



Anxiolytic effects of a yoga program in early breast cancer patients undergoing conventional treatment: A randomized controlled trial[☆]

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Available online 14 October 2008

KEYWORDS

Yoga;
Anxiety;
Cancer;
STAI;
CAM;
Relaxation

Summary

Objectives: This study compares the anxiolytic effects of a yoga program and supportive therapy in breast cancer outpatients undergoing conventional treatment at a cancer centre.

Methods: Ninety-eight stage II and III breast cancer outpatients were randomly assigned to receive yoga ($n=45$) or brief supportive therapy ($n=53$) prior to their primary treatment i.e., surgery. Only those subjects who received surgery followed by adjuvant radiotherapy and six cycles of chemotherapy were chosen for analysis following intervention (yoga, $n=18$, control, $n=20$). Intervention consisted of yoga sessions lasting 60 min daily while the control group was imparted supportive therapy during their hospital visits as a part of routine care. Assessments included Spielberger's State Trait Anxiety Inventory and symptom checklist. Assessments were done at baseline, after surgery, before, during, and after radiotherapy and chemotherapy.

Results: A GLM-repeated measures ANOVA showed overall decrease in both self-reported state anxiety ($p<0.001$) and trait anxiety ($p=0.005$) in yoga group as compared to controls. There was a positive correlation between anxiety states and traits with symptom severity and distress during conventional treatment intervals.

Conclusion: The results suggest that yoga can be used for managing treatment-related symptoms and anxiety in breast cancer outpatients.

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[☆] Sources of support: Central Council for Research in Yoga and Naturopathy, Ministry of Health and Family Welfare, Govt. of India.

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Background

Anxiety and depression are the commonest psychiatric problems encountered in cancer patients. Fear and anxiety associated with diagnosis of cancer, invasive treatment procedures, sexual dysfunction secondary to surgery and radiation, and aversive reactions to chemotherapy are among the common treatment-related side effects observed in cancer patients. Clinical descriptions have noted cancer patient's fears of the treatment (e.g., being "burned" or "equating radiotherapy with electric current"), causing sterility, sickness or vomiting and vast individual differences in their psychological reactions, which usually predisposes to anxiety.^{1–5} Apart from treatment-related anxiety the diagnosis of cancer itself is anxiety provoking.

Psychiatric disorders in cancer patients are often missed or untreated.⁶ Patients with breast cancer undergoing radiation treatment also report anxiety and depression before, during and after the treatment.⁷ The prevalence of anxiety and depression in cancer patients undergoing radiation treatment was 64% and 50%, respectively.¹

Earlier studies have shown that anxiety increases psychological distress and side effects following conventional treatment.^{8,9} This treatment-related distress is predictive of poorer treatment outcome, poor treatment compliance, greater pain, longer hospital stays, more postoperative complications and immune suppression.^{10,11} This has been attributed in part to subjects increased attentiveness to their somatic symptoms¹² and development of aversive conditioned responses induced by anxiety.¹³ Therefore, there is a need to reduce anxiety in these patients.

The literature on psychosocial treatment for breast cancer patients provides uniform evidence for an improvement in mood, coping, adjustment, vigour, and decrease in distressful symptoms using a variety of behavioural approaches including alternative medicine approaches such as yoga.^{14–21}

Yoga as a complementary and mind body therapy is being practiced increasingly across the world. It is an ancient Indian science that has been used for therapeutic benefit in numerous health care concerns in which mental stress was believed to play a role.²² This could be particularly useful in cancer patients who perceive cancer as a threat.

