Feasibility and Preliminary Efficacy of Tailored Yoga in Survivors of Head and Neck Cancer: A Pilot Study

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Melissa Adair, RN, CCRC¹, Barbara Murphy, MD², Sujatha Yarlagadda³, Jie Deng, PhD, RN, OCN¹, Mary S. Dietrich, PhD^{1,2}, and Sheila H. Ridner, PhD, RN, FAAN¹

Abstract

Purpose: Treatment for head and neck cancer (HNC) results in long-term toxicities and increased physical and psychosocial survivor burden. There are a limited number of treatments for these late effects. Yoga postures, breath work, relaxation, and meditation, may improve these late effects. The purpose of this study was to examine the feasibility of a tailored yoga program in HNC survivors and obtain preliminary efficacy data. **Methods:** This was a randomized wait-list control study of yoga-naive HNC survivors who were >3 months post-cancer treatment. Baseline data were collected. Participants were collected. At 4 and 8 weeks, patients underwent a repeat assessment of health. Wait-list control group participants were offered the yoga program after data collection. Descriptive statistics evaluated feasibility. Mixed effects general linear models were used to generate estimates of the efficacy outcomes. **Results:** Seventy-three individuals were screened and 40 were eligible. All eligible individuals consented and enrolled. Five of the intervention group discontinued early and none in the wait-list control group. Feasibility was affirmed as participants were recruited and retained in the study, there were no adverse events, fidelity to protocol was demonstrated, and satisfaction rates were high. Efficacy measures indicated potential benefit for shoulder range of motion (d = 0.57-0.86, P < .05), pain (d = 0.67-0.90, $P \le .005$), and anxiety (d = 0.59, P = .015). **Conclusion:** A tailored hatha yoga program is feasible and potentially efficacious for HNC survivors. Preliminary data supports further investigation of yoga in this population is needed.

Keywords

hatha yoga, head and neck cancer, tailored yoga, feasibility, efficacy, function

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Introduction

Combined modality therapy is used in the treatment of the majority of patients with locally advanced head and neck cancer (HNC).^{1,2} Unfortunately, these treatment regimens result in substantial acute and late effects.^{3,4} While many acute toxicities subside on completion of cancer therapy, HNC survivors frequently experience late effects that result in symptom burden, functional deficits, and decreased quality of life (QOL).^{1,2,5} Musculoskeletal impairment (MSI) is a critical yet under reported and understudied complication of HNC therapy. It is most commonly manifested as soft tissue damage and dysfunction involving the jaw, neck, shoulders, and chest. Although soft tissue damage due to cancer and surgery have long been known to cause MSI, the

critical role of lymphedema and fibrosis are just now being appreciated. Regardless of cause, MSI results in a myriad of problems, including pain, postural abnormalities,⁶ and loss of critical functions such as jaw or neck range of motion (ROM).⁷ Furthermore, MSI may also contribute to psychological distress (eg, anxiety, body image disturbance),^{8,9} increased health care expenses,¹⁰ and loss of work.¹¹ MSI

¹School of Nursing, Vanderbilt University, Nashville, TN, USA ²School of Medicine, Vanderbilt University, Nashville, TN, USA ³Patanjali Yoga Center, Nashville, TN, USA

Corresponding Author:

Melissa Adair, School of Nursing, Vanderbilt University, 523 Godchaux Hall, 461 21st Avenue South, Nashville, TN 37240, USA. Email: melissa.a.adair@vanderbilt.edu

Creative Commons Non Commercial CC BY-NC: This article is distributed under the terms of the Creative Commons Attribution-NonCommercial 4.0 License (http://www.creativecommons.org/licenses/by-nc/4.0/) which permits non-commercial use, reproduction and distribution of the work without further permission provided the original work is attributed as specified on the SAGE and Open Access pages (https://us.sagepub.com/en-us/nam/open-access-at-sage). itself may be exacerbated by muscular tension and fear of movement resulting from states of high anxiety and distress. The clinically observed consequence is a self-perpetuating spiral that results in worsening functional loss and increasing symptom burden over time.^{12,13}

