

*Original Article*

# Music Therapy Reduces Pain in Palliative Care Patients: A Randomized Controlled Trial

Kathy Jo Gutsell, RN, MT-BC, Mark Schluchter, PhD,  
Seunghye Margevicius, MA, MSN, Peter A. DeGolia, MD, Beth McLaughlin, MD,  
Mariel Harris, MD, JD, Janice Mecklenburg, CNP, CHPN, and  
Clareen Wiencek, PhD, CNP, CHPN

*University Hospitals Case Medical Center (K.J.G., P.A.D., B.M., M.H., J.M.) and Case Western Reserve University (M.S., S.M.), Cleveland, Ohio; and Virginia Commonwealth University (C.W.), Richmond, Virginia, USA*

---

## Abstract

**Context.** Treatment of pain in palliative care patients is challenging. Adjunctive methods of pain management are desirable. Music therapy offers a nonpharmacologic and safe alternative.

**Objectives.** To determine the efficacy of a single music therapy session to reduce pain in palliative care patients.

**Methods.** Two hundred inpatients at University Hospitals Case Medical Center were enrolled in the study from 2009 to 2011. Patients were randomly assigned to one of two groups: standard care alone (medical and nursing care that included scheduled analgesics) or standard care with music therapy. A clinical nurse specialist administered pre- and post-tests to assess the level of pain using a numeric rating scale as the primary outcome, and the Face, Legs, Activity, Cry, Consolability Scale and the Functional Pain Scale as secondary outcomes. The intervention incorporated music therapist-guided autogenic relaxation and live music.

**Results.** A significantly greater decrease in numeric rating scale pain scores was seen in the music therapy group (difference in means [95% CI]  $-1.4 [-2.0, -0.8]$ ;  $P < 0.0001$ ). Mean changes in Face, Legs, Activity, Cry, Consolability scores did not differ between study groups (mean difference  $-0.3$ , [95% CI]  $-0.8, 0.1$ ;  $P > 0.05$ ). Mean change in Functional Pain Scale scores was significantly greater in the music therapy group (difference in means  $-0.5$  [95% CI]  $-0.8, 0.3$ ;  $P < 0.0001$ ).

**Conclusion.** A single music therapy intervention incorporating therapist-guided autogenic relaxation and live music was effective in lowering pain in palliative care patients. *J Pain Symptom Manage* 2013;45:822–831. © 2013 U.S. Cancer Pain Relief Committee. Published by Elsevier Inc. All rights reserved.

---

*Address correspondence to:* Kathy Jo Gutsell, RN, MT-BC, Music Therapy Department, Seidman Cancer Center at University Hospitals Case Medical Center, 11100 Euclid Avenue, Mailstop: wrn

---

5065, Cleveland, OH 44106, USA. E-mail: [kathy.gutsell@uhhospitals.org](mailto:kathy.gutsell@uhhospitals.org)

*Accepted for publication:* May 14, 2012.

**Key Words***Music therapy, pain, palliative care, randomized controlled trial***Introduction**

Pain management in palliative care is very challenging. Although patients desire to have their pain managed, they also hope for lucidity and good quality of life as well as a sense of control over their lives. Medications that lower pain may lower patients' sense of control and have unwanted side effects such as sedation, nausea, and constipation. In addition, patients and families may fear addiction to opioids. Pain medications primarily target the sensory (intensity) dimension of pain.<sup>1</sup> Music therapy, defined as the clinical and evidence-based use of music interventions to accomplish individualized goals within a therapeutic relationship by a credentialed professional who has completed an approved music therapy program,<sup>2</sup> offers a low-risk, low-cost, nonpharmacologic adjunct to standard care.<sup>3</sup> The goals of music therapy in pain management are to assist the patient in regaining self-control and becoming actively involved in the management of his/her pain. The music therapist engages patients in different types of music interventions (e.g., singing, listening to music, and song writing) to enhance relaxation, provide opportunities for self-expression, facilitate communication with loved ones, and to bring beauty to suffering. This helps to relieve the anxiety, fear, and other components of suffering.<sup>4</sup> According to the American Music Therapy Association (AMTA), "A diverse array of underlying theories forms the foundation for music therapy interventions. Examples include frameworks from behavioral, psychodynamic, psychological, and neurobiological theories. For the topic of pain and pain management, emerging findings from neuroscience with applied music therapy interventions are trending toward a fuller understanding of why certain music therapy interventions influence outcomes more favorably than others."<sup>5</sup> Examples of music therapy interventions that incorporate behavioral frameworks include: the AMTA fact sheet on pain management, which describes a music therapy protocol for pain management developed by Hanser based on a cognitive behavioral model of therapy.<sup>5</sup> In

a randomized trial, Tan et al.<sup>6</sup> measured pain, anxiety, and muscle tension levels of burn patients undergoing dressing changes and found that patients who practiced music-based imagery, a form of music-assisted relaxation with patient-specific mental imagery, had a significant decrease in symptoms. Loewy and Dileo<sup>7</sup> add that the music therapist incorporates techniques of muscle relaxation and instructions for integrating breathing with images of comfort to potentiate the effects of music in end-of-life care. In a 2011 Cochrane review of music interventions with cancer patients, four music therapy trials were examined whose interventions included music combined with imagery.<sup>8–11</sup>

