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*]

[1] Lecturer, Department of Midwifery, Faculty of Nursing and Midwifery, Tabriz University of Medical Sciences, Tabriz, Iran

[2] Senior Lecturer, School of Health Sciences, Institute of Nursing and Health Research, University of Ulster, London, United Kingdom

[3] Associate Professor, Social Determinants of Health Research Center, Tabriz University of Medical Sciences, Tabriz, Iran

[4] MSc Student in Midwifery, Student Research Committee, Faculty of Nursing and Midwifery, Tabriz University of Medical Sciences, Tabriz, Iran

* Correspondence author: anjomanazarizahra@gmail.com Tel:989141165680

Running Title

Short - term foot reflexology

Abstract

Objective: Reflexology is a popular type of complementary medicine in medical practices especially in midwifery fields.

Study design: This randomized controlled trial aimed to determine the effect of foot reflexology on idiopathic constipation symptoms and anxiety and fetal activity during pregnancy.

Methods: This study was conducted on seventy-four nulliparous women with constipation, referring to private and public health care centers in Tabriz-Iran, between 2017 to 2018. Participants were randomly assigned into foot reflexology or control groups. The intervention method was a short term of 12 minutes foot reflexology treatment that was given (weekly for six weeks) for intervention group.

Constipation symptoms were measured at baseline and 6 times (weekly) after the intervention by Constipation Assessment Scale (CAS). The State-Trait Anxiety Inventory (STAI) questionnaire was used to measure participant's anxiety at baseline and 6 weeks after completion of the study, and fetal movement was measured at baseline and 6 times (weekly) after the intervention using a kick chart.

Results: Ninety seven percent of women reported improvement in their CAS measures at the end of six weeks following reflexology. Mean scores of State-Trait Anxiety Inventory (STAI) at the end of intervention were 38.5 and 42.2 (State anxiety), and 39.1 and 40.2 (Trait anxiety) in the reflexology and control groups, respectively. Statistically significant difference in fetal movements between the two groups were seen only in the fourth (P= 0.001) and fifth weeks (P= 0.007) after intervention sessions. About 67% of mothers were satisfied with reflexology intervention for improvement in their constipation symptoms. No harmful side events were reported among women.

Conclusion: 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 required.

Introduction

Physical and psychological changes during pregnancy are remarkable [1]. Constipation as a prevalent symptom of gastrointestinal disorders impacts the general health and quality of life [2] and associated with bothersome consequences in the perinatal period [3]. In the second trimester [2], the prevalence rate ranges from 9% [4] to 40% [5, 6].

Constipation is defined as difficultly stool evacuation [7]. The modified Rome II criteria has been used in pregnancy and requires inclusion of at least 2 of 6 following symptoms: lumpy or arid feces, straining, incomplete evacuation sensation, digital efforts for evacuation, anorectal blockage, less than 3 evacuations in a week [8], in at least 25 percent of defecations within the last 1 month (rather than 3 months) [4]. Constipation is generally divided to: Primary (idiopathic) and Secondary groups; Primary or functional constipation is also categorized as: Normal-transit, Slow-transit, and Dyssynergic type which indicating an disturbance in rectal evacuation or functional impairment, with no anatomical or physiological cause for it [9]. Probable causes of functional constipation included: inadequate intake of fiber and water [10], inactive lifestyle and medication side effects such as iron [5, 11]. Compressive effects of the fetus [5, 6] and shifting levels of endocrinological hormones such as progesterone, may also decrease colonic movement specially within the second and third trimesters [11]. Abdominal distension, bloating, uncomfortable and pressure feelings in the pelvic floor, anal pain are significant constipation complications [4, 12].

Anxiety is a common emotional response during pregnancy [13, 14]. Anxiety related disorders are more often reported by patients with slow bowel function [15, 16] than those with normal [17]. In perinatal period a high prevalence of anxiety in patients with functional constipation has been reported [17, 18].