Yoga has been used to treat diseases in contemporary Western society with increasing frequency since the late 1970s.¹⁴ Yoga is often used as a reasonably safe complementary modality for health maintenance and restoration, as well as an adjunct tool in the chronically ill.¹⁵⁻²³ In cancer patients, the vast majority of yoga studies have been conducted in survivors of breast cancer.²⁴⁻²⁶ Studies suggest that yoga is an effective intervention for managing cancerrelated symptoms, ameliorating psychosocial distress, and enhancing overall QOL.¹⁵⁻²⁷ Key components of a yoga practice include: postures, breathing practice, relaxation techniques, and meditation.²⁸

Specifically, a growing body of literature supports the positive impact of yoga in reducing stress and improving systemic symptoms such as pain,²⁹ fatigue,³⁰ anxiety,³¹ depression,³² and insomnia.³³ In addition, through the practice of asanas, yoga may improve physical functionion.³⁴

The conceptual framework that guided the study was based on the assumption that yoga has the potential to improve MSI by addressing physical limitations, through the postures that improve ROM and lymph flow. It may decrease anxiety, fear, and muscle tension through meditation, awareness practice, and breathe work. Yoga may address the key factors that contribute to worsening MSI, potentially breaking the cycle that leads to deteriorating function over time. Studies exploring the feasibility, safety, and efficacy of hatha yoga HNC patients are lacking. We conducted a pilot study in HNC survivors to determine the following: (1) manifested physical impairments, (2) need for modified yoga postures, (3) feasibility of using a tailored hatha yoga program in the population, and (4) potential efficacy. In this article, we report on feasibility and preliminary efficacy outcomes.

Patients and Methods

This study used a wait-list control design. Consented patients were randomly assigned either to an 8-week yoga intervention group or to a wait-list group that completed study visits and was then offered the same yoga practice that the intervention group received. Approval for this study was obtained from the Vanderbilt-Ingram Cancer Center Scientific Review Committee, Nashville, Tennessee, USA under the Vanderbilt Institutional Review Board approval number 121357. The study was conducted at the Vanderbilt University School of Nursing.

Recruitment took place from October 2013 until July 2015. Inclusion criteria were (1) ≥ 18 years old, (2) ≥ 3 months post HNC treatment, (3) no active cancer, (4) English speaking, (5) willing/able to conduct home practice

and drive to the study site, (6) passing screening tool questions that included the Short Portable Mental Status Questionnaire, (7) completed medically indicated physical therapy, and (8) medical clearance. Exclusion criteria included (1) a prior cancer diagnosis \leq past 3 years, other than HNC; (2) previous radiation therapy or chemotherapy for other type of cancer; (3) medical conditions prohibiting safe implementation of yoga (eg, vertigo, suicidal ideations); or (4) active yoga practice of any frequency \leq past 6 months. Participants received compensation of \$110.

Data Collection

Feasibility Measures. Feasibility data were collected as follows:

Recruitment Log: Number screened, eligible, interested, not interested, and enrolled.

Participant Practice Log: Patients completed a self-reported home yoga practice log.

Guided Yoga Sessions Log: The yoga instructor recorded guided practice attendance and reasons for missed sessions.

Fidelity: The consultants reviewed 10% of the videotaped sessions.³⁵

Common Terminology Criteria for Adverse Events (*CTCAE Criteria version 4.0*): Adverse events were evaluated using the CTCAE grading (severity) scale.³⁶

Columbia Suicide Severity Rating Scale(C-SSRS): Trained staff administered this instrument.³⁷ A positive score required patient assessment.

Satisfaction Questionnaire Form: Patients completed a 9-question self-report rating scale with anchors of 0 totally unsatisfied to 10 highly satisfied with the yoga program, practice log, and yoga booklet.

