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Effect of binaural beats on pain, anxiety, and procedure tolerance in patients undergoing colonoscopy without sedation: A randomized controlled trial

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ABSTRACT

Objectives: This study aimed to investigate the effect of binaural beats on pain, anxiety,and tolerance during colonoscopy of patients without sedation.

Methods: This is a prospective, randomized, controlled, single-blind procedural study that included 92 Turkish patients who underwent colonoscopy. The patients were randomly divided into two groups: the binaural beat music group (n=46) and the control group (n=46). The binaural music group was subjected to music through headphones during the colonoscopy, while the control group was provided headphones without music. The anxiety levels were measured using a Visual Analog Scale for Anxiety (VAS-anxiety), while the pain levels were assessed using a Visual Analog Scale for Pain (VAS-pain). Hemodynamic changes, procedure tolerance, cecal insertion and withdrawal times, polyp detection, and patients' experiences related to colonoscopy were recorded. Likert scales, indicating procedure satisfaction, were also administered immediately after the colonoscopy.

Results: The music group demonstrated significantly lower anxiety scores compared to the control group, along with better tolerance scores, a higher willingness to repeat the procedure, and a significant preference to listen to the same music again for any upcoming unsedated colonoscopy procedures ($P<0.05$). No significant difference was observed between the groups in terms of pain experienced during the procedure, vital parameters, cecum insertion time, procedure time, and polyp detection rate ($P>0.05$).

Conclusions: For patients undergoing colonoscopy without being sedated, listening to music composed of binaural beats demonstrated a significant decrease in anxiety levels and improved patient tolerance during the procedure, presenting an alternative to sedative medications.

Keywords: Binaural beats, anxiety reduction, gastrointestinal endoscopy, sedation free procedures, non-pharmacological intervention

Colonoscopy remains the gold standard for both diagnosing and treating colorectal disorders. It is also considered the primary approach for detecting precancerous lesions and colorectal cancer [1]. However, the colonoscopy procedure itself can cause pain and discomfort, leading to anxiety for patients before the procedure. As a result, many at-risk patients tend to postpone undergoing colonoscopy [2]. Addi-

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tionally, anxiety and pain can decrease the patient's tolerance and satisfaction during the procedure. Endoscopists can use sedative drugs to reduce patient anxiety and discomfort to minimize any disruptions caused by sudden or involuntary movements during the procedure. However, due to rising labor costs and equipment needs, many centers struggle to provide anesthesia and sedation to all patients. Also, especially in older adults, sedatives may raise the risk of cardiovascular disease [3].

Music therapy has been proposed as a safe, cost-effective, non-pharmacological approachto alleviate anxiety and stress in patients undergoing various interventional procedures [4]. It has been shown that music therapy improves relaxation, reduces anxiety, and effectively distracts the patient from pain phobia [5]. Hence, utilizing music therapy as supportive management in addition to conventional therapy for pain and anxiety has been investigated in numerous disciplines, such as oncology [6], endocrinology [7], pediatrics [8], urology [9], and orthopedics [10].

Gerald Oster first introduced binaural beat music as a unique audio type fifty years ago. The effect of binaural beats is best perceived when listened to with headphones. When two sinusoidal tones of close but differing frequencies are independently delivered to each ear at a consistent intensity, a single illusory tone is perceived by the listener. This perceived tone has a frequency that matches the average of the two separate tones, and its amplitude modulates at a rate equal to the frequency difference between them [11]. The inferior colliculi and superior olivary nuclei in the brainstem are responsible for merging the auditory signals from each ear, leading to the initial perception of binaural beats. It then progresses as neural impulses traverse the reticular formation, ascending through the midbrain to reach the thalamus, auditory cortices, and additional cortical areas [12]. Numerous clinical studies have provided evidence supporting the efficacy of binaural beat interventions in mitigating pain and anxiety in diverse clinical settings [13].