Nulliparous women feel the fetal activities for the first time between 18 and 20 weeks, and 4-100 fetal movements per hour are considered normal [19]. Fetal movement counting by healthy pregnant women through "Kick-counting"[20] is commonly accepted and more applicable [21]. Less than three kicks per hour is considered as an abnormal result for fetal movement counting based on study by Sadovsky et al [22].

Reflexology is a common type of complementary medicine and healing method [23, 24]. Reflexologist applies controlled pressure on particular reflex zones often on the soles, which represent interconnected body systems [25]. The treatment purpose is re-balance the function of internal organs, stop stress and homeostasis [26]. Peripheral vasodilatation to eliminate local toxin accumulated and increasing connection of related neural pathways to the body organs may describe probable mechanisms of reflexology treatment [25, 27, 28].

Studies investigating the effects of foot reflexology on constipation symptoms [12] and fetal movements [29] during pregnancy are rare so this study was conducted to determine the effect of foot reflexology on constipation symptoms (primary outcome) and anxiety and fetal activity (secondary outcomes).

Methods

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

Inclusion criteria included: Nulliparous pregnant women at 23-28 weeks, single pregnancy, 16–45 years of age, middle school literacy, having a score of 9 to 16 based on a Constipation Assessment Scale (CAS), absence of pregnancy-related medical conditions such as a history of abortion or bleeding in the present pregnancy. Exclusion criteria were: previous abdominal or pelvic radiation therapy, neurological diseases, history of inflammatory bowel disease, fungal foot infections or verrucae in the leg, currently use of foot reflexology, diabetes/gestational diabetes, current treatment for thyroid disease, history of bowel surgery (other than appendectomy), regular narcotic use, cardiac diseases and high blood pressure, Placenta Previa and abdominal pain with unknown cause.

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. study [12] with considering m_1=16.3 and $sd_1 = sd_2$=8 and assuming 30% reduction in the scores following intervention (m_2=11.41), $\alpha = 0.05$ and β= 0.2. The final sample size was calculated as 37 per group with estimating 10% dropout rate.

Before sampling, ethics code was obtained from Tabriz University of Medical Sciences' Ethics Committee. (IR.TBZMED.REC.1396.682) and registered on the Iranian Registry of Clinical Trials (IRCT20100109003027N40).

A convenience sample (N = 74) was recruited from 35 out-patient public and private healthcare centers in Tabriz-Iran between October 2017 to December 2018. Eligible participants after informed consent, completed the outcome measures. Participants were followed up weekly for six weeks. Of 74 participated women, 72 (97.3%) person completed all treatments. One women in each group was excluded from the study due to decline to continue their participation (Fig. 1). A researcher who was blinded to the intervention allocation, analyzed the results Random allocation was done by a noninvolved individual in sampling and data collection Participants were assigned into two groups ; foot reflexology (intervention) and standard care (control group) through blocked randomization methods with block sizes of four and six and a 1:1 allocation ratio. Random allocation was performed by a person unaware of the research. Sealed opaque

envelopes were used for allocation concealment and the type of intervention was written on a paper and placed in envelopes.

A socio-demographic questionnaire was completed by participants before the study started. The primary outcome measure was constipation severity, assessed weekly using the Constipation Assessment Scale (CAS) in both study groups for six weeks [30]. The scale included eight items. The recorded scores were 0, 1, 2, 3 and 4, respectively. The total CAS score ranged from 0 to 32, higher scores indicate worse constipation symptoms.

The secondary outcomes were 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 again on week six, after intervention. This inventory contains 20 questions that are scored ranging from 20 to 80, and higher scores correlated with greater anxiety levels [31]. A "kick-chart" based on Sadowsky method [32] was given to the mothers to count the number of fetal movements, and record the results. These Data were gathered at baseline (before the intervention) and then every week for six weeks of follow up in the two groups (twenty minutes after each reflexology session in intervention group).

