Cognitive Behavioral Group Therapy vs Phenelzine Therapy for Social Phobia

12-Week Outcome

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Background: This article presents results of the acute treatment phase of a 2-site study comparing cognitive behavioral group therapy (CBGT) and treatment with the monoamine oxidase inhibitor phenelzine sulfate for social phobia.

Methods: One hundred thirty-three patients from 2 sites received 12 weeks of CBGT, phenelzine therapy, pill placebo administration, or educational-supportive group therapy (an attention-placebo treatment of equal credibility to CBGT). The "allegiance effect," ie, the tendency for treatments to seem most efficacious in settings of similar theoretical orientation and less efficacious in theoretically divergent settings, was also examined by comparing responses to the treatment conditions at both sites. 1 Known for pharmacological treatment of anxiety disorders and the other for cognitive behavioral treatment.

Results: After 12 weeks, phenelzine therapy and CBGT led to superior response rates and greater change on dimensional measures than did either control condition. However, response to phenelzine therapy was more evident after 6 weeks, and phenelzine therapy was also superior to CBGT after 12 weeks on some measures. There were few differences between sites, suggesting that these treatments can be efficacious at facilities with differing theoretical allegiances.

Conclusions: After 12 weeks, both phenelzine therapy and CBGT were associated with marked positive response. Although phenelzine therapy was superior to CBGT on some measures, both were more efficacious than the control conditions. More extended cognitive behavioral treatment and the combination of modalities may enhance treatment effect.

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Social phobia is prevalent, begins early, and follows a chronic course. It is often comorbid with other disorders and increases the odds of the occurrence of the secondary disorder. Impairment is substantial and inability to work, attend school, or marry is common. Controlled trials support the efficacy of pharmacotherapy for social phobia. One of the most thoroughly studied treatments is cognitive behavioral group therapy (CBGT), a multicomponent package including (1) training in cognitive coping skills, (2) multiple exposures to simulations of feared situations in session, (3) homework assignments for exposure to feared situations, and (4) use of cognitive coping skills in conjunction with exposures. Cognitive behavioral group therapy has been evaluated in several studies. CBGT was more effective than attention-placebo treatment after 12 weeks, and patients continued to do well at 4.5- to 6.23-year follow-up.

Few studies have compared pharmacological and cognitive behavioral treatments for social phobia. Results of 2 studies showed better outcomes with cognitive behavioral treatments. However, the medications studied were
PATIENTS AND METHODS

We compared CBGT, phenelzine therapy, placebo administration, and educational-supportive group therapy (ES), an attention-placebo procedure. All treatments were conducted at both sites (Figure 1). Eligible patients met DSM-III-R criteria for social phobia. At the Center for Stress and Anxiety Disorders of the State University of New York at Albany, the Anxiety Disorder Interview Schedule–Revised (ADIS-R) was administered. At the Anxiety Disorders Clinic of the New York State Psychiatric Institute, New York, either the Schedule for Affective Disorders and Schizophrenia–Lifetime version (modified for the study of anxiety disorders) or the Structured Clinical Interview for DSM-III-R was administered. In each setting, the social phobia section of the other site’s diagnostic interview was administered to ensure that similar patients were enrolled at both sites. Patients underwent physical examinations and satisfied relevant inclusion and exclusion criteria. Pretreatment assessment included an independent assessor interview, self-report questionnaires, and a behavioral test. Groups of 5 to 7 patients, stratified by social phobia subtype, were then randomly assigned to 12 weekly sessions of 1 of the 4 treatments. Phenelzine and double-blind pill placebo were administered by a psychiatrist, and CBGT and ES were conducted by a psychologist and cotherapist. Assessments were repeated after 6 (interview and questionnaires only) and 12 weeks of treatment. Thereafter, nonresponders to the active treatments and patients who received ES or pill placebo were removed from the study. Responders to CBGT or phenelzine therapy were eligible for the long-term phase of the study, described in a separate article.

