

**THE EFFECT OF MUSIC THERAPY ON POSTOPERATIVE PAIN, ANXIETY AND
VITAL SIGNS IN PATIENTS UNDERGOING SPINAL ANAESTHESIA: A
RANDOMIZED CONTROLLED TRIAL**

Effect of Music in Intraoperative Period

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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. There are studies reporting that post-operative anxiety levels are lower in patients who listen to music during spinal surgeries (Koc et al., 2009; Sener, Koçlu, Ustun, Kocamanoglu, & Ozkan, 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, Kharrod, Sanwatsarkar, Patel, & Kamat H, 2010).

The benefits of music therapy include regulation of blood pressure, reduction of pulse rate (Liu & Petrini, 2015), controlling number of breaths and elevation of oxygen saturation. Thus, music is used as an assisting method for patient care (Allen et al., 2001; Bae, Lim, Hur, & Lee, 2014). Studies of Bae et al. (Bae et al., 2014), Komurcu et al. (Komurcu et al., 2015),

and Sarkar et al. (Sarkar et al., 2015) 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. As a result, the patient's anxiety was reduced. The anxiety experienced during the preoperative period and during the operation also causes problems in the postoperative period. A study by Chou and Lin reported that people, who listened to music, were relaxed and felt more powerful (Chou & Lin, 2006). 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 [11,17].

In the literature, there are studies supporting the views that the music played during operation reduces the patient's anxiety and the result is a reduced use of anesthetics and analgesics. However, it has been determined that there are not enough randomized controlled trials to generate strong evidence on the subject.

The aim of this study was to investigate the effects of intraoperative music played during spinal anesthesia operation on patients' intraoperative vital signs, postoperative pain, and anxiety level.

Hypotheses of the Study

H_{1A}: In spinal anesthesia, the music played during the operation has an effect on the intraoperative vital signs of the patients.

H_{1B}: In spinal anesthesia, the music played during the operation has an effect on the postoperative pain of the patients.

H_{1C}: In spinal anesthesia, the music played during the operation has an effect on the postoperative anxiety level of the patients.

Methods

The type of study

This study is a randomized controlled clinical trial. The aim of this study was to investigate the effects of intraoperative music on the patients' vital signs and postoperative pain as well as anxiety levels following an orthopedic surgery with spinal anesthesia (Figure 1).

