

## RESEARCH ARTICLE

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# Effect of Kangaroo Care on Pain in Infants: A Randomized Controlled Trial

## Bebeklerde Kanguru Bakımının Ağrı Üzerine Etkisi: Randomize Kontrollü Çalışma

### ABSTRACT

#### Aim

This study was conducted to determine the effect of kangaroo care on pain during vaccination in infants.

#### Method

The study was conducted as a randomised controlled trial with 128 healthy one-month-old infants and their mothers. Sociodemographic information form, Neonatal Infant Pain Scale, pulse oximetry and stopwatch were used for data collection.

#### Results

Statistically significant differences were found between the groups before, during and after vaccination in terms of Neonatal Infant Pain Scale scores, oxygen saturation rates and crying times. While there was no significant difference between the groups in terms of heart rate before and during the vaccination procedure, a statistically significant difference was found after vaccination.

#### Conclusion

Kangaroo care has been found to decrease crying time, heart rate and pain in vaccinated infants, while also increasing blood oxygen saturation levels.

#### Keywords

Evidence-based practices, infant, kangaroo care, pediatric nursing, pain, vaccination

## ÖZ

### Amaç

Bu çalışma bebeklerde aşılama sırasında uygulanan kanguru bakımının ağrı üzerine etkisini belirlemek amacıyla yapılmıştır.

### Yöntem

Araştırma, sağlıklı bir aylık 128 bebek ve anneleri ile randomize kontrollü olarak yapılmıştır. Verilerin toplanmasında; sosyodemografik bilgi formu, Yenidoğan Bebek Ağrı Ölçeği, nabız oksimetresi ve kronometre kullanılmıştır.

### Bulgular

Aşılama öncesinde, sırasında ve sonrasında gruplar arasında; Yenidoğan Bebek Ağrı Ölçeği skorları, oksijen saturasyon oranları ve ağlama süreleri açısından istatistiksel olarak anlamlı farklılıklar tespit edilmiştir. Aşılama işlemi öncesinde ve sırasında gruplar arasında kalp atım hızı açısından anlamlı bir fark bulunmazken, aşılama sonrasında istatistiksel olarak anlamlı bir fark tespit edilmiştir.

### Sonuç

Kanguru bakımını aşılanan bebeklerde ağlama süresi, kalp atım hızını ve ağrıyı azaltırken kandaki oksijen saturasyon düzeylerini de artırdığı belirlenmiştir.

### Anahtar Kelimeler

Kanıt dayalı uygulamalar, bebek, kanguru bakımı, pediatri hemşireliği, ağrı, aşı

#### What is Known in the Field

- Kangaroo care is a nonpharmacological method actively used in the control of pain and physical parameters in term and preterm infants.
- It is seen that studies in which kangaroo care is applied are generally done with premature and hospitalized infants.
- It is stated that parents of premature infants are more willing to apply kangaroo care and cooperate with health workers, while other parents' cooperation in applying kangaroo care is low.

#### Contribution of the Article to the Field

- In the study, kangaroo care was applied to healthy and full-term infants during normal routine vaccination instead of premature infants.
- Kangaroo care was applied by ensuring that mothers of infants without any health problems participated in the study, not mothers of infants with health problems.

## INTRODUCTION

Infants undergo many painful procedures from the moment they are born, such as heel prick and vaccination. These procedures cause acute pain in infants (1), and can have adverse short and long-term effects on the infants' cerebral development (2,3). Pain management in infants is therefore quite important. A number of scales and parameters have been devised to evaluate pain in infants, the most commonly used of which are heart rate, oxygen saturation, and crying times (4,5). These indicators are used to assess the infant's pain so that appropriate procedures can be followed in terms of pain management. Many pharmacological and nonpharmacological methods are employed in pain management (6). Among pharmacological methods are anesthetics and anesthetics analgesics, whereas non-pharmacological include massage, music, breastfeeding, provision of sweet-tasting solutions, and kangaroo care (KC). The use of nonpharmacological methods in pain management may help to decrease the use of pain-reducing medication, and this is why hospitals should prioritize the use of non-pharmacological methods (7).