There are few quantitative music therapy studies on pain in hospice and palliative care. A 2010 Cochrane review of music therapy at the end of life included five trials. Only two small studies with a combined sample size of 45 examined the effect of music therapy on pain in hospice patients. Their pooled estimate indicated no strong evidence of effect of music therapy (standardized mean difference  $-0.33$ ; 95% CI  $-0.92, 0.26$ ;  $P=0.27$ ). The reviewers determined that more studies are needed to further evaluate the effects of music therapy on pain at the end of life.<sup>12</sup>

A 2011 Cochrane review examined the effects of music interventions on the psychological and physical outcomes of cancer patients. The review did not differentiate between music therapy studies using a trained music therapist and music medicine studies using prerecorded music offered by a medical professional. Five trials with a combined sample size of 391 measured the effect of music interventions on pain and found a moderate pain-reducing effect in both music therapy and music medicine studies (standardized mean difference  $= -0.59$ ; 95% CI  $-0.92, -0.27$ ;  $P=0.0003$ ). Evidence of the trials included in this review suggests that music interventions may be offered as a complementary treatment to people with cancer, but because most trials were at high risk of bias, that is, one or more of the following criteria were not met, the

results need to be interpreted with caution. The criteria assessed for risk of bias were random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment for objective and subjective outcomes, incomplete outcome data, selective reporting, and other biases. The main reason for receiving a rating of high risk of bias was the lack of blinding. Blinding is often impossible in music therapy and music medicine studies that use subjective outcomes such as pain. This is especially true for music therapy studies that use active music making. When participants cannot be blinded to the intervention, there is an opportunity for bias when they are asked to report on these subjective outcomes. Therefore, it appears impossible for these types of studies to receive a low or even moderate risk of bias even if all other risk factors (e.g., randomization, allocation concealment, and so on) have been adequately addressed.<sup>13</sup>

Analysis of the 2011 Cochrane review reveals that music therapy interventions used in research varied in frequency (single to multiple in number), length (20–120 minutes), live vs. recorded music, patient- vs. therapist-selected music, and the intervention itself (interactive music making with the participants, music-guided imagery, music-guided relaxation, and music-video making). Palliative care music therapy needs more rigorous research so that interventions are evidence based.<sup>14</sup> To better understand the impact of specific music therapy interventions, studies are needed that isolate the effects of one intervention.<sup>3,15</sup> The authors of the Cochrane review note as well that most studies are compromised by small sample size and lack of statistical power.<sup>12</sup>

The objective of the present study was to determine the efficacy of a single music therapy session to reduce pain in palliative care patients.

## Methods

### *Setting and Participants*

All participants were inpatients at University Hospitals Case Medical Center (UHCMC) in Cleveland, Ohio between September 2009 and August 2011. The principal investigator (K. J. G.), hereafter called the investigator, collaborated with the Palliative Care Team (three physicians and two nurse practitioners) and

attended Palliative Care rounds. The investigator received daily referrals for patients with advanced, potentially life-limiting illness who were in pain from the Palliative Care Team and from Nursing Services. The UHCMC did not have a dedicated Palliative Care Unit when the study was being conducted. The Palliative Care Team provides consultative services for patients throughout UHCMC in intensive care, general medical, surgical, rehabilitation, and oncology units.

After the initial referral, the investigator conducted a chart review and interviewed the participant and his or her nurse to determine if the following inclusion criteria were met: 1) a diagnosis of advanced, potentially life-limiting illness, 2) 18 years or older, 3) pain of three or greater as measured on a zero to 10 numeric rating scale (NRS), 4) able to understand English, and 5) alert and oriented to person and place and able to rate pain on the numeric scale. Patients were not excluded if they were on scheduled pain medications, although interventions were scheduled around the administration of breakthrough pain medications, with the intervention occurring immediately before the next dose of medication. The UHCMC Institutional Review Board approved the study. The investigator obtained written informed consent from all participants.

