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Cognitive Therapy Versus Fluoxetine in Generalized Social Phobia: A Randomized Placebo-Controlled Trial

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Sixty patients meeting *Diagnostic and Statistical Manual of Mental Disorders* (4th ed.; American Psychiatric Association, 1994) criteria for generalized social phobia were assigned to cognitive therapy (CT), fluoxetine plus self-exposure (FLU + SE), or placebo plus self-exposure (PLA + SE). At posttreatment (16 weeks), the medication blind was broken. CT and FLU + SE patients then entered a 3-month booster phase. Assessments were at pretreatment, midtreatment, posttreatment, end of booster phase, and 12-month follow-up. Significant improvements were observed on most measures in all 3 treatments. On measures of social phobia, CT was superior to FLU + SE and PLA + SE at midtreatment and at posttreatment. FLU + SE and PLA + SE did not differ. CT remained superior to FLU + SE at the end of the booster period and at 12-month follow-up. On general mood measures, there were few differences between the treatments.

Social phobia is a common and disabling disorder (Magee, Eaton, Wittchen, Gonagle, & Kessler, 1996) that is associated with marked vocational underachievement and an increased risk of depression, suicide, and alcohol abuse (Heckelman & Schneier, 1995; Rapee, 1995). Onset is typically in adolescence or earlier (Rapee, 1995). Perhaps because many patients see the disorder as part of their personality, treatment-seeking rates are low in comparison with other anxiety disorders, such as panic disorder (Fresco, Erwin, Heimberg, & Turk, 2000; Magee et al., 1996). However, in the past 15 years considerable progress has been made in developing effective pharmacological and psychological treatments.

Within pharmacological approaches (see Hood & Nutt, 2001, for a review), the three best validated interventions are benzodiazepines, monoamine oxidase inhibitors, and selective serotonin reuptake inhibitors (SSRIs). In several countries concerns about dependency have led to the recommendation that benzodiazepines should only be used for brief periods (e.g., Committee on Safety of Medicines, 1988), which limits their utility in treating a chronic condition such as social phobia. Phenelzine is the best validated monoamine oxidase inhibitor. Three controlled trials (Heimberg et al., 1998; Liebowitz et al., 1992; Versiani et al., 1992) have found phenelzine superior to placebo. A fourth trial (Gelernter et al., 1991) failed to find a significant difference between phenelzine and placebo on the main social phobia measures but did find a difference on a secondary measure of work and social disability. Among the SSRIs, controlled trials have established superiority over placebo medication for fluvoxamine (Stein, Fyer, Davidson, Pollack, & Wiita, 1999), sertraline (Blomhoff et al., 2001; Van Ameringen, Swinson, Walker, & Lane, 1999; Van Ameringen et al., 2001), and paroxetine (Allgulander, 1999; Baldwin, Bobes, Stein, Scharwächter, & Faure, 1999; Stein et al., 1998).

Within psychological approaches, the best validated treatments are behavioral and cognitive–behavioral. Five meta-analytic reviews (Chambless & Hope, 1996; Fedoroff & Taylor, 2001; Feske & Chambless, 1995; Gould, Buckminster, Pollack, Otto, & Yap, 1997; Taylor, 1996) have summarized studies comparing behavioral and cognitive–behavioral treatments (CBTs) with various control conditions, and each reached broadly similar conclusions. Exposure alone and exposure with cognitive restructuring are both associated with significantly greater effect sizes than are waiting list control conditions. Individual studies have failed to provide convincing evidence of a difference in efficacy between exposure alone and exposure with cognitive restructuring. However, in one meta-analysis (Taylor, 1996), only the combination of exposure and cognitive restructuring was superior to placebo control conditions. A particularly encouraging finding has been the excellent maintenance of gains after the end of effective psychological treatment. For example, Heimberg, Salzman, Holt, and Blendell

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(1993) found that patients who received cognitive–behavioral group treatment (CBGT) retained their gains at 5-year follow-up and remained significantly less symptomatic than patients who had received a control treatment (education-support).

Despite the positive findings reported for existing behavioral and cognitive–behavioral treatments, it is generally agreed that there is scope for further development. First, a significant subset of patients fail to achieve optimal benefit from the existing treatment programs. For example, in an intent-to-treat analysis, Heimberg et al. (1998) reported that fewer than 60% of patients who received CBGT were classified as treatment responders. Using a stricter improvement criterion, Mattick and Peters (1988) reported that only 38% of patients who completed their cognitive–behavioral program were considered optimally improved (achieved high end-state functioning). Second, one recent meta-analytic review (Fedoroff & Taylor, 2001) has concluded that pharmacotherapies (particularly SSRIs) yield the largest initial effect sizes in social phobia, although there is some evidence for greater relapse after discontinuation of medication than after termination of CBT (Liebowitz et al., 1999).

The present study reports a randomized controlled trial that evaluated a new CBT and compared it with treatment with an SSRI. The new CBT is the cognitive therapy (CT) program developed by Clark, Wells, and colleagues on the basis of their cognitive model of social phobia. Clark and Wells's (1995) cognitive model, which is very similar to the model described by Rapee and Heimberg (1997), is largely focused on the maintenance of social phobia and attempts to explain why patients with social phobia fail to benefit from the naturalistic exposure that is provided by their everyday interactions with other people. Four maintenance processes are particularly highlighted. The maintenance processes are (a) an increase in self-focused attention and monitoring with a linked reduction in observation of other people and their responses; (b) the use of misleading internal information (particularly anxious feelings and spontaneously occurring, distorted images of themselves seen from an observer perspective) to make excessively negative inferences about how one appears to others; (c) extensive use of safety behaviors that are intended to prevent feared catastrophes but have the consequence of maintaining negative beliefs, increasing feared symptoms, and making patients come across to others in ways that are likely to elicit less friendly responses (although termed *behaviors*, a substantial proportion of the safety behaviors are cognitive strategies); and (d) the use of negatively biased anticipatory and postevent processing. The CT program includes a series of procedures that are specifically focused on reversing the maintaining processes specified in the model.

