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The Effect of Music Therapy on Pain, Anxiety and Vital Signs in Patients Undergoing Spinal Anaesthesia: A Randomized Controlled Trial**

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ABSTRACT:
Purpose: Music therapy has a wide range of uses in health care practice. The aim of this study was to investigate the effects of intraoperative music played during spinal anesthesia operation on the patients' intraoperative vital signs, postoperative pain, and anxiety.
Material and Methods: A randomized controlled clinical trial was conducted in the knee replacement surgery with spinal anesthesia. 90 patients were recruited and randomly assigned to either music therapy group (n:30), non-sedated group (n:30) and sedated (n:30) group respectively. The music therapy group received standard care and music intervention (self-chosen) during the operation, the non-sedated group received only standard care and the sedation was performed to the sedated group. Measures include pain, anxiety, vital signs (systolic and diastolic blood pressure, heart rate and respiratory rate).
Results: Intraoperative respiratory rates of the music therapy group were significantly different in the three groups, but there was no difference between the groups in terms of vital signs. No complication was observed in the music therapy group during the operation, but complications were observed in the non-sedated and sedated groups. Similar postoperative pain was observed between the groups. However, the postoperative pain score was lower in the sedated group. The interventions in the music therapy group significantly altered the postoperative anxiety levels.
Conclusion: Music therapy performed during spinal anesthesia was found to be a cost-effective method that was as competent as sedation on vital signs, pain, and anxiety. Moreover, it also increased patient satisfaction.
Keywords: *Music Therapy, Postoperative Pain, Anxiety, Vital Signs, Spinal Anesthesia*

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INTRODUCTION

The surgical procedure is an important source of fear and anxiety for patients, in addition to the physical trauma. For this reason, the patients may be nervous, restless and anxious. Even though, spinal anesthesia is more advantageous compared to general anesthesia, the status of the patients' being awake and hearing all the voices and the conversations of the staff in the operation room may cause them to be afraid and uneasy about the intraoperative noise. Studies are reporting that post-operative anxiety levels are lower in patients who listen to music during spinal surgeries (Koc et al., 2009; Sener et al., 2010). Music therapy applications were first used in hospitals, mostly with anesthesia and analgesia. The researchers developed theories about the neurological effects of music therapy in the twentieth century and experimentally

investigated the physiological effects of music (Uyar & Korhan, 2011).

Music therapy affects the neuroendocrine and the autonomic nervous system, resulting in physiological and psychological changes. Music therapy, when it is listened to at low volumes and low tempos, has the ability to regulate disturbing emotions and reduce nervous transitions. As a result, it positively affects the emotional and limbic system, which is the center for excitement. Music therapy also increases endorphin release by activating the parasympathetic nervous system and stimulating the pituitary gland. Endorphin is a pain reliever and has a positive effect on perception (Bansal et al., 2010). People, who listened to music, were relaxed and felt more powerful (Chou & Lin, 2006). Music therapy has been reported in studies to be an effective method to reduce anxiety and increase relaxation levels (Scheufler et al., 2020). The benefits of music therapy include regulation of blood pressure, reduction of heart rate (Liu & Petrini, 2015), controlling respiration rate and elevation of oxygen saturation (Allen et al., 2001; Bae et al., 2014). Several studies have demonstrated that when listening to music patients shift away their attention from the noise in the environment and overheard conversation of the surgical team was also avoided or reduced (Bae et al., 2014; Kömürcü et al., 2015; Sarkar et al., 2017). The anxiety experienced during the preoperative period and the operation also causes problems in the postoperative period. The most important of these anxiety related complications are postoperative pain, weakening of the immune system, and the prolonged duration of recovery and the length of stay in the hospital. For this reason, controlling and/or eliminating anxiety is a consideration for the post-operative healing process (Chou & Lin, 2006; Vaughn et al., 2007).

Music therapy is one of the most common and oldest non-pharmacological methods used to control pain and anxiety (Karamızrak, 2014). It is an easy-to-apply, non-invasive method that has been reported to reduce surgical stress by using it without any side effects (Çelebi et al., 2020; Graversen & Sommer, 2013). Music therapy has been used in many different areas, including perioperative period anxiety and pain control, pregnant women, intensive care and colonoscopy, and has been found to have positive effects including patient satisfaction (Çelebi et al., 2020; Ko et al., 2019; Kühlmann et al., 2018; Lee et al., 2017; Nguyen et al., 2020; Surucu et al., 2018). Studies have shown that when listening to music during the surgery, the patient's anxiety decreases and accordingly, the need for analgesics and anesthetics decreases. (Bansal et al., 2010; Laframboise-otto et al., 2020). However, it has been determined that there are not enough randomized controlled trials to generate strong evidence on the subject.