Due to the excessive patient load in our clinic, the lack of appropriate restrooms for sedated patients, and insufficient anesthesia personnel, we face difficulties in performing colonoscopy procedures after sedating the patient. Therefore, we have been seeking alternative methods beyond anesthetic interventions to improve colonoscopic procedure tolerance and patient satisfaction. Theta and delta-band frequencies have been demonstrated as useful in reducing anxiety and raising hypnotic susceptibility [14, 15]. In this study, we utilized binaural beats at 5 Hz theta frequencies to investigate their effects on colonoscopic pain, anxiety, and tolerance.

METHODS

Study Design

This was a prospective, randomized, single-blind, controlled trial in which the physician performing the procedure were blinded. The study was conducted in the colonoscopy unit of the Gastroenterology Clinics of Abdurrahman Yurtaslan Oncology and Training Research Hospital in Ankara, Turkey, between October 2023 and November 2023. The study protocol was granted ethical approval (Approval number and date: 2023-10/418).

Sample and Setting

G*Power software version 3.1 was employed to carry out an a priori sample size calculation. In the referenced study, the mean VAS Pain score was reported as 5.19 for the experimental group and 6.65 for the control group. Based on these VAS values, a sample size calculation was performed using the "Difference between two independent means" test with a two-tailed approach. With an effect size (d) of 0.60, 80% statistical power, and a 0.05 margin of error, it was determined that a minimum of 45 participants per group, totaling 90 individuals, would be required for the study [16].

The study initially enrolled 98 patients. However, six patients were subsequently excluded as they did not fulfill the specified eligibility criteria. Sex or underlying diseases were not considered specifically. However, patients with a history of prior colonoscopic procedures, had anxiety or panic disorders, epilepsy, hearing impairments, ear canal disorders, or unwilling to undergo the procedure while listening to music were excluded from the study. Hence, this study assessed 92 Turkish patients aged 18 to 70 years with colonoscopy appointments scheduled at the above-mentioned location.

Procedure

The patients arriving for colonoscopy procedures at the location of intervention were included in the study. Authorized research personnel contacted eligible participants, explained the study in detail, and obtained their consent to participate. Following the acquisition of consent, participants were randomly split into two groups through a block randomization sampling technique: the binaural beat (music) group (n=46) and the control group (n=46). The block size for randomization was determined by the researchers, followed by the computation of all possible allocation combinations for the block, of which a random block combination was selected to split the patients into groups. A block size of four involved the random assignment of two patients to the group and two to the intervention. This random block-choosing procedure was repeated until all patients were allocated to a group at random. This division was facilitated by a computerized randomization sequence created by an independent researcher not directly engaged in the study; individuals assigned through computer randomization were provided sealed envelopes until the allocation phase. These envelopes were unsealed solely upon the agreement of eligible participants to take part in the intervention and after obtaining informed consent. Patients and colonoscopy nurses were aware of the study groups, but the outcome assessors and gastroenterologist performing the procedure were blinded. The colonoscopy nurse accompanied the patients throughout the entire procedure. The vital parameters and anxiety levels (measured using the VAS-anxiety) of all patients were measured by the colonoscopy nurse immediately before the procedure, and their demographic information was recorded. Subsequently, the patients were prepared for the colonoscopy procedure. Both groups received an MP3 player (Meizu Slim 8GB MP3 Player, Meizu Technology Co Ltd, China) and in-ear stereo headphones. The music group was exposed to binaural beats (relaxing theta waves at 5 Hz, MusicMindMagic Production) during the colonoscopy, while the control group wore headphones without auditory stimulation.No music was played for the control group to evaluate only the effects of binaural beats precisely. To prevent any influence on the results, the procedures were conducted by a single gastroenterologist. The colonoscopy nurse used the Modified Gloucester Comfort Scale to document and assess patient comfort, including levels of tolerance and compliance throughout the procedure. Neither the nurse nor the physician spoke to the patients during the procedure. After the procedure's completion, the patients' headphones were removed, and they were transferred to the recovery unit. Their vital parameters, VAS-anxiety and VAS-pain scores, were measured and recorded again 5 minutes after the colonoscopic procedure.All elective colonoscopies were scheduled between 8:30 AM and 12:30 PM and performed byan experienced endoscopist who was unaware of the group assignments.The Fujinon EC-590WL4 colonoscope (Fujinon Inc, Tokyo, Japan) was used in the procedures. The colonoscopy nurse recorded the examination time for all patients who underwent the procedure. The observed polyps were removed during the withdrawal of the colonoscope.

