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The effect of using maternal voice, white noise, and holding combination interventions on the heel stick sampling

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ABSTRACT

Background: Heel stick sampling, a common procedure in newborns, causes acute pain.
Aims: This study aims to measure the outcome of five various non-pharmacologic pain relief groups; maternal voice, white noise, holding, maternal voice+holding, and white noise+holding.
Methods: The study is an open label, randomized controlled trial. A total of 178 newborns were included in this study. Newborns were randomly allocated to each group; white noise ($n = 31$), maternal voice ($n = 31$), holding ($n = 30$), white noise+holding ($n = 29$), maternal voice+holding ($n = 28$), and control ($n = 29$) interventions. Newborns' pain responses were evaluated using the Neonatal Infant Pain Scale (NIPS), and the Premature Infant Pain Profile (PIPP). The primary measured outcomes were the newborns' pain levels, while the secondary outcomes were the heart rate and changes in oxygen saturation. The mean values of pain in neonates between groups were evaluated one minute before (Phase1), during (Phase2), and one minute after (Phase3) the procedure.
Results: The research results are given with comparisons in three time periods (Phase1, Phase2 and Phase3). White noise and white noise+holding were found to have the lowest mean NIPS and PIPP score ($p < 0.001$). The mean heart rate was found to be the lowest in the white noise+holding group ($p < 0.001$). There was no significant difference between the groups in terms of oxygen saturation score ($p = 0.453$).
Conclusion: The white noise+holding applied to newborns during heel stick sampling were effective in pain reduction. Nurses and midwives can use white noise+holding method.
Implications to practice: These results contribute to the pain management of newborns.

Introduction

The universally applied heel stick sampling provides early diagnosis of congenital disorders in newborns (Skrinska et al., 2020). However, it also causes acute pain (Carter & Brunkhorst, 2017; Ding, Huang, Li, Shen, & Yang, 2022; Peng et al., 2018) and harms the comfort level of newborns (Alemdar, 2018; Carter & Brunkhorst, 2017; Kahraman et al., 2020). Painful interventions in the neonatal period lead to metabolic or physiological problems in newborns (Hatfield & Ely, 2015). Pain management is required to relieve procedural pain and its adverse personal effects on newborns. Pharmacological and non-pharmacological methods are available to minimize pain in newborns within the scope of included newborns' family and individualized developmental care (McNair et al., 2019). Family-centered care (FCC) includes the family and the infant and promotes the use of evidence-based procedures in collaboration with the medical staff (Franck & O'Brien, 2019). Interventions based on FCC principles support the parental provision of interventions such as breastfeeding, skin-to-skin contact, developmental supportive care, positive sensory stimulation, massage, and pain management (Erdoğan et al., 2020; Franck et al., 2022). Non-pharmacologic methods are effective, easily applicable, and cost-effective for pain management in clinical practice. Therefore, non-pharmacologic management of pain is important in newborn care. Non-pharmacologic treatments involve auditory and tactile

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stimuli to provide pain relief during routine invasive procedures (Azarmnejad et al., 2017; Kahraman et al., 2020; McNair et al., 2019; Ross & Balasubramaniam, 2015). Non-pharmacologic methods containing auditory stimuli include the parent's voice, heartbeat in the womb, white noise, lullabies, listening to music, etc. (O'Toole et al., 2017; Sajjadian et al., 2017).

One of the non-pharmacologic methods is maternal voice. Non-pharmacological methods have been used to balance the vital signs and behavioral responses of newborns (Alemdar, 2018; Azarmnejad et al., 2017; Liao et al., 2021; Yu et al., 2022). Maternal voice significantly reduced neonatal pain during painful procedures (Ding, Huang, Li, Shen, & Yang, 2022). Another non-pharmacologic method is white noise. White noise is a continuous and regular humming sound like intrauterine sound and has been previously used to reduce physiological stress, crying, and sleeping durations to manage pain in the literature (Ren et al., 2019; Ross & Balasubramaniam, 2015; Sezici & Yigit, 2018). Known as a sound that is heard by the fetus in the womb is assumed to have a rhythmic and relaxing effect (Spencer et al., 1990), therefore it has been used as a pain reliever (Cetinkaya et al., 2022; Karakoç & Türker, 2014; Liao et al., 2021). Holding is a non-pharmacological method and its use by healthcare professionals has been increasing rapidly in recent years (Bembich et al., 2018; Inal et al., 2021; Obeidat & Shuriquie, 2015). Holding may reduce stress response, stimulus pain, and negative reactions by increasing the newborn's sense of safety and ease. It has also been reported to relax the mother (Wu et al., 2021; Wulff et al., 2021) and strengthen mother-infant attachment (Bembich et al., 2018; Johnston et al., 2017; Wulff et al., 2021). Literature has citations that white noise, maternal voice, and, holding groups are recommended as effective methods to reduce pain and physiological changes caused by some invasive procedures (Bembich et al., 2018; Chen et al., 2021; Kahraman et al., 2020; Liao et al., 2021; Obeidat & Shuriquie, 2015).

In clinical practice, more than one non-pharmacologic intervention can be applied simultaneously. In this context, the effectiveness of using single non-pharmacologic interventions as a combination in managing pain needs to be further emphasized. The combined non-pharmacologic interventions use of holding+oral sucrose (Bembich et al., 2018), holding+breast milk (Obeidat & Shuriquie, 2015), and holding+swaddling (Inal et al., 2021) are effective in reducing pain in newborns.

To our knowledge, there are no other randomized trials in which white noise, maternal voice, and maternal holding methods have been used in combination during the heel stick sampling. We planned the study to measure the outcome of five various non-pharmacologic pain relief groups: maternal voice, white noise, holding, maternal voice +holding, and white noise+holding.

Methods

Study design and setting

This is a randomized controlled study and six parallel groups in a 1:1 allocation ratio conducted with neonates hospitalized in the obstetrics and gynecology service of one hospital in XXX from March 2021 to January 2022, an open label. It has been registered in ClinicalTrials.gov Identifier: XXX.

The obstetrics and gynecology service has 34 beds and provides treatment and care to an average of 360 newborns annually. This study was reported according to the specific guidelines of Consolidated Standards of Reporting Trials (CONSORT) standards (Schulz et al., 2010). A total of 178 healthy newborns took part in this randomized, six-armed study.

