PERINATAL JOURNAL

Original Article

Perinatal Journal 2023;31(1):31–40

Comparison of the efficacy of non-pharmacological interventions during the heel stick procedure on pain level, duration of crying, and voice decibel of newborns: a randomized controlled trial

Pınar Duru[1], Zehra Akkoca[2], Özlem Örsal[1]

[1]Division of Public Health Nursing, Department of Nursing, Faculty of Health Sciences, Eskişehir Osmangazi University, Eskişehir, Türkiye
[2]Division of Child Health and Disease Nursing, Department of Nursing, Institute of Health Sciences, Kütahya Health Sciences University, Kütahya, Türkiye

Abstract

Objective: To compare the efficacy of different non-pharmacological interventions (kangaroo care, cuddling, playing white noise, ambient sound) applied to newborns during the heel stick procedure on newborns' pain level, duration of crying, and voice decibel.

Methods: This is a prospective, randomized controlled trial including pre- and post-tests of four groups. The setting is a neonatal intensive care unit in Türkiye. One hundred and thirty-six newborns were recruited. Newborns were randomly assigned to four groups *(i)* kangaroo care, *(ii)* cuddling, *(iii)* white noise, and *(iv)* ambient sound. Pain measures were recorded 1 minute before, during, and 3 minutes after blood collection based on the Neonatal Infant Pain Scale (NIPS).

Results: There was a significant difference between the pain levels (χ^2=16.910, p=.001) and durations of crying (χ^2=13.888, p=.003) during the heel stick procedure of the newborns depending on the non-pharmacological intervention. The pain levels of newborns who received kangaroo care were significantly lower compared to those who were listened to ambient sound during the procedure. The newborns' durations of crying who received kangaroo care and who were lapped by their mothers during the heel stick procedure were also lower than those who are listened to ambient sound. There was no significant difference between the highest sound decibel levels of newborns after the procedure due to the non-pharmacological intervention applied during the heel stick procedure.

Conclusion: Kangaroo care was more effective in reducing pain level and duration of crying. The non-pharmacological interventions had no effects on the highest sound decibel levels of newborns.

Keywords: Newborn, crying, pain, voice.

Introduction

Even after delivery without any complications, newborns, especially those who are hospitalized in intensive care units, are inevitably exposed to many iatrogenic painful procedures such as heel stick, vaccination, circumcision, intravenous procedures, gastric tube placement, etc.[1,2] Newborns can experience an average of 7.5–17.3 painful procedures per day. This number is actually much higher when unsuccessful and repetitive transactions are considered.[3] Also, the number of stressful and painful procedures increase by 10.9 and 2.2 for each day of hospitalization, respectively.[4] During their hospitalization, pain exposure of newborns ranges between 10 to 576. This is the evidence that vulnerable newborns are increasingly at risk for painful procedures with the increase in invasive procedures in diagnosis and treatment.[5] Exposing to pain in the early neonatal period results in long-term emotional, cognitive, and behav-

Correspondence: Pınar Duru, PhD. Department of Public Health Nursing, Eskişehir Osmangazi University, Meşelik Kampüsü, 26480 Eskişehir, Türkiye. **e-mail:** pduru@ogu.edu.tr / **Received:** July 31, 2022; **Accepted:** November 17, 2022

How to cite this article: Duru P, Akkoca Z, Örsal Ö. Comparison of the efficacy of non-pharmacological interventions during the heel stick procedure on pain level, duration of crying, and voice decibel of newborns: a randomized controlled trial. Perinat J 2023;31(1):31–40. doi:10.2399/prn.23.0311006

ORCID ID: P. Duru 0000-0002-3471-1383; Z. Akkoca 0000-0002-3950-2011; Ö. Örsal 0000-0002-4494-8587

ioral harmful outcomes, such as the development of pain hypersensitivity, detrimental psychological symptomology, and altered neurodevelopment.[1,2] While crying as a result of painful and stressful stimuli increases the heart rate, blood pressure, intracranial pressure, and respiratory rate due to the decrease in blood oxygen saturation, the brain (intraventricular hemorrhage), development of senses, growth, and development negatively affect, and therefore it causes physiological and metabolic problems in newborns.[6]

In the literature, a wide variety of non-pharmacological interventions are frequently used to reduce the pain level during invasive procedures applied to newborns,[7,8] increase the comfort level,[7] and improve physiological parameters.[8] Commonly used non-pharmacological interventions to reduce the level of pain during invasive procedures include strategies such as playing white noise, mother's voice and heart beatings, using neonatal noise attenuators,[7–9] swaddling, cuddling, facilitative tucking, kangaroo care, tactile stimulation, giving oral dextrose, oral glucose and oral sucrose, breastfeeding, giving a pacifier,[1,5] distraction, controlling ambient noise, lighting, and odors in the environment,[1] application of local heat, and multiple sensory stimulations (massage, sound, eye contact, and perfume scent).[10] Non-pharmacological methods, including many environmental and behavioral interventions, can be used alone, together, or in combination with pharmacological treatments.[2] Kangaroo care plays a role as an analgesic and relaxing experience in reducing neonatal pain through the modulation of the pain-related stress regulation system and multiple sensory stimulation inputs.[11] Auditory interventions such as white noise and mother's voice are more effective than reducing environmental sounds and reduce pain response by distracting through sound stimulation.[7]

