

# Efficacy of cognitive behavioral therapy with paroxetine and paroxetine only for social anxiety disorder: A behavioral, placebo-controlled study

## ABSTRACT

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**Background:** Individually, cognitive behavior therapy (CBT) and paroxetine (PX) are considered as frontline treatments for social anxiety disorder (SAD). However, the possibility of combined interventions of these might be more helpful than either intervention alone has met with mixed reviews. Hence, the goal of the current study was to examine whether combining CBT + PX would be superior to PX alone in the treatment of SAD in various stages of treatment. **Methodology:** The present study is a single-center, rater-blind, behavioral placebo (Bh. PBO)-controlled study. Sixty-seven participants were prospectively observed in two groups, one receiving CBT + PX and PX + Bh. PBO for 24 weeks. The Social Interaction Anxiety Scale (SIAS) was measured at pre, post (12 weeks), end of booster (24 weeks), and 2-month follow-up (32 weeks) stage. The SIAS was measured at pre, post (12 weeks), end of booster (24 weeks), and 2-month follow-up (32 weeks) stage. **Results:** Both treatment groups have significant difference in the mean scores of SIAS in posttreatment, booster, and follow-up stages from their respective mean scores at prestage. Mann-Whitney *U*-test found no significant differences in the mean scores of SIAS between CBT + PX and PX + Bh. PBO at posttreatment and booster phase, whereas a statistically significance difference ( $P = 0.03$ ) was found in 2-month follow-up stages. Both treatment groups have large effect size in posttreatment and end of booster phase. At 2-month follow-up stage, a large effect size of 1.11 was found in CBT + PX group as compared to medium size of 0.6 in PX + Bh. PBO group. **Conclusions:** Combined treatment of CBT + PX provided no advantage over PX + Bh. PBO in acute stages of treatment, but the former have significantly better maintenance of treatment gains in 2-month follow-ups than the latter.

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**Received:** 19 February 2019

**Revised:** 26 April 2020

**Accepted:** 07 May 2020

**Published:** 14 August 2020

**Keywords:** Behavioral placebo-controlled study, cognitive behavior therapy, paroxetine, social anxiety disorder

### Access this article online

#### Quick Response Code:



**Website:** [www.industrialpsychiatry.org](http://www.industrialpsychiatry.org)

**DOI:** 10.4103/ipj.ipj\_13\_19

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**How to cite this article:** Samantray N, Kar N, Singh P, Swain SP, Singh AR, Chaudhury S, *et al.* Efficacy of cognitive behavioral therapy with paroxetine and paroxetine only for social anxiety disorder: A behavioral, placebo-controlled study. *Ind Psychiatry J* 2019;28:211-7.

Social anxiety disorder (SAD) is highly prevalent in both clinical and community samples with a prevalence rate of 13%.<sup>[1]</sup> The course of social phobia is chronic and associated with low rates of recovery.<sup>[2,3]</sup> Functional impairment associated with it is severe.<sup>[4]</sup> Among psychological approaches, behavioral and cognitive – behavioral are considered to be the most effective as backed by many meta-analytic reviews.<sup>[5,6]</sup> These studies have summarized by comparing behavioral and cognitive-behavioral treatments (CBTs) with various control conditions, and each has more or less similar conclusions. Exposure therapy, with or without cognitive restructuring, had the largest mean effect size of all the psychotherapies.<sup>[5]</sup> One of the significant findings of psychological treatment has been the excellent maintenance of gains after the end of effective treatment.<sup>[7]</sup> Within pharmacological approaches, many controlled trials on selective serotonin reuptake inhibitors (SSRIs) have established its superiority over placebo (PBO) for the treatment of SAD such as fluvoxamine,<sup>[8]</sup> sertraline,<sup>[9]</sup> and paroxetine (PX).<sup>[9-11]</sup>

Though both CBT and SSRI, individually, were considered as frontline treatments for SAD, it pops up a logical inquisitiveness that combined interventions of both might be more helpful than either intervention alone. However, literature has mixed reviews regarding it. Meta-analytic methods<sup>[6]</sup> found no evidence that combined therapies had greater effects than each monotherapy alone in acute treatment stages. In another study,<sup>[8]</sup> patients were randomized to sertraline or PBO and separately to exposure or general medical care. While sertraline was associated with greater efficacy than PBO, the same was not for exposure alone. In another study,<sup>[12]</sup> the efficacy of fluoxetine, pill PBO, group CBT, CBT plus fluoxetine, and CBT plus pill PBO was examined and found that all active treatments though had greater efficacy than pill PBO, there were no differences among the active treatments.