The SSRI chosen for comparison with CT is fluoxetine. At the time the trial was conducted, no controlled trials of fluoxetine had been reported. However, five open trials of fluoxetine (Black, Uhde, & Tancer, 1992; Koponen, Lepola, & Juhani, 1995; Perugi et al., 1994; Schneier, Chin, Hollander, & Liebowitz, 1992; Van Ameringen, Mancini, & Streiner, 1993) had obtained promising results. Following the example of two previous pharmacotherapy trials in social phobia (Blomhoff et al., 2001, with sertraline; Gelernter et al., 1991, with phenelzine), fluoxetine was combined with weekly self-exposure assignments. Combining medication with self-exposure was intended to produce a closer approximation to routine clinical practice, as it was thought that many United Kingdom clinicians who use medication are likely to combine it with a simple practical procedure such as self-exposure. To estimate the extent to which improvements associated with fluoxetine plus self-exposure were active pharmacological effects, we also included a placebo plus self-exposure condition in the study.

Method

Design

Patients were initially randomly assigned to CT, fluoxetine plus self-exposure (FLU + SE), or placebo plus self-exposure (PLA + SE). Allocation to fluoxetine or placebo was double-blind. Patients had up to 16 weekly treatment sessions. After 16 weeks, the medication blind was broken. Patients who were allocated to FLU + SE continued their medication for 3 months and had up to three treatment sessions during this booster period. Patients who were allocated to CT had the same number of booster sessions. Patients initially allocated to placebo were withdrawn from the trial at 16 weeks and offered their choice of CT, FLU + SE, or a combination of both treatments. Assessments, which included ratings completed by an independent assessor, were at pretreatment, midtreatment, posttreatment (16 weeks), end of the booster period, and 12-month follow-up.

Patients

Local general practitioners, psychiatrists, and psychologists were sent a letter requesting referrals to a trial of psychological and pharmacological treatments for social phobia. Advertisements in the local press and shopping centers also brought the trial to the attention of potential participants (all of whom had to be referred by a clinician). Referrers were informed that open trials suggested that CT and fluoxetine were both effective, and it was not known which was more effective. Referred patients were assessed using a combination of the Anxiety Disorders Interview Schedule for *DSM–IV* (ADIS; Brown, Di Nardo, & Barlow, 1994) and the Structured Clinical Interview for *DSM–IV*, Axis-I disorders (SCID-I; First, Spitzer, Gibbon, & Williams, 1995). All patients were assessed with the overview module of the SCID-I and the social phobia module of the ADIS. If the SCID-I screener module indicated that another Axis-I disorder might be present, the SCID-I module for that disorder was also administered. All patients were also assessed with the Avoidant Personality Disorder section of the SCID: Axis-II Disorders Interview (SCID-II; First, Gibbon, Spitzer, Williams, & Benjamin, 1997). The Borderline Personality Disorder section of SCID-II was administered if it was clinically relevant. Diagnostic interviews were conducted by clinical psychologists who had received extensive training in the SCID and ADIS. All diagnoses were also checked with a senior clinician (David M. Clark). Patients were accepted if they met the following criteria: (a) *Diagnostic and Statistical Manual of Mental Disorders* (4th ed.; *DSM–IV*; American Psychiatric Association, 1994) criteria for generalized social phobia;[1] (b) condition duration of at least 6 months; (c) social phobia was considered their main problem; (d) age between 18 and 60 years; (e) willingness to accept random allocation; (f) no current major depressive disorder, bipolar disorder, psychosis, alcohol or substance dependency, or epilepsy; (g) not pregnant and had no intention to become pregnant; (h) social phobia had not been previously treated with an SSRI, CT, or exposure therapy; (i) no psychotropic medication use or,

[1] Following the *DSM–IV* (American Psychiatric Association, 1994, pp. 412–413), we diagnosed the generalized subtype of social phobia if the assessors considered that an individual's fears "related to most social situations" and involved fear of "both public performance situations and social interaction situations." Inspection of patients' pretreatment Liebowitz Social Anxiety Scales (LSAS; Liebowitz, 1987) indicated that accepted patients feared a median of 20 of the 24 situations specified on the scale (range: 12–24).

alternatively, willingness to be withdrawn from medication before the start of the trial (a minimum 4-week drug-free period was required before a patient could start trial treatment); and (j) agreed not to start any additional treatment during the trial. With the exception of borderline personality disorder, Axis II personality disorders were not a reason for exclusion.

Of 123 social phobia patients referred for possible inclusion in the trial, 63 did not meet entry criteria. Reasons for exclusion were as follows: social phobia was not the main problem (19 patients); participation was declined (14 patients); previous treatment with an SSRI (9 patients); social phobia was too mild or too specific (8 patients); use of medication with psychotropic effects that would be medically inappropriate to withdraw (6 patients); previous CBT for social phobia (3 patients); current major depressive disorder (3 patients); and borderline personality disorder (1 patient). The remaining 60 patients met entry criteria and were allocated to treatment (20 per condition) on a stratified random basis. Stratification variables were gender (male, female) and avoidant personality disorder (present, absent). Within each of the stratification cells, sealed allocations were drawn at random.

