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Randomized Controlled Trial

Comparison of the Effects of Foot Trigger Reflexology with Aromatherapy on Anxiety, Pain, and Outcomes of Pregnancy in Women: A Randomized Controlled Trial

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Abstract

Background: Reducing labor pain is known to be a challenging topic in modern midwifery. To reduce this pain, complementary medicine methods have attracted a great deal of attention. The present study aimed to compare the effect of reflexology of sole with non-aromatic oil (Olive) and aromatic oil (Lavender) on reducing labor pain and anxiety**.**

Methods: This multi-arm consecutive randomized controlled trial study of reflexology with non-aromatic oil and aromatic oil was carried out in 2020 on 99 primigravid mothers. They were divided into one control and two intervention groups, selected through random allocation. The data related to the mothers' pain and anxiety were collected via the Pain Visual Scale and Spielberger three times, once before and twice after the intervention at 4-5 and 7-8 cm dilation. This study was registered in the Iranian Registry of Clinical Trials with the code of IRCT20200810048357N1. The demographic characteristics, labor duration, and APGAR score were also recorded. Through the use of the SPSS version 16, parametric and non-parametric statistical tests, including paired and independent t-test, x^2 and ANCOVA, were utilized for analyzing the data.

Results: In the 99 participants with an average age of 25.98±5.80, there were no significant differences in terms of age (P=0.699), education level (P=0.504), or occupation (P=0.140). Additionally, no significant difference was seen in the duration of labor (P=0.194) and the APGAR score (P=0.066). According to the intergroup analysis of pain results in both stages of 4-5 cm and 7 -8 cm after the intervention, the aromatic oil group had a significant difference in terms of pain reduction with the other two groups (P<0.001, P=0.007, respectively). Although there was no significant statistical difference in the intergroup analysis, the increase in the rate of anxiety was significant in control group in different stages (P=0.002) while this factor remained fixed in the intervention groups.

Conclusions: The reflexology with aromatic oil was found to be more effective than that with non-aromatic oil. Furthermore, the pain rate at the time of labor reduced in the intervention groups compared to that in the control group.

Keywords: Reflexology, Aromatherapy, Labor pain, Anxiety, Labor

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1. Introduction

Delivery and labor are generally characterized by pain, which occurs following the stimulation of neuroreceptors due to uterine contractions in visceral, pelvic, and lumbosacral regions (1). Increased pain and anxiety during labor is caused by an increment in catecholamine secretion via stimulation of the sympathetic nervous system, which reduces effective uterine contractions, prolongs the first and second stages of labor, increases the need for interventions, such as Cesarean section, and finally, increases maternal dissatisfaction with delivery (2). Accordingly, the most important goal of birth centers is to ensure a pleasant childbirth experience for mothers, with the least possible pain.

Medical and non-medical methods of pain relief have been recommended to reduce pain (3, 4). Today, many women tend to avoid invasive medical methods of labor pain relief and show an inclination toward non-medical and non-invasive methods of pain relief. There are multiple non-medical methods of pain relief, which reduce physical pain and prevent the associated psychological suffering (5). Reflexology is one of these methods in complementary medicine. In reflexology, palms of the hands and soles of the feet represent a map of all body organs. In this technique, by using the thumbs and forefingers, deep pressure is applied on reflexology points, causing some changes in body organs associated with the reflexology points (6, 7).

Reflexology generates electrochemical messages

that are transmitted through specific nerve points, thereby reducing stress and creating balance in the body. Related theories suggest that reflexology exerts its effects via improvement of peripheral blood flow and the immune system and affecting the sensory signals and mechanisms of the pain gate, as well as the automatic nervous system. Additionally, reflexology can significantly reduce the severity and duration of labor; it has been also shown to be effective in the regulation of labor induction (8, 9).