It has been consistently found that, after treatment discontinuation, gains achieved with CBT (with or without pharmacotherapy) persist longer than do gains achieved with SSRI alone, however more studies supported larger effect sizes in CBT alone than CBT combined with pharmacotherapy.<sup>[5,13,14]</sup> Evidence that combined therapies had no greater effects than monotherapy alone was predominantly based on the comparison of CBT alone with combination of CBT + SSRI and very less on SSRI alone with CBT + SSRI. Hence, the objective of the current study was to examine whether combination CBT + SSRI would be superior to PX alone (SSRI group) in the treatment of SAD in both acute and maintenance stages of treatment.

## METHODOLOGY

Mental health professionals in Bhubaneswar and Cuttack, India, were requested to refer patients for the study involving a trial of psychological and pharmacological treatments of social anxiety. To encourage participation, lectures were given on “social anxiety” in Ravenshaw University, Cuttack. The center of the study was Mental Health Institute of S.C.B Medical College, Cuttack. Ethical clearance for the study was obtained from the Institutional Ethical Committee.

### Sample

The referred patients were assessed using Anxiety Disorders Interview Schedule (ADIS-IV)<sup>[15]</sup> and Mini International Neuropsychiatric Interview.<sup>[16]</sup> In total, 84 patients were assessed for eligibility, out of which 13 were ineligible and 4 were not comfortable for various interval visits to hospitals. Ethical principles were clearly explained to the participants, especially voluntary nature of their participation and option of withdrawal from the study at any time. Following which, informed consent was taken.

The inclusion criteria for selection of participants were (a) International Classification of Diseases-10 Classification of mental and behavioral disorders: diagnostic criteria for research<sup>[17]</sup> diagnosis of social phobia (SAD) (b) informed consent, and (c) age between 18 and 50 years.

Exclusion criteria were (a) current level of severe depression, (b) prominent risk of self-harm, (c) substance dependence; (d) lifetime psychosis; (e) lifetime mania; and (f) a previous adequate trial of cognitive behavioral therapy (four sessions) or SSRI treatment (40 mg/d for 4 weeks) for social phobia. On the basis of these, finally, 67 participants were selected for the study.

### Design

This was a singlecenter, raterblind, behavioral (Bh) PBOcontrolled, prospective observational study. Eligible participants were prospectively observed in two groups: CBT + PX (CBT + PX) and PX + Bh. PBO with 33 and 34 participants, respectively [Figure 1]. Primary outcome assessments were done at pretreatment, posttreatment (12 weeks), end of the booster period (24 weeks), and 2-month follow-up (32 weeks). CBT was administered by registered clinical psychologists and Master in Philosophy in clinical psychology trainees for 12 sessions on a weekly basis and two booster sessions, once in a month. In other group, Bh. PBO was administered in similar trends. PX was common in both groups, which was administered and monitored by psychiatrists. The enrollment began in November, 2015, and continued until September, 2017.

**Treatment administrations**

CBT was based on Clark and Well’s model for SAD.<sup>[18]</sup> The main steps in the treatment were as follows: (a) tailored cognitive conceptualization, (b) reducing safety behaviors, (c) practicing external focus of attention in social situation, (d) video feedback, (e) dealing with anticipatory and postevent processing, and (f) behavioral experiments or exposure sessions. CBT was administered by clinical psychologists for 12 sessions on a weekly basis and two booster sessions, once in 45 days. The sessions were approximately 60 min.

