

# Psychological Adjustment and Sleep Quality in a Randomized Trial of the Effects of a Tibetan Yoga Intervention in Patients with Lymphoma

Lorenzo Cohen, Ph.D.<sup>1,2</sup>  
 Carla Warneke, M.P.H.<sup>3</sup>  
 Rachel T. Fouladi, Ph.D.<sup>4</sup>  
 M. Alma Rodriguez, M.D.<sup>5</sup>  
 Alejandro Chaoul-Reich<sup>6</sup>

<sup>1</sup> Department of Behavioral Science, The University of Texas M. D. Anderson Cancer Center, Houston, Texas.

<sup>2</sup> Department of Palliative Care and Rehabilitation Medicine, The University of Texas M. D. Anderson Cancer Center, Houston, Texas.

<sup>3</sup> Department of Biostatistics, The University of Texas M. D. Anderson Cancer Center, Houston, Texas.

<sup>4</sup> Department of Psychology, Simon Fraser University, Burnaby, British Columbia, Canada.

<sup>5</sup> Department of Lymphoma, The University of Texas M. D. Anderson Cancer Center, Houston, Texas.

<sup>6</sup> Department of Religion, Rice University, Houston, Texas.

Presented in part at the Sixth World Congress of Psycho-Oncology, Banff, Alberta, Canada, April 23–27, 2003.

Supported in part by a grant from the Bruce S. Gelb Foundation.

The authors thank Beth Notzon (Department of Scientific Publications, The University of Texas M. D. Anderson Cancer Center, Houston, TX) for her helpful editorial comments and Rachel Boone for her assistance with data collection. They are grateful to Geshe Tenzin Wangyal Rinpoche for his intellectual support and keeping this study true to the tradition in which these practices are imbedded.

Address for reprints: Lorenzo Cohen, Ph.D., Department of Behavioral Science, Unit 243, The University of Texas M. D. Anderson Cancer Center, 1515 Holcombe Boulevard, Houston, TX 77030; Fax: (713) 745-4286; E-mail: lcohen@mdanderson.org

Received September 18, 2003; revision received February 24, 2004; accepted March 1, 2004.

**BACKGROUND.** Research suggests that stress-reduction programs tailored to the cancer setting help patients cope with the effects of treatment and improve their quality of life. Yoga, an ancient Eastern science, incorporates stress-reduction techniques that include regulated breathing, visual imagery, and meditation as well as various postures. The authors examined the effects of the Tibetan yoga (TY) practices of *Tsa lung* and *Trul khor*, which incorporate controlled breathing and visualization, mindfulness techniques, and low-impact postures in patients with lymphoma.

**METHODS.** Thirty-nine patients with lymphoma who were undergoing treatment or who had concluded treatment within the past 12 months were assigned to a TY group or to a wait-list control group. Patients in the TY group participated in 7 weekly yoga sessions, and patients in the wait-list control group were free to participate in the TY program after the 3-month follow-up assessment.

**RESULTS.** Eighty nine percent of TY participants completed at least 2–3 three yoga sessions, and 58% completed at least 5 sessions. Patients in the TY group reported significantly lower sleep disturbance scores during follow-up compared with patients in the wait-list control group (5.8 vs. 8.1;  $P < 0.004$ ). This included better subjective sleep quality ( $P < 0.02$ ), faster sleep latency ( $P < 0.01$ ), longer sleep duration ( $P < 0.03$ ), and less use of sleep medications ( $P < 0.02$ ). There were no significant differences between groups in terms of intrusion or avoidance, state anxiety, depression, or fatigue.

**CONCLUSIONS.** The participation rates suggested that a TY program is feasible for patients with cancer and that such a program significantly improves sleep-related outcomes. However, there were no significant differences between groups for the other outcomes. *Cancer* 2004;100:2253–60. © 2004 American Cancer Society.

**KEYWORDS:** yoga, Tibet, lymphoma, sleep, distress.

Yoga is an ancient Eastern tradition that usually includes regulated breathing, moving through various postures, and meditation.<sup>1</sup> Although different forms of yoga are practiced in many Eastern countries, the yoga practiced in the West primarily comes from the Indian tradition, specifically the form known as Hatha yoga. Hatha yoga typically focuses on postures (asanas) and breathing exercises (pranayama). Less commonly practiced are the yogic practices from Tibet, which are known best for their meditative techniques. Now, however, there is growing interest in the Tibetan physical yogas or mind-body practices. For thousands of years, Tibetans have been employing what we call *mind-body techniques* today. Two Tibetan practices, known as *Tsa lung* (*rtsa rlung*; channels and vital breath) and *Trul khor* (*'phrul 'khor*; magical wheel [of the channels and vital

breath)), originating from the Mother Tantra (*Ma rgyud*)<sup>2</sup> and the Oral Transmission of Zhang Zhung (*Zhang zhung snyan rgyud*),<sup>3,4</sup> respectively, incorporate controlled breathing and visualization, mindfulness techniques, and postures. Little is known about this form of yoga, however, and to our knowledge no research published to date has examined the benefits of Tsa lung or Trul khor. We believe that this form of yoga may be particularly useful for cancer patients who are undergoing and recovering from chemotherapy, because the movements are gentle and simple, and there is an emphasis on controlled breathing, visualization, and mindfulness techniques.