MATERIAL and METHODS

Purpose and Type of the Study

The aim of this study was to investigate the effects of intraoperative music played during spinal anesthesia operation on patients' vital signs, postoperative pain, and anxiety level. This randomized controlled trial was conducted between June 2016 and June 2017 in the Orthopedics and Traumatology Clinic of Bolu Abant Izzet Baysal University hospital.

Sampling and Participant

The universe of the study consisted of patients, who underwent a planned surgery, took spinal anesthesia and knee prosthesis operation. The sample size calculation was based on the difference by the heart rate in vital signs. Heart rate (experimental group 87.59±11.04, control group 88.79±12.37) was used based on the study of Liu et al. (2015). To detect a clinically significant difference between groups with 0.85 power and at the 0.05 significance level, and standard deviation (SD)±10, 26 patients were needed in each group. To be able to detect differences in some of the secondary outcomes we planned to randomize 30 patients per group. The allocation sequence was kept by researcher until interventions start. The study was closed when 30 patients in each group were reached. Patients were divided into three groups by randomization with a computer program. A permuted block randomization scheme was used with random block sizes to prevent researcher from guessing the next patient group (Figure 1). There was no blinding as the researcher and participants knew the allocation.

The inclusion criteria for participants included: a) the patients undergoing total knee arthroplasty under spinal anesthesia b) 18 years or older; c) able to understand, read and speak Turkish, so they may complete the informed consent and questionnaires; d) have a Body Mass Index (BMI) <40; e) American Society of Anesthesiologists (ASA) class I, II or III. Patients with vision and hearing problems, not have psychiatric disease history and psychiatric drug use, not have diseases that could be evaluated as severe (such as heart, kidney, liver failure) and emergency surgeries patients were excluded from the study. The majority of patients were operated on by the same team.

Data Collection Tools

The data were collected by the researcher through the face-to-face interview technique and using an information form, an observation form for vital signs, numeric rating scale for pain and State- Trait Anxiety Inventory (STAI).

Information Form; it includes information such as the sociodemographic characteristics of the patients, the duration and type of the surgery, the type of anesthesia, and the status of having a chronic disease. Observation form was related vital signs (heart rate, respiratory rate, systolic and diastolic blood pressure and oxygen saturation). Vital signs were recorded 15th, 30th, 60th minutes after surgery and 5th, 10th, 30th ,60th and 120 th minutes at during surgery on this form.

A Numeric Rating Scale was used by patients to rate pain intensity and pain distress. The scale begins with the absence of pain (0) and ends at the level of unbearable pain (Eti Aslan, 2002; Kömürcü et al., 2015).

State- Trait Anxiety Scale was developed by Spielberger et al. in 1970. The scale has 40 items in two constructs of state and trait. The Turkish validity and reliability studies of the scale were undertaken by Oner and Le Compte. The STAI state construct had satisfactory internal consistency (α=.90), test-retest reliability (r =.74), and concurrent validity of the STAI state construct. Cronbach's alpha coefficient was determined 0.65 for state anxiety in this study. The state anxiety scale consists of 20 items and the scale evaluate how the respondent's feeling at this moment. Each item had a 4-point Likert scale answer, from 1 (not at all) to 4 (very much so), and total score ranged from 20 (the lowest level of anxiety) to 80 (the highest level of anxiety) (Çelebi et al., 2020; Daniel T. L. Shek, 1993).

Statistical Analysis

The data analyzed using a statistical program. Continuous data were summarized as mean and standard deviation. Categorical data were summarized as frequency and percantages. If variables were normally distributed, one-way ANOVA analysis was used. Kruskal-Wallis, Wilcoxon signed rank tests were used for non-normal variables. Following the determination of the overall differences of variables, Tukey and Scheffe's test were performed for homogenous variables. Likewise, Games Howell test were performed for variables displayed non-homogenous distribution.

Ethical Approval

The ethical approval of the present study was obtained from the local ethical committee of the university hospital. The Regional Ethical Committee of Helsinki District approved the study protocol, and Registration number was (2016-89-27/07). Information was given to the patients, who were included in the study, and their written consents were obtained.

