Psychodynamic Therapy and Cognitive-Behavioral Therapy in Social Anxiety Disorder: A Multicenter Randomized Controlled Trial

Falk Leichsenring, D.Sc.

Simone Salzer, D.Sc.

Manfred E. Beutel, M.D.

Stephan Herpertz, M.D.

Wolfgang Hiller, Ph.D.

Juergen Hoyer, Ph.D.

Johannes Huesing, D.rer.medic.

Peter Joraschky, M.D.

Bjoern Nolting, M.D.

Karin Poehlmann, Ph.D.

Viktoria Ritter, M.Sc.

Ulrich Stangier, D.Sc.

Bernhard Strauss, Ph.D.

Nina Stuhldreher, M.Sc.

Susan Tefikow, M.Sc.

Tobias Teismann, Ph.D.

Ulrike Willutzki, Ph.D.

Joerg Wiltink, M.D.

Eric Leibing, D.Sc.

Objective: Various approaches to cognitive-behavioral therapy (CBT) have been shown to be effective for social anxiety disorder. For psychodynamic therapy, evidence for efficacy in this disorder is scant. The authors tested the efficacy of psychodynamic therapy and CBT in social anxiety disorder in a multicenter randomized controlled trial.

Method: In an outpatient setting, 495 patients with social anxiety disorder were randomly assigned to manual-guided CBT (N=209), manual-guided psychodynamic therapy (N=207), or a waiting list condition (N=79). Assessments were made at baseline and at end of treatment. Primary outcome measures were rates of remission and response, based on the Liebowitz Social Anxiety Scale applied by raters blind to group assignment. Several secondary measures were assessed as well.

Results: Remission rates in the CBT, psychodynamic therapy, and waiting list groups were 36%, 26%, and 9%, respectively. Response rates were 60%, 52%, and 15%, respectively. CBT and psychodynamic therapy were significantly superior to waiting list for both remission and response. CBT was significantly superior to psychodynamic therapy for remission but not for response. Between-group effect sizes for remission and response were small. Secondary outcome measures showed significant differences in favor of CBT for measures of social phobia and interpersonal problems, but not for depression.

Conclusions: CBT and psychodynamic therapy were both efficacious in treating social anxiety disorder, but there were significant differences in favor of CBT. For CBT, the response rate was comparable to rates reported in Swedish and German studies in recent years. For psychodynamic therapy, the response rate was comparable to rates reported for pharmacotherapy and cognitive-behavioral group therapy.

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Social anxiety disorder is one of the most prevalent mental disorders, with a lifetime prevalence of 12% and a 12-month prevalence of 7% (1, 2). The disorder has an early onset and a chronic course and can result in severe psychosocial impairments and high socioeconomic costs (3, 4). Social anxiety disorder has secondary effects on other mental disorders (e.g., depression), social role functioning, and help seeking (4). There is evidence from a large body of research that cognitive-behavioral therapy (CBT) is beneficial for patients with social anxiety disorder (5, 6). It has been noted, however, that many psychotherapy studies of social anxiety disorder used small samples or were carried out at only one site, thus limiting generalizability and statistical power (7). In a

meta-analysis by Acarturk et al. (6), for example, the sample size per group ranged from seven to 91, with a mean of 22.1, which allows detection of only a large effect size of 0.86 with a power of 0.80 (8). Psychodynamic therapy is frequently used, both in social anxiety disorder and in clinical practice in general (9–12). However, evidence for the efficacy of psychodynamic therapy in social anxiety disorder is scant (13). Thus, further studies of both CBT and psychodynamic therapy of social anxiety disorder are needed, using larger patient samples and multiple study sites.

The Social Phobia Psychotherapy Network (SOPHO-NET) was established to address some of these limitations (14). The SOPHO-NET encompasses several independent but interrelated studies of different aspects of social anxiety

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disorder, including psychotherapy, genetics, neural deviations, and health economics (14). We report here the results of the multicenter randomized controlled SOPHO-NET treatment study comparing CBT and psychodynamic therapy.

Method

Study Design and Implementation

Patients were recruited from April 11, 2007, to April 29, 2009, by outpatient clinics at the universities of Bochum, Dresden, Goettingen, Jena, and Mainz. Participants were recruited through advertisements or other information presented in the mass media or were referred by psychotherapists or physicians in private practice. At each of the five centers, one clinic performed CBT and another performed psychodynamic therapy. An investigator allegiance effect was controlled for by including experts in both CBT and psychodynamic therapy as local investigators at each center. The study protocol was approved by the Ethics Committee of the Medical Faculty of the University of Goettingen. The study was monitored by the Coordination Center for Clinical Trials (KKS Heidelberg), which is independent of the participating research centers. In addition, an independent data monitoring and safety committee was established.