There has been some research into the benefits of Indian-based yoga in healthy populations and medical populations. Early texts described yoga's physical and mental health benefits,<sup>1</sup> whereas modern studies of yoga-based interventions performed in healthy populations have shown that the interventions decrease depression and anxiety,<sup>5-7</sup> increase motor control,<sup>8,9</sup> improve subjective measures of well being,<sup>10</sup> and improve lung function.<sup>11</sup>

Although yoga has been used for centuries in the East to treat disease,<sup>12,13</sup> it has gained recognition for this purpose only recently in the West. In particular, it has been found that yoga is useful for treating various forms of arthritis,<sup>14</sup> lessening the severity of musculoskeletal disease,<sup>14,15</sup> decreasing the frequency and severity of asthma attacks,<sup>16</sup> improving peak expiratory flow rates in patients with bronchial asthma,<sup>17</sup> and improving the lipid profile of patients with coronary artery disease<sup>18</sup>; and one small study showed that yoga was useful for controlling aspects of hypertension.<sup>19</sup> There is also some research suggesting that yoga may be useful for decreasing the frequency and duration of epileptic seizures, although the findings remain equivocal.<sup>20</sup>

Although there has been interest in the therapeutic application of yoga to patients with cancer,<sup>21</sup> few studies actually have examined the benefits of yoga in this group. In an early study, 125 patients undergoing radiotherapy participated in group therapy, meditation, or yoga.<sup>22</sup> The patients in the yoga group found that their quality of life was improved during radiotherapy and for some time immediately after the completion of radiotherapy. In particular, the patients reported increased appetite, increased tolerance to radiotherapy, improved sleep, improved bowel habits, and a feeling of peace and tranquility. In a more recent trial, 109 patients with early-stage or late-stage cancer were randomly assigned to either a 7-week intervention, which included group support and discussion, mindfulness meditation, visualization and imagery, and yoga stretches, or to a wait-list control group.<sup>23</sup> At

the end of the 7-week program, participants in the intervention group were experiencing lower total mood disturbance and decreased overall distress compared with the experience in the control group.

In the current study, we conducted a clinical trial of Tibetan yoga (TY) in patients with lymphoma. We incorporated poses from the Tsa lung and Trul khor into a 7-week program that included controlled breathing, visualization, and mindfulness. The techniques were low impact and easy to integrate into daily living and could be particularly useful for patients with cancer who were either receiving treatment or had recently completed treatment. We hypothesized that patients assigned to the TY group would demonstrate better psychologic adjustment and lower levels of fatigue and sleep disturbances during the weeks after the intervention compared with patients in a wait-list control group.

## MATERIALS AND METHODS

### Participants

Patients with lymphoma who were either receiving chemotherapy or had received it within the past 12 months were recruited through the Lymphoma Center at The University of Texas M. D. Anderson Cancer Center. Patients had to be receiving either a regimen with combined cyclophosphamide, doxorubicin, vincristine, and prednisone (CHOP) or regimens with the same drug classes to control for the more severe side effects associated with certain regimens. Patients also had to be age  $\geq 18$  years and had to be able to read and speak English. Patients with any major psychotic illnesses were excluded. The proposed total sample size for the study was 38 evaluable patients. Nineteen patients per group provides 80% power to detect a difference of 0.82 standard deviation units, which is viewed as a large effect size.

### Procedures

Potential study participants were identified and either were approached in the clinic or were sent a letter about participating in the study. Patients who met the inclusion criteria and expressed an interest in the study were then scheduled for the baseline assessment, at which time the study was explained, patients' questions were answered, and written consent was obtained. The study was approved by the Institutional Review Board. The baseline assessment included a battery of questionnaires. Patients were assigned to either the TY group or the wait-list control group once they had completed the baseline questionnaires. Group assignment was conducted sequentially using minimization,<sup>24,25</sup> a form of adaptive assignment that results in better group balance on selected patient

characteristics compared with random assignment or stratification,<sup>26</sup> unbiased estimates of treatment effect, and as good as or better power than stratified randomization.<sup>26–29</sup> Patient characteristics used for group assignment were the type of cancer (Hodgkin or non-Hodgkin lymphoma), the status of treatment (active treatment or completed), gender, age, and baseline state anxiety scores. The allocation process was concealed from all investigators because all the relevant information was entered into a computer program and group assignment was determined by the program. Patients were notified of their group assignment by telephone, and patients in the TY group were scheduled for their first yoga session, which was held approximately 1–3 weeks after the baseline assessment. Three separate cohorts of patients were assigned to one of the two groups. After completion of the TY program, participants completed the postintervention assessment questionnaires. The follow-up assessments were conducted 1 week, 1 month, and 3 months after the last session. Patients in the wait-list control group completed these assessments at comparable intervals.

