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Effect of Raja Yoga Meditation on the Distress and Anxiety Levels of Women with Breast Cancer

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Abstract: Objective: To evaluate the effect of Raja yoga meditation on the level of distress and anxiety in women with breast cancer. Method: A randomized, controlled, clinical trial was carried out in a specialized center between February and December 2019. The patients in the intervention group (n = 25) participated in four group meditation sessions for one month, and the participants in the control group (n = 25) were exposed to an educational activity for the same period and frequency. Cohen's d was used to evaluate the effect size. Results: A significant reduction in the level of distress and anxiety was found in the intervention group ($p < 0.001$). The effect of meditation was average in reducing distress, anxiety, depression, and vital signs. There was also an average effect on the increase in saturation of peripheral oxygen (SPO2). Conclusion: The practice of meditation reduced distress and anxiety more effectively than the usual care practices.

Keywords: breast neoplasms; meditation; psychological stress; anxiety; nursing; complementary therapies

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1. Introduction

Despite advances in the treatment of breast cancer, such as the improvement of surgical techniques, chemotherapy, and interdisciplinary assistance (Instituto Nacional de Câncer 2019), it still has negative repercussions on the lives of women, including changes in the physical, psychological, social, and sexual aspects (Maass et al. 2019). Many women perceive cancer as a devastating disease and as a punishment involving feelings that are difficult to manage such as social stigma, fear of death, sadness, and shame (Cavalcante et al. 2016; Pereira et al. 2017). Distress, a multifactorial and emotional suffering that can be psychological, social, or spiritual, can also be experienced, affecting the ability to deal effectively with cancer and its physical changes, symptoms, and treatment (Ownby 2019).

Due to the high prevalence of distress in cancer patients, the National Comprehensive Cancer Network (NCCN) (Bultz 2016) recommended its routine and systematic screening in health services using the distress thermometer (DT). The DT is a simple and self-applicable tool that helps to identify vulnerable patients and related problems preventing debilitating situations (Oliveira et al. 2017) such as anxiety, depression, panic syndrome, social isolation, and existential/spiritual crisis (Espino-Polanco and García-Cardona 2018; da Mata et al. 2016).

Distress has also been associated with decreased quality of life, poor adherence, and treatment abandonment (Miranda et al. 2020). It is known that breast cancer can be related to stress and stressful situations experienced in childhood, repression of feelings, depression, and anxiety (Bahri et al. 2019), with the latter being characterized by a feeling

of intense, excessive, and persistent concern, with a negative influence on the quality of life (Regino et al. 2018). A study pointed out that 51.55% of cancer patients suffer from anxiety and 62.88% from depression, and that women are more likely to have these emotional problems (Veronese and Frade 2021).

Among the strategies to reduce the level of distress and anxiety in women with breast cancer, there is meditation, an ancient practice present in countless cultures and traditions used to calm the mind, balance the emotions, harmonize the mental state, and improve awareness, concentration, self-discipline, and self-care (Schlechta Portella et al. 2020). It is necessary to consider the existence of numerous meditative practices in the East and in the West, such as mindfulness. This meditative practice is aimed at reducing stress based on mindfulness (MBSR) (Schell et al. 2019), as described in the literature (Offidani et al. 2017; Johns et al. 2016; Boyle et al. 2017). There has been a beneficial effect of meditation on anxiety reduction (Johns et al. 2016), fatigue improvement (Johns et al. 2016), coping (Sarenmalm et al. 2017), pain relief (Saha et al. 2016), and reduced fear of recurrence (Soo et al. 2016) in women with breast cancer.

Raja yoga is one of the oldest systems of yoga and has been a well-known practice in India for millennia. It proposes building the spiritual world without requiring prior faith or belief (Vivekananda 2009; Agarwal et al. 2020), thus being accessible to people of all ages and contexts, without rituals or mantras, and can be practiced anywhere and at any time (Toutain et al. 2019).

Yoga is a practice used to silence the agitated mind and focus on positive thoughts to direct the mind's flow and fill the being with an inner stillness (Vivekananda 2009). Therefore, the aim is to obtain a moment for reflection and silence, away from the hustle and bustle of everyday life that often leads the individual to experience stress and, consequently, to develop mental, emotional, and physical imbalances (Toutain et al. 2019). The practice of yoga is structured in eight steps: (1) Yama, which consists of self-restraints (non-violence, truthfulness, non-stealing, control of the senses, and non-acceptance of gifts); (2) Niyama, which consists of religious observances (cleanliness, contentment, austerity, self-study, and surrender to God's will); (3) Asana, or yoga posture; (4) Pranayama, or control of prana (breathing exercises); (5) Pratyahara, or withdrawal of senses from objects; (6) Dharana, or progression in concentration; (7) Dhyana, or meditation; and (8) Samadhi, or achieving a superconscious state (Prabhavananda; Patanjali. 1981).

Most studies involving the practice of Raja yoga were developed in the United States (Nidich et al. 2009; Lengacher et al. 2012, 2014; Matchim et al. 2011; Hoffman et al. 2012; Charlson et al. 2014; Bower et al. 2015; Johns et al. 2016; Boyle et al. 2017), Denmark (Andersen et al. 2013), and Canada (Saha et al. 2016).

Studies already report several purposes for Raja yoga, including the improvement of chronic headache (Rajoria and Singh 2017); state of consciousness (Kiran et al. 2017); anxiety and stress reduction in patients undergoing myocardial revascularization surgery (Kiran et al. 2017); positive thinking, self-satisfaction, happiness, and prevention of relapses in individuals who use drugs (Mallik et al. 2019); and the happiness and well-being of older adults. Practicing Raja yoga (Pandya 2019) reduced glucose level in individuals with type 2 diabetes (Phatak et al. 2017). Despite this, there is still a gap in the literature regarding the existence of controlled and randomized clinical trials developed in the national and international context on the effect of Raja yoga meditation on women with breast cancer in terms of reducing stress and anxiety (Araújo et al. 2019).

However, Raja yoga is still little known and not widespread in the West. To date, no clinical trials have been identified using Raja yoga meditation to improve distress and anxiety in women with breast cancer. A previous study using interpretative phenomenological analysis conducted in the United States with breast cancer survivors found improvements in the participants' emotional, physical, and spiritual well-being, as well as their resilience (Agarwal et al. 2020).

Despite being considered a simple, low-cost, and safe intervention without contraindication and feasible to being conducted in several scenarios (Gurgel et al. 2019; Rajoria

and Singh 2017), there is still a need for scientific evidence to prove the effectiveness of this meditative practice (Abrahão et al. 2019). This study aimed to evaluate the effect of Raja yoga meditation on the level of distress and anxiety in women with breast cancer and, therefore, to fill in the gaps related to the needs of clinical trials on the topic under discussion.

2. Method

Design

A controlled, randomized, and blinded clinical trial was carried out in a high complexity oncology unit (UNACON in Portuguese) of a university hospital located in Teresina, Piauí, Brazil.

3. Ethical Aspects

The Research Ethics Committee of the of the university in which the study was undertaken approved the study (Certificate of Presentation for Ethical Consideration: 82/18; Brazilian Registry of Clinical Trials: RBR-7hxwxy). All participants included in the study signed an informed consent form.

