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# Effect of Mothers' Educational Supportive Care Program on Pain Intensity and Crying Duration Caused by Colic Pain in Infants Aged 1-5 Months

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## Abstract

**Background**: Baby colic is one of the most common digestive problems in infants. Due to its several and unknown causes, colic treatment depends on the parent's individual and social education and support.

**Aim:** This study aimed to determine the effect of mothers' educational supportive care program on the pain intensity and crying caused by colic in infants aged 1-5 months.

**Method**: This study was conducted based on a randomized controlled clinical trial. This study included 88 infants with colic who were referred to a specialized pediatric clinic at a public hospital in eastern Iran. The patients were randomly divided into the intervention and control groups. The educational supportive care program was implemented for eight days and the infant crying duration and frequency were recorded each day. On the other hand, the control group received the clinic routine care. Subsequently, the data were analyzed in SPSS software (Version 21).

**Results**: The two groups were homogeneous in terms of demographic variables (P<0.05). According to the results of the paired t-test, the infant pain intensity in the intervention and control groups was  $0.7\pm1.7$  and  $0.7\pm1.7$ , respectively (P<0.001). Moreover, the duration of the crying caused by colic pain based on the Wilcoxon test was  $6.2\pm22.8$  and  $6.2\pm8.9$  min in the intervention and control groups, respectively (P<0.001).

**Implications for Practice**: Individual education and provision of an educational supportive care program can affect infants' pain and cry. Therefore, it is suggested that further studies provide a group and peer educational supportive care program.

Keywords: Educational supportive care program, Infant, Infantile colic

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#### Introduction

Infantile colic is a common problem that is observed during the first three months of infants' birth. With regard to the studies conducted, this issue is one of the common causes of mothers' complaints and referrals that involves both the family (especially primiparous breastfeeding mothers) and the health system (1, 2). The word "colic" is used for infants who have long-term crying without any clear reason during the first three months of life (3).

Infantile colic is defined as periods of severe and insistent crying without any particular cause. Excessive crying appears three to 12 weeks after birth and then intensifies (4, 5). According to Wessel's diagnostic criterion, the healthy infant crying for more than three hours a day, three days a week, and three consecutive weeks is called infantile colic. Such cryings are frequently observed in the afternoon and night (3, 6). Other symptoms include flushing, parachroma around the lips, abdominal distension, lifting and pulling up the legs into the abdomen, the coldness of the ends and punching the hands. Attacks terminate when the infant is tired, or improve temporarily by discharging gas or stool from the intestine (7). Colic pain during infancy is the most common digestive problem in infants. According to the previous studies, this complication is one of the common causes of mothers' complaints and referrals that involves both the family and the health system (8).

Although colic improves automatically up to 2-3 months after birth, and it may last for 4 or 5 months in 20% of cases, it can cause severe concerns and unnecessary costs, such as visits to several physicians, different paraclinical interventions, and using different drugs due to the severe cryings of the infant (7). Colic causes stress in parents and other members of the family. A sense of incapability in satisfying the child's needs may cause sleep deprivation, sleep pattern disorder, and parental sleep pattern disorder, and fatigue. Infantile colic decreases maternal self-efficacy in lactation and enhances her depression risk (8). In addition, physicians must spend a lot of time to justify their families. With regard to the above discussion, it is necessary to find a method to treat this disease (9).

The incidence of colic in infants was estimated to be between 8% and 40%. There was no difference between genders, breastfeeding infants, infants fed by powdered milk, and premature and mature infants in terms of the incidence of colic (3). In a study conducted in Iran, about 40 to 50% of infants under 3 months of age suffer from colic (4). However, the disappointing fact is that although one out of five infants suffers from infantile colic and numerous studies have been conducted on this disease, there is no proven cause for it (7).

Due to its several and unknown causes, colic treatment depends on the parents' individual and social education and support (10). The colic is potentially affected families because of the lack of a definitive treatment, which indicates the significance of conducting other studies on this area (11). The determination of an effective strategy on infantile colic improves the quality of life of families (7, 12). Unfortunately, there is still no reason for the crying and pain in the colic. For this reason, it is suggested that colic may have a multifactorial cause (3, 11).