PX was administered by the consultant psychiatrists over 24 weeks following clinical guideline by Stein *et al.*<sup>[19]</sup> The initial dosage was 12.5 mg per day in a controlled release formulation and ranged from 12.5 to 50 mg/day.

Psychoeducational-supportive therapy (PST) as Bh. PBO: The PST program was considered as credible PBO and was based on the protocol by Heimberg *et al.*<sup>[20]</sup> It includes discussions on various topics relevant to SAD. Support was provided, but no specific advice, teaching skills, problem-solving, or exposures sessions were assigned.

**Primary outcome measure**

Assessment of fear and avoidance of social situations and diagnosis of SAD was done using the ADIS-IV.<sup>[15]</sup> Participants completed the Social Interaction Anxiety Scale (SIAS),<sup>[21]</sup> a standardized self-report scale, as the primary outcome measure at baseline (0 week), and posttreatment (12 weeks), booster phase (24 weeks), and follow-ups (32 weeks). It has high levels of internal consistency and discriminant validity.

**Statistical analysis**

Intent-to-treat analysis was used. Chi-square test was used to identify any differences in sociodemographic details. Mann-Whitney *U*-test was used to identify any differences between groups before treatment and any differences between both treatment groups at posttreatment, end of booster phase, and follow-up periods. Wilcoxon signed-rank test was used to identify significant within treatment changes in both groups. Cohen’s *d* formula was used to calculate effect sizes for both treatment groups at post, end of booster, and follow-ups stages. All data analyses were done using Microsoft Excel software and the SPSS for Windows, version 20.0 (IBM, Chicago, USA).

**RESULTS**

**Characteristics of patients**

The patients’ mean age was 32.2 years (standard deviation [SD] = 7.8). Fifty-five percent were male. Thirty-six percent were married. Thirty-seven percent

were student, 25% were employed, 60% were from nuclear family, and 69% were from urban areas. No significant differences in any of these characteristics were found between the treatment groups.

**Pretreatment group differences**

At pretreatment, there were no significant differences on SIAS between the two treatment groups.

**Treatment effectiveness and maintenance of treatment gains**

Table 1 shows the comparison of social anxiety measures at each time point between two treatment groups, and Table 2 shows the paired assessment of each treatment group at different time intervals. At postassessment (12 weeks), Wilcoxon signed-rank test revealed a significant treatment effect in the mean scores of primary measure (PM) SIAS in both treatment groups. On postassessment (12 weeks), Mann-Whitney test found no significant difference in the mean scores of SIAS between CBT + PX and PX + Bh. PBO.

At booster phase (24 weeks), Mann-Whitney test revealed a significant treatment effects in the mean scores of PM SIAS in both treatment groups. At booster phase (24 weeks),

**Table 1: Comparison of Social Interaction Anxiety Scale scores between treatment groups at different time (independent)**

Assessment phase (pairs)	Z score	P
Pre (CBT + PX and PX + Bh. PBO)	-0.33	0.72
Post (CBT + PX and PX + Bh. PBO)	0.38	0.69
Booster (CBT + PX and PX + Bh. PBO)	1.16	0.24
Follow-up (CBT + PX and PX + Bh. PBO)	2.15	0.03

SIAS – Social Interaction Anxiety Scale; CBT – Cognitive behavioral therapy; PX – Paroxetine; Bh. PBO – Behavioral placebo; BO – Booster phase; FU – End of 2-month follow-up phase

**Table 2: Paired group assessments**

Pairs	Mean score on SIAS	n	SD	Z score	P
Pre-CBT + PX	44.39	33	7.18	-4.69	0.001
Post-CBT + PX	34.72	33	12.92		
Pre-CBT + PX	44.39	33	7.18	-4.61	0.001
BO CBT + PX	32.42	33	13.73		
Pre-CBT + PX	44.39	33	7.18	-4.65	0.001
FU CBT + PX	31.06	33	15.39		
Pre-PX + Bh. PBO	43.5	34	6.46	-4.52	0.001
Post-PX + Bh. PBO	36.08	34	10.21		
Pre-PX + Bh. PBO	43.5	34	6.46	-4.44	0.001
BO PX + Bh. PBO	35.11	34	10.38		
Pre-PX + Bh. PBO	43.5	34	6.46	-3.08	0.002
FU PX + Bh. PBO	37.76	34	11.79		

