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The effects of foot reflexology on depression during menopause: A randomized controlled clinical trial



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ABSTRACT

Objective: The purpose of this study was to determine the effects of foot reflexology on depression during menopause.

Design: Randomized controlled clinical trial.

Setting: Gynecology outpatient clinic.

Interventions: We enrolled 90 menopausal women with depression. Participants were assigned to the intervention (n = 45) and control (n = 45) groups by block randomization. Participants in the intervention group received 15 min of foot reflexology on each foot for a total of 30 min in evenings, twice a week for six weeks. Participants in the control group received only the routine care for menopause patients.

Main outcome measures: The Beck Depression questionnaire was completed by all participants at the beginning of the trial and the end of the intervention and two months after completion of the intervention.

Results: A total of 121 patients were assessed for eligibility to participate in the study. One-hundred patients met the criteria to participate, and 90 participants—45 participants in each group—completed the study. In the intervention group, the mean scores of depression before, immediately after, and two months after the study were 26.97 ± 4.47 (95% CI = 25.3–28.3), 22.55 ± 5.18 (95% CI = 20.9–24.1), and 21.20 ± 5.74 (95% CI = 19.4–22.9), respectively. In the control group, these scores were 26.15 ± 5.01 (95% CI = 24.6–27.6), 26.22 ± 5.14 (95% CI = 24.7–27.7), and 26.66 ± 3.87 (95% CI = 25.5–27.8), respectively. Using Repeated Measures ANOVA, the comparison of the mean scores of depression in the two groups indicated that the scores were decreased over time.

Conclusion: The findings indicated that the foot reflexology technique can be effective for reducing women's depression during menopause. However, considering the study's limitations, including a small sample size and no intervention in the control group, more studies are needed to verify the findings.

1. Introduction

Menopause is known as the termination of fertility in women due to aging and is a part of women's normal developmental and biological process.¹ Menopause is manifested by permanent cessation of menstrual cycles caused by the natural depletion of ovarian oocytes. The diagnosis is based on the missed menstrual cycles for 12 consecutive months.¹ Menopause may occur in late 40s or early 50s.² The average age for manifestation of menopause is 51 years.¹ Although menopause is a natural process in women's life which is associated with hormonal fluctuations influencing the body and brain, this process may cause physical and emotional symptoms.^{3,4} These symptoms include hot

flashes, disturbed sleep, reduced level of energy, mood swings, difficulties with memory and concentration, anxiety, stress, irritability, altered body image and sexuality, feelings of sadness, infertility, and depression.^{1,3} Hormonal fluctuations include decreases in estrogen, prolactin, thyroid, and parathyroid hormones and increases in Follicle-stimulating hormone (FSH) and luteinizing hormone (LH).³

In general, the number of women with depression is about twice the number of men.¹ Among women after menopause, the incidence of depression is increased from 26% to 33%.² During this period, depression is the most common psychological problem.⁵ Universally, depression is the most common health problem and the number of people with depression around the world is estimated to be 350 million.⁵

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Depression is associated with multiple personal and social problems, including reduced interpersonal relationships, serious declines in psychosocial wellbeing and physical health, decreased capacity to work, increased rates of suicide, and financial burden for individuals and societies.^{3,5}

Medications can be effective in the treatment of depression. However, they cause multiple adverse and side effects, including headache, nausea, increased weight, fatigue and drowsiness, blurred vision, and constipation.⁶ Therefore, some patients and their providers seek alternative treatments.⁶ Complementary or alternative medicine (CAM), such as relaxation techniques, acupuncture, yoga, reflexology, regular exercise, balanced nutrition, omega 3 oil and vitamin E preparations, acids intake, herbal supplements, appropriate clothing, and frequent showers, have been shown to be effective in reducing symptoms associated with depression.^{7,8}

Reflexology has been an ancient and common method for treatment of psychological problems among people in different countries.^{6,8–10} Reflexology is a method that involves pressing the body's reflex points by hands and fingers that lead to stimulation of the nerves and blood circulation related to specific body parts, systems, and organs where pain or discomfort is felt.⁹ It is believed that reflexology is effective in reducing stress, tension, and fatigue, and increasing blood circulation.¹⁰ The effectiveness of this technique is reported to reduce premenstrual symptoms,¹⁰ increase quality of life of breast cancer patients,¹¹ improve quality of sleep among hemodialysis patients,¹² reduce labor pain,¹³ and relieve constipation in women.¹⁴

