The Effect of Reflexology on Fatigue in Cancer Patients Receiving Chemotherapy: A Randomized Controlled Trial

Mahin Hesami, Marya Kalhor, Daem Roshani, Mohammad Fathi

Abstract
Objectives: Fatigue is one of the most common complications of cancer and its related medications including chemotherapy. The present study aimed to investigate the effects of reflexology on the fatigue in cancer patients receiving chemotherapy.

Materials and Methods: The current randomized clinical trial was conducted on 80 cancer patients under chemotherapy in Tohid Medical Center affiliated with Kurdistan University of Medical Sciences in Iran during 2016-2017. The patients were randomly assigned to control and intervention groups in the form of quadruple blocks using the StatsDirect software. The data were collected by a personal information questionnaire and the fatigue severity scale (FSS). After questionnaire administration and collection, foot sole reflexology was performed on the intervention group during four consecutive days each session lasting for 30 minutes. Then, the severity of fatigue was once more measured in the patients of both groups.

Results: Based on the results, the mean and standard deviation in the investigated patients, before and after the intervention was 5.538±1.041 and 4.486±1.040 in the intervention group, respectively, indicating that the difference was significant \( (P=0.000) \). In addition, after the reflexology was performed, the mean and standard deviation of the intervention and control groups were 4.486±1.040 and 5.180±1.450, respectively, which demonstrated a significant difference between the two groups in terms of fatigue \( (P=0.016) \).

Conclusions: In general, based on the results, reflexology was found to have a positive effect on fatigue in cancer patients who underwent chemotherapy.

Keywords: Cancer, Chemotherapy, Fatigue, Reflexology

Introduction
Cancer is considered a major problem in the area of general health (1) and is of great importance since it is the second cause of mortality in the world and the third cause of death in Iran (2). The World Health Organization warned that the cancer wave is on its way and the number of people who are inflicted with this disease reaches 24 million people annually by 2035 (3). In addition, 100 people die due to cancer in Iran every day (4).

Cancer patients suffer from several symptoms throughout the diagnosis and treatment process (5). Chemotherapy is used for treating cancer which is associated with several side effects despite prolonging the life of the patient (6). Fatigue is considered one of the most widespread and annoying complications caused by cancer treatment, which is reported in 70-100% of the patients under treatment (7, 8). Damage to bone marrow and the side effects related to the treatment including nausea, vomiting, diarrhea, appetite loss, anemia, and the like are the reasons which cause and intensify fatigue (9). Patients suffering from cancer feel the fatigue more severely and persistently compared to healthy people, and sufficient sleep cannot alleviate the condition (10). The tiredness which is resulted from the disease or its treatments is referred to as cancer-related fatigue (5). The results of a study by Zaighami Mohammadi revealed that the mean fatigue severity before and after three periods of chemotherapy varied significantly (11). According to Steen et al, this fatigue is related to considerably low levels of health-related quality of life (12).

Methods which are used to alleviate cancer-related fatigue include pharmacologic and non-pharmacologic interventions (5). The pharmacologic treatment is the most effective way available to the nurses for reducing the fatigue. Further, using non-pharmacological treatment is very important since it reduces fatigue resulted from the side effects or the difference in response to the drug (13). Non-pharmacologic methods include a wide range of techniques which are relatively easy, non-invasive, and cheap and have fewer side effects (14). Massage is known as one of the effective non-pharmacologic treatments for fatigue (15). Nearly 20% of the cancer patients in the
United States seek massage and approximately 70% of the Sanatoria in England offer this method (16). Reflexology, as a type of massage, is a holistic health method (17) with a long history (18). The Chinese are reported to have first used the method in 3000 BC (19). Such holistic method is frequently accompanied by a kind of foot massage and uses hands in pressure techniques (20). Reflexive foot sole is based on the premise that it stimulates the flow of energy from the foot to the head and causes relief (14). Reflexology therapies are based on the belief that this method can relieve the stress and pain in different parts of the body through manipulating and pressing the foot so that the received pressure in the foot sends messages to the nervous system and creates balance while it reduces the stress and pain by releasing chemicals such as endorphin (21). This method is put forward as a clinical intervention and skill in nursing (15) and as a strategy which consolidates the relationship between the nurse and the patient (22).

