

The Effect of Foot Reflexology on Pain and Anxiety in Pregnant Women Candidates for Amniocentesis: A Randomized Clinical Trial

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ARTICLE INFO	ABSTRACT
Article type: Original article	Background & aim: Most pregnant women have anxiety regarding screening tests such as amniocentesis. The current research was carried out to examine the effect of foot reflexology on pain and anxiety in pregnant women candidates for amniocentesis.
Article History: Received: 15-Sep-2024 Accepted: 14-Apr-2025	Methods: This randomized clinical trial included 60 pregnant women candidates for amniocentesis at a training Hospital in Mashhad, Iran. The participants included in the study were randomly allocated to intervention (N=29) and control (N=31) groups. The participants in the intervention group performed 20 minutes of foot reflexology (10 minutes on each foot), daily in the solar plexus area for 10 consecutive days. The control group received no additional intervention beyond routine care. Data were collected using demographic and obstetrics questionnaires, the Spielberger State-Trait Anxiety Inventory, and the Visual Analogue Scale. The data were analyzed using SPSS 16 software with independent t-tests, chi-square tests, and covariance analysis.
Key words: Reflexology Amniocentesis Anxiety Pain	Results: The reflexology group had significantly lower mean state anxiety scores than the control group immediately and 10 days after amniocentesis ($P<0.001$ and $P<0.001$, respectively). The mean trait anxiety scores in the foot reflexology group were significantly lower at 10 days after amniocentesis ($P<0.001$). The reflexology group had significantly less pain intensity immediately after amniocentesis ($P=0.001$). Conclusion: Reflexology is an effective method to reduce pain and anxiety in pregnant women who underwent amniocentesis.

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Introduction

Amniocentesis is carried out at 15–20 weeks' gestation to diagnose fetal abnormality (1-2), in which a needle is inserted through the abdomen into the uterine cavity to take samples of the amniotic fluid (3). The results of amniocentesis are available 7-14 days after the test. Amniocentesis is associated with discomfort

and pain, and pregnant women undergoing the procedure often expect it to be painful (4). Severe pain may increase maternal anxiety, and anxiety and pain are known to have a bidirectional, mutually reinforcing relationship (5). Most pregnant women worry about fetal abnormalities and screening tests. In a study by Karimi et al.

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(2017), the mean score of state anxiety in pregnant women undergoing amniocentesis was 56.09, indicating a high level of anxiety in these women (6). Anxiety related to pregnancy is also associated with maternal and fetal complications (7). Furthermore, the waiting period for amniocentesis results can cause psychological distress, stress, and anxiety because women are concerned about future outcomes that they cannot predict or control. Therefore, the psychological aspects of invasive procedures and the waiting period for their results should be considered in women undergoing amniocentesis (8).

Pharmacological and non-pharmacological methods have been considered during pregnancy for managing anxiety and pain. For example, shorter-acting benzodiazepines have been used to manage anxiety; however, evidence regarding their safety during pregnancy is conflicting, and clear data on their use in pregnancy remain limited (9).

Reflexology is one of the commonly used approaches in complementary medicine and has been integrated into obstetric care in various settings worldwide. According to reports, this technique is safe and relatively easy to learn (10). Reflexology has been reported to reduce stress, anxiety, and tension, as well as to improve blood circulation (11). Although several mechanisms have been proposed, the precise mechanism underlying the effects of reflexology remains unclear. One proposed mechanism is the stimulation of the hypothalamus and pituitary gland, which may promote the release of endorphins and thereby reduce pain (12). Reflexology may also possibly facilitate the functions of neural pathways and trigger the secretion of endorphins and enkephalins that play a pivotal part in the pain-modulating process (13). Other mechanisms by which reflexology may contribute to stress and anxiety reduction consist of the activation of nervous system parasympathetic branches and suppression of sympathetic nervous system functioning (14). Four reflex points on the soles of the feet have been described in relation to the management of pain and anxiety: the solar plexus, heart, hypophysis,

and liver. Among these, the solar plexus point is an important area in foot reflexology. Solar plexus point massage has been reported not to be contraindicated in pregnant women before 18 weeks of gestation (15).

