

# The effects of the music intervention on anxiety, pain, vital signs, and patient satisfaction in intravitreal injection: a randomized controlled study



Intravitreal enjeksiyonda müzik müdahalesinin ağrı, anksiyete, vital bulgular ve hasta memnuniyetine etkisi: randomize kontrollü çalışma

## Abstract

**Aim:** This study aimed to investigate the effects of music intervention applied in two different periods Before intravitreal injection (IVTI) on anxiety, pain perception, vital signs, and satisfaction in patients receiving intravitreal injection..

**Methods:** This randomized controlled study was conducted with a total of three groups including two music intervention groups (pre-IVTI (group 1) and during IVTI (group 2)) and a control group (Group 1 n= 73, Group 2 n = 74, Control Group n =72). The patients' pain was evaluated with the Visual Analog Scale (VAS) pain, anxiety with the Visual Analog Scale Anxiety (VAS-A), and satisfaction with the IVTI procedure with a 5-point Likert scale.

**Results:** The anxiety and pain scores were lower in groups 1 and 2 than in the control group ( $p<0.001$ ). All three groups had low pain levels when their VAS-Pain scores were compared immediately and 15 minutes after IVTI. Group 2 was found to have a significant difference between the two measurements ( $p=0.009$ ). Further, Groups 1 and 2 had significantly higher patient satisfaction with the IVTI procedure than the control group ( $p<0.001$ ).

**Conclusion:** The study results showed that music intervention has positive effects on anxiety, pain perception, and satisfaction in patients receiving IVTI therapy. As a result, we recommend the use of listening to music on patients before and during the IVTI procedure.

**Keywords:** anxiety; intravitreal injection; music intervention; pain; patient satisfaction; vital sign

## Öz

**Amaç:** Bu çalışmanın amacı, intravitreal enjeksiyon (İTVE) girişimi yapılacak hastalara iki farklı dönemde (İTVE öncesi ve İTVE sırası) uygulanan müzik müdahalesinin, hastaların anksiyetesi, ağrı algısı, vital bulgular ve hasta memnuniyetine etkisinin incelenmesidir.

**Yöntemler:** Bu randomize kontrollü çalışma iki müdahale (İTVE öncesi (Grup 1) ve İTVE sırası (Grup 2) müzik müdahale grup) ve bir kontrol grubu olmak üzere toplam üç grup ile yürütüldü (Grup 1; n= 73, Grup 2; n = 74, kontrol grub; n =72). Hastaların ağrı ve anksiyetesinin değerlendirilmesinde Görsel Kıyaslama Ölçeği (GKÖ) ağrı ve GKÖ anksiyete (GKÖ-A) kullanıldı. İTVE prosedüründen memnuniyet ise 5'li likert özellikte olan bir soru ile değerlendirildi.

**Bulgular:** Anksiyete ve ağrı skorları Grup 1 ve 2'de kontrol grubuna göre daha düşüktü ( $p<0,001$ ). Üç gruptaki hastaların enjeksiyondan hemen ve 15 dakika sonraki GKÖ-ağrı skorları karşılaştırıldığında, bütün gruplarda hastaların ağrı düzeyleri düşüktü. Grup 2'nin iki ölçümü arasında anlamlı fark vardı ( $p=0,009$ ). Grup 1 ve 2'deki hastalar kontrol grubuna göre İTVE prosedüründen önemli ölçüde daha yüksek hasta memnuniyetine sahipti ( $p<0.001$ ).

**Sonuç:** Bu çalışmanın sonuçları İTVE uygulanan hastalarda müzik müdahalesinin, hastaların anksiyete, ağrı algısı ve hasta memnuniyeti üzerine olumlu etkilerinin olduğunu ortaya koymaktadır. Bu nedenle, İTVE öncesi ve sırasında hastalara müzik müdahale yapılmasını önermekteyiz.

**Anahtar Sözcükler:** ağrı; anksiyete; hasta memnuniyeti; intravitreal enjeksiyon; müzik müdahalesi; vital bulgu

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## INTRODUCTION

Intravitreal injection (IVTI) is the injection of medication directly into the vitreous cavity (1). This procedure has recently become one of the most rapidly emerging areas of ophthalmology (2). It is one of the most commonly performed invasive procedures in ocular diseases around the world, particularly in Turkey (3), as well as one of the most commonly practiced procedures in medicine (4).

