COMPARATIVE EVALUATION OF 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: A RANDOMIZED CLINICAL TRIAL

By

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ABSTRACT

AIM: The aim of the study is 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.

METHOD: In-vivo double-blind, three-arm, parallel-group randomized study was conducted in the department of pediatric and preventive dentistry. 75 participants were allocated into 3 groups as No music, Music of choice and Binaural auditory beats. The teeth with Class I cavity in primary and permanent molars were prepared and restored. Anxiety was measured pre- and post-intervention using Pulse oximeter and Venham's picture test.

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 no music (control) group. Children undergoing dental treatment using Binaural auditory beats showed statistically significant difference with a 'p' value of 0.0006 ($p<0.05$) as compared to no music group. Children undergoing dental treatment using Music of choice showed statistically significant results with p value of 0.0085*($p<0.05$) as compared to no music group. Among the Binaural auditory beats and Music of choice there was no statistically significant difference.

CONCLUSION: The results of our study conclude that Binaural auditory beats and Music of choice can be used effectively as a distraction type of behaviour management technique to reduce anxiety in apprehensive pediatric patients.

KEYWORDS: Anxiety, Audio distraction, Behaviour Guidance Technique, Binaural Auditory Beats, Children, Music of choice

LIST OF ABBREVIATIONS

Sl. No.	Abbreviation	Expanded Form
1.	ABS	Auditory Beat Stimulation
2.	AL	Anxiety Level
3.	ANS	Autonomic Nervous System
4.	AR	Augmented Reality
5.	BBM	Binaural Beat Music
6.	BP	Blood Pressure
7.	BPT	Bach Flower Therapy
8.	CARS	Clinical Anxiety Rating Scale
9.	CFSS	Child Fear Survey Schedule
10.	CFSS-DS	Child's Fear Survey Schedule-Dental Subscale
11.	DBP	Diastolic Blood Pressure
12.	DSM-IV	Diagnostic And Statistical Manual of Mental Disorders
13.	EEG	Electroencephalogram
14.	ELISA	Enzyme-Linked Immunosorbent Assay
15.	EMLA	Eutectic Mixture of Local Anesthetic Agents
16.	ERP	Event-Related Potentials
17.	FFR	Frequency Following Response
18.	FIS	Facial Image Scale
19.	GSR	Galvanic Skin Response
20.	HR	Heart Rate
21.	ICD-10	International Statistical Classification Of Disease
22.	IRB	Institutional Review Board

23.	LA	Local Anesthetic
24.	MCDAS	Modified Child Dental Anxiety Scale
25.	MCDASF	Modified Child Dental Anxiety Scale-Face Version
26.	MDAS	Modified Dental Anxiety Scale
27.	MT	Music Therapy
28.	PI	Principal Investigator
29.	PR	Pulse Rate
30.	SBP	Systolic Blood Pressure
31.	SF-MPQ	Short-Form McGill Pain Questionnaire
32.	STAI	State-Trait Anxiety Inventory
33.	TOVA	Test Of Variables of Attention
34.	VAS	Visual Analogue Scale
35.	VCRS	Venham's Clinical Rating Scale
36.	VPT	Venham Picture Test
37.	VR	Virtual Reality
38.	VRCA	Venham Rating of Clinical Anxiety

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INTRODUCTION

"Exploring the effectiveness of new ways to distract children during dental visits is like unlocking a treasure chest of possibilities"

-Dr. Smith

Fear is a reaction to a known or perceived threat or danger. It leads to a fight-or-flight situation. Fear and anxiety associated with visiting the dentist and receiving dental treatment are key factors leading to avoidance of dental care.[1] 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.[2] The prevalence of dental fear and anxiety has been reported to be around 5%–30% among different countries.[3] Phobia is characterized by an enduring, irrational, and intense fear of a particular stimulus, resulting in the avoidance of the perceived threat. The overwhelming and irrational fear of dentistry, accompanied by intense feelings of hypertension, terror, trepidation, and unease, is known as "odontophobia." This condition has been classified under specific phobias in both the Diagnostic and Statistical Manual of Mental Disorders (DSM-IV) and the International Statistical Classification of Diseases and Related Health Problems (ICD-10).[4]

Both dental anxiety and fear trigger physical, cognitive, emotional, and behavioral reactions in individuals. Anxiety is frequently associated with increased sensitivity to painful stimuli and an increased perception of pain. Consequently, individuals experiencing dental anxiety often experience more prolonged and intense pain, while also amplifying their recollection of painful experiences.[5,6]

The correlation between anxiety and pain in the dental context is well-established and multifaceted. 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. Recognizing and addressing this correlation is vital for comprehensive anxiety management in dental settings. According to McCaul and Mallot's theory, a patient's experience of pain is reduced when they are diverted from an unpleasant stimulus. Perception of pain is directly proportional to the amount of time patient concentrates on the painful stimulus.[7]

Children with dental fear and anxiety often try all means to avoid or delay dental treatment. Their unamenable behaviour leads to prolonged appointment duration which in turn results in an overall unpleasant experience primarily for the child as well as the dentist. This in turn worsens and strengthens their fear, ultimately resulting in complete avoidance in the future. Consequently, a vicious cycle of dental fear sets in if these patients are not managed appropriately[8]

Dental fear and anxiety negatively impact the quality of dental treatment performed. Cohen et al. reported that dental anxiety has various effects on an individual's life. Physiologically, it manifests through signs of the fright response and feelings of exhaustion post-dental appointments. Cognitively, it involves negative thoughts, beliefs and fears. Behaviorally, it leads to avoidance and affects eating habits and oral hygiene. Emotional responses like crying and sometimes aggression. Additionally, it can impact general health through disturbances in sleep.[9]

Dental anxiety can arise from various factors, including past negative or traumatic experiences, particularly during childhood (known as conditioning experiences), observing anxiety in family members or peers, individual personality traits like neuroticism and self-consciousness, lack of understanding, coping mechanisms, perception of body image and feeling vulnerable in the reclined position of a dental chair.[10-12] Additionally, sensory triggers such as the sight of needles and air-turbine drills, sounds of drilling and screaming, the smell of eugenol and cut dentine, and sensations of high-frequency vibrations in the dental environment can also provoke anxiety.[13-15]

Various common fears contribute to dental anxiety, including fear of pain, fear of blood or injury, lack of trust or fear of betrayal, fear of the unknown, fear of detachment during treatment, fear of choking or gagging, feeling helpless while in the dental chair and a sense of lack of control during treatment.

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.[16]

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 depending on the degree of dental anxiety, dentist's expertise and clinical situations.

Both non-pharmacological and pharmacological interventions demonstrate comparable efficacy in alleviating dental anxiety and phobia. While non-pharmacological interventions may not yield immediate results, multiple sessions are typically required to sustain initial treatment response. Research indicates low dropout rates and sustained reductions in anxiety or phobia over extended periods, with a higher percentage of patients returning for subsequent treatments.[17,18] Also, they bring change in disruptive behaviour by replacing the negative behaviour with more cooperative behaviour. On the other hand, treatment measures based on pharmacological methods are perceived as less favourable by patients and are effective primarily in the short term.[19,20] Also, it fails to cope with the child's fear and simply aims at carrying out dental treatment in a relatively short time.

Thus, non- pharmacological methods have proven effective to varying extents, but ongoing research seeks innovative and patient-centered strategies to further optimize anxiety reduction in dental settings. Therefore, pediatric dentists must efficiently and effectively manage patients by employing modern behavior guidance techniques. Recent years have witnessed notable advances in exploring novel techniques for minimizing dental anxiety. Innovations such as Animal assisted therapy, aroma therapy, Snoezelen sensory adapted dental environment, virtual reality, guided

imagery, etc have opened new avenues for comprehensive anxiety management. However, most of these methods need separate area or special equipment to bring about the successful results which could cost more for the dentist.

Distraction is one of the most commonly used non-pharmacological behaviour guidance technique to manage a child appropriately in dental clinic. It is a useful technique of diverting the patient's attention from what may be perceived as an unpleasant procedure. This enables decreased perception of unpleasantness and averting negative or avoidance behaviour.

Research has demonstrated that appropriate music can modulate human brain waves, inducing profound relaxation and mitigating pain and anxiety. Music distraction, a non-invasive technique, entails patients listening to pleasant music during stressful dental procedures. This technique is believed to reduce neuroendocrine and sympathetic nervous system activity through a combination of relaxation and distraction. Its efficacy has been observed in both pediatric and adult dental patients.[21,22] Music therapy can be categorized as either active, involving interactive communication with a music therapist, or passive, involving the passive listening to prerecorded music.

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 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.

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.

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. The individualized nature of this approach enhances its efficacy, catering to the diverse preferences of patients.

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. By systematically evaluating the impact of these interventions on anxiety levels and overall dental experiences, the

study seeks to bridge existing gaps in the literature and inform future practices in behaviour management for children in dental settings.

When the literature search was carried out there were no studies carried out in Indian Scenario or worldwide comparing anxiety level using Music of Choice and Binaural Auditory Beats as audio distraction behaviour guidance technique in children. So, an attempt was made to carry out this research to evaluate and compare anxiety level during restorative treatment using Music of Choice and Binaural Auditory Beats as audio distraction behaviour guidance technique in children.

AIM AND OBJECTIVES

AIM OF THE STUDY:

The aim of the study is 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.

OBJECTIVES OF THE STUDY:

- To evaluate the 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.
- To compare the 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.

RESEARCH HYPOTHESIS

NULL HYPOTHESIS:

There is no difference in 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.

ALTERNATIVE HYPOTHESIS:

There is statistically significant difference in 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.

REVIEW OF LITERATURE

"Music gives a soul to the universe, wings to the mind, flight to the imagination, and life to everything"

-Plato

With dental anxiety being a common concern among children, the literature search delves into uncharted territory, seeking to uncover the keys to a calmer, more enjoyable dental experience for young patients. Through innovative sound-based interventions, the research hopes to revolutionize pediatric dental care, transforming apprehension into relaxation one melody at a time.

