Effect of Single Session Receptive Music Therapy on Anxiety and Vital Parameters in Hospitalized Covid-19 Patients: A Randomized Controlled Trial.

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Abstract

Hospitalized COVID-19 patients are vulnerable to different degrees of stress disorders as well as depression, anxiety and fear. The aim of this study was to evaluate the feasibility of introducing Music therapy (MT) on site with Covid-19 patients and investigating the immediate effects a single session has on anxiety, heart rate (HR), oxygen saturation (O2Sat) and satisfaction compared to standard care. A randomized controlled trial of 40 patients was conducted. Participants were assigned to control group (CG) or the MT group (MG). MG received an individual single session of music therapy in presence. CG received standard care. MG and CG were subjected to identical measurements (pre-during-post) of the parameters STAI-Y, HR and O2Sat. Participants in MG were asked to fill in an optional open-ended question concerning their experience with MT. Significant difference in anxiety levels between scores in MG and CG (34.50 (23.25 - 40.00) vs 45.00(38, 25 - 54.00); p = 0.000) was observed. MG compared to CG had statistically significantly higher values of O2Sat (97.50 (96.25 - 99.00) versus 96.00 (96.00- 98.00); p = 0.026). Results show the feasibility of introducing MT as a supporting complementary/non-pharmacological intervention on site in Covid-19 patients. A single session of MT improves O2Sat and can significantly reduce anxiety.

Introduction

The outbreak of the coronavirus disease (COVID-19) has caused great public concern [1], unprecedented challenges to health care systems and huge psychological distress [2].

Hospitalized patients are extremely isolated from their families for a long and uncertain period of time [3]. They remain in an undefined mental space left to wonder if this is a temporary separation or a step towards death [4] which could take place without family or loved ones by their side [5]. This traumatic separation makes patients vulnerable to different degrees of stress disorders as well as depression and anxiety [6], fear of the unknown and dying, sleeplessness, agitation, discomfort, pain, immobility, frustration and inability to relax [7].

Music can be a complementary/non-pharmacological intervention to reduce anxiety and stress during hospitalization.

Music Therapy (MT) is defined as the systematic use of musical experiences aimed at achieving therapeutic goals by a trained music therapist (MTt) and implies the establishment of a relationship between patient, music and MTt, while Music Medicine (MM) is considered as passive listening to pre-recorded music provided to the patient by a nurse or other medical staff [8.]

MT has been shown to play a valuable role in the care of patients with serious illness, helping to address physical symptoms and psychological distress [9]. MT reduces pain, improves sleep quality, decreases anxiety during mechanical ventilation, and induces a relaxation response without the use of medication (Mofredj et al., 2016), lowers the respiratory rate and blood pressure, and has a possible positive impact

on the use of sedatives and analgesics among mechanically ventilated patients [10]. To date, however, there are no studies of MT application on-site with Covid 19 patients.

The primary aim of this study was to evaluate the feasibility of introducing MT on site with Covid 19 patients as a supporting complementary/non-pharmacological intervention.

The secondary aim was to investigate the immediate effects a single MT session has on anxiety, heart rate (HR), oxygen saturation (O2Sat) and satisfaction compared to standard care.

Methods

PARTECIPANTS

Over a 4-week period (from 15th April to 15th May 2021), all patients with SARS-COV2, hospitalized at Covid Hospital Bari, Italy were screend in the study.

Exclusion criteria were (a) age £18 years, (b) severe neurological or psychiatric conditions, (c) hearing impairment, (d) intubation.

Study protocol was approved by the Hospital Ethics Committee of Bari, (n° 6841-09/04/2021) and patients signed an informed consent form.

All methods were performed in accordance with the relevant guidelines and regulations

DESIGN AND PROCEDURE

A mixed-methods approach pre -post design was used to obtain and evaluate data in 2 areas: (1) the feasibility of delivering MT on site in the Codiv19 hospital and (2) the immediate effects of the intervention on patients' HR, O2Sat, anxiety, receptivity, and satisfaction.

This study employed a patient-centered approach in which the music therapist (MTt) tailored interventions to patients' individual needs in that moment (Bradt et al., 2016). An interactive relational approach of receptive MT (Bruscia, 1998a) (Grocke & Wigram, 2007), supplemented by adaptation of the Bonny Method Guided Imagery and Music in the medical setting (MED-GIM) was used (Bruscia & Grocke, 2002) [12].

