

The Effect of foot sole reflexology on the fatigue in the first half of pregnancy: A randomized clinical trial

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ABSTRACT

Background & aim: Fatigue is one of the most common complaints among pregnant women. Reflexology can be used to reduce the symptoms of fatigue. The purpose of this study was to measure the impact of foot sole reflexology on the intensity of fatigue in the first half of pregnancy.

Methods: This randomized clinical trial was conducted on 73 pregnant women with 8-20 gestational weeks who referred to urban health centers, Mashhad, Iran in 2018. The participants were randomly assigned to two groups of foot sole reflexology (n=36) and control (n=37) using a random number table. In the intervention group, in addition to routine care, foot sole reflexology was daily administered through a 20-minute session for 4 days. The control group only received routine care. The checklist of fatigue symptoms was daily completed by both groups up to seven day. The data were analyzed by SPSS software (version 25) using the Mann-Whitney U test, independent t-test, and analysis of covariance.

Results: The results showed that although the mean score of severity of fatigue after the intervention decreased in both groups, compared to those reported before the intervention, there was no significant difference between the two groups (P=0.87).

Conclusion: In this study, foot sole reflexology did not reduce fatigue in the first half of pregnancy. However, as most pregnant women reported more relaxation in the reflexology group than the control group, further research in this topic is recommended in the future.

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Introduction

Fatigue is reported as one of the most common symptoms of pregnancy by women. According to the North American Nursing Diagnostic Association, fatigue is a sustained sense of burnout that results in a decrease in physical and mental ability. Moderate to severe fatigue has been reported in pregnant women with a prevalence of 75% (1), and this fatigue had a significant impact on their ability in personal and social activities (2). It has been demonstrated that severe fatigue has a significant effect on reducing the quality of life of pregnant women

and decreases the ability of women to manage postpartum daily life (3). Various studies have reported positive associations between fatigue and preterm labor, low gestational age, premature rupture of membranes, hypertension, increased risk of cesarean section (C-section), and longer duration of postpartum hospital stay (1,4).

Fatigue as an indirect factor affecting basic metabolism and placental function can also affect fetal growth and reduce food absorption in mothers (5). Fatigue has no clear cause;

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nevertheless, there are some theories in this regard. The increased demand for metabolism and effects of hormones and other physiological changes during pregnancy, such as anemia, diabetes, or thyroid dysfunction, can partly explain pregnancy-related fatigue (6). Progesterone which is largely secreted from the placenta during pregnancy can be the cause of sleepiness or fatigue reported by women during pregnancy (7).

In recent years, given the growing popularity of comprehensive approaches for health emphasizing the integration of body, mind, and soul, as well as physical symptoms to improve healthcare and wellbeing, complementary medicine has occupied a special place among individuals. Recently, nursing interventions involving various aspects of complementary medicine have been better understood and accepted. According to the evidence, it was shown that most people who significantly suffer from chronic fatigue (8).

Although various methods, such as energy therapy, hydrotherapy, acupuncture, acupressure, massage therapy, and reflexology or a combination of these techniques, are used to reduce fatigue, there is still insufficient information about which method is better and more valuable(9), and it is necessary to carry out further studies in this field. One of the branches of complementary medicine is reflexology that various studies have reported its affirmative effect on many difficulties of pregnant women, including edema, constipation, sleeplessness, fatigue, and labor anxiety (10).

Reflexology is a procedure whereby the pressure is applied by fingers to specific points and is based on the assumption that the reflection spots are associated with the internal organs and glands and designed in a manner consistent with the body physics (11). One of the significant points in reflexology is the point of solar chakra which is one of the seven main body chakras located in a thoracic region at the upper part of the abdomen, in the back of the stomach and front of the aorta (12). To relax the sole point in reflexology, place the thumbs right in the reflection area and with one's breath apply firm and nonmoving pressure (continuous pressure on the points for 2 min). This can be repeated three times (13).

Numerous studies conducted by Ghaffari et al. on the fatigue of pregnant women (14), Choi et al. on the postpartum fatigue (15), and Kim et al. on the severity of fatigue in middle-aged women (16) have confirmed the positive effects of reflexology on fatigue severity in various conditions. However, Ernst in his review study in 2009 noted that there is no convincing evidence on the efficacy of reflexology in the treatment of medical conditions (17). Furthermore, Tiran in 2010 has emphasized to perform further randomized clinical trial studies on the effects of reflexology (18).

