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Vivekananda Yoga Program for Patients with Advanced Lung Cancer and their Family Caregivers

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Abstract

BACKGROUND—Although yoga practice may improve quality of life (QOL) in cancer patients, feasibility in patients with lung cancer is largely unknown. Moreover, previous research has excluded patients' family caregivers. Because caregivers are vulnerable to caregiver burden, a dyadic approach targeting QOL in both patient and caregiver may be particularly beneficial. Thus, the purpose of this study was to establish the feasibility of a couple-based Vivekananda Yoga (VKC) intervention in lung cancer patients and caregivers. Vivekananda Yoga may be suitable for a dyadic approach and address the multifaceted needs (e.g., emotional, physical, spiritual, and social) common among families coping with lung cancer.

METHOD—In this single-arm feasibility trial, patients with lung cancer undergoing radiotherapy and their caregivers participated in a 15-session VKC program focused on the interconnectedness of the dyad. The program consisted of four main components: 1) joint loosening with breath synchronization; 2) postures (asanas) and a deep relaxation technique; 3) breath energization (pranayama) with sound resonance; and 4) meditation. We assessed pre/post-intervention levels of fatigue (BFI), sleep disturbances (PSQI), psychological distress (BSI), overall mental and physical QOL (SF-36), spirituality (FACT-Sp) and relational closeness. We also tracked feasibility data, and participants completed program evaluations.

RESULTS—We approached 28 eligible dyads of which 15 (53%) consented and 9 (60%) completed the intervention. No adverse events were reported. Patients (mean age: 73 years, 63% female, all stage III) and caregivers (mean age: 62 years, 38% female, 63% spouses) completed a mean of 10 sessions (range: 4–14) and 95.5% of them rated the program as very useful. Paired t-tests revealed a significant increase in patients' mental health (d=.84, P=.04) and a significant decrease in caregivers' sleep disturbances (*d*=1.44, P=.02). Although not statistically significant, for patients, effect sizes for change scores were medium for benefit finding and small for distress

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(*d*=.65 and .37, respectively). For caregivers, medium effects were found for improvement in physical functioning (d=.50).

CONCLUSION—This novel supportive care program appears to be safe, feasible, acceptable, and subjectively useful for lung cancer patients and their caregivers and lends support for further study in a larger randomized controlled trial.

Keywords

Non-small cell lung cancer; mind-body medicine; family caregivers; dyadic intervention; feasibility; quality of life

INTRODUCTION

Although the literature suggests that mind-body practices (e.g., yoga, meditation, tai chi) may improve psychological and physical aspects of quality of life (QOL) in cancer patients and survivors, investigations have been almost exclusively patient-oriented.[1,2] In light of high symptom burden among family members, particularly spouses, there is a need to develop effective couple-based mind-body interventions.[3–5] Caregivers are vulnerable to clinical levels of depression, sleep disturbances and fatigue,[4] which may negatively impact their ability to provide care and support[6], and exacerbate patient distress.[7] Thus, programs are needed that help protect caregivers' health and their ability to provide quality care and support. Moreover, because patient and partner distress and QOL are interdependent (patient outcomes influence partner outcomes and vice versa) in couples coping with cancer, a couple-based practice may enhance treatment efficacy.[8–11]

The psychosocial intervention literature has increasingly recognized the need for and benefit of couple-based programs.[12] Yet, dyadic approaches are notably lacking in the integrative oncology literature.[13,14] This lack of a systemic supportive care approach is rather antithetical to the holistic philosophy of integrative medicine. In fact, patients consider their family members not only the most valued source of support, but also the greatest source of concern.[15] In order to deliver optimal patient care, dyadic interventions appear to be the next logical step in integrative oncology.

