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Effectiveness of multicomponent intervention on radiotherapy induced fatigue and its corelates among breast cancer patients

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ABSTRACT

Up to 80% and 30% of patients, respectively, reported experiencing radiotherapy-induced weariness during radiation therapy and at follow-up visits, which is a frequent early and chronic side-effect of irradiation. Medical and nursing personnel commonly underestimate it; just around 50% of patients discuss it with a doctor, and barely one-fourth of those cases result in the patient being recommended any intervention. Rarely do patients anticipate feeling tired as a side effect of treatment. Weak understanding exists on the genesis, correlates, and prevalence of this frequent symptom. Numerous studies have shown that the location of the tumor and the type of treatment used affect the degree and timing of fatigue. In contrast, individuals receiving radiotherapy for prostate cancer may experience exhaustion due to a reduction in neuromuscular efficiency rather than psychological factors. For instance, psychological mechanisms have been hypothesized to explain fatigue in women receiving radiation therapy for early breast cancer. More than pain, erectile dysfunction, and other cancer- or treatment-related symptoms, exhaustion can have an overall negative impact on quality of life. Recently published randomized studies on the management of radiotherapy-related fatigue have explored a number of strategies. Although the best approach has not yet been identified, relaxation treatment, group psychotherapy, physical activity, and sleep have all shown some encouraging outcomes. It is necessary to conduct additional methodologically sound research to better understand the causes, ideal prevention, and management of this symptom.

Keywords: breast cancer, guided imagery, radiation induced fatigue, sleep quality, depression, anxiety

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INTRODUCTION

Globally, cancer is the second most common cause of mortality around the world and is estimated to have been a reason for 9.6 million losses of lives in 2018 alone. Around 70% of cancer related deaths happen in under-developed and developing countries. According to World health Organization, cancer of the breast is on the fifth rank of cancer related mortality (627000 annual deaths). The treatment of any type of cancer depends on its type and location. Generally, patients get treatment that is combination of different techniques. The American Cancer Society says External Beam Radiation Therapy (EBRT) and Brachytherapy are the treatment of choice for breast cancer. In External Beam Radiation, a typical breast irradiation schedule is five days per week for six to seven weeks. "Hypofractionated radiation therapy", "Accelerated partial breast irradiation", "3D-conformal Radiotherapy", "Intensity-modulated Radiotherapy" are other options that vary based on doses and intensity. "Brachytherapy, also known as Internal Beam Radiation Therapy, is also given in many cases [1-10].

These patients experience many side effects of these treatments, like skin changes, hair loss, low blood count etc. Fatigue is one such usual and persistent side-effect of cancer treatments. Almost eighty percent to hundred percent of cancer patients report to have Fatigue. Radiotherapy Induced Fatigue (RIF) is defined as a persistent and subjective feeling of physical, emotional, and cognitive Fatigue which is the main side effect of radiation therapy. It can continue for months or years after completing treatment. Fatigue can be present before a patient even begins cancer treatment however it has been observed to increase during treatment. Patients receiving radiotherapy shows different prevalence and severity in Fatigue. In some cases, patient experiences it at week 3 of treatment, then it has been seen that by week 6, the severity is aggravated by the end of six week [11-15].

The cause of Radiotherapy Induced Fatigue has not been understood completely and is usually vague. Several hypotheses to explain its pathophysiology are there but have not yet been proved. Circadian rhythm, 5-HT (Serotonin) disruption, hypothalamic-pituitary-adrenal axis dysfunction, vagal-afferent nerve activation, muscle metabolism and cytokine dysregulation are some of the probable hypotheses. Normal protein and hormone levels that are connected to inflammatory processes if changed by either cancer itself or by cancer treatment can initiate or aggravate fatigue. Hence, understanding the cause of RIF can

be a tedious task all together.

RIF affects the life quality more than sexual changes, pain, and associated symptoms due to treatment modalities for cancer. Its prevalence and severity differ according to patient characteristics and type of treatment. RIF is prevalent approximately in about 48% patients, even though it is higher in certain malignancies of pancreas, breast and lymphomas. Breast cancer patients who are undergoing radiotherapy and chemotherapy experience RIF and other treatment side effects, which is a common phenomenon. Up to 99% of breast cancer patients experience Fatigue during radiation therapy and about 60% rate it as moderates to severe [16-21].

