

# Effect of music on anxiety and pain during ultrasound-guided core needle breast biopsy: a randomized controlled trial

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## PURPOSE

Although imaging-guided core needle breast biopsy is a minimally invasive diagnostic procedure, it is reported that patients may experience anxiety and pain. Interventions to reduce anxiety are important for high quality health services during imaging-guided core needle breast biopsy. The purpose of this study was to evaluate the effect of music intervention on anxiety and pain levels of patients undergoing ultrasound-guided core needle breast biopsy.

## METHODS

In a prospective randomized controlled design, patients who were referred for ultrasound-guided core needle breast biopsy were invited to the study and randomized into the intervention group who received standard care with classical music intervention before and during the biopsy procedure, and the control group who received only standard care. Both groups received local anesthesia. The Spielberger State-Trait Anxiety Inventory and the Visual Analogue Scale (VAS) were used for measuring anxiety and pain levels after the procedure. One-way multivariate analysis of variance test was used to find the effect of music intervention on patient anxiety and pain.

## RESULTS

There were 31 patients (48.4%) in the intervention group and 33 (51.6%) in the control group; the groups were similar in terms of sociodemographic characteristics and general (trait) anxiety levels. The patients in the music intervention group had significantly lower state anxiety score than the control group ( $p = 0.008$ ) with a mean difference of 3.8 (95% CI, 1.0–6.6). The mean difference of VAS pain score was 6.0 (95% CI, 2.2–14.2), which not statistically significant between groups ( $p = 0.150$ ). There was no significant correlation between the VAS and the state anxiety scale ( $r = 0.003$ ,  $p = 0.980$ ).

## CONCLUSION

Music reduced anxiety, but not pain during ultrasound-guided core needle breast biopsy. These results have implications especially for low and middle-income countries where low-cost and easily implemented interventions are needed to address patient anxiety during breast biopsy procedures.

Imaging-guided core needle breast biopsy is a safe and cost-effective procedure that is essential for managing suspicious breast lesions (1, 2). Although imaging-guided core needle breast biopsy is a minimally invasive procedure, patients may experience anxiety and distress (3). Reducing anxiety during biopsy procedures is important as higher anxiety during different biopsy procedures was found to be associated with higher pain (4, 5), and reducing anxiety may reduce the pain and increase the patient comfort. Furthermore, the regulation of anxiety during breast biopsy plays an important role in adherence to follow-up (6).

Music regulates emotions by affecting the expression of opiate, nitric oxide, cytokine, and hormone levels through neuroendocrinological pathways (7). Music has been shown to reduce anxiety and pain levels in different medical procedures like chemotherapy, chest tube removal, endoscopy, colonoscopy, magnetic resonance imaging, fine needle aspiration biopsy, transrectal ultrasound-guided prostate biopsy, bone marrow biopsy, surgery, labor and caesarian section (8–11). A systematic review recommended that music intervention should be applied to clinical management of biopsy patients (12). However, there

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is scarce research on the effect of music on ultrasound-guided core needle breast biopsy patients' anxiety and pain levels (13–15). Two of these trials showed that music reduced the anxiety levels of breast biopsy patients (13, 15), whereas one study reported that music intervention was not effective (14). All of the mentioned studies are from high income countries and have inconsistent results. There is no study on the effect of music intervention on anxiety and pain levels of ultrasound-guided core needle breast biopsy patients from low- and middle-income countries where there may be cultural and socioeconomical differences that may affect the patients' response to music interventions. Furthermore, these countries are in need of low-cost interventions to increase the quality of life of patients.

This study investigated whether or not classical music changed patient anxiety and/or pain levels of patients undergoing ultrasound-guided core needle breast biopsy in Turkey. It was hypothesized that music intervention will decrease the patients' anxiety and pain levels.

