Randomized, Controlled Trial of Yoga in Women With Breast Cancer Undergoing Radiotherapy

Kavita D. Chandwani, George Perkins, Hongasandra Ramaraao Nagendra, Nelamangala V. Raghuram, Amy Spelman, Raghuram Nagarathna, Kayla Johnson, Adoneca Fortier, Banu Arun, Qi Wei, Clemens Kirschbaum, Robin Haddad, G. Stephen Morris, Janet Scheetz, Alejandro Chaoul, and Lorenzo Cohen

ABSTRACT

Purpose
Previous research incorporating yoga (YG) into radiotherapy (XRT) for women with breast cancer finds improved quality of life (QOL). However, shortcomings in this research limit the findings.

Patients and Methods
Patients with stages 0 to III breast cancer were recruited before starting XRT and were randomly assigned to YG (n = 53) or stretching (ST; n = 56) three times a week for 6 weeks during XRT or waitlist (WL; n = 54) control. Self-report measures of QOL (Medical Outcomes Study 36-item short-form survey; primary outcomes), fatigue, depression, and sleep quality, and five saliva samples per day for 3 consecutive days were collected at baseline, end of treatment, and 1, 3, and 6 months later.

Results
The YG group had significantly greater increases in physical component scale scores compared with the WL group at 1 and 3 months after XRT (P < .05), with ST and WL differences at only 3 months (P < .02). The group differences were similar for general health reports. By the end of XRT, the YG and ST groups also had a reduction in fatigue (P < .05). There were no group differences for mental health and sleep quality. Cortisol slope was steepest for the YG group compared with the ST and WL groups at the end (P = .023 and P = .008) and 1 month after XRT (P = .05 and P = .04).

Conclusion
YG improved QOL and physiological changes associated with XRT beyond the benefits of simple ST exercises, and these benefits appear to have long-term durability.

INTRODUCTION

Radiotherapy (XRT) is often the final step in the multimodal treatment regimen for women with breast cancer. Patients often experience treatment-related adverse effects (fatigue, pain, lymphedema, neuropathy, cardiotoxicity, sleep disturbances, and cognitive problems) that negatively affect physical, psychological, social, and spiritual aspects of quality of life (QOL).3,4 and may create negative health consequences.3

Research on yoga (YG) in patients with cancer has increased considerably in the last decade, and a variety of YG programs studied in cancer have reported improvements in stress and QOL,4 fatigue and emotional health,5,6 pain, vitality, and QOL,7 positive affect,5 joint pain, fatigue, and sleep distur-

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The ST program included exercises recommended specifically for women undergoing or recovering from breast cancer treatment. The exercises included standing, lying down, and sitting positions and approximated the gross movements of the YG exercises (eg, horizontal arm stretch, breast stroke, neck stretch, quarterback throwing a football). Participants were introduced to the stretches in a stepped approach and learned all of the material over the course of the first four classes. Classes were taught by physiotherapists from Rehabilitative and Physical Therapy at MD Anderson.

**Measures**

General QOL was assessed by the Medical Outcomes Study 36-item short-form survey (SF-36). The SF-36 assesses PF, physical impediments to role functioning, bodily pain, GH, vitality, social functioning, emotional impediments to role functioning, MH, and includes an overall physical component scale (PCS) and mental component scale (MCS). The PCS and MCS were the primary outcomes. If the component scale was significant, then the subscales were analyzed as secondary outcomes. Higher scores reflect better QOL, with increases from baseline indicating improved QOL. Normed-based scoring is presented with a population mean = 50 and standard deviation = 10. A change of five points or more is considered clinically significant.

Sleep disturbances were assessed by using the Pittsburgh Sleep Quality Index (PSQI), a questionnaire that assesses sleep disturbances over a 1-month period. We report on the total score. Lower scores reflect fewer sleep disturbances.

Depression was assessed by using the Centers for Epidemiological Studies–Depression (CES-D) measures, a well-validated measure focusing on affective components of depression. Lower scores reflect fewer depressive symptoms.

**Cortisol**

Five saliva samples (waking, 45 minutes later, approximately 8 and 12 hours after waking, and at bedtime) were obtained for 3 consecutive days at each assessment. Participants chewed on a cotton swab (Salivette; Sarstedt, Newton, NC), placed it in a plastic tube (Sarstedt), and then it was frozen at −80°C for later time-resolved immunoassay with fluorescence detection performed at the University of Dresden. Values < 0.0001 and > 70 nmol/L were classified as missing. If patients missed a collection point, they were told to leave the tube empty. Of the data received, 2.8% of the saliva samples were classified as missing (either empty or not within range). Approximately 30% of the patients (21% to 34%, depending on the time point) did not provide saliva samples. There were no differences between patients providing samples and those who did not on the basis of group assignment, medical, demographic, or outcome measures. Slopes were calculated without the waking sample, using the other four samples throughout the day. A steeper, more negative cortisol slope indicates better cortisol regulation. Medical information was obtained from medical records.