SIAS – Social Interaction Anxiety Scale; CBT – Cognitive behavioral therapy; PX – Paroxetine; Bh. PBO – Behavioral placebo; BO – Booster phase; FU – End of 2-month follow-up phase; SD – Standard deviation

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however, Wilcoxon signed-rank test found no significant difference in the mean scores of SIAS between CBT + PX and PX + Bh. PBO.

At 2-month follow-up (32 weeks), a significant treatment effect in the mean scores of PM SIAS in both treatment groups was noticed. At 2-months follow-up, as shown in Table 1, Mann–Whitney test found a statistically significant difference in the mean scores of SIAS between CBT + PX and PX + Bh. PBO ( $P = 0.03$ ).

Hence, to sum up, in both treatment groups, significant difference in the mean scores of SIAS was seen in posttreatment, booster phase, and follow-up stages from their respective mean scores at prestage. However, no significant differences in the mean scores of SIAS between CBT + PX and PX + Bh. PBO at posttreatment and booster phase were found, but a significance difference in the mean scores of SIAS in these two treatment groups was found in 2-month follow-up stages.

### Effect size

For knowing the magnitude of the improvement in participants associated with both treatment conditions, we calculated pretreatment to posttreatment, end of booster, and follow-up effect sizes for the SIAS mean scores using the Cohen's  $d$  formula, which is determined by calculating the mean difference between the two treatment groups, and then dividing the result by the pooled SD. Cohen's  $d = (M_2 - M_1)/SD_{pooled}$  where  $SD_{pooled} = \sqrt{\frac{(SD_1^2 + SD_2^2)}{2}}$  where . We used Cohen's<sup>[22]</sup> threefold classification of effect sizes: small (0.20–0.49), medium (0.50–0.79), and large (0.80 and above).

In CBT + PX group, large effect sizes of 0.92, 1.09, and 1.11 were seen in postassessment, end of booster, and 2-month follow-up periods, respectively. In PX + Bh. PBO group, large effect sizes of 0.86 and 0.97 were seen in posttreatment and end of booster phase, respectively, however, at 2-month follow-up stage, a medium effect size of 0.6 was found [Table 3].

## DISCUSSION

The present study showed that both treatments of CBT + PX and PX + Bh. PBO are effective treatments for SAD as both lead to significant symptom reduction at posttreatment, booster phase, and follow-up stages. Both groups have large effect size in the posttreatment and booster phase. However, in follow-up stages, CBT + PX has high effect size, while PX + Bh. PBO has medium effect size. CBT + PX has better maintenance of treatment gains in follow-ups than PX + Bh. PBO.

**Table 3: Effect sizes for Social Interaction Anxiety Scale at posttreatment, end of booster, and 2-month follow-up**

Assessment	CBT + PX	PX + Bh. PBO
Posttreatment	0.92	0.86
End of booster session	1.09	0.97
Follow-up at 2 months	1.11	0.60

CBT – Cognitive behavioral therapy; PX – Paroxetine; Bh. PBO – Behavioral placebo

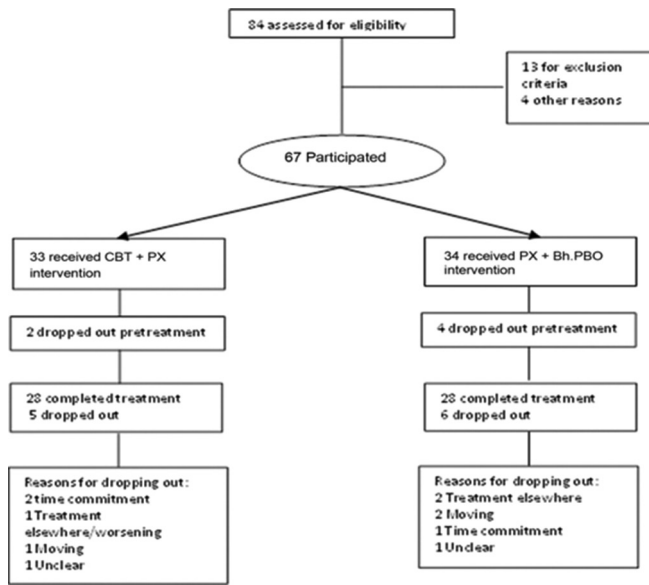
### Effectiveness of CBT + paroxetine and paroxetine + behavioral placebo: acute treatment stages