Anxiety can profoundly influence a person's behaviour, manifesting in a variety of ways that can range from subtle to overt. In response to perceived threats or stressors, individuals may exhibit avoidance behaviour, withdrawing from situations or people that trigger their anxiety. Conversely, some may display compulsive behaviour, seeking reassurance or engaging in repetitive actions as a means of managing their anxiety. Decision-making processes may become impaired, leading to indecisiveness or overthinking, as fear of potential negative outcomes amplifies. Additionally, heightened arousal levels can result in irritability, restlessness, or difficulty concentrating, impacting interpersonal relationships and daily functioning. Overall, anxiety can significantly alter behavioral patterns, often leading individuals to adopt coping mechanisms that may inadvertently exacerbate their distress.

The literature review presented herein is structured meticulously to dissect the multifaceted realm of pediatric dental anxiety and its potential improvement through auditory interventions. Each section of this review represents a distinct facet of this fundamental theme, aiming to unravel the complexities and nuances inherent in the

interplay between fear, anxiety, pain perception, and auditory stimuli in the context of pediatric dental care. The review has delved into the existing literature to explore the following areas:

I. Literature on to fear and anxiety in children

II. Literature on assessment of dental fear, dental anxiety and dental phobia in children

III. Literature on Audio analgesia (White noise)

IV. Literature in relationship between pain and audio analgesia

V. Literature on relationship between anxiety and audio analgesia

VI. Literature on effect of audio distraction on autonomic nervous system

VII. Literature on Music and sedation

VIII. Literature on Monaural beats

IX. Literature on 432 Hz frequency music

X. literature on Hindustani (Indian) music

XI. Literature on Binaural auditory beats

XII. Literature on Music of choice

I. LITERATURE ON FEAR AND ANXIETY IN CHILDREN

In order to investigate the hypothesised sequence of the "vicious cycle" of fear—in which dental fear, delayed dental visiting, increased dental problems, and symptom-driven treatment form an interconnected chain feeding back into the fear experience—a study was conducted to examine the relationship between dental fear and patterns of dental visits, prevalence of dental problems, and symptom-driven treatment. The study used a telephone interview survey with a random sample of 6,112 Australian residents aged 16 years and over was selected from 13 strata across all States and Territories. The findings showed that those who experienced more dental anxiety also anticipated awaiting longer to see a dentist in the future and visited the dentist less frequently. Greater perceived dental care needs, the social effect of oral illness, and lower self-rated oral health were all correlated with higher dental fear. Dental visits were more likely to be symptom-driven and related to problems or pain relief in visit patterns linked to higher levels of dental dread. A vicious cycle of dental fear took significance in all interactions. Overall, compared to 11.6% of persons who had no dental fear, 29.2% of those who experienced severe dental anxiety had poor oral health, delayed dental visits, and symptom-driven treatment seeking. The authors came to the conclusion that the data support a theory about a vicious cycle of dental fear, according to which patients who experience high levels of dental fear are more likely to put off receiving treatment, which can result in more serious dental issues and symptomatic visiting patterns that can exacerbate or maintain pre-existing dental fear [Figure No. 1].[8]

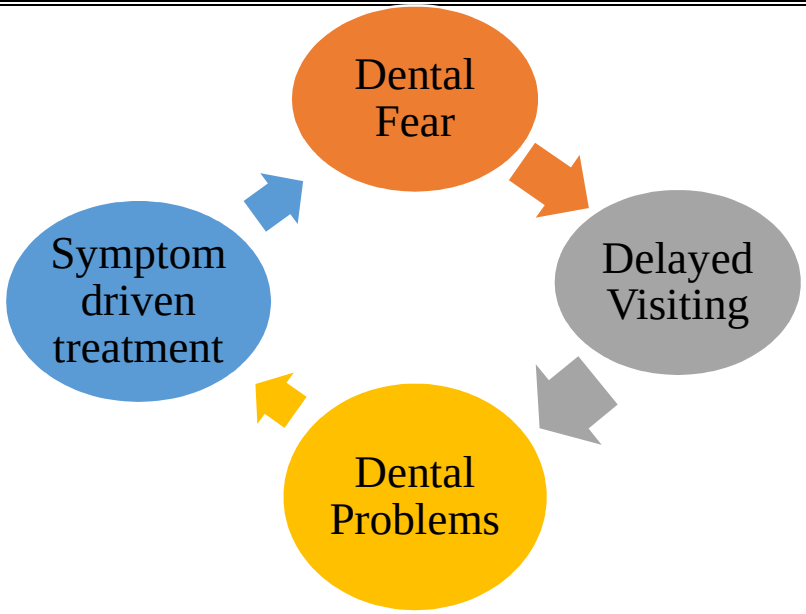

Figure No. 1: Photograph showing Vicious cycle of dental fear

Patients with anxiety may be subjectively assessed based on their behavioral, emotional, and psychophysiological reactions [Table No. 1][8]

Table No. 1: Table showing subjective assessment of anxious patients based on their psychophysiological, behavioural, and emotional responses

Psychophysiological Responses
• Muscle tightness, Hands unsteady, Restlessness, Clearing the throat • Sweating on the forehead, upper lip, and palms of hands, Pulsation in the carotid and temporal arteries, Depth and speed of respiration, Stiff posture • Holding things tightly, Frequent urination
Behavioural And Emotional Responses
• Hyperactivity, Walking or talking faster, In a hurry, Irritation with delays • Panicky, Blushing, Avoiding people, Nervous habits, Poor memory, Confusion, stumbling over words, Sitting on the edge of the chair, leaning forward, Inattentiveness, Excessive worrying, Outburst of emotions

II. LITERATURE ON ASSESSMENT OF DENTAL FEAR, DENTAL ANXIETY AND DENTAL PHOBIA IN CHILDREN

In Pediatric dentistry, disruptive behavior, anxiety and fear are common occurrences that have significant implications for the child and the dentist. Dental anxiety, fear or phobias have a significant detrimental influence on treatment outcomes and make dental care time-consuming, expensive, and demanding for both the kid and the practitioner. The first step in providing children with dental anxiety, fear, or phobia with a suitable and effective treatment plan should be to accurately assess the child's condition using an appropriate screening tool. Though they are related to one another, dental fear, anxiety, phobia and behaviour management issues are distinct concepts that might entail various physiological, cognitive, emotional, and behavioral elements.[23]

Anxiety represents a generalized reaction to an unidentified threat or internal conflict. Dental anxiety is specifically defined as the reaction to a stressful stimulus that is unique to the dental setting. Conversely, fear is a response to a recognized, particular, and genuine externally threatening event. Fear of the dentist is a common emotional response to potentially dangerous stimuli. Avoidance reduces fear in children. As a result, the initial reaction to an object or stimulus that causes fear is to escape or avoid the frightening circumstance. Stated differently, the anxiety response refers to the physiological and psychological reactions that come with the expectation of experiencing the feared stimuli or circumstance. Children who experience exaggerated fear responses that endure even in safe environments are more prone to develop phobias. Dental phobia is a severe and unique kind of dental fear that manifests as a persistent fear of things or events in the dental environment that are easily identifiable and confined. It is imperative to differentiate between dental anxiety, fear, and phobia in order to effectively establish and implement treatment plans for children.

A systematic review was conducted to assess whether current research in pediatric dentistry effectively distinguishes between dental anxiety, fear, and phobia. Out of 104 papers published between 1986 and June 2015, only five studies employed distinct clinical measures or criteria to discriminate between these constructs. These studies utilized a variety of assessment tools, including two self-styled tools and 24 established scales for dental anxiety, one scale for dental fear, and two scales for injection and blood phobias. Among the established scales, nine were psychometric tests, 10 were pictorial scales, and four were behavior rating scales. The CFSS-DS emerged as the most frequently used scale, employed in 40 studies (38%) to assess both dental anxiety and fear, followed by MCDAS, DFS, and CARS. The VPT was the second most used measure (in 13 studies, 12.5%) followed by the MCDASF (in 11 studies, 10.5%). Participants were categorized into three age groups: 3-6, 6-12, and 12-18 years old.[23]

Pictorial scales were the most commonly used measure type for children aged three to six. They were employed in 20% of the investigations, with the VPT being the most often used scale in 6% of the studies. In 15% of the research, psychometric scales were employed as the second most common form of measure, with the parental version of the CFSS-DS ranking highest. In 8% of the investigations, behavioral rating measures were employed. Psychometric tests and visual scales were the most often utilized scale types for assessing dental anxiety and terror in children aged 6 to 12 years. 50% and 33% research, respectively, made use of them. This age group mostly used the CFSS-DS child and parental versions. 6% studies made use of behavioral rating measures. The age group of 12 to 18 years old showed the same pattern as the preceding age range. Psychometric tests were used in 38% studies and followed by pictorial scales that were used in 13% studies. Interestingly, behavioral rating scales were not used in these children. Overall, the review revealed a lack of a precise and standardized method for discriminating between dental fear, anxiety, and phobia in pediatric dentistry research, leading to their interchangeable use.[23]

III. LITERATURE ON AUDIO ANALGESIA (WHITE NOISE)

"Audio analgesia," initially described by Gardner and Lickliderl in 1959, is the use of sound to reduce pain during painful dental treatment without the need for any pharmacological agents.[24] According to August, the hypnoanesthesia brought about by auditory analgesia arises from diverting the patient's focus from their pain response to a pleasant, abstract being.[25]

The origin of White noise can be traced back to the early 20th century, with its first formal definition by engineer Harold Stephen Black in the 1920s. Black's work laid the foundation for understanding white noise as a signal with equal intensity across all frequencies, essential in various fields such as telecommunications, acoustics, and neuroscience. Over the decades, white noise found applications ranging from its use in masking unwanted sounds to its incorporation into music and relaxation techniques.