Study Subjects

To be included in the study, patients had to be 18–70 years of age, have a diagnosis of social anxiety disorder according to the German-language edition of the Structured Clinical Interview for DSM-IV (SCID) (15), have a score >30 on the Liebowitz Social Anxiety Scale (16), and have a primary diagnosis of social anxiety disorder according to the rating on the Anxiety Disorders Interview Schedule (17). In order to obtain a clinically representative sample, we allowed recruitment of patients with all comorbid mental disorders less severe than social anxiety disorder (according to the Anxiety Disorders Interview Schedule rating) except those listed among the exclusion criteria, which were as follows: psychotic and acute substance-related disorders; cluster A and B personality disorders; prominent risk of self-harm; organic mental disorders; severe medical conditions; and concurrent psychotherapeutic or psychopharmacological treatments. Providing informed consent was required for inclusion.

Randomization

Randomization was carried out according to randomization lists that were computer-generated by and kept at KKS Heidelberg, which served as a central randomization unit disclosing the allocation after each patient was registered in the study. Lists were stratified according to center, age (<60 and ≥60), and Liebowitz Social Anxiety Scale total score at screening (<60 and ≥60). The original sequence of fixed-length blocks was locally exchanged to impede inferences on the next allocation. In order to avoid a lag at the end of the study, allocation to waiting list was terminated after the waiting list arm had achieved the necessary sample block lengths and distribution of arms within blocks were adapted to varying site-specific availability of therapists. Patients were allocated to psychodynamic therapy, CBT, or waiting list in a ratio of 3:3:1.

Treatments

The method of CBT applied in this study was based on Clark and Wells's model (18). This approach includes several components, such as establishing a personal version of the model, role-play-based behavioral experiments, practicing external focus of attention, and restructuring distorted self-image by video feedback or behavioral experiments (18). These procedures are assumed to reverse the maintaining factors identified in the Clark and Wells model of social anxiety disorder, especially safety behaviors and self-focused attention (18). Safety behaviors are a form of avoidance behavior by which an individual tries to reduce anxiety in a social situation (e.g., using make-up to reduce the fear of blushing). As an example of exploring safety behavior, the therapist may ask (19), "When you thought [specify the feared outcome] might/was happening, did you do anything to try to prevent it from happening? Did you do anything to try to prevent people from noticing?" We used the German version of the Clark and Wells manual published by Stangier, Clark, and Ehlers (20).

In order to make the results of psychodynamic therapy comparable with those of CBT, a manual-guided form of psychodynamic therapy was specifically developed for this trial. It was based on Luborsky's model of psychodynamic therapy (21) and specifically adapted to treat social anxiety disorder (22). This model encompasses both supportive and expressive interventions that are assumed to lead to therapeutic change (21, 22). Establishing a secure helping alliance is one of the model's most important supportive treatment elements. Expressive interventions relate the symptoms of social anxiety disorder to the patient's underlying core conflictual relationship theme in order to reduce the symptoms of social anxiety disorder (21, 22). A core conflictual relationship theme comprises three components: a wish (e.g., "I wish to be affirmed by others"), an anticipated response from others (e.g., "Others will humiliate me"), and a response from the self (e.g., "I am afraid of exposing myself") (21, 22). The response from the self represents the symptoms of social anxiety disorder. A therapist could link these components by an expressive intervention in the following way (22): "As we have seen, you are not only afraid of exposing yourself (response from the self), but you sometimes wish to be at the center of attention and to be affirmed by others (wish). However, you are afraid that they will humiliate you (response from others)." The intervention also includes a supportive component as it refers to the common work between patient and therapist ("As we have seen…") (21). The core conflictual relationship theme is worked through in present and past relationships as well as in the relationship to the therapist. The treatment procedures are described in detail in a manual (22).