Reflexology intervention is a different method from massage therapy.¹⁵ Massage leads to production of oxytocin in the body so that it can induce a calming sensation, reduce discomfort, and improve mood.¹⁶ However, Lee believed that the positive results of reflexology interventions are associated with an increase in the flow of energy that causes healing effects throughout the body.⁹ In this regard, they declared that stimulations of the feet's reflex points arouses the peripheral and central nervous systems. The nervous system transmits these messages to the visceral organs and the secretory glands. As a result, energy is released and circulates throughout the body.⁹ It is also indicated that placebo effects, therapeutic interactions, and the impacts of touch can have therapeutic effects when using the reflexology technique.¹³ Moreover, these effects have been explained by theories that address the balance of energy in the body. The theories include the gate control, the neural impulse, the lactic acid, and the endorphins theories.^{14,15} Accordingly, Tiran indicated that reflexology is effective in maintaining the body's balance through stimulating the inactive parts or suppressing the overactive parts of the body.¹³

Despite the reported positive effects and mechanisms regarding this technique, the definitive mechanisms related to these effects are still unknown. Additionally, other studies were conducted that showed no significant results of the reflexology technique among different patients.^{17–19} Taking the contradictory results of the studies into account, systematic reviews have indicated a need for more studies to confirm the effects of reflexology intervention on patients.^{20,21}

The existing literature regarding reflexology and the menopausal period have shown improvement in quality of life and reducing anxiety and depression among women.^{11,22} However, the number of studies that address the effects of reflexology on depression during the menopausal period is still insufficient in order to integrate the findings into the body of knowledge to advance evidence-based practice. This is the first study in Iran that aims to investigate the effects of reflexology on depression in women during the menopausal period. The use of complementary and alternative therapies to reduce patients' symptoms is a valuable part of nursing practice and within the scope of independent nursing roles.^{23–26} We selected an innovative approach based on individuals' values, needs, and available resources to address depression among women during their menopausal period.²⁷ The purpose of this randomized controlled trial is to identify the effects of foot reflexology on women's depression during the menopausal period.

2. Materials and methods

2.1. Study design and sampling

This randomized controlled clinical trial was conducted at the gynecology outpatient clinic affiliated with Kashan University of Medical Sciences, Iran. Using the Pocock's sample size formula,²⁸ the sample size of each group was estimated to be 37 participants. The sample size in each group was calculated based on the following assumptions: power = 0.80, $\alpha = 0.05$, the minimum expected difference in standard deviations = 2.9, and the minimum expected difference in means = 2.13.⁹ Considering a possible attrition rate of 25%, the optimal sample size was estimated to be 50 participants in each group.

A total of 121 women with depression during their menopausal period, 1–4 years after 12 missed menstrual cycles for 12 consecutive months, were assessed regarding the eligibility to enter the study. Twenty-one women were excluded from the study due to the failure to meet the criteria. The patients were randomly assigned to two groups of intervention ($n = 50$) and control ($n = 50$) groups by block randomization.²⁹ A total of 90 patients completed the study. In the intervention group, five patients were excluded because of their absence in reflexology sessions. In the control group, five patients were excluded due to a failure to complete the questionnaire at the end of the study (Fig. 1). Inclusion criteria for the participants were: stable vital signs, age between 40–60 years old, diagnosis of depression by a psychiatrist based on DSM-IV^{30,31} (depressed mood, loss of interest or pleasure, significant weight loss when not dieting or weight gain, a slowing down of thought and a reduction of physical movement, fatigue, feelings of worthlessness or excessive or inappropriate guilt almost every day), and the total depression score more than 14 based on the Beck Depression Inventory.³¹ The exclusion criteria were vascular disease in the lower extremities, impaired skin integrity, history of surgery, fractures, sprains or injuries in the lower extremity, diagnosis of diabetes, cigarette and alcohol consumption, and the use of other complementary therapies.

