

**Research Article**

Effects of Music Therapy on Vital Signs and Anxiety: A Study with Terminally Ill Patients

Barbara Antoniazza¹, Monica Patrício Pinto², Matteo Ferraraccio³, Massimo Damini⁴, Damini³, Alfonso Sollami⁴ and Giuseppe Marletta^{5*}

¹University of Parma, Independent researcher, Parma, Italy

²Centre of Palliative Care Piccole Figlie, Parma, Italy

³University of Parma, Centre of Palliative Care Piccole Figlie, Parma Italy

^{4,5}University of Parma, AziendaOspedaliera Parma, Parma, Italy

Aim

The aim of this study is to verify the effectiveness of an intervention of music therapy in reducing anxiety and its influence on hemodynamic values.

Methods

A pre and post-intervention study was adopted. Data was collected over a 6-month period and the sample consisted of 50 patients (convenience sampling) recruited in a Hospice from a northern-central Italian Region. The intervention, that consisted in a 30'-40' live musical performance conducted with various instruments, was preceded (T0) by anxiety assessment using the STAI-S anxiety scale and vital signs (SBP, DBP, HR and BOS) measurements. Eventually, 10 minutes after the end of the music performance (T1) we repeated the same measurements adding two questions regards the patients' acceptance and their willingness to repeat the experience.

Conclusions

Data suggested that the music intervention produced a noticeable effect on reducing anxiety ($p < 0.001$). We obtained a full level of acceptance and willingness to repeat the experience: 100% of the patients considered the session to their liking and only 2 out of 50 patients, declared that they did not want to repeat the experience. We also observed positive effects on both Systolic (SBP) and Diastolic (DBP) Blood Pressure and an improvement of Blood Oxygen Saturation (BOS). We therefore concluded that music could be a safe, simple, inexpensive and non-invasive complementary intervention that can significantly relieve terminally ill patients' anxiety and improve their quality of life.

Keywords: Anxiety; End of life care; Hospice; Music therapy; Nursing; Palliative care

Abstract**Background**

Over the last few years an improvement of healthcare for terminally ill patients has become necessary. This led to the opening of specialized centers in palliative care, the Hospice, in which it became clear that the traditional pharmacological medical approach could have been supported by several kinds of complementary treatments and therapies, such as music therapy, to offer a more effective assistance to improve the patients' quality of life and reduce the discomfort caused by the disease.

Type of Research: Quasi-experimental design, with a semi-structured questionnaire.

***Corresponding author:** Giuseppe Marletta, University of Parma, Azienda Ospedaliera Parma, Parma, Italy, Tel: +39 3394530227, E-mail: GMARLETTA@ao.pr.it

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Introduction

Cancer is one of the leading causes of mortality worldwide and the second leading cause of death. In 2012, there were 14.1 million new cancer cases worldwide, 8.2 million cancer deaths and 32.6 million people living with cancer within 5 years of diagnosis [1]. Although there has been a significant improvement in the survival of the disease, due to the development of new techniques, in both surgical and clinical care, neoplastic patients still have to face the fact that this disease could possibly end their life. This is a real and concrete problem that both health professionals and health organizations have to face every day. In order to cope with this situation, new centers have been created, specialized in treatment of neoplastic patients' end of life in a holistic view of them. Alongside the conventional medical treatments, there is an increase in the use of new, alternative and complementary methods. In fact those kind of treatments can help people with cancer to improve their quality of life and also to better cope with symptoms and/or side effects like anxiety and/or panic or other negative emotions caused by cancer and its related treatments. The world of complementary therapies is very vast and these treatments are used so much that World Health Organization (WHO) itself had to take into account the great use that is made of them (despite a certain

priori-skepticism in the scientific community about their scientific basis of real efficacy), drawing up a real strategy program for the 2014-2023 decade, aimed to try to regulate and redefine the objectives and the areas of complementary treatments. Many of them that are used today, such as acupuncture, traditional Chinese medicine, acupressure and others, have been recognized by some states as therapies only administered by specialists, usually specialized doctors and amortized by the relative National Health Systems [2]. Today music therapy isn't officially considered among the complementary therapies recognized by the WHO, mainly due to the lack of extensive supporting literature and experimental studies aimed to better understand the effects of this kind of supportive treatment. Nevertheless, especially recently, many authors have conducted and published studies concerning the use of music therapy and its effects mainly on anxiety and pain.