Treatments

CT. CT was based on Clark and Wells's (1995) model of the maintenance of social phobia and used a variety of procedures to reverse the maintaining factors identified in the model. The procedures were described in detail in a therapist manual (Clark, 1997) and can also be found in briefer form in Wells (1997, Chapter 7) and Clark (2001, pp. 419–427). The main steps in treatment were as follow: (a) *developing with patients a personal version of Clark and Wells's model* using their own thoughts, images, anxiety symptoms, safety behaviors, and attentional strategies; (b) *safety behaviors and self-focused attention experiment*: Key safety behaviors were identified and their adverse effects demonstrated with an experiential exercise in which patients role-played a difficult social situation while focusing attention on themselves and using their safety behaviors and then while focusing attention externally and attempting to drop their safety behaviors; (c) *shifting focus of attention to the social situation*: Patients were encouraged to focus their attention externally to reduce problematic self-monitoring and to obtain more accurate information about how they are responded to by other people; (d) *video feedback* was used to modify distorted self-imagery: Patients viewed a video of the safety behaviors and attention experiment and videos of other occasions in which they engaged in feared social tasks under an instructional set that was designed to make the discrepancy between patients' negative, distorted self-images and their objective social performance particularly evident (see Harvey, Clark, Ehlers, & Rapee, 2000, for a description and evaluation of this procedure); (e) *behavioral experiments*: Extensive use was made of behavioral experiments in which patients specified their feared outcomes for various social situations and tested out whether they occurred during planned exposure to the situations using in-session role-plays and in-session and homework-based in vivo assignments. To maximize disconfirmation, patients were encouraged to drop safety behaviors and focus their attention externally. "Widening bandwidth" exercises in which patients intentionally acted against their excessively rigid rules for social interaction while observing the consequences were included; (f) *problematic anticipatory and postevent processing was identified*: Discussion usually showed that the disadvantages of anticipatory and postevent processing greatly exceeded its advantages and, armed with this knowledge, patients were encouraged to drop it; and (g) *dysfunctional assumptions* were also identified and modified by behavioral experiments and by cognitive restructuring techniques. Sessions were approximately 75 min.

Medication and self-exposure (FLU + SE and PLA + SE). Patients who were allocated to medication and self-exposure instructions were started on identically packaged 20-mg capsules of either fluoxetine or placebo. Dose was increased to 40 mg in Week 2 or 3. A maximum dose of 60 mg was permitted. All but 1 patient in each group received the maximum dose (usually by Week 5 or 6). The remaining 2 patients reached 40 mg (FLU+ SE) and 20 mg (PLA + SE), respectively. At the start of the trial, patients were informed that they might be asked to provide a blood sample without advance warning during one of their treatment sessions. Blood was taken from 16 patients (80%) in each group during a session between Weeks 9 and 13. An independent laboratory, blind to allocation, assayed for fluoxetine and norfluoxetine levels. After the blind was broken, the assays indicated that no patients allocated to placebo had fluoxetine or its metabolite in their blood. All patients allocated to fluoxetine had significant blood levels of fluoxetine (M = 331.5 μg/ml, SD = 149.1 μg/ml) and norfluoxetine (M = 217.7 μg/ml, SD = 89.8 μg/ml). Prior to starting medication, patients were told that there is good reason to believe that social phobia is maintained by a neurochemical disturbance that can be rectified by fluoxetine. They were told that as the dose built up, fluoxetine should help make them more confident in social situations but that to gain the maximum benefit from the medication they would also need to systematically expose themselves to feared social situations, with exposure being organized in a graded way to progressively build self-confidence. From Session 3 onward, therapists set several new exposure assignments each week and reviewed the assignments during the next session. There were no therapist-accompanied or in-session exposure assignments. Sessions typically lasted 30–40 min.

Therapists and Supervision

CT was delivered by four clinical psychologists who were experienced in the use of CBTs for anxiety. The medication plus self-exposure treatments were delivered by four specialist registrars in psychiatry with several years of out-patient practice with a mixed caseload that included anxiety disorders. As do many pharmacotherapists, the psychiatrists had extensive prior experience with SSRIs but only modest formal training in CBT. All therapists treated at least two practice social phobia cases in the relevant treatment modality (CT or medication + SE) before the start of the trial. During the trial, all therapists had regular supervision with David M. Clark to check protocol adherence and assist with planning future sessions. A random selection of session tapes was also reviewed. In the medication conditions, additional supervision from a senior psychiatrist was provided. No protocol violations were detected.

Measures

Social phobia. Independent assessors rated patients' fear and avoidance across a range of social situations using the ADIS. The mean rating across all fear and avoidance items was analyzed. Patients completed five standardized self-report social phobia scales: Mattick and Clarke's (1998) Social Phobia Scale and Social Interaction Anxiety Scale; the LSAS; Marks and Mathews's (1979) Fear Questionnaire Social Phobia subscale (FQ-SOC); and the Fear of Negative Evaluation Scale (Watson & Friend, 1969). To date, the LSAS has most commonly been used as an assessor rating. However, Baker, Heinrichs, Kim, and Hofman (2002) have recently provided data that support its use as a self-report instrument. An additional self-report measure, the Social Phobia Weekly Summary Scale (SPWSS), which was developed by our group, was also included. The five-item SPWSS has good internal consistency (Cronbach's α = .81) and consists of 0–8 ratings of social anxiety, social avoidance, self-focused versus external attention, anticipatory processing, and postevent rumination.

General mood. The Beck Anxiety Inventory (BAI; Beck, Epstein, Brown, & Steer, 1988) and the Beck Depression Inventory (BDI; Beck, Rush, Shaw, & Emery, 1979) were used to assess anxious and depressed mood, respectively.