2.2. Ethics

The Institutional Ethics Committee of Kashan University of Medical Sciences (No: 9723, IRCT20111210008348N38) approved the study. Informed consents were obtained from the participants.

2.3. Measurements

The study measures included a sociodemographic questionnaire, including questions about age, marital status, job, level of education, the duration of menopause, and history of other diseases, and the standardized Persian version of Beck Depression inventory-second edition (BDI-II).³⁰ The BDI-II is a 21-items self-administered questionnaire for measuring the severity of symptoms of depression among individuals aged 13 and over. The instrument was developed to be used for identifying the presence and severity of symptoms consistent with the DSM-IV criteria.³¹ The instrument's total scores range from 0 to 63. The scores less than 14 are defined as non-depressed, 14–19 mild, 20–28 moderate, and 29–63 severe symptoms of depression. The BDI-II was completed by the participants at the beginning and the end of the intervention and two months after completion of the intervention. The partial ETA squared was used as effect size in repeated-measures analysis of variance. Cohen derived (anchored) classification standards of effect sizes from 0.2 to 0.49 as small, from 0.5 to 0.79 as moderate, and greater than 0.8 as large.^{32,33}

2.4. Intervention

This study was performed between January 1, 2017, and December 7, 2017, in Shahid Beheshti Hospital's gynecology outpatient clinic,

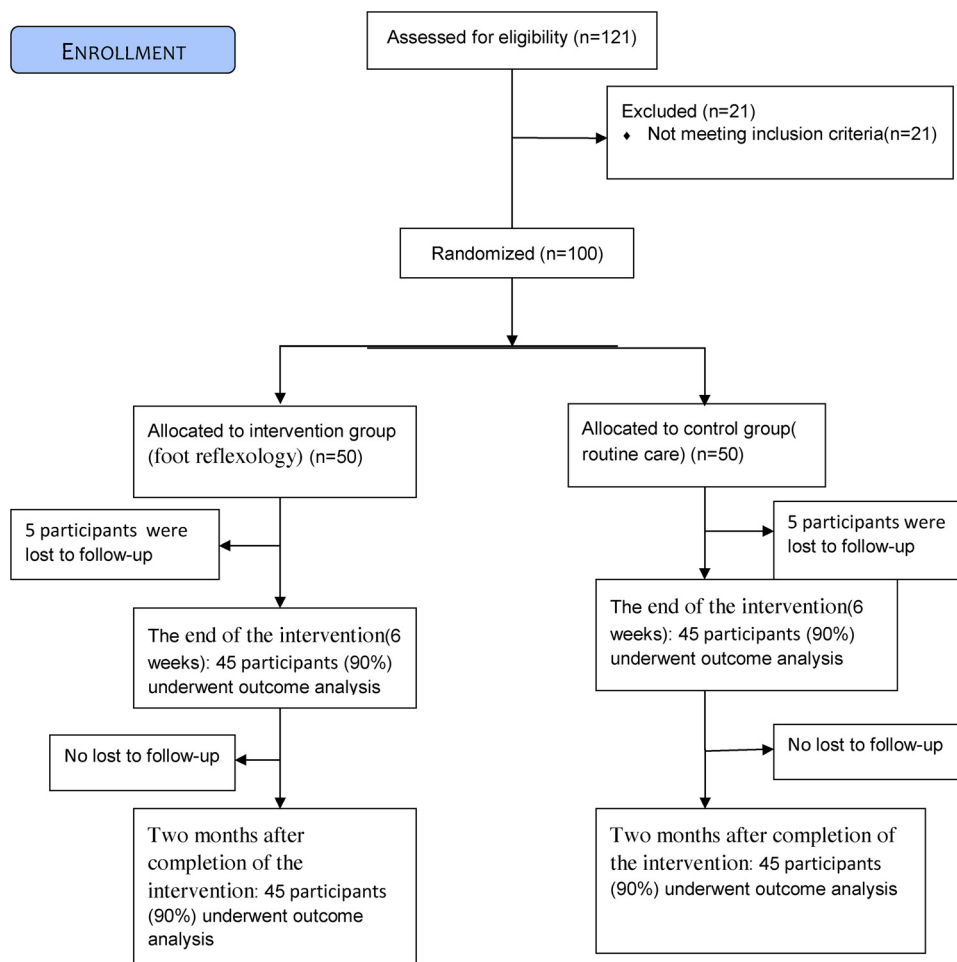


Fig. 1. CONSORT flowchart.

