The Effect of Short-term Foot Reflexology in Improving Constipation Symptoms During Pregnancy: A Two-Armed, Randomized Controlled Trial

Fahimeh Sehhatti[1] , Ciara Hughes[2] , Mojgan Mirghafourvand[3] , Zahra Anjoman Azari[4*]

Abstract
Objectives: Reflexology is a popular type of complementary medicine in medical practices, especially in midwifery fields.
Materials and Methods: This randomized controlled trial aimed to determine the effect of foot reflexology on idiopathic constipation symptoms, as well as anxiety and fetal activity during pregnancy. This study was conducted on seventy-four nulliparous women with constipation, referring to private and public health care centers in Tabriz-Iran, between 2017 and 2018. The participants were then randomly assigned to foot reflexology or control groups. The intervention group underwent 12 minutes of weekly foot reflexology treatment for 6 weeks. Constipation symptoms were measured at baseline and 6 times (weekly) after the intervention by the Constipation Assessment Scale (CAS). In addition, the State-Trait Anxiety Inventory (STAI) questionnaire was used to measure the participant's anxiety at baseline and 6 weeks after the completion of the study. Finally, fetal movements were measured at baseline and 6 times (weekly) after the intervention using a kick chart.
Results: Based on the results, 97% of women reported improvement in their CAS measures at the end of six weeks following reflexology. The mean scores of STAI at the end of the intervention were 38.5 and 42.2 (State anxiety), as well as 39.1 and 40.2 (Trait anxiety) in the reflexology and control groups, respectively. Statistically significant differences in fetal movements between the two groups were only observed in the fourth ($P=0.001$) and fifth weeks ($P=0.007$) after intervention sessions. The results further indicated that about 67% of mothers were satisfied with reflexology intervention for improvement in their constipation symptoms. Eventually, no harmful side events were reported among women.
Conclusions: Short-term foot reflexology in this context may have potential healing benefits in improving constipation and anxiety symptoms during pregnancy. However, further investigation for antenatal reflexology is necessary.
Keywords: Constipation, Foot massage, Anxiety, Fetal activity

Introduction

Constipation as a prevalent symptom of gastrointestinal disorders impacts the general health and quality of life (1). In the second trimester of pregnancy (1), the prevalence rate ranges from 9% (2) to 40% (3,4).

The modified Rome II criteria are used in pregnancy and require the inclusion of at least 2 out of 6 constipation symptoms of lumpy or arid feces, straining, incomplete evacuation sensation, digital efforts for evacuation, anorectal blockage, less than 3 evacuations in a week (5), and, at least, 25% of defecations within the last 1 month rather than 3 months (2). The probable causes of functional constipation include: inadequate intake of the fiber and water (6), an inactive lifestyle, and medication side effects such as iron uses (3,7). The compressive effects of the fetus (3,4) and the shifting levels of progesterone may also decrease colonic movements, especially within the second and third trimesters (7). Abdominal distension, bloating,

anal pain are significant constipation complications (2, 8).

Anxiety can affect health indexes (9) and anxiety-related disorders are more often reported by patients with slow bowel functions (10). Based on another report, in the perinatal period, a high prevalence of anxiety is observed in patients with functional constipation (11).

Nulliparous women feel fetal activities for the first time between 18 and 20 weeks and 4-100 fetal movements per hour are considered normal (12). Fetal movement counting through "Kick-counting" (13) is commonly acceptable (14) while less than three kicks per hour is considered as an abnormal result based on the study of Sadovsky et al (15).

The reflexology method is a common type of complementary medicine and a healing method (16). A reflexologist applies controlled pressure on particular reflex zones often on the soles (17). The treatment aims to re-balance the function of internal organs and stop stress

Key messages

► To measure objective outcomes, the use of reliable tools such as the Bristol Stool Scale and the effect of reflexology on the fetal heart rate and activity would also be recommended for further studies.

and homeostasis (18).

Rare studies investigated the effects of foot reflexology on constipation symptoms and fetal movements. Accordingly, this study was conducted to determine the effect of foot reflexology on constipation symptoms (primary outcomes) in addition to anxiety and fetal activity (secondary outcomes).