Kapıkıran et al. (2021) reported greater reductions in pain and greater increases in beta-endorphin and comfort levels among patients undergoing liver transplantation who received foot reflexology compared with those who did not (12). Yılar Erkek et al. (2018) reported that foot reflexology had positive effects on reducing women's anxiety scores during labor (13). Ghasemi et al. (2020) also showed that foot reflexology in hemodialysis patients reduced their levels of anxiety (16). However, Razmjoo et al. (2012) indicated that reflexology was ineffective in reducing anxiety regarding cesarean section (17).

Despite the high levels of anxiety experienced by pregnant women undergoing amniocentesis and during the waiting period, effective non-pharmacological approaches to reduce pain and anxiety remain limited. Previous studies have reported inconsistent findings. Hanprasertpong et al. (2015) found that aromatherapy with menthol did not significantly reduce the post-procedure pain or anxiety compared with the control group (18). However, Ventura et al. (2012) demonstrated that a relaxation intervention significantly decreased anxiety and cortisol levels in pregnant women awaiting amniocentesis (19). The results suggest that some non-pharmacological interventions may be effective in reducing anxiety in this context, but the evidence is inconsistent. Therefore, the current study was carried out to assess the effect of foot reflexology on pain and anxiety among pregnant women candidates for amniocentesis.

Materials and Methods

This two-group randomized clinical trial study was conducted on pregnant women candidates for amniocentesis from March 2019 to June 2020 in a training hospital in Mashhad, Iran. The clinical trial registration code was IRCT20190731044399N1.

The sample size was estimated as 31 for each group based on the formula for mean

comparison at a 95% confidence level and 80% power, and according to the study conducted by Chen et al., which evaluated the mean anxiety level in women after cesarean section ($S_1:3.33$, $S_2:0.96$, $X_1:5.07$, $X_2:3.33$) (20). To determine the sample size, the following formula was used:

$$n_1 = n_2 = \frac{(S_1^2 + S_2^2)(Z_{1-\frac{\alpha}{2}} + Z_{1-\beta})^2}{(\bar{X}_1 - \bar{X}_2)^2}$$

Then, considering the probability of a 10% dropout, the sample size was set at 33 subjects in each group, and a total of 66 pregnant women were assigned to the two groups.

Convenience sampling was performed, and pregnant women were randomly assigned to two groups to receive either foot reflexology or control.

Inclusion criteria were: gestational age of 15 to 18 weeks, having literacy, wanting pregnancy, score ≤ 53 in the Spielberger State-Trait Anxiety Inventory (STAI), no medical illness and obstetric problems, no smoking or substance abuse, no abnormal findings in the feet, and maternal Body Mass Index (BMI) of $18.5 < \text{BMI} < 30 \text{ kg/m}^2$. The subjects were excluded from the study for any of the following reasons: unwillingness to cooperate, history of 3 or more abortions, having active vaginal bleeding, history of amniocentesis in a previous or current pregnancy, history of hospitalization, history of mental disorders, use of psychiatric drugs, and traumatic events during the last 6 months, failure to perform the intervention twice in a row or three intermittent days during the study, attempting amniocentesis more than one time, and unusual sensitivity to touch at the point on the feet.

The researcher provided the research units with the necessary explanations regarding the purpose and method of the research. Also, it was explained that their participation in the study was completely voluntary and they would be free to withdraw from the study at any time if they did not want to continue the study. Pregnant women were enrolled after obtaining written consent. At the beginning of the study, the demographic and obstetric questionnaire and the State-Trait Anxiety Inventory (STAI) were completed for eligible

participants. The demographic and obstetric characteristics, such as education level, occupation, spouse's education level, gestational age, number of pregnancies and deliveries, number of abortions, number of disabled children, cause of amniocentesis, mothers' received information regarding fetal screening tests and amniocentesis, and source of this information, were recorded.