Despite worldwide efforts to improve pain management in newborns, the frequency of painful procedures is high while the use of analgesia is low.[3] Considering the multimodal approaches that emerge with multiple pain management techniques, their potential combinations, and the combination of specific pain management techniques, any review cannot address all of these combinations.[1] Although different results have been reported on the analgesic effects of various non-pharmacological methods with their combinations in the literature, there is still no optimal method or definitive recommendations for their regular use in everyday clinical scenarios. Therefore, many studies should be conducted on assessing the effectiveness of different non-pharmacological interventions together. This study aimed to compare the efficacy of different non-pharmacological interventions (kangaroo care, cuddling, playing white noise, ambient sound) applied to newborns during heel stick procedure on their pain level, duration of crying, and voice decibel.

Hypotheses of the study

- **H1:** Newborns who receive kangaroo care during heel stick procedure have less pain level than those who are cuddled by their mothers.
- **H2:** After heel stick procedure, newborns' durations of crying who receive kangaroo care are shorter compared to those who are cuddled by their mothers.
- **H3:** After heel stick procedure, newborns who receive kangaroo care have lower voice decibels during crying than those who are cuddled by their mothers.
- **H4:** Newborns who listen to white noise during heel stick procedure have lower pain levels than those who listen to ambient sound.
- **H5:** After heel stick procedure, newborns' durations of crying who listen to white noise are shorter compared to those who listen to ambient sound.
- **H6:** After heel stick procedure, newborns who listen to white noise have lower voice decibels during crying than those who listen to ambient sound.

Methods

Study design

This is a prospective, randomized controlled trial including pre- and post-tests of four groups, conducted between July 10, 2019, and August 02, 2020. The study was registered at ClinicalTrials.gov Protocol Registration Data Element Definitions for Interventional and Observational Studies database under identifier NCT04033874.

Participants and recruitment

The universe of the study consists of the newborns (N=2024) in the Eskişehir City Hospital's Neonatal Intensive Care Unit between the dates of the study. Before the study, the power analysis was made and 34

newborns were included in each group with a 95% confidence interval, 0.25 effect size, and 0.85 power according to the results. In total, 136 newborns were recruited from the neonatal intensive care unit for the study (**Fig. 1**).

Inclusion criteria

Newborns who met the following criteria were included: *(1)* having a gestational age between 34 and 42 weeks, *(2)* having a birth weight between 2500–4000 g, *(3)* having 1-minute and 5-minute Apgar scores 8 and above, *(4)* passing the hearing screening test, *(5)* being followed up in the Neonatal Intensive Care Unit, *(6)* being fed at least half an hour before the heel stick procedure, *(7)* having the approval of parents to participate in the study, *(8)* never receiving mechanical ventilator/nCPAP support since birth, *(9)* absence of congenital anomalies.

Exclusion criteria

Newborns were excluded under following conditions: *(1)* failure to draw blood at the first attempt as the level of pain may change, *(2)* inability of the newborn to pass

