Effects of music on the anxiety of blood donors: randomized clinical trial

Efeitos da música na ansiedade de doadores de sangue: ensaio clínico randomizado

Efectos de la música en la ansiedad de donantes de sangre: ensayo clínico aleatorizado

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How to cite:
Silva KF, Felix MM, Cruz LF, Barichello E, Pires PS, Mattia AL, et al. Effects of music on the anxiety of blood donors: randomized clinical trial. Acta Paul Enferm. 2021;34:eAPE00461.

DOI
http://dx.doi.org/10.37689/acta-ape/2021A000461

Keywords
Music; Anxiety; Blood donors; Vital signs; Hydrocortisone

Descritores
Música; Ansiedade; Doadores de sangue; Sinais vitais; Hidrocortisona

Descriptores
Musica; Ansiedad; Donantes de sangre; Signos vitales; Hidrocortisona

Submitted
March 9th, 2020

Accepted
June 1st, 2020

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Abstract

Objective: To evaluate the effects of music on state-anxiety, physiological and laboratory parameters in blood donors.

Methods: Randomized, double-blinded clinical trial, conducted in a regional blood bank, located in the interior of the state of Minas Gerais, Brazil. In total, 126 blood donors participated in the study, randomly divided into two groups, being one experimental group (musical intervention before blood donation) and one control group (standard routine). To assess the state-anxiety scores, the State-Trait Anxiety Inventory (STAI) was used. The musical intervention consists of a repertoire of classical songs played through headphones, lasting approximately 26 minutes. For the quantitative variables, descriptive analyses were used to analyze the differences between state-anxiety, heart rate and respiratory rate, *Student*'s t- test and *Mann-Whitney*'s nonparametric test to evaluate the difference between blood pressure, oxygen saturation and cortisol levels.

Results: The group submitted to musical intervention did not present a statistically significant reduction in state-anxiety scores ($p = 0.31$). Nevertheless, significant reductions in heart rate ($p=0.006$), respiratory rate ($p=0.007$) and blood cortisol levels ($p<0.001$) were observed.

Conclusion: Music did not reduce the state-anxiety levels. We were able to demonstrate the effectiveness of the intervention in reducing physiological and laboratory parameters though, which are altered in the face of anxiogenic situations.

Resumo

Objetivo: Avaliar os efeitos da música sobre a ansiedade-estado, parâmetros fisiológicos e laboratoriais, em doadores de sangue.

Métodos: Ensaio clínico randomizado, duplo-cego, realizado em um Hemocentro Regional, localizado no interior de Minas Gerais. Participaram do estudo 126 doadores de sangue, divididos aleatoriamente em dois grupos, sendo grupo experimental (intervenção musical antes da doação de sangue) e grupo controle (rotina padrão). Utilizou-se para a avaliação dos escores de ansiedade-estado, o Inventário de Ansiedade Traço-Estado (IDATE). A intervenção musical constitui-se de um repertório de músicas eruditas aplicadas através de fones de ouvidos, por aproximadamente 26 minutos. Para as variáveis quantitativas empregou-se análises descritivas, para análise das diferenças entre os escores de ansiedade-estado, frequência cardíaca e respiratória, utilizou-se Teste t *Student* e, Teste não paramétrico de *Mann-Whitney* para avaliar a diferença entre os valores de pressão arterial, saturação de oxigênio e níveis de cortisol.

Resultados: O grupo submetido à intervenção musical não apresentou redução estatisticamente significativa dos escores de ansiedade-estado ($p=0,31$). Entretanto, observou-se reduções significativas na frequência

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Conflicts of interest: *original article extracted from the doctoral dissertation - The effect of music on the anxiety of blood donors: randomized clinical trial – presented to the Graduate Program in Health Care at Universidade Federal do Triângulo Mineiro (UFTM), Uberaba, Minas Gerais, Brazil, in 2018.

cardíaca (p=0,006), frequência respiratória (p=0,007) e níveis de cortisol sanguíneo (p<0,001).