Efficacy Measures. Physical and emotional outcomes were assessed by trained staff at baseline, 4 weeks, and 8 weeks as follows:

Maximal interincisal opening (MIO), cervical range of motion (CROM), shoulder range of motion (SROM): Standard devices were used to obtain these measurements.³⁸⁻⁴¹

Posture assessment: Spinal deviation from proper alignment by use of photography against a grid and computer analysis of the body.⁴²

The Vanderbilt Head and Neck Symptom Survey (*VHNSS–Version 2*): This self-report validated measure assessed symptom burden.^{43,44}

Brief Pain Inventory–Short Form (BPI-SF): This self-reported survey captured participant's pain experience.⁴⁵

Hospital Anxiety and Depression Scale (HADS): This self-report survey measured anxiety and depression.^{46,47} The medical oncologist was notified if a participant scored 8 or higher on either scale.

Body Image Quality Life Instrument (BIQLI): Participants completed a self-report scale ranging from very negative (-3) to very positive (+3) effects of body image on 19 life domains.^{48,49}

Procedures

Baseline study measures were obtained. Participants were then randomized via a computer generated, permuted block program, to either an initial yoga evaluation and intervention group, or to a wait-list control group.

Intervention

The protocol addressed all traditional hatha yoga practice components: postures, breathing, relaxation techniques, and meditation. Sixteen core poses were chosen to comprise the head and neck yoga toolbox; these poses were selected because they involved structures critical for optimizing mobility or strength in the neck and shoulders. Participants were given a booklet and the Toolbox, which described the postures, awareness practice, breathing practice, relaxation practice and meditation.

Intervention Group. Prior to initiating the intervention, a comprehensive evaluation was undertaken by the yoga instructor. Evaluation included an assessment of the physical, mental, and psychological limitations with emphasis on jaw, neck, and shoulder dysfunction. The core 16 poses were modified as deemed necessary by the instructor based on this assessment so that they were safe and feasible for the patient to perform and medical approval was obtained for this practice plan. Limitations were discussed with the participant. The practice plan was revised at weeks 3 or 4, or when modifications were indicated. Participants underwent tailored yoga sessions 3 times a week for 4 weeks then 2 times a week for 4 weeks with home practice on all other days. Guided sessions were videotaped. The initial session began with education regarding yoga principles, practice guidelines, and safety. Participants were then guided to observe their physical, psychological, and energy states, in order to enhance self-awareness.²⁸ Participants with lower extremity or pelvic weaknesses initially used a chair for support. As strength improved, they graduated to a standing or a floor pose. Throughout the practice, emphasis was placed on proper alignment and recognition of physical limitations in order to avoid injury. For participants with severe trunk weakness, props (eg, a slightly reclining hard backed chair, pillows, and supports) were used to ensure spinal alignment.

Participants were taught breath awareness, diaphragmatic, thoracic, clavicular breathing, and the complete yoga breath.²⁸ Participants were instructed on tension/systematic relaxation and *yoga nidra* techniques, including guided imagery.²⁸ Sessions ended with meditation with either chanting a mantra silently or inner silence. At the start of all subsequent guided sessions, participants were queried about any concerns or yoga related adverse events. Sessions lasted 30 minutes for participants with significant limitations with gradual increase to no more than 90 minutes as physical and mental endurance improved. Physical and psychological limitations and barriers were documented. Personal daily home practice was encouraged.

Wait-List Control Group. Participants in the wait-list control group completed the baseline, 4-week, and 8-week followup assessments. They were then offered the tailored yoga program.