3.1. Participants and Sample

One of the researchers recruited the participants after consulting the medical records from the nursing office of the UNACON outpatient clinic of the XXXX. Women diagnosed with breast cancer who were starting chemotherapy treatment at the hospital selected for the study were considered eligible. Inclusion criteria were women aged 18 to 65 years with a first diagnosis of breast cancer who were starting chemotherapy, and who had a good performance (0–1) on the Eastern Cooperative Oncologic Group (ECOG) scale, also called the Zubrod score, which runs from 0 to 5, with 0 denoting a fully active patient capable of carrying out all activities without restriction, and 1 an individual with restriction from physically strenuous activities who is able to carry out work of a light or sedentary nature (Polo and de Moraes 2009).

Exclusion criteria were women with breast cancer on prophylactic hormone therapy, diagnosis of another type of associated cancer (except non-melanoma skin cancer), severe mental disability (depression, suicidal thinking, or bipolar disorder), continuous use of controlled medications (anxiolytics, antidepressants, or mood regulators), chronic or substance abuse (alcohol, smoking, or illicit drugs), cognitive impairment (hearing or language), and previous or current experience in meditation or yoga programs. As discontinuity criteria, we adopted absence in more than one of the group activities and changes in the participant's clinical condition (ECOG > 1) (Polo and de Moraes 2009) that could contraindicate the permanence in the activities.

The required sample size was based on the recommendations by Friston (2012), who considered that there is an optimal sample size for experimental studies in which there are statistically significant differences with clinical implications on the studied outcome. This sample size comprises a number between 16 and 32 participants. Initially, a sample calculation was performed based on the prevalence of stress among women with breast cancer, ranging from 25% to 45% (Oliveira et al. 2017; Villar et al. 2017). The parameters used were α of 0.05 (type I error), two-tailed, and β or power (type II error) of 0.80, and an estimated difference of 20% between the groups, resulting in a sample size of 25 patients.

3.2. Randomization, Allocation, and Blinding

From the 274 patients diagnosed with breast cancer and treated at UNCACON during the study period (February to December 2019), 85 women met the study's eligibility criteria. Of these, 35 were excluded (23 did not meet the inclusion criteria, and 12 refused to participate in the study before starting the interventions). Thus, 25 participants were randomly allocated to the intervention group (IG), who participated in meditation practices, and 25 to the control group (CG), who participated in educational activities belonging

to the integrative and complementary practices (ICPs) offered by the Brazilian Unified Health System (SUS) (Brasil 2018a). Throughout this study, there was no loss of follow-up or discontinuity, as shown in Figure 1.

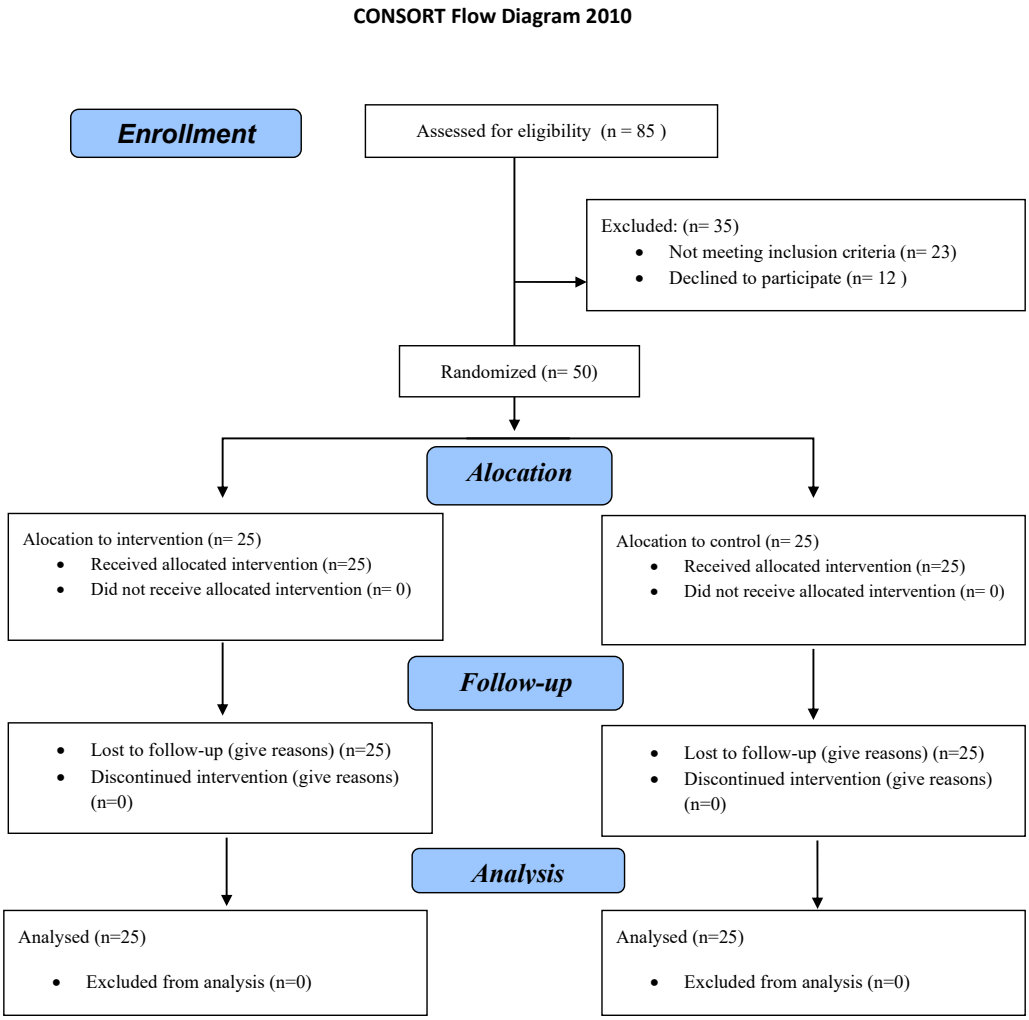


Figure 1. Follow-up of study participants according to the CONSORT 2010 flowchart.

The random allocation of participants was done with the aid of the Research Randomizer Quick Tutorial program available on the website https://www.randomizer.org/#randomize (accessed on 23 March 2019). This procedure was performed by a person with no clinical involvement in the study to ensure allocation confidentiality (Hulley et al. 2019). The generation of random sequences for each designation was placed individually in an opaque envelope, sealed, and numbered sequentially (Ferreira and Patino 2016). Block randomization was used using five blocks of varying sizes and named as follows: 08, 12, 10, 8, and 12. This randomization technique was used due to the specific characteristics of the proposed clinical trial, in which women should be undergoing chemotherapy. Therefore, it was necessary to wait for the start of therapy, which, in turn, was 15 to 30 days after the initial identification and selection of participants (Ferreira and Patino 2016).

The following research staff were blinded in the study: data collectors, primary/secondary outcome evaluators (IG and CG), the staff data scientist, and the statistician. It was not possible to blind the main researcher, as he was responsible for contacting the participants to inform them of the day, time, and place of the interventions, nor the oncologist nurse, as she had to adjust the chemotherapy schedule when it coincided with the intervention schedule. Participants were also not blinded, as they had to be informed about the intervention. In

non-pharmacological clinical trials, it is difficult or even impossible to blind the participants, whether for technical or ethical reasons (Hulley et al. 2019).

