EGYPTIAN
DENTAL JOURNAL
www.eda-egypt.org

VOL. 71, 1145:1155, APRIL, 2025

PRINT ISSN 0070-9484 • ONLINE ISSN 2090-2360

ORTHODONTICS, PEDIATRIC AND PREVENTIVE DENTISTRY

Submit Date : 09-02-2025 • Accept Date : 05-03-2025 • Available online: 01-04-2025 • DOI : 10.21608/edj.2025.358738.3375

EFFECT OF AUDIO ANALGESIA ON BEHAVIOR OF ANXIOUS CHILDREN UNDERGOING TOOTH EXTRACTION: A RANDOMIZED CONTROLLED CLINICAL TRIAL

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ABSTRACT

Background: Dental anxiety was described as a fear of the dentist and dental treatment, which is regarded as the major reason why patients of different ages avoid visiting the dental office. The literature describes the use of various behavior management techniques to reduce dental anxiety, including the Tell-Show-Do (TSD) and Audio analgesia techniques.

Aim: To evaluate the effect of binaural beats and white noise on behavior of anxious children undergoing tooth extraction.

Subjects and Methods: Ninety children aged 6 to 8 years requiring tooth extraction were randomly assigned to either control group (managed by TSD technique) or two experimental groups (managed by Audio analgesia using binaural beats or white noise). Assessment of child's behavior was done at arrival of the children, during local anesthesia, and during extraction, using Frankl Behavior Rating Scale (FBRS). Children Anxiety was evaluated using Venham's picture test (VPT), prior and following dental extraction. Also, heart rate readings were carried out for all children prior, during, and following the procedure. Results were collected and statistically analyzed.

Results: Regarding behavior, compared to TSD group a statistically significant improvement in behavior of FBRS scores at different time frame, Monge white noise and Binaural beats groups. Regarding anxiety, significant reduction was found in heart rate measures among Binaural beats and white noise. The least reduction of anxiety level was observed in TSD group.

Conclusion: Audio analgesia distraction can be regarded as a successful method to decrease anxiety among pediatric patients.

KEYWORDS: Audio analgesia, Behavior management, White noise, Pediatric dentistry.

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INTRODUCTION

Dental anxiety is a multifaceted, complex phenomenon that cannot be explained just by one aspect. Several factors have been consistently linked to increased dental anxiety in the literature. These include personality traits, fear of pain, and past negative dental experiences, particularly those occurring in childhood (conditioning). Observing anxious dental experiences in family members or peers can also contribute to the dental anxiety development through vicarious learning. Additionally, individuals with blood-injury phobias may also exhibit heightened dental anxiety.[1-3]

Managing dental anxiety in children presents a significant challenge for clinicians. Compared to adult patients, treating anxious or fearful children can be time- and cost-consuming.[4-5] Over time, many methods have been developed to manage the behavior of anxious pediatric children during dental procedures. Although several methods, such as sedatives and general anesthesia, are quite exciting with the assurance of findings, non-invasive psychotherapeutic approaches always come first. These approaches offer several advantages, including the mitigation of the negative consequences associated with drug administration and the avoidance of discomfort related to invasive modalities.[6]

Several pharmacological and non-pharmacological techniques have been developed to manage children's anxious behaviors. Pharmacological techniques as conscious sedation, general anesthesia, and nitrous oxide/oxygen inhalation sedation are used in case of children with special health care needs, uncooperative and very young children.[7] The American Academy of Pediatric Dentistry has recommended more focus on non-pharmacological techniques.[8] These techniques include non-verbal communication, voice control, distraction, Tell-Show-Do (TSD), and positive reinforcement are frequently used with children who obtained a certain level of skills for communicating. Less co-operative children may require alternative management strategies, such as the use of hand-over-mouth technique and physical restraints.

TSD approach is the most widely utilized technique in pediatric dentistry[9] . The method enables the child to gradually learn the procedure to minimize his/her fear and anxiety because introduction of new instruments and/or procedures may scare anxious children as they may not be aware of the specific use of these instruments or procedures[10].

Distraction techniques decrease anxiety by shifting patients' attention away from unpleasant procedures noxious stimuli[11,12].