The STAI was developed in 1964 by Spielberger et al (21). The scale has 40 items and measures anxiety. The items 1-20 are used to measure state anxiety, and the items 21-40 are used to measure trait anxiety. The items of this test have "very low, low, moderate, and high" scales, and each item of the test receives a score of 1 to 4 based on the answer. Score 4 is the highest level of anxiety. Scores were interpreted as follows: mild: 20-31, low to moderate: 32-42, moderate to high: 43-53, relatively severe: 54-64, severe: 65-75, and very severe state and trait anxiety > 76 (14). The validity and reliability of the scale were confirmed by Mahram et al. (1993) on 600 subjects in Iran. In Mehram's study, the reliability coefficient of the test was examined separately in two groups, norm and criterion. The reliability level of the norm group was calculated as the Cronbach's alpha coefficient of 0.9451. Moreover, this reliability was calculated for the criterion group separately, and its value was reported to be 0.9418 (22). The STAI scale is a frequently used reliable instrument in Iranian studies. The reliability of the questionnaire was calculated by Cronbach's alpha method and was equal to 0.85 in the present study.

The Visual Analog Scale (VAS) is a 10-cm horizontal line with 0-10, the two ends of which represent the minimum and maximum levels of pain, respectively. Visual Analogue Scale has been widely used in various studies. Various studies have confirmed the scale's reliability and validity (23-24). In an Iranian study, the VAS demonstrated good test-retest reliability ($\text{ICC} = 0.87$) when evaluated as part of the Iranian Short-Form McGill Pain Questionnaire (25).

For the randomization process, two bags were prepared. The first bag contained envelopes labeled with the days of the week, and the second bag contained two envelopes

labeled “intervention” and “control.” First, one envelope was randomly drawn from the first bag to determine the selected day and whether it was an even or odd day. Subsequently, one envelope was randomly drawn from the second bag to determine which study group would be assigned to the selected type of day. For example, if an even-numbered day was selected from the first bag and “intervention” was selected from the second bag, participants in the intervention group were recruited on even-numbered days, whereas participants in the control group were recruited on odd-numbered days. In contrast, if an odd-numbered day was selected from the first bag and “intervention” was selected from the second bag, participants in the intervention group were recruited on odd-numbered days, while participants in the control group were recruited on even-numbered days. Finally, the even days were assigned to recruit participants for the intervention group and the odd days were assigned to recruit participants for the control group. The allocation of participants to the intervention and control groups was performed by an independent researcher who was not involved in participant recruitment or intervention procedures. On the day of amniocentesis, the researcher was present at the center, and the research units completed the questionnaires 30 minutes before amniocentesis and immediately after the procedure. To minimize the potential effect of the researcher's presence in the intervention group, the researcher remained beside the research units for 20 minutes before amniocentesis.

In the intervention group, foot reflexology in the solar plexus (almost four fingers' width below the base of the toes, located in the center (middle of the diaphragm)) was performed once, 30 minutes before amniocentesis, by the researcher for 10 minutes on each foot (20 minutes in total) (26). The skill of the researcher in the field of correct general and specific reflexology of the solar plexus region of the soles of the feet was confirmed during the training course under the supervision of a specialist in

complementary medicine. Foot reflexology was performed by hand through the pressure and massage of the solar plexus area. At first, a general massage was performed for 2 minutes to prepare the feet. A general massage is a surface tactile massage in which the same background movements are used to warm the feet, including warming the feet by hand or performing specific movements and holding the face and underfoot with both hands, doing the rotation of the foot in and out, and movements in the heel as well as the foot massage. Then, a specific massage was performed on the point of the solar plexus as a general reflexology for 7 minutes, and in the last stage, a 1-minute gentle movement from top to bottom was performed on the entire back and sides of the foot with the help of the fingers of both hands and thumb supports (this massage procedure was separately performed for both feet). Then, the researcher asked the pregnant women to show the point where the massage was performed to confirm the correctness of the desired point (solar plexus). The participants were told that the intensity of the massage was such that it felt numb in the position; then the pregnant mother was directed to the amniocentesis room.

