

The effectiveness of foot reflexology in reducing anxiety and duration of labor in primiparas: An open-label randomized controlled trial

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ABSTRACT

Background and purpose: Reflexology alleviates anxiety and may shorten the duration of labor. We evaluated the effect of reflexology on anxiety level and duration of labor in primiparas with moderate-to-severe anxiety.

Materials and methods: In this open-label randomized-controlled trial, primiparas with moderate-to-severe anxiety were randomized into one of two groups: addition of reflexology to usual care, or usual care only. The primary outcome was a change in the level of anxiety during reflexology treatment.

Results: Ninety-nine women were assigned to reflexology treatment while ninety received usual care only. A larger alleviation of anxiety was observed immediately after reflexology treatment as compared to the control group during the 30 min following group assignment. Reflexology did not affect the length of delivery.

Conclusion: Foot reflexology had a positive short-term anxiolytic effect during labor in primiparas with moderate-to-severe anxiety but did not affect the duration of labor.

1. Introduction

Severe perinatal anxiety affects up to 15% of pregnant women [1]. This phenomenon involves various hormonal and inflammatory processes [2] and seems to have deleterious physical, behavioral, mental and medical effects on the infant [3]. For example, children born from anxious mothers have a higher rate of childhood and adulthood illnesses, particularly endocrine disorders that seem to be influenced by the high hypothalamic-pituitary-adrenal axis activity in response to high maternal anxiety [3]. Furthermore, severe anxiety has been shown to increase the rate of Caesarean sections [4] and to prolong the duration of labor [5,6]. The catecholamines that are secreted in response to anxiety have strong effects on the uterus, which exhibits greater sensitivity to beta-adrenergic as compared to alpha-adrenergic receptors [7,8]. Under these circumstances, the high level of epinephrine lowers uterine contractility, therefore prolonging the active phase of labor [7]. Since prolonged delivery may negatively impact maternal and neonatal

outcomes [9–11], early identification and management of maternal anxiety during pregnancy and labor is critical, particularly among primiparas who tend to be in the active phase of labor longer than multiparas [12].

Different approaches have been described to reduce the level of anxiety during labor, among them psycho-behavioral [13] or pharmacological [14] therapies. However, anxiolytic drugs may be harmful in pregnant women [15,16]. Another approach is Integrative Medicine (IM), which combines conventional and complementary therapies. IM has been defined as “a holistic, patient-focused approach to health care and wellness, treating the whole person rather than one organ system.” [17]. In recent years, IM practices have been integrated into patient care, including in the hospital [18–21]. Specifically for women during labor, different complementary medicine techniques have safely and effectively been coordinated with conventional medicine, including acupuncture, aromatherapy, mind-body therapies or dietary supplements [22–29].

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Reflexology, a touch-based IM technique, has been integrated into obstetric care in different parts of the world and is currently used by about 5% of pregnant women in Western countries [30] and by up to 30% in China [31]. This practice has been shown to be safe [20] and may be taught easily to healthcare professionals and to families. It entails applying pressure to specific areas of the feet or hands (reflex points), resulting in the stimulation of nerve points that mediate electrochemical messages [32]. Neuronal activation by direct pressure reduces tension and stress and maintains the balance of the body [33]. Hand reflexology seems to have some anxiolytic properties in different cardiac diseases [34–36]. Foot reflexology as well has exhibited positive anxiolytic effects in different clinical situations, such as malignancy or periprocedural anxiety [21,37,38]. Such reduction of anxiety seems to be mediated by activation of the parasympathetic and inhibition of the sympathetic nervous systems by stimulation of different reflex points [37,39]. These effects may therefore reduce the catecholamine surge associated with the prolonged active phase of labor. Indeed, in a recently published study, reflexology was shown to reduce the level of anxiety during labor among primiparas as compared with a control group [33]. Another study showed reduction in the level of labor anxiety in primigravida women after reflexology intervention, which was accompanied by a decrease in pain level, shortening of labor and improvement in labor outcomes (uncomplicated vaginal delivery, Apgar score), as compared to a control group [40]. These studies evaluated the effect of reflexology in primiparas in general and did not concentrate specifically on women with initial moderate to severe anxiety, a group that should be studied in larger cohorts.

Due to the potential deleterious consequences of anxiety on mother and infant and the potential effectiveness and safety of reflexology in this setting, the aim of our study was to determine the effect of reflexology on anxiety during labor among primiparas with moderate to severe anxiety at different time points after treatment, after correction for socio-demographic variables. In addition, we assessed the correlation between anxiety and pain levels as well as the patients' expectations from reflexology. Finally, we evaluated the impact of such an anxiolytic effect on the duration of the active phase and the second stage of labor.

2. Materials and methods

2.1. Study design

This is an open-label randomized controlled trial aimed at assessing the effectiveness of reflexology in the reduction of anxiety in primiparas during labor as well as the effect of reflexology on the duration of labor. The study took place from June 2015 to August 2016 in the Obstetrics Ward of Bnai Zion Medical Center, a tertiary academic hospital in Haifa, Israel.

