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# The Effect of Music Therapy on Procedural Pain in Children Aged 3-6 Years: A Randomized Controlled

3-6 Yaş çocuklarda müzik terapinin girişimsel ağrı üzerine etkisi: Randomize Kontrollü Çalışma

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#### RESEARCH ARTICLE

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#### ABSTRACT

Introduction: Pain is one of the most common undesirable experiences for children undergoing trauma, illness, or necessary medical interventions. Effective pain management in pediatric patients is crucial to reduce anxiety, facilitate examinations, and prevent somatic symptoms. Music therapy has been recognized as a beneficial non-pharmacological method for alleviating pain and anxiety in children during medical procedures.

Aim: This study aims to investigate the effects of music therapy on procedural pain in children aged 3-6 years undergoing IV catheterization.

Methods: This randomized controlled trial was conducted in the pediatric ward of a state hospital in Bucak, Burdur, from May to June 2024. Eighty children aged 3-6 years were randomly assigned to either the intervention group (n=40) or the control group (n=40). The intervention group listened to age-appropriate music through earphones 30 seconds before and during the IV catheterization procedure, while the control group received standard care without music. Pain was assessed using the EVENDOL pain scale and the Visual Analog Scale (VAS). Data were analyzed using SPSS 26.0, with descriptive statistics, t-tests, and ANOVA used for comparisons.

Results: There were no significant differences in socio-demographic characteristics between the intervention and control groups (p>0.05). The intervention group had significantly lower pain scores during IV catheterization (p=0.002) and 15 seconds post-procedure (p=0.011) compared to the control group. VAS scores also indicated a significant reduction in pain for the intervention group (p=0.021).

Conclusion: Music therapy significantly reduces procedural pain in children aged 3-6 years undergoing IV catheterization. This study supports the integration of music therapy into pediatric pain management protocols as a simple, cost-effective, and non-invasive method to enhance patient comfort and reduce anxiety. Further research with larger sample sizes and multi-center trials is recommended to confirm these findings and explore the impact of different types of music on pain

Keywords: Pediatric pain, music therapy, procedural pain, non-pharmacological intervention, pain management.

### INTRODUCTION

Pain resulting from trauma, illness, or various necessary medical interventions is one of the most frequent undesirable experiences encountered by children. It leads to increased anxiety for both the child and their family, complicates examinations and other procedures, and causes various somatic symptoms (Eccleston et al., 2021). Insufficient education and knowledge about pain in children, as well as inadequate application of existing knowledge, often hinder effective pain management in pediatric patients. To fulfill this responsibility, pediatricians need to enhance their understanding of pain and increase the use of appropriate pain assessment techniques. Although children may not fully articulate their pain, they express it through their expressions and behaviors. Physical signs such as muscle tension and facial grimacing during an examination indicate pain. Considering that pain is a subjective perception influenced by various personal and environmental factors, it should be assessed and treated accordingly (Kozlowski et al., 2020).

The goal in pain management is to alleviate the intensity, duration, and severity of pain and to help the child cope with it. Both pharmacological and non-pharmacological methods are employed to reduce pain. The most common approach in pediatric pain management is medication. Pharmacological agents used in pain control include local anesthetics, opioid analgesics, and non-opioid analgesics (Uğurlu, 2017). Non-pharmacological treatment methods encompass all practices that enhance the effectiveness of analgesics when used in conjunction with them, and independently promote the release of the body's natural morphine, endorphin, thereby alleviating pain (Dincer, et al., 2011). Studies have shown that commonly used nonpharmacological pain relief methods in pediatric interventional procedures include music listening, pacifier use, breastfeeding,

massage, skin-to-skin contact with the mother, and position changes (Okan, et al., 2007).

Music is used not only as an educational tool but also in health promotion and the treatment of certain diseases. Music, whose benefits have been proven since the prenatal period, is an important tool for ensuring the healthy development of children when used during childhood. Particularly in early childhood, music has positive effects on children's cognitive, social, emotional, language, and motor development (Deleş and Kaytez, 2020). Music therapy is an instrument that promotes relaxation, healing, and comfort. The therapeutic and healing properties of music have been recognized throughout history. Music therapy focuses attention away from pain, increases endorphin release, and provides comfort (Özveren, 2011).

