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Original Article

The Effect of Preferred Permissible Music on Pain and Anxiety in Patients Undergoing Extracorporeal Shock Wave Lithotripsy: A Randomized Clinical Trial

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Abstract

Introduction: Urolithiasis is one of the most common urinary tract disorders with high prevalence in developing countries, including Iran. Extracorporeal shock wave lithotripsy (ESWL) is a standard non-invasive treatment, but it often causes moderate to severe pain and anxiety. Non-pharmacological interventions, such as music therapy, have gained attention as safe and low-cost alternatives. This study aimed to evaluate the effect of preferred permissible music on pain and anxiety in patients undergoing ESWL.

Methods: This randomized controlled trial involved 80 adult patients undergoing ESWL at Alborz Hospital in Karaj from September to October 2025. Participants were selected consecutively and randomly assigned to intervention or control groups. The intervention group received preferred permissible music via noise-cancelling headphones during ESWL, while the control group received routine care. Pain was measured using the Visual Analog Scale (VAS), and anxiety was examined using the State-Trait Anxiety Inventory (STAI-State). Data were analyzed using SPSS version 26 with repeated measures ANOVA, ANCOVA, and Chi-square tests ($P<0.05$).

Results: No significant differences were found in baseline demographic and clinical characteristics between groups ($P>0.05$). Mean pain scores during ESWL were significantly lower in the intervention group (4.38±1.98) compared to controls (5.62±1.82; $P=0.003$; Cohen's d=-0.55). Similarly, anxiety scores during ESWL were lower in the intervention group (37.15±15.78) than in controls (44.92±15.65; $P=0.021$; Cohen's d=-0.52). No significant differences were observed between the groups pre- or post-procedure.

Conclusion: Preferred permissible music during ESWL effectively reduces pain and anxiety during the procedure. As a non-invasive cost-effective intervention, it can be integrated into nursing care protocols in Iranian ESWL centers to enhance patient experience.

Keywords: Urolithiasis, Music therapy, Pain, Anxiety, Lithotripsy

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Introduction

Urolithiasis is one of the most common urinary tract disorders with high prevalence in developing countries, including Iran. Recent national studies indicate a lifetime prevalence of approximately 6.6%, with an annual increase of 0.06% (1). Regional studies report an overall kidney stone prevalence of up to 15.6% in Iranian adults, influenced by various environmental, dietary, genetic, and climate factors (2, 3).

Extracorporeal shock wave lithotripsy (ESWL) is a standard non-invasive treatment for kidney and ureteral stones (4). However, the procedure often involves moderate to severe pain, significant anxiety, and patient discomfort, which can reduce tolerance, increase the need for sedatives or analgesics, lower satisfaction, and decrease willingness to repeat procedures (5-7).

The management of pain and anxiety during ESWL is crucial, as pharmacological interventions may cause side effects like hemodynamic changes or oxygenation reduction (8). Recently, non-pharmacological approaches, such as music therapy, have been recognized as safe, low-cost, and effective options (9, 10).

Recent systematic reviews and meta-analyses confirm that music therapy significantly reduces pain and anxiety. A meta-analysis of 10 randomized trials (879 patients) in 2024 showed that music therapy lowers pain scores

(VAS) (SMD = −1.00; 95% CI: −1.57 to −0.42), increases patient satisfaction, and improves procedure repeatability without increasing analgesic use or complications (11). Other meta-analyses report similar reductions in pain, anxiety, and dissatisfaction (9, 10).

Numerous randomized trials emphasize the effectiveness of music, particularly patient-preferred music. Studies show that preferred music reduces pain and anxiety more than other types (e.g., classical or standard instrumental) and increases satisfaction (12-14). Combining music with other non-drug interventions like aromatherapy shows synergistic effects (15).

Despite growing global evidence, most studies are from Western countries, Turkey, or East Asia, with limited attention to cultural differences in the selection of music. In Iran, cultural and religious considerations make preferred permissible music (e.g., traditional Iranian, instrumental, or religious) more acceptable and potentially effective, but no dedicated study exists in Iran, especially in centers like Alborz Hospital in Karaj. This knowledge gap, combined with the high prevalence of urolithiasis and high number of patients in ESWL centers in Alborz Province, justifies a randomized trial to examine the impact of preferred permissible music on pain and anxiety.

