



The effect of topical olive oil application on the symptoms of infantile colic: A randomized, double-blind, placebo-controlled clinical trial

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Abstract

Background and Aims: Infantile colic is one of the most common disorders in the first months of infants' lives. This condition hurts parents' moods. This study was carried out to investigate the effect of the topical use of olive oil on infantile colic symptoms.

Methods: The study was carried out on 80 infants 1–3 months old, randomly allocated into two groups, receiving abdominal massage with olive oil thrice a day in the intervention group ($n = 40$) and the same procedure with liquid paraffin in the placebo group ($n = 40$), for 14 successive days. During this period, the parents recorded the episodes of colic, duration of colic, crying intensity, and episodes of defecation. These variables were assessed and compared at the beginning and on the 7th and 14th days.

Results: The mean crying duration changed from 4.05 ± 2.44 to 1.41 ± 1.03 h/day (65% decrease) in the olive oil group and from 3.85 ± 1.37 to 1.60 ± 1.32 h/day (58% decrease) in the paraffin group ($p = 0.38$). The episodes of crying were reduced from 5.79 ± 4.56 to 2.51 ± 4.93 episodes/day ($\downarrow 57\%$) in the olive group and from 6.01 ± 3.40 to 3.01 ± 2.40 episodes/day ($\downarrow 50\%$) in the paraffin oil group ($p = 0.14$). Furthermore, the intensity of crying was decreased from 9.04 ± 1.54 to 4.48 ± 2.17

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($p < 0.001$) in the olive oil group and from 9.0 ± 1.20 to 4.77 ± 1.68 ($p < 0.001$) in the paraffin oil group. On the 14th day, the crying intensity showed no significant difference between the two groups.

Conclusion: Abdominal massage with olive oil has the same effect as massage with paraffin oil in reducing the symptoms of infantile colic.

KEYWORDS

abdominal massage, clinical trial, infantile colic, olive oil, Persian medicine

1 | INTRODUCTION

Infantile colic is one of the most common conditions in the first months of infants' life, affecting 3%–40% of infants. Typically, it occurs during their first 15 days of life.¹ However, this condition is self-limiting; the extreme crying of the newborn may impair the mood of the family members and possibly disrupt the bonding between parents and infant.² Therefore, the most recent criteria for the diagnosis of infantile colic are the ROME IV criteria, including frequent and protracted episodes of crying, irritability, or fussing observed in a newborn less than 5 months that cannot be prevented or soothed by caregivers in the absence of failure to thrive, fever, or apparent causes.³

The leading cause of infantile colic is not fully understood in conventional medicine. Therefore, its etiology is considered to be multifactorial. Some of these factors include incorrect breastfeeding techniques, the negative relationship between parents and child, immaturity of the central nervous system, maternal nicotine use, lactase insufficiency, cow's milk protein intolerance, changes in intestinal microbial flora, immaturity of the digestive system, and intestinal inflammation.⁴ In addition, the microbial flora of the infant's gut is influenced by factors such as stress, diet, antibiotic use (by the mother or the infant), type of delivery (cesarean section), and gestational age of birth (preterm). Changes in intestinal microbial flora lead to leaky gut syndrome and subsequent entry of large undigested proteins into the blood, immune system activation, intestinal inflammation, changes in nerve signals, changes in bowel movement, and stimulation of nociceptors.⁵

Moreover, more recent studies showed that maternal psychological stress and a diet containing high allergens had been associated with infantile colic.^{6,7} According to the perspectives of Persian medicine, the weakness of the digestive system, consuming too much milk, flatulence of milk, dystemperament of the mother, and changes in the quality of milk are among the leading causes of colic in children.⁸ Weakness of digestion leads to bloating and constipation, which leads to abdominal pain in infants. Excessive drinking of milk leads to bloating, laziness, sleepiness, restlessness, crying, and vomiting, and if it is just before bedtime, it causes the milk to spoil in the stomach and makes the infant experience scary dreams. Moreover, flatulence could lead to back pain in the infant's back muscles by transferring gas through blood vessels, nerves, and membranes.^{9–11} Consumption of

too much and thin mother's milk and flatulent foods by the mother leads to her milk becoming flatulent. Spoilage of milk causes it not to be digested properly, which generates flatulence in the infant. Excessive sexual activity, pregnancy, and the dystemperament of the mother are essential factors in milk spoiling.^{12–14}