The pattern of results indicates that combined treatment CBT + PX and PX + Bh. PBO is an effective treatment for SAD. Both treatment groups have significant difference in the mean scores of SIAS from pretreatment to posttreatment, booster phase, and follow-up stages. Both treatment groups have large effect size in the posttreatment. However, there was no significant difference in mean score of SIAS in the combined treatment of CBT + PX group and the PX + Bh. PBO group. Hence, we were unable to find evidence supporting a benefit that the combination of CBT + PX has any significant clinical advantages compared to PX alone at acute stage of treatment or posttreatment of SAD.

In literature, both CBT and PX were considered as first line of treatment, hence, a logical question comes whether combined interventions might be more helpful than either intervention alone. The present study supports the meta analysis findings of Mayo-Wilson *et al.*,<sup>[6]</sup> that although large effect sizes were seen with such combined treatment, there was no strong evidence that it was more efficacious than the leading pharmacological monotherapy in acute stages of treatment.

Findings from the present study are consistent with four previous studies that have assessed treatment response of SAD to only medication compared to combined medication and psychological treatments. Two of this studies involved SSRI<sup>[12,23]</sup> and two monoamine oxidase inhibitor (MAOI).<sup>[24,25]</sup> Response rates in the acute stages of treatment in all the four studies showed a nonsignificant trend in favor of combined medication/psychological treatments over medication alone, like in the present study. It should be noted that all studies were relatively small, like the present study, in size, and thus may not have a robust external validity.

Similarly, Davidson *et al.*<sup>[12]</sup> conducted a randomized controlled trial (RCT) on 295 adults with SAD to 14 weeks of fluoxetine, comprehensive cognitive behavioral group therapy PBO, or combinations of CCBT/fluoxetine or CCBT/PBO. All treatment groups were superior to PBO. At posttreatment, like the present study, all active



**Figure 1:** Flowchart of participants through phases of the study

treatments yielded significantly greater improvements, but did not differ. Unlike the present study, Davidson *et al.*'s study did not include a follow-up time point, so it is unclear about the maintenance of treatment gains.

Findings of the present study have variance with the study of Blanco *et al.*,<sup>[25]</sup> where superiority of a combined treatment over medication, psychotherapy, and PBO in the acute treatment of SAD was found. In that study group, CBT was combined with phenelzine, a MAOI (not combined with SSRI as in the present study). It would be difficult to compare with the findings of the present study because both used different pharmacological and psychological treatment (cognitive-behavioral group treatment in group).

The results in another study<sup>[26]</sup> showed that cognitive therapy (CT) was significantly more effective than PX and PBO at posttreatment and at follow-up. The combination of CT and PX was having no clinical advantages compared to CT alone at posttreatment. The combination treatment was superior to PBO and demonstrated better recovery rates but was not superior to PX on the measures of anxiety and interpersonal behavior. However, CT also led to higher rates of recovery than the other conditions. Combination of CT and PX yielded a lower effect size and significantly lower recovery rates than CT alone. This raises the possibility that the combined treatment is detrimental to CT alone. This finding was replicated in other studies presenting that exposure therapy in combination with SSRI in SAD has reduced effects.<sup>[12,13]</sup>

The results showed that patients in PX + Bh. PBO had significant improvements between pretreatment to

posttreatment (12 and 24 weeks) and 3-month follow-up on the mean scores of SIAS. Effect size was higher from pretreatment to posttreatment (12 and 24 weeks) but medium from pretreatment to follow-up period. Similar trends in various meta-analyses of PX and *post hoc* analysis of an RCT are seen.<sup>[9-11]</sup>

Thus, overall, the research suggests that combining medication and psychotherapy for SAD does not yield better results than each treatment alone. Furthermore, meta-analytic methods<sup>[6]</sup> found no evidence that combined therapies had greater effects than each monotherapy alone.

