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Effect of Foot Reflexology on Anxiety in Women with Breast Cancer: A Randomized-controlled Trial

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Abstract

Background: Anxiety is considered a common problem in women with breast cancer, and non-pharmacological interventions, such as reflexology, can contribute towards controlling.

Aim: This study aimed to determine the effect of foot reflexology on anxiety in women with breast cancer.

Method: In this randomized-controlled clinical trial, 66 women with breast cancer referred to Ayatullah Khansari Hospital, Arak, Iran, were selected based on the inclusion criteria by convenience sampling method and randomly assigned into intervention and control groups using a randomized block allocation method. In the intervention group, reflexology was then conducted by a trained nurse in the oncology department in a two-point morning and afternoon session for 40 min on the thumb and solar plexus of the feet. However, the control group did not receive any intervention and the Spielberger State-Trait Anxiety Inventory was completed again by the patients.

Results: The mean anxiety scores before reflexology were 48.27 ± 4.95 and 49.72 ± 4.18 in the intervention and control groups, respectively ($P=0.202$). Furthermore, the mean anxiety scores in the intervention and control group after reflexology were obtained at 47.03 ± 4.14 and 49.71 ± 4.28 , respectively.

Implications for Practice: As reflexology did not affect the anxiety of women with breast cancer, this method can be combined with other non-pharmacological interventions to control anxiety in women with this complication; however, it should not be utilized alone in the clinic to manage anxiety. Further studies are recommended to be conducted with larger sample sizes and extended periods on anxiety and mental health disorders in these women.

Keywords: Anxiety, Breast cancer, Nursing care, Reflexology

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Introduction

Breast cancer is one of the most common diseases in women and is the most common cause of cancer death in women worldwide (1). According to the published statistics, 180,000 women with cancer are diagnosed in the United States annually (2). Breast cancer in Iran is also the most common cancer in women (3). The incidence of cancer in Iranian women is lower than the mean age of the world (4).

Diagnosis of cancer in women is always a stressful process so that 70% of the patients report the mental stress experienced after diagnosis and treatment (1, 5). Breast cancer and its treatment methods are associated with some complications, such as concerns about illness and reduced health, disturbance in concentration, loss of appetite, depression, and anxiety (6, 7). The most important risk factors for breast cancer are genetic predisposition, exposure to estrogen (internal and external), ionizing radiation, eastern diet, obesity, and alcoholism (4). Psychological treatments, such as alternative therapies, are recommended along with clinical treatments to increase the survival rate of women with breast cancer and decrease the associated-psychological stress (7). The use of complementary medicine in the life of cancer patients has a special role with the usage of 36% of cancer patients (8, 9). One of the most common non-medical interventions in cancerous patients is massage therapy as massage can reduce anxiety, fatigue, stress, and psychological stress (6). In recent years, massage therapy as a topic of research is increasing, especially for the nurse field. The use of complementary therapies, such as massage therapy is a part of the nursing profession's goals, deeply embedded in the nursing tradition (10).

Reflexology is one of the complementary therapies used to control diseases and symptoms, such as migraine headaches, blood flow problems, pain relief, and post-surgical anxiety in cancer patients and childbirth. Different theories considered the effectiveness of reflexology. According to the regional theory, certain reflexes in the hands, ears, or legs associated with the energy channels or meridians in the glands, organs, and parts of the body are considered. During disease or imbalance in the body, opening up these blocked pathways leads to the free flow of energy in the body and causes the body to regain its health and balance (11).

Most studies have shown that women with cancer experience suffer from many psychological problems, such as anxiety, and reflexology can reduce anxiety based on the results of previous studies (6, 8, 12); moreover, according to a study, foot reflexology reduced anxiety in women (10). Furthermore, reflexology is effective in reducing symptoms, such as pain, fatigue, anxiety, high blood pressure, insomnia, and depression, known as a simple and non-invasive procedure. Few studies investigated the effect of foot reflexology on the anxiety of cancer patients (5, 13). Reflexology can be used as a simple, easy, and inexpensive intervention at all health centers, workplaces, or homes, welcomed by physicians and team members, especially by patients themselves (3). Since few studies have been conducted on the effect of these interventions on anxiety in women with breast cancer, this study seemed necessary. Therefore, this study aimed to determine the effect of foot reflexology on anxiety in women with breast cancer.

Methods

In this double-blind randomized controlled clinical trial, 66 women with breast cancer undergoing chemotherapy were referred to Ayatollah Khansari Hospital, Arak, Iran, from May 2018 to January 2020. The sample size was calculated according to similar studies; therefore, considering the test power of 0.80, $\alpha=0.05$, $\beta=0.2$, $S1=2.04$, and $S2=2.285$ and using the relevant formula, 33 people were included in each group (13).