## Methods

### Study design and participants

In this single-center, prospective randomized controlled trial, patients referred for ultrasound-guided core needle breast biopsy at the Yıldırım Beyazıt University Yenimahalle Training and Research Hospital Radiology Department in a four-month period between October 1<sup>st</sup> 2019 and February 1<sup>st</sup> 2020 were invited to the study before the procedure. Inclusion criteria were being older than 18 years, able to speak, understand and write Turkish and providing written informed consent. Exclusion criteria included known anxiety disorder, any other

psychiatric illness, hearing problems, use of anxiolytics and analgesics. The local clinical research ethics committee approved the study (protocol number: 2019/66, 01.09.2019). The research was conducted in accordance with the principles of the Declaration of Helsinki.

### Procedures

After obtaining the informed consent form, the participants were randomized to music intervention and control groups by block randomization, applying a random table. After block size was determined, all possible combinations of allocation for that block size was calculated, and block combination was then randomly chosen to state the patients' assignment into the groups. This study was non-blinded.

The intervention was listening to relaxing classical music before and during the procedure. The type of music was selected according to a meta-analysis which included 72 randomized controlled trials on pre-, during and post-operative music effects on patient recovery, anxiety and pain. The authors reported that almost half of the studies used relaxing, soft, instrumental, classical and soothing music types. A considerable amount of studies (22.2%) used music based on patient's choice. The authors recorded a slight but non-significant increase in anxiety when patients had a choice of music compared with when they had no choice (16). The rest of the studies used nonspecific or various music types. To use the same intervention in all patients; the Moonlight Sonata of Beethoven and Piano Concerto No.1 in E Minor, Op.11-2, Romance of Chopin were chosen for this study as relaxing classical music.

The music started immediately after the patient entered the biopsy room via a speaker which is clearly audible across the procedure room. The music intervention started 15 minutes before and continued during the biopsy procedure. The duration of the biopsy procedure was timed. Both the intervention and the control groups received a short standard supportive dialogue with the radiologist, who asked where the patient has come from and talked about the weather with a smiling facial expression. Ultrasound-guided core needle breast biopsy was performed by the researcher, an experienced radiologist, using aseptic technique and local anesthesia. Patients underwent high-resolution ultrasound examination of the breast with Toshiba Aplio 500 ultra-

sound machine (Toshiba Medical Systems) using a 14 MHz ultrasound probe. For local anesthesia, 2 mL of 2% prilocaine without epinephrine was administered superficially followed by 10 mL of 2% prilocaine around the lesion. After the biopsy and wound dressing, the participants were given a sociodemographic information form and the evaluation forms to fill.

### Outcome measures

*State-trait anxiety inventory (STAI)*. The STAI was developed by Spielberger and includes two scales: State Anxiety Scale (SAS) and Trait Anxiety Scale (TAS) (17). The STAI has been adapted to Turkish population and confirmed for reliability and validity (18). The statements in the SAS form measure how one feels at the moment whereas those in the TAS form measure how one feels generally as a self-report. The inventory uses one to four point Likert scale response format in which a score of 20 indicates the absence of anxiety, whereas a score of 80 indicates the highest anxiety. The following response choices are offered: not at all, somewhat, moderately so, and very much so. This measure is used to differentiate between long standing trait and temporary state anxiety. In this study, post biopsy anxiety of the participants was measured with SAS. TAS was used to assess the homogeneity of trait anxiety between intervention and control groups.

*Visual Analogue Scale (VAS)*. This scale was developed by Price et al. (19) in 1983. VAS has been shown to be accurate, valid, reliable, and used in hundreds of studies over the years (20). This scale consists of a 100 mm horizontal line with the two ends representing the minimum and maximum scores for pain. The patients were asked to draw a vertical line representing their pain levels in the horizontal scale ranging from 0 to 100. The ends of the scale were marked "no pain" and "most severe pain". There were no intermediary markings on the scale.

### Power and sample size analysis

The sample size of the study was determined using multivariate analysis of variance (MANOVA) test and PASS software program to determine the effect of music intervention on the STAI and VAS scores. The minimum sample size was calculated as 64 (32 patients in the intervention group, 32 patients in the control group) at 80% power, 0.16 effect size and 0.05 error level.