The reduction of pain by auditory stimuli appears to include multiple psychophysiological processes. Originally, Gardner and Lickliderl identified seven elements that contribute to the analgesic action of sound.[24]

1. The sound seems to immediately reduce the pain associated with dental procedures.
2. The loudness eliminates a cause of "conditioned anxiety" by drowning out the sound of the dental drill.
3. There is a calming quality to the music.
4. When there is both noise and music playing, the music must be followed through concentration, which takes the patient's focus away from the dental procedure.
5. The patient feels more in control of a situation that before seemed to be beyond his control when he actively participates.
6. By analyzing the intensity of each signal and noting whether the patient is using music or noise, the dentist can assess the patient's level of anxiety or discomfort.
7. Suggestion

Audio analgesia is linked to the activation of the auditory pathway in the brain which interacts with regions involved in pain processing, such as limbic system leading to pain relief. The cochlear division of the vestibulocochlear nerve (also known as the auditory nerve; VIII cranial nerve) is where fibers of the auditory pathway pass through. The thalamic region, midbrain, and medulla oblongata contain a significant portion of the auditory system. The temporal lobe of the cerebral cortex, where the auditory pathway's fibers ultimately end, is the higher center for hearing. Each cochlea is represented on both sides of the cortex by fibers that are both crossed and uncrossed. The receptors for hearing sensation are found in the hair cells of the Corti organ. nerve cells. Auditory nerve is made up of afferent nerve fibers from hair cells.[26]

The bipolar cells of the spiral ganglion, located in the modiolus of the cochlea, are the first order neurons in the auditory pathway. The second order neurons of the auditory pathway are found in the medulla oblongata and are found in the dorsal and ventral cochlear nuclei. The nuclei of the lateral lemniscus and superior olivary are home to third order neurons. The subcortical auditory center is formed by the medial geniculate body, where fibers of third-order neurons terminate. Via the internal capsule, fibers from the medial geniculate body travel to the temporal cortex as auditory radiation. A portion of the medial geniculate body's fibers travel to the midbrain's inferior colliculus of the tectum.

The ventral and dorsal cochlear nuclei, which are found in the upper region of the medulla, receive nerve fibers from the spiral ganglion of Corti. Here, all of the fibers synapse, and second-order neurons primarily travel to the brain stem's opposite side until ending in the superior olivary nucleus. On the same side, a small number of second-order fibers also connect to the superior olivary nucleus. The auditory route ascends via the lateral lemniscus from the superior olivary nucleus. While many fibers avoid the lateral lemniscus nucleus and continue on to the inferior colliculus, where all or almost all of the auditory fibers synapse, other fibers end there. The route then travels to the medial geniculate nucleus, the site of all fiber synapses. Ultimately, the channel travels through the auditory radiation to reach the auditory cortex, which is mostly found in the temporal lobe's superior gyrus.[27] [Figure No. 2]

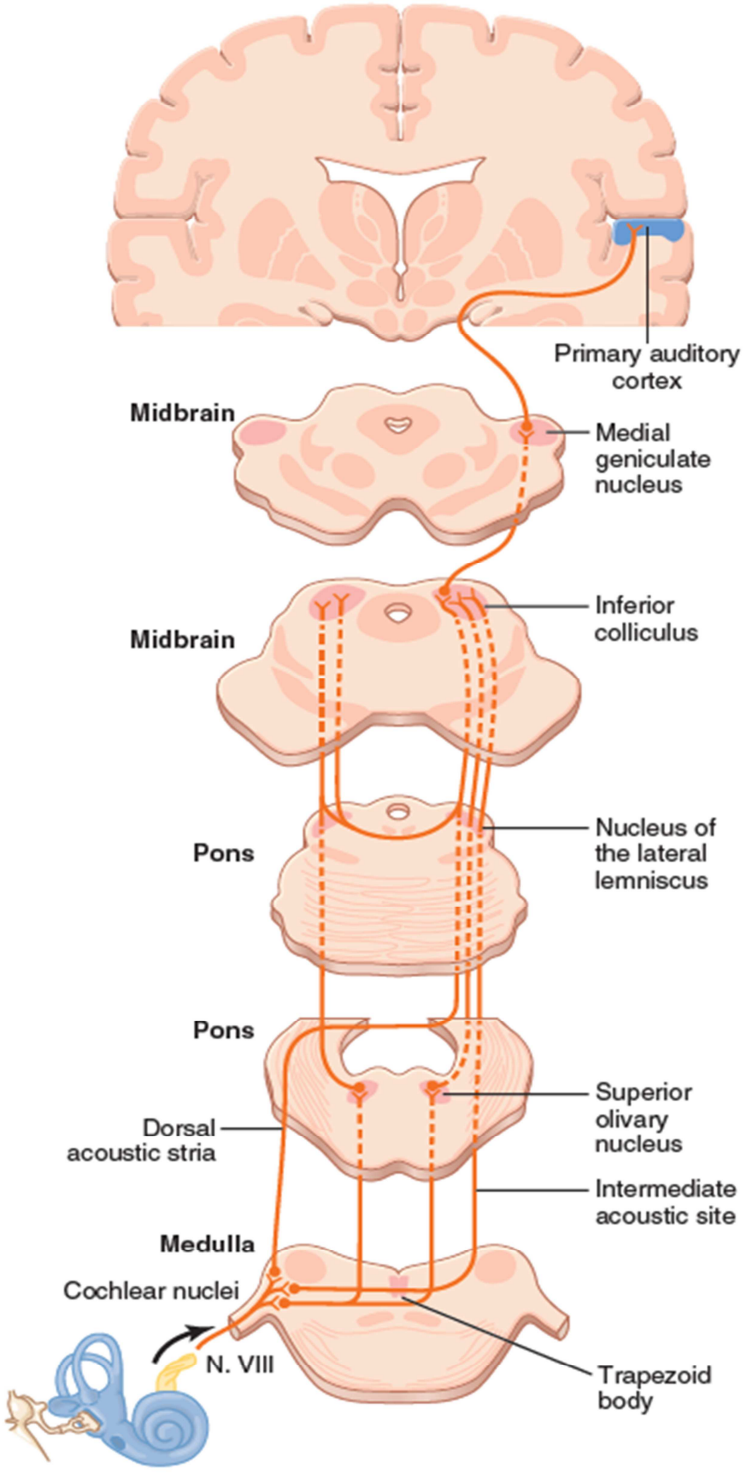

Figure No. 2: Photograph showing illustration of Auditory nervous pathways[26]

Sound waves cause vibrations in the tympanic membrane after passing through the external auditory meatus. Tympanic membrane vibrations pass through the malleus and incus before arriving at the stapes, where they cause the stapes to move. The fluids of the cochlea vibrate in response to movements of the stapes. The Corti organ's hair cells are stimulated by these vibrations. The auditory nerve fibers then produce action potentials, or auditory impulses, as a result of this. Hearing is perceived when audio impulses enter the cerebral cortex. [Figure No. 3]

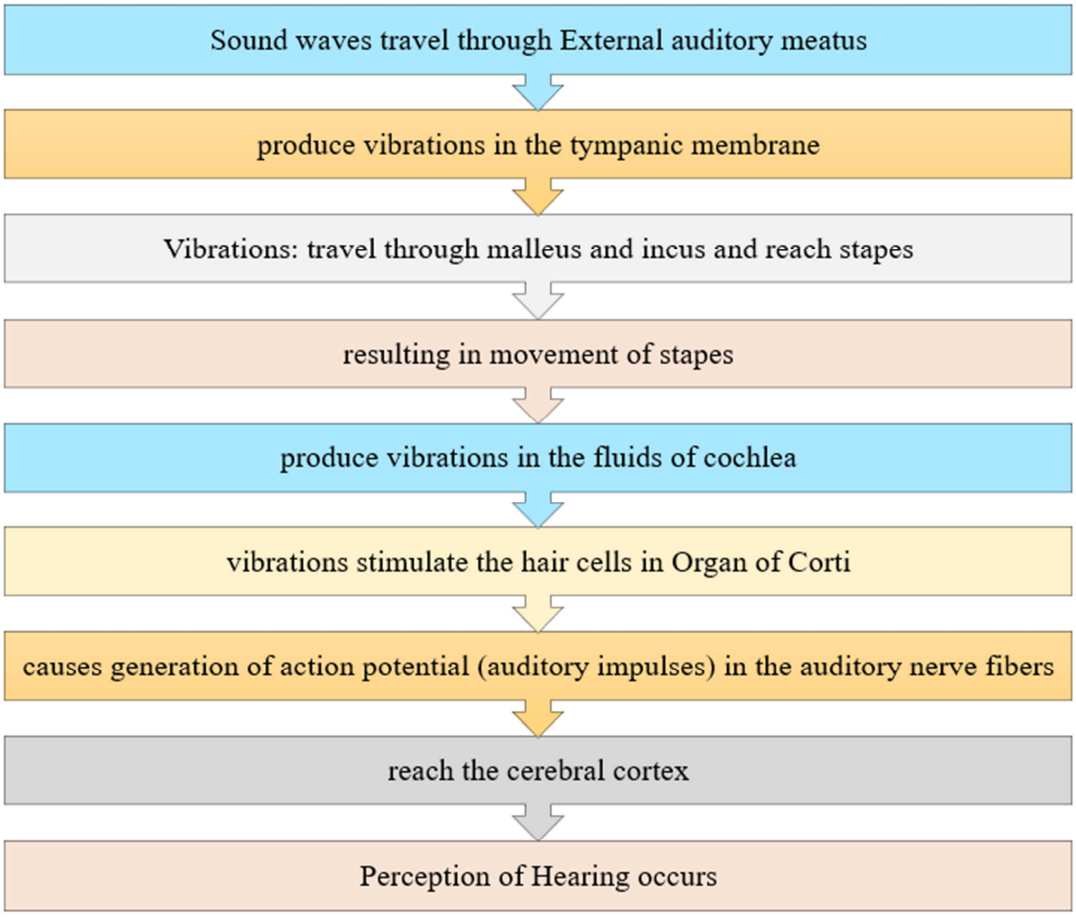

Figure No. 3: Photograph showing Mechanism of Sound Transduction[26]

As a result, the ear uses the energy of sound waves to cause action potentials in the fibers that make up the auditory nerve during listening. This process is referred as sound transduction.