Immediately after amniocentesis, the STAI scale and Visual Analogue Scale (VAS) were completed for both groups. Both groups received routine care. The intervention group performed foot reflexology for 20 minutes in the solar plexus area for 10 days every day. Participants did not receive their amniocentesis results online, and the researcher received the participants' amniocentesis results. Ten days after amniocentesis, the participants of both groups (the intervention group on even days and the control group on odd days) referred to the clinic, and the STAI scale was completed before the amniocentesis results were delivered to them by the researcher. Daily acupressure registration forms were given to the intervention groups, and the participants completed the daily performance or non-performance of acupressure by reporting the reasons. During the research, the researcher reminded the

participants to perform daily acupressure and complete the checklist via Short Message Service and answered their questions. The control group received no additional intervention beyond routine care.

The researcher contacted the research unit in the control group daily, answered their questions, and completed the research questionnaire over the phone. At the end of the 9th day, a phone call was made, and an appointment was set at the perinatology clinic of the hospital on the 10th day, and the Spielberger anxiety questionnaire was again completed in Both Groups. At the end of the study, the pamphlet on reflexology was given to the control group, and participants in both groups were given a gift. Data were analyzed using SPSS software (version 16, SPSS Inc., Chicago, IL, USA). The characteristics of the participants were described using descriptive statistics. The normal distribution of quantitative variables was assessed using Kolmogorov-Smirnov and Shapiro-Wilk tests. After checking the normality of the data, an independent t-test was used for quantitative variables and the Chi-square test for qualitative variables. Covariance analysis was used to reduce the effect of pre-intervention. A P-value of <0.05 was considered significant.

Results

Ninety-three women were screened for eligibility, 27 were excluded (did not meet inclusion criteria [n=22] and declined to participate [n=5]), and 66 women were randomized into the control (n=33) and intervention (n=33) groups. Two women in the control group dropped out of the study. One woman did not want to continue participating, and one woman underwent more than one amniocentesis. In the intervention group, four women dropped out of the study. Two did not want to continue participating, and two women did not perform the intervention two times in a row or on three intermittent days in the study. Finally, the study was completed by 60 women, 31 in the control group and 29 in the intervention group (Figure 1). Demographic and obstetric characteristics of the two groups are shown in Table 1. The two groups

were similar in terms of demographic and obstetric characteristics, with no statistically significant differences between them ($P>0.05$).

The mean score of state anxiety before the intervention in the intervention and control groups was not statistically significant ($t=1.78$, $df=58$, $P=0.081$). Immediately after amniocentesis, the mean state anxiety score was significantly lower in the foot reflexology group (40.70 ± 3.57) compared with the control group (49.07 ± 2.27) ($t=10.82$, $df=58$, $P<0.001$). Ten days after amniocentesis, the mean state anxiety score remained significantly lower in the foot reflexology group (33.90 ± 3.85) compared with the control group (50.90 ± 1.99) ($t=21.47$, $df=58$, $P<0.001$) (Table 2). Intragroup comparison showed that in the control group, the mean scores of state anxiety significantly increased 10 days after amniocentesis compared to immediately after amniocentesis ($P<0.001$). In the foot reflexology group, the mean state anxiety scores significantly decreased immediately after amniocentesis and 10 days after amniocentesis compared with baseline (before amniocentesis). Furthermore, the mean state anxiety score was significantly lower 10 days after amniocentesis compared with immediately after the procedure ($P<0.001$). Analysis of covariance was used to remove the confounding effect of the pre-amniocentesis state anxiety score. The results of the test showed that after adjustment, the mean score of state anxiety immediately and ten days after amniocentesis was significantly lower in the foot reflexology group ($P<0.001$).

Before the intervention, the mean score of trait anxiety in the foot reflexology group was 47.40 ± 3.25 and in the control group was 48.33 ± 2.63 , indicating no significant difference ($t=1.22$, $df=58$, $P=0.243$). The mean scores of trait anxiety were significantly lower in the foot reflexology group (36.73 ± 3.16) than in the control group (49.47 ± 2.39) at 10 days after amniocentesis ($t=17.60$, $df=58$, $P<0.001$).

