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Effect of Reflexology on the Quality of Sleep in Colorectal Cancer Patients: A Clinical Trial Study

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Abstract

Background: Sleep disorders are one of the most common unpleasant symptoms in cancer patients. Foot reflexology is a systemic practice based on the stimulation of nerves in the body.

Aim: This study aimed to determine the effects of foot reflexology massage on sleep quality in patients with colorectal cancer.

Method: This clinical trial study was conducted on 60 patients with colorectal cancer at the Oncology Ward of Imam Hossein Hospital, Tehran, Iran, who were selected based on inclusion and exclusion criteria and equally divided into two groups of control and intervention, based on medical file numbers. Pittsburgh Sleep Quality Index (PSQI) was completed for both groups before intervention. Foot reflexology massage was performed in the intervention group. The PSQI questionnaire was completed for both groups afterward. Data were analyzed using SPSS software through Chi-square test, Fisher's exact test, Mann-Whitney U test, Independent t-test, and Paired samples t-test.

Results: There was a significant relationship between the total score of sleep quality and its dimensions in the intervention group post-intervention ($P<0.05$). Foot reflexology massage significantly improved sleep quality in the intervention group ($P<0.05$). However, there was no significant relationship between the total score of sleep quality and its dimensions in the control group before and after the intervention ($P>0.05$).

Implications for Practice: Foot reflexology massage improves the quality of life and sleep in patients with colorectal cancer. Therefore, it is suggested that this technique be included in nursing practices as a simple, low-cost, and practical treatment.

Keywords: Colorectal cancer, Foot reflexology, Nursing, Quality of sleep

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Introduction
Cancer is one of the major causes of mortality worldwide and the second cause of death after heart disease (1, 2). The prevalence of different types of cancers is increasing due to population growth and aging, frequency of risk factors, such as smoking, obesity, inactivity, and lifestyle changes caused by economic growth and urbanization (3). The global burden of cancer is expected to reach 21.4 million by 2030 (1). In Iran, 40,000 people die due to cancer, and more than 70,000 new cases of cancer are diagnosed every year (4).

Based on the evidence, there are more than 200 types of cancer, the most common of which is colorectal cancer. In Iran, this cancer accounts for 6 to 8% of all cancers and is the third and fourth common cancer in Iranian men and women, respectively (5). Nausea, vomiting, fatigue, and sleep disorders are among the most common side effects in cancer patients (6, 7). Sleep is essential for maintaining physiological mental health. Studies show that about 50% of cancer patients complain of sleep problems that are more frequent among younger people. Sleep disorders lead to decreased immune function due to changes in cytokine secretion in the body. Insomnia is related to the elevated levels of norepinephrine, which results in abnormal cortisol synthesis and a decrease in the number and activity of normal killer cells (8). furthermore, sleep disorders are associated with depression, anxiety, burnout, pain, changes in biological rhythms, and hot flashes following cancer treatment (7).

Medication use is the most common way to cure or deal with insomnia (9). However, the use of complementary medicine and non-pharmacological therapies, such as reflexology increases due to potential problems and medications' side effects. Common interventions suggested for the improvement of sleep quality include aromatherapy (10), acupressure (11), psychodrama (12), yoga (13), and reflexology (14, 15). All mentioned methods have been effective in improving the sleep quality of patients; however, due to the low cost and availability of reflexology (16), this easy method has been used in this study to evaluate the sleep quality in patients with colorectal cancer.

Reflexology massage is a well-known method that is considered to be an alternative and complementary treatment at the international level (17). The first usage of reflexology massage was reported in China more than 3000 years before Christ (18, 19). Reflexology massage is the application of pressure by hands and fingers on all body parts and organs and reflex points of the hands and feet, using special physical techniques. Reflexology massage stimulates endocrine glands and maintains homeostasis by sustaining free energy flow in various organs and cells (15-19). Due to the presence of 7000 nerves in the foot, the massage leads to relaxation, reduction of stress, and stimulation of the parasympathetic nervous system by provoking these nerve cells. Therefore, reflexology massage improves immune function by decreasing cortisol and norepinephrine and increasing serotonin (17, 20). Non-pharmacological treatments, such as massage have longer effects and no dangerous side effects (9). Other benefits of reflexology massage include reduction of stress, improvement of blood flow and homeostasis, acceleration of wound healing, and enhancement of the immune system (21, 22). Accordingly, reflexology massage aims to reduce stress and pain, increase sleep and life quality, and cause relaxation. This technique opens blocked energy channels (similar to that in acupuncture), leads to the redistribution of energy throughout the body and reduces fatigue by removing toxins from the body (8).