PATIENTS

The sample consisted of 133 patients, 59 from Albany, NY, and 74 from New York, NY, who presented for treatment at 1 of the sites, were referred by local mental health or medical practitioners, or responded to advertisements in local media. For study inclusion, prospective patients had to meet criteria for social phobia and had to be between 18 and 65 years old, fluent in English, willing to provide written informed consent, and able to participate responsibly in treatment. Exclusions included schizophrenia, major depression, prominent risk of self-harm, organic mental disorder, history of bipolar I disorder, alcohol or substance abuse (within the past 6 months), or a previous adequate trial of cognitive behavioral therapy (≥6 sessions) or MAOI treatment (phenelzine sulfate, ≥45 mg/d, or the equivalent dosage of another MAOI for 4 weeks) for social phobia, or any serious medical condition that would increase the patient’s chances of being harmed by study participation. There were no significant demographic differences between patients at the 2 sites or among patients assigned to the 4 treatment conditions (Table 1). Patients from New York City were more severe on several pretreatment measures. However, patients assigned to the 4 treatment conditions did not differ overall or as a function of site on these measures.

TREATMENTS

Administration of Phenelzine or Pill Placebo

A psychiatrist monitored patients’ clinical state and offered support according to a manual adapted from the National Institute of Mental Health Treatment of Depression Collaborative Research Program.50 Visits lasted 30 minutes, except for a 45-minute initial visit. No systematic exposure instructions were offered.

Patients received 15-mg phenelzine sulfate tablets (n = 31) or matching placebo tablets (n = 33) in 1 morning dose; dosages of 60 mg/d (4 pills) and greater were split between morning and noontime. Dosages started at 15 mg/d and increased to 30 mg/d on day 4, to 45 mg/d on day 8, and to 60 mg/d on day 13. After 4 weeks, depending on symptoms and adverse effects, dosages could be raised to 75 mg/d. After 5 weeks, dosages could be raised to 90 mg/d. No other psychotropic medications were permitted, and patients followed MAOI dietary restrictions.50

Cognitive Behavioral Group Therapy

Cognitive behavioral group therapy was administered in 12 sessions of 2½ hours each to groups of 5 to 7 patients (n = 36). In the first 2 sessions, patients were taught to identify negative cognitions (“automatic thoughts” [ATs]), to observe the covariation between anxiety and ATs, to challenge logical errors in ATs, and to formulate rational alternatives. Thereafter, they confronted increasingly difficult feared situations (first in the session and then in real life) while applying cognitive skills. When patients worked on their personal target situations, a standard sequence was followed: (1) identification of ATs, (2) identification of logical errors in ATs, (3) disputation of ATs and formulation of rational responses, and (4) establishment of behavioral goals. Patients practiced cognitive skills while completing behavioral tasks (eg, conversing with another group member or giving a speech). Goal attainment and use of cognitive skills were reviewed. Behavioral experiments were used to confront specific reactions to the exposure. Patients were given assignments for exposure to real-life situations between sessions and were instructed to complete self-administered cognitive restructuring exercises before and after.

Educational-Supportive Group Therapy

In the first portion of ES sessions (n = 33), topics relevant to social phobia (eg, fear of negative evaluation, buspirone,19 and atenolol,57 neither of which surpassed the efficacy of placebo, limiting the value of these comparisons.

We compared phenelzine therapy and CBGT, pharmacological and cognitive behavioral treatments with previously demonstrated efficacy for social phobia. We also evaluated the “allegiance effect,” ie, the tendency for treatments to seem most efficacious in settings of similar theoretical orientation and less efficacious in theoretically divergent settings. Thus, the study was conducted at 2 centers: 1 known for cognitive behavioral treatment of anxiety disorders and the other for pharmacological treatment. Administration of each treatment at both sites, with appropriate quality controls and supervision, provides a stern test of allegiance effects and the utility of the treatments.
INTERVENTIONS

Therapists did not instruct patients to confront feared situations.

MEASURES

Independent Assessment

Criterion for Treatment Response. The independent assessor (IA), unaware of treatment condition, completed the 7-point rating of change from the Social Phobic Disorders Severity and Change Form. This rating was used to categorize treatment response. Patients rated 1 or 2 (markedly or moderately improved) were classified as respondents and patients rated 3 or higher were classified as nonresponders.

