Original Article

The Effects of a Blended Educational, Supportive, and Follow-Up Infantile Colic Program on Parents` Care Burden: A Randomized Controlled Trial

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Abstract

Background: Infantile colic (IC) imposes multifactorial problems on the parents, and appropriate interventions are needed to alleviate the care burden. **Objectives:** This study aimed to assess the effects of an educational, supportive, and follow-up IC program on the parents' caregiver burden (CB). **Methods:** This randomized controlled trial was conducted with 64 parents whose infants suffered from IC. Participants were randomly assigned to an intervention group (n = 32) and a control group (n = 32). The intervention group received a blended educational, supportive, and follow-up intervention for 2 weeks. The control group received routine care. Caregiver burden was assessed on three occasions, before, immediately after, and 1 month after the intervention, using the Zarit Burden Scale. Data were analyzed through repeated-measures analysis of variance, independent-samples t-test, Chi-square, Fisher's exact, and Mann–Whitney U tests. **Results:** There was a significant difference between the mean scores of CB in the two groups measured immediately and 1 month after the interventions ($P < 0.001$). The mean score of CB was significantly lower in the intervention group than in the control group after the intervention ($P < 0.05$). **Conclusion:** The blended educational, supportive, and follow-up program could help alleviate parental care burden. Implementing such a program is recommended to reduce CB and associated problems among parents.

Keywords: *Caregiver burden, Education, Infantile colic, Iran, Nurse, Support*

Introduction

Infantile colic (IC),[1] characterized by the cry of an infant for more than 3 h a day, more than 3 days a week, and for at least one long week, is the most common condition requiring exceptional medical help in the first 3 months of an infant's life. It imposes a heavy burden on both parents and the health-care system.[2] Colic crying is usually paroxysmal and inconsolable and may be manifested by grimacing, raising of the feet, and gas excretion.[3] IC occurs in 20% of infants under 3 months of age, particularly in the 8th week of life, and disappears spontaneously after the 12th week.[4]

The exact etiology of IC is still unknown. Nevertheless, some theories attribute it to factors such as cow's milk allergy, immaturity of the gastrointestinal tract, excessive intestinal gas production, lack of normal bacterial flora, intestinal spasms, air swallowing during feeding, improper feeding technique, ineffective mother–infant communication, maternal stress and anxiety, and mother's dietary regimen.[5] Various medical, dietary, and behavioral treatments have been

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developed to manage the problem, even though they are not fully adequate for all infants.[6]

IC imposes tension, sleep pattern disorder, fatigue, anger, anxiety, depression, ineffective caregiving, and reduced self-efficacy on the parents.[7] The disease also disturbs parent–infant relationships and negatively affects family life.[8] All these problems impose a heavy burden on parents.[9]

Caregiver burden (CB) is physical, mental, social, or financial reactions that appear during caregiving and is associated with stress and negative experiences.[10] A study reported that parents' CB is highly affected by the duration of caregiving, anxiety, general health, monthly income, social support, education level, infant's diet, and uncertainty over the effectiveness of caregiving.[11]

Nurses can provide parents with education and support and, thereby, help them cope with their stressful conditions.[10] Some studies show that education and support for parents help them better control their conditions and become more actively involved in the care of their infant.[12] Several studies found that education and support for parents reduced stress significantly during colic crying of the infant in parents, infants, and healthcare providers. Such interventions could also improve infants' sleep and crying problems, and increase parental self-confidence and self-efficacy.[13-15] Some studies also revealed that educational, supportive, and follow-up interventions can reduce the symptoms of IC and parents' referrals to health centers.[16,17] However, a study found that education did not significantly affect parental stress caused by infants' inconsolable cries.[18] Several studies have also investigated the burden of care among caregivers of infants with chronic disorders.[14,15,18] However, few studies have dealt with the effects of colic-relieving interventions on the burden perceived by parents.

Objective

This study aimed to assess the effects of a blended educational, supportive, and follow-up program on CB among the parents of infants with IC.

Methods

Study design and participants

This randomized controlled trial was conducted in 2018 on 64 mothers or fathers of infants with IC who received outpatient care for IC in the clinics of Amin and Imam Hossain hospitals in Isfahan, Iran. Inclusion criteria were participants' agreement, physical and mental ability to care for the infant, no substance abuse, no history of taking psychoactive medications and having an infant aged 2 weeks to 3 months. The only exclusion criterion was a refusal to attend the training sessions on a regular basis.