Studies in Iran have reported that reflexology massage can reduce fatigue and pain in patients and improve sleep quality (2, 14, 15). Another study in Turkey reported that foot reflexology massage can improve the sleep quality of patients with cancer and manage their sleep problems (8). Although the effect of foot reflexology on symptoms improvement had been evaluated in cancer patients, the review of the literature showed that there is a lack of study on the effect of sleep quality on colorectal cancer patients in Iran. Therefore, this study was performed to determine the effects of foot reflexology massage on sleep quality in patients with colorectal cancer.

Methods
This clinical trial study was performed in a university hospital in Tehran, Iran, between December and March 2018. The study population included all patients with colorectal cancer who were referred to the oncology department for chemotherapy. The sample size was determined using the mean and standard deviation (SD) scores selected from the literature (23), considering $\alpha=0.05$ and power=80%, according to the formula fused or comparison of means with a reference number (24). The minimum sample size was estimated at 50 (25 subjects in each group). However, the final sample size was

increased to 60, considering an attrition rate of 20% (30 subjects in each group).

The inclusion criteria included age over 18 years, lack of diabetes, mental disorders, or mental health problems, no history of taking psychiatric drugs, no history of foot disease and problems, such as lower extremity vascular disorders and amputation, the existence of sleep disorders (a score higher than 5, based on the Pittsburgh Sleep Quality Index, the ability to communicate verbally, and patients with stage 2 and 3 colorectal cancer. However, unwillingness to continue participation in the trial, complication, and disease in the patient's legs during the study, acute infectious diseases during the study, and early discharge were the criteria for exclusion.

Socio-demographic characteristics form and the Pittsburgh Sleep Quality Index (PSQI) were data collection tools in this study. Socio-demographic information included age, gender, marital status, level of education, the status of residence, the status of employment, duration of cancer diagnosis, history of cancer in first-degree relatives, cancer stage, and history of taking sleeping pills.

The Pittsburgh Sleep Quality Index (PSQI) questionnaire used in this study include 19 questions with seven dimensions of sleep quality, including subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleeping pills, and daytime dysfunction due to lack of sleep) (24). The nine main questions constitute the body of the questionnaire. Questions 1 to 4 are open-ended and required short and single answers, and questions 5 to 9 are four-answer questions, based on the Likert scale. Each question is scored a number from 0 to 3, indicating normal, mild, moderate, and severe sleep quality, respectively. The total score of the questionnaire is obtained by summing scores of the seven scales, which is a number from 0 to 21. A total score of 5 or higher indicates poor sleep quality (26). The validity and reliability of the PSQI Questionnaire have been reported by researchers in various countries, including Iran. Cronbach's alpha for the PSQI was estimated to be from 0.78 to 0.82 in the studies conducted in Iran (27).

The researcher referred to the place of study for data collection after obtaining the necessary permissions. The patients with colorectal cancer (n=60) in this study were randomly divided into two groups of 30 patients, based on the inclusion and exclusion criteria, using the medical file numbering (even numbers were assigned to the intervention group and odd numbers to the control group). The individuals in control and intervention groups were hospitalized in separate rooms. The informed consent was obtained from patients after explaining the study objectives. Afterward, the PSQI questionnaire was completed as a pre-test for both intervention and control groups one hour before intervention by interview. It should be noted that sampling of control and intervention groups was conducted intermittently to prevent the exchange of information among participants.