Numerous theories have been proposed to describe the process by which sound pitch is perceived or frequency is examined.[26] Generally speaking, these hypotheses fall into two categories. As to the first group, the cerebral cortex is responsible for analyzing sound frequency, while the cochlea just relays sound waves. The second set of hypotheses states that the cochlea does the frequency analysis and then transmits the data to the cerebral cortex.

The Telephone Theory (Rutherford, 1880) and the Volley Theory (Wever, 1949) are included in the first category of theories pertaining to auditory perception. Rutherford's Telephone Theory, commonly referred to as the frequency theory, compares the cochlea to a telephone transmitter in which sound waves are transformed into electrical impulses for transmission, just as a telephone does the same. This theory, however, is unable to account for the propagation of sound waves at frequencies higher than one thousand cycles per second. Wever responded by putting up the Volley Theory, which postulates that distinct nerve fiber groups convey the impulses of high-frequency sound waves.

The second set of theories explores Helmholtz's 1863 Resonance Theory, which later gave rise to the Place Theory and the Traveling Wave Theory. The cochlea analyzes sound frequency in a manner identical to the resonance of piano strings, whereby distinct basilar fibers respond to specific sound frequencies, according to Helmholtz's Resonance Theory. But this idea was modified into the more well recognized Place idea due to the inability to pinpoint specific resonators within the cochlea. Place Theory states that different sound frequencies cause different nerve fibers from different areas of the organ of Corti on the basilar membrane to react, giving the brain the appropriate information. Additionally, the Place Theory gave rise to the Traveling Wave Theory, which clarified how traveling waves are created inside the basilar membrane and improved our comprehension of auditory experience.[26]

Four phases of intellectual development are outlined in Piaget's Theory of Intellectual Development.[91] These phases align with children's musical growth. In addition to providing appropriate musical exercises that the clinician might use or recommend at each developmental level, Box 1 describes Piaget's phases of intellectual development. [Figure No. 4]

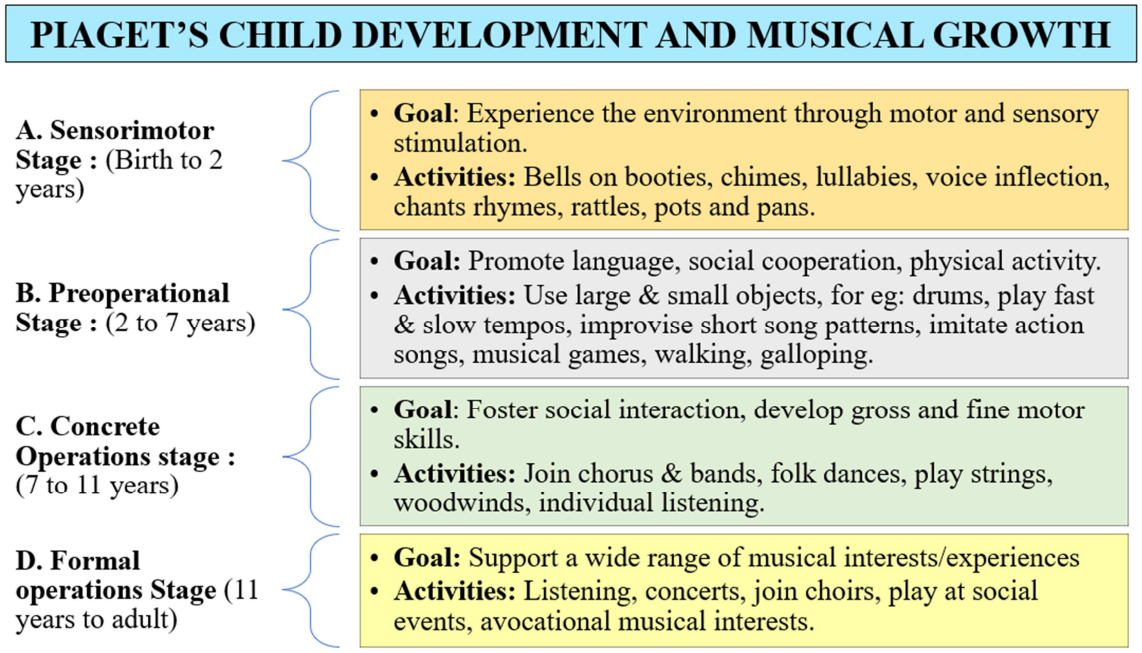

Figure No. 4: Photograph showing Piaget's phases of intellectual development and Musical growth

IV. LITERATURE IN RELATION TO THE RELATIONSHIP BETWEEN PAIN AND AUDIO ANALGESIA

Mechanism of suppression of pain pathway is explained according to Robert and Sowray's Cross-sensory mechanism which says physiologically, pain and auditory pathways are closely associated in reticular formation and lower thalamus and these two interactions are highly inhibitory. Suppression of pain sensation is due to stimulation of another sensory pathway which is inhibitory. This is due to the masking of pain impulses by the auditory stimulation leading to reduced dental anxiety. Both the direct suppression effect and the effects mediated through relaxation, reduction of anxiety and diversion of attention, can be explained by assuming that acoustic stimulation decreases the "gain" of pain relays upon which the branches of the auditory system impinge.[28]

Howitt experimented on 138 children to find out how different aspects of the audio analgesic experience affected their "clinical tolerance threshold" and "clinical response thresholds."[29] Clinical tolerance threshold was described as "that point where the patient refused to tolerate any more discomfort," and clinical response threshold as "the point where, by facial grimace, verbal exclamation, movement of the head or other sign, the patient indicated that he felt pain." The following is a summary of the findings:

1. The clinical effects of audio-analgesia treatments are real.

2. Rather than affecting response threshold, the impact of different interventions is more on pain tolerance.

3. Suggestion is mostly responsible for this effect.

4. Regardless of the presence or absence of music, sound, or suggestion, higher painful stimulation is accompanied by increased physiological responsiveness [measured as heart rate and galvanic skin reaction].

5. Psychological variables, not physiological ones, mediate the clinical effect of audio analgesia.

6. If and only if an audio-analgesic technique is combined with suitable suggestion, its effects can be shared by several aural stimulations rather of being limited to a certain instrument.[29]

The traditional notions of distinct "pain receptors," "pain pathways," and a "pain center" have been renounced by pain theory. Pain is most likely not a specific property that can be called "pain," but rather a psychophysiological interpretation of nerve impulses coming from common sensory detectors. This could partially explain the challenge of identifying a decrease in the "physiological" pain response brought on by audio analgesia. The victim's subjective response is the only accurate indicator of pain.

Individuals process sensory information differently. They have been divided into three perceptual "types" by Petrie et al.[30]

1. “Augmenters” subjectively tend to make sensory stimuli appear larger than it actually is.

2. “Reducers” frequently cause the perceived magnitude of sensory stimuli to be subjectively reduced.

3. “Moderates” barely change the perception of size.

Petrie conducted research on the effects of auditory analgesia on the increase and decrease of kinesthetic sensation. While moderates and reducers exhibited no

significant change, augmenters demonstrated a significant (at the 0.001 level) reduction in their mean ratings with audio analgesia. However, the effect on the augmenters was so strong that, at the 0.05 level, the entire group of 21 participants demonstrated an increase in reduction.[30]

A randomized controlled clinical trial aimed to examine the effectiveness of music listening on pain, anxiety, and vital signs among patient safter thoracic surgery. Hundred and twelve patients were recruited and randomly assigned to either experimental (n = 56) or control (n = 56) group respectively. For three days, the experimental group received routine care along with a 30-minute intervention using soft music, while the control group was given simply standard care. Parameters included blood pressure, heart rate, respiration rate, pain, anxiety, patient-controlled analgesia, and usage of suppositories containing diclofenac sodium. Comparing the experimental group to the control group over time, the former showed a statistically significant reduction in pain, anxiety, heart rate, and systolic blood pressure; however, no significant differences were found in respiratory rate, diastolic blood pressure, patient-controlled analgesia, or the use of diclofenac sodium suppository. Thus, the findings provide further evidence to support the practice of music therapy to reduce postoperative pain and anxiety, and lower systolic blood pressure and heart rate in patients after thoracic surgery.[31]

V. LITERATURE ON RELATIONSHIP BETWEEN ANXIETY AND AUDIO ANALGESIA

Perceived pain typically decreases in conjunction with decreased anxiety. Gardner and Licklider first used white sound in an effort to utilize auditory masking to block out one source of "conditioned anxiety," which is the sound of the dentist's drill." Since music was recognized to have a calming effect and white noise was uncomfortable to listen to for extended periods of time, music was eventually included. Gardner adds that there is a calming effect to the white noise, which mimics the sound of a waterfall.[24]

Gardner thought that another strategy for lowering anxiety was distraction. Carlin came to the conclusion that the analgesic effect of loud sound was caused by suggestion and distraction.[32] The placebo effect results from the idea that audio analgesia, or any other form of pain relief, can completely remove pain. This idea also lowers anxiety. Howitt's research established the audio-analgesic impact as a viable treatment option for suggestion. By allowing the patient to actively participate and adjust the sound level, you can help them feel less anxious since it gives them a sense of control over the stimulation that causes their pain.[29] According to an experiment by Harris E. Hill, that Melzack mentions, providing the patient a sense of control helps them feel less in pain. Therefore, it is obvious that suggestion and distraction are key components of audio analgesia.[33]

A cross-sectional study aimed to ascertain how music affected children' anxiety during dental procedures. The sample consisted of 50 children aged between 5 and 14 years. A survey questionnaire that was distributed to patients both before and after the treatment procedure was used to gather data. The Modified Child Dental