### *Outcome Measures*

**Primary Outcome: NRS.** The NRS is validated for use in adults and children aged nine years or older in all patient care settings who are able to use numbers to rate the intensity of their pain. It is recommended in the literature to measure short-term changes in pain and it is used throughout UHCMC.<sup>16</sup> Patients rate their pain from zero to 10, with zero reflecting no pain and 10 reflecting the worst possible pain.<sup>17</sup>

**Secondary Outcome: The Face, Legs, Activity, Cry, Consolability Scale.** The Face, Legs, Activity, Cry, Consolability (FLACC) Scale is a behavioral pain assessment in which pain is rated by observing the patient and assigning a number to one's findings. The scale is scored between a range of zero and 10, with zero representing no pain. The scale has five criteria: face, legs, activity, cry, and consolability, to which each is assigned a score of zero, one, or two.<sup>18</sup> Originally

validated in children with postoperative pain, the FLACC Scale has been recently validated in assessing pain in critically ill adults who are unable to self-report pain. Because Voepel-Lewis et al.<sup>19</sup> and others found that FLACC scores were comparable with those of the commonly used NRS, the authors selected this pain assessment to provide the behavioral component of the patient's pain experience. In addition, the FLACC Scale was shown to have excellent interrater reliability, criterion validity, and construct validity. Health care professionals who are trained in its use are qualified to perform the assessment. Because the FLACC Scale has not been validated in adults who are able to self-report pain, the present study used the FLACC Scale as a secondary outcome.

*Secondary Outcome: The Functional Pain Scale.* Patients are asked if their pain is tolerable or intolerable. From there, they describe whether or not pain keeps them from engaging in daily activities. A rating of zero reflects no pain. A rating of one indicates tolerable pain with no impact on activity. A rating of five reflects intolerable pain with a resulting inability to verbally communicate.<sup>20</sup> The Functional Pain Scale (FPS) assesses both the patient's subjective perception of pain and its impact on his or her level of functioning. Although the FPS was developed to determine pain in older people who are cognitively intact, the authors selected it as a secondary outcome for the present study because of its ability to help professionals understand how pain affects daily functioning in all their adult patients.

### *Intervention*

After the investigator obtained informed consent from an eligible participant, the investigator summoned a clinical nurse specialist (CNS) research assistant who assessed the patient's pain using the three measures: the NRS, the FLACC Scale, and the FPS. The CNS then left the hospital unit. If the participant's pain score was still three or greater on the NRS, the investigator immediately thereafter opened a serially numbered, sealed, opaque envelope to obtain the patient's assigned group. The investigator opened the sealed envelope containing group assignment (music therapy or control) in the presence of the patient but not the CNS to ensure blinding of

the CNS. Randomization assignments were generated using SAS software (SAS Institute, Inc., Cary, NC) by the study statistician, using a permuted block scheme with random block sizes of 20 or 30. Because the protocol specified the presence of a music therapist to facilitate the music therapy intervention, it was not possible for the participant to be blinded to his or her group assignment. If the participant's pain was less than three on the NRS, he or she was excluded from the study.

*Music Therapy Group.* The investigator, a professional music therapist, informed the patient of his or her assignment to the music therapy group and then proceeded with the intervention. After placing a "Do Not Disturb" sign on the door and preparing the patient and the environment (adjusting the lights, offering a blanket, turning off cell phones, and so on), the therapist briefly played the ocean drum to give the patient the choice of whether or not to include it in the intervention because some patients express aversion for it and find that it inhibits their ability to relax. The therapist then facilitated a single 20-minute music therapy intervention directed at lowering pain. The intervention, a standard protocol for all participants, began with verbal instructions for autogenic relaxation. The music therapist asked the patient to pay attention to breathing for approximately one minute. Then the therapist led the patient in autogenic muscle relaxation by asking the patient to pay attention to the scalp muscles and allow them to release, and moving down with similar focus on specific muscle groups, ending with the feet. Next, the patient was invited to imagine a safe place of his or her own choosing. The therapist asked the patient to imagine what he or she saw, smelled, heard, tasted, and felt on the skin at the safe place. Then the music therapist informed the patient that she would begin to play first the ocean drum, if chosen, and then the harp to support his or her exploration of the safe place. The therapist played the same harp pieces for every patient. The pieces for the present protocol were chosen based on the therapist's clinical experience in which patients had described them as soothing, peaceful, and calming. All pieces were played at a soft volume in a slow tempo and are described as follows: 1) an improvisation

in the mode of G Mixolydian with a duple meter, 2) four precomposed pieces in the key of C Major that can be described as “light classical” and are unfamiliar to most listeners: “Andante” by Waddington in duple meter, “Passing By” and “Reverie” by Grandjany in duple meter, and “Barcarolle” by Grandjany in triple meter. At the conclusion of the music, the therapist gently invited the participant to leave his or her imagined safe place and re-enter the hospital room, realizing that the safe place is a resource to which he or she can return at any time. Then the music therapist left the room and notified the same CNS to return to the patient to reassess pain using the same three measures: the NRS, the FLACC Scale, and the FPS. After completion of the post-tests, the therapist re-entered the patient’s room to verbally process the music therapy intervention and offer follow-up treatment. She gave each study participant a CD of the intervention for future use and provided a CD player on request. Interested readers may contact the investigator to request a recording of the intervention.