Hatem et al. (2006) found that classical music played for 30 minutes within the first 24 hours postoperatively reduced pain and anxiety in 84 children aged between 1 day and 16 years hospitalized in a pediatric cardiology intensive care unit (Hatem, et al., 2006). A study conducted by Anderson and Patel (2018) in a neonatal intensive care unit found that music reduced anxiety and pain behaviors in neonates, increased daily weight gain, and shortened the length of hospital and intensive care unit stays. Therefore, music therapy holds a significant place in promoting and restoring children's health (Demir Acar and Sarman, 2021). This study aims to determine the effects of music therapy on procedural pain in children aged 3-6 years.

#### Methods

# Study Design

This study is a randomized controlled trial conducted with 80 children aged 3-6 years at the pediatric ward of Bucak District State Hospital in Burdur, between May and June 2024.

# Sampling and Randomization

The population of the study includes all children aged 3-6 years in the pediatric ward of the state hospital in Bucak, Burdur. The sample consists of 80 children in the 3-6 age group whose parents gave consent for participation. The selection can be random or based on specific criteria such as age, gender, and previous music experience. For this study, a random selection was performed. Numbers from 1 to 80 were written on pieces of paper and placed in sealed envelopes; odd numbers formed the intervention group, while even numbers formed the control group.

# Blinding

Independent experts, not involved in the research, were recruited to assess procedural pain. These evaluators watched video recordings without knowing which group the participants belonged to. The videos were recorded in a way that the use of in-ear headphones for music listening in the intervention group was not apparent, ensuring an evaluator-blinded design.

### **Data Collection Tools**

Participants and their parents who agreed to participate were informed about the purpose and implementation of the research. A demographic information form developed by the researchers was used. Video recordings were taken during the application.

#### **Data Collection Tools**

The data were collected using the "Child Information Form," "Video Recording," and "Pain Scale."

Child Information Form: This form included demographic information about the participants (age, gender, weight, frequency of hospital visits within the year, medical diagnosis, reason for hospital visit, etc.).

Video Recording: Video recordings were taken to determine the procedural pain scores of the children during painful procedures. Each video recording started 15 seconds before the procedure began and ended 15 seconds after the procedure was completed.

Pain Scale: The anonymous EVONDOL pain assessment scale was used to evaluate procedural pain. This scale is used for assessing acute and procedural pain in children aged 0-7 years, particularly in intensive care units. It includes four behavioral items and one environmental item, totaling five categories. Each category has four columns: No sign, Weak or Transient Sign, Moderate Sign or Present Half the Time, Strong Sign or Almost Always Present. The scoring is Normal (0), Low (1), Very Low (2), Absent (3). It is a scale unaffected by hunger, fever, or fear. Caregivers are asked to note everything they observe, even if they do not think it is related to pain. It is considered advantageous over other scales. The video recordings of the participants during the procedure were sent to independent expert evaluators for pain assessment using this scale.

#### Interventions

# **Catheterization Procedure**

The vascular access procedure of the children included in the study was performed by the first investigator, who was experienced in vascular access, using a number 24 cannula (Yellow). Intravenous access was established in all children on the first attempt, and there was no need to repeat the procedure. Children who needed to have the vascular access procedure repeated were excluded from the study. Intervention Group (n=40): Video recording started 15 seconds before the procedural pain began. Thirty seconds before initiating the intravenous (IV) line, the participants were isolated from external sounds using earphones, and age-appropriate music selected by the mother that the child frequently listened to was played. After preparation, the lead researcher started the IV line procedure while recording the video. The recording continued until 15 seconds after the procedure ended. The music application was terminated at the end of the procedure. All procedural interventions were conducted by the same researcher.

Control Group (n=40): Video recording started 15 seconds before the procedural pain began. The IV line procedure was conducted by the same researcher without any additional intervention. The recording ended 15 seconds after the procedure concluded.