Sample size calculation

In this study, the G*Power (version 3.1.9.7) program was used to calculate the sample size (Faul et al., 2007). A prior analysis "Repeated measures, within-between interaction" test was performed used. Cohen's small-medium effect size (0.15) was used (Sullivan & Feinn, 2012) because, to our knowledge, there is no similar randomized controlled study in the literature. Type I margin of error of 0.05 and Corr among rep measure value of 0.5 was taken as reference, and it was calculated to reach a total sample size of 144 to achieve 85% power at the end of the study. However, against the possibility of 10% sample loss and 10% sample loss during repeated measurements, 175 term newborns were planned to be included in the study. A total of 46 newborns were excluded from the study because 22 parents did not accept the video recording, and 24 parents did not want to participate in the study. Accordingly, 216 newborns were recruited for the study. In the implementation phase of the study, 38 newborns could not be intervened due to decreased oxygen saturation, noise during the procedure, and more than one insertion of the lancet, so the study was completed with 178 newborns (Fig. 1).

Power analysis was calculated at the end of the study. Effect sizes were also calculated using NIPS and PIPP correlation values in accordance with the data from this study. Based on the Neonatal Infant Pain Scale (NIPS) correlation ($r = 0.326$) and the Premature Infant Pain Profile (PIPP) scores correlation ($r = 0.190$), the effect sizes were found to be 0.88 and 0.80, respectively. According to these effect sizes and the significance level of 0.05, the power of the study with 178 newborns was determined as 0.99. Based on the intra-group variances of the scores of the NIPS and PIPP scales due to the heel stick sampling procedure, the effect size was determined to be 0.55 and 0.31, respectively. Considering these results, the sample size of 178 newborns was considered sufficient.

Inclusion criteria

The inclusion criteria were being born between 38 and 40 weeks of gestation, postnatal age between 1 and 5 days, no opioid and non-opioid medication before the application, consent from the mother/caregiver, feeding the baby at least 30 min before the intervention, and passing a hearing screening test.

Exclusion criteria

The exclusion criteria were being on a mechanical ventilator, presence of neurological disease and a congenital anomaly, having undergone surgical intervention, multiple insertions of the lancet to collect heel blood, and being a baby of a diabetic mother. A related study showed that "Rates of adverse neonatal outcomes are 3-9 times greater in infants of diabetic mothers compared with those of nondiabetic mothers." Therefore, to ensure homogeneous distribution of the groups, babies of diabetic mothers were not included in the study (Yang et al., 2006).

Randomization and blinding

Eligible newborns were allocated to one of the intervention groups or the control group using computer-generated randomization (https://www.randomizer.org). Allocation details were placed in opaque and sealed envelopes by the principal investigator and kept confidential from others involved in the research. Before the heel stick sampling, the envelope was given to the researcher by a nurse blinded to the study group allocation and purpose. When the heel stick sampling procedure was planned, the researcher (XX) responsible for collecting the data opened the envelope. It was not possible to blind the researchers to the intervention and control groups due to the nature of the randomization. However, the outcome evaluation was blinded by video recording pre, intra, and post-procedure of the newborns. Also, data analysis was performed by a statistician with a Ph.D. degree who was blind to the researcher's purpose and method.

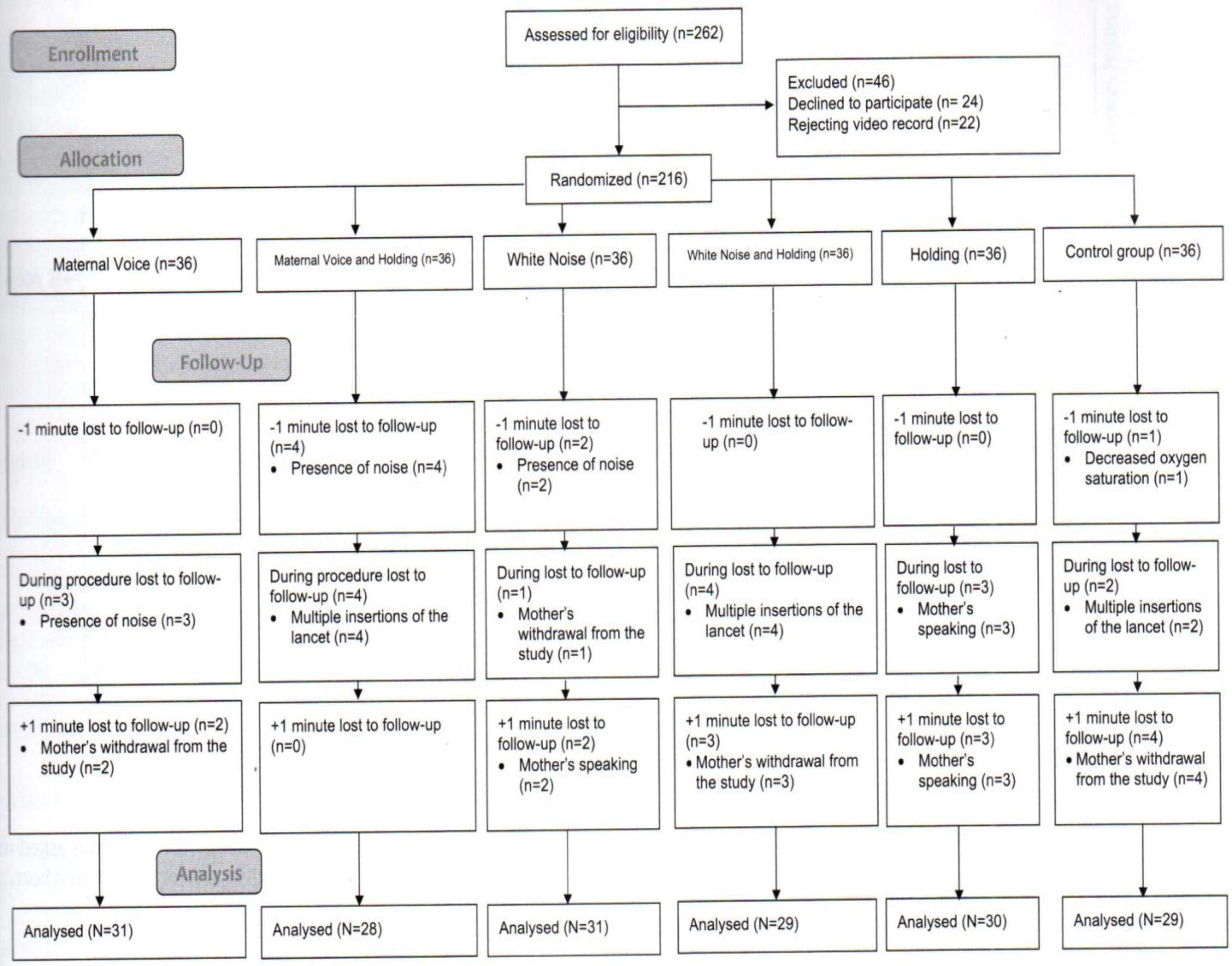

Fig. 1. Consolidated Standards of Reporting Trials (CONSORT) flow diagram of participants through trial [Colour figure can be viewed at wileyonlinelibrary.com].