Fatigue, in addition to its adverse effects on pregnancy, may impair memory and concentration, disturb the emotional and psychological balance, reduce libido, decrease the ability for judgment, reduce the quality of performance, and increase irritability, leading to irreparable damage to the individual, family, and community (19). In addition, due to doubts about the efficacy of reflexology in the reduction of fatigue, this study was performed to determine the effect of reflexology on fatigue in the first half of pregnancy in 2018.

Materials and Methods

This two-group randomized clinical trial was carried out on 73 pregnant women after the approval of the Ethics Committee of the University of Medical Sciences in Mashhad, Iran, within March 2018 to the end of June 2018. After clarifying the purposes of the study and obtaining written consent from the individuals, sampling was performed by the consideration of the ethical codes.

The target population in this study were all pregnant mothers with a gestational age of 8-20 weeks who referred to one of the three health centers of Najafi, Amir al-Momenin, and Vahdat. For this purpose, the name of five main health centers of Mashhad was written on paper, and a number or code was assigned to each of them. Then, the numbers were written on the fragments of paper, and the pieces of paper were put in a container. Afterward, a person not a member of the research team was asked to draw three sheets of paper. Therefore, three health centers were selected (centers no. 1, 2, and 3). Then, at the second stage, among the health centers covered by these three centers,

one center from each one and a total of three centers were randomly selected by lottery in the same way as the above-mentioned.

The sample size was determined using a pilot study on 10 research units using the comparison formula of means in the two independent groups. Finally, considering 0.7 effect size, 80% power, and 0.95% confidence coefficient, 36 subjects were assigned to each group. Considering 10% loss, the final sample size was 40 in each group and a total of 80 subjects in two groups.

The sampling in the present study was purposive. A random number table was utilized to randomly assign the samples using www.randomization.com. Firstly, the numbers of 1 to 80 were given to the software. Then, according to the random number table provided by the site, the first 40 numbers were assigned to the control group and the second 40 numbers to the reflexology group. Sampling was nonprobable, and the samples were chosen based on inclusion and exclusion criteria. The researcher referred to the selected health centers and selected any pregnant woman who completed the informed consent form and completely understood the aim of the study.

The study could not be blinded because the researcher was presented as a confounding person. The inclusion criteria were Iranian nationality and residency in Mashhad, willingness to participate in the study, no illiteracy, single pregnancy, gestational age less than 20 weeks based on LMP¹ or first-trimester ultrasound, no medical or midwifery sickness in the current pregnancy, no pregnancy following infertility, no intention in terminating pregnancy, no severe psychological problems, and no foot varicose. The exclusion criteria were wound, inflammation, or fracture in the site of intervention, symptoms of threatened abortion, psychological problems during the study, unwillingness to continue with the study, and nonreferral of the participants to the health center on the scheduled days.

Research tools were demographic-midwifery questionnaire and checklist of fatigue severity.

¹ Last menstrual period

Content validity was used to determine the validity of the demographic-midwifery questionnaire. The questionnaire was given to seven professors of Mashhad School of Nursing and Midwifery and then used after making modifications. The demographic-midwifery questionnaire is stable due to its frequent replication in previous studies. The standard checklist for fatigue severity has 30 items with a 5-point Likert scale in which the scores of 0 to 4 were assigned to each item. The total score of the checklist is 0-120. The scores between 0-40, 41-80, and 120-181 indicate mild, moderate, and severe fatigue.

The validity of the questionnaire was confirmed by Pugh and Milligan in the United States (20). In addition, Nashat et al. in Iran in 2001 confirmed the internal validity of 0.88 (21). In the present study, the reliability of the tool was calculated with Cronbach's alpha coefficient of 0.84 indicating the reliability of the checklist. The skill of the researcher in the correct method of administering general and particular reflexology of foot sole point was confirmed under the supervision of a complementary medicine specialist (third author).

The duration of the study was considered 7 days. The mean score of fatigue severity was evaluated 3 days before the intervention, and the duration of the study was 4 days. Therefore, the demographic-midwifery questionnaire was completed by the subjects on the first day of the study, and routine prenatal care was provided for both groups in a similar way. Then, three checklists of the severity of fatigue symptoms were given to the mothers to complete for three nights and deliver to the researcher on the fourth day. The routine prenatal care was conducted in both groups on the fourth day.

In the intervention group, reflexology was given by the investigator one session a day for 20 min in the health center. The subject was asked to lie down on the bed in a quiet room. Firstly, 10 min of general foot massage was given through the palm of the hand without direct pressure to a specific point. Then, the particular reflexology of the foot sole point was administered so that the thumb finger of the left hand pressed the specific point on the left leg, and the thumb finger of the right hand pressed

the specific point on the right leg as simultaneously for 2 min of constant and continuous pressure.