#### Main points

- This study evaluated the effect of classical music intervention on anxiety and pain levels of patients undergoing ultrasound-guided core needle breast biopsy.
- Music intervention, before and during ultrasound-guided breast biopsy reduced patient anxiety significantly.
- The results have implications especially for low- and middle-income countries where low-cost and easily implemented interventions are needed to address patient anxiety during breast biopsy procedures.

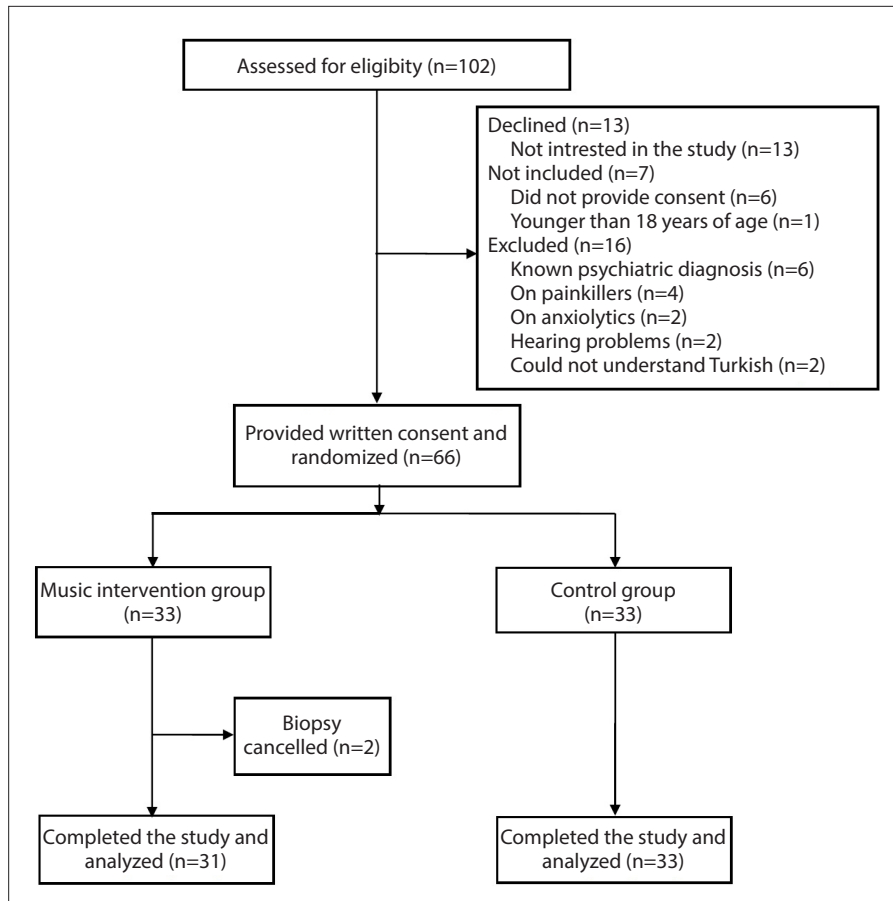


Figure 1. Flowchart of the study cohort.

### Statistical analysis

Statistical analyses were done using IBM SPSS 20.0 (IBM Corp.) package program. The Shapiro–Wilk test was used to determine whether the data (age, anxiety and pain scores) were normally distributed or not. Numerical variables were expressed as mean and standard deviation (SD) if distributed normally; median and minimum–maximum values if not. Categorical variables were given as numbers and percentages. The differences between intervention and control groups in terms of numerical variables were tested with Student-t test if distributed normally, with Mann–Whitney U test if not. Pearson correlation analysis was used for investigating the relationship between pain and anxiety scores. To find the effect of the independent variable (music intervention) on dependent variables (anxiety and pain levels) one-way MANOVA test was used. The results were considered statistically significant when  $p < 0.05$ .