2.2. Ethics review and informed consent

The study protocol was reviewed and approved by the Institutional Review Board of Bnai Zion Medical Center in accordance with the Helsinki Declaration (0041-09-BNZ) and registered at www.clinicaltrials.gov (NCT01733771). In the screening phase, all eligible participants were informed of the details of the study, including intervention and data collection procedures, potential risks and benefits. Women were randomized after signing the written informed consent.

2.3. Study population

Women were included if they fulfilled the inclusion/exclusion criteria.

2.3.1. Inclusion criteria

- Age ≥ 18 years

- Hospitalization in obstetrics ward during labor
- Primiparity
- Moderate to severe anxiety at admission: Visual Analogue Scale (VAS) ≥ 4
- Informed consent signing

2.3.2. Exclusion criteria

- Admission for primary Caesarian section (elective or emergent)
- Hemodynamic instability

2.4. Randomization

Women fulfilling the inclusion/exclusion criteria were randomized either to the intervention group (reflexology and usual care) or to the control group (usual care only). Women recruited on Sundays, Mondays, Tuesdays or Thursdays were assigned to the reflexology group, while women recruited on Wednesdays, Fridays or Saturdays were assigned to the control group. Weekday randomization was judged reasonable since appointments for follow-ups and for elective induction of labor were not assigned to a specific day of the week. Thus, delivery weekday did not predispose the primiparas to either of the study groups. Blinding of the reflexologists or patients was clearly not possible.

2.5. Measurements

Level of anxiety was measured according to the VAS anxiety scale ranging from 0 to 10 (0- no anxiety up to 10- maximum anxiety) by directly questioning the women upon admission (before intervention), immediately after reflexology treatment (in the reflexology group) or 30 min after admission (in the control group), and 1 h later (90 min measurement point). The VAS is a validated instrument for evaluating anxiety [41,42] and has even been used in previous studies for evaluation of anxiety during labor [43]. Moreover, because the VAS is short and easy to administer, it is suitable for daily administration in the delivery room. Since VAS-evaluated anxiety has not been divided into severity thresholds, we used the validated division of VAS for pain to project the following thresholds: VAS <4 : mild anxiety, VAS 4–7: moderate anxiety, VAS >7 : severe anxiety [44]. Only women with a baseline VAS anxiety score of 4 and above were recruited, as mentioned in the inclusion criteria. After recruitment, study investigators briefly interviewed each woman based on an informative questionnaire that was written after the five investigators reached consensus. The interview included questions on socio-demographic characteristics (age, familial status, education), cause of anxiety, prior reflexology treatment and a specific question on expectations from reflexology treatment as rated on a 1–5 Likert scale. Medical/obstetrical data were extracted from the patient's chart and included comorbidities, weeks of pregnancy, potential pregnancy complications, gravidity, reason for admission, opening and effacement status, time of admission, time of measured 4 cm dilation, time of measured 10 cm dilation and time of delivery, thus enabling the investigators to calculate the active phase (from 4 cm to 10 cm dilation) and the second stage (from 10 cm dilation to delivery) of labor. Note that the times of 4 cm and 10 cm dilation were not exact since they were based on periodic examination. Due to ethical and medical considerations, it was not possible to examine the women too frequently. Pelvic examination was therefore based on clinical necessity, with varying frequencies and generally once in 1–3 h.

2.6. Intervention

Reflexology: Women in the reflexology group were treated with foot reflexology according to a protocol based on the literature review and on clinical experience, after five reflexologists with at least five years of clinical experience reached consensus (Appendix). The duration of treatment was 30 min and the treatment depth was adapted to each

woman's clinical presentation and individual reaction to touch. Women were treated in different phases of labor (latent or active phase).

Usual care: Conventional therapy for anxiety was administered to all women in the obstetrics ward in both the reflexology and control groups according to the clinical evaluation of the medical staff. Women who exhibited at least a moderate level anxiety (VAS ≥ 4) were managed by means of calming and strengthening techniques. The midwives who provided these techniques had previously attended an 8-h training session administered by the study team (integrative medicine specialists, psychologists and physicians). The training was based on data from the literature [45] as well as on professional experience. Severe anxiety (VAS 7–10) that did not improve using these techniques was treated with pharmacological therapy at the physicians' discretion (regional anesthesia, meperidine). Concerning pain management, analgesics were given for pain according to VAS, as evaluated by the medical staff: mild pain (VAS 1–3) was treated with paracetamol or dipyrone, moderate pain (VAS 4–6) was treated with weak or low dose opioids (oxycodone 5–10 mg, tramadol 50 mg) and severe pain (VAS 7–10) was treated with higher dose opiates (oxycodone 10–20 mg, morphine).

2.7. Training

Reflexologists with at least five years of clinical experience in treating pregnant women administered the foot reflexology treatment. Pressure intensity was not standardized but rather adapted per patient in order to create a comfortable sensation rather than a painful one, as is customary in reflexotherapy. The five data collectors were healthcare providers who attended an 8-h training session on questionnaire administration. Dropout, withdrawal, undelivered intervention and uncollected data were recorded until completion of the study.