The level of pressure was in accordance with participant tolerance. The pregnant woman had 1 min rest after every 2 min pressure, and the technique was applied three times in each session. After the intervention, the checklist of the severity of fatigue symptoms was given to the pregnant woman to complete and submit to the researcher tomorrow. The intervention in the next three days was performed with a similar method.

In the control group on the fourth day of the study, four checklists of fatigue symptom severity were given to the subjects, and they were asked to complete one questionnaire every night and again refer to the health center on the seventh day and deliver the questionnaires to the researcher. All participants were revisited and received routine care on the seventh day. The data were analyzed using SPSS software (version 25). The Kolmogorov-Smirnov test was used to investigate the distribution of quantitative data. The variables with normal distribution were analyzed by the independent t-test, and the variables with nonnormal distribution were examined using the Mann-Whitney U test. Analysis of covariance (ANCOVA) with repeated data was used to control the confounding variables. P-value less than 0.05 was considered statistically

significant.

Results

A total of 115 pregnant women were initially evaluated in this study. Finally, 80 eligible individuals were included in the current study, and 40 patients were randomly assigned to each group.

Out of 80 subjects, 3 in the control group and 4 in the reflexology group were excluded from the study due to the reasons, such as unwillingness to continue the study, sensitivity to foot touch, and no attendance in all reflexology sessions. Therefore, the final analysis of the data was performed on 73 subjects according to the protocol of sampling flowchart (Figure 1).

The Kolmogorov-Smirnov test was used to investigate the normality of the distribution of quantitative variables. The obtained results showed that all quantitative variables except age had no normal distribution in at least one of the subgroups. In addition, there was no remarkable difference between demographic and midwifery characteristics of the participants. The two groups were also homogeneous in the intensity of fatigue before the intervention.

Most of the subjects in the reflexology (43.8%; n=17) and control (45.7%; n=18) groups were reported with high school education.

Table 1. Demographic and midwifery characteristics of study population

Variable	Reflexology		Control		Test results
	Mean± standard deviation	Frequency (%)	Mean±standard deviation	Frequency (%)	
Age	26.69±5.76		28.3±8.01		P-value*=0.42
Body mass index	22.88±2.99		26.6±24.03		P-value**=0.58
Number of pregnancy	1.78±0.79		2.57±1.25		P-value**=0.005
Number of delivery	0.59±0.79		1.24±1.11		P-value**=0.01
Type of pregnancy	Planned	17 (53.1)	23 (50)		P-value***=0.65
	Unplanned	5 (15.6)	11 (23.9)		
	Unwanted pregnancy	10 (31.3)	12 (26.1)		

*Independent t-test **Mann-Whitney U test ***Chi-square test

The majority of women in the reflexology (49.9%; n=19) and control (39.1%; n=16) groups were happy about the pregnancy. The majority of women in the reflexology (59.4%; n=23) and control (71.7%; n=31) groups had appropriate verbal communication with their

husbands. Almost half of the pregnant mothers in the reflexology (53.3%, n=21) and control (52.2%; n=20) groups were housewives. All of the aforementioned variables were homogeneous in the two groups (Table 1).

The obtained results showed that the severity of fatigue symptoms before the

intervention had normal distribution in two groups, and there was no considerable difference in this regard ($P=0.24$). The evaluation of the mean score of the severity of fatigue symptoms after the intervention showed

that the changes in the mean scores before and after the intervention were not significantly different between the two groups (Table 2; $P=0.64$).

Table 2. Comparison of mean±standard deviation of fatigue severity in pregnant women before and after intervention in two reflexology and control groups

Variable	Results		Test results	
	Reflexology Mean±standard deviation	Control Mean±standard deviation		
Severity of fatigue	Before intervention	23.59±8.87	21.17±9.14	Z*=1.17 P-value= 0.24
	After intervention	17.13±7.33	15.5±8.14	Z= 1.38 P-value= 0.16
	Changes before and after intervention	-6.46±6.82	-5.67±7.88	T**= 0.46 P-value= 0.64

*Mann-Whitney U test **Independent t-test

In ANCOVA, with controlling the variables of mean fatigue severity before the intervention ($P=0.001$), confounding variables of pregnancy type ($P=0.44$), number of pregnancies ($P=0.18$), history of unsuccessful pregnancy ($P=0.34$),

history of nausea ($P=0.13$), and emotional support of relatives ($P=0.07$), the results showed that the mean score of fatigue after the intervention had no significant difference in the reflexology group, compared to that in the control group (Table 3; $P=0.87$).