Data collection tools

The neonatal introductory information form

Developed by the researchers by reviewing the literature (Azarmnejad et al., 2017; Kahraman et al., 2020; Yilmaz & Inal, 2020; Yu et al., 2022), the form includes questions about gestational age (week), postnatal age (day), weight (g), height (cm), and gender. Five academicians in pediatric nursing were consulted, and the form was finalized.

The physiological parameters of the follow-up chart

Physiological variables of newborns related to the heel stick sampling procedure were evaluated and followed up. The physiological parameters of newborns measured with pulse oximetry before (1 min before), during, and after the procedure (1 min after) were recorded by a blinded nurse. The heart rate and oxygen saturation were measured with the Nellcor Oximax N-560 Quick Guide pulse oximeter device.

The premature infant pain profile

Developed by Stevens et al. (1996), the PIPP is used to evaluate the pain level of preterm and term infants in painful procedures. The PIPP consists of seven parameters, namely physiological and behavioral, including gestational age, behavioral state, heart rate, oxygen saturation, brow bulge, eye squeeze, and nasolabial furrow. Each parameter is evaluated between 0 and 3 points. High scores indicate severe pain. In this study, the Cronbach Alpha value was found to be 0.75.

The neonatal infant pain scale

The NIPS was developed by Lawrence et al. (1993). The NIPS is used to assess the pain level of preterm and term infants in painful procedures. While crying is evaluated as 0–1-2 points, facial expression, breathing pattern, arms and legs movements, and state of arousal are evaluated between 0 and 1 points. High scores indicate severe pain (Lawrence et al., 1993). In this study, the Cronbach Alpha value was found to be 0.84.

The reason for using two pain assessment tools in this study is that NIPS assesses pain according to the behavioral characteristics of newborns, while PIPP assesses pain according to both the behavioral and physiological parameters of the newborn. Thus, the study's internal validity is improved by doing a more thorough evaluation of neonates' pain scores.

Intervention

The standard heel stick blood procedure took place between 8.30 and 10 a.m. in the heel stick sampling room where appropriate environmental arrangements (room temperature, suitable lighting, etc.) are arranged. The heel stick sampling procedure was performed by the same nurse who had clinical experience in collecting heel blood for 8 years in the obstetrics ward. A pulse oximetry probe was attached to the right wrist extremity 10 min before the procedure. Newborns were fed at least 30 min before the procedure. The study protocol was developed for the procedure in newborns reviewing the literature (Alemdar, 2018; Bembich et al., 2018; Chen et al., 2021) and the World Health Organization (WHO) Guidelines (World Health Organization, 2010) (Fig. 2).

The decision about the procedure is made by a doctor. Blood was collected from the newborns for the Guthrie screening test. Newborns underwent a single heel stick sampling, and almost the same amount of blood samples were collected. Mothers were allowed to be with their babies during the procedure.

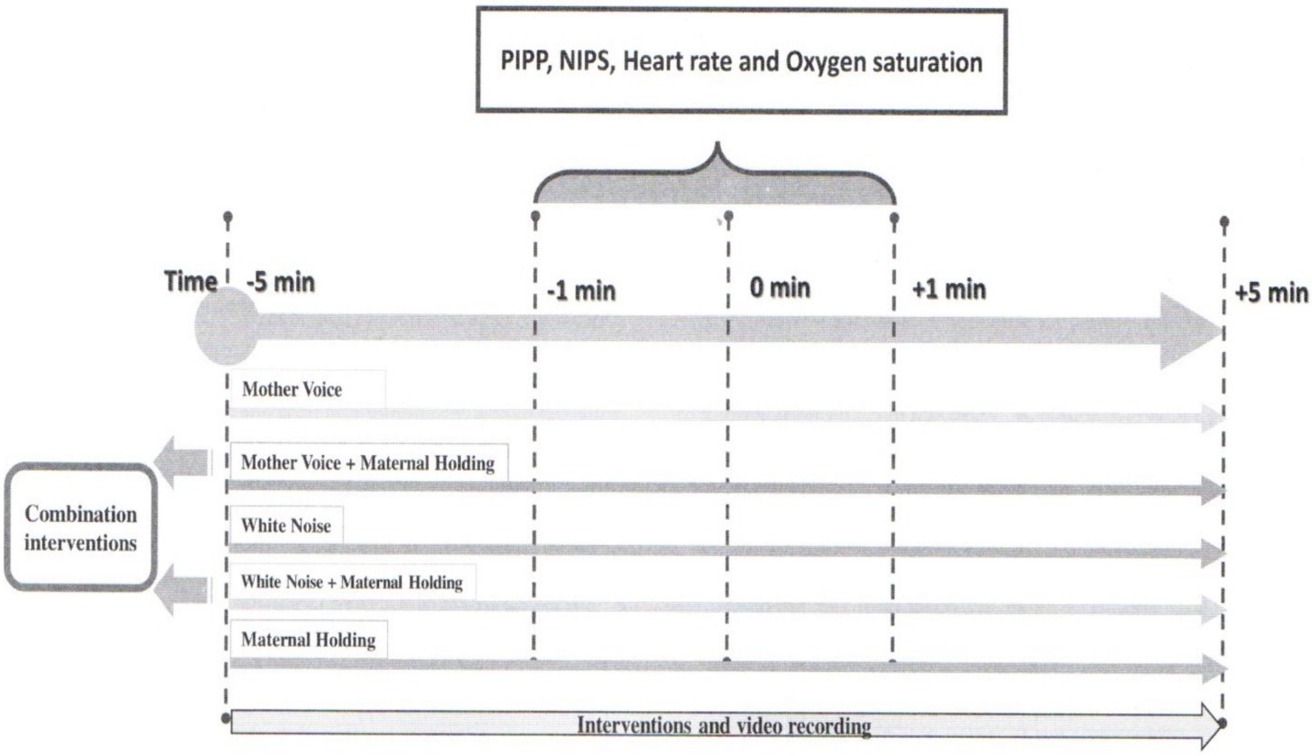

Fig. 2. The study protocol.

The camera angle was determined using a tripod to record behavioral and physiological parameters. The recording was carried out continuously 5 min before, during, and 5 min after the heel stick sampling using a digital color recording camera. The records were evaluated, and the pain was scored by two physicians who were researchers specializing in pain and neonatal pain. According to the Intraclass Correlation Coefficient (ICC) result, the inter-expert reliability was determined as 0.78 for pre-procedure, 0.88 for intra-procedure, and 0.84 for post-procedure. Physiological variables were recorded by an independent nurse blinded to the research purpose.

