Feasibility of implementing a community-based randomized trial of yoga for women undergoing chemotherapy for breast cancer

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Background Treatment-related symptoms and decreased health-related quality of life (HRQoL) frequently occur during chemotherapy for breast cancer. Although research findings suggest that yoga can reduce symptoms and improve HRQoL after treatment, potential benefits of yoga during chemotherapy have received minimal attention.

Objective To estimate accrual, adherence, study retention, and preliminary efficacy of a yoga intervention compared with an active control group for breast cancer patients during chemotherapy.

Methods Women with stage I-III breast cancer were recruited from 3 community cancer clinics and randomized to 10 weeks of gentle yoga or wellness education. Depressive symptoms, fatigue, sleep, and HRQoL were assessed at baseline, mid-intervention (Week 5), and after intervention (Week 10).

Results 40 women aged 29-83 years (median, 48 years; 88% white) were randomized to yoga (n = 22) or wellness education (n = 18). The groups did not differ significantly on baseline characteristics, adherence, or study retention. Participant feedback was positive and comparable between groups. Meaningful within-group differences were identified for sleep adequacy and quantity in yoga participants and for somnolence in wellness-education participants.

Limitations Small sample size and lack of a usual-care control group.

Conclusions This study established feasibility of a community-based randomized trial of yoga and an active comparison group for women undergoing chemotherapy for breast cancer. Preliminary efficacy estimates suggest that yoga improves sleep adequacy. Symptom severity and interference remained stable during chemotherapy for the yoga group and showed a trend toward increasing in the control group. The study highlighted obstacles to multisite yoga research during cancer treatment.

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Breast cancer is one of the most common cancers in women, with an estimated 231,840 new diagnoses in the United States in 2015.[1] About 33% of women with breast cancer receive chemotherapy,[2] which can cause fatigue, depressive symptoms, poor sleep, and lower health-related quality of life (HRQoL).[3] Interventions to address these side effects, which are particularly severe during chemotherapy, are needed.[3,4] Findings from previous studies suggest that breast cancer survivors are interested in using yoga to manage cancer-related symptoms and for their overall well-being.[5-7] Evidence supports the favorable effects of yoga on psychological functioning,[8-13] and recent meta-analyses also suggest that yoga has moderate benefits on global HRQoL and sleep.[8,9,14] Evidence is inconsistent for the influence of yoga on fatigue, with some trials reporting decreased fatigue[15-17] and others reporting nonsignificant results.[11,13,18,19] However, most of this research was conducted among women who had completed their treatment, when symptoms may be less severe. The efficacy of yoga to address distressing symptoms during chemotherapy has received scant attention,[20] and research implementing yoga interventions has been scarce in community oncology clinics[21] compared with academic medical settings.[18-20,22]

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The present study sought to address those gaps and build on growing evidence for the efficacy of yoga in cancer patients by targeting symptoms when they are most severe (ie, during chemotherapy) and by investigating the feasibility of offering yoga through community-based sites. Implementation was facilitated through the Community Clinical Oncology Program (CCOP) Research Base of the Comprehensive Cancer Center of Wake Forest University in Winston-Salem, North Carolina. The program is a member of the National Cancer Institute's CCOP network, which has been developed to increase community participation in cancer trials.[23] This feasibility study aimed to estimate retention in and adherence to a community-based randomized trial of yoga compared with an active control condition in women undergoing chemotherapy for stage I-III breast cancer and to obtain preliminary estimates of the efficacy of a community-based yoga intervention in women with breast cancer.

Methods

Study design

In this feasibility study, women were stratified by CCOP site and chemotherapy status (planned within 3 weeks vs already started) and then randomized to a 10-week gentle yoga or wellness-education (active control) group with equal probability, using block randomization with randomly varying block sizes. Measures were obtained at baseline (Week 0), mid-intervention (Week 5), and immediately after intervention (Week 10). Institutional Review Boards at Wake Forest Baptist Health and the three participating CCOP sites at Greenville Hospital System, SC; Mission Hospital, Asheville, NC; and High Point Regional Health System, NC, approved this study.