*Control Group.* The therapist informed the patient of his or her assignment to the control group and explained that he or she would receive the live music therapy intervention after reassessment for pain. Next, she facilitated the same comfort measures as for the music therapy group: adjusting the lights, providing a blanket, and turning off the telephones. Then the therapist invited the patient to relax, but gave no special instructions for doing so because the therapist-guided autogenic relaxation was integral to the music therapy intervention. She left the room and placed a “Do Not Disturb” sign on the door. After 20 minutes, she notified the same CNS to return to the patient to reassess pain using the three measures: the NRS, the FLACC Scale, and FPS. After post-test data were collected, the therapist provided the music therapy intervention for each control patient. The therapist gave each patient in the control group a CD of the intervention for future use and provided a CD player on request.

#### *Data Collection Procedure*

The CNS, blinded to treatment allocation, administered the pain assessment measures

immediately before and after the music therapy or control intervention. Each study participant was assessed by the same CNS pre- and post-intervention. In all but four cases, post-test data were obtained within 10 minutes of completion of the intervention. On three occasions, the CNS obtained post-test data in 15 minutes and on one occasion in 30 minutes because of schedule conflicts. For 11 patients, blinding of the research assistant was broken because the patients revealed their group assignment.

To attempt to control for bias, the therapist remained outside the room while the research assistant administered pre- and post-tests to the patient.

#### *Statistical Analysis*

Comparisons of baseline characteristics between groups were made using *t*-tests or Wilcoxon rank sum tests for continuous variables, and  $\chi^2$  tests for categorical or binary variables. The mean changes from pre- to post-test in each of the three pain scales (NRS, FLACC Scale, and FPS) were compared between the music therapy and control groups using an independent sample *t*-test. Two-way analysis of variance was used to examine whether treatment effects differed according to patient characteristics such as age, gender, and baseline pain level. All tests were two-sided with a significance level of 0.05. Statistical analyses were carried out using SAS version 9.2. Because there was a single primary outcome, no adjustment was made for multiple comparisons.

The sample size of 200 (100 per treatment arm) provided 80% power to detect between-group differences in mean post-test numeric pain scores of 0.40 standard deviations, using a two-sided test with a significance level of 0.05. The sample size of 100 per group was chosen partly on the basis of what was a feasible number to study and was justified by determining that it would provide 80% power to detect an effect size of 0.40 standard deviations, which is in-between what Cohen<sup>21</sup> considers a “small” and a “medium” effect size (0.2 and 0.5, respectively). We thus determined that this effect size was suitably low to justify the sample size. Primary analyses were carried out using intention-to-treat analysis, including all randomized patients on whom data were obtained. Statistical analysis of the final data

excluding: 1) the 11 patients who divulged group assignment to the CNS, 2) the four patients who had post-test assessments for more than 10 minutes after the intervention, and 3) the 10 patients who chose not to hear the ocean drum and the one patient who requested to “skip the talk and get right to the music,” did not alter the results.

## Results

Of the 400 referred patients, 200 signed informed consent and were enrolled in the study (Fig. 1). Of the 200 subjects screened but not enrolled, 20 were ineligible and 180 did not give consent. Reasons for ineligibility included pain score less than three ( $n = 15$ ), not oriented to person and place ( $n = 3$ ), did not speak English ( $n = 1$ ), and researcher error ( $n = 1$ ). The 180 subjects who did not consent gave various reasons including “I want to be alone now,” “It is a bad day,” “I do not like the harp,” “I am not interested,” “Music cannot help my pain,” “I brought my own music to listen to,” or “Music is not my thing.” Of the 100 subjects assigned to the music therapy group, all but one completed the music therapy session and completed all measurements. The patient who did not complete the post-test exhibited symptoms of confusion and agitation during the intervention and was excluded from the study. Of the 100 subjects in the control group, all completed the pretest. Postintervention scores were obtained on 99 subjects. One control patient who had been in severe pain fell asleep during the control session. His nurse requested that he not

be wakened for the post-test. The subjects assigned to music therapy and control groups did not differ according to gender, ethnicity, diagnosis, mean age, or baseline pain severity (Table 1). The pain duration variable had a skewed distribution in both groups, which is why the authors used a nonparametric Wilcoxon rank sum test to compare the groups at baseline. Because the median is a better measure of location than the mean for these data, we added the median pain duration to Table 1 for this variable. Note that the medians of the two groups are quite similar, reflecting the nonsignificant  $P$ -value from the rank sum test.