The sample size was calculated using the results of the former study where an education and telephone follow-up program reduced the mean caregiver burden from 33.28 ± 12.65 to 24.67 ± 9.01.[19] Then, using the formula for the comparison of two means and considering an α =0.05, and a β =0.2, a potential dropout of 25%, and a sample size of 32 was calculated for each group.

First, 125 cards were prepared and numbered. The cards with odd and even numbers were then assigned to the experimental and control groups, respectively. Each participant was asked to draw a card and was then listed in either the control or experimental group.

Data collection instruments

Data were collected by Zarit Burden Scale (ZBS)[20] before, immediately after, and 1 month after the intervention. The demographic data including age, sex, marital status, education level, employment status, caregiving background, duration of caregiving to their infant, history of multiple pregnancies, family history of IC, and medications used to treat IC, as well as infant's age, gender, IC duration, and diet, were asked in the questionnaire. The ZBS contains 22 items for assessing various aspects of CB, namely personal, social, emotional, and financial strains. Caregivers' answers to each item are rated on a Likert scale ranging from "0 = never" to "4 = always" with a total score ranging from 0 to 88. Higher scores mean higher levels of burden. Scores 61–88, 31–60, and ≤30 show high, moderate, and mild burden, respectively. Navidian *et al*. confirmed the validity of the Persian translation of the ZBS. They also assessed the reliability of the scale through test–retest, with a correlation coefficient of 0.94.[20]

Intervention

The intervention was a blended three-component program consisting of education, support, and follow-up, which was developed based on the existing literature and approved by the faculty members of the departments of pediatric nursing and psychiatric nursing at the Faculty of Nursing and Midwifery in Isfahan, Iran [Table 1]. The intervention was implemented by the researchers in four sessions, each lasting 30–45 min, and held in 2 weeks. Participants attended the sessions in groups of two or three. Education was provided face-to-face and through lectures, questions and answers, practical exercises, and puppet shows. At the end of each session, participants were also provided with an educational booklet and pamphlet on the signs and symptoms of IC, its management, baby crying

management, coping with IC and a baby crying, and help-seeking strategies for crying management. They were asked to that ensure they could use the provided education for IC management during daily caregiving. During the first 24 h after each session, we made telephone contact with participants to provide them with information and emotional support, to ensure that they had correctly understood the knowledge provided, to encourage them to use education for IC management, to answer their possible questions, and to provide them with the opportunity to express their feelings, concerns, fears, and problems in taking care of their infants. Follow-up telephone contacts or home visits were also made during the second 24 h after each session, 2 weeks, and 1 month after the intervention to evaluate the participants' progress in IC management, help them cope with their problems, and answer their questions. Participants in the control group just received routine care services such as breastfeeding, diaper changing, and bathing.

Ethical considerations

This study was approved by the Ethics Committee of Isfahan University of Medical Sciences, Isfahan, Iran (code: IR.MUI.REC.1396.3.224) and registered in the Iranian Registry of Clinical Trials (code: IRCT20190312043031N1). Participants received explanations about the aim and methods of the study. Written informed consent was obtained from each participant, and they were assured of voluntary participation and confidentiality of their personal information. At the end of the study, the educational booklet and pamphlet were also provided to the control group.

Data analysis

Data were analyzed using the SPSS software version 16 (Chicago, IL, USA). Numerical data were described using mean and standard deviation, and categorical data were described using absolute and relative frequencies. The independent samples *t*-test was used to compare the two groups concerning their demographic characteristics such as the age of parents and infants, duration of caregiving, and IC duration. The Mann–Whitney *U* test was used for education level, and infant feeding and gender were compared using the Chi-square test. Between-and within-group comparisons respecting the mean score of CB were made through the independent samples *t*-test and repeated-measures analysis of variance, respectively. The level of significance was set at <0.05.