#### ***TY program.***

Participants in the TY group were asked to attend seven weekly yoga sessions at The University of Texas M. D. Anderson Cancer Center in the Place...of *Wellness*, a center for the clinical delivery of complementary programs. Each class was conducted by an experienced TY instructor (A.C.R.). All of the practices come from a tradition practiced for centuries by Tibetan monks and lay practitioners and employ imagery and exercises that are not demanding physically. The program was divided into four aspects: 1) controlled breathing and visualization, 2) mindfulness, 3) postures from the Tsa lung, and 4) the preliminary set of postures from the Trul khor (*sngon 'gro*). The exercises are simple motions done with specific breathing patterns that are easy to perform by individuals undergoing cancer treatment. Participants also were provided with printed materials after each class that covered a new area of the program. After the last class, patients also were given an audiotape that walked them through all of the techniques. They were encouraged to practice the techniques at least once per day. Participants who missed a class were encouraged to attend a make-up class at another time.

#### ***Wait-list control group.***

Participants in the wait-list control group did not have any contact research personnel except during the follow-up assessments. They were offered the opportu-

nity to take part in the TY program after the 3-month follow-up assessment was completed.

#### **Measures**

Psychological adjustment was assessed across several domains, including distress (Impact of Events Scale [IES]), anxiety (Spielberger State Anxiety Inventory [STATE]), and depression (Centers for Epidemiologic Studies-Depression [CES-D]). Fatigue (Brief Fatigue Inventory [BFI]) and sleep disturbances (Pittsburgh Sleep Quality Index [PSQI]) were assessed, because these are common problems for patients with cancer. Because it is hypothesized that yoga has an affect on multiple outcomes and because, to some extent, this was a feasibility study, a primary outcome measure was not prespecified. Other measures assessing some proposed mediators of the benefits of the yoga program were administered but are not reported on here.

The IES is a 15-item, self-report scale that measures 2 categories of cognitive responses to stressful events: Intrusion (7 items assessing intrusively experienced ideas, images, feelings, or bad dreams) and Avoidance (8 items assessing consciously recognized avoidance of certain ideas, feelings, or situations).<sup>30</sup> Patients in the current study rated the frequency of intrusive thoughts and avoidance in relation to their cancer. Because the correlation between the Intrusion and Avoidance subscales at each time was modest (correlation coefficient [ $r$ ] = 0.21–0.59), the total and subscale scores are given. Higher scores indicate more intrusive thoughts and avoidance behaviors. In this study, the baseline Cronbach  $\alpha$  estimates were 0.87, 0.85, and 0.78 for the total IES score and for the Intrusion and Avoidance subscales, respectively.

The STATE is a 20-item scale that assesses an individual's current level of anxiety.<sup>31</sup> Participants rate the frequency of feelings or symptoms using a four-point scale, with higher scores indicating higher levels of anxiety. In this study, the baseline Cronbach  $\alpha$  estimate for the STATE was 0.95.

The CES-D is a well validated, 20-item, self-report measure of depression that focuses on affective components of depression.<sup>32</sup> Respondents rate the frequency of the specified behavior or feeling using a four-point, Likert-type scale. Higher scores indicate higher levels of depressive symptoms. In this study, the baseline Cronbach  $\alpha$  estimate for the CES-D was 0.93.

The BFI is a nine-item questionnaire that was designed to be used in the clinical setting to rapidly assess fatigue severity. The items are ranked from 0 to 10. Three questions ask patients to rate their fatigue at the moment and at its "worst" and "usual" over the past 24 hours. Four items ask patients to rate how

much in the past 24 hours their fatigue has interfered with their everyday life. In this study, the baseline Cronbach  $\alpha$  estimate for the BFI was 0.96.

The PSQI is an 18-item, self-rated questionnaire that assesses quality of sleep and sleep disturbances over 1 month.<sup>33</sup> A total score is derived as well as seven subscales that include Subjective Sleep Quality (1 item), Sleep Latency (2 items), Sleep Duration (1 item), Habitual Sleep Efficiency (ratio of 2 items), Sleep Disturbances (9 items), Use of Sleeping Medications (1 item), and Daytime Dysfunction (2 items). Scores  $\geq 5$  on the PSQI total scale, computed as a sum of the 7 subscales, are associated with clinically significant sleep disruptions, including insomnia and major mood disorders.<sup>33</sup> In this study, the baseline Cronbach  $\alpha$  estimate was 0.84 for the total scale, 0.79 for the 9-item Sleep Disturbance subscale, and 0.77 for the 2-item Sleep Latency scale, for which the interitem correlation was 0.70. There was no correlation ( $r = 0.00$ ) between the 2 items on the baseline Daytime Dysfunction subscale (trouble staying awake, trouble keeping enthusiasm).

Participants in the TY group also were asked about their satisfaction with the program, the perceived degree of benefit, and their frequency of practice outside the class for each of the four areas of practice (breathing and visualization, mindfulness, Tsa lung, and Trul khor). Participants were asked to indicate whether they felt any benefit from the practice on a scale from 1 to 5 (1 - "no, definitely not beneficial"; 2 - "no, not really beneficial"; 3 - "not sure if beneficial"; 4 - "yes, a little beneficial"; 5 - "yes, definitely beneficial"; they also could indicate "does not apply, I did not practice") and how often in the past week they had practiced on a scale from 1 to 6 (1 - not at all; 2 - once; 3 - twice; 4 - more than twice, but not every day; 5 - every day; 6 - more than once a day).

At baseline, all patients were asked whether they had ever practiced yoga. At each time point, patients also indicated whether they had engaged in any particular techniques to manage their stress (other than TY for the patients in the TY group).