All social phobia and general mood measures were given at each assessment except for the midtreatment assessment, when the ADIS (assessor rating) and the LSAS (patient self-report) were omitted.

Statistical Analysis

Analyses were intent to treat. All patients who started treatment and provided at least one postintake assessment were included in the analyses

with last available data carried forward, with the exception of the 12-month follow-up analysis, in which data for patients who failed to reach the posttreatment assessment were not carried forward.[2] To identify any differences between groups before treatment, we compared initial scores for the three treatment groups with the liberal procedure of separate one-way analyses of variance (ANOVAs) for each measure. To identify any differences between groups at midtreatment, posttreatment or follow-up, we used one-way analyses of covariance (ANCOVAs) with pretreatment scores as covariates followed by post hoc Duncan's multiple range tests when comparing more than two means. We used *t* tests to identify significant within-treatment changes. A two-step approach was adopted to deal with multiple measurement of social phobia. First, a single unweighted social phobia composite was created and analyzed. Only if the composite revealed significant between- or within-group differences were further ANCOVAs or *t* tests performed on individual social phobia measures. The composite was generated with the procedure recommended by Rosenthal and Rosnow (1991) and adopted in several previous trials (e.g., Clark et al., 1994, 1999; Hollon et al., 1992). Patients' scores on each (of seven) social phobia measures were standardized ($M = 0$, $SD = 1$) across pre- and posttreatment assessments by converting to *Z* scores. The composite at each assessment occasion was the mean of the *Z* scores on that occasion.

Results

Characteristics of Patients

Patients' mean age was 33.2 years ($SD = 8.1$). Mean duration of social phobia was 13.3 years ($SD = 11.3$). Fifty-two percent were women. Fifty percent were married or cohabiting. Seventy-two percent were employed, 12% were students, and 16% were unemployed. Thirty-three percent left school by age 16, 11% completed high school, and 56% had some higher education. Forty-three percent met criteria for avoidant personality disorder. Fourteen percent were taking psychotropic medication from which they had to be withdrawn before the start of the trial. There were no significant differences between the treatment groups in any of these characteristics.

Dropouts and Number of Sessions Attended

Four patients withdrew before the end of treatment: 2 because of side-effects (1 in FLU + SE, 1 in PLA + SE), 1 (PLA + SE) to seek treatment elsewhere, and 1 (PLA + SE) relocated for work. Two further patients (both FLU + SE) were withdrawn. One unexpectedly became pregnant, and the other became severely depressed and required additional emergency treatment. For these patients, assessments at the point of withdrawal (Weeks 6, 3, 5, 9, 7, & 12, respectively) were used in the posttreatment and end-of-booster-period analyses. Patients were offered up to 16 treatment sessions and 3 booster sessions. For completers, the mean numbers of sessions attended were CT, 15.1 ($SD = 1.7$) treatment sessions and 2.5 ($SD = 0.9$) booster sessions; FLU + SE, 13.5 ($SD = 1.8$) treatment sessions and 2.7 ($SD = 0.9$) booster sessions; and PLA + SE, 13.2 ($SD = 2.8$) treatment sessions. For dropouts, the mean numbers of treatment sessions attended were FLU + SE, 6.7 ($SD = 3.8$) and PLA + SE, 5.7 ($SD = 2.5$).

Effects of Treatment on Social Phobia

Figure 1 shows the social phobia composite, and Table 1 shows the individual social phobia measures at each time point. The social phobia composite was based on seven individual social phobia measures at all time points except for midtreatment, at which five individual measures were administered. At pretreatment, one-way ANOVAs indicated that there were no significant differences between the groups.

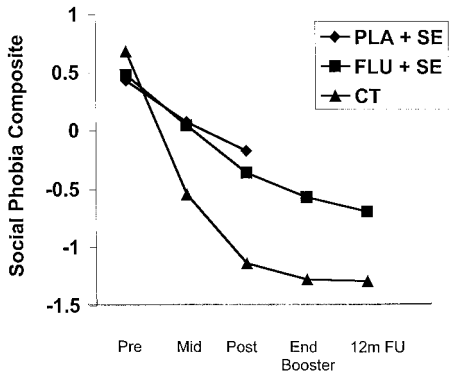

Figure 1. Social phobia composite scores at each assessment. CT = cognitive therapy; FLU + SE = fluoxetine plus self-exposure; PLA + SE = placebo plus self-exposure; pre = pretreatment, mid = midtreatment; post = posttreatment; 12m FU = 12-month follow-up.

At midtreatment (8 weeks), ANCOVA revealed a significant treatment effect on the social phobia composite. Paired comparisons indicated that CT was superior to FLU + SE and PLA + SE, which did not differ from each other. Analysis of the five individual social phobia measures indicated that CT was superior to FLU + SE on two measures and superior to PLA + SE on three measures. Within-group *t* tests were used to assess pretreatment to midtreatment change. All three treatments were associated with significant pretreatment to midtreatment improvement on the social phobia composite and most individual measures. The measures that were *not* significant were the Fear of Negative Evaluation Scale in the FLU + SE condition and FQ-SOC and SPWSS in the PLA + SE condition.

At posttreatment (16 weeks), there were significant ANCOVA treatment effects on the social phobia composite and all seven individual measures. Paired comparisons indicated that CT was superior to FLU + SE and PLA + SE on each measure. FLU + SE did not differ from PLA + SE.[3] The *t* tests indicated that the CT and FLU + SE conditions were associated with significant pretreatment to posttreatment improvement on the social phobia composite and all individual measures. PLA + SE was associated with significant pretreatment to posttreatment improvement on all measures except the FQ-SOC.