In standard practice, Intravitreal injection procedures, which often involve several doses, are performed under topical anesthesia (5,6). Pain and discomfort at the injection site are the most common side effects in patients receiving IVTI (5). It's very important to minimize the patient's pain during this procedure. Sudden movements of the eyes caused by the pain experienced during the injection may lead to complications such as the injection being administered to the wrong area, increasing the intraocular pressure, and endophthalmitis. Furthermore, patients who have had multiple injections may be incompatible with later procedures as a result of unpleasant experiences during prior injections (6).

Regardless of the disease's nature, patients may experience anxiety as a result of the hospitalization process, diagnostic procedures, and, in particular, surgical procedures (7). The use of topical anesthesia (8) and an eye drape (2), ocular injection (8), disease progression, needle phobia, the need for more frequent injections, and needing to take sick leave from work or ask family members or caregivers for assistance are the most common causes of anxiety in this group of patients (9,10). High levels of anxiety have been identified in patients before ophthalmic surgery or intervention (11).

There is an association between anxiety before invasive intervention and pain afterward (12-16). Patients, who are anxious before the operation, are also prone to the increased pain experience. As a result, the amount of analgesic and anesthetic drugs used in these patients increases, and the recovery period is prolonged (14-16). Determining the causes of patients' stress and anxiety, as well as taking the appropriate steps before implementing treatments, is thus critical. Music intervention, which is used to reduce patients' anxiety and pain, is a non-pharmacological complementary and alternative therapeutic approach that is

affordable, simple to use, and efficient (17).

Music interventions are known to have positive effects on patients' vital signs (blood pressure, heart rate, respiratory rate, body temperature) and satisfaction, in addition to reducing anxiety and pain (8,18,19). The vast majority of studies investigating the impacts of music intervention on patients undergoing ophthalmic surgery/intervention were performed on patients who had cataract surgery (20-24). Music that was listened to during surgery has been shown to reduce anxiety, systolic blood pressure, and heart rate in patients (20), have a significant effect on pain relief (21) and improve patient satisfaction levels (22). One study, however, found that listening to music via headphones during the intraoperative process had no benefit (23). In a study conducted with IVTI patients, the music listened to before the injection and throughout the procedure was found to decrease the anxiety of the patients and positively affected the music therapy preferences of the patients in their future injections. Both groups, however, were said to have similar levels of pain (8).

The literature review indicated the insufficiency of studies investigating the effects of music intervention in IVTI patients. In a study involving a music intervention, the pain, anxiety, and satisfaction of patients have been investigated. However, the implications of the music intervention on the Before-IVTI and During-IVTI phases have not been separately studied (8). In only one study in the field of ophthalmic surgery, music intervention was applied in two separate periods. Although it was found to reduce pain and anxiety in the preoperative period, it was not found to be beneficial in the intraoperative period as it weakened the communication between the patient and the surgeon (23). Furthermore, no study on the effects of music intervention on vital signs in patients receiving IVTI we could come across. Based on this requirement, this study was designed to investigate the effects of music intervention on anxiety, pain perception, vital signs, and satisfaction of patients undergoing IVTI during both Before-IVTI and During-IVTI periods.

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## MATERIALS AND METHODS

This study was carried out per the Helsinki Declaration. The written permission from the hospital

management, the ethical approval were obtained from the Afyonkarahisar Health Sciences University Clinical Research Ethics Committee (approval date: 12.02.2019, number: 2019/76). Before the study began, individuals who met the inclusion criteria of the study were briefed about the aims of the study, and the written consent of all patients who agreed to participate was obtained using the Informed Consent Form, which clearly states that participation in the study is voluntary and that each participant retains the right to refuse the participation or leave the study at any time.

### Design and Setting of the Study

This randomized controlled trial was conducted at the Ophthalmology Clinic of Afyonkarahisar Health Sciences University Hospital between March and May 2019.

### Participants Selection

#### Inclusion criteria

Patients who were  $\geq 18$  years old, had elective IVTI, had IVTI previously, and volunteered to participate were included in the study.

#### Exclusion criteria

Exclusion criteria included hearing/speech impairments, mental illness, diagnosed psychiatric disorders, and depression.

### Sample Size and Sampling

Sample size estimation was performed based on an expectation of moderate changes (Cohen  $d=0.5$ ) in anxiety scores at During-IVTI among Groups 1 and 2, and the control group ( $\alpha=0.05$ ,  $1-\beta=0.80$ ), and the minimum sample size was estimated at 64 for each group (8). Based on changes in anxiety scores at During-IVTI, post-hoc power was calculated as 0.99 for Group 1 and control group comparison and 0.90 for Group 2 and control group comparison. G-power package version 3.1.9.2 was used for power analysis. In the study, the sample size was 75 for each group and 225 patients in total (Figure 1).