Eligibility criteria

The eligibility criteria included: women aged 18 years or older; a diagnosis of stage I-III breast cancer; being 2-8 weeks after surgery (unless receiving neoadjuvant chemotherapy); receiving or scheduled to begin chemotherapy within 3 weeks of study registration; having an expectation of continued chemotherapy during the 10-week intervention; being physically able to participate in yoga classes (ie, sit on a chair or lie on the floor); having an Eastern Cooperative Oncology Group Performance Status (ECOG-PS) of 0-2;[24] and being able to understand an informed consent document in English. Women were excluded if they: had regularly (ie, more than once a week) practiced yoga in previous 4 weeks; had participated in moderate/vigorous physical activity 3 or more days a week (on average) in the previous 4 weeks; did not plan to receive adjuvant chemotherapy; or anticipated surgery or radiation therapy during the study.

Recruitment and data collection

Physicians and nurses at each CCOP site provided study referrals. Recruitment occurred shortly after surgery or within 3 weeks of initiating chemotherapy. That inclusion window was intentionally broad to enhance recruitment during a potentially overwhelming time. Participants were enrolled on a rolling basis to begin attending classes as close as possible to initiation of chemotherapy. All of the questionnaires were administered and collected by a research nurse or research assistant (not blinded to group assignment) at each site.

Yoga intervention

The yoga intervention consisted of weekly 75-minute yoga classes for 10 weeks. Participants who were randomized to yoga were asked to attend at least 8 of 10 classes. The classes were based in the Integral Yoga tradition, which has been used successfully in previous research.[11,25,26] Yoga instructors had completed the Yoga Therapy for People with Cancer and Chronic Illness certification program (www.yogaforpeoplewithcancer.com/) and were registered yoga teachers with Yoga Alliance, an association that represents the yoga community; had 3 or more years of experience teaching yoga; and had completed a training course on yoga therapy for individuals with cancer or chronic illness. Yoga postures were taught from a mat or chair and adapted to participant ability. All of the classes included: centering and meditation, neck and shoulder movement series, upper body range of motion stretch, leg stretch, side bend, seated twist, simple supported backbend, resting pose transition, legs up the wall pose, and supported bound-angle pose. Additional poses were included as time and participant mobility allowed.[11] Yoga participants were asked to practice yoga twice a week outside of classes. They received a mat, bolster, strap, and a 45-minute, study-specific yoga DVD.[27]

Wellness education (active control group)

Wellness education was designed to control for time, attention, and potential interactions of women in the yoga group. Participants were asked to attend at least 8 of 10 weekly, 75-minute sessions led by health educators/nurses that focused on common issues faced by women with breast cancer who were undergoing chemotherapy. The classes included guest speakers using standardized presentation materials on symptom management; finances/insurance; emotions and coping; communicating with providers and navigating the health care system; healthful eating, sexual issues, fertility, and body image; social support; survivorship and advocacy; and posttreatment concerns. Wellness-education participants were asked to spend 45 minutes twice a week reading the provided materials.

Measures

Demographic information was collected at baseline and included age, race/ethnicity, marital/partner status, education, and income. Clinical information was obtained from medical records and included the date and stage of the breast cancer diagnosis, treatment regimen, and current medications. The following measures were also used:

