

# Yoga of Awareness program for menopausal symptoms in breast cancer survivors: results from a randomized trial

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## Abstract

**Goal of work** Breast cancer survivors have limited options for the treatment of hot flashes and related symptoms. Further, therapies widely used to prevent recurrence in survivors, such as tamoxifen, tend to induce or exacerbate menopausal symptoms. The aim of this preliminary, randomized controlled trial was to evaluate the effects of a yoga intervention on menopausal symptoms in a sample of survivors of early-stage breast cancer (stages IA–IIB). **Materials and methods** Thirty-seven disease-free women experiencing hot flashes were randomized to the 8-week Yoga of Awareness program (gentle yoga poses, meditation, and breathing exercises) or to wait-list control. The primary outcome was daily reports of hot flashes collected at baseline, posttreatment, and 3 months after treatment via an interactive telephone system. Data were analyzed by intention to treat.

**Main results** At posttreatment, women who received the yoga program showed significantly greater improvements relative to the control condition in hot-flash frequency, severity, and total scores and in levels of joint pain, fatigue, sleep disturbance, symptom-related bother, and vigor. At 3 months follow-up, patients maintained their treatment gains in hot flashes, joint pain, fatigue, symptom-related bother, and vigor and showed additional significant gains in negative mood, relaxation, and acceptance.

**Conclusions** This pilot study provides promising support for the beneficial effects of a comprehensive yoga program for hot flashes and other menopausal symptoms in early-stage breast cancer survivors.

**Keywords** Breast cancer · Hot flashes · Pain · Yoga · Meditation

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## Introduction

Breast cancer survivors currently have limited options for the treatment of troublesome menopausal symptoms such as hot flashes, joint pain, fatigue, sleep disturbance, and negative mood. Menopausal symptoms in these women are often especially prevalent and severe, yet hormone therapy is contraindicated for most breast cancer survivors [5, 26]. Furthermore, medications commonly used to prevent reoccurrence of breast cancer, such as tamoxifen and aromatase inhibitors, frequently induce or exacerbate menopausal symptoms [5].

Yoga is an increasingly popular mind/body discipline which holds promise for reducing menopausal symptoms in breast cancer survivors. Although no studies have yet addressed yoga's effects on menopause symptoms in breast cancer survivors, a randomized controlled trial (RCT) and

two small uncontrolled studies have examined these effects in normal healthy women. In the RCT, 164 low-active middle-aged women who had experienced at least one hot flash or night sweat during the past month were randomized to yoga, walking, or wait-list control [12]. Mental health measures were the primary outcomes in this study, and results showed improvement in mood and menopause-related quality of life. While menopausal symptoms themselves did not significantly improve, the inclusion of women with low levels of these symptoms was problematic, and the study's authors acknowledged the trial was underpowered for detecting effects on menopausal symptoms. In contrast, one of the two uncontrolled pilot studies reported that among 14 postmenopausal women experiencing  $\geq 4$  hot flashes per day, pre- to postreductions were observed in hot-flash frequency and severity, along with improvements in sleep quality, musculoskeletal symptoms, and menopause-related quality of life [3]. Similarly, the other pilot study examined a sample of 12 peri- or postmenopausal women experiencing  $\geq 4$  hot flashes per day on at least 4 days/week and reported pre- to postreductions in the severity of hot flashes and sweats and improved sleep quality [9]. Evidence suggesting yoga could be helpful for menopausal symptoms in breast cancer survivors also comes from recent breast cancer trials in which yoga interventions have demonstrated positive effects on symptoms that commonly accompany menopausal hot flashes, including negative mood [1, 11, 24] and pain and fatigue [7].

In recent years, yoga—practiced for millennia in India for its proposed physical, mental, and spiritual benefits [31]—has been adopted by large numbers of US cancer patients of all cultural backgrounds [21]. Yoga is now offered as a complementary therapy at many major treatment centers (e.g., M.D. Anderson, Memorial Sloan-Kettering). There are a number of potential pathways by which yoga could have a beneficial effect on women experiencing menopausal symptoms. Firstly, studies have demonstrated that yoga produces the relaxation response (an integrated set of changes that includes increased breath volume, decreased heart rate, etc) [32]. Given that heightened sympathetic activation has been implicated in the generation of hot flashes, researchers have posited that relaxation techniques are likely to reduce hot flashes and related symptoms [13].