Conclusão: A música não reduziu os níveis de ansiedade-estado. Contudo, foi possível demonstrar a eficácia da intervenção na redução de parâmetros fisiológicos e laboratoriais, os quais apresentam-se alterados frente a situações ansiogênicas.

Registro Brasileiro de Ensaios Clínicos (ReBEC): RBR-6tvbdn

Resumen

Objetivo: Analizar los efectos de la música sobre la ansiedad-estado, parámetros fisiológicos y de laboratorio en donantes de sangre.

Métodos: Ensayo clínico aleatorizado, doble ciego, realizado en un centro de donación de sangre regional, ubicado en el interior del estado de Minas Gerais. Participaron en el estudio 126 donantes de sangre, divididos aleatoriamente en dos grupos: un grupo experimental (intervención musical antes de la donación de sangre) y un grupo de control (rutina normal). Para analizar la puntuación de la ansiedad-estado, se utilizó el Cuestionario de Ansiedad Estado Rasgo (IDATE). La intervención musical estaba compuesta por un repertorio de música erudita aplicada con auriculares, durante 26 minutos aproximadamente. Para las variables cuantitativas, se emplearon análisis descriptivos. Se utilizó el test-T *Student* para analizar las diferencias entre la puntuación de la ansiedad-estado, la frecuencia cardíaca y respiratoria y la prueba no paramétrica de *Mann-Whitney* para analizar la diferencia entre los valores de presión arterial, saturación de oxígeno y niveles de cortisol.

Resultados: El grupo sometido a la intervención musical no presentó reducción estadísticamente significativa en la puntuación de la ansiedad-estado (p=0,31). Sin embargo, se observaron reducciones significativas en la frecuencia cardíaca (p=0,006), frecuencia respiratoria (p=0,007) y niveles de cortisol sanguíneo (p<0,001).

Conclusión: La música no redujo los niveles de ansiedad-estado. No obstante, fue posible demostrar la eficacia de la intervención para la reducción de parámetros fisiológicos y de laboratorio, que se presentan alterados ante situaciones ansiógenas.

Introduction

Anxiety is considered one of the main factors that can negatively affect the process of blood donation, especially the donors' return, and is also correlated with the occurrence of adverse events.[1] Anxiety before blood donation was related to symptoms of vasovagal reactions and was considered to have a negative influence on the probability of donors' return, especially young, female and first-time donors.[2]

In recent years, the results of several studies have demonstrated the effectiveness of music in the control and reduction of anxiety, in various contexts. Studies have shown a reduction in anxiety scores in surgical, oncological patients, in patients with renal insufficiency undergoing hemodialysis, when confronted with invasive procedures and diagnostic tests.[3-9]

There are certain indications that music, especially relaxing music, produces anxiolytic effects by promoting the control of seizure and activation of the autonomic nervous system.[10] Studies have shown that music is able to lower high levels of stress and that certain types of music, such as meditative or slow classical music, reduce neurohormonal markers of stress and, consequently, physiological indicators such as blood pressure, respiratory rate and heart rate.[11,12]

Music therapy is considered an autonomous intervention of the nurse, which focuses, according to the *Nursing Interventions Classification* (NIC) system, on "the use of music to help achieve a specific change in behavior, feeling or physiology".[13]

In fact, studies highlight that the use of music as a light technology has been beneficial in the context of nursing, being considered, therefore, as a simple, safe, low-cost and effective non-pharmacological intervention, which the nursing team can use as a complementary tool in care.[14]

In view of the above, this study aimed to evaluate the effects of music on state-anxiety, physiological and laboratory parameters in blood donors.

Methods

This is a randomized, double-blind, prospective clinical trial (RCT) conducted in a blood bank located in the interior of the state of Minas Gerais, between February and May 2018. Research conducted according to the recommendations of the *Consolidated Standards of Reporting Trials (CONSORT)* for trials that evaluate non-pharmacological treatments,[15,16] registered in the Brazilian Clinical Trials Registry Platform (REBEC), with the primary identifier, RBR-6TVBDN.