Conventional treatments include anti-flatulent, anti-spasmodics, sedatives, probiotics, and nondrug treatments, including parental reassurance and support, use of a sound therapeutic approach, warm baths, dietary modification, and food supplements.^{15–17} In addition, Persian medicine recommends the following treatments for children's abdominal cramps: warming the belly, rubbing rose oil on paravertebral regions, abdominal anointment with olive, chamomile, lily, fennel, or mastic oil; and feeding the newborn fennel, anise, or mastic.¹⁸ Treatment of colic caused by hot dystemperament includes placing a cloth dipped in cold water or santalum and rose water on the belly. If the condition is accompanied by constipation or the ineffectiveness of other treatments, using laxative suppositories or inserting the little finger dipped in violet oil in the anus is recommended. Additionally, adding cumin (*Cuminum cyminum*), thyme (*Thymus vulgaris*), and marjoram (*Origanum majorana*) to meals, consuming easily digestible foods by the mother, and avoiding putting the newborn to sleep immediately after breastfeeding could be beneficial.^{8,10,17,18}

Olive oil contains monounsaturated fatty acids, particularly oleic acid, and a small amount of polyunsaturated fatty acids, steroids, and natural anti-oxidants, including tocopherols, carotenoids, and phenolic compounds.^{16,19} It has anti-inflammatory, analgesic, and antimicrobial effects and vigorous antioxidant activity, which improves cellular functions.^{11,17,20} In comparison to refined olive oil, virgin, and extra-virgin olive oil have much greater levels of the essential bioactive components of olive fruit.^{11,18,21} In traditional medicine, obtained olive oil from ripe olives is warm and dry with little astringent properties and is helpful in healing the pains caused by cold dystemperament; if it is obtained from unripe olives, it is mild or cold and dry with more potent astringent properties and could strengthen the organs.^{11,22}

Due to the biological effects of olive oil and its therapeutic effect in traditional medicine, the current clinical trial was designed to evaluate the effect of olive oil anointment on infantile colic symptoms. To our best knowledge, this is the first research that assessed the impact of abdominal massage with olive oil on infantile colic symptoms.

2 | MATERIALS AND METHODS

2.1 | Study design

The current study is a randomized, double-blinded, and placebo-controlled clinical trial conducted between May 2021 and 2022. Eighty infants between 1 and 3 months were enrolled in the study. All subjects received ColicEZ[®] drops (Vitabiotics Co) three times daily as a routine treatment. Participants were randomly assigned to receive either olive oil or a placebo with a 1:1 allocation ratio. In the intervention group, olive oil was applied thrice daily on the belly, while liquid paraffin was used thrice daily in the placebo group. During 2 weeks of trial, the parents recorded the frequency of colic episodes, duration of colic episodes, and frequency of defecation on a checklist. These variables were evaluated at the beginning and on Days 7 and 14. In addition, the crying intensity was evaluated at the beginning and the end of the trial.

Noteworthy, the extra-virgin olive oil was purchased from Fadak Company. The chromatographic analysis is shown in Table 1.

2.2 | Ethical statement

The study complied with Mashhad University of Medical Sciences guidelines (Ethical approval code: 980998, Approval date: 15-2-2020, Approval ID: IR.MUMS.REC.1398.300). The study also received the Iranian Registry of Clinical Trials (IRCT) code with IRCT20200528047585N1 (<https://en.irct.ir/trial/48502>).

2.3 | Inclusion and exclusion criteria

A neonatologist examined infants whose parents complained of excessive crying of their newborn. Those diagnosed with infantile colic according to the Rome IV criteria were the candidate to

enter the study. After obtaining informed consent from the legal guardian, infants were evaluated for inclusion and exclusion criteria. Inclusion criteria comprised age between 4 and 12 weeks, term birth, birth weight over 2500 g, and good general condition and breastfeeding. Furthermore, infants should not have underlying diseases, malnutrition, and skin lesions in the abdomen. Their mothers also should not have severe depression and stress of the mother (based on the Beck questionnaire), maternal smoking, and the mother being employed at the time of the study. Additionally, infants were excluded from the study and took other medications for colic, who became ill during the study, developed an allergic reaction to the oils, and parents unwillingness to continue the clinical trial.

2.4 | Randomization and blinding

The samples were identified by the random block method with blocks of 4 and 6 and using the random numbers table of Allocation Random Software. A person not engaged in the study conducted the blocking and allocation sequence to ensure allocation concealment. Each group was assigned a unique code, which was only known to the research assistant. Topical oils were poured into identical and opaque jars to ensure that both the patients and the researchers were blinded regarding the medicine.