Materials and Methods
Study Design and Setting
This randomized controlled trial was conducted on 74 nulliparous women with constipation diagnosis, who were recruited from 35 out-patient public and private healthcare centers in Tabriz, Iran.

The inclusion criteria included being nulliparous pregnant women at 23-28 weeks, experiencing a single pregnancy, being within the age range of 16-45 years, having middle school literacy, having a score of 9 to 16 based on a Constipation Assessment Scale (CAS), and having no medical conditions such as a history of abortion or bleeding in the present pregnancy. On the other hand, the exclusion criteria were undergoing previous abdominal or pelvic radiation therapy, suffering from neurological diseases, having a history of inflammatory bowel disease and surgery (other than appendectomy), having fungal foot infections or verrucae in the leg, currently using foot reflexology and treatment for thyroid disease and regular narcotic use, suffering from diabetes/gestational diabetes, cardiac diseases, and high blood pressure, and experiencing placenta previa and abdominal pain with an unknown cause.

Sample Size Estimation
The sample size was calculated based on the mean scores of CAS. The minimum calculated sample size for each group was 34 according to the Ghaffari et al (8) by considering $m_1 = 16.3$ and $sd_1 = sd_2 = 8$ and assuming a 30% reduction in the scores following intervention ($m_2 = 11.41$), $\alpha = 0.05$ and $\beta = 0.2$. Therefore, the final sample size was computed as 37 per group by estimating a 10% dropout rate.

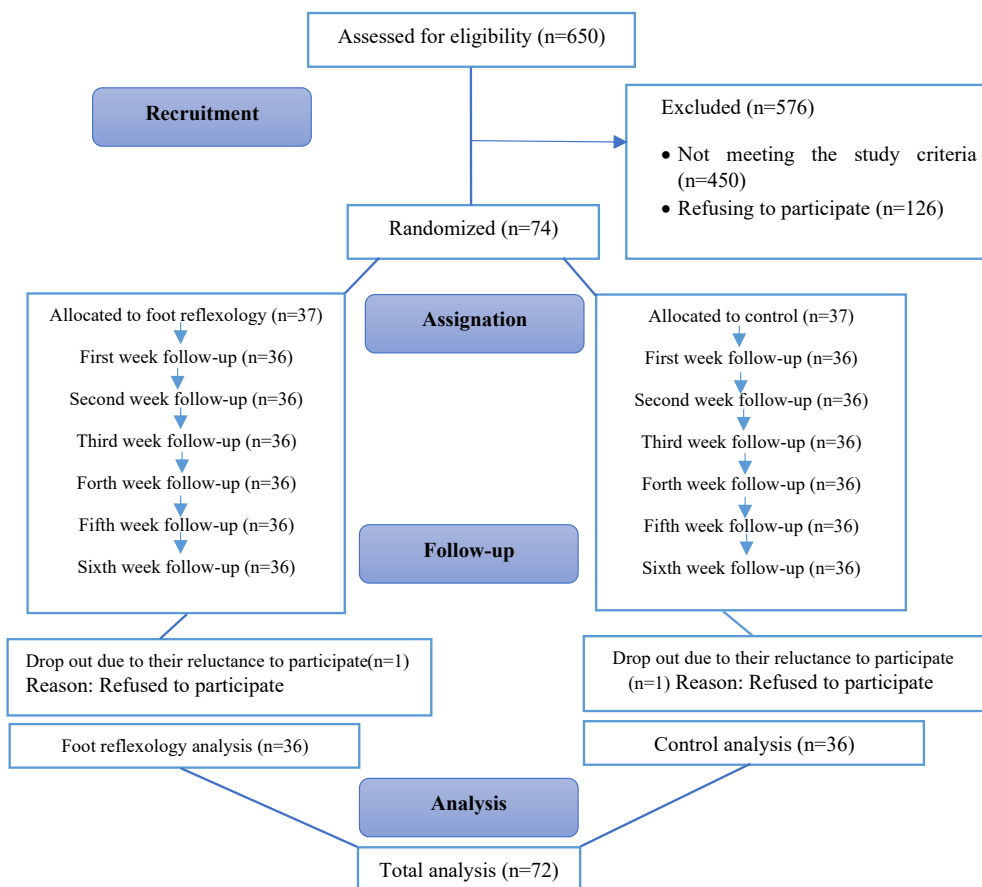As shown in Figure 1, a convenience sample (N = 74) was recruited from 35 out-patient public and private