- Functional Assessment of Cancer Therapy–Breast (FACT–B),[28] a 36-item measure with established reliability and validity for measuring cancer-related quality of life. Physical, social, emotional, and functional well-being subscales, plus a breast cancer-specific subscale, are summed to compute the total FACT–B score ranging from 0-144, with higher scores indicating better QoL.
- FACT–Fatigue,[29] a 13-item instrument with excellent internal consistency (α = .93-.95) and test-retest reliability (r = .90) in assessing fatigue in people with cancer. Scores ranging from 0 (not at all) to 4 (very much so) are summed to yield a total score of 0-52. Higher scores indicate lower fatigue.
- Center for Epidemiologic Studies–Depression Scale (CES–D),[30] a 20-item self-report measure of depressive symptoms with excellent reliability and validity in community and oncology samples.[30,31] Total scores range from 0-60, with higher scores indicating greater depressive symptoms.
- MD Anderson Symptom Inventory (MDASI),[32] a 19-item measure of cancer-related symptoms. Thirteen items assessing worst severity of symptoms in the previous 24 hours are averaged to provide a score of 0-10; higher scores represent greater symptom severity. The MDASI also measures symptom interference with 6 daily activities (general activity, mood, work, relations with others, walking, enjoyment of life) in the previous 24 hours. The mean of the 6 items ranges from 0-10; higher scores indicate higher symptom interference.
- Medical Outcomes Study Sleep Scale (MOS Sleep),[33,34] containing 12 items that reference the previous 4 weeks. Participants report time to fall asleep and average hours of sleep per night (sleep quantity). Scores on the remaining 10 items generate a 9-item Sleep Problems Index and 6 additional subscales. The current analysis includes sleep disturbance, sleep adequacy, and daytime somnolence. Scores range from 0-100, with higher scores indicating more of the concept being measured. Spritzer and colleagues reported that internal consistency reliability in individuals with chronic illness (N = 3,445) ranged from .75-.85.[35]

Feasibility measures

We obtained data on retention by tracking completion of study measures. Adherence was measured by total number of classes attended. Reasons for missed classes were also assessed by research nurses/assistants who called participants within 1-2 days of a missed class. The participants completed tracking forms to assess their adherence to home activity. Participants provided feedback after the intervention (at Week 10), by rating classes and facilitators (eg, liked class, class helpful, teacher competent) on a scale of 0 (not at all) to 4 (very much). They also responded to open-ended questions about perceived benefit and aspects of the program they liked best or least.

Statistical analyses

Accrual of 40 participants was targeted to produce reasonably tight estimates of the parameters of interest, including attrition estimates to within 16% with 95% confidence and estimation of group means of outcome measures at each time point with a 95% confidence interval. Chi-square and Kruskal-Wallis tests assessed baseline group differences in categorical and continuous variables, respectively. Chi-square tests assessed group differences in retention and adherence proportions. T-tests assessed group differences in adherence when treated as a continuous measure. These statistical comparisons were done at the alpha = 0.05 level of significance. Although the study was not powered to detect significant differences between groups, these tests were performed for exploratory purposes and to allow estimation of treatment differences. Linear mixed effects models were used to assess treatment differences in outcomes. Models included a class variable for strata (ie, site and chemotherapy status) and were adjusted for baseline values of the outcome measure. Confidence intervals for the least squares (LS) means for outcome measures were calculated from model estimates at mean levels of covariates. Longitudinal within-group differences were evaluated using a meaningful difference criterion of 0.5 SD.[36] All analyses were performed using SAS statistical software (SAS Institute, Cary, North Carolina).

Results

Sample

In all, 40 participants were accrued during January 2010 and August 2011 (2.1 participants/month). Of those, 22 participants were randomized to yoga and 18 to wellness education (Table 1). Their age range was 29-83 years (median, 48). Most of the participants (88%) were white and married (70%). There were no significant group differences.

Study retention

Four yoga participants dropped out of the study (3 after baseline visit; 1 after Week 5). Of the 2 women who reported a reason, 1 reported fatigue and the other, difficulty attending regularly. Two wellness-education partici-

TABLE 1 Baseline characteristics of sample (N = 40)

Characteristic	Yoga, n (%) (n = 22)	Wellness education, n (%) (n = 18)	*P*
Age, y			
Median (range)	50 y (29-83)	45 y (30-65)	.53
≥ 50	11 (50)	8 (44)	.73
Strata			.68
Asheville			
Planning chemo	5 (23)	1 (6)	
Started chemo	4 (18)	4 (22)	
Greenville			
Started chemo	7 (32)	7 (39)	
High Point			
Planning chemo	2 (9)	2 (11)	
Started chemo	4 (18)	4 (22)	
Race/ethnicity			0.47
Black	2 (9)	3 (17)	
White	20 (91)	15 (83)	
Marital status			0.43
Single	1 (5)	3 (17)	
Married	16 (73)	12 (67)	
Separated/ divorced/widowed	5 (23)	3 (17)	
Surgeries			
Biopsy only	14 (64)	13 (72)	0.56
Lumpectomy	7 (32)	10 (56)	0.13
Mastectomy	11 (50)	7 (39)	0.48
Disease stage			0.70
I	3 (14)	4 (22)	
II	11 (50)	7 (39)	
III	8 (36)	7 (39)	