Other IA Measures. The IA also administered the Liebowitz Social Anxiety Scale (LSAS), a 24-item scale that provides separate scores for fear (0-3 indicate none, mild, moderate, and severe, respectively) and avoidance (0-3 indicate never, occasionally, often, and usually, respectively) of social interaction and performance situations. The LSAS has been widely used in studies of pharmacotherapy of social phobia and has demonstrated good psychometric properties.

The IA also administered the ADIS-R social phobia module and completed the ADIS-R Clinician’s Severity Rating, a rating from 0 to 8 of the severity of symptoms and impairment associated with social phobia, and the 7-point rating of severity from the Social Phobic Disorders Severity and Change Form.

The IA also administered the avoidant personality disorder module from the Personality Disorders Examination. The number of criteria satisfied by each patient and a dimensional score derived by summing the ratings assigned to each item were examined.

Self-report Measures

Patients completed (1) the Social Avoidance and Distress Scale; (2) the Fear of Negative Evaluation Scale; (3) the social phobia subscale and 0 to 8 self-rating of avoidance from the Fear Questionnaire; (4) the Social Interaction Anxiety Scale, a measure of anxiety in dyads and groups; (5) the Social Phobia Scale, a measure of anxiety when being observed by others; and (6) the interpersonal sensitivity, depression, anxiety, and phobic anxiety subscales of the Symptom Checklist-90-Revised.

Individualized Behavioral Test

Before and after acute treatment, each patient participated in an individualized behavioral test. A real-life anxiety-evoking situation was selected for each patient for reenactment. Patients rated their anxiety on a scale from 0 to 100 three times before (anticipatory period) and 3 times during (performance period) the 4-minute test situation. Afterward, patients rated their performance on a scale from 0 to 100.

In-Session Measures

Patients completed the Reaction to Treatment Questionnaire, which assesses treatment credibility and patients’ confidence that treatment will be helpful, after sessions 1 and 4. Patients in group therapy completed the 9-item Gross Cohesion Scale, which asks patients to rate how positively involved they are with their group, after sessions 4 and 8.

DATA ANALYSES

All statistical analyses were conducted twice, first only for patients who completed treatment and again including dropouts (intent-to-treat analysis [ITT]). Patients undergoing CBGT and ES were classified as dropouts if they missed more than 3 sessions. Patients receiving medication were classified as dropouts if they missed more than 3 visits, did not take medication for 5 consecutive days or a total of 10 days, or did not receive a dosage of at least 45 mg/d (or 3 placebo tablets) for at least 4 weeks. In the ITT analysis of treatment response, dropouts were considered failures. In the ITT analyses of dimensional measures, the patient’s last available score was carried forward.

Categorical analyses were conducted using χ2 or Fisher exact tests. Dimensional measures from the IA interview, questionnaire battery, and behavior test were each submitted to multivariate analyses of covariance (MANCOVAs), controlling for pretreatment scores, separately for the 6- and 12-week assessments. For each set of measures at each assessment, 2 (site) × 4 (treatment) MANCOVAs were originally conducted. However, because site did not interact significantly with treatment, 1-way MANCOVAs with treatment as the independent variable are reported here. Significant MANCOVAs were followed by univariate ANCOVAs and post hoc Duncan multiple range tests. Significance levels were set at P < .05, 2-tailed. Heterogeneity of regression was evaluated but was not significant.