Instruments

The Visual Analog Scale (VAS), created by Price *et al*. [17] in 1983, has been utilized to assess patients' subjective feelings of anxiety and pain. This scale features a 10-cm line that can be oriented vertically or horizontally, with the two ends indicating the highest and lowest levels of anxiety and pain (0: no anxiety /no pain, 10: extreme anxiety/ the most severe pain).

Table 1. Modified Gloucester comfort scale

Score	Scale	Description
1	No	No discomfort-resting comfortably throughout
2	Minimal	One or two episodes of mild discomfort, well tolerated
3	Mild	More than two episodes of discomfort, adequately tolerated
4	Moderate	Significant discomfort, experienced several times during the procedure
5	Severe	Extreme discomfort, experienced frequently during the procedure

The patients' self-reported levels of anxiety and pain were recorded on this scale by the colonoscopy nurse. This indicator serves as a dependable tool for evaluating anxiety and pain [17, 18].

The Modified Gloucester Comfort Scale is a tool used to evaluate patient tolerance and compliance throughout the procedure [19]. This scale assesses discomfort, characterized by coughing, retching, belching, and non-compliance, using a 5-point Likert scale, where 1 indicates no discomfort and 5 represents extreme discomfort during the procedure. (Table 1).

Post-procedure, patients responded to a series of questions designed to evaluate their satisfaction with the unsedated colonoscopy experience and their willingness to undergo the unsedated procedure again for health reasons (yes, maybe, or no). Additionally, the music group was queried with a three-option response (yes, not sure, or no) regarding whether the music enhanced relaxation and if they would be interested in listening to the same music in future procedures.

Statistical Analysis

Data was analyzed using IBM SPSS Statistics version 27. Measurements were taken from two groups (music vs. control) at two different time points, encompassing diastolic and systolic blood pressure, heart rate, and VAS scores. Continuous variables were presented as mean±standard deviation or median (25%-75% interquartiles). Normal distribution was determined using the Kolmogorov-Smirnov test. Categorical data were analyzed using the Chi-square test, while continuous variables were evaluated with either the Student's t-test or the Mann-Whitney U test, depending on data distribution. Repeated measures ANOVA was conducted to evaluate the intervention's effects, examining the influence of group, time, and the interaction between group and time (group×time effect). Statistical significance was defined as $P<0.05$.

RESULTS

Data were collected between October 2023 and November 2023, through which 98 patients were evaluated, with 6 excluded from the study due to not meeting the eligibility criteria. The rest of the 92 patients (46 in the music group, 46 in the control group, as originally assigned) included in the study under-