The main inclusion criteria were: 1) patient's willingness to participate in the study, 2) a minimum of three months of cancer diagnosis, 3) no history of diabetes or active psychological diseases, 4) lack of participating in any anxiety management training classes, 5) no opioid addiction with healthy feet, and 6) age range from 20 to 60 years. The ability to read and write is considered with a moderate to high anxiety score. On the other hand, the unwillingness of the women to admit or continue the study, irregular presence at massage therapy sessions, transfer to another city, immigration, and patient's death were regarded as the exclusion criteria.

Based on the CONSORT Flow chart, 86 patients were first considered for eligibility in this study (Figure 1). Ultimately, this study was conducted on 66 women who were selected based on the inclusion criteria by the convenience sampling method. Additionally, the participants were assigned to intervention ($n=33$) and control ($n=33$) groups using a randomized block allocation method. The

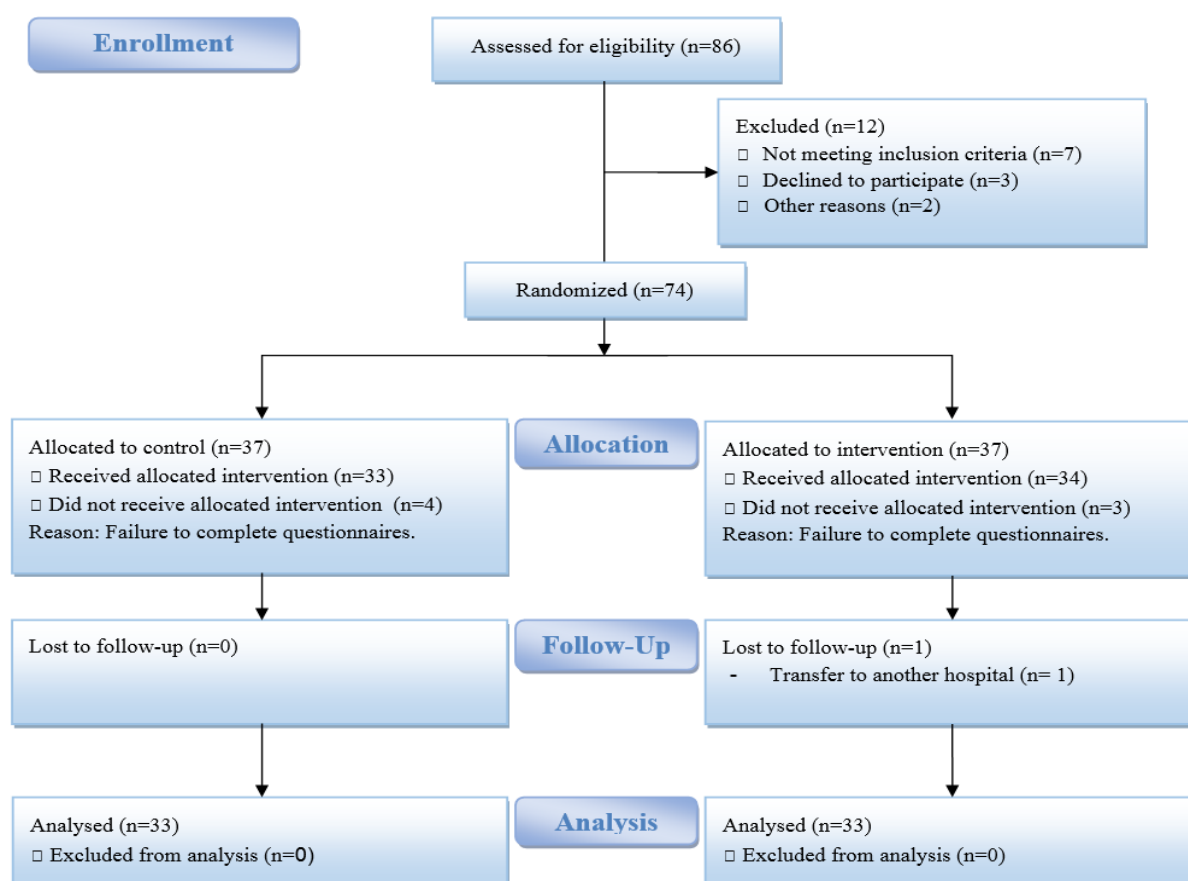


Figure 1. CONSORT flow chart of the study

randomization list was provided to the researcher at the beginning of the study using a statistician and R software.