Audioanalgesia, pioneered by Gardner and Lickliter in 1959, is a non-pharmacological pain management technique that utilizes auditory stimuli, such as music or white noise, to releive pain during medical procedures including dental procedures[13]. This approach aims to distract the patient from the painful sensations and promote relaxation, thereby reducing the perception of pain[14-15].

Binaural beats, first described by Dove in 1939, arise when two auditory stimuli with similar intensities but various frequencies are presented separately to each ear[16]. This results in the perception of the difference frequency of the two tones. This phenomenon requires the collaborative processing of auditory information by both ears within the brain[17]. For instance, if a 152 Hz tone is presented to one ear and a 150 Hz tone to the other, the perceived beat frequency in the brain would be 2 Hz[18]. Depending on the difference in frequency, different types of brainwaves (alpha, beta, gamma, delta, epsilon, and theta) may be created which, in turn, stimulate comparable cognitive and behavioral reactions, and this method is known as "brainwave entrainment"[19] .

White noise is defined as music with unaltered frequency or amplitude, sound parameters, and masks the other unwanted noises in the environment.

The term "white noise" derives its name from the analogous concept of white light. White light is composed of a spectrum of colors, each representing a different frequency. Similarly, white noise encompasses a broad spectrum of sound frequencies. This amalgamation of sounds, such as the gentle patter of rain or the soothing murmur of ocean waves, creates a uniform and continuous auditory experience [20].

Anxiety can be evaluated utilizing physiological measures and anxiety scales. Anxiety scales are accurate and useful for evaluating children's response to dental stress [21]. There are various measures and scales have been created to classify the dentally anxious patients and to evaluate their behavior and anxiety level during dental visits such as Behavior Profile Rating Scale, Frankl Behavior Rating Scale (FBRS), Venham Behavior Rating Scale (VBRS), Facial Image Scale (FIS), Visual Analogue Scale (VAS), Modified Child Dental Anxiety Scale (MCDAS), Global Rating Scale, and Child Drawing: Hospital Scale (CD:H scale).[22] Direct evaluations of the child's physiological condition, such as pulse/heart rate, neural activity, and muscle activity, may allow for real-time and continuous assessment at various phases of treatment [23] .

MATERIAL AND METHOD

Study design:

The study conducted is a randomized clinical and controlled trail.

Simple size:

The sample size was determined using a power analysis based on the findings of Isik et al. (2017). This analysis, conducted with a statistical power software (PS), yielded a required sample size of 27 participants per group, assuming a significance level of 5% and a power of 90%.

The sample size was increased to 30 participants for each group (total 90) to compensate for incomplete data and to increase the study power.

Ethics approval and consent to participates:

The study protocol was approved by the Research Ethics Committee (REC)

Approval code: (A02011023PP) *date: -Novmber2023, Faculty of Dentistry Mansoura University.

A Written informed consent was provided by the parents prior to the examination and treatment of their children.

Eligibility criteria:

The qualifying requirements were the following: children aged 6-8 years old with definitely negative behavior according to the FBRS, physical status according to American Society of Anesthesiologists (ASA) indicated for extraction. The study excluded those with a history of underlying illnesses such epilepsy, mental, or hearing impairments

Material:

A-Experimental tools:

1. Frankle Behavior Rating Scale (FBRS).
2. Finger Pulse Oximeter (PO) (Jumper, JPD-500E).
3. Venham's Picture Test (VPT).
4. Wireless headphones or earphones (SODO, SD-1002).
5. "Brain Waves - Binaural Beats" (MynioTech Apps, Santa Catarina, Brazil) software compatible with smartphones.
6. White noise at 432 Hertz, Available from: https://www. YouTube/YGfc3kBVrck
7. Alcohol-based sanitizer wipes.

B- Procedural tools:

1. Topical Anesthesia (20 % Benzocaine topical anesthetic gel).
2. Local Anesthesia (articaine 4% solution).
3. Forceps (Pakistan).

