Research Paper

The Effects of Foot Reflexology and Simple Foot Massage on Fatigue and Pain in Children With Leukemia: A Randomized Control Trial

Mahnaz Shoghi[1] Asma Asadian[2] Motahareh Kheradmand[3*]

1. Department of Pediatric, Nursing Care Research Center, School of Nursing & Midwifery, Iran University of Medical Science, Tehran, Iran.
2. Department of Pediatric, School of Nursing & Midwifery, Iran University of Medical Science, Tehran, Iran.
3. Health Sciences Research Center, Addiction Institute, Mazandaran University of Medical Sciences, Sari, Iran.

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ABSTRACT

Background and Purpose: Chemotherapy is one of the main options in treating childhood cancers. Fatigue and pain are common symptoms of cancer and one of the major complications experienced during chemotherapy. This study aimed to determine the effect of foot reflexology and simple foot massage on fatigue and pain in children with leukemia.

Materials and Methods: This randomized clinical trial was performed on 99 children with leukemia aged 4-14 years, undergoing chemotherapy in the oncology departments of Hazrat Ali Asghar Hospital and Children's Medical Center, Tehran City, Iran, in 2019. The sampling was sequential, and participants were assigned into three groups by block randomization: Foot reflexology, simple foot massage, and control group. The foot reflexology and simple foot massage were performed for 5 consecutive days. Participants were asked to report the intensity of pain and fatigue over the past 48 hours using the pain visual and child fatigue scales. Statistical analysis was conducted with SPSS software, version 22. Quantitative variables were reported as the Mean±SD. The chi-square test, analysis of variance, and repeated measures tests were used for data analysis.

Results: Demographic characteristics in three groups were not significantly different except for gender (P=0.011). There was no significant difference in pain (P=0.67) and fatigue (P=0.45) before the intervention. The Mean±SD pain scores on the third day in foot reflexology, simple foot massage, and control group were 4.4±1.9, 5.2±1.79, and 6.3±1.76, respectively (P<0.001). The Mean±SD pain scores on the fifth day in foot reflexology, simple foot massage, and control group were 2.7±1.4, 3.9±1.83, and 6.7±1.5, respectively (P<0.001). The Mean±SD fatigue scores on the third day in foot reflexology, simple foot massage, and control group were 2.36±0.55, 2.95±0.6, and 3.65±0.32, respectively (P<0.0001). The Mean±SD fatigue scores on the fifth day in foot reflexology, simple foot massage, and control group were 2.14±0.42, 2.67±0.73, and 4.12±0.16, respectively (P<0.0001).

Conclusion: Our results showed that foot reflexology and simple foot massage can decrease pain and fatigue in children with leukemia. Performing foot reflexology could be recommended as a complementary intervention to reduce pain and fatigue in children with leukemia.

Keywords: Pain, Fatigue, Leukemia, Children

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*** Corresponding Author:**
Motahareh Kheradmand, Assistant Professor.
Address: *Health Sciences Research Center, Addiction Institute, Mazandaran University of Medical Sciences, Sari, Iran.*
Tel: *+98 (911) 2256368*
E-mail: *elham.kherad@gmail.com*

Introduction

Chemotherapy is one of the main options in treating childhood cancers. Although the drugs used in therapeutic protocols have been improved profoundly in recent years, and their side effects have decreased, chemotherapy is often associated with a decline in quality of life following adverse effects from the treatment [1].

Pain is a well-known complication of cancer and chemotherapy [2], as the affected child often reports it during the disease process (diagnosis, treatment, and even years after cessation of therapy) [3]. Chronic pain tolerance during chemotherapy affects a child's level of adjustment, performance, and behaviors. It may lead to sleep disturbances, short-term and long-term emotional distress, avoidance of social activities, increased sensitivity, and low quality of life [3, 4]. On the other hand, sedatives are associated with numerous side effects and can change the level of fatigue, appetite, nausea, and vomiting in children [5].