Secondly, research has shown that yoga produces invigorating effects on mental and physical energy, which are similar to some of the effects of aerobic exercise [2], and thereby may improve sleep and fatigue [7, 10]. A sense of refreshed vitality and decreases in sleep disturbances and fatigue could hence be postulated as potential outcomes.

Thirdly, historically, yoga has placed an emphasis on accepting one's moment-to-moment experiences, whatever they may be [7]. This is because struggling to control one's

sensations, thoughts, or emotions is often counterproductive. Research shows such control efforts produce heightened psychological distress and increased sympathetic activation [18]. Psychological distress is a common trigger of hot flashes [20], and the role of a healthy sense of acceptance in decreasing distress in the face of unpleasant symptomatology has received increasing research and clinical attention [23].

Taken together, then, it seemed possible that, through increases in relaxation, vigor, and acceptance, yoga could have a beneficial impact on survivors experiencing menopausal symptoms. The present study was designed as a pilot investigation of the feasibility and potential effects of a comprehensive yoga program, "Yoga of Awareness," in which postures are complemented by meditation techniques, breathing exercises, didactic presentations, and group discussions [7]. This program draws strongly on the Kripalu school of yoga, which emphasizes not only the proper mechanics of postures but also the calm observation of mental and emotional fluctuations. The program was tailored for this study to address hot flashes and other menopausal symptoms in breast cancer survivors. We hypothesized the intervention would be superior to a wait-list control condition on measures of menopausal symptoms (i.e., hot flashes, joint pain, fatigue, negative mood, sleep disturbance, night sweats, and symptom-related bother) at posttreatment and 3 months follow-up. Hot flash total scores, computed as frequency  $\times$  severity, was the primary outcome [30].

## Materials and methods

### Participants and setting

Volunteers for this study included 37 adult women survivors of early-stage breast cancer referred by oncologists at the Duke University Medical Center breast oncology unit between June 2005 and October 2006. To be eligible, patients had to meet the following criteria: experiencing at least one hot flash per day on four or more days per week; no signs of active breast cancer; no current cytotoxic chemotherapy; diagnosed with breast cancer at stages IA–IIB  $\geq 2$  years before (2 years was chosen to help ensure relatively stable menopause processes, as women may recover ovarian function after chemotherapy); no hormone replacement therapy currently or within prior 3 months; stabilized on a constant regimen of menopausal symptom medications and supplements for at least 3 weeks; and if taking antidepressants, stabilized at a fixed dose for at least 3 months. Patients were excluded if they resided  $>70$  miles from the research site and thus were less likely to attend intervention sessions; if they were unavailable to attend the intervention on the day and at

the time offered (most yoga groups were scheduled so as to be accessible to women holding full-time day jobs); if they were currently engaged in intensive yoga practice (>3 days/week); if they had received treatment for serious psychiatric disorders (e.g., schizophrenia) in the previous 6 months; or if they were not English speaking.

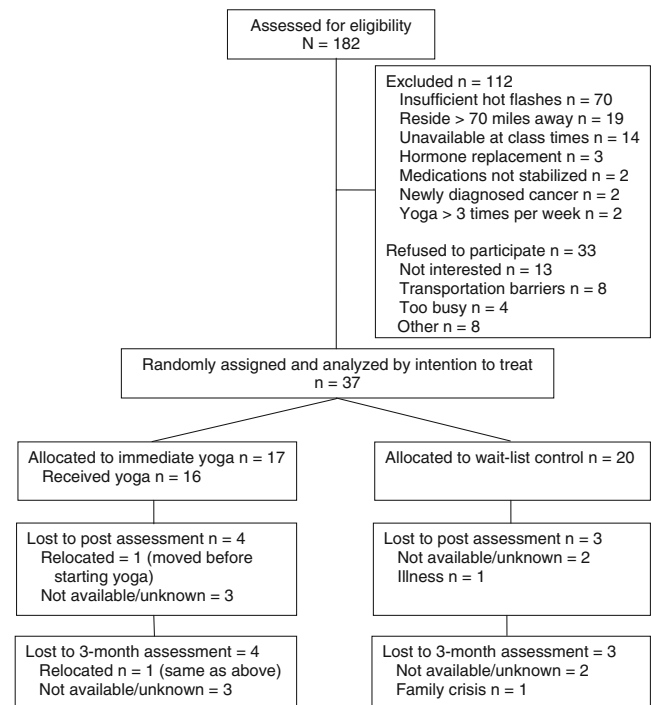
We included women taking medications affecting menopausal symptoms (e.g., antidepressants, clonidine) or supplements that might affect their symptoms (e.g., black cohosh, phytoestrogens) because (a) given the pilot nature of this trial and the rapidly growing use of medications and supplements among women experiencing menopausal symptoms [5], we preferred to avoid restricting a significant portion of women from enrolling in the study; and (b) though several antidepressants (e.g., venlafaxine, fluoxetine) have been shown to moderately reduce menopausal symptoms, they do not eliminate them [5], hence our proviso that women be actively experiencing hot flashes assured the possibility that the intervention could further reduce women's symptoms.