Results from earlier studies provide preliminary support for anxiolytic effects of yoga interventions in cancer patients. Positive effects have been seen on a variety of outcomes, including sleep quality, mood, stress, cancer-related distress, cancer-related symptoms, and overall quality of life, as well as functional and physiological measures.²³ Further, results from cancer trials are bolstered by studies conducted with non-cancer populations, which have demonstrated positive effects on similar outcomes (e.g., improvements in mood and fatigue). These studies were typically more methodologically rigorous than those conducted with cancer populations and often included active control groups (e.g., relaxation,²⁴ exercise,²⁵ and wait listed controls²⁶) lending further support to the results.²⁷

An earlier uncontrolled study with cancer patients in India also reported mood-enhancing effects with yoga intervention.²⁸ Being diagnosed with cancer is in itself anxiety-provoking, and we hypothesize that yoga intervention may be effective for reducing general anxiety

associated with the having cancer and those related to cancer treatment.

In this study, we compared the effects of a 24-week "Integrated yoga program" with "Brief supportive therapy" control intervention in early operable breast cancer patients undergoing surgery, radiotherapy, and chemotherapy.

Methods

This is a single centre randomized controlled trial which recruited 98 recently diagnosed women with stage II and III operable breast cancers. The institutional ethics committee of the recruiting cancer centre approved the study. Patients were included if they met the following criteria: (i) women with recently diagnosed operable breast cancer, (ii) age between 30 and 70 years, (iii) Zubrod's performance status 0–2 (ambulatory >50% of time), (iv) high school education, (v) willingness to participate, and (vi) treatment plan with surgery followed by adjuvant radiotherapy and chemotherapy. Patients were excluded if they had (i) a concurrent medical condition likely to interfere with the treatment, (ii) any major psychiatric, neurological illness or autoimmune disorders, and (iii) secondary malignancy. The details of the study were explained to the participants and their informed consent was obtained in writing.

Assessments were done prior to their surgery, following surgery, during and following radiotherapy and chemotherapy. All participants in the study received the same dose of radiation (50 cGy over 6 weeks) and prescribed standard chemotherapy schedules (cyclophosphamide, methotrexate, fluorouracil or fluorouracil, adriamycin and cyclophosphamide—six cycles). Subjects in both groups (control 45%, yoga 39%) received anxiolytic medications during their chemotherapy to prevent aversive responses (alprazolam 0.5 mg once daily for 1 week following chemotherapy infusion). The subjects received anxiolytics as a co-medication for only one to two cycles of chemotherapy. However, co-medication was given only to prevent aversive responses such as chemotherapy induced nausea and vomiting following chemotherapy.

Measures

Before randomization demographic information, medical history, clinical data, intake of medications, investigative notes and conventional treatment regimen were ascertained from all consenting participants. Participants completed the state trait anxiety inventory (STAI) that consists of a separate self-report scale for measuring two distinct anxiety concepts: state anxiety and trait anxiety.²⁹

The A trait scale asks subjects to describe how they generally feel, an attempt to tap individual differences in "anxiety proneness" where as the A-state scale asks the subjects to indicate how they feel at a particular moment in time. Subjects are asked to rate on a 4-point scale (almost never/not at all to almost always/very much) whether or not each statement best describes their feelings. Because the state measure is regarded similar to mood measures that have expectedly low test–retest reliabilities, comparison of internal consistencies between the state and trait measure

is more appropriate. Coefficient alpha values for the state measure range from 0.86 to 0.92 and those for trait measure are equally high.

The subjective symptom checklist was developed during the pilot phase to assess treatment-related side effects, problems with sexuality and image, and relevant psychological and somatic symptoms related to breast cancer. The checklist consisted of 31 such items each evaluated on two dimensions; severity graded from no to very severe (0–4) and distress from not at all to very much (0–4). These scales measured the total number of symptoms experienced, total/mean severity and distress scores and were evaluated previously in a similar breast cancer population.³⁰ The patients from both groups were briefed together by investigators on filling the questionnaire. These self-report questionnaires were filled by patients themselves at assessment intervals.

Randomization

A person who had no part in the trial randomly allocated consenting participants ($n=98$) to either yoga ($n=45$) or supportive therapy groups ($n=53$). Participants were randomized at the initial visit before starting any conventional treatment. Following randomization participants underwent surgery followed by radiotherapy (RT) and chemotherapy (CT) or any other treatment schedule as shown in Table 1. There were 12 dropouts in yoga and 17 dropouts in control group, respectively following surgery. Another 15 subjects and 13 subjects in yoga and control arm who did not receive the above treatment sequence were not considered for analysis (see Fig. 1: trial profile).