The Community Preventive Services Task Force (CPSTF) recommends multicomponent interventions to increase screening for breast, cervical, or colorectal cancers, based on a systematic review that found these interventions are effective. Multicomponent interventions to promote breast, cervical, or colorectal cancer screening combine two or more intervention approaches from eleven possible individual approaches. These interventions are classified into three strategies: increasing community demand, increasing community access, and increasing provider delivery of screening services.

This study was aimed at determining the both effectiveness and acceptability of multi-component approach in tackling the most commonly appearing debilitating symptom associated with radiation therapy treatment among breast cancer patients.

MATERIAL AND METHOD

Design

A Randomized Controlled Pilot Trial was conducted at a single medical center from April 2022 until July 2022. The present study design has all the properties of RCT such as randomization, control and manipulation and it followed the guidelines of Consolidated Standards of Reporting Clinical Trials (CONSORT). Figure 1 and is registered in the Clinical Trial Registry of India (CTRI) under Indian Council of Medical Research with the number REF/2022/02/052031.

The institutional ethics committee approved the study protocol, in accordance with the ethical standards of the responsible committee on human experimentation. The sample (breast cancer patients undergoing radiation therapy) were selected from the same setting and randomly allocated into experimental and control group using computer generated block randomization. The experimental group received Multi Component Intervention (MCI) and routine care whereas, the subjects in the control group only received routine care. The investigator provided the participants with information regarding the study, including its purpose, the associated risk and benefits, as well as procedures for confidentiality, data collection and treatment allocation. Voluntary participation in the study was emphasized and participants' concerns were addressed by the investigator. After obtaining written documentation of informed consent, the subjects were asked to complete questionnaires administered by the research coordinator. Treatment allocation was concealed from the subjects. The pre-determined time points for assessment of primary outcomes included baseline (Pre-test-post-surgery/ pre-radiation) testing, mid of radiation treatment (post-test I), and at end of RT (post-test II). Screening for physical assessment and clinical variables was done at each time point by the investigator and radiation oncologist at all three time points. Primary outcome measure: Cancer Fatigue Scale (CFS) for fatigue levels. Secondary measures for corelates of fatigue: Zung Self Rating Depression Scale (ZSDS), Zung Self Rating Anxiety Scale (ZSAS), Pittsburgh Sleep Quality Index (PSQI) & Scored Patient-Generated Subjective Global Assessment (PG-SGA) were measured on pre-determined time points for assessment.

Sample

Female patients were recruited from the Department of Radiation Oncology, Fortis Hospital.

Eligibility criteria included:

A diagnosis of stage I to III breast cancer by Canadian Cancer Society standards and confirmed through pathology; above the age of 18 years at time of diagnosis receiving adjuvant radiotherapy treatment (with or without chemotherapy) in post-surgical treatment plan; having smartphone with cut off scores of the Cancer Fatigue Scale (CFS); that is 31 or below, Zung Self-Rating Anxiety Scale (SAS); that is 20-44 Zung Self-Rating Deperession Scale (SDS); that is <50, Pittsburg Sleep Quality Index (PQSI); that is <09 and Scored Patient-Generated Subjective Global Assessment (PG-SG©) that is Zero.

Exclusion criteria were women with:

A diagnosis of stage IV breast cancer (metastatic disease) significant cardiac, pulmonary or metabolic co-morbidities prior breast cancer diagnosis and treatment any contraindication to physical activity unable to follow instructions owing to compromised physical and mental health. Adult BC patients who met the inclusion and exclusion criteria were identified prior to commencing radiotherapy and consented to participate in this pilot trial. The recruitment goal was 10 patients per arm in this pilot which is 10% of the full-scale study sample size, which is commonly accepted as sufficient for the purpose of analysis. 26 However, the lengthy accrual time obliged us to limit our population sample to 08/08 patients per arm which is sufficient for significance testing of differences between study groups.

Treatment

Participants randomized into the Multi Component Intervention (MCI) intervention group (E) received Multi Component Intervention (MCI) that included One individualized session of guided meditation by investigator, a pre-recorded guided meditation video, informational booklet containing information to manage common side effects of radiation therapy and thrice a week instant message reminders and routine care. Participants were encouraged to listen to the pre-recorded video on their smart phones at their leisure time with the help of weekly reminders for the duration of the 05-week trial period. Participants recorded the frequency, duration and compliance to using guided imagery in a weekly log given with the information booklet.