TABLE 2 Adherence[a]

Measurement	Yoga, n (%) (n = 21)	Wellness education, n (%) (n = 17)	*P*
Mean (range)	5.8 (0-10)	6.7 (0-10)	.39
8+ classes	10 (45)	7 (39)	.68
10 classes	2 (9)	3 (17)	.47

[a]Attendance data used to calculate adherence was missing for 1 participant in each group.

pants dropped out (1 after baseline visit; 1 after Week 5). The only woman who specified a reason reported scheduling conflicts. Retention at Week 10 was 85% and did not differ significantly between groups (82% yoga, 89% wellness education).

Class adherence

Adherence did not differ significantly between groups (Table 2), with 10 yoga participants (45%) and 7 (39%) wellness-education participants attending 8 or more classes. Two yoga and 3 wellness-education participants attended all 10 classes. The most common reasons given for absences included: illness or fatigue (56.2%), scheduling conflicts (17.8%), class canceled by teacher/facility (9.6%), child-care conflicts (5.5%), forgetting (5.5%), and weather (5.5%).

Among the participants who provided self-report data about home activity (55%), women in the yoga group averaged 2.0 days a week (SD, 2.0; range, 0-7) for an average of 98.4 min/week (SD, 62.8; range, 5-285; equivalent of two 45-minute sessions a week, as instructed). Wellness-education participants averaged 1.1 days a week (SD, 1.5; range, 0-6) for an average of 79.4 min/week (SD, 63.4; range, 15-240).

Intervention evaluation

Participant feedback was positive and comparable between groups. On all rated items, more than 90% of participants in both groups provided favorable ratings of "quite a bit" or "very much." Yoga participants reported that they enjoyed classes, felt better after class, appreciated time for self-care, noticed decreased (fewer and less intense) symptoms and improved physical function, and liked relaxing mind and body. Suggestions for improving the yoga intervention included providing a hand-out of class components, a video that offers varied yoga poses and sequences, offering more than 1 class a week, and modifications to intensify the class for women who could be more active.

Wellness-education participants reported they liked the detailed information, the time to have questions answered, and the discussions with group leaders and other participants. Suggestions to improve this program included increasing group size, providing more detailed information (eg, nutrition for estrogen-receptive positive cancer), varying the order of topics to align with women's treatment, and providing materials online.

Preliminary efficacy results

Baseline descriptive statistics and preliminary outcome data at Weeks 5 and 10 are shown in Table 3. Because the study was not powered to detect statistically significant group differences, *P* values are not reported. Nonetheless, a few statistically significant within-group differences were identified, along with clinically meaningful differences using a criterion of 0.5 SD of the baseline measure.[36] Yoga participants reported statistically significant and clinically meaningful improvement in sleep adequacy from baseline to weeks 5 and 10 (Figure 1) and a statistically significant and clinically meaningful decrease in sleep quantity from baseline to Week 5. Wellness-education participants reported a clinically meaningful pre- to postintervention decrease in somnolence (Figure 2), while their increase in sleep dis-

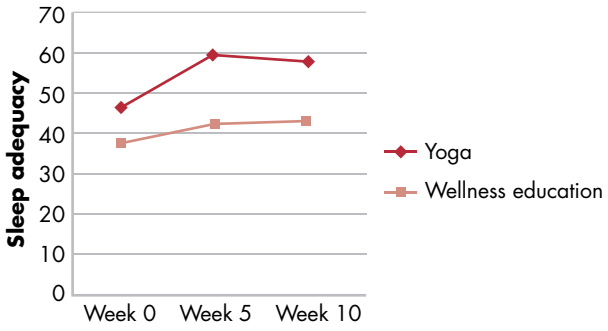

FIGURE 1 Sleep adequacy. Baseline (Week 0) scores are raw means. Scores at Weeks 5 and 10 are least-squares means.