2.5 | Intervention

Both groups received a dosage of five drops three times a day of ColicEZ drops (Vitabiotics Co). In the intervention group, abdominal massage with olive oil (Fadak Co) was performed three times a day (two times during the day and once at night before sleep) when the infant relaxed. In the placebo group, abdominal massage was performed with liquid paraffin, similar to the intervention group. A uniform technique for applying the massage and anointment was instructed to the mothers to ensure that the same procedure was carried out on all participants. First, allergic sensitivity was assessed by rubbing a few drops of oil on the arms of infants. The baby would be allowed to receive the treatment if there were no allergic symptoms such as redness or rashes. Next, six to seven drops of oil were rubbed on the infant's belly and massaged in a clockwise direction for about 5 min with moderate pressure, and then the mothers massaged the abdomen from top to bottom several times. Finally, they bent the children's legs inside their abdomen, which helped the gas escape. The trial period was 2 weeks. Mothers in both groups were explained about psychological issues, peace at home, and proper emotional bonding. Also, it was explained to them how to breastfeed correctly, including putting the areola in the infant's mouth and burping after breastfeeding. Furthermore, researchers' phone numbers were provided to answer parents' questions.

TABLE 1 Ingredients of olive oil.

Ingredient	Result	Unit	Limit
Palmitic acid	10.59	%	7.5–20
Palmitoleic acid	0.72	%	0.3–3.5
Stearic acid	3.85	%	0.5–5
Oleic acid	66.83	%	55–83
Linoleic acid	16.95	%	3.5–21
Peroxide value	1.24	mEq/kg	≥20
Acid value	0.36	-	≥2
Non-saponin contents	8.81	g/kg	≥15
Total sterol contents	1128.4	mg/kg	≤1000
Total tocopherols content	N/A	ppm	>200

2.6 | Primary and secondary outcomes

The primary outcome was the duration of crying in 24 h. Secondary outcomes comprised episodes of crying per day, crying intensity, and episodes of defecation per day. Parents recorded these items in a researcher-designed checklist. The mean of these variables was assessed and compared before the treatment initiation (based on parents' verbal reports) and during the first and second weeks. In addition, the intensity of colic was assessed at the beginning and the end of the trial based on the visual analog scale (VAS).

2.7 | Sample size and statistical analysis

According to Salehipour et al.²³ research and considering 80% power and a 95% confidence level, a sample size of 34 participants was estimated. By assuming a 20% dropout rate, 40 participants were enrolled in the study.

Data were analyzed using SPSS version 16.0 (SPSS Inc.). Continuous data were represented by mean, standard deviation, and categorical variables with frequency and percentage. The Kolmogorov–Smirnov test was used to assess normality. The Mann–Whitney *U* test (not normally distributed data) and independent *t* test (normally distributed data) were used for continuous variables. The chi-square and Fisher exact tests were applied for categorical variables, as appropriate. Additionally, for repeated

measurement data, repeated variance analysis was used. A $p < 0.05$ was considered statistically significant.

3 | RESULTS

Between May 2021 and 2022, 80 participants diagnosed with infantile colic were eligible to enroll in the study, of whom 40 were assigned to the olive oil group and 40 to the placebo group. Ten infants were excluded from the trial due to insufficient application of topical oil, five due to unwillingness of parents, four due to hypersensitivity reaction to the oils, two due to use of not allowed concomitant treatment, and one due to not responding. Finally, 58 patients completed the study, including 27 infants in the olive oil group and 31 infants in the placebo group (Figure 1).

The mean age of infants was 46.97 ± 16.31 and 47.55 ± 17.14 days in the intervention and placebo groups, respectively, which the difference was insignificant ($p = 0.71$, Table 2). Twenty-one infants were male in the olive oil group (56.76%) and 19 in the placebo group (51.35%), which did not differ significantly ($p = 0.52$, Table 2). The mean of the mother's age was 29.32 ± 6.32 years in the olive oil group and 28.69 ± 5.59 years in the paraffin group ($p = 0.64$, Table 2).

The mean crying episodes in 24 h were 5.79 ± 4.56 in the intervention group compared to 6.01 ± 3.41 in the placebo ($p = 0.81$, Table 3). The mean duration of crying in the olive oil group was 4.05 ± 2.44 h/day, compared to 3.85 ± 1.37 h/day in the placebo