The data were collected through a demographic characteristic form and Spielberger State-Trait Anxiety Inventory (STAI). The demographic characteristic form covered such information as age, gender, marital status, number of children, level of education, occupational status, and insurance status. The STAI is a standard questionnaire with 20 items, assessing the individual's emotions at present and the response time (the situational anxiety). Validity and scientific reliability of the STAI were evaluated and approved by Khodayarifard et al. in Iran (12) with scores of 20-31 (mild anxiety), 32-42 (low to moderate anxiety), 43-53 (moderate to high anxiety), 64-64 (severe anxiety), 65-75 (high severe anxiety), and more than 76 (extreme anxiety) (12).

A trained nurse (first author) with a reflexologist who had a valid reflexology certificate from Shahid Beheshti University of Medical Sciences, Tehran, Iran, conducted reflexology in an intervention group in a room in the oncology department. At first, the woman was lying on her back in a comfortable position in a private setting, and a small pillow was placed under her knees. The nurse was at the bottom of her bed, and then the soles of the feet were cleaned with a wet sponge. Afterward, the soles of the feet were rubbed with sesame oil, and reflexology was started with a mild massage of all feet sole (by relaxation techniques that loosened the foot and prepared it to do specific reflexology techniques). Following that, constant or rotational pressure was applied on the pituitary gland (pituitary gland is located in the center of thumb), followed by solar plexus for 40 min (20 min for each foot) in a two-point morning and afternoon session (8). During this period, the control group received routine nursing care. Furthermore, the researcher stood at the patient's bedside without any interventions to control the effect of the researcher's presence for matching the two groups. STAI was completed at baseline in the morning before intervention and again after reflexology in the afternoon.

This study was approved by the Ethics Committee of Arak University of Medical Sciences, Arak, Iran. Before the intervention, the study procedure was explained, and the informed consent form was

obtained from all participants. The present study was registered in the Iranian clinical trials registry, and the data were analyzed using the SPSS software (version 16.0.). The independent sample t-test and Chi-square test were used for demographic variables. The mean anxiety score was also expressed using descriptive indices, including mean \pm SD. The normality of the data was determined utilizing the Kolmogorov-Smirnov test, and the two groups were compared using an independent t-test. Furthermore, the results within a group (before and after) were compared by the paired t-test.

Results

A total of 66 patients were randomly divided into intervention and control groups with a mean age of 49.58 \pm 4.26 years. Most of the patients undergoing breast surgery were housewives (92.42%), urban residents (87.87%), and married (92.42%). In addition, 85.35% and 48.48% of the patients received chemotherapy, as well as chemotherapy and radiotherapy, respectively. It is worth mentioning that the majority of the cases (83.33%) had no family history of breast cancer. Before the intervention, no statistically significant difference was observed between the two groups in terms of demographic variables (age, marital status, number of children, family history of cancer, and income level), cancer stage, duration of disease, and type of treatment; accordingly, the two groups were homogeneous (Table 1).

Table 1. Comparison of the demographic characteristics of the participants in the two groups

Variable	Categories	Intervention group	Control group	P-value
		Frequency (%)	Frequency (%)	
Marital status	Single	1(3.03)	2(6.06)	0.671
	Married	31(93.90)	29(87.90)	
	Divorced	1(3.03)	1(3.03)	
	Widowed	0(0.00)	1(3.03)	
Educational level	Primary school	13(39.30)	16(48.50)	0.953
	High school	17(51.50)	14(42.40)	
	Academic	3(9.09)	3(9.09)	
Stage of cancer	1	13(39.30)	19(57.60)	0.616
	2	18(54.50)	8(24.20)	
	3	1(3.03)	5(15.10)	
	4	1(3.03)	1(3.03)	
Age (year)		Mean \pm SD 51.84 \pm 18.6	Mean \pm SD 56.34 \pm 19.2	0.710
Duration of illness (months)		32.87 \pm 18.14	21.90 \pm 20.86	0.942

According to this study, the mean anxiety scores at the beginning of the study were 49.72 \pm 4.18 and 48.27 \pm 4.95 in the intervention and control groups, respectively. Independent t-test showed no significant difference between the intervention and control groups in the pre-intervention stage regarding the mean anxiety scores (P=0.202). Moreover, 1 h after the intervention, no significant difference (P=0.117) was found in the two groups regarding the mean anxiety scores. Paired t-test also indicated no significant difference before and after reflexology in the intervention group in terms of the mean changes in anxiety scores. Furthermore, no significant difference was observed before and after the intervention in the mean anxiety scores in the control group (P=0.844) (Table 2).