According to previous studies (26, 27), foot reflexology massage was performed for 8 sessions (each session lasted 20 min) in the intervention group during the administration of the chemotherapy by a certified researcher, who had received theoretical and practical training in a reflexology course. The sessions were held in a special room in the Chemotherapy Unit on the patient's bed, and the patient was asked to lie down in a position that felt comfortable. The patients' legs were placed above the body surface with putting a pillow under them so that the legs were placed in front of the researcher. The researcher performed a relaxing massage on both feet for 3-4 min after preparing the patient and lubricating her/his feet with odorless massage oil. Relaxing massage was performed by practicing specific movements, including holding the foot with both hands and creating movements, such as bending the sole of the foot, turning it in and out, and movements in the heel of the foot, as well as massaging the leg. The control group did not receive any special intervention, except routine oncology care. The PSQI questionnaire for the intervention and control groups was completed again by the researcher eight weeks post-intervention (Figure 1).

In this study, data were analyzed using SPSS software (Version 23). Descriptive data were presented as mean, variance, and standard deviation. Chi-square test, Fisher's exact test, and Mann-Whitney U test were used to compare groups in terms of demographic characteristics. A paired- samples t-test was used to compare the mean scores of quality of sleep in each group before and after the intervention. Moreover, an independent t-test was used to compare the mean scores of quality of sleep dimensions in the intervention and control groups. A p-value less than 0.05 (P<0.05) was considered statistically significant.
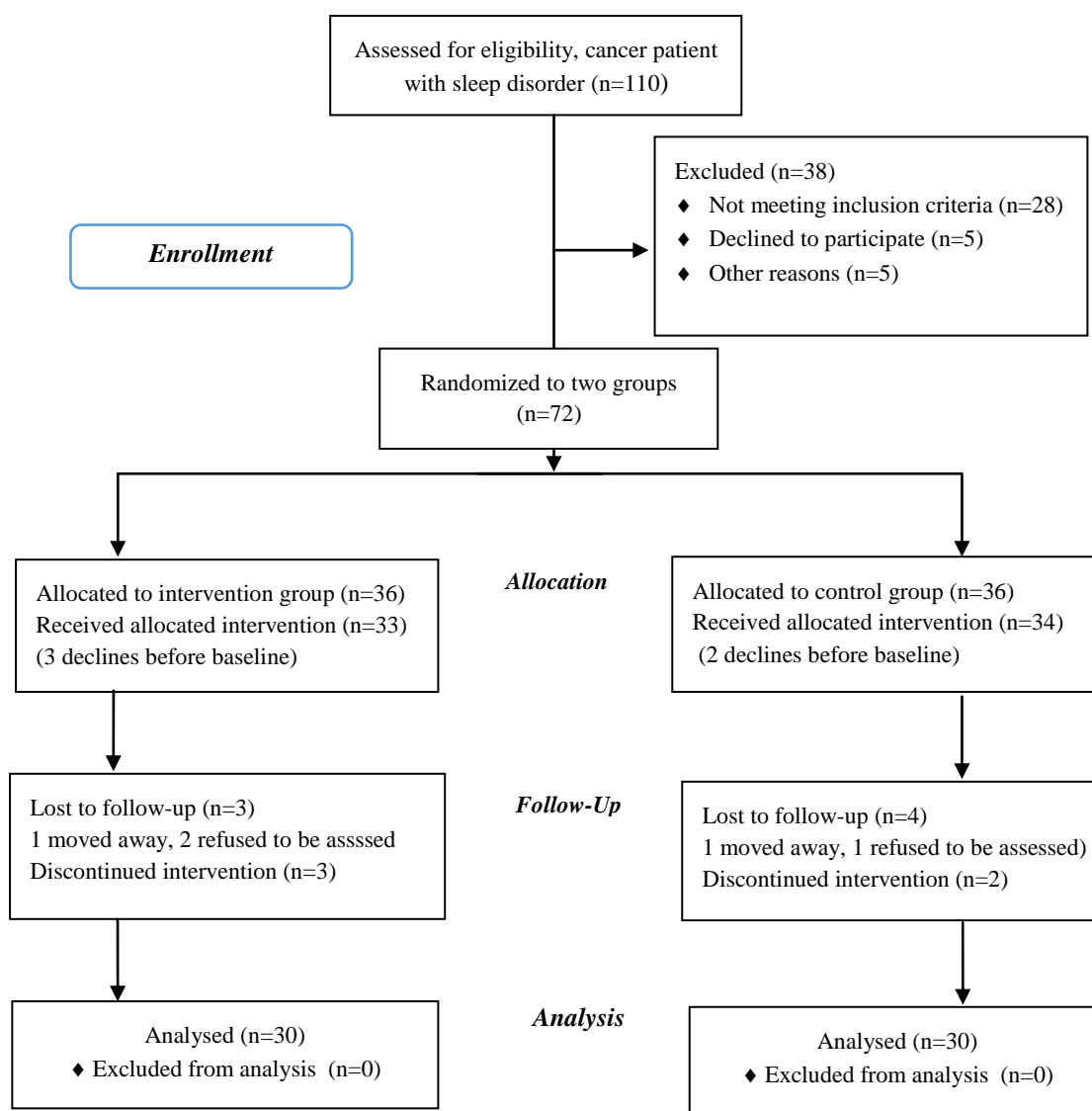
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                    ┌─────────────────────────────────┐
                    │  Assessed for eligibility, cancer patient │
                    │  with sleep disorder (n=110)       │
                    └─────────────────────────────────┘
                                                    ┌──────────────────────────────────┐
                                                    │ Excluded (n=38)                    │
      ┌─────────────────┐                           │  ♦ Not meeting inclusion criteria (n=28) │
      │   Enrollment    │                           │  ♦ Declined to participate (n=5)   │
      └─────────────────┘                           │  ♦ Other reasons (n=5)             │
                                                    └──────────────────────────────────┘
                    ┌─────────────────────────────────┐
                    │  Randomized to two groups         │
                    │  (n=72)                            │
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Allocation

