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intervention using Pulse oximeter and Venham's picture test.



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Binaural auditory beats vs music of choice as audio distraction behaviour guidance technique among children: A randomized controlled trial

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ABSTRACT

Background: Binaural beat is created by presenting two different pure-tone sine waves with less than a 30Hz difference dichotically. In dental settings, children listening to familiar music during treatments gain control over the anxiety caused by tools like the airotor or syringe, creating a comforting, familiar environment.

Aim: To evaluate and compare anxiety level during restorative treatment using No Music, Music of choice and Binaural Auditory Beats as Audio distraction behaviour guidance technique in children aged 6–12 years.

Methods: In-vivo, double-blind, three-arm, parallel-group randomized study was conducted in the department of pediatric and preventive dentistry where 75 participants were allocated into 3 groups. The teeth with Class I cavity in primary and permanent molars were prepared and restored. Anxiety was measured pre- and post-

Results: Children who were treated with Binaural beats and Music of choice showed reduction in anxiety levels as indicated by lower anxiety scores in Venham picture test and pulse rate values as compared to the control group. Conclusion: Binaural auditory beats and Music of choice can be used effectively as a non-invasive treatment modality to reduce anxiety in apprehensive pediatric patients.

1. Introduction

Fear is a reaction to a known or perceived threat or danger. Fear and anxiety associated with visiting the dentist and receiving dental treatment are key factors leading to avoidance of dental care. Dental fear is a normal emotional reaction to threatening stimuli while undergoing any dental treatment. Dental anxiety is the term used to describe the anxiety experienced when undergoing dental procedures. Agras et al. have identified dental anxiety as the fifth-most common cause of anxiety.

Psychological factors, such as anxiety and stress, can amplify the perception of pain through complex neurobiological mechanisms. Increased sympathetic nervous system activity, alterations in pain modulation pathways and heightened pain sensitivity contribute to the mutually reinforcing relationship between anxiety and pain.²

Milgrom et al. identified four distinct groups of anxious patients based on the source of their fear, known as the "Seattle system" developed at the University of Washington: 1) those anxious about specific dental stimuli, 2) those who distrust dental personnel, 3) those with

generalized dental anxiety and 4) those anxious about catastrophic outcomes. $\!\!^3$

Owing to such extensive and significant impacts described, it is crucial to effectively identify individuals experiencing dental anxiety and provide appropriate treatment upon their arrival at the dental office. Practitioners should strive to alleviate anxiety and fear in a manner that fosters long-term positive motivation for future dental visits among these patients.

The development of dental anxiety is influenced by multiple factors, indicating that there is no single therapy approach for its management. Over the years, dental professionals have implemented various measures to minimize dental anxiety and enhance patient comfort. Broadly, dental anxiety can be managed by non-pharmacological or pharmacological interventions or a combination of both.

The therapeutic effects of music in reducing anxiety have been recognized across various medical and psychological domains. In dentistry, the integration of music into the clinical environment has shown positive outcomes in mitigating anxiety and enhancing patient

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comfort. The rhythmic and melodic elements of music can induce a sense of calmness, distract from external stressors, and modulate emotional responses, making it a valuable adjunct to traditional anxiety management approaches.⁴

Within the realm of music therapy, binaural auditory beats have gained attention as a potential tool for anxiety reduction. Discovered in the mid-19th century, binaural beats involve the presentation of slightly different frequencies to each ear, creating a perceived third frequency – the binaural beat. This auditory phenomenon has been explored or its ability to modulate brainwave patterns and induce states of relaxation and focus. ⁵

In addition to binaural auditory beats, the concept of providing patients with a selection of music of their choice has emerged as a personalized approach to anxiety reduction. Recognizing the individuality of musical preferences, this method allows patients to create an auditory environment that aligns with their comfort and relaxation preferences. The mechanism by which music of choice contributes to anxiety reduction involves the activation of brain regions associated with pleasure, emotion regulation, and attention. By engaging the auditory and emotional processing centers of the brain, preferred music serves as a powerful distractor, diverting attention away from the dental procedure and fostering a positive emotional state. ⁶

Despite the progress in understanding and addressing dental anxiety, there remains a notable paucity in the scientific literature comparing novel behaviour management techniques in pediatric dentistry. Recognizing the unique challenges posed by pediatric dental anxiety, this study aims to contribute valuable insights into the effectiveness of innovative approaches such as binaural auditory beats and personalized music choices that is Music of choice.