Aromatherapy, which refers to the use of aromatic herbal extracts, is another non-medicinal method of pain relief and anxiety control (10, 11), using methods, such as massage, dermal absorption, inhalation, and compression. A previous study reported that application of oil essences causes endorphin production and leads to a reduction in pain and anxiety (5). Lavender oil is one of the aromatic herbal oils with extensive applications in aromatherapy. This plant belongs to the Lamiaceae family, with analgesic, antifungal, anti-inflammatory, and muscle-relaxant properties. Although the precise mechanism of lavender still remains unknown, its effects are generally attributed to benzodiazepines and the enhanced effects of gamma-aminobutyric acid.

In this regard, Tafazoli and colleagues reported that lavender essence can decrease labor anxiety (12). With this background in mind, the present study, as a clinical trial, aimed to determine and compare the effects of two methods of reflexology with lavender oil as an aromatic oil (AO) and olive oil as a non-aromatic oil (NAO) on the severity of pain, duration of the first and second stages of labor, and anxiety in primigravida pregnant women.

2. Methods

This non-blinded, multi-arm, randomized clinical trial, which consisted of one control and two intervention groups, was performed in the central maternity ward of a third-level hospital in Firoozabad, Fars Province, Iran from June 2019 until February 2020. This study was registered in the Iranian Registry of Clinical Trials with the code of IRCT20200810048357N1. Also, the Ethics Committee of Islamic Azad University approved the present study, which was conducted in accordance with the Declaration of Helsinki. The study setting was the maternity ward of the hospital, consisting of five labor, delivery, and recovery rooms (LDR) with similar physical conditions and facilities. The participating mothers had no relationship. The labor administration protocol of the maternity ward included active labor management.

The inclusion criteria were as follows: primigravidity; having a single-term pregnancy with a cephalic presentation and 4-5 cm dilation at minimum (onset of the active phase of delivery); no medical, surgical, or pregnancy-related problems, such as cardiac disease, preeclampsia, and fetal complications; not taking analgesics or anesthetics; not using any medications affecting pain perception; ability to cooperate psychically and cognitively; and signing an informed consent form. On the other hand, the exclusion criteria were unwillingness to participate in or continue the study, having medical, pregnancy-related, or fetal complications, and emergence of any problems during labor indicating Cesarean section or deviating labor from its normal process (e.g., dystocia, non-reassuring fetal status, placental abruption, cord prolapse, and meconium staining).

2.1. Measurement of Sample Size, Sampling Method, and Random Allocation

According to a study by Dolatian and colleagues (8) (M1=6.25, SD1=0.84, M2=7.23, SD2=0.83; α=0.05; power=90%), the minimum sample size was estimated at 26 people per group, using the following equations:

$$n = \frac{2S^2 \left(Z_{1-\alpha/2} + Z_{1-\beta}\right)^2}{\left(M_1 - M_2\right)^2}$$

$$n' = n * \sqrt{k-1}$$

where k=3, and n represents the number of groups. To increase the accuracy of subgroup analysis, a sample size of 35 was measured for each group, considering a 20% attrition rate. Sampling was carried out by allocating 29, 35, and 35 participants to group 1 (AO group) receiving reflexology with lavender oil, group 2 (NAO group) receiving reflexology with olive oil, and control group (C group), respectively.

A trained midwife conducted convenience and consecutive sampling daily from June 2019 to February 2020 in the morning and afternoon shifts. Among mothers referred to the maternity ward of the hospital, those who met the inclusion

criteria were enrolled in the study after giving consent and receiving full explanations about the study. Next, each mother was randomly allocated to the intervention and control groups. For random allocation, a total of 105 identical cards were placed in an opaque box; there was an equal number of AO, NAO, and C cards (35 each). After shaking the box to shuffle the cards, the participants blindly picked up a card without returning it to the box; accordingly, the random sequence was not predictable.

Group C (n=35) received routine maternity care (i.e., control of contractions, monitoring of fetal heart rate, monitoring of labor progress, and no sedative drug interventions). On the other hand, the group 2 (n=35) received routine care, along with reflexology of trigger points on the soles of the feet with olive oil, and the group1 (n=29) received routine care along with reflexology of trigger points on the soles of the feet with lavender. In Figure 1, the CONSORT flowchart of the study illustrates the allocation process and intervention steps. The participants' demographic information, duration of the first and second stages of labor, and one- and two-minute APGAR scores were recorded.