Results

Four participants from the intervention group and five from the control group were excluded due to incomplete

Table 1: The outline of the educational supportive sessions

Sessions	Objectives and content
Session 1	Introducing the parents to the researcher, research, goals and content
	Getting information and upgrading knowledge about infantile colic, ways of diagnosis, its signs and symptoms, treatment methods and their success rate
	Completing the ZBS and the demographic form by the caregivers
	Introducing the parents with drug therapies and their side effects
	Telephone support and follow-up
Session 2	Familiarizing parents with sleep patterns, crying, natural feeding of infants and proper breastfeeding
	Exercises on how to feed and putting the baby to sleep
	Follow-up and review of the previous session and fixing the bugs
	Homework presentation
Session 3	Increasing parental readiness for infant care and promoting their confidence and control over the colic care, positioning and relationship with the infant
	Correcting the wrong techniques used by parents in caring for and calming infant's crying and falling the infant asleep
	Use of appropriate strategies to alleviate the infant's crying and overcoming the problems
	Sharing of parent's experiences with each other and with the researcher
	Practicing relaxation and feedback strategies with the help of pamphlets and educational booklets
	Homework presentation
	Follow-up the instructions of the previous session and fixing the bugs
Session 4	Informing parents of available support resources and how to access them
	Self-care training (i.e., adequate sleep and rest, activity and exercise, proper diet)
	How to provide and access support from family and support groups
	Completing the CB questionnaire

ZBS: Zarit Burden Scale, CB: Caregiver burden

answers to the study instruments or absences from the intervention sessions [Figure 1].

The mean age of parents in the intervention group and control group was 29.64 ± 5.80 and 30.24 ± 4.77, respectively (P = 0.67). Furthermore, only 32.1% and 25.9% of infants in the intervention and control groups were exclusively breastfed. Parents and infants in the two groups did not differ significantly in their demographic characteristics [Table 2].

In repeated-measures analysis, Mauchly's test showed that sphericity was not assumed (P = 0.001). Therefore, the degrees of freedom were corrected using the Greenhouse–Geisser test. The results showed that over time the mean CB scores significantly decreased in the intervention group, whereas it did not change significantly in the control group (F = 50.20, df = 2, and P = 0.001).

Due to the significant interaction between the measurement time and the type of intervention (P = 0.001), the t-test was used for pairwise comparisons between the two groups. The results showed that the mean baseline score of CB did not significantly differ between the two groups (P = 0.95), however, the mean score of CB was significantly lower in the intervention group than in the control group at both the second and third measurement time points [P < 0.001; Table 3].

Discussion

This study revealed that a comprehensive program consisting of the three critical components of education, support, and follow-up can tremendously reduce the burden of parental care. Previous studies contained one or two components of the program. For instance, a study showed that excessive infant crying posed significant challenges and anxiety for mothers and that mothers needed education and support to cope with IC-induced crying.[18] Another study reported that supportive-educational programs improved parents' knowledge of colic-related crying, thereby, improved their relationships with their infants, reduced their stress and CB, and reduced the workload of healthcare providers.[21] Contrastingly, another study revealed that educational and supportive interventions failed to help parents reduce their IC-related stress and depression.[20-23]

Our intervention consisted of three blended components that positively affected CB among parents of infants with IC. Previous studies reported that single educational or supportive interventions had little if any, effect on parents and their infants. For example,

