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Original Article

Active Versus Passive Distraction for Anxiety Reduction During Cast Removal in Children: A Randomized Clinical Trial

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Abstract

Introduction: Pediatric procedures, particularly cast removal, often provoke anxiety in children, negatively affecting their cooperation and emotional responses during the procedure. Therefore, this randomized clinical trial aimed to compare active versus passive distraction for anxiety reduction during cast removal in children.

Methods: This randomized controlled trial was conducted on 105 children aged 8–12 years undergoing cast removal at Valiasr Hospital in Arak, Iran. Participants were randomly assigned to three groups: passive distraction with music, active distraction with tablet-based video games, and a control group receiving routine care. Anxiety was assessed using the Facial Anxiety Scale and the Children's Emotion Management Scale (CEMS). Data were analyzed using the chi-square test, Fisher's exact test, paired t-test, one-way analysis of variance, and Tukey's post hoc test.

Results: Post-intervention heart rate was significantly lower in the music group (108.22 ± 9.59 bpm) than in the active distraction group (114.62 ± 11.10 bpm) and the control group (115.45 ± 10.99 bpm), with a mean difference of −7.23 bpm versus the control group (95% CI, −13.25 to −1.21; $P=0.014$). Emotional expression scores were also lower in the music group (14.77 ± 4.16) than in the active distraction group (16.65 ± 4.91) and the control group (17.68 ± 4.43), with a mean difference of −2.91 versus the control group (95% CI, −5.48 to −0.35; $P=0.022$). Mean anxiety rank was significantly lower in the music group (43.69) than in the control group (63.23; $P=0.006$).

Conclusion: Passive distraction with music was associated with lower anxiety than routine care and a lower heart rate than active distraction with tablet-based video games during cast removal in children. Music-based distraction may represent a simple, feasible, and low-cost supportive strategy in pediatric orthopedic settings.

Introduction

Anxiety associated with plaster cast removal, particularly due to the noise and vibration of the cast saw, can be distressing for children and their caregivers.[1] Due to their age-related conditions, children are likely to experience higher levels of anxiety associated with this procedure.[2] Anxiety during this process can impede its effective completion and even pose risks.[3] An anxious child during cast removal may withdraw, increasing the likelihood of additional movements that could exacerbate the risk of epidermal burns, necrosis, and deep tissue injuries with the saw blade.[4] This non-compliance due to anxiety may lead to the potential for self-harm, harm to others, and equipment damage.[5]

Anxiety related to cast removal can manifest through increased respiratory rate, tachycardia and elevated blood pressure.[6] In vulnerable pediatric patients, severe anxiety during cast removal may adversely affect physiological stability and procedural safety. Therefore, effective management of anxiety during cast removal is essential.[7]

Non-pharmacological methods for managing anxiety in children include psychological interventions such as distraction or diversion of attention, which can be active or passive.[8] Distracting attention can divert the child from interpreting what they perceive as an unpleasant action and break the cycle of anxiety and distress.[9] Watching cartoons or movies, and listening to music are examples of passive distraction techniques.[10] A study showed that listening to music through headphones during plaster room procedures can reduce anxiety.[4] In another study, using headphones and ear protectors to prevent hearing additional sounds related to the saw during cast removal was reported to effectively reduce children's heart rate and anxiety.[11] Technologies such as animation displays

Research Highlights

What is the current knowledge?

- Pediatric procedures such as cast removal can cause significant anxiety in children.
- Distraction techniques are commonly used to reduce procedural anxiety in pediatric care.

What is new here?

- Passive distraction through music reduced anxiety more effectively than video game–based active distraction during cast removal.
- Music therapy was associated with lower heart rate and emotional distress scores during cast removal. Implementing music therapy in cast rooms may provide a simple, low-cost strategy to improve pediatric procedural experiences.

and tablet games are ways to actively divert attention in children as therapeutic interventions.[12] Play can prepare children to cope with medical interventions, including procedures related to plaster rooms, and significantly reduce their anxiety by fostering a sense of control.[13] Burns-Nader et al[14] demonstrated that distraction through tablet games could play an effective role in controlling pain and anxiety in children undergoing hydrotherapy for burn treatment.