### Results

Totally, 102 patients were considered for eligibility as seen in Fig. 1. Of these, 66

(64.7%) eligible patients who provided written consent for the study were allocated to the intervention and the control groups equally ( $n=33$ ,  $n=33$  respectively). The biopsy was cancelled for two patients from the music intervention group. Of the remaining 64 patients (62.7%) that comprised the study cohort, 31 (48.4%) patients were in the music intervention group, while 33 (51.6%) were in the control group. The mean age of the cohort was  $43.7 \pm 11.7$  years. Most of the patients (62.5%) had less than 12 years of education. Sociodemographic characteristics of the study cohort are summarized in Table 1. The duration of the biopsy procedure was  $16.8 \pm 3.3$  minutes. All participants in the intervention group received music intervention 15 minutes before and during the biopsy procedure. The age, sex, work status, education status, biopsy duration, biopsy result and trait anxiety levels in TAS were not statistically significantly different between the intervention and control groups ( $p > 0.05$ ). Sociodemographic and biopsy related variables of intervention and control groups are summarized in Table 2.

Table 1. Sociodemographic characteristics of the study cohort

Sociodemographic characteristics	
Age (years), mean $\pm$ SD	43.7 $\pm$ 11.7
Gender, n (%)	
Female	64 (100.0)
Male	0 (0)
Education, n (%)	
Primary school	22 (34.4)
Secondary school	18 (28.1)
High school	19 (29.7)
University	5 (7.8)
Work status, n (%)	
Not working (housewife)	40 (62.5)
Working/ Employed	19 (29.7)
Retired	5 (7.8)

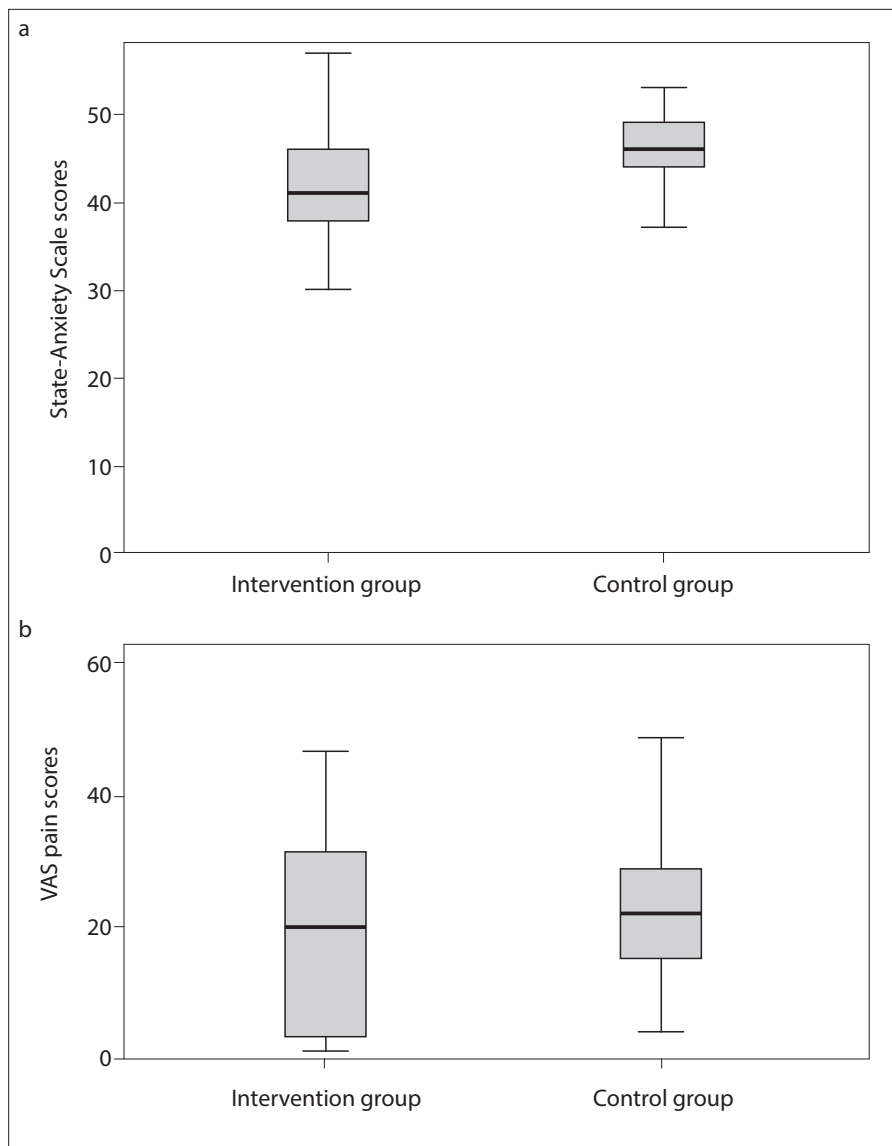
SD, standard deviation.