Participants were assigned to control group (CG) or the music therapy group (MG) by computer simple randomization. Participants in MG received an individual bedside single session of receptive music therapy (RMT) by a certified MTt- GIM fellow in presence. Each session consisted of 4 parts:

(1) patient assessment and prelude to create a safe container in which the patient was able to disclose a concern, facilitating or encouraging a state of mind of wellbeing or enjoyment that is known to the patient [12];(2) induction by brief relaxation exercise to help patients find an image as the focus with a positive

outcome; (3) music listening, prepared and selected by MTt on the basis of these steps, with dialogue between patient and MTt; (4) postlude to validate feelings and reinforce a positive experience [14].

Participants listened to the playlist with bone conduction headphones from Ipod® and volume was controlled by the MTt. The MTt tailored music for each participant was based on the results of patient assessment (Robb, Carpenter, & Burns, 2011). The MTt used music selected from classical music of the Western tradition, pop, rock, new age, soundtrack, light jazz

CG received standard care.

MEASURE

State Trait Anxiety Inventory Y-1(STAI-Y1) was used to measure how the subject felt in that moment. Subjects were asked to rate the intensity of their anxious feelings on 20 items on a four point scale: not at all, somewhat, moderately so, or very much so.

MG and CG were subjected to identical measurements of the parameters STAI-Y, HR and O2Sat.

STAI-Y values <40 defined absence of anxiety, between 40 and 50 mild anxiety, 51-60 moderate anxiety, and> 59 severe anxiety.

From the variables under study the parameter ΔSTAI-Y was derived, defined as the difference between the value of STAI-Y calculated at time T2 minus the value of STAI-Y calculated at time T0. Similarly, the parameters ΔO2Sat% and Δ H.R. were calculated. ΔO2Sat% was defined as the difference between the value of O2 Sat calculated at time T2 minus the value of O2Sat at time T0. ΔHR was defined as the difference between the value of O2Sat calculated at time T2 minus the value of O2Sat at time T0. STAI Y-1 was administered 5 min. before session (STAI Y-1 PRE) and 15 min. after session (STAI Y-1 POST) in paper form in MG and CG.

HR and O2Sat were recorded from the bedside monitor 3 times: start session (T0), 10 min. (T1), end session (T2). At the same time, STAI Y-1, O2Sat and HR were recorded in CG. Participants in MG were asked to fill in an optional open-ended question concerning their experience with RMT. Data collection was carried out by MTt and psychologist researcher.

STATISTICAL ANALYSIS

Continuous variables were expressed as Mean ± SD and median (IQ25, IQ 75) depending on whether they were with normal or non-normal distribution. The dichotomous or non-continuous variables were expressed as%. We verified the non-normal distribution of the continuous variables under study using the One Sample Kolmogorov-Smirnov test.

The dichotomous variables were compared with the Chi Square test.

Variables with normal distribution were compared with the Student's T-test for independent samples and variables with non-parametric distribution were compared with the Mann-Whitney U test. Non-parametric analysis was carried out by means of the Friedman test, and subsequently, if a significance emerged, the two-by-two comparison between the times was carried out with the Wilcoxon test.

To correctly classify the music therapy group with the control group, linear canonical discriminant analysis was used to create a model that optimizes the between sample classes and within-sample class distances. The cross validated accuracy percentage (CVA, %) was calculated.

All analyzes were conducted with the SPSS 23 software. Statistical significance was assumed for p value <0.050.

Results

Forty subjects were randomized into two homogeneous subgroups of 20 patients each.

Patients in MG compared to CG had comparable values of age, sex, P / F ratio (300.56 ± 101.89 vs 267.40 ± 94.65; p = 0.293), use of CPAP or NIV (15% vs 20%; p = 0.500) (Table1).

Subjects in MG immediately prior to the start of the session had similar medians of STAI-Y values with similar percentages of absence of anxiety and mild anxiety. They had higher rates of severe anxiety values (25% vs 0%; p = 0.024) and lower rates of intermediate anxiety values (10% vs 45%; p = 0.015). MG compared to CG also had similar median values of O2Sat and HR.

After 10 minutes from the beginning of the session, the patients in MG compared to those of CG had similar values of HR. It also emerged, however, that in MG the O2Sat was slightly, yet significantly, higher (98.00 (97.00 - 99.00) versus 96.00 (96.00- 98.00); p = 0.026).

At the end of the session, it emerged that the medians of STAI-Y of the subjects who carried out a music listening session compared to the others showed significantly lower values of anxiety (34.50 (23.25 - 40.00) vs 45.00 (38, 25 - 54.00); p = 0.000) and at this time 70% had no anxiety, 30% had low anxiety values and none had moderate or severe anxiety values. In subjects of CG, on the other hand, 35% did not show anxiety, 20% showed low values, 40% moderate values, and 5% severe values. Similarly, MG compared to CG had statistically significantly higher values of O2Sat (97.50 (96.25 - 99.00) versus 96.00 (96.00- 98.00); p = 0.026).

