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Alves Firmeza, Mariana; Bezerra Rodrigues, Andrea; Alcântara Alencar Melo, Geórgia; Freire de Aguiar, Maria Isis; da Cunha, Gilmara Holanda; Peres de Oliveira, Patrícia; de Moura Grangeiro, Alex Sandro

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Control of anxiety through music in a head and neck outpatient clinic: a randomized clinical trial

Uso da música no controle da ansiedade em ambulatório de cabeça e pescoço: ensaio clínico randomizado

Uso de música en el control de la ansiedad en clínicas externas de cabeza y cuello: ensayo clínico aleatorizado

Mariana Alves Firmeza¹, Andrea Bezerra Rodrigues¹, Geórgia Alcântara Alencar Melo¹, Maria Isis Freire de Aguiar¹, Gilmara Holanda da Cunha¹, Patrícia Peres de Oliveira², Alex Sandro de Moura Grangeiro³

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- ¹ Universidade Federal do Ceará, Fortaleza, CE, Brazil.
- ² Universidade Federal de São João Del-Rey, Divinópolis, MG, Brazil.
- ³ Universidade Federal da Paraíba, João Pessoa, PB, Brazil.

ABSTRACT

Objective: Evaluating the effectiveness of a musical intervention in reducing anxiety and vital parameters in people suffering from head and neck cancer. Method: A randomized controlled clinical trial, performed in a head and neck outpatient clinic with 40 participants, subdivided into two groups (intervention and control). The classical music "Spring" from The Four Seasons by Vivaldi was used as an intervention. The State-Trait Anxiety Inventory (STAI) was used as the data collection instrument, along with an inventory of socio-demographic and clinical data. Student's t-test was used to verify intragroup and intergroup statistical significance. Results: Participants presented a statistically significant reduction in levels of perceived anxiety (t = 12.68; p<0.001), as well as blood pressure levels (t = 4.56; p<0.001); pulse (t = 6.15; p<0.001) and respiratory rate (t = 5.10; p<0.001). Conclusion: Music has proven to be an effective non-pharmacological therapeutic resource in managing anxiety in an outpatient setting for people with cancer, as well as in reducing blood pressure, pulse and respiratory rate. Brazilian Registry of Clinical Trials: RBR-7W4YJJ.

DESCRIPTORS

Music Therapy; Anxiety; Head and Neck Neoplasms; Humanization of Assistance; Oncology Nursing.

Corresponding author:

Andrea Bezerra Rodrigues Rua Alexandre Baraúna, 1115 Sala 12 – Rodolfo Teófilo CEP 60177-415 – Fortaleza, CE, Brazil andreabrodrigues@gmail.com

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INTRODUCTION

Physiological and psychological effects of using music have been described in different publications, including changes in blood pressure, heart rate, respiratory rate, muscle relaxation, pain reduction, and hormonal secretion including endorphins, among others⁽¹⁻⁴⁾. Some authors claim that music produces an anxiolytic effect for being related to an affective meaning, and that by generating pleasure, it lessens anxiety. In addition to activating other areas of the brain, its processing has an effect on the mesolimbic dopaminergic pathways, which justifies its anxiolytic effect for generating positive reinforcement and reward responses⁽⁵⁾. In that sense, in addition to being an excellent and affordable easy-to-use therapeutic tool that has no side effects, it can also be used in various contexts and for various diseases^(2,3).

The term anxiety comes from the Greek *anshein*, which means to oppress, to suffocate, and can cause changes in the body such as increased heart and respiratory rates⁽⁶⁾. The presence of anxiety in cancer patients, as well as their negative implications in the experience of the disease ratifies the importance of identifying suitable instruments for its evaluation and diagnosis⁽⁷⁾. In addition, an increase in the survival of this population justifies the search for non-pharmacological methods that lead to an improvement in their quality of life⁽⁸⁾.

Anxiety brings with it neurophysiological changes, influencing blood pressure which causes tachycardia, altering pulse and respiratory rates. Thus, anxious individuals experience higher expectations and may present variations in their vital signs, thus requiring professionals to monitor them more closely⁽⁹⁾. In addition to monitoring, interventions in order to reduce anxiety can and should be applied, as in the case of music; an intervention recommended by the *Nursing Interventions Classification* (NIC) and defined as "the use of music to help achieve a specific change in behavior, feeling, or physiology"⁽¹⁰⁾.