Anxiety Scale facial version (MCDASf) was used in the questionnaire to measure respondents' anxiety levels in relation to dental care. The results revealed that 62% of participants were relaxed when asked about their feelings toward dentists in general after music therapy, compared to 44% before music therapy. When asked how they felt about inspecting their teeth after receiving music therapy, 72% of them felt at ease, compared to 48% before to the intervention. 50% of patients felt at ease prior to receiving music therapy, whereas 78% did so after. Eighty percent of patients said that listening to music during therapy helped them feel at ease and relaxed. The scientists came to the conclusion that pediatric patients' stress and anxiety levels during dental treatment could be reduced by music distraction.[34]

A clinical study aimed to evaluate the impact of music on anxiety during dental treatment among 40 children aged between 5 to 11 years. They were randomly allotted into 2 groups of 20 participants in each group. In group 1 children were subjected to music therapy and in group 2 children were not subjected to music therapy. Heart rate, oxygen saturation, and Corah pain and anxiety scale scores were measured. There was a significant decrease in heart rate in children who listened to music during dental treatment ($p = 0.05$). Heart rate did not alter in the music-free group over the course of the treatment ($p = 0.53$). There was no significant difference in oxygen saturation or Corah anxiety and pain scores in children who listened to music during dental treatment ($p > 0.05$). Thus, the authors concluded that music could serve as a non-pharmacological alternative to reduce anxiety levels in children undergoing dental treatment.[35]

In a pilot study assessing the impact of music on physiological and psychological parameters during periodontal surgery, sixty patients were randomly assigned to either a control group (without music) or a test group (with music). Blood

pressure (BP) and heart rate (HR) were recorded before and after the procedure for both groups. Anxiety levels (AL) were assessed using a facial image scale (FIS) before and after surgery. In the test group, BP, HR, and AL were additionally evaluated after listening to music before and during the procedure. Results showed that systolic blood pressure (SBP) increased in both groups, with no statistically significant difference between them ($p>0.05$). Diastolic blood pressure (DBP) increased after treatment, but the difference between the test and control groups was not statistically significant ($p>0.05$). Heart rate decreased after the procedure in both groups, with no significant difference between them ($p>0.05$). Anxiety levels decreased after the procedure in both groups, but the difference was not statistically significant ($p>0.05$). The authors concluded that music intervention led to a decrease in heart rate and anxiety levels. However, there were no significant differences in blood pressure, heart rate, and anxiety levels between the groups with and without music.[36]

In this randomized controlled trial, the objective was to evaluate the impact of music therapy on dental anxiety levels in patients undergoing extractions. A total of 50 patients were randomly assigned to either the Test group (N = 25), where music was played during extractions, or the Control group (N = 25), which had no music exposure. Dental anxiety levels and hemodynamic changes, including systolic pressure, diastolic pressure, and heart rate, were measured before and after the extraction procedure. The results revealed that the Control group experienced increased hemodynamic changes, particularly in systolic and diastolic blood pressure, as well as heart rate, with a significant rise in diastolic pressure. Conversely, the Test group showed a decrease in hemodynamic changes, including systolic and diastolic blood pressure and heart rate, all of which were statistically significant. This trend

was consistent with the modified dental anxiety scale. In conclusion, the authors proposed that music, acting as a psychological and spiritual means, can alleviate anxiety and, consequently, suggested its use as an anxiolytic agent for stress relief during dental procedures.[37]

This in vivo study examined the efficacy of audio-distraction aids in alleviating anxiety during pediatric dental procedures. A total of 150 children (aged 6 to 12 years) undergoing their first dental check-up were randomly assigned to five groups: control, instrumental music, musical nursery rhymes, movie songs, and audio stories. The control group received standard treatment, while the audio groups listened to diverse presentations. Over four visits, anxiety levels were assessed using Venham's Picture Test (VPT), Venham's Clinical Rating Scale (VCRS), and pulse rate measurements. A significant increase in mean pulse rate across visits was observed in all groups, but no significant differences were found in VPT and VCRS scores. Overall, audio aids, particularly audio stories, significantly reduced anxiety compared to the control group. The study concludes that audio distraction is effective in reducing anxiety, with audio stories proving to be the most effective method.[38]

An experimental study aimed to investigate the impact of a music intervention on reducing pre-radiotherapy anxiety in oncology patients. Participants were divided into a music group ($n = 100$), which received 15 minutes of music therapy before radiation, and a control group ($n = 100$), which underwent 15 minutes of rest before radiation. Both groups were assessed for pre- and post-test anxiety using the State-Trait Anxiety Inventory and physiological indicators of anxiety were measured before and after the tests. The results indicated that baseline State/Trait scores and vital signs were comparable between the two groups ($p > 0.05$). Both groups exhibited

significant decreases in mean pre- and post-test State/Trait anxiety scores from baseline to post-test (all $p < 0.05$). However, a statistically significant difference was observed between the music therapy and control groups in the mean change of State anxiety scores ($p < 0.001$) and Trait anxiety scores ($p = 0.036$). In terms of vital signs, both groups showed significant decreases in pre- and post-test heart rate and respiration rate ($p < 0.05$), with a statistically significant difference in the mean change of systolic pressure between the music and control groups ($p = 0.009$). Consequently, the authors concluded that music therapy led to decreased levels of state anxiety, Trait anxiety, and systolic blood pressure in oncology patients who received the intervention before radiotherapy. This study suggests that pre-radiotherapy music therapy reduces anxiety in oncology patients, improving their overall treatment experience and potentially lowering physiological stress. This non-pharmacological intervention offers a cost-effective approach to enhancing patient well-being, indicating a need for further research into its long-term effects and optimal implementation strategies.[39]

A randomised controlled trial aimed to evaluate the impact of passive music intervention in patients with moderate to high dental anxiety undergoing ultrasonic scaling procedure. Eighty healthy subjects with an anxiety score of 13-25 by Modified Dental Anxiety Scale (MDAS) were recruited into study and control groups. Study group of 40 subjects underwent ultrasonic scaling procedure with pre-recorded instrumental music intervention. 40 subjects in control group received the same dental treatment without music intervention. Physiologic parameters such as pulse rate (PR), systolic blood pressure (SBP), and diastolic blood pressure (DBP) were recorded twice (before and at the end of procedure) for both groups. The mean values of PR (pre and post) as well as SBP and DBP (pre and post) were statistically significant for

study group as compared to control group. Mean values of PR (pre and post) and SBP and DBP (pre and post) showed statistically significant reduction in study group compared to control group. The study group's post-therapy VAS score was considerably lower than the control group. The authors concluded that music intervention during ultrasonic procedure helps reduce dental anxiety in subjects with moderate to high dental anxiety levels.[40]

This in vivo study aimed to evaluate and compare the efficacy of two distraction techniques, audio distraction and audio-visual distraction, in mitigating anxiety among 75 pediatric patients aged 4-8 years. The participants were stratified into three groups (n=25 each): a control group (Group A) receiving treatment without distraction aids, a second group exposed to audio distraction (nursery rhymes in English or regional language), and a third group to audio-visual distraction (cartoons in English or regional languages). The Venham Picture Test (VPT), Venham Rating of Clinical Anxiety (VRCA), Pulse Rate, Oxygen Saturation, and Child Fear Survey Schedule (CFSS) were used to measure the participants' anxiety levels over the course of four sessions. Results indicated the significant superiority of Venham's Picture Test (VPT) in both inter and intra-group analyses, underscoring that audio-visual distraction surpassed audio distraction alone in effectively managing pediatric anxiety.[41]

VI. LITERATURE ON EFFECT OF AUDIO DISTRACTION ON AUTONOMIC NERVOUS SYSTEM

Variations in the frequency of music can cause changes in the heart rate and blood pressure.[42] It is possible to regulate heart rate using music since it has been shown to synchronize natural cardiac rhythms. A person's emotional state or mood can also be influenced by music, and this can cause alterations to the sympathetic and parasympathetic nerve systems of the autonomic nervous system (ANS). Music listening is a stress-reduction catalyst. According to White et al., listening to calming music might cause a relaxation response, which in turn lowers heart rate (HR) by arousing the PNS.[43]

Oxytocin is a neurohormone that has calming and bonding properties, making it a potential explanation for the music effect.[44] Research has demonstrated that engaging in any type of musical stimulation does cause oxytocin levels to rise. So, a study was conducted to test the authors' theory that listening to music will raise the release of oxytocin, promote the activities of the parasympathetic nervous system, and lower sympathetic arousal.

Thus, the study aimed to evaluate whether listening to low frequency music has cardiovascular benefits among 16 participants aged 20 to 50 years with high blood pressure. The protocol consisted of 2 visits (experimental & control). Every ten minutes, the frequency of the music, which was tuned between 440 and 432 Hz, was altered. Heart rate (HR) variability, diastolic function, oxytocin and amylase were recorded at each phase. Mental arithmetic significantly increased BP and HR (all p's <0.01). There were significant differences between the stress condition and all other conditions (all p's < 0.02). There was a significant main effect for Music Order, ($p = 0.047$). Participants had lower HR listening to 432 Hz music than 440 Hz music ($p =$

0.04). The authors concluded that listening to low frequency music has cardiovascular benefits including slowing heart rate and promoting relaxation.[4]

Steelman stated that music can lower blood pressure by stimulating peripheral vasodilation, lowering heart rate, and producing a profound sensation of well-being.[46] Peripheral neuro-vascular processes would seem to be significant in evaluating a potential explanation for the relaxation caused by music, aside from the dominant central nervous system output via the autonomic nervous system. Stefano recently reviewed the connections between listening to music, emotional states, and belief systems, as well as the shared neural pathways within the central nervous system.[47] It concluded that the brain's motivation and reward circuits, as well as the existence of morphine immunoreactive neurons and fibers in limbic structures, indicate that music has a substantial opiate signalling component. This emotional component contributes significantly to the soothing effects of music.[48] [Figure No. 5]

The cerebral cortex may be the starting point for the ability of music to calm and lower blood pressure, and this ability may involve both insular and cingulated, amygdalar, and hypothalamic processes [Figure No. 5]. Numerous subcortical descending connections from the forebrain and hypothalamus are likely involved in the hardwiring of emotion/music and cardiovascular neural circuits. Due to its strong connections to the limbic system, the insular cortex plays a significant role in cardiac regulation. This suggests that the insula is engaged in the regulation of heart pace and rhythm during emotional stress. Cochlear nerve fibers enter the brainstem and travel to the auditory cortex via the thalamus. Research has shown that this is the route by which the limbic system's emotion centers are triggered. The feeling of music enters the diagrammatic neural pathway at the limbic system. These links show that the modulation of vascular tone is associated with these locations. This pathway explains

how music's emotional impact and listening response may have top-down control over vasomotor activity.