#### Data analyses

Descriptive analyses were conducted to characterize the study participants and the feasibility of conducting a TY trial in patients with lymphoma. Analyses of the impact of the TY intervention relative to a wait-list control group were conducted on follow-up IES, state anxiety, depression symptomology, fatigue, and sleep disturbance scores using mixed-model regression analyses by regressing follow-up assessments on group, time of follow-up assessment, and the corresponding baseline measure as well as the patient char-

acteristics used in the minimization-adaptive assignment procedure.<sup>34</sup> The presence of group by time interactions also was assessed for each outcome measure; however, no statistically significant interactions were obtained (all group-by-time interaction  $P$  values were  $> 0.05$ ). Thus, the results are reported for the models with main-effect terms, and the group effect represents the average intervention effect across all follow-up time points adjusted for covariates. Correlations among observations from the same individual were modeled using a first-order, autoregressive form across the follow-up assessments; inspection of Akaike Information Criteria (AIC), Small-Sample (AICC), and Bayesian Information Criteria (BIC) values were used to select the optimal within-subject correlation structure to be used across the set of outcome measures. The implementation of mixed-model regression analysis in SAS 8.02 of restricted maximum-likelihood estimation with profile residual variances was used; tests of model fixed-effects parameters were conducted using the Prasad-Rao-Jeske-Kackar-Harville method for obtaining fixed-effects standard errors, and the Kenward-Roger approach was used to calculate degrees of freedom; this approach has been shown to yield good performance characteristics under small sample conditions in longitudinal analyses.<sup>35,36</sup>

#### RESULTS

Twenty patients were randomized to the TY group, and 19 patients were randomized to the wait-list control group. One participant in the TY group dropped out of the study before attending any classes, making the number of patients in that group 19; therefore, we did not collect any follow-up data for this patient. There were no statistically significant differences between the groups with respect to any medical or demographic characteristics or the baseline dependent measures (for descriptive statistics on measures of adjustment and sleep quality, see Table 1). In both groups, the average patient age was 51 years, 12 patients were female, 7 patients had Hodgkin lymphoma, and 15 patients were not actively receiving treatment for their cancer. There also was an even distribution across disease stages between the groups (TY group: Stage I, 22%; Stage II, 39%; Stage III, 17%; Stage IV, 22%; control group: Stage I, 22%; Stage II, 33%; Stage III, 12%; Stage IV, 33% Ann Arbor Criteria). A chart review indicated that 10 patients in the TY group and 11 patients in the control group were not taking any medications. Medications that patients were taking included antidepressants (TY group, 2 patients; control group, 2 patients), supplements (TY group, 2 patients; control group, 3 patients), thyroid medication (TY group, 2 patients; control group, 3 patients), hormone therapy (TY group, 1 patient; control group, 2 patients), neupo-

**TABLE 1**  
**Baseline and Follow-Up Adjustment and Sleep Quality Scores by Intervention Group<sup>a</sup>**

Measure	Yoga group (mean ± SD)		Wait-list control group (mean ± SD)		P value	95% CI
	Baseline	Follow-up	Baseline	Follow-up		
Impact of Events Scale						
Total score	21.5 ± 14.8	10.2 ± 8.2	18.7 ± 11.1	10.5 ± 8.5	0.92	-5.4 to 4.9
Intrusive thoughts	9.0 ± 6.7	3.7 ± 4.4	9.1 ± 6.6	4.2 ± 4.6	0.77	-3.2 to 2.4
Avoidance	13.1 ± 9.2	6.1 ± 6.0	10.6 ± 6.6	6.1 ± 6.0	0.99	-3.8 to 3.7
State Anxiety	34.3 ± 12.3	34.1 ± 8.4	37.8 ± 14.6	33.8 ± 8.5	0.90	-5.0 to 5.7
Depression (CES-D)	10.2 ± 11.0	9.0 ± 4.2	9.6 ± 8.57	9.7 ± 3.8	0.56	-3.3 to 1.9
BFI	3.1 ± 2.4	3.1 ± 1.5	2.8 ± 2.2	3.1 ± 1.5	0.93	-0.99 to 0.9
Sleep disturbance (PSQI)						
Total score	6.5 ± 5.0	5.8 ± 2.3	7.2 ± 4.7	8.1 ± 2.4	0.004	-3.8 to -0.8
Sleep quality	0.90 ± 0.85	0.81 ± 0.52	1.11 ± 0.94	1.22 ± 0.56	0.02	-0.7 to -0.08
Sleep latency	1.10 ± 0.97	0.75 ± 0.68	1.05 ± 0.91	1.33 ± 0.71	0.01	-1.0 to -0.1
Sleep duration	0.85 ± 1.09	0.89 ± 0.64	1.32 ± 1.29	1.35 ± 0.64	0.03	-0.9 to -0.04
Sleep efficiency	0.65 ± 1.09	0.87 ± 0.68	0.84 ± 1.07	0.95 ± 0.67	0.72	-0.5 to 0.4
Sleep disturbances	1.40 ± 0.68	1.23 ± 0.40	1.37 ± 0.76	1.33 ± 0.37	0.47	-0.3 to 0.16
Sleeping medications	0.80 ± 1.28	0.48 ± 0.88	0.58 ± 1.07	1.21 ± 0.93	0.02	-1.3 to -0.2
Daytime dysfunction	0.80 ± 0.62	0.96 ± 0.60	0.95 ± 0.71	0.93 ± 0.64	0.89	-0.4 to 0.4

SD: standard deviation; 95% CI: 95% confidence interval; CES-D: Centers for Epidemiologic Studies-Depression; BFI: Brief Fatigue Inventory; PSQI: Pittsburgh Sleep Quality Index.