RESULTS

Attrition (n = 26) did not differ across conditions. Eight patients discontinued CBGT, 5 discontinued phenelzine therapy, 6 discontinued placebo use, and 7 discontinued ES. Five patients were noncompliant, 5 patients discontinued therapy because of positive treatment effects, 3 because of lack of efficacy, 5 because of adverse effects, 2 because of nontreatment-related events, and 6 because of unknown reasons. There were no severe adverse effects; adverse effects were as expected for administration of an MAOI. Completers and dropouts did not differ on demographic or pretreatment clinical measures or group cohesion. Dropouts rated their assigned treatments as less credible than completers at session 4 (t98 = 2.02; P < .05).
Treatment credibility was further evaluated in a 4 (treatment) × 2 (session 1 vs 4) repeated-measures analysis of variance. Group cohesion was further evaluated in a 2 (CBGT and ES) × 2 (session 4 vs 8) repeated-measures analysis of variance. There were no significant effects in these analyses, suggesting that these variables do not underlie differences in treatment efficacy. However, treatments differed in attendance (F3,101 = 5.81; P < .002). Patients receiving phenelzine (mean ± SD, 11.38 ± 0.88) and placebo (mean ± SD, 11.48 ± 1.05) attended more sessions than patients undergoing CBGT (mean ± SD, 10.39 ± 1.20). Patients receiving placebo attended more sessions than patients undergoing ES (mean ± SD, 10.77 ± 1.24). Mean week 12 phenelzine dose was 59.64 mg/d; however, week 12 dose was unrelated to response among patients receiving phenelzine. Patients receiving phenelzine and placebo did not differ in number of prescribed tablets.

IA RATINGS

Responder/Nonresponder Analyses

Midtreatment (6-Week) Assessment. Among 6-week completers (n = 113), 10 (35%) of 29 patients undergoing CBGT, 16 (59%) of 27 patients taking phenelzine, 9 (31%) of 29 patients taking placebo, and 6 (21%) of 28 patients undergoing ES were classified as midtreatment responders. Among 6-week completers (n = 113), 10 (35%) of 29 patients undergoing CBGT, 16 (59%) of 27 patients taking phenelzine, 9 (31%) of 29 patients taking placebo, and 6 (21%) of 28 patients undergoing ES were classified as midtreatment responders.