The mean SAS and VAS scores of the music intervention group were lower than the control group (Table 3). In the one-way MANOVA analysis, the effect of music intervention group was significant ( $F [2,61] = 4.973$ ,  $p = 0.01$ ). The patients in the music intervention group had significantly lower anxiety levels than the control group ( $p = 0.008$ ) with a mean difference of 3.8 (95% CI, 1.0–6.6) in SAS scores as shown in Fig. 2a. The mean difference in VAS scores of pain was 6.0 (95% CI, 2.2–14.2), which was not statistically significant between the groups ( $p = 0.150$ ) as shown in Fig. 2b. There was no significant correlation between VAS and SAS scores ( $r = 0.003$ ,  $p = 0.980$ ).

### Discussion

This study addressed the effect of classical music intervention on anxiety and pain levels of Turkish patients undergoing ultrasound-guided core needle breast biopsy. In this study, music intervention before and during ultrasound-guided core needle breast biopsy significantly reduced patient anxiety but did not significantly reduce pain.

Ultrasound-guided core needle breast biopsy is the preferred method for diagnosis and management of suspicious breast lesions. Music has the potential to decrease patient discomfort and anxiety. Three other trials investigated the effect of music on anxiety levels of imaging-guided breast biopsy patients. Haun et al. (13) from the US



**Figure 2. a, b.** The difference of (a) state anxiety scale scores ( $p = 0.008$ ) and (b) visual analogue scale (VAS) pain scores ( $p = 0.150$ ) between intervention and control groups.

reported that women who had music intervention had lesser anxiety levels consistent with this study. However, the authors did not specify whether the procedure was imaging-guided core needle breast biopsy or surgical biopsy. Bugbee et al. (14) reported from the US that music intervention did not have a significant effect on the anxiety levels compared with the control group. Music intervention group listened to classical music and ocean sounds before and during the biopsy, while standard care control group received alprazolam; the authors found that medication was the only significant factor affecting anxiety. The post biopsy SAS results of music intervention group ( $34.02 \pm 12.1$ ) and the control group ( $34.13 \pm 13$ ) in the study of Bugbee et

al. (14) seem almost 10 points lower than the SAS results of this study. This difference can be explained by cultural differences; in a recent study on anxiety of breast cancer patients from China and US, higher anxiety levels were found in patients from China (21). Soo et al. (15) studied the difference of anxiety and pain levels between interventions of guided meditation, music and control groups. They measured pre-biopsy and post-biopsy anxiety levels in women undergoing imaging-guided core needle breast biopsy and reported that anxiety decreased significantly in guided meditation and music groups when compared with the control group. Both Bugbee et al. (14) and Soo et al. (15) investigated the difference between pre-biopsy and post-bi-

opsy anxiety levels from the US, and found discordant results. Although this study did not report pre-biopsy anxiety levels, general anxiety traits were measured and were similar between intervention and control groups. The findings of this study are consistent with and comparable to Soo et al. (15) due to the use of same biopsy technique and tools measuring pain and anxiety; both studies found that music decreased anxiety levels but not pain levels of patients undergoing imaging-guided core needle breast biopsy.