Sample size

Earlier studies have reported very large effect size (>1) for anxiety scores with yoga intervention.³¹ We therefore used a conservative estimate of effect size/standardised difference = 1 for our study. The sample size needed in our study based on formula³² is 17 subjects in each arm with p at 0.05 and 80% power. There were 18 subjects in yoga and 20 subjects in control group who contributed data to the study.

Interventions

The intervention group received an integrated yoga program and the control group received supportive therapy sessions, both imparted individually. Yoga practices consisted of a set of asanas (postures), breathing exercises, pranayama (voluntarily regulated nostril breathing), meditation and yogic relaxation techniques with imagery. The details of these practices are described elsewhere.³³ These practices were based on principles of attention diversion, awareness and relaxation to cope with stressful experiences. The subjects were given booklets, audiotapes with instructions on these practices for home practice using the instructors voice so that a familiar voice could be heard on the cassette.

The subjects underwent four in-person sessions during their pre- and postoperative period and were asked to undergo three in-person sessions/week for 6 weeks dur-

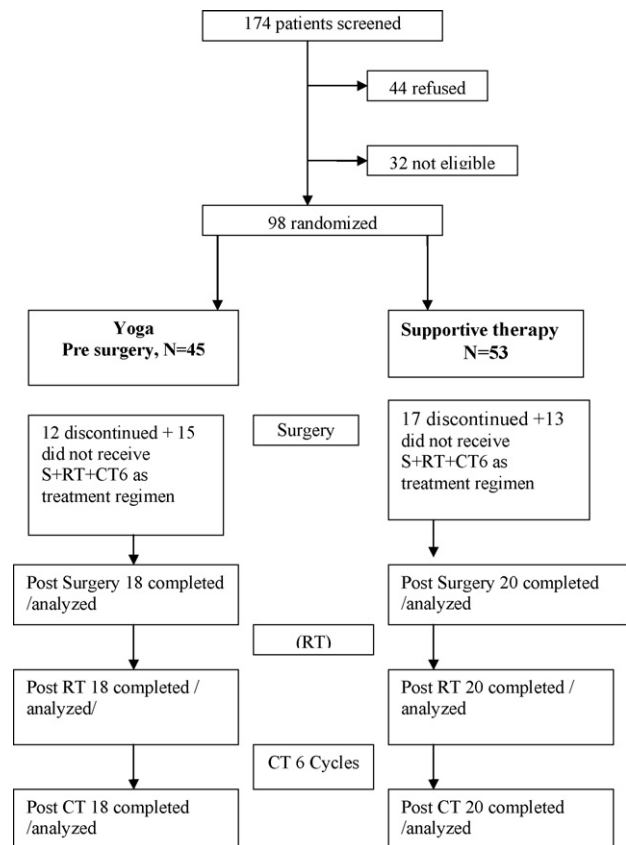


Figure 1 Trial profile.

ing their adjuvant radiotherapy treatment in the hospital with self-practice as homework on the remaining days. During chemotherapy, subjects underwent in-person sessions during their hospital visits for chemotherapy administration (once in 21 days) and were imparted in-person sessions by their trainer once in 10 days. The instructor monitored their homework on a day-to-day basis through telephone calls and house visits. Participants were also encouraged to maintain a daily log listing the yoga practices done, use of audiovisual aids, duration of practice, experience of distressful symptoms, intake of medication and diet history. There were two instructors, one being a physician in naturopathy and yoga and the other a trained and certified therapist in yoga from the yoga institute. They together supervised and imparted the yoga and supportive therapy intervention with help from trained social workers and counsellors at the hospital.

