

Music as a therapeutic intervention in the pediatric intensive care unit: a randomized clinical trial

A música como intervenção terapêutica em unidade de terapia intensiva pediátrica: ensaio clínico randomizado

La música como intervención terapéutica en la unidad de cuidados intensivos pediátricos: un ensayo clínico aleatorizado

RESUMO

Objetivo: Avaliar os efeitos de uma intervenção musical sobre parâmetros clínicos em crianças hospitalizadas em Unidades de Terapia Intensiva Pediátrica. **Método:** Foi conduzido um ensaio clínico randomizado que avaliou a efetividade da música como instrumento terapêutico versus nenhuma intervenção em lactentes hospitalizados na Unidade de Terapia Intensiva Pediátrica, Hospital Regional de Assis, São Paulo. **Resultados:** Verificou-se que a música sugere alguns sinais como melhora gradativa dos aspectos clínicos, redução da dor, e percepções emocionais positivas como sorrir, e dormir. **Conclusões:** A música deve ser utilizada como um instrumento terapêutico em lactentes hospitalizados, como em unidades de terapia intensiva pediátrica.

DESCRIPTORES: Criança; Música; Terapêutica; Unidades de Terapia Intensiva Pediátrica

ABSTRACT

Objective: In this context, music is considered an important strategy for communication and entertainment for the care of children in various aspects such as pain relief and acceptance of hospitalization. **Methods:** We conducted a randomized clinical trial that evaluated the effectiveness of music as a therapeutic tool versus no intervention in infants hospitalized in the Pediatric Intensive Care Unit, Hospital Regional de Assis, São Paulo. **Results:** It was found that the music suggests some signs of gradual improvement and clinical aspects, pain reduction, and positive emotional perceptions as smiling and sleeping. **Conclusions:** The music should be used as a therapeutic tool in hospitalized infants, as in the pediatric intensive care units.

DESCRIPTORS: Child, music, alternative therapies; Pediatric Intensive Care Units

RESUMEN

Objetivo: En este contexto, la música se considera una estrategia importante para la comunicación y el entretenimiento para el cuidado de los niños en diversos aspectos, como el alivio del dolor y la aceptación de la hospitalización. **Métodos:** Se realizó un ensayo clínico aleatorizado que evaluó la efectividad de la música como herramienta terapéutica versus ninguna intervención en los recién nacidos hospitalizados en la Unidad de Cuidados Intensivos Pediátricos del Hospital Regional de Assis, São Paulo. **Resultados:** Se encontró que la música sugiere algunos signos de mejora gradual y los aspectos clínicos, la reducción del dolor, y las percepciones positivas emocionales (es decir, sonreír, dormir). **Conclusiones:** La música debe ser utilizado como una herramienta terapéutica en niños hospitalizados, como en las unidades de cuidados intensivos pediátricos.

DESCRIPTORES: niño, la música, terapias alternativas; Unidades de Cuidados Intensivo Pediátrico.

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INTRODUCTION

The Child and Adolescent Statute in accordance with the regulation on the rights of the child emphasizes the right to play, play sports and have fun. Rest and leisure are essential to maintain a satisfactory quality of life and emotional balance. (1)

It is observed, however, that none of the legislation mentions the place where these rights should be exercised, which implies that they must be respected in all places, including hospitals. Therefore, a Pediatric Intensive Care Unit also has a duty to guarantee these rights. (1)

Considering a child who has changes in their basic needs or is ill, getting sick and being hospitalized provide unpleasant physical, psycho-emotional sensations, which trigger challenging problems, requiring a professional position in relation to this process.(2-3)

Analyzing this reality, a study portrays the importance of monitoring the emotional state of hospitalized children, through a qualitative literature review, which verified the productions on the psychological assessment of hospitalized children under 12 years of age. It was identified that most of the studies were carried out by nursing professionals who use the assessment as a process of building knowledge about the behavior and emotional responses of hospitalized children. Therefore, it highlights the relevance of psychological assessment in the hospital context, understood by the study as an interventional and facilitating strategy for communication between patients, health professionals and family members. (4)

Childhood, according to Marcondes (5) is divided into phases, the latency phase (29 days to two years) is considered a phase of vulnerability in relation to child morbidity and mortality in pediatric ICU admissions, and it is important to use alternative therapies to improve these children. (6)

There are several professionals who work with play as a tool for child care as a means of communication, developmental assessment, data collection, preparation for