2.8. Outcomes

The primary outcome was the mean difference in anxiety level during labor from baseline until the end of the reflexology treatment (30-min measurement). Secondary endpoints included the effectiveness of reflexology in reducing anxiety in the hour following treatment (30-90-min period) and in reducing the duration of both the active phase and the second stage of labor. These outcomes were corrected for different socio-demographic and medical/obstetrical characteristics, as well as for other variables, such as cause of anxiety, pain, prior experience with reflexology and women's expectations from reflexology therapy, by specifically analyzing the described outcomes in subgroups of patients with these specific variables as well as by calculating *r* scores. These sub-analyses allowed the researchers to delineate which subgroups of primiparas benefited most from reflexology treatment of anxiety during labor.

2.9. Safety and adverse events

All adverse events (e.g., dizziness, pain, exacerbation of anxiety) were assessed by direct questioning, as well as by an open question asking whether the patient attributed any other adverse effect to reflexology. Serious adverse events requiring patient exclusion from the clinical trial included deleterious changes in fetal monitor (late or variable decelerations) or hemodynamic instability during reflexology treatment [20].

2.10. Criteria for discontinuation

Women were discontinued from the study if they voluntarily withdrew informed consent, due to safety concerns (e.g. hemodynamic instability, fetal pulse deceleration), or due to significant non-compliance with the study protocol as determined by the Principal Investigator (not finishing the 30-min reflexology treatment, not answering at least two of the three VAS anxiety evaluations).

2.11. Sample size calculation

In a study that evaluated the effect of reflexology on anxiety in primiparas, the level of anxiety (Spielberger State-Trait Anxiety Inventory) after intervention was 45.97 ± 6.43 in the reflexology group as compared to 48.94 ± 6.05 in the control group. Considering a Type I error (α) of 0.05 and a power of 0.80, we calculated that a minimal sample size of 69 patients per group was necessary to obtain a statistically significant difference in anxiety level between our study groups. We added 20% more patients to each group for the sub-analyses on confounding variables, so we needed at least 83 women per group.

2.12. Statistical methods

Data were analyzed using IBM SPSS® Statistics software version 25. Intention-to-treat analysis was used to provide more information on the effect of the intervention, considering possible confounders such as missing data, protocol deviations and withdrawal. Socio-demographic and clinical data were analyzed at baseline to measure the balance between the groups. The results were described by mean with standard deviation for continuous data, and by frequency and percentage for categorical data. The Pearson Chi-square test and Fisher's exact test were used to detect differences in the prevalence of categorical variables, a *t*-test was conducted to determine whether there were any differences in the continuous variables between the two groups, and *r* correlation coefficient was used to determine whether there is a linear correlation between two continuous variables, such as age and level of anxiety (VAS 0–10). Finally, a multivariate analysis concentrating on women recruited in the latent phase of labor was used to determine which variables influenced anxiety immediately after treatment (0-30-min period). Odds-ratios (OR) with their 95% Confidence Intervals (CI) were calculated in the intervention group as compared with the control group. The level of significance was reported at $p < 0.05$.

3. Results

3.1. Baseline characteristics

Overall, 257 women were approached to participate in the study during the period from June 2015 through August 2016. Of these, 68 were excluded for various reasons: 12 did not agree to participate (response rate: 95%) and 56 had an initial VAS anxiety score lower than 4. One hundred eighty-nine women reporting an initial VAS anxiety score of 4 and above were recruited. Ninety-nine of them received reflexology treatment in addition to usual care during labor, while 90 received usual care only. No women were excluded after recruitment; the analysis was conducted on the data of all 189 recruited women (Fig. 1).

No between-group differences were found concerning socio-demographic or medical/obstetrical characteristics, and the percentage of primiparas whose labor was induced was similar in both groups. The reasons for anxiety were similar in both groups and mainly included pain, not knowing what to expect ("the unknown") and fear for the baby (Table 1).

3.2. Effectiveness of reflexology on level of anxiety during labor

Reflexology significantly reduced the level of anxiety immediately after treatment (0-30-min period) as compared to the control group (-2.4 ± 2.4 vs -0.7 ± 2.4 , $p = 0.0002$). This positive effect was observed particularly in women with professional or academic education, less in women with high school education only and in women admitted with rupture of membranes or post-term pregnancy and less in women admitted with contractions. The maximal effect of reflexology on anxiety reduction immediately after treatment was observed when the reflexology treatment was administered in the latent phase (0–3 cm

