Music Therapy Reduced Nauseas and Pain Of The Patients Undergoing Hematopoietic Stem Cells Transplantation Autologous (Randomized Clinical Trial)

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Abstract

Purpose: The autologous hematopoietic stem cell transplantation (HSCT Aut) is a therapeutic medical treatment for various neoplastic hematologic, congenital, genetic or acquired disorders. In this procedure which combines high-dose chemotherapy and/or radiotherapy and has a high degree of cytotoxicity, the patient experiences solitary confinement, which causes psychological distress, anxiety, mood, fatigue, nauseas, pain and can lead him/her to depression. Music therapy applied with the purpose of decreasing this social confinement. This is a randomized clinical trial.

Method: n=45 patients were selected randomly. n=24 were selected for the Experimental Music Therapy Group (EMG) and n=21 received music therapy intervention for the Control Group (CG) who received the standard treatment. The intervention of live music was applied using music therapy methods and techniques. Assessment and quantification made using the visual analog scale (VAS). The dependent variables were nauseas and pain of patients.

Results: The student t test applied, (p <0.05) considered statistically significant when comparing the groups, reducing nauseas and pain significantly

Conclusion: Music therapy reduced nausea and pain of the patients undergoing hematopoietic stem cells transplantation autologous, providing bio-psychosocial welfare.

Introduction

The motivation to carry out this investigation took place through the music therapy sessions applied in a previous study during the trajectory in the master's degree, developed at the bone marrow transplant service of the clinical hospital complex of the Federal University of Paraná. Variables that were not, investigated but that provoked reflections, due to the patients' reports. Many reported having slept better on the days when music therapy was applied others forgot about the pain during the music therapy experience there were also reports of decreased nausea and expressions of relaxation.

Hematopoietic Stem Cell Transplantation (HSCT) is a therapeutic clinical treatment that consists of replacing hematopoietic stem cells of the diseased bone marrow, or deficit, with healthy cells [1].

This procedure combines high doses of chemotherapy, radiotherapy and has a high degree of toxicity, causing damage to the quality of life of patients for 100 days after transplantation. [2].

The Autologous Transplant is based on the removal of progenitor cells, or hematopoietic stem cells, from the patient's own marrow that undergoes a cryopreservation process and intracellular protection such as DMSO and freezing at 196º C in Nitrogen, while the patient undergoes a conditioning regimen that receives high doses of chemotherapy through the catheter. To eradicate the diseased cells that populate the bloodstream [3].

The authors above and his collaborators point out that organic toxicity causes heart problems, osteoporosis, infections, cataracts, infertility. In addition, pulmonary and other organ complications occur. This condition often results in worsening quality of life, secondary to the transplantation process and possible the post-transplantation in the short, medium and long term.

[4] highlights the patient's fragility in the face of a malignant disease that threatens life causing physical, social and emotional changes from diagnosis to more advanced stages of the disease.

There are countless works involving music therapy in the relief of human suffering. [5] Carried out a research in order to determine how the intervention of this specialty could help in the prevention or reduction of
psychophysiological stress in adolescent patients with cancer, during the hospitalization period. The results found evidenced the beneficial effects that music therapy brought to the development of strategies to cope with stress during hospitalization. In addition, the reduction of suffering was identified through the inclusion of moments of distraction, entertainment, tranquility, physical and emotional well-being.

However, in the hospital context, the premise that music by itself does not have the same scope that it can have when applied with the specific knowledge of music therapy and the competence of the Music Therapist is considerable.

In Brazil, hospital institutions at the national level still lack the effectiveness of music therapy as a profession. At the same time, it appears that publications with research, related to music therapy in journals with respected scientific impact, are increasingly rising to the top of current therapy modalities. However, the contribution of this specialty to the patient’s psycho-emotional balance can be more effective, since it provides comfort, welcoming decreased morbidity, inherent to the treatment and, consequently, improves the quality of life.

The study is also justified by the perspective of more humanized care, and in the context of bone marrow transplantation, music therapy has enabled patients to undergo this treatment that causes a lot of suffering, with greater emotional balance and bio psychosocial well-being.

[6] Show in his study of the music therapy intervention in this population submitted hematopoietic stem cells transplantation allogeneic, results of improved mood, decreased anxiety and pain relief.

The contribution of music therapy intervention in reducing negative effects the nausea and pain disorders was measured and analyzed statistically and resulting the decreased nausea and pain.