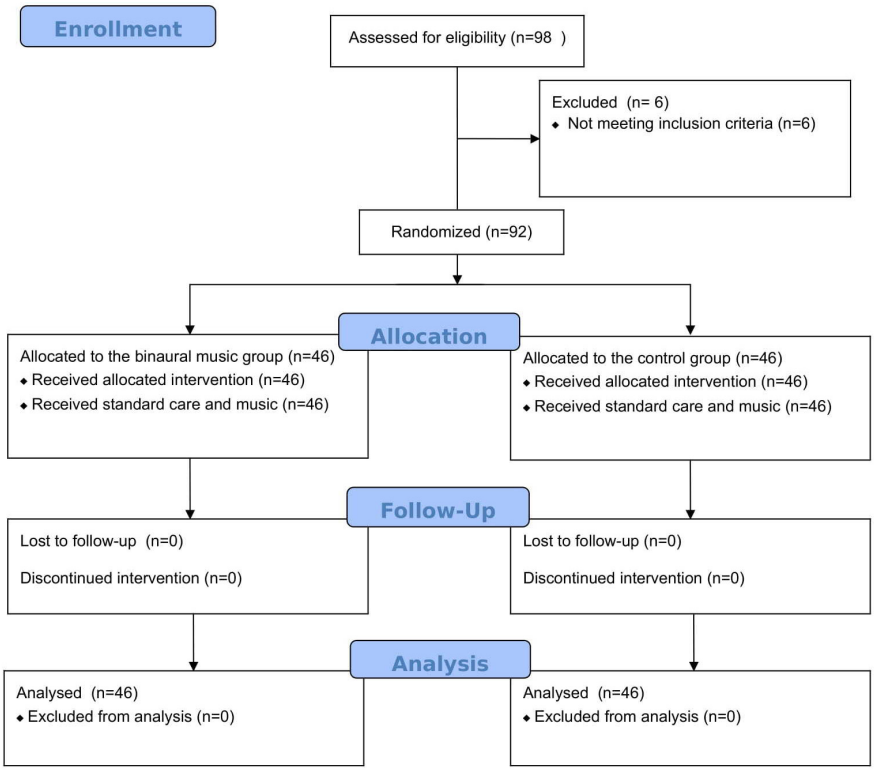

Fig. 1. CONSORT flowchart for participant flow.

went the procedure, and all colonoscopic interventions were successfully performed. The study was concluded when the target sample size was reached. With regard to the binaural music intervention, no subjects reported any discomfort (Fig. 1).

A summary of the demographics of patients and procedure related parameters has been presented in Table 2. Statistical analysis revealed no significant differences in age, sex, or education level, nor in the specific indications for colonoscopy (P>0.05), indicating a similar demographic profile across both groups. Upon analysis of procedural parameters, no significant differences were observed between groups with respect to VAS pain scores, polyp rates, or procedure duration (P>0.05). Based on the Modified Gloucester Comfort Scale, the music group demonstrated significantly higher procedural tolerance compared to the control group (P=0.020).

Table 3 presents the changes in systolic and diastolic blood pressure, heart rate, and VAS-anxiety

Table 2. Baseline characteristics of patients and procedure related parameters

Characteristics	Music (n=46)	Control (n=46)	P value
Age(years)	49.17±10.83	53.54±13.11	0.085
Sex			
Female	16(34.8)	19(41.3)	0.519
Male	30(65.2)	27(58.7)	
Education level			
Elementary school	15(32.6)	19(41.3)	0.576
Secondary school	6(13)	7(15.2)	
High school	9(19.6)	10(21.7)	
University	16(34.8)	10(21.7)	
Colonoscopy indication			
Iron deficiency	8(17.4)	13(28.3)	0.699
Dyspepsia	7(15.2)	5(10.9)	
Symptoms (pain, flatulence)	5(10.9)	5(10.9)	
Chronic diarrhea	8(17.4)	4(8.7)	
Chronic constipation	4(8.7)	7(15.2)	
Rectal bleeding	6(13)	5(10.9)	
Cancer screening	8(17.4)	7(15.2)	
Diabetes mellitus	6(13)	9(19.6)	
VAS-pain	5.22 ± 2.53	5.65 ± 2.55	0.415
Procedure duration(minutes)	11.04 (10.47, 12.14)	11.24(10.69,12.94)	0.266
Patients with polyps	10 (21.7)	17 (37)	0.109
Modified gluocester comfort scale			
1	16 (34.8)	7 (15.2)	**0.020**
2	18 (39.1)	12 (26.1)	
3	6 (13)	12 (26.1)	
4	6 (13)	12 (26.1)	
5	0 (0)	3 (6.5)	

Values are presented as mean±standard deviation or median (25-75 inter-quartiles) or number (%). VAS, visual analog scale. Bold indices P<0.05

Table 3. Descriptive statistics and effects of intervention in control and music groups over time