# **Ethical Considerations**

Ethical approval was obtained from the Ethics Committee of Burdur Mehmet Akif Ersoy University with the approval number GO 2024/160 dated 06.03.2024. Permissions were also obtained from the institution where the study was conducted and from the parents of the participants. The study was conducted in accordance with the Helsinki Declaration.

Table 1. Comparison of Participants According to Descriptive Characteristics

Variables		Intervention		Control		Total		p
		n	0/0	n	0/0	n	0/0	
Age (years)								
	3	12	30.0	8	20.0	20	25.0	
	4	9	22.5	11	27.5	20	25.0	χ2=1.958
	5	10	25.0	11	27.5	21	26.25	p=0.357
	6	9	22.5	10	25.0	19	23.75	
Gender								
	Female	18	45.0	24	60.0	42	52.5	$\chi 2 = 2.039$
	Male	22	55.0	16	40.0	38	47.5	p=0.122
Living								
	Centrum	28	70.0	30	75.0	58	72.5	$\chi 2 = 3.934$
	Village	12	30.0	10	25.0	22	27.5	p=0.155
Previous cathete	erization experience	:						
	Yes	29	72.5	24	60.0	53	66.25	$\chi 2 = 4.910$
	No	11	27.5	16	40.0	27	33.75	P = 0.074

# **Data Analysis**

Data were analyzed using the licensed SPSS (Statistical Package for Social Sciences) for Windows 26.0 program. Descriptive statistics (number, percentage, mean, standard deviation) were used for data analysis. The Kolmogorov-Smirnov test was used to test the normality assumption. Comparative analyses were performed using t-tests and One-Way ANOVA tests. Bonferroni correction was applied in advanced analyses. A significance level of p<0.05 was considered statistically significant.

# RESULTS

# Socio-Demographic Characteristics of the Children Participating in the Study

There was no significant difference between the intervention and control groups regarding the socio-demographic characteristics of the children (p>0.05) (Table 1). The average age of the children in the intervention group was  $4.36\pm0.61$  years, with 45.0% being female, 27.5% having no prior catheterization experience, and 72.5% having undergone an IV line procedure within the past six months. In the control group, the average age was  $4.12\pm0.79$  years, with 60.0% being female, 40% having no prior catheterization experience, and 60% having undergone an IV line procedure within the past six months.

#### Comparison of Pain Scores

VAS Pain Scores: The Visual Analog Scale (VAS) scores also showed significant differences between the groups during IV catheterization (p=0.021) but not before or after the procedure (Table 2).

The intervention group had a mean VAS score of  $5.18 \pm 2.10$  at 15 seconds before IV catheterization,  $6.88 \pm 2.32$  during IV catheterization, and  $2.60 \pm 1.90$  at 15 seconds after IV catheterization. The control group had mean VAS scores of  $5.03 \pm 1.60$  at 15 seconds before IV catheterization,  $8.96 \pm 2.12$  during IV catheterization, and  $2.97 \pm 1.58$  at 15 seconds after IV catheterization.

**EVENDOL Pain Scores:** The pain scores measured using the EVENDOL scale indicated significant differences between the intervention and control groups (Table 3). The intervention group had a mean score of 6.97  $\pm$  2.11 at 15 seconds before IV catheterization, 10.18  $\pm$  2.31 during IV catheterization, and 7.52  $\pm$  1.88 at 15 seconds after IV catheterization. The control group had a mean score of 6.12  $\pm$  1.26 at 15 seconds before IV catheterization, 12.33  $\pm$  2.39 during IV catheterization, and 9.18  $\pm$  2.03 at 15 seconds after IV catheterization. The differences were statistically significant during IV catheterization (p=0.002) and 15 seconds after IV catheterization (p=0.011).