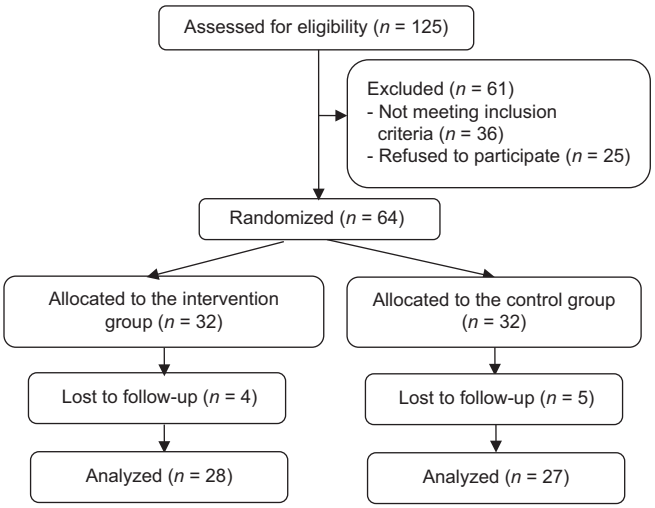

Figure 1: The flow diagram of the study

Table 2: Between-group comparisons respecting participant's characteristics

Characteristics	Group		*P*
	Intervention	Control	
Parental age (years)	29.64 ± 5.80	30.26 ± 4.77	0.67[a]
Duration of caregiving per 24 h	15.46 ± 3.49	16.15 ± 2.28	0.40[a]
Infant's age (weeks)	5.36 ± 1.75	4.85 ± 1.65	0.28[a]
IC duration (weeks)	2.93 ± 1.66	3.36 ± 1.75	0.35[a]
Parent's employment status, *n* (%)			
Employed	8 (28.6)	11 (40.7)	0.34[b]
Housewife	20 (71.4)	16 (59.3)	
Parent's educational level, *n* (%)			
Below diploma	2 (7.1)	4 (14.8)	0.53[c]
Diploma	11 (39.3)	5 (18.5)	
University	15 (53.6)	18 (66.7)	
History of IC in other children, *n* (%)	8 (28.6)	10 (37)	0.50[b]
History of multiple pregnancy, *n* (%)	1 (3.6)	1 (3.7)	0.74[b]
Kinship with infant, *n* (%)			
Father	2 (7.1)	4 (14.8)	0.48[b]
Mother	26 (92.9)	23 (85.2)	
Infant's gender, *n* (%)			
Male	21 (75)	17 (63)	0.33[b]
Female	7 (25)	10 (37)	
Feeding type, *n* (%)			
Breastfeeding	9 (32.1)	7 (25.9)	0.61[b]
Bottle-feeding	13 (46.4)	11 (40.7)	
Both	6 (21.5)	9 (33.4)	
Infants received medications for IC, *n* (%)	17 (60.7)	14 (51.9)	0.51[b]
Educational level, *n* (%)			
Below diploma	2 (7.1)	4 (14.8)	0.53[c]
Diploma	11 (39.3)	5 (18.5)	
University	15 (53.6)	18 (66.7)	

[a]*t*-test, [b]Chi-square test, [c]Mann–Whitney *U*-test. Data presented as mean ± SD or *n* (%). SD: Standard deviation, IC: Infantile colic

Table 3: Within- and between-group comparisons of the mean caregiver burden

Time	Group		*P* (*t*-test)	The effect of group	The interaction between time and group
	Intervention	Control			
Baseline	50.12 ± 10.94	49.93 ± 10.38	0.95	< 0.001	< 0.001
Immediately after the intervention	28.25 ± 7.36	48.30 ± 11.24	< 0.001	-	-
One month after the intervention	23.63 ± 7.57	46.26 ± 10.69	< 0.001	-	-
P (ANOVA)	< 0.001	0.15		-	-

Data presented as mean ± SD. SD: Standard deviation

a study showed that the education did not significantly reduce inconsolable infant crying and maternal anxiety, although it improved mothers' knowledge about infant crying and shaken-baby syndrome prevention.[16] Another study found that supportive interventions had no significant effect on the stress of parents of infants with colic.[17] Similarly, a study showed that single educational interventions were ineffective in reducing colic crying and suggested using multi-component educational, supportive interventions to reduce parents' CB.[9]

We also found that only 32.1% of infants in the intervention group and 25.9% in the control group were exclusively breastfed. Such a low rate of exclusive breastfeeding may play a role in IC. The World Health Organization also highlights the importance of breastfeeding in preventing IC. Nevertheless, a study showed that despite the extraordinary efforts of breastfeeding promotion initiatives, only 25% of infants in European countries received exclusive breastfeeding for 6 months.[24] Bottlefeeding might increase the risk of IC.[25-27] All of these findings highlight the importance of and the need for comprehensive educational and supportive programs for parents to improve their knowledge of breastfeeding and IC and support them in IC management.

This study was subject to some limitations. Some mothers obtained information from various websites and social media, resorted to self-treatment, and hence, dropped from the study. In addition, mothers in Iran are under the influence of family members, particularly their husbands; hence, some of our participants might not have closely adhered to our educations. Therefore, we suggest that parents be trained when the infant is hospitalized. Finally, we could not blind the intervention group due to the nature of the study.

Conclusion

The blended three-component educational, supportive, and follow-up program could reduce CB in parents whose infants suffered from IC. Nurses are suggested to implement similar programs for parents with a similar problem. Empowering and supporting parents can reduce the number of medical visits, reduce their stress, give them a sense of comfort, and enable them to cope with their IC-related problems.

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Conflicts of interest

There are no conflicts of interest.

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