Statistical Analysis

Frequency distributions were used to summarize the nominal and ordinal categorical data. Normally distributed continuous data were summarized using mean and standard deviation. However, most of the continuous distributions were skewed. Those were summarized using median and interquartile range (IQR). Comparisons of the demographic and clinical characteristics of the study groups were conducted using chi-square tests of independence (nominal, ordinal data) and Mann-Whitney tests (continuous data). Mixed-level generalized linear modeling with the log-link function was used to assess differences in the patterns of change in the study outcome variables between the two groups. The key effect of interest in these analyses was the interaction effect of group and time of assessment. This effect would indicate that the pattern of change in the intervention group was different from that observed in the control group over the same time period. Cohen's d effect index was generated for all findings. While this index was the most important statistic used in evaluating the effects of yoga in this preliminary study, a maximum alpha of .05 (P <.05) was used for conclusions of statistical significance.

Results

Participant Characteristics

The study consisted primarily of older, white males living in rural/suburban areas. Summaries of the demographic and disease/treatment, characteristics of the 35 patients who participated in the study (intervention group n = 15, control group n = 20) are shown in Table 1. Fifty-seven percent (24 of 35) had been diagnosed with oropharynx cancer and approximately 74% had stage IV disease, 20% (7 of 35) had a tracheotomy and 17.1% (6 of 35) had a feeding tube during the study.

Feasibility

Recruitment. Seventy-three individuals were screened, of whom 40 were eligible. Eleven were ineligible due to

Table 1. Demographic and Clinical Characteristics by Study Group (N = 35).

Characteristic	Overall (N = 35)	Intervention ($n = 15$)	Control (n = 20)	Р
Age, y, mean (SD)	63.2 (8.5)	65.0 (7.4)	61.8 (9.2)	.268
Years of education, mean (SD)	14.4 (2.8)	15.1 (3.0)	13.8 (2.5)	.163
Gender, n (%)				.267
Female	3 (37.1)	4 (26.7)	9 (45.0)	
Male	22 (62.9)	(73.3)	(55.0)	
Race, n (%)				.265
Black or African American or Asian	5 (14.3)	l (6.7)	4 (20.0)	
White	30 (85.7)	14 (93.3)	16 (80.0)	
Marital status, n (%)				.486
Single/Widowed/Other	14 (40.0)	7 (46.7)	7 (35.0)	
Married/Partnered	21 (60.0)	8 (53.3)	13 (65.0)	
Employment, n (%)				.503
Employed	15 (42.9)	5 (33.3)	10 (50.0)	
Not employed	17 (48.6)	9 (60.0)	8 (40.0)	
Other	3 (8.6)	l (6.7)	2 (10.0)	
Income, \$, n (%)	(),			.534
≤30 000	(3 .4)	5 (33.3)	6 (30.0)	
>30 000	19 (54.3)	9 (60.0)	10 (50.0)	
Don't care to respond	5 (14.3)	l (6.7)	4 (20.0)	
Residence, n (%)	()		()	.486
Urban	14 (40.0)	7 (46.7)	7 (35.0)	
Rural/Suburban	21 (60.0)	8 (53.3)	13 (65.0)	
Time since diagnosis, mo, median [IQR]	35.7 [9-63]	45.7 [9-63]	28.4 [10-67]	.764
Time since last treatment, mo, median [IQR]	19.8 [4-52]	43.3 [5-59]	17.0 [3-43]	.286
Location of primary lesion, n (%)		[]		.564
Oral cavity	7 (20.0)	2 (13.3)	5 (25.0)	
Oropharynx	20 (57.1)	10 (66.7)	10 (50.0)	
Larynx	4 (11.4)	I (6.7)	3 (15.0)	
Salivary gland	3 (8.6)	2 (13.3)	I (5.0)	
Other	I (2.9)	0 (0.0)	I (5.0)	
Stage, ^a n (%)	· (=)	0 (0.0)	1 (0.0)	.235
I-II	2 (5.9)	0 (0.0)	2 (10.5)	.200
 III	7 (20.6)	2 (13.3)	5 (26.3)	
IV	25 (73.5)	13 (86.7)	12 (63.2)	
Tumor-expressed virus, n (%)	20 (70.0)		12 (00.2)	.994
None	7 (20.0)	3 (20.0)	4 (20.0)	
Human papilloma virus	12 (34.3)	5 (33.3)	7 (35.0)	
Not tested	16 (45.7)	7 (46.7)	9 (45.0)	
Total treatment received, n (%)	10 (13.7)	7 (10.7)	7 (13.0)	.744
Surgery only	2 (5.7)	0 (0.0)	2 (10.0)	., 1
Surgery + radiotherapy	I (2.9)	0 (0.0)	I (5.0)	
Surgery + CCR	7 (20.0)	3 (20.0)	4 (20.0)	
Induction + CCR	6 (17.1)	3 (20.0)	3 (15.0)	
Surgery + induction + CCR	12 (34.3)	6 (40.0)	6 (30.0)	
CCR only	6 (17.1)	3 (20.0)	3 (15.0)	
Other	l (2.9)	0 (0.0)	I (5.0)	