Intervention

At the beginning of the study, the purpose of the study was explained to each patient. Then, verbal and written consent of the patients was obtained. The information form was completed in the in orthopedics and traumatology service before surgery via face-to-face interviews by the researchers. STAI was applied to determine the anxiety levels of the patients before surgery. Patients were divided into three groups by randomization with a computer program. The patients in the music therapy group, before the surgery, how to use the headphones was explained and questions were answered. Patients in the music therapy group chose the music they wanted to listen from among four different music groups (relaxing, classical, mystical and Turkish folk music) and self-selected a volume

level. Music lists were selected by the researcher under the guidance of an expert. This expert works as a professor in the music department and has studies on the modes and effects of music. Music content in created groups with 60–80 beats per minute or less was offered because this rhythms has shown to yield a calming effect and a sense of well-being (Allred et al., 2010; Liu & Petrini, 2015). After spinal anesthesia was applied to the patients who were taken to the operating room music therapy was started. Music application was performed with a disposable headphones cover. Music therapy was applied until the end of surgery. The researcher was in the operating room until the end of the surgery.

Sedation (dormicum) was performed to the sedated group after spinal anesthesia based on the height and weight data and the doctor's decision. Sedation was decided during the operation. It had no effect on randomization. The patients in the non-sedated group were followed without any procedure (sedation and music). The music therapy group received standard care and music intervention (self-chosen) during the operation, the non-sedated group received only standard care and the sedation was performed to the sedated group. Standard care is nursing interventions performed before and during surgery (patient education, information). Intraoperative and postoperative vital signs (systolic and diastolic blood pressure, heart rate and respiratory rate) of patients were monitored and recorded in all three groups. The pain was assessed for all groups; firstly at the end of the operation, secondly with the transfer of the patient to the service and followed by the second evaluation at 8 hours postoperative period. STAI was applied to all three groups in postoperative periods (Figure 1).