Although existing studies on distraction techniques for managing pediatric anxiety during plaster cast removal have demonstrated positive effects.[15,16] However, direct comparative evidence from randomized clinical trials evaluating active versus passive distraction techniques during pediatric cast removal remains limited. While both approaches have been explored independently, systematic evidence evaluating their relative effectiveness in clinical settings is lacking. This gap hinders the ability to make informed decisions regarding the optimal intervention for reducing anxiety in pediatric patients, particularly in high-pressure clinical environments such as plaster rooms.

The present study focuses on children aged 8 to 12 years. Results from a recent study indicated that the highest incidence of forearm fractures occurs within this age group.[17] Similarly, findings from a retrospective study showed that limb fractures are more prevalent among children aged 8 to 12 years, and the incidence of sports-related injuries also increases in this age range.[18] These data underscore that children in this developmental stage represent a population at higher risk for injuries requiring plaster cast procedures, supporting the rationale for selecting this specific age group. This randomized clinical trial aimed to compare active versus passive distraction for anxiety reduction during cast removal in children aged 8–12 years.

Materials and Methods

Study Design and Participants

This randomized clinical trial was conducted with three groups from December 2021 to November 2022 on 105 children requiring cast removal from the upper or lower limbs at Valiasr Hospital, Arak, Iran. The study was conducted in accordance with the CONSORT statement.[19] Figure 1 presents the clinical trial flowchart. The required sample size was estimated based on a similar study .[20] A two-sided α level of 0.05, 95% power, and a 10% anticipated attrition rate were assumed. Accordingly, 35 participants were enrolled per group using the following formula:

$$n \geq 2\frac{\left(z_{\alpha}+z_{\beta}\right)^{2}\sigma^{2}}{\left(\mu_{1}-\mu_{2}\right)^{2}}$$

Inclusion & Exclusion Criteria

The study population consisted of all children referred for cast removal. Inclusion criteria were: age between 8 and 12 years, willingness to participate in the study, written informed consent obtained from the parents at the beginning of the study, the presence of a cast on an upper or lower limb, ability to speak and understand Persian, absence of hearing, visual, or cognitive impairments, ability to respond appropriately to the researcher's questions, cooperation during the intervention process, and ability to play a video game.

Exclusion criteria included: lack of cooperation from the parent or child at any stage of the intervention, removal of headphones before the end of the procedure in the music group, non-participation or inability of the child in the gaming group, use of sedative medications before cast removal, presence of pathological fractures, having a cast on more than one limb, coexisting conditions other than fractures (e.g., underlying diseases, compartment syndrome), a history of psychological trauma, or the loss of a family member within the past six months.

Blinding & Randomization

Participants were selected through convenience sampling from children referred for cast removal at Valiasr Hospital, Arak. The samples were then randomly assigned into three groups, passive distraction (music), active distraction (play therapy), and control (35 participants per group) using block randomization with the aid of random allocation software. Blocks of six were generated, each consisting of the letter's A, B, and C in all possible permutations. Allocation concealment was maintained using sealed, opaque, numbered envelopes, which remained undisclosed until the intervention was performed. Randomization was carried out by an independent statistician who was not part of the research team. Participants were randomized in a 1:1:1 ratio.