Effects of music on pain, anxiety and other self-report data

In literature we discovered that music therapy both in live and pre-recorded forms has been experimented in various healthcare contexts. The findings demonstrate that it can have positive effects on anxiety of patients awaiting surgical procedures [3-5]. In general, positive effects can be observed on anxiety and pain in patients with Coronary Heart Disease (CHD), especially with a myocardial infarction [6]; furthermore music therapy can reduce anxiety [7] and increase well-being in patients during Percutaneous Transluminal Coronary Angioplasty (PTCA) procedures [8]. It has been observed that music can have positive effects on burn victims, which is usually very challenging because of the actual injuries, that represent one of the most severe and painful conditions experienceable. Particularly a reduction of anxiety and pain [9], moreover an improvement in relaxation levels [10], and lastly heart rate reduction [11]. The effects of music therapy have also been studied in Intensive Care Units (ICUs), where patients usually experience high levels of anxiety and confusion. Also in these cases it has been demonstrated that music can reduce anxiety and pain levels and improve the patients' comfort [12,13]. Beneficial effects on anxiety levels were reported in mechanically ventilated patients [14] and a significant reduction in pain and anxiety was observed during paediatric medical procedures performed with [15]. We found that the majority of studies of music application regarded cancer care units/centers probably because we can observe a frequent care integration with music programs as supportive procedures for their inpatients during the treatment processes [16]. In an experimental study the authors tried to understand, with an interview, the perceptions of the meaning of music in the view of patients and their caregivers. Music has been defined, by the caregivers, as a channel or a journey, able to bring both the patient and the caregivers back to temples and 'beautiful and happy' places. In this way, music represented a means of rebuilding, a link between patients and caregivers that allowed them to find themselves 'in themselves'; eventually music could support caregivers in the process of mourning [17]. Other studies with cancer patients showed positive effects on relaxation, physical comfort and pain control [18], mood and quality of life [19]. Lee et al., proved that the relaxation produced by listening to music was similar to that obtained through the techniques of progressive muscle relaxation [20]; eventually Mabel et al., occupied in reviewing qualitative studies, concluded that patients, thanks to music, managed to improve social interaction and communication with the people around them, and felt a more holistic care for their physical, psychological and spiritual needs [21].

Effects of music on vital signs and other quantitative data

As mentioned above, the scientific community usually when doubting complementary treatments (including music) for which scientific evidence proven by solid data is lacking, shows its skepticism. Almost to answer the criticism received, other research fields have been implemented to try to measure the effects on objective and measurable data such as vital signs. They usually report conflicting results and don't confirm with absolute certainty the positive correlation between music and benefits on parameters considered from time to time. The first example is represented by Fooroghy et al., who performed a randomized clinical trial on patients undergone PTCA to evaluate the efficacy of music on anxiety and haemodynamic parameters. The experimental group received a music therapy treatment lasting 20-40 minutes, while the control group maintained standard care. It was found that music has proven to be a safe, simple, inexpensive and non-invasive intervention that can significantly reduce anxiety levels. On the other hand, it was not possible to demonstrate the efficacy on hemodynamic parameters as they were monitored and kept stable throughout medical interventions, to avoid possible dangerous complications for their life [22]. We observed similar results with Taylor-Pilie and Chair with a sample of Chinese male patients undergoing cardiac catheterization. The results of the study showed that the music intervention on the experimental group that was performed before the intervention regarding the control group, wasn't effective in reducing anxiety levels or improving mood, nor did they affect vital parameters [23]. Maybe the most significant evidence shown in literature regarding the effects of music therapy administered both in 'live form' (music interventions performed by trained music therapists) and pre-recorded music (predisposed by medical staff), is the review of Brandt et al., that resumes the production in literature in the last years regarding cancer patients. The evidences highlighted the positive effects (from moderate up to strong) of music both on anxiety levels and pain reduction. Moderate effects were shown on depression; not one effect on mood and distress. The study reported small or moderate effects on fatigue but of scarce influence for improvement in physical functioning. Generally the effects on the patients' quality of life were positive. As for vital signs they observed a small reduction in heart rate, respiratory rate and systolic or diastolic blood pressure but not significant impact on oxygen saturation level [24]. Based on these findings, it was decided to investigate, with our study, if music could be an effective intervention able to reduce anxiety in terminal patients hospitalized in a hospice environment, if it could have an effect on vital parameters such as blood pressure, heart rate and saturation and for how many patients it would be an appreciable and helpful intervention, and also how many would be willing to repeat it.

Methods

Ethical issues

The Hospital's Ethics Committee was informed before the study began; because the research projects did not include invasive methodology and we didn't use personal information to identify the respondent, the ethics committee gave the necessary approval to perform the study. Participation in the study was voluntary.