Figure 1. CONSORT Flow Diagram.

healthcare centers in Tabriz-Iran between October 2017 and December 2018. After obtaining informed consent, eligible participants completed outcome measures and then were followed up weekly for 6 weeks. Of 74 women, 72 (97.3%) participants completed all treatments. One woman in each group was excluded from the study due to a decline in continuing their participation. A researcher, who was blinded to the intervention allocation, analyzed the results. Thirty-seven participants were assigned to foot reflexology (the intervention group received brief 12-minute foot reflexology) and standard care (the control group received conventional care for constipation) groups through blocked randomization methods with block sizes of 4 and 6 and a 1:1 allocation ratio. Random allocation was done by a noninvolved individual in sampling and data collection. Then, sealed opaque envelopes were used for allocation concealment and the type of intervention was written on a paper and placed in sequenced envelopes.

Questionnaire Description

Participants completed a socio-demographic questionnaire before study initiation. The primary outcome measure was constipation severity, which was assessed weekly using the CAS in both study groups for six weeks (19). The scale included eight items and the recorded scores were 0, 1, 2, 3, and 4, respectively. The total CAS score ranged from 0 to 32 and higher scores indicated worse constipation symptoms.

Data Collection

The secondary outcomes were the mean score of anxiety and frequency of fetal movements. All participants completed the State-Trait Anxiety Inventory (STAI) questionnaire at baseline (before the intervention) and on week six (after the intervention). This inventory contained 20 questions that were scored ranging from 20 to 80 and higher scores correlated with greater anxiety levels (20). A "kick-chart" based on Sadowsky's method (21) was given to the mothers to count the number of fetal movements and record the results. These data were gathered at the baseline (before the intervention) and then every week for six follow-up weeks in both groups (twenty minutes after each reflexology session in the intervention group).

Then, participants were asked to report any intervention-related adverse events or unpleasant effects such as local or whole-body heat sensation, sweating, and the sensation of cold, chilling, and other adverse events using a checklist of side effects based on an overview of the literature (22) during the intervention. Further, the mother's satisfaction with foot reflexology was assessed on the sixth week following intervention by a self-administered checklist.

A Chinese traditional medicine practitioner trained the researcher who performed the intervention. The reflexology intervention was delivered in such a way to minimize confounder contextual factors, therefore, no background music or aromatherapy oil was used within

the treatments, and each session of reflexology lasted for 12 minutes. Each participant was asked to lie on the examination bed in a quiet room with closed eyes, two pillows were placed behind and between the legs to fix the body in the lateral position. Furthermore, each sole was given a one-minute relaxation massage with the massage oil, then foot reflexology was performed using the "Metatarsal kneading" method described by Byers (23). Moreover, first, the pressure was applied at a tolerable depth with the distal part of the first inter-phalangeal 2 and 5 joints of the right hand on the intestine and colon area on the right sole. Then, slow speed movements from the top downward long the sole with the regular rhythm were continued for five minutes. The blinding of participants and the intervention provider was impossible due to the probable interference of sham reflexology effects. The control group only received conventional care.

The validity of the CAS and STAI questionnaire was determined with the test-retest method on 20 women with constipation. Additionally, Cronbach's alpha (ICC, 95% confidence interval) was 90.3% (0.83), 94% (0.92), and 93% (0.87) for a total score of constipation, state anxiety, and trait anxiety, respectively.

Statistical Analysis

SPSS software package (version 21) was used for analysis. In addition, the Kolmogorov-Smirnov test was used to confirm the normality of quantitative data. Further, the chi-square test, chi-square for trend, Fisher exact test, and an independent t-test were applied to compare socio-demographic data between the groups. Furthermore, the basic score was used to adjust through the Analysis of covariance (ANCOVA) test, and then the Mann-Whitney test was employed to compare CAS severity and the number of fetal movements between the groups. Eventually, an independent t test and the ANCOVA test were used to compare the mean scores of STAI between the groups before and after the intervention, respectively.