Iran. During the study, the intervention group received the foot reflexology intervention in addition to the routine care they were receiving for the treatment of menopause symptoms in the gynecology clinic. The intervention group participants received 15 min of foot reflexology on each foot for a total of 30 min in the evening. The intervention was performed twice a week over a period of six weeks. The participants in the control group received no intervention.

2.4.1. Foot reflexology protocol

The first author who has a certificate of reflexology training performed the foot reflexology method on the participants based on Embong et al.³⁴ The intervention sessions were held in a private room with sufficient lighting and heat with attendance of the researcher and a participant. Before the intervention, the foot hygiene (washing and drying the feet and cutting the nails if needed) was performed. No cream or lotion was applied on the participants' feet. The foot reflexology was performed on the participants' bare feet at least an hour after meals in bed and supine position. The participants' legs were positioned via smooth lifting of the feet and placing a small pillow under knees to prevent muscle strains and fatigue. The study design and intervention techniques were explained for each participant before signing the informed consent forms.

A three-stage foot reflexology was applied on each foot for 15 min twice a week for 6 weeks.⁹ The stimulating points that are related to the reduction of depression were selected.^{21,31} According to Lee⁸ the foot reflexology included: (1) General foot massage, including the foot rotation, Achilles stretching, and the foot extension and stretching, was performed for a minute on each foot. In the right foot, the bottom of the

heel was kept with the left hand, and the metatarsal arch of the same foot was held with the other hand. Then, the foot was rotated clockwise and counter clockwise three times each direction. The same technique was performed on the left foot. (2) The solar plexus (the relaxation point) was stimulated for 12 min on each foot. This point is related to calm, balance, relaxation, reduced panic reaction, and reducing depression and stress. Stimulation of the solar plexus was performed through applying rotational pressure with thumb. (3) Stimulation of the reflex point is related to the hypothalamus gland, pituitary gland, heart, lung, and adrenal gland. The hypothalamus gland is responsible for secretion of hormones and the balance of autonomic nervous system. The pituitary gland controls other endocrine glands, balances the secretion of hormones, and promotes emotional and physical balance. The lung and heart regulate breathing and the oxygen level. The adrenal glands are responsible for the secretion of adrenaline and hydrocortisone, creating balance, and combating depression and stress (see Figs. 2 and 3).²²

In these points, the stimulation was performed by applying circular pressure with the thumb for two minutes. The stimulation of the areas related to the lungs and heart was performed by pulling back the toes and performing biting movements from above the diaphragm area of the sole towards the toes by the thumbs.^{21,31} The organs at each side of the body side are corresponded to the foot at the same side. Therefore, the heart point was stimulated in the left foot. In this study, the location of the reflex points were selected based on the map presented based on Figs. 2 and 3.³⁵



Fig. 2. Reflex points.

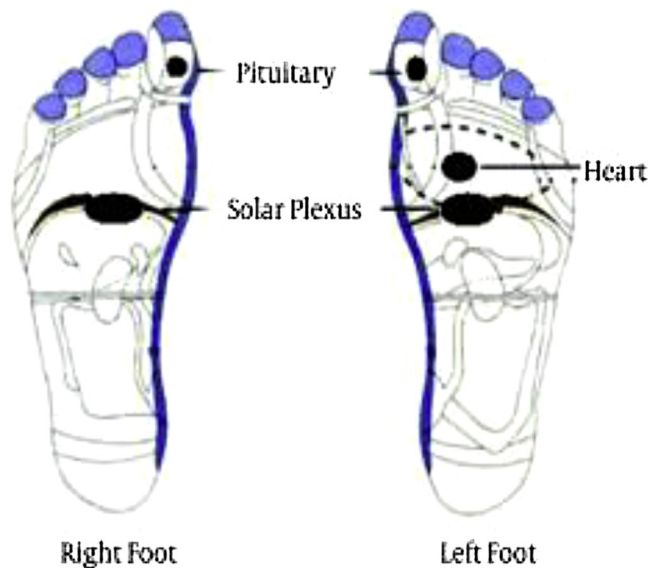


Fig. 3. Solar plexus, heart, and pituitary reflex points.