2. Methods

The study included children aged 6-12 visiting a dental clinic for their first visit, needing restoration for Class 1 cavity in primary/permanent molar teeth with moderate caries in enamel and dentin. Excluded were children with special health needs, those with negative behaviour ratings, visual or auditory impairments, and those or their parents unwilling to participate. Our study focused on children aged 6-12 years due to their significant cognitive advancements, allowing better comprehension and articulation of pain and anxiety. This age group can reliably self-report anxiety using standardized scales, as they understand questions and provide accurate responses. Their developed language skills facilitate detailed expression of feelings, aiding data collection during dental procedures. Additionally, they begin to develop coping mechanisms for stress, such as music or relaxation techniques, offering insights into effective interventions. Including this age range ensured more dependable assessment of anxiety levels during restorative treatments, given their cognitive development, language proficiency, coping strategies, and clinical relevance in pediatric dentistry.

All 75 samples were randomly divided into three equal groups using simple random sampling. Group I received no music intervention, Group II received their choice of music, and Group III received binaural auditory beats consisting of 400 Hz and 412 Hz frequencies, combined with soft, relaxing music through over-the-ear headphones using a mobile device. The treatment procedure began after administering the

interventions. A trained assistant provided interventions to Groups II and III while keeping the principal investigator blinded. Group I participants were provided with over-the-ear headphones for blinding purposes but received no music intervention. Similarly, the data analyst was blinded to the interventions. Fig. 1 illustrates a CONSORT flow diagram.

Children meeting the selection criteria settled into the dental chair while the Principal Investigator (PI) explained the procedure to both children and parents. A systematic case history was recorded, followed by clinical examination under standard protocol. Behaviour of the patient prior to the study was evaluated using the FRANKL Behavior Rating Scale for participant selection whereas anxiety levels were assessed by a trained Pediatric dentist before and after treatment using Venham's Picture Test as a self-administered anxiety scale (Fig. 2). Physiological parameters like pulse rate were recorded using a fingertip pulse oximeter. Informed consent was obtained from all participating parents/guardians.

The Principal Investigator performed the restorative procedure under Standard Operating Protocols. The procedure was carried out in 45 min for each patient in all the three groups. The teeth selected for the study were isolated using Rubber dam and the tooth preparation for Class I cavity was carried out in primary or permanent molars. Teeth were restored using Posterior High Strength Glass Ionomer for Primary molars and Composite resin for Permanent molars (Fig. 3). In our study, restorative treatment was chosen as a standard modality as it reflects common procedures in pediatric dentistry, often evoking anxiety in children due to factors like fear of needles and unfamiliarity with the environment. Furthermore, these treatments, involving drills and needles, can provoke physiological symptoms and behavioral problems.

At the end of the restorative procedure, anxiety was again assessed using Venham's Picture Scale and Pulse oximeter and the post-operative recordings were noted for further analysis. The data obtained was analysed statistically using SPSS software version 20.0 (SPSS Inc., Chicago, IL, USA).

3. Results

Graph No. 1 presented the demographic profile, showcasing the age distribution among the three groups: No music (Group I), Music of choice (Group II), and Binaural auditory beats (Group III). Seventy-five patients with a mean age of 9.25 \pm 2.06 were included. Similarly, the gender distribution, showed 49.33 % male and 50.67 % female participants, ensuring equitable representation across groups and maintaining standardization in participant selection.

Upon comparing baseline and post-operative Venham's picture test scores, the Kolmogorov-Smirnov test revealed a highly significant difference in the Binaural auditory beats group (p = 0.0001), indicating its efficacy in anxiety reduction. This was followed closely by the Music of choice group (p = 0.0020), while no significant difference was observed in the Control group. Pulse rate scores, however, showed no significant differences among the groups (Table 1).

Further pairwise comparisons using the Mann-Whitney U test indicated significant anxiety reduction in both Music of choice and Binaural auditory beats groups compared to the Control group (p = 0.0001). Notably, no significant difference was found between Music of choice and Binaural auditory beats groups (p = 0.8462) (Table 2).