3.3. Intervention Protocol

The IG members participated in Raja yoga meditation practices once a week for 40 to 50 min, with a one-month follow-up. In total, the intervention group participated in four guided meditative practices. It is necessary to highlight that practice at home was encouraged; however, it was not possible to assess the impact since some did not perform it during the study. According to the literature recommendation, the practices were directed by a qualified teacher with training in the meditation program and extensive experience in the area, with over 20 years of experience (Bower et al. 2015; Carlson et al. 2016). The practice was standardized with patients sitting in a supported chair in order to avoid discomfort or complications associated with the fully implantable central venous catheter (Zerati et al. 2017). The following steps were carried out: relaxation, concentration, contemplation, self-realization, and inner silence (Sharma et al. 2020). The intervention was carried out in a hospital meeting room.

CG participants participated in an educational activity conducted as part of the National Policy of Integrative and Complementary Practices (PNPIC in Portuguese) and the ordinances that expand these practices in Brazil (Brasil 2018b). The meetings lasted 40 to 50 min and were conducted over four weeks. The study's main researcher exposed the educational activity topics using audiovisual resources and informational brochures.

3.4. Measuring Instruments

The following parameters were evaluated before and after the educational interventions/activities in both groups: heart rate (HR), systolic and diastolic blood pressure, and saturation of peripheral oxygen—pulse oximetry (SPO2), according to the current guidelines (Melo et al. 2020; Sociedade Brasileira de Cardiologia (SBC) 2016, 2019). A distress thermometer validated and adapted for use in Brazil in cancer patients was used to assess the level of distress (Decat et al. 2009). The Hospital Anxiety and Depression Scale (HADS) validated in Brazil for hospitalized patients was used to measure the level of anxiety (Botega et al. 1995). One of the advantages of the HADS scale is that it is self-administered and can assess anxiety in sick or healthy patients (Marcolino et al. 2007). Both instruments had good values of internal consistency and replicability in studies developed with cancer patients. The instruments were applied at the beginning and end of the follow-up.

The collection of socioeconomic, cultural, demographic, and clinical data, as well as variables related to breast cancer (treatment, staging, and classification) started after the start of chemotherapy. Before data collection, a pilot study was carried out with five women to organize the study and test the instruments. The pilot data were not used in this study. The research team was composed of the main researcher, an oncologist nurse from UNACON, and eight research assistants trained to apply the instruments and the research checklist and standard operating procedure.

The primary outcome was a score less than or equal to 3 (absence of distress), a score greater than or equal to 4 (presence of distress) (Oliveira et al. 2017), and a score equal to or greater than eight (presence of anxiety or depression) (Botega et al. 1995). The secondary outcome considered vital sign parameters as follows: normotension, systolic BP $\leq$ 120 mmHg, and diastolic BP $\leq$ 80 mmHg; hypertension, systolic BP = 140–159 mmHg, and diastolic BP = 90–99 mmHg (Sociedade Brasileira de Cardiologia (SBC) 2019); normocardia: HR = 50–100 bpm; bradycardia, HR < 50 bpm; tachycardia, HR > 100 bpm (Sociedade Brasileira de Cardiologia (SBC) 2016); normal oximetry, saturation of peripheral oxygen (SPO2) = 95–100%; and low oximetry, saturation of peripheral oxygen (SPO2) < 95% (Botega et al. 1995).

3.5. Data Analysis

Quantitative variables were described with medians and interquartile ranges, and qualitative variables were expressed as absolute numbers and percentages. The Shapiro–Wilk test was used to verify adherence to the normal distribution. The Student's *t*-test for independent samples with normal distribution and the non-parametric Mann–Whitney U test were used for independent variables without normality assumption for comparison between the two groups.

The Chi-square or Fisher's exact test was used for analysis involving independent categorical variables, whereas the McNemar test was used for dependent categorical variables. The paired t-test and the Wilcoxon test were used to compare distress and anxiety levels in women with breast cancer in both groups. The effect size was calculated based on the Cohen's d index. The following values were considered: insignificant: less than 0.19, small: 0.20–0.49, medium: 0.50–0.79, large: 0.80–1.29, and very large: greater than 1.30 (Santo and Daniel 2017). The results were analyzed using the Statistical Package for Social Sciences (SPSS) version 21. A significance level of 5% ($p < 0.05$) was adopted for all analyses.

4. Results

The homogeneity and sociodemographic characteristics of the intervention and control groups are shown in Table 1. The median age of the participants was 47 years, with a predominance of white women (72%), living with a partner (54%), with a high school level of education (76%), having a paid occupation (64%), surviving on one minimum wage or less (66%), and Catholic (72%). The groups were homogeneous concerning marital status, education, income, and religion ($p > 0.05$).

Table 1. Characterization and homogeneity of the participants in the intervention and control groups.

Variables	Total $n = 50$	Group		*p*-Value
		Intervention $n = 25$	Control $n = 25$	
	Median (P25–P75)	**Median (P25–P75)**	**Median (P25–P75)**	
Age (years)	47 (40.8–56)	46 (38.5–56)	47 (43.5–55.5)	0.4311 [1]
	***n* (%)**	***n* (%)**	***n* (%)**	
Ethnicity				0.2082 [2]
White	36 (72.0)	16 (64.0)	20 (80.0)	
Non-white	14 (28.0)	9 (36.0)	5 (20.0)	
Marital status				0.7772 [2]
Living with a partner	27 (54.0)	14 (56.0)	13 (52.0)	
Living without a partner	23 (46.0)	11 (44.0)	12 (48.0)	
Educational level				1.0002 [2]
Low	12 (24.0)	6 (24.0)	6 (24.0)	
High *	38 (76.0)	19 (76.0)	19 (76.0)	
Occupation				0.2392 [3]
Unpaid	18 (36.0)	11 (44.0)	7 (28.0)	
Paid	32 (64.0)	14 (56.0)	18 (72.0)	
Family income				0.7652 [3]
Up to 1 minimum wage	33 (66.0)	17 (68.0)	16 (64.0)	
>1 minimum wage	17 (34.0)	8 (32.0)	9 (36.0)	
Religion				0.5292 [2]
Catholic	36 (72.0)	17 (68.0)	19 (76.0)	
Protestant	14 (28.0)	8 (32.0)	6 (24.0)	

[1] Mann–Whitney U test; [2] Chi-square test; [3] Fisher's exact test; P25–P75: interquartile range; minimum wage: USD 1045.00. * High school or higher.

Table 2 shows homogeneity in the distribution of participants in the two groups concerning the two quantitative variables and all qualitative variables. The participants' median age at menarche was 13 (12.5–15%) years and at menopause 46 (44.8–49.3%) years.

Among the main predictive factors for breast cancer in the population studied, the most prevalent were physical inactivity (76%), overweight (44%), and having a relative with breast cancer (22%).

Table 2. Predictive factors for breast cancer in the participants.