Patients with head and neck cancer (HNC) in outpatient treatment may experience anxiety due to several factors. HNC encompasses the lips, oral cavity, oropharynx, nasopharynx, hypopharynx, nasal cavities, paranasal sinuses, larynx and salivary glands⁽¹¹⁾. In epidemiological terms, there is a Brazilian estimate by the National Institute of Cancer (INCA) of 596 thousand new cases diagnosed for the disease in the 2016-2017 biennium⁽¹²⁾. Due to its anatomical location, such cancers can promote functional changes related to feeding, breathing, communication, and it can also affect social interactions between other spheres. The different forms of treatment also generate the possibility of several complications such as xerostomia, radiation caries, osteorradionecrosis, mucositis, and it may compromise significant psychosocial functions for the patient and their families⁽¹³⁾.

Among the different treatments widely used for head and neck cancer are surgery, radiotherapy and chemotherapy. The surgeries to which these patients are submitted to generate speech, chewing and swallowing impairments, palate alteration, and edema due to the lymph nodes being removed, among others, leading to a marked decrease in quality of

life⁽¹⁴⁻¹⁵⁾. In addition to these factors, cancer is a disease that causes changes in the quality of life, leading to depression and anxiety^(6,8), which can influence control over their own lives and the treatment^(6,15).

At the same time, outpatient care may generate anxiety related to expecting bad news and disinformation regarding procedures by the professionals involved in outpatient care. Many of the patients treated present a high level of stress, regardless of the disease degree of complexity⁽¹⁶⁾.

Providing dignified and humanized care to people affected by cancer is fundamental, since the conditions caused by an oncological disease are not restricted to the physical dimension. Thus, minimizing suffering and the consequences that arise from the disease and its treatment is important; in this context, nurses must also analyze their role, seek to identify changes and seek interventional measures aiming to reduce them, as in the case of anxiety. In view of the reported benefits of music in reducing anxiety, our objective was to investigate its influence in reducing anxiety and vital parameters in HNC patients in outpatient treatment, considering that studies in this specialization scenario are scarce.

METHOD

This is a randomized, controlled clinical trial. The study was developed in an outpatient clinic for treating patients with head and neck cancer of a university hospital in the state of Ceará, Brazil. This outpatient clinic attends patients in post-surgical, radiotherapeutic or chemotherapeutic treatment.

The population was composed of patients undergoing outpatient care and who met the following inclusion criteria: patients with head and neck cancer in the post-surgical period, undergoing chemotherapy or radiotherapy; over 18 years of age, literate, with a score equal to 15 on the Glasgow scale and preserved auditory acuity according to propaedeutic tests (Weber's test and Rinne's test).

Patients who had used anxiolytics within 24 hours before application of the music intervention were excluded, along with those with thyroid cancer due to extremely different biological behavior of other described anatomical sites. Individuals who were in palliative care were also excluded.

For comparing means between control and experimental groups in the sample calculation using a 95% confidence level and statistical power of 80%, and considering a minimum difference to be detected of 5 points in the outcome variable, it was found that an amount of 38 patients would be effective for this study. However, we aimed to reach a higher number for greater efficacy, meaning 40 patients.

For those who met the inclusion criteria, the randomization process was performed using the random number table generated in the Epi-Info program version 7.1.4. We emphasize that in order to guarantee concealment of the participant's allocation, their designation was only known to the study administrator after opening a properly sealed envelope which contained the condition selected for that participant.

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The research stages were carried out based on this procedure and after designating the participants for each of the groups (Control group – CG, and Experimental group – EG), which included measuring vital signs and applying the instruments and music to the EG. After the experimental manipulation was performed, a second measurement (retest) was carried out in which the previously reported measurements were measured again.

Data collection took place from March to June 2015. Two instruments were used for data collection: the first containing sociodemographic and clinical data, and the second being the self-applied STAI scale (*State-Trait Anxiety Inventory*)⁽¹⁷⁾, translated and adapted for Brazil⁽¹⁸⁾. STAI is comprised of two scales (anxiety-trait and anxiety-state), each consisting of 20 items with assertions for the subjects to describe how they feel. State Anxiety refers to a transient emotional state, characterized by subjective feelings or tension that may vary in intensity over time. Trait Anxiety refers to a relatively stable disposition to respond to stress with anxiety, and a tendency to perceive a greater range of threatening situations.