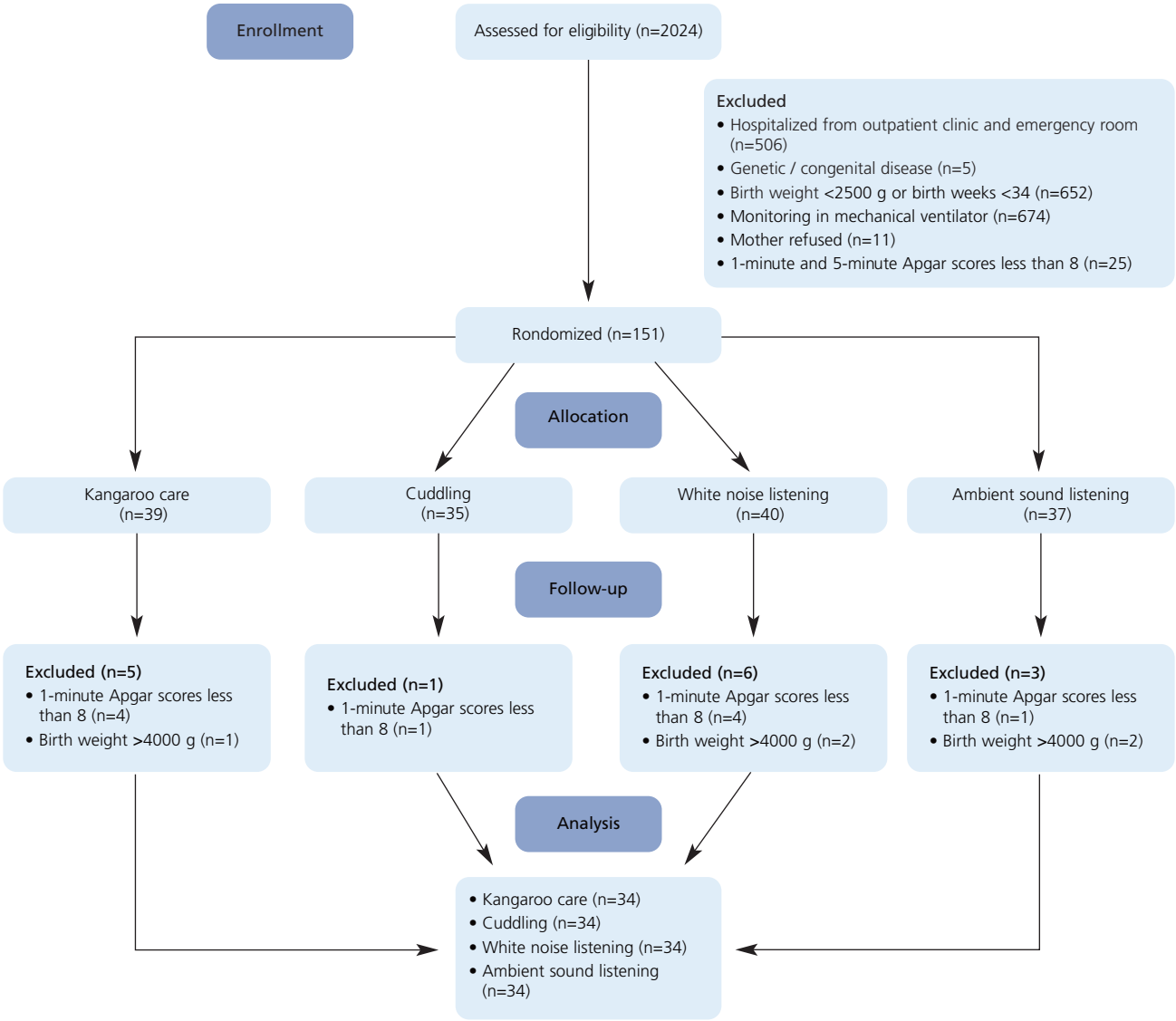

Fig. 1. CONSORT flow diagram of randomized controlled trial.

the hearing screening test, *(3)* being hospitalized at the polyclinic and emergency room because of taking heel stick procedure before, *(4)* parents' refusal to participate in the study.

Randomization

Newborns who met the inclusion criteria were randomly assigned to the groups. There are four different intensive care rooms in the clinic where the study was conducted. The heel stick procedure was carried out in the room where the newborn was. In the randomization process, the rooms were randomly assigned to the experimental groups by lot to eliminate the interaction between the newborns in the four-group design. To ensure full randomization and to prevent the Rosenthal effect, internal blinding was used as a method of blinding, and the randomization was performed by the responsible nurse who was unaware of the pre- and post-tests of the study. The following issues were taken into consideration while the researchers evaluated the effect of the newborn's heel stick procedure on the pain level, duration of crying, and voice decibels in a four-group experimental design: *(1)* four different groups were formed to prevent concerns about the randomization of newborns in the neonatal intensive care unit who were graded according to their clinical condition, *(2)* in the absence of ambient noise in the neonatal intensive care unit, four groups were considered due to the limitations in explaining the benefit, contribution, and effect of white noise, kangaroo care, and being cuddled by the mother in reducing pain, *(3)* the newborns who received procedure of kangaroo care and being cuddled by their mother constituted the control groups of each other; the newborns who received procedure of playing white noise and ambient sound constituted the control groups of each other.

Procedure

Kangaroo care. Kangaroo care was applied to the newborns in this group by their mothers 30 minutes before the heel stick procedure. Kangaroo care continued during the heel stick procedure.

White noise. The track "Don't let your baby cry, pt.3" from the music album of KOLİK - Relaxing Music for Your Newborn Baby from ON Music Production, prepared by Orhan Osman, was played to the newborns in this group before and during the application. Orhan Osman benefited from the album of "The Happiest Baby" prepared by Dr. Harvery Karp, which consists of only intrauterine sounds for calming newborns for preparing his album. Unlike this album, Orhan Osman added sounds such as white noise by making frequency studies besides intrauterine sounds and added music made of his own compositions under the frequencies. The sound level of white noise was set to an average of 55 decibels.

During the application, a pulse oximeter device was placed on the right wrist of each newborn in four groups, and heart rate and SpO_2 values were recorded before, during, and after the procedure. During the procedure, this device was kept on the wrists of the newborns. Then, the pain levels were evaluated with the Neonatal Infant Pain Scale (NIPS), the heel stick procedures for blood collection were started, and measuring devices were turned on to determine the voice decibel and duration of crying.

The general pain level of the newborns was evaluated by observing for one minute before the procedure while their responses to pain were evaluated by observing for three minutes during and after the procedure. The heel stick procedure was performed by one of the researchers (ZA, also the neonatal nurse) in all newborns. Before the application, the heels of the newborns were heated in the palm, the skin was cleaned with alcohol, and blood was taken from the left heel of all newborns. A standard 21 G needle tip was used for the heel lance.

Outcome measurements

In the study, the Data Collection Form prepared by the researchers in line with the purpose of the study and the Neonatal Infant Pain Scale (NIPS) were used to evaluate the pain level of the newborns.