This study could enhance nursing care quality, reduce drug dependency, increase Iranian patient satisfaction, and provide local evidence.

Materials and Methods

This single-blinded randomized controlled trial with two parallel groups was designed based on the Helsinki Declaration and CONSORT guidelines. It was conducted from September to October 2025 in the ESWL unit of Alborz Hospital, Karaj. The protocol was approved by the Ethics Committee of Asadabad School of Medical Sciences (IR.ASAUMS.REC.1404.003) and registered in the Iranian Registry of Clinical Trials (IRCT20120215009014N567).

The study population included adult patients referred to the ESWL unit at Alborz Hospital with diagnosed upper ureteral or kidney stones suitable for extracorporeal lithotripsy.

Inclusion Criteria

- Age 18-60 years
- Written informed consent
- Normal or near-normal hearing (no severe impairment)
- Ability to understand and select preferred permissible music
- Not taking sedative or strong analgesic in the 24 hours before the procedure
- Confirmed kidney stone by urologist
- No prior history of ESWL

Exclusion Criteria

- Severe psychiatric disorders or psychotropic drug use
- Hearing impairment or hearing aid use preventing headphone wear
- History of chronic severe pain or high pain sensitivity
- Pregnancy or breastfeeding
- Unwillingness to continue at any stage
- Complications during procedure requiring a halt in ESWL
- Sample size was calculated based on minimum clinically important difference (MCID). Given that there were two primary outcomes, pain intensity and state anxiety, the sample size was computed separately, selecting the larger one for adequate power.

The following formula was used for comparing means between independent groups:

$$n = \frac{2 \times (Z_{1-\alpha/2} + Z_{1-\beta})^2 \times SD^2}{\Delta^2}$$

Where α = 0.05 (two-tailed, Z_{1-α/2} = 1.96); power = 80% (Z_{1-β} = 0.84); SD from similar ESWL studies; Δ = MCID.

For pain (VAS 0-10), MCID = 1.5 units (16), Bozkurt et al (2022) reported post-ESWL pain as SD = 2.23 for music group and SD = 2.19 for control group; higher SD = 2.23 was used conservatively (13). The sample size was calculated to be 35 participants per group. Considering a 10% dropout rate, the needed sample size for examining pain was determined to be 39 participants per group.

For anxiety (STAI-State), MCID = 8 points per Cochrane review was suggested as meaningful (17). Bozkurt et al. (2022) reported control anxiety as SD = 9.24 (13). The sample size was calculated to be 21 participants per group. Considering a 10% dropout rate, the needed sample size for examining anxiety was determined to be 24 participants per group. Finally, the larger sample size was selected (40 per group, total 80).

Eligible participants were recruited using a convenience sampling method and randomized to the intervention and control groups (40 each) using random number tables. Allocation was concealed using opaque sealed envelopes. This study was a single-blinded randomized controlled trial, in which the outcome assessor was blinded to group allocation. Participants were unaware of the other group's intervention (Figure 1).

Data Collection Tools

Demographic and Clinical Characteristics

Demographic and clinical data of the participants, including age, gender, BMI, education, stone size, and affected kidney, were collected using a 6-question form designed for this study. Additionally, 5 nursing/urology experts confirmed the face and content validity of the tool after revisions. The descriptive nature of the tool precluded the calculation of reliability.