The primary aim of this study was to test whether changes in hot flash total scores would be significantly different in the yoga vs. control group at posttreatment and follow-up. Of the 182 women who were assessed for eligibility (Fig. 1), 112 did not meet criteria (primarily because of insufficient hot flashes). Of the remaining 70 potential participants, 33 declined (39% not interested, 24% transportation barriers, 12% too busy, 9% other medical conditions (e.g., severe osteoporosis), 3% poor health in family, 12% passive refusal/no response). Declining to participate was not significantly related to any prescreening variables (i.e., patients' age, race, disease stage, or years since diagnosis).

Of the 37 who consented, 100% completed baseline measures and were randomized (yoga=17, wait-list=20). Power calculations had suggested that an initial sample of 40, with approximately 20 per group, would provide >80% power to detect a moderate size (e.g., 0.50) between-groups effect. Thus, due to recruitment issues, power in this study fell narrowly short of the 80% criterion. The completion rate at both the posttreatment and 3-month assessments was 81% and similar across the yoga (13/17=76%) and control (17/20=85%) conditions ( $\chi^2=0.436$ ;  $p=0.509$ ). In most cases, non-completers were lost to contact (e.g., telephone disconnected, no response to messages),  $n=5$  at posttreatment,  $n=5$  at 3 months. Other reasons cited were relocation ( $n=1$  at post), illness ( $n=1$  at post), and family crisis ( $n=1$  at 3 months). No demographic, medical, or baseline-dependent variables were significantly predictive of assessment completion.

## Procedure

The protocol for this study was approved by the Duke Institutional Review Board. After signing informed consent



**Fig. 1** Flow diagram of study enrollment and attrition

forms, patients completed the baseline assessment. Patients were then randomly assigned to either start the yoga program immediately (yoga group) or 6 months later (wait-list control group). Randomization assignments were generated by an individual not involved in the study using a random number table. Assignments were concealed in envelopes that were not opened until patients had completed their baseline assessment. Patients completed additional assessments at posttreatment and at 3 months follow-up. The research assistant collecting assessment data was kept blind with regard to patient condition assignments. Patients received up to \$80 for completing assessments (\$20 each at baseline, posttreatment and 3 months, plus an added incentive for each completed data diary, see description below). Throughout their participation in the study, patients continued to receive the standard care provided by their health care providers.

**Yoga of Awareness program** The intervention consisted of eight weekly 120-min group classes (5–10 patients per group) at the Duke Pain Prevention offices. The groups were jointly led by a certified yoga teacher who holds a master's degree in health behavior and education (K.M.C.) and a clinical health psychologist (J.W.C.). Both intervention leaders were experienced in teaching yoga and meditation techniques to medical patients and had undergone comprehensive training in traditional schools of yoga. To standardize delivery of the intervention, a manual was developed which provided detailed class guidelines fol-

lowed by the intervention leaders. All classes were videotaped, and the treatment team met weekly to review classes. On average, participants attended six of the eight classes (range 0 to 8). Only three women attended <4 classes: one relocated to another state before her first class; one did not return after the first class and cited chronic noncancer-related pain (also unrelated to yoga practice); one did not return after the first two classes and cited marital problems.