Abbreviations: CCR, concurrent chemo radiation; IQR, interquartile range. $^{a}N = 34$, Control = 19.

recurrence of disease (n = 5), unstable medical condition (n = 2), had not completed physical therapy (n = 2), practiced yoga within the past 6 months (n = 1), and <3 months posttreatment

(n = 1). Twenty-two were not interested because of work obligations (n = 4), illness (n = 3), distance to site (n = 7), time commitment (n = 4), and no stated reason (n = 4) (Figure 1).



Figure 1. Screening, enrollment, and withdrawal.

Table 2.	Patient	Adherence to	Supervised	and Home	Sessions	Protocol	(Intervention	Group	Only).
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	n	Median	Interquartile Range	Minimim	Maximum
Supervised sessions ^a					
Number expected	19	20.0	20-20	3	20
Number documented	19	19.0	15-20	3	20
Percent compliance per participant	19	100.0	85-100	44.4	100.0
Home sessions ^b					
Number expected	16	36.0	36-36	11	36
Number documented	16	35.0	31-36	5	41
Percent compliance per participant	16	97.2	87-100	45.5	100.0

^aNineteen participants received some yoga; 1 participant discontinued prior to starting yoga.

^bSixteen intervention participants returned their home practice diaries.

Forty HNC survivors signed consent, enrolled and were randomized to the study. Five intervention patients withdrew early: returned to work (n = 2), disease recurrence (n = 1), and developed nonstudy-related unstable medical conditions (n = 2) (Figure 1). There were no statistically significant differences in demographic and disease/treatment characteristics between withdrawals and the remainder of the sample (P > .05). Three enrolled patients required financial assistance with transportation. All wait-listed participants began yoga at the conclusion of their wait-list period.

Patient Adherence (Intervention Group Only). Adherence to the on-site, supervised and home sessions practice was excellent as noted in Table 2. It appeared that the perceived benefits of the practice were not gender specific. One of the male patients summarized his perceptions as, "I used to laugh when someone even mentioned yoga. That happens

Table 3. Intervention Group Participant Satisfaction (N = 15).