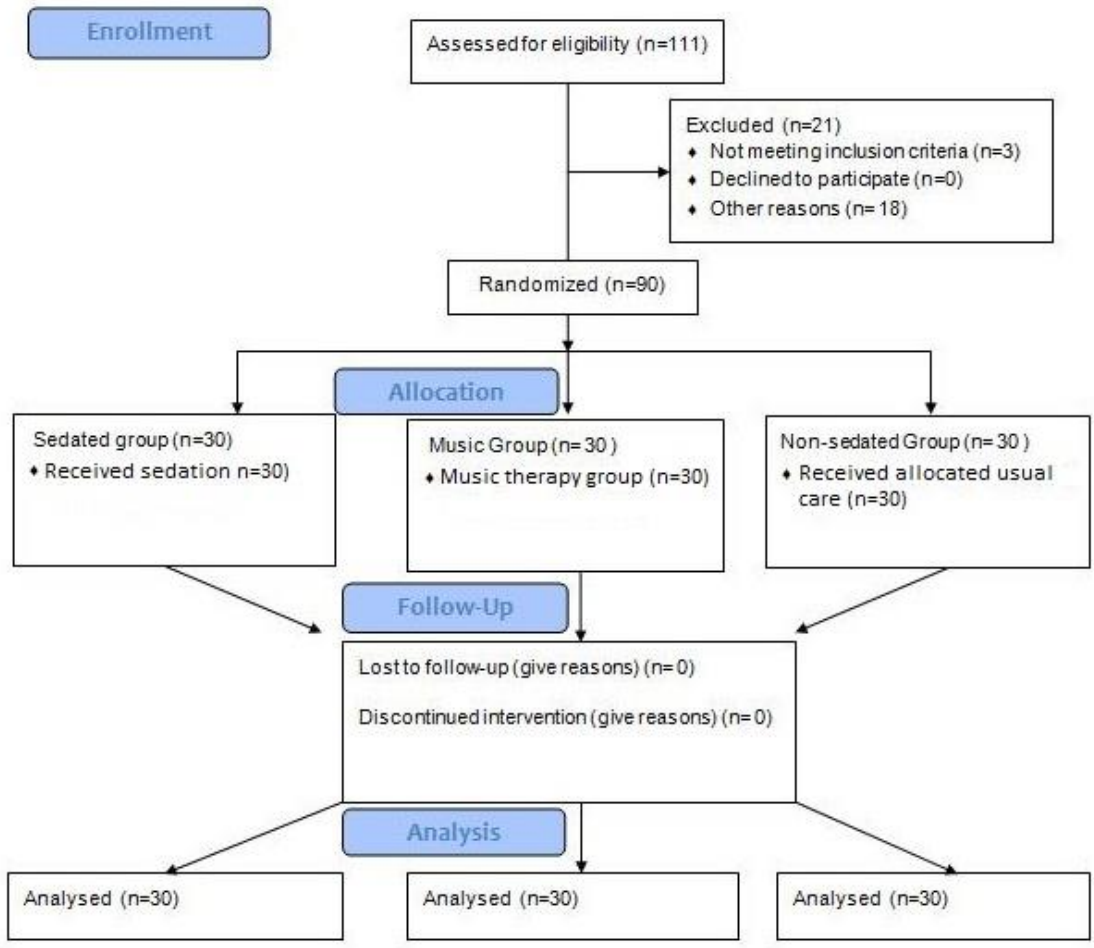

Figure 1. Flowcart of work with consort diagram

RESULTS

This study was carried out with 90 patients divided in three groups of 30 people. There was no significant difference between groups of demographic characteristics (Table 1).

In the study, it was seen that most of the patients in the music group chose mystical music (66.7%) that is followed by folk music (30.0%) and relaxing music (water and ocean sound) (3.3%). None of the patients preferred classical music.

Table 1. Demographic and introductory characteristics of the patients (n: 90)

		Music therapy group (n=30)	Sedated group (n=30)	Non-sedated group (n=30)	P value
Age (years)		68.5 (7.1)	65.8 (6.9)	66.5 (6.7)	0.313
Male/Female		7/23	3/27	3/27	0.495
BMI (kg/m^2)		30.9 (3.7)	32.8 (3.8)	32.8 (4.8)	0.120
Duration of the Operation (min)		98.6 (21.0)	98.2 (24.7)	98.7 (27.2)	0.564
Presence of Chronic Diseases (Yes/No)		19/11	22/8	23/7	0.495
Previous Operation Under Spinal Anesthesia (Yes/No)		8/22	15/15	9/21	0.124
Surgical treatment	Right TKA**	7	11	17	0.022
	Left TKA**	22	16	9	
	Bilateral TKA**	1	3	4	
ASA***	I	1	0	1	0.794
	II	22	25	22	
	III	7	5	7	

*BMI: Body Mass Index; **TKA: Total Knee Arthroplasty; ***ASA (American Society of Anaesthesiologists) Classification

Table 2. Distribution of systolic blood pressure, diastolic blood pressure, pulse rates and respiratory rates of patients in the sedated, music and control groups in intraoperative and postoperative period follow-ups (n: 90)

	Music therapy group (n=30)	Sedated group (n=30)	Non-sedated group (n=30)	p value
Intraoperative				
Pulse	75.8 (8.9)	74.4 (13.5)	76.6 (10.7)	0.730[a]
Systolic blood pressure	132.4 (1.1)	131.1 (16.5)	134.3 (12.5)	0.689[a]
Diastolic blood pressure	73.8 (7.2)	75.1 (12.5)	75.4 (6.6)	0.794[a]
Oxygen saturation	98.5 (1.0)	98.3 (1.5)	98.3 (1.4)	0.869[a]
Respiratory rate	18.5 (2.4)	20.1 (1.9)	19.0 (2.6)	0.038[b]
Postoperative				
Pulse	76.2 (10.0)	74.2 (10.6)	78.2 (10.9)	0.348[a]
Systolic blood pressure	130.6 (14.6)	126.8 (19.5	130.3 (16.9)	0.631[a]
Diastolic blood pressure	73.6 (7.2)	72.4 (9.7)	78.2 (10.9)	0.839[a]
Oxygen saturation	95.8 (1.9)	95.9 (1.8)	95.2 (1.9)	0.371[a]
Respiratory rate	20.9 (0.9)	20.6 (1.3)	20.3 (0.9)	0.101[a]

a: ANOVA test; b: Scheffe's test

Table 3. Distribution of pain scores according to groups (n: 90)

	Music therapy group (n=30)	Sedated group (n=30)	Non-sedated group (n=30)	p value
At the end of the surgery	0.1±0.7	0.2±0.9	0.5±1.3	0.321[a]
When first taken to bed at the service	0.4±1.2	0.2±0.8	0.4±1.2	0.622[a]
Pain rates (postoperative 8th hour)	5.0 ±1.3	4.9 ±1.6	5.8 ±1.6	0.051[b]

a: Kruskall Wallis; b: ANOVA test

After the intervention, a significant difference between groups regarding respiratory rates (F;2.685, p:0.04) was noted throughout the operation. Post Hoc Scheffe's test was used to determine the difference between the groups. The results showed that the music therapy group had significantly lower intraoperative mean number of respirations compared to the sedated and non-sedated groups. No significant difference existed in respect to vital signs in postoperative period (p>0.05) (Table 2).