Table 2. Mean \pm SD and significant level of anxiety in two groups before and after reflexology

Variable	Time	Intervention group	Control group	P-value*
		Mean \pm SD	Mean \pm SD	
Anxiety	Before reflexology	48.27 \pm 4.95	49.72 \pm 4.18	0.202
	After reflexology	47.03 \pm 4.14	49.71 \pm 4.28	0.117
	P-value**	0.840	0.844	-

*Independent t-test

** Paired t-test

Discussion

This study aimed to determine the effect of foot reflexology on anxiety in women with breast cancer referred to Ayatollah Khansari Hospital in Arak, Iran. Based on the results, no significant difference was observed between the intervention and control groups in terms of age, gender, level of education, and occupational status at the beginning of the study. Most of the participants (88%) were urban residents in the present study. Furthermore, the results of the current study showed no significant difference between the two intervention and control groups in terms of the mean anxiety scores at the beginning of the study, and the levels of anxiety were moderate to high in both groups. Additionally, although the mean anxiety in the intervention group was lower than that in the control group at the end of the study, this difference was not statistically significant between the two groups.

Comparison of the mean anxiety scores before and after the intervention in the reflexology group leads to lower anxiety after the intervention, compared to those at the baseline; however, the comparison of the mean anxiety before and after the intervention in the control group did not show any difference.

The results of a study by Yilmaz et al. showed a mean anxiety score (39.5) of patients with breast cancer (13), which was consistent with the findings in the current study. In addition, in a study conducted by Park et al., a significant proportion of women who were diagnosed with breast cancer showed anxiety symptoms (4). Ozturk et al. in a study stated most women undergoing mastectomy surgery had clinical anxiety since the breast is a symbol of femininity, and women undergoing mastectomy surgery experience very unpleasant feelings.

One of these emotions is the fear of rejection by the husband, resulting in suffering. All of these emotions can be added to anxiety, depression, and mental health problems (14). Anxiety is more prevalent among women with breast cancer than other women. The results of this study showed that at the end of the study, although the mean anxiety score in the intervention group was lower than that in the control group, this difference was not statistically significant ($P=0.117$). Gunnarsdottir et al. in a study also showed that foot reflexology was not effective in reducing the anxiety of patients undergoing coronary artery bypass graft surgery, which was in line with the results of the current study (15).

However, the results of some previous studies indicated a positive effect of foot reflexology on reducing anxiety in patients (14, 15). Ramezani Badr et al. showed the effectiveness of reflexology in the anxiety of men under coronary angiography that reduced their anxiety 1 h after reflexology and before angiography (16). Additionally, the results of a study conducted by Samir et al. in hemodialysis patients showed a significant difference in the anxiety score of the patients in the intervention group before and after the reflexology; therefore, reflexology reduced the anxiety level of the patients (17).

In this study, the mean anxiety score decreased after reflexology in the intervention group, compared to the time before this intervention. Furthermore, no significant difference was found before and after the intervention in the control group regarding the mean anxiety scores. Moreover, the results of this study are inconsistent with the findings of a study conducted by Bastani et al. who investigated the effect of reflexology on the anxiety severity in mothers who gave birth to vulnerable neonates through cesarean section (10). In the same line, Davoodabadi et al. showed that foot reflexology reduced the severity of anxiety in patients with burns before dressing, which was not in line with the results of the current study (18).

However, the actual mechanism of the reflexology is still unknown, and neural theory states that stimulating certain reflexes on the legs can affect the nervous system and cause a fight or flight response. Reflexologists believe that reflexology stimulates endorphin secretion, leading to pain reduction and good feeling (16).

Regarding the limitations of this study, one can refer to 1) the study population (women) (i.e., as a part of the society, 2) study field (in an educational center), affecting the generalizability of the results, and 3) the intervention that was conducted in a short time; therefore, it seems necessary to investigate the long-term effects of reflexology, and more research is recommended to be conducted on the effects of reflexology on the anxiety of women and men. The current study showed that foot reflexology did not reduce patients' anxiety, probably due to the short duration of the intervention. Therefore, reflexology should be used for a longer period in combination with other interventions to control anxiety in women with breast cancer.

Implications for Practice

Reflexology did not affect the anxiety of women with breast cancer, and the proposed method should be combined with other non-pharmacological interventions to control anxiety in women with this complication; however, it should not be utilized alone in the clinic to manage anxiety. Therefore, more research should be performed with larger sample sizes and longer time on women with breast cancer to investigate the effectiveness of the current method.

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This study was approved by the Student Research Committee of Arak University of Medical Sciences, Arak, Iran (Ethics approval No: IR.ARAKMU.REC.1396.139) and registered in the Iranian Clinical Trials Registry (registration No: IRCT20161210031328N6). The authors would like to express their appreciation to the honorable Vice-Chancellor for Research of Arak University of Medical Sciences, Arak, Iran, and women who participated in this study.

Conflicts of Interest

All authors declare that they have no conflicts of interest.

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