (26.72–21.28)	21.86 (4.67) (26.18–17.54)	2.14 (5.24 (6.99–2.71)	
PIL				
Group 1	97.0 (19.27) (114.82–79.18)	107.29 (18.65) (124.54–90.04)	-10.29 (5.91) (-4.82–15.76)	0.071
Group 2	89.14 (12.13) (100.36–77.92)	90.14 (11.81) (101.06–79.22)	1.00 (10.91) (9.09–11.09)	

Y-BOCS=Yale-Brown Obsessive-Compulsive Scale; SCL-90-R=Symptom Checklist 90-Revised; OC=obsessive-compulsive; GSI=global severity index; POMS=Profile of Moods Scale; PSS=Perceived Stress Scale; PIL=Purpose in Life test.

Mean values, standard deviations (SDs), and 95% confidence intervals (CIs) for groups 1 and 2 for each test at the 0-month and 3-month test periods. The 0-month means minus the 3-month means are expressed as the difference scores (change scores) for each group and scale. The independent groups Student's *t*-test (two-tailed) was used to calculate the significant differences for improvement for each group. The *P* values are provided for the Y-BOCS, SCL-90-R-OC and SCL-90-R-GSI, POMS, PSS, and PIL. Group 1 improvements were significantly greater than group 2 for the Y-BOCS, SCL-90-R-OC and SCL-90-R-GSI, and POMS. Group 1 improved more than group 2 on the PSS and PIL; the differences, however, were not significant.

3.9%, -3.87%, 0.63%, -2.51%, 8.92%, and 1.10%. Based on the Y-BOCS results, the groups were merged at the 3-month period.

Analysis of Phase 2

After merging, the study population included 14 patients who completed 3 months (67% of the original 21 adults). One of the adult women from group 2 who withdrew prior to 3 months (patient 21) chose to reenter. Also, three new candidates, who could not participate earlier due to time conflicts, entered the trial in phase 2: two women (patient 23, aged 66 years; and patient 22, aged 30 years) and one adolescent boy with Tourette syndrome (patient 25, aged 14 years). Patients 22 and 25 were taking medication for OCD. Eighteen patients started phase 2, but three (patients 21, 22, and 25) withdrew after several weeks.

The 3-month means, SD, and 95% CIs from month 0 to month 15 for all subjects completing tests for at least two intervals are presented in Table 4. The multiple-range test results for significance (0.05 level Tukey test) for comparing the mean scores at the various intervals are in the legend. An analysis of variance (ANOVA) demonstrated improvements for these patients on the Y-BOCS ($F[5,45]=18.529$, $P<0.001$); SCL-90-R-OC ($F[5,45]=7.901$, $P<0.001$); SCL-90-R-GSI ($F[5,45]=5.567$, $P<0.001$); POMS TMD scale ($F[5,45]=4.215$, $P<0.003$); PSS ($F[5,45]=5.792$, $P<0.001$); and PIL ($F[5,45]=8.36$, $P<0.001$). In addition, a subgroup analysis of the seven patients initially in group 2 showed a 44% improvement in the Y-BOCS for the first 3 months using the KY protocol. This paralleled the 38% improvement for the seven patients originally in group 1 during their first 3 months.

We also calculated the statistics separately for those subjects who were originally in group 1 over their 15 months of KY and those originally in group 2 (including patient 23, who entered the study at month 3) for their 12 months of KY. The one-way repeated measures ANOVA for the Y-BOCS, SCL-90-R-OC scale, SCL-90-R-GSI scale, POMS, PSS, and PIL tests, respectively, for group 1, months 0 to 15, were: $F(5,20)=8.155$, $P<0.001$; $F(5,20)=8.694$, $P<0.001$; $F(5,20)=4.565$, $P=0.006$; $F(5,20)=6.749$, $P<0.001$; $F(5,20)=3.477$, $P<0.020$; and $F(5,20)=8.05$, $P<0.001$. The respective group 2 values for months 3 to 15 (ie, 12 months of KY therapy) were: $F(4.20)=10.708$, $P<0.001$; $F(4,20)=6.914$, $P<0.001$; $F(4,20)=4.362$, $P=0.011$; $F(4,20)=3.558$, $P=0.024$; $F(4,20)=3.027$, $P=0.042$; and $F(4,20)=7.023$, $P<0.001$.