Data Collection Form: It was prepared by the researchers to collect data on the groups, the dates of the procedures, the ages of the mothers and fathers, the number of maternal pregnancies of the mothers, the number of children, the birth dates of the newborns, the genders of the newborns, the weeks of gestation of the newborns, the postnatal ages of the newborns, the modes of deliveries, 1-minute and 5-minute Apgar scores, birth weight, birth length, head circumference, chest circumference, feeding style, the first time to start sucking, duration of crying, and the highest levels of voice decibels after the procedure.

Neonatal Infant Pain Scale (NIPS): It was developed by Lawrence et al. (1993) to assess interventional pain in premature and term newborns and adapted into Turkish by Akdovan and Yıldırım (1999). The general conditions of newborns are evaluated before the intervention, and the changes during and after the procedure are observed. In scoring, the facial expression, crying condition, breathing patterns, movement of arms, movement of legs, and state of arousal are evaluated. All behavioral indicators should be monitored for one minute to be evaluated fully and reliably. The total score ranges from 0 to 7. Higher scores indicate increased pain level. The Cronbach's alpha coefficients of NIPS before, during, and after procedures were reported 0.83, 0.83, and 0.86, respectively.[12] For this study, the Cronbach's alpha coefficients of the NIPS before, during, and after the procedure were 0.83, 0.94, and 0.99, respectively.

A pulse oximeter device (Philips Medizin Systeme, Böblingen, Germany) was used to determine the oxygen saturation levels and heart rates of the newborns; a voice recorder (Sony Corp., Tokyo, Japan) was used for recording and determining the duration of crying; an MP3 player (Sony Corp., Tokyo, Japan) was used for playing white noise; a measuring device (CEM DT-805, CEM Instruments, Shenzhen, China) was used to measure voice decibel.

Ethical considerations

The study was approved by the ethical committee from the Non-Invasive Clinical Research (Date: 13.05.2019, No: 56894). Institutional permission (Date: 08.07.2019) was obtained from the Provincial Directorate of Health to collect the data, and permission (Date: 01.04.2019) was also obtained from the owner of the white noise to use it. Written consent was obtained from the mothers of the newborns in the study by signing an informed consent form.

Data analysis

The homogeneity of the groups in the study was evaluated by chi-square, Fisher's exact, and Kruskal-Wallis H tests in socio-demographic variables. Friedman's analysis of variance was used to compare repeated measurements due to different non-pharmacological interventions during the heel stick procedure of newborns. When the p-value was found to be significant as a result of Friedman's variance analysis, Wilcoxon signed-rank test was applied with Bonferroni correction as a post-hoc analysis. The effect size was calculated by using the formula of $r=Z/\sqrt{n}$ for the value of z. Cohen's (1988) effect size (r) values in interpreting the results were considered as "0.1 = low", "0.3 = medium", "0.5 = large".[13]

Results

Of the newborns, 59.6% (n=81) were male, the mean week of gestation was 37.71±1.80 (34.00–41.00) weeks, and the mean postanal age at the time of the procedure was 3.83±1.35 (2.00–11.00) days. The mean time of heel stick procedure was 3.17±1.12 (2.00–7.00) days after birth. The mean NIPS scores of the newborns before, during, and after the procedure were 0.04±0.43 (0.00–5.00), 3.71±2.90 (0.00–7.00), and 0.49±1.60 (0.00–6.00), respectively. The mean duration of crying after the procedure was 91.59±91.69 (0.00–360.00) seconds, and the mean highest voice decibel was 44.34±34.86 (0.00–86.00) decibels.

The demographic characteristics of the newborns are presented in **Table 1**. The data were homogeneously distributed in terms of relevant values in four groups.

There were statistically significant differences between pain levels (χ^2=16.910, p=.001) and duration of crying (χ^2=13.888, p=.003) due to non-pharmacological interventions applied during the heel stick procedure of newborns. The pain levels of newborns who received kangaroo care during the procedure were significantly lower compared to those who listened to the ambient sound during the procedure (Z=-3.716, p=.000, r=.63). The newborns who received kangaroo care during heel stick procedure had less pain compared to those who were cuddled by their mothers (Z=-2.400, p=.016, r=.41). According to the effect size, kangaroo care was moderately effective in reducing the level of pain compared to cuddling. H_1 hypothesis was accepted. There was no difference between the pain levels of the newborns who listened to white noise and those who listened to ambient sound during heel stick procedure (Z=-1.700, p=.089). H_4 hypothesis was rejected (**Table 2**).

The newborns' durations of crying who received kangaroo care (Z=-3.911, p=.000, r=.67) and cuddling (Z=-3.160, p=.002, r=.54) were shorter than those who listened to ambient sound. There was no difference between the newborns' durations of crying who received kangaroo care after heel stick procedure and newborns who were cuddled by their mothers after the heel stick

Table 1. The distribution of the demographic characteristics of the newborns in the groups.