2.5. Data analysis

Results were analyzed using the SPSS V18 (IBM SPSS Statistics, Armonk, NY).The normal distribution of data was tested using the

Table 1 Demographic Characteristics of the Groups.

Variables	Groups		test
	Intervention (n = 50)	Control (n = 50)	
Age ^a (year)	54.18 ± 3.90	52.23 ± 11.6	T = 1.61 p = 0.10
Duration of menopause ^a (year)	5.44 ± 2.85	5.77 ± 2.37	T = 0.61 p = 0.52
Education ^b			χ ² = 0.89 p = 0.61
Marital status ^b	Elementary	39 (78)	χ ² = 0.25 p = 0.91
	Higher than elementary	11(22)	
Occupational status ^b	Unmarried	26 (52)	χ ² = 0.71 p = 0.82
	Married	24 (48)	
History of disease ^b	Employed	31 (62)	Fisher's exact = 1.26 p = 0.24
	Housewife	19 (38)	
	Yes	18 (36)	
	No	32 (64)	

Note. Continuous data are presented using means ± standard deviations (SD); categorical data are presented using numbers (percent). T = Independent samples t-test, χ² = chi-squared test.

^a = Continuous data are presented using means ± standard deviations (SD).
^b = Categorical data are presented using numbers (percent).

Kolmogorov-Smirnov test. The between group similarity of data was evaluated using t-test and chi-square/Fisher exact tests (p > 0.05).Repeated measures ANOVA was used to compare the intervention and control groups' mean depression scores before, immediately after, and two months after the intervention. Cronbach α was conducted to measure the internal consistency or reliability of the instrument. The significance level of the test was set at 0.05.

3. Results

In our study, the instrument's internal consistency using Cronbach α was 0.819. A total of 90 women in the menopausal stage with depression participated in this controlled trial. The results showed that the effect size for time was 0.12, for groups was 0.16, and for interaction time and groups was 0.16. It is not significant because it is less than 0.2.^{32,33}

The mean ages of the intervention and control groups were 54.18 ± 3.90 and 52.23 ± 11.6, respectively. The mean scores of menopause duration in the intervention and control groups were 5.44 ± 2.85 and 5.77 ± 2.37, respectively. Among the participants, 48.9% in the intervention and 51.1% in the control group were married (Table 1).In intervention group, the mean scores of depression before, immediately after, and two months after the study were 26.97 ± 4.47 (95% CI = 25.3–28.3), 22.55 ± 5.18 (95% CI = 20.9–24.1), and 21.20 ± 5.74 (95% CI = 19.4–22.9), respectively. In the control group, these scores were 26.15 ± 5.01(95% CI = 24.6–27.6), 26.22 ± 5.14 (95% CI = 24.7–27.7), and 26.66 ± 3.87 (95%CI = 25.5–27.8), respectively. Using Repeated Measures ANOVA, the comparison of the mean scores of depression in the two groups indicated that the scores were decreased over time (p < 0.05).

Before the intervention, the mean scores of depression in the intervention and control groups were 26.97 ± 4.47 and 26.15 ± 5.01, respectively. Results of the t-test showed that there was no significant difference between the two groups in terms of depression scores before intervention. However, this difference between intervention and control groups at the end of the intervention was 22.55 ± 5.18 and 26.22 ± 5.14, respectively. Results of the t-test showed that there was a significant difference between the two groups' depression scores at the end of the intervention (p < 0.01). Mean depression scores in the intervention and control groups two months after the intervention were 21.20 ± 5.74 and 26.66 ± 3.87, respectively. Results of the t-test showed that there was a significant difference between the two groups' depression scores two months after the intervention (p < 0.01) (Table 2).