1. The study participants were repeat blood donors, sporadic and first-time donors, who donated at the blood bank during the data collection period. The sample size was calculated for both groups, assuming a level of significance equal to $\alpha = 0.01$ and statistical power

of 90%, considering the results obtained in a pilot study, which showed a mean reduction in the state-anxiety score of 1.60 (±1.14) for the experimental group and a mean reduction of 0.60 (±1.67) for the control group. Thus, a sample size of 126 donors was obtained, being 63 donors in the experimental group (EG) and 63 in the control group (CG).

2. The inclusion criteria were: candidates for blood donation aged 18 years or older, male and female, apt in clinical and hematological screening and not using anxiolytic drugs. Candidates for donation with self-reported hearing loss or impairment were excluded.
3. In total, 126 candidates for blood donation were selected for the study, from 1,089 eligible candidates, as shown in Figure 1.

The randomization scheme used in this study was simple randomization, performed with the help of a *website* [http://www.randomization.com], which provides online and free randomization services.[17] This process was performed by a statistician without clinical involvement in the research. After producing the random sequence, a sequentially numbered list was generated to allocate the donors to the groups. To guarantee the concealment of the participants' randomization, their designation was only known to the researcher responsible for the application of the intervention, after contacting the statistician, who kept the list and was responsible for providing this designation when requested.

The researcher who applied the instrument and the laboratory technicians who determined the cortisol levels were masked to the type of intervention each participant received, which characterizes this research as a double-blind study.

For the data collection, a specific instrument was developed, which three experts knowledgeable on the issue submitted to content validation. This instrument consisted of questions related to the participants' identification, sociodemographic variables (age, sex, level of education, marital sta-