According to numerous studies, fatigue is the most common symptom of distress in children hospitalized with cancer [4, 6-8]. Fatigue from illness and chemotherapy can reduce the energy level, causing mood swings, sadness, muscle weakness, especially in limb muscles, sleep disturbances, tendency to stay in bed, abandoning daily activities, and child irritability [9].

Controlling and minimizing the side effects of chemotherapy and trying to provide comfort and relaxation to the child during the treatment are the responsibilities of the healthcare team, especially nurses [10]. Various pharmacological and non-pharmacological approaches to relieve pain and fatigue have been studied in these children [11]. Non-pharmacologic therapies are another option for controlling complications and providing comfort for patients undergoing chemotherapy. Non-pharmacologic therapies often have no serious side effects or drug interactions, are easier to administer, and are well-accepted by patients and families [12].

Reflexology massage is one of the methods of complementary medicine. Foot reflexology massage, a systematic approach, is characterized by applying pressure on the specific reflection points on the feet to promote body homeostasis [13]. The effect of this method has been shown in different studies on improving constipation, incontinence status [14], spasticity and function of children with cerebral palsy [15], reducing the symptoms of adolescents with cancer [16], reducing pain and anxiety, and improving vital signs during injection of chemotherapy drugs in children [17], improving vital signs, and reducing anxiety after blood transfusion in children with thalassemia [18].

Nurses play a major role in caring for children undergoing chemotherapy [19]. Well-trained nurses in complementary medicine might play an even more important and effective role in reducing symptoms and solving problems in this group of patients, improving the quality of nursing care [20, 21].

Based on the effect of reflexology on energy balance, pain relief, detoxification, relaxation, and blood circulation [22], the researchers have postulated that reflexology massage may be effective in reducing fatigue and pain in children with cancer who suffer from pain and fatigue during chemotherapy. To the best of our knowledge, the research conducted on children with leukemia is limited. Therefore, this study aimed to investigate the effect of foot reflexology massage on pain and fatigue severity in children with leukemia undergoing chemotherapy.

Materials and Methods

This randomized clinical trial was performed on 99 children with leukemia aged 4-14 years, undergoing chemotherapy in the oncology departments of Hazrat Ali Asghar Hospital and Children's Medical Center, Tehran City, Iran, 2019. The sampling was sequential, and participants were randomly (3-block randomization) divided into three groups: A) Foot reflexology group, B) simple foot massage group, C) Control group. The inclusion criteria were as follows: Having healthy feet and absence of any ulcers on the massage site, no foot reflexology massage or similar treatments during the study, and children without any problem in verbal, visual, hearing, or mental status. The exclusion criteria included child discomfort during the massage or foot manipulation, child restlessness during the massage or foot manipulation, deterioration of the child's condition due to chemotherapy during the intervention, and the physician's decision to discontinue the intervention.

Sample size

The sample size was calculated with 95% confidence interval and 80% test power to detect at least 2.5 scores differences of fatigue and pain severity in the three groups (reflexology, simple massage, and the control), using the following formula (Equation 1) [23]:

1. $\frac{\left(Z^2_{1-\alpha/2}+Z^2_{1-\beta}\right)^2 * \left(s_1^2+s_2^2\right)}{d^2}$,

Where S1=3.02 and S2=3.88.

Due to the possibility of dropout (10%), the final sample size was determined to be 33 participants in each group.

Study instruments

We utilized a demographic information questionnaire about the child (age, sex, type of leukemia, and disease duration). The child fatigue scale (CFS) questionnaire was used to measure the child's fatigue. In a study conducted on 149 children aged 6-12, the internal correlation and reliability coefficients were reported as 0.84 and 0.8, respectively [24]. The questionnaire consists of 14 questions. The child was asked to answer "yes" or "no" to the existence or absence of the problem, and then the severity of the problem was marked with a 5-point Likert scale (0=no, 1=almost no, 2=very little, 3=low, 4=high, 5=very high). This scale ranges from 0 to 14; higher scores indicate greater fatigue levels. The questionnaire was a self-report questionnaire whose questions had to be answered by the individual [25]. The visual analog scale (VAS) measured the pain on a 10-cm scale; the left side [0] indicated no pain, and the right [10] indicated severe pain. Scores of 1-3 indicate mild pain, 4 to 7 moderate pain, and 8 to 10 severe pain. The correlation between self-report and the VAS was variable and ranged from 0.23 to 0.83. The concurrent validity of the VAS and other pain instruments ranged from 0.42 to 0.86 [26]. Older children answered the questionnaires, but for young children, the child's mother was asked to answer questionnaires.

