PILOT STUDY

Efficacy of Live Versus Recorded Harp Music in Reducing Preoperative Stress and Fear Related to Minor Surgery: A Pilot Study

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ABSTRACT

Context • Before surgery, people can become concerned about risks that may arise, experiencing fear and stress. It is possible to implement nonpharmacological interventions to reduce fear and preoperative stress using expressive arts, including music therapy.

Objective • The aim of this study was to assess the effectiveness of live harp music and compare it with that of recorded harp music in reducing preoperative stress and fear and changes in blood pressure (BP) and heart rate (HR).

Design • The study was a pilot study, with a quasi-experimental design.

Setting • The study took place in a surgery unit's clinic, held weekly, in a teaching hospital in Milan, Italy.

Participants • Participants were 46 people undergoing day surgery, divided into 2 groups: 24 in the intervention group and 22 in the control group. No one dropped out of the study.

Intervention • The intervention group listened to live harp music and the control group listened to recorded harp music, immediately before a surgical intervention. The research team had defined a musical protocol based on the theoretical principles of harp therapy.

Outcome Measures • Before and after the musical intervention, the research team investigated each patient's level of fear and stress, using the same self-evaluation questionnaire (HR) and blood pressure (BP).

Results • Of the 46 participants, 46% were male, and 54% were female. Fear values were reduced significantly and in equal measure in the intervention (P = .001) and control (P = .0001) groups. The live harp music was more effective in reducing HR (P = .001) and diastolic BP (P = .007), than was recorded harp music, with P = .151 and P = .164, respectively. Based on the results, the research team determined that a randomized controlled trial (RCT) would require 90 patients for both the intervention and control groups.

Conclusions • Harp therapy brought benefits by significantly reducing fear and stress and HR and BP. It would be useful to perform a multicenter RCT to confirm these results. (*Altern Ther Health Med.* 2020;26(3):10-15).

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INTRODUCTION

People undergoing a surgical intervention can experience sensations of fear at increasing levels. These feelings can influence personal well-being and cause complications during perioperative and postoperative phases.[1,2]

The preoperative period is commonly associated with the worst sensations, defined as anxiety or stress, probably due to an unfamiliar environment, fear of pain, and concerns about complications.[3] High levels of stress also can induce alterations in vital signs, due to the activation of the sympathetic nervous system; increasing blood pressure (BP) and heart rate (HR) and preparing the body to react to perceived threats.[4] The stress may be managed with a pharmacological intervention, but a paradoxical reaction can occur[3]; patients themselves seem to prefer nonpharmacological interventions.[5]

Music is frequently used to promote a state of relaxation and is associated with healing processes.[3] Some researchers indicate that music can act as a distraction, helping patients to think less about their fears.[6] Others underline the effects of music on brain activity,[7] vital signs,[8] the immune system,[9] and modulation of stimuli perceptions.[10]

The selection of adequate musical parameters is particularly important. The ideal seems to be 60 to 80 beats per minute (BPM), a maximum intensity of 60 dB, and moderate use of percussion and low frequencies. The patient's choice of music did not seem to influence the treatment.[11,12]

The harp seems to be particularly effective in reducing anxiety, probably due to its wide range of vibrations and harmonics and their interaction with the body's vibrations, according to the phenomenon of entrainment as described in physics.[13]

The relevant literature shows evidence of the beneficial effects of music,[14] but based on the research team's knowledge, few studies exist about use of harp music (HM) and even fewer about live HM.[13,15,16]

The study aimed to evaluate the effectiveness of HM on preoperative fear, comparing live and recorded HM, to determine whether live music gave better results. The research team chose to perform a pilot study due to a lack of literature on the comparison between recorded and live HM. The team defined a protocol that it plans to use a larger sample, preferably in a multicentric study.

METHODS

Participants

The study took place in a surgery unit's clinic, held weekly, in a teaching hospital in Milan, Italy, from January 2 2016 to February 2016. Participants were patients who were undergoing day surgery at the hospital. They had to be able to read and understand the Italian language. The study excluded patients younger than 18 years and those who could not understand Italian or could not answer the questionnaire for any other reason.

All the potential participants (46) during the observation period accepted to participate in the pilot study. The interventions were coordinated by a nurse student who was about to graduate and who presented the project to patients, collected data, measured vital signs, and dealt with communication with the staff, under the supervision of a tutor for the nursing-degree course at the University of Milan (Milan, Italy).

According to local regulation, no formal approval of the ethics committee was necessary for a pilot study. The medical director and the nursing director of the hospital authorized the study. The study was led in compliance with the Helsinki Declaration's principles and with current regulations on privacy.

All involved patients were asked to sign a written informed consent that explained aims and methods of the study.