KC (often defined as skin-to-skin contact between a mother and her infant) is one of the nonpharmacological methods that are effective in alleviating pain (6). KC is effective both in preterm and in term infants (8, 9). KC has many advantages, including the alleviation of pain (10,11), maintaining respiration and heart rate under control, and regulating oxygen saturation (12,13). One of the most common invasive procedures in infants is vaccination, and KC is highly effective in reducing the pain that results from vaccination. Therefore, the application of KC should be supported by health personnel. Therefore, they need to receive the required training in KC. Evidence-based guidelines and protocols must also be prepared (2). Pediatrics nurses also have important duties in pain management. They need to provide mothers with information on the purpose, benefits, and risks of KC, as well as instructions on how to go about giving it. Therefore, pediatrics nurses play an important role in the use of KC in pain management (14). The study aims to determine the effect of KC on pain in infants. We tested the hypothesis that "KC reduces crying duration, heart rate, and pain in infants receiving vaccinations and increases oxygen levels in the blood" and discuss the data gathered in accordance with this hypothesis.

## METHOD

### Study Design

The study was conducted as a randomized controlled trial (1:1).

### Participants

The study was conducted in two largest family health centers (FHC). FHC are first level healthcare institutions that lack patient beds. They provide outpatient

health care and vaccination is performed in a vaccination the vaccine room. There is a stretcher in the vaccination room. Criteria for inclusion in this study; the infant must be one-month-old and healthy, and the parents must agree to participate in the study.

### Sample Size

The average NIPS scores in the study conducted by Saeidi et al. (15) were used to calculate the sample size.

The sample size was determined using the G\*Power 3.0 program with a 5% margin of error and 95% confidence level for an effect size of 0.5. As a result of the power analysis, it was decided to include a total of 128 mothers and their infants in the study. The study was conducted with 64 mothers and infants in the intervention group and 64 mothers and infants in the control group (total sample size: 128).

