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Research paper

The effect of a live music therapy intervention on critically ill paediatric patients in the intensive care unit: A quasi-experimental pretest–posttest study

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ABSTRACT

Background: Music therapy as a nonpharmacological means of managing patient pain, anxiety, and discomfort is a recognised technique, although it is not widely used in the paediatric intensive care unit (PICU).

Aim: The aim of this study was to assess the clinical effect of a live music therapy intervention on vital signs and levels of discomfort and pain for paediatric patients in the PICU.

Methods: This was a quasi-experimental pretest–posttest study. The music therapy intervention was carried out by two music therapists who were specifically trained, each possessing a master's degree in the field of hospital music therapy. Ten minutes before the start of the music therapy session, the investigators recorded the vital signs of the patients and assessed their levels of discomfort and pain. The procedure was repeated at the start of the intervention; at 2, 5, and 10 min during the intervention; and at 10 min following the conclusion of the intervention.

Results: Two hundred fifty-nine patients were included; 55.2% were male, with a median age of 1 year (0–21). A total of 96 (37.1%) patients suffered a chronic illness. The main reason for PICU admission was respiratory illness, at 50.2% ($n = 130$). Significantly lower values were observed for heart rate ($p = 0.002$), breathing rate ($p < 0.001$), and degree of discomfort ($p < 0.001$) during the music therapy session.

Conclusions: Live music therapy results in reduced heart rates, breathing rates, and paediatric patient discomfort levels. Although music therapy is not widely used in the PICU, our results suggest that using interventions such as that used in this study could help reduce patient discomfort.

1. Introduction

The attention and care provided to critically ill paediatric patients are based on the recognition that their pathology has become serious enough to constitute a real threat to their lives, with the possibility of pain, suffering, and death. The diagnosis and treatment of these patients must take into consideration the critical situation of the current risk or potential complications that may put their lives in danger and the reversible nature of the pathological process. This critical situation involves their care being provided in the paediatric intensive care unit (PICU).[1] Further, we note that patients admitted to the PICU are particularly vulnerable and prone to developing a maladaptive, stressful response to their circumstances.[2] This may be explained by their perception of being in a hostile environment surrounded by unknown technology, which leads to anxiety disorders and discomfort, both for the child and his/her family.[3–5] Additionally, the physical space is noisy and characterised by physical, familial, and social isolation; it is closed to the world, with strict controls on movement.[1,4–8] There also may

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be an absence of windows and natural light, as well as separation from family in some PICUs, which will cause discomfort. This is a common denominator in critically ill patients, who are particularly vulnerable to being overwhelmed by a situation over which they have no control.

With the aim of easing this stress and discomfort, the National Association for Music Therapy of Spain and the American Music Therapy Association offer music therapy as an effective strategy to restore and maintain the physical, emotional, cognitive, and social wellbeing of the individual.[9] Music therapy is a discipline practised by professionals widely versed in music and having the capacity to understand and create the therapy. It consists of the use of music and/or musical elements in the process of facilitating and promoting communication, learning, mobilisation, expression, and organisation with the goal of effecting change and satisfying physical, emotional, mental, social, and cognitive needs.[10,11] Several studies have noted the positive effect that music therapy has in reducing the level of anxiety and discomfort of patients, both adult and newborn,[12–16] with some authors suggesting the need to establish specific protocols to systematise the use of music therapy in the critical care unit.[16]

1.1. Background

The beneficial effect of music therapy as part of the total management of the patient has been understood since the 18th century,[17] including the use of music therapy as a nonpharmacological means of managing patient pain.[18–21] It is a recognised technique for anxiety and discomfort control, although it is not widely used in the PICU. Music therapy has been shown to be effective in neonatal intensive care units (NICUs) with premature and newborn babies,[14,22] resulting in significant weight gain, a reduction in stress, and an increase in oxygenation levels. Other studies have shown that nonpharmacological interventions such as music therapy reduce neonatal stress and, thus, may improve neurodevelopmental functioning and reduce adverse effects on brain development.[23–25]

At the same time, the effects of music intervention are well noted by parents. Kehl et al., in their mixed-method pilot study, concluded that music therapy improved the parent–infant relationship and encouraged parents to interact more profoundly with their children.[26] Similarly, Cousin et al. determined that parents perceived that music therapy helped their children communicate, feel less isolated, and reduce their hospitalisation stress.[27]

Music therapy has also proven to be useful for a variety of clinical situations and pathologies, such as palliative care of paediatric patients,[28] dementia, autism, and psychiatric disorders,[29] as well as for patients undergoing surgery, those under mechanical ventilation,[30] and those suffering from cancer.