Variables	Study groups					
	Kangaroo care (1)	Cuddling (2)	White noise listening (3)	Ambient sound listening (4)	Test statistics	
Gender	n (%)	n (%)	n (%)	n (%)	Chi-square	
Female	14 (25.5)	10 (18.2)	15 (27.3)	16 (29.1)	χ^2=2.534	
Male	20 (24.7)	24 (29.6)	19 (23.5)	18 (22.2)	p=.469	
Mode of delivery	n (%)	n (%)	n (%)	n (%)	Fisher's exact test	
Normal	13 (21.0)	13 (21.0)	21 (33.9)	15 (24.2)	χ^2=23.436	
Epidural analgesia	1 (6.3)	1 (6.3)	8 (50.0)	6 (37.5)	p=**.000**	
Cesarean section	20 (34.5)	20 (34.5)	5 (8.6)	13 (22.4)		
	Med (min–max.)	**Med) (min–max.)**	**Med (min–max.)**	**Med (min–max.)**	**Kruskal-Wallis H test**	**Pairwise comparisons**
Gestational age (weeks)	37.90 (34.00–40.00)	38.00 (34.00–40.20)	39.00 (34.00–41.00)	37.00 (34.00–40.00)	χ^2=10.867, p=**.012**	(4-3) p=**.007**
Postnatal age	3.00 (2.00–10.00)	4.00 (2.00–7.00)	3.00 (2.00–11.00)	3.50 (2.00–6.00)	χ^2=1.235, p=.745	
Birth weight (g)	3155 (2500–3950)	3105 (2500–3980)	3135 (2500–3940)	2572 (2500–3850)	χ^2=10.324, p=**.016**	(4-1) p=**.037**
Birth length (cm)	49.00 (45.00–53.00)	50.00 (45.00–53.00)	49.00 (42.00–53.00)	48.00 (42.00–52.00)	χ^2=12.004, p=**.007**	(4-2) p=**.008**
Head circumference (cm)	34.00 (21.00–39.00)	35.00 (31.00–37.00)	34.00 (32.00–37.00)	33.00 (31.00–38.00)	χ^2=11.788, p=**.008**	(4-1) p=**.024** (4-2) p=**.015**
Chest circumference (cm)	32.00 (30.00–35.00)	33.00 (30.00–35.00)	33.00 (30.00–36.00)	32.00 (30.00–35.00)	χ^2=13.576, p=**.004**	(4-3) p=**.017** (4-2) p=**.015**
1-minute Apgar score	9.00 (8.00–9.00)	9.00 (8.00–9.00)	9.00 (8.00–9.00)	9.00 (8.00–9.00)	χ^2=1.268, p=.737	
5-minute Apgar score	10.00 (9.00–10.00)	10.00 (9.00–10.00)	10.00 (8.00–10.00)	10.00 (8.00–10.00)	χ^2=3.024, p=.388	

procedure (Z=-1.343, p=.179). H_2 hypothesis was rejected. There was no difference between the newborns' durations of crying who listened to white noise after the heel stick procedure and those who listened to ambient sound (Z=-1.847, p=.065). H_5 hypothesis was rejected (**Table 2**).

There was no statistically significant difference between the highest crying decibels of the newborns in terms of the non-pharmacological interventions applied during the heel stick procedure (χ^2=4.024, p=.259). There was no difference between the highest crying decibels of the newborns who received kangaroo care after heel stick procedure compared to the newborns who were cuddled by their mothers (Z=-1.198, p=.231). H_3 hypothesis was rejected. There was no difference between the highest crying decibels of the newborns who listened to white noise after the heel stick procedure compared to the newborns who listened to ambient sound after the heel stick procedure (Z=-1.677, p=.093). H_6 hypothesis was rejected (**Table 2**).

The pain levels of the newborns during heel stick procedure were significantly higher than before and after the procedure, regardless of which type of non-pharmacological intervention was used (for each, p<.05; **Table 2**).

The comparison of the physiological parameters of the groups in which different non-pharmacological interventions were applied is presented in **Table 3**.

Discussion

Although there are strong pieces of evidence for the presence and management of pain associated with invasive procedures, it is seen that pharmacological and non-pharmacological interventions are rarely applied before invasive procedures, and newborns often do not benefit from this information.[3] However, it is important for the neurological and behavioral development of newborns that nurses are aware of pain during invasive interventions they apply to newborns and use various methods to reduce this pain.[7]

Table 2. Distribution and comparison of the median scores of the study groups on pain level, duration of crying and voice decibel of newborns.

Measurements		Study groups: Kangaroo care (1)	Study groups: Cuddling (2)	Study groups: White noise listening (3)	Study groups: Ambient sound listening (4)	Friedman F test	Post hoc analysis (Wilcoxon signed-rank test)
		Med (min–max.)	Med) (min–max.)	Med (min–max.)	Med (min–max.)	χ^2, p	Z, p, r
GestaPain level (NIPS)							
Before procedure[a]		0.00 (0.00–0.00)	0.00 (0.00–0.00)	0.00 (0.00–5.00)	0.00 (0.00–1.00)	2.000, .572	
During procedure[b]		1.00 (0.00–7.00)	4.00 (0.00–7.00)	6.00 (0.00–7.00)	6.00 (0.00–7.00)	16.910, **.001**	(4-1) -3.716, **.000**, .63
After procedure[c]		0.00 (0.00–0.00)	0.00 (0.00–6.00)	0.00 (0.00–6.00)	0.00 (0.00–6.00)	12.134, .007	-
Pairwise comparisons	χ^2, p	44.000, **.000**	59.363, **.000**	34.289, **.000**	56.186, **.000**		
	Z, p, r	(b-a) -4.136, **.000**, .70	b-a) -4.828, **.000**, .83	(b-a) -4.193, **.000**, .72	(b-a) -4.930, **.000**, .84		
		(c-b) -4.136, **.000**, .70	(c-b) -4.831, **.000**, .83	(c-b) -3.853, **.000**, .66	(c-b) -4.765, **.000**, .82		
Hypothesis tests	Z, p, r	H_1 (Accepted) 2.400, **.016**, .41		H_4 (Rejected) -1.700, .089			
Duration of crying							
After procedure		0.00 (0.00–180.00)	25.50 (0.00–270.00)	121.50 (0.00–360.00)	180.00 (0.00–360.00)	13.888, **.003**	(4-1) -3.911, **.000**, .67 (4-2) -3.160, **.002**, .54
Hypothesis tests	Z, p, r	H_2 (Rejected) -1.343, .179		H_5 (Rejected) -1.847, .065			
Voice decibel							
After procedure		0.00 (0.00–80.00)	63.00 (0.00–76.00)	68.50 (0.00–81.00)	70.20 (0.00–86.000)	4.024, .259	
Hypothesis tests	Z, p, r	H_3 (Rejected) -1.198, .231		H_6 (Rejected) -1.677, .093			