The control intervention consisted of brief supportive therapy with education as a component that is routinely offered to patients as a part of their care in this centre. We chose to have this as a control intervention mainly to control for the non-specific effects of the yoga program that may be associated with factors such as attention, support and a sense of control. Subjects and their caretakers underwent counselling by a trained social worker (once in 10 days, 15 min sessions) during their hospital visits for adjuvant radiotherapy/chemotherapy. Subjects in the supportive therapy group also completed daily logs or dairies on treatment-related symptoms, medication and diet during their chemotherapy cycles. The subjects were also given homework based on education component and were also

Table 1 Demographic characteristics of the initially randomized sample ($n = 98$)

	All subjects		Yoga group		Control group	
	<i>n</i>	(%)	<i>n</i>	(%)	<i>n</i>	(%)
Stage of breast cancer						
II	47	47.9	24	53.3	23	43.4
III	51	52.1	21	46.7	30	
Grade of breast cancer						
I	1	1	1	2.2	0	0
II	11	11.2	6	13.3	5	9.4
III	86	87.8	38	84.4	48	90.6
Menopausal status						
Pre	44	44.9	27	60	17	32.1
Post	50	51.1	15	33.3	35	66
Peri	2	2	2	4.4	0	0
Post-hysterectomy	2	2	1	2.2	1	1.9
Histopathology type						
IDC	75	76.5	38	84.4	37	69.8
ILC	14	14.3	5	11.2	9	17
IPC	6	6.1	2	4.4	4	7.5
IDC-P	3	3.1	0	0	3	5.6
Treatment regimen						
S + RT + CT6	49	50	22	48.9	27	50.9
S + CT6	7	7.1	4	8.9	3	5.6
S + CT3 + RT + CT3	28	28.6	12	26.7	16	30.2
S + RT	10	10.2	5	11.1	5	9.4
S + CT6 + RT	4	4.1	2	4.4	2	3.8
Stressful life events past 2 years						
Yes	27	28	10	22.2	17	32.1
No	71	72	35	77.8	36	67.9

Control group = Supportive Therapy, IDC = Infiltrating Ductal Carcinoma, ILC = Infiltrating Lobular Carcinoma, IPC = Infiltrating Papillary Carcinoma, IDC-P = Infiltrating Ductal Carcinoma-Papillary type, S = Surgery, RT = Radiotherapy, CT = Chemotherapy.

followed up with telephone calls and house visits. While the goals of yoga intervention were stress reduction and appraisal changes, the goals of supportive therapy were education, reinforcing social support and coping preparation.

Statistical methods

Data were analyzed using Statistical Package for Social Sciences version 10.0. We used a per protocol analysis in this study analyzing only those subjects who underwent surgery followed by radiotherapy and six cycles of chemotherapy (in this order) for the study as heterogeneity in treatment modalities and sequence could have confounded the results. A GLM-repeated measures ANOVA was done with the within-subjects factor being time/assessments at six levels and between-subjects factor being groups at two levels (yoga and supportive therapy). Both within-subjects and between-subjects effect and group by time interaction effects were assessed. Post hoc tests were done using Bonferroni correction for changes at different time points between groups. Intention to treat analysis was also done on the initially randomized sample ($n = 98$) with baseline measure and post-measure (post-CT) for all subjects. Baseline

value was carried forward for subjects who did not have a post-measure (including those who received other treatment schedules and study drop outs). Pearson correlation analysis was used to study the bivariate relationships of anxiety state and trait scores with treatment-related symptom severity and distress at various conventional treatment intervals (post-surgery/mid-RT/mid-CT).

Results

The subjects in our study were recruited and followed-up between January 1999 and June 2004. The groups were comparable with respect to socio-demographic and medical characteristics (see Table 1). Subjects in both groups (control 45%, yoga 39%) received anxiolytic medications during their chemotherapy to prevent aversive responses (alprazolam 0.5 mg once daily for 1 week following chemotherapy infusion). The subjects received anxiolytics as a comedication for only one to two cycles of chemotherapy.