Pain was not affected significantly from the music intervention. A literature search revealed that only one trial investigated the effect of music intervention on pain experienced during breast biopsy procedure. Soo et al. (15) studied the difference of anxiety and pain levels in patients undergoing imaging-guided core needle breast biopsy between interventions of guided meditation, music and control groups. They reported that pain was not different between music and control groups but meditation group had significantly lesser pain in imaging-guided core needle breast biopsy. Based on the former study and Soo et al. (15) study, pain may be more difficult to intervene with music than anxiety. Further studies on the effect of different interventions like meditation on pain are needed in different cultures for breast biopsy patients.

This study has important implications. Music is a free intervention which can easily be implemented and is found to be effective in reducing anxiety during breast biopsy procedure. This intervention can be considered as an effective method especially for low- and middle-income countries where the health systems are different from developed countries. Further studies are needed to compare the effects of different music types on breast biopsy patients' anxiety and pain across cultures and countries. Also, studies are needed to investigate whether this anxiety reduction is associated with better patient compliance and follow-up.

This study has several limitations. It is limited in generalizability because the study cohort represents an urban population in the capital of Turkey and does not include males. There was no blinding. The same researcher applied music intervention and collected the data with the STAI and VAS forms which may affect the results. In addition, the type of music was chosen by the researcher, not by the patients. Indi-



**Table 2.** Differences in sociodemographic and biopsy-related variables between intervention and control groups

Variables	Intervention group (n=31)	Control group (n=33)	p
<b>Sociodemographic</b>			
Age (years), mean±SD	44.2±11.0	43.1±12.4	0.692
Gender (female), n (%)	31 (100.0)	33 (100.0)	-
Education <12 years, n (%)	20 (64.5)	20 (60.6)	0.800
Working / Employed, n (%)	7 (22.5)	12 (36.3)	0.280
Housewife, n (%)	19 (61.3)	21 (63.6)	1.000
<b>Medical</b>			
Biopsy time (min), mean±SD	16.3±3.0	17.4±3.6	0.171
Trait anxiety score, mean±SD	49.8±7.7	50.7±6.3	0.625

SD, standard deviation.

**Table 3.** Difference of outcome measures between intervention and control groups

Variables	Intervention group (n=31)	Control group (n=33)	p
<b>Outcome measures</b>			
State anxiety scale score	42.3±6.5	46.2±4.5	0.008
Visual analogue scale score	19.6±15.0	25.5±17.6	0.150

vidual taste of music may limit the results. Although the biopsy duration was similar between groups, individual differences in biopsy duration might have affected the duration of intervention. Although the power of this study is sufficient, studies with higher sample size and power are needed to support the results of the study. Lastly, since the data was collected using the written forms, the reliability of the data was limited to the information provided by the patients.

In spite of these limitations, this study has many strengths. The music intervention and control groups were almost identical in sex, age, work and education status. In the previous studies low level of education, female sex and age were found to be associated with perioperative anxiety and pain (22–24). Accordingly age, education level, working status were chosen as sociodemographic characteristics. The similarity of factors related to procedure anxiety minimized susceptibility bias. Furthermore, the patients' general tendency to anxiety in terms of "trait anxiety" scores and biopsy duration were similar between groups. The similarity of trait anxiety scores and sociodemographic characteristics between groups minimized the effect of clustering anxiety trait in one of the groups.

In conclusion, this study shows that music intervention, before and during ul-

trasound-guided breast biopsy, reduces patient anxiety significantly. Music is an easy to implement intervention for low- and middle-income countries and can be considered as an effective method for reducing patient anxiety during breast biopsy.

#### Conflict of interest disclosure

The author declared no conflicts of interest.

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