Subsequently, Tukey's multiple posthoc analysis elucidated significant anxiety reduction between the No music group and both Music of choice and Binaural auditory beats groups (p=0.0001). However, no significant difference was observed between the Music of choice and Binaural auditory beats groups (p=0.9634) (Table 3).

4. Discussion

Dental anxiety can be particularly pronounced among children, especially during certain dental procedures that are commonly

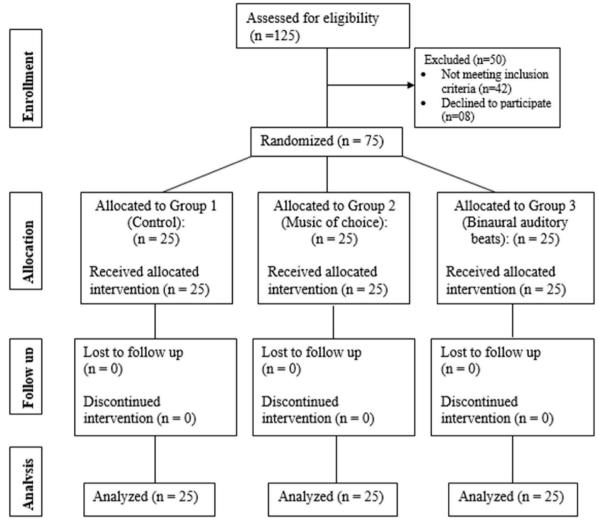


Fig. 1. Illustrates a CONSORT flow diagram.

perceived as uncomfortable or frightening. Patients experiencing anxiety before undergoing restorative procedures are commonly addressed using the "4 S" principle. The idea is to remove four main sensory stimuli that cause dental anxiety in the dentist office: sights (such as air turbine drills and needles), sounds (such as drilling), sensations (such as high-frequency vibrations), and smells (such as cut dentine).⁸

Distraction stands as a cornerstone among the array of non-pharmacological behavior guidance techniques employed in dental clinics to effectively manage children. Serving as a valuable tool, distraction works by redirecting the child's focus away from potentially distressing procedures. Consequently, this redirection leads to a diminished perception of discomfort, effectively circumventing negative or avoidant behaviors.

Unlike many other distractions based non-pharmacological interventions, Music can be implemented with minimal outlay, utilizing existing dental equipment such as the dental chair. This cost-effective approach makes it particularly appealing for dental practices seeking to enhance patient comfort and reduce anxiety without incurring substantial financial investments.

The present study sought to validate the clinical efficacy of music of choice and binaural auditory beats as audio distraction techniques in lowering anxiety during pediatric dental procedures, given the paucity of research comparing anxiety levels in children using these two interventions. Our study incorporated Binaural auditory beats as an intervention as it offers a novel and promising approach to reduce dental anxiety in children. Its non-invasive nature, potential of superimposition

for soothing experience and compatibility with other anxiety-reducing techniques make it a valuable addition to the toolkit for managing pediatric dental anxiety.

The findings of the present study, which indicate a significant reduction in anxiety among participants exposed to binaural auditory beats, are consistent with a significant amount of prior research. Notably, studies conducted by Rathi et ^{al}, ⁹ Salehabadi et ^{al}, ¹⁰ Shehani A et ^{al}, ¹¹ Wang et ^{al12}, Isik et al., ¹³ Singh et al., ⁷ Chairinkam et al., ¹⁴ Menziletoglu et al., ¹⁵ Padmanabhan et al., ¹⁶ Mallik and Russo, ¹⁷ Aly et al., ¹⁸ Perales et al. ¹⁹ and Padawe et al. ²⁰ all corroborate the effectiveness of binaural beats in reducing anxiety across various contexts, ranging from dental procedures to virtual reality environments.

The likely explanation for the effective reduction of anxiety when employing binaural auditory beats is that audio containing tones that cause binaural beats in the listener's brain results in a consistent change in brain-wave activity. The frequency of the binaural beat causes this brain activity to synchronize, a phenomenon referred to as a frequency-following response. By engaging the reticular-thalamic activating system, persistent binaural beat frequencies that resonate throughout the brain through the "frequency following response" (FFR) can change arousal levels. ²⁰ These different binaural beat ranges can produce stimulus waves that can synchronize a listener's brainwave activity and have associated psychophysiological consequences.