Anxiety state

A repeated measures analysis of variance was done on anxiety state scores. Sphericity was assumed with Hyun

feldt η^2 at 0.6. Though group by time interaction effects were not significant, the between-subjects effect was significant $F(1, 35)=10.8$, $p=0.002$. Post hoc tests using Bonferroni correction showed significant decrease in anxiety states in yoga group as compared to control at post-surgery (mean change \pm S.E., p value, 95% CI), (4.3 ± 1.96 , $p=0.04$, $0.2-8.3$), mid-RT (5.7 ± 2.2 , $p=0.01$, $1.3-10.2$), post-RT (5.5 ± 2.1 , $p=0.01$, $1.3-9.7$), mid-CT (8.9 ± 2.2 , $p<0.001$, $4.3-13.3$), and post-CT (8.9 ± 2.6 , $p=0.002$, $3.6-14.2$) (see Table 2). However, intention to treat analysis done on the initially randomized sample showed a significant change between groups on state measure following intervention (4.7 ± 2.1 , $p=0.05$, $1.1-6.4$) (Table 3).

Anxiety trait

A repeated measures analysis of variance was done on anxiety trait scores. Sphericity was assumed with Hyun feldt η^2 at 0.75. Though group by time interaction effects was not significant, the between-subjects effect was significant $F(1, 35)=8.2$, $p=0.007$. Post hoc tests using Bonferroni correction showed significant decrease in anxiety trait in the yoga group as compared to controls at post-surgery (mean change \pm S.E., p value, 95% CI), (6.9 ± 2.4 , $p=0.007$, $2-11.8$), post-RT (5.8 ± 2.1 , $p=0.01$, $1.5-10.1$), and post-CT (8.2 ± 2.8 , $p=0.005$, $2.6-13.8$) (see Table 2). However, intention to treat analysis done on the initially randomized sample did not show any significant change between groups on trait measure following intervention (Table 3).

Symptom distress

A repeated measures analysis of variance was done on symptom distress scores. Sphericity was assumed with Hyun feldt η^2 at 1. Group by time interaction effects was significant and between subjects effect was significant $F(1, 35)=14.5$, $p=0.001$. Post hoc tests using Bonferroni correction showed significant decrease in symptom distress in yoga group as compared to controls at post-surgery (mean change \pm S.E., p value, 95% CI), (6.4 ± 2.3 , $p=0.009$, $1.7-11.1$), mid-RT (10.1 ± 2.8 , $p=0.001$, $4.3-15.8$), post-RT (4.8 ± 1.7 , $p=0.009$, $1.4-8.2$), mid-CT (16.3 ± 3.5 , $p<0.001$, $9.3-23.3$), and post-CT (7.7 ± 2.9 , $p=0.01$, $1.6-13.7$) (Table 2).

There was a significant bivariate relationship between anxiety states and traits with severity and distress of treatment-related symptoms during various stages of conventional treatment (see Table 4).

Discussion

We compared the effects of a 24-week yoga program with supportive therapy in 38 recently diagnosed breast cancer outpatients undergoing surgery, radiotherapy, and chemotherapy. The results suggest an overall decrease in both anxiety state (reactive anxiety) and trait with time in both the groups. Yoga intervention reduced anxiety state scores by 0.5% following surgery, 4.9% and 6% during and following radiotherapy and 8.5% and 11.6% during and following chemotherapy from their respective baseline means than

Table 2 Comparison of scores for anxiety state, trait and symptom distress at various stages of conventional treatment using GLM-repeated measures ANOVA