Participants were informed that all received information was confidential and no personal information could be used to identify the respondent. Consent to participate was assumed on the basis of both of acceptance of active or passive participation to the music activities and filling in and returning of the questionnaire.

Design and data collection

A pre and post-intervention study (single arm) was adopted. Data were collected over a 6-month period in 2017 and the sample consisted of patients (convenience sampling) recruited in a hospice from a Northern-Central Italian Region. The inclusion criteria for participating in this study were as follows, patients not treated with blood pressure and/or heart rate medications, patient without priority diagnosis of COPD, competence to give informed consent, fully competent to stand trial, perfect knowledge of the Italian language. No other patient condition or variable was applied to select the final sample. After receiving their acceptance to the participation, the therapist and the nurse, showed the standard procedure for all participants (including verbal instructions on what to expect before, during and after the musical performance) and they all decided which kind of music should be performed (patient-preferred music). The participants could decide to be actively (playing with) or passively (listening) involved; furthermore the participants could decide the location where the intervention would be performed, either directly inside their hospital room or inside the sitting room (obligatory if piano was required). If they chose to go to the sitting room, they were invited to rest for at least 10 minutes before to perform vital signs measurements and to assess state anxiety. At the very beginning (T0) we proceeded with vital signs measurements and data record: Systolic and Diastolic Blood Pressure (SBP and DBP), Heart Rate (HR) and Blood Oxygen Saturation (BOS); then we assessed state anxiety (under the supervision of a physician) with a validated patient-reporting tool. The subsequent intervention consisted in a 30'-40' period of live musical performance conducted with various instruments (guitar, long and/or wooden flute, maracas, drums, piano) by a therapist and a nurse, both graduates of an Italian music Conservatory. Eventually, 10 minutes after the end of the music performance (T1) and prior to move the patients back to their room (if they were in the sitting room to play piano or flute), we again performed the measurements at baseline: Vital signs and state anxiety, and two questions were added, to evaluate the level of acceptance and their willingness to repeat the experience. Only 2 (1%) patients have chosen the active participation playing piano and/or flute; 48 (99%) patients have preferred to remain in their room and listen music.

Measures

State anxiety

To assess state anxiety, we used a validated patient-reporting tool, extensively used in research and practice, the State Anxiety Inventory-Y1 Italian version [25]. It is a 20-item (e.g., 'I feel calm' or 'I feel safe'), self-report instrument with higher scores reflecting higher levels of anxiety. All responses were on a four-point Likert type scale, in which one indicated lower levels of the measured construct and four indicated higher levels. The scale, in line with the authors, measures only 1 factor (explaining variance pre-intervention 48.0%, post-intervention 48.3%). The internal consistency of the 20 items, was determined through the use of Cronbach's α coefficient and showed that the reliability of the scale was very satisfactory (pre-intervention $\alpha=0.93$; post-intervention $\alpha=0.93$).

Vital signs

Prior vital signs measurements, all the patients had the opportunity to sit for approximately five minutes; all measurements were taken

while the patients were seated and with the arms and the hands at the level of the heart. To evaluate the SBP and DBP, we used a single aneroid sphygmomanometer checked and calibrated [26]. Measurements of SBP and DBP were made sequentially in both arms and registered as the greater values. We measured the HR by palpating the radial impulse of the same arm where the SBP was greater. Lastly, in the same arm, using a pulse oximeter equipped with a disposable adhesive sensor, we took the BOS from forefinger or middle finger, removing anything on the site of application that could absorb light [27]. At the end of the music performance? in addition to the questionnaire, we proposed a single question both to evaluate (T1) the level of liking 'How did you like the music performance?' and to understand their willingness to repeat the experience 'would you like to repeat the experience?'; responses were on a four-point Likert type scale similar to the one used before.

Statistical Analyses

Descriptive statistics, confirmatory factorial analysis, internal consistency and Wilcoxon signed-rank test were computed using IBM SPSS Statistics version 23.0 software package (IBM Corp. 2014). None of the participants were excluded (nobody missed one or more items of the single scale). Means and frequencies were calculated for the demographic data. Since several measures were not normally distributed, because they showed both asymmetry and kurtosis higher than 2 or lower than -2 [28], Wilcoxon's matched-pairs signed rank test were used to determine if changes in scores differed between the pre-intervention (T0) and post-intervention (T1).

