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The Impact of Baby-Doll-Assisted Therapeutic Play on Fear, Anxiety and Pain During Peripheral Venous Catheterization in 4-6 Year-Old Children

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ABSTRACT

Objective: The study was performed to investigate the impact of demonstrating and expressing the peripheral venous catheter practice on doll-assisted therapeutic play on children aged between 4 to 6 years. Parents who agreed to participate in the study and 98 children who met the selection criteria were included in the study.

Methods: The procedure was explained to the children who were included in the study on a doll-assisted therapeutic play before peripheral venous catheter placement. In the study, Children's Fear Scale (CFS), Children's State Anxiety (CSA) and Wong-Baker FACES Pain Rating Scale were applied before and after the procedure. Moreover, the effect of the applied procedure on pulse and respiratory rate was evaluated.

Results: The sociodemographic characteristics of children in the experimental and control groups are similar. After the intervention, the fear, anxiety and pain levels of the children in the experimental group were lower than those in the control group. While the pulse rate did not show a statistically significant difference between the experimental and control groups, the respiratory rate was found to be significantly lower. Although the anxiety levels of the children in the experimental group were higher than those in the control group before the procedure, the anxiety levels of the children in the experimental group were lower after the procedure.

Conclusion: The study demonstrated that explaining the peripheral venous catheter procedure using a doll-assisted therapeutic play significantly reduced fear, anxiety, and post-procedure pain levels in children aged 4 to 6, as measured by the CFS, CSA, and Wong-Baker FACES scales.

Keywords: Anxiety, dramatization, fear, pain, therapeutic play.

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Introduction

Children occasionally experience acute or chronic illness and might require hospitalization. Upon being hospitalized, they experience negative emotions such as fear, anxiety, and pain (Başbakkal et al, 2010; Caleffi et al, 2016; Gültekin & Baran, 2005). For the children, hospital means unpleasant experiences such as fear, uncertainty, unsettling procedures, and breaking out of the routine. In children, hospitalization may cause trauma as well as emotional, behavioral, and physiological problems (Çelebi et al., 2015; Girgin et al., 2020; Francischinelli et al., 2012; Santos et al., 2013).

Children are exposed to a variety of painful procedures in the hospital. Of these procedures, pain due to peripheral venous catheterization is the most common one. A child experiencing anxiety due to pain might display behaviors such as refusing treatment, crying, and fear of healthcare personnel (Bergs et al., 2022; Lemos et al., 2016). The child who has experienced a painful intervention in the past is adversely affected by pain, fear, and anxiety (Lemos et al., 2016). Traditional approaches to pediatric procedural preparation often fail to address the emotional needs of young children. For this reason, child-centered and non-pharmacological interventions—especially those based on play—have gained increasing attention in pediatric nursing care (Koller & Goldman, 2012). Among play-based methods, therapeutic play using dolls or puppets has shown promise in reducing fear and anxiety in children undergoing medical procedures (Li et al., 2021; Matsumori, 2014). These interventions have been mostly implemented and studied in high-income countries such as Japan (Matsumori, 2014), Canada (Koller & Goldman, 2012) and China (Li et al., 2021), where structured child life or pediatric psychosocial care are more integrated into healthcare systems. They enable symbolic play and medical role enactment, which have been shown to facilitate emotional regulation and procedural coping in preschool-aged children (Lima et al., 2020).

However, while distraction techniques such as tablet use, music therapy or cartoon watching have been extensively studied (Koller & Goldman, 2012; Özdemir & Çevik, 2020), therapeutic demonstration using doll-assisted therapeutic play remains underexplored—particularly in low- and middle-income countries, where access to child life specialists is limited and culturally adapted play-based interventions are scarce. Existing studies often examine general play therapy or distraction methods, but few directly compare the efficacy of baby-doll-based procedural preparation to other non-pharmacological techniques in reducing not only fear and anxiety but also physiological stress responses such as pulse and respiratory rate. This study aims to fill this specific gap by evaluating the effectiveness of baby-doll-assisted demonstration in preschool children undergoing peripheral venous catheterization. Unlike impersonal distractions, doll-assisted therapeutic play offer a concrete, engaging tool that supports emotional connection and understanding through play and demonstration.