Both populations showed significant improvements with use of the KY protocol for all scales using an ANOVA. When the 0-month baseline (N=14) mean was compared with the 15-month mean (N=11), the improvements at 15 months were: 70.62% on the Y-BOCS, 61.96% on the SCL-90-R-OC scale, 66.16% on the SCL-90-R GSI scale, 73.90% on POMS, 39.03% on PSS, and 22.97% on the PIL test. For these 11 patients, the Y-BOCS totals included three scores of 0, one score of 1, two scores of 5, one score of 6, and one score each of 11, 14, 15, and 16.

Six of the 12 patients who entered the protocol while taking medication completed the study. Three of these six were free of medication for a minimum of 6 months prior to study end. The others were able to reduce their medication dosage. ▶

TABLE 4. ALL PSYCHOLOGICAL SCALE 3-MONTH INTERVAL MEAN VALUES AND 95% CONFIDENCE INTERVALS

	0-month (SD) (95% CI)	3-month (SD) (95% CI)	6-month (SD) (95% CI)	9-month (SD) (95% CI)	12-month (SD) (95% CI)	15-month (SD) (95% CI)
Y-BOCS (totals)	22.57 (4.43) (25.13–20.01)	16.6 (4.73) (19.22–13.98)	12.80 (6.83) (16.58–9.02)	9.92 (6.74) (13.99–5.85)	7.50 (6.59) (11.69–3.31)	6.6 (6.33) (10.85–2.35)
SCL-90-R						
OC scale	1.843 (0.670) (2.23–1.46)	1.427 (0.725) (1.83–1.03)	1.197 (0.719) (1.64–0.76)	1.092 (0.885) (1.63–0.56)	0.908 (0.786) (1.41–0.41)	0.700 (0.527)(1.05–0.35)
GSI scale	1.048 (0.373) (1.26–0.832)	0.766 (0.472) (1.03–0.51)	0.709 (0.531) (1.00–0.42)	0.675 (0.683) (1.09–0.26)	0.491 (0.499) (0.81–0.17)	0.353 (0.285) (0.55–0.16)
POMS (TMD)	56.07 (31.72) (74.38–37.76)	40.87 (40.15) (63.11–18.64)	30.07 (40.12) (52.29–7.85)	34.77 (57.87) (69.74–0.20)	18.67 (36.85) (42.08–4.74)	14.64 (28.27) (33.63 to -4.35)
PSS	22.21 (4.32) (24.70–19.72)	18.27 (6.20) (21.70–14.84)	16.00 (8.19) (20.54–1.47)	14.85 (10.95) (21.47–8.23)	12.33 (7.64) (17.18–7.48)	11.18 (7.33) (16.1–6.26)
PIL	93.07 (16.0) (102.31–83.83)	99.53 (12.1) (106.23–92.83)	103.53 (22.19) (115.82–91.24)	105.15 (24.28) (119.82–90.47)	111.42 (19.7) (123.94–98.90)	114.46 (20.95) (128.53–100.39)

Y-BOCS=Yale-Brown Obsessive Compulsive Scale; SCL-90-R=Symptom Checklist 90-Revised; OC=obsessive-compulsive; GSI=global severity index; POMS=Profile of Mood States; PSS=Perceived Stress Scale; PIL=Purpose-in-Life scale.

The mean and standard deviation (SD) and 95% confidence intervals (CIs) are provided for each scale for all 3-month interval measures. N=14, 15, 15, 13, 12, and 11 for the 0-, 3-, 6-, 9-, 12-, and 15-month measures, respectively. Reflects participants who remained in the study for at least two 3-month test intervals. The Y-BOCS multiple range test results for significance (0.5 level, Tukey test) show that 0-month <> 3-month <> 6-month <> 9-month <> 12-month=15-month. The SCL-90-R-OC scale shows that 0-month <> 3-, 6-, 9-, 12-, 15-month; 3-month <> 12-, 15-month; 3-month=9-month, and the SCL-90-R-GSI scale shows that 0-month <> 12-, 15-month; The POMS (TMD) scores show that 0-month <> 3-month <> 9-month=6-month <> 12-month=15-month. The PSS shows that 0-month <> 3-month <> 6-month=9-month <> 12-month=15-month. The PIL shows that 0-month <> 3-month <> 6-month <> 9-month <> 12-month <> 15-month.