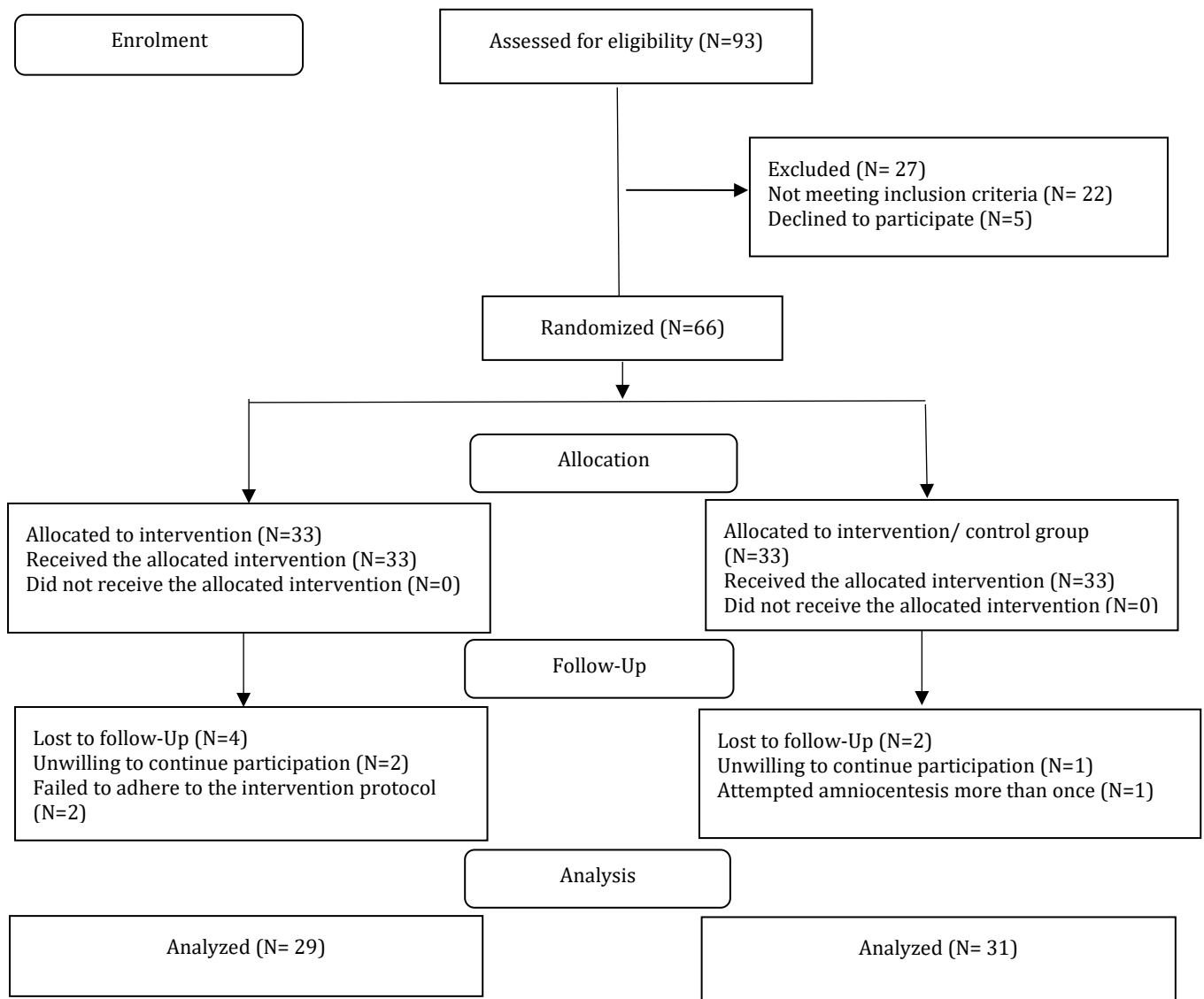


Figure 1. CONSORT Flowchart of the study

Table 1. Demographic and obstetric characteristics in the two groups

Variable	Groups		P-Value
	Control (N=31)	Foot Reflexology (N=29)	
Age(year)	4.80±31.83	6.43±31.93	P=0.950
Educational level			
Reading and writing	2(6.45)	2(6.89)	P=0.749
Primary school	2(6.45)	4(13.79)	
Secondary and high school degree	15(48.38)	11(37.93)	
Academic	12(38.70)	12(41.37)	
Occupation			
Housewife	27(87.09)	21(72.41)	0.364
Student	1(3.22)	2(6.89)	
Employee	3(9.67)	6(20.68)	
Husband's educational level			
Reading and writing	2(6.45)	3(10.34)	0.651
Primary school	6(19.35)	4(13.79)	
Secondary and high school degree	16(51.61)	12(41.37)	
Academic	7(22.58)	10(34.48)	
Gestational age			
15-16 weeks	24(77.41)	21(72.42)	0.596
More than 16 weeks	7(22.58)	8(27.58)	
Number of pregnancies			
1-2 times	14(45.16)	14(48.27)	0.741
3-4 times	13(41.93)	13(44.82)	
5 and more	4(12.90)	2(6.89)	
Number of deliveries			
None	8(25.80)	8(27.58)	0.957
1	8(25.80)	7(24.13)	
2	10(32.25)	8(27.58)	
3-4	5(16.12)	6(20.68)	
History of abortion			
No	23(74.19)	23(9.31)	0.640
Yes	8(25.80)	6(20.68)	
Disabled child			
No	30(96.77)	27(93.10)	0.514
Yes	1(3.22)	2(6.89)	
Information about fetal screening tests			
No	18(58.06)	19(65.51)	0.553
Yes	13(41.93)	10(34.48)	
Information about amniocentesis			
Little	21(67.74)	16(55.17)	0.231
Moderate	7(22.58)	12(41.37)	
Much	3(9.67)	1(3.44)	
Cause of amniocentesis			
Abnormal first -trimester screening results	13(41.93)	13(44.82)	0.352
Abnormal second-trimester screening results	6(19.35)	2(6.89)	