Intervention

The researcher invited the parents to participate in the study after expressing their goals and obtaining their written and verbal consent from the children. Participants were randomly assigned into three groups. By pulling out each envelope (3-block randomization), the position of the three participants in the groups was determined, and this method continued until the sample size was reached. On the first day before the intervention, the participants in all three groups were asked to answer the questions about their CFS in the past 48 hours, considering their pain and fatigue, and mark the VAS tool. The foot reflexology and simple foot massage were performed by the researcher (one person) for both intervention groups A and intervention B on 5 consecutive days between 5 and 7 PM due to having more fatigue at this time. The massage was performed by a trained person from the research team for 30 minutes (15 minutes per foot) [27]. Participants in the third and fifth days of the massage before performing the foot reflexology and simple massage were asked to respond to their CFS and mark the VAS questionnaire again in the past 48 hours. The control group received routine care in the ward and completed the questionnaire like the two intervention groups.

To perform the reflexology massage (group A), the child was first placed supine with a pillow underneath her head and a towel below the knees to relieve pressure on the waist and pelvis. Heating techniques were performed after lubricating the dorsal and plantar region of the feet with sesame oil starting from the dominant foot (three points of the pituitary gland, solar plexus, and spinal cord) and then massaging the reflection points (Figure 1). After massaging the dominant foot, the towel was separated from the non-dominant foot. The lubrication, warming, and massage of the reflection points were performed similarly to the dominant foot.

For intervention group B, the preparation and foot warming was done with towel wrapping and simple foot massage regardless of the reflection points. After finishing the task, the children in both groups were given a glass of water and asked to stay supine for about three to four minutes.

Data analysis

Statistical analysis was conducted using SPSS software, version 22. Quantitative variables were reported as the Mean±SD. The chi-square test, analysis of variance, and repeated measures ANOVA were used for data analysis. In this study, we recorded the patients' data more than two times. In such a situation, using the standard ANOVA procedures is not appropriate as it does not consider dependencies between observations within subjects. To deal with these data, we utilized repeated measure ANOVA. The significance level was considered 0.05 for all tests.

Results

In total, 99 children with leukemia were included in this study (Figure 2). Demographic characteristics of children in three groups are shown in Table 1. As results show, there was no significant difference between the three groups except for gender (P=0.011).