Finally, the patients undergoing RMT presented similar values of HR.

Intra-group comparison between the times T0, T1 and T2

Within the group of patients undergoing RMT there was a significant reduction (p = 0.000) in the anxiety values in the period of time between the end of the music session at time T2 [34.50 (23.25 - 40 , 00)]

compared to the beginning of the session at time T0 [42.00 (38.25 - 60.50)] (Fig. 1A, Fig 2 A). On the other hand, no difference emerged in CG.

As can be seen in Fig.1B, fig. 2B, in Group 1 the O2 Sat% after 10 minutes from the start of the music session (time T1) improved significantly statistically [T0 vs T1: 96.50) vs 98.00%; p = 0.000]. Similarly, at the end of the session (time T2) the significant increase in O2Sat was maintained compared to time T0 [T0 vs T2: 96.50% versus 97.50%; p = 0.000]. The same trend could be seen in HR.

Discriminant Analysis

The derived parameters ΔSTAI-Y and Δ O2 Sat were used to verify how much the improvement in anxiety and oxyhemoglobin saturation were able to discriminate the group undergoing music therapy compared to the control group. As can be seen from Figure 2, 90% of the subjects were correctly classified within the two groups starting from the parameters ΔSTAI-Y and ΔO2Sat. There is no overlap between the two figures as can be seen graphically (Fig. 3)

Discussion

This study supports the feasibility of introducing MT on site in Covid-19 patients as a supporting complementary/non-pharmacological intervention. Results show that a single session of RMT improves O2Sat and can significantly reduce anxiety.

All patients in MG completed the session of RMT and engaged openly with the MTt, with interest and receptivity. The RMT intervention did not prevent standard health procedures and did not hinder the work of health personnel, who proved to be available and collaborative

Results show that MG patients, compared to CG, not only had significantly lower anxiety values in T2 than T0, but 70% had no more anxiety, and 30% had low anxiety values. Considering that anxiety can impose harmful effects on the course of recovery and overall well-being of covid -19 patients, the significant reduction we found in anxiety suggests that MT was particularly helpful and highlights how the RMT intervention can support and contain the numerous stressful factors to which these patients are subjected.

Anxiety and stress affect and arouse sympathetic nervous system with numerous adverse responses including arterial and venous constriction, myocardial stimulation, and bronchoconstriction [15]. Music could have a positive effect on the para-sympathetic system, resulting in a relaxation response characterized by alpha brain wave frequency on the electroencephalogram, and physiologically manifesting itself as a state of muscular relaxation with regular deep breathing and lowered heart rate [16]. These physiological manifestations could be the reason why in MG there was a greater increase in O2Sat in T2 and T1 than T0. This data is important if we consider that increased breathing difficulty and fatigue were two of the most common symptoms in Covid-19 patients.

Previous studies on MT found improvements in anxiety, pain, quality of life, small positive effects on heart rate, respiratory rate, blood pressure, fatigue [17] and positive changes on emotional state, social interaction, and spiritual well-being [1819]. Furthermore, when compared to pharmacological sedation, MT is cost-effective, has no apparent risks and can provide patients and families with physical, emotional, and cultural benefits [20]. However, no studies have yet been conducted with Covid-19 patients in such a complex and difficult setting, both for patients and for the therapists themselves.

The emotional perception of music and its associated physical effects seem to involve catecholamines, but to be engaged in an MT session is first and foremost an experience with music and MTt, and cannot be reduced to physical mechanisms alone. Its therapeutic potential must principally implicate other aspects characteristic of this experience—attitudes, expectations, affects, the imagination, memory, bodily self-awareness-[21]. RMT technique used in this study, together with direct interaction with MTt, helped the patient, stimulated by the music, to find and connect to internal resources of confidence, to cope with the present stress [12] and to facilitate psychodynamic responses.

Our intervention was made up of 4 closely related steps (prelude-induction-listing to music -postlude).

The strength of this approach was in systematically and specifically combining imagery and selected music by MTt and patients. The listening experience involved thoughts, feelings, emotions and all the senses - visual, auditory, kinesthetic, gustatory, olfactory..

As the surrounding environment was filled with artificial light and was distracting, patients were invited to close their eyes and to keep in touch with the images of their focus. All the patients who were involved found a focus with images from nature (sea, meadow, forest). The music prepared and selected by the MTt then began and continued for about 15 to 20 minutes. While listening to the music, a dialogue between the patient and the MTt was possible, encouraging patient's self-exploration. The patient's images that emerged while listening were guided, rather than controlled, by the MTt. In the postlude, the patient was able to validate his/her feelings, reinforcing the positive experience.

