

The Impact of Music Therapy on Alleviating Pain in Preterm Neonates during Painful Medical Procedures: A Quasi-Experimental Research Study

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ABSTRACT

Background: Preterm neonates routinely undergo many painful procedures in the neonatal intensive care unit. Due to their nonverbal state, these neonates are unable to express their pain, resulting in underestimation and insufficient pain relief. Neglecting pain may lead to complications affecting neurodevelopment and causing permanent injuries to the brain. Music therapy provides sensory stimulation to preterm neonates, resulting in improved physiological and behavioral responses and reduced pain perception. To assess the impact of music therapy on alleviating pain in preterm neonates during painful medical procedures. The study utilized a quasi-experimental research design with a two-group post-test-only approach.

Methods: In the present study, a total of 60 preterm neonates were divided equally into a control group and an experimental group (30 participants per group). The intervention and control groups were matched before the intervention. The experimental group received music therapy during painful procedures, while the control group received routine care during the same procedures. The Neonatal Pain Agitation and Sedation Scale (NPASS Tool) was used to measure pain levels during painful procedures.

Results: The intensity of pain in both groups was the same before the intervention. In this study, the mean±SD values of intra-test pain level were 8.63±0.56 and 2.96±0.89 in the control and experimental groups, respectively. Moreover, the mean±SD values of the post-test pain level in the control and experimental groups were 7.53±0.89 and 1.1±0.88, respectively. The obtained t-test value in the intra-test was obtained at 29.57 (P<0.05), thereby stating that music therapy was effective in the reduction of pain levels among preterm neonates during painful procedures.

Conclusion: This study has important implications for healthcare professionals who care for infants and should prompt the integration of music therapy into routine care for this vulnerable population.

Keywords: Music therapy, Painful procedures, Preterm neonates

Introduction

Preterm neonates, defined as infants born before 37 weeks of gestational age, are at risk of organ immaturity and heightened pain sensitivity, compared to their full-term counterparts. As such, these neonates are frequently exposed to a range of painful procedures while receiving care in the neonatal intensive care unit (NICU). These

procedures include heel pricking, venepuncture, peripheral venous catheter insertion, arterial blood gas analysis, and umbilical vein catheterization, among others. Unfortunately, preterm neonates are unable to verbally communicate their pain, which often leads to the underestimation of their discomfort and inadequate pain management.

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Furthermore, untreated pain may negatively impact neurodevelopment and potentially cause long-term brain damage (1-3).

Untreated pain can have numerous detrimental effects on physiological, behavioral, and cognitive outcomes, as highlighted by clinical studies. These effects include impaired brain growth, poor executive functions, attention deficit disorder, poor socialization skills, impaired visual-perceptual ability, and impaired short-term memory (3). Pain may manifest in behavioral changes, such as vocalization (crying), facial expression (grimace, wrinkled forehead, tightly closed eyes), and changes in extremity tone and physiological parameters (increasing heart and respiratory rates, decreasing oxygen saturation) (4). Recent scientific research has further demonstrated that preterm neonates are particularly sensitive to nociceptive stimuli, which may badly affect physiological, behavioral, hormonal, and metabolic responses to such stimuli, which may have various adverse effects (5).

Pain management in preterm neonates is challenging for nurses due to variations in pain experience and responses to medication and techniques. Pharmacologic and non-pharmacologic interventions, including physical and behavioral measures, such as touch, massage, diversion therapy, and application of cold and heat, have been effective in reducing pain. Music therapy is a promising non-pharmacological intervention that has demonstrated positive outcomes in pain management (6,7).

Several studies have suggested that music therapy can be a successful approach to managing pain in preterm neonates. Music stimulates sensory responses in patients, resulting in a reduction of perceived pain, relaxation, rhythmic breathing, and relief from anxiety and stress (8). Music therapy has been found to have numerous positive effects on preterm neonates, including improving physiological outcomes, such as heart rate, respiratory rate, and stress levels. It has also been shown to increase oral feeding volume and improve overall well-being and quality of life in the NICU. In addition, music has been used as an early intervention program to reduce pain, stress, and anxiety in both neonates and preterm neonates (9). In the NICU, music therapy is used as a special intervention to reduce pain associated with painful procedures, and specialized music and equipment are used for this purpose (10). The benefits of music therapy include reducing pain, promoting good sleep, improving physiological

parameters, increasing oral feeding volume, reducing hospital stay, stimulating brain development, and aiding language development.