High NT	12(38.70)	14(48.27)	
Source of information			
Physician	9(29.03)	8(27.58)	0.695
Midwife	7(22.58)	4(13.79)	
Acquaintances	6(19.35)	6(20.68)	
The media	9(29.03)	9(31.03)	

Variable	Groups		P-Value
	Control (N=31)	Foot Reflexology (N=29)	
Two sources	0 (0)	2 (6.89)	

Quantitative variables are expressed as mean $\pm$ SD, and qualitative variables are expressed as No. (%)

Table 1. Comparison of the mean scores of state anxiety in both groups before, immediately after, and ten days after amniocentesis

Group	Time of assessment			P-value related to the analysis of covariance test	
	Before amniocentesis	Immediately after amniocentesis	Ten days after amniocentesis		
	Mean $\pm$ SD	Mean $\pm$ SD	Mean $\pm$ SD	Anxiety before	Group
Control	50.00 $\pm$ 2.15	49.07 $\pm$ 2.27	50.90 $\pm$ 1.99		
Foot reflexology	48.97 $\pm$ 2.36	40.70 $\pm$ 3.57	33.90 $\pm$ 3.85	F=1.22	F=309.10
P-value of independent t	.781t=	t=10.82	t=21.47	df=1	df=1
	df=58	df=58	df=58	P=0.275	P<0.001
	P=0.081	P<0.001	P<0.001		

Intragroup comparison showed that in the control group, the mean scores of trait anxiety significantly increased 10 days after amniocentesis compared to before amniocentesis ($P=0.019$), but significantly decreased in the foot reflexology group ($P<0.001$). Analysis of covariance was used to

remove the confounding effect of the trait anxiety score before amniocentesis. The test results revealed that after adjustment, the mean score of trait anxiety ten days after amniocentesis was significantly lower in the foot reflexology group ($P<0.001$) (Table 3).