For the present study, only the state anxiety scale (20 questions) was used, since the objective was to evaluate anxiety during outpatient treatment. The responses were scored by Likert scale, as follows: 1 – almost never; 2 – sometimes; 3 – often; 4 – almost always. The total scale ranges from 20 to 80 points. Ten questions had inverted weight for anxiety-state (questions: 1, 2, 5, 8, 10, 11, 15, 16, 19, 20). The total score is a simple sum of the normal and the inverted weights obtained. A relaxing type of music was chosen as recommended in a previous study which demonstrated that relaxing music is best suited to provide feelings of tranquility as it can reduce agitation, anxiety and promote relaxation and pleasure⁽¹⁹⁾.

Classical music was used as the musical intervention; "Spring" from the four seasons composition by Vivaldi⁽²⁰⁾ was chosen for having the desired characteristics for the study. It also has 60 to 80 beats per minute, which corroborates the assertion that songs with 60 to 70 beats per minute contribute to a relaxing effect⁽²⁰⁻²²⁾. In its first musical movement, (Allegro) has an E Major tonality and quaternary

rhythm (4/4). In the second movement (Largo), the tonality changes to C minor, and the rhythm becomes ternary (3/4). In its last movement (Allegro Pastorale), the tonality returns to E Major, and the rhythm becomes quaternary again (12/8)⁽²³⁾.

The song was played with an MP3 player through headphones for a period of 30 minutes in a room reserved for this purpose. The volume was controlled by the participant, and in that period they had no contact with health professionals or companions. The researcher remained close to the participant for the first 5 minutes and the last 5 minutes of the listening.

Data were analyzed using the Statistical Package for Social Sciences (SPSS) version 20.0. All the anxiety-state scale items were added to calculate the anxiety level. Student's t-test was performed in order to verify the intragroup and intergroup statistical significance.

Ethical approval was obtained by the Research Ethics Committee of the Universidade Federal do Ceará under number 1.108.036. All ethical precepts for national and international research were followed.

RESULTS

The sample consisted of 40 people with head and neck cancer. Fifty-five (55) patients were evaluated for eligibility; of these, 11 did not meet the inclusion criteria and four quit participating.

The majority of the participants were female (80.0%), predominantly Catholic, with age ranging from 33 to 80 years of age. Distribution by treatment type was: surgery (47.5%), surgery associated with chemotherapy (25.0%), chemotherapy associated with radiotherapy (12.5%), surgery associated with chemotherapy and radiotherapy (7.5%), and exclusively chemotherapy (5.0%).

In comparing pre- and post-intervention periods of the anxiety-state scale, all participants (100.0%) of the experimental group had a reduction in the measured anxiety levels. This represented an average reduction of 10.5 points between the values observed between the first and second applications (Figure 1).

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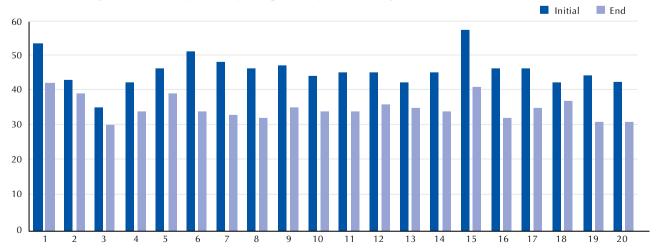


Figure 1 – Total STAI scores (anxiety-state subscale), first and second applications (experimental group) – Fortaleza, CE, Brazil, 2015.

It was observed that there was a 15.0% increase in anxiety levels in the CG participants between the first and second measurements; there was no change in 10.0%, and there was a decrease in 75.0%. In general terms, we observed a mean reduction of three points between the values observed in the first and second applications.

Although the musical intervention was performed in only one of the groups (EG), a decrease in mean anxiety

scores was found for both CG and EG. However, in comparing the magnitudes of these reductions through the Student's t-test, it was possible to verify that the participants allocated in the experimental group ($M_{difference}$ = 10.5; $SD_{difference}$ = 3.72) presented a statistically superior reduction (t = 6.68; p<0.001) in the level of reported anxiety compared to participants allocated to the Control condition ($M_{difference}$ = 3.00; $SD_{difference}$ = 3.41) (Table 1).

Table 1 – Comparison of mean difference between anxiety-state scores in pre and post-intervention periods for the control and experimental conditions – Fortaleza, CE, Brazil, 2015.

Groups	N	M _{difference*}	SD _{difference**}	4.7-1)	_	CI 95%	
				t (gl)	p	Inf	Sup
Experimental	20	10.5	3.72	((0 (20)	0.001	5.26	9.83
Control	20	3.00	3.41	6.68 (38)	< 0.001		

^{*}Mean of the differences observed in scores between first and second application of the Anxiety-State Scale.