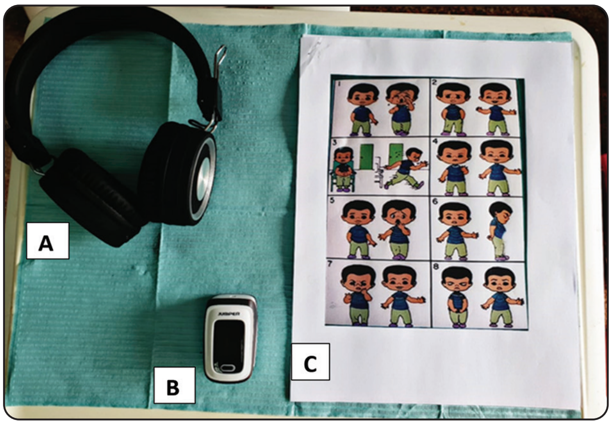

Fig. (1) A) wireless headphones, B) Pulse Oximeter, C) Venham's Picture Test (VPT)

METHODS:

Randomization: -

Simple randomization using opaque envelopes was selected by the child who was involved in the intervention before treatment. Following the parent signed the informed consent, the child selected an envelope to be allocated in either control or experimental group[24] .

Grouping of children:

Control group (TSD group, group A): Thirty children received TSD technique. Before tooth extraction children of this group were demonstrated to the dental clinic, dental chair, dental tools, and the topical anesthetic gel as tooth sleeping drug in very simple terms.

The child was able to hold the tools and experience the feeling of pressure that occurs during tooth extraction. Finaly the work was completed exactly as specified to the patient, in the same sequence.

Experimental Groups:

1. **(Binaural beats, Group B):** Thirty children received Binaural beats as a behavior management technique, before and during extraction. Participants listened to binaural beats generated by the "Brain Waves - Binaural Beats" software (MynioTech Apps, Santa Catarina, Brazil) delivered via wireless headphones for ten minutes. These beats, presented at 344 Hz to the left ear and 340 Hz to the right ear, were designed to induce a theta wave frequency of 4 Hz.
2. **(White noise, Group C):** Thirty children received White noise technique as a behavior management technique. White noise of 432 Hz was used with smartphones and used in patients. White noise has been shown to effectively facilitate faster and more restful sleep in children, thus in the present study it was used just during the induction procedure and then withdrawn during the actual therapy since conscious sedation needs the child to listen to and follow the operator's instructions.

The patient's oxygen saturation and pulse rate were measured using a Finger Pulse Oximeter (PO) and the value was recorded before the Local anesthesia and before and after extraction.

The experiment:

Children fulfill the criteria, were treated by local anesthesia and extraction using their different behavior management techniques.

First, behavior of all children was recorded at their clinic entry, the PO was attached to the index finger and heart rate and oxygen saturation were recorded.

They topical and local anesthesia were given to the target tooth for extraction. Behavior and anxiety of the child were recorded by FBRS and pulse oximeter during local anesthesia and during extraction. before and after extraction anxiety of children were recorded using VPT.

Fig. (2) A) before beginning the treatment procedure in the audio group Child. B) Evaluate of pulse rate by pulse oximeter. C) Subjective evaluate of anxiety level by Venham's picture test.

Statistical Analysis:

Data analysis was carried out using IBM SPSS Statistics software, version 18. Descriptive statistics were employed: frequencies and percentages for qualitative variables, and median (minimum, maximum, and interquartile range) for non-normally distributed quantitative variables. For normally distributed data, mean and standard deviation were used. Normality was evaluated using the Shapiro-Wilk and Kolmogorov-Smirnov tests. Statistical significance was determined at the 0.05 level

RESULTS

Table (1): Illustrates no statistically significant difference between different studied groups as regard heart rate before local anesthesia (p=0.274), within group significance demonstrates no statistically significant difference between each pairs A statistically significant higher mean heart rate among control group followed by white noise group then binaural beats group before extraction and after extraction. Tukey's post-hoc test demonstrates statistically significant difference between control group and binaural beats and between control & white noise group for before extraction and after extraction readings.

TABLE (1) Comparison of heart rate change among studied groups.