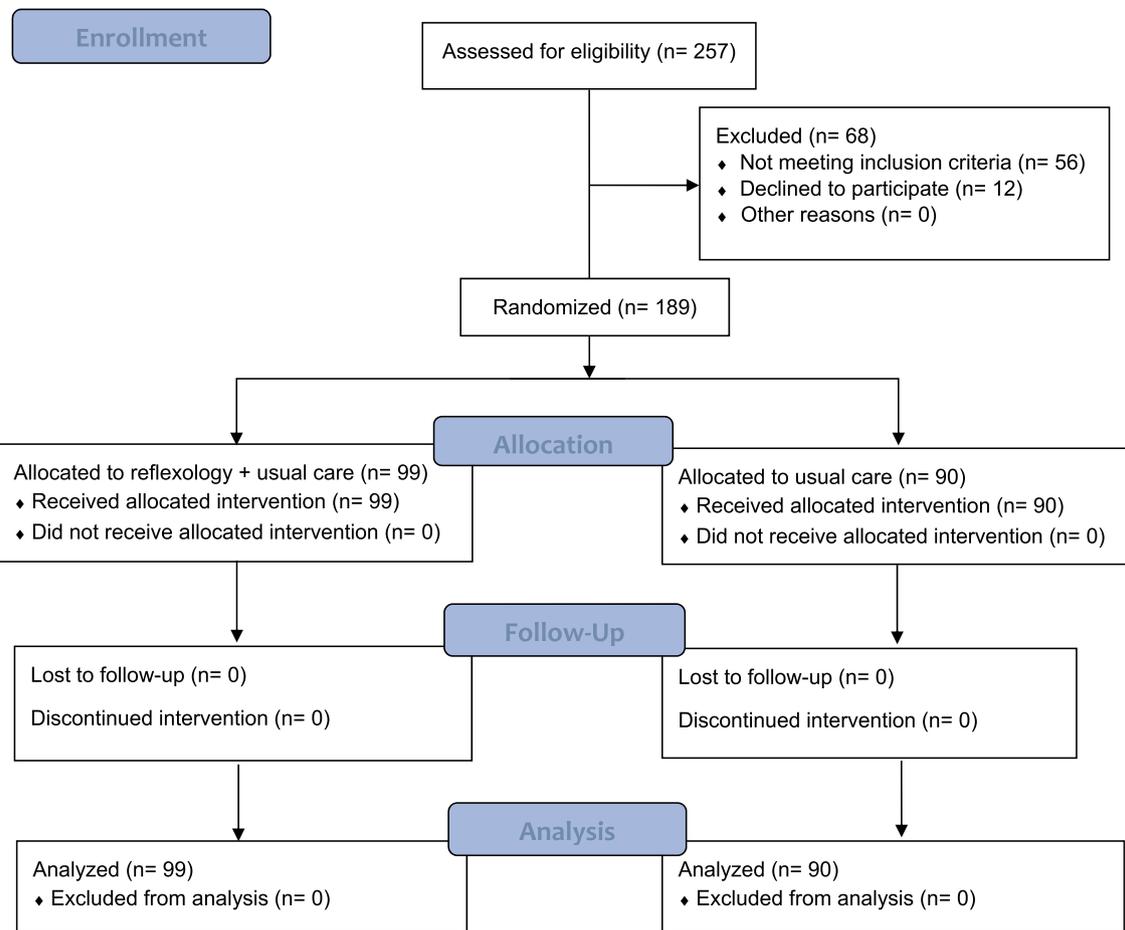


Fig. 1. CONSORT flow diagram.
Legend: VAS: Visual Analogue Scale.

Table 1
Baseline characteristics.

Characteristics	Reflexology n = 99	Control n = 90	P
Age	28.6 ± 4.4	27.9 ± 4.5	0.28
Family status (married)	89 (90%)	85 (94%)	0.29
Education			
High school	23 (23%)	34 (38%)	0.06
Professional	10 (10%)	9 (10%)	1.00
Academic	61 (62%)	46 (51%)	0.07
No data	5 (5%)	1 (1%)	0.11
Comorbidities (healthy)	87 (88%)	69 (77%)	0.08
Spontaneous pregnancy	87 (89%)	81 (91%)	0.64
Gestational age (years)	39.7 ± 1.4	39.3 ± 1.3	0.11
Gravidity (G1)	79 (80%)	76 (84%)	0.45
Normal gestation	82 (84%)	68 (76%)	0.24
Reason for hospitalization			
Rupture of membranes	35 (35%)	38 (43%)	0.26
Contractions	31 (31%)	21 (23%)	0.22
Post-term pregnancy	14 (14%)	10 (11%)	0.54
Oligohydramnios	5 (5%)	5 (6%)	0.76
Other	16 (16%)	15 (17%)	0.85
Opening status (cm)	3.6 ± 2.8	3.7 ± 2.8	0.85
Effacement status	85.4% ± 13.4%	82.1% ± 22.0%	0.36
Labor induction (Oxytocin)	78 (79%)	68 (76%)	0.62
Initial VAS anxiety score	7.9 ± 1.8	7.9 ± 2.0	1.00
Reason for anxiety			
Pain	33 (33%)	22 (24%)	0.17
“The unknown”	18 (18%)	23 (26%)	0.18
Fear for baby	14 (14%)	14 (16%)	0.70
Other	34 (34%)	31 (34%)	1.00

cervix dilation) rather than in the active phase (4–10 cm cervix dilation) of labor. However, these results may have been affected by the low number of patients in the reflexology group evaluated for anxiety immediately after treatment who were in the active phase of labor (8 women) (Table 2). A multivariate analysis concentrating on women recruited in the latent phase found that reflexology treatment was the only variable that influenced anxiety reduction immediately after treatment (0-30-min period), with OR = 5.15 (95% CI = 1.31–20.3, p = 0.019), as compared with the control group.