Table 1. Demographic Characteristics of the Study Sample*

<table>
<thead>
<tr>
<th></th>
<th>CBGT (n = 36)</th>
<th>Phenelzine Sulfate (n = 31)</th>
<th>Pill Placebo (n = 33)</th>
<th>ES (n = 33)</th>
<th>Full Sample (N = 133)</th>
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</thead>
<tbody>
<tr>
<td>Women, No. (%)</td>
<td>20 (55.6)</td>
<td>14 (45.2)</td>
<td>14 (42.4)</td>
<td>18 (54.4)</td>
<td>65 (49.6)</td>
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<tr>
<td>Age, y</td>
<td></td>
<td></td>
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<tr>
<td>Mean ± SD</td>
<td>37.0 ± 9.7</td>
<td>32.1 ± 8.4</td>
<td>36.1 ± 10.2</td>
<td>34.0 ± 9.6</td>
<td>34.9 ± 9.6</td>
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<tr>
<td>Range</td>
<td>19-53</td>
<td>19-52</td>
<td>23-60</td>
<td>19-61</td>
<td>19-61</td>
</tr>
<tr>
<td>Duration of social phobia, mean ± SD, y</td>
<td>20.8 ± 14.2</td>
<td>21.1 ± 11.7</td>
<td>21.1 ± 10.2</td>
<td>13.3 ± 8.9</td>
<td>19.5 ± 11.8</td>
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<td>Marital status, No. (%)</td>
<td></td>
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<tr>
<td>Married</td>
<td>11 (30.5)</td>
<td>10 (32.3)</td>
<td>9 (27.2)</td>
<td>10 (30.3)</td>
<td>40 (30.1)</td>
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<td>Single, never married</td>
<td>18 (50.0)</td>
<td>18 (58.1)</td>
<td>18 (54.5)</td>
<td>20 (60.6)</td>
<td>74 (55.6)</td>
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<tr>
<td>Separated/divorced</td>
<td>3 (8.3)</td>
<td>3 (9.7)</td>
<td>4 (12.1)</td>
<td>2 (6.1)</td>
<td>12 (9.0)</td>
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<tr>
<td>Failed to report</td>
<td>4 (11.1)</td>
<td>0 (0)</td>
<td>2 (6.1)</td>
<td>1 (3.0)</td>
<td>7 (5.3)</td>
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<td>Living situation, No. (%)</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Alone</td>
<td>9 (25.0)</td>
<td>11 (35.5)</td>
<td>12 (36.4)</td>
<td>12 (36.4)</td>
<td>44 (33.1)</td>
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<tr>
<td>With parents</td>
<td>4 (11.1)</td>
<td>6 (19.4)</td>
<td>6 (18.2)</td>
<td>2 (6.1)</td>
<td>18 (13.5)</td>
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<tr>
<td>With spouse/significant other</td>
<td>11 (30.5)</td>
<td>11 (35.5)</td>
<td>9 (27.2)</td>
<td>10 (30.3)</td>
<td>41 (30.8)</td>
</tr>
<tr>
<td>Other</td>
<td>12 (33.3)</td>
<td>3 (9.7)</td>
<td>6 (18.2)</td>
<td>9 (27.2)</td>
<td>30 (22.6)</td>
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<td>Employment, No. (%)</td>
<td></td>
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<tr>
<td>Full-time employment</td>
<td>23 (63.9)</td>
<td>16 (51.6)</td>
<td>14 (42.4)</td>
<td>25 (75.8)</td>
<td>78 (58.6)</td>
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<tr>
<td>Full-time student</td>
<td>6 (16.7)</td>
<td>7 (22.6)</td>
<td>6 (18.2)</td>
<td>1 (3.0)</td>
<td>20 (15.0)</td>
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<tr>
<td>Part-time/homemaker/retired</td>
<td>0 (0)</td>
<td>5 (16.1)</td>
<td>8 (24.2)</td>
<td>3 (9.1)</td>
<td>16 (12.0)</td>
</tr>
<tr>
<td>Unemployed</td>
<td>6 (16.7)</td>
<td>3 (9.7)</td>
<td>5 (15.2)</td>
<td>4 (12.1)</td>
<td>18 (13.5)</td>
</tr>
<tr>
<td>Failed to report</td>
<td>1 (2.8)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>1 (0.8)</td>
</tr>
<tr>
<td>Education, No. (%)</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>College graduate</td>
<td>23 (63.9)</td>
<td>17 (54.8)</td>
<td>21 (63.6)</td>
<td>17 (51.5)</td>
<td>78 (58.6)</td>
</tr>
<tr>
<td>Some college</td>
<td>5 (13.9)</td>
<td>10 (32.3)</td>
<td>8 (24.2)</td>
<td>7 (21.2)</td>
<td>30 (22.6)</td>
</tr>
<tr>
<td>High school or less</td>
<td>5 (13.9)</td>
<td>4 (12.9)</td>
<td>3 (9.1)</td>
<td>8 (24.2)</td>
<td>20 (15.0)</td>
</tr>
<tr>
<td>Social phobia, No. (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Generalized</td>
<td>20 (55.6)</td>
<td>24 (77.4)</td>
<td>26 (78.8)</td>
<td>24 (72.7)</td>
<td>94 (70.7)</td>
</tr>
<tr>
<td>Treated at each site, No.}%</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Albany, NY</td>
<td>18 (50.0)</td>
<td>15 (48.4)</td>
<td>15 (45.5)</td>
<td>11 (33.3)</td>
<td>59 (44.4)</td>
</tr>
<tr>
<td>New York, NY</td>
<td>18 (50.0)</td>
<td>16 (51.6)</td>
<td>18 (54.5)</td>
<td>22 (66.7)</td>
<td>74 (55.6)</td>
</tr>
</tbody>
</table>

*CBGT indicates cognitive behavioral group therapy; ES, educational-supportive group therapy.
scores for all measures are presented in administration on LSAS performance fear. Baseline behavior group therapy was also superior to placebo were more improved than patients in any other condi-
tion, and performance avoidance and the IA rating of severity of the patient's social phobia fell short of signifi-
cance (P = .06). The test of the IA rating of severity of social phobia fell short of signifi-
cance (P < .06).

Posttreatment (12-Week) Assessment. The MANCOVA of IA dimensional ratings revealed a significant treatment effect (Wilks λ = .583; Fl 21,227 30 = 2.24; P < .002). Univariate follow-ups revealed significant differences on all measures except measures of avoidant personality disorder (Table 4). Patients receiving phenelzine were rated less symptomatic than other patients on most measures. Patients undergoing CBGT were less impaired than those receiving placebo or ES on the ADIS-R Clinician's Sever-
ity Rating and LSAS social avoidance and less anxious than patients undergoing ES on LSAS social fear, performance fear, and performance avoidance and the IA rating of severity of social phobia. The ITT analyses revealed the same outcome.