Although several studies indicated the positive effect of music on pain control in infants, most of the studies were conducted on term neonates with a small sample size. Moreover, data regarding the role of music therapy in preterm neonates is limited. This necessitates doing this interventional study. To fill the gap in this knowledge, the present study was conducted to determine the effectiveness of music therapy on pain reduction during painful procedures among preterm neonates.

Methods

Study Design

This quasi-experimental study was conducted in the NICU of SVBCH Hospital, Silvassa, DNH & DD from July 2022 to September 2022. The objective of the study was to compare the effectiveness of music therapy during painful procedures in preterm neonates with routine care. Ethical approval for this study was obtained from the Institutional Ethics Committee, NAMO MERI & SVBCH Hospital, (Ref: DMHS/IEC/2016/214/3922, dated-30/06/2022).

Inclusion Criteria

The study included preterm neonates with a gestational age between 30 and 37 weeks and birth weight between 1500 and 2500g. Willing mothers were also included in the study.

Exclusion criteria

On the other hand, critically-ill babies, those with congenital anomalies, auditory disabilities, intracranial hemorrhage, and neurological problems, as well as preterm neonates on sedative drug support were excluded from the study.

Sample Size

In the present study, a total sample size of 60 preterm neonates was divided equally into a control group and an experimental group (30 participants per group). It is common in research studies to employ a combination of convenience sampling and inclusion criteria to select participants. Convenience sampling may have been used to select preterm neonates who were available and willing to participate within the study's timeframe. The study's location, the NICU of SVBCH Hospital, may have been a convenient setting for recruitment.

In addition, inclusion criteria were applied to ensure that the selected participants met specific

characteristics, such as a gestational age between 30 and 37 weeks and a birth weight between 1500 and 2500 g. The inclusion of willing mothers in the study might suggest an additional element of convenience sampling.

One of the reasons for this sample size choice was to ensure adequate statistical power, allowing for the detection of meaningful differences or effects between the control and experimental groups. Additionally, the inclusion of 30 participants in each group aimed to obtain a representative sample of preterm neonates, ensuring that the participants' characteristics and experiences were diverse and reflective of the broader population. This enhances the generalizability of the study's findings. A sample size of 30 participants in each group also strikes a balance between precision and feasibility. It provides more precise estimates and reduces the margin of error in the study's results, increasing confidence in the findings and strengthening the validity of the conclusions drawn.

Finally, practical considerations, such as resource constraints, time limitations, and the availability of participants, might have influenced the decision to include 30 participants in each group. It was a manageable number that could be reasonably recruited and followed throughout the study period.

Intervention

The intensity of pain was the same in both groups before the intervention. The present study refers to lullaby with instrumental music (pre-recorded music) to reduce the pain level of preterm neonates. The researcher's music was prepared by an expert musician. After preparing the music, a certificate was obtained from the concerned authority to provide music therapy in the NICU. The experimental group received music therapy during painful procedures (i.e., intravenous cannulation, blood sampling, arterial blood gas analysis, and PICC line insertion), while the control group received routine care during the same procedures. Two sets of wireless speakers were arranged with music. The volume of the music was maintained by the sound meter. Music therapy was provided to the preterm neonates during and after the painful procedure for 5 minutes in the experimental group.

Data Collection

The Neonatal Pain Agitation and Sedation Scale (NPASS Tool) (11) was used to measure pain levels during painful procedures. Tool filling was

done using a checklist. Demographic information, such as gestational age, birth weight, type of delivery, and residence was collected. The NPASS evaluates pain levels in neonates based on five parameters, including crying irritability, behavioral state, facial expression, extremity tone, and vital signs. Each parameter is scored on a scale of 0-2, with a total score of 3 or more indicating pain. The scale also includes an additional parameter for sedation. The behavioral parameters are observed, while physiological parameters are monitored using a cardiac monitor. The scale is used to assess pain levels in preterm neonates not receiving sedative treatment. Pain levels are classified as no pain (0), mild pain (1-3), moderate pain (4-6), or severe pain (7 or more). The level of pain was assessed by the NPASS for both groups during the procedure and after 5 minutes of painful procedures.