### Numeric Rating Scale

Both music therapy and control groups showed significant declines from pre- to post-test (mean change [95% CI]  $-1.94$  [ $-2.37, -1.52$ ] for music therapy and  $-0.56$  [ $-0.92, -0.19$ ] for control). However, a significantly ( $P < 0.0001$ ) greater change was seen in the music therapy group (difference in means [95% CI]  $-1.39$  [ $-1.95, -0.83$ ]).

### Face, Legs, Activity, Cry, Consolability Scale

The FLACC Scale scores declined significantly in both the music therapy and control groups. However, the mean change in scores did not differ significantly between the two groups (difference in means [95% CI]  $-0.3$  [ $-0.8, 0.1$ ],  $P > 0.05$ ).

### Functional Pain Scale

There was a significant decline in the functional pain score in the music therapy group, but not in the control group. The mean

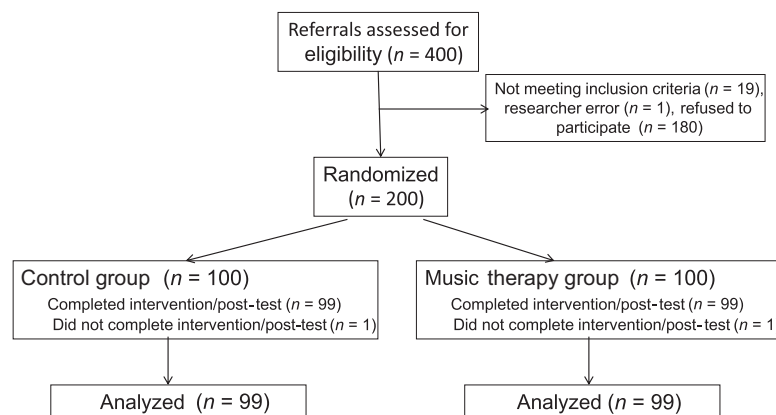


Fig. 1. Flowchart of patients through the study.

Table 1  
Demographic Variables of the Study Participants

Variables	All Patients	Study Group		P-value
		Music Therapy (n = 100)	Control (n = 100)	
Age (mean ± SD)	56.09 ± 15.08	57.45 ± 14.76	54.72 ± 15.34	0.20 <sup>a</sup>
Gender, n (%)				
Male	62 (31)	31 (31)	31 (31)	>0.999 <sup>b</sup>
Female	138 (69)	69 (69)	69 (69)	
Race, n (%)				
White	135 (67.5)	66 (66)	69 (69)	0.65 <sup>b</sup>
Nonwhite	65 (32.5)	34 (34)	31 (31)	
Diagnosis, n (%)				
Cancer	174 (87)	91 (91)	83 (83)	0.09 <sup>b</sup>
Noncancer	26 (13)	9 (9)	17 (17)	
Pain severity (mean ± SD)	6.44 ± 1.82	6.48 ± 1.68	6.39 ± 1.95	0.73 <sup>a</sup>
Pain duration (wk)				
Mean ± SD	14.04 ± 36.83	8.49 ± 14.50	19.58 ± 49.54	0.51 <sup>c</sup>
Median	4.00	3.50	4.00	

<sup>a</sup>P-value from *t*-test.

<sup>b</sup>P-value from  $\chi^2$  test.

<sup>c</sup>P-value from Wilcoxon rank sum test.

decline was significantly greater ( $P < 0.0001$ ) in the music therapy group than in the control group (difference in means [95%CI]  $-0.52$  [ $-0.78, -0.25$ ]; Table 2 and Fig. 2).

Further analyses were carried out to examine whether baseline characteristics of the patients were related to the efficacy of the intervention. These analyses present the mean change in pain score for both music therapy and control groups, stratified by levels of each of the baseline factors being examined. Factors examined were age ( $\leq 55$  and  $> 55$  years), gender (male and female), race (white and nonwhite), diagnosis (cancer and noncancer), pain severity (mild [0–3], moderate [4–6], and severe [7–10]), and duration of pain at baseline ( $\leq 4$ , 5–12, 13–24, and  $> 24$  weeks). A significant *P*-value for the test for interaction indicates that the efficacy of the intervention differed across levels of the baseline factor being examined. Interaction tests for the analyses of NRS and FPS scores were not significant, indicating that effects of music therapy did not vary across levels of the baseline factors. In the analysis of FLACC Scale scores, the interaction test for age was significant ( $P = 0.03$ ) and results indicate that the effect of music therapy was greater in those aged  $\leq 55$  years (95% CI  $-1.57, -0.27$ ) compared with those aged  $> 55$  years ( $-0.59, 0.85$ ). This result should be interpreted with caution given that multiple tests were done and we did not correct for multiple testing.