Results

Patients characteristics

The characteristics of the patients are shown in table 1. The sample was composed of 50 participants; so were collected a total of 50 (T0)+50 (T1) questionnaires; none of the questionnaires was excluded (no missing values). The sample comprised 23 men (46%), and 27 women (54%). With respect to the participants' age, they all reported their age; 2 (4%) of the participants were 50 or younger than 50, 6 (12%) were between 51 and 60, 13 (26%) were between 61 and 70, 14 (28%) were between 71 and 80, the last 15 (30%) of them were 81 or older.

Characteristics (Entire Cohort N=50)	
Age by group	
< 50 y	2 (4%)
51-60 y	6 (12%)
61-70 y	13 (26%)
71-80 y	14 (28%)
> 80 y	15 (30%)
Gender	
Male	23 (46%)
Female	27 (54%)

Table 1: Patient characteristics.

Vital signs and anxiety measurements

Vital signs and anxiety levels measurements are shown in table 2. We observed, in general, a certain variation (in most cases as we

will show in a positive sense) of the values detected. In fact both SBP (mean pre-intervention=120.40 mmHg, SD=19.92; mean post-intervention 119.56, SD=14.68) and DBP (mean pre-intervention=71.50, SD=10.99; mean post-intervention=70.60, SD=8.96) and lastly, HR (mean pre-intervention=85.94, SD=14.89; mean post-intervention=79.66, SD=12.32), presented lower values between pre and post intervention; on the contrary BOS (mean pre-intervention=95.22, SD=2.86; mean post-intervention=96.60, SD=2.35) presented increased values. The levels of anxiety showed, in average, marked a lowering (mean pre-intervention=2.95, SD=0.569; mean post-intervention=1.834, SD=0.531). Eventually the approval of the music performance by the participants, seemed evident enough (mean post-intervention=3.72, SD=0.45); at the same time, the data showed a clear willingness of the respondents to repeat the performance (mean post-intervention=3.72, SD=0.54).

	Max	Min	Mean	SD	P Value
SBP pre-test (mmHg)	160	85	120.40	19.92	*p=0.82
SBP post-test (mmHg)	160	90	119.56	14.68	**p<0.01
DBP pre-test (mmHg)	100	50	71.50	10.99	*p=0.45
DBP post-test (mmHg)	95	50	70.60	8.96	**p<0.05
HR pre-test (bpm)	120	57	85.94	14.89	*p<0.01
HR post-test (bpm)	107	50	79.66	12.32	
BOS pre-test (%)	99	89	95.22	2.86	*p<0.01
BOS post-test (%)	100	90	96.60	2.35	**p<0.01
State anxiety (STAI-Y1) pre-test	4	1	2.957	0.569	
State anxiety (STAI-Y1) post-test	4	1	1.834	0.531	**p<0.01

Table 2: Vital signs and State Anxiety Inventory (STAI-Y1) measurements (N 50).

Note:

SBP = Systolic Blood Pressure

DBP = Diastolic Blood Pressure

HR = Heart Rate

BOS = Blood Oxygen Saturation

* Considering the entire pre-test and post-test measurements

** Considering only the pre-test and post-test measurements higher/lower than the reference ranges

Systolic Blood Pressure (SBP)

Regarding to all the vital signs, we performed a Wilcoxon matched-pairs signed rank test. Data suggested that in general, median of differences between the pre-test level of SBP (max=160 mmHg, min=85 mmHg, mean rank=18.85) and post-test (max=160 mmHg, min=90 mmHg, mean rank=24.71), wasn't statistically significant ($p=0.822$, $Z=-0.228$). Nevertheless, considering only the SBP levels higher than the reference range [29] (17 out of 50 cases) we observed that the median of differences between the SBP pre-test (max=160 mmHg, min=130 mmHg, mean=143.8 mmHg) and post-test (max=160 mmHg, min=110 mmHg, mean=132.4 mmHg) was highly significant ($P=0.005$, $Z=-2.834$). Among those in 1 case we observed the same levels pre-test and post-test; in only 2 cases we observed higher post-test values (max=+10 mmHg, min=+5 mmHg, mean=+7.5 mmHg) than lower values in the other 14 cases (max=-40 mmHg, min=-5 mmHg, mean=-18.6 mmHg).