In both CBT and psychodynamic therapy, up to 25 individual 50-minute treatment sessions were applied. (In addition, up to five preparatory sessions were conducted, which are compulsory in the German health care system and cover diagnostic and administrative issues.) In CBT, up to six sessions lasted for 100 minutes, counted as twelve 50-minute sessions. Thus, the dose of treatment (sessions minutes) was consistent with Clark et al. (23), who applied up to fourteen 90-minute sessions plus up to three booster sessions. In CBT, sessions were conducted weekly; in psychodynamic therapy, sessions were also weekly, except during the middle part of the treatment (sessions 7 to 16), which allowed for two sessions a week in order to intensify the treatment. By these procedures, an identical weekly dose and length of treatment was ensured for CBT and psychodynamic therapy. The calendar minimum duration of both treatments was 6 months. After the five preparatory sessions, however, the start of the treatment was regularly delayed by administrative procedures inherent in the German health care system (up to 6 weeks). Further delays resulted from vacations or illness of patients or therapists. Thus, the actual calendar treatment duration (time between the first preparatory session and the end of treatment) was longer than 6 months.

Therapists

All therapists held degrees as clinical psychologists or physicians and had completed their psychotherapeutic training or were in advanced psychotherapeutic training. They regularly conducted either CBT or psychodynamic therapy. Fifty-five

cognitive-behavioral therapists conducted CBT (37 of them women) and 53 psychodynamic therapists conducted psychodynamic therapy (30 of them women). No therapist conducted both CBT and psychodynamic therapy.

The mean age of the cognitive-behavioral therapists was 31.1 years (SD=4.98), and that of the psychodynamic therapists was 39.4 years (SD=8.06). The average general clinical experience was 1.7 years (SD=0.9) for the cognitive-behavioral therapists and 8.0 years (SD=9.0) for the psychodynamic therapists (p=0.0002). On the other hand, significantly more cognitive-behavioral therapists reported having already used both manual-guided psychotherapy in general (67% compared with 24%; χ^2=14.40, p<0.0001) and specifically the manual-guided approach applied in this study (35% compared with 0%, p<0.0001) before the trial.

Before inclusion in the trial, therapists were specifically trained in their respective treatment approach by authors of the treatment manuals (U.S., M.B., F.L.). To be included in the trial, therapists were required to treat two pilot cases in accordance with the respective manual. In order to maintain treatment fidelity during the trial, therapists received regular site-level and cross-site supervision, which was comparable in structure and amount between treatments. At each center, supervision of therapists was performed as a 90-minute group supervision conducted by supervisors specifically trained by the authors of the treatment manuals. Supervision was performed every 2 weeks during the first 6 months of the trial, and monthly thereafter. All treatment sessions were videotaped. Videotapes were used for both supervision and the assessment of treatment integrity. For assessing treatment integrity, established instruments were used: the Penn Adherence and Competence Scale for Supportive-Expressive Therapy (24) adapted for social phobia; and the Cognitive Therapy Competence Scale for Social Phobia (25). To ensure treatment fidelity during the trial, two tapes from every second treatment carried out by a therapist were randomly selected and rated for adherence and competence—two tapes each of the early, middle, and late phases of therapy. As a minimum target for competence, a rating of ≥3 on a 7-point Likert scale (0=poor, 6=excellent) was used for both psychodynamic therapy and CBT (25). In the case of therapists falling below this level, feedback was given to both the therapist and the supervisor. For cases of therapists who continued to fall below that level, the study procedures allowed for the treatment to be excluded from the trial, but this proved unnecessary, and no specific treatments were excluded. The procedures and results of treatment integrity assessments are described in more detail below.

Assessment and Blinding

Assessments were conducted at baseline, at weeks 8 and 15 of treatment, and at end of treatment. Analogous to the procedure used by Davidson et al. (26), the assessments at weeks 8 and 15 were carried out to compensate for possible missing data. In these additional assessments, only the Liebowitz Social Anxiety Scale was administered. Diagnoses were made using the SCID (15). The primary (i.e., most severe) mental disorder was assessed using the Anxiety Disorders Interview Schedule severity rating scale (17). Twenty-three specifically trained and independent assessors (clinical psychologists) blind to treatment condition conducted the interviews. All interviews were videotaped in order to assess interrater reliability. Reliability for the Liebowitz Social Anxiety Scale was assessed by comparing the individual results of 23 diagnosticians with an expert's rating of three videotaped interviews. High interrater reliability was observed for the Liebowitz Social Anxiety Scale score (Kendall's W=0.98, df=2, p<0.001). Blinding was ensured by instructing the patients not to discuss their treatment during assessment. Furthermore, personnel involved in handling study documentation and

scheduling interviews were required to keep all treatment-specific documents separate from other patient information. Waiting list status was kept open-label.