Participants randomized to the control group received routine care included radiotherapy treatment, pharmacological management by radiation oncologists and occasional notes of any changes observed by patient, radiation oncologists and radiotherapy unit staff (nurses and technicians). Participants were not restricted in their activity and a fatigue level were recorded at each of the three points in time (Figure 1).

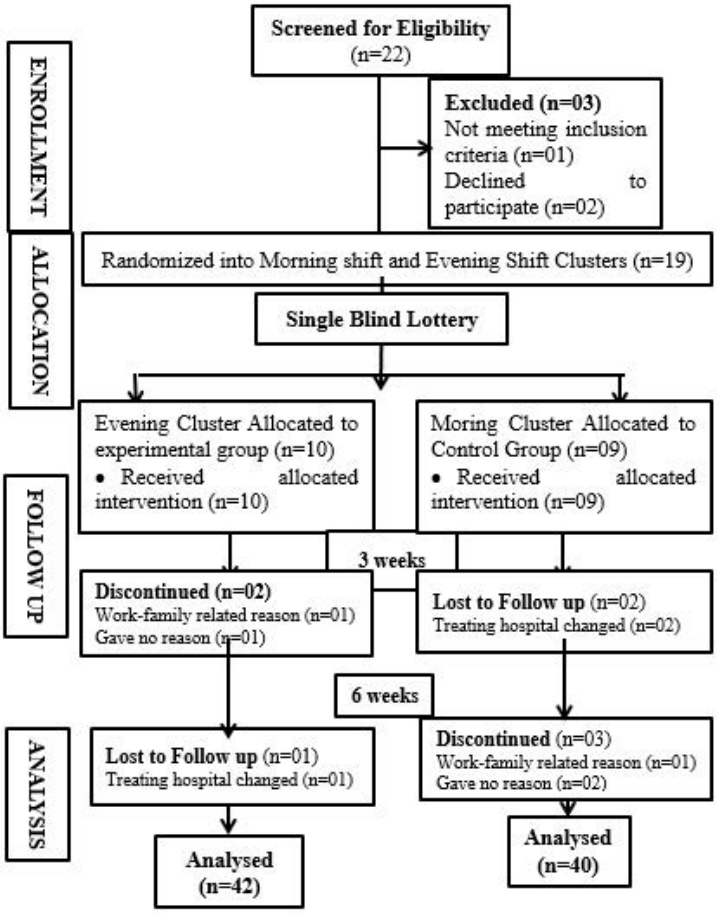

Fig. 1. Schematic representation of the RCT design on effect of CBT among breast cancer patients undergoing radiation therapy using CONSORT guidelines 2010

PROCEDURE

Variables and measures

Clinical characteristics:

Clinical characteristics including subtype of breast cancer, cancer stage, hormonal and HER status, surgery (i.e., mastectomy or lumpectomy), and treatment types (i.e., EBRT/Brachytherapy), Dose/ fractions to RT, Taking nutritional supplements, Mucositis, Dermatitis, Lymphedema, Hemoglobin, Red blood cells count, Total Leukocyte count, Lymphocytes count, Platelets counts were assessed with standard questions (Age, Education, Type of employment, Place of Residence, Marital status, Monthly income, Dietary habits, Physical activity, Tobacco and Alcohol consumption) and verified using a chart review.

Radiotherapy induced fatigue

Cancer Fatigue Scale:

Cancer Fatigue Scale (CFS) developed by Toru Okuyama, Hitoshi Okamura, Takashi Hosaka (2000) is a standardized scale designed specifically to reflect the nature of fatigue experienced by cancer patients. The CFS is a 15-item scale composed of 3 subscales (physical, affective, and cognitive subscales) was utilized to measure the fatigue levels of patients at three designated time-points. The CFS is a widely used scale with good stability and good internal consistency recommended for assessing women having undergone breast cancer treatment [22-30].

Anxiety

Zung SAS:

The Zung SAS a 20 items self-report scale was used to assess anxiety symptoms, both psychological (e.g., "I feel afraid for no reason at all" and "I feel like I'm falling apart and going to pieces") and somatic (e.g., "My arms and legs shake and tremble" and "I feel my heart beating fast.") in nature. Participants were instructed to base their answers on their experiences over the last week. The SAS has satisfactory internal consistency, concurrent validity [14].

Depression

Zung Self-Rating Depression Scale (SDS):

Zung SDS is a commonly utilized norm-referenced 20-item Likert scale covering symptoms of depression [11]. Items tap psychological and physiological symptoms and were rated by respondents according to how each applied to them within the past week.