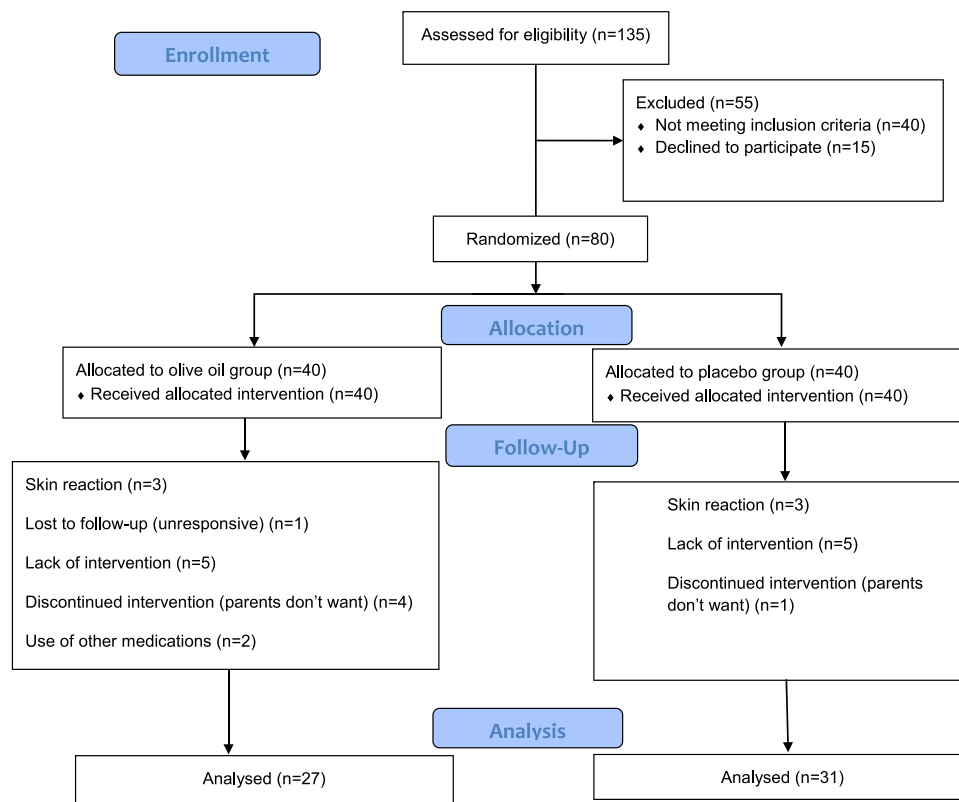


FIGURE 1 Diagram flow of patients in the study.

TABLE 2 Demographic characteristics of the study groups

Variable	Intervention (N = 40), n (%)	Placebo (N = 40), n (%)	p Value
Age at the study entry (days; mean ± SD)	46.97 ± 16.31	47.55 ± 17.14	0.71
current weight (g; mean ± SD)	5016.71 ± 1171.65	4837.27 ± 681.45	0.52
Birth order			
First	19 (51.35)	21 (53.85)	0.91
Second	12 (32.43)	13 (33.33)	
Third or above	6 (16.22)	5 (12.82)	
Gender			
Male	21 (56.76)	19 (51.35)	0.64
Female	16 (43.24)	18 (48.65)	
Delivery type			
NVD	14 (45.16)	14 (43.75)	0.91
CS	17 (54.84)	18 (56.25)	
Nutritional diet			
Exclusively breastfed	26 (72.22)	26 (66.67)	0.60
Mostly breastfed	10 (27.78)	13 (33.33)	
Mother's age (years; mean ± SD)	29.32 ± 6.32	28.69 ± 5.59	0.64
Mother's education level			
Under diploma	3 (8.33)	5 (12.82)	0.23
Diploma and associate degree	14 (38.89)	21 (53.85)	
Bachelor's degree and above	19 (52.78)	13 (33.33)	

Note: Analyzed by Mann–Whitney test.

TABLE 3 Primary and secondary outcomes of the study groups at the beginning, 7th, and 14th day.

	Group	First day	7th day	14th day	p Value
Crying duration (h/day)	Intervention	4.05 ± 2.44	2.54 ± 1.22	1.41 ± 1.03	0.38 ^a
	Placebo	3.85 ± 1.37	2.61 ± 1.22	1.61 ± 1.32	
p Value ^b		0.65	0.82	0.56	
Crying frequency (episodes/day)	Intervention	5.79 ± 4.56	3.94 ± 2.71	2.51 ± 1.93	0.14
	Placebo	6.01 ± 3.41	4.58 ± 2.41	3.01 ± 2.40	
p Value ^b		0.81	0.35	0.41	
Crying intensity (VAS)	Intervention	9.04 ± 1.54	–	4.48 ± 2.17	<0.001 ^c
	Placebo	9.0 ± 1.20	–	4.77 ± 1.68	
p Value ^b		0.91		0.59	
Defecation frequency (episodes/day)	Intervention	3.06 ± 2.32	2.91 ± 1.47	2.65 ± 1.59	0.24
	Placebo	3.84 ± 2.37	3.38 ± 1.97	2.77 ± 1.96	
p Value ^b		0.20	0.34	0.82	

^aRepeated measurement ANOVA.