Rates of remission and response were used as the primary outcome measures. Following recommendations by Liebowitz et al., remission was defined as a score ≤30 on the Liebowitz Social Anxiety Scale (16, 27). We assessed response rates so that results could be compared with those from other studies of social anxiety disorder. Response was defined as a reduction of at least 31% in Liebowitz Social Anxiety Scale score, which is demonstrably comparable to a Clinical Global Impression improvement subscore ≤2, the measure usually used to define response (28). As secondary outcome measures, well-established self-report instruments were used, such as the Social Phobia and Anxiety Inventory, the Beck Depression Inventory, and the Inventory of Interpersonal Problems (29–31).

Adverse Events

Adverse events were defined as any significant unfavorable change in the patient's pretreatment mental condition, regardless of its relationship to treatment, in particular the occurrence of any additional mental disorder. Serious adverse events included mortality, hospitalization, suicide, or attempted suicide. Adverse events and serious adverse events were reported to an independent data and safety monitoring board.

Statistical Analysis

Based on previous studies of the Clark and Wells approach (23, 32, 33), we hypothesized that patients in the CBT and waiting list groups would have response rates of 70% and 5%, respectively. We expected the new psychodynamic therapy method to achieve response a rate slightly lower than that of CBT, at 55%. For differences in proportions, h is the appropriate measure of effect size (34). A difference of 15% (70% for CBT and 55% for psychodynamic therapy) corresponds to an effect size (h) of 0.30 (34). We defined a difference 0.30 in h values as meaningful; h=0.30 can be considered a small effect size (34). In order to detect a difference in h of 0.30 with a power of 0.80, we determined that 174 patients were required in each active treatment group when using two-tailed tests at an alpha level of 0.05 (8). Following the study protocol, we planned to compensate for dropouts by including additional patients. Previous studies suggest a dropout rate of 15% (6), so we planned to include 31 additional patients per treatment arm (174+31=205).

The data were analyzed using SAS 9.2 (SAS Institute, Cary, N.C.). Categorical data were analyzed using the chi-square test, Fisher's exact test, or mixed-effects logistic regression models, as appropriate, and dimensional measures were analyzed by mixed-effects linear regression models. We also performed sensitivity analyses. All regression-based analyses included study center and baseline scores as covariates. In addition, therapists were included as a random factor in the mixed-effects model (35). Model-based pairwise comparisons were planned a priori. To analyze remission and response, alpha was set at 0.05. For the comparison of CBT and psychodynamic therapy with regard to the secondary outcome measures, alpha was adjusted for multiple comparisons (alpha=0.01; 0.05/4). For categorical data, between-group differences were assessed using Cohen's h and odds ratios, and for dimensional data, Cohen's d was used, with d based on mixed-model-analysis-adjusted means (34). For the intent-to-treat analysis, we applied multiple imputation by chained equations to account for the uncertainty resulting from missing outcome data (36, 37). Multiple imputation is superior to the last-observation-carried-forward procedure for several reasons. First, multiple imputation adequately incorporates the uncertainty arising from missing information and introduces additional variance leading to larger standard errors. Furthermore,

TABLE 1. Baseline Characteristics and Site Distribution of Patients With Social Anxiety Disorder Assigned to Receive Cognitive-Behavioral Therapy or Psychodynamic Therapy or to a Waiting List (Intent-to-Treat Sample)

Variable	Group							
	Cognitive-Behavioral Therapy (N=209)		Psychodynamic Therapy (N=207)		Waiting List (N=79)		All Subjects (N=495)	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Age (years)	34.85	12.03	34.37	12.12	38.48	12.32	35.23	12.18
	N	%	N	%	N	%	N	%
Female	113	54.1	111	53.7	46	58.2	270	54.6
Center								
University of Bochum	44	50.0	29	33.0	15	17.0	88	17.8
University of Goettingen	37	43.0	33	38.4	16	18.6	86	17.4
University of Dresden	45	41.3	46	42.2	18	16.5	109	22.0
University of Jena	40	36.7	52	47.7	17	15.6	109	22.0
University of Mainz	43	41.8	47	45.6	13	12.6	103	20.8

under the assumption of missing at random, multiple imputation yields unbiased results that are more accurate than those provided by the last-observation-carried-forward procedure (38). To generate conservative estimates, 50 imputations were created and all available variables were included in the imputation process. We also report data from an analysis of participants who completed treatment, for which no imputation method was applied.