Variables	Group	Before	After	P value
SBP(mmHg)	Music	148.93±23.88	147.26±22.75	T; F=1.353, P=0.248
	Control	147.02±15.35	144.07±17.58	G; F=0.473, P=0.493
				G×T; F=0.104, P=0.748
DBP(mmHg)	Music	89.98±11.68	93.09±13.07	T; F=0.007, P=0.934
	Control	90.28±11.51	92.54±10.02	G; F=1.912, P=0.170
				G×T; F=0.085, P=0.771
HR(beats/min)	Music	95.76±13.74	96.28±14.83	T; F=3.072, P=0.083
	Control	96.28±14.83	94.85±17.78	G; F=1.099, P=0.297
				G×T; F=1.746, P=0.190
VAS - anxiety	Music	6.67±2.09	2.03±1.56	T; F=267.363, **P<0.001**
	Control	6.54±2.32	3.41±2.03	G; F=2.797, P=0.098
				G×T; F=9.294, **P=0.003**

Values are presented as the mean±standard deviation. SBP=systolic blood pressure, DBP=diastolic blood pressure, HR=heart rate, VAS=visual analog scale, G=groups, T=time (before-after), G×T=group × time. Bold indicates P<0.05

scores before and after the procedure, as well as the interaction effect (group × time) between the groups. In the music group, the mean VAS-anxiety score showed a decrease of 4.64 points. The interaction effect for VAS-anxiety scores was statistically significant (group × time; F(1,90)=9.294, P=0.003). In contrast, no significant interaction effects were found for the other parameters (P>0.05).

Table 4 displays the patient satisfaction results. The percentage of those in the music group expressing willingness to undergo the colonoscopic procedure again without sedation and those stating that the procedure went better than expected was significantly higher compared to the control group(P<0.05). Additionally, most patients in the music group expressed a desire to listen to the same music again if they required a sedation-free colonoscopic procedure in the future.

Table 4. Patient satisfaction

	Music (n=46)	Control (n=46)	P value
Willing to repeat the procedure			
Yes	35(76.1)	21(45.7)	**0.010**
Maybe	3(6.5)	9(19.6)	
No	8(17.4)	16(34.8)	
Patient experience			
Better than expected	36(78.3)	22(47.8)	**0.009**
As expected	5(10.9)	9(19.6)	
Worse than expected	5(10.9)	15(32.6)	
Would listen to the music again			
Yes	33(71.7)		
Not sure	6(13.0)		
No	7(15.2)		

Data are presented as number (%). Bold indicates P<0.05

DISCUSSION

Pain and distress are typical challenges in colonoscopy. Non-pharmacological approaches are essential to alleviate pain and distress in patients, reducing the need for increased sedative use. In this context, music plays a significant role in managing emotional states and promoting mind-body interactions, widely recognized for fostering relaxation in healthcare. In this context, various music genres have been employed to assess relaxation and tolerance in patients undergoing colonoscopy [4].

This prospective randomized single-blind controlled trial shows that when patients have a colonoscopy without sedation, adding binaural beats to their music significantly reduces their anxiety and increases their tolerance. The use of binaural beats is relatively new, and few publications are associated with its use during colonoscopy. Tani *et al.* [16] segregated patients undergoing unsedated colonoscopy into a music group (n=42) and a control group (n=48). They played binaural music (theta frequencies) from 5 minutes before starting the colonoscopy in the music group till the procedure was completed, while the control group did not receive the intervention. Measurements of anxiety and pain using the VAS scale and of patient satisfaction on a Likert scale revealed that the music group showed significantly higher levels of comfort and lower pain during the procedure [16]. Though no significant differences were observed between the music and control groups of our study in terms of pain during the procedure, the music group exhibited a significant reduction in post-procedural anxiety levels and a significant increase in procedure satisfaction. The willingness to repeat the procedure without sedation and the proportion of those in the music group who wished to listen to the same music if they were to undergo the procedure again were significantly higher.