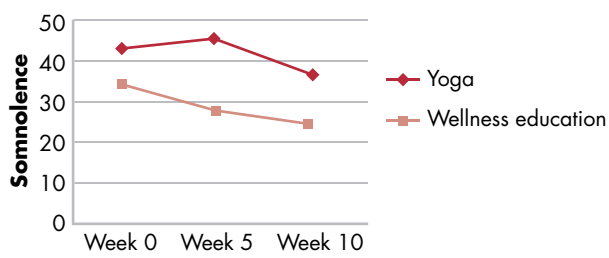

FIGURE 2 Somnolence. Baseline (Week 0) scores are raw means. Scores at Weeks 5 and 10 are least-squares means.

turbance approached clinical significance. HRQoL showed a trend toward minimal decline among yoga participants (Table 3). Data were not suggestive of meaningful changes in depressive symptoms or fatigue for either group. In addition, symptom severity/interference remained essentially unchanged for yoga participants, whereas interference trended toward a temporary increase in wellness-education participants.

Discussion

This study confirms the feasibility of implementing a community-based randomized trial of yoga and an active comparison group for women undergoing chemotherapy for breast cancer. Although the study accrued the targeted 40 participants, recruitment took longer to complete compared with previous yoga trials for women with breast cancer.[11] Women who are undergoing chemotherapy may have more demands on their time and energy than do posttreatment survivors, which possibly contributed to the protracted accrual time. These issues also were a factor in the relatively low adherence (<50%) in both groups, given that the most common reasons for missing classes were illness and/or fatigue and scheduling conflicts. Attrition was comparable between groups, and women who completed the postintervention survey provided overwhelmingly positive feedback. Still, participants in both groups made recommendations for improvement, including more varied content of classes and home practice materials, more individually tailored activity (yoga) or information (wellness education), and more detailed guides (yoga) or accessible guides (wellness education; eg, online) for home use.

We found preliminary support for yoga to improve sleep adequacy and for wellness education to decrease somnolence. Of note, in the yoga group, women reported improvements in sleep adequacy and decreased sleep quantity, perhaps indicating that as they slept better, they needed to spend less time sleeping. In addition, symptom interference among wellness-education participants trended toward a temporary increase, whereas symptom severity and interference among yoga participants remained unchanged from baseline. Given previous evidence for yoga to improve HRQoL, depressive symptoms and fatigue in oncology samples,[11,37,38] the lack of improvement among yoga participants on these measures was surprising. The lack of power in this pilot study may explain the inability to confirm previous support for the efficacy of yoga. Limited efficacy for improving HRQoL in this sample may also be explained by the gentle nature of both interventions, as more traditional physical activity for women with breast cancer tends to have greater HRQoL effects than interventions without an active exercise component.[39] Furthermore, treatment-related and depressive symptoms often correlate with HRQoL,[40,41] indicating that increased HRQoL would have been more likely if participants' symptoms had significantly improved.

Because this study was conducted at a time in the disease continuum when side effects increase and HRQoL typically declines,[3] the absence of such worsening may suggest that the intervention minimized or even prevented common negative sequelae of chemotherapy. However, this possibility could not be confirmed in the current study because it did not have a usual-care control group. Moreover, although the wellness-education group was designed to control for nonspecific effects of the group format such as social support, compared with the yoga group, the structure of the wellness-education group allowed for more interaction among participants, several of whom mentioned this as a benefit of the control group. Considering evidence for the benefits of social support[42] in women with breast cancer, this element might explain some of the favorable outcomes in the wellness-education group. Although the active control group in this study controlled for effects of time and attention, future studies could increase comparability of the nonspecific components across intervention groups to better isolate the specific effects of yoga. For example, yoga and active control groups should involve equivalent amounts of discussion. Future research also should include a usual-care group that controls for both nonspecific and specific effects.