Results

Participants

A total of 1,450 potential patients were screened. Of these, 495 patients met the inclusion criteria and did not meet any exclusion criteria (a diagram of participant flow through the study is available in the data supplement that accompanies the online edition of this article). Initially, 209, 207, and 79 patients were randomly assigned to CBT, psychodynamic therapy, and waiting list, respectively. Eight percent of the patients assigned to CBT and 5% of those assigned to psychodynamic therapy stopped treatment but were included in the assessment (treatment withdrawals). In the CBT, psychodynamic therapy, and waiting list groups, 24%, 28%, and 27%, respectively, of patients stopped treatment or assessment (treatment or study withdrawals). Fisher's exact test revealed no significant differences between groups for study or treatment withdrawals. The outcome data of these dropouts were included in intent-to-treat analyses using multiple imputation. Thus, data analysis was based on all patients who were assigned to one of the three study arms.

Demographic and Clinical Characteristics

Table 1 summarizes age and sex of the participants, along with the distribution of treatment assignments by study site. The sample included a relatively high rate of patients suffering from comorbid mental disorders; 63% of the sample had at least one comorbid disorder, 25% at least two, 7% at least three, and 1% at least four. The most frequent comorbid disorders were avoidant personality disorder (25%), major depressive disorder (21%), dysthymia (11%), specific phobia (7%), agoraphobia (5%), and generalized anxiety disorder (2%). Personality disorders other than avoidant personality disorder were seen in 2% of the patients.

Treatment

The mean number of sessions completed was 25.8 (SD=9.13) for CBT and 25.7 (SD=9.61) for psychodynamic therapy. The mean duration of treatment was 38.7 weeks (SD=16.03) for CBT and 37.4 weeks (SD=18.03) for psychodynamic therapy.

To examine treatment integrity, videotapes of 50 randomly selected treatments (25 each from the CBT and psychodynamic therapy groups) were rated by trained evaluators (clinical psychologists) who were blind to treatment condition. One session was randomly selected from each treatment. Three evaluators trained in CBT rated the Cognitive Therapy Competence Scale for Social Phobia, and another three evaluators trained in psychodynamic therapy rated the Penn Adherence and Competence Scale for Supportive-Expressive Therapy. These scales allow the assessment of both adherence to the manual and competence in delivery of interventions. Evaluators received 10 hours of training in rating the scales, by experts in the respective approach (U.S., M.B., J.W.). Each evaluator rated 34 sessions, half of them psychodynamic therapy sessions and half CBT sessions. Each session was rated four times, twice by psychodynamic therapy raters and twice by CBT raters. For statistical analyses, the ratings of the respective pair of raters were averaged. Each pair of raters included one experienced rater who had rated between 183 and 194 training sessions. Mean interrater reliability values (intraclass correlation coefficient) for adherence and competence were 0.59 and 0.58, respectively, for the Penn scale and 0.98 and 0.94, respectively, for the Cognitive Therapy Competence scale. For the Penn scale, interrater reliability was comparable to that reported by Barber and Crits-Christoph (24). Consistent with the treatment models, cognitive therapists used significantly more interventions of the CBT approach (Cognitive Therapy Competence scale, adherence subscale mean score, 2.00 compared with

TABLE 2. Rates of Remission and Response, by Time, Among Patients With Social Anxiety Disorder Assigned to Receive Cognitive-Behavioral Therapy or Psychodynamic Therapy or to a Waiting List (Intention-to-Treat Sample)[a]

Measure and Assessment Time	Cognitive-Behavioral Therapy (N=209)		Psychodynamic Therapy (N=207)		Waiting List (N=79)	
	%	95% CI	%	95% CI	%	95% CI
Remission						
At week 8 of treatment	5	2–9	5	2–7		
At week 15 of treatment	12	7–17	8	4–12		
At end of treatment	36	30–43	26	19–32	9	0.9–16
Response						
At week 8 of treatment	1	10–20	7	4–11		
At week 15 of treatment	31	24–38	20	14–25		
At end of treatment	60	53–67	52	44–60	15	5–26

[a] Remission was defined as a score ≤30 on the Liebowitz Social Anxiety Scale, and response was defined as reduction of at least 31% in score on the Liebowitz Social Anxiety Scale. Scores on the Liebowitz Social Anxiety Scale range from 0 to 144, with higher scores indicating greater pathology. Assessments were not conducted for the waiting list group at weeks 8 and 15.