Procedures

For the intervention group, live sessions occurred on 6 days. For the control group, recorded music sessions occurred on 6 other days, using a stereo speaker and the same music that the harp-therapy student and professional harper had previously recorded during the live sessions. In both cases, the music was played at a volume of a minimum of 60 dB and a maximum of 85 dB.

In the surgery unit, admissions are for 1 day only, and no patient could attend the treatment 2 times; given that intervention group and control group were admitted to the hospital each in 6 different days, as previously explained, we were able to conduct a blind study. Participants were divided in 2 groups, using a convenience sampling, with the intervention group listening to live HM, and the control group listening to recorded HM.

Before the musical intervention, the research team administered a questionnaire to obtain demographic information and participants' self-evaluations related to fear and stress. After the musical intervention, the nurse student verbally asked the participants to indicate their current level of fear, using the same 0 to 10 scale. The nurse student measured each patient's BP and HR before and after the musical intervention. An anonymous questionnaire was also handed out to the staff—physicians, nurses, and nurse's aides—concerning their opinions about the project and any criticalities or suggestions.

The musical sessions were led by a harp-therapy student and a professional harper, supervised by a harp-therapist instructor at the Arpamagica Center for music-therapy research in Milan, Italy. In the beginning, the research team chose a quiet waiting room as the setting, but not all patients wanted to use it, and the musical sessions, both live and recorded, took place in the patients' rooms.

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Intervention

The musical protocol was defined based on the theoretical principles of harp therapy, under the supervision of a harp therapist instructor; every intervention was carried out according to the protocol and respecting some specific guidelines such as a gradual creation of the therapeutic sound space (regular beat, soft musical inputs—mainly 1st/5th intervals and almost no melody at first), a careful observation of the patient's reactions to the musical stimuli, the use of tunes in modal scales and subsequent modal improvisations on the basis of the perceived or declare mood of the patient, a constant attention towards the respiratory patterns, and verbal feedback of the patient.

The musical interventions, each 15 to 20 minutes long, followed 3 phases: creation of a listening space, proper music production, and a conclusion.

The first phase aimed at preparing patients for the listening experience, helping them to focus on the music and experience a specific and regular tempo, to set their heart and breath rates. The harpers used light and gentle sounds, without defined melodic lines or themes for this first phase, to help patients relax and regulate their breathing. The main aim was the creation of a rapport with the therapist and a psychological and physical willingness to open up to the experience. This first stage used no specific melody, and the main focus was on the tempo, the scale used (often modal), and most of all, the "double resonance" (both the emotional resonance with the patient and the room resonance).

Moving from the first to the second phase, the music becomes gradually more structured, with tunes played on the harp using the left and right hands with a clear melody. Modal scales were used to match and change the patient's state, paying particular attention to fear and overall anxiety. In particular, Ionian, Mixolydian, and Dorian scales were used for this phase, with some tunes, followed by light improvisations on a canvas of chords that the harp therapist had previously facilitated.

In the third phase, the melodic structure gradually fades, and the music goes back to the initial listening experience, charged with sounds and resonances. The volume was kept low, and in the live sessions, the harpers were asked to regulate dynamics and the choice of tunes according to the perceived mood of the patient(s) and their breathing as well as a general perception of their overall state and well-being.

Outcome Measures

Questionnaire. The questionnaire was created by the authors and tested in a pilot phase with 5 patients similar to the ones involved in the study and five expert nurses, to test its readability and completeness. The questionnaire administered before the musical intervention was divided in 2 sections: (1) descriptive variables—age, gender, kind of surgical intervention, previous surgical interventions, correlated pathologies, and kind of anesthesia; and (2) subjective variables, asking participants to quantify certain variables on a 0 to 10 scale. The variables included the patient's (1) concern about pain that could happen during the surgical intervention, (2) concern about accidents that could happen during the surgical intervention, (3) level of fear about the surgical intervention in the week prior to the surgery, and (4) level of fear about the surgical intervention at the time of completing the questionnaire using an 0 to 10 scale.

Participants were asked to answer the questionnaire before the musical intervention; after the musical intervention and before entering the operating room patients were asked to indicate their current level of fear, using the same 0 to 10 scale.

BP (mm Hg) and HR (BPM). Contemporaneously to the administration of the questionnaire before the intervention, the nurse student measured each patient's BP and HR and wrote it on the same sheet. The student also measured them after the musical intervention, recording them in the data sheet previously described.

Staff Questionnaire. An anonymous questionnaire was also produced and handed out to the staff (physicians, nurses and nurses' aides), to evaluate the indirect influence of this project on the personnel; it included four open questions concerning (1) the opinion about the project; (2) the usefulness or not of intervention (specifying motivations); (3) any criticalities of the intervention; and (4) any suggestions.