Prado et al. assessed distraction techniques like audio songs, 3D glasses, eyeglasses, and AVD (Audiovisual distraction) on dental anxiety, cooperation, and pain. Results showed a slight anxiety reduction

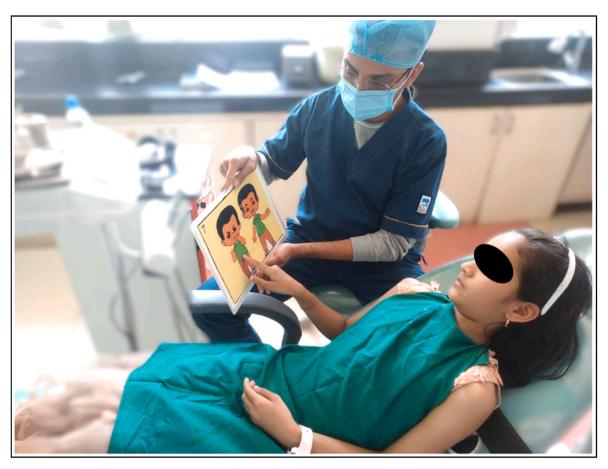


Fig. 2. Figure showing evaluation of preoperative anxiety using Venham picture test.

with audio songs and a small effect from AVD, 3D glasses, and eyeglasses on anxiety and cooperation. 21 According to a survey of AAPD members, pediatric dentists most frequently use technology-based distraction methods, with 50.9 % employing music/audio songs and 77 % using AVD. 22,23

However, it's important to acknowledge the contrasting findings from studies conducted by Kennel et al., ²⁴ Pratt et al., ²⁵ and Vernon et al. ²⁶ Kennel et al. did not find significant reductions in inattention symptoms among children and adolescents with attention-deficit/hyperactivity disorder exposed to binaural beat stimulation. Pratt et al. suggested similarities in cortical processing between binaural beats and acoustic beats, potentially questioning the unique efficacy of binaural beats. Additionally, Vernon et al. found limited evidence of significant EEG changes induced by interleaved alpha and beta binaural beats, raising questions about their practical applications in behavioral change scenarios.

Music is known to reduce anxiety and combining binaural beats with light music may enhance this effect. In our study, we investigated the effectiveness of superimposed binaural beats a novel method involving additional beats synthesized from traditional instruments alongside original binaural beats. Previous research found no significant difference between the two types of beats. ¹⁸ However, it is anticipated that the quality and efficiency of superimposed beats will surpass those of the original ones.

Our study incorporated Music of choice as another intervention for children undergoing dental treatment as allowing children to listen to their preferred music, help them gain a sense of control over their environment, empowering them and enhancing their engagement and satisfaction with the treatment process.

Recent research findings on music selection's influence on children's anxiety align with prior studies by Marwah, Singh, and Jomon,

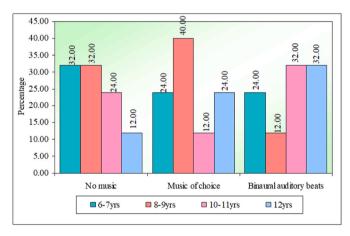
suggesting that allowing children to choose their music can alleviate anxiety. Marwah's study on pediatric dental patients showed reduced anxiety levels, though not statistically significant. Singh's research supported music of choice in significantly reducing anxiety among such patients, while Jomon's study found both music of choice and Anandabhairavi raga equally effective. However, Karbandi's exploration on hospitalized children favored distraction cards over music therapy, and Kaur's study on pediatric dental patients found audiovisual distraction more effective than music selection.

In our study, we employed Venham's Picture Test to subjectively assess anxiety levels in children, chosen for its validity in clinical contexts. This method's projective and self-measuring characteristics make it widely used in pediatric dental trials. Its simplicity accommodates varying ages and cognitive abilities, while presenting scenarios through pictures allows nuanced expression of feelings, particularly beneficial for children struggling to articulate emotions. The child-friendly approach enhances engagement, reducing stress and ensuring more accurate responses. Studies such as Venham et al. demonstrated testretest reliability in measuring anxiety in children.³² This established the scale's stability in measuring the same construct at different time points. Studies such as Schuurs et al. reported Cronbach's alpha values in the range of 0.80 or higher, suggesting that the items (facial expressions) on the scale are reliably measuring the same underlying emotional anxiety.³³ Brunetto et al. in a hospital setting, reported the Venham Picture Test was found to be a reliable tool for measuring pre-operative anxiety in children.³⁴ Additionally, Murray et al. confirmed its strong construct validity and consistency in measuring emotional responses. These studies validate the reliability of the tool and justify its use in our study.3

In our study, we employed a Finger Pulse Oximeter to objectively measure anxiety levels in children, focusing on heart rate changes as a



Fig. 3. Figure showing patient undergoing dental treatment.