Variables	Total *n* = 50	Group		*p*-Value
		Intervention *n* = 25	Control *n* = 25	
	Median (P25-P75)	**Median (P25-P75)**	**Median (P25-P75)**	
Age at menarche	13 (12.5–15)	14 (13–14)	13 (12–15)	0.8621
Age at menopause	46 (44.8–49.3)	46 (45–50.0)	45 (39–49)	0.2751 [1]
	***n* (%)**	***n* (%)**	***n* (%)**	
Ever having had children				1.000 [2]
Yes	38 (76.0)	19 (76.0)	19 (76.0)	
No	12 (24.0)	6 (24.0)	6 (24.0)	
First pregnancy after 30 years				0.699 [3]
Yes	7 (15.7)	3 (13.0%)	4 (18.2%)	
No	38 (84.4)	20 (87.0%)	18 (81.8%)	
Ever having breastfed				0.488 [3]
Yes	38 (95.0)	19 (90.5)	19 (100.0)	
No	2 (5.0)	2 (9.5)	0 (0.0)	
Use of oral contraceptives				0.564 [2]
Yes	20 (40.0)	11 (44.0)	9 (36.0)	
No	30 (60.0)	14 (56.0)	16 (64.0)	
Physical activity				0.508 [2]
Yes	12 (24.0)	5 (20.0)	7 (28.0)	
No	38 (76.0)	20 (80.0)	18 (72.0)	
BMI				0.447 [2]
Adequate	14 (28.0)	5 (20.0)	9 (36.0)	
Overweight	22 (44.0)	12 (48.0)	10 (40.0)	
Obesity	14 (28.0)	8 (32.0)	6 (24.0)	
Habits				0.429 [3]
Smoking	4 (57.1)	2 (100.0)	2 (40.0)	
Alcohol drinking	3 (42.9)	0 (0.0)	3 (60.0)	
Having a relative with breast cancer				0.306 [2]
Yes	11 (22.0)	7 (28.0)	4 (16.0)	
No	39 (78.0)	18 (72.0)	21 (84.0)	

[1] Mann–Whitney U test; [2] Chi-square test; [3] Fisher's exact test.

Table 3 shows that the participants in both groups (IG and CG) were homogenous in the following characteristics: having breast surgery, affected breast, surgical information, current treatment, port-cath implantation, metastasis, purpose of chemotherapy, and TNM staging ($p = 1.000$).

Table 3. Data related to the disease, treatment, and staging.

Variables	Total *n* (%)	Group		*p*-Value
		Intervention *n* (%)	Control *n* (%)	
Having breast surgery				
Yes	7 (14.0)	3 (12.0)	4 (16.0)	1.00
No	43 (86.0)	22 (88.0)	21 (84.0)	
Affected breast				
Right	26 (52.0)	13 (52.0)	13 (52.0)	1.00
Left	24 (48.0)	12 (48.0)	12 (48.0)	
Surgery information				
Total mastectomy	2 (4.0)	1 (4.0)	1 (4.0)	1.00

Table 3. *Cont.*

Variables	Total *n* (%)	Group		*p*-Value
		Intervention *n* (%)	Control *n* (%)	
Quadrandectomy	1 (2.0)	0 (0.0)	1 (4.0)	
Sectorectomy	3 (6.0)	2 (8.0)	1 (4.0)	
Lymphaticectomy	5 (10.0)	3 (12.0)	2 (8.0)	
Breast reconstruction	1 (2.0)	1 (4.0)	0 (0.0)	
Current treatment				
Chemotherapy	48 (96.0)	23 (92.0)	25 (100.0)	1.00
Radiotherapy	4 (8.0)	2 (8.0)	2 (8.0)	
Surgery	5 (10.0)	2 (8.0)	3 (12.0)	
Hormone therapy	4 (8.0)	3 (12.0)	1 (4.0)	
Immunotherapy	4 (8.0)	1 (4.0)	3 (12.0)	
Port-cath implantation				
Yes	21 (42.0)	10 (40.0)	11 (44.0)	
No	29 (59.0)	15 (60.0)	14 (56.0)	
Metastasis				
Yes	7 (14.0)	4 (16.0)	3 (12.0)	1.00
No	43 (86.0)	21 (84.0)	22 (88.0)	
Purpose of chemotherapy				
Neoadjuvant	37 (74.0)	18 (72.0)	19 (76.0)	1.00
Adjuvant	6 (12.0)	3 (12.0)	3 (12.0)	
Palliative	7 (14.0)	4 (16.0)	3 (12.0)	
TNM staging				
IA—T1 N0 M0	1 (2.0)	0 (0.0)	1 (4.0)	1.00
IIA—T1 N1 M0	1 (2.0)	0 (0.0)	1 (4.0)	
IIA—T2 N0 M0	11 (22.0)	5 (20.0)	6 (24.0)	
IIB—T2 N1 M0	8 (16.0)	2 (8.0)	6 (24.0)	
IIB—T3 N0 M0	5 (10.0)	1 (4.0)	4 (16.0)	
IIIA—T2 N2 M0	2 (4.0)	0 (0.0)	2 (8.0)	
IIIA—T3 N1 M0	7 (14.0)	6 (24.0)	1 (4.0)	
IIIA—T3 N2 M	1 (2.0)	1 (4.0)	0 (0.0)	
IIIB—T4N0	1 (2.0)	1 (4.0)	0 (0.0)	
IIIB—T4N1	3 (6.0)	3 (12.0)	0 (0.0)	
IIIB—T4N2	2 (4.0)	2 (8.0)	0 (0.0)	
IV—TX NX M1	8 (16.0)	4 (16.0)	4 (16.0)	

Chi-square test.

Table 4 shows the level of distress before and after the intervention in the IG and CG. There was a reduction in the level of distress in the IG after practicing meditation and, therefore, a positive effect of meditation for reducing the level of distress in those women.

Table 4. Comparison of distress levels before and after interventions between the two groups. Teresina, Piauí, Brazil. 2020.

Assessment of Distress Level	Intervention Group				Control Group			
	Total *n* (%)	Presence of Distress after	Absence of Distress after	*p*-Value *	Total *n* (%)	Presence of Distress after	Absence of Distress after	*p*-Value *
Presence of distress before	23 (100)	13 (56.5)	10 (43.5)	0.002	21 (100)	21 (100.0)	0 (4.0)	1.000
Absence of distress before	2 (100)	0 (0.0)	2 (100.0)		4 (100)	0 (0.0)	4 (100.0)	

* McNemar test.

The two groups were homogeneous with respect to the presence of distress before the interventions. The most frequent problems/situations reported by the participants and related to distress were taking care of the house (67%), sadness (60%), worry (62%),

memory/concentration disorders (54%), nervousness (48%), subsistence (48%), dry/itchy skin (48%), fear (46%), appearance-related problems (44%), fatigue (48%), loss of interest in usual activities (38%), breathing disorders (36%), health and financial problems (34.7%), and transportation difficulties (32%). There was statistical significance ($p < 0.001$) in the improvement of some problems associated with distress after the intervention in the IG, among them taking care of the house, spiritual/religious involvement, subsistence, and sleeping ($p < 0.001$). In the bivariate analysis, only the variable "ever having had children" ($p < 0.005$) was statistically associated with a reduction in the level of distress among the participants in the IG; therefore, the multiple regression was not performed.