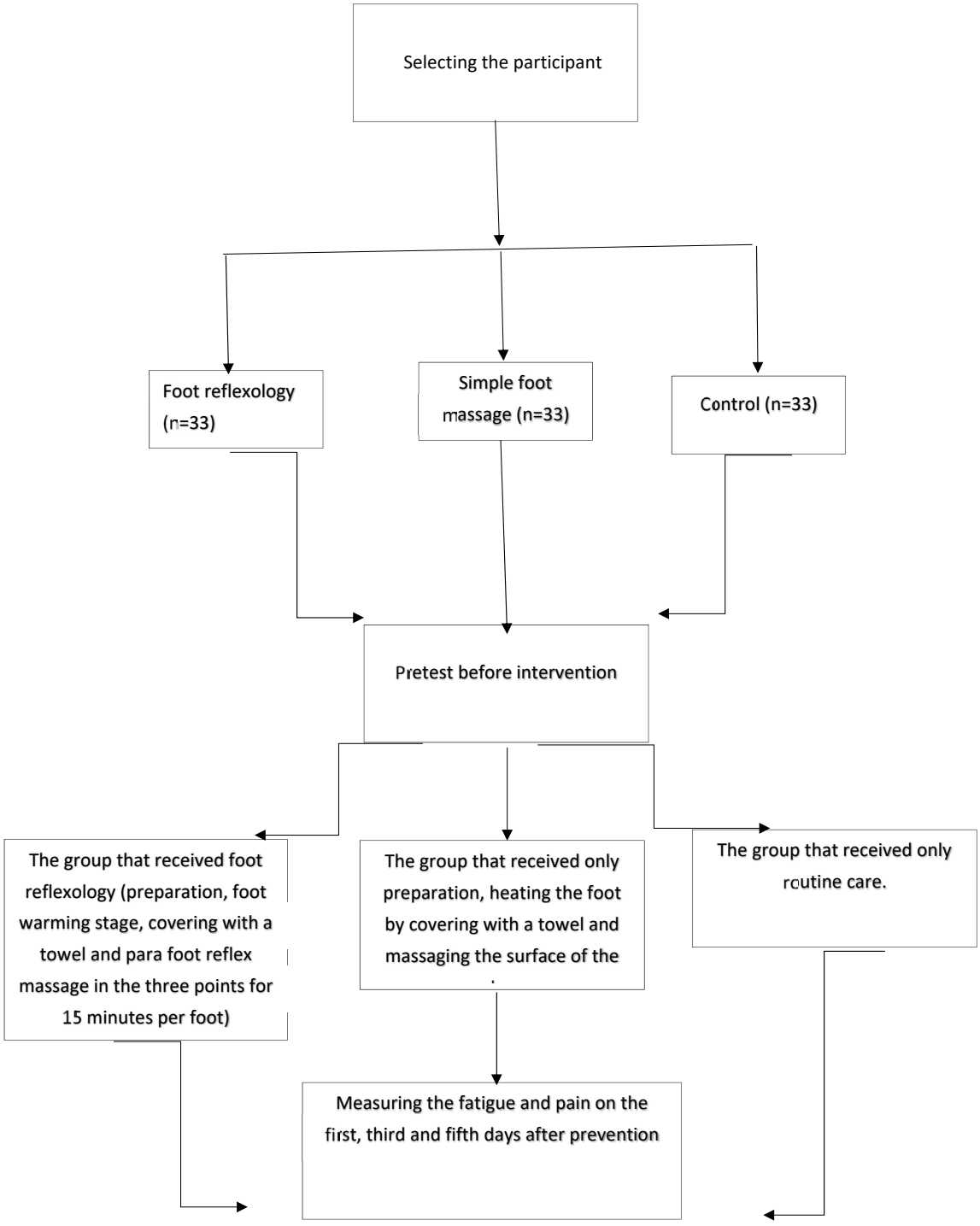

Figure 1. CONSORT flowchart

The Mean±SD of pain severity and fatigue are presented in Table 2, according to the group and time of measurement. Before the intervention, all three groups had no significant difference in pain (P=0.67) and fatigue (P=0.45).

Repeated measure ANOVA was used to compare the pain and fatigue during the study in the three groups (foot reflexology, simple foot massage, and control). According to the results of this test, there was a significant difference between the three groups regarding the mean intensity of pain and fatigue. Over time, there was a downward trend in reflexology and simple massage groups (Figures 3 and 4). Pain severity in the foot reflexology group decreased from 5.8±2.2 on the first day to 4.4±1.9 on the third day and

Table 1. Demographic characteristics of children with leukemia in the reflexology, simple foot massage, and control groups