Results

Based on the results of Table 1, no statistically significant difference was found between the 2 groups in terms of socio-demographic parameters ($P > 0.05$). The mean (standard deviation, SD) of participants' age was 26.3 (4.6) and 24.5 (4.6) in the reflexology and control groups, respectively. Moreover, the mean (SD) of the gestational age was 24.6 (2.0) and 25.0 (2.0) in intervention and control groups, respectively. Similarly, the mean (SD) of the body mass index was 25.1 (3.7) and 25.5 (4.6) in intervention and control groups, respectively. Thirty-four (94.4%) of women in the intervention group and 35 (97.2%) of them in the control group were housekeepers. Additionally, 13 (36.1%) and 19 (52.8%) cases had a diploma in intervention and control groups, respectively. Likewise, 22 (61.1%) women in intervention group and 25 (69.4%) women in the control group had incomes equal to

Table 1. Baseline Characteristics of Foot Reflexology in Pregnancy Study Participants at 23-28 Weeks of Gestation

Variable	Foot Reflexology (n = 36)	Control (n = 36)	P Value
Age (y), (+/- SD)	26.3 (4.6)	24.5 (4.6)	0.107[a]
Gestational age (wk), (+/- SD)	24.6 (2.0)	25.0 (2.0)	0.307[a]
Marriage age (y), (+/- SD)	22.5 (5.1)	20.3 (4.7)	0.057[a]
Body mass index (kg/m²), (+/- SD)	25.1 (3.7)	25.5 (4.6)	0.649[a]
Mother's occupation, n (%)	34 (94.4)	35 (97.2)	1.000[c]
Housekeeper	2 (5.6)	1 (2.8)	
Employed			
Mother's education level, n (%)	5 (13.9)	6 (16.7)	0.558[d]
Middle school	5 (13.9)	3 (8.3)	
High school	13 (36.1)	19 (52.8)	
Diploma	13 (36.1)	8 (22.2)	
University			
Husband's job, n (%)	0 (0.0)	3 (8.3)	0.3500[c]
Unemployed	3 (8.3)	3 (8.3)	
Employee	18 (50.0)	14 (38.9)	
Worker	2 (5.6)	5 (13.9)	
Shopkeeper	13 (36.1)	11 (30.6)	
Other			
Husband's educational level, n (%)			0.100[d]
Middle school	8 (22.2)	11 (30.6)	
High school	2 (5.6)	7 (19.4)	
Diploma	14 (38.9)	11 (30.6)	
University	12 (33.3)	7 (19.4)	
Economic status, n (%)			0.371[d]
Income equal to the cost	22 (61.1)	25 (69.4)	
Income more than the cost	1 (2.8)	2 (5.6)	
Income less than the cost	13 (36.1)	9 (25.0)	
Diet, n (%)			0.569[c]
Meat diet	3 (8.3)	5 (13.9)	
Vegan diet	3 (8.3)	1 (2.8)	
Both	30 (83.3)	30 (83.3)	
History of constipation, n (%)			1.000[b]
Yes	23 (63.9)	23 (63.9)	
No	13 (36.1)	13 (36.1)	
Anti-vomiting drug consumption, n (%)			1.000[c]
Yes	5 (13.9)	4 (11.1)	
No	31 (86.1)	32 (88.9)	
Smoking, n (%)			1.000[c]
Yes	1 (2.8)	0 (0.0)	
No	35 (97.2)	36 (100.0)	
Caffeine consumption, n (%)			0.165[b]
Yes	25 (69.4)	30 (83.3)	
No	11 (30.6)	6 (16.7)	
Participation sessions in preparation for delivery, n (%)			
Yes	6 (16.7)	10 (27.8)	0.257[b]
No	30 (83.3)	26 (72.2)	
Physical activity, n (%)			
Yoga	0 (0.0)	1 (2.8)	
Swim	1 (2.8)	0 (0.0)	0.136[c]
Walking	17 (47.2)	9 (25.0)	
Special exercise for constipation	1 (2.8)	2 (5.6)	
Lack of exercise	17 (47.2)	23 (63.9)	
Exercise for constipation and walking	0 (0.0)	1 (2.8)	
Total	36	36	