Program Evaluation	Median	Interquartile Range	Minimum	Maximum
General satisfaction	10.0	10-10	9	10
Instruction satisfaction	10.0	10-10	10	10
Physical progress satisfaction	10.0	8-10	7	10
Emotional progress satisfaction	10.0	9-10	7	10
Mental progress satisfaction	10.0	9-10	7	10
Asanas satisfaction	10.0	8-10	6	10
Breath work satisfaction	10.0	9-10	8	10
Meditation/Relaxation satisfaction	10.0	9-10	7	10
Likelihood of continuing yoga	10.0	10-10	8	10
Booklet Evaluation	Strongly Disagree, n (%)	Not Sure, n (%)	Agree, n (%)	Strongly Agree, n (%
Wealth of information	l (6.7)	3 (20.0)	7 (46.7)	4 (26.7)
Helpful tips	l (6.7)	5 (33.3)	3 (20.0)	6 (40.0)
Motivation	l (6.7)	2 (13.3)	3 (20.0)	9 (60.0)
Good pictures	l (6.7)	4 (26.7)	5 (33.3)	5 (33.3)
Encouraged to examine status	l (6.7)	4 (26.7)	4 (26.7)	6 (40.0)
Engaging, appealing	l (6.7)	4 (26.7)	6 (40.0)	4 (26.7)
Easy to read, understand	I (6.7)	3 (20.0)	7 (46.7)	4 (26.7)
	Median	Interquartile Range	Minimum	Maximum
Booklet time in minutes	30.0	15-130	3	420
Practice Log Evaluation	Disagree, n (%)	Not Sure, n (%)	Agree, n (%)	Strongly Agree, n (%
Self-explanatory	4 (26.7)	2 (13.3)	6 (40.0)	3 (20.0)
Easy to complete	0 (0.0)	l (6.7)	8 (53.3)	6 (40.0)
Didn't take too much time	0 (0.0)	0 (0.0)	7 (46.7)	8 (53.3)
Helped focus	0 (0.0)	4 (26.7)	4 (26.7)	7 (46.7)
Helped see progress			7 (46.7)	4 (26.7)
Worth my time	0 (0.0)	3 (20.0)	4 (26.7)	8 (53.3)
Comment section helpful	l (6.7)	3 (20.0)	5 (33.3)	6 (40.0)
Log reflects practice	0 (0.0)	4 (26.7)	5 (33.3)	6 (40.0)
	Median	Interquartile Range	Minimum	Maximum
Time to complete log each time in minutes	10.0	5-20	5	30

no longer . . . Yoga has given me much needed positive reinforcement both mentally and physically."

Fidelity. The principal investigator met with the external consultants and then separately with the yoga instructor to discuss findings and review videos. The external yoga consultants summarized fidelity as: Awareness practice was consistent with protocol and excellent breathing techniques were always taught. Posture techniques and practice order were tailored based on patient status. The yoga instructor used touch assistance when required. Relaxation and meditation appeared effective. Nostril breathing was seldom taught due to the short duration of the study; however, it could potentially be incorporated into posture, or alternatively, be removed from the protocol. The yoga instructor was encouraged to be more permissive, more open-ended, and less directive, but patients rated the instructor high.

Safety. No adverse events or suicidal ideations were identified. Eleven patients were referred to the oncologist based on HADS scores. At baseline, 4 of the 15 participants in the intervention group (27%) and 3 of the 20 in the control group (15%) had a score of 8 or higher on either the anxiety or the depression component of the HADS. Those respective numbers at week 4 were 2 of 15 in the intervention (13%) and 5 of 20 in the control (25%); at week 8, were 1 of 15 in the intervention (7%) and 6 of 20 in the control (30%). Overall, 4 patients in the intervention group accounted for all referrals in that group, and only 1 had a score of 8 or higher at week 8. Seven patients in the wait-list group accounted for all referrals, and 6 continued to have high scores at week 8.

Participant satisfaction. The median value satisfaction with all aspects of the program was 10.0 (the highest possible value). See summaries in Table 3.