Yoga of Awareness is an innovative, comprehensive yoga program, which for this study was tailored to address hot flashes, fatigue, and mood disturbances. Each class included approximately 40 min of gentle stretching poses<sup>1</sup>, 10 min of breathing techniques, 25 min of meditation, 20 min of study of pertinent topics, and 25 min of group discussions (further details of the program have been published elsewhere [7]). Patients were supplied with yoga mats, blankets, and bolsters for doing yoga poses. During classes, the intervention leaders highlighted the need for gentle practice when one's body is challenged, and they modified instructions as appropriate to individual patients' needs (e.g., discomfort related to reconstructive surgery). Participants were encouraged to spend time practicing yoga strategies daily at home with the aid of CD recordings and illustrated handbooks, and applications to daily life were assigned each week (e.g., in-the-moment acceptance of hot flash events).

*Wait-list control group* Patients assigned to the wait-list condition were contacted by the research assistant as needed to remind them of the posttreatment and 3 months assessments. After completing the 3 months assessment, these women were invited to participate in the yoga program. However, they were not asked to complete further outcome assessments.

## Measures

Treatment outcomes were assessed via a brief daily diary measurement strategy. Similar diaries are widely employed in menopause studies to evaluate symptom outcomes [30]. Advantages of daily diary data include their demonstrated reliability and validity for hot flashes, their ability to capture reports of internal events (e.g., pain, emotions) in individuals' natural settings, and provide increased statisti-

cal power when analyzing a small clinical sample [29, 30]. We have used daily measures in prior studies and have found excellent compliance (e.g., 89% complete data [7]).

In this study, daily diaries were collected prior to the intervention for 2 weeks (baseline), during the final 2 weeks of the 8-week intervention (posttreatment), and 3 months after the intervention ended for 2 weeks (follow-up). Diary data was collected via an interactive telephone voice system. Participants were provided a toll-free number to call each day during diary collection periods. A computer responded and used prerecorded voice prompts to ask participants to enter responses to diary items by pressing numbers on their telephone. Data from responses were automatically transferred into a computerized database. This method of collecting diary data minimizes errors and marks each data bit with a precise date and time of collection.

Participants were trained at baseline by a research assistant to use the interactive telephone voice system. Patients were also called during the first week of each recording period to inquire about any difficulties. To further facilitate motivation and compliance, patients were paid \$0.25 for each completed daily diary. The baseline diary completion rate was good, 87% (449 of 518 potentially reportable days across 37 participants, range 57% to 100%). Among patients who completed the posttreatment assessment, the diary completion rate was 94% (396 of 420 potentially reportable days across 30 participants, range 57% to 100%). Among patients who completed follow-up assessment, the diary completion rate was 91% (393 of 420 potentially reportable days across 30 participants, range 50% to 100%). Completion rates were not significantly related to treatment condition at any time period.

*Daily menopausal symptoms* Using 0–9 scales in which higher scores reflected greater amounts, the telephone voice system diaries assessed the following common menopausal symptoms across the preceding 24 h: hot flash frequency, hot flash severity, joint pain, fatigue, negative mood, sleep disturbance, night sweats, and bother (menopausal symptom-related distress). The primary outcome of hot flash total scores was computed as frequency  $\times$  severity [30].

*Daily therapeutic processes and yoga practice* Using 0–9 scales in which higher scores reflected greater amounts, three therapeutic processes targeted by the Yoga of Awareness program—relaxation, vigor, and acceptance—were assessed by the telephone voice system diaries. Participants assigned to the intervention condition were also asked to record minutes spent in daily yoga practice (post and follow-up assessments only).

*Treatment credibility* Prerandomization expectations with regard to the yoga intervention's potential for relieving

<sup>1</sup> Yoga poses consisted of either a mat-based sequence (Warm-ups, Child's pose, Table, Downward-Facing Dog Flow, Half Moon, Warrior 1 Flow, Extended Side Angle, Modified Locust, Supine Squats, Supine Big-Toe, Supine Sage Twist with Bolster, Corpse) or a chair-based sequence (Warm-ups, Cat/Cow, Thoracic Spine Twist Flow, Sun Salutation, Standing Wide Angle Fold, Standing Wide Angle Fold with Thoracic Twist, Prayer Flow, Seated Wide Angle Fold, Head To Knee, Pigeon, Forward Fold, Modified Sage Twist, Seal of Yoga, Corpse).

menopausal symptoms were measured by a credibility questionnaire [4] which was completed by all patients based on a description of the program provided during the initial study interview.