However, despite 40 years of studies, its etiology is still ambiguous. Researchers considered three causes for this disease, namely intestinal causes, behavioral problems as a result of the lack of proper relationship between parents and infants, and a set of different causes that cannot be clinically diagnosed easily. Due to different etiologies, different treatments are available, including replacement of cow's milk protein with soybean, reduction of milk lactose, fiber-rich enriched powdered milk, herbal tea, pain medications (e.g., dicyclomine), and behavioral interventions (lullaby, massage).

On the other hand, the unconfirmed cause for colic has led to a wide range of treatments for this issue. These treatments can be divided into three major groups of pharmaceutical treatment, nutritional treatment, and treatment via parental care (13-15). One of the pharmaceutical treatments is dicyclomine, which is the only drug affecting this disorder. Unfortunately, rare dangerous side effects such as apnea, coma, seizure, and even mortality have been reported in 5% of the infants treated with this drug. With regard to the above-mentioned side effects and benignity of colic, the use of this drug is not recommended (16), and it is prohibited in infants less than 6 months old (17).

It was found that nutritional treatments, especially the use of probiotics, are safer than pharmaceutical treatments (18). Although there may be widespread disorders about the real causes of colic, it has been widely demonstrated that probiotics can have a positive effect on the infants' gastrointestinal system. Probiotics affect the increase in the growth of gut flora (9). One of the treatments mentioned as parental care is infant massage. It can be effective in treating colic via decreasing the stress on the muscles and internal organs, as well as accelerating blood supply to the tissues and organs (19).

Moreover, massage can improve the relationship between infant and mother and plays a role in gaining the infant's weight, resolving digestive problems, and improving their immune system (20). Infants massage does not only have any side effects it can also be useful for infants and mothers in many cases. Massage can lead to the reduction of intense crying and increase of the sleep duration. Therefore, massage can be recommended as a successful treatment for infants' colic (13).

Mother's diet is effective for the treatment of infantile colic; accordingly, some studies believe that risk factors for colic are observed during pregnancy or after birth. Furthermore, the most important cause that has been suggested so far is the allergy to cow's milk. A diet free of cow's milk is recommended as a primary treatment for infantile colic in the infants fed by breast milk (4, 21). Colic treatment is a multifaceted one due to its several and unknown causes; therefore, pharmaceutical treatments, nutritional treatments, and treatment via parental care can simultaneously affect infants' health (8). One of the factors ensuring social health is to deal with the infantile colic. With regard to the importance of training nurses, they should be trained to deal with colic which is one of the central tasks of nurses. Therefore, this study aimed to determine the effect of educational supportive care program for mothers on the sleep, pain, and amount of crying caused by colic in infants aged 1-5 months.

#### Methods

This randomized clinical trial aimed to determine the effect of educational supportive care program on the reduction of the intensity of crying and pain caused by infantile colic from January 2017 to May 2018. Statistical population of the study included infants aged 1-5 months who were referred to a specialized pediatric clinic (in the outpatient department) at a public hospital in eastern Iran. All infants with the first referral to the clinic, whose pain caused by colic was confirmed by the physician, were included in this study.

The inclusion criteria were: 1) exclusive breastfeeding, 2) infants aged 1-5 months, 3) lack of infant nutrition and congenital autoimmune disease, 4) infants with normal birth weight (gestational age greater than 37 weeks and birth weight of more than 2500 grams should be recorded on the infant vaccination card appropriate weighing of the infant at that age is based on the percentile), and 5) lack of mothers' addiction.

On the other hand, the participants with 1) noncompliance with exclusive breastfeeding, 2) acute diseases, including colds, 3) the use of chemical medicines without a physician's prescription, such as carminatives at the time of intervention, 4) unwillingness to participate in the study, and 5) unwillingness to complete the checklist were excluded from the study.

The sample size was determined for crying duration and colic pain according to a study conducted by Sheidaei et al. (13) with 95% and 90% confidence and power of a test, respectively. The highest sample size was related to the amount of infant sleep, and 39 infants were assigned to each group. However, 44 infants were included in each group by considering 20% of the sample attrition.

In total, 88 infants with colic were included in this study who were randomly divided into intervention and control groups. All mothers collaborated in both groups. Given the fact that Saturday, Monday, and Wednesday were considered for one group, and Sunday, Tuesday, and Thursday were considered for another group, it was not possible to blind the study. Therefore, the groups did not know each other. Accordingly, the individuals who came on Sunday, Tuesday, and Thursday, and those who came on Saturday, Monday, and Wednesday were included in the control and the intervention groups, respectively.