Data Analysis

Descriptive statistics, including frequency, mean, and standard deviation, were used to describe the demographic characteristics of the participants in this study. Inferential statistics were used to reach conclusions that extend beyond the immediate data alone. Inferential statistics were used to make a judgment of the probability observed between groups. The effectiveness of music therapy in reducing pain among pre-term neonates in the control and experimental groups was tested using an unpaired t-test. Associations were measured using a Chi-square test between demographic variables and the level of pain among preterm neonates. The statistical analysis was conducted using SPSS software (version 20).

Ethical approval

Ethical approval for this study was obtained from the Institutional Ethics Committee, NAMO MERI & SVBCH Hospital, (Ref: DMHS/IEC/2016/214/3922, dated-30/06/2022).

Results

The demographic variables of the control and experimental groups were compared using Table 1. The results showed that the majority of preterm neonates in both groups had a gestational age between 30 and 33 weeks and a birth weight of 1500-2000g. The type of delivery was varied, with 66.66% in the control group and 50% in the experimental group being delivered normally. The majority of subjects in both groups were from

Table 1. Distribution based on demographic variables of preterm neonates (n=60)

Demographic variables		Control group (n=30)	Experimental group (n=30)	χ^2
Gestational age	30-33 weeks	20(66.66%)	23(76.66%)	0.71
	34-37 weeks	10(33.33%)	7(23.33%)	
Birth weight	1500-2000 gm	26(86.66%)	27(90%)	0.5
	2000-2500 gm	4(13.3%)	3(10%)	
Mode of delivery	Normal vaginal delivery	20(66.66%)	15(50%)	1.7
	Caesarean section delivery	10(33.33%)	15(50%)	
Residence	Rural	9(30%)	5(16.66%)	1.49
	Urban	21(70%)	25(83.3%)	

urban areas, indicating that the distribution of demographic variables was similar in both groups.

The pain levels of the preterm neonates in the control and experimental groups were compared using descriptive statistics. During the intervention, all 30 neonates in the control group experienced severe pain, with 27 of them still experiencing severe pain after the intervention. Three neonates experienced a reduction in pain from severe to moderate. In the experimental group, 9 out of 30 neonates experienced no pain after the intervention, 20 had mild pain, and only 1 had moderate pain (Table 2).

In the control group, the mean±SD values for crying irritability, behavior state, facial expression, extremities tone, and vital signs during the intra-test were obtained at 1.2 (SD 0.41), 1.8 (SD 0.41), 1.9 (SD 0.31), 1.97 (SD 0.18), and 1.77 (SD 0.43), respectively. During the post-test, the mean±SD values were 1.03 (SD 0.18), 1.73 (SD 0.45), 1.73 (SD 0.45), 1.33 (SD 0.48), and 1.7 (SD 0.47), respectively. Therefore, the intra-test values were higher than the post-test values in the control group. In the experimental group, the mean±SD values for crying irritability, behavior

state, facial expression, extremities tone, and vital signs during the intra-test were determined at 0.03 (SD 0.18), 0.3 (SD 0.46), 1 (SD 0), 0.7 (SD 0.47), and 0.93 (SD 0.25), respectively. During the post-test, the mean±SD values were 0 (SD 0), 0.07 (SD 0.25), 0.67 (SD 0.47), 0.13 (SD 0.34), and 0.23 (SD 0.43), respectively. Therefore, the intra-test values were higher than the post-test values, except for crying irritability in the experimental group. Furthermore, the comparison of the control and experimental groups using NPASS showed that the intra- and post-test values were higher in the control group than in the experimental group. Hence, the difference in pain reduction with music therapy is statistically significant ($P < 0.05$) (Figure 1).

Table 2. Distribution of intra- and post-test pain levels during painful procedures.