The maternal voice group (M)

The mothers were first taken to a comfortable room. A voice recorder was given. They were asked to tell their babies whatever they wanted. The speaker was placed approximately 30 cm away from the infant's ear five minutes before the heel stick procedure and started to be played (Kahraman et al., 2020). The *recorded maternal voice was played to the newborns during and 5 min after the procedure. The sound level of the decibel meter was set to 50–60 dB on average.* According to the American Academy of Pediatrics (AAP), the sound level was adjusted to 50 dB using the Decibel Meter (Cesva SC310) for the maternal voice and white noise groups (Chen et al., 2009; Parra et al., 2017).

The white noise group (W)

"The Happiest Baby," was used in the study (Karp, 2012). The speaker system was placed approximately 30 cm away from the newborn's ear five minutes before the heel stick procedure and started to be played (Kahraman et al., 2020). White noise was played to the newborns during and 5 min after the procedure.

The holding group (H)

After the mothers sat in a comfortable chair where they could feel comfortable, the babies were given to them, and the baby underwent heel stick sampling. The mother held the baby five minutes before the procedure and the holding continued during the procedure and until five minutes after the procedure. The mother held the newborn at a 45-degree angle before, during, and after the procedure. Among the parameters in the NIPS used to assess the pain is the evaluation of the arm and leg movements of the newborn. Therefore, the mother was asked to release the newborn's arms and legs while supporting the newborn's back and hips.

The white noise+holding group (WH)

After the mothers sat in a comfortable chair 5 min before where they could feel comfortable, the baby was placed in the mother's arms, white noise was played, and the heel stick sampling was performed. The same combination of white noise and holding was continued for another five minutes during and after the procedure.

The maternal voice+holding group (MH)

Mothers in this group were seated in a comfortable chair 5 min before the heel stick sampling procedure, the baby was placed in the mother's arms, the recorded maternal voice was played, and the heel stick sampling was performed. The same combination of maternal voice+holding was continued for another five minutes during and after the procedure.

The control group (C)

The newborns in the control group were given routine hospital care during the heel stick procedure. Additionally, the newborns in this group were allowed to touch softly/kindly by the mothers to avoid an ethical problem during the heel stick procedure.

Ethical considerations

Ethical approval was obtained from the (XXX) university (number = XXX) (date = 13.01.2021), and institutional permission was obtained from the hospital. The mothers of newborns were informed about the study, and their verbal and written consent was obtained. The study was conducted in accordance with the ethical principles outlined in the Declaration of Helsinki.

Data analysis

SPSS Statistics Package Program, Version 24, and SAS Statistical Analysis Software were used for statistical analysis. Numbers, percentages, mean, and standard deviation were used to analyze the descriptive characteristics data. One Way ANOVA test was used to determine the difference between six groups of continuous variables (birth weight, postnatal age, weight, height, etc.) in more than two groups. Repeated measure analysis was used to compare repeated measures of interventions between groups. Post-hoc comparisons were made to determine which groups the difference originated from. Generalized Estimating Equations (GEE) regression models to estimate odds ratios (ORs) and 95% confidence intervals (CI) for risk factors (method, time, type of delivery, diet, gestational age, postnatal age, weight, and height) were used. ICC analysis was performed to determine the agreement of pain raters. Therefore, the evaluation results of the 1st specialist doctor were taken as a basis. A statistically significant value was accepted as $p < 0.05$.

Results

Characteristics of term infants in the groups

A total of 178 newborns were included in this study. The socio-demographic features of the newborns are presented in Table 1. While there was no significant difference between the intervention groups and the control group in terms of gestational age, type of delivery, and postpartum age, there was a significant difference in terms of gender, weight, and height (Table 1).

Comparison of term infants' NIPS and PIPP scale scores in groups

The mean values of pain in neonates between groups were evaluated before ($Phase_1$), during ($Phase_2$), and after ($Phase_3$) the procedure. Inter group comparisons of NIPS and PIPP are given in Table 2.

Comparison of the mean NIPS and PIPP scores of newborns in the intervention and control groups showed that the mean values were statistically different between the groups ($F = 122.26$, $p < 0.001$; $F = 47.37$, $p < 0.001$). It was observed that NIPS mean scores in W and WH groups were lower than the other groups (W, WH < H, M, MH < C), and PIPP mean scores in W and WH groups were lower than the other groups (W, WH < M, MH < H, C). The time effect was found to be statistically significant in repeated measurements of NIPS and PIPP total mean scores of intervention and control groups ($F = 1446.34$, $p < 0.001$; $F = 872.50$, $p < 0.001$). The time group interaction effect was found to be statistically significant in repeated measurements of the mean NIPS total scores of the intervention and control groups ($F = 25.95$, $p < 0.001$; $F = 12.12$, $p < 0.001$). The variation in NIPS and PIPP scores are given in Fig. 3 and Fig. 4.

Comparison of term infants' heart rate, and oxygen saturation

The descriptive statistics of heart rate, oxygen saturation values, and variance analysis results of newborns according to groups and measurement times are given in Table 2. According to this table, the heart rate of newborns shows statistically significant differences according to the groups and different measurement times ($F = 57.19$, $p < 0.001$). Comparisons of the mean heart rate in this table showed that the WH ($F = 57.19$, $p < 0.001$) mean was statistically significantly lower heart rate than the other groups (WH < W < M < H, MH, C).

The effect of time was statistically significant in repeated heart rate measurements of the intervention and control groups ($F = 116.64$, $p < 0.001$). The time group interaction effect was not statistically significant in repeated heart rate measurements of intervention and control groups ($F = 0.86$, $p = 0.572$). The variation in heart rate scores is given in Fig. 5.

While oxygen saturation did not show statistically significant differences according to the groups ($F = 0.94$, $p = 0.453$), it shows significant differences between the means according to different measurement

Table 1
Characteristics of term infants in the groups.

Variable	M (*n* = 31)		W (n = 31)		H (n = 30)		WH (n = 29)		MH (n = 28)		C (n = 29)		Total (*n* = 178)		*F*	*p*
	Mean ± SD		Mean ± SD		Mean ± SD		Mean ± SD		Mean ± SD		Mean ± SD		Mean ± SD			
Gestational age (week)	38.52 ± 0.85		38.77 ± 1.20		38.67 ± 0.76		38.38 ± 0.98		38.68 ± 0.94		38.76 ± 0.87		38.63 ± 0.94		0.771	0.5721
Postnatal age (day)	1.00 ± 0.00		0.97 ± 0.18		1.07 ± 0.25		1.00 ± 0.00		1.00 ± 0.00		1.03 ± 0.19		1.01 ± 0.15		0.18	0.8373
Body weight (g)	3108.87 ± 283.09		3225.97 ± 472.11		3350.40 ± 395.68		3093.28 ± 300.35		3275.00 ± 387.93		3405.86 ± 299.90		3241.95 ± 376.57		7.14	0.0010
															M,WH < H,MH,W < C	
Height (cm)	49.74 ± 1.12		49.65 ± 1.02		50.17 ± 1.09		49.14 ± 1.33		49.79 ± 1.23		50.34 ± 1.34		49.80 ± 1.24		5.90	0.0033
															M,W,WH,MH < H,C	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	χ2	p
Gender																
Male	14	45.2	19	61.3	21	70	12	41.4	14	50	24	82.8	104	58.4	15.361	0.009
Female	17	54.8	12	38.7	9	30	17	58.6	14	50	5	17.2	74	41.6		
Type of delivery																
Normal	7	22.6	4	12.9	4	13.3	7	24.1	25	10.7	5	17.2	30	16.9	3.190	0.671
Cesarean	24	77.4	27	87.1	26	86.7	22	75.9	3	89.3	24	82.8	148	83.1		