In the hour following treatment (30-90-min period), the inverse phenomenon was observed: The level of anxiety worsened in the reflexology group as compared to a slight improvement in the control group (0.8 ± 2.4 vs -1.1 ± 2.6, p = 0.01) (Table 2, Fig. 2), particularly among women with academic education (0.6 ± 2.6 vs -1.6 ± 2.8, p = 0.049) and among G1 (first pregnancy/gravidity) women (0.8 ± 2.6 vs -1.1 ± 2.4, p = 0.01) (Table 2).

Global analysis of the effect of reflexology from recruitment until 1-h post-treatment (0-90-min period) revealed no significant reduction of anxiety in the women who received reflexology treatment compared to those in the control group (-1.4 ± 2.4 vs -1.7 ± 3.0, p = 0.67) (Fig. 2, Table 2). However, after correcting for various variables, we observed that for women with professional education, reflexology significantly reduced anxiety in the 0-90-min period compared to the control group (-3.5 ± 1.3 vs -0.2 ± 0.5, p = 0.003). On the other hand, among women whose cause of anxiety was fear for their baby, reflexology significantly increased anxiety 90 min after treatment initiation compared to the control group, in which the level of anxiety was reduced (1.7 ± 2.9 vs -3.7 ± 3.4, p = 0.03) (Table 2).

Expectations from reflexology treatment, prior reflexology treatment

Table 2
Immediate and delayed anxiety reduction during labor.

Anxiety reduction	0–30 min			30–90 min			0–90 min		
	Reflex	Control	p	Reflex	Control	p	Reflex	Control	p
General	-2.4 ± 2.4	-0.7 ± 2.4	<u>0.0002</u>	0.8 ± 2.4	-1.1 ± 2.6	<u>0.01</u>	-1.4 ± 2.4	-1.7 ± 3.0	0.67
Age	r = 0.13	r = -0.05	0.17	r = -0.06	r = -0.05	0.49	r = 0.06	r = -0.11	0.25
Education									
High school	-2.7 ± 3.3	-1.2 ± 2.9	0.22	1.5 ± 2.6	-0.4 ± 1.8	0.08	-1.0 ± 1.8	-1.2 ± 3.1	0.88
Professional	-2.4 ± 2.6	0.5 ± 1.1	<u>0.02</u>	0.5 ± 2.1	-0.2 ± 0.5	0.52	-3.5 ± 1.3	-0.2 ± 0.5	<u>0.003</u>
Academic	-2.2 ± 2.1	-0.7 ± 2.0	<u>0.003</u>	0.6 ± 2.6	-1.6 ± 2.8	<u>0.049</u>	-0.9 ± 2.6	-2.4 ± 3.0	0.13
Gravidity									
G1	-2.1 ± 2.0	-0.7 ± 2.5	<u>0.001</u>	0.8 ± 2.6	-1.1 ± 2.4	<u>0.01</u>	-1.3 ± 2.5	-1.8 ± 3.0	0.52
G2+	-4.1 ± 3.6	-0.8 ± 2.0	<u>0.01</u>	0 ± 0	-1.2 ± 3.3	0.63	-1.5 ± 1.7	-1.8 ± 2.9	0.85
Admission									
ROM	-2.6 ± 3.1	-0.8 ± 2.2	<u>0.02</u>	0.62 ± 2.9	-1.6 ± 3.1	0.09	-1.2 ± 2.8	-1.9 ± 3.3	0.55
Contractions	-2.2 ± 1.5	-0.7 ± 3.2	0.16	0.50 ± 0.7	-1.1 ± 2.1	0.32	-0.25 ± 0.5	-2.0 ± 3.7	0.37
Post-term	-2.9 ± 2.5	-0.2 ± 1.6	<u>0.04</u>	1.0 ± 1.4	-0.7 ± 1.2	0.24	-3.0 ± 2.8	-0.8 ± 1.5	0.25
Opening									
0–3 cm	-2.4 ± 2.1	-0.8 ± 2.7	<u>0.02</u>	0.3 ± 3.0	-1.1 ± 2.4	0.20	-1.5 ± 2.1	-1.7 ± 3.5	0.85
4–10 cm	-2.5 ± 3.4	-0.6 ± 2.0	0.08	0 ± 0	-1.2 ± 3.1	0.62	-0.5 ± 0.7	-2.8 ± 1.9	0.16
Anxiety cause									
Pain	-2.1 ± 1.7	-1.0 ± 2.7	0.17	0.5 ± 2.6	-1.0 ± 2.3	0.26	-1.8 ± 1.8	-1.9 ± 2.8	0.92
“The unknown”	-2.6 ± 2.4	-1.2 ± 2.5	0.20	-1.0 ± 1.7	-0.4 ± 1.0	0.46	-2.7 ± 2.1	-1.4 ± 3.1	0.51
Fear for baby	-1.9 ± 2.2	-1.3 ± 3.0	0.62	0.5 ± 2.4	-2.3 ± 3.7	0.25	1.7 ± 2.9	-3.7 ± 3.4	<u>0.03</u>
Pain	r = 0.30	r = 0.54	0.08	r = -0.15	r = 0.39	0.052	r = 0.42	r = 0.32	0.33
Expectations	r = 0.05	r = 0.08	0.44	r = -0.17	r = 0.39	0.13	r = -0.13	r = 0.22	0.20
Prior reflex	-1.5 ± 1.7	-0.9 ± 1.8	0.32	0.9 ± 2.9	-1.8 ± 3.0	0.11	-1.7 ± 1.8	-2.6 ± 3.0	0.48