Statistical Analysis

Continuous and discrete variables were described by mean, standard deviation, median and quartiles, and nominal and categorical variables with frequencies and percentages. The demographic characteristics of participants were compared to determine whether any significant differences existed between the 2 groups at baseline. Continuous variables with normal distribution were compared by means of the *t* test.

Categorized variables were compared with Pearson's χ^2 test. The main dependent variables—fear and vital signs, before and after surgical intervention—were compared using the Mann Whitney test in the comparison between groups and the Wilcoxon test in the comparison of members of the same group. Statistical significance was defined as $P \leq .05$. All analyses were made with SPSS 21.0 software.[17]

RESULTS

Of the 46 people recruited, the intervention group included 24 participants, 13 males and 11 females, and the control group included 22 participants, 8 males and 14 females. No one dropped out of the study. No significant differences were found at baseline between the 2 groups with respect to the demographic variables (Table 1).

No significant differences existed between the 2 groups in fear levels or vital signs at baseline or postintervention (Table 2).

Between baseline and postintervention, using combined data from both groups, a significant decrease in the fear levels and vital signs occurred after music listening (Table 3).

In the intervention group, fear and the systolic, diastolic, and average BPs decreased significantly between baseline and postintervention. In the control group, fear and the systolic and average BPs showed a significant decrease between baseline and postintervention, but not the diastolic BP or HR (Table 4).

The results of questionnaires completed by staff showed general approval of the use of music in the operative unit.

DISCUSSION

The aim of this study was to compare the effects of live and recorded HM on preoperative fear, based on patients' self-perceptions and measurements of vital signs. The research team had chosen a pilot design to assess the feasibility of a multicenter RCT.

No randomization occurred either for the days or the participants involved, but the intervention and control group

Table 1. Description of Participants

Demographic	Intervention Group (n = 24) n (%)	Control Group (n = 22) n (%)	*P* Value
Age (y), mean ± SD	54.1 ± 19.8	48.5 ± 18	.32[a]
Gender			.23[b]
Males	13 (54.2)	8 (36.4)	
Females	11 (45.8)	14 (63.6)	
Anesthesia			.87[b]
General	19 (79.2)	18 (81.8)	
Local	3 (12.5)	3 (13.6)	
Spinal	2 (8.3)	1 (4.6)	
Kind of surgical intervention			.77[b]
Abdominal	2 (8.3)	3 (13.6)	
Endoscopy	1 (4.2)	1 (4.5)	
Inguinal hernia	1 (4.2)	0 (0)	
Breast	6 (25)	8 (36.4)	
Ear, nose, and throat	5 (20.8)	3 (13.6)	
Thyroid	4 (16.7)	1 (4.5)	
Tonsils	1 (4.2)	2 (9.2)	
Urology	4 (16.6)	4 (18.2)	
No. of previous interventions, median (Q1; Q3)	1 (1.5; 2.25)	2 (0.25; 3)	.66[c]

[a]*t* student test.
[b]Pearson $\chi 2$ test.
[c]Mann Whitney test.

Abbreviations: SD, standard deviation; Q1, first quartile; Q3, third quartile.

Table 2. Comparison Between Groups Before and After Musical Intervention

Baseline	Intervention Group (n = 24) Median (Q1; Q3)	Control Group (n = 22) Median (Q1; Q3)	*P* Value[a]
Concern about pain	4 (0; 5.8)	4 (2.5; 5.3)	.585
Concern about accidents	6.5 (4; 7.8)	5 (3; 7)	.477
Fear previous week	5 (1.3; 8)	4 (3; 7)	.658
Present fear	5 (4; 7.8)	5.5 (4; 7)	.912
Systolic blood pressure	122.5 (110; 133.8)	125 (110; 140)	.739
Diastolic blood pressure	80 (75; 85)	82.5 (68.8; 91.3)	.527
Average blood pressure	95 (86.7; 101.3)	97.5 (84.6; 104.6)	.659
Heart rate	66 (60; 69.5)	68 (60; 80)	.368
Postintervention	**Intervention Group (n = 24) Median (Q1; Q3)**	**Control Group (n = 22) Median (Q1; Q3)**	***P* Value[a]**
Fear	4 (1; 5.8)	3.5 (2; 4.3)	.781
Systolic blood pressure	120 (105; 125)	115 (110; 130)	.799
Diastolic blood pressure	75 (66.2; 83.8)	82.5 (73.8; 85)	.200
Average blood pressure	90 (83.7; 96.3)	93.3 (82.5; 102.5)	.360
Heart rate	60 (60; 66)	66 (60; 80)	.082

[a]Mann-Whitney test.

Abbreviations: Q1, first quartile; Q3, third quartile.