Table 3. Estimation of analysis of covariance parameters regarding effect of sole reflexology on fatigue severity at first half of pregnancy

Variable	Results		Test result	
	Regression coefficient	Criteria error		
Severity of fatigue before intervention	Reflexology	-0.24	1.59	t=0.15 P-value=0.87
	Control	0.53	0.08	t=6.33 P-value<0.001

*Variables of fatigue severity before intervention, type of pregnancy, number of pregnancy, history of unsuccessful pregnancy, history of nausea and emotional support of relatives entered to the model and removed from model due to no significance

The obtained findings revealed that women in the reflexology group felt more relaxed and comfortable after the intervention than before the intervention.

Discussion

According to the obtained results of this study, despite the decrease in the severity of fatigue symptoms after the intervention, there was no remarkable difference between the two groups. Ernst in his review study in 2009 noted the lack of convincing evidence on the efficacy of reflexology in the treatment of medical conditions (17). Tiran in 2010 has also

emphasized on performing more randomized clinical trial studies on the efficacy of reflexology (18).

Ghaffari et al. (2010) in a study comparing the effect of foot sole reflexology and counseling on fatigue in pregnant women reported that sole reflexology significantly reduced fatigue severity ($P=0.001$) (14). The method of the aforementioned study was the administration of reflexology for 30 min twice a week for 5 weeks; however, in the present study, reflexology was daily given for 4 days. The difference in the results of the study by Ghaffari et al. and those of the present study may be due to the difference in the method.