Graph. 1. Graphical representation of Age wise distribution of patients in three groups namely No music [Group I], Music of choice [Group II] and Binaural auditory beats [Group III].

physiological marker. This method offers several advantages, providing a safe, non-invasive, and real-time measure of anxiety. Its simplicity and portability enable dynamic monitoring and statistical analysis across participants and time points. Moreover, its affordability enhances accessibility in diverse clinical and research settings, contributing to the generalizability of study findings.

Therefore, it can be useful to combine psychometric and physiological methods of assessment in order to provide both quantitative and qualitative estimates of anxiety.

The study employed a sound pressure level of 60 dB since prior

research indicated that this level of auditory beat stimulation is sufficient to produce noticeable electrophysiological effects.³⁶ It has been proposed that tones in the 200–900 Hz range are more effective for evoking binaural beats. In dental settings, a brief 10-min period has been shown to be effective in considerably lowering pre-operative anxiety.¹³

In our study we opted for headphones over speakers in the intervention group for several reasons. Firstly, headphones provide a controlled audio environment, ensuring consistent sound quality and volume levels for all participants, maintaining experimental consistency. They also reduce noise, minimizing external disturbances and enhancing focus on the intervention stimuli. For binaural beats, crucial to the intervention, over-the-head headphones are preferred due to their superior isolation, consistency, spatial separation, and comfort compared to other audio delivery methods. These features optimize intervention delivery, potentially reducing anxiety levels and improving the overall dental experience for pediatric patients.

The study's inclusion criteria were carefully chosen to target a specific subset of the pediatric population and dental conditions relevant to pediatric dentistry. By including first-time dental visitors, potential biases from prior treatment experiences are minimized. The focus on Class 1 cavity restorations in primary or permanent molar teeth allows for concentrated research on a common pediatric dental issue. Additionally, selecting cases with moderate dental caries involving enamel and dentin ensures the study examines cases where caries have progressed but not to the extent requiring pulp therapy.

Our study's findings hold significant clinical significance in dentistry, offering multifaceted impacts. Firstly, by exploring various audio distraction techniques, we can markedly enhance children's comfort during restorative dental procedures, fostering greater satisfaction with dental visits. Tailoring anxiety management approaches to individual preferences optimizes treatment outcomes. Moreover, our randomized clinical trial strengthens evidence supporting audio distraction efficacy in pediatric dentistry, promoting evidence-based practice and innovative anxiety management. Non-pharmacological alternatives like binaural auditory beats show promise for anxiety reduction, potentially decreasing reliance on sedation. Cultivating positive dental experiences in childhood can improve long-term oral health by encouraging regular dental care and streamlining procedures, leading to potential cost savings in pediatric dental care.

Our research opens valuable avenues for future exploration in the realm of binaural beats and sedation procedures, particularly within the context of Nitrous oxide conscious sedation. This dual approach could provide a novel and potentially synergistic pathway for improving patient experience, offering an alternative or complementary method to traditional sedation techniques. Additionally, binaural beats provide pediatric dentists with a cost-effective, non-invasive distraction method, reducing reliance on pharmacological sedation and enhancing patient comfort in a clinical setting. This approach offers significant potential for improving pediatric dental experiences while minimizing clinical and financial burdens.

Limitations of the study were like every other technique, this too had its drawbacks, none of which are insurmountable. The dentist and child's ability to communicate may be hampered by music. Also, the study's sample size might be limited, potentially affecting the generalizability of the findings to a broader population. Furthermore, study was conducted among children, may not be appropriate to generalize the findings to other age-group population.