[2] The main reason for the 12-month follow-up was to determine whether treatment gains were maintained. In this context, we considered carrying forward the last observation for patients who did not attend the 12-month follow-up problematic, as it assumes that such individuals did not relapse. As a consequence, the extent to which treatment gains were maintained could be overestimated. At the request of an anonymous reviewer, a reanalysis of the 12-month follow-up data using the carried forward strategy was also conducted. The results were essentially the same as those reported in the text. CT remained superior to FLU + SE on the social phobia composite, but the number of individual social phobia measures that showed a significant difference between the two treatments increased from four to six. The additional measures were the ADIS and LSAS.

[3] A completers-only analysis in which the patients who had less than 16 weeks on medication were excluded produced essentially similar results, with FLU + SE and PLA + SE failing to differ on any measure.

Table 1
Outcome Measures at Each Assessment

Assessment	Cognitive therapy			Fluoxetine and self-exposure[a]			Placebo and self-exposure			Group effect[b]
	n	*M*	*SD*	*n*	*M*	*SD*	*n*	*M*	*SD*	
Social phobia composite										
Pretreatment	20	0.69	0.69	20	0.49	0.63	20	0.44	0.94	$F(2, 57) = 0.6$
Midtreatment	20	-0.54_a	1.02	20	0.05_b	0.97	20	0.08_b	1.11	$F(2, 56) = 8.4$***
Posttreatment	20	-1.13_a	0.99	20	-0.35_b	1.12	20	-0.16_b	1.18	$F(2, 56) = 9.5$***
End of boosters	20	-1.27_a	0.83	20	-0.56_b	1.14				$F(1, 37) = 7.7$**
12-month follow-up	20	-1.28_a	0.86	17	-0.68_b	1.01				$F(1, 35) = 6.4$*
Anxiety Disorders Interview Schedule, Fear and Avoidance										
Pretreatment	20	3.37	1.27	20	3.07	1.07	20	3.10	1.38	$F(2, 57) = 0.4$
Posttreatment	20	1.58_a	1.23	19	2.33_b	1.33	20	2.60_b	1.57	$F(2, 55) = 5.6$**
End of boosters	20	1.43	1.15	19	2.01	1.25				$F(1, 36) = 3.6$†
12-month follow-up	20	1.55	1.18	17	2.06	1.24				$F(1, 35) = 2.3$
Social Phobia Scale										
Pretreatment	20	30.20	14.79	20	31.33	13.39	20	36.10	18.31	$F(2, 57) = 0.8$
Midtreatment	20	17.44_a	13.24	18	24.39_b	11.48	19	30.42_b	18.00	$F(2, 53) = 4.1$*
Posttreatment	20	10.87_a	11.36	19	21.04_b	14.67	20	27.50_b	18.95	$F(2, 55) = 6.8$**
End of boosters	20	9.80_a	9.51	19	16.05_b	10.51				$F(1, 36) = 4.6$*
12-month follow-up	20	8.90_a	7.57	17	14.59_b	10.69				$F(1, 34) = 4.2$*
Social Interaction Anxiety Scale										
Pretreatment	20	48.30	12.26	20	43.85	12.72	20	41.96	14.02	$F(2, 57) = 1.2$
Midtreatment	20	34.02	13.93	18	38.42	13.67	19	35.29	14.67	$F(2, 53) = 2.8$†
Posttreatment	20	24.51_a	13.76	19	32.79_b	15.93	20	33.05_b	14.56	$F(2, 55) = 5.9$**
End of boosters	20	23.73	11.94	20	27.76	15.41				$F(1, 37) = 2.8$†
12-month follow-up	20	23.65_a	14.44	17	29.59_b	13.79				$F(1, 34) = 4.5$*
Liebowitz Social Anxiety Scale										
Pretreatment	20	78.65	25.56	20	75.34	17.63	20	71.05	26.67	$F(2, 57) = 0.5$
Posttreatment	20	35.41_a	22.90	19	56.16_b	30.61	20	55.34_b	31.17	$F(2, 55) = 5.7$**
End of boosters	20	31.42_a	23.55	20	52.44_b	32.36				$F(1, 37) = 6.5$*
12-month follow-up	20	34.75	23.21	17	46.46	24.77				$F(1, 34) = 2.6$
Social Phobia Weekly Summary Scale										
Pretreatment	20	5.08	1.46	20	4.58	0.93	20	4.66	1.64	$F(2, 57) = 0.8$
Midtreatment	20	2.48_a	1.76	20	3.74_b	1.78	20	3.86_b	2.11	$F(2, 56) = 6.8$**
Posttreatment	20	1.91_a	1.50	20	3.18_b	1.74	20	3.65_b	1.85	$F(2, 56) = 7.8$**
End of boosters	19	1.91_a	1.12	18	2.93_b	1.67				$F(1, 34) = 5.7$*
12-month follow-up	19	1.66_a	1.31	17	2.88_b	1.76				$F(1, 33) = 7.2$*
Fear Questionnaire Social Phobia Subscale										
Pretreatment	20	22.39	6.37	20	19.43	8.28	20	19.00	7.44	$F(2, 57) = 1.2$
Midtreatment	20	14.20_a	7.03	19	$15.46_{a,b}$	7.67	19	18.58_b	10.01	$F(2, 54) = 4.4$**
Posttreatment	20	9.20_a	7.26	20	13.60_b	8.01	20	16.25_b	10.26	$F(2, 56) = 7.6$**
End of boosters	20	8.45	6.49	18	10.56	7.63				$F(1, 35) = 2.8$
12-month follow-up	19	8.11	6.43	17	10.94	6.51				$F(1, 33) = 2.6$
Fear of Negative Evaluation										
Pretreatment	20	25.16	5.18	20	25.70	5.36	20	23.55	6.92	$F(2, 57) = 0.7$
Midtreatment	20	19.50	8.70	18	23.94	6.01	19	21.16	8.11	$F(2, 53) = 2.6$†
Posttreatment	20	15.28_a	9.00	19	21.31_b	9.24	20	20.30_b	8.11	$F(2, 55) = 3.8$*
End of boosters	20	12.94_a	7.82	18	18.46_b	8.92				$F(1, 35) = 4.4$*
12-month follow-up	19	12.32_a	9.06	17	18.76_b	9.25				$F(1, 33) = 4.4$*
Beck Anxiety Inventory										
Pretreatment	20	17.60	9.51	20	17.40	7.42	20	19.75	11.92	$F(2, 57) = 0.4$
Midtreatment	20	7.70	9.53	20	9.15	5.65	20	9.80	8.19	$F(2, 56) = 0.3$
Posttreatment	20	5.50	5.93	20	7.95	7.20	20	9.50	7.32	$F(2, 56) = 1.6$
End of boosters	20	5.05	5.73	18	8.22	6.55				$F(1, 35) = 3.9$†
12-month follow-up	19	4.79_a	3.81	17	7.29_b	4.73				$F(1, 33) = 4.5$*