The study aimed to examine the impact of explaining the peripheral venous catheterization procedure using a baby doll on children aged 4–6 who were hospitalized in the Pediatric Health and Diseases Service. To ensure standardization, the procedure was explained to all children by the researcher nurse using a scripted, literature-based guide titled "Guide for the Child," which included age-appropriate information about what a peripheral catheter is, why it is performed, its benefits, and how it would be applied. The explanation was delivered in a consistent format across all participants and lasted approximately five minutes on average. The study evaluated the effects of this structured, doll-assisted explanation on children's fear levels (Children's Fear Scale – CFS), state anxiety (Children's State Anxiety Scale – CSA), pain perception (Wong-Baker FACES Pain Rating Scale), and physiological responses (pulse and respiratory rate).

Methods

Research Design

The research was designed as a randomized controlled trial.

Study Setting

The study was conducted in the pediatric health and diseases department of a teaching and research hospital between December 20, 2019, and April 30, 2020.

Study Population and Sample

The study population consisted of children aged four to six years who were admitted to the department during the specified dates. The sample group consisted of children who met the inclusion criteria and whose parents agreed to participate in the study.

To determine the sample size, the effect value was specified as 0.55, α (alpha) margin of error as 0.05, and Power as 0.80 using the software of 'GPower 3.1.9.2', and the sample size was determined to be 84. Ninety-eight children were reached during the study period. 10 of these children were involved for preliminary consideration and included in the study. Ten children were included in the pilot study and later included in the main study. Since no changes were made to the data collection tools as a result of the initial assessment, these children were included in the study.

Sampling Criteria

Inclusion Criteria for the Children:

- Being in the age group of 4-6 (including 4 and 6 years old),
- Being hospitalized at the Pediatric Health and Diseases Service,
- The peripheral venous catheterization procedure will be performed,
- Having mental competence to communicate,
- To not have a hearing and speech impairment.

Inclusion Criteria for Parents:

- Agreeing to participate in the study,
- Not having a psychological disorder.

Dependent and Independent Variables of the Research

The independent variables of the study are the therapeutic play method (doll-assisted therapeutic play). Descriptive characteristics of the children (e.g., age, gender) were also considered in group distribution.

Additionally, potential confounding variables that could affect the outcome (such as the child's previous medical or hospital experience, the number of times the peripheral venous catheter was inserted) were noted.

Dependent variables of the study are the scores of The Children's State Anxiety (CSA) used to measure children's present anxiety level, Children's Fear Scale (CFS) used to measure fear level, Wong-Baker FACES Pain Rating Scale used to measure pain severity, pulse and respiratory rates.

Ethical Aspect of Research

In order to conduct the study, an informed consent form was obtained from the mother or father of the children, and ethical approval of Sakarya University Faculty of Medicine Clinical Research Ethics Committee, and official permission from Sakarya University Training and Research Hospital were obtained (Date: May 27, 2020, Ethics committee number: 16214662/050.01.04/101). All steps of the research were carried out in accordance with the Declaration of Helsinki.

Data Collection

Data were collected after obtaining written and verbal informed consent from the parents and verbal Informed Consent Form from children. Children meeting the inclusion criteria were randomly assigned to the experimental or control group through a card selection method. The researcher held two identical cards (one blue and one green), and each child was asked to randomly choose one without any guidance or suggestion. Those who selected the blue card were allocated to the experimental group, while those who selected the green card were allocated to the control group. This method ensured an unbiased and truly random allocation process. The door of the treatment room was closed while performing the invasive procedure so that the children would not be affected by each other. The procedure was performed on each child separately.

In the experimental group, the procedure was explained using a baby doll. Peripheral venous catheters were placed after demonstrating the process. Vascular access materials (cannula, cotton, plaster, alcohol, gloves, tourniquet) were applied on the doll under the researcher's supervision, ensuring no harm to the children. The explanation took about 5 minutes.

In the control group, only a verbal explanation of the procedure was provided, followed by the invasive intervention. All children received the same standardized explanation of the peripheral catheter procedure, including its purpose, benefits, and steps. A data collection form was used to gather the children's descriptive information. Five minutes before the procedure, pulse and respiratory rates were measured, fear was evaluated using the Children's Fear Scale (CFS), anxiety was measured using the Children's State Anxiety Scale (CSA) and pain was assessed using the Wong-Baker FACES Pain Scale. Five minutes after the procedure, these assessments were repeated, and results were recorded.

Data Collection Tools

Data Collection/Descriptive Form: The data collection form, developed by the researcher based on literature, consists of two sections. The first section includes five questions about the child's diagnosis, gender, age, previous invasive interventions, and details about when and what procedure was applied if any.