Note. SD: Standard deviation; [a]Independent *t* test; [b]Chi-square test; [c]Fisher's exact test; [d]Chi-square for the trend test.

the cost. The diet of 30 (83.3%) women in the two groups included meat and vegan foods. In addition, a history of constipation in 23 (63.9%) women was reported in both groups. The consumption of anti-vomiting drugs was also reported in 5 (13.9%) and 4 (11.1%) cases in intervention and control groups, respectively. Only 1 (2.8%) woman in the intervention group used tobacco. Further, caffeine consumption was reported in 25 (69.4%) and 30 (83.3%) women in intervention and control groups, respectively. Participation sessions in preparation for delivery were reported by 6 (16.7%) women in the intervention group and 10 (27.8%) cases in the control group. The lack of any exercise was reported by 17 (47.2%) and 23 (63.9%) women in intervention and control groups, respectively.

According to Figure 2, constipation symptom severity improved in both groups over time. However, based on the results of Table 2, the comparison of CAS severity frequency at six time points (weekly intervention) using the Mann-Whitney test showed a statistically significant difference between the groups in the third, fifth, and sixth weeks after the intervention ($P < 0.05$). Sixty-one percent of participants had moderate constipation at week one. In the reflexology group, improvements were observed in 66.7%, 72.2%, 67%, and 86% of participants at weeks 2, 3, 4, and 5, and 97.2% of them had improvements in constipation symptoms by week 6.

Based on the data in Table 3, there was no significant difference between the mean score of state anxiety ($P = 0.438$) and trait anxiety ($P = 0.628$) between the two groups before the intervention. Conversely, a significant difference was observed between the two groups in terms of the SATI mean score, state anxiety ($P = 0.003$), and trait anxiety ($P = 0.010$) after the intervention at week 6.

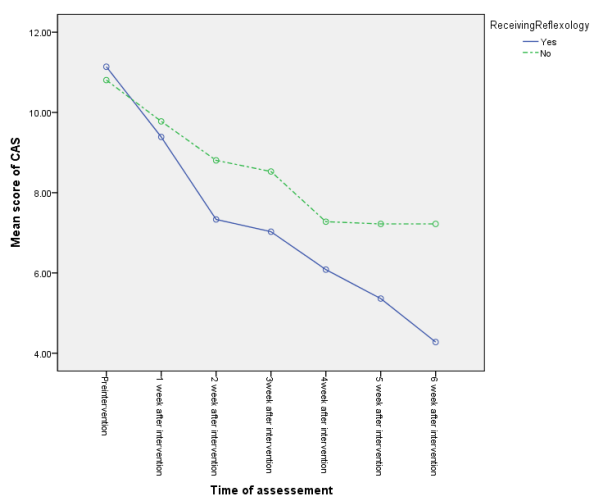Similarly, the Mann-Whitney test was used to compare the frequency of fetal movements in the two groups over

seven time points, the results of which (Table 4) showed that statistically significant differences between the groups were only apparent in the fourth ($P = 0.001$) and fifth weeks ($P = 0.008$).

Of 36 participants who received foot reflexology, 24 (66.7%) cases were satisfied with their treatment for improving the symptoms of constipation. None of the participants were dissatisfied with treatments. By the end of the 6th week, no adverse effects were reported by the participants.

Discussion
In general, the findings of this study revealed significant improvements in 97.2% of women in their CAS measures at the end of sixth weeks following reflexology in comparison with the standard care.

The detected potential healing in constipation symptoms was not only related to bowel frequency but also to bloating that participants mostly considered more painful. These findings are consistent with the results of the study by Gordon, which included 184 children with functional constipation and showed significant improvements in the total scores of constipation and related symptoms such as bowel frequency following 12 weeks of foot reflexology. Gordon further applied a diary form and the Bristol stool chart for assessing bowel movements (24). In

Figure 2. Line Graph for CAS Mean Scores in the 2 Groups at 7 Time Points (Before Intervention and 6 Times After Each Weekly Intervention). *Note*. CAS: Constipation assessment scale.