**Demographic and history information** Information about demographics, breast cancer treatment, and timing of menopausal symptoms onset was collected from the patients and from medical chart review. Also, at each of the three assessments, information was collected about patients' use of medications and supplements and any recent use of yoga (to monitor possible contamination in the control condition).

## Results

A series of regression and chi-square analyses determined that there were no statistically significant differences between the yoga and wait-list control groups in demographic and medical characteristics, baseline dependent

measures, and prerandomization treatment credibility. Patients' average daily frequency of hot flashes at baseline was 4.33 (yoga=4.40, range=1.56 to 8.64; control=4.27, range=1.21 to 8.71). The average prerandomization credibility rating across the study participants was high, 8.0 out of potential range of 0.0 to 10.0 (yoga=8.4, SD=1.5; control=7.6, SD=1.9). Many patients were concurrently taking antidepressants or other medications that tend to decrease hot flashes (overall=40.5%, yoga=35.3%, control=45.0%), and most participants were taking medications that have the contrasting effect of increasing hot flashes, specifically aromatase inhibitors (overall=59.5%, yoga=58.8%, control=60.0%) or tamoxifen (overall=13.5%, yoga=11.8%, control=15.0%) [5, 25]. Along with testing for baseline between-group differences in these two medication categories, an analysis of pre- to postchanges in these categories—scored as increased, decreased, or no change in the number of medications fitting each category [19]—showed no significant differences between treatment conditions at either posttreatment or follow-up.

The characteristics of the sample are summarized in Table 1. The mean age of the 37 patients in the study was

**Table 1** Baseline sociodemographic and medical characteristics of breast cancer survivors: means (standard deviations) for continuous variables and frequencies (percentages) for categorical variables

Characteristic	Total sample (N=37)	Yoga group (n=17)	Wait-list group (n=17)
Age (years)	54.4 (7.5)	53.9 (9.0)	54.9 (6.2)
Years since diagnosis	4.9 (2.4)	4.6 (2.2)	5.1 (2.5)
Years since LMP	6.4 (4.6)	5.7 (4.7)	7.0 (4.5)
Race/ethnicity			
African American	7 (18.9%)	2 (11.8%)	5 (25.0%)
White	30 (81.1%)	15 (88.2%)	15 (75.0%)
Education			
Less than college	11 (29.7%)	6 (35.3%)	5 (25.0%)
College degree	15 (40.6%)	7 (41.2%)	8 (40.0%)
Graduate studies	11 (29.7%)	4 (23.5%)	7 (35.0%)
Marital status			
Partnered	28 (75.7%)	12 (70.6%)	16 (80.0%)
Not partnered	9 (24.3%)	5 (29.4%)	4 (20.0%)
Stage of disease			
IA	15 (40.5%)	7 (41.2%)	8 (40.0%)
IIA	11 (29.7%)	5 (29.4%)	6 (30.0%)
IIB	11 (29.7%)	5 (29.4%)	6 (30.0%)
Surgery			
Lumpectomy	11 (29.7%)	6 (35.3%)	5 (25.0%)
Mastectomy	24 (64.9%)	10 (58.8%)	14 (70.0%)
Oophrectomy	11 (29.7%)	5 (29.4%)	6 (30.0%)
Cancer treatments			
Current tamoxifen	5 (13.5%)	2 (11.8%)	3 (15.0%)
Current AI	22 (59.5%)	10 (58.8%)	12 (60.0%)
Prior radiation	18 (48.6%)	7 (41.2%)	11 (55.0%)
Prior chemotherapy	26 (70.3%)	14 (82.4%)	12 (60.0%)

LMP last menstrual period, AI aromatase inhibitor

54.4 years (SD=7.5), and average time since diagnosis was 4.9 years (SD=2.4). Participants were 81.1% Caucasian and 18.9% African American, 75.7% were currently married or in a partnered relationship, and most were well educated (70.3%  $\geq$  college degree).