Table 2. Comparison of the mean scores of trait anxiety in the participants before and ten days after amniocentesis

Group	Time of assessment		P-value related to the analysis of covariance test	
	Before amniocentesis	Ten days after amniocentesis		
	Mean $\pm$ SD	Mean $\pm$ SD	Anxiety before	Group
Control	48.33 $\pm$ 2.63	49.47 $\pm$ 2.39		
Foot reflexology	47.40 $\pm$ 3.25	36.73 $\pm$ 3.16	F=7.20	F=142.50
P-value of independent t	t=1.22	t=17.60	df=1	df=1
	df=58	df=58	P=0.009	P<0.001
	P=0.243	P<0.001		

The mean pain intensity immediately after amniocentesis in the control group was 6.41 $\pm$ 1.83, and in the intervention group was 4.96 $\pm$ 1.49. Immediately after amniocentesis,

the pain was significantly lower in the foot reflexology group than in the control group ($P=0.001$) (Table 4).

Table 3. Comparison of the mean pain score in the participants after amniocentesis

Stage Group	Control Mean $\pm$ SD	Foot reflexology Mean $\pm$ SD	P-value of independent t
After amniocentesis	6.41 $\pm$ 1.83	4.96 $\pm$ 1.49	t=3.34 df=58 P=0.001

Discussion

The present study aimed to determine the effect of foot reflexology on pain and anxiety in pregnant women undergoing amniocentesis. The findings indicate that foot solar plexus reflexology is associated with decreased pain intensity and state-trait anxiety related to amniocentesis. The present results can be interpreted in accordance with previous research on the effects of reflexology on pain and anxiety in pregnancy, with some studies supporting our findings and others reporting different results.

The reduction of anxiety observed in the present study is consistent with findings from several clinical trials performed among pregnant women. Levy et al. (2020) demonstrated a positive short-term effect of foot reflexology on anxiety during labor in primiparous women with moderate to severe anxiety. Moghimi Hanjani et al. (2014) showed that the reflexology of the solar plexus, pituitary gland, and uterus decreased the labor anxiety of primigravidas (27). Moreover, El-Fekey et al. (2018) found that combining foot reflexology with diaphragmatic breathing exercises for six weeks led to a highly significant reduction in the level of anxiety in 50 primigravida women in the third trimester compared to only breathing exercises (28). Navaee et al. (2020) reported that foot reflexology massage considerably reduced the anxiety of primiparous women before caesarean section (29). In the present study, foot reflexology likewise reduced anxiety among pregnant women undergoing amniocentesis. Although these studies differed in clinical setting as well as the reflexology points used, duration and frequency of the intervention, and timing of treatment, their findings consistently suggest that reflexology may help reduce anxiety during stressful periods of pregnancy and childbirth.

This finding is further supported by recent systematic reviews and meta-analyses of randomized controlled trials. A systematic review and meta-analysis of six studies by Abbaszadeh et al. reported that reflexology considerably reduced maternal anxiety during labor when compared with routine care or simple massage (30). Likewise, a

systematic review and meta-analysis of thirteen randomized controlled trials that included 1,189 pregnant women, conducted by Yang et al. In 2024, found that foot reflexology significantly reduced anxiety compared with control interventions (31). Also, a systematic review in 2023 concluded that reflexology may be effective in reducing anxiety during pregnancy (32). Reviews show a potential anxiolytic effect of reflexology, but due to methodological limitations and heterogeneity of available evidence, it should be interpreted with caution. Moreover, most previous studies have focused on anxiety associated with labor, whereas evidence regarding anxiety related to amniocentesis remains limited. The present study adds to the existing evidence by examining the effect of foot reflexology in pregnant women undergoing amniocentesis, a procedure that can be associated with uncertainty about fetal health and considerable psychological distress.