Table 2. Comparison Frequency of Constipation Severity Levels by Study Groups at 6 Time Points

CAS	Foot Reflexology No. (%)	Control No. (%)	P Value*
First week			0.702
No problem	13 (36.1)	12 (33.3)	
Moderate	22 (61.1)	22 (61.1)	
Severe	1 (2.8)	2 (5.6)	
Second week			0.519
No problem	24 (66.7)	22 (61.1)	
Moderate	12 (33.3)	12 (33.3)	
Severe	0 (0.0)	2 (5.6)	
Third week			0.042
No problem	26 (72.2)	18 (50)	
Moderate	10 (27.8)	16 (44.4)	
Severe	0 (0.0)	2 (5.6)	
Forth week			0.538
No problem	29 (80.6)	27 (75.1)	
Moderate	7 (19.4)	8 (22.2)	
Severe	0 (0.0)	1 (2.8)	
Fifth week			0.054
No problem	31 (86.1)	24 (66.7)	
Moderate	5 (13.9)	12 (33.3)	
Severe	0 (0.0)	0 (0.0)	
Sixth week			< 0.001
No problem	35 (97.2)	23 (63.9)	
Moderate	1 (2.8)	13 (36.1)	
Severe	0 (0.0)	0 (0.0)	

Note. CAS: Constipation assessment scale; *Mann-Whitney test. The CAS questionnaire was used to determine constipation.

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Table 3. Comparison of the Mean Scores of STAI in the 2 Groups Before and 6 Weeks After the Intervention

STAI	Foot Reflexology (n=36) Mean (SD)	Control (n=36) Mean (SD)	Mean Difference (CI)	P Value
State anxiety				
Before the intervention	39.9 (9.2)	41.5 (8.3)	(-5.7 to 2.5) -1.6	0.438[a]
Six weeks after intervention	38.5 (8.4)	42.2 (8.7)	(-3.7 to -0.8) -2.2	0.003[b]
Trait anxiety				
Before the intervention	44.8 (5.4)	44.2 (4.7)	(-1.8 to 3.0) 0.6	0.628[a]
Six weeks after intervention	39.1 (8.6)	40.2 (7.3)	(-3.3 to -0.46) -1.9	0.010[b]

Note. CI: confidence interval; SD: standard deviation; STAI: State-trait anxiety inventory. The range of scores for each subtest is 20-80 and the higher score indicates greater anxiety.
[a] Independent t-test; [b] ANCOVA test.

another study, Woodward et al conducted a pilot study on 19 women who referred to biofeedback services with idiopathic constipation. The outcomes were assessed using an 11-point numerical rating scale and demonstrated that foot reflexology had beneficial effects on idiopathic constipation symptoms (25).

Table 4. Comparison of the Frequency of Fetal Movements in the 2 Groups at 7 Time Points (Before the Intervention and Weekly Intervals after Each Intervention)

Fetal Movements	Foot Reflexology No. (%)	Control No. (%)	P Value[a]
Before intervention			0.157
Less than 3 kicks	1 (2.8)	0 (0.0)	
Between 3 to 10	21 (58.3)	15 (41.7)	
More than 10 kicks	14 (38.9)	21 (58.3)	
1 week after intervention			0.059
Less than 3 kicks	0 (0.0)	0 (0.0)	
Between 3 to 10	23 (63.9)	15 (41.7)	
More than 10 kicks	13 (36.1)	21 (58.3)	
2 weeks after intervention			0.633
Less than 3 kicks	0 (0.0)	0 (0.0)	
Between 3 to 10	16 (44.4)	14 (38.9)	
More than 10 kicks	20 (55.6)	22 (61.1)	
3 weeks after intervention			0.804
Less than 3 kicks	0 (0.0)	0 (0.0)	
Between 3 to 10	12 (33.3)	13 (36.1)	
More than 10 kicks	24 (66.7)	23 (63.9)	
4 weeks after intervention			0.001
Less than 3 kicks	0 (0.0)	0 (0.0)	
Between 3 to 10	12 (33.3)	12 (33.3)	
More than 10 kicks	24 (66.7)	24 (66.7)	
5 weeks after intervention			0.008
Less than 3 kicks	0 (0.0)	0 (0.0)	
Between 3 to 10	11 (30.6)	12 (33.3)	
More than 10 kicks	25 (69.4)	24 (66.7)	
6 weeks after intervention			0.234
Less than 3 kicks	0 (0.0)	0 (0.0)	
Between 3 to 10	9 (25.0)	5 (13.9)	
More than 10 kicks	27 (75.0)	31 (86.1)	

Note. * Mann-Whitney test.