Variables	Groups	No. (%)			P
		Foot Reflexology	Simple Foot Massage	Control	
Sex	Boy	17(51.5)	21(63.6)	9(27.3)	0.011
	Girl	24(72.7)	12(36.4)	16(48.5)	
Age (y)	≤7	15 (45.5)	16(48.5)	18(54.5)	0.059
	8-11	3(9.1)	8(24.2)	10(30.3)	
	≥12	15(45.5)	9(15.3)	5(15.2)	
Education level	Elementary school	14(42.4)	18(54.5)	18(54.5)	0.23
	Middle school	8(24.2)	5(15.2)	3(9.1)	
	Preschool	11(33.4)	10(30.3)	12(36.5)	
Duration of disease (m)	≤12	6(18.2)	4(12.1)	3(9.1)	0.05
	13-24	10(30.3)	14(42.4)	16(48.5)	
	25-35	16(48.5)	12(436)	8(24.2)	
	≥36	1(3.0)	3(9.1)	6(18.2)	
No. of chemotherapy	≤5	8(24.2)	8(24.2)	6(18.2)	0.053
	6-11	21(63.6)	19(57.6)	13(39.84)	
	≥12	4(12.1)	6(18.2)	14(42.4)	

2.7±1.4 on the fifth day. Pain severity in the simple massage group decreased from 6.2± 2.03 on the first day to 5.2±1.79 on the third day and 3.9±1.83 on the fifth day. Fatigue severity in the reflexology massage group decreased from 3.47±0.24 on the first day to 2.36±0.55 on the third day and 2.14±0.42 on the fifth day. Also, fatigue severity in the simple massage group decreased from 33.45±0.18 on the first day to 2.95±0.6 on the third day and 2.67±0.72 on the fifth day. Differences between the mean severity of pain and fatigue in 3 groups during study time are presented in Table 3.

According to the repeated measures test, the time trend for pain and fatigue was significant (P<0.001). The difference in severity of pain and fatigue recorded in the three phases of the study was statistically significant (P<0.001) among the 3 groups (Figures 3 and 4).

Discussion

The present study was a randomized clinical trial to determine the effect of foot reflexology massage on the severity of fatigue and pain in children with leukemia undergoing chemotherapy.

Before the intervention (first data collection), most participants reported moderate pain, and pain severity was not significantly different among the three groups. Mean pain scores in the foot reflexology group on the third and fifth days were significantly lower than those of the simple foot massage group, and the scores of this group were also significantly lower than those of the control group. The score difference increased with the number of interventions.

The present study's findings are consistent with several studies on the effect of foot reflexology massage on pain. However, studies employed different numbers of reflexology massage sessions and study populations [17, 28, 29]. Other studies using physiological criteria have also suggested the effective role of reflexology massage in reducing pain. Even though simple foot massage intervention showed significant results compared to the control group, pressure on reflexology points seems to induce considerable pain relief [17, 18].

Consistent with this study, the results of a study showed that performing a massage protocol helps reduce walking pain in children with cancer [30]. Other studies have also demonstrated the positive effect of massage on pain relief

Table 2. Comparing the mean score of pain and fatigue during study time in three groups

Variables	Time	Group	Mean±SD	Group Effect	Time Effect	Time and Group Interaction Effect
Pain	1st day	Foot reflexology	5.8±2.2	P<0.001	P<0.001	P<0.001
		Simple foot massage	6.2±2.03			
		Control	5.8±1.82			
	3rd day	Foot reflexology	4.4±1.9			
		Simple foot massage	5.2±1.79			
		Control	6.3±1.76			
	5th day	Foot reflexology	2.7±1.4			
		Simple foot massage	3.9±1.83			
		Control	6.7±1.5			
Fatigue	1st day	Foot reflexology	3.47±0.24	P<0.001	P<0.001	P<0.001
		Simple foot massage	3.45±0.18			
		Control	3.53±0.32			
	3rd day	Foot reflexology	2.36±0.55			
		Simple foot massage	2.95±0.6			
		Control	3.650.32			
	5th day	Foot reflexology	2.14±0.42			
		Simple foot massage	2.67±0.72			
		Control	4.12±0.16			