Outcome measures	Pre-surgery ^a	Post-surgery ^a		During radiotherapy ^a		Post-RT		During chemotherapy ^a		Post-CT	
		Pre-RT		Mid-RT		Pre-CT		Mid-CT		Post-CT	
STAI-anxiety state											
Yoga, mean (S.D.)	43.9 \pm 11	34 \pm 3.2	34 \pm 3.2*	29.3 \pm 3.6*	29.3 \pm 3.6*	29.1 \pm 3.6	29.1 \pm 3.6	29.3 \pm 3.3***	29.3 \pm 3.3***	24.1 \pm 3.1***	24.1 \pm 3.1***
Control, mean (S.D.)	48.7 \pm 11.6	38.3 \pm 7.4	38.3 \pm 7.4	35.3 \pm 8.2	34.3 \pm 8.2	34.3 \pm 7.8	34.3 \pm 7.8	38.2 \pm 8.5	38.2 \pm 8.5	33.1 \pm 10.5	33.1 \pm 10.5
STAI-anxiety trait											
Yoga, mean (S.D.)	42.1 \pm 8.8	33.4 \pm 3.9	33.4 \pm 3.9***	—	—	30.1 \pm 3.9**	30.1 \pm 3.9**	—	—	26.7 \pm 3.9***	26.7 \pm 3.9***
Control, mean (S.D.)	46.8 \pm 10.9	40.6 \pm 9.2	40.6 \pm 9.2	—	—	35.7 \pm 7.8	35.7 \pm 7.8	—	—	34.9 \pm 10.8	34.9 \pm 10.8
Symptom distress											
Yoga, mean (S.D.)	13.9 \pm 9.5	9.2 \pm 8.3	9.2 \pm 8.3***	10.1 \pm 6.5***	5.4 \pm 5.6***	31.8 \pm 4.7	31.8 \pm 4.7	15.3 \pm 9.7***	15.3 \pm 9.7***	5.1 \pm 6.5*	5.1 \pm 6.5*
Control, mean (S.D.)	15.8 \pm 8.5	34.4 \pm 8.7	15.3 \pm 5.7	19.8 \pm 10.1	10.1 \pm 4.7	37.6 \pm 7.8	37.6 \pm 7.8	31.6 \pm 11.1	31.6 \pm 11.1	12.8 \pm 10.7	12.8 \pm 10.7

* p values < 0.05 , ** p values < 0.01 , *** p values < 0.001 , for post hoc tests comparing groups at different time points using Bonferroni correction. y = yoga, c = control/supportive therapy group.

^a Y (n = 18), C (n = 20).

Table 3 Comparison of scores between yoga and control groups at baseline and following intervention on intention to treat analysis using RMANOVA in the initially randomized sample ($n = 98$)

Measures	Baseline (mean \pm S.D.)	Post-intervention (mean \pm S.D.)
Anxiety state		
Yoga ($n = 45$)	47.7 \pm 11.1	37.8 \pm 11.6*
Control ($n = 53$)	51.1 \pm 10.9	45.9 \pm 14.2
Anxiety trait		
Yoga ($n = 45$)	45.7 \pm 10.8	37.9 \pm 13.8
Control ($n = 53$)	48.5 \pm 10.3	41.5 \pm 12.3

y = yoga, c = control/supportive therapy group.

* $p < 0.05$ for post hoc tests comparing groups at different time points using Bonferroni correction.

the control group. There was also a corresponding decrease in anxiety trait scores by 7% following surgery, 8.1% following radiotherapy, and 10.4% following chemotherapy from their baseline means as compared to controls. However, the decrease was less on intention to treat analysis. Our results are bolstered by other studies in non-cancer populations using yoga intervention that have clearly demonstrated both change in state and trait anxiety following 10 days to 6 months of intervention.^{31,34–38}

In all these studies the effect size for reduction in anxiety by yoga were large (>0.8), where as in our study the effect size (Cohen's f) for anxiety state was 0.33 and trait was 0.24. Another randomized controlled trial in cancer patients using the anxiety subscale of the Profile of Moods Scale also reported large effect size with MBSR intervention.^{39,40} High effect sizes seen with the above intervention could be due to absence of an effective control intervention. It can be argued that a modest effect size (<0.5) seen with our intervention could be due to the fact that we controlled for education, support and attention in these subjects that could have reduced the effects of our intervention. Another reason could also be for the fact that patients were followed over a long period and repeat measurements could have reduced the effect size of our intervention. Nevertheless, our finding that yoga helped reduce treatment-related dis-

tress and severity at various treatment follow-up intervals support the anxiolytic effects of our intervention.