#### Treatment effects on daily outcomes

The outcome analyses for this study are based on an advanced statistical approach called multilevel modeling which is especially advantageous for analyzing data sets with many repeated measures [8, 29]. In multilevel models, regression values are independently computed for each patient in the sample and then aggregated to derive adjusted means (i.e., intercepts) for the average patient. Intention-to-treat methods were followed, using the last-observation-carried-forward method. Because this was a pilot study and we were concerned about the need to balance committing type 1 error against the possibility of dismissing potentially important findings, a minimum alpha level of 0.05 was used for all analyses. Two-sided statistical tests were used throughout. For a more complete description of the multilevel equations reported herein, readers may contact the first author.

To examine treatment effects, models tested whether adjusted means (i.e., intercepts) for daily outcomes changed differentially in the two groups from baseline to posttreatment and baseline to follow-up [6, 8]. Table 2 shows the baseline and posttreatment adjusted means by group and the time  $\times$  treatment effect values at posttreatment. Results demonstrated significant improvements in the yoga condition vs. the control condition in daily hot flash frequency, severity, and in the primary outcome of hot flash total

scores (frequency  $\times$  severity). Figure 2 displays a graph of daily hot flash total scores at baseline and posttreatment. The yoga group in addition showed significant posttreatment improvements relative to the controls in daily joint pain, fatigue, sleep disturbance, symptom-related bother, and vigor. Trends approaching significance were apparent for negative mood and acceptance.

Table 3 shows the outcome values at 3 months follow-up. At follow-up, patients in the yoga condition maintained their treatment gains in hot flashes, joint pain, fatigue, symptom-related bother, and vigor and showed additional significant gains in negative mood, relaxation, and acceptance.

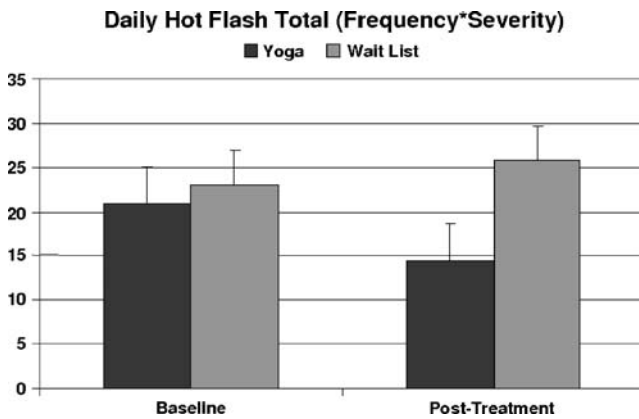
#### Supplementary outcomes analyses

Two supplementary outcomes analyses were performed to ascertain whether findings differed substantially when (a) data were from completed assessments only, or (b) data excluded three wait-list participants who reported at the posttreatment assessment that they had been engaging in yoga practice to some extent (one practiced meditation daily, one attended two yoga classes per week, one attended occasional yoga classes). With several exceptions, the results from both supplementary analyses were nearly identical to those obtained from intent-to-treat analyses. The only difference in findings for the completers-only analysis was that at posttreatment there was significantly higher acceptance in the yoga group ( $p=0.024$ ). When we excluded the three wait-list participants practicing yoga, the only difference in findings was that significantly lower negative mood ( $p<0.001$ ) and significantly higher acceptance was found at posttreatment for participants in the yoga group ( $p<0.001$ ).

**Table 2** Baseline adjusted means (Pre), posttreatment adjusted means (Post), and time  $\times$  treatment effect values

Variable	Yoga		Control		$\beta$	$t$	$p$
	Pre	Post	Pre	Post			
Hot flash frequency	4.44	3.73	4.29	4.40	-0.83	-3.25	0.0017**
Hot flash severity	4.16	3.21	4.67	4.41	-0.65	-3.23	0.0019**
Hot flash total	20.92	14.46	23.01	25.81	-9.27	-4.67	<0.0001***
Joint pain	3.69	2.87	3.76	4.35	-1.41	-6.63	<0.0001***
Fatigue	3.08	2.87	3.80	4.34	-0.76	-3.42	0.0010**
Negative mood	3.17	2.64	3.51	3.33	-0.36	-1.69	0.0954 <sup>^</sup>
Sleep disturbance	3.82	3.29	4.21	4.37	-0.68	-2.77	0.0071**
Night Sweats	3.02	2.87	3.74	3.42	0.18	0.77	0.4457
Symptom-related Bother	3.13	1.99	3.60	3.50	-1.04	-4.29	<0.0001***
Relaxation	5.25	5.93	4.37	4.90	0.15	0.61	0.5431
Vigor	5.04	5.79	4.40	4.50	0.61	2.93	0.0046*
Acceptance	6.63	7.06	5.78	5.77	0.44	1.93	0.0571 <sup>^</sup>