<sup>a</sup> P values and 95% confidence intervals are in relation to the group comparisons for the follow-up data. Note that follow-up adjustment scores represent least-squares means adjusted for the baseline value of the outcome measure and state anxiety, age, gender, treatment status, and the type of cancer (Hodgkin or non-Hodgkin lymphoma) using the final, mixed-model regression models ( $n = 16$  patients in the yoga group;  $n = 14$  patients in the control group).

gen/procrit (TY group, 2 patients; control group, 1 patient), hypertension medication (TY group, 2 patients; control group, 1 patient), steroids (TY group, 2 patients), antiemetic medication (TY group, 1 patient), diabetes medication (TY group, 2 patients; control group, 1 patient), cholesterol medication (TY group, 2 patients), antiseizure medication (control group, 1 patient), and antibiotics (control group, 2 patients).

Three patients in each group also indicated that they had practiced yoga in the past; however, none were practicing yoga currently. Nine patients in the TY group and 14 patients in the control group indicated that they did something to manage their stress before the start of the study, including exercise (TY group, 4 patients; control group, 8 patients), meditation (TY group, 1 patient), breathing exercises (TY group, 1 patient; control group, 2 patients) relaxation tapes (control group, 1 patient), and hobbies (TY group, 3 patients; control group, 3 patients). Eight patients in the TY group and nine patients in the control group indicated that they used some technique(s) to manage their stress at some time during the follow-up period, including exercise (TY group, 7 patients; control group, 7 patients), meditation (TY group, 1 patient; control group, 1 patient), breathing exercises (control group, 2 patients), support group (control group, 1 patient), and hobbies (TY group, 3 patients; control group, 2 patients).

All 19 TY participants attended at least 1 yoga session. Six participants (32%) attended all 7 sessions through attendance at either the primary session or through a make-up class; 5 participants (26%) attended 5 or 6 sessions; 6 participants (32%) attended 2 or 3 sessions; and 2 participants (10%) attended only 1 session. Patients missed classes for the following reasons: they were out of town, they had conflicts with their work schedule, they had a cancer treatment-related reason, they were too busy, they had transportation problems, or they had a health problem (not cancer-related). Sixteen of 19 patients (84%) in the TY group and 14 of 19 patients (74%) in the control group completed at least 1 of the 3 follow-up assessments, with an average of 2.0 (standard deviation [SD], 0.82) and 2.4 (SD, 0.65) assessments completed in the TY group and the control group, respectively ( $P = 0.13$ ). There were no significant demographic, medical, or psychosocial differences between the 9 patients who did not complete any follow-up assessments and the 30 patients who did complete the assessments.

In their evaluations, participants indicated that they found the TY program beneficial. In fact, none of the participants had responses of 0 ("does not apply, I did not practice") or 1 ("no, definitely not beneficial") for any of the 4 aspects. Pooling across the postintervention assessments, the modal response for each of the 4 aspects was 5 ("yes, definitely beneficial"); 73%,

**TABLE 2**  
**Perceived Benefit and Practice Rates for Breathing and Visualization, Mindfulness, Tsa Lung, and Trul Khor**

Exercise	Benefit <sup>a</sup>		Practice <sup>b</sup>	
	Mean	Median	Mean	Median
Breathing and visualization	4.7	5.0	3.5	3.8
Mindfulness	4.5	4.7	3.1	3.3
Tsa lung	4.5	4.7	2.9	3.0
Trul khor	4.6	5.0	2.8	2.9

Tsa lung (*risa lung*): channels and vital breath; Trul khor (*phrul khor*): magical wheel of the channels and vital breath.

<sup>a</sup> Benefit: 1 - no, definitely not beneficial; 2 - no, not really beneficial; 3 - not sure if beneficial; 4 - yes, a little beneficial; 5 - yes, definitely beneficial.

<sup>b</sup> Practice: 1 - not at all; 2 - once; 3 - twice; 4 - more than twice, but not every day; 5 - every day; 6 - more than once daily.

64%, 64%, and 82% of respondents indicated 5 (“yes, definitely beneficial”) to breathing and visualization, mindfulness, Tsa lung, and Trul khor, respectively. The mean and median responses were between 4 (“yes, a little beneficial”) and 5 (“yes, definitely beneficial”) (see Table 2). Similarly, pooling across intervention and postintervention periods, the participants indicated a fair amount of practice in each of the four aspects, averaging two times per week (see Table 2). The modal response regarding average weekly practice of breathing and visualization, Tsa lung, and Trul khor was 4 (“more than twice, but not every day”), with that level of specific practice reported by 39%, 31%, and 29% of participants, respectively; the second most common level of practice reported was 3 (“twice a week”; breathing and visualization, 28%; Tsa lung, 27%; Trul khor, 21%). For weekly practice of mindfulness, 31% of participants averaged practicing “more than twice, but not every day,” and the same percentage averaged “twice a week.”