### Effectiveness of CBT + paroxetine and paroxetine + behavioral placebo: Maintenance stages

Results at the 2-month follow-up stages showed that the patients getting combined treatment of CBT + PX and PX + Bh. PBO both have significant difference between pretreatment and 2 months of follow-up stages. Hence, both groups have maintained significant treatment gains till follow-up. However, CBT + PX treatment group has larger effect size as compared to moderate effect size of PX + Bh. PBO group. Hence, treatment gains are better maintained in CBT + PX group than the PX + Bh. PBO group.

In other studies, maintenance gains of CBT gains have been studied in two ways, either used alone or in combination with SSRI. In both ways, the treatment gains achieved with CBT appear to be maintained during various durations of follow-up; however, these results are based on modest sample sizes.<sup>[5,13,14]</sup>

In a study by Haug *et al.*,<sup>[13]</sup> follow-up was conducted after 52 weeks; patients from the exposure-only had significantly maintained the improvements. However, those in the combined treatment and sertraline-only groups had significantly deteriorated as compared to those in exposure alone, suggesting that exposure is more efficacious than sertraline or combined treatment in the long term. A major difference between Haug *et al.*<sup>[13]</sup> and the present study is that the present study did not have a separate CBT only group; it compared combined CBT and pharmacological treatment with only pharmacological treatment. However, the study by Clark *et al.*,<sup>[14]</sup> found that both CT alone and combined treatment of SSRI and exposure have higher effect sizes in 12-month follow-up period. However, CT alone (2.53) had higher efficacy than combined treatment of SSRI and exposure (1.36).

The present study has variance with the study of Nordahl *et al.*,<sup>[26]</sup> where CT group maintained significant better benefits at 12-month follow-up than PBO and PX alone, but they found no significant differences among combined

treatment, PX alone, and PBO, whereas in the present study, the combination treatment even have better maintenance of treatment gains, but the comparison of follow-up findings of the present study to that of Nordahl *et al.*<sup>[26]</sup> may not be apt as the present study have only 2-month follow-up as compared to theirs 12--month follow-up.

It has consistently been found that, after treatment discontinuation, gains achieved with CBT (with or without pharmacotherapy) persist longer than do gains achieved with SSRI alone, however more studies supported larger effect sizes in CBT alone than CBT combined with pharmacotherapy.<sup>[5,13,14]</sup>

### Limitations

Interpretations of the present study have to be done keeping the limitations in frame. First, the sample size was relatively modest. Second, some CBT treatment sessions were delivered by postgraduate clinical psychology trainees. Third, a major difference between this and other studies that it did not have a separate CBT-only group, rather it compared combined frontline psychological and pharmacological treatment with only frontline pharmacological treatment. Hence, in future research, one may have a complete factorial design involving CBT only, PX only, and a combination of both and PBO for more substantiality of claims of CBT's larger role in the maintenance of treatment gains in follow-ups than other leading or combination of treatments. Fourth, for maintenance of treatment gains, only 2-month follow-up results were assessed as comparison to longer periods, like 12 months, in other studies. Finally, in future researches, it would be better to use multiple outcome measures than one.

### CONCLUSIONS

This study adds to the growing body of evidence that though both treatments of CBT + PX and PX are effective treatments for SAD, combination of CBT + PX is not superior to PX alone in the acute stages of treatment, while CBT + PX has significantly better maintenance of treatment gains in follow-ups than PX alone.

### Acknowledgment

The authors thank Quality of Life Research and Development Foundation, India, for technical support.

### Financial support and sponsorship

Nil.

### Conflicts of interest

There are no conflicts of interest.

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