Heart rate	Control (Tell Show Do) N=30	Binaural beats N=30	White noise N=30	Test of significance
Before the local anesthesia	99.83±14.24	94.90±13.44	99.7±12.81	F=1.32 P=0.274
Before extraction	112.30±17.48	101.0±13.67	102.20±12.25	F=5.39 P=0.006*
After extraction	111.93±18.42	96.17±13.39	98.33±13.04	F=9.55 P=0.001*
##	pa=0.017* pb=0.01* pc=0.326	pa=0.002* pb=0.001* pc=0.375	pa=0.001* pb=0.001* pc=0.083	

P ≤ 0.05 *: significant at P ≤ 0.05;

TABLE (2) Illustrates statistically significant difference between different studied groups as regards FBRS scores ranged from 1(definitely negative) to 3(positive), at arrival (p=0.045). Tukey post-hoc test demonstrates statistically significant difference between control and white noise group (p=0.03). FBRS during local anesthesia (LA) demonstrates a statistically significant difference between control and white noise groups (p=0.029).

For control group; statistically significant change in FBRS between at arrival and during LA (P=0.017) and between at arrival and during examination (P=0.01).

For Binaural beats group; statistically significant change in FBRS between at arrival and during LA (P=0.002) and between at arrival and during extraction (P=0.001).

For White noise group; statistically significant change in FBRS between at arrival and during LA (P=0.001) and between at arrival and during extraction. (P=0.001).

TABLE (2) Comparison of children's behavior at arrival, during anesthesia and during extraction stages in each group using FBRS.

FBS	Control(Tell Show Do) N=30	Binaural beats N=30	White noise N=30	Test of significance
At arrival				
Definitely negative	3(10.0)	0	0	MC=6.21
Negative	27(90.0)	30(100)	30(100)	P=0.045*
During LA				
Definitely negative	3(10.0)	3(10.0)	2(6.7)	MC=7.37
Negative	18(60.0)	11(36.7)	9(30.0)	P=0.118
Positive	9(30.0)	16(53.3)	19(63.3)	
During extraction				
Definitely negative				
Negative	6(20.0)	4(13.3)	1(3.3)	MC=4.56
Positive	8(26.7)	6(20.0)	8(26.7)	P=0.336
	16(53.3)	20(66.7)	21(70.0)	
	pa=0.017*	pa=0.002*	pa=0.001*	
	pb=0.01*	pb=0.001*	pb=0.001*	
	pc=0.326	pc=0.375	pc=0.083	

MC: Monte Carlo test , *statistically significant

p1: difference between control(Tell Show Do) versus Binaural beats .

p2: difference between control versus white noise group.

p3: difference between binaural beats and white noise group.

pa: difference between at arrival and during LA

pb: difference between at arrival and during extraction

pc: difference between during LA and during extraction

Table (3) demonstrates no statistically significant difference between studied groups as regards VPT test before extraction (p=0.861).

VPT test after extraction illustrates a statistically significant difference between studied groups (p=0.005). Tukey Post-hoc test shows statistically significant difference between the difference between binaural beats and white noise group (p=0.001).

TABLE (3) Evaluation of the anxiety levels before and after extraction in each group using of Venham's Picture Test (VPT) among studied groups.

VPT	Control (Tell Show Do) N=30	Binaural beats N=30	White noise N=30	Test of significance
Before extraction				MC=0.30
Non anxious	20(66.7)	19(63.3)	21(70)	P=0.861
Anxious	10(33.3)	11(36.7)	9(30)	
After extraction				MC=10.63
Non anxious	17(56.7)	22(73.3)	28(93.3)	P=0.005*
Anxious	13(43.3)	8(26.7)	2(6.7)	
#	pa=0.264	pa=0.326	pa=0.006*	

DISCUSSION

Effective management of dental anxiety in children is crucial for pediatric dentists. Unmanaged dental fear can significantly hinder a child's access to necessary oral healthcare, potentially leading to long-term oral health problems.[25]

The TSD technique was used as a comparator in this study. It is one of the children's widely utilized techniques of behavior control. Since then, it has been among the most widely utilized techniques when compared to other behavior control techniques, and it is still the most commonly used technique globally. These findings are in line with previous results [26-28].