While listening to the first music track, many patients began to cry, then became reflective, sharing feelings, thoughts, and memories [11]. Patients reported how crying helped them release stress, anxiety and how they felt safe and secure crying along with the music. None of them stopped listening before the session ended. Within this specific approach to music, the presence of the MTt could provide support, validating the patients' own emotional states through active listening, attunement, and verbal acknowledgment of feelings expressed. Music and images allowed patients to live an experience beyond that of the ward, as if they were in another place, away from the worries and tiredness of the present situation. The music played the role of the co-therapist. In this complex period of emergency, care and human needs, when Healthcare workers are called to respond to the pandemic both clinically and humanely, complementary and interdisciplinary therapies, such as music therapy (MT) can offer a valid support, facilitating the expression of emotions and memories and strengthening patients' self-awareness, social connection, and sense of personal support [22]. Thanks to this individual and

customized intervention, patients in MG were able to express and communicate their feelings, shifting from an anxious and worried state, to feeling calm and content after the session. By the end of the session, many patients appeared soothed, displayed positive affect such as smiling and laughing, and shared appreciative comments about the session (Tab.2).

Limitations

It was not possible to enroll a greater number of participants. Any long-term effects of our single RMT intervention were not evaluated. The duration of the anxiety-reducing effects cannot be determined. Since all of the participants were enrolled from the same hospital, their demographic characteristics might be somewhat similar and might not reflect the characteristics of the broader population. It is also possible that patients' responses could have been biased due to the attention they were receiving from the researcher. Reports of better performance in post intervention questionnaires could have been biased and the Hawthorne effect cannot be excluded.

Conclusions

This study provides important preliminary data that support and encourage the integration of MT into clinical practice. Despite the difficulties of working conditions (IPE) and despite the absence in literature of experiences of MT on site with covid patients, this study demonstrates the feasibility of introducing MT as an important form of support provided in unexpected and unpredictable extreme situations, when applied appropriately and judiciously.

The positive feedback of patients and the indication of a positive clinical impact would suggest the importance of further investigation into how MT can promote comfort and relaxation, lower anxiety, affect physiological outcomes and enhance psychosocial support.

Declarations

AUTHOR CONTRIBUTIONS

F.G. conceived and designed the study, performed all MT session, edited the manuscript; A.L. data collection and analysis ; V.Q. conducted data analysis and Statistical analysis ; N.C. critically reviewed ; E.C. contributed to design sessions, critically reviewed ; A.D. critically reviewed ; L.G. contributed to design sessions, critically reviewed ; A.M. contributed to design sessions, critically reviewed ; N.B. conceived and designed the study, drafted the manuscript

COMPETING INTERESTS STATEMENT

The authors declare no conflict of interest or funding to disclose

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Tables

Table n.1 Comparison of Music Therapy Group(MG) versus Control Group(CG)

	MG n=20	CG n=20	P Value
Age			0,215
M ± DS	57,63 ± 9,00	61,35 ± 9,41	
Sex F %	55,00	25,00	0,100
P/F ratio			0,293
M ± DS	300,56 ± 101,89	267,40 ± 94,65	
NIV/CPAP yes %	15,00	20,00	0,500
STAI-y value pre			0,775
M ± DS	45,95 ± 14,52	44,80 ± 10,42	
median (IQ 25, IQ 75)	42,00 (38,25 – 60,50)	45,00 (36,75 – 54,00)	
SATI-Y <40 pre %	35,00	35,00	0,629
Low SATI-Y pre %	30,00	20,00	0,358
Intermediate STAI-Y pre %	10,00	45,00	0,015
high STAY_Y pre %	25,00	0,00	0,024
STAI value post			0,000
M ± DS	33,60 ± 9,54	46,15 ± 9,16	
median (IQ 25, IQ 75)	34,50 (23,25 – 40,00)	45,00 (38,25 – 54,00)	
STAY<40 post %	70,00	35,00	0,028
LOW STAI-Y post %	30,00	20,00	0,358
Intermediate STAI-Y post %	0,00	40,00	0,002
high STAY_Y post %	0,00	5,00	0,500
FC pre			0,897
M ± DS	81,05 ± 12,38	80,50 ± 14,28	
median (IQ 25 -IQ 75)	78,00 (72,25 – 88,75)	78,50 (73,50 – 82,75)	
FC during	75,25 ± 11,05		0,157
M ± DS	73,00 (68,50,00 -84,50)	81,05± 14,14	
median (IQ 25 -IQ 75)		79,50 (74,25 – 82,75)	