Pain level	Control group (n=30)		Experimental group (n=30)	
	Intra	Post-test	I Intra	Post-test
No	0(0%)	0(0%)	9(30%)	28(93.3%)
Mild	0(0%)	0(0%)	20(66.7%)	2(6.7%)
Moderate	0(0%)	3(10%)	1(3.3%)	0(0%)
Severe	30(100%)	27(90%)	0(0%)	0(0%)
Overall	30(100%)	30(100%)	30(100%)	30(100%)

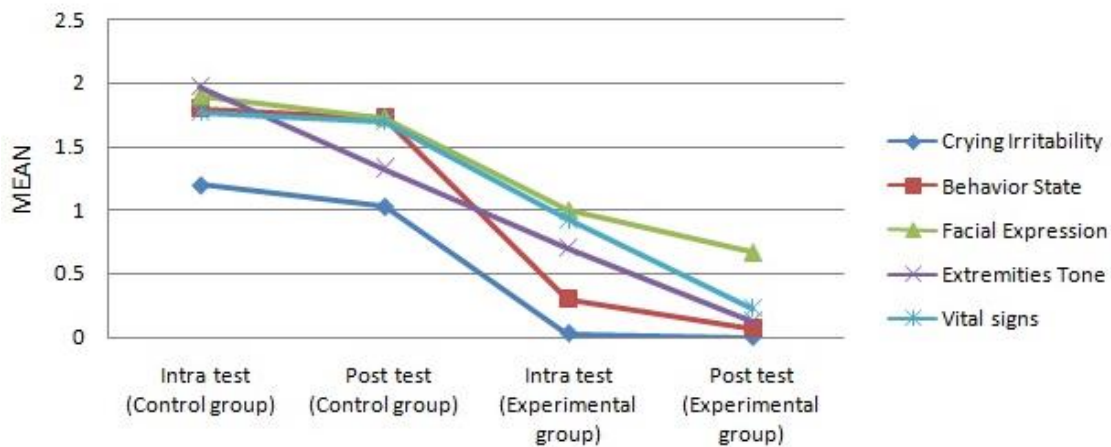
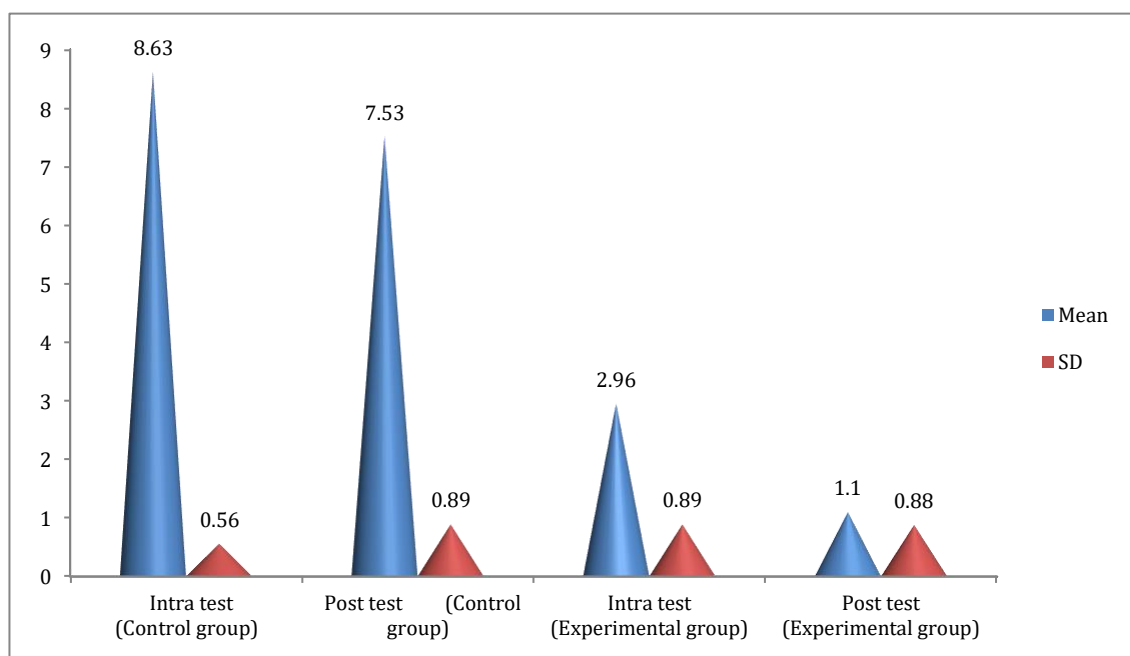
**Figure 1.** Comparison of pain level in the preterm neonates using NPASS in both groups

Table 3. Comparison of intra- and post-test pain levels in the control and experimental groups.