### Randomization

Participants were divided into three groups by block randomization using a statistical package program. The block size was determined by the researchers. Once the block size was determined, all possible allocation combinations for this block size were calculated

with Medcalc package version 11.5.1. Then, a random block combination was chosen to indicate the assignment of patients to groups. One patient was randomly allocated to Group 1, one to Group 2, and the other to the control group in three blocks of the same size.

### Measurements

#### Patient information form

The form consists of 17 items aiming to evaluate the age, gender, educational status, marital status, smoking habits, chronic disease status, previous hospitalization, previous surgery, eye surgery, number of injections, the type of music they prefer to listen to, and pain expectation of the included patients. The data were collected through face-to-face interviews with the patients on the day of admittance.

#### Visual analog scale anxiety (VAS-A)

It is a 10-cm long measurement tool developed by Cline et al. with a scoring range of 0 to 10, with a score of 0 representing "not anxious at all" and a score of 10 representing "feeling very anxious" (25). The closer the score is to ten, the higher the patient's level of anxiety (26). In the literature, it has been reported to be a successful scale for relieving patient symptoms and assessing fast-acting drug treatments (27). There is a concurrent validity correlation between VAS-A and Spielberger State-Trait Anxiety Inventory (from  $r = 0.49^{16}$  to  $r = 0.82^{19}$ ) (28). This indicates that the VAS-A scale, although brief, is a reliable and accurate measurement tool. Patients rated their anxiety levels on the scale by putting a vertical mark in a 10 cm line before, immediately after, and 15 minutes after injection.

#### Visual analog scale for pain (VAS)

The VAS scale is a unidimensional scale commonly used today in the assessment of pain severity. The validity and reliability study has been conducted for its applicability in Turkey. According to VAS, pain severity is rated from 0 (no pain) to 10 (worst pain) (29). Pain severity ranges determined by VAS-P were considered as mild pain below 3 points, moderate pain between 3 and 6 points, and severe pain above 6 points (30). Patients were asked to rate the severity of pain by putting a vertical mark on a 10 cm horizontal VAS (immediately after the injection and 15 minutes later).