The Visual Analog Scale (VAS)

The pain intensity was measured using a 10-cm line ranging from 0 (no pain) to 10 (worst pain). Patients made marks on the line, and scores were measured in

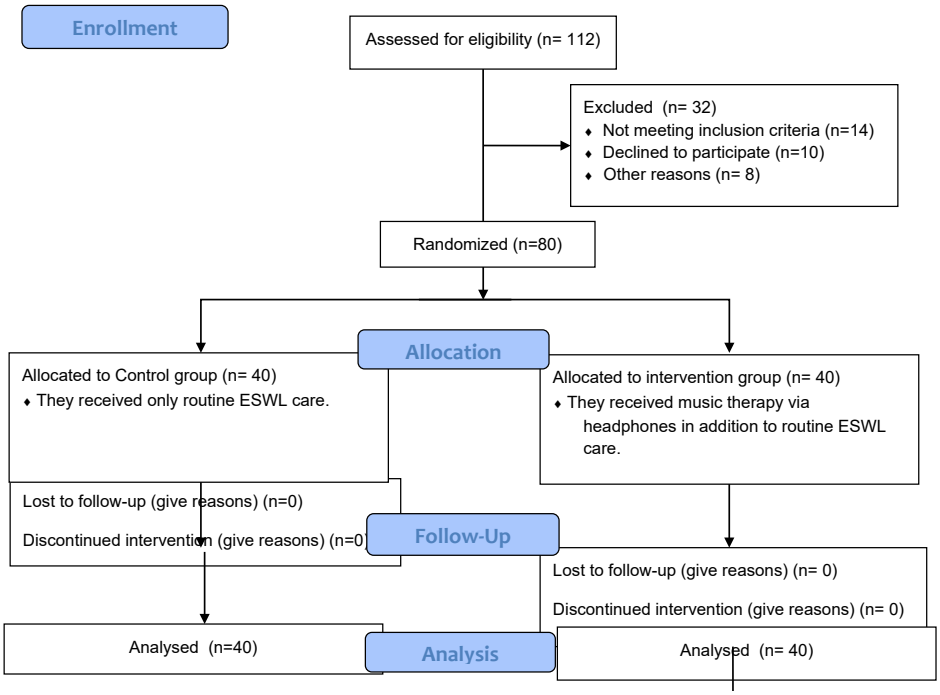

Figure 1. CONSORT Diagram

cm. Previous studies have confirmed construct and convergent validity of the tool. Huskisson reported high validity, and Bijur et al reported a test-retest reliability of 0.97 (16, 18). A Cronbach's alpha coefficient of 0.87 was also found in the present study.

Spielberger State-Trait Anxiety Inventory (STAI-State)

Anxiety was measured using the 20-item State Form Y. Items were rated on a 4-point Likert scale (1 = not at all to 4 = very much). Scores ranged from 20 to 80, with higher scores indicating more anxiety. Abdoli et al reported a Cronbach's alpha coefficient of 0.84 for the Persian version of the questionnaire, indicating good construct validity (19). A Cronbach's alpha of 0.89 was found in the present study.

Intervention

The intervention group selected preferred permissible music 60 minutes before the procedure from a pre-prepared list provided at admission. Preferred permissible music in this study refers to audio selections that are culturally and religiously appropriate according to Islamic guidelines commonly observed in Iran. This includes traditional Iranian instrumental music, calming non-vocal tracks, religious recitations (such as nohe or azan-style melodies without rhythmic elements that are considered haram), and other soothing non-entertaining audio content free from lyrics or rhythms associated with prohibited entertainment or stimulation of base desires. Participants were assisted by a trained nurse in selecting their preferred track from this culturally compliant list sourced from reliable Iranian platforms. Music was delivered at an appropriate volume (based on patient preference, maximum 70 dB) through Sony WH-1000XM4 noise-cancelling headphones from the start of ESWL until the end of the procedure. Headphones were disinfected before each use. Patient comfort, sound tolerance, and the ability to communicate with the treatment team were continuously monitored. In case of any discomfort, the intervention was immediately discontinued to prioritize patient safety and care.

The control group received routine ESWL care (cardiorespiratory monitoring) without additional non-drug intervention.

Measurement of Pain and Anxiety

Pain intensity and state anxiety were assessed at three standardized time points by a trained research nurse blinded to group allocation as follows:

Pre-procedure (baseline)

Immediately before ESWL commencement, after patient positioning and preparation.