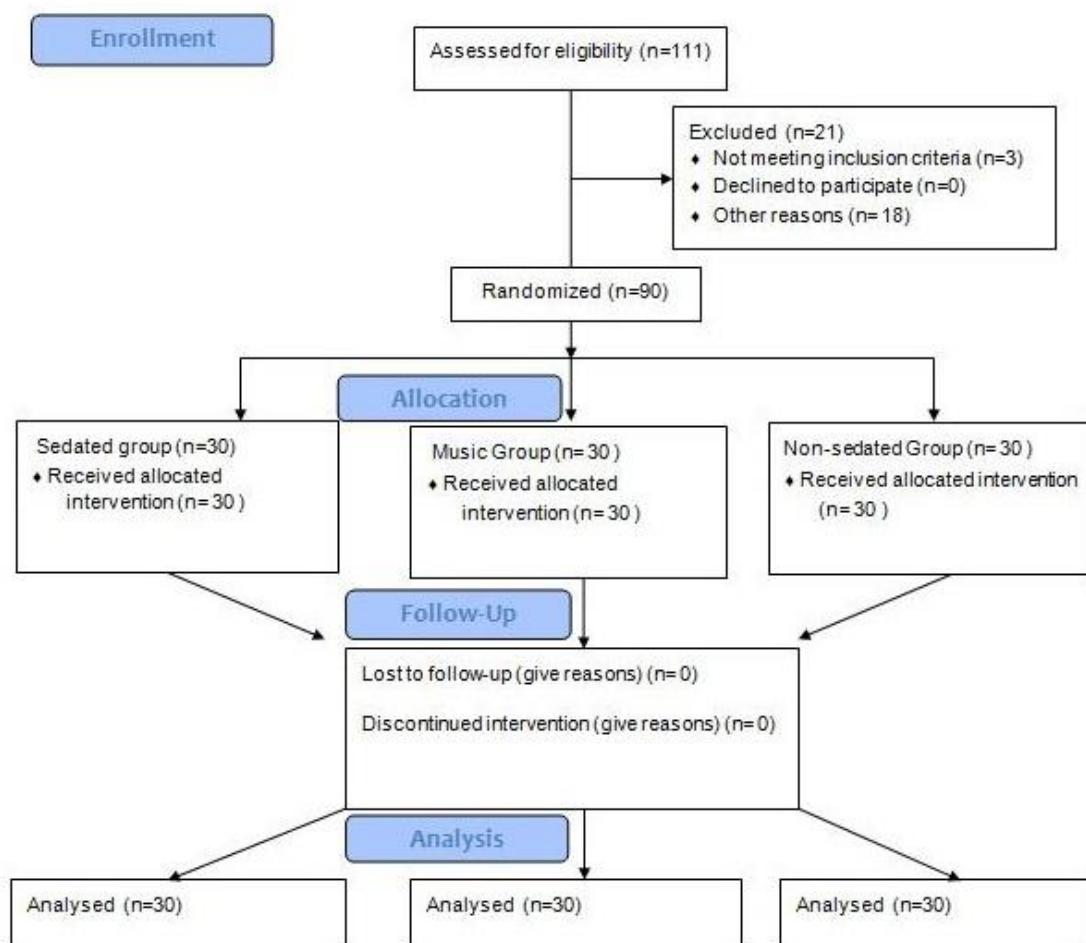


Figure 1: Flowcart of work with consort diagram

Time and place of the study

The study was conducted between June 2016 and June 2017 at a university hospital.

Study design and samples

The universe of the study consisted of patients, who underwent a planned surgery, took spinal anesthesia and knee prosthesis operation in the Orthopedics and Traumatology Clinic at a university hospital.

In the study, 30 patients were assigned to the music group, 30 patients were assigned to the group that received sedation and 30 patients were assigned to a group that was not sedated, all occurred in a randomized controlled way.

Patient selection criteria of the present study were as follows: the patients that had an orthopedic operation, took spinal anesthesia, gave consent after being informed, were above 18 years of age, can speak and read Turkish fluently, did not have vision and hearing problems, have a Body Mass Index (BMI) <40, did not have psychiatric disease history and psychiatric drug use, did not have diseases that could be evaluated as severe (such as heart, kidney, liver failure), and had the ASA (American Society of Anaesthesiologists) I-II-III statuses.

Data collection

The data collection form was prepared by the researchers. First part of the form contained certain demographic information of the patients. Vital signs and the numerical pain scale that evaluated the postoperative pain were present in the second part. Preoperative and postoperative anxiety levels were measured in the third part of the form through State and Trait Anxiety Scales.

Numerical Pain Scale: It is used by the patient himself/herself to assess and measure severity of the pain. The scale begins with the absence of pain (0) and ends at the level of unbearable pain (Eti Aslan, 2002; Komurcu et al., 2015).

State- Trait Anxiety Scale: This scale was developed by Spielberger et al. in 1970 to determine the level of the individual anxiety state. It has 40 items in two constructs of state and

trait. Since state anxiety scale was emphasized in the present study, only 20-item state scale construct was used. Each item had a 4-point Likert scale answer, from 1 (almost never) to 4 (almost always), and the possible total score ranged from 20 (the lowest level of anxiety) to 80 (the highest level of anxiety). The STAI state construct had satisfactory internal consistency ($\alpha=.90$), test-retest reliability ($r =.74$), and concurrent validity of the STAI state construct (Daniel T. L. Shek, 1993).

Data collection method

The data were collected by the researcher on the weekdays through the face-to-face interview technique. The majority of patients, who underwent spinal anesthesia within the scope of the study, were operated on by the same team. 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. The sample size calculation was based on the difference by the heart rate in vital signs. To detect a clinically significant difference between groups with 85% power and at the 5% significance level, and a difference in heart rate between groups of 10 (standard deviation (SD) ± 10), 26 patients were needed in each group. To be able to detect differences in some of the secondary outcomes and to compensate for dropouts, we planned to randomize 30 patients per group. The patients were randomly divided into groups with a computer program by the researcher and interventions were applied. The allocation sequence was kept by researcher until interventions start. The trial was closed when ≥ 30 patients in each group were reached.

The music were chosen by a researcher under guidance of an expert and grouped as relaxing, classical, mystical, and Turkish folk music. One of them was chosen by the patients following the application of spinal anesthesia in the music group. Sedation (Dormicum) was performed to the sedated group after spinal anesthesia based on the height and weight data and the doctor's decision. The patients in the non-sedated group were followed without any

procedure (sedation and music). Intraoperative and postoperative vital signs of patients were followed and recorded in all three groups. The pain was assessed at the end of the operation, which was started 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 preoperative and postoperative periods.

There are no side effects that may arise from the application of music in the intervention group. When patients did not want to continue listening to music, the application was terminated and the patient was excluded from the study. Sedation was applied to the sedated group based on the height and weight data and the doctor's decision. The patients in the non-sedated group was followed up throughout the operation. they felt pain or were intervened immediately in a different complication.

The analysis of the data

The data obtained were coded in a statistical program. The data were expressed as the percent, mean, and standard deviation. For the statistical evaluation, one-way ANOVA analysis, Kruskal-Wallis, Wilcoxon signed rank test and MANOVA (Multivariate Analysis of Variance) tests were used. 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.

Limitations of the Study

The inability to equalize the ambient sounds of the operating room for the control groups constitutes the limitations of the study.

The Ethical Aspects of the Study

Ethical approval of the present study was obtained from the local ethical committee of the university hospital. Information was given to the patients, who were included in the study, and their written consents were obtained.