2.2. Time and Method of Intervention and Evaluation of Pain and Anxiety

Before the onset of reflexology, the severity of

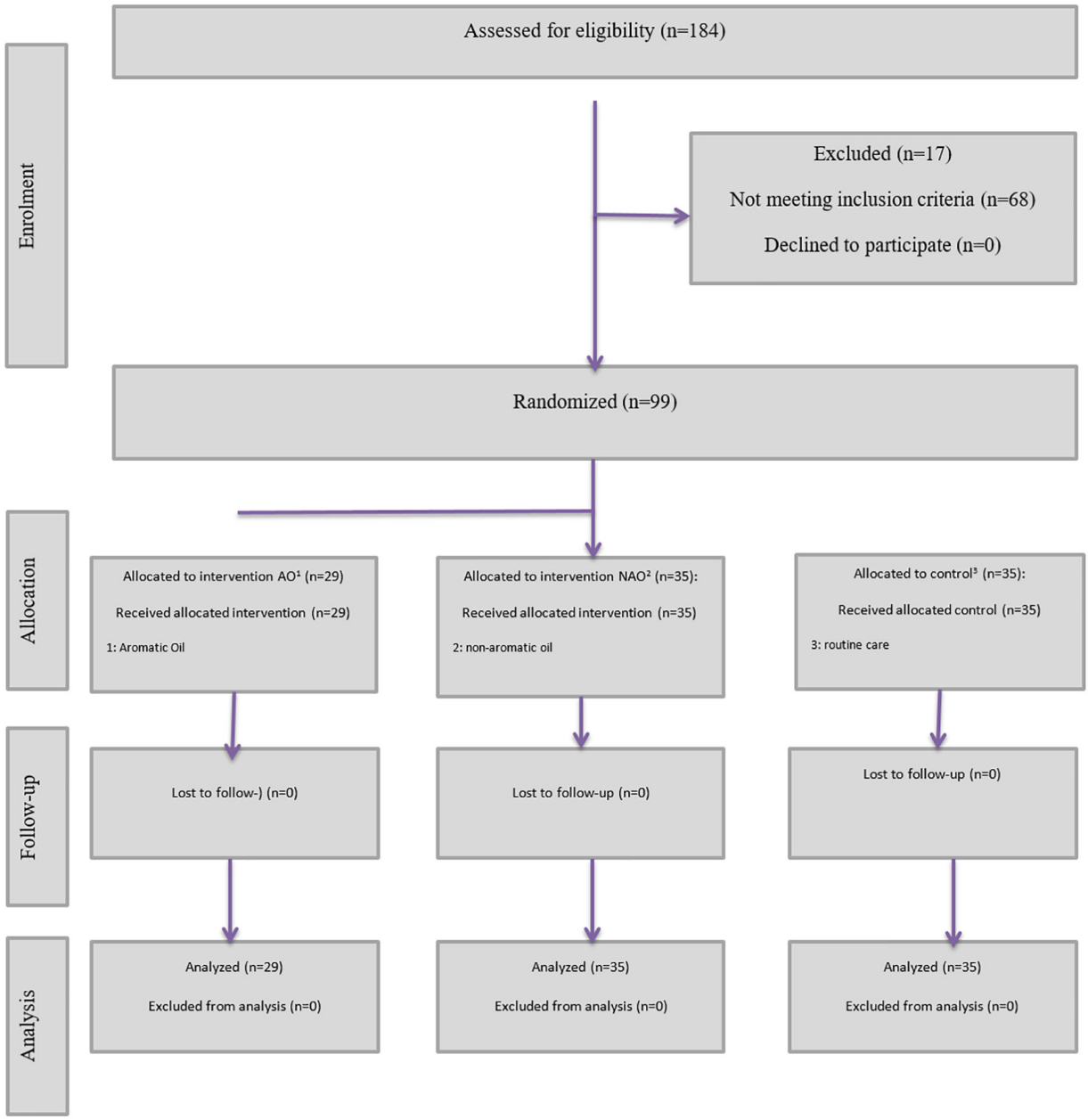

Figure 1: The figure shows the CONSORT flowchart.