Kangaroo care is different from cuddling; the baby lies face down between the breasts of the parent in an upright position in kangaroo care, and thus skin-to-skin contact is provided.[14] In our study, we observed that kangaroo care applied during the heel stick procedure was moderately effective in reducing the pain level compared to the cuddling, and therefore the H_1 hypothesis was accepted. Similarly, there are studies reporting that kangaroo care is effective in reducing the pain level of newborns and their biological and behavioral responses to pain during heel stick procedure.[15–17]

The combination of all tones that can be heard by the human ear with equal intensity is called white noise. The spectral energy density is a frequency-independent noise that does not change.[18] The sound heard by the baby in the mother's womb (the sound of the intestines, heartbeat sound, sound from the amniotic fluid) is an example of white noise. In our study, we found no difference between the pain levels of the newborns who listened to white noise and ambient sound during heel stick procedure (H_4). Possible reasons for the inefficacy of white noise in pain management are the fact that the invasive procedure was limited to heel stick procedure and the repetition of the same sound in a loop in white noise may have disturbed newborns. However, there are studies reporting that white noise is one of the effective auditory interventions in reducing the level of pain in newborns.[7,9,19]

In our study, there was no difference between the newborns' duration of crying who received kangaroo care after heel stick procedure and those who were cuddled by their mothers; there was also no difference between those who listened to white noise and those who listened to ambient sound. Accordingly, the H_2 and H_5 hypotheses were rejected. This finding is consistent with the results of Maitre et al. They compared crying in

Table 3. Distribution and comparison of the median scores of the study groups on physiological parameters of the newborns in the groups.

Measurements	Study groups				Test statistics (Friedman F test <)	Post hoc analysis (Wilcoxon signed-rank test)
	Kangaroo care (1)	Cuddling (2)	White noise listening (3)	Ambient sound listening (4)		
	Med (min–max.)	Med) (min–max.)	Med (min–max.)	Med (min –max.)	χ^2, p	Z, p, r
Pulse						
Before procedure[a]	138.50 (107.00–156.00)	137.50 (110.00–167.00)	142.00 (103.00–163.00)	142.50 (104.00–161.00)	1.419, .701	
During procedure[b]	152.00 (118.00–180.00)	156.00 (128.00–193.00)	160.00 (107.00–200.00)	172.00 (131.00–200.00)	13.216, **.004**	(4-1) -3.405, **.001**, .58
After procedure[c]	135.50 (109.00–155.00)	137.00 (105.00–154.00)	134.00 (114.00–183.00)	139.50 (107.00–160.00)	.994, .803	
χ^2, p	41.143, **.000**	33.542, **.000**	21.634, **.000**	48.176, **.000**		
Z, p, r *(for b)*	(2-1) -4.506, **.000**, .77		(4-3) -1.939, .052			
Body temperature / Fever (°C)						
Before procedure[a]	36.80 (36.60–37.00)	36.70 (36.60–37.80)	36.75 (36.60–37.00)	36.80 (36.60–37.00)	2.471, .481	
During procedure[b]	36.90 (36.60–37.50)	36.70 (36.60–37.80)	36.75 (36.60–37.00)	36.80 (36.60–37.10)	11.266, **.010**	(4-1) -2.932, **.003**, .50
After procedure[c]	36.80 (36.60-37.10)	36.70 (36.60-37.80)	36.70 (36.60-37.00)	36.80 (36.70-37.00)	4.534, .209	
χ2, p	30.025, **.000**	6.250, **.044**	2.000, .368	12.600, **.002**		
Z, p, r *(for b)*	(2-1) -2.217, **.027**, .38		(4-3) -1.302, .193			
Systolic blood pressure						
Before procedure[a]	74.50 (52.00–98.00)	72.50 (44.00–90.00)	67.00 (33.00–84.00)	64.00 (42.00–96.00)	17.402, .001	(3-1) -3.274, **.001**, .56 (4-1) -3.335, **.001**, .57 (4-2) -2.922, **.003**, .50
During procedure[b]	80.50 (60.00–99.00)	73.50 (60.00–114.00)	75.00 (54.00–92.00)	68.00 (53.00–95.00)	14.171, **.003**	(4-1) -3.549, **.000**, .60
After procedure[c]	75.00 (49.00–100.00)	69.50 (45.00–89.00)	68.50 (50.00–92.00)	67.50 (46.00–83.00)	5.536, .137	
2, p	23.746, **.000**	9.450, **.009**	9.783, **.008**	2.297, .317		
Z, p, r *(for b)*	(2-1) -1.768, .077		(4-3) -2.198, **.028**, .37			
Diastolic blood pressure						
Before procedure[a]	45.50 (28.00–68.00)	47.00 (29.00–70.00)	42.00 (25.00–61.00)	40.00 (23.00–78.00)	7.067, .070	
During procedure[b]	52.50 (31.00–74.00)	51.00 (24.00–97.00)	47.50 (25.00–72.00)	44.50 (32.00–61.00)	5.210, .157	
After procedure[c]	46.00 (28.00–78.00)	46.50 (29.00–65.00)	42.00 (20.00–70.00)	42.00 (23.00–71.00)	1.302, .729	
χ^2, p	10.800, **.005**	3.418, .181	15.203, **.000**	11.474, **.003**		
Z, p, r *(for b)*	(2-1) -1.428, .153		(4-3) -1.654, .098			
Oxygen saturation						
Before procedure[a]	98.00 (95.00–100.00)	99.00 (93.00–100.00)	100.00 (96.00–100.00)	99.00 (92.00–100.00)	8.447, **.038**	(4-1) -2.913, **.004**, .49
During procedure[b]	96.50 (90.00–100.00)	94.50 (89.00–100.00)	98.00 (80.00–100.00)	95.00 (84.00–100.00)	2.573, .462	
After procedure[c]	99.00 (96.00–100.00)	99.00 (95.00–100.00)	99.00 (85.00–100.00)	98.50 (88.00–100.00)	1.866, .601	
χ^2, p	25.746, **.000**	23.638, **.000**	11.697, **.003**	20.407, **.000**		
Z, p, r *(for b)*	(2-1) -1.785, .074		(4-3) -.863, .368			