Overall, the results suggest that anxiolytic effects of yoga program could be attributed to stress reduction rather than mere social support and education in conformity with earlier studies.^{41,42} Scores on anxiety state and trait correlated directly with symptom severity and distress at various stages of conventional treatment further supporting the idea that reductions in anxiety could contribute to decrements in treatment-related distress and outcomes.⁴³ Earlier studies also show that state and distressful symptoms can also change an individual's personality trait⁴⁴ and hence trait changes can also be seen with our intervention. Earlier studies have shown that though distressful symptoms do influence traits, they are independent of each other and changes could be actually related to test retest issues and the inadequacy of the trait scale itself and not related to change in distressful symptoms. However, trait changes were not significant on intention to treat analysis and the results must therefore be viewed with caution. We have shown earlier that yoga has been helpful in reducing aversive reactions to chemotherapy such as nausea and vomiting.³³ A reduction in symptom distress and subjective severity is an important benefit to be gained via stress reduction techniques such as yoga.

We chose to have individual yoga therapy and supportive counselling sessions as compared to group therapy as being in a group could have confounded the benefits conferred by our interventions.⁴⁵ Moreover, these individual sessions also helped to understand the specific needs and concerns of participants and monitor individual progress in practice. Finally, none of the patients in our study reported any musculoskeletal complaints or any other adverse event that may be related to yoga practice indicating that the yoga module developed for cancer patients was safe.

We have also demonstrated that this yoga intervention package could be used in a cancer centre along with the routine treatment without any need for additional expensive infrastructure. This would be feasible and cost effective especially in a developing country where supportive services for cancer patients are rarely available and access to care is not affordable for the majority of the cancer population.

One of the major limitations in our study is the inequality in contact duration of interventions. Supportive therapy interventions were used only with an intention of negating the confounding variables such as instructor–patient interaction, education, and attention.⁴⁶ However, inequality in contact duration of this intervention could have affected its effectiveness as successes of such interventions depend mainly on contact duration and content. Similar supportive sessions have been used successfully as a control comparison group to evaluate psychotherapeutic interventions^{46,47} and have been effective in controlling chemotherapy related side effects.⁴⁸ Secondly; it was not possible to mask the yoga intervention from the study participants. Blinding in yoga studies is a topic of intense discussion in yoga research. As yet there has been no perfect method for blinding yoga therapy from the participants because of the nature of the therapy itself, which involves the patients being asked to perform asanas as well as a spiritual component that includes the knowledge that they are performing yoga.

Table 4 Pearson correlation (r values) between anxiety scores and treatment-related symptoms (severity and distress) at various conventional treatment intervals

	Symptom severity r (95% CI)	Symptom distress r (95% CI)
Post-surgery		
Anxiety state	0.66 (0.62–1.1)	0.65 (0.34–0.84)
Anxiety trait	0.68 (0.77–1.3)	0.69 (0.66–1.2)
During radiotherapy		
Anxiety state	0.73 (0.62–0.98)	0.73 (0.5–0.79)
Anxiety trait	0.60 (0.62–1.15)	0.58 (0.67–1.15)
During chemotherapy		
Anxiety state	0.58 (0.27–0.57)	0.64 (0.26–0.70)
Anxiety trait	0.49 (0.31–1.1)	0.50 (0.41–1.1)

Conclusions

In summary, our yoga-based intervention was effective in reducing reactive anxiety and trait anxiety in early breast cancer patients undergoing conventional cancer treatment. This was probably facilitated through stress reduction and helping the cancer patients to cope better with their illness at various stages of their conventional treatment. Future studies should explore the putative neurophysiologic mechanisms underlying the anxiolytic effects conferred by yoga intervention.

Acknowledgements

We are thankful to Dr Jayashree, Mrs. Anupama for imparting the yoga intervention. We are thankful to Dr. B.N. Gangadhar, Prof and Head, Department of Psychiatry for editing this manuscript. We are thankful to Central Council for Research in Yoga and Naturopathy, Ministry of Health and Family Welfare, Govt. of India for funding this study.

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