Different questionnaires were applied in this study, including a questionnaire for the demographic characteristics of the mother and infant, which was prepared by the researcher and completed on a health card based on interviews with the infants ' mothers. In addition, opinions of 10 nursing professors of the Faculty of Nursing and Midwifery of Mashhad and Gonabad Universities of Medical Sciences, Mashhad, Gonabad, Iran, were used to assess the face and content validity of the infantile colic questionnaire. The required eliminations and revisions were applied as far as possible.

With regard to the measurement of the reliability of the questionnaires, 10 mothers were chosen and the questionnaires were given to them. Two weeks later the same mothers were asked to re-complete them. The reliability of the tool was confirmed using the test method. The correlation coefficient was estimated at 0.90.

Visual Analogue Scale (VAS) was the main instrument for the measurement of infantile colic, which assessed the intensity of infants' pain before and after the intervention in both groups. The VAS is a standard instrument for the measurement of pain which is the most commonly used instrument worldwide (22, 23). Finally, a checklist was used for registering the crying duration. The intensity of crying (i.e., less than 60 min, between 60-120 min, and more than 120 min) in 24 h was marked during one week in the respective form before and after intervention in two groups.

At the beginning of the study, intervention and control groups were provided with the probiotic drop (Pedilact Zisttakhmir. Co. Iran) that was given to mothers as a gift by the researcher. The mothers in both groups were given necessary instructions on how to complete the questionnaire and dosage, frequency, and the administration of the medicine according to the physician's instructions. In both groups, the duration of infant crying in 24 h, the intensity of colic pain in 24 h, and demographic data of the mothers and infants for 8 days were recorded in the checklists.

The intervention group consisted of a feasibility session, a 90-min educational supportive care program, in person and single, providing educational materials and manuals that included the elimination of cow's milk and dairy products from the mother's diet, the use of PediLact drops, correct technique for breastfeeding, kangaroo mother care, massage therapy, and modifications in the mother's diet. The mothers were recommended to implement the educational supportive care program for 8 days (21, 24) (Table 1). Subsequently, the mothers were asked to observe the above issues on alternate days during a week, one of the children was asked to answer the above questions on the phone, and in the case of failure to observe the educational points in two consecutive days, the participant was excluded from the study. The control group received only routine treatment for 8 days. The intensity of colic pain and duration of crying during 24 h were compared before and eights after the treatment. Data analysis was performed in SPSS software (Version 24). It consisted of two descriptive and analytical sections. Descriptive statistics included central indices and dispersion, such as mean, standard deviation, and frequency distribution which were used to describe the participants' characteristics. Analytical section initially examined the homogeneity of the two groups in terms of underlying and interventional variables. The Chi-square and Fisher's exact tests were used to investigate the homogeneity of qualitative variables of colic symptoms. Moreover, independent t-test was utilized for age, gestational age, infancy, birth weight, and infant weight. The number of pregnancies and children was evaluated using the Mann-Whitney U test. Subsequently, the independent and the paired t-tests were applied to compare the groups and intra-group, respectively. Confidence coefficient of the tests was estimated at 95%.

Program's aspects	Inte	ervention Interventions protocol	
Educational	The elimination of cow's milk and dairy products from the mother's diet	Mothers of the intervention group were recommended to remove cow's milk and dairy products from their diet for 8 days that was related to the educational supportive care program. Mothers were recommended to receive one gram of calcium per day.	
Caring	The use of probiotics	How to pour the drops, the amount of its use according to the physician, as well as how to keep it was taught to the mothers.	
Supportive	Correct breastfeeding technique	Suitable position during breastfeeding, correct breastfeeding, improper nutrition methods	
Caring	Kangaroo care	Kangaroo mother care includes three components, skin contact, exclusive breastfeeding, and support of couples and infants.	
Caring	Massage therapy	The correct method of massage was taught to the mothers	
Educational	Modification in mother's diet	Some of the materials that cause colic include allergens in eggs, cereals, cakes, fish, spices and preservatives, vegetables and some cucurbits, such as eggplants that cause colic. If these items are eliminated from or reduced in the mothers' diet, the colic pain will be declined in infants.	