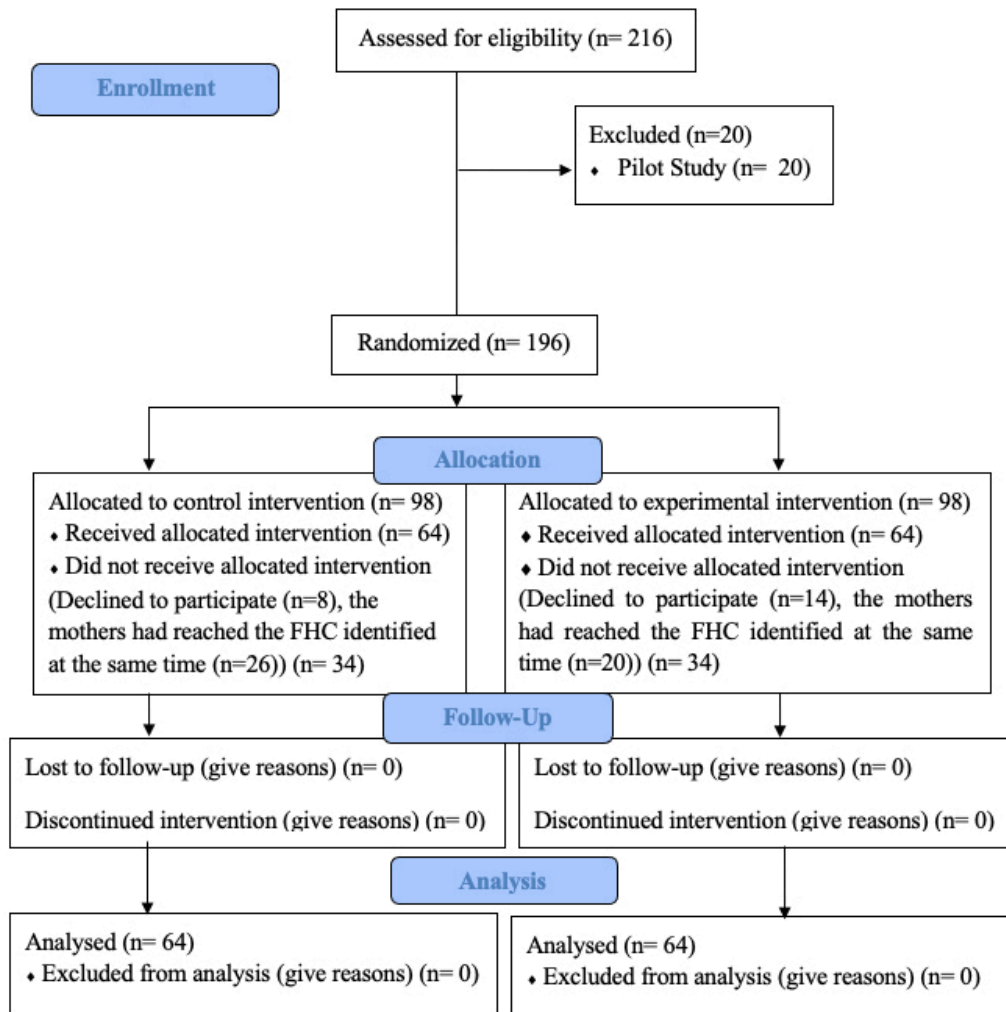


Figure 1. CONSORT, Consolidated Standards of Reporting Trials

During the period May-September 2016, Hepatitis B vaccine was administered to 216 infants at the designated FHC. A pilot study was conducted with 20 infants presenting at the designated FHC on May. Fourteen mothers in the intervention group and 8 mothers in the control group did not agree to participate in the study. During the study, 20 mothers in the intervention group and 26 mothers in the control group were not able to participate in the study because they arrived to determined FHC at the same time. The work flow is presented in Figure 1.

### Outcomes

The main outcome measures for this study were the infants' NIPS (Neonatal Infant Pain Scale) scores,

oxygen saturations, heart rates, and crying durations. These measurements were monitored by a researcher five minutes prior to the start of the vaccination procedure, during the vaccination, and three minutes after the vaccination (a total of three times).

### Procedures

In this pilot study, it was confirmed that the questionnaires were easily comprehended by the mothers and that KC could be implemented during vaccination procedures (the infant's position was suitable and the application time adequate). No changes were made to the methodology of the research used in the pilot study. After the pilot study, a simple randomization method was employed for deriving random numbers

on an Excel. Accordingly, the study and control groups were determined monthly. Mothers were trained with the KC pre-implementation training brochure. Education brochure: It contains information about the definition of KC, its application, benefits and risks. Mothers who agreed to participate in the study filled out the "Sociodemographic Questionnaire".

The mothers in the study group were subsequently brought into the room where the KC would be carried out. Heart rates, oxygen saturations, crying times, and NIPS scores of the infants were monitored five minutes before the start of KC. Care was taken to ensure that the room temperature was suitable for KC (23°C) and that the mother's privacy was respected. The infant's clothing was removed. It was only a diaper remaining. Care was taken to ensure that the mother was comfortable and in a sitting position during the application. Infant was placed face down on the midline of the mother's chest. The infant was thus placed in skin-to-skin contact with the mother. A blanket was then placed over the infant's back, leaving the face and all extremities exposed, and a hat was placed on the infant's head. The infants in the intervention group were given KC for five minutes, which was followed by vaccination. Administration of the vaccine (Hepatitis-B) was performed by FHC health personnel. The third measurement was taken three minutes after vaccination. On completion of vaccination, infants continued to receive KC for 15 minutes there after without interruption. When observing the infants, a researcher noted the NIPS score and used a pulse oximeter to determine heart rate and oxygen saturation. Crying time was recorded from the start of the infant's crying during the vaccination procedure, and was continued until the infant stopped crying. A chronometer was used to track this period.