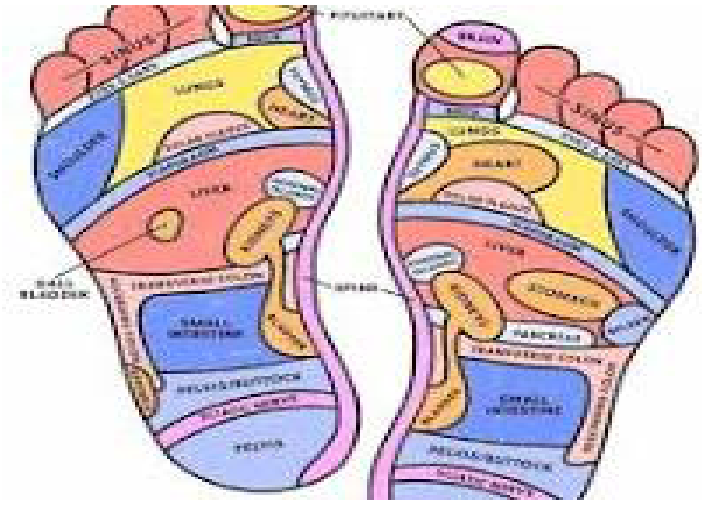

Figure 2. Points of pressure in foot reflexology

Table 3. Difference between mean severity of pain and fatigue during study time in three groups

Variables	Group	Mean Difference (1st day vs 3rd day)	P	Mean Difference (3rd day vs 5th day)	P
Pain	Foot reflexology	-1.42(4.39-5.81)	<0.001	-1.72(2.67-4.39)	<0.001
	Simple foot massage	-0.97(5.21-5.18)	<0.001	-1.24(3.97-5.21	<0.001
	Control	0.55(6.33-5.78)	<0.001	0.33(6.66-6.33)	<0.001
Fatigue	Foot reflexology	-1.09(2.38-3.47)	<0.001	-0.23(2.15-2.38)	<0.001
	Simple foot massage	-0.5(2.95-3.45)	<0.001	-0.27(2.68-2.95)	<0.001
	Control	0.14(3.67-3.53	<0.001	0.45(4.12-3.67)	<0.001

in different groups and patients with cancer [31, 32]. However, foot reflexology massage and emphasis on pressuring specific foot points seem more effective in relieving pain than simple foot massage [33, 34]. Some reviewed studies have shown that reflexology massage does not affect acute pain after surgery [27, 35]. However, our findings align with a study by Lee et al., which shows that foot reflexology massage effectively reduces pain in children undergoing chemotherapy. Despite the effect of simple foot massage, foot reflexology massage was more effective [36].

Our data also showed a significant decrease in fatigue intensity in the foot reflexology massage group compared to the control and simple foot massage groups. The results also showed less fatigue in the simple foot massage group than in the control group. Few studies are available on the effect of foot reflexology massage on the fatigue of children with cancer. Still, in an adult study (using a similar measurement tool), a 4-week reflexology massage showed effectiveness in reducing fatigue in the hands of patients [23]. Studies on patients with colorectal cancer [33], patients undergoing hemodialysis [34], and patients with cancer undergoing chemotherapy [15] are also consistent with our study.

Some studies have also shown the positive effect of simple massage on fatigue reduction in different groups and patients with cancer [37, 38]. A similar finding has been reported in a study demonstrating a more significant effect of reflexology massage compared to classical massage on reducing fatigue in patients with colorectal cancer [33].

It is worth mentioning that the noise of the study setting and the physical and mental condition of children and their mothers may affect the quality of answering the questions. The researcher sought to increase cooperation and respond to questions by providing appropriate communication and creating a relaxed environment for the child. However, the complete management of this situation was out of the researcher's control.