Table 1 (*continued*)

Assessment	Cognitive therapy			Fluoxetine and self-exposure[a]			Placebo and self-exposure			Group effect[b]
	n	*M*	*SD*	*n*	*M*	*SD*	*n*	*M*	*SD*	
Beck Depression Inventory										
Pretreatment	20	13.25	7.48	20	12.75	6.98	20	12.69	8.07	$F(2, 57) = 0.1$
Midtreatment	20	6.95	7.60	20	8.60	7.12	20	8.00	8.34	$F(2, 56) = 0.5$
Posttreatment	20	4.70	5.60	20	7.70	7.64	20	7.90	8.57	$F(2, 56) = 1.9$
End of boosters	20	4.45	5.19	18	6.61	5.97				$F(1, 35) = 2.6$
12-month follow-up	19	4.53	3.99	17	5.65	5.27				$F(1, 33) = 0.8$

Note. Within an assessment occasion, means with no subscripts and those that share the same subscript do not differ. Means with nonoverlapping subscripts differ at $p < .05$ or better.

[a] Two fluoxetine and self-exposure patients restarted fluoxetine between the end of the booster period and the 12-month follow-up. Patients were asked to refrain from seeking any additional nontrial treatment during the follow-up period. No cognitive therapy patient had additional trial or nontrial treatment. Two fluoxetine and self-exposure patients started a course of psychological treatment between the end of the booster period and the 12-month follow-up. Both had a full assessment, data from which were used for the 12-month follow-up analysis, before starting the additional treatment.

[b] At pretreatment, group effect was based on one-way analysis of variance. At all other assessment points group effect was based on one-way analysis of covariance, with pretreatment scores as the covariate. Significant ($p < .01$) analysis of variance or analysis of covariance main effects were investigated with post hoc Duncan's multiple range tests when more than two means were involved.

† $p < .1$. * $p < .05$. ** $p < .01$. *** $p < .001$.

Effects of Treatment on General Mood

In contrast to the social phobia measures, ANCOVAs indicated that the three treatments did not differ in their effects on the general mood measures (BAI and BDI) at either midtreatment or posttreatment (see Table 1). However, in all three treatments there were significant pretreatment to midtreatment and pretreatment to posttreatment improvements on the BAI and the BDI (all *p*s < .05).

Maintenance of Treatment Gains

At 16 weeks the medication blind was broken and patients on placebo were withdrawn from the trial. Patients who had received CT or FLU + SE entered a 3-month booster phase during which they received up to three additional sessions. Fluoxetine was maintained at full dose in the booster phase. At the end of the booster phase, no further treatment sessions were offered and fluoxetine was gradually withdrawn over a 3- to 6-week period.

End of booster phase. For the social phobia measures, ANCOVA indicated that CT was superior to FLU + SE on the social phobia composite and four of seven individual social phobia measures (see Table 1). The *t* tests comparing posttreatment and end of booster phase scores were used to determine whether treatment gains were maintained or improved on in the booster period. For CT none were significant, indicating that treatment gains were maintained. For FLU + SE significant improvement was observed in the social phobia composite, $t(19) = 3.02$, $p < 0.1$; the ADIS, $t(18) = 3.02$, $p < .01$; the FQ-SOC, $t(17) = 2.68$, $p < .05$; and the Social Interaction Anxiety Scale, $t(18) = 3.66$, $p < .001$. For the general mood measures, ANCOVA indicated that CT did not differ from FLU + SE. The *t* tests comparing posttreatment and end of booster scores were nonsignificant, indicating that for both CT and FLU + SE treatment gains in general mood were maintained.

12-month follow-up. For the social phobia measures, ANCOVA indicated that CT remained superior to FLU + SE on the social phobia composite and four of seven individual social phobia measures. For both treatments, *t* tests comparing 12-month follow-up scores with patients' scores at posttreatment and at the end of the booster phase were all nonsignificant, indicating that the treatment gains were maintained at 12-month follow-up, but there was no evidence of further, sustained improvement. For the general mood measures, CT was superior to FLU + SE on the BAI but not the BDI.