#### **Table 1: Intervention protocol during meetings**

### Results

This study included 88 infants who attended until the end of the study. Table 2 summarizes and compares the demographic characteristics of the mothers and infants. In total, 23 infants (52.3%) in the intervention and control groups were female. The Chi-square test did not show any significant difference in terms of the infants' gender between the two groups (P=0/001) and the two groups were homogeneous. The mean age of the infants in the intervention and control groups was  $57.6\pm22.7$  and  $61.1\pm27.2$  days, respectively. The number of infants in both groups was equal in terms of gender, and each group consisted of 23 female (52.3%) and 21 males (47.7%). Accordingly, the two groups were homogeneous in terms of demographic characteristics (Table 2).

control groups							
	Gr						
Variable	Intervention	Control	Result				
	Mean±SD	Mean±SD					
Mother's age (old)	6.2±29.4	5.8±30.0	P=0.61*				
Number of pregnancies	1.3±2.2	0.9±2.2	P=0.71**				
Number of children	0.8±1.9	0.9±2.1	P=0.40**				
Gestational age (weeks)	$1.0\pm 38.8$	1.0±38.4	P=0.15*				
Infant's age (days)	22.7±57.6	27.2±61.1	P=0.49*				
Weight at birth (g)	439.6±3257.1	328.6±3140.8	P=0.16*				
Weight at the time of referral (g)	940.3±5149.8	1128.0±5149.8	P=0.52*				

Table 2: Comparison of demographic characteristics in mothers and infants in the intervention and						
control groups						

\*Independent t-test

\*\* Mann-Whitney U test

Fisher's exact test did not show any significant difference between the two groups in symptoms of colic including crying more than three hours a day, three days a week, and three weeks, flushing, parachroma around the lips, abdominal distension, lifting and pulling up the legs into the abdomen, coldness of the ends, and punching the hands. (Table 3).

	Grou		
Variable	Intervention Control		Result
	Number (%)Number (%)		
Crying more than three hours a day	44 (100.0)	43 (97.7)	*P=1.00
Crying more than three days a week	40 (90.9)	42 (95.5)	* P=0.676
Crying more than three weeks	32 (72.7)	29 (65.9)	**P=0.49
Flushing	42(95.5)	37 (84.1)	*P=0.16
Parachroma around the lips	23 (52.3)	14 (31.8)	**P=0.05
Abdominal distension	35 (79.5)	40 (90.9)	**P=0.11
Lifting and pulling up the legs into the abdomen	43 (97.7)	39 (88.6)	*P=0.22
Coldness of the ends	15 (34.1)	13 (29/5)	**P=0.65
Punching the hands	33 (75.0)	30 (68.2)	**P=0.48

Table 3: Symptoms of colic in both intervention and control groups before intervention

\* Fisher's exact test

\*\* Chi-square test

According to the results of this study, the mean pain intensity score of infants was  $5.4\pm1.0$  and  $5.6\pm1.0$  in the intervention and control groups, respectively. The mean pain intensity score by independent t-test was not significant (P=0.59). The mean pain intensity after the intervention was  $3.7\pm0.8$  and  $4.8\pm0.9$  in the intervention and control group, respectively. This difference was found to

be significant using independent t-test (P<0.001). The pain intensity after intervention decreased by  $0.7\pm1.7$  in the intervention group and  $0.7\pm0.7$  in the control group. According to the result obtained by the independent t-test, this difference was significant. The pain reduction in the intervention group was significantly higher (P<0.001). Duration of crying caused by colic in infants before and after the intervention in the control and intervention groups was  $89.4\pm2.2$  and  $88.1\pm4.1$  min, respectively. The Mann-Whitney U test did not show a significant difference (P=0.07).

Duration of crying after intervention in the intervention and control groups were equal to  $66.6\pm6.2$  and  $79.2\pm4.5$ , respectively, which is statistically significant (with the use of the Mann-Whitney U test (P<0.001). Moreover, the duration of crying after intervention decreased by  $22.8\pm6.2$  min in the intervention group. It also decreased by  $8.9\pm6.2$  min in the control group. This difference was statistically significant (with the use of the Mann-Whitney U test (P<0.001). The decreased duration of crying was significantly higher in the intervention group (Table 4).