The control group consisted of mothers and infants meeting the inclusion criteria. Mothers and infants in the control group were brought to the vaccination room, and the infant was laid on a stretcher and only the area required for vaccination was exposed. Care was taken to ensure that the mother was with infant during vaccination. The administration of the vaccine (Hepatitis-B) was performed by the FHC health-care personnel. After the vaccination of infant on the stretcher was completed, the mother held her infant. The NIPS scores, oxygen saturation, and heart rates of the infants in the control group were monitored five minutes prior to the start of the vaccination procedure, during the vaccination, and at three minutes after the vaccination (a total of three times). Crying time was recorded from the start of the infant's crying during the vaccination procedure and continued, continuing until the infant stopped crying. The researchers monitored all the measurements of the control group.

## Data Collection Tools

The data collection tools developed by the researcher in accordance with the literature consisted of a Sociodemographic Questionnaire, NIPS, a chronometer and a pulse oximeter.

**Sociodemographic Questionnaire:** This questionnaire consists of 15 items querying information such as the age of the infant's mother and father, their occupations, educational status, employment status, number of children, the infant's gender, gestational age, and birth weight. The questions were created by the researchers in line with the literature (2-5).

**NIPS:** Lawrence et al. developed this scale in 1993 to evaluate the physical and behavioral pain responses of infants undergoing painful procedures. The Cronbach alpha values of the scale that was developed were found to be 0.95, 0.87 and 0.88 (16). Akdovan tested the validity and reliability of the scale in Türkiye in 1999; its Cronbach alpha internal consistency coefficient is in the range of 0.83-0.86 (17). In this evaluation, six behaviors indicating the infants' reaction to the pain are observed to determine the severity of the pain. These behaviors are the way the infant is breathing, the facial expression, the state of wakefulness, crying, movements of the arms and legs. The total score on the scale varies between 0-7 with the pain being more severe as the score increases (18). Cronbach alpha of our study internal consistency coefficient is in the range of 0.80-0.88.

**Chronometer:** A chronometer showing hours/minutes/seconds. A chronometer was used to measure the length of crying time. The measurements showed good agreement with the values measured using a Voit (8073) chronometer. The chronometer has a CE certificate and was calibrated to minimize errors.

**Pulse oximeter:** A pediatric version of this instrument was used to assess heart rate and oxygen saturation (Contec Brand: CMS60D). The probe of the pulse oximeter is fabricated from a soft plastic and therefore does not disturb the infant. Use of pulse oximeter with a soft plastic probe was preferred as this reduces measurement errors. The instrument is practical, reliable, easy to use, and has a CE certificate.

## Ethical Considerations

In order to conduct the study, written informative consent forms were obtained from the parents, permissions for the scales used, institutional permissions (FHC, public health directorate), and ethics committee permissions (Dumlupınar University Clinical Studies Ethics Board 14.04.2016/issue 2016-5-7).

## Data Analysis

Statistical analyses were performed using SAS (Statistical Analysis Software) 9.3 and IBM SPSS (Statistical Package for Social Sciences) Statistics 22 software (IBM Corp., Armonk, NY, USA). Descriptive statistics (means, standard deviations, frequencies, percentages) were used to evaluate the findings. Normality tests (Kolmogorov-Smirnov test) were performed on all continuous variables. Comparisons between groups for normally distributed variables were performed using an independent samples t test and one-way ANOVA. An independent samples t test was employed to compare differences in crying duration between groups. A dependent samples t test was used for between-group comparisons before, during, and following the vaccination procedure in terms of

the infants' NIPS scores, oxygen saturation values, and heart rates, whereas variance analysis (Repeated Measures ANOVA) and Tukey's posthoc test were used for intra group comparisons. A chi-square test was used in the comparisons of qualitative data. Statistical significance was accepted as  $p < 0.05$ .