Table 2

Comparison of the mean of depression by BDI-II before, immediately after the last session and two months after the study in the two groups.

Variables	Before the intervention	At the end of the intervention	Two months after the intervention	RM ANOVA p Value		
	(Mean ± SD) (n = 50)	(Mean ± SD) (n = 45)	(Mean ± SD) (n = 45)	Time	Time x group	Group
Intervention group	26.97 ± 4.47 (95% CI = 25.3–28.3)	22.55 ± 5.18 (95% CI = 20.9–24.1)	21.20 ± 5.74 (95% CI = 19.4–22.9)	p < 0.001	p < 0.001	p < 0.001
Control group	26.15 ± 5.01 (95% CI = 24.6–27.6)	26.22 ± 5.14 (95% CI = 24.7–27.7)	26.66 ± 3.87 (95% CI = 25.5–27.8)			

Note: T = Independent samples t-test, RM ANOVA = Repeated Measures ANOVA.

4. Discussion

Our findings are in line with the results of the studies that reported the positive effects of foot reflexology on depression scores in menopausal women. The intervention group's depression was significantly decreased after the foot reflexology in 12 sessions. Similarly, Lee indicated that 12 sessions of foot reflexology over six weeks had positive effects on stress management among women during their menopausal period.⁹ Gozuyesil and Baser showed that 12 sessions of foot reflexology over six weeks was effective in reducing vasomotor problems and increasing quality of life among women in their menopausal period.²² Choi and Lee showed that foot reflexology once a day for three days is an effective nursing intervention to relieve fatigue, stress, and depression for postpartum women.³⁶ Also, Aydin et al indicated that foot reflexology was effective in reducing depressive symptoms and had a positive effect on quality of life in woman.³⁷

However, in contrast to the studies that show the positive effects of the foot reflexology intervention, there are studies reporting that this intervention had no significant effects on patients. Williamson et al indicated that nine sessions of foot reflexology over 19 weeks among women during the menopausal period had no significant effect on their anxiety and depression level.¹⁶ In another randomized controlled trial, it was shown that a 12-session foot reflexology for six weeks was not significant for reducing pain, depression, and tension, and improving relaxation and rest among patients following cardiac surgery.¹⁶ The differences among the studies, including sample sizes or duration of interventions, may explain the discrepancy of the results of different clinical trials.

A limited number of studies regarding reflexology interventions have been conducted in women. McCullough et al indicated the positive effects of reflexology, 30 min twice a week for six weeks, on women's stress.¹³ Li et al also showed the positive effects of foot reflexology, 30 min in five consecutive evenings, on reducing stress level and improving quality of sleep in postpartum women.³⁸ However, Moyle et al indicated no significant effects of foot reflexology on reducing agitation and depression among women with dementia.¹⁷ The contradictory results among the studies may be due to methodological limitations of the studies or differences among their reflexology designs. The differences among reflexology designs may include the number of reflexology sessions, training duration, and intervals between the sessions.

There are arguments about real predictors of the positive results regarding interventions in clinical trials. For example, one of the predictors that might interfere with the results of reflexology interventions is the communication between researchers and participants for follow-up and intervention purposes. A sense of connection to a therapist may bias the results regarding the intervention group participants' lower depression scores.⁷

5. Conclusion

In the current study, the foot reflexology intervention was found to be effective in decreasing menopausal women's depression. As a safe and non-invasive intervention, the foot reflexology is recommended to be included in the plan of treatment for reducing depression among

menopausal women. However, further clinical trials are recommended to verify and confirm the intervention design.

6. Limitations and recommendations

This study had limitations. The participants in the control group received no intervention; therefore, we cannot distinguish that the positive effect of the intervention was associated with the reflexology or therapeutic contacts between the participants and the investigator. Also Intention-to-treat (ITT) analysis was not performed regarding the sample attrition. However, limitations due to lack of blinding and small sample size was not mentioned.

It is recommended that in future trials, participants in the control group receive an intervention in order to reduce confounding variables and biases regarding the interpretation of the results.

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Declaration of Competing Interest

The authors declared no conflicts of interest in this study.

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