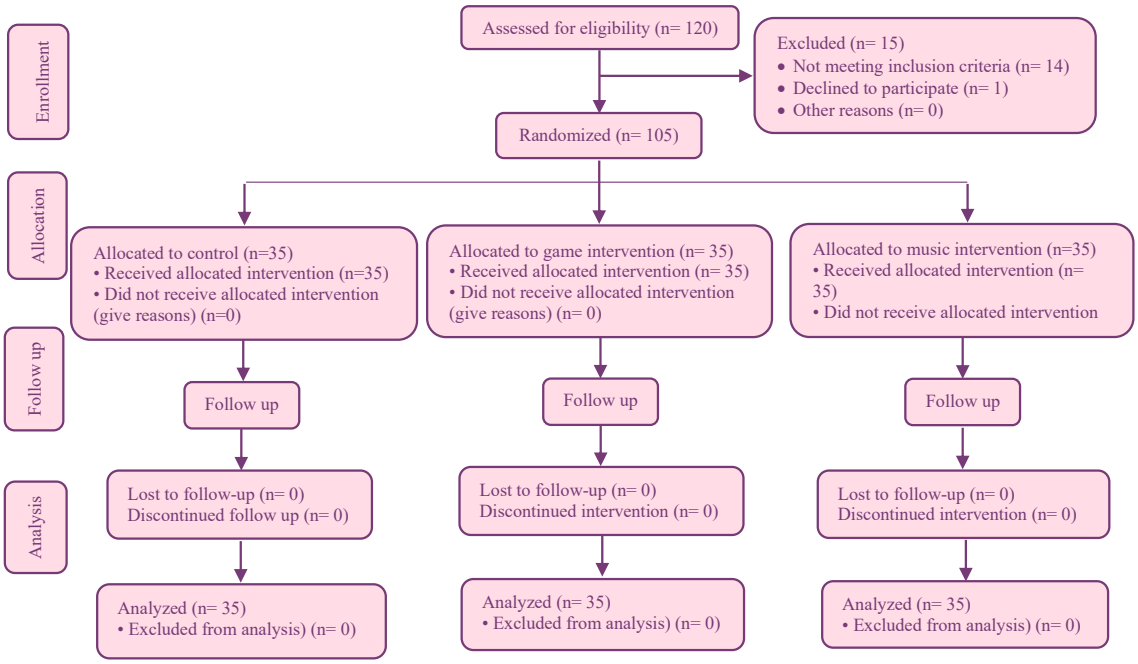

Figure 1. Consort diagram

However, outcome assessment was performed by a blinded assessor, and the statistician responsible for data analysis was also blinded to group allocation.

Study Measures & Instruments

Data collection instruments in this study consisted of two sections. The first section was a demographic and clinical information form that collected data on sex, age, type of cast, affected limb, indication for casting, cast material, and duration of immobilization. The second section comprised the outcome measures. The primary outcome was children's anxiety during cast removal, assessed using the Facial Anxiety Scale (FAS). The secondary outcomes were children's emotional manifestations, measured using the Children's Emotional Manifestation Scale (CEMS), and heart rate as a physiological indicator of anxiety.

Cast removal was performed by a hospital-employed technician. Outcome measures were assessed at two time points: immediately before cast removal and post-procedure after the start of the procedure. All measurements were recorded by the research assistant.

Children's Emotional Expression Measurement (CEMS)

In this study, children's emotional expressions were assessed using the Children's Emotional Manifestation Scale (CEMS). This tool, developed by Li & Lopez, [21] is a simple and objective instrument used to evaluate children's emotional responses during stressful medical procedures. The CEMS evaluates five observable behaviors: facial expression, vocalization, activity, interaction, and level of cooperation. Each behavior is rated on a 5-point scale (from 1 to 5). The total score thus ranges from 5 to 25, with higher scores reflecting greater emotional intensity. A total score of 5 indicates minimal emotional expression, whereas a score of 25 denotes the highest level of emotional intensity.

The validity and reliability of this tool were confirmed in a study by Çimke & Bayat[22] in Turkey, conducted on children aged 7 to 12 years. The reliability of the scale was assessed using Cronbach's alpha ($\alpha = 0.94$) and inter-rater reliability (ICC ranging from 0.970 to 0.981). The Persian version of this tool was validated by Khanjari et al[23] demonstrating good psychometric properties. In their study, Cronbach's alpha was 0.87, and inter-rater reliability was $r = 0.89$.