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exams, and thus, it is up to the nurse to use the technique through the toy/therapeutic toy in the care of hospitalized children and families. (7)

A systematic review evidenced complementary therapies to improve pain in adult cancer patients identified that therapeutic massage associated with muscle relaxation brought pain relief in this population, while acupuncture also found results that were divergent in pain improvement. (8)

Another study, with 78 children aged 3 to 11 years, was distributed between the group that used combined therapy with art therapy and a visit with clowns to reduce preoperative anxiety in the separation of parents before induction of anesthesia and the control group. Children in the group showed a significant reduction in anxiety compared to the control. (9)

Therefore, play is considered a strategy that facilitates the interrelationships between the team and the child's development. From the playful strategies, music has been used as a care model. (10,11)

An extension project used music in hospitalized children in order to answer whether the joy of music could help in the sensitivity and humanization of hospitalized children? The results showed that music in the hospital environment is relevant in the treatment and well-being of patients, regardless of age, for children it has even more meaning and scope, promoting a feeling of peace, tranquility and acceptance of the unfavorable condition of the hospital routine. (12)

Two studies evaluated the effects of music on children. Hatem (10) examined the effect of music in children after cardiac surgery by applying three consecutive interventions, followed by a 30-minute music control. Franco (11) evaluated music in the context of pain relief in adult cancer patients. Both had positive conclusions with reduced pain, SSVV and anxiety.

From this perspective, the need to define music as a therapeutic tool in children hospitalized in pediatric intensive care units is perceived.

Thus, this study aims to demonstrate the effectiveness of the use of music compared

to the control group in the clinical response in children hospitalized in the Pediatric Intensive Care Unit.

METHOD

A prospective, single-center, comparative, open, randomized and controlled study was carried out in infants in the lactating phase (29 days to two years), hospitalized in a Pediatric Intensive Care Unit of a Regional Hospital and allocated through a simple numerical random draw, for one of the following groups: group I received the music intervention and group II did not receive any intervention (control).

A musician specializing in this theme evaluated the chosen musical scheme and made her nominations suggesting orchestrated classical music in sessions lasting 30 minutes. Music reproduction was carried out through individual headphones, connected to an MP3 brand MOX model MO-58, according to the child's acceptance.

Study Population

Thirty-one children hospitalized in the Pediatric Intensive Care Unit of the Hospital Regional were included in the study and observed for four sessions over five consecutive days and the outcomes were recorded before, during and after the intervention.

A randomized clinical trial was carried out in infants in the lactating phase (29 days to 2 years), hospitalized in a Pediatric Intensive Care Unit of Hospital Regional de Assis. The recruitment period was from March 30th to November 20th of the year 2010.

Inclusion criteria were: (a) child hospitalized in the Pediatric Intensive Care Unit; (b) in the latency phase established by Marcondes (5); (c) be released by the medical team to participate in the study; (d) Informed Consent Form signed. The exclusion criterion was the child being sedated.

Thirty-one children were allocated by simple numerical random drawing to one of the following groups: group I received the music intervention and group II did

not receive any intervention (control). A musician specializing in this theme evaluated the chosen musical scheme and made her nominations suggesting orchestrated classical music in sessions lasting 30 minutes. Music reproduction was carried out through individual headphones, connected to an MP3 brand MOX model MO-58, according to the child's acceptance.

Reference criteria were used on the daily exposure limits for continuous and inter-

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mittent noise according to the Brazilian Association of Technical Standards (13) and the American Academy of Pediatrics and the World Health Organization.

The groups were followed for four sessions for five consecutive days and outcomes were recorded before, during and after the intervention.

The evaluated outcomes were clinical variables: heart rate, temperature, respiratory rate, blood pressure, Lactate, Sodium, Potassium, Glucose, Pain facies which was

assessed by the Wong – Baker pain scale considering as the fifth vital sign. Another variable was the severity of the case, which was defined by the medical team on duty when the child was included in the study, which used the parameters of the Brazilian Association of Intensive Care as a reference. The researcher's perception variable comprises the investigator's observation in the moments before, during and after the intervention, where the perception in relation to the children's emotional responses was registered. The children were followed for five sessions, where the intervention was applied from the first session sequentially on four consecutive days counting with the first. It is noteworthy that the investigators who evaluated the outcomes were unaware of the purpose of the study to avoid possible bias.