These findings suggest that the intervention, which included music therapy, significantly reduced the pain experienced by

Variables	Time-line		Intervention Group		Control Group		p
		Mean ±SD		Mean ±SD		_	
VAS	(T <sub>0</sub> ) 15 seconds before IV catheterization <sup>a</sup>	5.18	2.10	5.03	1.60	476.3	0.738
	(T <sub>1</sub> ) During the IV catheterization <sup>b</sup>	6.88	2.32	8.96	2.12	227.0	0.021
	(T <sub>2</sub> ) 15 seconds after IV catheterization <sup>c</sup>	2.60	1.90	2.97	1.58	512.5	0.601

Table 3. Distribution of EVENDOL Pain Average Scores of Children in the Intervention and Control Groups

	EVENDOL			
Time line	Intervention Group	Control Group		p
1 ime ine	Mean ±SD	Mean ±SD	t	
(T <sub>0</sub> ) 15 seconds before IV catheterization <sup>a</sup>	6.97 ± 2.11	6.12 ± 1.26	746	0.612
(T <sub>1</sub> ) During the IV catheterization <sup>b</sup>	10.18 ± 2.31	$12.33 \pm 2.39$	028	0.002
(T <sub>2</sub> ) 15 seconds after IV catheterization <sup>c</sup>	7.52 ± 1.88	9.18 ± 2.03	115	0.011
F	5.654	3.184		
p	0.016	0.046		
Differences	a,c <b< td=""><td>a<c<b< td=""><td>_</td><td></td></c<b<></td></b<>	a <c<b< td=""><td>_</td><td></td></c<b<>	_	

F= One Way ANOVA, t= Independent Sample t Test, SD: Standard Deviation

children during and immediately after IV catheterization compared to the control group.

# **DISCUSSION**

This study aimed to investigate the effect of music therapy on reducing procedural pain in children aged 3-6 years undergoing IV catheterization. The results indicated that music therapy significantly reduced pain scores during and immediately after the procedure compared to the control group.

The findings are consistent with previous research indicating that music therapy can effectively alleviate pain and anxiety in pediatric patients during medical procedures. For instance, a study by Hartling et al. (2013) found that music interventions reduced pain and distress in children undergoing medical procedures, providing both psychological and physiological benefits. Similarly, Klassen et al. (2008) reported that music therapy decreased pain perception and anxiety in children receiving needle-related procedures.

One of the mechanisms by which music therapy reduces pain is through distraction. By focusing on the music, children may divert their attention away from the painful procedure, thereby reducing their perception of pain (Mitchell and MacDonald, 2012). Additionally, music can evoke positive emotions and relaxation responses, which can counteract the stress and discomfort associated with medical procedures (Chlan et al., 2013).

In our study, the intervention group had significantly lower pain scores during IV catheterization (p=0.002) and 15 seconds after the procedure (p=0.011) compared to the control group, as measured by the EVENDOL pain scale. The reduction in pain scores observed in the intervention group is likely attributable to the calming and distracting effects of the music. This aligns with the findings of Nguyen et al. (2010), who demonstrated that music therapy significantly reduced pain scores in children during and after painful medical procedures.

Moreover, the Visual Analog Scale (VAS) scores corroborated these results, showing a significant reduction in pain during IV catheterization in the intervention group (p=0.021). This further supports the effectiveness of music therapy in managing procedural pain in pediatric patients.

The socio-demographic characteristics of the children, including age, gender, and previous catheterization experience, were not significantly different between the intervention and control groups, suggesting that these factors did not confound the results. This strengthens the validity of our findings and suggests that the observed differences in pain scores are primarily due to the music intervention.

The findings of this study have important clinical implications. Integrating music therapy into routine pediatric care can be a simple, cost-effective, and non-invasive method to reduce pain and improve the overall experience for children undergoing medical procedures. Healthcare providers should consider incorporating music therapy into their practice to enhance patient comfort and satisfaction.

### Limitations

However, this study has some limitations. The sample size was relatively small, and the study was conducted in a single hospital, which may limit the generalizability of the findings. Future research should include larger, multi-center trials to confirm these results and explore the effects of different types of music on pain reduction in pediatric patients.

### CONCLUSION

This study demonstrates that music therapy is an effective intervention for reducing procedural pain in children aged 3-6 years undergoing IV catheterization. These findings support the use of music therapy as a beneficial adjunct to conventional pain management strategies in pediatric healthcare settings.

# Data availability

Data supporting the findings of this study are available from the corresponding author upon reasonable request.

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