SELF-REPORT MEASURES

Midtreatment (6-Week) Assessment

The midtreatment MANCOVA was not significant (Wilks λ = .589; Fl 21,167 11 = 1.23; P = .16). No further analyses were undertaken.

Posttreatment (12-Week) Assessment

The posttreatment MANCOVA was significant (Wilks λ = .434; Fl 27,149 59 = 1.83; P < .02). After 12 weeks, pa-
tients taking phenelzine reported less anxiety than other patients on the Social Avoidance and Distress Scale, Fear of Negative Evaluation Scale, and Social Interaction Anxiety Scale. Patients undergoing CBGT reported less fear of negative evaluation than patients receiving placebo. On the Fear Questionnaire self-rating, patients receiving phenelzine and those undergoing CBGT rated their avoidance as less severe than patients receiving placebo or ES, but did not differ from each other. No differences were noted on the Symptom Checklist-90–Revised (Table 4).

In the ITT analysis, the univariate test of the Social Phobia Scale was significant (P < .03). Patients receiving phenelzine scored significantly lower than other pa-
tients. Other outcomes were similar to those of the com-
plete analyses.
Duncan multiple range tests were conducted only after significant F tests; means with different subscripts are significantly different (P < .05). Patients receiving phenelzine reported less anxiety than other patients during the behavior test performance. Patients undergoing CBGT reported less anxiety than patients receiving placebo or ES. Analysis of patients' performance ratings also revealed significant differences. Cognitive behavioral group therapy and phenelzine therapy resulted in significantly greater performance satisfaction than placebo or ES but did not themselves differ. In the ITT analysis, the multivariate analysis of variance including this measure was nonsignificant. No other pretreatment differences were significant.

Table 2. Adjusted Means and Analyses of Covariance for Independent Assessor Measures at Midtreatment (6-Week) Assessment for Patients Receiving Cognitive Behavioral Group Therapy (CBGT), Phenelzine, Pill Placebo, and Educational-Supportive Group Therapy (ES): Completers Only

<table>
<thead>
<tr>
<th>Measure</th>
<th>CBGT (n = 28)</th>
<th>Phenelzine Sulfate (n = 26)</th>
<th>Pill Placebo (n = 27)</th>
<th>ES (n = 26)</th>
<th>F†</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADIS-R Clinician Severity Rating</td>
<td>5.56 ± 1.05</td>
<td>5.71 ± 0.97</td>
<td>5.45 ± 1.23</td>
<td>5.42 ± 1.25</td>
<td>4.97‡</td>
</tr>
<tr>
<td>LSAS social fear</td>
<td>15.08 ± 7.01</td>
<td>17.52 ± 6.42</td>
<td>16.52 ± 7.55</td>
<td>15.09 ± 7.95</td>
<td>4.04§</td>
</tr>
<tr>
<td>LSAS social avoidance</td>
<td>13.14 ± 7.68</td>
<td>15.71 ± 7.20</td>
<td>15.12 ± 8.20</td>
<td>13.91 ± 7.86</td>
<td>4.18‡</td>
</tr>
<tr>
<td>LSAS performance fear</td>
<td>17.03 ± 5.55</td>
<td>18.61 ± 5.26</td>
<td>18.15 ± 7.06</td>
<td>16.97 ± 7.05</td>
<td>4.18‡</td>
</tr>
<tr>
<td>LSAS performance avoidance</td>
<td>13.75 ± 5.96</td>
<td>15.52 ± 6.39</td>
<td>15.30 ± 7.61</td>
<td>14.69 ± 7.72</td>
<td>4.18‡</td>
</tr>
<tr>
<td>Overall severity of social phobia</td>
<td>4.75 ± 0.91</td>
<td>5.03 ± 0.71</td>
<td>4.97 ± 0.92</td>
<td>5.03 ± 0.87</td>
<td>4.18‡</td>
</tr>
<tr>
<td>No. APD criteria met</td>
<td>2.06 ± 1.91</td>
<td>2.29 ± 1.64</td>
<td>2.03 ± 1.86</td>
<td>1.85 ± 1.87</td>
<td>4.18‡</td>
</tr>
<tr>
<td>APD dimensional score</td>
<td>5.75 ± 3.72</td>
<td>6.90 ± 3.45</td>
<td>6.06 ± 3.67</td>
<td>5.61 ± 3.77</td>
<td>4.18‡</td>
</tr>
</tbody>
</table>