Facial Anxiety Scale (FAS)

The Facial Anxiety Scale (FAS) was used to assess children's anxiety levels through self-reporting. This scale consists of a series of cartoon faces arranged in a continuum, ranging from a relaxed face at one end to a highly anxious and tearful face at the other. Each face corresponds to a score from 1 to 5. This tool has been widely used in multiple studies to measure anxiety levels in children across different settings, demonstrating strong psychometric properties.[24,25] The reliability of the Persian version of this scale was reported as $r = 0.85$.[25]

Before the intervention, children were given instructions on how to use the scale to report their anxiety levels. During the intervention, they were asked to select the face that best represented their anxiety.

Heart Rate Measurement

Based on previous similar studies, heart rate was used as an objective physiological indicator of anxiety during the

cast removal procedure.[6,7] Given the need for rapid heart rate measurement without interfering with the procedure, a calibrated and standardized portable pulse oximeter (Beaver fingertip pulse oximeter) was used to measure children's heart rates.

Pre-Intervention Phase

Eligible participants were enrolled in the study after obtaining written informed consent from their parents and the child's assent. Following random allocation into the control and intervention groups, the researcher collected demographic and clinical data of the children through interviews with their parents. Before the cast removal procedure, the child, accompanied by the researcher and parents, was taken to the casting room, where the researcher familiarized the child with the environment and equipment to reduce anxiety.

Interventions

Passive Distraction Group

Children in the music intervention group listened to their preferred music starting 5 minutes before, during, and 2 minutes after the cast removal procedure. Music was played through wireless over-ear noise-minimizing headphones (Sony Wireless Headphones WH-CH510). To standardize the intervention and minimize bias, a preselected list of 10 age- and gender-appropriate songs was provided, similar to previous studies.[4,10] All selected music tracks were approved by the Children and Youth Organization and maintained a volume level between 40–50 dB.[4]

Active Distraction Group

Following the same timing protocol as the music group, children in the active distraction group engaged in age-appropriate tablet-based video games for 5 minutes before, during, and 2 minutes after cast removal. The games were presented on a Samsung Galaxy Tab A 8.0 (2019 LTE, SM-T295), which was mounted on a holder to facilitate comfortable use. Each child was allowed to choose one game from a list of 10 pre-approved age-appropriate games. The tablet was configured to restrict access exclusively to these games. To maintain hygiene, a single-use plastic cover was placed on the tablet and replaced for each child. In addition, all equipment was disinfected between participants. Throughout the intervention, the researcher remained present to address any technical issues and to ensure standardized implementation of the intervention.

Control Group

Children in the control group received routine care, including standard post-fracture care instructions regarding avoiding pressure or impact on the affected limb, as per the physician's recommendations.

Data Analysis

Data were analyzed using SPSS software version 23. Descriptive statistics were presented as frequencies and percentages for categorical variables, means ± standard deviations for continuous variables, and medians with interquartile ranges (IQRs) for ordinal variables. The normality of continuous variables was assessed using the Shapiro–Wilk test. Homogeneity of variances was evaluated using Levene's test. Baseline demographic and clinical characteristics were compared among groups using the Chi-square test or Fisher's exact test for categorical variables, and one-way analysis of variance (ANOVA) or the Kruskal–Wallis test for continuous variables, as appropriate. Within-group comparisons between pre- and post- procedure were performed using the paired-samples t-test for normally distributed data and the Wilcoxon test for ordinal variable. Between-group comparisons were conducted using one-way ANOVA followed by Tukey's post hoc test for normally distributed variables. For ordinal variable, the Kruskal–Wallis test was applied, followed by pairwise Mann–Whitney U tests with Bonferroni adjustment for multiple comparisons. A significance level of 0.05 was considered for all tests.