Allocated to intervention group (n=36)
Received allocated intervention (n=33)
(3 declines before baseline)

Allocated to control group (n=36)
Received allocated intervention (n=34)
(2 declines before baseline)

Follow-Up

Lost to follow-up (n=3)
1 moved away, 2 refused to be assssed
Discontinued intervention (n=3)

Lost to follow-up (n=4)
1 moved away, 1 refused to be assessed)
Discontinued intervention (n=2)

Analysis

Analysed (n=30)
♦ Excluded from analysis (n=0)

Analysed (n=30)
♦ Excluded from analysis (n=0)

Figure 1. Flow diagram of the study

Results

The mean±SD age of study participants was obtained at 56.6±11.8 and 55.5± 10.1 years in the intervention and control groups, respectively. The majorities of participants in the intervention and control groups were female (63.3% and 60%, respectively). The duration of cancer diagnosis in the intervention and control groups was less than one year (76.7% and 73.3%, respectively). Most patients were in the third stage of disease in both intervention and control groups (53.3% and 50%, respectively). In addition, according to other results, both intervention and control groups were homogeneous in terms of demographic and clinical characteristics, and there was no significant relationship between them (Table 1).

This study aimed to investigate the effect of foot reflexology massage on sleep quality in patients with colorectal cancer in 2018. According to the findings, there was a statistically significant difference between the mean total score of sleep quality and its dimensions in the intervention and control groups post-intervention (P<0.05). Other findings of this study showed that there was a significant relationship between the mean score of sleep quality in the intervention group, before and after the atervention. However, there was no significant relationship between the mean scores of sleep quality in the control group before and after the study.