	Baseline	4 Weeks	8 Weeks			
Passive abduction, right ^b	(Arm to side, palm up, moving arm away from body toward head as far as possible					
Intervention	141.0 [127-155]	145.0 [138-152]	154.5 [143-160]			
Control	144.5 [138-161]	140.0 [132-163]	135.0 [124-158]			
Passive abduction, left	(Arm to side, palm up, mo	oving arm away from body toward	head as far as possible)			
Intervention	136.5 [131-155]	149.0 [139-163]	146.5 [140-162]			
Control	130.5 [122-156]	135.0 [114-150]	133.5 [116-150]			
Passive external rotation, right ^b	(Arm straight out, bent at	elbow with hand up, moving hand	back toward head)			
Intervention	68.5 [63-79]	74.0 [68-84]	79.0 [70-82]			
Control	80.5 [69-87]	78.8 [71-87]	76.3 [70-86]			
Passive external rotation, left	(Arm straight out, bent at	elbow with hand up, moving hand	back toward head)			
Intervention	69.5 [60-77]	71.0 [68-78]	72.0 [67-80]			
Control	71.3 [54-84]	68.3 [56-75]	71.3 [60-77]			
Active abduction, right ^b	(Arm to side, palm up, mo	oving arm away from body toward	head as far as possible)			
Intervention	140.0 [127-148]	149.0 [137-160]	152.5 [141-162]			
Control	146.0 [139-162]	140.5 [131-157]	139.0 [124-158]			
Active abduction, left ^b	(Arm to side, palm up, moving arm away from body toward head as far as possible					
Intervention	139.0 [126-151]	143.5 [133-157]	147.5 [142-162]			
Control	140.0 [118-152]	139.5 [118-148]	132.0 [123-148]			
Active external rotation, right ^b	(Arm straight out, bent at elbow with hand up, moving hand back toward head)					
Intervention	72.5 [64-78]	76.0 [69-87]	80.0 [72-84]			
Control	79.0 [74-89]	77.5 [73-86]	77.0 [70-85]			
Active external rotation, Left	(Arm straight out, bent at elbow with hand up, moving hand back toward head)					
Intervention	71.0 [60-74]	71.0 [62-78]	72.0 [63-78]			
Control	71.5 [50-84]	66.5 [56-77]	69.8 [63-76]			

Table 4. Selected Shoulder Range of Motion Summaries (N = 35; Intervention n = 15, Control n = 20).^a

^aValues are given as median [interquartile range].

^bStatistically significant (P < .05) differences in the patterns of change in the intervention group compared with that in the control group.

Limitations and Modifications. The majority of patients demonstrated MSI that limited movement to the extent that modifications in the core poses were needed. These will be detailed in a separate manuscript.

Efficacy

Jaw, Shoulder Cervical Range of Motion, and Posture. The most consistent effects were observed in the shoulder region for abduction and external rotation on the right side (Table 4). The statistically significant effects (effect sizes Cohen's d = 0.57-0.86) were those of the intervention group demonstrating generally improving ROM while the control group remained stable or decreased in ROM. No statistically significant effects on jaw (Cohen's d = 0.20-0.45) or cervical (Cohen's d = 0.39) ROM were observed (P > .05). However, baseline dysfunction was low. No significant changes in posture were detected.

Symptoms. There were statistically significant differences between the study groups in patterns of change in pain (VHNSS General Pain, P < 0.001, effect size Cohen's d = 0.90) and pain interference with activities of daily living

(BPI Interference, P = .005, effect size Cohen's d = 0.67). The VHNSS General Pain levels decreased for the intervention group, but increased over the same time period for the controls (Figure 2). Median BPI Interference scores were variable and low for both groups. Intervention group variability decreased. Those participants reporting higher levels of interference at baseline tended to demonstrate a decrease in those levels over the course of the study. The opposite pattern was observed for the participants in the control group.

A statistically significant interaction effect of the yoga intervention was observed for the HADS anxiety scores (P = .015, effect size Cohen's d = 0.59) but not the depression scores (P = .290, effect size Cohen's d = 0.31). The intervention participants reported higher anxiety scores at baseline, decreased at 4 weeks and, increased again at 8 weeks. Participants in the control group tended to follow an opposite pattern in that their scores were lower than the intervention group at baseline, increased at 4 weeks, and reduced to baseline levels at 8 weeks (Figure 2).

Body Image. No statistically significant effects on body image were observed in this study (P = .647, effect size Cohen's d = 0.18).