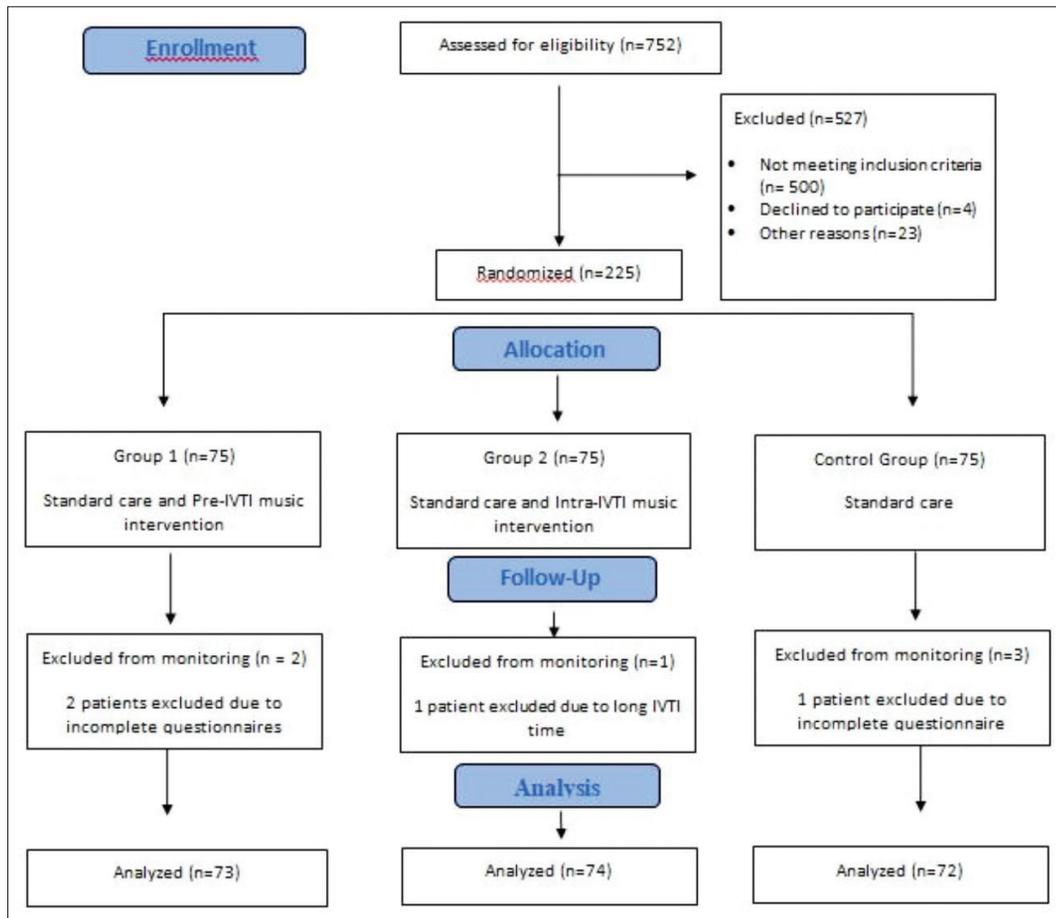


Figure 1. Randomized controlled study flowchart.

### Vital signs

The researchers measured the patients' systolic and diastolic blood pressure, heart and respiratory rates, SpO<sub>2</sub>, and body temperature 15 minutes before and during the injection procedure (3rd minute, one time).

### Patient satisfaction with IVTI procedure

In studies examining the effect of music intervention, it was seen that patient satisfaction was seen to be evaluated with different methods developed by the researchers such as 4-Likert type or yes/no (14,31-33). In this study, based on reference studies in the literature, satisfaction with the IVTI procedure was evaluated with a 5-point Likert question ("Very Dissatisfied", "Dissatisfied", "Unsure", "Satisfied" and "Very Satisfied"). Patients rated their satisfaction levels 15 minutes after injection.

### Data Collection and Interventions

The patients were divided into three groups, each consisting of 75 participants, and interviewed (MH) after admission to the Ophthalmology Clinic (the morning of the day of IVTI). The patients were informed verbally and in writing by the researcher (MH) about the procedure to be performed for the group in which they were included and their voluntary participation was ensured. Patients who were admitted to the clinic for IVTI and were part of the music intervention groups (Before-IVTI and Intra-IVTI) were taken to a waiting room. This was done to ensure that patients in the control group were not adversely affected by the fact that they did not receive the music intervention that the other groups did. Following admission to the Ophthalmology Clinic, all patients in the study received standard treatment protocol. Injections were

given by the same surgical team to all patients while under topical anesthesia and awake. A protocol unique to Afyonkarahisar Health Sciences University Hospital Ophthalmology Clinic was applied to all patients, which included the following information:

- Before the injection, all patients were informed about the IVTI treatment and complications by the Ophthalmology Clinic team. They were also informed about the study protocol by the investigators. The patients, however, had no idea which group they belonged to.
- The patients were informed that the IVTI would be performed in a special room inside the Ophthalmology Clinic. It has been explained that sedation will not be administered before IVTI, a drop of topical anesthetic Proparacaine HCL (0.05%) will be dripped into their eyes to prevent pain about one and a half minutes before the injection, and the medication they should use during and after the treatment, probable complications they might encounter and whom to apply in the case of a complication.
- Vital signs of the patients were checked before and during IVTI.
- None of the patients was administered any analgesic medicine before or during the IVTI except ones used in the routine clinical practice.

### **Music Intervention**

Music intervention is especially effective when the music is individualized and the preferences and experiences of the listener are taken into account (34). Therefore, the wishes or choices of patients should be taken into account in order to obtain maximum benefit from the music intervention (35). Besides, It is reported that music therapy would be more effective if it is carried out by a trained therapist following a structured protocol (36). Considering this information, the music intervention in this study was created under the guidance of music therapist Özgür Salur.

After patients were admitted to the clinic, the type of music they wanted to listen to at that moment was determined by asking them the type of music they listened to in their daily lives and was familiar with during the interview with the patients. For this study, playing music through a music-streaming application on an electronic device, which was either a handheld

tablet or a smartphone, was the definition of music listening. The patients listened to the selected music with headphones. Disposable earpads were used for headphones, which were replaced for each patient. Patients in the Before-IVTI group listened to music for 15 minutes, 30 minutes before the injection, while those in the During-IVTI group listened to music while the injection was taking place (approximately 5 minutes).

### **The protocol for the control group**

Only standard care was provided to the patients in the control group.