Children's State Anxiety (CSA): The CSA, developed by Ersig et al. (2013), measures a child's current state anxiety. Its validity and reliability were confirmed by Gerçeker et al., with a content validity index (CVI) of 1.00.

Children's Fear Scale (CFS): Developed by McMurty et al. (2011), the CFS includes five facial expressions ranging from neutral (0 = no fear) to extremely scared (4 = severe fear). Its validity and reliability were studied by Gerçeker et al., with a CVI of 0.89.

Wong-Baker FACES Pain Rating Scale: This scale, created by Donna Wong and Connie Morain Baker in 1981 and revised in 1983, assesses pain in children aged 3–18 years. Its concurrent validity ranges from 67–78, and test-retest reliability is 0.83 (8 hours) and 0.90 (15 minutes).

Doll-assisted therapeutic play: A doll-assisted therapeutic play was used as training material to demonstrate the peripheral venous catheter procedure. The doll was procured from a toy company, helping children understand the procedure through hands-on demonstration.

Pulse Oximeter: A portable monitor used to measure the child's pulse and oxygen saturation before and after the procedure.

Measurement of Respiratory Rate: Respiratory rate was counted and averaged for one minute by two nurses while the child was sitting and unaware of the observation. Chest and abdominal movements were observed, with each full inhalation and exhalation counted as one breath.

Data Analysis

All data were input to the software of the Statistical Package for Social Sciences (IBM SPSS Corp., Armonk, NY, USA) 22 and analyzed.

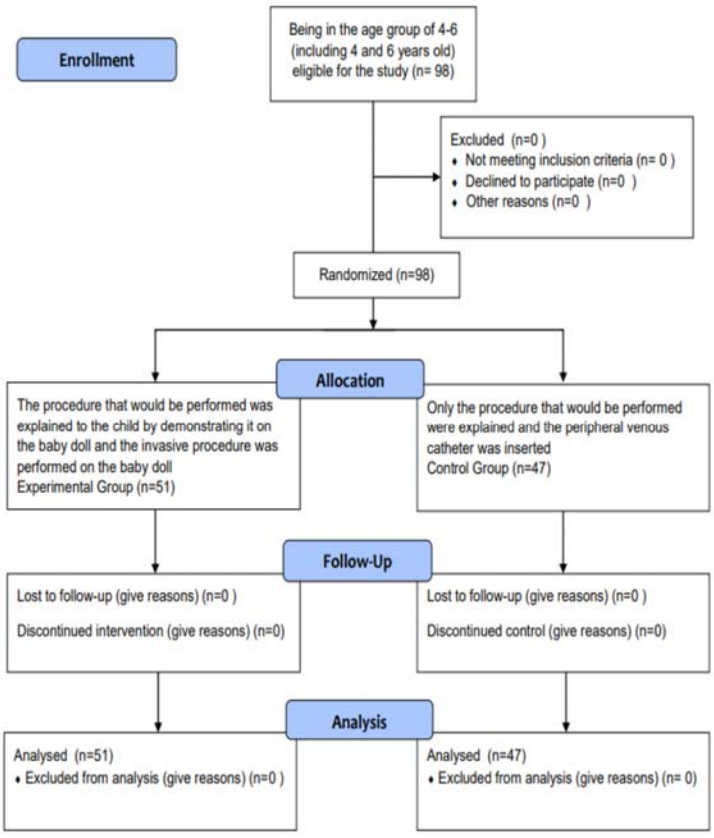

Figure 1. *CONSORT diagram*

Results

Results related to the descriptive characteristics of the children, such as age, gender, family structure, etc. are presented in the following table (Table 1). A total of 98 children (45.9% female, 54.1% male) participated in the study. The experimental group included 52% (51 children), while the control group included 48% (47 children). Most children (51%) were 6 years old, and 59.2% had two siblings. Additionally, 95.9% had a nuclear family structure, and 61.2% had no previous peripheral catheter placement. Mothers were the attendants for 71.4% of children, and 76.5% had successful catheter placement on the first attempt. All children had undergone invasive procedures (e.g., IM or vaccination) prior to the study.