Regarding the effect of the musical intervention on the reported level of anxiety, it was specifically verified for the EG participants that the anxiety levels in the post-intervention period (M = 34.9; SD = 3.29) were statistically lower (t = 12.68, p<0.001) to those reported before the intervention (M = 45.4, SD = 4.58). We also sought to verify the effects of the musical intervention when considering the participants' category regarding their anxiety level (low, moderate, high or very high), according to the (STAI) instrument's original proposition.

In the first measurement, 17 CG participants were classified as having a moderate anxiety level, while three had a high level. In the second measurement, all 20 participants of this condition were classified as having a moderate anxiety level. For EG patients, a similar distribution to CG at the first measurement was observed, where 17 participants

were classified as having a moderate level and three were classified as having high level of anxiety. However, after the intervention (2nd measurement), 11 participants (55.0%) were reclassified as having a low anxiety level, while nine participants (45.0%) presented a moderate anxiety level.

Regarding vital parameters, a similarity was found in relation to anxiety levels. Participants exposed to the musical intervention generally presented a reduction in all parameters measured: 95.0% presented a reduction of systolic blood pressure; 55.0% had reduced diastolic blood pressure; 100.0% had reduced heart rate and 85.0% had an observed reduction of respiratory frequency (Figure 2). This represented an average decrease of 10.95 mmHg in systolic blood pressure; 3.85 mmHg in diastolic blood pressure; 7.50 beats per minute in heart rate and 2.25 inspirations per minute.

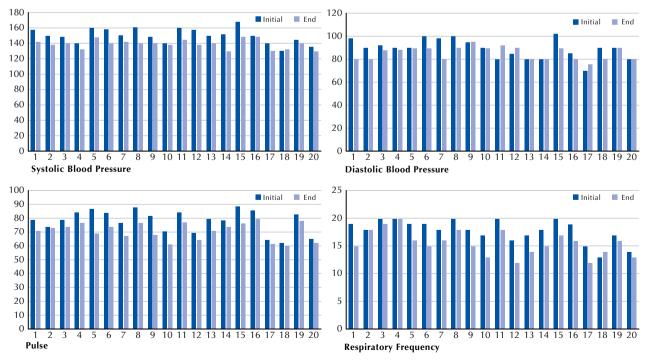


Figure 2 – Vital parameters in the pre and post-intervention periods (experimental group) – Fortaleza, CE, Brazil, 2015.

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^{**} Standard deviation of the differences observed in the scores between the first and second application of the Anxiety-State Scale. Note: (N = 40).

Regarding the vital parameters of CG participants, 55.0% presented a reduction in systolic blood pressure; 30.0% had reduced diastolic blood pressure; 55.0% presented reduced heart rate and 35.0% had reduced respiratory

frequency (Figure 3). This represented an average decrease of 2.75 mmHg in systolic blood pressure; 1.00 mmHg in diastolic blood pressure; 1.05 heart beats per minute and an average increase of 0.15 inspirations per minute.

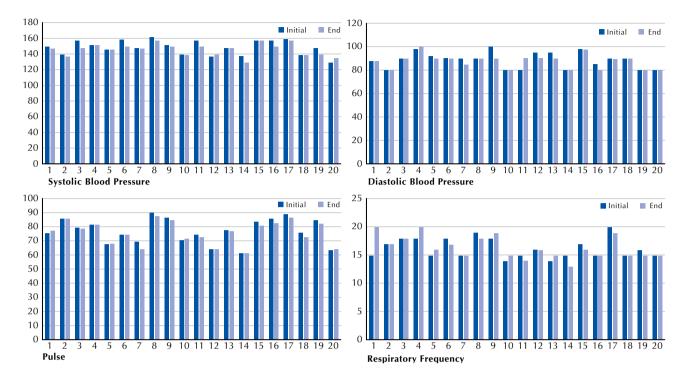


Figure 3 – Vital parameters in the pre- and post-intervention periods (control group) – Fortaleza, CE, Brazil, 2015.

EG participants had a greater reduction in all observed parameters when compared with CG participants. Student's t-test (Table 2) was used in order to verify statistical difference, demonstrating that the reductions observed in the experimental condition were statistically higher than those observed in the Control group for systolic blood pressure (t = 4.56; p<0.001), pulse (t = 6.15; p<0.001) and respiratory frequency (t = 5.10; p<0.001). No significant difference were

observed regarding diastolic blood pressure (t = 1.47; p = 0.14) between the reduction level occurring in the Control and Experimental groups.