		Group		Results of the			
	Intervention	Control	between-group test				
		SD±Mean		SD±Mean			
Intensity of pain	Before intervention	5.4±1.0	5.6±1.0	*P=0.58			
	After intervention	3.7±0.8	4.8±0.9	*P<0.001			
	Difference between before intervention and after intervention	-1.7±0.7	-0.7±0.7	*P<0.001			
	Results of the intra-group test	#P<0.001	#P<0.001	-			
Duration of crying in minutes	Before intervention	89.4±2.2	88.1±4.1	** P= 0.07			
	After intervention	66.6±6.2	79.2±4.5	**P<0.001			
	Difference between before intervention and after intervention	-22.8±6.2	-8.9±6.2	**P<0.001			
	Results of the within-group test	##P<0.001	##P<0.001				

# Table 4: Mean of pain intensity and duration of crying in infants before and after intervention in the control and intervention groups

\* Independent t-test

\*\* Mann-Whitney U test

## Wilcoxon test

# Paired t-test

#### Discussion

This study aimed to determine the effect of mothers' educational supportive care program on colic pain and the amount of crying in infants aged 1-5 months. The results of the study indicated that the mean pain intensity in the intervention group significantly declined after the intervention, compared to the control group. Therefore, it can be claimed that the educational supportive care program can affect improving colic symptoms. Moreover, it was found that there is a significant difference between the mean duration of crying after intervention in both intervention and control groups. Duration of the crying after the intervention was significantly lower than that in the control group.

Studies showed that the improvement of breastfeeding in infants can decline infantile colic (8, 25). These studies are consistent with the present study due to the effect of breastfeeding training on colic pain. Imaniye et al. (2004) mentioned that sensitivity to cow milk is one of the factors causing infantile colic. It was also found that infants with colic whose mothers did not consume dairy products for 2 weeks did not improve significantly, compared to the control group. They concluded that the elimination of dairy products from the diet of lactating mothers did not improve colic pain (26). The reason for differences between the results of this study and the present study may be caused by differences in the methodology. Dairy products were eliminated from the diet of the intervention group in this study, which was one of the educational supportive care programs in the intervention group.

Therefore, colic pain was reduced in this study, which may be due to other supportive care actions of a comprehensive program, including diet modification, and kangaroo mother care. In a systematic study conducted by Sung et al. (2013), the effect of probiotic products with Lactobacillus reuteri was evaluated on infantile colic. This meta-analysis collected the results of 12 studies (1825 infants). According to the results of their study, only 6 cases of probiotic reduced the crying. Finally, it was

concluded that although probiotics affected removing infantile colic symptoms in some studies, there are still inadequate reasons and further studies should be conducted in this domain (12). This finding is consistent with the results obtained from this study.

Probiotics can reduce the duration of crying of infants within 24 h; however, the use of probiotic is one of the items of mothers' educational supportive care programs in the intervention group. Although the infants in the control group consumed probiotic drops for one week, the pain caused by infantile colic did not significantly decrease in the intervention group.

David J et al. (2005) determined the effect of the mothers' low-level allergen diet on colic among breastfeeding infants. This randomized controlled trial was conducted on the infants less than 6 weeks of age with breast milk feeding. It was concluded that eating allergens by mothers is an important factor causing colic in infants fed by breast milk (24). Their findings are in line with the results of this study.

The limitations of the study include differences in the responses to pain, previous experience of pain by the infants, and treatment of infantile colic pain under the mothers' care at home. Therefore, the implementation of all the trained principles and the non-use of traditional treatments are based on the mother's statements.

### **Implications for Practice**

This study aimed to determine the effect of educational supportive care program on the intensity of pain and the duartion of crying caused by colic in infants aged 1-5 months. Infantile colic is a multi-factor problem, and the obtained results cannot confirm or reject the role of other causes for this problem. Therefore, it can be concluded that maternal compliance with a healthy diet, massage therapy, and kangaroo mother care can be effective for the treatments of colic pain in infants. In addition, an educational supportive care program can be used as a suitable and convenient method to treat infantile colic. On the other hand, this study showed that educational supportive care program can affect the reduction of the intensity of crying and pain. It also can improve symptoms of colic in infants. Moreover, the significance of the role of a continual and effective education is highlighted. It is suggested that further studies examine the long-term effects of this supportive package and its effect on the mothers' mental state. Moreover, further studies should provide a group and peer educational supportive care program.

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## **Conflict of interest**

The authors declare that there is no conflict of interests regarding the publication of this study.

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