Parameter	Control group (n=30)		Experimental group (n=30)		t-test value	P-value
	Mean	SD	Mean	SD		
Pain score (Intra)	8.63	0.56	2.96	0.89	29.57	<0.001
Pain score (Post)	7.53	0.89	1.1	0.88	27.92	<0.001

Table 3 and Figure 2 compare the intra-test pain levels between the groups. The mean±SD of the intra-test pain level in the control group was 8.63 ± 0.56 , while in the experimental group, it was 2.96 ± 0.89 . In the post-test, the mean±SD values of pain level in the control and experimental groups were 7.53 ± 0.89 and

1.1 ± 0.88 , respectively. The calculated t-test value for the intra-test pain level was 29.57 ($P<0.00001$). Similarly, in the post-test, the calculated t-test value was obtained at 27.92 ($P<0.00001$). This indicates a significant difference between both groups in terms of pain reduction using music therapy.

**Figure 2.** Comparison of pain score in the control and experimental groups during painful procedures

Discussion

This study investigated the impact of music therapy on pain management in preterm neonates. The control and experimental groups were similar in terms of demographic characteristics, such as gestational age, birth weight, and delivery type. The results revealed that the intra-test pain level mean±SD value in the control group was 8.63 ± 0.56 , while the experimental group mean±SD was obtained at 2.96 ± 0.89 . Furthermore, the post-test pain level mean±SD value in the control group was 7.53 ± 0.89 , while the experimental group mean±SD value was determined at 1.1 ± 0.88 . The t-test value of 29.57 ($P<0.05$) indicated that music therapy significantly reduced pain levels during

painful procedures in preterm neonates.

In a study by S. Ragasivamalini et al. (12) comparing the pain perception of neonates undergoing intravenous needle puncture, those who received music therapy had significantly less pain than those in the control group ($P<0.05$). Additionally, the music group had significantly lower scores in all five domains of the NPASS ($P<0.001$).

A cross-over clinical trial conducted by Fidan Shabani et al. (13) found significant differences between the experimental and control groups regarding heart rate during needle extraction and the infant's sleep-wake state. The study also observed significant differences in infants' facial

expressions of pain after sampling. These findings suggest that music therapy can be an effective intervention to reduce pain and promote relaxation in preterm neonates.

Chen Y et al. (14) conducted a study demonstrating that recorded maternal voice intervention during venipuncture resulted in significantly lower scores on the Neonatal Infant Acute Pain Assessment Scale, as well as behavioral and physiological indicator scores, compared to routine care.

A systematic review by Pölkki T et al. (15) reports the positive effects of music therapy on preterm infants. Various studies indicate that music therapy improves physiological outcomes (e.g., heart rate, oxygen saturation, and respiratory rate), behavioral states (e.g., crying, body movements, and facial expression), pain scores, length of hospital stay, and oral feeding rates. The review concludes that music therapy may have beneficial effects on pain severity in preterm neonates.

A study was performed by Qiu J et al. (16) to analyze the effect of combined music and touch intervention on pain response. According to the results, during the neonates' hospitalization, a total of 3,707 painful procedures were performed on 62 neonates. The average number of painful procedures in the control group was 35.5, which was higher than the experimental group's average of 29.0; however, the difference was not significant ($P>0.05$). After two weeks, the Premature Infant Pain Profile scores were significantly higher in the control group (13.000 ± 0.461), compared to the experimental group (10.500 ± 0.850) ($P<0.05$). However, the experimental group had a higher serum β -endorphin concentration than the control group at the beginning of hospitalization (1.640 ± 0.390 vs. 1.179 ± 0.090 , respectively) and two weeks later (2.290 ± 0.740 vs. 1.390 ± 0.410 , respectively) ($P<0.05$).

Our results are consistent with the findings from these studies, indicating that music therapy can be an effective non-pharmacological intervention for managing pain in infants during painful procedures. Furthermore, additional research is needed to identify the most effective types of music and the optimal timing and duration of music therapy interventions for infants undergoing painful procedures.

Conclusion

This study suggests that music therapy can have significant positive effects on the various

responses of infants during painful procedures. This study has important implications for healthcare professionals who care for infants and should prompt the integration of music therapy into routine care for this vulnerable population. Further research is warranted to refine the optimal music therapy intervention for infants undergoing painful procedures.

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Conflicts of interest

The authors declare that they have no conflict of interest.

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