The PRISM Prognostic Index (14), which assesses the risk of mortality in the Pediatric Intensive Care Unit through clinical variables, and the study by Hatem (10) were support instruments for the construction of the score of this study, being validated in the pilot project. A field diary was used to record relevant information, photographic records as a source of analysis through a Sony 7.2 Mega Pixels camera, 2.4 LCD Monitor, High Sensitivity ISO 1000, Cyber Shot, DSC – 5700. Time, number of sessions and songs were determined based on previous studies and defined after the pilot project. (10,11)

Asepsis care was performed during the use of the equipment and earphones, and each child had their earphone protector (foam) for single use.

The research project was approved by the Research Ethics Committee of the Hospital Regional de Assis with Opinion n. 316/2009.

RESULTS

Of the 31 children participating in the study, 19 were allocated to the music group and 12 to the control group (no music). There were no exclusions in the study, however, there was a decrease in the number of children under observation throu-

ghout the sessions, this was due to hospital discharge and death of the child from the pediatric intensive care unit before the end of the number of sessions.

During the study period, there was a predominance of respiratory system pathologies in 57,89% in the group of children who received the intervention with music.

The results in Table 1 show the distribution of emotional responses in the researcher's perception of the children, according to group and evaluation moment. Thus, there is a statistically significant increase $p < 0,01$ in M3 and M4 of positive emotional responses in children after receiving music therapy. It is also noticed that during the musical sessions, that is, from M0 to M4 there was a reduction in negative emotional responses. The RR resulting from the comparison between the two groups in M3 is 2,20 and in M4 is 1,47.

The results show that the children in the group with music were mostly using antibiotic therapy, however, it was noticed that most were concentrated in the M0 in both groups, with $p < 0,05$ being significant (RR = 0,57; 95% CI) and over time its use was reduced in moments M1 Before (RR = 0,63; 95% CI), M3 After (RR = 0,66; 95% CI), M4 Before (RR = 0,68; 95% CI) and M4 Afterwards ($p < 0,05$ (RR= 0,71; 95%

CI).

Regarding oxygen therapy, the data show that there was a predominance in children belonging to the group that received the music intervention, its use being significantly reduced at $p < 0,01$ in M3 (RR= 2,22; 95% CI) and M4 After (RR= 5,87; 95% CI) and during the musical sessions.

When evaluating the child's pain according to group and evaluation moment, they revealed an improvement immediately after each session and after the four sessions in the group that received the music intervention. While for the group without music intervention, the children showed a slight decrease in pain after the four sessions.

It is noteworthy that, both physiological signs, systolic blood pressure (SBP), diastolic blood pressure (DBP), heart rate (HR), respiratory rate (RR), oxygen saturation (Sat%O₂), temperature (T), and serum lactate concentration (Lac), sodium (Na), Potassium (K) and Glucose were important for the analysis of the assessment of the child's clinical improvement.

In the descriptive measures of SBP, there was a reduction in SBP throughout the sessions, however, attention is drawn to an increase in pressure at M2, despite not having statistical significance.

Descriptive measures, in relation to HR, reflect an oscillation during the sessions of the two groups, however, what caught our attention was the verification of a slight and immediate increase after the music sessions and with a reduction throughout the sessions, however only in M4 Before does this data become statistically significant at $p < 0,05$.

The results of the RR variable show that, in both groups, there was an immediate increase after each session, however, only the group that received the musical intervention showed a reduction throughout the sessions.

It was observed, in the descriptive measures of Sat%O₂, an improvement in oxygen saturation throughout the sessions and, immediately after each moment, in the group with music. While in the group without music there was a slight improvement after M1 and M2 and a worsening after each session.

The results related to the lactate variable show a significant reduction in the standard deviation at $p < 0,01$ from one moment to the other and, throughout the sessions, in the group that received the music intervention, showing a reduction even starting the sessions with children in more serious conditions. As for the group

Table 1 - Distribution of emotional responses in the researcher's perception of children, according to group and evaluation moment. Assis, 2011

Evaluation Moment	Study Group						p-value
	With Music			Without Music			
M0	n=19	11/8	(57,89/42,11)	n=12	6/6	(50,00/50,00)	$p > 0,05$
M1 Before	n=19	8/11	(42,11/57,89)	n=12	7/5	(58,33/41,67)	$p > 0,05$
M1 After	n=19	16/3	(84,21/15,79)	n=12	8/4	(66,67/33,33)	$p > 0,05$
M2 Before	n=17	13/4	(76,47/23,53)	n=12	10/2	(83,33/16,67)	$p > 0,05$
M2 After	n=16	13/3	(81,25/18,75)	n=11	9/3	(75,00/25,00)	$p > 0,05$
M3 Before	n=16	11/5	(68,75/31,25)	n=11	7/4	(63,64/36,36)	$p > 0,05$
M3 After	n=15	15/0	(100,00/0,00)	n=11	5/6	(45,45/54,55)	$p < 0,01$
M4 Before	n=14	13/1	(92,86/7,14)	n=11	9/2	(81,82/18,18)	$p > 0,05$
M4 After	n=15	14/1	(93,33/6,67)	n=11	7/4	(63,64/36,36)	$p < 0,01$