### **Statistical Analysis**

Statistical Package for the Social Sciences package program version 20.0 (SPSS Inc., Chicago, IL, USA) was used to perform statistical analysis the study results. The mean and standard deviation were used to describe continuous variables, while frequency and percentage were used to describe categorical variables. Normal data distribution was analyzed using the Shapiro-Wilk test. Repeated Measures Two-Way ANOVA was used to compare VAS-A and VAS scores by both groups and time. It was tested whether the effect of group (1st factor), the effect of time (2nd factor), and group-time interaction are important. For VAS-A and VAS, the Tukey Test (A, B) was used to show differences between groups, and Bonferroni Post Hoc Test (a, b, c) was used to show differences between times. The Kruskal Wallis test was used to compare the vital signs and surgeon-patient cooperation scores of the groups, and the Bonferroni post hoc test (a, b) was used to show the differences between the groups. One-Way ANOVA was used to compare the mean scores of anxiety and pain of the intervention groups according to the types of music listened to. Comparison of patient satisfaction related to the method applied and the future method preferences between the groups were analyzed by the chi-square test. p-value < 0.05 was considered statistically significant.

## **RESULTS**

### **Patients' Characteristics**

The characteristics of the groups are presented in Table 1. There was no statistically significant difference between groups in terms of demographic characteristics.

### Anxiety Evaluation

Patients' anxiety levels are presented in Table 2. VAS-A scores of the intervention groups immediately and 15 minutes after IVTI (Group 1:  $2.2 \pm 1.62$ ,  $0.74 \pm 1.13$ , Group 2:  $2.51 \pm 1.8$ ,  $0.57 \pm 0.97$ , respectively) were significantly lower than the control group ( $3.56 \pm 2.11$ ,  $1.59 \pm 1.55$ , respectively) ( $p_{\text{Group}} = 0.001$ ). VAS-A scores of the patients in the intervention groups showed a positive change after the injection. However, in the control group, anxiety scores showed an increase immediately after injection while they decreased after 15 minutes ( $p_{\text{time}} = 0.001$ ). The group-time interaction was found to be statistically significant ( $p_{\text{time} \times \text{group}} = 0.002$ ). Furthermore, no significant difference was found between the types of music they preferred to listen to and the anxiety scores of the intervention groups ( $p > 0.05$ ).

### Pain Evaluation

When the groups were compared in terms of pain sensation immediately after IVTI, the intervention groups (25.4% and 29.1%, respectively) had fewer patients experiencing pain than the control group (45.5%), and the difference was statistically significant ( $p < 0.001$ ). Immediately and 15 minutes after IVTI, the VAS-pain scores of the patients in the intervention groups (Group 1:  $1.13 \pm 1.52$ ,  $0.95 \pm 0.93$ , Group 2:  $1.34 \pm 1.53$ ,  $0.91 \pm 0.87$ , respectively) were significantly lower than the control group ( $2.47 \pm 1.91$ ,  $2.01 \pm 1.32$ , respectively) ( $p^a < 0.001$ ). When the VAS-Pain scores of patients in three groups immediately and 15 minutes after injection were compared, the pain levels of patients in all groups were found to be low. There was a significant difference between the two measurements of group 2 ( $p^b = 0.009$ ). However, there was no statistically significant difference between the VAS scores of Group 1 and the control group ( $p > 0.05$ ) (Table 3). Additionally, no significant difference was found between the types of music they preferred to listen to and the pain scores of the intervention groups ( $p > 0.05$ ).

### Vital Signs

The vital sign parameters of the groups are presented in Table 4. When vital signs were compared according to groups and times, there was no significant difference in parameters measured before injection between groups. There was a difference found between the

groups for systolic-diastolic blood pressure and heart rate changes measured during the injection ( $p < 0.001$ ). The difference was determined to be between the control group and the intervention groups (a, b). When the mean values were examined, they were seen to be lower in the intervention groups.

### Patient Satisfaction Distribution

Patients in groups 1 and 2 were significantly more satisfied with the IVTI procedure than those in the control group ( $p < 0.001$ ) (Table 5).

## DISCUSSION AND CONCLUSION

This study has revealed positive effects of music intervention in regards to pain, anxiety, vital signs (systolic and diastolic blood pressure, heart rate), patient-surgeon cooperation, and satisfaction in patients undergoing IVTI.

Music intervention is a complementary and alternative treatment method that can be applied to patients of all age groups, with different clinical conditions, in inpatient treatment, or outpatient units (37,38). This method is a non-pharmacological, easily tolerated, low risk, inexpensive and noninvasive intervention (16,38). Music intervention used to reduce the stress and anxiety experienced by the patient brings down the cortisol level that increases in the body as a result of stress. It is stated that by creating physiological changes in the body, music ensures the stability of vital signs and can accelerate the healing process (7,33,39,40). Music has also been shown to have anxiolytic and analgesic effects, in addition to lowering heart rate, respiratory rate, and blood pressure in perioperative patients (41-43). In the literature, it has been reported that a temporary increase has been recorded in systolic and diastolic blood pressure in the period following the preparation before IVTI until the injection (44). Therefore, music can be used as an effective intervention to help the treatment of patients who face many health problems due to their illnesses or treatments (16,38,45).