**Data Analyses**

For analysis of the self-report measures, we examined change from baseline to follow-up. To test group differences, PROC MIXED procedures in SAS version 9.2 were used. Changes from baseline were regressed on group, time (treated as categorical), and group × time interaction; the intercept was treated as random effect; the covariance structure was unstructured. There were no significant group × time interactions, and group comparisons at each assessment are presented from the mixed models. Because of non-normality, cortisol levels were log-transformed, and slopes were calculated and regressed on saliva collection time (hours after waking up in the morning); the slopes were then used as the dependent variable in the general linear model analyses as described above, examining slopes covarying for baseline levels. All analyses were controlled for randomization factors. We also controlled for baseline SF-36 GH scores in the SF-36 GH analyses due to imbalances across groups. The primary and secondary outcomes remained the same, and we present the results without covariates.

The primary outcomes were the PCS and MCS subscales of the SF-36 at 1 month post-XRT. Although our pilot work only found group differences in

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**PATIENTS AND METHODS**

**Patients**

Women with stages 0 to III breast cancer were recruited before XRT. Inclusion criteria were ≥ 18 years old; ability to read, write, and speak English; and scheduled to undergo daily adjuvant XRT for 6 weeks at MD Anderson Cancer Center. Patients with lymphedema; metastatic bone disease; deep vein thrombosis; documented diagnosis of a formal thought disorder (eg, schizophrenia); extreme mobility problems; or who had practiced YG in the year before diagnosis were excluded. The protocol was approved by the institutional review board.

**Randomization and Schedule**

Eligible patients were identified through an institutional database or by referring physicians and were approached at their simulation appointment. After giving written informed consent, participants completed a baseline assessment including self-report measures and provided saliva samples to assess diurnal cortisol rhythm. Blood samples for future assays, an actigraphy watch for sleep disturbances, or pranayama; and (5) meditation. The program was taught by VYASA-trained teachers.
PCS measures at the end of XRT, we hypothesized that increasing the amount of YG from two to three times a week would result in more lasting effects (ie, at least 1 month post-XRT). The end of XRT time point and the longer term follow-up at 3 and 6 months were designated as secondary time points. We adjusted the α level for significance to \( P = 0.029 \) by conducting a Bonferroni correction taking into account the correlation between the two variables. Assuming a two-tailed significance level of \( P = 0.029 \), with 50 patients per group and 80% power, we would detect differences between any pair of group means of 0.63 standard deviation units, a similar effect size to that found in our previous study (range, 0.44 to 0.47). The secondary outcomes of the subscales from the component scores of the SF-36, Brief Fatigue Inventory, PSQI, CES-D, and cortisol slope at each time point were regarded as exploratory analyses.

RESULTS

Two hundred ninety-four eligible women were approached and 191 consented to participate. Thirteen dropped out before, and 15 after, they were randomly assigned, for a final sample size of 163 (YG = 53, ST = 56, WL = 54; Fig 1). Retention was high, with no group differences in loss to follow-up or number of classes attended on the basis of whether patients provided follow-up data or not. In addition, there were no differences between patients with and without missing data on the basis of medical, demographic, or baseline outcome measures.

All groups were similar in baseline demographic, medical, self-report measures (except for SF-36 GH), and cortisol slopes (Tables 1 and 2). Eighty-seven percent of YG and 85% of ST participants attended ≥ 12 classes (mean, YG = 13.8; ST = 14.7). Only three patients in each group attended fewer than half the classes. Practice outside of class was high (> twice per week) for the YG group 1 month post-treatment and then declined at 3 and 6 months (71%, 55%, and 45%, respectively). Practice outside of class (> twice per week) for the ST group was lower at 1 month and then increased somewhat at 3 and 6 months (53%, 69%, and 60%, respectively). Baseline and follow-up means of self-report measures are presented in Table 2.

**SF-36**

Significantly greater increases from baseline were observed in PCS scores for the YG group compared with the WL group at 1 and 3 months (\( P = 0.01 \) and \( P = 0.01 \), respectively; Fig 2). No other comparisons reached significance. There were no significant effects for the MCS.