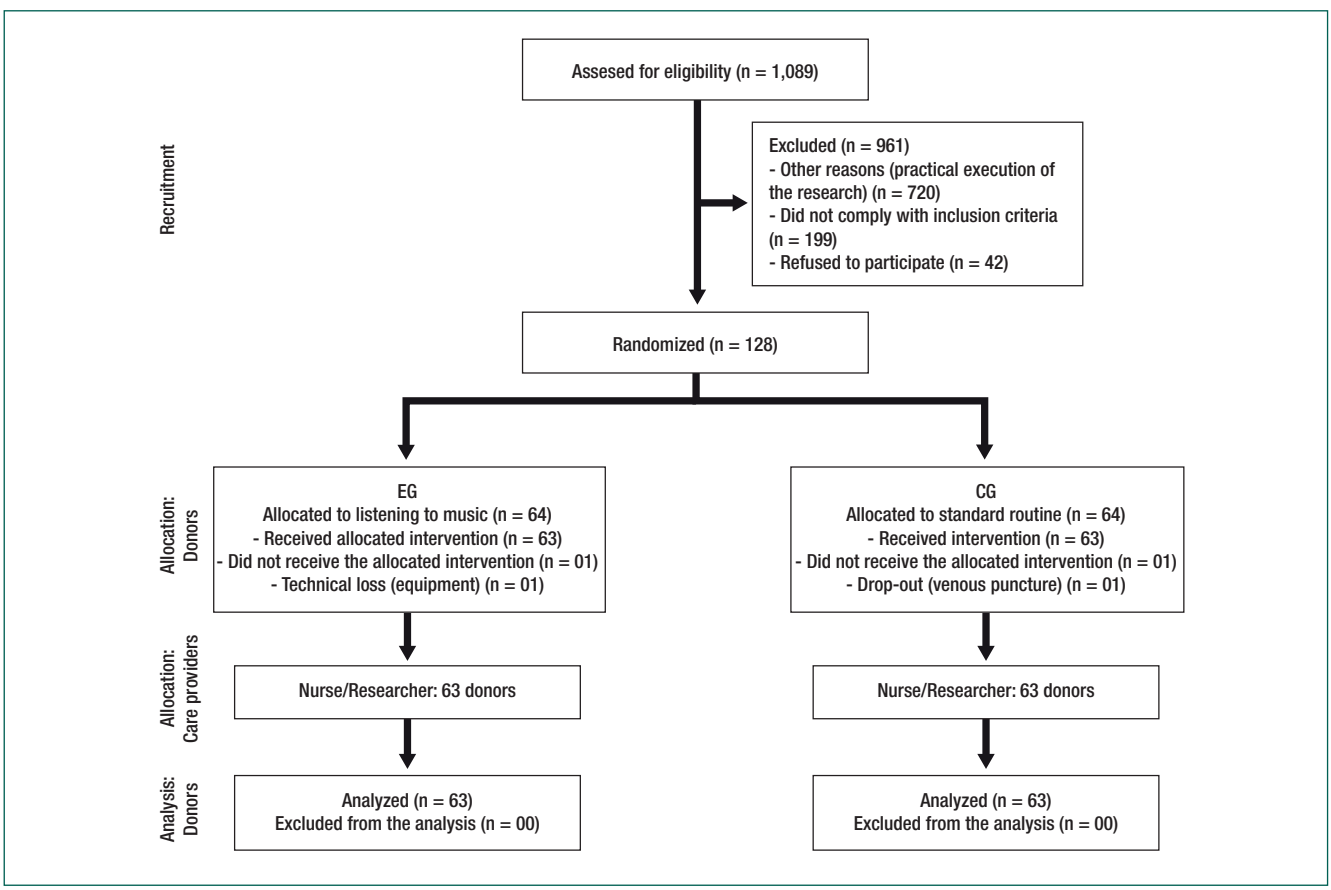

Figure 1. Flowchart of participants involved in the study, as recommended by the *CONSORT Statement*

tus, profession) and variables related to the donation process (shift and type of donation, number of donations). To assess the levels of anxiety, we used the State-Trait Anxiety Inventory (STAI). This instrument has been translated and validated for the Portuguese language and consists of two scales developed to measure two different concepts of anxiety: trait anxiety, (STAI-T), that is to say, the individual's normal state, or a personality trait, and state anxiety (STAI-S), which is defined as a transitory cognitive-affective condition, the current state of the anxiety, or feelings of the individual at that time.[18]

In this study, the anxiety scores of STAI-S were analyzed, in which the response options are: absolutely not (=1); a little (=2); quite a lot (=3) and very much (=4). The total score ranges from 20 to 80 points. After adding up the scores, for correction purposes, the scores of items 1,2,5,8,10,11,15,16,19 and 20 (1=4, 2=3, 3=2 and 4=1) need to be reversed.[19,20]

Regarding the measurement of physiological parameters (blood pressure, oxygen saturation, heart rate and respiratory rate), all were verified before and after the intervention or standard routine and before the blood donation. The pressure measurement technique followed a protocol recommended by the Guidelines for Arterial Hypertension Management in Primary Health Care in Portuguese Language Countries.[21] The More Fitness® portable adult pulse oximeter was used to measure the heart rate and oxygen saturation. On the other hand, the respiratory rate was measured by observing the respiratory movements (inspiration and expiration) for one minute.

Blood cortisol levels were measured before and after the intervention or standard routine. Nursing professionals collected the blood samples (3 to 5 ml) at two different times. The first sample was collected in the hematological screening sector, after obtaining the identification data and measuring the anxiety scores and physiological parameters. The second sample was obtained in the collection room, in the donation chair, after evaluating the state-anxiety scores and measuring the physiological parameters, before the blood donation.

Data collection took place before the blood donation procedure. Participants were selected in the donor care sector, after being screened for clinical and hematological aptitude. One of the researchers, who is a member of the team, approached the candidates, informing and inviting them to participate in the study. Candidates who met the inclusion criteria were asked to sign the Informed Consent Form (ICF).

The data collection tool and STAI were applied to the participants in both groups, their physiological parameters were measured and their blood cortisol was dosed. The donors allocated to the EG listened to the music before they donated blood. One of the researchers conducted the intervention in a private room, where the donors received the headset connected to an MP3-player, with an audio-recording of a collection of instrumental and classical songs.