Using chemotherapy for treating and taking care of the patients is necessary for a large number of cancer patients while its undesirable complications make the patients feel helpless and frustrated. Furthermore, nurses who are responsible for alleviating fatigue in these patients, are expected to take effective actions by using touching and massaging the patients, which is of great importance in this method. However, no study was found regarding the effects of reflexology on fatigue in Kurdistan province, especially in Clinical Care Research Center of Kurdistan University of Medical Sciences. Therefore, the current study sought to evaluate the effects of reflexology on fatigue in cancer patients under chemotherapy in Tohid hospital in Sanandaj during 2017.

Materials and Methods

After obtaining the written permission from the research department of the university, the study was conducted in Oncology and Chemotherapy Wards of Tohid Medical Center, a state center affiliated with Kurdistan University of Medical Sciences, during (January) 2016-(September) 2017. The ward of oncology had 49 beds and 16 employees whereas the chemotherapy department encompassed 25 beds and 9 staff members. The samples size included 80 cancer patients. The inclusion criteria were receiving at least one period of chemotherapy, volunteering to participate in the study, having no history of underlying diseases or conditions affecting the fatigue (e.g., cardiovascular, respiratory, and psychological diseases) or a history of using supplementary therapies (e.g., pressing and reflexology), having no injuries in the foot sole area, and finally, being within the age range of 18 to 65 years. Those patients who demonstrated an unwillingness to continue participating in the study for any reason or reported a change in their health conditions were excluded from the study. The patients were randomly divided into control and intervention groups by quadruple blocks using the stat direct software.

The following formula was employed to determine the required sample size based on the study by Sadeghi et al (23) and with a type I error of 0.05 and a power size of 0.95. Therefore, the minimum sample size was estimated to be 40 patients in each group.

\[
 n = \frac{(Z_{\alpha/2} + Z_{\beta})(\sigma^2 + \sigma_1^2)}{(\mu_1 - \mu_2)^2}
\]

Two instruments were applied to collect the required data. A demographic information questionnaire was administered to obtain information regarding the patients’ age, gender, marital status, educational level, employment status, and place of residence, along with their clinical features (Table 1). Additionally, a fatigue severity scale (FSS) was utilized based on the purpose of the study. This scale measured fatigue using nine statements ranging from 1–7 on a Likert-type scale. In each of the grades, score 1 was the lowest while score 7 represented the highest fatigue. The reliability and validity of FSS, as a highly credible and specialized instrument, were previously confirmed by several national (24, 25) and international (26-29) studies.

Those patients who met the inclusion criteria and willingly agreed to participate in this study were asked to sign written informed consent. Then, foot sole massage was performed for the intervention group by the researcher who passed a reflexology training course in an official center and two research assistants who were trained in 8 sessions each last 2 hours. Then, the researcher attended the first massage sessions of the colleagues after implementing the above-mentioned actions in order to ensure that they perfectly acquired the skill. The intervention was held during four consecutive days and the patients were transferred to a suitable room after washing their feet. The patients were first prepared for the massage by having their foot soles greased with sweet almond oil which is believed to be mild in terms of temperament and can be used for all kinds of temperaments (30). Next, the foot sole massage was performed for 30 minutes in each session, including 10 minutes of pacifying massage and 20 minutes of massaging the medical spots on both feet. Reflexology was first conducted for the right foot and then for the left one with proper movements such as direct pressure, stretching, and rotational movements in the therapeutic areas using the fingers and palms. Throughout this time, the control group only received routine nursing care in the department. Finally, 3-5 hours after the last massage session, the patients filled the FSS questionnaire to re-measure their fatigue. In addition, the control group completed the FSS questionnaire for the second time four days after the first completion. Patients in both control and intervention groups completed the FSS questionnaire twice, once at the first session before the intervention and the second time at the fourth session.
after the last intervention.