In this study, the anxiety mean scores of Groups 1 and 2 were significantly lower than the control group. This suggests that patients in the music intervention group had lower anxiety than the control group. More-

Table 1. Characteristics of the patients (n=219)

	Group 1 (n= 73)		Group 2 (n= 74)		Control Group (n= 72)		p
	n	%	n	%	n	%	
<b>Demographic Characteristics</b>							
<b>Gender</b>							
Female	38	52.1	36	48.6	35	48.6	0.892
Male	35	47.9	38	51.4	37	51.4	
<b>Marital Status</b>							
Single	6	8.2	11	14.9	13	18.1	0.213
Married	67	91.8	63	85.1	59	81.9	
<b>Educational Status</b>							
Illiterate	5	6.8	8	10.8	6	8.3	0.585
Primary Education	39	53.4	34	45.9	34	47.2	
Secondary Education	24	32.9	25	33.8	30	41.7	
University	5	6.8	7	9.5	2	2.8	
<b>Occupation</b>							
Housewife	34	46.6	35	47.3	28	38.9	0.575
Retired	27	37.0	26	35.1	33	45.8	
Driver, storekeeper, farmer	9	12.3	8	10.8	10	13.9	
Worker, civil servant, engineer	3	4.1	5	6.8	1	1.4	
<b>Type of music listened to</b>							
Religious music (Devotional Music, Sufi Music, Listening to Quran)	38	52.1	50	67.6			0.224
Turkish folk music	18	24.7	15	20.3			
Turkish classical music	6	8.2	3	4.1			
Pop music (Turkish, and other)	7	9.6	2	2.7			
Turkish arabesque music	4	5.5	4	5.4			
	<b>Mean ± SD</b>		<b>Mean ± SD</b>		<b>Mean ± SD</b>		
Average Age (year)	64.80±2.55		64.57±2.89		65.21±2.83		0.339
Number of injections	10.23±2.89		10.14±3.14		10.84±3.09		0.231

n: number, SD: Standart deviation.

Table 2. Comparison of the anxiety scores of the IVTI patients before, during and after IVTI.

Group	Time		
	Before-IVTI	Immediately After IVTI	15 min. After IVTI
	Mean ± SD	Mean ± SD	Mean ± SD
Group 1	2.85±1.65 <sup>Aa</sup>	2.2±1.62 <sup>Ab</sup> (MD=-0.65)	0.74±1.13 <sup>Ab</sup> (MD=-2.11)
Group 2	2.67±1.66 <sup>Aa</sup>	2.51±1.80 <sup>Aa</sup> (MD=-0.16)	0.57±0.97 <sup>Ab</sup> (MD=-2.10)
Control Group	3.18±1.6 <sup>Aa</sup>	3.56±2.11 <sup>Ba</sup> (MD=0.38)	1.59±1.55 <sup>Ba</sup> (MD=-1.59)

$P_{group} = 0.001, P_{time} = 0.001, P_{time*group} = 0.002$

IVTI, Intravitreal Injection; MD, mean difference (for Before IVTI). Two-way Repeated Measure of ANOVA; LSD test for interaction term; <sup>a,b,c</sup> The difference between the times; <sup>A,B</sup> The difference between the groups

**Table 3.** Comparison of the pain scores of the IVTI patients during and after IVTI.

Group	Time		<i>p</i> <sup>b</sup>
	Immediately After IVTI	15 min. After IVTI	
	Mean ± SD	Mean ± SD	
Group 1	1.13±1.52 <sup>A</sup>	0.95±0.93 <sup>A</sup>	0.407
Group 2	1.34±1.53 <sup>A</sup>	0.91±0.87 <sup>A</sup>	<b>0.009</b>
Control Group	2.47±1.91 <sup>B</sup>	2.01±1.32 <sup>B</sup>	0.052
<i>p</i> <sup>a</sup>	<b>&lt;0.001</b>	<b>&lt;0.001</b>	

Bold *p* values are statistically significant ( $p < 0.01$ ). IVTI, Intravitreal Injection. <sup>a</sup> Kruskal Wallis test; *p*<sup>a</sup> This shows the difference between the groups for each time. <sup>b</sup> Mann whitney *u* test; *p*<sup>b</sup> This shows the difference between the times for each group. <sup>A,B</sup> The difference between the groups.