Table 2 presents the comparison of mean±SD scores of sleep quality dimensions before and after the

intervention, in the 8th session of reflexology in both intervention and control groups. The mean scores of subjective sleep quality, sleep latency, sleep duration, sleep sufficiency, sleep disturbance, sleep medication, daytime dysfunction, and total sleep quality were significantly lower in the intervention group (1.03 ± 0.71, 2.06 ± 1.17, 1.4 ± 1.1, 1.03 ± 1.35, 1.76 ± 0.43, 1 ± 0.74, 1.2 ± 0.48, 9.5 ± 2.8, respectively) compared to the control group (1.8 ± 0.73, 2.8 ± 1.07, 2.2 ± 1.1, 2.6 ± 0.80, 2.3 ± 0.53, 1.07 ± 1.05, 1.9 ± 0.69, 15.6 ± 2.2, respectively) after the application of intervention ($P<0.05$). The results of the independent t-test showed that there were no significant differences between the intervention and control groups in terms of total sleep quality score and its dimensions before intervention ($P>0.05$). In addition, the results of the independent t-test showed that there were significant differences between the total score of sleep quality and its dimensions in the intervention and control groups, after the intervention ($P<0.05$).

According to other findings, the results of paired samples t-test showed that there was a significant difference in the mean total score of sleep quality and its dimensions in the intervention group before and after intervention (Table 2) ($P<0.05$). Furthermore, according to the findings of paired samples t-test, there were no significant differences between the total score of sleep quality and its dimensions in the control group before and after the intervention ($P>0.05$). The only significant difference was observed between the mean score of sleep duration and sleep sufficiency in the control group, before and after the intervention ($P<0.05$).

Table 1. Descriptive information of the Patients

Variable		Intervention		Control		P-value
		n	%	n	%	
Age	<35	1	3.3	2	6.7	0.994[*]
	35-49	11	36.7	9	30	
	50-64	10	33.3	14	46.7	
	65-80	8	26.7	5	16.7	
Gender	Male	11	36.7	12	40	0.791[**]
	Female	19	63.3	18	60	
Marital Status	Single	3	10	5	16.7	0.743[*]
	Married	24	80	20	66.7	
	Divorced	3	10	5	16.6	
Education Level	Illiterate	3	10	6	20	0.225[***]
	High school	8	26.7	10	33.4	
	Diploma	14	46.7	10	33.4	
	Bachelor and higher	5	16.6	4	13.2	
Place of Residence	City	23	76.7	25	83.3	0.519[**]
	Rural	7	23.3	5	16.7	
Employment status	Employee	1	3.3	3	10	0.340[*]
	Housewife	16	53.3	12	40	
	Self-employee	8	26.7	12	40	
	Retired	5	16.6	3	10	
Duration of cancer diagnosis	<1 year	23	76.7	22	73.3	0.784[***]
	1 to 2 year	5	16.6	6	20	
	>2 year	2	6.7	2	6.7	
History of cancer	Yes	10	33.3	11	36.7	0.787[**]
	No	20	66.7	19	63.3	
Cancer stage	2	5	16.7	3	10.1	0.347[***]
	3	16	53.3	15	50	
	4	9	30	12	40	
Taking sleeping pills	Yes	25	83.3	26	86.7	0.924[**]
	No	5	16.7	4	13.3	

*Fisher's exact test, **Chi-square, ***Mann-Whitney

Table 2. Comparison of the mean scores of sleep quality and its dimensions in the intervention and control groups before and after the intervention

Variables		Before		After		P-value[*]
		$\bar{X}$	SD	$\bar{X}$	SD	
Subjective sleep quality	Intervention	1.4	1.1	1.03	0.71	<0.001
	Control	1.7	1.8	1.8	0.73	0.614
	P-value[**]		0.356		<0.001	
Sleep latency	Intervention	3.1	1.01	2.06	1.17	<0.001
	Control	2.9	1.08	2.8	1.07	0.835
	P-value[**]		0.393		0.008	
Sleep duration	Intervention	2.2	1.6	1.4	1.1	0.013
	Control	1.9	1.24	2.2	1.1	0.039
	P-value[**]		0.319		0.006	
Sleep sufficiency	Intervention	2.36	1.12	1.03	1.35	<0.001
	Control	2.23	1.19	2.6	0.80	0.021
	P-value[**]		0.519		<0.001	
Sleep disturbance	Intervention	2.26	0.52	1.76	0.43	<0.001
	Control	0.5	0.48	2.3	0.53	0.161
	P-value[**]		0.186		<0.001	
Sleep medication	Intervention	1.66	1.12	1	0.74	0.016
	Control	1.50	1.04	1.07	1.05	0.536
	P-value[**]		0.554		0.004	
Daytime dysfunction	Intervention	2.16	0.69	1.2	0.48	<0.001
	Control	2.06	0.69	1.9	0.69	0.514
	P-value[**]		0.652		<0.001	
Total sleep quality	Intervention	15.3	3.2	9.5	2.8	<0.001
	Control	14.4	3.5	15.6	2.2	0.128
	P-value[**]		0.382		<0.001	