Descriptive and inferential statistics were used for data analysis by the SPSS software, version 21. Descriptive statistics such as frequency distribution and the measures of central tendency (i.e., mean and standard deviation) and inferential statistics including independent and paired-samples t-tests were employed to compare the variables and discover the relationships among them. Further, the covariance analysis was utilized to compare the mean fatigue intensity after the intervention in both groups.

**Results**

The current study included 120 participants 40 of whom were excluded as they declined to cooperate (n = 8) or failed to meet the inclusion criteria (n = 32). During the study, all the participants were present until the end of the interventions. Finally, 80 participants completed the study (Figure 1).

The results of the data analysis demonstrated that the number of women was higher than that of the men and the majority of the investigated individuals were married, housewife, illiterate, and lived in urban areas. Furthermore, the type of cancer and the number of chemotherapies in the intervention and control groups were the same, based on the values P=0.26 and P=0.79.

Comparing the mean and standard deviation for the investigated patients in the control group represented a significant difference in terms of fatigue, which was 5.000±1.398 and 5.18±1.450 before and after the intervention, respectively (P=0.036). In the intervention group, these indices were 5.538±1.041 and 4.486±1.041, respectively, indicating a significant difference regarding fatigue (P=0.000). Additionally, the results revealed that there was no significant difference between the two groups concerning fatigue before the intervention (P=0.054). However, performing the reflexology led to a significant difference between the two groups in terms of fatigue (P=0.000). The comparison between the mean and standard deviation of fatigue scores in both groups are provided in Table 2. There was a significant difference between the intervention and control group in terms of fatigue after the intervention, given that the fatigue level before the intervention was a confounding variable.

Based on the results, the fatigue level was higher before the intervention in the intervention group compared to the control group. However, after the intervention, the level of fatigue increased in the control group compared to before the intervention while its level considerably decreased (P=0.000) in the intervention group as a result of the intervention (Figure 2).

**Discussion**

Based on the results, reflexology affected fatigue and significantly reduced it in cancer patients under chemotherapy. In addition, considering the participants’ comments, it is regarded as an effective method for reducing nausea and vomiting while enhancing the quality of sleep and relaxation.

Numerous studies investigated the effects of reflexology on the symptoms of different diseases yielding different

<table>
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<td>% No.</td>
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<tr>
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<td>50 20</td>
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<td></td>
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<td>50 20</td>
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<td>42.5 17</td>
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<td></td>
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<td>20 8</td>
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<td>10 4</td>
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results. For example, Nesami et al investigated the effect of reflexive foot sole massage on the pain and fatigue levels of the patients after coronary artery bypass surgery and reported that reflexive foot sole massage led to a significant reduction in the patients’ fatigue after the surgery (13), this is in line with the results of the present study. Further, Pourghaznain and Ghaffari found the significant impact of reflexology on fatigue in pregnant women (31). Furthermore, Izadpanah et al confirmed the effect of reflexive foot massage on reducing fatigue in women (15). Additionally, Pedram et al studied the effects of reflexology on the quality of life in patients with breast cancer under chemotherapy, who viewed fatigue as one of the symptomatic dimensions of the quality of life. Their results are in conformity with those of the current study (6).

Evaluating the effects of reflexology on nausea, vomiting, and fatigue in patients with breast cancer under chemotherapy, Yang observed a significant difference in reducing fatigue among the patients in the intervention group compared to the control group, the findings of which corroborates with the results of the present study (32). However, this finding is inconsistent with the results of Ozdemir et al who investigated the effects of reflexology on fatigue, pain, and cramp in hemodialysis patients and highlighted a significant difference between fatigue score before and after reflexology (19).