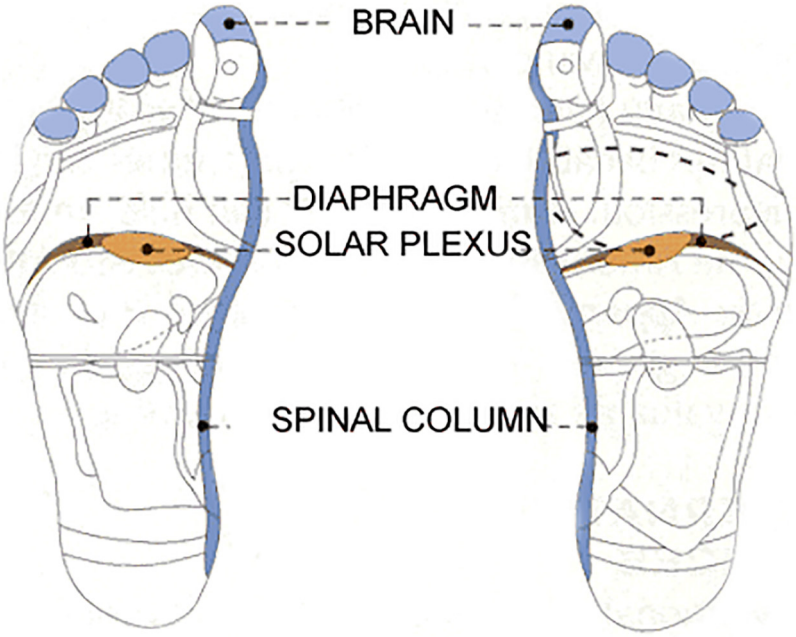

Figure 2: The figure shows the reflexology point.

pain and anxiety were examined and recorded for all three groups, using the Visual Analogue Scale (VAS) and Spielberger's questionnaire. After explaining the reflexology technique to the participants in the intervention groups, reflexology was initiated by a trained LDR midwife, who massaged the entire sole of the foot with lavender or olive oil. Subsequently, rotational pressure was applied on the points of solar grid (on the border of the upper and middle third of the sole), pituitary gland (middle of the big toe), and uterus (between the inner ankle and the heel) for 20 minutes for each foot (Figure 2). This technique was applied once at a 4-5 cm dilation. The pain and anxiety questionnaires were completed again at a dilation of 4-5 cm for the control and intervention groups immediately after the intervention. They were completed for the last time at a dilation of 7-8 cm by conducting interviews.

2.3. Measurement Scales

The Spielberger's State-Trait Anxiety Inventory with 20 items was employed to evaluate anxiety based on a Likert scale, ranging from one ("not at all") to four ("very much"). This questionnaire is widely employed by psychologists, experts, and researchers. The validity and reliability of the Persian version of this scale were reviewed and approved by the faculty members of Shahid Beheshti University (Tehran, Iran), as well as the faculty members of Tehran Psychiatric Institute (13). The validity and reliability of this questionnaire were confirmed in a study by Shahri for localization of the scale in Iran, with a Cronbach's alpha >0.9 (14). Moreover, Alipour and colleagues reported a Cronbach's alpha of 0.86 (15). The VAS, as one of the most widely used pain measurement tools, was also employed to evaluate the severity of pain (16-18). This scale is a graduated line, where the left end is marked as zero, and the right end is marked as 10. Scores of 1-3, 4-7, and 8-10 represent mild, moderate, and severe pain, respectively.

2.4. Statistical Analysis

The collected data were analyzed using descriptive methods, as well as parametric and non-parametric tests, including paired and independent t-test, Chi-square, ANCOVA, Tukey's post-hoc test, and repeated measures ANOVA. Regression models were also plotted at a significance level of 0.05. SPSS version 16 (SPSS Inc., Chicago, IL, USA) was used for all statistical analyses.