No complications were observed during the surgery in the music therapy group. However, in the sedated group bradycardia, low blood pressure, and indications for intubation due to respiratory depression were observed in three patients. Likewise, two patients had high blood pressure and one patient had tachycardia in the non-sedated group. Postoperative pain scores of patients that were measured when the patients transferred to the service rooms were similar between the groups (p≥0.05). However, postoperative pain scores were significantly different between the groups at the postoperative 8th hour (p=0.05). Following the determination of homogenous distribution of postoperative pain data (p>0.05), Scheffe's test was performed to determine the groups with significantly different postoperative pain scores. The results showed that the sedated group had a statistically lower mean score compared to the music and non-sedated groups. The mean pain score of the music therapy group was statistically lower than the non-sedated group (Table 3).

There was no statistically significant difference between the groups in terms of preoperative and postoperative state anxiety scores (p= 0.99). However, the group with the lowest postoperative state anxiety score was the music therapy group (Table 4).

Table 4. Distribution of preoperative and postoperative state anxiety scores according to groups (n: 90)

	Music therapy group (n=30)	Sedated group (n=30)	Non-sedated group (n=30)	p value
Preoperative STAI Score	43.2 (6.4)	43.1 (5.3)	43.0 (5.0)	0.993
Postoperative STAI Score	43.2 (5.4)	45.2 (6.0)	44.4 (4.3)	0.530

The experiences of the patients participating in the study with the sounds in the operating room; 66.7% (n: 20) of the patients in the non-sedated group were uncomfortable to hear voices in the operating room ("I was scared, I wondered, I did not want to hear, I was bothered by the sounds, I became worse, it was better if I didn't hear them, I was excited, I was nervous, I panicked, the voices caused a headache, I was worried about pain in every move"), 66.7% (n: 20) of the patients in the sedation group were not affected by the sounds they heard in the operation room ("I was not affected, I liked their talks among themselves, I communicated with them, I did not feel uncomfortable, I didn't hear them), while 70.0% (n:21) of the patients in the music therapy group stated that (I slept when I listened to music, I felt peaceful, I prayed, it made me feel better, I felt like I'm in another environment because I like to listen to music) listening to music during the operation made them relax, and not hearing the sounds related to operation made them feel more peaceful.

DISCUSSION

Music therapy has positive effects on patients undergoing knee replacement surgery with spinal anesthesia on pain and stress reduction (Laframboise-otto et al., 2020). Studies have shown that music therapy is a non-pharmacological method that reduces the effects of stress on the body, regulates blood pressure, heart rate, breathing, and the emotional state of patients (Çelebi et al., 2020; Gökçek & Kaydu, 2020; Nguyen et al., 2020). In a study of Sarkar et al. (2015), vital signs of orthopedic surgery patients' under musculoskeletal spinal anesthesia were similar between music and control groups. Bae et al. (2014), reported significant

reductions in systolic and diastolic blood pressures of patients, who listened to music through the surgery. Bansal et al. (2010), reported that music had positive effects on various physiological and emotional parameters, including arterial blood pressure, heart rate, and decreased anxiety. However, in the study of Lepage et al., systolic blood pressure, pulsation, and respiratory rates were similar between the control and patient groups who listened music during intraoperative sedation under spinal anesthesia (Lepage et al., 2001). Similarly, Sarkar et al. (2015) also reported that listening music under spinal anesthesia throughout orthopedic operations did not have any significant effects on patients vital signs at any measurement time compared to the standard-care group of patients. In the current study, systolic and diastolic blood pressures, intraoperative heart rate and oxygen saturation averages were similar between groups. On the other hand, music therapy group demonstrated significantly reduced respiratory rates compared to the respiratory rate of the sedated and non-sedated groups. Knee prosthetics are postoperative pain generating surgeries due to impaired muscle integrity, bone damage, and prolonged bone healing (Zhu et al., 2017). Chen et al. (2015) stated that there was no significant difference in pain perception in the music therapy group and control group in patients, who underwent knee replacement operation. However, they stated that listening to music postoperatively resulted in less requirement for pain relievers. In a study by Sendelbach (2006), examining the effects of music on patients undergoing cardiac operation and found that the patients in the music group had lower pain and anxiety levels. Ozdemir et al. (2019) found that classical Turkish music reduced the severity of pain but increased the levels of anxiety in patients undergoing bone marrow aspiration and biopsy.