Current Research

To address this gap in the literature, we pilot-tested a Vivekananda couple-based yoga program (VKC). This program was particularly designed to address physical symptoms (e.g., dyspnea, fatigue) and psychological needs (e.g., distress, blame) common among lung cancer patients and their caregivers, a vulnerable yet understudied population.[16,17] This intervention is based on our Tibetan Yoga program for couples, which is performed in a seated position and focuses primarily on breathing exercises, gentle upper body movements and breathing exercises.[14] Because this very gentle practice was well tolerated, we examined a more physically rigorous practice with the goal to improve participants' physical well-being. Additionally, compared to the Tibetan practice, this Indian practice more readily allows for dyadic components, such as partner postures and guided visualizations involving the partner (described below). Additionally, Vivekananda Yoga has been rigorously studied in the East and West. Community uptake of an Indian practice in later phases of this program may be high given its popularity in the western countries such as the United States. We examined the feasibility and preliminary efficacy regarding QOL outcomes (symptoms and wellbeing) of this dyadic approach. We incorporated the intervention into patients' 6-week radiation treatment plans, as the program may be especially useful at this time to buffer treatment side effects and the psychological distress that ensues.

METHODS

Participants

Patients with non-small cell lung cancer (NSCLC) stages I through IIIB who were going to receive at least 5 weeks of radiotherapy with a consenting family caregiver (e.g., spouse, sibling, parent) were eligible. Both patients and caregivers had to be at least 18 years old, proficient in English, and able to provide written informed consent. Patients were excluded if they were not oriented to time, place, and person; practiced any form of yoga on a regular basis (self-defined) in the year prior to diagnosis; had a physician-rated Eastern Cooperative Oncology Group performance status score of greater than 2; and/or a life expectancy of less than 6 months.

Procedure

Prior to enrollment, the MD Anderson Institutional Review Board approved all procedures. Research staff identified potentially eligible patients through the institution's electronic medical records system. During clinic visits, research staff approached patients and caregivers, confirmed study eligibility, and obtained written informed consent prior to data collection. Both patients and caregivers completed survey measures at baseline (T1) and during the last week of patients' radiotherapy (T2). Feasibility data were tracked over the course of the study.

VKC Program

Participants attended two to three weekly sessions (60 minutes each) over the course of the 5–6 weeks of radiotherapy. The program consisted of four main components: 1) joint loosening with breath synchronization; 2) postures (asanas) and a deep relaxation technique; 3) breath energization (pranayama) with sound resonance; and 4) meditation.

Sessions 1–4 focused on gradually introducing the various practices. Once participants learned the techniques, the rest of the sessions (session 5–15) focused on refining practice, and answering questions related to the practice and participants' experiences. Starting with session 1, instructors conveyed the notion that the practice is intended to target the needs of *both* members of the dyad with a focus on their interconnectedness. (Please contact the first author for a detailed description of this yoga program).

Participants received printed materials at session 1 and were encouraged to practice on their own (individually and/or together) on the days when they did not meet with the instructor. If patients experienced respiratory distress (e.g., coughing) in the supine position during deep relaxation, a rolled-up towel was placed under the patients' head, which alleviated the distress.

QOL Measures

Both patients and caregivers completed the following standard QOL measures at T1 and T2.

A. Symptomology: *Psychological Distress* was assessed with the Brief Symptom Inventory-18 (BSI-18) consisting of 18 items and three dimensions (depression, anxiety, and somatization).[18] *Sleep disturbances* were assessed using the Pittsburgh Sleep Quality Index (PSQI). *Fatigue* was assessed using the Brief Fatigue Inventory (BFI). Higher scores on these measures denote greater symptom burden.

B. Well-Being: *Health-related QOL* was assessed with the Medical Outcomes Study 36-item short-form survey (SF-36) using the Physical Component (PCS) and Mental Component (MCS) Summaries. *Spiritual well-being* was measured with the Functional Assessment of Cancer Therapy Spiritual Well-Being Scale (v4). *Benefit Fniding* was measured using the Benefit Finding in Cancer Scale developed by Antoni et al.[19] *Emotional intimacy* was measured with 5 items from Laurenceau's perceived closeness and responsiveness measure[20] which have been validated in cancer samples.[21] Higher scores denote greater well-being

Demographic and Medical Factors and Feasibility Data—Demographic items (e.g., age, marital status) were included in the baseline questionnaires. Patients' medical data were extracted from their medical records. Feasibility data were kept regarding consent rates, class attendance, program evaluations, completion of questionnaires, and attrition.