^bTwo independent t test and Mann–Whitney test.

^cPaired t test and Wilcoxon test.

group ($p = 0.65$, Table 3). During three time points of measurement, the mean duration of crying reduced from 4.05 ± 2.44 h/day to 1.41 ± 1.03 h/day ($\downarrow 65\%$) and from 3.85 ± 1.37 h/day to 1.61 ± 1.32 h/day ($\downarrow 58\%$) in paraffin group ($p = 0.38$; Figure 2A). Similarly, the mean episodes of crying in the intervention group decreased from 5.79 ± 4.56 to 2.51 ± 1.93 ($\downarrow 57\%$) and from 6.01 ± 3.41 to 3.01 ± 2.40 ($\downarrow 50\%$) in placebo ($p = 0.14$; Figure 2B). Also, the Mann-Whitney test results showed no significant difference between the two groups in the intensity of crying at the beginning and the end of the study ($p = 0.91$ at the beginning, $p = 0.59$ at the end; Figure 2C). The intra-group comparison showed that crying intensity was reduced significantly in both groups (from 9.04 ± 1.54 h/day to 4.48 ± 2.17 h/day in the intervention group, $p < 0.001$; and from 9.0 ± 1.20 h/day to 4.77 ± 1.68 h/day in the placebo group, $p < 0.001$, Table 3). Regarding defecation, there was no significant difference between the two groups ($p = 0.24$, Table 3).

In this clinical trial, 22 infants withdrew from the study, of whom 13 participants (59.1%) were in the olive oil group, and 9 (40.9%) were in the placebo. The mean age of the mothers was higher in the discontinued group, which was statistically significant (32.33 ± 6.67 years in the discontinued group versus 27.75 ± 5.17 years in the

continued group, $p = 0.002$). In other baseline characteristics, there were no significant differences between the two groups who withdrew from the study and those who remained in the study ($p > 0.05$, Table 4).

Three infants in the treatment group and three in the placebo group showed allergic skin reactions (small maculopapular rash) to the oils. Out of three patients in the olive oil group, one patient withdrew from the study, and two continued. In this regard, the two groups did not show significant differences ($p > 0.05$).

Due to the regression relationship between the episodes, duration, and intensity of crying, the least-squares error method was used for missing value imputation. In the first measurement, two missing values were found whose participants were excluded from the analysis. In the second measurement, another 20 items were missing. Finally, 25 missing items were observed in the third measurement, 20 of which were the same as in the second measurement, and 5 items were new. There was no significant difference between the intervention and placebo groups in terms of these variables after missing value imputation (Table 5). It should also be noted that there was no regular order for the appropriate imputation regarding the intensity of crying.