## Discussion

The results of this research appear to indicate that a single music therapy intervention lowered pain in hospitalized palliative care patients. A noteworthy finding is the efficacy of the intervention itself. Evidence-based music therapy practice often uses patient-preferred music as part of an individualized treatment plan.<sup>22</sup> In contrast, the present research intervention was a standard protocol and varied little from one patient to another. Examples of variations included the music therapist giving each patient the option of including the ocean drum in the intervention. Of 100 patients in the music therapy group, 10 declined its inclusion. The rationale for providing this choice was that some patients express aversion for the sound of the ocean drum, finding that it interferes with their ability to relax. In another example of variation, one patient requested that the therapist “skip the relaxation talk” and “get right to the music.” The therapist chose to honor his request and not add to the distress he already experienced from being in pain. In addition, the therapist individualized each intervention by matching her breathing with the patient and adjusting the tempo and cadence of the spoken script to meet the patient’s needs. Other than the patients described above, the verbal instructions, the harp music selections, and the length of the intervention were consistent from patient to patient.

Table 2  
Summary of NRS, FLACC, and FPS Scores by Study Group

Study Group	Test	NRS			FLACC			FPS		
		N	Mean $\pm$ SD (95% CI)	N	Mean $\pm$ SD (95% CI)	N	Mean $\pm$ SD (95% CI)	N	Mean $\pm$ SD (95% CI)	N
Music therapy	Pre	100	6.69 $\pm$ 1.72 (6.35, 7.03)	100	1.81 $\pm$ 1.86 (1.44, 2.18)	100	2.38 $\pm$ 1.01 (2.18, 2.58)	100	2.38 $\pm$ 1.01 (2.18, 2.58)	100
	Post	99	4.74 $\pm$ 2.59 (4.23, 5.26)	99	0.78 $\pm$ 1.56 (0.47, 1.09)	99	1.76 $\pm$ 1.01 (1.56, 1.96)	99	1.76 $\pm$ 1.01 (1.56, 1.96)	99
	Difference from post to pre	99	-1.94 $\pm$ 2.14 (-2.37, -1.52)	99	-1.01 $\pm$ 1.56 (-1.32, -0.70)	99	-0.62 $\pm$ 0.96 (-0.81, -0.43)	99	-0.62 $\pm$ 0.96 (-0.81, -0.43)	99
Control	Pre	100	6.41 $\pm$ 1.91 (6.03, 6.79)	100	1.72 $\pm$ 2.09 (1.31, 2.13)	100	2.30 $\pm$ 0.97 (2.11, 2.49)	100	2.30 $\pm$ 0.97 (2.11, 2.49)	100
	Post	99	5.86 $\pm$ 2.42 (5.38, 6.34)	99	1.04 $\pm$ 1.66 (0.71, 1.37)	99	2.19 $\pm$ 1.04 (1.99, 2.40)	99	2.19 $\pm$ 1.04 (1.99, 2.40)	99
	Difference from post to pre	99	-0.56 $\pm$ 1.83 (-0.92, -0.19)	99	-0.67 $\pm$ 1.80 (-1.02, -0.31)	99	-0.10 $\pm$ 0.93 (-0.29, 0.08)	99	-0.10 $\pm$ 0.93 (-0.29, 0.08)	99
Difference in mean change between music therapy and control groups		99	-1.39 $\pm$ 1.99 <sup>a</sup> (-1.95, -0.83)	99	-0.34 $\pm$ 1.68 (-0.81, 0.13)	99	-0.52 $\pm$ 0.95 <sup>a</sup> (-0.78, -0.25)	99	-0.52 $\pm$ 0.95 <sup>a</sup> (-0.78, -0.25)	99

NRS = numeric rating scale; FLACC = Face, Legs, Activity, Cry, Consolability Scale; FPS = Functional Pain Scale.  
<sup>a</sup> $P < 0.0001$  from *t*-test.

Although it is true that music therapists commonly assess for patient preferences and then design interventions that include such music, there are precedents to therapist-selected music that are documented in the literature. The Bonny Method of Guided Imagery and Music (GIM) was developed by music therapist Helen Bonny. The GIM is fully integrated into and endorsed by the AMTA. The GIM uses specifically sequenced classical music programs to stimulate inner experience to meet clinical goals. The GIM uses Western classical music because it is the field of expertise of the persons who developed and tested the programs. This music contains elemental, harmonic, rhythmic, and structural patterns that have stood the test of time, effectively engaging persons in exploration during altered states of consciousness, and which consistently evoke imagery responses of therapeutic value.<sup>23</sup>

Mandel et al.<sup>24</sup> found that cardiac rehabilitation patients who listened to prerecorded instrumental music interspersed with spoken suggestions at home for at least three months to relax their body and mind had significantly more improvement in systolic blood pressure, anxiety, and stress than those who only attended cardiac rehabilitation. The music therapists carefully selected the music with attention to properties that research suggests are conducive to relaxation, including slow tempo, soft dynamics, and long phrases.