\* $p<0.05$ ; \*\* $p<0.01$ ; \*\*\* $p<0.001$ ; <sup>^</sup> $p<0.10$  (trend)



**Fig. 2** Daily hot flash total scores at baseline and posttreatment in the yoga and wait-list groups ( $p < 0.001$ ). Values are multilevel random effects for adjusted means, with bars showing standard errors

#### Relationship of yoga practice rates to outcomes

Post hoc correlational tests, excluding noncompleters and three wait-list women doing yoga, showed mean yoga practice time (minutes spent in formal use of the yoga postures, breathing, and meditation exercises) was significantly correlated at posttreatment with fatigue, symptom-related bother, and acceptance scores, such that greater practice was associated with less fatigue ( $r[27] = -0.413$ ,  $p = 0.032$ ), less bother ( $r[27] = -0.376$ ,  $p = 0.050$ ), and more acceptance ( $r[27] = 0.442$ ,  $p = 0.021$ ). Posttreatment trends also suggested greater practice was associated with less sleep disturbance ( $r[27] = -0.342$ ,  $p = 0.081$ ). At 3 months follow-up, mean practice time was significantly correlated with fatigue and symptom-related bother, again with greater practice associated with less fatigue ( $r[26] = -0.439$ ,  $p = 0.025$ ) and bother ( $r[26] = -0.409$ ,  $p = 0.038$ ). Trends at 3 months also suggested associations between greater

practice and more relaxation ( $r[26] = 0.351$ ,  $p = 0.079$ ) and more acceptance ( $r[26] = 0.370$ ,  $p = 0.063$ ). Yoga participants ranged in practice between 7.3 and 64.6 min daily ( $M = 30.15$ ,  $SD = 14.23$ ) at posttreatment and between 0 min and 40.7 min daily ( $M = 16.10$ ,  $SD = 14.13$ ) at 3 months.

#### Discussion

This pilot study examined the impact of a yoga intervention on menopausal symptoms in a sample of early-stage breast cancer survivors. Our findings provide preliminary evidence that the intervention may be helpful for improving hot-flash frequency, severity, and total scores, as well as joint pain, fatigue, sleep disturbance, symptom-related bother, and vigor. With the exception of relief from sleep disturbance, improvements observed at postintervention continued to be evident 3 months later, plus negative mood, relaxation, and acceptance also demonstrated significant gains at 3 months. Thus, along with obtaining promising evidence for menopausal symptom improvements, we found empirical support for three therapeutic changes—increases in relaxation, vigor, and acceptance—that yoga appears to promote.

Although yoga has been practiced for millennia, only recently have researchers begun to demonstrate yoga's effects on patients with cancer [1, 10, 11, 24, 28] and other conditions (e.g., osteoarthritis, low back pain, multiple sclerosis [16, 27, 33]). Yoga trials targeting menopausal symptoms in normal healthy women have produced mixed results, with two pilot observational studies reporting improvements in hot flashes and sleep quality but one underpowered RCT showing no effect on menopausal symptoms [3, 9, 12]. The present trial differed substantially from those not only in its population—i.e., breast cancer

**Table 3** Baseline adjusted means (Pre), 3 months follow-up adjusted means (FU), and Time  $\times$  Treatment effect values