Figure 2. Summaries of self-reports of pain (VHNSS General Pain), interference from pain (BPI-SF), and anxiety over the study period (HADS) (N = 35; Intervention n = 15, Control n = 20). BPI-SF, Brief Pain Inventory–Short Form; HADS, Hospital Anxiety and Depression Scale; VHNSS, Vanderbilt Head and Neck Symptom Survey.

All demonstrated statistically significant (P < .05) differences in the patterns of change in the intervention group compared with that in the control group.

Discussion

Tailored yoga appears to be safe and feasible in the posttreatment HNC population. No adverse events occurred. Recruitment rates were high as was adherence with guided sessions and home practice. Participants expressed high levels of satisfaction with the yoga instruction and study related tools. Preliminary data indicated that yoga may improve mood, symptom burden, and shoulder function.

Recruitment of HNC survivors to a yoga study was a concern. This population is predominantly male, generally older, and often plagued by late effects that might prove to be barriers to study participation (eg, tracheostomy tubes, feeding tubes). When this study commenced, the majority of yoga studies in the oncology population had been conducted in female survivors of breast cancer.^{24,25} No known studies had been reported in survivors of HNC. Our study demonstrated that men were willing to participate and were adherent to an intensive yoga program that required both frequent one-on-one guided sessions and daily home practice. However, patients indicated that the duration of the supervised and daily home practice was burdensome. Shorter supervised and tailored home practice should be considered in future studies.

Tracheostomies and feeding tubes presented safety concerns. As such, we incorporated a number of safety measures. The yoga instructor had 500 hours of advanced training in therapeutic aspects of yoga in cancer and chronic illness and spent a year-long preceptorship in the HNC clinic prior to study initiation in order to gain insight into the issues facing this population. Participant's physical and emotional limitations were thoroughly assessed. One-onone instruction was given to ensure proper alignment and timely modifications. A registered nurse was on-site during yoga sessions. Although the sample was small, the findings suggested that with modifications, patients with implanted devices can safely participate in a tailored yoga program. Furthermore, issues such as xerostomia did not impair practice. Few community instructors have the skill sets or training to deal with this complex patient population. Ensuring adequate training of yoga instructors in order to maintain safety and efficacy is likely to be a challenge, but possible.

Consistent with studies conducted in other cancer populations,^{26,30,50-52} we observed improvement in the region of function we anticipated to be most impacted by yoga practice, shoulder range of motion. Lack of measured change in posture may indicate the need for an alternative measurement method. Pain also demonstrated increased improvement in the practice group compared with the control group. Reduced anxiety in the practice group was noted during the 4 weeks when participants underwent 3 supervised sessions a week. It returned to near baseline levels when supervised sessions were reduced. Thus, 3 supervised yoga sessions a week appear to be more effective in decreasing anxiety than 2 sessions per week.

This was a feasibility study; findings should be considered in light of its limitations. The convenience sample may have resulted in selection bias, as participants who agreed to participate may not have been representative of the entire HNC population. A small sample size, only 8 weeks of yoga, and no follow-up after yoga completion should also be considered. Findings from this pilot study may not generalize to other populations. A larger dose of yoga may have yielded better outcomes; however, patients did not desire a more extensive program. The lack of longer term follow-up leaves unanswered questions regarding the uptake of yoga into the daily lives of the participants and fails to capture long-term outcomes. Many of these limitations can be addressed in a larger study that follows participants for an extended period of time. These limitations are also somewhat offset by strengths of the study that include participation by both genders, strict fidelity oversight, and high patient satisfaction.

Conclusion

A tailored yoga program administered by a trained instructor is safe and feasible for HNC survivors. Patient demographics did not limit recruitment. Men and women were eager to participate due to bothersome late effects from their cancer treatment. Some of the late effects such as; mood, symptom burden, and shoulder function improved through the use of yoga. Significant limitations in movement requiring modifications in poses were found. Preliminary efficacy data support further investigation of yoga in this and other chronically ill populations.

Authors' Note

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

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ORCID iD

Melissa Adair (D) https://orcid.org/0000-0002-4973-9231

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