Likewise, Karagozoglu and Kahve examined the effects of back massage on anxiety and fatigue related to chemotherapy and emphasized the positive effects of back massage on the fatigue felt the day after the chemotherapy performed during chemotherapy compared to previous chemotherapy sessions (33). In addition, Unal and Akpinar evaluated the influence of both reflexive foot sole massage and back massage on fatigue and sleep quality of

Table 2. Comparing the Mean and Standard Deviation of Fatigue Scores Before and After the Intervention in Both Groups

<table>
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<th>After Intervention</th>
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<td>0.000</td>
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<td>Control, Means±SD</td>
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<tr>
<td>P value</td>
<td>0.016</td>
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Figure 1. The flow Chart of the Recruitment and Retention of Participants.

Figure 2. Changes in Fatigue Scores in the Intervention and Control Groups Before and After the Intervention.
hemodialysis patients who were included in 2 intervention groups and one control group. The results demonstrated a significant difference among the three groups after the intervention so that the groups who received the back massage and the reflexology intervention experienced reduced fatigue while improved sleep quality compared to the control group. Further, reflexology had a greater effect on reducing fatigue whereas increasing energy compared to back massage, which could be due to the limited effect of back massage compared to reflexology; in fact, reflexology affects all parts of the body since different parts of the foot sole are connected to all parts of the body (34). Matin and Ozdemir assessed and compared the effects of aromatherapy massage and reflexology on pain and fatigue in patients suffering from rheumatoid arthritis. The results indicated that fatigue scores began to decrease from the fourth week of the study in the aromatherapy group while such a reduction was observed from the first week of the study in the reflexology group. This could be attributed to the effects of reflexology on the nerves and joints and that it stimulated the whole body of the patient after the intervention (35). Cassileth and Vickers investigated the effects of different types of massage therapy on cancer symptoms including pain, fatigue, anxiety, nausea, and depression in a major cancer center on hospitalized and unhospitalized patients. The greatest effect was observed on anxiety while the smallest changes were observed with respect to fatigue. Furthermore, the results represented that the effects of Swedish massage and gentle massage were greater compared to the foot massage. Regarding the difference between the results of the above-mentioned study and those of the present study in terms of fatigue, it can be claimed that fatigue requires more massage sessions to reduce compared to other symptoms of chemotherapy (16). Based on the results of a review study by Lee et al, foot reflexology was more efficient on fatigue and sleep. Additionally, those massages which lasted 50 minutes or more were noticeably more effective compared to those which lasted 20 minutes or less. As a result, foot reflexology seems an effective nursing intervention employed for decreasing fatigue whereas improving the quality of sleep (36). Finally, Ozdelikara and Tan reported the positive effect of reflexology on fatigue and thus, the quality of life, which is consistent with the result of the present study in this respect (37).

Conclusions
In general, based on the results, the positive effect of reflexology on fatigue was observed in patients under chemotherapy. Therefore, future studies are suggested to apply longer periods and higher numbers of sessions of massage and investigate its effects in the long term. Eventually, based on the observations and the comments of the patients, the researchers are recommended to investigate the effects of reflexology on reducing other complications caused by chemotherapy in cancers inflicting different body systems.

Limitations of the Study
Several factors affect fatigue including cultural, mental, and psychological factors. The researcher was unable to control these actors.

Suggestions for Future Studies
Regarding the chronic nature of the fatigue, the duration of sessions and massage sessions are suggested to be increased in future studies in order to examine its long-term effects. In addition, further studies are required to evaluate the effects of reflexology on diminishing other chemotherapy complications in cancers concerning various systems of the body. Finally, the importance of non-pharmacological treatments, along with specific treatments for relieving fatigue are subject to further investigation.

Conflict of Interests
None.

Ethical Issues
The present randomized clinical trial including intervention and control groups was approved by the Ethics Committee of Kurdistan University of Medical Sciences under the ethical code of 334 and registered with the code of IRCT2017021232518N1 in the Iranian Registry of Clinical Trials website (https://www.irct.ir/trial/25314).

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