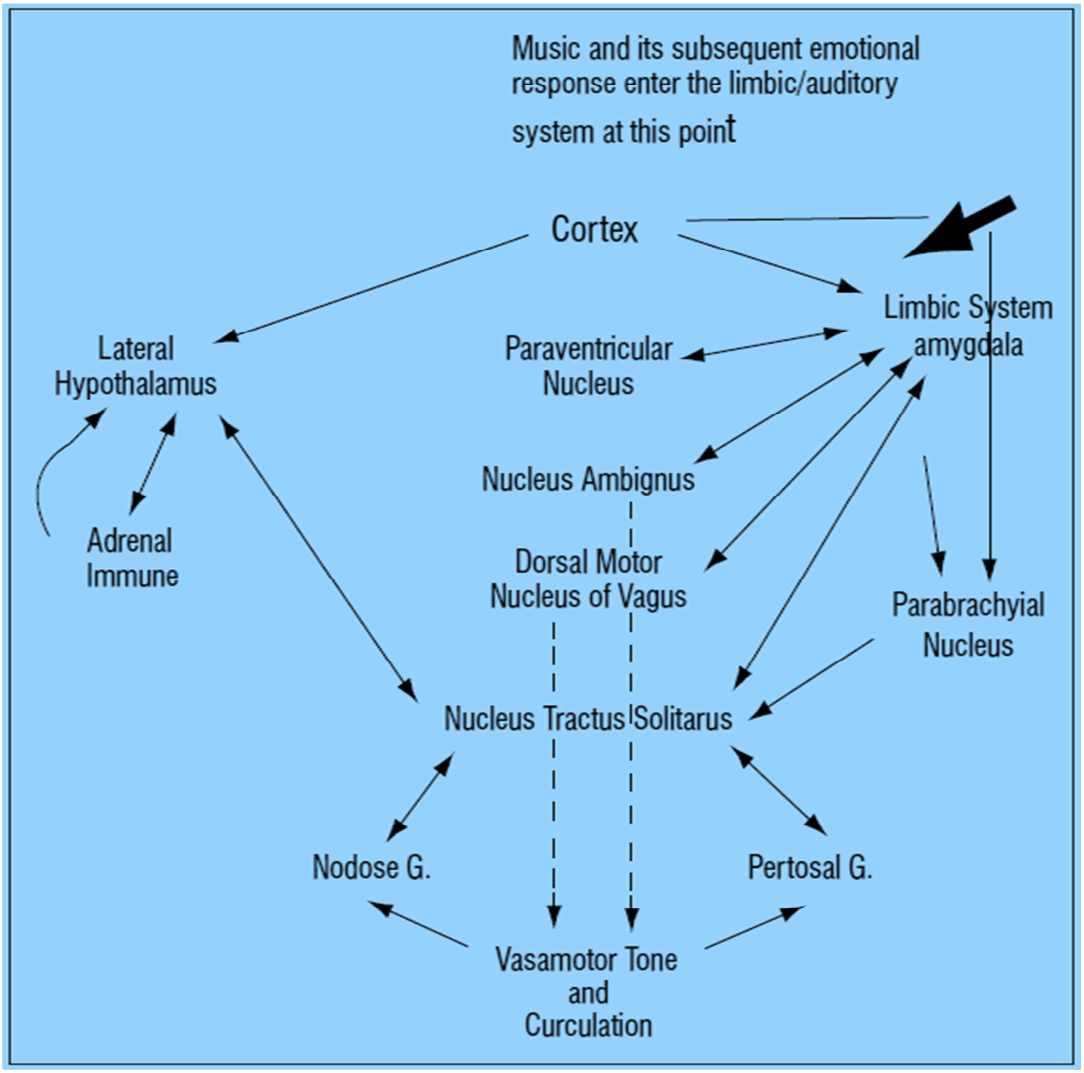

Figure No. 5: Photograph showing representative connections among the limbic–hypothalamic pituitary adrenal axis.

A randomized, experimental, and prospective study was conducted to investigate the impact of music therapy on dental anxiety in patients and explore the correlation between salivary cortisol and other physiological parameters. 34 participants were randomly assigned to either the control or experimental group. Various measures, including salivary cortisol, stimulated salivary flow, blood pressure, heart rate, oxygen saturation, and body temperature, were taken for each patient. Initially, both groups exhibited similar anxiety levels. However, during the second measurement, significant differences were observed in salivary cortisol concentration, systolic and diastolic pressure, heart rate, body temperature, and stimulated salivary flow in the group treated with music therapy. The conclusion drawn by the authors was that music therapy had a positive effect on the control of dental anxiety.[49]

This prospective study investigated the effects of music listening on the autonomic nerve system and psychological state during impacted mandibular third molar extraction. Forty patients scheduled for extraction were randomized into control (no music) and music groups. Recorded were heart rate variability, ratings on the State-Trait Anxiety Inventory (STAI), and the Modified Dental Anxiety Scale. The control group exhibited an increased low-to-high frequency ratio during specific procedure stages, while the music group showed a significant decrease at these points ($p < 0.05$). Compared to the control group, the music group experienced a significantly greater reduction in postoperative STAI scores ($p < 0.05$). The study suggests that listening to music during impacted mandibular third molar extraction suppresses sympathetic nerve activity during specific procedure stages and alleviates post-treatment anxiety.[50]

VII. LITERATURE ON MUSIC AND SEDATION

The interplay between music and sedation has garnered significant attention in medical research and clinical practice due to its potential to enhance patient comfort and improve procedural outcomes. An intriguing aspect of music's influence on sedation is its potential to reduce the need for anesthetic and analgesic drugs administered during surgical procedures performed under general anesthesia or sedation.[95] By incorporating music into the intraoperative environment, healthcare providers can create a conducive atmosphere that promotes patient comfort and minimizes the requirement for pharmacological agents. This phenomenon not only contributes to improved patient outcomes but also highlights the role of music as a cost-effective and non-invasive adjunctive therapy in anesthesia management. The proposed explanation for the calming effect of music during sedation procedures is grounded in the Gate Control Theory of pain modulation. According to this theory, pain perception is modulated by an integrated sensory-affective-motivational system that regulates noxious input and attenuates nociceptive stimuli. Music's ability to engage the auditory pathway may inhibit the central transmission of nociceptive stimuli, thereby reducing pain perception and promoting relaxation during sedation. It's possible that during sedation, the stimulation of the auditory system prevents nociceptive sensations from being transmitted centrally and increase the depth of sedation levels.[51]

This prospective, randomized, and controlled study aimed to assess the impact of music and sound isolation on sedation depth and sedative requirements in pediatric dental patients. 180 participants were divided into three groups: music, isolation, and control. Music group patients listened to Vivaldi's The Four Seasons via sound-

isolating headphones, isolation group wore the headphones without music, and all received sedation with midazolam and propofol. Bispectral index measured sedation depth, and propofol dosage indicated sedative needs. Heart rates, oxygen saturations, and sedation scales were similar across groups. Propofol usage was comparable. The control group showed significantly more prolonged postoperative recovery ($p = 0.004$). The study concluded that music or sound isolation during pediatric dental procedures didn't significantly affect sedation levels, medication amounts, or hemodynamics, possibly due to reaching deep sedation. However, both interventions may contribute to shortened postoperative recovery durations.[52]

VIII. LITERATURE ON MONAURAL BEATS

Monaural beat stimulation occurs by giving the same amplitude-modulated signal to both ears concurrently. When the brain combines these frequencies, it produces an auditory sensation that pulses rhythmically and are adjusted at the cochlear level. Monaural beats can be experienced when both frequencies are presented simultaneously through a single channel, such as a single speaker or earphone, as opposed to binaural beats, which need different frequencies to be presented to each ear.