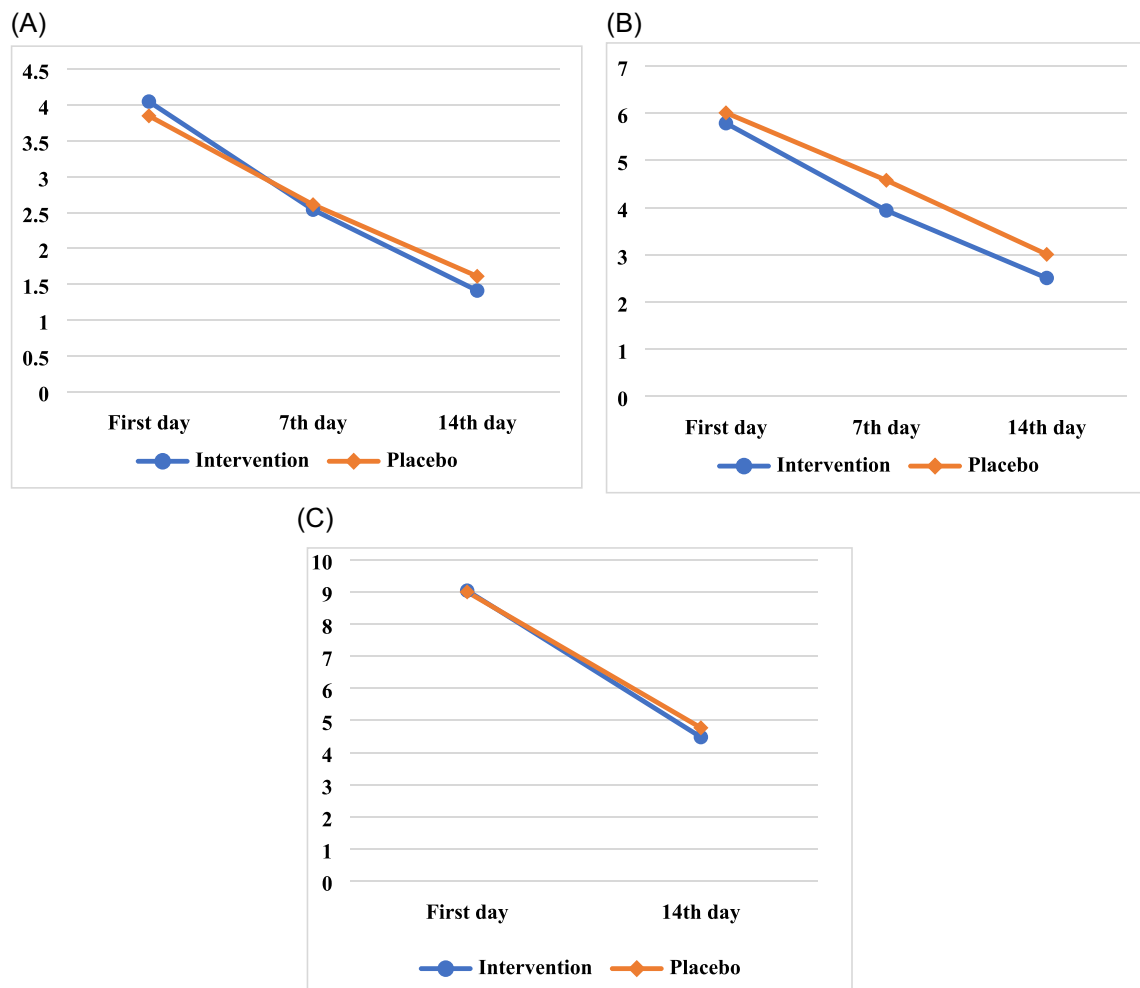


FIGURE 2 The effects of olive oil anointment and placebo upon the duration of crying (A), episodes of crying (B), and intensity of crying (C).

TABLE 4 Baseline characteristics of included and withdrawn participants.

		Discontinued (N = 22), N (%)	Continued (N = 58), N (%)	p Value ^a
Group	Intervention	13 (59.1)	27 (46.6)	0.45
	placebo	9 (40.9)	31 (53.4)	
Infant gender	Male	10 (45.4)	33 (56.8)	0.25
	Female	12 (54.5)	25 (43.1)	
Crying duration (h/day; mean ± SD)		3.93 ± 3.01	3.96 ± 1.7	0.92
Crying frequency (episodes/day; mean ± SD)		4.98 ± 5.0	6.21 ± 3.57	0.23
Crying intensity (mean ± SD)		9.8 ± 1.41	9.02 ± 1.37	0.98
Mother's age (years; mean ± SD)		32.33 ± 6.67	27.75 ± 5.17	0.002
Mother's education	Under diploma	3 (14.3)	6 (10.70)	0.87
	Diploma and associate degree	8 (38.1)	27 (48.2)	
	Bachelor's degree and above	10 (47.6)	23 (41.10)	

^aChi-square test, two independent t test, and Mann-Whitney test.

TABLE 5 Duration and intensity of crying at the beginning, 7th, and 14th days (after missing value imputation).

	Group	First day	7th day	14th day	p Value
Crying duration (h/day)	Intervention	4.05 ± 2.44	2.54 ± 1.22	1.52 ± 0.16	0.38
	Placebo	3.85 ± 1.37	2.61 ± 1.22	1.54 ± 0.15	
p Value		0.65	0.82	0.95	
Crying frequency (episodes/day)	Intervention	5.79 ± 4.56	3.94 ± 2.71	2.73 ± 0.32	0.14
	Placebo	6.01 ± 3.41	4.58 ± 2.41	2.77 ± 0.32	
p Value		0.81	0.35	0.93	

4 | DISCUSSION

This study investigated the effect of the topical application of olive oil on infantile colic symptoms. Our findings showed that abdominal massage with olive oil has the same effect as paraffin oil in improving the symptoms of infantile colic. The duration and frequency of crying improved significantly in both groups, these changes were slightly more in the olive oil group, but there were no statistically significant differences (65% vs. 58% decrease in crying duration and 57% vs. 50% decrease in crying episodes). The crying intensity showed a substantial reduction in both groups ($p < 0.001$) with no significant intergroup difference ($p > 0.05$).