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**Fig 1.** Flow of study participants over study period.
Analyses of the PCS subscales revealed significant effects for the PF and GH. Group differences in PF scores revealed significantly greater increases for the YG group compared with the WL group at 1, 3, and 6 months ($p < .002; p < .0001; p < .001$, respectively), with marginal group differences at the end of treatment ($p = .08$); greater increases for the YG group compared with the ST group at 1 and 3 months ($p < .01$; $p < .05$, respectively), with marginal group differences at 6 months ($p = .08$); and greater increases in the ST group compared with the WL group at 3 months ($p = .02$; Fig 2). GH outcomes followed a similar pattern, with significantly greater increases in GH scores for the YG group compared with the WL and ST groups at 1 and 3 months ($p < .01$; $p < .01$, respectively). No significant group effects were found for other SF-36 subscales.

**Fatigue**

Significantly greater decreases in fatigue were observed for the YG and ST groups compared with the WL group by the end of treatment ($p = .04; p = .02$, respectively), with marginally significant differences observed for the YG group compared with the WL group at 1 month ($p = .09$) and for the ST group compared with the WL group at 3 months ($p = .07$; Fig 3). There were no significant group differences at any time point for CES-D or PSQI scores.

**Salivary Cortisol**

GLM analysis of cortisol slopes, covarying for baseline, revealed a group main effect at the end of treatment (adjusted means: YG $-0.104$, SE 0.011; ST $-0.072$, SE 0.009; WL $-0.064$, SE 0.010; $p = .02$), with the YG group having a significantly steeper slope than the ST and WL groups ($p = .023$ and $p = .008$, respectively). There was also a marginally significant group main effect at the 1-month follow-up (adjusted means: YG $-0.104$, SE 0.011; ST $-0.073$, SE 0.010; WL $-0.073$, SE 0.010; $p = .07$), with the YG group having a significantly steeper slope than the ST and WL groups ($p = .05$ and $p = .04$, respectively; Fig 4). There were no differences in slope at the other time points.

### Table 1. Baseline Characteristics of Study Participants by Group

<table>
<thead>
<tr>
<th>Patient Demographics and Clinical Characteristics</th>
<th>Yoga (n = 53, 33%)</th>
<th>Stretch (n = 56, 34%)</th>
<th>Waitlist (n = 54, 33%)</th>
<th>$P$</th>
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<tr>
<td><strong>Age</strong></td>
<td>Mean ± SE</td>
<td>52.38 ± 1.35</td>
<td>51.14 ± 1.32</td>
<td>52.11 ± 1.34</td>
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<tr>
<td>Range, years</td>
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<td>25-79</td>
<td>30-69</td>
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<tr>
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<td></td>
<td></td>
<td></td>
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<tr>
<td>0</td>
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<td>11</td>
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<tr>
<td>I</td>
<td>16</td>
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<td>18</td>
<td>32</td>
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<tr>
<td>II</td>
<td>15</td>
<td>28</td>
<td>14</td>
<td>25</td>
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<tr>
<td>III</td>
<td>17</td>
<td>32</td>
<td>18</td>
<td>32</td>
</tr>
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<td><strong>Surgery</strong></td>
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<tr>
<td>Mastectomy (without reconstruction)</td>
<td>12</td>
<td>23</td>
<td>17</td>
<td>31</td>
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<tr>
<td>Mastectomy (with reconstruction)</td>
<td>6</td>
<td>11</td>
<td>3</td>
<td>5</td>
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<tr>
<td>Breast conserving</td>
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<td>66</td>
<td>36</td>
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<td><strong>Marital status (n = 151)</strong></td>
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<tr>
<td>Married and living together</td>
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<td>67</td>
<td>37</td>
<td>71</td>
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<tr>
<td>Not cohabitating</td>
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<td>33</td>
<td>15</td>
<td>29</td>
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<td>Black/African American</td>
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<td>19</td>
<td>9</td>
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<td>White</td>
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<td>31</td>
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<tr>
<td>Employed part-time</td>
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<td>2</td>
<td>4</td>
<td>8</td>
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<tr>
<td>Employed, taken time off</td>
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<tr>
<td>Not employed</td>
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<td>18</td>
<td>37</td>
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<td><strong>Education (n = 152)</strong></td>
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<td>High school or technical school</td>
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<td>21</td>
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<td>23</td>
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<td>Some college</td>
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<td>36</td>
<td>14</td>
<td>27</td>
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<tr>
<td>Higher education</td>
<td>20</td>
<td>43</td>
<td>26</td>
<td>50</td>
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<td><strong>Income (n = 149)</strong></td>
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<td>$&gt; $75,000</td>
<td>31</td>
<td>67</td>
<td>26</td>
<td>51</td>
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<tr>
<td>$&lt; $75,000</td>
<td>15</td>
<td>33</td>
<td>25</td>
<td>49</td>
</tr>
</tbody>
</table>