Legend: G1: first pregnancy; G2+: second pregnancy at least; Reflex: reflexology; ROM: rupture of membranes.

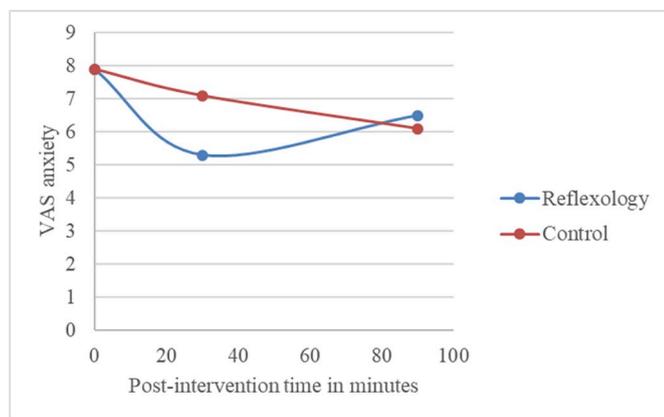


Fig. 2. Evolution of anxiety in both study groups.

and reflexology effect on pain during labor did not affect the variation in the level of anxiety in the reflexology group as compared to the control group in the three studied time frames (Table 2).

3.3. Effect of reflexology on duration of labor

Foot reflexology did not affect the duration of the active phase (5:09 ± 4:05 vs 5:10 ± 3:57, p = 0.98) or second stage (2:26 ± 1:21 vs 2:16 ± 1:24, p = 0.41) of labor compared to the control group, even when correcting for socio-demographic or medical/obstetrical characteristics as well as for the cause of anxiety. Neither expectations from reflexology treatment nor prior reflexology treatment affected the duration of delivery (Table 3).

3.4. Safety

No adverse events, either serious or minor, were reported throughout the study.

Table 3
Duration of the active phase and second stage of labor.

Duration of labor	Active phase			Second stage		
	Reflex	Control	p	Reflex	Control	p
General	5:09 ± 4:05	5:10 ± 3:57	0.98	2:26 ± 1:21	2:16 ± 1:24	0.41
Age	r = -0.10	r = 0.15	0.07	r = 0.12	r = 0.31	0.12
Education						
High school	4:49 ± 3:34	6:06 ± 4:36	0.32	2:35 ± 1:26	2:12 ± 1:29	0.39
Professional	8:58 ± 7:29	6:05 ± 4:33	0.43	2:32 ± 1:53	2:03 ± 1:14	0.60
Academic	4:44 ± 3:10	4:12 ± 3:21	0.79	2:26 ± 1:21	2:21 ± 1:21	0.78
Gravidity						
G1	5:15 ± 4:28	5:01 ± 3:42	0.76	2:28 ± 1:20	2:12 ± 1:23	0.28
G2+	4:46 ± 1:51	5:50 ± 5:02	0.47	2:19 ± 1:26	2:40 ± 1:24	0.53
Admission						
ROM	4:29 ± 5:24	5:13 ± 4:12	0.61	2:13 ± 1:26	2:26 ± 1:25	0.59
Contractions	5:51 ± 3:33	4:58 ± 3:27	0.42	2:18 ± 1:09	2:06 ± 1:24	0.61
Post-term	6:18 ± 3:57	7:56 ± 5:39	0.43	2:35 ± 1:30	2:40 ± 1:18	0.91
Opening						
0–3 cm	4:35 ± 2:55	5:26 ± 3:42	0.28	2:23 ± 1:23	1:58 ± 1:20	0.19
4–10 cm	6:44 ± 5:12	5:29 ± 4:54	0.43	2:39 ± 1:07	2:35 ± 1:23	0.86
Anxiety cause						
Pain	4:39 ± 3:00	4:38 ± 3:34	0.99	2:30 ± 1:28	2:08 ± 1:30	0.63
“The unknown”	5:49 ± 4:46	5:22 ± 3:17	0.76	2:40 ± 1:31	1:55 ± 1:21	0.13
Fear for baby	4:37 ± 2:36	4:19 ± 2:07	0.84	2:09 ± 1:12	2:22 ± 1:13	0.78
Expectations	r = -0.17	r = 0.09	0.13	r = -0.15	r = -0.04	0.31
Prior reflex	4:04 ± 2:47	5:27 ± 5:00	0.33	2:12 ± 1:28	2:12 ± 1:29	1.00

Legend: G1: first pregnancy; G2+: second pregnancy at least; Reflex: reflexology; ROM: rupture of membranes.