Sleep quality:

The PSQI is a standardized measure of sleep quality that has been widely used in sleep research. It consists of 19 items that produce a Global Sleep Quality Index (GSQI) and 7 component scores reflecting sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbance, use of sleeping medications, and daytime dysfunction. High scores on the GSQI and the sleep quality component score represent poorer sleep quality.

Nutritional status:

Nutritional status was assessed using the PG-SGA available at www.pt-global.org. The PG-SGA includes a patient component, to evaluate weight history (score ≤ 5 points), food intake (score ≤ 4 points), nutrition impact symptoms (score ≤ 24 points), and activities and function (score ≤ 4 points). The professional component evaluates the presence of catabolic conditions increasing nutritional requirements (score ≤ 10 points), metabolic demand (score ≤ 3 points), and a physical examination (score ≤ 3 points) to evaluate nutritional deficit. The PG-SGA generates two scores: a global assessment category (PG-SGA Stage A: well nourished, PG-SGA Stage B: moderate/suspected malnutrition, or PG-SGA Stage C: severely malnourished) and a numerical score facilitating triage for interventional recommendations. The scores for the questionnaire items were added to give a total score, whereby the higher the score, the greater the nutritional risk.

DATA ANALYSIS

Participant characteristics were data and data entry were done. The SPSS software version 25.0 was used for statistical analysis, performed by one of the authors on de-identified data. Descriptive statistics were calculated for all variables in the study as means and standard deviations for continuous measures and counts and percentages for categorical variables. As the dependent variable was not normally distributed and the sample size was small (n=08 in each group), non-parametric tests were used. Data was tested for significance through the use of the chi-square test (Categorical), ANOVA and the nonparametric Wilcoxon tests. A p-value of 0.05 or less was considered significant.

RESULTS

A total of 16 female patients maximum belonging to age group 44 years-56 years were randomized into control (n=08) and intervention (n=08) group. There were no statistically significant differences between characteristics of the control and intervention group at baseline (Table 1). Table 2 shows that most of the subjects (87%) in both experimental and control group had Stage I cancer diagnosis. There were no statistically significant differences between radiotherapy induced fatigue and it's correlates of the control and intervention group at baseline. Independent sample t test was calculated in order to check the equality of means between the two groups proved the equality of outcome variables in experimental and control group (p>0.05) and hence the two groups were considered equal (Table 3).

Tab. 1. Demographic characteristics of breast cancer patients undergoing radiotherapy in experimental and control group N=16

Variables	Items	Experimental (n=8) f (%)		Control (n=8) f (%)		χ^2
Age	18 Years-30 Years	0	0	0	0	NA
	31 Years-43 Years	0	0	0	0	
	44- Years-56 Years	6	-75	6	-75	
	Above 56 Years	2	-25	2	-25	
Education	No formal education	0	0	0	0	NA
	Primary	0	0	0	0	
	Matric	0	0	0	0	
	Graduation or above	8	-100	8	-100	
Type of Employment	Private Job	0	0	0	0	NA
	Government Job	0	0	1	-13	
	Self employed	0	0	0	0	
	Home maker	8	-100	7	-88	
Place of Residence	Rural	0	0	0	0	NA
	Urban	8	-100	8	-100	
Marital Status	Unmarried	0	0	0	0	NA
	Married	8	-100	8	-100	
	Divorced/Separated	0	0	0	0	
	Widow/ Widower	0	0	0	0	
Monthly Income	<Rs 20000	0	0	0	0	NA
	Rs 20000-40000	0	0	0	0	
	Rs 40000-60000	8	-100	8	-100	
	>Rs 60000	0	0	0	0	

Tab. 2. Description of clinical variables of breast cancer patients undergoing radiotherapy in experimental and control group N=16

Variables	Items	Experimental (n=8) f (%)		Control (n=8) f (%)		χ^2
Stage at Cancer Diagnosis	Stage 0	0	0	0	0	0.000 1.000[NS]
	Stage 1	7	-87.5	7	-87.5	
	Stage 2	1	-12.5	1	-12.5	
	Stage 3	0	0	0	0	
	Stage 4	0	0	0	0	
Duration of Cancer Diagnosis	<6 months	1	-12.5	0	0	1.067 0.302 NS
	6 months-12 months	7	-87.5	8	-100	
	>1 year	0	0	0	0	
Type of Radiotherapy Treatment	3DCRT	0	0	0	0	0.254 0.614 NS
	IMRT	4	-50	3	-37.5	
	VMAT	4	-50	5	-62.5	
	DIBH	0	0	0	0	