In addition to these benefits, it is also of note that music therapy is one of the interventions described in the Classification of Nursing Interventions (NIC) (4400: Music therapy), defined as the use of music to help achieve a specific change in the physiological, emotional, or behaviour domain.[31]

1.2. Justification

Music therapy is one of the complementary interventions that nurses may utilise when treating patients or while assisting another professional specialised in hospital music therapy. It is a resource demonstrated to be effective for the physical and psychological needs of neonates and adult patients. Confirmation of the beneficial effects of music therapy is lacking in the literature for the critically ill paediatric population.

2. Aim

The aim of this study was to assess the clinical effects of a live music therapy intervention on vital signs and levels of discomfort and pain for paediatric patients in the PICU.

3. Materials and methods

3.1. Research questions

- What is the change in the vital signs and level of discomfort of critically ill paediatric patients admitted to a PICU during a music therapy intervention?
- What is the correlation among the music therapy session, vital signs, degree of discomfort, and critically ill paediatric patients' sociodemographic and clinical variables?

3.2. Study design and participants

A quasi-experimental pretest–posttest study was carried out with a single group in a PICU with 24 beds in a university children's hospital from November 2019 to February 2022. To enhance transparency of reporting, the Transparent Reporting of Evaluations with Nonrandomized Designs (TREND) checklist was used.

Using a nonprobabilistic sampling approach, patients meeting the following inclusion criteria were selected consecutively: (i) 0–18 years of age, (ii) minimum stay in the PICU of 72 h, (iii) neurologically conscious or sedated, (iv) negative result on neonatal screening for deafness, (v) haemodynamically stable at the time of the study (not being treated with vasoactive or complex cardiovascular medication), (vi) undergoing noninvasive or invasive mechanical ventilation, and (vii) acceptance and signing of informed consent by family member/legal guardian and signing or assent by the patient if aged 12 years or older. Patients who had been administered muscle-relaxing medications were excluded. Finally, the criteria for withdrawal from the study were (i) verbal expression of desire to withdraw from the study by the patient or family member and (ii) haemodynamic worsening of the patient during the music therapy intervention.

To calculate the sample size, GRANMO (Program of Research in Inflammatory and Cardiovascular Disorders, Institut Municipal d'Investigació Mèdica, Barcelona, Spain), version 7.12, was used for two independent means. Estimating a study population of 1200 patients, corresponding to the number of admissions in 2019 in the study setting, we determined that a sample of 150 individuals was needed to estimate the effect with a confidence level of 95%, precision of ±5%, population percentage of 80%, and replacement rate of 5%.

The following sociodemographic and clinical variables were recorded: (i) sex (male/female), (ii) age (in months, classified in accordance with the World Health Organization standards for subsequent analysis as 0 to 2; 3 to 6; 7 to 12, and >13 years), (iii) chronic pathology (yes: specify/no), (iv) previous admissions to the PICU (yes/no), (v) reason for the present admission (respiratory, cardiological, oncological, neuromuscular, other), (vi) analgesia/sedation (yes: specify drug/no), (vii) respiratory support (yes: specify whether invasive or noninvasive mechanical ventilation), (viii) accompaniment by a family member (yes: specify/no), and (ix) length of stay in the PICU (days). The independent variable was the music therapy intervention. The following were the dependent variables: (i) vital signs (respiratory rate (RR), heart rate (HR), blood pressure (average systolic and diastolic), and haemoglobin saturation (Sat Hb) measured using pulse oximetry; (ii) degree of pain

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determined with the pain scales and classified as mild (1–3 points), moderate (4–7), or severe (>8 points);[19–21] and (iii) degree of discomfort assessed with the COMFORT Behavior Scale—Spanish version (CBS–S).[22]