Data Analyses

To establish feasibility, we calculated descriptive statistics of consent rate, class attendance, assessment completion, and program evaluations. We examined paired (pre/post) t-tests analyses separate for patients and caregivers. For patients, we controlled for pharmacological interventions that were prescribed to manage either sleep disturbances or respiratory distress as reported in patients' medical records. We calculated the effect size (Cohen's d[22]) for each paired difference by dividing the mean difference by the standard deviation of the difference and interpreted the effect size in terms of Cohen's taxonomy ("small" effect, $d \le 0.2$; "medium" effect, $d \le 0.5$; and "large" effect, $d \le 0.8$).

RESULTS

Recruitment and Sample Characteristics

Fifteen of the 28 eligible dyads approached consented (54%) and 9 (60%) completed the VKC program (2 became ineligible; 4 withdrew) including the baseline and end-of-treatment assessments. Refusal reasons included time constraints (n=9) and lack of interest (n=4). Dyads withdrew because of time constraints (n=2), patient's change in interest (n=1) and caregiver-related interferences (n=1). Patients who withdrew did not differ in demographic or medical factors from those completed the study. Baseline sample characteristics for patients and caregivers are illustrated in Table 1.

Session Attendance, Perceived Benefit, and Program Evaluation

Dyads completed a mean of 10 VKC sessions (SD=3.15; range: 4–14) with 78% of dyads attending more than 50% of all sessions. All session lasted approximately 60 min. Between sessions, participants practiced primarily individually with a mean of 2.18 times (SD=1.94; range 0–7) and less frequently as dyads (mean=0.52 times, SD=1.04, range=0–4). The majority of participants (89%) rated the program as "very useful." All participants indicated that each aspect of the practice (i.e., breathing exercises, physical exercises, relaxation and mediation) was beneficial to them. Immediately after the sessions, 89% of participates reported feeling "relaxed"; 75% calm, 68% content; and, 46% happy. On a 0 to 10 Borg Rating of Perceived Exertion Scale, participants rated the session as "easy" to "moderate" effort (patients: mean=2.65, SD=1.41 range 0–5; caregivers: mean =1.62, SD=1.19, range: 0–3).

Preliminary Efficacy Findings

Table 2 presents means and standard deviations for each outcome measure at baseline and end-of-treatment as well as paired t-test results, p-values, and effect sizes for patients and caregivers. For patients, paired t-tests revealed a significant decrease in anxiety (*t*=2.41, P=.04; *d*=.81) and a significant increase in mental health aspects of QOL (t=2.51, P=.04; *d*=.84). There were also improvements in benefit finding (medium effect; *d*=.64), sleep disturbances and spiritual well-being (small effects; *d*=.36 and .31, respectively). Although there was a medium effect for somatization (*d*=.65), it was in the unexpected direction. For caregivers, there was a significant reduction in sleep disturbances (*t*=3.04, P=.02; *d*=1.01). A medium effect size was found for improved physical aspects of QOL (*d*=.50) and small effect sizes for depressive symptoms and spiritual well-being.

Dose Effect

For patients, greater yoga session attendance was marginally correlated with greater reductions in sleep disturbances (r=.68, P=.06). For caregivers, greater attendance was significantly related to greater reductions in fatigue (r=.71, P=.03) and depressive symptoms (r=.80, P=.02) and marginally related to improvements in mental QOL (r=−.62, P=.08).