*Minority representation reflects that of women diagnosed with breast cancer in Harris County.*
### Table 2. Raw Means and Standard Deviations of Self-Report Measures at Baseline and Follow-Up Time Points

<table>
<thead>
<tr>
<th></th>
<th>Baseline</th>
<th>Last Week of Treatment</th>
<th>1 Month Post-Treatment</th>
<th>3 Months Post-Treatment</th>
<th>6 Months Post-Treatment</th>
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<tbody>
<tr>
<td></td>
<td>YG</td>
<td>ST</td>
<td>WL</td>
<td>YG</td>
<td>ST</td>
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<tr>
<td>PCS</td>
<td>41.8</td>
<td>1.3</td>
<td>43.0</td>
<td>1.1</td>
<td>44.9</td>
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<tr>
<td>PF</td>
<td>41.9</td>
<td>1.3</td>
<td>44.7</td>
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<td>45.9</td>
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<td>GH</td>
<td>44.8</td>
<td>1.5</td>
<td>50.4</td>
<td>1.2</td>
<td>47.7</td>
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<tr>
<td>RF</td>
<td>36.8</td>
<td>1.5</td>
<td>37.1</td>
<td>1.3</td>
<td>38.3</td>
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<tr>
<td>BP</td>
<td>44.2</td>
<td>1.4</td>
<td>44.8</td>
<td>1.2</td>
<td>44.6</td>
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<tr>
<td>MCS</td>
<td>42.2</td>
<td>1.7</td>
<td>45.8</td>
<td>1.4</td>
<td>42.0</td>
</tr>
<tr>
<td>CES-D</td>
<td>15.4</td>
<td>1.5</td>
<td>11.7</td>
<td>0.8</td>
<td>15.1</td>
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<tr>
<td>PSQI</td>
<td>83.0</td>
<td>0.6</td>
<td>85.5</td>
<td>0.5</td>
<td>82.0</td>
</tr>
<tr>
<td>BFI</td>
<td>3.2</td>
<td>0.3</td>
<td>3.0</td>
<td>0.3</td>
<td>2.6</td>
</tr>
</tbody>
</table>

**NOTE.** The baseline $P$ values are from analysis of variance of raw scores. The follow-up $P$ values represent the group main effects from the MIXED models analyses of change scores and the noted group differences are from the same MIXED models. Significant group differences are labeled below.  
Abbreviations: BFI, Brief Fatigue Inventory; BP, Medical Outcomes Study 36-Item Short-Form Survey (SF-36) Bodily Pain; CES-D, Center for Epidemiologic Studies-Depression; GH, SF-36 General Health; MCS, SF-36 Mental Component Score; PCS, SF-36 Physical Component Score; PF, SF-36 Physical Functioning; PSQI, Pittsburgh Sleep Quality Index; RP, SF-36 Role-physical; ST, stretching; WL, waitlist; YG, yoga.  
*YG versus WL, $P \leq .05$.  
†YG versus ST, $P \leq .05$.  
‡ST versus WL, $P \leq .05$.  
$^{*}$Denotes groups with significant differences at $P \leq .05$.  
$^{†}$Denotes groups with significant differences at $P \leq .05$.  
$^{‡}$Denotes groups with significant differences at $P \leq .05$.
Although there were no group differences between patients with and without missing data on demographic, medical, or the outcome variables at baseline, we imputed the missing data by using multiple imputations (SAS version 9.2 MI procedure) with Markov Chain Monte Carlo method and then used the MIANALYZE procedure to generate statistical inferences. All the analyses remained the same or resulted in smaller $P$ values except for cortisol slopes, but the pattern remained the same (end of treatment: $YG \times ST$, $P < .05$; $YG \times WL$, $P = .05$; 1-month follow-up: $YG \times ST$, $P < .05$; $YG \times WL$, $P = .14$).

**DISCUSSION**

To our knowledge, this is the first study to compare the effects of YG against active ST and WL control groups in a cancer population. Compared with the WL group, the YG group had higher PCS scores 1 and 3 months after XRT (primary outcome), better PF at 1, 3, and 6 months, better GH at 1 and 3 months, less fatigue by the end of XRT, and steeper cortisol slopes at the end of XRT and 1 month later. Compared with the ST group, the YG group reported better PF 1 and 3 months after XRT, GH at 1 and 3 months, and had steeper cortisol slopes by the end of treatment. The improvement in PF in the YG group is also considered clinically significant because there was ≥ five-point increase, which was not the case for the other two groups. Although the ST group reported less fatigue by the end of XRT and improved PF 3 months after treatment relative to the WL group, no other differences emerged between the ST and WL groups. There were no significant group differences for MH outcomes or sleep disturbances.