There is a high relationship between the cultural background and the individual music preference in music preference (Tang & Vezeau, 2010). Bansal et al. (2010) reported that the patients in the music group preferred to listen to religious music (48%) and folk music (22%). The study of Ovayolu et al. shows that the need for sedation in Turkish classical music listeners is reduced during colonoscopy (Ovayolu et al., 2006). Bae et al. found that when they asked the music preferences of the patients in their study, which was carried out to investigate the influence of the music on the intraoperative anxiety level, they found that they rather preferred local music (Bae et al., 2014). Consistent with the literature, in this study, it was seen that the patients in the music therapy group chose to listen to music in the form of mystical music (66.7%) and folk music (30.0%) among four music options. The music choices of patients are affected by age, culture, socio-cultural structure and religious beliefs (Bae et al., 2014; Bansal et al., 2010). It has been reported that patients listen to their choice of music over the course of the operation more effectively than standard relaxing music (Sarkar et al., 2015).In the current study, postoperative pain scores were similar between groups at the end of the surgery as well as when the patients were transferred to the bed following surgery. This might be caused by the long-lasting effects of spinal anesthesia, which can least at least four hours. Pain evaluation of patients performed at postoperative 8th hour demonstrated significant differences between groups. The sedated group had a significantly reduced compared to the music and non-sedated groups. This is most likely caused by the muscle tone control of a sedative drug used. Moreover, the mean score of pain was significantly decreased in the music therapy group compared to the non-sedated group. Leodoro et al. found that use of music in women who underwent gynecologic surgery reduced anxiety and stabilized physiologic parameters throughout the preoperative period (Labrague & McEnroe-Petitte, 2016).

According to the study of Jimenez-Jimenez et al. (2013), music therapy is considered to be advantageous without causing any adverse effects in controlling anxiety throughout the operation compared to using anxiety-relieving drugs. Bansal et al. (2010) reported that music therapy is supportive in patients undergoing regional anesthesia, such as sedative drugs for reducing anxiety and stress. Sarkar et al. (2015) found that music in orthopedic surgery patients, who were under spinal anesthesia, was effective in reducing operation-associated anxiety. Bae et al. (2014) reported significant differences in anxiety between the music and the control groups in

patients undergoing local anesthesia. In the present study, the mean postoperative anxiety scores were not significantly changed in the music therapy group; however, they were increased in the other groups. In present study, the state anxiety scores of the patients in the music therapy group did not change between pre and postoperative period, but it was increased in the other groups. The preoperative and postoperative anxiety scores of the patients did not differ between the groups, whereas the patients without sedation had lower postoperative anxiety scores.

CONCLUSION

This study is a randomize controlled trial and provides further evidence to support the practice of music therapy. Intraoperative music therapy is thought to be effective in reducing the intraoperative anxiety levels of the patients by directing their attention to other points and reducing their postoperative pain by positively affecting the vital signs of the patients. In our study, no complications were observed in the music therapy group in patients, who were followed-up throughout the operation. It was found that the majority of the patients in the non-sedated group were uncomfortable with the sounds in the operating room during the operation, and the majority of the patients in the sedated group were not affected by the sounds. Most of the patients in the music therapy group were pleased to listen to music during the surgery. As there were only postoperative findings in favor of pain as well as changes in vital signs in the patients in the sedated group, it was thought that musical therapy during surgery was as effective as sedation on pain control, anxiety, and vital signs. The patients in the music therapy group reported that listening to music during the operation relieved them. In the light of these results, music therapy is a cost-effective, reliable, non-pharmacological method for patients receiving local anesthesia. This method can be used to reduce the pain and anxiety of patients and positively affect various physiological parameters. In hospitals, it is suggested that music therapy applications can be used in patients, who do not require patient cooperation and undergo surgical operation by receiving local anesthesia. For the development of these practices, it is recommended to encourage nurses and to obtain strong evidence with a larger number of randomized controlled trials, with pre- and post-operative studies on specific groups of patients, with larger sample sizes.

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Conflict of Interest

None declared.

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