DISCUSSION

The present investigation and our uncontrolled study[13] yielded similar results, demonstrating reproducibility and suggesting that the KY protocol has therapeutic value without apparent side effects. Since the group using RR and MM showed no significant improvement, it can be assumed that the improvements in the KY group are not the consequence of a placebo effect or of attention, but rather a therapy-specific factor. While the KY protocol included a technique claimed by yogis to be specific for OCD,[21] this protocol was complex; therefore, it is not clear which components led to efficacy. Studies evaluating subjects on the basis of electroencephalography,[28] magnetoencephalography (MEG),[16] cognitive performance,[29,30] and mood[31] all demonstrate that left-nostril breathing techniques selectively stimulate the right hemisphere of the brain. The results of other reviews[13] identify right-hemispheric abnormalities with OCD,[32] suggesting that the efficacy of this yogic technique may be due to a related effect. Our preliminary unpublished MEG results on the effects of the purportedly OCD-specific left-nostril breathing technique in a trained normal subject suggest that, while stimulation of the right hemisphere is diffuse and dramatic, a strong effect on the frontal and prefrontal right hemisphere may help to compensate for the OCD-related defect.

"The present investigation and our uncontrolled study yielded similar results, demonstrating reproducibility and suggesting that the KY protocol has therapeutic value without apparent side effects."

Our results are encouraging when compared with those from a recent multicenter, double-blind, placebo-controlled fluvoxamine study[33] that showed a 17.5% Y-BOCS improvement for active therapy (n=78, mean change=3.95) and a 7% improvement for placebo (n=78, mean change=1.71). Our mean Y-BOCS change of 2.86 (13.9%) over 3 months with our control group may be a placebo effect. However, the KY protocol change at 3 months (38.36%, n=7, mean change=9.43), and 15 months (71%, n=11, mean change=16.79) is also well beyond the 3% to 13% placebo effect observed in a double-blind, placebo-controlled study of clomipramine.[34] In addition, in a comparison of results from four multicenter, placebo-controlled trials of clomipramine, fluoxetine, fluvoxamine, and sertraline, Griest et al[35] found respective Y-BOCS improvements of 39%, 27%, 20%, and 26% for the best-dose comparisons.

Among the published studies on BT, Marks[36] concluded that this intervention consistently achieves a rating of much improved in 60% to 70% of patients following brief treatment. These improvements are maintained after 2 to 3 years of follow-up. Summarizing studies of BT conducted mostly on an inpatient basis around the world over the last 2 decades, Baer[37] concluded that approximately 75% of OCD patients "get control of their symptoms," and that 80% are able to complete BT. Of the remaining 20%, most succumb to extreme fear. In addition, Cottraux[38] found that one quarter of patients either refuse treatment or drop out early in BT therapy. Of those remaining in therapy, 25% do not improve, and 20% of the improved patients require "booster treatment" for some subsequent loss of gains.

The majority of the above BT studies, however, included patients whose primary OCD rituals were cleaning (66%) and checking (22%), which are the most easily treated forms of OCD using BT.[39] In addition, the earlier BT studies did not use the Y-BOCS, the current gold standard for measuring OCD severity. Furthermore, the acute effects of exposure and response prevention often lead to an immediate and increased level of fear and anxiety affecting the patient's willingness to comply with treatment.

Our patients had diverse and multiple OC symptoms. For the 11 patients who completed 15 months of therapy, the mean Y-BOCS obsession score decreased from 11.45 (SD=1.92; 95% CI, 12.74–10.16) at baseline to 2.55 (SD=3.14, 95% CI, 4.66–0.44) at 15 months; compulsion scores decreased from 11.64 (SD=2.98; 95% CI, 13.64–9.64) to 4.09 (SD=3.86; 95% CI, 6.68–1.5). All patients were treated identically, thus eliminating the need for an individualized treatment plan.

Group therapy reduces the financial cost to the patient and minimizes therapist time; however, the time course for treatment is long and requires near-weekly attendance and considerable homework, comparable to BT. Our experience shows that approximately 1 year is required to achieve maximal outcomes. This research is preliminary, and further investigation must be conducted with larger populations testing various combinations of KY techniques to perhaps refine the protocol and attempt treatment with younger patients. CNS

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