**Table 4.** Comparison of the vital signs of the IVTI patients before and during IVTI.

Parameters	Groups			<i>p</i>
	Group 1 (n=73) Mean ± SD	Group 2 (n=74) Mean ± SD	Control Group (n=72) Mean ± SD	
<b>Before-IVTI</b>				
SBP (mmHg)	142.25±16.84	142.43±19.06	142.99±19.1	0.922
DBP (mmHg)	83.41±12.56	83.45±13.39	84.63±11.96	0.868
HR (min)	74.47±7.58	76.11±8.92	75.01±8.41	0.625
RR (min)	22.9±1.63	22.95±1.63	22.75±1.73	0.773
SpO2 (%)	93.71±1.67	94.05±2.04	93.74±1.79	0.273
Body temperature (C°)	36.57±0.18	36.57±0.21	36.6±0.18	0.214
<b>During IVTI (3rd minute, one time)</b>				
SBP (mmHg)	158.89±18.28 <sup>b</sup>	161.53±14.88 <sup>b</sup>	182.04±20.84 <sup>a</sup>	<b>&lt;0.001</b>
DBP (mmHg)	90.86±10.16 <sup>b</sup>	92.32±9.9 <sup>b</sup>	99.49±8.8 <sup>a</sup>	<b>&lt;0.001</b>
HR (min)	83.32±10.39 <sup>b</sup>	85.62±10.14 <sup>b</sup>	90.19±11.3 <sup>a</sup>	<b>&lt;0.001</b>
RR (min)	23.29±2.27	23.54±1.95	23.78±2.36	0.370
SpO2 (%)	93.67±1.8	93.88±1.74	93.67±1.86	0.719
Body temperature (C°)	36.39±0.25	36.23±1.14	36.39±0.22	0.659

Bold *p* values are statistically significant ( $p < 0.01$ ). Kruskal Wallis test; <sup>a,b</sup> The difference between the groups. IVTI, Intravitreal Injection; SBP, Systolic Blood Pressure; DBP, Diastolic Blood Pressure; HR, Heart Rate; RR, Respiratory Rate, SpO2, Percentage of Oxygenated Hemoglobin.

over, in this study, the music intervention used before the IVTI procedure was observed to reduce the anxiety levels of the patients during the injection, while the music intervention used during the IVTI reduced the anxiety levels of the patients after the injection. This suggests the music intervention as a method that can be used to reduce patients' anxiety both before and during IVTI. Our study findings support the positive effects of music intervention on anxiety, which have also been reported in the literature (8,20). However, Marekou et al. found similarities between the groups in terms of their ability to cope with stress, different from our study (24). Further, in contrast to our find-

ings, Bellan et al. found that music that was listened to before surgery was more effective in reducing patients' anxiety levels (23). This difference is thought to be attributed to the difference in the patient group in which the studies were conducted. The most common side effect caused by IVTI is pain at the injection site (5). The pain that occurs during the injection can affect the general comfort of the patients and may reduce patient cooperation in repeated injections (12). In this study, when the patients were asked whether they felt pain during injection, fewer patients in intervention groups were determined to experience pain compared to the control group. When patients were asked about the

Table 5. Comparison of the patient satisfaction of IVTI procedure

Variables	Group 1 (n=73)		Group 2 (n=74)		Control Group (n=72)		p
	n	%	n	%	n	%	
Very unsatisfied	-	-	-	-	-	-	
Unsatisfied	-	-	-	-	10	13.9	
Indecisive	4	5.5	4	5.4	35	48.6	<b>&lt;0.001</b>
Satisfied	58	79.5	52	70.3	26	36.1	
Very satisfied	11	15.1	18	24.3	1	1.4	

Bold p values are statistically significant ( $p < 0.01$ ). IVTI, Intravitreal Injection. <sup>a</sup> Chi-Square Test

severity of the pain experienced during and after injection, all patients reported having mild pain in both periods. This result is similar to the literature (5). Also, in our study, the severity of pain of patients in groups 1 and 2 was lower than reported in the literature for patients receiving IVTI (46). This finding suggests that music intervention may have positive effects on reducing the severity of pain in patients. In addition, music intervention during injection was found to be more effective in reducing the intensity of pain in patients in our study. The patients' pain scores were  $4.162 \pm 0.4762$  for the music intervention group and  $4.542 \pm 0.5100$  for the control group in a study evaluating the impact of music on the same group as ours, and the difference was not significant (8). Our study results differ from the study of Chen et al. in terms of both lower pain scores and significant differences between music intervention groups and control groups (8). The lower pain scores of the patients in this study may be related to the topical anesthesia given to them before IVTI. Furthermore, a relationship has been reported to be present in the literature between anxiety before invasive procedures and acute pain experienced after invasive procedures (17). The low anxiety scores of the patients in this study may have affected their pain scores.