Results

Of the 120 children assessed for eligibility, 105 were randomly assigned in equal numbers to the music, video game, and control groups (n = 35 per group) (Figure 1). No participants withdrew after randomization or were lost to follow-up; therefore, all randomized participants were included in the analysis. No adverse events related to the distraction interventions or the cast removal procedure were observed or reported. Table 1 presents the demographic characteristics of the participants. The mean (SD) age of children in the music, play, and control groups was 9.94 (1.25), 9.88 (1.43), and 9.77 (1.37) years, respectively. Statistical tests revealed no significant differences in age, gender, or limb under cast removal among the groups ($P > 0.05$) (Table 1).

The primary outcome was post-procedure anxiety, assessed using the Facial Anxiety Scale (FAS). Secondary outcomes included children's emotional distress, measured by the Children's Emotional Manifestation Scale (CEMS), and heart rate.

Primary Outcome

Facial Anxiety Scale (FAS) Scores

There was no significant difference in the FAS anxiety scores among the three groups before the intervention ($P > 0.05$). However, post-intervention anxiety ranks in the music, play, and control groups were 43.69, 52.09, and 63.23, respectively, showing a statistically significant difference ($P < 0.05$) (Table 2).

Post hoc analysis revealed a significantly lower anxiety rank in the music group compared to the control group (mean rank difference: −12.77; $P = 0.006$). The difference

between the music and active distraction group was not significant ($P=0.209$), nor was the difference between the play and control groups ($P=0.093$) (Table 3).

Secondary Outcomes

Children's Emotional Expressions (CEMS Score)

Before the intervention, baseline CEMS scores were similar across the three groups, indicating clinical comparability with no important imbalance at baseline; no statistically significant difference was observed ($P>0.05$). Although emotional distress increased after cast removal in all groups, reflecting the inherently stressful nature of the procedure, the increase was significantly lower in the music intervention group compared with the control groups. However, the post-intervention scores differed significantly among the three groups ($P<0.05$) (Table 2).

CEMS total score: 5–25; higher scores indicate greater emotional distress. FAS total score: 1–5; higher scores indicate greater anxiety. Abbreviations: SD = Standard Deviation.

Post hoc analysis revealed that the mean (SD) CEMS score was significantly lower in the music group 14.77 (4.16) compared to the play 16.65 (4.91) and control groups 17.68 (4.43). The mean difference between the music and play groups was −1.88 (95% CI: −4.45 to 0.68; $P=0.193$), and between the music and control groups was −2.91 (95% CI: −5.48 to −0.35; $P=0.022$). No significant difference was found between the play and control groups ($P=0.608$) (Table 3).

Mean differences (I–J) and 95% confidence intervals (CI) are presented. CEMS range: 5–25; FAS range: 1–5. Higher scores indicate greater emotional distress (CEMS) and greater anxiety (FAS).

Heart Rate Changes

Data analysis showed no significant difference in the mean heart rate of children across the three groups before the intervention ($P>0.05$). Heart rate increased during the cast removal procedure across all groups ($P<0.05$); however, the increase was significantly smaller in the music intervention group (Table 2).

Post hoc comparisons showed that the music group had a significantly lower heart rate than the play group (mean difference: −6.40 bpm; 95% CI: −12.42 to −0.38; $P=0.034$) and the control group (mean difference: −7.23 bpm; 95% CI: −13.25 to −1.21; $P=0.014$). The difference between the play and control groups was not statistically significant ($P=0.943$) (Table 3).