FC post	75,40 ± 10,83		0,166
M ± DS	73,50 (67,50 – 85,00)	80,95 ± 13,83	
median (IQ 25 -IQ 75)		78,50 (73,75 – 83,00)	
O2 Sat pre			0,283
M ± DS	96,15 ± 1,78	96,70 ± 1,38	
median (IQ 25 -IQ 75)	96,50 (95,00 – 97,75)	97,00 (96,00 – 98,00)	
O2Sat during session			0,002
M ± DS	97,95 ± 1,35	96,60 ± 1,23	
median (IQ 25 -IQ 75)	98,00 (97,00 – 99,00)	96,00 (96,00- 98,00)	
O2Sat post			0,026
M ± DS	97,65 ± 1,30	96,65 ± 1,42	
median (IQ 25 -IQ 75)	97,50 (96,25 – 99,00)	96,00 (96,00- 98,00)	
Δ O2 Sat%			0,000
M ± DS	1,50 ± 1,00	-0,050 ± 0,60	
median (IQ 25, IQ 75)	1,50 (1,00 – 2,00)	0,00 (0,00 – 0,00)	
ΔSTAI-Y			0,000
M ± DS	-12,35 ± 8,61	1,35 ± 2,90	
median (IQ 25, IQ 75)	-13,00 (-17,00 - -3,25)	0,00 (0,00 – 0,00)	
Δ H.R.			0,000
M ± DS	-5,65 ± 1,19	0,45 ± 1,27	
median (IQ 25, IQ 75)	-4,50 (-8,00 - -2,00)	0,00 (0,00 – 1,00)	

Abbreviations: P/F ratio: PaO2/FiO2; STAI-y: STAI-y: State-Trait Anxiety Inventory - y form; H.R.: heart rate; O2Sat: oxyhemoglobin saturation; Δ O2 Sat%: difference between the value of O2 Sat calculated at time T2 minus the value of O2 Sat at time T0; TO: time at the start of the session; T1: time during the session; T2: Time at the end of the session ; ΔH.R.: difference between the value of O2 Sat calculated at time T2 minus the value of O2 Sat at time T0; Δ STAI-Y: difference between the value of STAI-Y calculated at time T2 minus the value of STAI-Y calculated at time T0

Significance was assumed for p values <0.050

TAB 2.

1	It was a pleasant experience listening to the music. I felt different feelings and emotions depending on the rhythms, melodies and frequencies I listened to, I associated each track with a particular moment experienced here in the intensive care ward. Some music reminded me of the first phase, when all my thoughts were negative. Then, after going through the psychological and physical trauma that covid induces, the music moved towards recovery. The last track made me cry because I lost my parents to covid.The overall feeling was not of pain but of pleasant memories and associations. I imagined many scenes from nature.
2	I think this is a really useful experience to find peace again. It offered essential psychological support for me. Even though I had my own earphones and access to my music, I had never been able, to reach this level of peacefulness since being here. Thank you.
3	The music upset me a bit at first, but then it helped me reconnect with a part of myself.
4	An incredible experience. I took a trip away from this place
5	It's a very worthwhile experience, almost like being tele-transported to feelings and happy times in our past lives. It's a mental and almost physical escape from a painful place, that doesn't affect your ability to react to such critical moments. Actually, it helps you to escape and distracts your mind from all the problems of the moment
6	Music is a wonderful thing
7	I like this kind of mental escape that you have with music because it helps you forget the negative things here and to think of a better future. On all fronts, from health, to life in general. Thank you ... what a wonderful experience
8	The first thing I felt was curiosity. Imagination. It was like diving. the second track was amazing, relaxing, free... It was like flying like a butterfly, emptied out inside. I felt reborn, clean, completely free.
9	It was wonderful to listen to this music... I 'm crying with joy
10	I imagined myself riding my motorbike with my wife. It's a really positive experience. I recommend it if you're hospitalised here. It helps to escape.
11	Life, love and music is about sharing with the people who matter to you. Being able to share the images and feelings you have with those close to you is definitely a great approach to the world and our lives.
12	A sublime experience. From the first note the music gave me a sense of well-being accompanied by flashes of light. Then it sort of brought me energy. During the third song I thought of death, of sadness, but then I felt serene. At the end I felt reborn. The notes gave me strength, awareness, inner energy. I felt a little stronger. Thank you for letting me be a part of this experience. It made me feel intensely alive and peaceful.
13	On the streets of New York, I imagined being in the middle of the skyscrapers and walking along the boulevards, seeing the shop windows and Italian restaurants... And talking to other Italians like me...
14	After such a long time, from death to life
15	Music not just for patients .. I recommend it for the practitioners too
16	You are giving me so much joy. Thank you for the time you've given me and for this surprise.
17	It was a positive adventure. Music relaxes you and makes you feel good in these moments.