During the Procedure

- Pain was measured using the Visual Analog Scale (VAS) at regular 5-minute intervals throughout the entire ESWL session. Given the natural variability in procedure duration (typically 20–50 minutes), the number of measurements varied between patients (e.g., 4–5 measurements for shorter sessions and 8–10 for longer ones). For each participant, the mean VAS score during the procedure was calculated by averaging all intra-procedural measurements. This method ensured that longer procedures were not disproportionately weighted, as the mean reflects the average pain intensity experienced rather than cumulative burden.

- State anxiety was assessed only once during the procedure at the approximate midpoint of the session using the State-Trait Anxiety Inventory (STAI-State) to reduce patient burden and procedural interference. To facilitate data collection while preserving patient comfort and minimizing disruption, pain ratings were obtained verbally or via a handheld tablet when appropriate, without requiring movement or interruption of clinical communication.
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Immediately Post-procedure

Both pain (VAS) and anxiety (STAI-State) were reassessed within 5 minutes after the completion of ESWL.

Both groups underwent standard ESWL (same device and operator). All ESWL sessions were held in a fixed room with uniform conditions.

Data Analysis

SPSS version 26 was used for data analysis. Data were presented as mean ± SD and frequency/percent for quantitative and qualitative variables, respectively. Kolmogorov-Smirnov test was used to investigate the normality of data distribution. Statistical analysis was carried out using independent *t*-test and Mann-Whitney U test for quantitative variables, as well as Chi-square and Fisher's exact tests for qualitative variables.

Repeated measures ANOVA was used to investigate the effects of the intervention on pain and anxiety. The Friedman test was used for within-group comparisons, and Kruskal-Wallis was used for between-group comparisons. Post-intervention scores (during and post-procedure) were compared between groups while controlling for baseline (pre-procedure) values using Analysis of Covariance (ANCOVA), with post-intervention score as the dependent variable, group as the independent variable, and baseline score as the covariate.

Clinical significance was determined based on the minimum clinically important difference (MCID), defined as a reduction of ≥1.5 points in pain intensity (VAS) and ≥8 points in state anxiety (STAI-State). For each participant, the change from baseline was calculated, and achievement of MCID was determined. The proportion of patients achieving MCID in each group was compared using the Chi-square test (or Fisher's exact test when expected frequencies were low). Effect sizes were calculated using Cohen's d. A p-value of less than 0.05 was considered statistically significant.

Ethical Considerations

The study was approved by the Ethics Committee of Asadabad School of Medical Sciences. Additionally, written informed consent was obtained from all participants. Data confidentiality was assured, and voluntary withdrawal was permitted at any stage. No extra costs were incurred.

Results

The study included 80 patients (40 intervention, 40 control) and was conducted from September to October 2025. The mean age of the participants was 42.05 ± 9.75 years. Groups were homogeneous at baseline ($P > 0.05$ for all variables). Table 1 shows baseline characteristics.

Pain Intensity (VAS)

Baseline pain scores were similar in both groups ($P = 0.168$). During the procedure, the mean pain score was lower in the intervention group ($P = 0.003$; Cohen's d = -0.55). No difference was found between the groups post-procedure ($P = 0.398$). Table 2 shows comparisons.

Table 1. Demographic and Clinical Characteristics of Participants (N = 80)

Variable	Intervention group (n = 40)	Control group (n = 40)	*P*-value
Age (years, mean ± SD)	41.8 ± 9.6	42.3 ± 9.9	0.81
Gender (male/female, n (%))	23(57.5)/17(42.5)	24(60)/16(40)	0.82
BMI (kg/m², mean ± SD)	25.9 ± 3.8	26.1 ± 4.0	0.79
Education (university/non-university, n (%))	18(45) /22(55)	17(42.5)/23 (57.5)	0.84
Stone size (mm, mean ± SD)	11.2 ± 3.4	11.5 ± 3.6	0.74
Affected kidney (right/left/bilateral, n (%))	18(45)/19(47.5)/3(7.5)	17(42.5)/20(50)/3(7.5)	0.91

Table 2. Mean Pain Scores (VAS) across Stages (N = 80)