TABLE 3. Outcomes for Cognitive-Behavioral Therapy, Psychodynamic Therapy, and Waiting List Among Patients With Social Anxiety Disorder (Intent-to-Treat Sample; N=495)[a]

Measure and Assessment Time	Cognitive-Behavioral Therapy (N=209)			Psychodynamic Therapy (N=207)			Waiting List (N=79)		
	Mean	SD	95% CI	Mean	SD	95% CI	Mean	SD	95% CI
Liebowitz Social Anxiety Scale									
Baseline	72.06	22.39	69.00–75.11	73.26	22.13	70.22–76.30	73.32	20.93	68.66–77.99
Week 8 of treatment	67.49	23.12	64.25–70.74	71.88	24.47	68.46–75.29			
Week 15 of treatment	59.10	24.03	55.70–62.49	66.32	26.67	62.54–70.10			
End of treatment	42.94	25.41	39.25–46.64	50.71	27.49	46.52–54.90	68.13	25.34	61.82–74.45
Social Phobia and Anxiety Inventory									
Baseline	90.19	19.26	87.34–93.04	90.09	19.88	87.12–93.07	89.91	18.09	85.58–94.24
End of treatment	66.28	26.86	62.26–70.31	76.67	24.89	72.58–80.76	85.70	22.17	80.09–91.31
Beck Depression Inventory									
Baseline	14.78	8.94	13.38–16.19	14.18	9.93	12.64–15.72	15.14	9.16	12.86–17.42
End of treatment	10.40	10.98	8.53–12.27	12.58	12.40	10.48–14.68	15.37	11.74	12.36–18.37
Inventory of Interpersonal Problems									
Baseline	14.27	3.52	13.73–14.81	14.11	3.69	13.56–14.66	14.53	3.83	13.63–15.44
End of treatment	11.67	4.83	10.92–12.42	13.12	4.38	12.45–13.80	13.82	3.98	12.77–14.87

[a] Mean scores were determined by linear-effects model analysis. Assessments with the Liebowitz Social Anxiety Scale were not conducted for the waiting list group at weeks 8 and 15. Scores on the Liebowitz Social Anxiety Scale range from 0 to 144, with higher scores indicating greater pathology. Scores on the Social Phobia and Anxiety Inventory range from 0 to 132, with higher scores indicating greater pathology. Scores on the Beck Depression Inventory range from 0 to 63, with higher scores indicating greater pathology. Scores on the Inventory of Interpersonal Problems range from 0 to 32, with higher scores indicating greater pathology.

0.12; t=13.42, p<0.001) and applied them more competently (Cognitive Therapy Competence scale, competence subscale mean score, 3.19 compared with 1.26; t=10.68, p<0.001). In contrast, psychodynamic therapists used significantly more interventions of the psychodynamic therapy model (Penn scale, adherence subscale mean score, 3.02 compared with 2.23; t=5.48, p<0.001) and applied them more competently (Penn scale, competence subscale mean score, 3.27 compared with 2.20; t=6.23, p<0.001). Thus, the treatments differed significantly in accordance with the treatment model.

Outcomes

Tables 2 and 3 present the key outcome data for the CBT, psychodynamic therapy, and waiting list groups. Remission rates for the three groups were 36%, 26%, and 9%, respectively, and the corresponding response rates were 60%, 52%, and 15%. Pairwise comparisons from a logistic regression model including study center, baseline Liebowitz Social Anxiety Scale score, and therapist as covariates showed that both CBT and psychodynamic therapy were superior to waiting list with regard to remission and response rates (CBT: remission, h=0.71, p<0.0004; odds ratio=7.42, 95% CI=2.45–22.51; response, h=0.98, p<0.0001; odds ratio=8.63, 95% CI=3.53–21.08; psychodynamic therapy: remission, h=0.50, p=0.011; odds ratio=4.27, 95% CI=1.39–13.14; response, h=0.82, p<0.0001; odds ratio=6.28, 95% CI=2.54–15.54). For the comparison of CBT and psychodynamic therapy, logistic regression models revealed significant differences in favor of CBT for remission rates (h=0.22, p=0.034; odds ratio=1.75, 95% CI=1.04–2.92) but not for response rates (h=0.16, p=0.198; odds ratio=1.36, 95% CI=0.85–2.18). The differences of 10% and 8% in remission and response rates correspond

to between-group effect sizes (h) of 0.22 and 0.16, which are below the value of 0.30 defined a priori as clinically meaningful. For the completer analysis, we included those patients who completed treatment per protocol, that is, those who either received 25 sessions or who remitted before completion. The completer analysis yielded the same pattern of results for CBT and psychodynamic therapy, with remission rates of 42% and 30%, respectively, and response rates of 66% and 56%, respectively. Thus, no differences in the pattern of results were observed between the intent-to-treat analysis using multiple imputation and the completer analysis.