Table 3. Adjusted Means and Analyses of Covariance for Independent Assessor Measures at Midtreatment (6-Week) Assessment for Patients Receiving Cognitive Behavioral Group Therapy (CBGT), Phenelzine, Pill Placebo, and Educational-Supportive Group Therapy (ES): Completers Only

<table>
<thead>
<tr>
<th>Measure</th>
<th>Phenelzine Sulfate (n = 26)</th>
<th>CBGT (n = 28)</th>
<th>Pill Placebo (n = 27)</th>
<th>ES (n = 26)</th>
<th>F†</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADIS-R Clinician Severity Rating</td>
<td>3.63 ± 1.10</td>
<td>4.34 ± 0.97</td>
<td>4.54 ± 1.02</td>
<td>4.87 ± 1.06</td>
<td>4.97‡</td>
</tr>
<tr>
<td>LSAS social fear</td>
<td>10.86 ± 5.47</td>
<td>13.73 ± 5.77</td>
<td>14.44 ± 5.15</td>
<td>15.34 ± 5.77</td>
<td>4.94‡</td>
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<td>LSAS social avoidance</td>
<td>8.88 ± 4.98</td>
<td>11.36 ± 5.91</td>
<td>12.02 ± 5.80</td>
<td>14.04 ± 5.75</td>
<td>4.18‡</td>
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<tr>
<td>LSAS performance fear</td>
<td>11.77 ± 5.31</td>
<td>13.61 ± 4.80</td>
<td>14.61 ± 4.79</td>
<td>15.46 ± 3.91</td>
<td>3.78‡</td>
</tr>
<tr>
<td>LSAS performance avoidance</td>
<td>10.34 ± 5.16</td>
<td>10.84 ± 4.75</td>
<td>12.21 ± 5.53</td>
<td>12.97 ± 4.20</td>
<td>1.54</td>
</tr>
<tr>
<td>Overall severity of social phobia</td>
<td>3.80 ± 0.71</td>
<td>4.14 ± 0.76</td>
<td>4.36 ± 0.47</td>
<td>4.46 ± 0.58</td>
<td>3.78§</td>
</tr>
</tbody>
</table>

BEHAVIORAL TEST

The behavioral test was administered only at pretreatment and posttreatment assessments. The posttreatment MANCOVA revealed a significant treatment effect (Wilks λ = .708; \( F_{9,207.02} = 3.51; P < .001 \)). Analyses of anticipatory anxiety ratings revealed no differences. Patients receiving phenelzine reported less anxiety than other patients during the behavior test performance.
Duncan multiple range tests were conducted only after significant F tests; means with different subscripts are significantly different (P < .05). According to the following formula: d = (Mplacebo − M treatment)/SDpooled. Cohen68 provides conventional definitions for small (0.10), medium (0.25), and large (0.40) effects. Furthermore, a medium effect is defined as one that is apparent, ie, “visible to the naked eye.” These conventions have historically worked well in the behavioral sciences. Complete effect size data are available from the authors (R.G.H.).

**MAGNITUDE OF EFFECT**

We examined the between-groups magnitude of effect of phenelzine therapy and CBGT above the effect of placebo after acute treatment. The effect size (d) was calculated according to the following formula: d = (Mplacebo − M treatment)/SDpooled. Cohen68 provides conventional definitions for small (0.10), medium (0.25), and large (0.40) effects. Furthermore, a medium effect is defined as one that is apparent, ie, “visible to the naked eye.” These conventions have historically worked well in the behavioral sciences. Complete effect size data are available from the authors (R.G.H.). Effect sizes for phenelzine therapy over placebo use were large, eg, 0.71 for the ADIS-R Clinician’s Severity Rating and 0.58 to 0.69 for the LSAS subscales. The corresponding figures for CBGT were 0.44 and 0.10 to 0.31, more variable than for phenelzine therapy and generally in the medium range.