Our study delves into futuristic concepts geared towards enhancing anxiety reduction in pediatric dental patients. Firstly, we propose investigating the synergistic effects of merging binaural auditory beats with visually relaxing stimuli, such as nature scenes or abstract patterns, to create a multisensory intervention. Additionally, we intend to leverage advanced technologies like virtual reality (VR) or augmented reality (AR) to customize immersive relaxation experiences tailored to individual patient preferences. Secondly, we plan to conduct a systematic review and meta-analysis of existing trials to assess the impact of

Table 1
Table showing the normality of baseline and post-test Venham's picture test and baseline and post-test Pulse rate scores in three groups namely No music [Group II], Music of choice [Group II] and Binaural auditory beats [Group III] by Kolmogorov Smirnov test.

Variables	Times	No music		Music of choice		Binaural auditory beats	
		Z-value	p-value	Z-value	p-value	Z-value	p-value
Venham's picture	Baseline	0.8440	0.4750	1.2220	0.1010	0.7750	0.5860
	Post-operative	0.7180	0.6820	0.8630	0.4450	1.1080	0.1710
	Difference	1.1850	0.1200	1.8480	0.0020*	1.0220	0.0010*
Pulse rate	Baseline	0.6710	0.7580	0.4360	0.9910	0.5360	0.9360
	Post-operative	0.5780	0.8920	0.5890	0.8790	0.5800	0.8890
	Difference	0.9070	0.3820	0.9800	0.2920	1.0130	0.2560

^{*}p < 0.05.

 Table 2

 Table showing pair wise comparison of three groups namely No music [Group I], Music of choice [Group II] and Binaural auditory beats [Group III] with baseline and post operative Venham's picture scale scores by Mann-Whitney U test.

Interval	Groups	No music		Music of choice		Binaural auditory beats	
		Z-value	p-value	Z-value	p-value	Z-value	p-value
Baseline	Median	3.00		3.00			
						3.00	
	IQR	2.00		1.00			
						2.00	
	No music	_	_				
	Music of choice	-0.9313	0.3517	-	-		
	Binaural auditory beats	-0.2619	0.7934	0.6500	0.5157	-	_
Post operative	Median	3.00		1.00			
						1.00	
	IQR	2.00		1.00			
						2.00	
	No music	-	-				
	Music of choice	3.8612	0.0001*	-	-		
	Binaural auditory beats	4.2395	0.0001*	0.7567	0.4492	-	-
Difference	Median	0.00		2.00			
						2.00	
	IQR	2.00		0.00			
						0.00	
	No music	-	-				
	Music of choice	-5.7432	0.0001*	-	-		
	Binaural auditory beats	-5.7432	0.0001*	0.1940	0.8462	_	-

^{*}p < 0.05.

Table 3Table showing pair wise comparison of three groups namely No music [Group I], Music of choice [Group II] and Binaural auditory beats [Group III] with baseline and post operative Pulse rate scores by Tukey's multiple posthoc procedures.

Interval	Groups	No music	Music of choice	Binaural auditory beats
Baseline	Mean	95.56	96.40	94.12
	SD	12.54	9.68	10.25
	No music	_		
	Music of choice	P =	_	
		0.9599		
	Binaural	P =	P = 0.7406	_
	auditory beats	0.8868		
Post	Mean	96.24	87.36	84.72
operative	SD	12.44	9.53	8.26
	No music	_		
	Music of choice	P =	_	
		0.0085*		
	Binaural	P =	P = 0.6344	-
	auditory beats	0.0006*		
Difference	Mean	-0.68	9.04	9.40
	SD	6.43	3.94	3.83
	No music	_		
	Music of choice	P =	_	
		0.0001*		
	Binaural	P =	P = 0.9634	_
	auditory beats	0.0001*		

^{*}p < 0.05.

specific binaural beat frequencies on relaxation and anxiety reduction. Our analysis will delve into the neurophysiological mechanisms underlying these effects, focusing on frequency-specific modulations of brainwave activity. By employing advanced statistical techniques, such as network meta-analysis, we aim to determine the optimal binaural beat frequencies for clinical practice, providing evidence-based recommendations for effective anxiety management.

5. Conclusion

In conclusion, dental anxiety continues to be a significant concern in dentistry, impacting individuals across age groups. The integration of music therapy, including binaural auditory beats and music of choice, represents a promising avenue for anxiety reduction. Both these modalities, found to be highly effective in reducing anxiety during dental treatment, are novel methods that can efficiently serve as safer and effective adjuncts for the behavior management of children.

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Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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