Table 1 shows the overall follow-up results on psychologic adjustment, fatigue, and sleep disturbances by intervention group. The values are least-squares means that have been adjusted for the baseline value of the outcome measure and the minimization adaptive allocation factors (i.e., state anxiety, age, gender, status of treatment, and type of cancer [Hodgkin or non-Hodgkin lymphoma]), as well as time of follow-up assessment, which was not a statistically significant effect in any of the models. The mixed-model regression analyses revealed a statistically significant adjusted group effect for the PSQI total score ( $P < 0.004$ ) and for 4 of the subscales, including Subjective Sleep Quality ( $P < 0.02$ ), Sleep Latency ( $P < 0.01$ ), Sleep Duration ( $P < 0.03$ ), and Use of Sleep Medications ( $P < 0.02$ ). This suggests that,

during follow-up, the TY group had significantly better overall sleep quality and that they perceived better sleep quality, fell asleep more quickly, slept longer, and used fewer sleep medications compared with patients in the control group (see Table 1). There were no statistically significant differences between the groups in terms of the Intrusion or Avoidance scores, state anxiety, depression, or fatigue scores.

## DISCUSSION

The feasibility of conducting the seven-session TY program in patients with lymphoma was demonstrated clearly. In particular, although  $> 20\%$  of patients were undergoing chemotherapy, the majority of patients attended  $> 50\%$  of sessions. Patients also indicated that they found the program useful, and  $> 80\%$  said they practiced some aspect of the program at least once per week during the 3-month follow-up. Most importantly, there was some indication that the TY program reduced patients' sleep disturbances. In particular, patients in the TY group reported significantly better overall sleep quality and subjective sleep quality, faster sleep latency, longer sleep duration, and less use of sleep medications during the follow-up compared with patients in the control group. However, there were no statistically significant group differences for the measures of psychological adjustment or fatigue.

To our knowledge this is the first study to examine TY in any population and one of the few studies to examine the effects of yoga in a cancer population. In other studies that have examined the benefits of including yoga, yoga constituted only one aspect of the intervention. For example, Speca et al.<sup>23</sup> designed an intervention that included group support and discussion, mindfulness meditation, visualization and imagery, and yoga stretches. Although they found that the participants in the intervention group experienced lower total mood disturbance and decreased overall distress, it is not clear whether the benefits were due to the yoga per se. It is noteworthy that the form of yoga we used in the current study was presented and taught in its traditional format, which includes a number of components (e.g., breathing and visualization, mindfulness, Tsa lung, and Trul khor). However, although the TY program that we designed appeared to be useful for this population, we cannot tell which particular aspects of the program were more or less useful for the participants.

There are several possible explanations for why we did not find an effect of TY on the measures of psychological adjustment (intrusion or avoidance, state anxiety, and depression) and fatigue. First, the TY program truly may not affect these outcomes for this population. Alternatively, the lack of effect also may reflect low sensitivity of the measures. For example, because both the

CES-D and the STATE are often used as clinical screening measures of mental health (for depression and anxiety, respectively), these instruments may not detect only subtle changes in mental health in a nonmental health population. Less clinically oriented measures, such as the Profile of Mood States<sup>37</sup> used by Spica et al.,<sup>23</sup> might have detected group differences in our population. Along these same lines, there also might have been a floor effect for some of these measures, because the scores were quite low at baseline and follow-up. In addition, most patients were off treatment at the start of the study (15 patients in each group), which may have contributed further to a floor effect. It is important to note that the study also may have been underpowered to detect differences for these outcomes when the effect size may have been smaller than the effect of the TY program on the measure of sleep disturbances.

There are several limitations to the current study, most significantly, the small sample size of just 30 patients for whom we had follow-up data on any of the selected outcome measures; however, as recent studies have shown, this level of sample size can yield adequate Type I error control and power.<sup>35,36</sup> Nonetheless, this is one of the only studies examining the benefits of yoga in a cancer population, and 14–15 patients per group provides 80% power to detect a population effect size of 1.1 and 50% power to detect a population effect size of 0.7, with sample effect sizes  $\geq 0.7$  achieving statistical significance. It is also important to note that we had several outcome measures of interest in this trial. However, despite the examination of multiple outcomes, the strength of the finding that the TY intervention had an effect on sleep quality is greater than would be expected by chance alone. The study also was limited by the fact that we relied on self-reports to determine compliance and to assess the main outcomes. Although research using the PSQI suggests there is a good association between self-reports and polysomnographic sleep measures, future studies should incorporate some objective outcomes. We also cannot know from our data whether the benefits of the program were attributable directly to TY as a whole or to some nonspecific aspect of the program, such as attention, social support, relaxation, or stretching. To determine this, future studies will need to use more complex research designs.