In addition, the investigator, a trained music therapist, observed in years of clinical practice that patients in pain are often vulnerable and their desire to manage pain overrides personal preferences in music. Many patients reported lower pain perception after her intervention of carefully selected music. Therefore, on the strength of the literature cited above, on the clinical experience of the investigator, and to limit the variable of music selections in order to demonstrate scientific rigor, the authors designed the present study with no assessment for patient preference in music. The only options allowed were choice of ocean drum and shortening the autogenic relaxation, but only when their inclusion would have increased patient distress.

A finding of this study is that pain also decreased significantly ( $P < 0.05$ ) in the control group on two of the three measures (NRS and FLACC Scale). It appears that the simple act

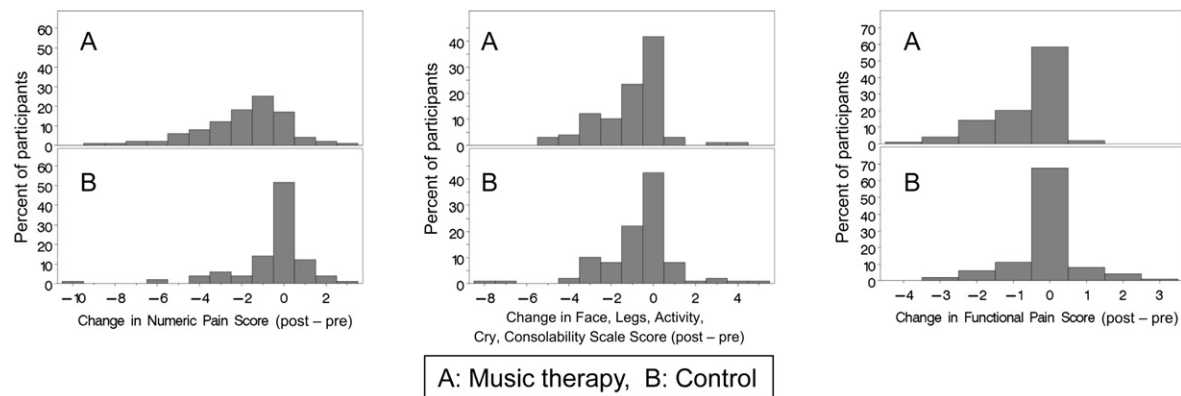


Fig. 2. Changes in pain scores of the participants.

of inquiring about pain and then instructing the patient to relax is in some instances enough to lower pain significantly, as long as it includes offering to make adjustments to the environment such as turning down the lights, pulling the window shades, supplying a blanket, turning off cell phones, reassuring the patient that someone will reassess his or her pain in 20 minutes, and putting a “Do Not Disturb” sign on the door to ensure privacy.

Although all attempts were made to minimize risk of bias, two risks remained, which are implicit in music therapy research. The first is the blinding of participants and personnel. Because music therapy requires the presence of the music therapist, both the therapist and the patient were not blinded to group assignment. The second risk is the blinding of outcome assessment. When participants cannot be blinded to the intervention, there is definitely an opportunity for bias when they are asked to report on subjective outcomes such as pain.<sup>13</sup>

A limitation of the study is that it may be difficult to generalize the results to all palliative care patients in pain, as 45% of the referred patients did not consent to participate. For consenting patients who choose to be less actively involved in a music therapy session, the intervention used in this study has clinical significance. Further research is needed to replicate the study so that its results may be generalized to other music therapists and musical instruments.

Additional research also is needed to: 1) measure the length of time pain is reduced after a music therapy intervention. In the present study, in all but four cases, post-test data

were obtained within 10 minutes of the completion of the music therapy session. On three occasions the CNS obtained post-test data in 15 minutes and on one occasion in 30 minutes as a result of schedule conflicts; 2) address whether patients request fewer breakthrough pain medications after music therapy; 3) find out whether successive interventions have a cumulative pain-lowering effect; 4) examine whether a therapist-created recording of an intervention has the same pain-lowering effect if the patient listens to it after a live session with the same therapist; and 5) address whether pain is lowered in control group patients who later receive music therapy.

The strengths of the present study are its large sample size, its use of one music therapy intervention, and its attempt to meet scientific standards of a quality randomized controlled trial. Because of these features, it provides a valuable addition to the literature. Based on the results, palliative care clinicians may confidently refer trained music therapists to treat pain in this vulnerable population.