18	How wonderful. Thank you
19	How wonderful. A beautiful moment. There was the sea. I'll always carry this moment with me; every time I'll see the sea I'll remember this moment. It gave me a little extra strength. Thank you
20	Thank you so much

Figures

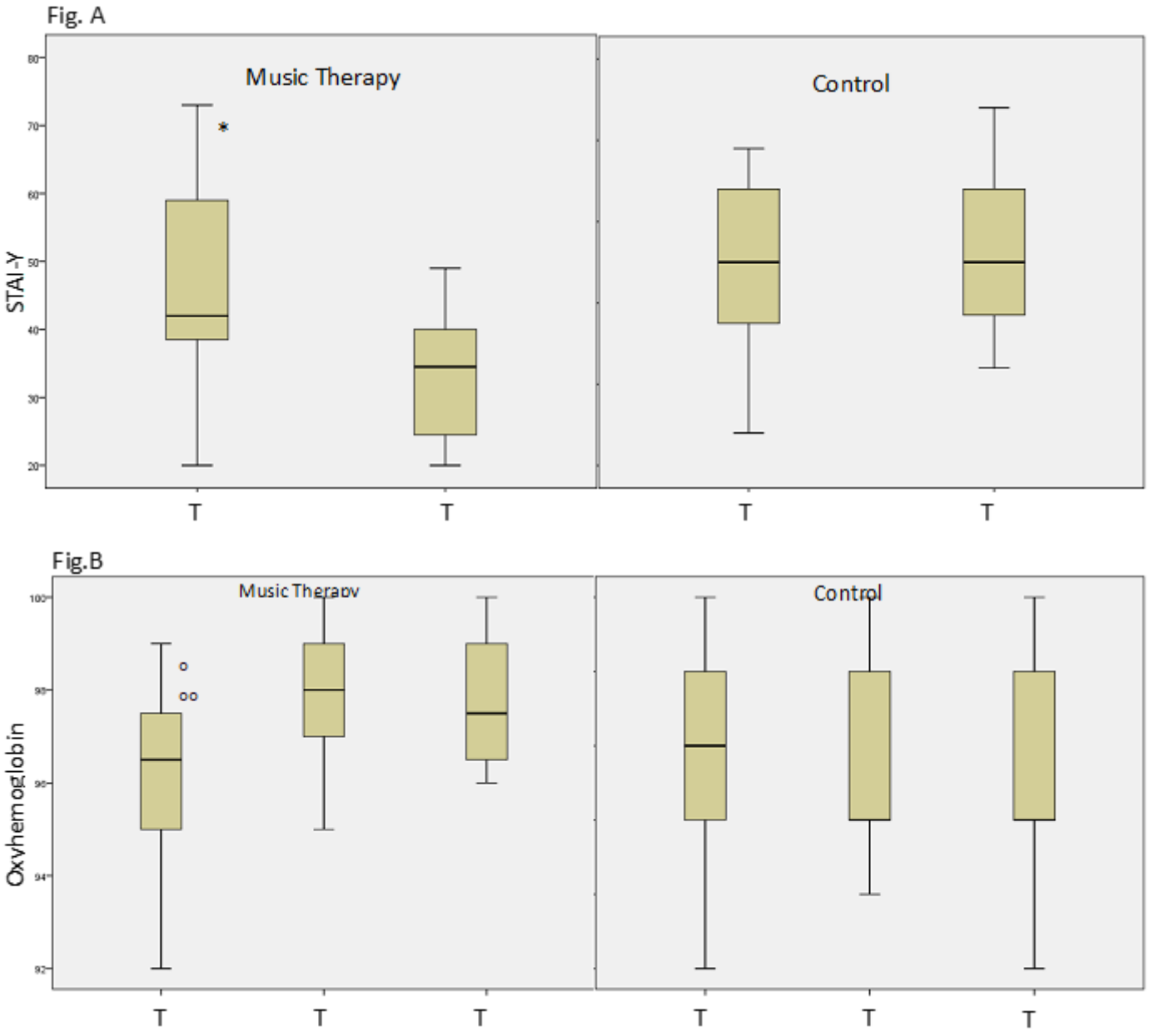

Figure 1

Comparison Box Plot at different times of the MG and of the CG for the STAI-Y parameters and percentage of Oxyhemoglobin Saturation Fig. 1A: Comparison between time T2 and time T0 of the STAI-Y score respectively within the music therapy group and in the control group. Music therapy group. *: T0 vs T2 = [42.00 (38.25 - 60.50) vs 34.50 (23.25 - 40.00); p = 0.000]. Fig.1B: Comparison between the time