## RESULTS

A total of 128 infants and mothers were recruited for the study: 64 infants and their mothers into the intervention and 64 infants and their mothers into control groups. There were statistically no significant differences between the groups in terms of the sociodemographic variables ( $p > 0.05$ ) (Table 1).

**Table 1.** Sociodemographic Variables (n=128)

Descriptive Characteristics	Control Group		Intervention Group		$\chi^2$	p
	n	%	n	%		
<b>Mother's Age</b>						
Ages 19-24	24	37.5	22	34.4	4.225	0.121
Ages 25-30	22	34.4	32	50.0		
Age 31 and above	18	28.1	10	15.6		
Total	64	100	64	100		
<b>Mother's Education</b>						
Elementary school	27	42.2	21	32.8	4.033	0.258
High School	21	32.8	32	50.0		
University	14	21.9	10	15.6		
Other	2	3.1	1	1.6		
Total	64	100	64	100		
<b>Mother's Employment Status</b>						
Employed	22	34.4	25	39.1	0.134	0.714
Unemployed	42	65.6	39	60.9		
Total	64	100	64	100		
<b>Number of children</b>						
1	26	40.6	33	51.6	3.420	0.181
2	28	43.8	27	42.1		
3 or more	10	15.6	4	6.3		
Total	64	100	64	100		
<b>Father's Age</b>						
Ages 19-24	12	18.8	13	20.3	0.776	0.855
Ages 25-30	23	35.9	24	37.5		
Ages 31-35	13	20.3	15	23.4		
Age 36 and above	16	25.0	12	18.8		
Total	64	100	64	100		
<b>Father's Education</b>						
Elementary school	19	29.6	17	26.5	4.198	0.241
High School	33	51.6	33	51.6		
University	9	14.1	14	21.9		
Other	3	4.7	0	0		
Total	64	100	64	100		
<b>Father's Occupation</b>						
Civil servant	22	34.4	19	29.6	0.518	0.772
Laborer	29	45.3	33	51.6		
Self-employed	13	20.3	12	18.8		
Total	64	100	64	100		
<b>Family Type</b>						
Nuclear family	40	62.5	43	67.2	0.137	0.711
Extended family	24	37.5	21	32.8		
Total	64	100	64	100		
<b>Infant Gender</b>						
Female	27	42.2	34	53.1	1.127	0.288
Male	37	57.8	30	46.9		
Total	64	100	64	100		
	$\bar{x} \pm SD$		$\bar{x} \pm SD$		t*	p
<b>Infant's Gestational Age</b>	38.730 $\pm$ 1.073		38.640 $\pm$ 0.982		0.516	0.607
<b>Infant's Birthweight</b>	3261.020 $\pm$ 325.214		3253.050 $\pm$ 257.805		0.154	0.878

Note: \*Independent samples t test



### Effect of the Procedure

Statistically significant differences were detected between the groups before, during, and after the vaccination procedure in terms of NIPS scores ( $p=0.041$ ,  $p<0.001$ , and  $p<0.001$ , respectively) and oxygen saturation values ( $p<0.001$ ,  $p<0.001$ , and  $p<0.001$ , respectively). A statistically significant decrease was found in the pain levels of infants during and following the intervention procedure, and a statistically significant increase was determined in the oxygen saturation levels of the intervention group of infants compared to the control group, both during and following the vaccination procedure. Whereas no statistically significant differences were observed between the groups in terms of heart rates before and during the vaccination procedure ( $p=0.056$  and  $p=0.535$ , respectively).