Table 1.
Results Related to Descriptive Characteristics

Variable	Group	n*	%
Research Group	Experimental Group	51	52.0
	Control Group	47	48.0
Gender	Male	53	54.1
	Female	45	45.9
Age	4	20	20,4
	5	28	28.6
	6	50	51.0
Number of siblings	No	31	31.6
	2	58	59.2
	More than 2	9	9.2
Family structure	Nuclear family	94	95.9
	Extended family	4	4.1
Peripheral catheter experience	Yes	38	38.8
	No	60	61.2
Attendant Parent	Mother	70	71.4
	Father	20	20.4
	Other	8	8.2
At Which Attempt the Peripheral Catheter Could Be Inserted	1st Attempt	75	76.5
	2nd Attempt	14	14.3
	3rd Attempt	8	8.2
	4th Attempt	1	1.0
Having a Medical History of Previous Invasive Procedure (Being vaccinated, Im injection, sc injection, undergoing venipuncture, etc.)*	Yes	98	100.0
Diagnsosis	Fever	16	16.3
	Circumcision	14	14.3
	Emesis/Enterit	12	12.2
	Others	56	57.2

*n: Number of persons, Im: intramuscular, sc: subcutaneous

The most common diagnoses were fever, circumcision, emesis, and enteritis (Table 1). Descriptive sociodemographic characteristics of the experimental and control groups were similar (p>.05) based on Chi-Square and

Fisher's Exact Test results (Table 2). Power analysis confirmed a 100% test power (Type I error = 0.05), calculated using GPower 3.1.9.2. Before the procedure, there was no statistically significant difference between the experimental and control groups in terms of fear levels (CFS) (p=.11), pulse rate (p=.62), and respiratory rate (p=0.07).

Table 2.
Sociodemographic Characteristics of Children in the Experimental and Control Groups

Variable	Category	Experimental Group (n=51)	Control Group (n=47)	Statistical Test	*p*-value
Gender	Male	30 (58.8%)	23 (48.9%)	χ^2= 0.963	.33*
	Female	21 (41.2%)	24 (51.1%)		
Age (years)	4	10 (19.6%)	10 (21.3%)	χ^2= 0.409	.815*
	5	16 (31.4%)	12 (25.5%)		
	6	25 (49.0%)	25 (53.2%)		
Peripheral IV	Inserted	20 (39.2%)	18 (38.3%)	χ^2= 0.009	.926*
	Not Inserted	31 (60.8%)	29 (61.7%)		
Family Structure	Nuclear	48 (94.1%)	46 (97.9%)	Fisher's Exact	.62**
	Extended	3 (5.9%)	1 (2.1%)		
Accompanying Person	Mother	36 (70.6%)	34 (72.3%)	χ^2= 2.011	.396**
	Father	9 (17.6%)	11 (23.4%)		
	Other	6 (11.8%)	2 (4.3%)		

* Chi-square test (χ^2), ** Fisher's Exact Test (used due to expected frequency <.5)

However, anxiety levels (CAM-S) were found to be significantly higher in the experimental group compared to the control group (p=.03). Pain scores, measured using the Wong-Baker FACES Pain Rating Scale, were 0 in both groups; therefore, no statistical comparison was conducted (Table 3).

Table 3.
Results Related to the Pre-Procedure Vital Signs, Anxiety-State and Fear Levels of the Experiment and Control Groups

Variable	Group	N	$\bar{X}$ ± SDMR	Statistical test	*p*
CFS	Experimental	51	2.019±1.104	t: 1.59	.11
	Control	47	1.659±1.128		
CAM-S	Experimental	51	5,098±2.264	t: 2.194	.03
	Control	47	4,085±2.301		
Wong Baker FACES Pain Rating Scale	Experimental	51	0	Pain scores were measured as 0 in both groups. Therefore, no comparison was made between the groups / no statistical test was applied.	
	Control	47	0		
Pulse Rate	Experimental	51	87.84±1.42	z: -0.488	.62
	Control	47	88.04±1.35		
Respiratory Rate	Experimental	51	24.05±1.434	t: -1.830	.07
	Control	47	24.57±1.347		

t: Independent sample t-test, z: Mann Whitney-U test, $\bar{X}$: Mean, SD: Standard deviation, MR: Mean rank, p: Significance value.