3.3. Instruments for data collection

Instruments used to assess pain and comfort were as follows: the COMFORT Behaviour Scale-Spanish Version and paediatric pain scales of the Face, Legs, Activity, Cry, Consolability (FLACC) scale for children between the ages of 1 month and 4 years or individuals who were unable to communicate; the faces scale for children over 4 years, and the numerical pain scale for children over 8 years.[32–34] The FLACC scale is reliable and sensitive to pain for procedural pain assessment.[35] The inter-rater and intrarater reliability coefficients obtained during the determination of psychometric properties were high (0.92 and 0.87, respectively). The CBS-S with a Cronbach's alpha of 0.715 was also used.[36] This scale assesses comfort from a psychological perspective as behaviours with negative effects and associated with fear, anxiety, and pain in critically ill paediatric patients.[37] It is also used to assess the level of sedation and pain in critically ill paediatric patients.[38] The CBS-S consists of three factors with two items each: (i) alertness and physical movement; (ii) calm/agitation and respiratory response/crying; and (iii) muscle tone and facial tension, each assessed with a Likert scale from 1 to 5. On the CBS-S, scores <10 points correspond to the absence of discomfort, 11–22 to slight discomfort, and >23 to serious discomfort.[36] A purposefully developed data collection document was also created for the remaining study variables.

3.4. Intervention

The intervention with live music therapy was carried out by two music therapists specifically trained, each possessing a master's degree in the field of hospital music therapy. One session per patient per week was held, consisting of children's songs chosen in the patient's native language (Spanish or Catalan), with the age group, interests, and emotional state in mind, in combination with vocal and instrumental music. Each session lasted 10 min and included five songs. Each session began with an introductory song, followed by an instrumental, two songs both played and sung, and then a concluding farewell song. The intervention took place at the foot of the patient's bed. At all times, the sound level was controlled to ensure that it did not exceed 35–45 dB, in accordance with the recommendations of the American Academy of Pediatrics.[39]

3.5. Procedure for data collection

Each morning, two nurses, along with the principal investigators, assessed the candidates for the intervention based on the established criteria. Once they were chosen, the family members and the young conscious patient were informed verbally and in writing about the study, and their consent was requested. Patients provided their consent by putting their name or making a tick in a box included in their specific consent form.

All of the patients in the study were monitored with the multiparameter Mindray® monitor. This was used to obtain and record vital signs; RR, HR, blood pressure (both systolic and diastolic averaged), and haemoglobin saturation measured using pulse oximetry.

Ten minutes before the start of the music therapy session, the principal investigator and/or collaborator recorded the vital signs of the patient and assessed, by means of the CBS-S and the pain scale corresponding to the patient's age, the degree of discomfort and pain the child was experiencing. This procedure was repeated at the start of the intervention; at 2, 5, and 10 min during the intervention; and at 10 min following the conclusion of the intervention. Data were collected from 2 to 4 p.m. (depending on the availability of the music therapists).

3.6. Data analysis

Analysis of the data was carried out using the program IB SPSS Statistics for Windows (version 25; IBM Corp., Armonk, NY). The numerical variables are expressed with descriptive statistics (mean,

Table 1
Clinical and sociodemographic characteristics of the sample (n = 259).