While the cause of infantile colic is yet to be determined, a multifactorial etiology has been proposed for this condition. The rationale for selecting olive oil in this study is related to several suggested etiologies for infantile colic, and olive oil's known therapeutic properties. The infant's gastrointestinal system's immaturity, leaky gut syndrome, and the impairment of gut-brain axis performance are some of the etiologies proposed for infantile colic.^{4,5} According to Persian medicine references, one of the causes of pain is the separation of junctions in the tissues,²⁴ which could

lead to leaky gut syndrome or/and stretching of the walls of the intestines due to the gas. Olive oil strengthens tissues (tightening intercellular junctions)²² and improves cellular functions.²⁰ Another hypothesis suggested for infantile colic is the inflammation and subsequent pain sensation in the intestines.⁴ The phenol compounds present in olive oil, especially in extra-virgin olive oil, have potent anti-inflammatory and pain-relieving features.²⁵

Massage is widely used to treat infantile colic. Massage impacts parasympathetic system activation similarly and helps with intestinal relaxation, food digestion, and decreased flatulence. It also improves the hypothalamus-pituitary-adrenal axis function. Reduced infant stress, improved infant-parent bonding, better sleeping, and reduced crying are other positive impacts that could expect from massage.^{26,27} In one study, the researchers implemented the following routine for colicky infants: a 15-to-20-min belly massage with baby oil three times a day during the time the infant is relaxed for one week. Compared to the alternative treatment (holding and gently rocking the baby), belly massage showed a significant decrease in the duration (73%–28%) and the frequency of crying.²⁸ In a 3-week trial, the whole-body massage for 5 min at the time of diaper change was compared to a body massage at the time of colic onset and the

control group in which the crying duration decreased by 61%, 26%, and 27%, respectively.²⁷

The therapeutic use of oil anointment for the treatment of infantile colic was described in previous studies. Chamomile oil is one of the oils previously studied on colicky infants and significantly improved their symptoms. The probable mechanisms responsible for the chamomile effects on infantile colic are its anti-spasmodic (regarding the supposed role of intestinal hypermotility caused by nervous system immaturity within the first weeks of life), anti-inflammatory and anti-flatulent properties.^{23,29} Prior studies showed that Inhalation and anointment of lavender oil could ameliorate infantile colic symptoms. Its anti-spasmodic and sedative properties are probably responsible for alleviating infantile colic symptoms.^{30,31} Persian medicine experts believe that flatulence and constipation due to the weakness of the infant's digestive system are the main contributors to infantile colic and recommend belly massages with olive oil as a treatment option.⁸ The results of the Arman-Asl et al. study confirmed the prior claim and showed that infant belly massages with olive oil reduced constipation in children between 1 and 4 years old.³²

In our study, oral drop, massage, and dietary modifications were presented in both groups, which improved the outcomes in the placebo group compared to similar studies and reduced the observed differences between the olive oil group and the placebo group (65% vs. 58% reduction in crying duration). In the study of Salehipur et al., belly massages with chamomile oil for 2 weeks without any oral medication caused a 58% reduction in crying duration compared to the 29% reduction observed in the placebo group.²³ In another research, covering the babies' belly and flank with chamomile oil without massage for 1 week with a simethicone oral drop resulted in a 36% reduction in crying duration compared to the 18% reduction in the placebo group.²⁹ In Cetinkaya et al. study, a 5- to 15-min belly massage at the time of symptoms onset with lavender oil for 4 weeks showed higher effectiveness than what was observed in the control group, which received no interventions (52% vs. 0%).³⁰ Unlike these studies, in our study, nutritional recommendations were given to the mothers, and oral drops and massage were recommended simultaneously. This different design may increase the observed differences between intervention and control groups in those studies. Also, we investigated the crying intensity in the two groups, which is very important in the infantile colic evaluation. Our findings highlighted a similar decrease in both groups (50% reduction in the intervention group and 47% in the control group). This parameter has not been investigated in other similar studies.

According to Persian medicine references, some infants develop infantile colic symptoms due to their hot temperaments, which could be observed by findings such as body warmth and skin rashes if the mother has a diet of warm-temperament foods. In these cases, massage with neutral or cold-temperament oil, like violet oil, has much better effects than topical olive oil. Therefore, determining the infant's temperament could help select the appropriate treatment. In our study, the oral drop we used contained dill and fennel, which had

warm temperaments, and simethicone. In previous studies which used chamomile or lavender oil, either simple dimethicone drops or no oral drop was given to the infants.