Table 3. Changes Between Baseline and Postintervention for Both Groups Combined

Overall Data	Baseline Before Music Median (Q1; Q3)	Postintervention After Music Median (Q1; Q3)	*P* Value[a]
Fear	5 (4; 7)	4 (1.8; 5)	.001
Systolic blood pressure	125 (110; 136.3)	120 (108.8; 126.3)	.001
Diastolic blood pressure	80 (73.8; 90)	80 (70; 85)	.004
Average blood pressure	96.7 (86.7; 103.3)	90.8 (83.3; 98.8)	.001
Heart rate	66 (60; 72)	63 (60; 70)	.001

[a]Wilcoxon test.

Abbreviations: Q1, first quartile; Q3, third quartile.

Table 4. Comparison of Changes Between Baseline and Postintervention for the Intervention and Control Groups

Intervention Group	Baseline Before Music Median (Q1; Q3)	Postintervention After Music Median (Q1; Q3)	*P* Value[a]
Fear	5 (4; 7.8)	4 (1; 5.8)	.001
Systolic blood pressure	122.5 (110; 133.8)	120 (105; 125)	.005
Diastolic blood pressure	80 (75; 85)	75 (66.3; 83.8)	.007
Average blood pressure	95 (86.7; 101.3)	90 (83.8; 96.3)	.002
Heart rate	66 (60; 69.5)	60 (60; 66)	.001
Control Group	**Before Music Median (Q1; Q3)**	**After Music Median (Q1; Q3)**	***P* Value[a]**
Fear	5.5 (4; 7)	3.5 (2; 4.3)	.001
Systolic blood pressure	125 (110; 140)	115 (110; 130)	.003
Diastolic blood pressure	82.5 (68.8; 91.3)	82.5 (73.8; 85)	.164
Average blood pressure	97.5 (84.6; 104.6)	93.3 (82.5; 102.5)	.022
Heart rate	68. (60; 80)	66 (60; 80)	.151

[a]Wilcoxon test.

Abbreviations: Q1, first quartile; Q3, third quartile.

were homogeneous at baseline with respect to demographic variables: age, gender, kind of anesthesia, kind of surgical intervention, and previous surgical interventions.

The data showed that no significant differences existed between the 2 groups in the investigated variables—fear, BP, and HR—either at baseline or postintervention and that both groups showed a decrease in all values. Therefore, the research team states that both live and recorded music can have positive effects in reducing those variables.

Analysis of the results of the 2 groups separately showed that live HM provided better results, particularly in reduction of diastolic BP and HR. For fear, BP, and HR, a statistically significant difference existed between baseline and postintervention for the intervention group, with a reduction of all medians after music listening.

It is important to underline that the recorded music was not only a set of pieces and songs but rather a specific musical path designed to induce a state of relaxation and played by the same harpist and harp therapy intern.

Although the related literature shows much evidence about music's effectiveness in reducing preoperative stress, also considering variables similar to the current study's,[3] few studies have occurred about HM's effect.[16,18] It is difficult then to compare the current results with analogous data. The current study also used some features to take into consideration while analyzing results: the meticulous planning of the music protocol and the presence of a harp therapist, with a specific training to manage the therapeutic relationship. These elements might have had an influence on results, enhancing the relaxing effects of HM as did the adaptation of HM therapy to meet an individual participant's specific needs, as had been suggested by other authors who have analyzed the effects of live HM on managing stress and anxiety in surgical patients.[18]

The main limitation of the current study was the lack of a randomized sample; however, the 2 groups were similar for the main characteristics at baseline, and, therefore, the results may not be due to previously different characteristics.

These results will be used to define the intervention protocol for a new study, with a larger and probabilistic sample and an experimental design, preferably multicenter, to strengthen the evidence about the effects of live harp therapy. Based on the current results, considering an effect size of 0.5, to reach a power of 90%, with an alpha level of 0.05 and a 2-tailed test, the sample size needed should be 90 participants for each group.

Other possible research goals can be reached by increasing the number of evaluated parameters, concerning both individual experiences and biological characteristics.[9]

CONCLUSIONS

The original contribution of this pilot study to scientific research is the use of live harp music in a preoperative phase. It is a kind of music that particularly fits the purpose of helping patients cope with fear and anxiety. Another peculiarity of the current study was the comparison of the effects on patients who listened to live versus recorded HM.

The positive results of the interventions are probably due to the acoustics of the harp, which is certainly more powerful and effective during live sessions; the presence in the setting of the harp therapist allows her or him to evaluate the moods of the patients and their reactions and elements of nonverbal communication and to adapt the intervention to every specific case. It is important, however, to underline that the study used a defined musical protocol and that the same structure was respected in every session.

AUTHOR DISCLOSURE STATEMENT

The authors declare there are no conflicts of interest.

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