Participants were asked to report any intervention related adverse events or unpleasant effects such as: local or whole-body heat sensation, sweating, and sensation of cold, chilling and other adverse events using a checklist of side effects based on an overview of the literature [33] during intervention. Mother's satisfaction with the foot reflexology and gut transition assessed on the sixth week following intervention by a self-administered checklist.

Chinese Traditional medicine (TCM) practitioner, trained the researcher who performed the intervention. The reflexology intervention was delivered in such a way as to minimize confounder contextual factors, therefore no background music or aromatherapy oils was used within the treatments. The intervention group received reflexology treatment that each session lasting 12 minutes. The participant was asked to lie on a bed in a quiet room, closing her eyes, two pillows were placed behind and between legs to fix her body in

lateral position., each foot was given one minute relaxation massage with massage oil, then foot reflexology was performed using the "Metatarsal kneading" method described by Byers and on right sole of foot at first [34]. Pressure was applied at a tolerable depth with the distal part of the first inter-phalangeal 2 and 5 joints of right hand, on the intestine and colon area on the sole. Slow speed movement from the top downwards long the sole with the regular rhythm were continued for five minutes. Blinding of participants and the intervention provider were not possible due to probable interference of sham reflexology effects, however Control group received conventional care.

The validity of the Constipation Assessment Scale (CAS) and State-Trait Anxiety Inventory (STAI) questionnaire determined with test and re-test on 20 women with constipation. Cronbach's alpha and ICC (95% Confidence Interval) for a total score of constipation was 90.3 percent and 0.83, and for state anxiety 94 percent, 0.92 and 93 percent, 0.87 for trait anxiety respectively.

Statistical analysis

SPSS 21 software package was used for analysis. Kolmogorov–Smirnov (K-S) test was used to confirm normality of the quantitative data. The chi-square, Chi-square for trend, Fisher's exact and independent t tests were used to compare the socio demographic data between groups. The basic score was used to adjust through ANCOVA test. Mann-Whitney test was used to compare CAS severity and also the number of fetal movements between groups. Independent t-test and the ANCOVA test were used to compare mean scores of STAI between groups before and after intervention respectively.

Results

No statistically significant difference was found in terms of the socio-demographic parameters between the two groups (P> 0.05). The mean age of the participants in the reflexology group was 26.3 and 24.5 in the control group. The mean (SD) of gestational age in intervention group was 24.6 (2.0) and 25.0 (2.0) in control group. The mean (SD) of body mass index (BMI) in the intervention group was 25.1 (3.7) and in the control group was 25.5 (4.6). Thirty four (94.4%) of women in intervention group and 35 (97.2%) in

control group were housekeeper. In intervention group 13 (36.1%) and 19 (52.8%) in control group had diploma. Twenty two (61.1%) women in intervention group and 25 (69.4%) were Income equal to the cost. Diet of 30 (83.3%) women in two groups was meat and vegan diet. History of constipation in 23 (63.9%) women was reported in two groups. (Table 1).

Table 2 shows the CAS severity by study groups at the six time points (weekly intervention). Constipation symptom severity improves in both groups over time, however comparison of CAS severity frequency between groups using Mann-Whitney test showed a statistically significant difference between groups in the third, fifth and sixth weeks after the intervention (P<0.05). Sixty one percent of the participants had moderate constipation at week one. In the reflexology group, improvement were observed in 66.7% of participants at week 2, 72.2% at week 3, 67% at week 4, 86% at week 5 and 97.2% of participants had improvement in constipation symptoms by week 6. A line graph for the CAS mean scores in the two groups at the seven time points (before the intervention and six time once a week after the intervention), showed the severity of constipation was significant lower in reflexology group in comparison with the control group over time (Fig. 2).

Table 3 shows that there was no significant difference between the mean score of state anxiety (P=0.438) and trait anxiety (P=0.628) between two groups before intervention. 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 intervention at week 6.