Music can provide an interpretable stimulus that can prevent or alleviate anxiety by changing the focus of attention and eliciting positive memories from an earlier period in one's life. It is also believed that when the chosen music type is personalized and based on the patient preference, it evokes positive memories and leads to comfort in the listener (47). In the literature, it is stated that each individual may have a unique biological system that responds to a particu-

lar stimulus with a unique but consistent physiological response and perceived psychological experience. Therefore, patients' preferences, familiarity, cultural context, and past experiences are among the factors that can increase the success of music interventions (48). Considering the literature information, in this study, the patients listened to music they were familiar with and preferred to listen to in daily life. In the study, the pain and anxiety scores of the intervention groups were lower than the control group. Analysis was performed to determine whether the music type listened to affected this decrease. Although the scores were observed to be lower in some music types, the type of music listened to was determined not to have any effect on the anxiety and pain scores of the patients. This result suggests that listening to music is more effective than the music type. Besides, the fact that all the participants of the study have the same culture and that this type of music is widely listened to in this culture could have been an effective factor in this result. In order to reveal the effect of music types that change with the cultures, we believe that examining the effect of music types will contribute to the literature through studies to be conducted with patient groups with different cultural structures.

Furthermore, blood pressure values of all patients increased during injection compared to pre-injection levels. The intervention group, on the other hand, had significantly lower blood pressure (both systolic and diastolic) than the control group. Similar results were observed in the heart rate values of the patients. Heart rate and systolic blood pressure were found to decrease significantly in a study investigating the effect of music on cataract surgery compared to the control

group (20). Heart rate and systolic blood pressure did not vary between the groups in another study (21). Different results in the literature indicate the need for further studies to investigate the effects of music intervention on vital signs in detail.

Patients in the intervention groups were statistically significantly more satisfied than those in the control group ( $p < 0.001$ ). Chen et al. investigated the effects of music intervention in IVTI patients and found that there was no statistically significant difference in patient satisfaction between the intervention and control groups ( $p = 0.6275$ ) (8). The findings we obtained in the study in regards to patient satisfaction showed similarities with the literature, and satisfaction varied significantly among music intervention groups and controls, which was not the case in the literature. Unlike other studies involving ophthalmic surgery patients, the patient's music preference was entirely up to them in our study. It has been shown that the form of music preferred by patients may reduce anxiety and improve pain perception and tolerance (49). This is due to factors such as the individual's familiarity with the music they enjoy, as well as a sense of history and culture. With this knowledge, the significant difference may be attributed to the lower levels of pain and anxiety encountered by patients in the music interventions groups.

Turkish patients who received IVTI in the eye surgery clinic of a university hospital in western Turkey formed the sample of the study. Therefore, the results cannot be generalized to all IVTI patients. Although music intervention using the preferred music type of the patients has been revealed to have positive effects on pain, anxiety, blood pressure (systolic, diastolic) and heart rate values, and patient satisfaction, these positive effects can not be attributed to music intervention only. The fact that the researchers were not blinded to the experimental conditions may have also affected the result due to minor biases. Another limitation of the study is that measurable stress parameters (adrenocorticotrophic hormone and cortisol) could not be analyzed due to the limited budget. Last, the reliability of the data was limited to the information given by the patients since the data were obtained through a face-to-face interview method.

The study results proved that music intervention in IVTI patients reduces anxiety and pain levels. At the

same time, music intervention both before and during the injection had a positive effect on bringing down the anxiety level. It also showed that music intervention especially during the injection had a positive effect on bringing down the pain level. Additionally, results indicated that music intervention had a positive effect on heart rate and blood pressure values during the injection procedure. Based on the results of this study, music intervention may be considered an effective and reliable method to bring down the anxiety and the pain levels of the IVTI patients. Therefore, we suggest having music interventions both before and during the injection for the IVTI patients with the music type chosen by the patient itself.

### Conflict-of-interest and financial disclosure

The author declares that she has no conflict of interest to disclose. The author also declares that she did not receive any financial support for the study.

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