Discussion

The present study extends the literature by directly comparing active and passive distraction techniques during

Table 1. Demographic and clinical characteristics of the participants across study groups

Characteristic	Music (n = 35)	Play (n = 35)	Control (n = 35)	*P* value
Gender				
Boy	20 (57.1)	18 (51.4)	16 (45.7)	0.634*
Girl	15 (42.9)	17 (48.6)	19 (54.3)	
Type of Cast				
Fiberglass	15 (42.9)	11 (31.4)	13 (37.1)	0.613*
Plaster	20 (57.1)	24 (68.6)	22 (62.9)	
Limbs				
Right Upper Limb	9 (25.7)	7 (20.0)	9 (25.7)	0.944*
Left Upper Limb	11 (31.4)	11 (31.4)	10 (28.6)	
Right Lower Limb	7 (20.0)	11 (31.4)	10 (28.6)	
Left Lower Limb	8 (22.9)	6 (17.1)	6 (17.1)	
Indication for Cast Application				
Bone fracture	22 (62.9)	25 (71.4)	22 (62.9)	0.912**
Joint dislocation	5 (14.3)	3 (8.6)	5 (14.3)	
limb alignment	3 (8.6)	1 (2.9)	3 (8.6)	
More than one reason	5 (14.3)	6 (17.1)	5 (14.3)	
Cast anatomical location				
Upper long cast	10 (28.6)	8 (22.9)	14 (40.0)	0.688*
Upper short cast	10 (28.6)	10 (28.6)	5 (14.3)	
Lower long cast	7 (20.0)	8 (22.9)	8 (22.9)	
Lower short cast	8 (22.9)	9 (25.7)	8 (22.9)	
Duration of Immobilization				
Less than two weeks	4 (11.4)	1 (2.9)	3 (8.6)	0.787****
2-3 weeks	7 (20.0)	9 (25.7)	9 (25.7)	
3-4 weeks	20 (57.1)	19 (54.3)	16 (45.7)	
More than 4 weeks	4 (11.4)	6 (17.1)	7 (20.0)	
Mean (SD)				
Age	9.94 (1.25)	9.88 (1.43)	9.77 (1.37)	0.865***

*Chi-square test; **Fisher's Exact Test; ***One-way ANOVA; ****Kruskal-Wallis test.

Table 2. Comparison of heart rate, emotional distress, and anxiety levels in children across three groups before and after treatment

Variable	Mean (SD)			*P* value
	Music (n = 35)	Play (n = 35)	Control (n = 35)	
Heart rate (bpm)				
Pre-procedure	95.28 (10.01)	94.77 (10.58)	96.88 (11.80)	0.696**
Post-procedure	108.22 (9.59)	114.62 (11.10)	115.45 (10.99)	0.009**
P value*	<0.001	<0.001	<0.001	
Child's emotional distress (CEMS)				
Pre-procedure	10.11 (3.50)	11.22 (3.71)	10.00 (3.03)	0.258**
Post-procedure	14.77 (4.16)	16.65 (4.91)	17.68 (4.43)	0.026**
P value*	<0.001	<0.001	<0.001	
Facial anxiety scale (Median (IQR))				
Pre-procedure	3 (1)	2 (2)	2 (1)	0.492***
Mean rank	54.54	48.31	56.14	
Post-procedure	4 (1)	4 (2)	4 (1)	0.018***
Mean rank	43.69	52.09	63.23	
P value****	<0.001	<0.001	<0.001	

*Paired t-test, **One-way ANOVA, ***Kruskal-Wallis test, ****Wilcoxon test.

Table 3. Results of post-hoc test for comparison of heart rate, emotional distress, and anxiety levels in children across three groups after treatment

Comparison Groups		Heart Rate		Child's Emotional Distress (CEMS)		Facial Anxiety Scale (FAS)	
Group (I)	Group (J)	Mean difference (I-J)	*P* value*	Mean difference (I-J)	*P* value*	Mean rank difference (I-J)	*P* value**
Music (n=35)	Play (n=35)	-6.40 (-12.42, -0.38)	0.034	-1.88 (-4.45, 0.68)	0.193	-5.86	0.209
Music (n=35)	Control (n=35)	-7.23 (- 13.25, - 1.21)	0.014	-2.91 (-5.48, -0.35)	0.022	-12.77	0.006
Play (n=35)	Control (n=35)	-0.83 (- 6.85, 5.19)	0.943	-1.03 (- 3.60, 1.54)	0.608	-7.69	0.093