*p-value significant at 0.05, [NS]Notsignificant

Tab. 3. Repeated measures ANOVA (RM ANOVA) showing comparison of radiotherapy induced fatigue and its corelates among breast cancer patients: Pre-Test *vs* Post Test I *vs* Post Test II scores in experimental group *vs* control group N=16

Group	Time Points	Mean ± SD	F-value	p-value
Cancer Fatigue				
Experimental N=8	Pre Test	54.63 ± 3.021	32.94	<0.001*
	Post Test 1	44.63 ± 3.021		
	Post Test 2	44.63± 3.021		
Control N=8	Pre Test	54.38 ± 2.504	22.4	<0.001*
	Post Test 1	56.38 ± 3.249		
	Post Test 2	54.38 ± 3.249		
Depression				
Experimental N=8	Pre Test	59.38 ± 7.328	11.95	<0.001*
	Post Test 1	55.13 ± 0.120		
	Post Test 2	46.25 ± 1.909		
Control N=8	Pre Test	64.88 ± 2.949	4.2	0.029*
	Post Test 1	62.633 ± 3.378		
	Post Test 2	62.633 ± 3.378		
Anxiety				
Experimental N=8	Pre Test	71.88 ± 1.458	58.47	<0.001*
	Post Test 1	66.13 ± 3.271		
	Post Test 2	52.13 ± 5.939		
Control N=8	Pre Test	72.13 ± 1.458	23.63	<0.001*
	Post Test 1	71.00 ± 0.926		
	Post Test 2	73.75 ± 0.886		
Sleep Quality				
Experimental N=8	Pre Test	12.38 ± 4.207	14.29	<0.001*
	Post Test 1	12.38 ± 4.207		
	Post Test 2	8.88 ± 4.155		
Control N=8	Pre Test	13.25 ± 3.694	1.32	0.288 [NS]
	Post Test 1	13.25 ± 2.375		
	Post Test 2	14.38 ± 2.264		
Nutritional Status				
Experimental N=8	Pre Test	6.75 ± 2.1213	13.01867	0.000639*
	Post Test 1	3.5 ± 1.6036		
	Post Test 2	3 ± 0.7559		

Control N=8	Pre Test	8.25 ± 2.6049	2.296103	0.162912[NS]
	Post Test 1	5.625 ± 2.4458		
	Post Test 2	6.25 ± 2.1213		

*p-value significant at 0.05, [NS]Notsignificant

On day 0 of radiation therapy, i.e. the day that they go for simulation, Pre-test assessment of radiotherapy induced fatigue and its correlates was done. After which they were provided a personalised Guided imagery session was provided to the patient. They were also provided with an Information booklet on management of sideffects of radiation therapy with the help of nutritional modification and their mobile number was enrolled for weekly reminders via broadcast through whatsapp. Post test I assessment of radiotherapy induced fatigue and its correlates was done at mid of RT and compliance monitioring diary was also checked. Post test II assessment of radiotherapy induced fatigue and its correlates was done at end of RT and compliance monitioring diary was also checked to know whether cancer fatigue increased or decreased RM ANOVA was applied.

Table 1 shows the demographic characteristic showing the study population total 16 patients among which 08 were from the Experimental arm and 08 belonged to the Control arm. Most of the subjects (75%) belonged to the age group 44 years-56 years in both experimental and control group. All (100%) of the subjects had an educational level of graduation and above. All (100%) subjects of experimental group were homemakers while 01 of the subjects of control group had a government job. The subjects in both experimental and control group belonged to urban area and were married, with a monthly income of Rs. 40,000/- Rs. 60,000/-. Table 2 shows the description of clinical variables characteristics of breast cancer patients undergoing radiotherapy in experimental and control group. Most of the subjects (87%) in both experimental and control group had Stage I cancer diagnosis. Most of the subjects duration of cancer of 6 months to 1 year in experimental (87%) and control group (100%).