Mann Whitney test was used to compare the frequency of fetal movements in the two groups over the seven time points, results showed that statistically significant differences between groups were only apparent in the fourth (P=0.001) and fifth weeks (P=0.008) (Table 4).

Of the 36 participants who received foot reflexology, 24 (66.7%) were satisfied from their treatment for improving 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

Significant improvement in 97.2% of women in their CAS measures at the end of sixth weeks following reflexology in comparison with the standard care was shown by the findings of this study.

The detected potential healing effects in constipation symptoms was related not only to bowel frequency, but also to other symptoms including bloating that participants mostly regard as more painful. These findings are consistent with the results of the study by Gordon (2007), who included 184 children with functional constipation and showed significant improvements in the total scores for constipation and related symptoms such as bowel frequency following 12 weeks foot reflexology. Gordon applied a diary form and Bristol Stool chart for assessing the bowel movements [35]. Woodward et al (2010) conducted the pilot study on 19 women who referred to biofeedback service with idiopathic constipation assessed constipation outcomes using 11 point numerical rating scale and demonstrated that foot reflexology had benefit effects on the idiopathic constipation symptoms [36]. Gillespie et al (2016) also aimed to determine the effect of foot reflexology and abdominal massage on the severity of constipation based on CAS tool and assessed 60 hospitalized patients. There was a significant difference in severity of constipation between the two intervention groups (foot reflexology and abdominal massages) and control group [37].

In our study, twenty three (63.9%) mothers in control group reported that the severity of constipation was improved. Probable reasons may incorporated with the Hawthorne effect which is common in trials because of participant expectations and learning effect [38, 39].

Reflexologist performs systematic controlled pressure to particular points on the feet and hands bringing impact on the health of relevant body organs; each point on the feet is linked with representative

parts of body. The exact mechanism of action has yet to be confirmed. Various theories have been proposed including the "hemodynamic theory" which has been supported by Doppler blood flow studies [40, 41] and the "nerve impulse theory" suggests that stimulation of specific points on the feet enhance nervous connection to the corresponding body parts and is therefore effecting the autonomic nervous system (ANS) [26, 42, 43].

McCullough (2014) completed a systematic review investigating the physiological and biochemical outcomes associated with a reflexology treatment. Twelve randomized controlled trials and five pilot controlled trials were included and the results of four trials showing a significant difference between reflexology and control groups in terms of salivary amylase concentrations, systolic and diastolic blood pressure, and cardiac index. However the review concluded that it is still unclear precisely how reflexology impacts physiological and biochemical parameters. Interestingly, none of the 17 trials reported side effects from reflexology which is in agreement with our study. In addition, reflexology was demonstrated to have a positive effect on general health, quality of life, anxiety and pain levels among participants in these studies. This review supports the findings of our study in terms of reducing anxiety levels.[42] Our study found that reflexology as a specific technique can reduces STAI score, which has also been found in studies by Yilar et al.[44] and McVicar et al.[45] In the study by Yilar et al. (2018) on pregnant women in labor, the primary outcome was anxiety which assessed through the STAI TX-1 and showed that foot reflexology has a positive effect in reducing anxiety in pregnant women [44].

One study showed that using acupuncture on reflex points during pregnancy can increase fetal movements in comparison with control group [46]. Diego et al. (2002) investigated the fetal response to foot massage and abdominal vibration stimulation during pregnancy. Mother's anxiety was measured using STAI and fetal movements were evaluated using Real-Time sonography. Analysis of STAI anxiety scores obtained before and after ultrasound showed a significant reduction in anxiety after abdominal vibration, however the effect of vibrational stimulation on fetal movements was not significant. A significant decrease in STAI scores and a significant increase in overall the fetal movements occurred after foot massage (48).

The results from this study are not consistent with the results of the present study as although both studies demonstrated a reduction in maternal anxiety, the present study did not show a significant effect of foot reflexology on fetal movements [29].