When solely evaluating EG participants and comparing pre- and post-intervention periods, a statistically significant reduction was observed for systolic blood pressure (t = 7.13; p<0.001), heart rate (t = 7.71; p<0.001) and respiratory frequency (t = 6.78; p<0.001) between the two periods.

Table 2 – Comparison of the vital parameters difference between the pre- and post-intervention periods for Control and Experimental conditions – Fortaleza, CE, Brazil, 2015.

D	C	N		CD	4 (-1)	_	CI 95%	
Parameters	Condition		M _{difference*}	SD _{difference**}	t (gl)	p	Inf	Sup
Custolia Bland museums	Experimental	20	10.95	6.87	4.56	< 0.001	4.56	11.84
Systolic Blood pressure	Control	20	2.75	4.16	(31)			
Diagnolic Pland procesure	Experimental	20	3.85	7.73	1.47	0.14	-1.07	6.77
Diastolic Blood pressure	Control	20	1.00	3.89	(28)			
Heart rate	Experimental	20	7.50	4.35	6.15	< 0.001	4.33	8.57
neart rate	Control	20	1.05	1.76	(25)			
Pagniratory Eroquancy	Experimental	20	2.25	1.48	5.10	< 0.001	1.45	3.35
Respiratory Frequency	Control	20	-0,15	1,50	(38)			

^{*}The mean of the differences observed in the scores between the first and second application of the Anxiety-State Scale. ** Standard deviation of the differences observed in the scores between the first and second application of the Anxiety-State Scale. Note: (N = 40).

DISCUSSION

Laryngeal and oral cavity cancers are the most frequent of the head and neck region, having worldwide incidence of 455,805 cases, of which 78,958 occur in the Americas (the study site)⁽²⁴⁾. Women predominated in this study, which is due in part to smoking and alcohol habits which have been increasing in both genders⁽¹²⁾.

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Considering EG participants, the anxiety state reduction was remarkable when comparing the means in the pre-test and post-test periods. This fact corroborates the literature, which shows that musical interventions are capable of producing various therapeutic effects, such as reducing pain, stress and anxiety, promoting comfort, and muscle relaxation, among others⁽²⁵⁾. The person in a stressful situation such as in the treatment of cancer, seeks support in coping mechanisms such as family, a belief or listening to music that calms them down⁽¹⁶⁾.

Regarding anxiety, it was possible to notice a slight, yet statistically significant reduction of CG mean score, where participants remained at rest for 30 minutes in a room without receiving the musical intervention. This effect can be related to the attention given by the researcher to the individual, who stayed near them in the initial 5 minutes and the final 5 minutes. Calming and reassuring approaches, as well as active listening can reduce anxiety⁽⁶⁾.

Praying is a strategy used by some people to meet their spiritual needs⁽⁶⁾, as mentioned by the CG participants. They reported that during the 30 minutes without musical intervention they used religiousness, which may justify the slight reduction in anxiety when analyzing the means of this group, considering all followed some type of religion.

A study that proposed and validated a functional approach model and qualification of nursing care at a cancerology institute in Colombia has identified that in the experience of care where a cure is not always possible, as in the case of oncology, there is a deep sense of spirituality that unites the being with a superior force that helps them to rethink their relations with themselves and with others⁽²⁶⁾.

The data were in agreement with the literature in analyzing the effects of a musical intervention considering participants' categorization regarding their anxiety levels⁽⁸⁾. Regarding vital parameters, it was not possible to identify a statistically significant reduction in the means presented in the pre-test and post-test period.

In the EG, a statistically and clinically significant reduction of systolic blood pressure, heart rate and respiratory frequency averages were found comparing the pre and posttest periods. This reduction corroborates a study that affirms the effective effect of music in reducing these parameters⁽²⁷⁾. Other studies have also been successful in reducing anxiety

symptoms and vital parameters; mainly in blood pressure, heart rate and chemotherapy⁽²⁸⁾, and after radical mastectomy surgery⁽²⁹⁾.

All health professionals need to be aware of the many effective strategies they can implement to enhance patients' quality of life, whether through music, effective interpersonal communication or other methods in order to improve health outcomes and the provision of care in a safe manner.