Our findings that the TY program was associated with a decrease in overall sleep disturbances and an improvement in subjective sleep quality, sleep latency, sleep duration, and use of sleep medications are particularly salient in a cancer population. This is because sleep disturbances are a common and underinvestigated problem among cancer patients.<sup>38</sup> Indeed, in some studies, up to 75% of the cancer patients surveyed experienced disturbances in their sleep and rest cycle.<sup>39</sup> Eng-

strom et al.<sup>40</sup> found that the most common sleep problems were awakening during the night and difficulty falling back to sleep as well as not sleeping enough. Of particular concern is the possibility that there may be profound consequences of disturbed sleep for cancer patients, because sleep may mediate both psychologic health and physical health.<sup>38,41,42</sup> In fact, sleep disturbances have been associated with worse quality of life in cancer patients, including increased depression and higher pain levels,<sup>40,43</sup> and with depression in noncancer patients.<sup>42</sup> Persistent sleep disturbances also may increase a cancer patient's risk for mood disorders, altered metabolic and endocrine function, and compromised immune functioning.<sup>38,41,43,44</sup> It is noteworthy that sleep disruptions have been associated with adverse physical health outcomes, including increased morbidity and mortality.<sup>45–47</sup> Potential changes in metabolic, endocrine, and immune function may have particularly important health consequences for patients with hematologic malignancies.

Although research into the efficacy and mechanisms of yoga is in its beginning stages, the findings reported to date are supportive<sup>13</sup> and, along with our finding of improved sleep, suggest that the health effects of yoga in cancer patients should be explored further. The benefits that have been documented and the potential impact of these benefits on the psychologic and physical sequelae of cancer are important enough to warrant the further study of developing such programs for cancer patients.

## REFERENCES

1. Taimini I. The science of yoga. Madras: The Theosophical Publishing House, 1961.
2. Samlek M. The three basic Mother Tantras with commentaries (reproduced from the original XI century manuscript belonging to the Monastery of Samling, Dolpo, Nepal) [in Tibetan]. New Delhi: Bonpo Monastic Centre, 1971.
3. Chandra L, Namdak T, editors. The magical wheel oral wisdom quintessential instructions from the Great Perfection Oral Transmission of Zhang Zhung (reproduced from an original XI century manuscript). In: Chandra L, Mandak T, editors. History and doctrines of Bonpo Yoga (Satapitaka series, volume 73) [in Tibetan]. New Delhi: International Academy of Indian Culture, 1968:631–643.
4. Sonam N, Gyaltzen PL, Gyatso K, editors. The Magical Wheel, channels and vitalbreath of the Oral Transmission of Zhang Zhung. (Commentary on: The Magical Wheel oral wisdom quintessential instructions from the Great Perfection Oral Transmission of Zhang Zhung) [in Tibetan]. In: Sonam N, Gyaltzen PL, Gyatso K, editors. The vast treasury of profound space. New Thobgyal: Tibetan Bonpo Monastic Centre, 1974:321–346.
5. Janakiramaiah N, Gangadhar BN, Naga Venkatesha Murthy PJ, Harish MG, Subbakrishna DK, Vedamurthachar A. Antidepressant efficacy of Sudarshan Kriya Yoga (SKY) in melancholia: a randomized comparison with electroconvulsive therapy (ECT) and imipramine. *J Affect Disord.* 2000;57:255–259.