### Disclosures and Acknowledgments

This research was supported by a grant from the Kulas Foundation in Cleveland, Ohio. The authors declare no conflicts of interest.

The authors would like to thank the Kulas Foundation, all of the patients who participated in the study, the Clinical Nurse Specialists who assisted in gathering data, the Core Library, and the Art and Music Therapy Department at University Hospitals Case Medical Center for its support and encouragement throughout the study.

## References

1. Kwekkeboom K. Oncology nurses' use of non-drug pain interventions in practice. *J Pain Symptom Manage* 2008;35:83–94.
2. American Music Therapy Association. Definition of music therapy. 2011. Available from <http://www.musictherapy.org>. Accessed September 16, 2011.
3. Groen K. Pain assessment and management in end of life care: a survey of assessment and treatment practices of hospice music therapy and nursing professionals. *J Music Ther* 2007;44:90–112.
4. Bailey LM. Music therapy in pain management. *J Pain Symptom Manage* 1986;1:25–28.
5. American Music Therapy Association. Music therapy and pain management fact sheet. 2010. Available from <http://www.musictherapy.org>. Accessed February 27, 2012.
6. Tan X, Yowler CJ, Super DM, Fratianni RB. The efficacy of music therapy protocols for decreasing pain, anxiety, and muscle tension levels during burn dressing changes: a prospective randomized crossover trial. *J Burn Care Res* 2010;31:590–597.
7. Loewy JV. In: Dileo C, Loewy JV, eds. Music therapy at the end of life. Cherry Hill, NJ: Jeffrey Books, 2005.
8. Allen J. The effectiveness of group music and imagery on improving the self-concept of breast cancer survivors [unpublished PhD thesis]. Philadelphia, PA: Temple University, 2010.
9. Burns DS. The effect of the Bonny method of guided imagery and music on the mood and life quality of cancer patients. *J Music Ther* 2001;38: 51–65.
10. Burns DS, Azzouz F, Sledge R, et al. Music imagery for adults with acute leukemia in protective environments: a feasibility study. *Support Care Cancer* 2008;16:507–513.
11. Montserrat G, Domènech M. The effect of music and imagery to induce relaxation and reduce nausea and emesis in cancer patients undergoing chemotherapy treatment [unpublished PhD thesis]. Stockton, CA: University of the Pacific, 2008.
12. Bradt J, Dileo C. Music therapy for end-of-life care. *Cochrane Database Syst Rev* 2010;1:CD007169.
13. Bradt J, Dileo C, Grocke D, Magill L. Music interventions for improving psychological and physical outcomes in cancer patients. *Cochrane Database Syst Rev* 2011;8:CD006911.
14. Hilliard RE. The use of music therapy in meeting the multidimensional needs of hospice patients and families. *J Palliat Care* 2001;17:161–166.
15. Gallagher LM, Lagman R, Walsh D, Davis MP, LeGrand SB. The clinical effects of music therapy in palliative medicine. *Support Care Cancer* 2006; 14:859–866.
16. Caraceni A, Cherny N, Fainsinger R. Pain measurement tools and methods in clinical research in palliative care: recommendations of an expert working group of the European Association of Palliative Care. *J Pain Symptom Manage* 2002;23:239–255.
17. McCaffery M, Beebe A. Pain: Clinical manual for nursing practice. St. Louis, MO: CV Mosby Co., 1989.
18. Merkel SI, Voepel-Lewis T, Shayevitz JR, Malviya S. The FLACC: a behavioral scale for scoring postoperative pain in young children. *Pediatr Nurs* 1997;23:293–297.
19. Voepel-Lewis T, Zanolli J, Dammeyer JA, Merkel S. Reliability and validity of the faces, legs, activity, cry, consolability behavioral tool in assessing acute pain in critically ill patients. *Am J Crit Care* 2010;19:55–61.
20. Gloth FM III, Scheve AA, Stober CV, Chow S, Prosser J. The Functional Pain Scale: reliability, validity, and responsiveness in an elderly population. *J Am Med Dir Assoc* 2001;2:110–114.
21. Cohen J. Statistical power analysis for the behavioral sciences, 2nd ed. Hillsdale, NJ: Lawrence Erlbaum Associates, 1988.
22. Magill L. The use of music therapy to address the suffering in advanced cancer pain. *J Palliat Care* 2001;17:167–172.
23. Association for Music and Imagery. Definition of the Bonny method of guided imagery and music. 2012. Available from <http://www.ami-bonnymethod.org/faq.asp>. Accessed May 4, 2012.
24. Mandel SE, Hanser SB, Ryan LJ. Effects of a music-assisted relaxation and imagery compact disc recording on health-related outcomes in cardiac rehabilitation. *Music Ther Perspect* 2010;28:11–21.