Findings in previous research have emphasized the

TABLE 3 Preliminary efficacy

Measure (scale)	Week	Mean baseline score (SD) [Week 0][a] and change from baseline (range) [Weeks 5, 10][b]		Difference between adjusted group means[b]
		Yoga	Wellness education	
HRQOL (FACT-B)	0	107.79 (14.36)	103.70 (17.13)	–
	5	-6.8 (-15.7–2.0)	-0.01 (-9.9–9.9)	-6.8 (-19.8–6.2)
	10	-3.9 (-12.9–5.0)	-1.1 (-11.2–9.1)	-2.8 (-16.1–10.4)
Fatigue (FACT-Fatigue)	0	31.73 (10.40)	32.94 (11.31)	–
	5	-1.7 (-6.9–3.6)	-0.9 (-6.6–4.8)	-0.8 (-8.2–6.7)
	10	-1.4 (-6.7–3.9)	-1.5 (-7.3–4.4)	0.1 (-7.5–7.7)
Depressive symptoms (CES-D)	0	15.05 (8.33)	16.00 (8.72)	–
	5	-1.8 (-6.0–2.4)	-1.7 (-6.2–2.8)	-0.1 (-6.0–5.8)
	10	0.1 (-4.2–4.3)	-0.8 (-5.5–3.9)	0.9 (-5.2–7.0)
Treatment-related symptoms (MDASI)				
Symptom severity	0	2.00 (1.24)	2.27 (1.05)	–
	5	-0.09 (-0.78–0.60)	0.17 (-0.59–0.92)	-0.26 (-1.25–0.74)
	10	-0.04 (-0.74–0.66)	0.21 (-0.56–0.99)	-0.25 (-1.27–0.76)
Interference	0	2.15 (2.26)	3.31 (2.32)	–
	5	-0.19 (-1.31–0.93)	0.52 (-0.68–1.73)	-0.71 (-2.33–0.90)
	10	-0.13 (-1.27–1.00)	-0.10 (-1.34–1.14)	-0.04 (-1.69–1.62)
Sleep quality (MOS-Sleep)				
Sleep disturbance	0	40.45 (26.38)	25.07 (13.40)	–
	5	5.1 (-5.1–15.5)	0.3 (-10.3–10.9)	4.8 (-9.9–19.5)
	10	1.6 (-8.9–12.0)	6.4 (-4.7–17.5)	-4.8 (-20.1–10.5)
Sleep adequacy	0	45.91 (22.39)	37.22 (19.65)	–
	5	13.4 (3.6–23.1)[cd]	3.9 (-6.7–14.4)	9.5 (-4.5–23.6)
	10	12.2 (2.3–22.2)[cd]	4.9 (-6.1–15.9)	7.3 (-7.2–21.9)
Somnolence	0	43.03 (23.07)	34.07 (15.99)	–
	5	3.0 (-5.6–11.6)	-5.8 (-15.4–3.9)	8.7 (-3.9–21.4)
	10	-6.2 (-15.0–2.6)	-8.4 (-18.4–1.6)[d]	2.2 (-10.9–15.3)
Sleep problems index	0	39.29 (18.04)	29.29 (11.36)	–
	5	5.0 (-2.3–12.4)	0.2 (-7.7–8.0)	4.9 (-5.8–15.5)
	10	0.3 (-7.2–7.8)	1.6 (-6.6–9.8)	-1.3 (-12.4–9.8)
Sleep quantity , raw score, h	0	6.91 (1.48)	7.39 (1.54)	–
	5	-0.8 (-1.5 – -0.2)[cd]	-0.1 (-0.8–0.6)	-0.7 (-1.6–0.2)
	10	-0.6 (-1.3–0.1)	0.1 (-0.6–0.8)	-0.7 (-1.7–0.2)

CES-D, Center for Epidemiologic Studies – Depression; FACT, Functional Assessment of Cancer Therapy; FACT-B, Functional Assessment of Cancer Therapy–Breast; HRQOL, health-related quality of life; MDASI, MD Anderson Symptom Inventory; MOS-Sleep, Medical Outcomes Study Sleep Scale