Stage	Intervention(mean ± SD)	Control(mean ± SD)	*P*-value	Cohen's d
Pre-ESWL	2.10 ± 1.82	2.58 ± 1.75	0.168	-0.27
During ESWL	4.38 ± 1.98	5.62 ± 1.82	0.003	-0.55
Post-ESWL	3.35 ± 2.12	3.02 ± 2.10	0.398	0.15

Table 3. Mean State Anxiety Scores (STAI-State) across Stages (N = 80)

Stage	Intervention (mean ± SD)	Control (mean ± SD)	*P*-value	Cohen's d
Pre-ESWL	40.45 ± 9.12	42.30 ± 11.55	0.385	-0.17
During ESWL	37.15 ± 15.78	44.92 ± 15.65	0.021	-0.52
Post-ESWL	27.05 ± 10.68	30.95 ± 11.02	0.068	-0.35

State Anxiety (STAI-State)

Baseline anxiety scores were similar ($P = 0.385$). During the procedure, the mean anxiety score was lower in the intervention group ($P = 0.021$; Cohen's d = -0.52). However, the difference in scores was near-significant post-procedure ($P = 0.068$). Table 3 shows comparisons.

Preferred permissible music was effective only during procedure, with a medium effect size indicating clinical relevance. No baseline/post differences align with transient ESWL-related pain/anxiety. The findings of this study support the practical use of music as a low-cost non-invasive nursing intervention.

Discussion

The findings of the present study demonstrated that playing preferred permissible music via noise-cancelling headphones during extracorporeal shock wave lithotripsy (ESWL) significantly reduced pain intensity (Cohen's d = −0.55) and state anxiety (Cohen's d = −0.52) during the procedure, with no significant differences pre- or post-procedure. These results highlight the medium and immediate clinical impact of the intervention on the management of acute pain and anxiety, consistent with the role of nurses in non-pharmacological supportive care.

The results align with existing evidence on non-pharmacological auditory interventions for reducing pain and anxiety in ESWL patients. Previous studies have shown that listening to music can effectively alleviate these symptoms. For instance, a recent meta-analysis of multiple randomized trials reported that music therapy significantly decreased pain and improved patient satisfaction (11). Similar findings from other systematic reviews confirm reductions in pain and anxiety with medium to large effect sizes (10).

Numerous clinical trials also support the superiority of patient-selected music. In one study comparing music types, the preferred music group experienced the lowest pain and anxiety levels (12). Similar results were observed in another trial introducing music therapy as a cost-effective method for reducing perceived pain and anxiety (13). Additionally, comparing auditory and visual distraction indicated that auditory methods (including music) were more effective in reducing symptoms (20).

Our findings are consistent with those of a recent study on white noise, which showed significant reductions in pain during and after the procedure and anxiety post-procedure (21). However, the focus on preferred permissible music in this research likely offers higher cultural acceptance among Iranian patients, as it aligns better with personal preferences and religious-cultural considerations, unlike uniform white noise.

Mechanistically, preferred permissible music likely operates through cognitive distraction and reduction in sympathetic nervous system function, leading to endorphin release and diminished pain signal transmission (22, 23). The role of the noise-cancelling headset in minimizing device noise further enhanced the efficacy.

Based on the literature, several randomized controlled trials have explored the impact of music on pain and anxiety during ESWL, with titles and designs closely resembling the present work. For instance, in a study titled "Effect of Different Musical Types on Patient's Relaxation, Anxiety and Pain Perception during Shock Wave Lithotripsy: A Randomized Controlled Trial", Çift et al (2020) reported that patient-preferred music was superior to standardized types (12). In a similar study titled "The Effect of Listening to Music on Reducing Anxiety and Pain During Extracorporeal Shock Wave Lithotripsy:

A Randomized Controlled Study", Bozkurt et al (2022) reported significant reductions in both outcomes (13). A recent meta-analysis by Wang et al (2024) titled "Efficacy of music therapy for pain control of extracorporeal shock wave lithotripsy: A meta-analysis" also found similar findings across multiple trials (10).