Some limitations of this study were the sample for this study that may not be representative of the all pregnant women with constipation, because the sample was drawn from women referring to a city health centers. The use of sham reflexology did not possible due to probable interventional effect on reflex points on the soles. The use of quality of life measures, may be beneficial in further studies [47]. Shorter duration of intervention is a perfect point in present study for perinatal practices. In order to measure objective outcomes of constipation symptoms, the use of reliable tools such as the Bristol Stool Scale and the effect of reflexology on the number of fetal heart rate and activity would also be recommended for further studies.

This study demonstrated a significantly improvement in severity of constipation and anxiety symptoms in pregnant women, following a reflexology intervention in comparison with usual care and reflexology may be a safe and effective method for the treatment of constipation and anxiety symptoms in pregnant women.

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Ethical review

This study was registered in the Iranian Registry of Clinical Trials (IRCT code: IRCT20100109003027N40), and ethical approval was granted by ethics committee of Tabriz University of Medical Sciences (Ethics code: IR.TBZMED.REC.1396.682). Informed consent was obtained from the participants.

Disclosure statement

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ORCID

Fahimeh Sehhatie Shafaie; https://orcid.org/0000-0001-9583-1437

Ciara Hughes;

Mojgan Mirghafourvand; http://orcid.org/0000-0001-8360-4309

Zahra Anjoman Azari; https://orcid.org/0000-0002-3465-7356

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Assessed for eligibility (n=650)

Recruitment

Excluded (n=576)

- Not meet the study criteria (n=450)
- Refused to participate (n=126)

Randomized (n=74)

Allocated to foot reflexology (n=37)

First week follow up (n=36)

Second week follow up (n=36)

Third week follow up (n=36)

Forth week follow up (n=36)

Fifth week follow up (n=36)

Sixth week follow up (n=36)

Assignation

15

Follow up

Allocated to control (n=37)

First week follow up (n=36)

Second week follow up (n=36)

Third week follow up (n=36)

Forth week follow up (n=36)

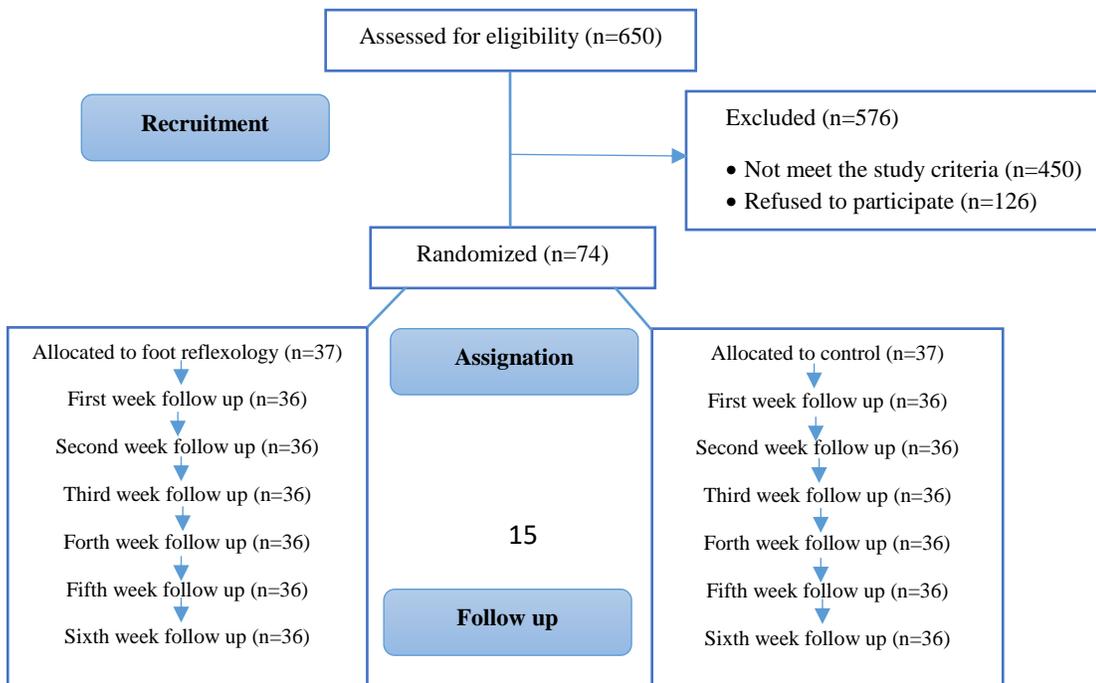Fifth week follow up (n=36)