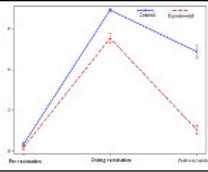
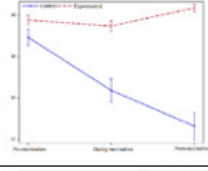
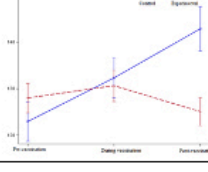
There was a statistically significant difference following the procedure ( $p<0.001$ ) (Table 2). A statistically significant decrease in heart rate was observed following the vaccination procedure in infants who had received KC. For the control group, the results of repeated measures ANOVA were statistically significant for all three measures ( $F=1119.840$ ;  $F=59.980$ ;  $F=19.970$ ;  $p<0.001$ , respectively). After further analysis, all pair-

wise differences between pre-vaccination, vaccination, and post-vaccination were found to be statistically significant (Table 2).

In the intervention group, all of the repeated measures showed statistically significant ANOVA results ( $F=862.680$ ;  $F=15.170$ ;  $F=3.110$ ;  $p<0.005$ , respectively). After further analysis, a statistically significant difference in NIPS scores was detected for each of the pre-vaccination, vaccination, and post-vaccination measurements. There was no statistically significant difference in oxygen saturation and heart rate levels between pre-vaccination and the vaccination procedure ( $t=1.837$ ,  $p=0.067$ ;  $t=-1.183$ ,  $p=0.238$ , respectively) (Table 2).

There was a statistically significant difference between the intervention and control groups in terms of post-vaccination total crying duration ( $t=12.658$ ,  $p<0.001$ ) (Table 3). It was found that the crying times of infants who had received KC were significantly shorter than those in the control group of infants.

**Table 2:** Comparison of NIPS Scores, Oxygen Saturation and Heart Rates

Groups		Pre-vaccination $\bar{x} \pm SD$	During vaccination $\bar{x} \pm SD$	Post-vaccination $\bar{x} \pm SD$		F** / p	t*** Test / p	
NIPS Score	Control	0.328 $\pm$ 0.473	6.910 $\pm$ 0.294	4.880 $\pm$ 1.279		1119.840/ .000	Pre - During	-46.212/ 0.000
							Pre - Post	-31.942/ 0.000
	Intervention	0.171 $\pm$ 0.380	5.530 $\pm$ 0.942	1.050 $\pm$ 0.898		862.680/ 0.000	During - Post	14.269/ 0.000
		$t^*=2.060$ ; $p=0.041$	$t^*=11.140$ ; $p=0.000$	$t^*=19.600$ ; $p=0.000$			Pre - During	-38.713/ 0.000
Oxygen Saturation	Control	96.920 $\pm$ 1.616	94.360 $\pm$ 2.228	92.630 $\pm$ 2.717		59.980/ 0.000	Pre - Post	10.885/ 0.000
							During - Post	4.393/ 0.000
	Intervention	97.770 $\pm$ 0.955	97.470 $\pm$ 1.038	98.340 $\pm$ 0.718		15.170/ 0.000	Pre - During	1.837/ 0.067
		$t^*=-3.600$ ; $p=0.000$	$t^*=-10.120$ ; $p=0.000$	$t^*=-16.280$ ; $p=0.000$			Pre - Post	-3.578/ 0.000
Heart Rate	Control	122.950 $\pm$ 16.860	132.340 $\pm$ 17.399	142.88 $\pm$ 19.186		19.970/ 0.000	During - Post	-3.338/ 0.001
							Pre - During	-2.977/ 0.003
	Intervention	128.000 $\pm$ 12.444	130.640 $\pm$ 13.346	125.08 $\pm$ 12.028		3.110/ 0.046	Pre - Post	-1.183/ 0.238
		$t^*=-1.930$ ; $p=0.056$	$t^*=0.620$ ; $p=0.535$	$t^*=6.290$ ; $p=0.000$			During - Post	2.493/ 0.013

Note: \*Independent samples t test

\*\* Repeated Measures ANOVA

\*\*\*Dependent samples t test

**Table 3.**Comparison of Total Crying Durations

Groups	Control Group (n=64) $\bar{x} \pm SD$	Intervention Group (n=64) $\bar{x} \pm SD$
Crying Duration	141.500 $\pm$ 51.108	52.810 $\pm$ 23.018
$t^*=12.658$ ; $p=0.000$		
Note: *Independent samples t test		