4. Discussion

According to our study, foot reflexology eases anxiety immediately after treatment when compared to usual care only in primiparas with moderate to severe anxiety. This effect is not associated with patients' expectations from reflexology, prior reflexology treatment or reflexology's effect on pain during delivery. This effect does not continue into the hour following reflexology treatment. Reflexology treatment seems safe during labor, and no adverse events were reported. Finally, reflexology treatment does not seem to impact duration of the active phase or the second stage of labor.

4.1. Time effect of reflexology

When observing the 0–30 and 30–90-min periods, we were able to delineate an immediate positive effect of reflexology on anxiety, while in the following hour anxiety level increased again, reaching similar levels as those in the control group. Similar to the findings of previous studies [33,40], these findings suggest that reflexology has a short-term anxiolytic effect during labor. It is possible that a longer reflexology session, variation in reflex point stimulation, or repeating the reflexology treatment 30–60 min after the first session would have had a longer effect. These factors may also influence the duration of labor, which was not shortened in our study as opposed to other studies [40]. Indeed, a recent review underlined the importance of repeating reflexology sessions to increase effectiveness [32]. Labor is a highly dynamic process in which pain and anxiety increase over time [46]. Therefore, repeated intervention seems highly reasonable. Our study also indicated that reflexology intervention in the latent phase appears to be more effective in reducing anxiety immediately after treatment than intervention in the active phase of labor. These findings underline the importance of timing in reflexology interventions. It is reasonable to suggest that reflexology treatment should be performed early during labor (latent phase) to achieve a short-term effect on stress reduction and then repeated later to strengthen this effect. Measuring surrogate markers of anxiety such as plasma catecholamines, cortisol or β -endorphins [47] in both groups at different points of time may have helped to further quantify the physiological and anxiolytic effects of reflexology in this setting. These markers should be assessed in further studies [48]. Indeed, norepinephrine seems to be related both to anxiety in labor and to its impact on prolonged labor and may be the mechanism of reflexology action in this setting [7,37,39].

4.2. Relevance of cause of anxiety

An important point emerging from our study is that a woman's reaction to reflexology depends on the cause of her anxiety. When the cause of anxiety was fear for the baby, anxiety was not relieved by reflexology, compared to the control group 90 min post-recruitment. For other causes of anxiety, such as the more prevalent fear of pain during labor [49], reflexology seems to have positive anxiolytic effects, particularly immediately after intervention. Drawing conclusions from subgroup analysis of causes for anxiety is limited due to the small sample size, though this conclusion does seem logical. Fear of labor pain also entails distress over losing control [50,51], and reflexology may assist in establishing a better sense of control during labor pain [52]. But a mother who has fears about her baby can only be reassured once she sees that her baby is healthy. All in all, fear of labor pain is the most prevalent feature of tokophobia (fear of childbirth) and has deleterious consequences to both the woman and her baby [53]. According to our study's results, reflexology can address such anxiety and possibly prevent its complications.

4.3. Unraveling specific anxiolytic effects of reflexology

Our study demonstrated that women's expectations from reflexology

treatment did not have an impact on the effect of the treatment on reducing anxiety or on its lack of effectiveness in reducing the duration of labor, nor did prior patient experience with reflexology. This finding shows that the specific anxiolytic effects of reflexology immediately after intervention were not influenced by such non-specific components. Nevertheless, our assessment of patients' expectations should be improved. Indeed, a 16-item questionnaire was recently validated as a reliable tool for evaluation of inpatients' expectations, beliefs and attitudes towards reflexology [54]. Use of such a questionnaire in our study may have improved the ability to detect women's expectations from reflexology treatment during labor.

The anxiolytic effect of reflexology was not affected by its analgesic effects as compared to the control group. Unlike a preceding study showing positive effects of reflexology on the severity of pain, anxiety and duration of labor [40], we isolated the anxiolytic effect of this practice and showed its lack of influence on the duration of labor. It is possible that the shortening of the active phase of labor observed in the preceding study was related to the effects of reflexology on pain rather than on anxiety. Reflexology treatment focusing on pain reduction during labor may, therefore, shorten the duration of labor, as shown in a previous study [55].