*Tukey HSD, **Mann-Whitney Test.

cast removal, a brief yet anxiety-provoking procedure in pediatric orthopedic care. This distinction is clinically relevant, as identifying feasible nonpharmacological strategies may improve the child's procedural experience without increasing the complexity of routine care. In our sample, music-based distraction was associated with lower post-procedure anxiety compared with routine care; however, this apparent benefit was not consistently significantly greater than that observed with video game–based distraction.

Regarding physiological responses, children in the music group exhibited lower heart rates than those in the game and control groups. Although this finding is in line with some previous studies, the broader literature remains mixed. For example, Georgiadis et al[26] and Poppelaars et al[15] found no significant between-group differences in heart rate during cast-related procedures using VR-based interventions, whereas Liu et al[7] reported lower heart rates in the music group, although the difference was not statistically significant. Rather than indicating true inconsistency in the effect of distraction, these differences may reflect methodological and contextual variation across studies, including sample size, age range, intervention modality, degree of sensory immersion, and the procedural context itself. Importantly, the effectiveness of auditory distraction may also depend on the extent to which the stimulus is meaningful and engaging to the child. In studies where music was not selected according to children's preferences, the emotional salience of the intervention may have been weaker, potentially limiting attentional engagement and allowing greater focus on the procedure. In contrast, allowing children to choose preferred music may enhance familiarity, perceived control, and emotional regulation, thereby strengthening the distraction effect during stressful procedures.

This interpretation is also consistent with studies showing beneficial effects of distraction under conditions that promote stronger engagement. Desai et al[27] reported significant reductions in heart rate with VR-based distraction during orthopedic procedures, and Goktas and Avci[28] similarly concluded that visual and auditory distraction techniques can reduce anxiety, fear, and pain during invasive procedures. Music has also been reported to improve children's cooperation during anesthesia induction.[29] By contrast, Daşar et al[30] found no significant differences in anxiety between children with and without headphones during cast removal, and Guingo et al[31] found no overall difference between VR and tablet games, although older children in the VR group appeared to benefit more. Taken together, these findings suggest that the effectiveness of distraction may be moderated by factors such as developmental stage, novelty of the intervention, and the level of cognitive or sensory engagement required, rather than by intervention category alone.

Although music intervention was associated with reduced anxiety, heart rate increased relative to pre-intervention values across all groups, including the music group, although the magnitude of increase was smaller in this group. This pattern should be interpreted cautiously because heart rate is a nonspecific index of autonomic activation rather than a direct measure of anxiety alone. In the context of cast removal, elevated heart rate may reflect procedural anticipation, environmental stimulation, emotional arousal, or even engagement with the distraction task itself. Therefore, physiological activation and subjective anxiety should not be assumed to move in parallel, and the modest heart rate increase observed even in the music group does not necessarily contradict the lower self-reported anxiety observed in that group.

The results of this study also indicated significant differences in children's anxiety levels, as measured by the Children's Emotional Manifestation Scale (CEMS), across groups. Although CEMS scores increased in all groups after the procedure, the magnitude of increase was significantly smaller in the music-with-headphones group than in the control group. Similarly, children in the music group reported significantly lower anxiety on the Facial Anxiety Scale than those in the control group. Prior studies generally support the value of distraction for reducing distress during pediatric procedures, but the magnitude and consistency of benefit vary. VR-based games have been reported to reduce anxiety during cast removal and other pediatric clinical procedures,[16,32] and positive effects of tablet-based games have also been described in contexts such as burn hydrotherapy[14] and preoperative anxiety.[33] At the same time, some studies suggest that simpler distraction methods may be as effective as more technologically immersive approaches. Fabricant et al[34] found that watching videos on a tablet was comparable to VR for reducing pain and anxiety during cast removal and pin extraction, indicating that high-tech interventions

may not always offer additional benefit in brief orthopedic procedures. Similarly, Akan et al [35] reported that animated videos decreased pain and anxiety during pin removal in children with supracondylar humerus fractures.