## DISCUSSION

KC is an effective nonpharmacological method that is used in infant pain management, and accordingly, it is important that pediatric nurses use this method routinely in hospitals. In the present study, we observed a statistically significant decrease in the pain levels of infants during and following use of this procedure. In studies (11, 15, 19-21), have stressed that KC for infant' results in a lower degree of physical and behavioral reactions toward pain during the heel prick sampling procedure. The findings of the present study are consistent with those reported in the literature. The results showed that KC is an effective procedure for reducing pain in infants. The significantly reduced pain levels observed in infants that were offered KC may be a result of sensory stimulation.

A significant increase was noted in the oxygen saturation levels of the intervention group of infants compared with the control group, both during and following the vaccination procedure, which is consistent with the results of previous studies (10, 12). Saeidi et al (15) reported higher oxygen saturation levels in infants given KC during an invasive procedure. A study by Okan et al (20) demonstrated that the changes in oxygen saturation levels in infants given KC were lower during heel-pricking sampling, and Sajedi et al (22) have indicated that infants given KC have higher levels of oxygen saturation. Other studies have also reported that KC is an effective procedure for regulating oxygen saturation levels during invasive procedures (23, 24). This finding is supported by the fact that infants receiving KC cry for shorter periods of time following vaccination.

A statistically significant decrease in heart rate was observed following the vaccination procedure in infants who had received KC. The literature emphasizes the effectiveness of KC in maintaining heart rate under control (13, 26, 27). In their studies, Okan et al (20), Sajedi et al (22), and Gray et al (28) have reported that KC is an effective means of controlling heart rate during invasive procedures. The findings of other studies (24, 25, 27, 29) are also consistent with the results of the present study. Collectively, the research indicates a relationship relation between KC and a decrease in heart rate, reduced pain, and shorter duration of crying after the vaccination procedure. It was found that the crying times of infants who had received KC were significantly shorter than those in the control group of infants. Consistently, previous studies have reported that KC is effective in reducing the duration of crying during invasive procedures (26, 30). In studies (20, 22, 27, 28, 31) have stressed in their studies that infants receiving KC exhibited shorter crying times during invasive procedures, and a further study has reported that KC is effective in reducing crying times during invasive procedures. The most pronounced and trackable behavioral response of infants to pain is crying (29). In our study, this finding

was demonstrated by the fact that the infants receiving KC cried less after vaccination than infants in the control group.

## Limitations

The fact that infants are vaccinated by different nurses can be considered a limitation.

## CONCLUSION AND RECOMMENDATIONS

It was observed that KC reduced crying duration, heart rate, and pain in vaccinated infants, whereas it increased oxygen saturation levels in the blood. The results of the study indicate that KC is an effective non-pharmacological method in pain management. The results of the study show the short-term benefit of KC on acute pain. Therefore, it is recommended to increase the number of studies examining the long-term effects of KC. KC is effective in the invasive procedures. It also may reduce other forms of distress or pain. KC training should be offered to parents and nursing professionals as a routine practice, and hospitals should draw up evidence-based guidelines and protocols for KC. The face-down kangaroo position may be employed in infants receiving vaccinations in the vastus lateralis muscle.

## Ethical Considerations

In order to conduct the study, written informative consent forms were obtained from the parents, permissions for the scales used, institutional permissions (FHC, public health directorate), and ethics committee permissions (Dumlupinar University Clinical Studies Ethics Board 14.04.2016/issue 2016-5-7).

## Author Contributions

Concept: DY,ES Design: DY,ES Supervision: DY,ES Data collection and/or processing: DY,ES Analysis/Interpretation: DY,ES Literature search: DY,ES Writing of the article: DY,ES Critical review: DY,ES.

## Conflict of Interest

The principles of publication ethics were followed during the creation of this article, and there is no conflict of interest between the researchers related to the study.

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