DISCUSSION

The aim of our pilot study was to examine the feasibility and preliminary efficacy of a couple-based yoga program for lung cancer patients undergoing radiotherapy and their caregivers on QOL outcomes by evaluating levels of distress, fatigue, sleep disturbance, benefit finding and relational closeness. For a supportive care intervention to have value in the health care setting, it must not only be efficacious but must also feasible, acceptable, and safe for the population being targeted. Findings suggest that it is feasible to successfully incorporate a dyadic intervention into patients' 6-week radiation treatment plan as supported by adequate consent and completion rates. The program was also well accepted with the majority of participants (89%) rating it as very useful. Considering the historically high symptom burden of the targeted patient population, the program was well tolerated -- both patients and caregivers rated the program as requiring easy to moderate effort -- and no adverse events were reported. Our findings also suggest preliminary intervention efficacy.

For patients, a significant reduction in anxiety and increase in mental health aspects of QOL were observed with medium effect sizes in benefit finding and small effect sizes in sleep disturbance and spiritual well-being. For caregivers, there was a significant reduction in sleep disturbance and a medium effect size for physical health aspects of QOL. As patient QOL typically deteriorates across 6 weeks of radiotherapy, it is remarkable that we noted it improved or remained stable on all but one variable. Comparison with a usual care control group may reveal significant differences across a number of outcomes.

Although the testing of this intervention is in its initial stages, this study has laid an important foundation to systematically examine the role of dyadic approaches to mind-body medicine. Integrative oncology focuses on whole person care yet has limited offerings to enhance relational wellbeing and support caregivers. Our results suggest further study is warranted and that dyadic programs may have a place in integrative oncology approaches dedicated to whole person care. Challenges will include development of strategies to routinely assess caregiver and couple needs in the traditional setting of patient-centered care. Improved routine assessment of caregiver needs as part of supportive care/integrative oncology practice can contribute to a better understanding of other cancer or disease populations that may benefit from such a couple-based approach.

This research points to a potentially new and exciting treatment approach; however, prudence is warranted in interpreting these preliminary results. For one, this pilot study included a small sample size and reported means may thus be unstable. Additionally, the study lacked a control group. Thus, it cannot be ruled out that patients improved as a function of time as opposed to practicing yoga; however, considering that all patients were treated aggressively (i.e., chemoradiation) for stage III NSCLC and a decrease in QOL across the treatment trajectory has been documented, improvement as a function of time is unlikely.[23–25] Nevertheless, only a future a randomized controlled trial (RCT) design with adequate statistical power and control group(s) can establish treatment efficacy. Future research is also needed to address concerns regarding optimal dosing of the intervention. For instance, participants may need to attend classes more often than biweekly to experience treatment gains as this study revealed a dose effect for some of the outcomes. As our participant population was primarily retired, white, with a high level of education and household income, a future, larger trial with greater diversity could allow us to more closely analyze subgroups to better understand intervention effects. A larger trial will also allow examining gender differences in treatment response. By identifying specific components of the intervention providing the greatest benefit, we could more effectively tailor the intervention to the specific needs of the lung cancer patient population. Future studies can include longer follow up periods and strategies to help prolong the observed beneficial effects, which may include placing a greater emphasis on practice between sessions for both participants and dyads.

In conclusion, a dyadic mind-body intervention delivered to lung cancer patients and caregivers while undergoing radiotherapy was feasible and potentially effective. Development of an RCT design is warranted. Increased understanding of the impact of dyadic interventions on patient and caregiver QOL will only be possible through further study of thoughtfully designed mind-body approaches tailored to the individual needs of the patient population with an emphasis on safety and acceptability.

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Table 1

Patient and Caregiver Demographics and Patient Medical Factors of Study Completers