In the present study, both state and trait anxiety decreased after the intervention. However, some studies have yielded inconsistent findings on the effect of reflexology on anxiety. McVicar et al. (2007) found state anxiety was reduced, but trait anxiety was not significantly affected (33). Yilar Erkek et al. (2018) found that the state anxiety scores of women who received foot reflexology were lower than the control group after the intervention and in the active phase of labor, but the difference in anxiety scores before and after the intervention was not statistically significant ($p = 0.820$) in the reflexology group (14). Moreover, Razmjoo et al. (2012) found that foot reflexology reduced the pain intensity in women after cesarean section, but did not significantly decrease anxiety (17). Such differences may be attributable to differences in the study population, clinical setting, timing and frequency of the intervention, duration of treatment, and instruments used to measure anxiety. For example, in study by Razmjoo et al., anxiety was measured by a visual analog scale, while in the present study, the Spielberger State-Trait Anxiety Inventory was used, which measures state and trait anxiety separately. Moreover, reflexology was performed only once for 20 minutes, two hours after cesarean section in their study, whereas participants in the present study performed reflexology daily for 10 days, with an additional session 30 minutes before amniocentesis. Another possible explanation for

these inconsistent findings may be related to differences in the characteristics of anxiety being assessed. State anxiety is a temporary response to a stressful situation, whereas trait anxiety reflects a more general and lasting tendency to feel anxious. Thus, trait anxiety may be less responsive to short-term interventions and may require repeated or longer-term interventions to show measurable changes. The repeated intervention used in the present study, with reflexology performed daily for 10 days by the participants, may have contributed to reducing both types of anxiety. Repeated practice, as opposed to single-session interventions, may allow more sustained opportunity for relaxation and may be able to influence anxiety responses over time. However, this explanation should be interpreted with caution, and further studies are needed to clarify whether repeated reflexology has a sustained effect on state and trait anxiety.

Regarding pain, the findings of the present study are also consistent with recent evidence in pregnant women. Mohamed et al. (2023) demonstrated that foot reflexology reduced low back pain and improved functional abilities in 90 pregnant women (34). Similarly, Mohan and Varghese (2020) reported that 20 minutes of foot reflexology at five points of the foot significantly reduced labor pain at the 20th minute and at the 40th minute after treatment in 50 primigravida mothers (35). Furthermore, Liang et al. (2023), in their systematic review, supported the impact of reflexology on labor pain, but stated that well-conducted and larger studies are needed (32). In the present study, despite the use of only one reflexology point (the solar plexus) and a relatively short 20-minute intervention, pain intensity associated with amniocentesis was reduced. This finding suggests that a brief reflexology intervention may have potential as a supportive approach for procedural pain, although the effect of this specific protocol should be confirmed in future studies.

In the current study, participants in the intervention group did not report any local complications related to foot massage, and the intervention could be performed without specialized equipment. These characteristics can make foot reflexology a simple and fairly accessible complementary therapy for pregnant women. However, personal differences in pain perception,

baseline anxiety, sociocultural background, and psychological characteristics may contribute to responses to the intervention. A strength of this study was using random allocation, which could have reduced the effect of previously mentioned factors between groups; however, the absence of blinding of participants and the intervention provider is a limitation.

Given the limited evidence specifically addressing non-pharmacological interventions for pain and anxiety associated with amniocentesis, further well-designed randomized controlled trials with larger sample sizes are warranted.

Conclusion

The results of this study demonstrated that reflexology was effective in reducing pain and anxiety in women undergoing amniocentesis. Therefore, foot reflexology can be considered a simple, non-invasive, accessible, and self-administered technique to help reduce pain and anxiety associated with amniocentesis.

Declarations

Acknowledgements

The authors are grateful to all the women who participated in this study.

Conflicts of interest

The authors declared no conflicts of interest.

Ethical approval

At the beginning of the study, the participants were informed about the purpose and procedures of the research, their right to participate voluntarily, and their right to withdraw from the study at any time without consequences. Written informed consent was obtained from all participants before enrollment. They were also assured that their personal information would be kept confidential.

Code of Ethics

The approval code of this research from the Ethics Committee of Mashhad University of Medical Sciences is IR.MUMS.NURSE.REC.1398.042.

Use of Artificial Intelligence

The use of artificial intelligence (ChatGPT and Grammarly) in this study is restricted to grammar and language editing.

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Authors' contributions

ZA and MS contributed to the conception and design of the study. ZA, SRM, and HA supervised the study. MS, MS, and FT participated in data collection. SRM analyzed and interpreted the data. MS drafted the manuscript. All authors read and approved the final manuscript.

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