3. Results

A total of 99 participants in the age range of 16-39 years (mean, 25.98±5.80 years), who met the inclusion criteria, were allocated to three groups. The participants' demographic characteristics are summarized in Table 1. The results revealed that the mean age of the three groups was not significantly different (P=0.699). Also, the education level

Table 1: The demographic data of the participants in the intervention and control groups

Variable	Groups			P value
	2 (n=35)	1 (n=29)	C (n=35)	
Age	25.40± 5.89	26.03±5.67	26.63±5.96	0.699
Education				0.504
Under diploma	21(60)	15(51.7)	20(66.7)	
Diploma/college	14(40)	14(48.3)	10(33.3)	
Job status				0.140
Housewife	27(77.1)	27(93.1)	27(90)	
Employed	8(22.9)	2(6.9)	3(10)	

Data are presented as Mean±SD; Intervention groups: Group 1 received reflexology with lavender oil and group 2 received reflexology with olive oil.

Table 2: The APGAR score and duration of labor in the intervention and control groups

Variable	Group			P value
	2 (n=35)	1 (n=29)	C (n=35)	
APGAR				
First minute*	8.91±0.16	8.96±0.18	8.83±0.37	0.066
Duration				
1st stage (hour)	5.22±1.59	5.43±1.52	5.96±1.85	0.194
2nd stage (hour)	0.85±0.64	0.82±0.59	1.07± 0.64	0.258

Data are presented as Mean±SD; Intervention groups: Group 1 received reflexology with lavender oil and group 2 received reflexology with olive oil.

Table 3: Evaluation of pain in the intervention and control groups in three stages of the study

Variable		Group			P value /CI
		2 (n=35)	1 (n=29)	C (n=35)	
Pain	Before intervention	6.62±1.83	6.34±1.49	4.66±1.21	<0.001
	Dilatation 4-5	5.42±1.24	4.55±1.12	5.86±1.45	<0.001
	Dilatation 7-8	6.31±1.36	5.96±1.54	7.1±1.24	0.007
P value		<0.001	<0.001	<0.001	

Data are presented as Mean±SD; Intervention groups: Group 1 received reflexology with lavender oil and group 2 received reflexology with olive oil.

(P=0.504) and occupational status (P=0.140) of the participants in the three groups did not show significant differences.

No significant difference was found between the three groups in the first (P=0.194) and second (P=0.258) stages of labor. All participating women had a normal vaginal delivery and episiotomy. The one-minute APGAR score was 8.91±0.16, 8.96±0.18, and 8.83±0.37 in the groups 2 and 1, and C group, respectively, and there was no significant difference between the three groups (P=0.066). Also, the mean five-minute APGAR score of the groups was 10 (Table 2).

3.1. Analysis of Pain-related Findings in the Pre-intervention Stage

Table 3 presents the pain-related findings of the three groups in the pre-intervention stage and immediately after it at dilations of 4-5 and 7-8 cm.

The results of pain analysis in the pre-intervention stage indicated a significant difference between the control and two intervention groups in terms of pain (lower average pain in C group). According to the results of Tukey's post-hoc test, the observed difference in the pre-intervention stage was attributed to differences between groups 2 (95% CI: 1.04-2.88, P<0.001) and 1 (95% CI: 0.71-2.64, P<0.001) and C group regarding pain severity (Table 3).

3.2. Analysis of Pain-related Findings in the First Stage After the Intervention (4-5 cm Dilation)

The results of intergroup analysis of pain following the intervention at 4-5 cm dilation

demonstrated significant pain reduction in the two intervention groups. The difference in the average pain was more significant in the group 1 (-1.79) compared to the group 2 (-1.2). However, the average pain severity increased significantly in C group (+1.2) (Table 3).

Based on the intergroup analysis, there were significant differences between groups 2 and 1 (95% CI: 0.11-1.64, P=0.021) and between group 1 and C group (95% CI: 0.52-2.10, P<0.001). At this stage, group 2 and C group were not significantly different regarding pain severity (95% CI: -1.19–0.32, P=0.358). At this stage, the pain severity significantly reduced in the group 1 compared to the other two groups. Although the pain severity was significantly lower in C group compared to the other two groups before the intervention, the post-intervention findings revealed pain-reducing effects in both intervention groups, with the group 1 showing more significant changes.