While these studies provide strong foundational evidence for music therapy in ESWL, the current study introduces several innovations and methodological differences. First, unlike Çift et al (2020) and Bozkurt et al (2022), who used general patient-preferred music without cultural adaptations, we focused on "preferred permissible music" tailored to Iranian religious and cultural norms, including traditional instrumental tracks and religious recitations, enhancing acceptability in a conservative setting. Second, we incorporated noise-cancelling headphones (Sony WH-1000XM4) to actively reduce ESWL device noise, a feature not emphasized in prior studies, potentially amplifying the distraction effect. Third, pain assessment during the procedure was conducted at 5-minute intervals with mean scores calculated to account for variable session durations, offering a more granular intra-procedural analysis compared to single or end-of-procedure measurements in previous works. These adaptations provide novel context-specific evidence for culturally sensitive interventions in Iran, addressing a gap in the global literature and demonstrating superiority in applicability to diverse populations.

Conversely, some studies reported limited impact. In one study, combining music with standard medications showed no notable difference (24). In another study, white noise was effective only post-operation in reducing anxiety, not during (25). These inconsistencies may stem from concurrent analgesic or sedative use in those studies, whereas the present study proceeded without additional pharmacological intervention.

Study limitations include moderate sample size (80 participants), single-center setting, and reliance on self-reported assessments potentially influenced by reporting bias. The trial was single-blinded, with only the outcome assessor being blinded to group allocation. Participants in the intervention group were informed 60 minutes before selecting and listening to music, potentially introducing performance bias and expectation/placebo effects. This awareness may have influenced self-reported outcomes, as patients knew they were receiving an active intervention. An ideal design would include an active auditory placebo (e.g., white noise via the same headphones) for the control group to minimize this bias, as suggested in some studies on auditory interventions (25). However, implementing white noise was not pursued due to cultural and religious sensitivities in selecting "permissible" neutral sounds, which could complicate standardization and ethical approval in the Iranian context. Despite these limitations, the cultural adaptation and real-world applicability of the procedure remain strengths of the study. Long-term follow-up was not performed.

It is recommended that further studies should be conducted with larger sample sizes, double-blind designs, and direct comparisons of preferred music with white noise or virtual reality. Assessing long-term effects on patient satisfaction and reduced analgesic needs would also be beneficial.

Ultimately, the results indicate that preferred permissible music is a safe, simple, and low-cost intervention that can be integrated into nursing care in Iranian ESWL centers to enhance patient therapeutic experience.

Conclusion

The results of this randomized clinical trial demonstrated that preferred permissible music delivered via noise-cancelling headphones during extracorporeal shock wave lithotripsy (ESWL) meaningfully reduces patients' pain intensity and state anxiety levels during the procedure, with no notable differences observed before or after the procedure.

Preferred permissible music, as a non-pharmacological, safe, low-cost, and complication-free intervention feasible in all treatment centers, can easily be integrated into care protocols for lithotripsy units. This method not only alleviates acute procedure-related pain and anxiety but also improves the overall patient treatment experience and likely increases willingness to repeat sessions.

Given the high prevalence of urinary stones in Iran and the considerable number of ESWL patients, nurses and treatment teams are recommended to incorporate preferred permissible music (considering cultural and religious factors) as part of standard supportive care. This intervention can decrease dependency on analgesics and sedatives and enhance nursing care quality.

To confirm sustained effects and greater generalizability, future studies with larger sample sizes, double-blind designs, and long-term follow-up are recommended. Overall, preferred permissible music represents a simple and effective strategy that can improve quality of life in patients undergoing non-invasive painful treatments.

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Authors' Contribution

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Methodology: Afshin Khazaei
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Competing Interests

No conflict of interests exist among the authors.

Ethical Approval

This study was approved by the Ethics Committee of Asadabad School of Medical Sciences (IR.ASAUMS.REC.1404.003). It was also registered in the Iranian Registry of Clinical Trials (IRCT20120215009014N567). Study objectives were explained to participants, and written informed consent was obtained from all

participants. Confidentiality was also assured.

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