A study aimed to examine the impact of monaural beat stimulation on anxiety, mood and memory performance among 25 individuals as well as two different kinds of memory tasks (long-term and working memory) and a vigilance task. Monaural beats were generated at frequencies of Theta (6 Hz), alpha (10 Hz) and gamma (40 Hz) beat frequencies around centre frequencies between 110 Hz and 220 Hz, as well as a control stimulus were applied to healthy participants for 5 min. Following each stimulation session, participants completed a vigilance task, cognitive tests that looked at working and long-term memory, and an assessment of their present mood. It was found that gamma (40 Hz), theta (6 Hz), and alpha (10 Hz) monaural beat stimulation was useful in lowering state-anxiety levels. However, no discernible effects were observed in terms of working memory (accurately maintained digits and reaction timings in a modified Sternberg task), long-term memory (number of correctly recalled words), or vigilance (accurate button presses and response latencies). It was found that in healthy human subjects, a brief application of monaural beat stimulation can lessen anxiety.[53]

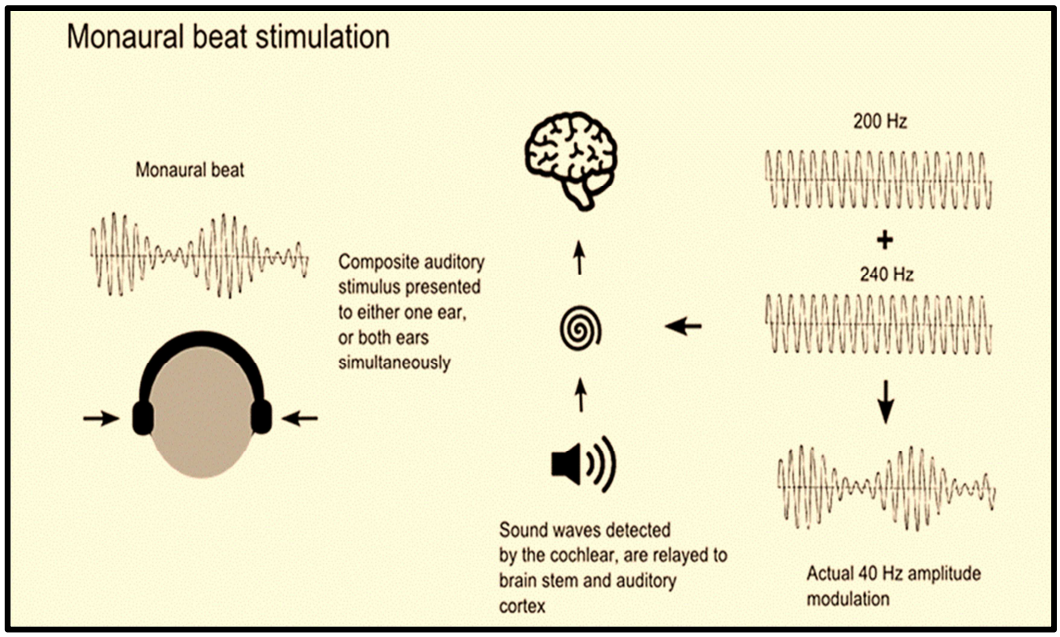

Figure No. 6: Photograph showing Application of monaural beats[53]

Superposition of amplitude modulated signals of adjacent frequencies applied to one or both ears can produce monaural beats. Here is an example of carrier tones of 200 Hz and 240 Hz producing a 40 Hz rhythm. [Figure No. 6]

IX. LITERATURE ON 432 HZ FREQUENCY MUSIC

The International Organization for Standardization (ISO) has set the pitch standard for the musical note A at 440 Hz.[54] However, observations have indicated that the tones produced at this frequency can be perceived as uncomfortable, irritating, and unpleasant. In contrast, tuning to 432 Hz is reported to yield tones and intervals that are more peaceful, pleasant, and harmonious. This suggests that tuning the A note to 432 Hz may be preferable, as it could reduce strain on singers' voices and enhance musical quality.[55] The spectral centroid theory, which suggests that the musical note A=432 Hz has distinct or superior sound qualities and describes how the perception of a sound can be significantly altered when the frequency spectrum changes, may provide an explanation for the effect of music tuned at 432 Hz for anxiety control.[56]

Salivary cortisol levels play a significant role in the evaluation of anxiety due to the intricate relationship between stress, cortisol secretion, and the body's physiological responses. Cortisol, often referred to as the "stress hormone," is a steroid hormone released by the adrenal glands in response to stressors, including psychological stress and anxiety. As such, measuring salivary cortisol levels provides valuable insights into an individual's stress response and can serve as a non-invasive biomarker for assessing anxiety levels.[57]

The mechanism of action underlying the relationship between salivary cortisol levels and anxiety can be explained with the following flowchart: [Figure No. 7]

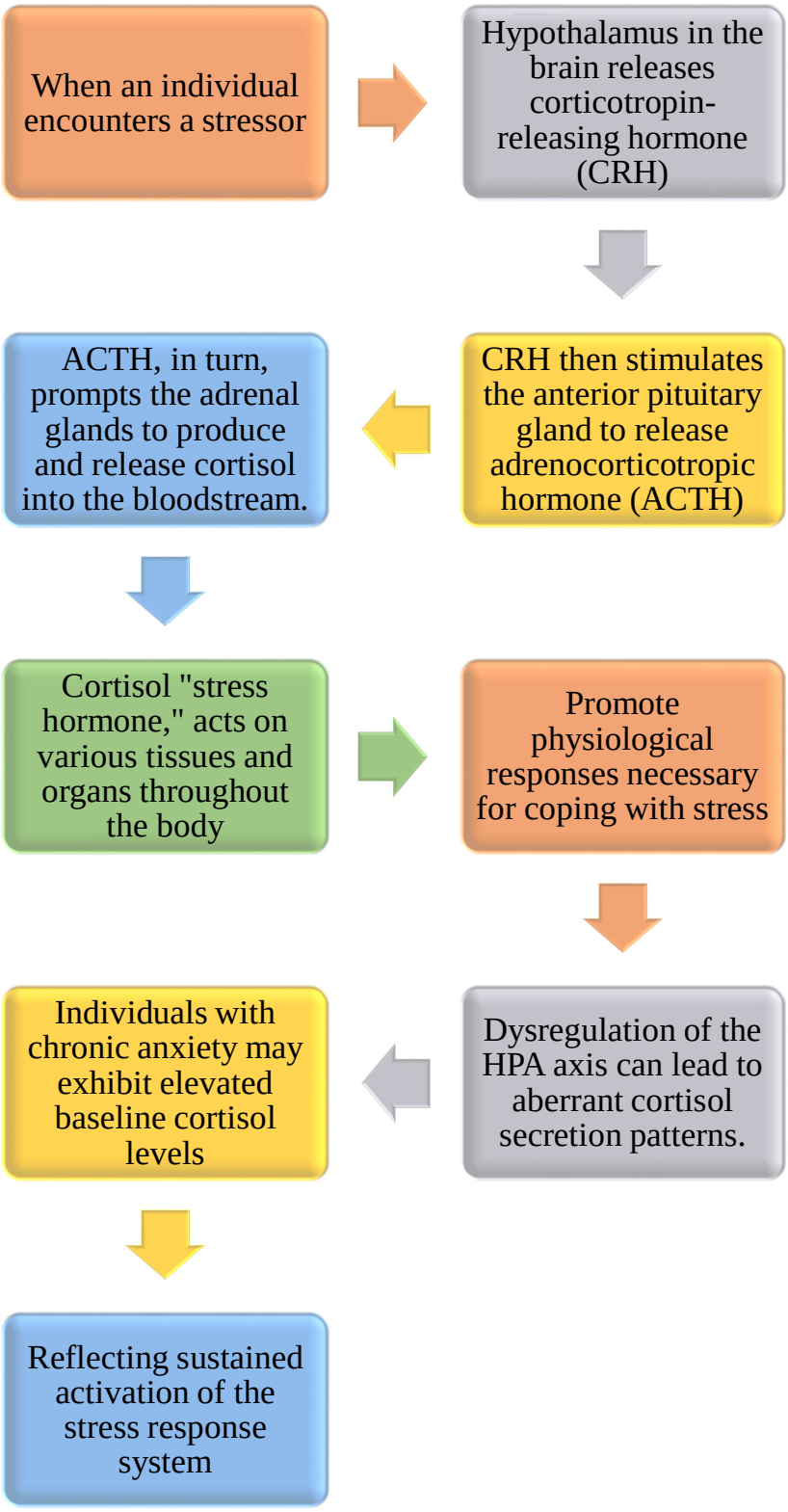

Figure No. 7: Photograph showing mechanism of action underlying the relationship between salivary cortisol levels and anxiety[57]

A parallel-group randomized clinical trial aimed to compare the effects of music at 432 Hz, 440 Hz, and no music on anxiety and salivary cortisol levels in patients undergoing tooth extraction. 42 patients were divided into three groups: 15 minutes of music at a frequency of 432 Hz (n = 15), 440 Hz (n = 15), and no music (n = 12). Before and after the music intervention, the CORAH Dental Anxiety Scale and salivary cortisol levels were assessed and compared between groups using the solid phase enzyme-linked immunosorbent assay (ELISA). The results revealed that significantly lower anxiety level values were observed at 432 Hz and 440 Hz compared to the control group ($p<0.05$). The salivary cortisol level at 432 Hz was significantly lower than 440 Hz and the control group ($p<0.05$). The researchers came to the conclusion that 432 Hz was an excellent frequency for lowering salivary cortisol levels before to tooth extraction, and that listening to music greatly reduced clinical anxiety levels.[58]

The purpose of a cross-over pilot study was to find variations in critical parameters and perceptions following music listening at two different frequencies 440 Hz and 432 Hz. Thirty-three individuals listened to two sets of music on various days. The same soundtracks from movies were utilized in both sessions, however on one day they were set to 440 Hz and on the other to 432 Hz. The primary outcome measures included vital measurements such as blood pressure, heart rate, respiratory rate, and oxygen saturation; perceptions such as physical and emotional symptoms including weariness and tension; levels of concentration during the listening session and overall satisfaction with the experience. 432 Hz tuned music was associated with a slight decrease of mean (systolic and diastolic) blood pressure values (although not significant), a marked decrease in the mean of heart rate ($p = 0.05$) and a slight decrease of the mean respiratory rate values ($p = 0.06$), compared to 440 Hz. The

subjects were more focused about listening to music and more generally satisfied after the sessions in which they listened to 432 Hz tuned music. The authors concluded that 432 Hz tuned music can decrease heart rate more than 440 Hz tuned music.[55]

In a randomized controlled clinical trial, the impact of 432 Hz music as a nonpharmacologic adjuvant was examined regarding systolic blood pressure (SBP), diastolic blood pressure (DBP), and heart rate (HR) changes before, during, and after endodontic treatment in individuals with varying levels of anxiety, assessed using the Corah Dental Anxiety Scale. A total of 100 recruited patients were randomly assigned to two groups—one listening to music and the other not. Vital signs (DBP, SBP, and HR) were recorded before, during, and after the endodontic procedures, and results were statistically analyzed. The analysis revealed a significant decrease in all measured vital signs in the music-listening group during and after canal therapy, leading the authors to conclude that administering 432 Hz music during root canal treatment significantly reduces SBP, DBP, and HR.[59]

X. LITERATURE ON HINDUSTANI (INDIAN) MUSIC

In Indian music, the concept of raga, or melody, is extremely profound and significant. Music comes to life through the melodic patterns' vibrant ascents and descents and harmonic interactions.[100] There are ragas in Indian music that are suitable for specific times of the day. Ragas are sung or played on instruments at certain times of the day, including morning, noon, evening, and midnight. In reality, repeating, slow-motion music can serve as a kind of mantra, comforting listeners into a meditative state of calm.[60]

Indian instrumental music has the potential to be more calming than lyrics-accompanied music which could be due to the fact that the right cerebral hemisphere processes auditory stimuli in the form of musical notes and chord progressions, while the left cerebral hemisphere, which is more skilled in verbal acuity, might intercept some auditory stimulation of music with lyrics.[61]

A slower, more natural homeostatic rhythm is entrainable with the raised body beat, which is why slow-paced music may have a relaxing effect. A relaxed human body produces a single, coherent series of oscillations at 7.8 Hz, which is referred to as the "frequency of human homeostasis." The average heart beats between 60 and 80 beats per minute. This aligns with the frequency of the resting human brain's alpha waves. This kind of rhythmic music is thought to have the biggest impact on physiological balance by many therapists.