Characteristics	Values
Stay (in days)[c]	12 (1–102)
Sex (n/%)[b]	
Female	114 (44%)
Male	143 (55.2%)
Lost	2 (0.8%)
Age (years)[c]	1 (0–21)
Categorised age[b]	
Newborn and nursing	153 (59%)
Preschool	32 (12.4%)
School age	28 (10.8%)
Teenage	45 (17.4%)
Lost	1 (0.4%)
Reason for admission[b]	
Respiratory	130 (50.2%)
Postoperative	76 (29.3%)
Infectious	11 (4.2%)
Oncological	12 (4.6%)
Others: metabolic, neurological, cardiac	29 (11.2%)
Chronic illness[b]	
Yes	96 (37.1%)
No	162 (62.5%)
Type of chronic illness[b]	
Congenital heart disease	35 (36.4%)
Respiratory	29 (30.2%)
Neuromuscular	15 (15.6%)
Metabolic/digestive	6 (6.2%)
Malformations: oesophageal, rectal	4 (4.2%)
Renal	2 (2.1%)
Neurological	2 (2.1%)
Immunodeficiency	2 (2.1%)
Unrelated syndrome	1 (1.1%)
Patient on ventilation support[b]	
Yes	184 (71%)
No	74 (28.6%)
Lost	1 (0.4%)
Type of ventilation[b]	
Noninvasive mechanical	90 (48.9%)
Invasive	60 (32.6%)
Oxygen therapy	34 (18.5%)
Sedation/analgesia[b]	
Yes	171 (66%)
No	85 (32.8%)
Lost	3 (1.2%)
[a]Type of sedation/analgesia[b]	
Midazolam	30 (11.6%)
Fentanyl	44 (17%)
Diazepam	50 (19.3%)
Levomepromazine	62 (23.9%)
Clonidine	7 (2.7%)
Remifentanil	1 (0.3%)
Morphine	14 (5.4%)
Chloral hydrate	21 (8.1%)
Dexmedetomidine	3 (1.2%)
Propofol	30 (11.6%)
Chlorpromazine	4 (1.5%)
Ketamine	4 (1.5%)
Others	52 (20.1%)

Lost: corresponds to variables not recorded or missing data.
[a] A majority of patients were administered more than one drug at the same time.
[b] Frequency (percentage).
[c] Median and interquartile range.

standard deviation, median, and quartiles), while the categorical variables are represented as frequency tables with percentages. The values for a numerical variable in paired samples were compared using the Wilcoxon test for two samples and the Friedman test for more than two samples. In cases of two independent samples, the Mann–Whitney U test was used, and in cases with more than two samples, the Kruskal–Wallis test was used. To determine whether there was dependence between two categorical variables, the chi-square (χ^2) test was used, and in the case of two numerical variables, the Spearman correlation test was used. Finally, a mixed analysis of variance or analysis of variance model was established using the measurements of the variables of interest and the established recording times for them. Statistical significance was set at $p < 0.05$.

3.7. Ethical considerations

This study was approved by the clinical research and ethics comittee of Sant Joan de Déu Hospital (PIC-166_20).

4. Results

4.1. Sociodemographic and clinical characteristics of the sample

Two hundred fifty-nine patients were included in the study; 55.2% were boys, with a median age of 1 year (0–21). A total of 96 (37.1%) patients suffered a chronic illness, with congenital heart disease being the most prevalent (13.5%, n = 35), followed by respiratory illness (11.2%, n = 29). The main reason for PICU admission was respiratory illness (50.2%, n = 130), followed by postoperative care (29.3%, n = 76).

Of the patients in the PICU, 71% (n = 184) were ventilated. A total of 90 (34.7%) were on spontaneous noninvasive mechanical ventilation, and 60 (23.2%) were on volume-controlled invasive mechanical ventilation with synchronised intermittent mandatory ventilation (SIMV) or automode rate. Sixty-six percent (n = 171) of the patients were receiving analgesia/sedation; the most commonly used drugs were levomepromazine (23.9%, n = 62), diazepam (19.3%, n = 50), fentanyl (17%, n = 44), and midazolam (11.6%, n = 30). The median length of stay in the PICU was 12 days (1–102) (Table 1).

4.2. Changes in vital signs and level of discomfort during the music therapy session

For the sample overall, the mean HR over all time points was 123.8 ± 26.4 beats per minute (bpm), R was 33.3 ± 12.0 breaths per minute, and saturation was 96.3 ± 5.0% for haemoglobin. The mean systolic blood pressure was 102.6 ± 21.4 mm of mercury (mmHg), the mean diastolic pressure was 55.8 ± 16.6 mmHg, and the mean arterial pressure was 77.9 ± 17.3 mmHg. Table 2 shows the mean vital sign scores obtained according to time points.

Table 2
Vital sign scores according to time points (n = 259).