A marked reduction in anxiety was identified in the IG. Therefore, a positive effect of meditation in reducing the level of anxiety in women with breast cancer in the IG was found, as well as an improvement in the percentage of symptoms related to anxiety (Table 5).

Table 5. Comparison of the level of anxiety before and after the intervention in the two groups.

Anxiety	Intervention Group				Control Group			
	Total ***n*** **(%)**	**Presence of Anxiety after** ***n*** **(%)**	**Absence of Anxiety after** ***n*** **(%)**	***p*-Value ***	**Total** ***n*** **(%)**	**Presence of Anxiety after** ***n*** **(%)**	**Absence of Anxiety after** ***n*** **(%)**	***p*-Value ***
Presence of anxiety before	9 (100)	1 (11.1)	8 (88.9)	0.008	8 (100.0)	7 (87.5)	1 (12.5)	1.000
Absence of anxiety before	16 (100)	0 (0.0)	16 (100.0)		17 (100.0)	1 (5.9)	16 (94.1)	

* McNemar test.

There was a statistical significance in the systolic blood pressure reduction after the interventions (Figures 2–9). A reduction in blood pressure was observed throughout the interventions.

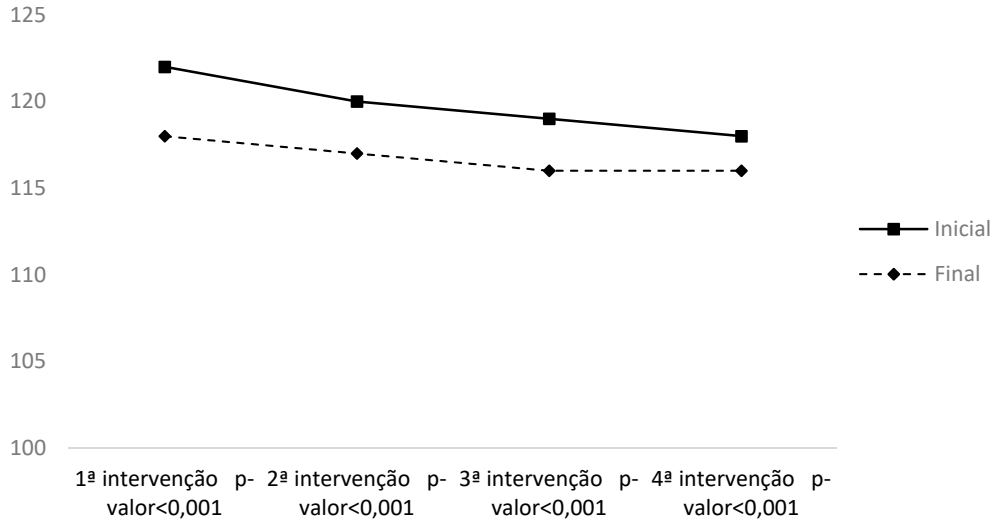
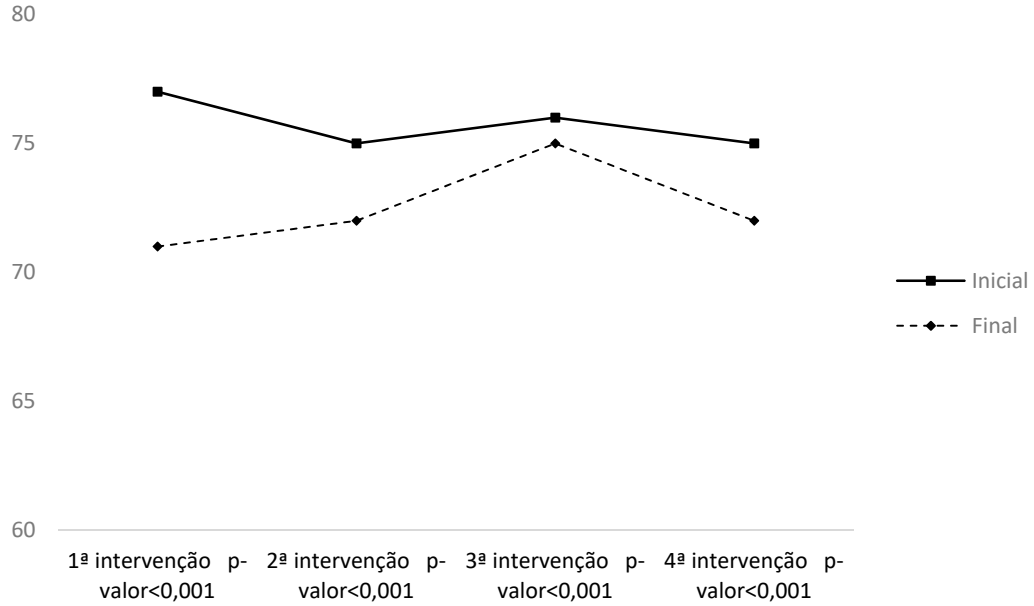
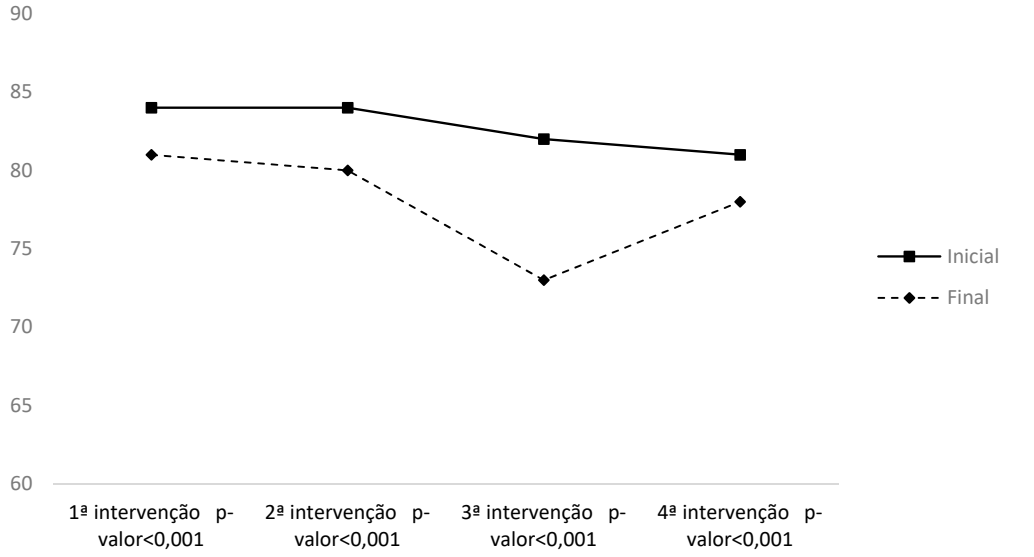


Figure 2. Median values of systolic blood pressure (SBP) before and after the four interventions in the IG (Raja yoga meditation).



Wilcoxon test

Figure 3. Median values of diastolic blood pressure (DBP) before and after the four interventions in the IG (Raja yoga meditation).



Wilcoxon test

Figure 4. Median values of heart rate (HR) before and after the four interventions in the IG (Raja yoga meditation).