The present findings of improvements in PF and GH are consistent with the results of the pilot study using the same YG intervention. There was, however, a more lasting effect of delivering YG three times a week in the current study versus two times a week in the pilot study, with group differences in PF lasting through the 6-month follow-up versus just 1 week after the end of XRT. Although the minimum frequency of YG practice to achieve positive benefits has yet to be determined, it is generally believed that daily practice is ideal. Class attendance was extremely high, as was observed in the pilot study, and higher than that reported by other studies.

The lack of benefit for measures of MH, fatigue, and sleep disturbances is also consistent with the pilot trial. Even though the YG
program included components to address aspects of MH through relaxation and meditation, this was a minor component relative to the physical movements the women practiced. In addition, MCS scores of the women by the end of XRT were not clinically significantly different than the general population, and they improved across the course of 6 months, suggesting a possible ceiling effect for MH. The same pattern was seen for fatigue and sleep disturbances. Although some studies show that YG improves these outcomes, most research has been conducted in cancer survivors after treatment has ended, used YG programs that were perhaps less physical with more of a focus on relaxation,5,6 or targeted specific symptoms.9,33,34 In addition, improvements in PF may become more apparent over time with other outcomes being more stable.35 Yet, it may be beneficial to examine if programs placing a greater emphasis on relaxation and meditation may have resulted in improved MH and sleep quality outcomes.

The current study also examined an objective measure of stress arousal by assessing the diurnal changes in circulating cortisol levels during waking hours. Although there was a blunting of the cortisol slope by the end of XRT, participants in the YG group had a significantly steeper cortisol slope than the other groups. Although the clinical significance of this finding is unclear, it does suggest the positive effects of YG on the stress hormone cortisol. There is evidence that a blunted cortisol slope is associated with tumor progression18 and decreased survival17 in patients with breast cancer, so maintaining a sustained steep cortisol slope may therefore have prognostic implications.

Although this study controlled for the ST and attention components associated with the YG program, the ST group did not learn any aspects of relaxation. However, the YG group resulted in greater improvement in PF, likely resulting from the physical aspects of YG. Study groups were not blinded, and treatment expectations were not assessed. In addition, because of the number of secondary outcomes and multiple comparisons, significant group differences for secondary outcomes (fatigue and cortisol slope) should be interpreted cautiously.

The current study found that, for some outcomes, YG yielded better subjective and objective results than either ST or usual care. There were fewer differences between ST and WL groups. Although physical therapy is a reimbursable expense in the United States and will likely help patients recover faster, expanding to include services such as YG should be considered. Future studies should examine methods to increase practice frequency outside of class, examine the benefits of different YG components by using appropriate controls, conduct such trials in a blinded manner, assess expectations, and conduct multilevel cost-benefit analyses.

The author(s) indicated no potential conflicts of interest.

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**AUTHORS’ DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST**

The author(s) indicated no potential conflicts of interest.

**AUTHOR CONTRIBUTIONS**

Conception and design: Kavita D. Chandwani, George Perkins, Hongasandra Ramarao Nagendra, Nelamangala V. Raghuram, Raghuram Nagarathna, Banu Arun, G. Stephen Morris, Janet Scheetz, Alejandro Chaoul, Lorenzo Cohen

Financial support: Lorenzo Cohen

 Provision of study materials or patients: George Perkins, Banu Arun, Clemens Kirschbaum, G. Stephen Morris, Janet Scheetz, Lorenzo Cohen

Collection and assembly of data: Kavita Chandwani, Amy Spelman, Kayla Johnson, Adoneca Fortier, Qi Wei, Clemens Kirschbaum

Data analysis and interpretation: Kavita Chandwani, Qi Wei, Robin Haddad, Lorenzo Cohen

Manuscript writing: All authors

Final approval of manuscript: All authors

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**Fig 4.** Log-transformed cortisol level daily curves. (A) Daily log-cortisol mean at baseline. No group differences. (B) Daily log-cortisol mean at end of radiotherapy. Yoga has steeper slope than stretch and waitlist groups ($P = .027$ and $P = .008$, respectively). (C) Daily log-cortisol mean at 1 month. Yoga has steeper slope than waitlist ($P = .05$ and $P = .04$, respectively). Significance values are from the GLM analysis of cortisol slopes at each time point, covarying for baseline.
REFERENCES

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