SD = Standard Deviation, F = Bonferroni correction for multiples comparisons, χ2 = Pearson Chi-Square, M = Maternal voice group, W = White noise group, H = Holding group, WH = White noise+Holding group, MH = Maternal voice+Holding group, C = Control group.

Table 2
Comparison of term infants' NIPS and PIPP scale score, heart rate and, oxygen saturation in groups.

Variable	M (n = 31)	W (n = 31)	H (n = 30)	WH (n = 29)	MH (n = 28)	C (n = 29)	Group effects	Time effects	Time*group interaction effect
	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD	F/p value	F/p value	F/p value
NIPS									
Phanse$_1$	0.52 ± 1.36	0.00 ± 0.00	0.33 ± 0.92	0.03 ± 0.19	0.50 ± 1.40	0.31 ± 0.66	122.26	1446.34	25.95
Phanse$_2$	5.23 ± 0.72	3.90 ± 0.75	5.50 ± 0.57	3.34 ± 0.72	4.14 ± 0.89	6.48 ± 0.51	$p < 0.001$	$p < 0.001$	$p < 0.001$
Phanse$_3$	3.55 ± 0.62	1.74 ± 0.77	3.73 ± 0.74	0.72 ± 0.59	3.14 ± 0.65	4.97 ± 0.94	W,WH < H,M,MH < C		
PIPP									
Phanse$_1$	2.19 ± 1.35	1.58 ± 1.03	1.87 ± 1.04	1.86 ± 1.16	2.25 ± 1.04	2.03 ± 1.02	47.37	872.50	12.12
Phanse$_2$	11.39 ± 2.76	8.90 ± 1.37	12.33 ± 2.88	6.76 ± 1.38	11.07 ± 2.39	14.28 ± 1.49	$p < 0.001$	$p < 0.001$	$p < 0.001$
Phanse$_3$	6.29 ± 2.51	4.35 ± 1.52	6.73 ± 3.87	3.62 ± 1.37	5.71 ± 2.73	8.17 ± 1.91	W,WH < M,MH < H,C		
Heart rate (beats/min)									
Phanse$_1$	132.26 ± 16.58	123.55 ± 9.70	141.87 ± 12.69	113.45 ± 6.25	138.54 ± 17.36	137.03 ± 15.05	57.19	116.64	0.86
Phanse$_2$	160.06 ± 13.41	146.58 ± 10.88	165.87 ± 12.66	133.03 ± 9.19	160.43 ± 24.38	169.52 ± 16.42	$p < 0.001$	$p < 0.001$	0.572
Phanse$_3$	144.32 ± 21.30	135.03 ± 15.46	153.93 ± 16.99	123.24 ± 10.13	151.54 ± 19.77	157.59 ± 16.48	WH < W < M < H,MH,C		
Oxygen saturation (%)									
Phanse$_1$	93.90 ± 15.95	96.32 ± 3.39	94.37 ± 12.33	95.93 ± 2.51	95.54 ± 2.78	97.24 ± 2.05	0.94	28.24	1.32
Phanse$_2$	87.87 ± 15.36	92.52 ± 5.28	90.60 ± 5.74	92.14 ± 3.31	90.18 ± 4.73	88.83 ± 4.33	0.453	$p < 0.001$	0.215
Phanse$_3$	96.32 ± 2.98	95.10 ± 2.93	94.70 ± 3.44	94.07 ± 3.00	93.54 ± 3.70	94.28 ± 3.82			

PIPP: The Premature Infant Pain Profile, NIPS: Neonatal Infant Pain Scale, Phase $_1$: The baseline/one min before heel stick procedure, Phase $_2$: Heel stick procedure, Phase $_3$: One min after heel stick procedure, Bonferroni correction for multiples comparisons, M = Maternal voice group, W = White noise group, H = Holding group, WH = White noise+Holding group, MH = Maternal voice+Holding group, C = Control group.

times (F = 28.24, p < 0.001) (Fig. 4). The variation in physiological parameter points is given in Figs. 5–6.

Table 3 shows the phase-phase comparison of heart rate, oxygen saturation, NIPS, and PIPP scale scores during the heel stick procedure. NIPS, PIPP, and heart rate mean scores were found to be highly significant in all phase-phase comparisons in line with the results obtained in three different time measurements ($p < 0.0001$). Oxygen saturation mean scores were compared phase by phase, and a highly significant difference was found in phase 1-phase 2 and phase 2-phase 3 (p < 0.0001). However, no statistically significant difference was found in the phase 1-phase 3 comparisons. ($p < 0.2216$) (Table 3).

Generalized estimating equation analyses predicting pain (PIPP)

We determined a statistical difference between gender, body weight, and height groups in Table 1. However, according to the generalized estimating equation analysis, the newborn's gender, type of delivery, gestational age, postnatal age, body weight, and height did not influence the newborn's pain score. In contrast, both group and measurement times had profound effects on pain.

The odds ratios of moderate-to-severe pain (PIPP ≥ 12) for H, M, MH, W, and WH interventions vs the control group were 0.044 (p < 0.0001), 0.049 ($p = 0.0003$), 0.046 ($p = 0.0002$), 0.014 (p < 0.0001) and 0.003 (p < 0.0001), respectively, after adjusting for the effects of other factors.

Thus, moderate-to-severe pain of infants in holding, maternal voice, maternal voice+holding, white noise, and white noise+holding interventions vs. routine care conditions decreased 95.6%, 95.1%, 95.4%, 98.6%, and 99.7%, respectively (Table 4). According to the measurement times in Table 4, it was determined that the newborns felt 62.06 times more pain during the heel stick sampling procedure compared to the 1-min measurement after the procedure.

Discussion

This study is an open label randomized controlled trial comparing more than one non-pharmacological method and evaluating their superiority to each other. To our knowledge, this is the first study to compare multiple non-pharmacologic methods in combination.