The volume was tested and adjusted beforehand to enhance the listener's comfort and the room was prepared with closed doors, lights off and a comfortable position, as recommended in the guidelines for the use of musical intervention for the purpose of relaxation.[13] The donors were instructed to switch off their mobile devices while listening to music and to remain in a comfortable position in the reclining chair with their eyes closed. The environment was prepared for the intervention with reduced luminosity and closed door and window shutters. The room temperature was kept at 23º C and the air-conditioning was adjusted. The researcher timed and remained close to the donor only during the first five minutes of the intervention, in order to certify the proper functioning of the equipment used, as well as the satisfactory adjustment of the music volume.

The repertoire for this study consisted of six instrumental and classical songs: *Cello Suite No. 1, Prelude* (Johann Sebastian Bach); *Nocturne Op. 9 No. 2* (Frédéric Chopin); *Clarinet Concerto In A Major K 622 Adagio* (Wolfgang Amadeus Mozart); *Gymnopédie No. 1* (Erik Satie); *The Carnival of the Animals - Le Cygne* (Camille Saint-Saëns) and *Piano Concerto No. 21, k 467, 2nd movement* (Wolfgang Amadeus Mozart).

The total duration of the collection was 26 minutes and 24 seconds. A minimum of 20 minutes of uninterrupted listening time is required to induce relaxation, accompanied by deep breathing before starting the musical intervention.[13]

After the end of the music, the participant was taken to the collection room to donate blood. In the donation room, immediately before the venous puncture, the instrument for assessing state-anxiety scores was again applied, as well as the verification of physiological parameters. After the venous puncture for blood donation, when the samples were collected for blood typing and serology, a new blood sample was collected for blood cortisol dosage.

The participants allocated to the CG did not listen to music before donating and followed the usual flow to the collection room for the blood donation procedure, according to the standard routine recommended by the institution, in which the candidate for donation, after screening for clinical and hematological fitness, proceeds to the collection room for the blood collection procedure. In the collection room, immediately before the venous puncture, the instrument was again applied to assess the state-anxiety scores, verify the physiological parameters and dose the blood cortisol.

The primary outcome of the study was the reduction (difference) of state-anxiety scores, obtained after subtracting the state-anxiety scores, pre- and post-intervention or standard routine, in both groups. The secondary outcomes refer to the reduction (difference) between the systolic blood pressure (SBP), diastolic blood pressure (DBP), heart rate (HR), respiratory rate (FR), oxygen saturation (sat. O2) and blood cortisol. The independent variable consists of the repertoire of instrumental and classical songs.

For the data analysis, we used *Statistical Package for the Social Sciences (SPSS 21.0)* software. The double-typing technique was applied and the significance level used was α=0.01. To test the hypothesis of homogeneity of the two groups (control and experimental), the t-test for independent samples was used for the quantitative variables (age and number of donations) and the Chi-Square homogeneity test for categorical variables (sex and first donation). The continuous variables were submitted to the normality test using the *Shapiro-Wilk* Test.

For the quantitative variables, descriptive statistics were used, through descriptive central trend and dispersion measures. *Student*'s t-test for independent samples was used, in order to analyze the mean difference between pre-and post-intervention state-anxiety scores or standard routine between the groups and evaluate the effectiveness of the intervention on state-anxiety (outcome variable), HR and RF. *Mann-Whitney*'s nonparametric test was used to analyze the mean difference between SBP, DBP, O2 saturation and cortisol levels, pre- and post-intervention, or standard routine between groups, also aiming to evaluate the effectiveness of listening to music on these variables.

This study complied with the national standards for research involving human beings and was submitted to the Research Ethics Committees of the Universidade Federal do Triângulo Mineiro, CAAE: 63470216.4.0000.5154, opinion n. 1.916.589 and Hemominas Foundation, CAAE: 63470216.4.3001.5118, opinion 2.155.174.

Results

The study sample consisted of 126 blood donors, being 63 donors in the EG and 63 in the CG. Table 1 shows the data for the sociodemographic characteristics, donation process and homogeneity tests.