The opportunity to converse and use communication as a support for treating anxiety and fear related to cancer treatment was evidenced in the reports of patients from a high complexity oncology unit⁽³⁰⁾, suggesting that these patients feel this need.

CONCLUSION

All EG participants had reduced anxiety status. Among those who received the musical intervention, 85% were classified as having a moderate level of anxiety before applying the music. After the intervention, the majority (55%) were classified as having a low anxiety level. Moreover, they presented a statistically significant reduction in almost all the evaluated symptoms in comparison with CG. An average reduction of 10.95 mmHg in systolic blood pressure, 3.85 mmHg in diastolic blood pressure, 7.50 heartbeats per minute for pulse and 2.25 inspirations per minute in respiratory frequency were verified.

In the CG, a decrease with statistical and clinical significance was also observed, also slight in almost all vital parameters, with an average of 2.75 mmHg in systolic blood pressure, 1.00 mmHg in diastolic blood pressure, 1.05 heartbeats per minute and a mean decrease of 0.15 inspirations per minute in the respiratory frequency.

The results cannot be generalized to all institutions since the study was conducted in only one Brazilian institution. Despite this limitation, the results are relevant for nurses' knowledge and for practice on the use of music for controlling anxiety in an outpatient care setting. Nurses should observe problems arising from anxiety, identify changes in their clinical practice, and implement strategies for its control in the various spheres of care in oncology. Organizational support and training for oncological nurses are needed to improve adherence to these strategies.

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RESUMO

Objetivo: Avaliar a efetividade de uma intervenção musical na redução de ansiedade e parâmetros vitais em pessoas acometidas por câncer de cabeça e pescoço. Método: Ensaio clínico controlado, randomizado, realizado em ambulatório de cabeça e pescoço com 40 participantes, subdivididos em dois grupos (intervenção e controle). Foi utilizada como intervenção a música clássica "Suave primavera" das quatro estações de Vivaldi. Como instrumento de coleta de dados foi empregado o Inventário de Ansiedade Traço-Estado (IDATE) e um inventário de dados sociodemográficos e clínicos. O teste t de Student foi utilizado para verificar a significância estatística intragrupo e intergrupos. Resultados: Os participantes apresentaram redução estatisticamente significante nos níveis de ansiedade percebida (t = 12,68; p < 0,001), bem como nos níveis de pressão arterial (t = 4,56; p < 0,001); pulso (t = 6,15; p < 0,001) e frequência respiratória (t = 5,10; p < 0,001). Conclusão: A música mostrou-se um recurso terapêutico não farmacológico eficaz no manejo da ansiedade em contexto ambulatorial para pessoas com câncer, bem como na redução de pressão arterial, pulso e frequência respiratória. Registro Brasileiro de Ensaios Clínicos: RBR-7W4YJJ.

DESCRITORES

Musicoterapia; Ansiedade; Neoplasias de Cabeça e Pescoço; Humanização da Assistência; Enfermagem Oncológica.

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RESUMEN

Objetivo: Evaluar la eficacia de una intervención musical en la reducción de la ansiedad y los parámetros vitales en personas que sufren de cáncer de cabeza y cuello. Método: ensayo clínico controlado, aleatorizado, realizado en un ambulatorio de cabeza y cuello con 40 participantes, divididos en dos grupos (intervención y control). Fue utilizado como intervención la música clásica "Suave Primavera" de Las Cuatro Estaciones de Vivaldi. Como instrumento de recolección de datos se utilizó el Inventario de Ansiedad Estado-Rasgo (STAI) y un inventario de datos socio-demográficos y clínicos. Se utilizó la prueba t de Student para evaluar la significación estadística intra-grupo y entre grupos. Resultados: Los participantes mostraron una reducción estadísticamente significativa en niveles percibidos de ansiedad (t = 12,68; p <0,001), así como en los niveles de presión arterial (t = 4,56; p <0,001); pulso (t = 6,15, p <0,001) y la frecuencia respiratoria (t = 5,10, p <0,001). Conclusión: La música demostró ser una herramienta terapéutica no farmacológica eficaz en el tratamiento de la ansiedad en el ámbito ambulatorio para personas con cáncer y también en la reducción de la presión arterial, el pulso y la frecuencia respiratoria. Registro Brasileño de Ensayos Clínicos: RBR-7W4YJJ.

DESCRIPTORES

Musicoterapia; Ansiedad; Neoplasias de Cabeza y Cuello; Humanización de la Atención; Enfermería Oncológica.

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