T2, T1 and T0 of the O2 Sat% respectively within the music therapy group and in the control group. Music therapy group. °: T0 vs T1 = [96.50 (95.00 - 97.75) vs 98.00 (97.00 - 99.00; p = 0.000] °°: T0 vs T2 = [96.50 (95.00 - 97.75) vs 97.50 (96.25 - 99.00); p = 0.000]. Significance was assumed for p values <0.050 Abbreviations: STAI-y: State-Trait Anxiety Inventory - y form; TO: time at the start of the session; T1: time during the session; T2: Time at the end of the session

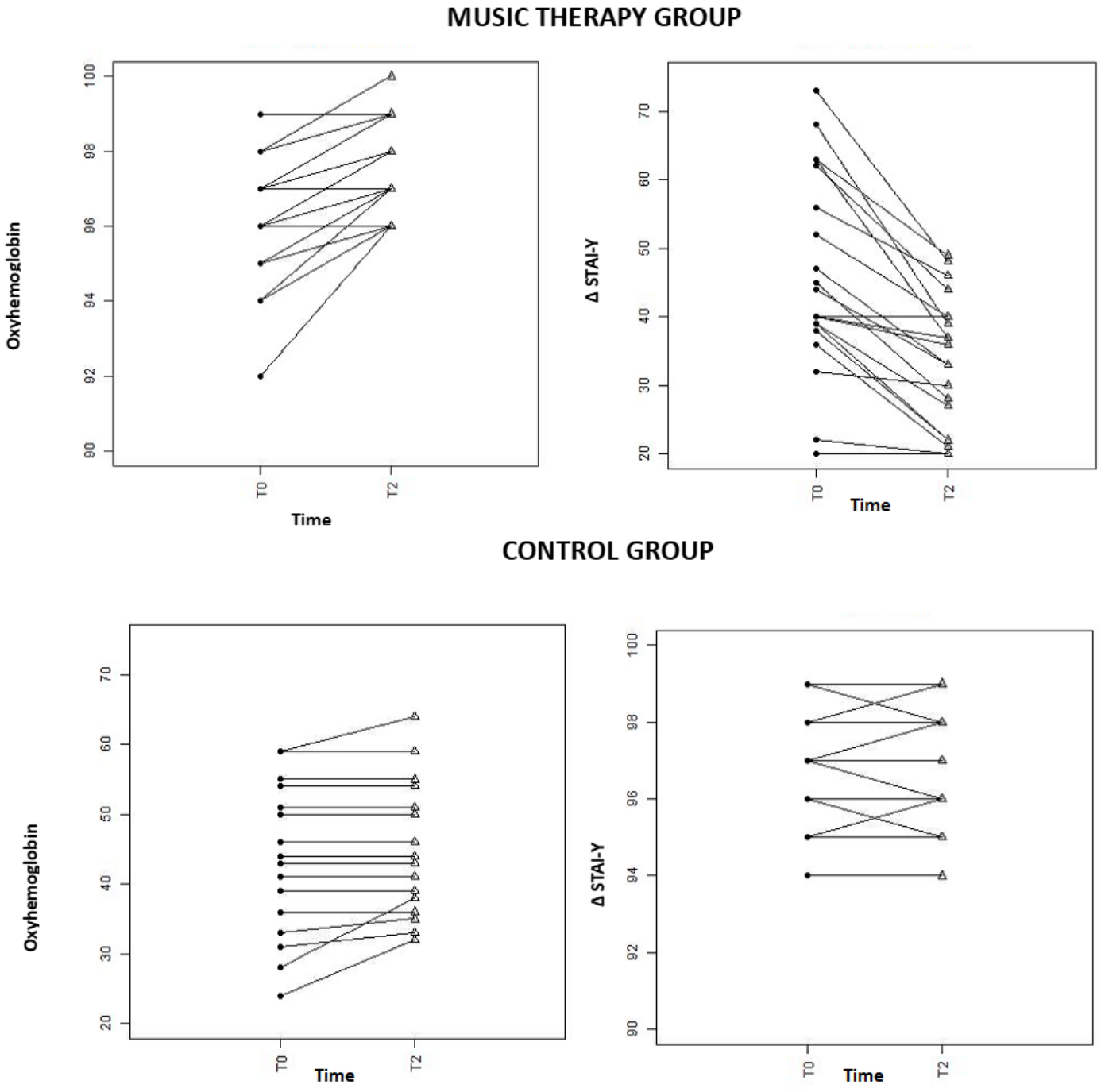

Figure 2

Trend of STAI-Y and oxyhemoglobinic saturation between the beginning and the end of the session in the 20 patients of the MG and in the CG. Abbreviations: STAI-y: State-Trait Anxiety Inventory - y form; TO: time

at the start of the session; T1: time during the session; T2: Time at the end of the session