M0: moment zero; M1 - moment one; M2: moment two; M3: moment three; M4: moment four
n: number of children
Source: Authors, 2011.

without music, despite starting the sessions with children with a lower degree of severity, the standard deviation increased during the sessions, that is, the health condition was aggravated, however, in these other moments there was no statistical difference. The serum concentration of Na, K and glucose did not show statistically significant results in the groups.

DISCUSSION

The results, regarding the diagnoses found, indicated a predominance of pathologies of the respiratory system in the group with music, in relation to the total of pathologies in this group. These data lead the group to be more vulnerable to complications due to the severity of pathologies of the respiratory system, which are normally part of pediatric intensive care units, even though the collection period coincided with the period of predominance of respiratory diseases, or that is, it is related to the seasonal period. These data are in line with those already existing in the literature, when it describes a study on the use of inhaled oxygen therapy in pediatric patients admitted to a university hospital who, when looking for the correct oxygen therapy prescriptions, found a frequency of respiratory pathologies in 84% of children admitted to the studied hospital, corresponding to the period of greatest collection – the seasonal. (15)

The significant increase in positive emotional responses in the group that received music therapy reinforces the data in the literature, when it portrays, in one of several studies found, the beneficial effect of a musical visit to children hospitalized in a pediatric clinic unit, in which the music promoted expressions of emotion portraying joy, pleasure, strengthening communication and interaction between participants, reducing negative feelings such as fear, anger and sadness. Furthermore, the results draw attention to the analysis of negative emotional responses that were reduced throughout the music sessions, showing once again the beneficial effect of music on emotional and developmental aspects. The-

It was noticed that, due to randomness, the children drawn in the group with music were in greater use of antibiotic therapy, but most of them were concentrated in M0 in both groups, a fact that made it possible to infer the reduction in antibiotic use at the time from music

se data, therefore, corroborate those already described in the literature, in which a work that applies music as a therapeutic in care and teaching brings as a result the benefit of this practice, both for the children and for the team. (16)

Regarding the results of antibiotic therapy, greater use is evidenced because it is critically ill patients who need a more invasive and aggressive treatment; however, the same study highlights the risk of using antibiotic therapy prior to acquiring multi-resistant bacteria. (17)

These data contribute to a reflection of what was found in the research field of this study, regarding the greater number of children using antibiotic therapy. Thus, innovative therapy was used in an attempt to change the scenario in the use of antibiotic therapy.

It was noticed that, due to randomness, the children drawn in the group with music were in greater use of antibiotic therapy, but most of them were concentrated in M0 in both groups, a fact that made it possible to infer the reduction in antibiotic use at the time from music. However, it is noteworthy that the N changed, due to discharge or death, this may have caused a measurement bias when we identified a reduction in the use of antibiotic therapy together with a reduction in N in children.

When analyzing the use of oxygen therapy, it was evident that most children used this resource, a fact that reinforces the data found in the literature when using oxygen therapy (64%) in a study of pediatric patients, whose study population was composed of children in the latency stage of development. (15)

In the graph of the distribution of the pain scale, according to group and time of assessment, it can be seen that in M1 and M2, when the pain classification was unbearable and strong, there was no change when receiving therapy, but when the classification was moderate and mild, there was a reduction in pain. These data corroborate the findings in the literature that describe the effect of music in reducing pain in critically ill children, as well as improving vital signs, making it beneficial to these children.

(10)

Another study brings findings of this beneficial effect in the oncologic population over 20 years of age who suffer from chronic pain, using the analogue pain scale for evaluation after music sessions, the research identified the influence of music on pain intensity, which was reduced. (11)

This study also corroborates a review of publications on the use of music in nursing care in Brazil, published in 2008, which brings 12 selected works, of which 11 show the beneficial effect of music as an improvement in emotional state and pain reduction. (18)

Despite the work on pain assessment being carried out in different environments, the data from this study contributes to those in the literature regarding the use of the facial pain scale (19), when it comes to the latency phase (20), choosing a methodology that ensures reliable measurement.