In this study, white noise, maternal voice, and holding methods were found to be more effective compared to the control group. Additionally, in this study, the pain scores of newborns in the combined (white noise +holding and maternal voice+holding) groups were found to be lower than the control group. However, the white noise+holding method was found to decrease the pain scores of newborns more than maternal voice+holding. The combination of white noise+holding and white noise alone methods was the best to reduce heel stick sampling pain in newborns.

In the literature, maternal voice (Azarmnejad et al., 2017; Chirico et al., 2017; Filippa et al., 2021; Liao et al., 2021; Yu et al., 2022), white noise (Kahraman et al., 2020), and holding (Bembich et al., 2018; Obeidat & Shuriquie, 2015; Pillai Riddell et al., 2015) are effective in reducing the procedure pain. In this study, it was found that the heel stick sampling procedure pain of newborns who received white noise was less than the other single and mother voice+holding groups. In the literature, white noise is reported to be effective in reducing pain symptoms in newborns (Cetinkaya et al., 2022; Karakoç & Türker, 2014).

In the 24-25th gestational week of the intrauterine period, newborns can hear and react to bowel sounds, maternal heart sounds, and maternal voice in intrauterine life (El-Metwally & Medina, 2020). The infant is exposed to white noise during the intrauterine period. Newborns listen to the mother's heartbeat, blood flow in large vessels, and uterine and digestive system movements as white noise in intrauterine life (Alemdar, 2018; El-Metwally & Medina, 2020; Karakoç & Türker, 2014). Since newborns are familiar with these sounds, white noise may be effective in reducing pain associated with the heel stick sampling procedure.

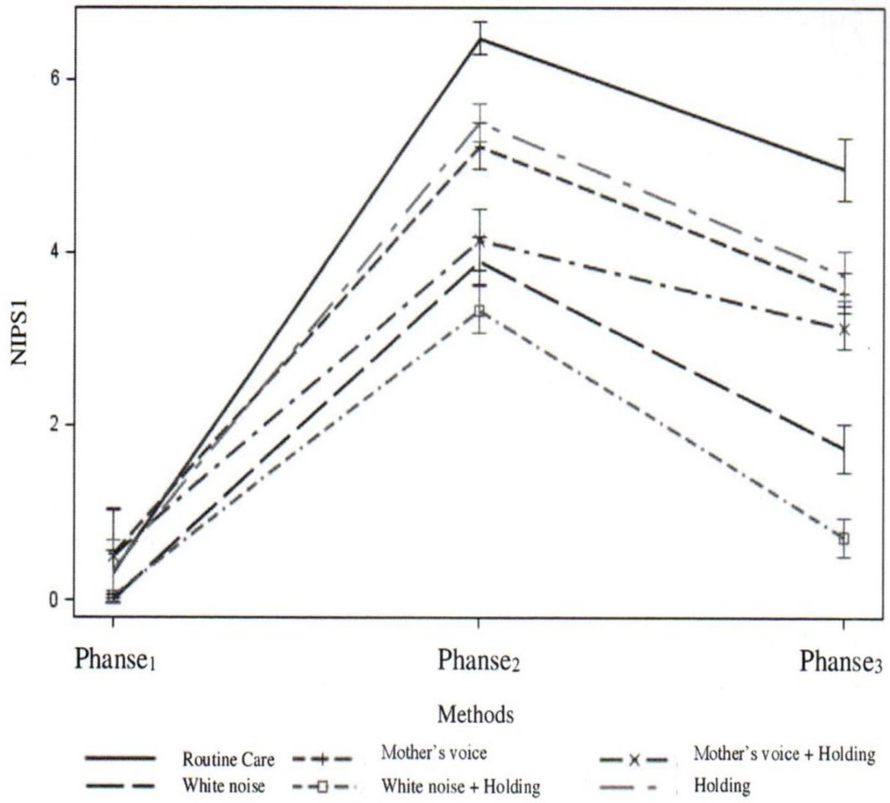

Fig. 3. Graph of newborns' NIPS1.
Phase 1: One minute before the procedure; Phase 2: During; Phase 3: One minute after the procedure.

Similar to the results of our study, previous studies have shown that different combined methods are more effective in reducing the pain of minimally invasive procedures in neonates (Bembich et al., 2018; Gao et al., 2018; Leng et al., 2016; Obeidat & Shuriquie, 2015; Peng et al., 2018). Bembich et al. (2018) suggested that the pain scores of the holding+oral sucrose method were more effective in reducing pain than the oral glucose method alone. Obeidat and Shuriquie (2015) stated that the holding+breastmilk method, one of the non-pharmacologic combined methods, is more effective than only the holding method in reducing the pain scores of newborns. Yılmaz and İnal (2020) reported that the swaddling+holding+breastfeeding method was the most effective method in reducing the pain associated with the heel stick sampling procedure. In parallel with the literature, it was determined that combined methods were effective in the results of this study. Unlike

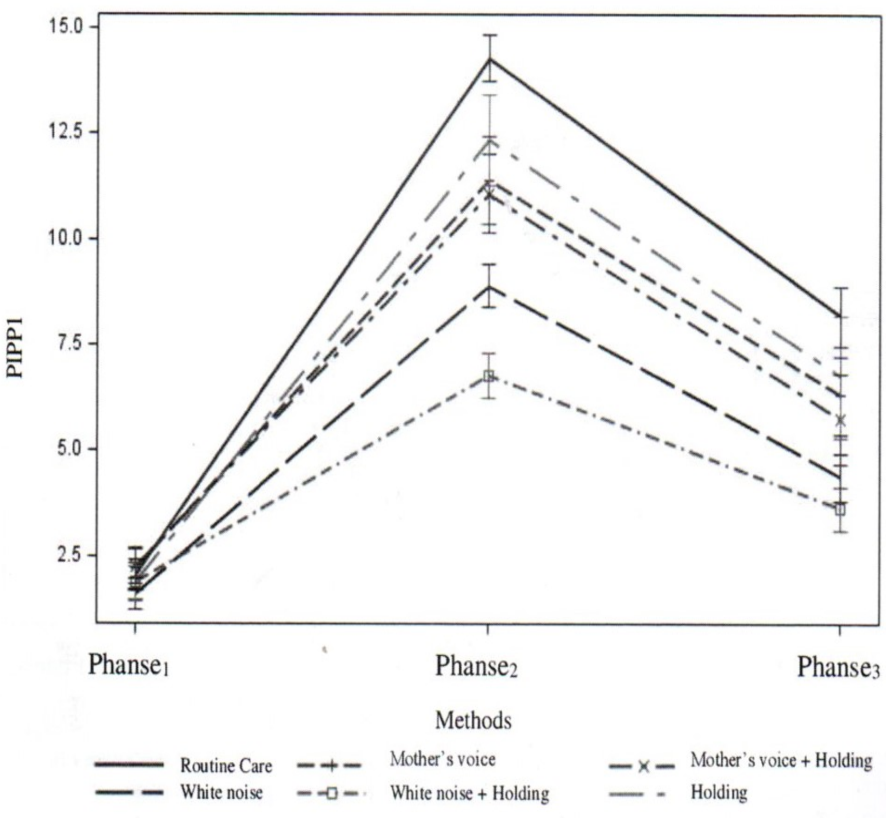

Fig. 4. Graph of newborns' PIPP1.
Phase 1: One minute before the procedure; Phase 2: During; Phase 3: One minute after the procedure.