We investigated the homogeneity of the study sample regarding sex and first-time donations (Chi-Square test) and age and number of blood donations (t- test). The tests showed that the control and experimental groups were comparable when considering these variables.

Most of the blood donors participating in the study were female (50.8%), married/fixed partner (59.5%), with higher education degree (43.7%), age group between 30 and 49 years (59.5%), with a mean age of 33.81 years (SD=9.34). Regarding the blood donation process, the participants donated in the morning (53.2%), the majority being spontaneous donations (65.10%). Regarding the number of blood donations, 57.9% of the donors had al-

Table 1. Sociodemographic characteristics, characteristics of the donation process and homogeneity tests for the variables age, number of blood donations, sex and first donation; considering the control and experimental groups

Sociodemographic and donation process variables	CG (n=63)		EG (n=63)		p-value
	Mean	SD‡	Mean	SD‡	
Age in years	35.13	9.22	32.49	9.34	0.114‖
Number of blood donations	6.90	11.17	6.52	9.53	0.837‖
	n(%)		n(%)		
Sex					
Female	27 (42.9)		37 (58.7)		0.075¶
Male	36 (57.1)		26 (41.3)		
Level of education					
Elementary School	11 (17.4)		10 (15.9)		-
Secondary education	26 (41.3)		24 (38.1)		
Higher education	26 (41.3)		29 (46.0)		
Marital status					
Married/fixed partner	38 (60.3)		37 (58.7)		-
Single	21 (33.3)		23 (36.5)		
Divorced (a)	04 (6.4)		03 (4.8)		
Type of donation					
Replacement	18 (28.6)		14 (22.2)		-
Spontaneous	38 (60.3)		44 (69.9)		
Call	07 (11.1)		05 (7.90)		
First blood donation					
Yes	14 (22.2)		14 (22.2)		1.00¶
No	49 (77.8)		49 (77.8)		

‡SD = standard deviation; ‖ - homogeneity test (p-value) for the calculation of the T-test; ¶ - homogeneity test (p-value) referring to the calculation of the Chi-Square Test.

ready donated between one and 10 times, with a mean attendance of 6.71 (SD=10.34).

When investigating the effectiveness of listening to music on the mean difference (reduction) in the state-anxiety scores, physiological parameters and cortisol level before and after the intervention (intergroup analysis), the results of Table 2 showed that the reduction in the state-anxiety scores was greater in the group submitted to the intervention, without a significant difference (p = 0.31). In relation to the systolic blood pressure, the mean reduction was greater in the experimental group, without statistical significance (p = 0.17). As for the diastolic blood pressure, the mean difference was equal for both groups, with an increase in mean values (p = 0.98).

In the analysis of the effectiveness of the intervention for the heart rate and respiratory rate, a greater mean reduction was observed in the experimental group, with a statistically significant difference (respectively, p = 0.006; p=0.007). O_2 saturation values showed that the mean was higher in the experimental group, but without statistical significance (p = 0.31). As for the blood cortisol levels, the results also showed a greater reduction in the experimental group, with a significant difference between the groups (p<0.001) (Table 2).

Table 2. Intergroup comparison of the difference in state-anxiety scores, levels of physiological parameter and blood cortisol, pre-and post-intervention, considering the control and experimental groups

Variables/Groups		n*	$M_{difference}$†	Median	SD‡	p-value§
State-Anxiety	Control	63	-0.38	-1.00	6.07	0.31β
	Experimental	63	0.70	1.00	5.85	
Blood pressure (systolic)	Control	63	0.79	0.00	9.89	0.17Ω
	Experimental	63	2.68	0.00	7.90	
Blood pressure (diastolic)	Control	63	-1.75	0.00	8.71	0.98Ω
	Experimental	63	-1.75	0.00	9.25	
Heart rate	Control	63	4.73	4.00	7.01	0.006β
	Experimental	63	8.70	9.00	8.74	
Respiratory rate	Control	63	-1.40	-2.00	2.64	0.007β
	Experimental	63	0.03	0.00	3.15	
O2 saturation	Control	63	-0.21	0.00	1.65	0.31Ω
	Experimental	63	-0.35	0.00	1.08	
Cortisol	Control	63	-1.07	-0.06	4.82	<0.001Ω
	Experimental	63	2.40	1.29	7.97	

* n = number of participants; † = mean difference (reduction); ‡ = standard deviation of differences; § = p-value; β = Student's t-test; Ω = Mann-Whitney test.