Diastolic Blood Pressure (DBP)

We can observe the same results considering DBP values. In general the Wilcoxon matched-pairs signed rank test suggested that median of differences between the pre-test level of DBP (max=100 mmHg, min=50 mmHg, mean rank=14.18) and post-test (max=95 mmHg, min=50 mmHg, mean rank=20.00) wasn't statistically significant ($p=0.472$, $Z=-0.719$). Here again, though, considering only the DBP levels higher than the reference range [29] (19 out of 50) we observed that the median of differences between the DBP pre-test (max=100 mmHg, min=80 mmHg, mean=82.37 mmHg) and post-test (max=95 mmHg, min=50 mmHg, mean=76.05 mmHg) was significant ($P=0.010$, $Z=-2.575$). Among these in 6 cases we observed the same levels pre-test and post-test; in 4 cases we observed higher post-test values (max=+40 mmHg, min=+5 mmHg, mean=+8.75) and lower values in the other 9 cases (max=-30 mmHg, min=-5 mmHg, mean=-13.5 mmHg).

Heart Rate (HR)

As regards HR values in general we already could observe that the median of differences between the pre-test level of HR (max=120 bpm, min=57 bpm, mean rank=14.18) and post-test (max=107 bpm, min=50 bpm, mean rank=24.68) was statistically significant ($p<0.000$, $Z=-3.698$). Lastly, considering only the higher levels than the reference range [30] (9 out of 50), we couldn't proceed with an evaluation of the median of differences because of the scarcity of the sample ($N<16$). In no case we observed equal levels between pre-test and post-test nor higher (max=-42 bpm, min=-3 bpm, mean=-20 bpm).

Blood Oxygen Saturation (BOS)

As regards BOS, we observed that considering the whole median sample of differences between the pre-test levels (max=99%, min=89%) and post-test (max=100%, min=90%) was statistically significant ($p<0.000$, $Z=-4.218$). Patients with pre-test lower levels with respects to reference range [31] were 17 (max=94%, min=89%, mean=91.82%); the difference between pre-test and post-test (max=98%, min=90%, mean=94.35%) was statistically significant ($p<0.000$, $Z=-4.218$). Among those in 2 cases we observed the same values pre-test and post-test; in 2 cases lower values (max=-2%, min=-1%, mean-1.50%) in the other 13 cases we observed higher post-test values (max=+7%, min=+1%, mean+3.53%).

State anxiety level

Our findings showed a relevant reduction in state anxiety levels pre-test and post-test; the Wilcoxon matched-pairs signed rank test suggested that the median of differences between the pre-test level of state anxiety and post-test were highly significant ($p<0.000$, $Z=-5.891$).

Liking and willingness to repeat the experience

Results about liking and willingness to repeat the experience are shown in table 3. We underline the general approval of the music performance by the participants: We can in fact observe that more than two-third of patient expressed their top liking and none of them rated the experience negatively. Even more important the willingness of the respondents to repeat the performance; with only two patient that expressed a certain disagreement to repeat the experience.

	1	2	3	4
Liking helpfulness	0	0	14 (28%)	36 (72%)
	0	2	10 (20%)	38 (80%)

Table 3: Liking and willingness to repeat the experience (N 50).

Discussion

The collected data, in line with the literature, gave a certain confirmation of the possible positive effects of music on terminally ill patients, above all, towards anxiety. The effects on objectively measurable parameters, represented by the four vital parameters examined, have given in general results of improvement, although it is right to underline the scarcity of the sample above all considering the pre-test altered parameters. Nevertheless we can emphasize one aspect, the fact of not having caused worsening conditions of the patients examined, can undoubtedly interpret the data in a positive sense. The good acceptance among patients, the active participation and the availability expressed to replicate the session, highlight the need to share their path of illness and the request to still be considered a whole and aware by people and eager to live emotions and cultivate wishes. It was easy to notice how the initial embarrassment that was felt during a session of music therapy, was soon diluted by the pleasure of listening or playing the melodies, songs that were thought lost in the memory were seen resurfaced as life memories, inextricably linked to the emotions of the moment and the fears that the disease can cause.

Conclusion

The study aims to represent a strong scientific contribution to the full recognition of the value of music that, like other complementary treatments, to this day meet with the scientific community's skepticism. Music and the other complementary treatments/therapies, can greatly improve the emotional conditions of terminal patients and therefore, on the basis of these and other scientific evidence, should be implemented internally in every health setting and not just for terminal cancer patients.

Further studies examining the impact of music interventions on the quality of life of terminally ill patients are necessary. If, on the one hand, we can confirm the positive effect on anxiety, (as a lot of studies have already evaluated), it is also necessary to find further confirmation on the effects on vital signs (or other objectively detectable data) including, for example, a larger sample with initial altered values for pre-test and post-test data comparison.

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- Aquaculture & Fisheries
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- Orthopedic Research & Physiotherapy
- Otolaryngology, Head and Neck Surgery
- Pathology: Clinical & Medical Research
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