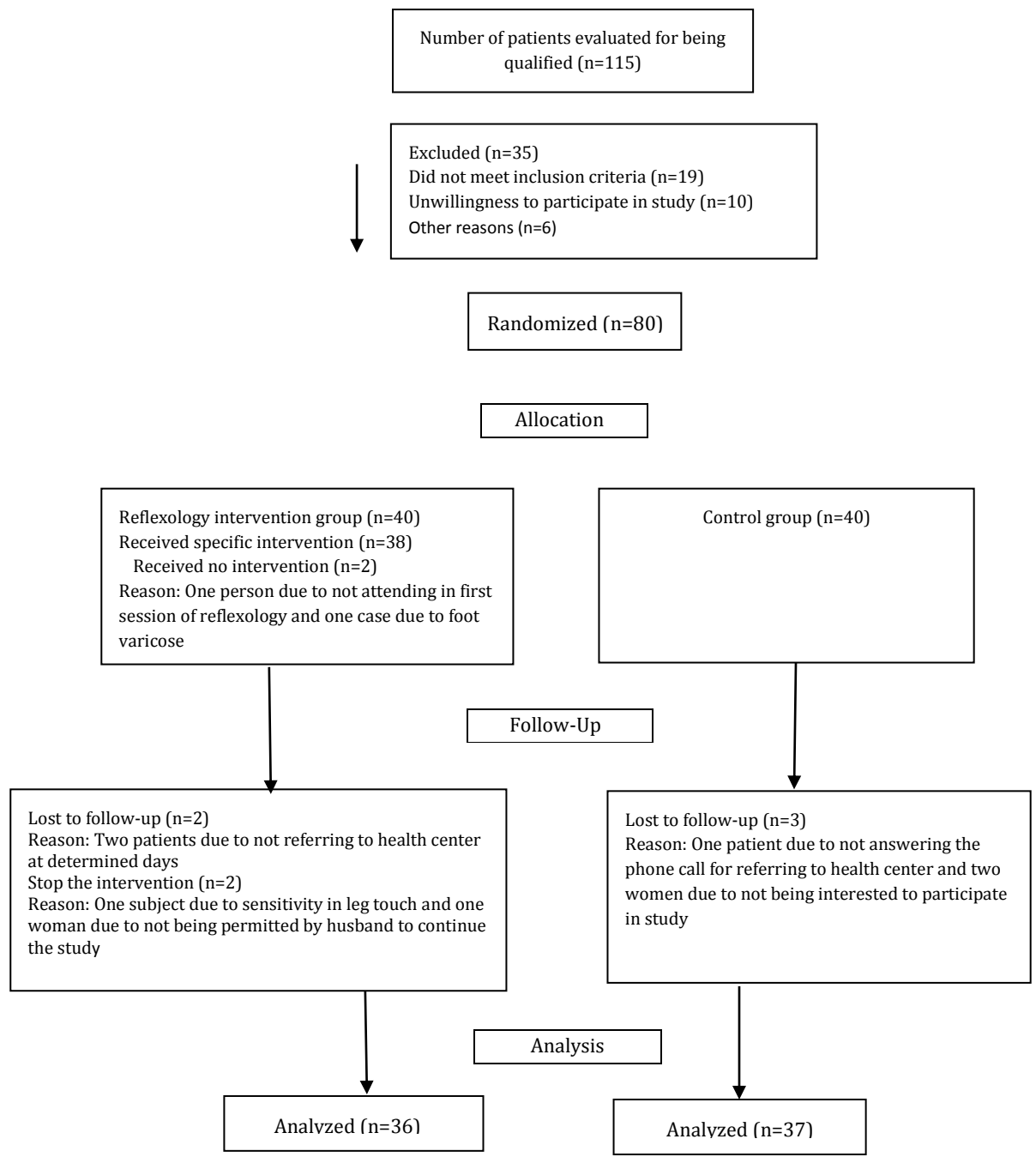


Figure 1 Registration and follow-up process

gestational age of fewer than 20 weeks participated. The severity of fatigue in the first

In addition, one of the inclusion criteria in the study by Ghaffari et al. was pregnant women with a gestational age of 18-30 weeks; nonetheless, in the present study, women with a

and second trimesters of pregnancy may be different, this difference in the target group may lead to differences in the final results.

On the other hand, the results of the present study are not in line with the findings of a study by Bagheri-Nesami et al. (2012) that evaluated the effect of foot reflexology on pain and fatigue on 84 patients undergoing coronary artery bypass. It is noteworthy that in the aforementioned study, reflexology was administered for 20 min from the second day after the operation for 4 consecutive days, and in the control group, the oil was applied on the left leg of the patient without any pressure. The results showed a significant difference in fatigue scores between the two groups (22). One of the most important reasons for inconsistency in the findings of the study by Bagheri-Nesami et al. with those of the present study may be the difference in the target group.

In a study carried out by Shobeiri et al. (2011) on the evaluation of the effect of foot sole reflexology and counseling on the severity of fatigue in pregnant women, a statistically significant difference was also reported between the case and control groups after the intervention ($P=0.01$) (23). These results are inconsistent with the findings of the present study. In the study conducted by Shobeiri et al., the target groups were pregnant women with a gestational age of 18-30 weeks; however, in the present study, the target group included pregnant women with a gestational age of fewer than 20 weeks.

In the current study, only reflexology was given to the case group; nevertheless, in the study by Shobeiri et al., the intervention was performed twice a week for 5 weeks. Firstly, counseling was performed for 15 min, and then, sole reflexology was administered for 30 min. The decrease in fatigue score in the case group may not be due to reflexology alone, and counseling has been also effective in the improvement of the fatigue score after the intervention.

Asgharpour et al. (2015) also conducted a study to investigate the effect of foot reflexology focusing on a sole point on the fatigue severity of patients undergoing hemodialysis. In the aforementioned study, reflexology was given twice a week for 5 weeks, and the fatigue assessment questionnaire was completed by the control and case groups in the first, third, and fifth weeks. The results showed no significant difference between the two groups in the first

and third weeks ($P=0.81$). However, the findings were statistically significant in the fifth week ($P=0.002$). The findings of the study carried out by Asgharpour et al. are consistent with the results of the present study in this regard (24). Although the target groups of the two studies were different; nevertheless, in both studies, the short-term reflexology was not effective.

The results of the present study are in contrast to the findings of a study by Bastani et al. (2015), which investigated the effect of foot reflexology on the severity of fatigue score in mothers who underwent C-section. Bastani et al. reported that the severity of fatigue score after the intervention was significantly lower in the intervention and placebo groups, compared to that in the control group ($P=0.001$) (25). In the present study, the case and placebo groups received foot reflexology and leg massage, respectively. The used tools in their study included a visual assessment questionnaire; however, the tool in the present study was a modified checklist of fatigue symptoms. On the other hand, in the study performed by Bastani et al., the reflexology duration was 40 min, which was longer than that reported in the present study.

It seems that given the contradictory reports regarding the efficacy of reflexology on fatigue, it is required to carry out further studies with longer intervention duration for the more accurate evaluation of the effects of this intervention. One of the limitations of the present study is the short duration of intervention due to environmental limitations.

Conclusion

According to the obtained results of this study, foot sole reflexology did not significantly reduce the severity of fatigue symptoms in pregnant women who daily received one session of 20-minute reflexology during 4 days. However, given that reflection therapy is a relatively easy, noninvasive, and low-cost method without side effects, compared to the commonly used methods, and apart from its effect on fatigue, it can cause a positive relationship between patient and caregiver. On the other hand, most participants reported more relaxation in the reflexology group; therefore, it is recommended to apply reflexology as a supportive and palliative

approach by healthcare providers. It is necessary to perform further studies with larger sample size, longer duration, and longer follow-up in order to obtain more definitive results.

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Conflicts of interest

Authors declared no conflicts of interest.

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