6. Vahia NS, Doongaji DR, Jeste DV, Ravindranath S, Kapoor SN, Ardhapurkar I. Psychophysiologic therapy based on the concepts of Patanjali. A new approach to the treatment of neurotic and psychosomatic disorders. *Am J Psychother.* 1973;27:557-565.
7. Malathi A, Damodaran A. Stress due to exams in medical students—role of yoga. *Indian J Physiol Pharmacol.* 1999;43:218-224.
8. Telles S, Hanumanthaiah BH, Nagarathna R, Nagendra HR. Plasticity of motor control systems demonstrated by yoga training. *Indian J Physiol Pharmacol.* 1994;38:143-144.
9. Dash M, Telles S. Yoga training and motor speed based on a finger tapping task. *Indian J Physiol Pharmacol.* 1999;43:458-462.
10. Malathi A, Damodaran A, Shah N, Patil N, Maratha S. Effect of yogic practices on subjective well being. *Indian J Physiol Pharmacol.* 2000;44:202-206.
11. Joshi LN, Joshi VD, Gokhale LV. Effect of short term “Pranayam” practice on breathing rate and ventilatory functions of lung. *Indian J Physiol Pharmacol.* 1992;36:105-108.
12. Nagendra HR, Nagarathna R. Applications of integrated approach of yoga therapy—a review. A new light for asthmatics. Bangalore: Vivekananda Kendra, 1986.
13. Telles S, Naveen KV. Yoga for rehabilitation: an overview. *Indian J Med Sci.* 1997;51:123-127.
14. Garfinkel M, Schumacher HR Jr. Yoga. *Rheum Dis Clin North Am.* 2000;26:125-132.
15. Garfinkel MS, Schumacher HR Jr., Husain A, Levy M, Reshetar RA. Evaluation of a yoga based regimen for treatment of osteoarthritis of the hands. *J Rheumatol.* 1994;21:2341-2343.
16. Vedanthan PK, Kesavalu LN, Murthy KC, et al. Clinical study of yoga techniques in university students with asthma: a controlled study. *Allergy Asthma Proc.* 1998;19:3-9.
17. Nagarathna R, Nagendra HR. Yoga for bronchial asthma: a controlled study. *Br Med J (Clin Res Ed).* 1985;291:1077-1079.
18. Mahajan AS, Reddy KS, Sachdeva U. Lipid profile of coronary risk subjects following yogic lifestyle intervention. *Indian Heart J.* 1999;51:37-40.
19. Murugesan R, Govindarajulu N, Bera TK. Effect of selected yogic practices on the management of hypertension. *Indian J Physiol Pharmacol.* 2000;44:207-210.
20. Ramaratnam S, Sridharan K. Yoga for epilepsy. *Cochrane Database Syst Rev.* 2000;(3):CD001524.
21. Collins C. Yoga: intuition, preventive medicine, and treatment. *J Obstet Gynecol Neonatal Nurs.* 1998;27:563-568.
22. Joseph CD. Psychological supportive therapy for cancer patients. *Indian J Cancer.* 1983;20:268-270.
23. Speca M, Carlson LE, Goodey E, Angen M. A randomized, wait-list controlled clinical trial: the effect of a mindfulness meditation-based stress reduction program on mood and symptoms of stress in cancer outpatients. *Psychosom Med.* 2000;62:613-622.
24. Taves DR. Minimization: a new method of assigning patients to treatment and control groups. *Clin Pharmacol Ther.* 1974;15:443-453.
25. Pocock SJ, Simon R. Sequential treatment assignment with balancing for prognostic factors in the controlled clinical trial. *Biometrics.* 1975;31:103-115.
26. Rovers MM. Comparison of balanced and random allocation in clinical trials. *Eur J Epidemiol.* 2000;16:1123-1129.
27. Forsythe AB. Validity and power of tests when groups have been balanced for prognostic factors. *Comput Stat Data Anal.* 1987;5:193-200.
28. Birkett NJ. Adaptive allocation in randomized controlled trials. *Control Clin Trials.* 1975;6:146-155.
29. Thernau TM. How many stratification factors are “too many” to use in a randomization plan? *Control Clin Trials.* 1993;14:98-108.
30. Horowitz M, Wilner N, Alvarez W. Impact of Events Scale: measure of subjective stress. *Psychosom Med.* 1979;41:209-218.
31. Spielberger CD, Gorsuch R, Lushene RE. STAI manual for the State-Trait Anxiety Inventory. Palo Alto: Consulting Psychologists Press, 1970.
32. Radloff LS. The CES-D scale: a new self-report depression scale for research in the general population. *Appl Psychol Meas.* 1977;1:385-401.
33. Buysse DJ, Reynolds CF, Monk TH, Berman SR. Pittsburgh Sleep Quality Index: a new instrument for psychiatric practice and research. *Psychiatr Res.* 1989;28:193-213.
34. Friedman LM, Furberg CD, Demets DL. Fundamentals of clinical trials, 3rd ed. New York: Springer-Verlag, 1998.
35. Fouladi RT, Shieh YY. Power profiles of modified likelihood ratio tests on mixed linear model parameters. American Statistical Association, editor. Proceedings of the Joint Statistical Meetings, Biometrics Section [CD Rom]. Alexandria: American Statistical Association, 2001.
36. Kenward MG, Roger JH. Small sample inference for fixed effects from restricted maximum likelihood. *Biometrics.* 1997;53:983-997.
37. McNair DM, Lorr M, Droppleman LF. Profile of mood states. San Diego: Educational and Industrial Testing Service, 1981.
38. Savard J, Morin CM. Insomnia in the context of cancer: a review of a neglected problem. *J Clin Oncol.* 2001;19:895-908.
39. Malone M, Harris AL, Luscombe DK. Assessment of the impact of cancer on work, recreation, home management and sleep using a general health status measure. *J R Soc Med.* 1994;87:386-389.
40. Engstrom CA, Strohl RA, Rose L, Lewandowski L, Stefanek ME. Sleep alterations in cancer patients. *Cancer Nurs.* 1999;22:143-148.
41. Hall M, Baum A, Buysse DJ, Prigerson HG, Kupfer DJ, Reynolds CF. Sleep as a mediator of the stress-immune relationship. *Psychosom Med.* 1998;6:48-51.
42. Dew MA, Reynolds CF, Buysse DJ, Houck PR, Monk TH, Kupfer DJ. Electroencephalographic sleep profiles during depression. Effects of episode duration and other clinical and psychosocial factors in older adults. *Arch Gen Psychiatry.* 1996;53:148-156.
43. Koopman C, Nouriani B, Erickson V, et al. Sleep disturbances in women with metastatic breast cancer. *Breast J.* 2002;8:362-370.
44. Spiegel K, Leproult R, Van Couter E. Impact of sleep debt on metabolic and endocrine function. *Lancet.* 1999;354:1435-1439.
45. Dew MA, Hoch CC, Buysse DJ, et al. Healthy older adults' sleep predicts all-cause mortality at 4 to 19 years of follow-up. *Psychosom Med.* 2003;65:63-73.
46. Newman AB, Enright PL, Manolio TA. Sleep disturbance, psychosocial correlates and cardiovascular disease in 5201 older adults: the Cardiovascular Health Study. *J Am Geriatr Soc.* 1997;45:1-7.
47. Eaton WW, Badawi M, Melton B. Prodromes and precursors: epidemiologic data for primary prevention of disorders with slow onset. *Am J Psychiatry.* 1995;152:967-972.