3.3. Analysis of Pain-related Findings in the Second Stage of the Intervention (7-8 cm Dilation)

In the second stage of the intervention (dilation of 7-8 cm), increase in the average pain was justifiable in the intervention and control groups compared to the first stage. The analysis of pain severity in the second stage revealed a significant difference between group 1 and C group (95% CI: 0.27-1.99, P=0.006). Although the difference in pain severity was not statistically significant between group 2 (mean, 6.31±1.36) and C (mean, 7.1±1.24) group (95% CI: -0.64–1.21; P=0.784), it was considerable. At this stage, no significant difference was observed in terms of pain severity between groups 2 and 1 (95% CI: -0.48–1.17; P=0.578) (Table 3).

3.4. Summary of Pain-related Findings

Figure 3 presents a linear increase in the pain severity in all stages (average range, 4.66-7.1). Moreover, the pain severity was compared between the groups in each stage. In both stages, there was a significant reduction in the pain severity compared to the control group. However, in the group 2, despite pain alleviation, no significant difference was observed, while pain reduction was quite significant in the group 1.

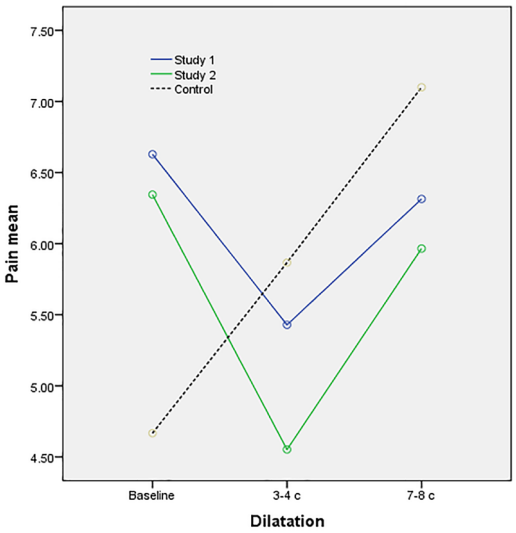

Figure 3: The figure shows linear illustration of the mean pain scores before and after the intervention in the study groups.

3.5. Analysis of Anxiety-related Findings

Regarding anxiety, no significant difference was found between the three groups in any of the stages. However, according to the intragroup analysis, anxiety increased significantly in C group (mean 1=49.36±5.24; mean 2=50.96±4.29; and mean 3=53.4±5.97; P<0.002), while in the intervention groups, it remained almost unchanged (Table 4).

4. Discussion

In the current study, the groups were not significantly different regarding the demographic characteristics, neonatal APGAR score, duration of delivery, and anxiety. All the participants had a normal vaginal delivery and episiotomy. The similar mode of delivery in women can be attributed to the inclusion criteria, such as the

Table 4: Evaluation of anxiety in the intervention groups and control group.

Variable		Group			P value
		2 (n=35)	1 (n=29)	C (n=35)	
Anxiety	Before the intervention	51.22±6.27	49.58±5.52	49.36±5.24	0.358
	Dilatation 4-5	51.37±7.22	48.96±5.59	50.96±4.29	0.240
	Dilatation 7-8	52.85±8.06	51.65±7.97	53.4±5.97	0.564
P value		0.171	0.121	0.002	

Intervention groups: Group 1 received reflexology with lavender oil and group 2 received reflexology with olive oil.

absence of pregnancy complications. Comparison of findings between the three groups in three stages of the study, that is, pre-intervention, after the first intervention (4-5 cm dilation), and after the second intervention (7-8 cm dilation), indicated a significant difference in the average pain reduction between the intervention groups and the control group. The pain reduction was more significant in the group1 receiving aromatic lavender oil.