**THE IMPACT OF SITE**

At midtreatment, there were no significant site effects. MANCOVAs at posttreatment revealed significant main effects of site in each analysis but no significant site × treatment interactions. Significant univariate main effects of site were found on 3 IA measures, 1 questionnaire, and 1 behavior test rating, with patients from New York City rated as more severe in 4 of 5 cases. However, sites did not differ in attrition or response to particular treatments.

**COMMENT**

Both phenelzine therapy and CBGT seem to be effective for social phobia. Compared with pill placebo and attention-placebo conditions, both were associated with higher rates of response after 12 weeks. At this global level of response, the 2 treatments produced equivalent outcomes. Seventy-seven percent of patients receiving phenelzine and 75% of patients undergoing CBGT who completed treatment (65% and 58% of enrolled patients, respectively) were classified as responders, significantly more than for placebo use or ES. Patients receiving phenelzine were also less anxious than control patients on most IA, self-report, and behavior test measures. Cognitive behavioral group therapy surpassed 1 or both control conditions on many of these measures as well.
Although rates of response to phenelzine therapy and CBGT were similar after 12 weeks, the pattern of response was different. Fifty-two percent of patients taking phenelzine but only 28% of patients undergoing CBGT were classified as responders after 6 weeks. Expressed otherwise, 80% of 12-week phenelzine responders reached that threshold after 6 weeks, whereas only 48% of 12-week CBGT responders did so. On several IA ratings, patients receiving phenelzine were rated as less anxious than patients in the other conditions after 6 weeks. Patients undergoing CBGT were rated as less anxious on most ratings than patients receiving ES but were rated as less anxious than patients taking placebo on only 1 midtreatment measure. After 12 weeks, the superiority of CBGT to the control conditions was greater.

Despite similar percentages of response after 12 weeks, phenelzine therapy was also superior to CBGT on several measures. On the whole, phenelzine therapy responders seemed to be “better responders” than CBGT responders. Because CBGT was characterized by an increased rate of response between midtreatment and posttreatment, it is unclear whether patients receiving CBGT had achieved “the maximum” after 12 weeks. An extended period of intensive treatment may benefit CBGT efficacy, a proposition we are currently evaluating. We are also studying the utility of combination treatment, which may be especially relevant for the most impaired patients.

Adverse effects are always a concern in studies of MAOI treatment. However, we observed few serious problems. No hypertensive crises occurred, and no patient was precluded from dosage escalation because of adverse effects. Two events of significance occurred. One patient receiving phenelzine was removed from the study in week 11 because of hypomanic symptoms. One patient taking placebo withdrew after week 6 because of headache.

Evaluation of CBGT in New York City (expert in biologic approaches) and of phenelzine therapy in Albany (expert in cognitive behavioral treatments) posed a difficult test of the treatments’ efficacy. However, there were no significant site × treatment interactions, suggesting that both sites were able to implement the treatments with equivalent quality. We believe that it was important to undertake a study that, by virtue of its collaborative nature, might have heightened credibility to mental health professionals from medical and nonmedical disciplines.

Limitations of the study design are as follows. First, we did not conduct weekly assessments of patients’ status. To do so would have provided a more fine-grained analysis of patient progress and made the data more amenable to other statistical approaches (eg, survival analysis). We also did not include adequate measurement of patient disability, functional impairment, or lowered life satisfaction. These types of data are increasingly recognized as important and have been related to outcome of treatment of social phobia. Furthermore, we were not able to examine outcomes of other disorders that may have been comorbid with patients’ social phobia, and this remains an area for future research.

This article focused on the report of outcome during the first 12 weeks of the study comparing phenelzine therapy and CBGT. However, the treatments may have different effects over time, and subsets of patients (eg, patients with generalized vs nongeneralized social phobia) may have more or less unique patterns of response to the treatments. These important issues are discussed in a forthcoming article.

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