Variable	Time point	Value
Heart rate[a] (beats per minute)	10 min before session	124.3 ± 26.4
	Start of session	122.3 ± 25.9
	Two minutes after start	123.4 ± 25.7
	Five minutes after start	121.5 ± 24.6
	Ten minutes after start	122.2 ± 25.6
	After 10 min	122.0 ± 25.3
Respiratory rate[a] (breaths per minute)	10 min before session	31.8 ± 11
	Start of session	33.0 ± 11
	Two minutes after start	33.3 ± 11.5
	Five minutes after start	32.5 ± 10.7
	Ten minutes after start	32.0 ± 10.9
	After 10 min	31.6 ± 10.6
Haemoglobin saturation[a] (%)	10 min before session	97.5 ± 2.3
	Start of session	97.7 ± 2.2
	Two minutes after start	97.7 ± 2.2
	Five minutes after start	97.6 ± 2.1
	Ten minutes after start	97.7 ± 2.1
	After 10 min	97.6 ± 2.1
Systolic arterial blood pressure[a] (mmHg[b])	10 min before session	101.6 ± 19.5
	Start of session	101.6 ± 19.9
	Two minutes after start	102.9 ± 20.1
	Five minutes after start	102.3 ± 19.9
	Ten minutes after start	101.6 ± 19.3
	After 10 min	101.3 ± 19.6
Diastolic arterial blood pressure[a] (mmHg[b])	10 min before session	59.2 ± 15.6
	Start of session	59.4 ± 17.0
	Two minutes after start	59.4 ± 16.9
	Five minutes after start	57.9 ± 17.1
	Ten minutes after start	58.7 ± 16.9
	After 10 min	58.7 ± 16.2
Mean blood pressure[a] (mmHg[b])	10 min before session	70.5 ± 15.4
	Start of session	70.2 ± 16.7
	Two minutes after start	71.1 ± 16.6
	Five minutes after start	70.4 ± 16.7
	Ten minutes after start	70.1 ± 16.4
	After 10 min	69.8 ± 15.8

[a] Mean and standard deviation.
[b] Millimeters mercury.

The mean HR decreased from 122.27 ± 25.91 bpm at the beginning versus 122.22 ± 25.58 bpm at the end of the music therapy intervention. Statistically significantly lower values were observed for HR ($p = 0.002$) at all time points.

The mean RR decreased from 33.08 ± 11.08 breaths per minute at the beginning versus 32.04 ± 10.92 at the end of the music therapy session. Focussing on control invasive mechanically ventilated patients, values of 31.59 ± 9.98 versus 31.01 ± 9.08 breaths per minute were noted. Statistically significantly lower values were also observed for RR ($p < 0.001$) over all time points of the intervention, but not when comparing spontaneous or controlled ventilated patients.

The Sat Hb variable remained constant throughout the session (NS, $p = 0.11$). No significant changes were observed for blood pressure, systolic ($p = 0.16$), diastolic ($p = 0.09$), or mean ($p = 0.3$). Table 5 details the level of significance of HR, RR, and the degree of discomfort according to time point.

The mean CBS-S values decreased from 11.39 ± 3.29 points at the beginning of the intervention versus 11.19 ± 3.03 at the end. There were statistically significant lower rates of discomfort values ($p < 0.001$) at all time points of the music therapy session. Table 3 displays the number of patients experiencing an absence of discomfort (scores <10 on the CBS-S) versus those experiencing slight (values 11–22) and moderate (scores >23) discomfort.

For the level of pain reported, 98.1% ($n = 254$) of patients reported none, with mean scores of 0.06 (0–7) before the music therapy session. At the end of the intervention, we observed the same patients with no pain. No significant changes were observed for levels of pain. Table 4 details the patients with mild pain (score on the pain scale 1–3), moderate pain (score 4–7), and severe pain (score >8).

4.3. Correlation among the music therapy session, vital signs, degree of discomfort, and sociodemographic and clinical variables

There was no statistically significant relationship observed between HR and gender ($p = 0.68$), age group ($p = 6.36$), chronic illness ($p = 0.68$), analgesia/sedation ($p = 0.29$), type of respiratory support ($p = 3.65$), family member presence ($p = 0.82$), prior admissions ($p = 0.09$), or length of stay in the PICU ($p = 0.86$).