Discussion

The findings of this study showed that listening to a pre-selected repertoire of instrumental and classical songs before donating blood, assessed through the IDATE, did not significantly reduce state-anxiety scores. Nevertheless, there was a positive impact on physiological parameters and objective measures, with significant reductions in heart rate, respiratory rate and blood cortisol levels.

These results corroborate other studies that focused on the use of musical intervention as proposed here, but were developed with patients in different contexts or clinical situations. Clinical trials conducted with adult cancer patients and patients with chronic kidney disease on hemodialysis indicated that the group subject to classical music showed statistically significant reductions in the physiological parameters evaluated (BP, RF, HR), cortisol and state-anxiety levels.[4,8,22]

Significant reductions in the vital parameters, as well as in state-anxiety scores, were evidenced in other studies, either in the context of invasive procedures, such as endoscopy,[23] aspiration and bone

marrow biopsy, [9] and, in the preoperative surgical context.[14]

Other studies have also confirmed that intervention using relaxing songs did not only reduce physiological parameters, but also decreased cortisol levels.[8,22-25] Specifically regarding the impact of listening to music on cortisol levels, other studies also showed significant reductions in the levels of this marker.[26-28] According to Suzuki et al.,[29] music has a direct influence on the reduction of cortisol, which is the stress hormone.

Although responses to music are often considered subjective, research suggests that cardiorespiratory variables respond to musical stimulation in an objective way, that is, the subjective responses of music have shown very objective physical effects, both of which are certainly mediated by the brain.[30]

Scientific evidence shows that music serves as complementary therapy that favors the relief of anxiety. Although some studies do not indicate significant reductions in mean state-anxiety scores, it is important to highlight the satisfaction, cooperation and comfort the patients reported when this tool is used before and during the procedures.[31-33]

It is emphasized that one determining aspect in the use of musical intervention for anxiolytic purposes is the choice of the musical genre or style. According to Krout,[34] classical music is often used for relaxation purposes, being considered a broad musical style, composed of some musical elements, which causes the listeners to perceive the music as relaxing. In their systematic review, Idrobo-Avila et al.[35] highlighted the use of classical music in musical interventions as the most used musical style, played mainly through headphones, with the listener in the sitting position more often than in the supine position and with listening sessions lasting around 15 to 30 minutes in most studies. These findings corroborate the intervention proposed in this research and reaffirm the results found.

The following were considered as limitations of this study: the conduct of the research in a single center; the choice of a pre-selected repertoire of instrumental and classical songs, because the individualized choice of music is still a controversial factor in the literature; in addition to the losses of potential participants, due to the limited physical space at the place of study.

Conclusion

Based on this study, we can conclude that hearing a repertoire of preselected instrumental and classical songs was not effective to control and reduce the state-anxiety scores. Nevertheless, there was a statistically significant reduction between the groups concerning the physiological and laboratory parameters, such as heart rate, respiratory frequency and blood cortisol levels.

Acknowledgements

The authors declare that part of this research received financial support from the Pro-Rectory for Research and Undergraduate Studies (PROPPG) of Universidade Federal do Triângulo Mineiro (UFTM), Call PROPPG/UFTM N.02, of January 09, 2017, Call for Funding to UFTM Researchers.

Collaborations

Silva KFN, Felix MMS, Barbosa MH declare that they contributed to the design of the study; data collection, analysis and interpretation, writing of the article, relevant critical review of the intellectual content and final approval of the version for publication. Hass VJ, Cruz LF declare that they contributed to the design of the study; data collection, analysis, and interpretation; final approval of the version for publication. Barichello E, Pires PS, Mattia ALD declare that they contributed to the writing of the article, relevant critical review of the intellectual content and final approval of the version for publication.

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