In our study, the VAS-anxiety scores of both the music and control group patients before the colonoscopy procedure were similar and moderate. Being an invasive diagnostic intervention, sedation-free colonoscopy often induces anxiety in patients due to the accounts of excessively painful procedures they hear from others, the possibility of experiencing negative outcomes, or the information they gather from online research [2]. The moderate anxiety observed in both groups before the procedure in our study is likely associated with the above-mentioned reasons. Despite the lower VAS-anxiety scores in both groups post-procedure, the reduction in anxiety in the music group was significantly greater. This result demonstrates the anxiety-reducing effect of binaural music associated with the procedure. Similar results have been obtained in studies where various types of music were applied during colonoscopy, confirming the anxiety-reducing effect of music therapy [20-22].

Several studies have been reported in existing literatures that assess the efficacy of music therapy in mitigating pain during colonoscopy procedures. Costa *et al*. [23] reported that offering a selection of blues, country, classic, swing, jazz, reggae, and instrumental music to the music group reduced sedation requirements and pain levels. In another study, Çelebi *et al*. [24] demonstrated that listening to Turkish classical music significantly lowered pain scores in the intervention group during colonoscopy. However, in studies where local and classical music were played for patients by Harikumar *et al*. [25] and classical music was played by Martindale *et al*. [26], no significant difference in pain during the procedure was found compared to the control group. Similarly, despite the satisfactory comfort scores during the procedure in our study, and the high willingness to undergo the procedure again, no significant difference was perceived in the maximum pain levels experienced during the procedure. Dabu-Bondoc *et al*. [27] and Kliempt *et al*. [28] conducted measurements on the anesthesia dosage administered to patients who were provided with intricate binaural beats music (Hemi-sync), encompassing multi-layered frequencies such as alpha, beta, delta, theta, and gamma during the interventional procedure. The findings of the study demonstrated that individuals in the intervention group, who listened to binaural beats, required significantly less analgesia compared to those in the control group, who did not receive any auditory stimulus. In our study, we attribute the lack of a significant decrease in pain scores to the music being only in the theta frequency. We think the good comfort score and the high desire to repeat the procedure to the anxiolytic and hypnotic effects of binaural music in the theta frequency [15].

In a meta-analysis conducted by Bechtold *et al*. [29] evaluating the impact of music therapy (classical, relaxing, variety radio station, variety per patient) on

procedure duration in patients undergoing colonoscopy, no significant differences in procedure duration were found in 6 studies. In contrast, a reduction in procedure duration was identified in only one study [29]. Procedure duration in colonoscopy varies with patient tolerance and factors such as colonic cleanliness, polyp detection, and the number of interventions. In our study, despite similar polyp detection rates and pain scores in both groups, no significant difference was observed in procedure duration and polyp detectionrates. Although not statistically significant, we believe that the higher polyp detection rate observed in the control group in our study could be reversed in larger-scale patient studies.

Limitations

This study has certain limitations that deserve to be highlighted. This study was conducted on a small scale at a single center. This study's reliability and quality could be enhanced through a larger-scale, double-blind, multicenter trial. In addition, only binaural music in the theta frequency was used in the study. The effects of binaural music in other frequencies were not compared.

CONCLUSION

This randomized controlled trial demonstrated that binaural beat therapy effectively reduces anxiety and enhances tolerance during colonoscopy, as evidenced by lower VAS-anxiety scores and higher patient satisfaction. While it did not significantly impact physiological measures such as heart rate or blood pressure, its psychological benefits improved patient comfort and willingness to undergo future procedures without sedation. Binaural beats offer a promising, cost-effective, non-pharmacological alternative for enhancing patient experience during medical procedures. Further research is warranted to explore their anxiolytic and analgesic potential in colonoscopy and other interventions.

Ethical Statement

Ethical approval was obtained from the Health Sciences University Dr. Abdurrahman Yurtaslan Ankara Oncology Health Application and Research Center Clinical Research Ethics Committee (Approval No: 2023-10/418).

Authors' Contribution

Study Conception: SD; Study Design: FPS; Supervision: SD; Funding:N/A; Materials: N/A; Data Collection and/or Processing: SD, SS; Statistical Analysis and/or Data Interpretation: SD; Literature Review: FPS, SS; Manuscript Preparation: SDand Critical Review: FDS, SS.

Conflict of interest

The authors disclosed no conflict of interest during the preparation or publication of this manuscript.

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