Variable	**Patient (n=15)**	**Caregiver (n=15)**
Gender, n (%)		
Female	4 (44.4)	6 (66.7)
Mean age, years ±SD, (range)	62.16±14.03 (33–81)	58.95±15.67 (28–78)
Length of marriage if married to caregiver, years ±SD, (range)	8.19±22.50 (3–58)	
Marital Status, n (%)		
Married	4 (77.8)	7 (77.8)
Relationship to Patient, n (%)		
Spouse	6 (66.7)	
Other family member	3 (33.3)	
Ethnicity, n (%)		
White	8 (88.9)	9 (00.0)
Latino/Hispanic	1 (11.1)	
Highest Level of Education, n (%)		
Some college or higher	7 (77.8)	5 (55.6)
Household Income, n (%)		
50,000 or more	7 (77.8)	6 (66.7)
Declined to answer	2 (22.2)	2 (22.2)
Employment Status, n (%)		
Full-time	4 (44.4)	5 (50.0)
Retried	4 (44.4)	2 (20.0)
Stage at Diagnosis, n (%)		
IIIA	5 (55.6)	
IIIB	4 (44.4)	
Resection, n (%)	3 (20.0)	
Chemoradiation, n (%)	15 (100.0)	
Time since diagnoses, months ±SD, (range)	2.88±1.36 (1.13–5.97)	
Pharmacology intervention for respiratory distress, n (%)	3(20.0)	
Pharmacology intervention for insomnia, n (%)	3 (20.0)	
Clinical level of sleep disturbances[a], n (%)	5 (44.4)	9 (90.0)
Clinical level of fatigue[b], n (%)	6 (66.7)	3 (33.3)

Abbreviations: SD, Standard deviation;

[a] score >3 on the Brief Fatigue Inventory;

[b] score ≥10 on the Pittsburgh Sleep Quality Index

Table 2

Raw Means for Study Completers at Each Assessment Point, Results of Paired t-Tests, and Effect Sizes for Patients and Caregivers

Measure	Patients							Caregivers						
	Baseline		Post Program					Baseline		Post Program				
	Mean	SD	Mean	SD	*t*	P-value	*d*	Mean	SD	Mean	SD	*t*	P-value	*d*
BSI-Dep	0.28	0.40	0.20	0.27	0.88	0.40	0.28	0.29	0.39	0.38	0.28	−0.71	0.50	0.25
BSI-Anx	0.54	0.59	0.18	0.19	2.41	0.04*	0.81	0.44	0.50	0.46	0.52	−0.08	0.94	0.03
BSI-Som	0.74	0.54	1.00	0.57	−1.98	0.08	0.65	0.31	0.44	0.34	0.28	−0.19	0.86	0.06
BFI	3.79	2.16	3.98	2.57	−0.37	0.72	0.12	2.46	2.15	2.31	2.24	0.25	0.81	0.08
PSQI	12.00	5.04	11.00	4.93	1.02	0.34	0.36	13.00	3.57	11.56	3.84	3.04	0.02*	1.01
PCS	37.47	15.22	36.04	11.32	0.45	0.66	0.15	45.30	7.59	49.10	10.21	−1.51	0.17	0.50
MCS	44.88	11.05	50.02	8.49	−2.51	0.04*	0.84	46.92	9.24	47.79	10.40	−0.24	0.82	0.08
FACT-Sp	37.11	7.10	39.89	6.92	−0.94	0.37	0.31	35.57	9.55	37.00	8.81	−0.63	0.55	0.24
BF	40.71	21.69	53.86	16.11	−1.71	0.14	0.64	50.33	13.26	51.00	12.08	−0.30	0.77	0.12
Close	6.82	0.41	6.89	0.18	−0.63	0.55	0.19	6.80	0.28	6.83	0.24	−0.26	0.81	0.07

Note: Abbreviations: ES, effect size; d, Cohen's d. Small effect, *d*≤.2; medium effect, *d*≤.5; and large effect, *d* ≤.8[22]. BSI-Dep, Brief Symptom Inventory- Depression Dimension; BSI-Anx, Brief Symptom Inventory-Anxiety Dimension; BSI-SOM, Brief Symptom Inventory- Somatization Dimension; BFI, Brief Fatigue Inventory; PSQI, Pittsburgh Sleep Quality Index; PCS, SF-36 Physical Health Component Summary; MCS, SF-36 Mental Health Component Summary; FACT-Sp, Spiritual well-being subscale; BF, Benefit Finding Scale; Close, perceived closeness and responsiveness measure;

* denotes significant paired t-test at P<0.05.