The variability across studies may be partly explained by differences in intervention novelty, procedural intensity, and outcome measurement. For example, one study suggested that games or videos delivered via iPad did not significantly change anxiety because children were already highly familiar with such devices in everyday life, thereby reducing novelty and attentional capture.[36] Similarly, toy-based distraction was not found to significantly affect anxiety during intravenous catheter placement.[37] These contrasting findings imply that distraction effectiveness is likely to be context-dependent: interventions that are sufficiently novel, immersive, or personally relevant may work better in highly stressful settings, whereas in shorter or less painful procedures such as cast removal, simpler interventions may provide comparable benefit. In addition, differences between self-reported scales and observer-rated instruments may contribute to variation in reported outcomes across studies.

Overall, there was no significant difference in mean anxiety levels between the music and game groups in our study. Although some previous evidence suggests that active distraction techniques may outperform passive ones,[9,38] our findings do not clearly support that distinction in the context of cast removal. A more plausible interpretation is that, during this specific procedure, the relative effectiveness of distraction may depend less on whether the modality is active or passive and more on how well it matches the child's attentional capacity, preferences, and procedural circumstances. For example, extraneous procedural noise may reduce the quality of engagement with games, and the brief, procedure-focused nature of cast removal may limit the advantage of more interactive distraction. Further research is warranted to clarify which characteristics of distraction interventions are most important for optimizing anxiety reduction during pediatric cast removal.

This study has several limitations that should be acknowledged. Some potentially important confounding variables, including previous cast removal experience, baseline anxiety traits, prior hospitalization experiences, and pain sensitivity, were not assessed. These factors may have influenced children's anxiety responses and may therefore have contributed to residual confounding. In addition, because anxiety outcomes were measured observationally using the Children's Emotional Manifestation Scale (CEMS), the possibility of observer bias should be considered. Complete blinding of outcome assessors was difficult during intervention implementation, and this may have influenced CEMS scoring. The potential influence of novelty effects should also be taken into account, as children's prior familiarity with tablets, games, or headphones was not evaluated and may have affected their engagement with the interventions. Future studies should assess these variables prospectively and use blinded outcome assessment whenever feasible.

Conclusion

The findings of this study suggest that distraction interventions, particularly music, may help reduce anxiety-related responses during cast removal in children and may be a feasible, low-cost supportive strategy in pediatric orthopedic settings. However, evidence regarding play-based distraction remains inconclusive in our study and warrants further investigation. Future research with rigorous designs and broader pediatric orthopedic contexts is recommended to clarify comparative effectiveness across distraction modalities and outcomes.

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Conflict of Interests

There is no conflict of interest among the authors of this article.

Data Availabilty Statement

The analyzed datasets in the current study are available through the corresponding author upon reasonable request. The data are not publicly available due to restrictions, as they contain information that could compromise the privacy of research participants.

Ethical Approval

This study was approved by the Ethics Committee of Arak University of Medical Sciences (IR.ARAKMU.REC.1399.163) under the code 3486. The protocol for this clinical trial was registered in the Iranian Registry of Clinical Trials under the number IRCT20180523039793N2. The researchers ensured adherence to the principles outlined in the Helsinki Declaration throughout all stages of the study. Before the study's initiation, detailed information regarding the study's objectives and the nature of the interventions was provided to the participants and their parents. Written consent was obtained from the parents, and the children's assent was also secured. Parents were assured that their data would

remain confidential and would only be used for research purposes. They were also informed of their right to withdraw from the study at any stage without affecting their access to standard medical care.

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