The baseline score were similar at baseline, it was therefore concluded that the group was homogenous at baseline. Table 4 shows the comparison pre test To post test I and post test II mean scores of radiotherapy induced fatigue and its corelates among breast cancer patients in Experimental Group and Control Group using Repeated Measures ANOVA (RM ANOVA). The difference in the mean cancer fatigue scores at three points if time was found to be statiscally significant ($p<0.001^*$) in control group. It was therefore inferred that scores of Cancer fatigue in the control group were different at three points of time and Cancer fatigue scores increased significantly control group. Also scores of depression and anxiety in the control group were different at three points of time and scores increased significantly incontrol group. Scores of sleep quality were different in experimental group at three points of time and scores decreased significantly. Sleep quality in the control group was not different at three points of time and sleep quality scores didnot change significantly in control group. The difference in the mean nutritional status scores at three points if time was not found to be statiscally significant (p-0.0564 NS) in control group. It was therefore inferred that scores of nutritional status in the control group were not different at three points of time and nutritional status scores didnot change significantly in control group.

DISCUSSION

Patients with cervical cancer suffer from the aggressiveness of radio chemotherapy, changes in daily life activities, and live with anxiety throughout the therapeutic course. Therefore, the healthcare team should be attentive to these modifications and offer interventions that minimize anxiety and provide overall well-being. Our find-ings corroborate with the profile of women from other continents affected by BC: age between 40 years and 49 years old and in the workforce. The socioeconomic impact generates negative feelings of stress, anxiety, and delay in diagnosis [22, 23]. The presence of a partner is associated with a lower incidence of anxiety, early detec-tion, and better prognosis. In unmarried women, there is an increased risk of delayed diagnosis, lower survival, and economic and educational insufficiency relat-ed to delayed treatment [24-27]. Radiotherapy in advanced disease (IIB-IVA) presents a worse prognosis, with improved survival in 5 years, prevalence of genito-urinary sequelae, higher toxicity in elderly individuals, lower treat-ment adherence, limitations for surgical treatment indication, and decline in QoL. The presence of comorbidities and sedentary life-style results in a higher incidence of psychiatric symptoms and risk of mortality [28-30]. The results of the study illustrate the positive impact of Guided Imagery (GI) in the form of MCI. The overall global reduction in the radiation therapy induced fatigue reflects patients' positive response and incentive to learn. By the third integrative oncology nurse-guided session, patients self-regulated their autonomic re-sponse as noted through biofeedback. This allowed a shift from feelings of fear and apprehension to that of strength and calmness, likely surrogates for a feeling of empowerment. The reduction of the anxiety response is reflective of a measurable sympathetic physiologic response. This was determined by a non-invasive mea-surement, an advantage to both patients and clinicians. In addition, the positive objective outcomes of improvement in sleep quality demonstrated the helpful nature of GI in the setting of radiotherapy. The results from the The Zung Self Rated Depression Scale (Zung SDS) and the Zung Self Rated Anxiety Scale (Zung SAS) showed a reduction in anxiety and depression, further sup-porting the use of GI. The current study showed the importance of treating not only the cancer, but the emotional, psychological, and spiritual components of having cancer.

LIMITATIONS

The study did not have a long-term flow up plan. This prevented the observation of changes that occur in quality of life over time. The other challenges related to the number of interventional meetings, which averaged three to five sessions. A dose response may exist with more frequent meetings, increasing the ability of participants in mastering the self-regulation technique. Also, the individualized motivation of each participant in the use of home practice also would increase internalization of the new behavioural skill.

CONCLUSION

The goal of the GI study was to teach patients stress reduction in the midst of their radiation therapy treatment. The program began in the department of radiation oncology as a pilot program investigating the efficacy of holistic modalities for patients during treatment. The need for a holistic approach was based on initial observations of the integrative oncology nurse encountering many patients with breast cancer who expressed a lack of control regarding their diagnosis and treatments. The initial modality of GI was chosen because of its unique feature of self-empowerment, self-regulation, and effectiveness in reducing anxiety. The use of a simple thermal biofeedback device also was chosen because of its ability to give instant feedback to the patients. The patients were able to observe their initial level of tension. After the implementation of GI technique, the thermal biofeedback device assisted in the learning curve as an objective measurement and motivational tool. Both the quantitative and qualitative results demonstrated the usefulness of GI to reduce radiation induced fatigue, depression and anxiety and improve sleep and nutrition thereby overall quality of life during radiation treatment. This pilot study demonstrated the need for additional research with a larger population using a control group. Nurses have differentiated their professional role as attending the broader illness experience to complement medicine through a more focused role on the diagnosis and treatment.

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