Table 4.
Results Related to Pre-Procedure and Post-Procedure Vital, State Anxiety and Fear Levels of Experimental and Control Groups

Group	Variable	Pre-Post	$\bar{X}$ ± SDMR	n	Test	*p*	Effect Size
Control Group	CFS	Pre-Procedure	1.659±1.128	47	t:1.062	.29	
		Post-Procedure	1.91±1.41	47			
Experimental Group		Pre-Procedure	2.019±1.104	51	t: -5.51	.01	.48
		Post-Procedure	0.94±1.19	51			
Control Group	CAM-S	Pre-Procedure	4,08±2.30	47	t:1.162	.25	
		Post-Procedure	4.54±2.73	47			
Experimental Group		Pre-Procedure	5.098±2.264	51	t:-6.5	.001	1.06
		Post-Procedure	2.71±2.24	51			
Control Group	Wong Baker FACES Pain Rating Scale	Pre-Procedure	0	47	t:9.52	.001	1.39
		Post-Procedure	1.78±1.28	47			
Experimental Group		Pre-Procedure	0	51	t:6.54	<.001	0.94
		Post-Procedure	1.13 ±1.2	51			
Control Group	Pulse Rate	Pre-Procedure	88.04±1.35	47	t:6.1	<.001	1.12
		Post-Procedure	90.21±11.83	47			
Experimental Group		Pre-Procedure	87.84±1.42	51	t:-13.03	<.001	1.83
		Post-Procedure	85.96±11.01	51			
Control Group	Respiratory Rate	Pre-Procedure	24.57±1.47	47	t:7.467	<.001	0.69
		Post-Procedure	25.65±1.784	47			
Experimental Group		Pre-Procedure	24.05±1.43	51	t:-1.08	.29	
		Post-Procedure	23.86±1.68	51			

Following the procedure, a statistically significant decrease was observed in the experimental group's fear levels (CFS) (p=.01, d=0.48) and anxiety levels (CAM-S) (p<.001, d=1.06). In contrast, the control group showed no significant change in either fear (p=.29) or anxiety (p=.25) levels.

Additionally, pain scores significantly increased after the procedure in both groups; however, the increase was lower in the experimental group (p<.001, d=0.94) compared to the control group (p<.001, d=1.39).

In terms of physiological parameters, post-procedural pulse rate decreased significantly in the experimental group (p<.001, d=1.83), while it increased in the control group (p<.001, d=1.12). Respiratory rate increased significantly in the control group (p<.001, d=0.69), whereas no significant change was found in the experimental group (p=.29) (Table 4).

Table 5.
Results Related to the Comparison of Post-Procedure Variables Between Experimental and Control Groups

Variable	Group	*n*	$\bar{X}$ ±SDMR	Test	*p*	Effect Size
CFS	Experimental Group	51	0.941±1.190	t:-3.70	.01	0.35
	Control Group	47	1.914±1.411			
CAM-S	Experimental Group	51	2.71±2.24	z:-3.45	.01	0.37
	Control Group	47	4.54±2.73			
Wong-Baker FACES Pain Rating Scale	Experimental Group	51	1.13±1.2	t:-2.58	.01	0.25
	Control Group	47	1.78±1.28			
Pulse Rate	Experimental Group	51	85.96±11.01	t:-1.84	.07	
	Control Group	47	90.21±11.83			
Respiratory Rate	Experimental Group	51	23.86±1.685	t:-5.12	.01	0.46
	Control Group	47	25.65±1.784			

t: Independent sample t-test, z: Mann-Whitney U test, MR: Mean rank

Post-procedural comparisons between the experimental and control groups revealed that children in the experimental group had significantly lower levels of fear (CFS) (p=.01, d=0.35), anxiety (CAM-S) (p=.01, d=0.37), and pain (Wong-Baker FACES Pain Rating Scale) (p=.01, d=0.25) compared to those in the control group. Additionally, respiratory rates were significantly lower in the experimental group than in the control group following the procedure (p=.01, d=0.46). Although the experimental group showed a lower mean pulse rate after the procedure, the difference between groups was not statistically significant (p=.07) (Table 5).

Discussion

Medical procedures like venipuncture, injections, peripheral venous catheter placement, and vaccinations are common in hospitalized children and constitute the main sources of pain (Aydın et al., 2016; Canbulat et al., 2014; Pillai et al., 2011; Schreiber et al., 2016). The Federal Council of Nurses (COFEN) recommends pediatric nurses use therapeutic play techniques during care, but many nurses do not adopt this method due to time constraints or lack of preparedness (Barroso et al., 2019). Florence Nightingale also emphasized the importance of play for hospitalized children.