For continuous measures, planned pairwise comparisons for posttherapy data via linear-effects models with study center, baseline score, and therapist as covariates revealed significant differences in favor of CBT for the scores on Liebowitz Social Anxiety Scale (p=0.01, d=0.25, 95% CI=0.06–0.44), the Social Phobia and Anxiety Inventory (p=0.0009, d=0.33, 95% CI=0.13–0.52), and the Inventory of Interpersonal Problems (p=0.003, d=0.29, 95% CI=0.10–0.49). No significant differences were observed for the Beck Depression Inventory. Again, all between-group effect sizes were small (d values ≤0.33) (34). The proportion of variance explained by treatment condition was between 1% and 3% (34). The proportions of variance (intraclass correlation coefficients) explained by therapist for the Liebowitz Social Anxiety Scale, the Social Phobia and Anxiety Inventory, the Beck Depression Inventory, and the Inventory of Interpersonal Problems were 0.05, 0.07, 0.05, and 0.07, respectively. There was neither a center-by-treatment interaction nor a significant center effect in any of the analyses. Within-group effect sizes for the Liebowitz Social Anxiety Scale score were large for both CBT and psychodynamic therapy (d values, 1.32 compared with 1.02) and small for the waiting list (d=0.24) (34). CBT was associated with a reduction in Liebowitz Social Anxiety Scale score by 29.12 points (95% CI=25.50–32.73), psychodynamic therapy by 22.55 points (95% CI=18.96–26.13), and waiting list by 5.19 points (95% CI=–0.14 to 10.52).

In a sensitivity analysis using logistic regression with baseline Liebowitz Social Anxiety Scale score as a covariate, we found that general clinical experience (in years) was not associated with either remission or response. This was also true for having used treatment manuals in general, and it applied to all other outcome measures as well. Having already used the specific manuals applied in this study had a significant impact on outcome on ratings on the Social Phobia and Anxiety Inventory (p=0.003) and the Inventory of Interpersonal Problems (p=0.013), but not on other measures. Controlling for this variable, however, showed that results remained stable, with CBT superior to psychodynamic therapy (p values, 0.005 and 0.006).

Serious Adverse Events

Serious adverse events occurred in seven patients (1%) during the trial, including psychiatric hospitalization for

the following conditions: major depression (one each in the CBT and psychodynamic therapy groups), acute stress disorder (one in the psychodynamic therapy group), alcohol abuse (one in the CBT group), severe increase in severity of social anxiety disorder symptoms (one in the CBT group), deliberate self-poisoning (one in the psychodynamic therapy group), and diverticular disease (one in the CBT group).

Adverse Events

Adverse events occurred in seven patients (1%) during the trial, including major depression (three in the CBT group, two in the psychodynamic therapy group, and one in the waiting list group) and adjustment disorder (one in the psychodynamic therapy group). Given the small number of participants with adverse events and serious adverse events, no significance tests were performed.

Discussion

In this multicenter randomized controlled trial, we found both CBT and psychodynamic therapy to be superior to waiting list. Comparing CBT and psychodynamic therapy, we found significant differences in favor of CBT for remission and secondary measures of social phobia and interpersonal problems. For response rates and improvements in depressive symptoms, we observed no significant differences between CBT and psychodynamic therapy. All differences between CBT and psychodynamic therapy in terms of between-group effects sizes were small (≤0.37). With proportions of variance explained by treatment condition ranging from 1% to 3%, the differences between treatments were smaller than that between therapists (5%–7%). Differences between therapists were comparable to those reported in other studies (35).

The response rate of 60% achieved by CBT is comparable to the rate reported in the most recent study of the Clark and Wells approach (65.8%) (39). Thus, in this large multicenter study, the results of German and Swedish trials evaluating the Clark and Wells approach were corroborated (32, 33, 39). As we applied a different definition of response, some caution is required in comparing our response rates with those of other studies. Our definition of response, however, has been shown empirically to correspond well to response defined as a Clinical Global Impression improvement score ≤2, leading to comparable results (28). With a mean duration of 38.7 weeks for CBT, the mean calendar duration of CBT (time between the first preparatory session and end of treatment) was longer than in other studies because of the conditions of the German health care system. With a mean of 25.8 sessions, however, the net dose of CBT was comparable to that delivered by Clark et al. (23), who applied a mean of 12.76 90-minute sessions plus 2.24 50-minute

sessions, which corresponds to a total of 25.2 50-minute sessions (25.2 compared with 25.8 50-minute sessions).