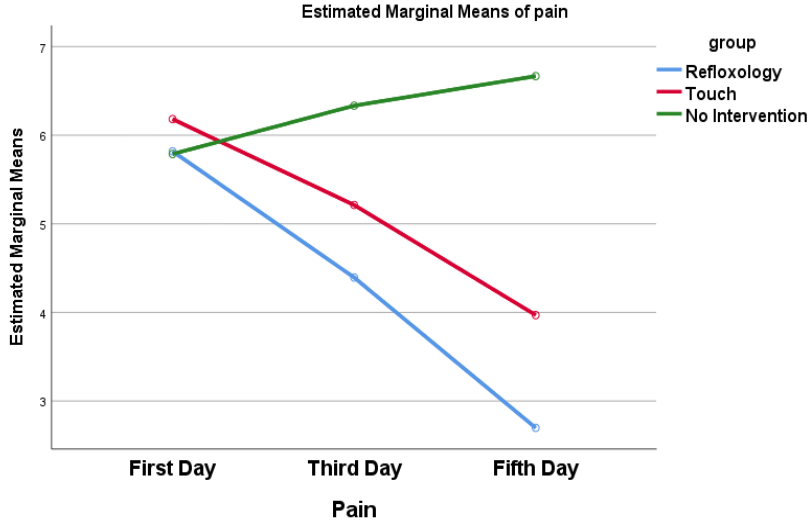

Figure 3. Pain in the three groups during the study period

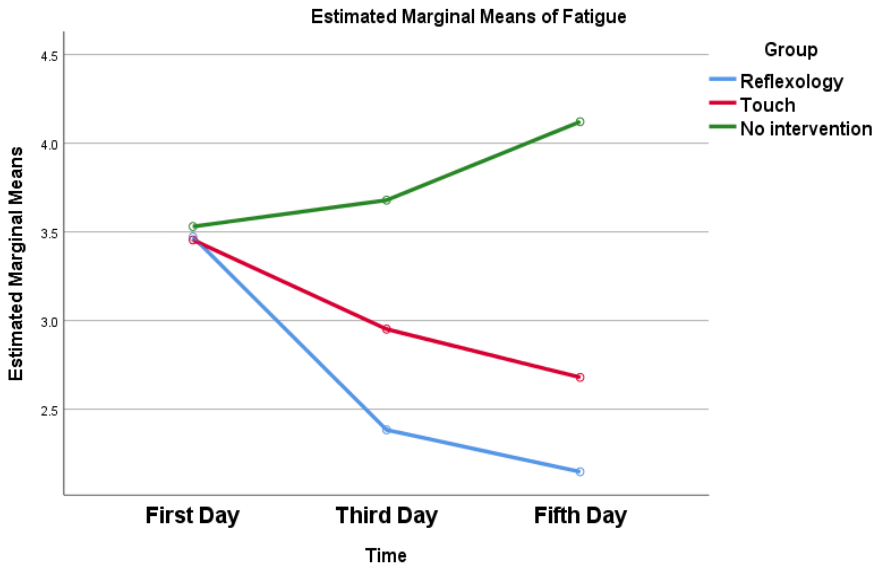

Figure 4. Fatigue in the three groups during the study period

We recommend studies aimed at evaluating the effect of foot reflexology massage on other aspects of cancer disease, such as stress, depression, and anxiety. Studies on the evaluation of the impact of foot reflexology massage on acute pain, such as pain during burn dressing replacement and pain during procedures requiring needles, such as access to the vein, bone marrow aspiration, and arterial bleeding in children, will also be useful.

Conclusion

The foot reflexology massage had a positive effect on reducing pain and fatigue in children with leukemia under chemotherapy. Simple foot massage also effectively reduced pain and fatigue in these children. According to the results, foot reflexology massage and emphasis on foot pressure points are more effective in relieving pain and fatigue than simple foot massage. Since reflexology is an inexpensive, affordable, and safe method, it would be beneficial for children with leukemia undergoing chemotherapy.

Ethical Considerations

Compliance with ethical guidelines

The current study was approved by the Ethics Committee of Iran University of Medical Sciences (Code: IR.IUMS.REC.1397.525) and was registered by the Iranian Registry of Clinical Trials (IRCT) (Code: IRCT.36983).

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Authors contributions

Study design and interpreting the results: Mahnaz Shoghi and Motahareh Kheradmand; Conducting the study: Asma Asadian; Writing the manuscript: All authors; Final approval: All authors.

Conflict of interest

The authors declared no conflict of interest.

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