Several studies (19-21) have compared reflexology using AOs with control groups and investigated pain reduction. Nevertheless, only the present study included two parallel groups of reflexology interventions to compare the efficacy of reflexology with AO and NAO and also compare these interventions with a control group. The present results provided some evidence on the effects of reflexology massage alone and reflexology massage with AOs, such as lavender oil. Lavender oil, in addition to its aromatizing activity through which it affects pain perception (based on the neuromatrix theory), is believed to play a role in pain relief owing to the presence of antioxidant, anti-ischemic, and oxidative anti-stress compounds (11, 22, 23); the present findings related to pain relief following reflexology with lavender oil during labor confirmed this result.

In this regard, Dolatian and co-workers investigated pain severity following reflexology in two intervention groups of psychological support and routine care. Their results suggested significant pain reduction in three stages of pain assessment in the reflexology groups, as well as reduction in the duration of the first, second, and third stages of labor (8). In the present study, the AO reflexology group was significantly different from the other groups in terms of pain severity. Although the intragroup analysis indicated pain reduction in the NAO reflexology group (olive oil), there was no significant difference between this group and the controls. Also, no significant difference was observed between the groups in different stages of labor. It should be noted that in the present study, active labor management with oxytocin infusion was conducted, which might have led to insignificant differences during labor.

A study by Smith and colleagues regarding the effects of massage therapy and reflexology on labor found no effects on the duration of labor and delivery, which is consistent with the present results (24). Moreover, Dyer and co-workers conducted a study on two intervention groups of aromatherapy and massage therapy for cancer patients and compared their effects. After four stages of interventions, the results indicated similar effects on the alleviation of symptoms in the groups of aromatherapy and massage therapy (25). In the present study, reflexology with AO significantly affected pain reduction compared to the reflexology and control groups, as the combination of massage therapy with aromatherapy techniques, besides the use of lavender oil with exclusive pain-relieving properties, has been shown to be more effective in numerous studies (5-9).

In this regard, Lamadah and Nomani evaluated the application of back massage with lavender and compared the results with a control group (only back massage) during labor. They found a significant difference in the severity of pain, anxiety, and duration of labor between the groups (26); their findings are in line with the present research, except for labor duration. Although in the current study, anxiety was not significantly different between the groups, the intragroup analysis showed that anxiety remained unchanged during labor in the intervention groups; meanwhile, it increased in the control group. In another clinical trial, Levy and co-workers investigated the effects of reflexology on anxiety in primiparous women. They reported the temporary effect of reflexology (up to 30 minutes after reflexology) on the reduction of anxiety in the intervention group, which did not persist throughout labor (27). It is worth mentioning that in their study, the anxiety measurement tool was VAS, which differs from our study.

Additionally, a quasi-experimental study (9) on primiparous women, evaluating the effectiveness of reflexology on anxiety based on the Spielberg's scale, reported no change in anxiety after reflexology in the intervention group, which is consistent with the results of the present study. On the other hand, the analysis of case and control groups showed a significant difference in terms of anxiety between the case group after reflexology and the control group, which is inconsistent with the current findings; the type of research method and tools of anxiety measurement can explain the contradictory findings of these studies (26, 27). Also, differences in the results can be attributed to variations in routine labor management in maternity wards (active or physiological),

differences in the staff's attitude toward mothers, and various environmental factors, such as hospital atmosphere and maternity room layout.

4.1. Limitations

First, it was not possible to blind the participants due to the aromatic properties of lavender oil and the type of intervention. Second, this study was limited by frequent midwifery manipulations by the staff and students, which disturbed the mothers' peace of mind. Third, the current study only focused on primiparous women, who had no pregnancy complications or diseases. Therefore, further research is suggested, focusing on multiparous women or mothers with obstetric problems.

5. Conclusions

Reflexology with aromatic oil was found to be more effective than reflexology with non-aromatic oil, as it could result in further pain alleviation during labor compared to the control group. Despite the lower average stress scores of the intervention groups compared to the control group, no significant difference was found. Also, the duration of labor and APGAR score were not significantly different between the groups.

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Ethical Approval

The Ethics Review Board of the university approved the present study with the code of IR.IAU.KAU.REC.1398.060. Also, this clinical trial was registered in the Iranian Registry of Clinical Trials with the code of IRCT20200810048357N1. Written informed consent was obtained from the participants.

Conflict of Interest: None declared.

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