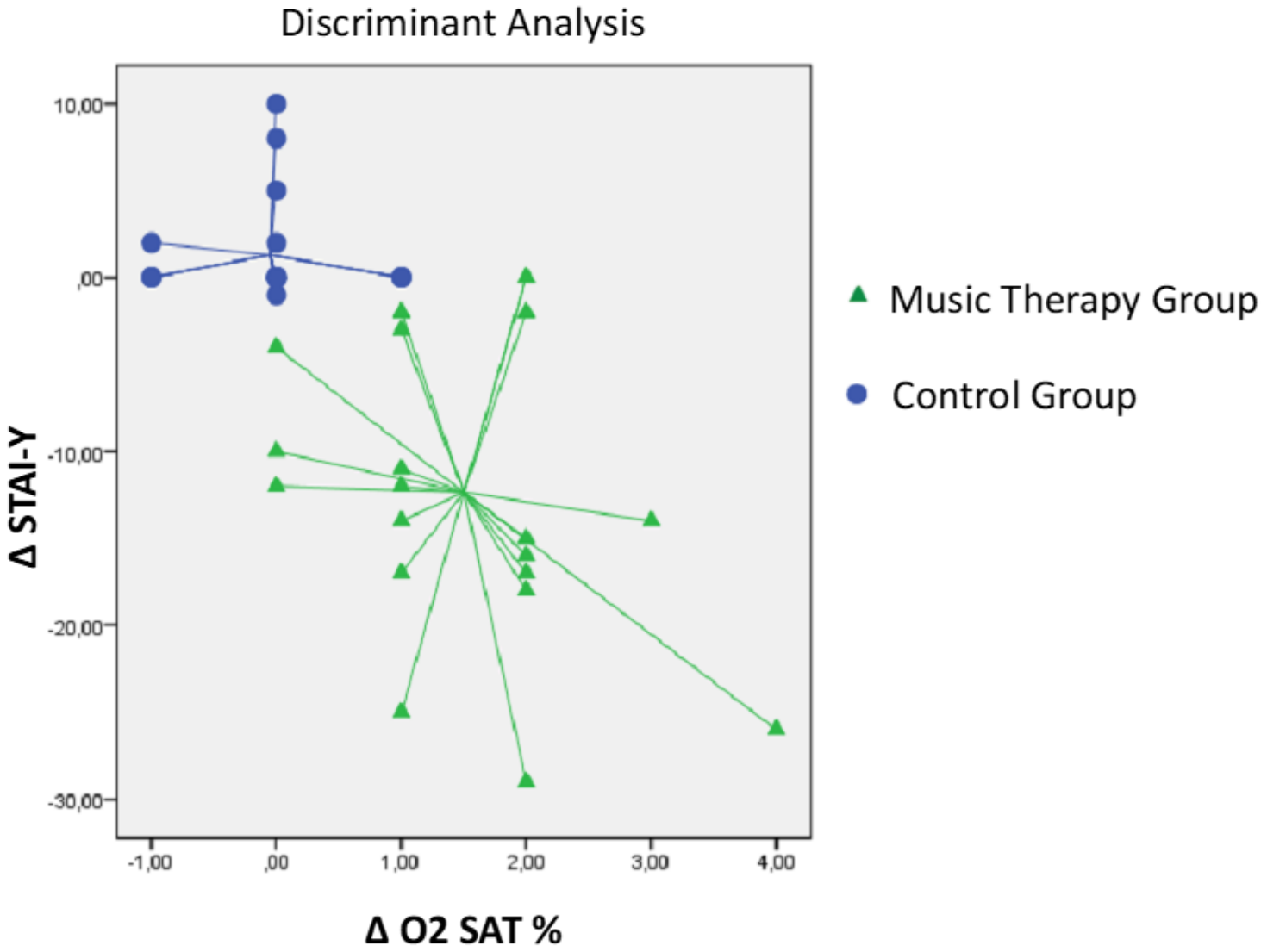

Figure 3

Discriminating analysis between the music therapy group and the control group. Abbreviations: STAI-y: State-Trait Anxiety Inventory - y form; TO: time at the start of the session; T1: time during the session; T2: Time at the end of the session; Δ STAI-Y: difference between the value of STAI-Y calculated at time T2 minus the value of Δ STAI-Y calculated at time T0; Δ O2 Sat%: difference between the value of O2 Sat calculated at time T2 minus the value of O2 Sat at time T0 The cross validate value able to discriminate the music therapy group compared to the control group starting from parameters Δ STAI-Y and Δ O2 Sat% was 90%