Effect Sizes

To gain a clearer impression of the magnitude of the improvement in social phobia associated with each treatment condition, we calculated uncontrolled pretreatment to posttreatment, end of booster, and follow-up effect sizes for the social phobia composite using the following formula: Effect size = (mean social phobia composite at pretreatment – mean social phobia composite at posttreatment, end of booster, or follow-up) ÷ pooled standard deviation. Table 2 shows the data. Depending on the assessment point, uncontrolled effect sizes ranged from 2.14 to 2.53 for CT and from 0.92 to 1.36 for FLU + SE. Controlled effect sizes in which the posttreatment means for CT and FLU + SE were compared with PLA + SE were also computed using the following formula: Controlled effect size = (PLA + SE posttreatment covariance adjusted mean − CT or FLU + SE posttreatment

Table 2
Effect Sizes for the Social Phobia Composite at Posttreatment, End of Booster Period, and 12-Month Follow-Up

Assessment	CT	FLU + SE	PLA + SE
Posttreatment	2.14	0.92	0.56
End of booster period	2.57	1.14	
12-month follow-up	2.53	1.36	

Note. CT = cognitive therapy; FLU + SE = fluoxetine plus self-exposure; PLA + SE = placebo plus self-exposure. Effect size = (mean composite at pretreatment minus mean composite at posttreatment, end of booster or at follow-up) ÷ pooled standard deviation.

covariance-adjusted mean) ÷ pooled standard deviation. Cohen (1988) proposed a threefold classification of effect sizes: small (0.20–0.49), medium (0.50–0.79), and large (0.80 and above). According to this system, the posttreatment controlled effect size for CT (1.31) is large, and the posttreatment controlled effect size for FLU + SE (0.21) is small.

Predictors of Treatment Response

Multiple regression was used to identify possible predictors of treatment response in the total sample. Six possible predictors (initial level of depression, duration of social phobia, and presence of avoidant personality disorder and patient age, gender, and marital status) were entered, with the dependent variable being the social phobia composite residualized gain scores at posttreatment. None of the predictors were significant.

Equivalence Analysis for FLU + SE Versus PLA + SE

To investigate the apparent lack of difference between FLU + SE and PLA + SE, we conducted an equivalence analysis (see Rogers, Howard, & Vessey, 1993) on the social phobia composite data for the two medication conditions. Equivalence analysis allows one to further explore a null result by calculating the largest possible difference between two conditions that a study may have missed because of limitations of statistical power. Setting alpha at .05 and using equivalence analysis, we reject the hypothesis that FLU + SE has a posttreatment adjusted mean on the social phobia composite that is more than 0.70 superior to that for PLA + SE. However, we are not able to reject the hypothesis that FLU + SE is more effective than PLA + SE but the difference is less than 0.70. If we convert this calculation into controlled effect sizes, our sample size does not allow us to reject the hypothesis that, compared with the PLA + SE control condition, FLU + SE has a positive effect size of up to 0.56 (a medium effect size in Cohen's classification).

Discussion

Effectiveness of Cognitive Therapy

The overall pattern of results indicates that CT is an effective treatment for generalized social phobia. Patients treated with CT improved significantly more than patients who received self-exposure instructions combined with fluoxetine or placebo. In addition, the gains obtained in treatment were well maintained at 1-year follow-up.

In line with routine clinical practice, CT sessions were longer than medication plus self-exposure sessions. This raises the possibility that the superiority of CT could have been due to greater therapist contact. A further trial with a control treatment involving an identical amount of therapist contact is required to definitively address this question. However, there are two reasons for supposing that therapist contact alone is unlikely to explain the superiority of CT. First, in a recent social phobia trial, Heimberg et al. (1998) found that 150-min sessions of education and support were no more effective than 30-min sessions devoted to administering a pill placebo, and both conditions were inferior to 150-min sessions of CBGT. Second, therapy experiments that attempt to assess the short-term impact of discrete therapy maneuvers have shown that several of the procedures involved in the CT program (dropping safety behaviors, shifting to an external focus of attention, and using video feedback) have beneficial effects over and above those obtained with a similar duration control procedure (Harvey et al., 2000; Morgan & Raffles, 1999; Wells et al., 1995; Wells & Papageorgiou, 1988).

Meta-analyses of other CBTs for social phobia (Fedoroff & Taylor, 2001; Feske & Chambless, 1995; Gould et al., 1997; Taylor, 1996) have reported mean pretreatment to posttreatment effect sizes between 0.80 and 1.08 for social phobia measures. In trials that have focused exclusively on generalized social phobia (Hope, Herbert, & White, 1995; Salaberria & Echeburua, 1998; Scholing & Emmelkamp, 1993), CBT pretreatment to posttreatment effect sizes on the social phobia measures that were used in the current trial have ranged from 0.56 to 1.31. The pretreatment to posttreatment effect size observed with CT in the current trial (2.14) is substantially larger, which raises the possibility that the new CT program has enhanced efficacy. However, comparisons between trials are fraught with difficulty because of differences in selection criteria, patient demographics, and other characteristics. For this reason, a within-trial comparison between CT and other established behavioral and cognitive–behavioral programs is required.

Effectiveness of Medication Plus Self-Exposure

Patients who received medication plus self-exposure showed significant and substantial improvements on almost all social phobia measures between pretreatment and posttreatment. The improvement observed with PLA + SE was not surprising given the established efficacy of self-exposure in phobic disorders. At the time the trial was planned, five open trials (Black et al., 1992; Koponen et al., 1995; Perugi et al., 1994; Schneier et al., 1992; Van Ameringen et al., 1993) suggested that fluoxetine is effective. Since the start of the trial, several randomized controlled trials establishing the effectiveness of other SSRIs have been published. Given these points, we were surprised to find that FLU + SE was not more effective than PLA + SE. This finding cannot be attributed to inadequate dosage, as almost everyone was prescribed the maximum of 60 mg and plasma analysis indicated excellent compliance, with all patients in the fluoxetine condition having suitable blood levels of fluoxetine and its metabolite (norfluoxetine). There are at least three other (possibly interacting) explanations for the lack of difference between FLU + SE and PLA + SE.