**Materials And Methods**

**Study Design**

It is a randomized clinical trial

**Place:** Erasto Gaertner Hospital Bone Marrow Transplant Unit. The research developed between May/2018 and August/2019

**Population:** Adult patients undergoing hematopoietic stem cell transplantation (HSCT) Autologous.

Approved by the ethics committee in the research of the Erasto Gaertner Hospital Certificate of Ethical Presentation and Appreciation (CAAE) number 82882017.6.0000.0098 and Registered in (REBEC) Registration Brazilian Clinical Trials RBR 3h4csb

**Sample Calculation:** The calculation of the sample size based on a previous pilot study for which an average of 2.9 identified for the pain score with a standard deviation of 2.4. It was felt that this group corresponded to the control group of the new study, and a minimal difference in the pain score of 1 point higher in the Experimental group would be clinically relevant. For a significance level of 5% and a test power of 80%, it would require at least 20 cases in each group (Control Group and Experimental Music therapy Group).

**Randomization:** Before starting the research, the randomization of 45 numbers. Carried out by the program http://www.randomizer.org, which were inserted into an opaque envelope in the randomized order and the envelopes numbered from the outside in the sequential order from 1 to 45.

The random selection for allocation of the patient to the groups took place as follows: After the patient agreed to participate in the research and having signed the FICF, the envelope was opened in front of the patient and it was agreed that the “even” number would comprise the group that will receive the music therapy intervention, referred to as the Experimental Music Therapy Group (GEM), and the 'odd' number will make up the
Control Group (GC), the group that will not receive the music therapy intervention.

**INCLUSION CRITERIA**

The invitation made to each patient submitted to (HSCT) Autologous between 18 and 70 years of age, if the patient accepted to participate in the research, he/she would then have to sign a free, prior and informed consent form (FPIC).

**METHOD**

Live music through music therapy techniques provided by a qualified music therapist performing popular songs that are part of the social musical cultural identity of the patient. For example: the music therapist and patient sing together the latter’s preferred songs with guitar accompaniment, with the patient following the rhythm of the music playing percussion instruments such as: bongo, tambourine, bells, triangle or maracas, among others, in an interactive process, using music therapy techniques such as: Popular songs chosen by patients with singing and improvisation with rhythmic production activities. The sessions were individual and took place in the room beside the patient's bed, three times a week, with each session in the Experimental Music Therapy Group lasting 30 minutes.

A one-hour session would be ideal, but due to bone marrow aplasia conditions (low immunity), this would cause excessive fatigue in patients. Through an earlier pilot study, found that one hour per week, divided into two 30-minute sessions, one on Tuesday and another on Thursday, would be more appropriate given the patients’ conditions.

Live music has tremendous power to energize patients and provides greater emotional impact. In addition, the human presence of the music therapist results in patients feeling welcome, clinical listening, attention, resonance and enhancement of the interactive expressions of the patient.

Nausea and pain levels in the Experimental Music Therapy Group measured using a visual analogue scale (VAS) [7], before and after the music therapy session.

Apply the visual analog scale (VAS), to measure the levels of nausea and pain in the Control Group (CG) that received just the standard treatment.

**MATERIAL**

[7] Visual Analog Scale (VAS) was used to assess the dependent variables nausea and pain. It was collected quantitative data regarding the subjective responses of patients to visual analog scale (VAS) applied before and after the intervention in EMG. And the data collected also in the CG did not receive music therapy.

(VAS) visual analog scale, is a numerical scale ranging from 0 to 10, it is widely used to measure the intensity of pain, but also can be used to measure pain, breathlessness, anxiety, fatigue, and moods.

Operating range (nausea=0 “no nausea” nausea=10 “extreme nausea”), (pain=0 “no pain”, pain=10 “extreme pain”).

**Demographic Questionnaire Clinical** It was also collected personal data and clinical patient demographics, such as name, address, age, sex, religion, Education, Social Class, diagnosis and resources cells.

**Questionnaire of music therapy** to collect musical information, musical preferences, the family, the parents and patients. Possession of musical information the music therapist preparing a unique repertoire for each patient, and Thus begins the process of the sessions interventions production of live music by the techniques of music therapy recreation of songs and improvisation with rhythmic production activities.
Prior and informed consent form (FPIC) All patients signed an informed consent.

Results

For a description of the quantitative variables the statistics, mean, minimum, maximum and standard deviation were considered. For the summarization of the qualitative variables, frequencies and percentages were considered. To evaluate the homogeneity of the groups in relation to the distribution of scores of qualitative variables the Chi-square test was considered. For comparison of groups, in relation to quantitative variables, the student t test was considered. P values less than 0.05 indicated statistical significance.

EVALUATION OF HOMOGENEITY OF GROUPS WITH RESPECT TO DEMOGRAPHIC AND CLINICAL VARIABLES

For each of the qualitative variables analyzed, we tested the null hypothesis of equal distribution of ratings in both groups versus the alternative hypothesis of different distributions.

(Table 1)

COMPARISON OF EXPERIMENTAL MUSIC THERAPY GROUP AND CONTROL GROUP IN RELATION TO ASSESSMENTS OF NAUSEAS AND PAIN

The tables below shows the descriptive statistics for this varibles at the two moments evaluated as well as the p value of the statistical EMG.