There was no statistically significant relationship observed between RR in volume-controlled ventilated patients compared with those with another respiratory support. There were no statistically significant differences for gender ($p = 0.90$), age group ($p = 5.49$), chronic illness ($p = 0.80$), analgesia/sedation ($p = 0.15$), prior admission ($p = 0.09$), and length of stay in the PICU ($p = 0.10$).

For discomfort, lower scores on the CBS-S pre and post intervention and statistical significance ($p < 0.001$) for all time points were observed when comparing the different types of oxygen delivery: oxygen (12.68 ± 2.25 points pre therapy versus 12.59 ± 2.16 post music therapy); noninvasive ventilation (11.53 ± 3.33 versus 11.16 ± 2.78 points), and controlled ventilation (9.48 ± 3.57 points versus 9.17 ± 3.13 post intervention). There was no statistically significant relationship observed between the degree of discomfort and gender ($p = 0.72$), age ($p = 0.77$), presence of chronic illness ($p = 0.21$), prior admissions ($p = 0.74$), analgesia/sedation ($p = 0.45$), ventilation support ($p = 0.63$), or length of stay in the PICU ($p = 0.69$).

5. Discussion

We found that music therapy resulted in a reduction in HR, RR, and mean scores for discomfort in critically ill paediatric patients. If we liken psychological discomfort with the stress and anxiety associated with admission to the PICU, these findings are in agreement with those of a study that used a modified version of the Yale Paediatric Anxiety tool to measure the effectiveness of music therapy in a presurgical setting. The research demonstrated reduced preoperative levels of anxiety post music therapy ($p < 0.001$).[40] Vital sign reductions were also found in a recent systematic review that showed improvement HR, RR, blood pressure, and oxygen saturation as well as the subjective (patient self-report) levels of pain in patients with cancer.[41] Our findings suggest that an intervention using music therapy may reduce children's conscious perception of hostile PICU environment and decrease discomfort.

In the present study, the HR decrease pre to post intervention was in contrast to another article that also determined the impact of

Table 3
All patients and degree of discomfort[a] by time points ($n = 259$).

Type of discomfort	Time point for data					
	10 min before	Start	2 min	5 min	10 min	10 min after
No discomfort (scores of 10 or less on the CBS-S)[b]	80 (31%)	77 (29.8%)	76 (29,4%)	78 (30.5%)	74 (28.9%)	79 (31.5%)
Slight discomfort (scores of 11–22 on the CBS-S)[b]	175 (67.8%)	180 (69.8%)	180 (69.8%)	177 (69.1%)	181 (70.7%)	172 (68.5%)
Moderate discomfort (scores greater than 23 on the CBS-S)[b]	3 (1.2%)	1 (0.4%)	2 (0.8%)	1 (0.4%)	1 (0.4%)	0 (0%)
TOTAL[b]	258 (100%)	258 (100%)	258 (100%)	256 (100%)	256 (100%)	251 (100%)

[a] Determined with the COMFORT Behavior Scale—Spanish version.
[b] Expressed in n/%.

Table 4
All patients and degree of pain by time points.

Degree of pain[a]	Time point for data					
	10 min before	Start	2 min	5 min	10 min	10 min after
No pain (score of 0)[b]	253 (97.7%)	254 (98%)	254 (98%)	254 (98.4%)	254 (98.4%)	250 (98.4%)
Mild pain (scores 1–3)[b]	4 (1.5%)	3 (1.2%)	3 (1.2%)	3 (1.2%)	3 (1.2%)	3 (1.2%)
Moderate pain (scores 4–7)[b]	2 (0.8%)	2 (0.8%)	2 (0.8%)	1 (0.4%)	1 (0.4%)	1 (0.4%)
Severe pain (scores 8 or more)[b]	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Total[b]	259 (100%)	259 (100%)	259 (100%)	258 (100%)	258 (100%)	254 (100%)

FLACC, Face, Legs, Activity, Cry, Consolability.
[a] Determined by pain scale adapted to age of patient (FLACC, face or numerical).
[b] Expressed in n/%.