Considering the results of the physiological variables SBP, DBP, HR, FR, SatO₂, T, Lac, Na, K, Glucose, which at times during the sessions increased their value in HR, Na, Lac, K, FR, SBP/PAD and at the end of the sessions returned to normal; these data suggest a positive finding, because when compared to the literature it was found that metabolic alterations are found in the production of blood lactate, increased plasma levels of adrenaline, cortisol, potassium due to some emotional exposure. (21) In this research, the stress the child is subjected to comes from the hospitalization itself and from the procedures performed and from the change in the child's life dynamics.

Studies consider stress a reaction triggered by any event, which confuses, frightens, and excites markedly. These real or imagined events produce responses, which can be emotional, physiological or behavioral. (22)

Given the findings, it can be said that children subjected to music presented, at times, situations of eustress, since this is considered a sign perceived in children when faced with exciting daily situations, such as unexpected situations, which are perceived as a challenge, which the individual is ca-

Another experimental study shows that patients with AMI were submitted to music as an inducer of relaxation, in an attempt to avoid the harmful effects of stress on these patients. The experiment evaluated 45 patients randomly distributed in 15 per group, and anxiety levels and physiological indicators were measured, obtaining in response a reduction in HR and RR over time

pable of solving and which incurs a lower risk of becoming ill and is considerable, even healthy for the body. (22)

In this study, it was possible to observe a reduction in SBP throughout the sessions, the same happened with RR and temperature, in relation to oxygen saturation, there was an improvement, but without statistical significance, but there were statistically significant results in the variables HR $p < 0,05$ in M4 before and lactate $p < 0,01$ in M0.

The findings of this study, regarding the physiological aspects of HR, SBP and DBP, RR, SatO₂ and T are similar to other investigations that also show the decrease and contribution of music in improving these variables in the ICU. A study (20) uses music therapy in a coronary care unit for adult patients admitted with a diagnosis of Acute Myocardial Infarction (AMI). In this case, an experimental study was carried out with 80 patients randomized into groups and controls, who participated in three music sessions, and HR, T, cardiac complications and the quality of the evaluation data were evaluated. The research obtained as a result a decrease in RH and a reduction in stress, which is in line with the finding of this study, and regarding the increase in temperature, this item differs from the results found here, which registered a reduction in the temperature of the children under study.

Another experimental study (23) shows that patients with AMI were submitted to music as an inducer of relaxation, in an attempt to avoid the harmful effects of stress on these patients. The experiment evaluated 45 patients randomly distributed in 15 per group, and anxiety levels and physiological indicators were measured, obtaining in response a reduction in HR and RR over time. Experimental study data (23) are in line with the findings of this study, while in relation to SBP, the results differ from those found in this study, as no pressure changes were found. They also observed a reduction in anxiety in the first hour after music therapy, concluding that patients with AMI can benefit from this therapy.

The results presented on lactate in the group that received the musical intervention show a significant reduction in the

standard deviation at $p < 0,01$ at M0, a reduction was also noticed during the sessions that were not statistically relevant, but it is important to consider, since lactate is a marker of severity of which is being discussed and is consistent with the severity already discussed above. So, this significance is important for this study, since, observing the control group, it was found that even starting therapy with less severe patients, demonstrated by the lower standard deviation of lactate and the severity of the case between moderate and mild, the standard deviation increased during the sessions, thus, the child's disease state worsened. Perhaps music sessions can have lactate-

-lowering effects.

Lactic acidosis is not uncommon and can take the mortality rate to a level higher than 60%, reaching 100% when combined with other factors. For this reason, serum lactate is considered a prognostic marker in critically ill children, being a tissue hypoperfusion marker, therefore, the choice of lactate as an evidence variable for clinical improvement is relevant. (24,25) In the development of the research, it was noticed an increase in the use of music as a playful activity, as it improves mood and allows for a moment's oblivion of the complexity of the environment in which it is found. (26)

CONCLUSION

Music is more effective compared to no intervention in pain reduction, HR, lactate, oxygen therapy and antibiotic therapy; trigger positive emotional reactions in children hospitalized in the PICU; establish communication; cause eustress that is beneficial to the human organism. It is considered the need for further investigations with a higher N and studies that go deeper into the laboratory physiological responses in critically ill patients who receive music intervention.

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