In the control group, 23 (63.9%) mothers reported an improvement in the severity of constipation. Probable reasons may incorporate with the Hawthorne effect which is common in trials because of participant expectations and learning effects (26).

Likewise, Gillespie and Aydinferd conducted a study on 60 hospitalized patients in orthopedic wards in order to determine the effect of foot reflexology, in comparison with abdominal massage, on constipation severity. Participants in foot reflexology and abdominal massage groups received daily interventions for 6 days. Then, constipation severity was assessed by CAS before and daily after the intervention until day sixth. Significant differences were found between the intervention and control groups regarding constipation severity from the 3rd until the 6th days after the intervention. The findings of the above-mentioned study showed that both foot reflexology and abdominal massage methods can have positive effects on the severity of constipation in hospitalized patients (27).

Nonetheless, the exact mechanism of the reflexology action needs further confirmation. Various theories have been proposed in this regard, including the "hemodynamic theory", which was supported by Doppler blood flow studies (28,29), and the "nerve impulse theory" which suggests that the stimulation of specific points on the feet enhances nervous connections to the corresponding body parts and is therefore effective on the autonomic nervous system (18,30,31).

McCullough completed a systematic review investigating physiological and biochemical outcomes associated with a reflexology treatment. To this end, 12 randomized and 5 pilot controlled trials were included and the results of four trials represented a significant difference between reflexology and control groups in terms of salivary amylase concentrations, systolic and diastolic blood pressure, and the cardiac index. However, it was concluded that it is still unclear how precisely reflexology affects physiological and biochemical parameters. Interestingly, none of the 17 trials reported side effects from reflexology, which is in agreement with the findings of our study. In addition, reflexology was demonstrated to have a positive effect on general health and the quality of life, as well as anxiety and

pain levels among participants in these studies. This review supports the findings of our study in terms of reducing anxiety levels (30). Our study results demonstrated that reflexology as a specific technique can reduce the STAI score, which was also found in studies by Yilar Erkek and Aktas (32) and McVicar et al (33). In the study by Yilar Erkek and Aktas on pregnant women in labor, the primary outcome was anxiety which was assessed through the STAI TX-1 and it was shown that foot reflexology has a positive effect on reducing anxiety in pregnant women (32).

Moreover, Diego et al investigated the fetal response to foot massage and abdominal vibration stimulation during pregnancy. Accordingly, the mother's anxiety and fetal movements were measured using STAI and real-time sonography, respectively. The analysis of the obtained STAI anxiety scores before and after an ultrasound showed a significant reduction in anxiety after abdominal vibrations. Additionally, a significant decrease was found in STAI scores while a significant increase occurred in overall fetal movements after foot massage. In general, both studies demonstrated a reduction in maternal anxiety although the present study did not show the significant effect of foot reflexology on fetal movements (34).

Implications to Practice
The use of the quality of life measures may be beneficial in further studies (35).

Strengths and Limitations
The shorter duration of the intervention is a perfect point in the present study for perinatal practices. This study had some limitations. The sample for this study may not be representative of all pregnant women with constipation, because it was only drawn from women referring to the health centers of only one city. In addition, the use of sham reflexology was not possible due to the probable interventional effect on reflex points on the soles.

Conclusions
The results of this study demonstrated that reflexology may be a safe and effective method for the treatment of constipation and anxiety symptoms in pregnant women. Short-term reflexology can be an applicable method in midwifery practices and may also be used even by pregnant women's partners.

Conflict of Interests
Authors declare that they have no conflict of interests.

Ethical Issues
The data were collected after explaining the purpose of the study and obtaining written informed consent from all patients and assuring them of data confidentiality. This study was registered in the Iranian Registry of Clinical Trials (identifier: IRCT20100109003027N40), and ethical approval was granted by the Ethics Committee of Tabriz University of Medical Sciences (Ethics code: IR.TBZMED.REC.1396.682).

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