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Table 5
Level of significance of heart rate (HR), breathing rate (BR), and degree of discomfort[a] according to time points.

Time point	Variable	10 min before	Start of session	2 min after start	5 min after start	10 min after start
Start	HR	0.411	–	–	–	–
	BR	0.110	–	–	–	–
	Discomfort	1.000	–	–	–	–
2 min after start	HR	1.000	1.000	–	–	–
	BR	0.061	1.000	–	–	–
	Discomfort	0.302	0.813	–	–	–
5 min after start	HR	**0.040**	1.000	0.553	–	–
	BR	1.000	1.000	1.000		
	Discomfort	**0.006**	**0.013**	0.069	–	–
10 min after start	HR	0.090	1.000	0.715	1.000	–
	BR	1.000	0.221	0.096	1.000	–
	Discomfort	**0.025**	0.069	0.713	1.000	–
10 min after finish	HR	**0.056**	1.000	0.590	1.000	1.000
	BR	1.000	**0.031**	**0.019**	0.632	1.000
	Discomfort	**0.006**	**0.011**	0.072	1.000	0.259

Statistically significant time points in bold.
[a] Determined with the COMFORT Behavior Scale—Spanish version.

music therapy intervention.[42] In addition, the decreased breaths/minute pre and post music therapy intervention we found was less than reported in two meta-analyses with preterm infants.[42,43] One pilot study of five paediatric patients in a cardiac intensive care unit showed a reduction in HR and BR for four of five children, as well as a reduction in blood pressure and an increase in oxygen saturation.[44]

Although we performed a live music therapy intervention, another investigation reported the benefits of music via MP3 players and headphones for children receiving mechanical ventilation.[45,46] In our study, lower scores for the CBS-S pre and post intervention were observed over all the time points when comparing the different types of ventilation. This is in contrast to Kühlmann et al. in 2020 in a surgical setting, which found no statistically significant differences in the scores for the COMFORT-Behaviour scale between the control and intervention groups before and after a music therapy intervention.[47] Both live and recorded music therapy interventions are used. Recorded music is more patient accessible, but further research should examine the main differences between the live and recorded music therapy.

Almost all patients (98.1%, n = 254) reported no pain, although a slight improvement in this area was noted over the course of the music therapy session. This is similar to findings demonstrated in two systematic reviews that examined the effects of music intervention in psychological and physiological terms and on the quality of life of children undergoing cancer treatment.[48,49] Several studies performed in neonatal intensive care units that included preterm infants[50–53] are in agreement that after a music therapy session, there were lowered levels of stress, suggesting that music therapy sessions may be effective as a nonpharmacological treatment for pain.[54–58] Analgesia and sedation reduce pain and discomfort felt by children admitted to the PICU. The differences between analgosedation protocols among countries could explain the low level of pain experienced by children included in our study. This highlights the importance of guiding analgesia and sedation protocols taking into account international recommendations and practices.

5.1. Limitations

The main limitation of the study is that interrater reliability of the use of scoring tools was not established prior to data collection. Additionally, the assessors were not blinded. Although we included 259 patients, another limitation is the sample size and the fact that the data were obtained in the critical care unit of a single centre.

6. Conclusions

Live music therapy carried out by trained music therapists under the supervision of nurses is a nonpharmacological means of lowering HR, RR, and paediatric patient discomfort levels. Although music therapy is not widely used in PICUs, our results suggest that using interventions such as the one we used in this study could help reduce discomfort and the traumatic impact of admission to the PICU for children.

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CRediT authorship contribution statement

María Mata Ferro and Alejandro Bosch: Conceptualisation, Methodology, Validation, Formal analyses, Investigation, Resources, Data curation, Writing- Original draft preparation and Writing-Reviewing and Editing. Anna Falcó Pegueroles and MªÁngeles Saz Roy: Methodology, Writing- Reviewing and Editing. Rocío Fernández Lorenzo, Carmen Maria Estrada Jurado, and Omar Rodríguez Forner: Investigation, Data curation and Writing- Reviewing and Editing. Núria Bonet Julià, Carles Geli Benito, and Raül Hernández Hernández: Data curation and Writing- Reviewing and Editing.

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