In this study, the following dietary restrictions were instructed to mothers: avoiding foods that cause bloating (such as legumes, beans, cucumbers, apples, and bananas), foods with extremely hot temperament (such as raw garlic and onion, pepper, and ginger), food with extremely cold temperaments (such as watermelon and cucumber), foods that are hard to digest (such as fast foods and baguette), allergens (such as peanut, egg white, and fish), foods containing conservatives, carbonated drinks, and nonhome baked pastries. The mothers were also advised to eat slowly, chew the food enough before swallowing, and avoid drinking or eating yogurt and salad while having the main course. We also asked mothers to have a healthy diet and consume enough fruits and natural drinks. This is the first study in which dietary recommendations based on Persian and conventional medicine have been used to treat colic in infants. The mothers should also write down the foods that aggravate their infant's conditions in a checklist. According to the final checklist, the following dietary products worsened infantile colic; foods containing peas, beans, cotyledons, lentils, cabbage, eggplant, pastries, ice creams, carbonated drinks, cocoa, coffee, strong tea, cucumber, chicken nuggets, sausages, milk, yogurt, iron, canned tuna fish, kebab koobideh, porridge, potato, and egg. These findings are consistent with the results of prior studies. One study investigated 272 mothers and their under 4-month-old infants who were only breastfed. The results showed that the presence of cabbage, onion, and cow's milk in the mother's diet might aggravate infantile colic.³³ In Hill et al. study, the results demonstrated that a low-allergen diet improved the symptoms of colicky infants. Low-allergen diet in this study included eliminating milk, eggs, wheat, peanuts, nuts, and fish from the mother's diet.⁶

Our study had several limitations. One of the limitations we faced in carrying out this project was the lack of similar studies investigating the effect of abdominal massage with olive oil on colicky infants. Thus, the comparison was difficult. Also, simultaneous interventions in this study might have influenced the outcomes. Last but not least is the fact that olive oil and oral drop had warm temperaments, which caused reduced effectiveness of treatment in infants with warm temperaments.

This study also demonstrated a slight decline in the episodes of defecation in both groups during the study period, which was not statistically significant. This decrease was more prevalent in the placebo group. Oral paraffin oil uses for constipation in children. However, according to the findings of our study, the topical application of paraffin oil may have a contrary effect on constipation. Consumption of olive oil could also improve the symptoms of constipation. Regarding Persian medicine, topical olive oil is recommended for constipation caused by cold, wetness, and weakness of the intestines. However, in the current study, this intervention showed a slight decrease in episodes of defecation, which was inconsistent with the results of the survey conducted by Arman-Asl et al.³²

5 | CONCLUSION

The results of this trial show that abdominal massage with olive oil has the same effect as massage with paraffin oil in reducing the symptoms of infantile colic. Since no standard management protocol exists for infantile colic symptoms, numerous interventions have been suggested. However, more study is needed in this field to confirm or reject the findings of our study. Therefore, for future studies, we recommend the following: topical oil and oral medications are chosen according to the infant's temperament, the studies compare the effects of different types of olive oil (extra virgin oil or oil obtained from unripe olives), the effectiveness of Persian medicine and modern medical treatments be compared, the breast milk of mothers with colic infants be compared to the breast milk of mothers with normal infants, the prevalence of gastrointestinal disorders in mothers with colic infants and mothers with normal infants be analyzed, the studies investigate the effects of maternal gastrointestinal conditions on breast milk quality, the impacts of treating pre-existing gastrointestinal and psychological disorders in mothers before conception on infantile colic prevention be evaluated.

AUTHOR CONTRIBUTIONS

Maryam Mohammadian-Dameski: Data curation; investigation; writing – original draft. **AhmadShah Farhat:** Data curation; investigation; supervision; validation. **Monavar Afzal Aghaee:** Formal analysis; methodology; software; validation; visualization. **Zohreh Nademi:** Data curation; investigation; supervision; validation. **Ali Hadianfar:** Data curation; formal analysis; writing – original draft. **Matin Shirazinia:** Formal analysis; software; visualization; writing – original draft. **Maliheh Motavasselian:** Conceptualization; data curation; formal analysis; funding acquisition; project administration; software; supervision; writing – original draft. **Vahid Reza Askari:** Data curation; software; writing – review and editing.

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CONFLICT OF INTEREST STATEMENT

The authors declare no conflicts of interest.

DATA AVAILABILITY STATEMENT

The data sets generated and analyzed during the current study are available from the corresponding author upon reasonable request.

ETHICS STATEMENT

The study complied with Mashhad University of Medical Sciences guidelines (Ethical approval code: 980998, Approval date: 15-2-2020, Approval ID: IR.MUMS.REC.1398.300). The study also received the Iranian Registry of Clinical Trials (IRCT) code with IRCT20200528047585N1 (<https://en.irct.ir/trial/48502>). Informed consent was obtained from the legal guardian of the infant.

TRANSPARENCY STATEMENT

The lead author Maliheh Motavasselian, Vahid Reza Askari affirms that this manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

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