Sixth week follow up (n=36)
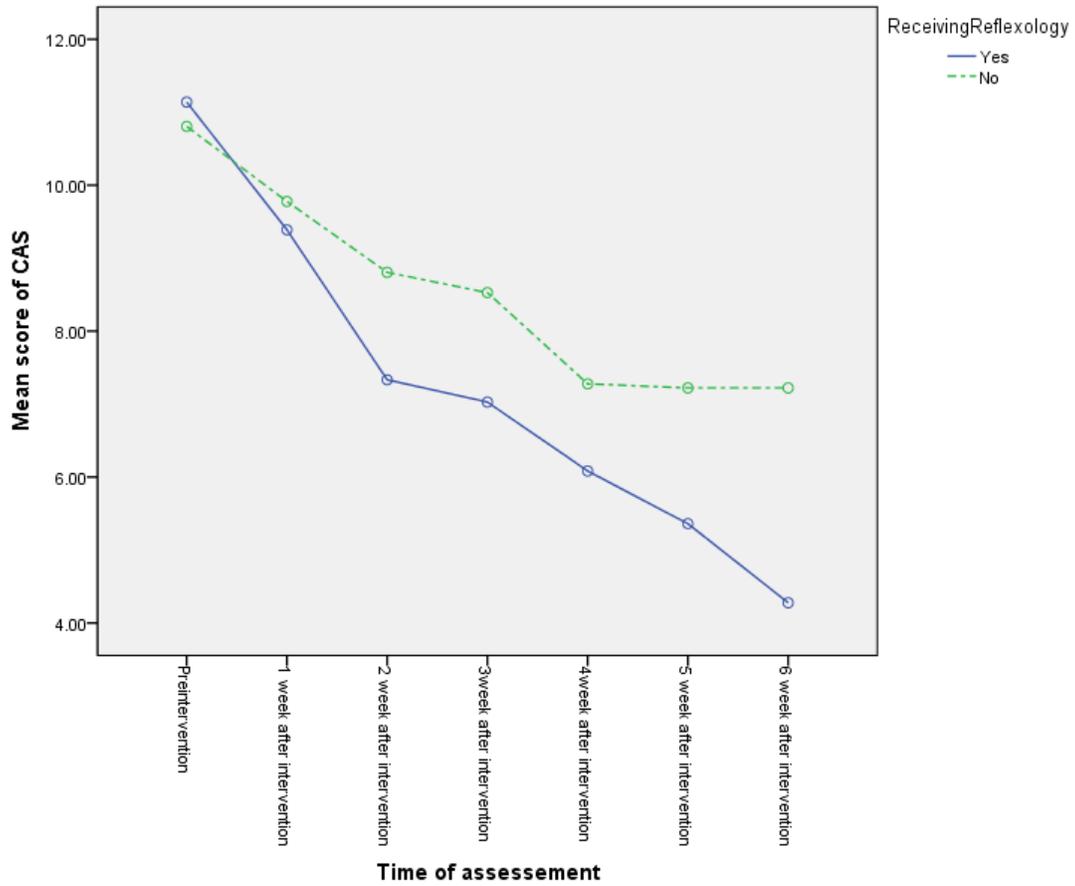
Fig. 1. CONSORT flow diagram

Fig. 2. Line graph for Constipation Assessment Scale (CAS) mean scores in the two groups at seven time points (before intervention and six times after each weekly intervention)

Table 1
Baseline characteristics of the foot reflexology in Pregnancy Study participants at 23-28 weeks gestation.