[a]Baseline scores reported as M (SD). [b]Change and difference scores reported as least-squares mean (95% CI). [c]Indicates statistically significant within-group difference. [d]Meaningful within-group change using 0.5 SD criterion (based on Week 0 SD values).

importance of class attendance for improving outcomes such as HRQoL.[11] Efficacy could have been hampered by low class attendance, with fewer than half of the participants in both groups attending the recommended 8 or more weekly classes. Adherence is especially problematic for time-intensive behavioral interventions if participants experience barriers identified in previous research.[13,43-45] Several such barriers affected the current study, because illness/symptoms and scheduling conflicts were reported as the primary obstacles to attendance and study completion. Yoga participants were able to complete, on average, the recommended amount of weekly home activity, lending further support to the high acceptability of yoga among female cancer survivors[46] and suggesting that home-based yoga interventions may facilitate greater adherence than those requiring in-person attendance. Future studies might also improve adherence by incorporating participants' suggestions for improving the intervention, such as offering multiple classes a week to allow flexibility in scheduling around illness or other commitments (eg, child care), providing more variety in both the

group classes and home practice, offering more strenuous yoga classes for participants with greater fitness, tailoring education to individual participants' phase of treatment, and supplying written and online materials.

Future research should consider use of innovative methods for delivering interventions. For example, videoconferencing technologies that allow class participation from home could enhance recruitment and adherence.[47] Online platforms could maintain nonspecific effects such as social interaction and support[48] that may contribute to the efficacy of group-based interventions. Such delivery systems could also enhance treatment standardization by facilitating regular monitoring of treatment fidelity (eg, via recommendations from the National Institutes of Health Behavior Change Consortium)[49,50] and by allowing a smaller number of well-trained instructors to lead yoga interventions, regardless of location. Comparing this mode of delivery to in-person interventions remains an important direction for future research.

A primary limitation of this study is the small sample size. As a feasibility study, it lacked power to make definitive conclusions about intervention efficacy for women undergoing chemotherapy for breast cancer. Power to detect effects was also limited by inclusion of women with minimal impairment at baseline. Relatively few psychosocial oncology intervention studies have addressed patients with significant baseline levels of a particular symptom, despite evidence that effect sizes are highest when symptoms are elevated at baseline.[51,52] The lack of power may partly explain the lack of significant improvements in fatigue, given that a recent meta-analysis identified a medium effect size of mind-body techniques such as yoga for decreasing fatigue during adjuvant therapy for breast cancer.[53] With mostly nonminority participants, generalizability of results is limited, although recruitment of black participants (n = 5) in this study surpassed the study goal (n = 2). Results should be replicated in fully powered studies that include minority-based community sites and tailored strategies to enhance minority participation.[54] Fully powered trials with a more diverse sample also will facilitate analysis of differential effects of the intervention in population subgroups.

Another limitation is the lack of a usual-care control group. Including such a group in future research would help to determine whether the interventions prevented an exacerbation of symptoms and to estimate the non-specific intervention effects. Especially given the difficulty of blinding participants in yoga trials, methodological precision could be further improved by blinding study staff who obtain outcome data and by including objective measures. For example, objective measures of sleep disturbance, such as actigraphy, are an important complement to self-report scales.[55] Moreover, inflammatory cytokines may be a common mechanism linked to depression, fatigue, and sleep disturbance,[56] and evidence for the ability of yoga to reduce inflammation in breast cancer survivors is beginning to emerge.[57]

Conclusions

This study demonstrated the feasibility of implementing a community-based randomized trial of yoga and an active comparison group for women undergoing chemotherapy for breast cancer and provided preliminary efficacy data. Fully powered trials with a usual-care control group and objective measures are needed to confirm the potential for yoga to improve sleep and mitigate treatment-related symptoms during chemotherapy. Obstacles to conducting yoga research during breast cancer treatment include fatigue and scheduling difficulties among participants, as well as limited access to cancer-specific yoga classes. To reach women with breast cancer during the critical time of chemotherapy treatment, future studies will need to use novel methods to enhance adherence by increasing access to and variety in yoga classes and materials.

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