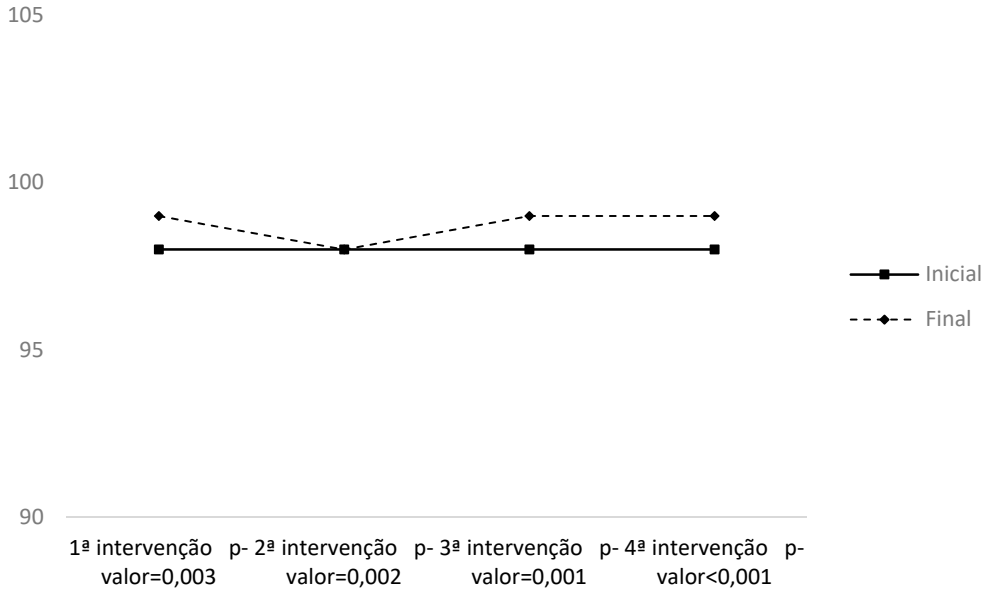


Figure 5. Median values of pulse oximetry (SPO2) before and after the four interventions in the IG (Raja yoga meditation).

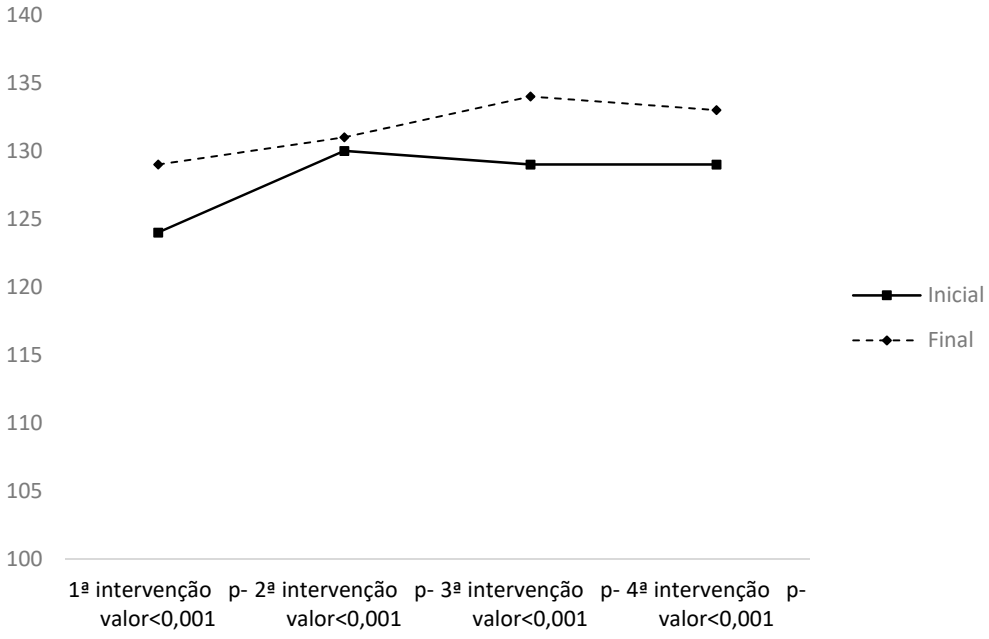
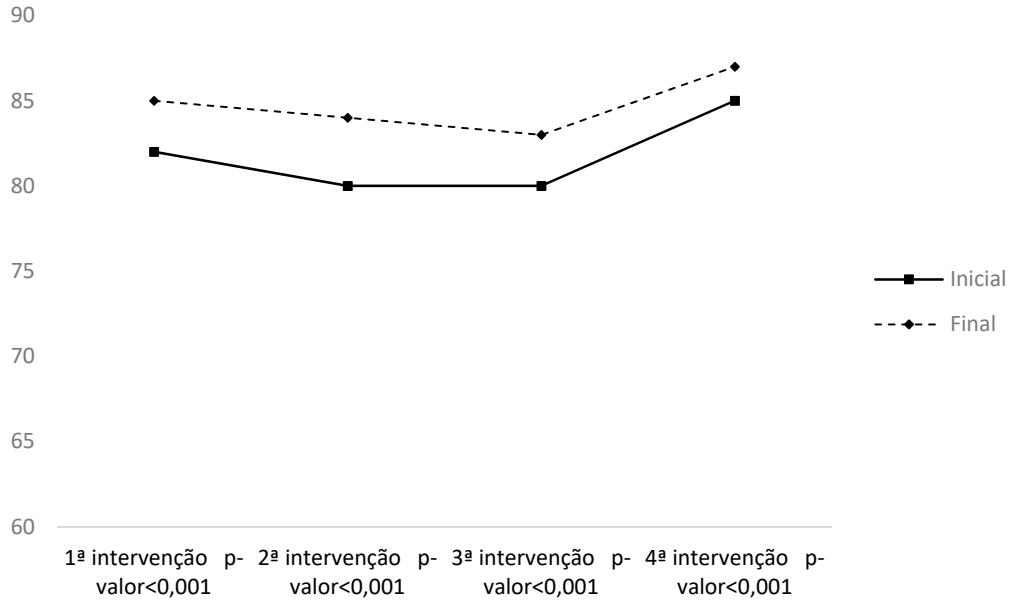
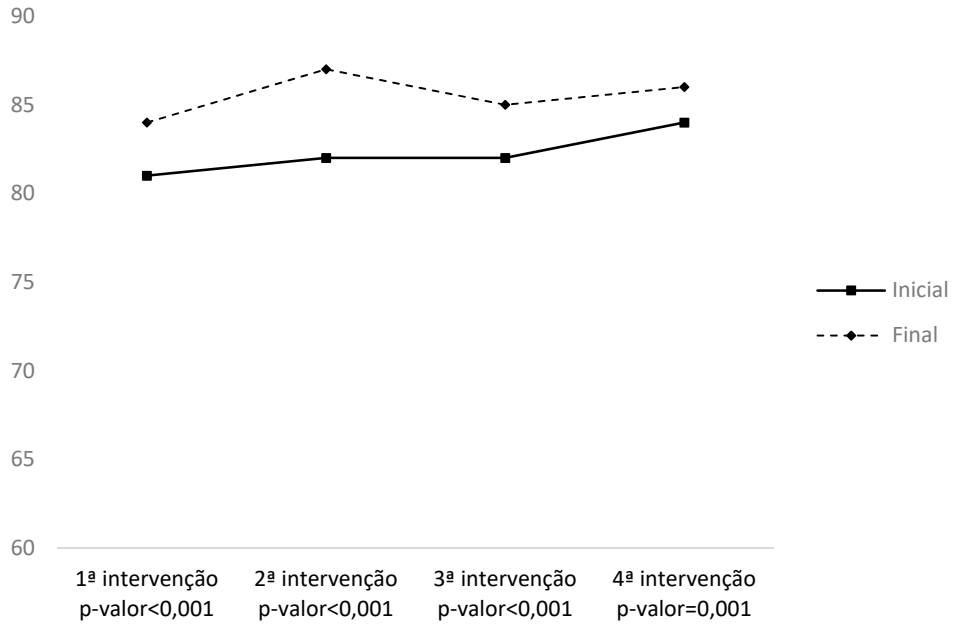