First, the present trial is underpowered relative to most recent medication trials that routinely have larger cell sizes. Our equivalence-testing analysis indicated that with our cell size of 20 patients, a difference between FLU + SE and PLA + SE equivalent to a medium controlled effect size (Cohen, 1988), could have been missed. Since the completion of the trial, two other groups have reported fluoxetine versus placebo comparisons. The results obtained by these two groups are consistent with the reduced power argument. In a published study using cell sizes of 30 per group, Kobak, Greist, Jefferson, and Katzelnick (2002) failed to find a significant difference between fluoxetine and placebo. By contrast, in a conference paper, Huppert, Roth, Keefe, Davidson, and Foa (2002) reported obtaining some significant differences between fluoxetine and placebo when a larger cell size (approximately 60 patients per group) was used.

Second, fluoxetine may be less effective in social phobia than the three other SSRIs (fluvoxamine, sertraline, paroxetine) that have been shown to be effective in randomized controlled trials. Consistent with this suggestion, the controlled effect sizes observed with fluoxetine in the present trial and in Kobak et al.'s (2002) trial are generally lower than those reported in trials of the other SSRIs (see Fedoroff & Taylor, 2001; Gould et al., 1997). A trial involving a direct comparison between fluoxetine and the other SSRIs is required to clarify this point. If fluoxetine does turn out to be less effective, the finding may be an important lead in helping clarify the neurobiology of social anxiety. For example, fluoxetine differs from fluvoxamine, sertraline, and paroxetine in the relative balance of its noradrenergic and serotinergic effects (Leonard, 1996; Stahl, 1998).

Third, the fluoxetine versus placebo contrast in the present trial may have been shorter than ideal. Kobak et al.'s (2002) main contrast was after 14 weeks and ours was after 16 weeks. However, patients in the present trial who stayed on fluoxetine after the medication blind was broken (at 16 weeks) showed further significant improvement between that point and the end of the booster period (28 weeks). It is therefore possible that a significant difference between fluoxetine and placebo might have emerged between 16 and 28 weeks.

The present trial was relatively unusual in combining medication with self-exposure. Only two previous social phobia medication trials (Blomhoff et al., 2001; Gelernter et al., 1991) have had a similar design. However, it seems unlikely that adding self-exposure contributed to lack of difference between fluoxetine and placebo, as Kobak et al. (2002) did not use self-exposure and still failed to find a significant difference between fluoxetine and placebo.

Contrast Between Social Phobia and General Mood Measures

In contrast to the results obtained with standardized measures of social phobia, at posttreatment there were no significant between-group differences on the two general mood measures (BDI and BAI). The substantial improvements in depression that were observed with all three treatments are consistent with the view that much of the depressed mood observed in our patients was secondary to their social phobia. This is perhaps not surprising when one recalls that patients with concurrent major depressive disorder were excluded from the study. The observed lack of difference between the three treatments on the BDI in our sample could be viewed as an indication of the treatments' particularly specific effects on social phobia or it could be the consequence of a floor effect. Consistent with the latter suggestion, in all three treatments the posttreatment means for the BDI were in the nonclinical range. Similarly to the BDI, the BAI showed substantial but broadly similar improvement in all three treatments, with CT differing from FLU + SE only at the 12-month follow-up. Posttreatment means for the BAI were in the minimal or mild anxiety range (Beck & Steer, 1993), suggesting a floor effect on this measure as well. In addition, the BAI may have relatively poor sensitivity as an outcome measure in phobic disorders because the extensive avoidance of feared situations shown by severe phobics can result in low pretreatment scores on general measures of anxious mood such as the BAI.

Stability of Therapeutic Gains

In CT and FLU + SE the improvements obtained at the end of treatment were maintained at 1-year follow-up. The CT finding is in line with other CBT research (see Fedoroff & Taylor, 2001; Taylor, 1996). For medications, some studies (e.g., Liebowitz et al., 1999) have shown an increased relapse rate following discontinuation. It is encouraging that this did not happen in the present study, perhaps because medication was combined with self-exposure. Further studies could explore this issue by comparing long-term outcome of medication alone versus medication plus self-exposure.

Limitations

Four limitations need to be borne in mind when interpreting the study. First, as mentioned above, the sample size for a drug–placebo comparison was relatively modest, and a medium size active medication effect could have been missed. Second, it is possible that fluoxetine is less effective than some other SSRIs and, as a consequence, one cannot assume that the observed difference between CT and FLU + SE would generalize to other SSRIs. Third, the exposure element in the medication + SE groups was less extensive than in most formal exposure programs. There were no therapist-assisted or in-session exposure exercises. In addition, as do many pharmacotherapists, the psychiatrists who delivered the medication treatments had little previous formal training in CBT. It is possible that both fluoxetine and placebo would have been associated with greater improvement if they had been combined with a more extensive exposure program delivered by therapists with specialized training in CBT. Fourth, it is unclear whether the results can be generalized to patients with specific social phobia or to patients with generalized social phobia and concurrent major depression, as both types of patient were excluded from the study. Specific social phobia was excluded because it is generally less disabling and was also considered less likely to respond to medication, but no studies have formally tested this suggestion. Comorbid major depression was excluded to ensure that any medication effect was not an indirect consequence of treating depression rather than a direct effect on social phobia.

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