$\bar{X}$: Mean, SD: Standard Deviation, [*]Paired Samples T-TEST, [**]Independent T-TEST

Discussion

According to the review of literature, few studies have investigated the effect of reflexology on the quality of sleep in cancer patients. Most studies have examined reflexology effects on the quality of sleep in patients with other diseases. Based on the obtained results, the application of foot reflexology on colorectal cancer patients significantly reduced sleep disorders in these patients. Consequently, it can be stated that reflexology can lead to improvement of sleep quality in patients with colorectal cancer. This finding is consistent with the results obtained in some previous studies. In this regard, findings obtained by Tarrasch et al. showed that reflexology massage after five weeks of radiotherapy reduced the level of fatigue in the intervention group compared with the control group. In addition, a significant improvement in the sleep quality of patients was observed after 10 weeks of radiotherapy treatment in the intervention group (28). Additionally, a study by Farrokhian et al. reported that foot reflexology massage can improve sleep quality in dialysis patients (27). Furthermore, according to Kheyri et al., there was a significant relationship between the sleep quality score of elderly women undergoing abdominal surgery in the intervention group before and after the intervention, indicating the positive effect of massage and improved sleep quality in these patients (29). In another study, Valizadeh et al. reported the positive effect of both reflexology and foot bath interventions on the improvement of sleep quality in the elderly. In their study, the comparison of the scores of the components of questionnaires before and after intervention showed that intervention was effective on two components of subjective sleep quality and delays in falling asleep, in the reflexology group (9). Asltoghiri et al. reported that there was a significant reduction in sleep disorders of menopausal women after reflexology massage intervention (30). Moreover, in a study by Wang et al., it was

reported that reflexology massage interventions reduced adult depression and anxiety and increased sleep quality (31). Sajadi et al. reported that there was a significant improvement in physical fatigue, sleep quality, and anxiety after reflexology massage intervention in patients with multiple sclerosis (32). Another study showed significant differences in the mean scores of sleep quality in patients with breast cancer. In this study, results from the aspects of PSQI before and after intervention in the experimental group showed the significance of all dimensions of this index, except the application of hypnotics (33).

Reflexology has been evaluated in many contexts, and reflexologists believe that it can be useful in all these contexts, while according to physicians, treatment should be evidence-based (34). However, the results of some other studies do not show any significant differences in the improvement of sleep quality. The results of a study conducted by Wiliams on the effect of massage with aromatic oils on the onset of sleep, sleep period, and sleep disturbances of children with autism showed that massage does not influence sleep improvement in children with autism (35). Moreover, the study conducted by Fazlollah et al. reported that foot reflexology was not effective in reducing delirium and improving sleep quality (36), which was inconsistent with the results of the current study. These inconsistencies may be attributed to different types and duration of intervention, small sample size, or different types of community.

Regarding the limitations of this study, one can refer to the small sample size. Moreover, lack of follow-up of interventional effects means that long-term effects of reflexology cannot be judged. Therefore, it is recommended that further studies should have a larger sample size and longer durations and be conducted on different types of cancers.

Implications for Practice
Based on the obtained results, foot reflexology massage improves sleep quality in patients with colorectal cancer undergoing chemotherapy. Therefore, it is necessary to implement educational and supportive interventions, such as foot reflexology to assess the sleep quality of cancer patients and determine its compliance with standard tools that are designed to improve sleep quality and quality of life in these patients.

Acknowledgments

Conflicts of Interest
The authors declare that they have no conflict of interest regarding the publication of this study.

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