The response rate of 52% achieved by psychodynamic therapy is comparable to rates reported for selective serotonin reuptake inhibitors (55%) (40), for pharmacotherapy in general (55%) (26, 40, 41), and for cognitive-behavioral group therapy (52.9%, 51.7%) (26, 41). The remission rate of 27% was also comparable to rates reported for cognitive-behavioral group therapy (23.5%) (41) and phenelzine (25.7%) (41). The 52% response rate for psychodynamic therapy clearly exceeded that reported for pill placebo (31%) (40); this also applies to the psychodynamic therapy remission rate (27% compared with 7%) (27). The psychodynamic therapy response rate was somewhat higher than that recently reported for interpersonal therapy (42%) (39). It is of note that the method of manual-guided psychodynamic therapy for social anxiety disorder was only recently developed (22) and tested for the first time.

Further research will be carried out to enhance the efficacy of the psychodynamic therapy approach in social anxiety disorder. It would also be of interest to see how effective other methods of psychodynamic therapy are in social anxiety disorder, such as the model of McCullough et al. (42).

Interestingly, whereas general clinical experience or having previously used treatment manuals was not associated with outcome, having already used the specific manuals applied in this study had a significant impact on outcome, at least on some measures. For this reason, it would be of interest to examine whether differences between CBT and psychodynamic therapy decrease with increasing experience on the part of psychodynamic therapists in use of the applied manual.

A limitation of our study is that it did not include pharmacotherapy or its combination with psychotherapy as a study condition. Moreover, we excluded patients with concomitant pharmacotherapy. As many patients with social anxiety disorder use pharmacotherapy, this may limit generalization (external validity). However, we wanted to be able to attribute the effects observed solely to the applied methods of psychotherapy (internal validity). As in many studies, the requirements of internal and external validity are in conflict in our design. Despite some limitations, however, our study also had several strengths. As shown by Luborsky et al. (43) and recently corroborated by Munder et al. (44), investigator allegiance heavily influences results of psychotherapy outcome studies. Our trial is one of the few studies comparing CBT and psychodynamic therapy that controlled for an investigator allegiance effect by including experts of the two approaches. Furthermore, our trial included several research centers, a large number of therapists, and a large sample of patients. Although we included a relatively large number of therapists, no significant effect for study center was observed. Thus, the relatively large numbers of patients, research

centers, and therapists support the generalizability of our results. Additionally, treatment fidelity data show that both treatments were carried out in accordance with the respective approach and could be significantly differentiated. Consistent with the manual (22), for example, the psychodynamic therapist verbally encouraged the patient to confront a feared situation, but never accompanied her or him when confronting the situation or carried out exercises or role playing. As shown by the data on adherence, CBT therapists used more interventions of the psychodynamic therapy model than vice versa.

A considerable proportion of the patients (40%–48%), however, did not sufficiently respond to either treatment. This finding is consistent with studies of psychotherapy and pharmacotherapy in general (2, 40), although higher success rates were reported by Clark et al. (23). These nonresponders may need a different form of treatment that may be more specific, more intensive, or of longer duration. One of our next steps is to examine the characteristics of nonresponding patients in this trial.

Further results of the SOPHO-NET (e.g., follow-up studies on genetics, neuroimaging or process research) will be reported in the near future. In addition, process analyses will be carried out examining mechanism of change—for example, the relationship between adherence and competence on outcome of CBT and psychodynamic therapy.

Stangier, Katrin von Consbruch; psychodynamic therapy treatment implementation unit: Manfred E. Beutel, Jörg Wiltink; study coordinators: Eric Leibing, Simone Salzer, Falk Leichsenring; local representatives of cognitive therapy: Wolfgang Hiller, Jürgen Hoyer, Eric Leibing, Ulrich Stangier, Ulrike Willutzki; local representatives of psychodynamic therapy: Manfred E. Beutel, Peter Joraschky, Falk Leichsenring, Björn Nolting, Bernhard Strauss.

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Clinical Guidance: CBT vs. Psychodynamic Therapy for Social Anxiety Disorder

Both cognitive behavioral therapy (CBT) and targeted psychodynamic therapy improve symptoms of social anxiety disorder in large proportions of patients. In the comparison by Leichsenring et al., 25 treatment sessions produced response rates of 60% for CBT, 52% for supportive-expressive psychodynamic therapy, and 15% for a waiting list control condition. CBT is more likely to produce remission, but the response rate for psychodynamic therapy is comparable to rates for pharmacotherapy and group CBT. Milrod (p. 703) notes in her editorial that therapists should be vigilant for signs of separation anxiety and rage during termination, as these dynamics are frequent in social anxiety disorder patients.