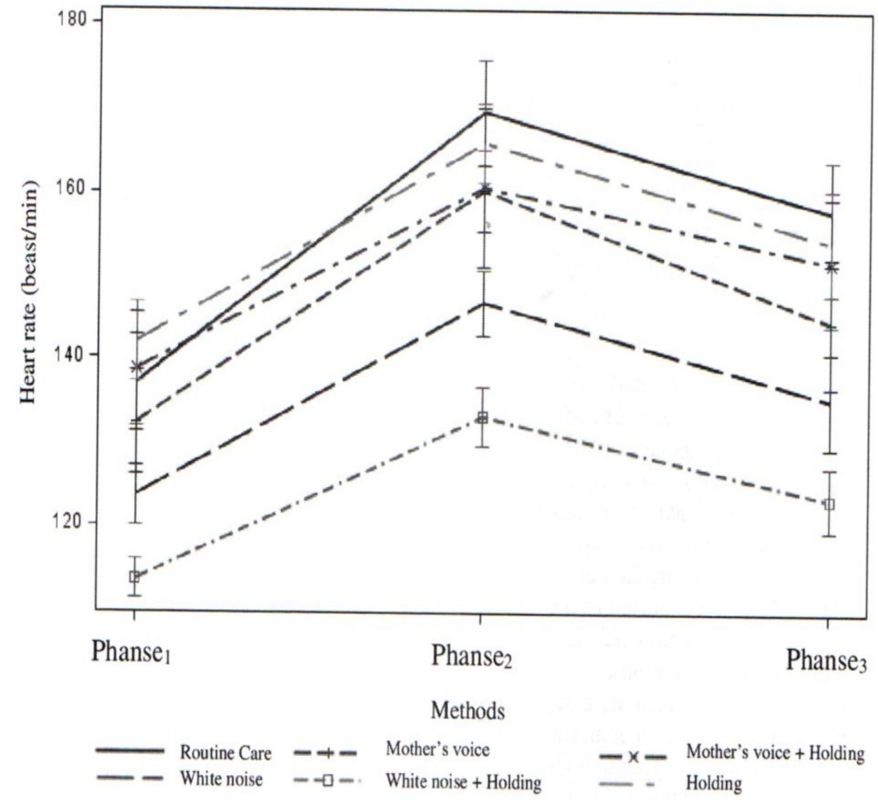

Fig. 5. Graph of newborns' heart rate.
Phase 1: One minute before the procedure; Phase 2: During; Phase 3: One minute after the procedure.

our study results, Karakoç and Türker (2014) found that white noise reduced heel stick sampling pain scores of newborns more than the white noise+holding group.

Parental engagement in infant care is one of the FCC's key tenets (Gomez-Cantarino et al., 2020). Close collaboration with parents' intervention improves FCC in pain management in the newborn (Toivonen et al., 2020). The significance of FCC in the treatment of newborn pain is stressed in the literature (Casper & Kuhn, 2017; Franck & O'Brien, 2019; Gomez-Cantarino et al., 2020). In this study, the FCC approach was provided by including mothers in the pain management of newborns. In addition, it is thought that the white noise+holding method can create positive feelings in the mother. Mothers are involved in the pain management of newborns with the white noise+holding method. This intervention achieves interaction between the mother, and

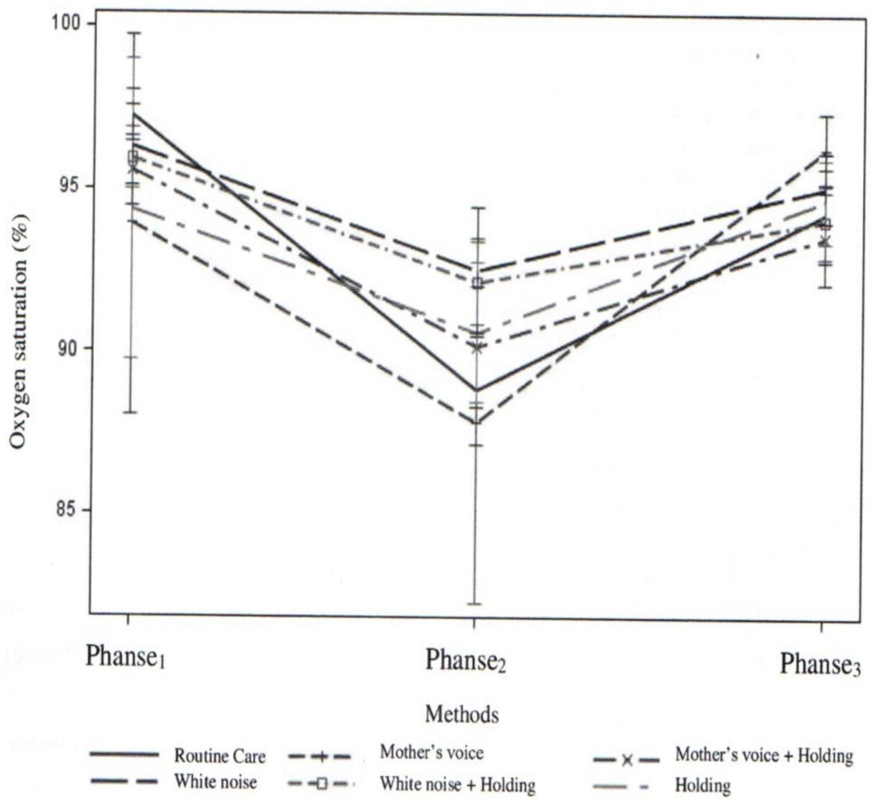

Fig. 6. Graph of newborns' oxygen saturation.
Phase 1: One minute before the procedure; Phase 2: During; Phase 3: One minute after the procedure.

Table 3
Phase–phase comparison of heart rate, oxygen saturation, NIPS and PIPP scales score during heel stick procedure.