Variable	Foot reflexology (n=36)	control (n=36)	P value
Age (Years) (+/- SD)	26.3 (4.6)	24.5 (4.6)	0.107[*]
Gestational age (Weeks) (+/- SD)	24.6 (2.0)	25.0 (2.0)	0.307[*]
Marriage age (Years) (+/- SD)	22.5 (5.1)	20.3 (4.7)	0.057*
Body Mass Index (Kg/m2) (+/- SD)	25.1 (3.7)	25.5 (4.6)	0.649[*]
Mother's occupation, n (%)			1.000[‡]
Housekeeper	34 (94.4)	35 (97.2)	
Employed	2 (5.6)	1 (2.8)	
Mother's education level, n (%)			0.558[§]
Middle school	5 (13.9)	6 (16.7)	
High school	5 (13.9)	3 (8.3)	
Diploma	13 (36.1)	19 (52.8)	
University	13 (36.1)	8 (22.2)	
Husband's job, n (%)			0.3500[‡]
Unemployed	0 (0.0)	3 (8.3)	
Employee	3 (8.3)	3 (8.3)	
Worker	18 (50.0)	14 (38.9)	
Shopkeeper	2 (5.6)	5 (13.9)	
Other	13 (36.1)	11 (30.6)	
Husband's educational level, n (%)			0.100[§]
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[§]
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[‡]
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[†]
Yes	23 (63.9)	23 (63.9)	
No	13 (36.1)	13 (36.1)	
Anti-vomiting drugs consume, n (%)			1.000[‡]
Yes	5 (13.9)	4 (11.1)	
No	31 (86.1)	32 (88.9)	
Smoking, n (%)			1.000[‡]
Yes	1 (2.8)	0 (0.0)	
No	35 (97.2)	36 (100.0)	
Caffeine consumption, n (%)			0.165[†]
Yes	25 (69.4)	30 (83.3)	
No	11 (30.6)	6 (16.7)	

Participation sessions in the preparation for delivery, n (%)			$0.257^{\dagger}$
Yes	6 (16.7)	10 (27.8)	
No	30 (83.3)	26 (72.2)	
Physical activity, n (%)			$0.136^{\ddagger}$
Yoga	0 (0.0)	1 (2.8)	
Swim	1 (2.8)	0 (0.0)	
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)	

*Independent t test t test; †Chi-Square test; ‡Fishers exact test; §Chi- Square for trend test.

Table 2

Comparison frequency of the constipation severity levels by study groups at six time points.

CAS	Foot reflexology	Control	P- value[*]
	N (%)	N (%)	
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)	

[*]Mann-Whitney test. The Constipation Assessment Scale (CAS) questionnaire was used to determine constipation.

Table 3

Comparison of the mean scores of STAI in the two groups in before and at six weeks after 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[†]
six weeks after intervention	38.5 (8.4)	42.2 (8.7)	(-3.7 to -0.8) -2.2	0.003[‡]
Trait anxiety				
Before the intervention	44.8 (5.4)	44.2 (4.7)	(-1.8 to 3.0) 0.6	0.628[†]
six weeks after intervention	39.1 (8.6)	40.2 (7.3)	(-3.3 to -0.46) -1.9	0.010[‡]

[†]Independent t-test; [‡]ANCOVA test. The State-Trait Anxiety Inventory (STAI) was used. Range of scores for each subtest is 20–80, the higher score indicating greater anxiety.

Table 4

Comparison of the frequency of fetal movements in the two groups at seven time points; before intervention and weekly intervals after each intervention

Fetal movements	Foot reflexology n (%)	control n (%)	P- value*
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)	

* Mann-Whitney test.