Variable	Yoga		Control		$\beta$	$t$	$p$
	Pre	FU	Pre	FU			
Hot flash frequency	4.46	3.19	4.34	4.42	-0.67	-5.17	<0.0001***
Hot flash severity	4.11	3.17	4.71	4.40	-0.32	-3.14	0.0024**
Hot flash total	20.90	13.80	23.13	24.18	-4.08	-4.36	<0.0001***
Joint pain	3.68	3.16	3.83	4.48	-0.59	-4.72	<0.0001***
Fatigue	3.08	3.01	3.86	4.58	-0.40	-3.42	0.0010**
Negative mood	3.11	1.94	3.54	3.44	-0.54	-4.46	<0.0001***
Sleep disturbance	3.80	3.01	4.23	3.79	-0.17	-1.37	0.1740
Night sweats	3.02	2.68	3.77	3.28	0.07	0.58	0.5606
Symptom-related bother	3.12	1.93	3.65	3.50	-0.53	-4.17	<0.0001***
Relaxation	5.25	6.25	4.35	4.81	0.27	2.18	0.0324
Vigor	5.05	6.12	4.37	4.19	0.62	5.85	<0.0001***
Acceptance	6.65	7.44	5.78	5.56	0.51	4.46	<0.0001***

\* $p < 0.05$ ; \*\* $p < 0.01$ ; \*\*\* $p < 0.001$

survivors, who typically experience more severe menopausal symptoms than most women—but also in the form of the intervention. Whereas yoga instruction was largely limited to postures in the cited studies (with brief attention to breathing exercises in one case [3]), the Yoga of Awareness program employed in the present study emphasized not only postures but also meditation, breathing techniques, didactic presentations, and group discussions. Time commitment for the Yoga of Awareness program (eight weekly 120-min classes) was intermediate relative to the cited studies (ranging from 8 weekly 90-min classes [9], to 10 weekly 75-min classes [3], to 16 twice weekly 90-min classes [12]). Future studies are needed to sort out whether (a) a similarly comprehensive and time-intensive approach is efficacious when applied to normal healthy women or (b) perhaps only the yoga postures (or other components) are needed to effectively impact menopausal symptoms among normal women as well as breast cancer survivors.

Regarding the improvement seen in pain in this study, this is in keeping with an earlier, uncontrolled trial in which Yoga of Awareness was modified to target pain in metastatic breast cancer patients [7]. These consistent findings on cancer-related pain, coupled with pain improvements reported in yoga trials with other populations [16, 17, 33], raise the intriguing possibility that yoga may be helpful in counteracting the arthralgia syndrome associated with aromatase inhibitors and in ameliorating corresponding medication compliance problems [25].

Our findings confirmed the feasibility of conducting further studies of Yoga of Awareness with breast cancer patients. Accrual and retention rates were acceptable (cf. [12]). Attendance at classes was good (average six out of eight sessions), as was adherence to yoga practice (average 30 min/day at post and 16 min at 3 months). Notably, those who practiced yoga more had better outcomes on several measures. Patients' anecdotal reports also suggested that they found the yoga training useful in managing their symptoms. For example, one patient remarked that "I can see a hot flash coming and say, 'oh yeah I can ride this wave,'" and another commented that the crucial aspect for her was "the acceptance part, that it is alright to let go."

Important limitations of our study should be noted. The generalizability of these preliminary findings is restricted by the small sample and resultant limits on statistical power, absence of long-term follow-up, and exclusive reliance on self-report data [26]. Another important limitation comes from the lack of an attention placebo control condition. The 31% reduction in hot flash total scores observed in this study fits within the range of changes often reported when placebos are administered in medication trials [22]. However, placebo effects may be smaller for behavioral interventions such as yoga than those seen in

drug studies [9]. In previous trials of nonpharmacological interventions for hot flashes, no significant improvements were reported for active control conditions such as muscle relaxation and biofeedback [15]. Inclusion of an active control condition is hence crucial for a larger, more thorough study of yoga for menopausal symptoms in survivors. Such a trial should also incorporate sternal skin conductance monitoring, a validated objective measure of hot flash frequency (but not severity) [14]. Further methodological improvements for such a study could include analyses of potential mechanisms of therapeutic effects—including both physiological (e.g., changes in anterior insular cortex activation as measured by functional magnetic resonance imaging [14]) and psychological mechanisms (e.g., relaxation, invigoration, acceptance), analyses of moderators of treatment outcome (e.g., is yoga more helpful for patients with greater vs. lower body mass index), and of the types (e.g., postures vs. meditation) and doses of yoga practice needed to achieve adequate symptom reductions.

In conclusion, the findings of this pilot study provide promising preliminary support for the beneficial effects of yoga on hot flashes and related symptoms in breast cancer survivors. The improvements documented herein are important enough to warrant further study.

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