r= effect size.

infants during painful procedures with other somatosensory inputs such as pressure and temperature changes, and found that the crying response was not related to the cortical intensity of nociceptive signals in the brain, in other words, it was not specific to pain.[20] However, both kangaroo care and cuddling had a great effect on shortening the duration of crying compared to listening to ambient sound. Similarly, Gao et al. and Kostandy et al. found that kangaroo care shortened the duration of crying;[16,21] Roshanray et al. determined that cuddling by the mother shortened the duration of crying.[22]

In our study, there was no difference between the highest voice decibels during the crying of those who received kangaroo care and those who were cuddled by their mothers after heel stick procedure; there was also no difference between the highest voice decibels during the crying of those who listened to white noise and those who listened to ambient sound. Accordingly, H_3 and H_6 hypotheses were rejected. Maitre et al. stated that the acoustic amplitude during crying (directly proportional to the increase in sound decibels) is not a behavioral marker reflecting the pain experience.[20] Therefore, detecting no difference between the highest voice decibels during crying after the procedure may be meaningful.

Limitations of the study

The study included newborns with gestational ages with a minimum of 34.00 and a maximum of 41.00 weeks. The change in physiological parameters (pulse rate etc.) according to week of gestation is the limitation of this study. Including newborns only with a specific gestational age in future studies may help provide evidence to determine which intervention is suitable for which week of gestation. In addition, the balanced block randomization method could eliminate the difference between the groups when studying in a wide range of weeks of gestation such as 34–42 weeks. Monocentricity is another limitation of this study. Therefore, the results cannot be generalized to all newborns. Also, only one procedure was applied to each newborn, and consequently, we did not evaluate the effects of combined interventions in this study. Other limitations of the study are that we did not take into account the previous pain experiences of the newborns as well as the physiological parameters such as body temperature and heart rate of the mothers who gave kangaroo care.

Clinical implications

Recognizing the pain, evaluating its severity, planning and applying pharmacological and non-pharmacological treatments, and evaluating their effectiveness, in other words, pain management is one of the independent roles of the nurse. The results of this study provided a piece of scientific evidence to support the use of kangaroo care in reducing neonatal pain level during heel stick procedure, and the use of kangaroo care and cuddling in reducing the duration of crying. The findings may also contribute to the development of evidence-based clinical practice guidelines for non-pharmacological treatments.

Conclusion

This study showed that kangaroo care applied to newborns during heel stick procedure was more effective in reducing pain levels and shortening the duration of crying. No efficacy of non-pharmacological interventions was detected on the highest voice decibels during crying of the newborns.

Funding: This work did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Compliance with Ethical Standards: The authors stated that the standards regarding research and publication ethics, the Personal Data Protection Law and the copyright regulations applicable to intellectual and artistic works are complied with and there is no conflict of interest.