Figure 6. Median values of systolic blood pressure (SBP) before and after the four interventions in the CG (educational activity).



Wilcoxon test

Figure 7. Median values of diastolic blood pressure (DBP) before and after the four interventions in the CG (educational activity).



Wilcoxon test

Figure 8. Median values of heart rate (HR) before and after the four interventions in the CG (educational activity).

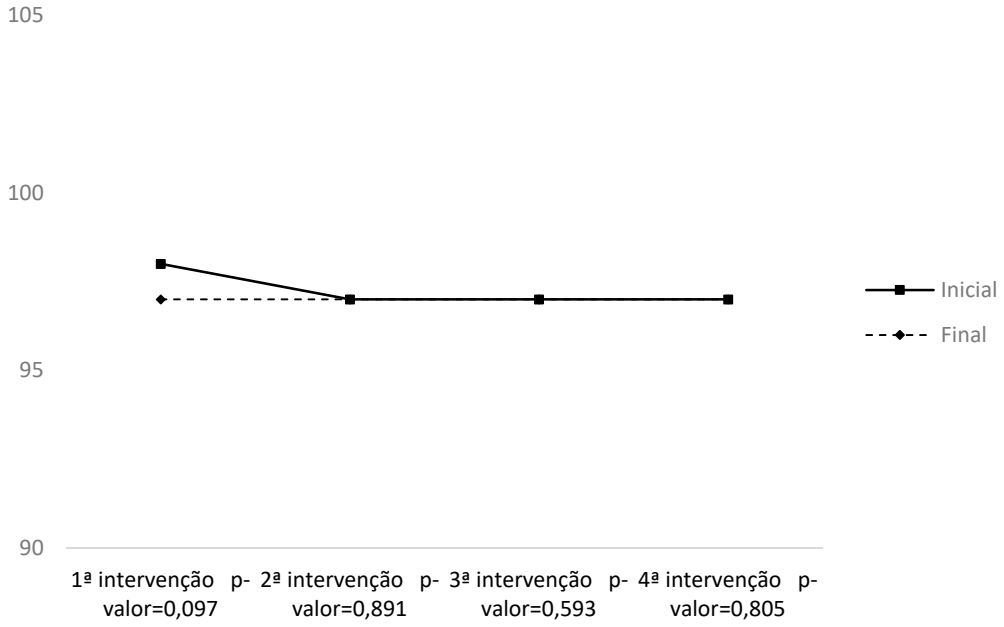


Figure 9. Median values of pulse oximetry (SPO2) before and after the four interventions in the CG (educational activity).

At the end of the follow-up, there was an average effect of Raja yoga meditation on reducing distress, anxiety, depression, and all vital signs evaluated in the two groups. There was also an average effect on the increase of saturation of peripheral oxygen (SPO2), as shown in Table 6.

Table 6. Effect size (Cohen's d) of the interventions on the level of distress, anxiety, SBP, DBP, HR, and SPO2 in the two groups.

Variables		Intervention Group	Control Group	Cohen's d	Effect Size
Distress thermometer	1st moment	6.52 (± 2.23)	6.70 (± 2.49)	−0.079	−0.03
	2nd moment	3.72 (± 1.54)	6.75 (± 2.41)	−1.49	−0.59
Anxiety	1st moment	6.32 (± 4.62)	6.24 (± 4.69)	0.017	0.008
	2nd moment	3.12 (± 2.55)	6.20 (± 4.70)	−0.814	−0.37
Depression	1st moment	5.48 (± 4.32)	5.16 (± 4.20)	0.075	0.03
	2nd moment	3.16 (± 2.62)	5.76 (± 4.17)	−0.746	−0.34
Systolic blood pessure	1st moment	121.64 (± 19.28)	132.40 (± 19.85)	−0.549	−0.26
	2nd moment	117.8 (± 15.53)	132.24 (± 11.68)	−1.05	−0.46
Diastolic blood pressure	1st moment	70.08 (± 19.98)	78.12 (± 17.01)	−0.433	−0.21
	2nd moment	72.28 (± 9.57)	85.20 (± 7.57)	−1.497	−0.59
HR	1st moment	82.92 (±12.43)	79.62 (±10.80)	0.283	0.14
	2nd moment	79.08 (±9.52)	85.50 (±9.78)	−0.66	−0.31
SPO2	1st moment	97.72 (±1.02)	97.12 (±2.17)	0.353	0.17
	2nd moment	97.80 (±0.70)	97.25 (±0.94)	0.663	0.31

5. Discussion

The results of the present study show that distress was present in most participants in the IG. These results are consistent with a previous study (da Mata et al. 2016) that pointed out that such suffering is frequent among cancer patients. The study participants listed situations and emotions as possible causes of distress, including taking care of the house, taking care of young children, having feelings of sadness, having concerns, and having memory and concentration problems, fear, and nervousness.

Researchers explain that concerns involving children are frequent among women with cancer, and that those women often face difficulties in reconciling chemotherapy schedules, medical consultations, and exams with domestic chores and childcare (Miranda et al. 2020; Oliveira et al. 2017). The above-mentioned situations combined with symptoms such as fatigue, malaise, nausea, vomiting, and diarrhea generate distress in women with cancer who have children (Espino-Polanco and García-Cardona 2018). In the literature, there is a list of other problems associated with distress, such as prolonged waiting times to start treatment, family conflicts, lack of family support, young children, pain, sleep disorders, interruption of family projects, and financial problems (da Mata et al. 2016; Offidani et al. 2017).

A previous study found a possible relationship between distress and the emergence of breast cancer, such as the experience of stressful situations in childhood, the repression of feelings, tension, depression, and anxiety (Amorim and Siqueira 2017; Espino-Polanco and García-Cardona 2018). Researchers say that distress is also related to lower adherence to cancer treatment, loss of quality of life, and immunological alterations (da Mata et al. 2016; Miranda et al. 2020; Ownby 2019). Given these implications, the importance of screening distress in cancer patients is emphasized (Oliveira et al. 2017). Although the investigation of distress is complex and often neglected by oncology professionals, the importance of early identification of individuals at risk and who are vulnerable is emphasized in order to prevent complications such as post-traumatic stress, anxiety, depression, and suicidal thoughts (Bultz 2016; Santiago et al. 2019; Yee et al. 2017). In the present study, it was observed that most participants were young. The results obtained are in line with the literature. A higher prevalence of distress was found in a prior study among young women with a recent diagnosis of breast cancer and problems at work (Offidani et al. 2017).