The findings of this study showed that the intervention applied to the experimental group significantly reduced the children's fear, anxiety, and pain during peripheral intravenous catheterization. Post-procedural results revealed that children in the experimental group had lower levels of emotional responses (as measured by CFS, CAM-S, and Wong-Baker Pain Scale) as well as lower physiological indicators (pulse and respiratory rates) compared to the control group. These results are consistent with the principles of atraumatic care, which aim to minimize the psychological and physical distress experienced by children during medical procedures (Dogan et al., 2021; Koller & Goldman, 2012).

It is well established in the literature that fear and anxiety experienced during medical procedures may increase pain perception in children (Çavuşoğlu & Arslan, 2022). Accordingly, the significant decrease in fear and anxiety observed in the experimental group was also reflected in their lower pain scores. The differences observed in CAM-S and Wong-Baker scores support the strong relationship between emotional state and pain perception in children (Fortier et al., 2011). Children in the experimental group reported higher preprocedural anxiety scores, which may reflect a limitation in random group balancing. However, this may also indicate that these children were more expressive or self-aware when using the anxiety scale rather than experiencing objectively higher anxiety. The greater anxiety in the experimental group did not affect the study results; on the contrary, the experimental group was less anxious.

Physiologically, the pulse rate decreased significantly in the experimental group, while it increased in the control group. A similar pattern was observed in respiratory rate, which significantly increased only in the control group. These physiological findings demonstrate the influence of emotional stress on the autonomic nervous system. Previous studies have shown that stress and anxiety are associated with elevated heart and respiratory rates (Özkan et al., 2020; Shen et al., 2020). The physiological stabilization

seen in the experimental group further supports the positive impact of the intervention not only on emotional but also on physical stress responses.

Recent studies emphasize that non-pharmacological interventions such as distraction, therapeutic play, breathing techniques, and parental presence significantly reduce procedural distress in pediatric populations (Dinda et al., 2022). These approaches support the principles of family-centered and atraumatic care by empowering children and their caregivers during stressful medical interventions. The findings of the current study align with this literature, suggesting that interventions that involve emotional support and distraction not only reduce children's fear and anxiety but also improve their cooperation during procedures.

Moreover, the growing body of evidence highlights the clinical importance of monitoring both subjective and physiological responses in pediatric patients. As demonstrated by Mathias et al. (2023), interventions that lower heart and respiratory rates during procedures contribute to more stable vital signs and enhance patient safety. The current study similarly found that children in the experimental group maintained lower post-procedural pulse and respiratory rates, indicating reduced sympathetic arousal. These results reinforce the recommendation that pediatric healthcare professionals should incorporate evidence-based, non-invasive comfort measures as part of standard procedural care.

This study has certain limitations. First, it was conducted in a single center with a relatively small sample size of children aged 4–6 years, which may limit the generalizability of the findings. Second, although random allocation was ensured through the card selection method, blinding was not possible for the participants or researcher. Third, outcomes were evaluated only before and immediately after the procedure, so the long-term effects of the intervention remain unknown. Finally, the intervention was tested within a specific cultural context, and the findings may not be directly applicable to different cultural or healthcare settings.

Conclusion and Recommendations

This study demonstrated that baby-doll-assisted therapeutic play before peripheral venous catheterization effectively reduced fear, anxiety, pain, and respiratory rate in children aged 4–6 years, with positive changes also observed in other physiological indicators. These findings support the use of structured, child-centered, non-pharmacological interventions to minimize procedural distress and enhance cooperation during medical procedures.

Integrating therapeutic play into routine pediatric nursing care may improve both the emotional well-being and physiological stability of children, thereby contributing to better short- and long-term outcomes. Future research should examine its effects in different age groups, cultural settings, and with other non-pharmacological methods to further strengthen the evidence for atraumatic pediatric care.

Ethics Committee Approval: Ethics committee approval was received from Sakarya University Clinical Research Ethics Committee (Date: May 27, 2020, No: 16214662/050.01.04/101).
Informed Consent: Written informed consent was obtained from all participants prior to enrollment in the study.
Peer-review: Externally peer-reviewed.
Author Contributions: Concept-BİY; Design-BİY; Supervision RK-ÖÖ; Resources - BİY; Data Collection and/or Processing - BİY; Analysis and/or Interpretation- BİY; Literature Search - BİY; Writing Manuscript -BİY; Critical Review - BİY-RK-ÖÖ.
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