References

1. Bucsea O, Riddell RP. Non-pharmacological pain management in the neonatal intensive care unit: managing neonatal pain without drugs. Semin Fetal Neonatal Med 2019;24:1010173. [PubMed] [CrossRef]
2. Carbajal R. Nonpharmacological treatment of neonatal pain. In: Buonocore G, Bellieni CV, editors. Neonatal pain. Suffering, pain, and risk of brain damage in the fetus and newborn. Cham: Springer; 2017. p. 125–140. [CrossRef]
3. Cruz MD, Fernandes AM, Oliveira CR. Epidemiology of painful procedures performed in neonates: a systematic review of observational studies. Eur J Pain 2016;20:489–98. [PubMed] [CrossRef]
4. Ramos MCM, deCandido LK, Costa T, Letie AC, Manzo BF, Duarte ED, et al. Painful procedures and analgesia in hospitalized newborns: a prospective longitudinal study. J Neonatal Nurs 2019;25:26–31. [CrossRef]
5. Orovec A, Disher T, Caddell K, Campbell-Yeo M. Assessment and management of procedural pain during the entire neonatal

intensive care unit hospitalization. Pain Manag Nurs 2019;20:503–11. [PubMed] [CrossRef]
6. Törüner EK, Büyükgönenç L. Çocuk sağlığı temel hemşirelik yaklaşımları. Amasya: Göktuğ Yayıncılık; 2013.
7. Kahraman A, Gümüş M, Akar M, Sipahi M, Yılmaz HB, Başbakkal Z. The effects of auditory interventions on pain and comfort in premature newborns in the neonatal intensive care unit; a randomised controlled trial. Intensive Crit Care Nurs 2020;61:102904. [PubMed] [CrossRef]
8. Sarhangi F, Azarmnejad E, Javadi M, Tadrisi SD, Rejeh N, Vaismoradi M. The effect of the mother's heartbeat sound on physiological parameters and pain intensity after blood sampling in neonates in the intensive care unit: a randomized controlled clinical trial. J Neonatal Nurs 2021;27:123–8. [CrossRef]
9. Cetinkaya S, Yavas Celik M, Ozdemir S. Effect of white noise on alleviating the pain of new-born during invasive procedures. J Matern Fetal Neonatal Med 2022;35:1426–32. [PubMed] [CrossRef]
10. Tural-Büyük E. The effect of local application of heat before heel lancing procedure on duration of crying and procedure. Int J Caring Sci 2018;11:1526–30.
11. Cong X, Ludington-Hoe SM, McCain G, Fu P. Kangaroo care modifies preterm infant heart rate variability in response to heel stick pain: pilot study. Early Hum Dev 2009;85:561–7. [PubMed] [CrossRef]
12. Akdovan T, Yıldırım Z. Assessment of pain in healthy neonates, investigation of the effects of pacifying and holding in the arms. [Article in Turkish] Perinatoloji Dergisi 1999;7:107.
13. Fritz CO, Morris PE, Richler JJ. Effect size estimates: current use, calculations, and interpretation. J Exp Psychol Gen 2012;141:2–18. [PubMed] [CrossRef]
14. WHO. Kangaroo mother care: a practical guide. Geneva: Department of Reproductive Health and Research, World Health Organization; 2003. https://www.who.int/reproductivehealth/publications/maternal_perinatal_health/9241590351/en/
15. Cong X, Ludington-Hoe SM, Walsh S. Randomized crossover trial of kangaroo care to reduce biobehavioral pain responses in preterm infants: a pilot study. Biol Res Nurs 2011;13:204–16. [PubMed] [CrossRef]
16. Kostandy RR, Ludington-Hoe SM, Cong X, Abouelfettoh A, Bronson C, Stankus A, et al. Kangaroo care (skin contact) reduces crying response to pain in preterm neonates: pilot results. Pain Manag Nurs 2008;9:55–65. [PubMed] [CrossRef]
17. Nimbalkar SM, Chaudhary NS, Gadhavi KV, Phatak A. Kangaroo mother care in reducing pain in preterm neonates on heel prick. Indian J Pediatr 2013;80:6–10. [PubMed] [CrossRef]
18. Güler Ç, Acar-Vaizoğlu Ç. Gürültü. In: Güler Ç, Acar-Vaizoğlu Ç, editors. Halk sağlığı: Temel Bilgiler. Ankara: Hacettepe University Publications; 2012. p. 860–75.
19. Karakoç A, Türker F. Effects of white noise and holding on pain perception in newborns. Pain Manag Nurs 2014;15:864–70. [PubMed] [CrossRef]
20. Maitre NL, Stark AR, Menser CCM, Chorna OD, France DJ, Key AF, et al. Cry presence and amplitude do not reflect cortical processing of painful stimuli in newborns with distinct responses to touch or cold. Arch Dis Child Fetal Neonatal Ed 2017;102:F428–F433. [PubMed] [CrossRef]
21. Gao H, Xu G, Gao H, Dong R, Fu H, Wang D, et al. Effect of repeated Kangaroo Mother Care on repeated procedural pain in preterm infants: a randomized controlled trial. Int J Nurs Stud 2015;52:1157–65. [PubMed] [CrossRef]
22. Roshanray A, Rayyani M, Dehghan M, Faghih A. Comparative effect of mother's hug and massage on neonatal pain behaviors caused by blood sampling: a randomized clinical trial. J Trop Pediatr 2020;66:479–86. [PubMed] [CrossRef]