Phases	Heart rate (beats/min)		Oxygen saturation (%)		NIPS		PIPP	
	t	p	t	p	t	p	t	p
$Phases_1$–$Phases_2$	−24.91	0.0001	5.94	0.0001	−39.33	0.0001	−36.32	0.0001
$Phases_1$–$Phases_3$	−11.44	0.0001	1.23	0.2216	−21.49	0.0001	−16.79	0.0001
$Phases_2$–$Phases_3$	10.55	0.0001	−7.27	0.0001	23.87	0.0001	23.70	0.0001

PIPP: The Premature Infant Pain Profile, NIPS: Neonatal Infant Pain Scale, $Phase_1$: The baseline/one min before heel stick procedure, $Phase_2$: Heel stick procedure, $Phase_3$: One min after heel stick procedure.

newborn will increase. The white noise+holding method is provided in a physiological relationship between the mother and the newborn.

In this study, the white noise+holding method decreased the heart rate of newborns more than the other groups. In a study, similar to our results, different combined methods were shown to decrease heart rate (Leng et al., 2016). However, Obeidat and Shuriquie (2015) found that the combined method of breastfeeding+holding did not influence the heart rate of newborns. Nevertheless, it is reported in the literature (Hashemi et al., 2016; Leng et al., 2016) that combined methods are effective in reducing heart rate in painful interventions.

In this study, no difference was found between the groups in terms of the oxygen saturation level of newborns. Liao et al. (2021) found that white and maternal voices did not affect oxygen saturation in newborns. However, the results of other studies in the literature are not consistent with our results (Azarmnejad et al., 2017; Chirico et al., 2017; Kahraman et al., 2020; Rand & Lahav, 2014; Sajjadian et al., 2017). The newborns included in this study were healthy and had high oxygen saturation levels at baseline. Therefore, it was not possible to change the oxygen levels of newborns statistically significantly with repeated analysis of variance measurements.

Implications for practice

The use of non-pharmacologic methods to reduce and manage pain caused by invasive interventions in newborns requires a multidisciplinary approach. Nurses and midwives have a critical role as they both assess the pain levels of newborns and help them cope with pain. Non-pharmacologic methods should be part of routine care to reduce and manage pain caused by invasive interventions in newborns. Our results demonstrate that white noise alone or combined with holding can effectively lessen newborns' suffering during procedural treatments. Nurses and midwives can readily access and use these techniques. It would be beneficial for pediatric nurses to manage neonates' discomfort using family-centered non-pharmacological techniques.

Limitations

Several limitations should be considered when interpreting the findings of this study. First, this study was conducted with neonates born at 38–40 weeks of gestation and cannot be generalized because it is a single-center study. In addition, the experts assessed the pain levels of neonates according to the NIPS and PIPP. Pulse oximetry can reduce the reliability of measurements of heart rate and oxygen levels due to infant responses during heel stick procedures. The experts who evaluated the pain scores thought that there might be a limitation in the evaluation of the pain scores of the groups as there was no holding in the videos of the white noise, mother's voice, and control groups and there was a holding in the other groups.

Implications to Practice: This study provides data for evidence-based practice using the white noise and white noise+holding groups to reduce pain caused by heel stick sampling. Future studies may evaluate the effects of these methods in preterm neonates. It is recommended that nurses and midwives receive training on these methods in neonatal pain management and use them in routine practices.

Conclusion

Our study is the first study to examine the effect of white noise, maternal voice, holding, white noise+holding, and maternal voice+holding methods on reducing heel stick procedure pain in newborns using NIPS, PIPP, and physiological parameters (heart rate, oxygen saturation). The study showed that infants in the white noise and white noise+holding groups had the least pain in the postpartum period. The second most effective interventions were found to be the maternal voice and maternal voice+holding. Healthcare professionals can use white noise+holding during the heel stick sampling procedure. Nurses and midwives can use maternal voice+holding when they do not have the opportunity to use white noise. Within the scope of family-centered

Table 4
Generalized estimating equation analyses predicting pain (PIPP).

Variable		Estimate	Standard Error	%95 Confidence Limits		Odds Ratio	Wald	p
Intercept		20.8800	9.5545	2.1536	39.6065		2.19	0.0289
Group	H	−3.1312	0.7234	−4.5489	−1.7134	0.044	−4.33	<0.0001
	M	−3.0084	0.8234	−4.6222	−1.3945	0.049	−3.65	0.0003
	MH	−3.0778	0.8386	−4.7214	−1.4343	0.046	−3.67	0.0002
	W	−4.2615	0.7915	−5.8129	−2.7102	0.014	−5.38	<0.0001
	WH	−5.7410	0.8406	−7.3886	−4.0934	0.003	−6.83	<0.0001
	C	0.0000	0.0000	0.0000	0.0000		.	.
Time	Intervention	4.1282	0.5719	3.0073	5.2491	62.066	7.22	<0.0001
	Pre-intervention	−5.5296	1.0355	−7.5591	−3.5001	0.004	−5.34	<0.0001
	Post-intervention	0.0000	0.0000	0.0000	0.0000		.	.
Gender	Male	0.0934	0.3355	−0.5641	0.7509	1.097	0.28	0.7806
	Female	0.0000	0.0000	0.0000	0.0000		.	.
Type of delivery	Normal	−0.3720	0.5043	−1.3605	0.6165	0.689	−0.74	0.4607
	Cesarean	0.0000	0.0000	0.0000	0.0000		.	.
Gestation age (week)		−0.1523	0.1687	−0.4830	0.1784	0.857	−0.90	0.3668
Postnatal age (day)		−0.7831	0.7637	−2.2800	0.7137	0.457	−1.03	0.3052
Birth weight (g)		−0.0012	0.0004	−0.0020	−0.0003	0.998	−2.63	0.0086
Height (cm)		−0.1523	0.1563	−0.4588	0.1541	0.858	−0.97	0.3299

M = Maternal voice group, W = White noise group, H = Holding group, WH = White noise+Holding group, MH = Maternal voice+Holding group, C = Control group.

care in newborns, it is recommended to include the mother in the management of pain caused by invasive procedures (Erdoğan et al., 2020). In this context, the study demonstrated that combined non-pharmacologic methods involving the mother are effective in reducing pain in newborns. Thus, individualized developmental care is provided in collaboration with parents to reduce the pain of newborns. It is recommended that other combined non-pharmacologic methods be used and evaluated among newborns born at different birth weeks to reduce and manage the pain caused by invasive procedures in newborns.

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Author contributions

All authors have agreed on the final version and meet at least one of the following criteria [recommended by the ICMJE (http://www.icmje.org/recommendations/)]: 1.substantial contributions to conception and design, acquisition of data or analysis and interpretation of data; 2. drafting the article or revising it critically for important intellectual content.

Ethical statement

Ethical approval was obtained from the Akdeniz University Clinical Research Ethics Committee of the university where the study was conducted on 13.01.2021 (Document ID: KAEK-48), and institutional permission was obtained from the hospital. The mothers of newborns involved in the study were informed about the research process, and their consent was obtained. Parents were also informed that they could leave the study at any time. The study was conducted in accordance with the ethical principles outlined in the Declaration of Helsinki.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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