In the present study, the age of children selected in the study was in the range of 6-8 years old since this age exhibits more disruptive behavior and dental anxiety. This age group also demonstrates the cognitive capacity for self-reporting anxiety levels and comprehending behavior-shaping strategies. This result is in agreement with that of previous studies [29-30]

On the other hand, this study excluded individuals with compromised medical conditions, cognitive impairments, or mental health issues, as well as those with hearing impairments because patients with personal experiences of a mental illness frequently report feeling ignored and rejected, which has been recognized as a key obstacle to accessing treatment and lead to increased anxiety[31]**.** This agree with the results of **Padawe et al** [32] and **Isik et al**[33]**.**

In the present study, FBRS was used in the current study to categorize children behavior. The FBRS is one of the best commonly used behavior rating scales in pediatric dentistry through which the child's attitude and cooperation during dental visits are assessed **Frankl et al** [34] **and Noel, et al.**[35]. Only children with FBRS score of 1 or 2 were included in the current study. This comes in agreement with the results of **Padawe et al** [32].

In this study, VPT anxiety scale was used by children there were asked to indicate the figure that best represented how they felt at that moment. This method was adopted similar to different study as **Krishnappa et al**[36]; **Oliveira et al** [37]and Mukundan **et al** [38].

An additional assessment of anxiety evaluated by pulse oximeter; the patient's pulse rate was measured using a Finger PO. Changes in pulse rate are often linked to variations in an individual's stress levels, allowing for an objective assessment of anxiety changes throughout the treatment process. This comes agreement with **James et al**[39], **Thakkar et al**[40].

Binaural auditory beats have been utilized to reduce anxiety in many research studies. Prior study has assessed and compared binaural auditory beats in children during dental procedures [31,34]. The findings suggest that binaural auditory beats may be an effective intervention for reducing anxiety, as demonstrated by a significant difference in anxiety scores compared to the control group. These results come in agreement with the studies done previously[33,41-44].

An effective alleviation of anxiety through binaural auditory beats may be due to their ability to enhance functional connectivity in the auditory cortex, leading to a brainwave entrainment effect that releases endorphins. Additionally, these beats can inhibit pain-related neural functions triggered by auditory stimuli in the posterior group nuclei of the thalamus and the cerebral cortex, as noted by Mountcastle[45], which could contribute to the relaxation experienced by the child.[41]

White noise served as the auditory distraction technique in the present study maintains a consistent amplitude or intensity across the entire audible frequency range (20 to 20,000 Hertz). It is called white noise because it is similar to white light, which consists of a combination of all visible wavelengths[46]. Numerous examples of white noise include the beach noises, sound of waves, heartbeat noise that mimics the mothers, and instrumental songs to sleep. White noise is used to help children sleep quicker and better, thus it was only utilized during the induction procedure and then stopped during treatment since conscious sedation needs the child to listen to and follow the operator's instructions.

This distraction technique helped decrease patient anxiety, according to both the dentist and the patient. The effects they were most obvious for patients initially classified as definitely negative. This comes agreement with the results of **Aitken et al** [47], **Gandhi et al.**[48].

Regarding the results of this study, the TSD (control group), was the least relaxed group during dental treatment according to FBRS. This might be explained by the fact that the TSD technique lacks the joy, interaction and distraction that comes in agreement with **Ibrahim** et al[26].

The results of the binaural beats and white noise groups showed better reduction in anxiety levels during dental treatment according to FBRS. This may be explained by its usefulness for the sound has Calming effects and helps ease anxiety by influencing the brain's limbic system, leading to the release of endorphins and enkephalins, which can reduce dental anxiety. Additionally, sound activates the parasympathetic nervous system, resulting in lower physiological responses including blood pressure, pulse, and respiration, further alleviating dental anxiety, that comes in agreement with, **Weiland et al**[49] and **Wiwatwongwana et al** [50].

In respect of the results of this study, VPT after extraction, showed a statistically significant difference between studied groups. Audio analgesia group can significantly Change the pain threshold and pain tolerance. This expanded the decrease of anxiety in a painful condition and affected the reaction component of pain. That came agreement with previous results[51-54].

Limitations

The Sound can influence the communication between dentist and child. A 10-minute exposure duration may be inadequate to get the desired impact of binaural beats.

CONCLUSION

Audio analgesia distraction is an effective way to reduce anxiety during dental treatments, allowing patients to have a more enjoyable experience at the dental visit.

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