(Table 2 and Table 3)

Discussion

The patient with neoplastic hematologic disease goes through great emotional, physical, psychological and social distress. It was, observed, that patients experience a lot of anxiety, pain and mood disorders, nausea, insomnia, and fear of death. The action of Music therapy interventions enabled the reduction of symptoms, side effects of the treatment, redeeming the socio-cultural-sound contact, through the recreation of songs, their cultural environment and reducing the feeling of social confinement imposed by the (HSCT Aut) procedure. In this randomized experimental trial, the visual analog scale (VAS) [7] used to assess the dependent variables of nausea and pain, which showed a statistically significant decrease.

The presence of the professional in interactive activity with the patient, singing and playing an instrument, percussion and accompanying himself on the guitar, listening to their musical expressions and giving emphasis to the patient's experience, this provides presence and care. Although all the studies published around the world come showing that despite they are methodologically diverse, but with similarities in relation to patients facing cancer treatment is a focal point in common with the present study; The results of quality of life and well-being, bio psychosocial of all the patients that submitted for this treatment.

Conclusion

Music therapy showed decreased in the results the nausea and pain with significance statistical in this present study. More results maybe with number patients bigger are interesting for the contributing growing this modality of therapy. Because it is non-expensive and non-invasive very well accepted by patients and does not offer any risks in this extremely controlled environment. I hope that other music therapists around the world can
reapply more studies.

Declarations

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AUTHOR DISCLOSURE STATEMENT

RESEARCHER:
CARLOS ANTONIO DÓRO = No competing financial interests exist.

TUTOR:
DR. JOSÉ ZANIS NETO = No competing financial interests exist.

COTUTOR:
SERGIO KOWALSKI = No competing financial interests exist.

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Tables

TABLE 1
| Gender | EMG          | CG          |
|--------|--------------|-------------|
|        | N    | %      | N    | %      |
| Female | 10   | 41.7%  | 7    | 33.3%  |
| Male   | 14   | 58.3%  | 14   | 66.7%  |
| Total  | 24   | 100%   | 21   | 100%   | P: 0.565 |

| Age    |              |            |
|--------|--------------|-------------|
|        | N    | %      | N    | %      |
| Adult  | 12   | 50.0%  | 16   | 76.2%  |
| Elderly| 12   | 50.0%  | 5    | 23.8%  |
| Total  | 24   | 100%   | 21   | 100%   | P: 0.186 |

| Schooling |            |            |
|-----------|--------------|-------------|
| First Degree | 11   | 45.8%  | 8    | 38.1%  |
| High School   | 5    | 20.8%  | 7    | 33.3%  |
| University Degree | 8    | 33.3%  | 6    | 28.6%  | P: 0.639 |
| Total         | 24   | 100%   | 21   | 100%   |

| Social Class |            |            |
|--------------|--------------|-------------|
| Low         | 9    | 37.5%  | 16   | 76.2%  |
| Average     | 15   | 62.5%  | 5    | 23.8%  |
| Total       | 24   | 100%   | 21   | 100%   | P: 0.009 |

| Religion |            |            |
|----------|--------------|-------------|
| Evangelical | 7    | 29.2%  | 11   | 52.4%  |
| Catholic  | 17   | 70.8%  | 10   | 47.6%  |
| Total     | 24   | 100%   | 21   | 100%   | P: 0.43  |

| Diagnostic |            |            |
|------------|--------------|-------------|
| Non-hodgkin lymphoma | 6    | 25.0%  | 10   | 47.6%  |
| Multiple myeloma   | 17   | 70.8%  | 10   | 47.6  |
| Testicular Tumor    | 1    | 4.2%   | 1    | 4.8%   |
| Total               | 24   | 100%   | 21   | 100%   |

### TABLE 2

| Group EMG         | n   | Mean | Median | Minimum | Maximum | Standard Deviation |
|-------------------|-----|------|--------|---------|---------|--------------------|
| Nausea before     | 24  | 4.30 | 4.19   | 1.00    | 7.75    | 2.05               |
| Nausea after      | 24  | 0.91 | 0.69   | 0.00    | 3.13    | 0.77               |
| Reduction         | 24  | 3.39 | 3.31   | 0.38    | 6.63    | 1.74               |

(*) Student t test for paired sample; p<0.05

### TABLE 3
| Group EMG     | n  | Mean | Median | Minimum | Maximum | Standard Deviation |
|--------------|----|------|--------|---------|---------|-------------------|
| Pain before  | 24 | 3.29 | 3.25   | 0.00    | 7.50    | 1.93              |
| Paind after  | 24 | 1.37 | 1.06   | 0.00    | 5.25    | 1.16              |
| Reduction    | 24 | 1.92 | 1.69   | 0.00    | 4.63    | 1.22              |

(*) Student t test for paired sample; p<0.05