4.4. Limitations

Our study was conducted at a single medical center in Israel, which may have limited its generalizability. Nevertheless, the heterogeneity of our study population (socio-demographic and medical/obstetrical characteristics) allows for generalizability. Another potential limitation refers to the effectiveness of our exploratory methodology, which did not include integration of a sham-controlled group. However, finding a perfect "placebo" in IM practices is much more complex than in conventional drug clinical trials [56,57], and the sub-analyses we conducted on different confounding variables helped us isolate some of the specific as opposed to non-specific effects of reflexology in this clinical setting. The absence of participant blinding is another study limitation that is inherent to the study design, with the consequent risk of social desirability response [58]. This response is particularly prevalent in people with higher education [59] and may explain the relationship between reduction of anxiety and education level in the reflexology group. In order to avoid such bias, future studies should include an active control (e.g., guided meditation) that would allow patient blinding. The absence of assessor blinding may be the source for selection biases as well. However, since all primiparas were approached to participate in the study, such bias was minimized. In addition, the large number of statistical tests may substantially increase the risk of type 1 error, although adjustment for multiple comparisons reduces this kind of error. The measurements of the active phase and second stage of labor were not exact since vaginal examinations could not be performed too frequently due to ethical considerations. Furthermore, the beginning of the active phase of labor has been debated and the 4-cm-dilation cut-off we used has been contested recently [60]. Therefore, a more thorough measurement of duration of the active phase of labor should be assessed in future studies. Data on specific pharmacological therapy in each primipara were not collected and should be analyzed in further studies in order to evaluate the influence of reflexology on anxiolytic dosage and frequency in primiparas. Although the study focused on primiparas, it also included G2 women with previous gravidity who experienced prior pregnancies that ended in loss. Depending on the etiology of the pregnancy loss, these G2 women may have experienced their labor and delivery very differently than the G1 primiparas, thus possibly influencing the study results. Nevertheless, due to the low number of such women in the current study, the impact is probably minimal. Finally, as mentioned earlier, the assessment of women's expectations from reflexology can be improved by using a recently validated questionnaire [54].

5. Conclusion

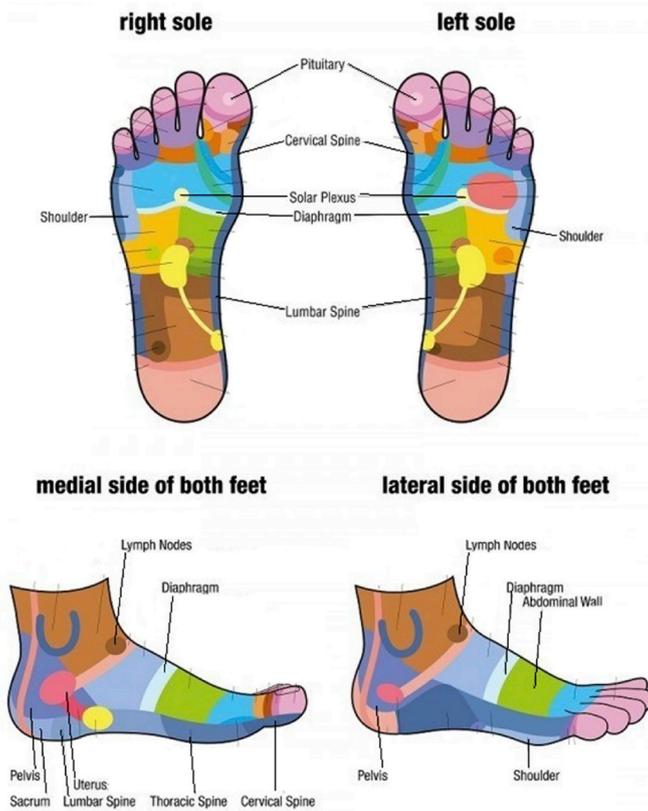
In conclusion, foot reflexology seems to have a positive but short-term effect on reducing anxiety during labor in primiparas with moderate to severe anxiety, and it is safe. Further studies should examine various timings of reflexology treatments during labor, as well as repeat interventions. Developing a valid sham reflexology procedure is critical in order to establish the specific versus non-specific effects.

Ethical approval

The study protocol was reviewed and approved by the Institutional Review Board of Bnai Zion Medical Center in accordance with the Helsinki Declaration (0041-09-BNZ) and registered at www.clinicaltrials.gov (NCT01733771).

Appendix. Foot reflexology protocol

Category	Reflex points
Lower abdomen	Lower lymph nodes Plantar fascia Pelvis Achilles tendon
Endocrine system	Pituitary Uterus Cervix
Nervous system	Cranial nerves Spinal nerves Shoulder belt Diaphragm Solar plexus



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Declaration of competing interest

The authors have no conflicts of interest to declare.

CRedit authorship contribution statement

Ilana Levy: Formal analysis, Writing - review & editing. **Samuel Attias:** Project administration, Formal analysis, Writing - review & editing. **Tamar Stern Lavee:** Writing - review & editing. **Ofri Avneri:** Writing - review & editing. **Gil Cohen:** Project administration, Writing - review & editing. **Shosh Balachsan:** Writing - review & editing. **Shlomi Sagi:** Project administration, Writing - review & editing. **Elad Schiff:** Project administration, Formal analysis, Writing - review & editing.

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