In the present study, more than half of the women in the IG reported symptoms of anxiety before the intervention. Scientific evidence has pointed out that emotional problems such as anxiety and depression are frequent in cancer patients (Regino et al. 2018). A literature review that included 36 studies and 16,298 patients with breast cancer found a prevalence of anxiety in 41.9% of the participants (Hashemi et al. 2020). Thus, it is worth emphasizing the importance of tracking anxiety in women with breast cancer to prevent implications such as depression and post-traumatic stress disorder (Regino et al. 2018; Silva et al. 2017).

In the current study, there was an improvement in the percentage of symptoms related to anxiety after the intervention (IG), such as fear, worry, and the sensation of cold in the stomach. In a multicenter study conducted in Korea, an association of depressive symptoms with anxiety and quality of life was identified in women who survived breast cancer (Shim et al. 2020). Research has shown that women with a low level of education and patients undergoing chemotherapy are more likely to experience fatigue, depression, and anxiety (Li et al. 2020). Research shows that breast cancer survivors are at higher risk for depression and severe anxiety symptoms (Maass et al. 2019). It is necessary to emphasize that it is crucial to identify women at risk and therefore plan and implement interventions to prevent and better manage anxiety symptoms (Li et al. 2020).

Participants of a previous study (Bharshankar et al. 2015) were divided into an intervention group that practiced Raja yoga meditation and a control group that received an educational intervention offered by the Brazilian public health system. At the end of the four-week follow-up, there was a very large effect of Raja yoga meditation on reducing distress and a great effect on reducing anxiety in the IG, as well as improving symptoms related to distress, such as taking care of the house, fear, sadness, worry, memory, and concentration. The results obtained are consistent with the current literature (Phatak et al. 2017). In the present study, the positive results obtained can be related to the effect size, considered moderate for the variables of distress and diastolic blood pressure, and small for anxiety, depression, systolic blood pressure, and heart rate.

Raja yoga meditation has been applied in several scenarios, such as in the work environment, oncology, psychiatry, and others (Pillai et al. 2015; Goyal et al. 2018). This

practice has been related to several beneficial effects, including satisfaction and happiness in life (Pandya 2019).

In the current study, it was found that the participants in the IG showed a reduction in blood pressure and heart rate, and an improvement in oxygen saturation levels. A study carried out in India with 90 participants found beneficial effects of Raja yoga on systolic and diastolic blood pressure parameters and on the respiratory function of individuals with type 2 diabetes (Chawla et al. 2020). Another study conducted in India found a significant reduction in blood glucose levels, glycated hemoglobin, total cholesterol, serum triglycerides, and stress in individuals practicing Raja yoga (Phatak et al. 2017). The literature points out that Raja yoga also contributes to improving leadership and crisis management (Pillai et al. 2015).

In a retrospective study conducted in Canada, 34% of psychiatric outpatients who participated in the Raja yoga meditation group had immediate and substantial improvement in well-being compared to standard psychotherapy (Bhopal et al. 2018). In a randomized clinical trial to evaluate the role of Raja yoga meditation in improving anxiety and reducing cortisol in patients undergoing coronary artery bypass graft surgery, it was observed that on the second postoperative day, patients who underwent Raja yoga presented a reduction in the level of anxiety compared to the control group (3.12 ± 1.45 vs. 6.12 ± 0.14, $p < 0.05$) and a reduction in the level of cortisol (Kiran et al. 2017).

In a review study, the beneficial effects of Raja yoga on the nervous, immune, circulatory, respiratory, digestive, and endocrine systems were presented as well as in the treatment and prevention of neurodegenerative, cardiovascular, and psychosomatic disorders, and in promoting an analgesic effect (Rajoria and Singh 2017). Longitudinal research in Brahmakumari centers located in India, Australia, Belgium, Botswana, Canada, France, Japan, South Africa, and the United States pointed out that Raja yoga has the potential to improve the reduction of anxiety and stress, and promote mental health, spiritual well-being, and awareness (Pandya 2019). Scholars highlight the importance of assessing spirituality to provide holistic care for people at risk of spiritual suffering (Martins et al. 2020). Researchers support integrating these self-care strategies into the patients' treatment plans to improve emotions and reduce financial costs with health care (Agarwal et al. 2020). Thus, the importance of more consistent studies that prove the benefits and costs of meditation programs is reinforced (Gurgel et al. 2019; Pandya 2019). A clinical trial carried out in the United States to compare the effect of Raja yoga on the improvement of withdrawal crises compared to relaxation techniques and standard treatment showed that there were no significant differences in withdrawal among individuals who participated in relaxation and usual treatment (Mallik et al. 2019).

The practice of Raja yoga meditation has also been shown to be effective in controlling cardiopulmonary functions. It was found that individuals diagnosed with diabetes and practitioners of Raja yoga had significantly lower values of systolic and diastolic BP and HR when compared to individuals who did not practice meditation ($p < 0.05$). Variables related to respiratory function, including forced vital capacity (FVC), forced expiratory volume in 1 s (FEV1), maximum voluntary ventilation (MVV), expiratory reserve volume (ERV), forced expiratory flow (FEF 25–75%), and peak expiratory flow rate (PEFR) were considerably reduced in the group of diabetic individuals practicing Raja yoga compared to healthy and non-meditating individuals ($p < 0.05$) (Chawla et al. 2020).

Given the above, a minimum level of knowledge about integrative and complementary practices and its indications is expected from professionals working in oncology settings. The current study employed a meditative practice little known in Western countries but that is simple, safe, and without contraindications (Rajoria and Singh 2017), and that can be implemented in healthcare settings.

Some limitations of the study include the short follow-up period, justified by the difficulties reported by the participants in reconciling chemotherapy sessions, consultations, exams, domestic chores, and obstacles to traveling to the hospital. However, it should be noted that this limitation did not affect the study results, considering that the follow-up

time of four to eight weeks was sufficient to assess the outcomes. Another limitation in the study was the non-blinding of participants in the groups, which is expected in non-pharmacological clinical trials due to ethical or technical issues.

One of the study's strengths is the absence of a loss of participants in the intervention and control group during the study, as well as the absence of any type of adverse or undesirable event related to the intervention, which contributes to a better understanding of the importance of the systematic screening of distress and anxiety in women with breast cancer, as well as the need to incorporate meditation and other integrative practices into the routine of oncology services.

6. Conclusions

The results indicate a beneficial effect of Raja yoga meditation conducted once a week for 40 to 50 min, with a one-month follow-up, on reducing distress and anxiety in women with breast cancer undergoing chemotherapy and on improving factors related to distress and anxiety. It was noticed that maintaining the usual care and participating in educational activities did not influence the level of distress and anxiety in women with breast cancer.

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Informed Consent Statement: Informed consent was obtained from all subjects involved in the study.

Conflicts of Interest: The authors declare no conflict of interest.

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