In a prospective randomized clinical trial, the comparative efficacy of local anesthetic cream (Eutectic mixture of local anesthetic agents - EMLA), Indian classical instrumental music, and a placebo was investigated for reducing pain during venipuncture in children aged 5-12 years. In the present study, raga *Desi-Todi*, a sort

of slow-paced music that consists of a series of repetitive notes or beats was used. The participants were randomly assigned to one of three groups, and pain assessments were conducted by the parent, patient, investigator, and an independent observer at the time of cannula insertion (0 min), and at 1- and 5-minute intervals using a Visual Analog Scale. Each group consisted of fifty subjects. The results indicated significantly higher VAS scores in the placebo group at all time points. The local anesthetic (LA) group consistently exhibited the lowest VAS scores at all intervals. However, the differences in VAS scores between the LA group and the music group were significantly lower only at certain time points. Consequently, the authors concluded that instrumental classical Hindustani music, specifically raaga-Todi, could be considered as an alternative for mitigating pain associated with venipuncture when the application of EMLA cream is impractical, undesirable, or unfeasible.[62]

This case report aimed to assess the influence of Indian instrumental music on dental anxiety in children with mild intellectual disabilities during dental procedures, using electrical skin resistance measured by a biofeedback machine. Twenty children (6–14 years) with mild intellectual disabilities were randomly assigned to two groups of 10 each in a cross-over design. Dental examinations, oral prophylaxis, and auditory operative stimuli were administered in two appointments, one with and one without music distraction, spaced 1 month apart. Electrical skin resistance, measured by a galvanic skin response (GSR) biofeedback machine, showed a statistically significant increase during music distraction, indicating reduced anxiety. The authors concluded that the elevated electrical skin resistance, indicative of lower anxiety, supports the positive impact of music distraction in intellectually disabled children.[63]

This study aimed to assess psychophysiological responsiveness to Indian instrumental music, specifically the effects of the Desi-Todi raga played on a flute. The investigation included three physiological measures (alpha EEG frequency, systolic and diastolic blood pressure, and heart rate) and three psychological assessments (depression, state and trait anxiety, and four anxiety components: somatic, cognitive, behavioral, and affective). Postgraduate male university students participated in the study, listening to instrumental music (without lyrics) for 30 minutes daily over a 20-day period. Pre- and post-treatment procedures were employed to record physiological and psychological assessments. Results revealed a significant increase in alpha EEG frequency and a significant decrease in scores related to depression, state and trait anxiety, and the four anxiety components. However, systolic and diastolic blood pressure and heart rate remained unaffected by the instrumental music.[64]

Dr. Edward Bach introduced Bach flower therapy or BFT.[65] According to him, the majority of illnesses in humans are the result of poor mental states and can be resolved by using flower remedies made from naturally occurring wild flowers to lessen the associated negative emotions.

A randomized controlled trial aimed to compare the efficacy of Bach flower therapy (BFT) and music therapy (MT) in reducing dental anxiety among pediatric patients. A total of 120 children (aged 4–6 years) were randomly assigned to three groups: BFT, MT, and a control group. Children from music therapy group were provided with Indian classical instrumental music (Raag Sohni played by Pandit Shiv Kumar Sharma on santoor). All participants received oral prophylaxis and fluoride treatment. Dental anxiety was assessed using the North Carolina Behavior Rating

Scale, Facial Image Scale (FIS), and physiological parameters. Results indicated significantly improved behavior in the BFT group compared to the control group (P = 0.014). Postoperative FIS scores did not differ significantly among the groups. Both BFT and MT groups showed a significant intraoperative decrease in pulse rates compared to the preoperative period. Intraoperative systolic blood pressure in the MT group was significantly lower than in both the BFT and control groups. Diastolic blood pressure increased significantly in the control group intraoperatively, while the other groups exhibited a decrease. The study concludes that both a single dose of BFT and exposure to MT significantly reduce dental anxiety in children aged 4 to 6 years.[66]

XI. LITERATURE ON BINAURAL AUDITORY BEATS

Heinrich Wilhelm Dove initially described binaural auditory beat in 1939. Oster provided a detailed description of it in 1973. It is an auditory illusion perceived when two distinct pure-tone sine waves are supplied to each ear at a constant frequency and strength.[67] The perception that result is of a single tone that requires the collective action of both ears. This tone has a frequency that is midway between the two carrier tones and amplitudes that wax and wane at a pace equal to the difference between them. For instance, the brain perceives a beat of 4 Hz when the left ear receives a tone at 344 Hz and the right ear receives a tone at 340 Hz. A binaural tone that corresponds to the alpha brainwave frequency (8–12 Hz) can be used to induce relaxation. The binaural beats have been shown to have strong brainwave entrainment effects and the ability to modify the functional connections at the auditory cortex.[68] Overall, in addition to core scientific idea of brainwave entrainment, binaural beats offer the additive benefits of traditional distraction audio analgesia. [Figure No. 8]

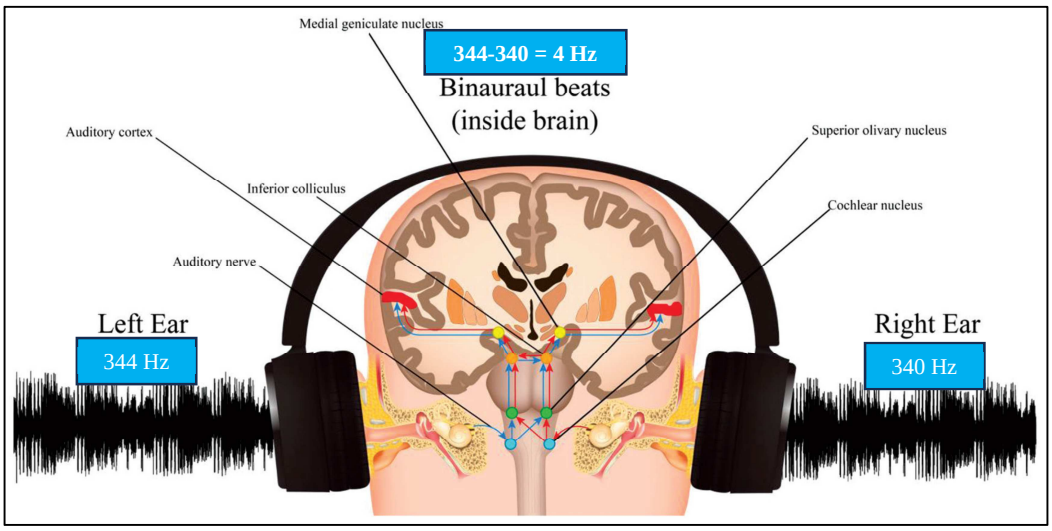

Figure No. 8: Photograph showing illustration of Binaural beats generated by the brain

The binaural beats have been shown to have strong brainwave entrainment effects and the ability to change the functional connections between the brain regions. In order to affect cognitive and behavioral functioning, brainwave entrainment uses a variety of brainwave frequencies, including delta, gamma, epsilon, theta, and beta. This synchronization within the brain facilitates balanced neural activity.

Typically, EEG signal spectral constituents can be separated into five frequency bands[69]: [Table No. 2]

Sl. No.	Brainwaves	Frequency bands	Range of benefits
1.	Delta waves	0.5-3.9 Hz	Deep dreamless sleep and relaxation
2.	Theta waves	4-7.9 Hz	Deep meditation, intuition, and profound relaxation
3.	Alpha waves	8–11.9 Hz	Induces relaxation and tranquillity
4.	Beta waves	12–29.9 Hz	Improve concentration and awareness
5.	Gamma waves	30 and above Hz	Support cognitive processing, memory, and creativity

Table No. 2: Table showing Brainwaves with their frequency bands and range of benefits

By harnessing these frequencies, brainwave entrainment achieves synchronization within the brain, promoting balanced neural activity.

An in-vivo study sought to determine whether binaural beats may effectively lower anxiety in thirty fearful pediatric children between the ages of three and ten. The patients were presented with binaural beats of frequencies 344 Hz and 340 Hz in

the left and right ears respectively superimposed on soft, relaxing music by means of over-the-ear headphones. Pre-operative, intra-operative and post-operative scores of Visual facial anxiety scale and Pulse rate were recorded. The results revealed that Binaural beats was effective in in 86.67% of the cases in reduction of anxiety within 10 minutes. The study hypothesized that the induction of brainwave entrainment through theta wave stimulation might trigger the release of endorphins, potentially leading to the therapeutic outcome of patient relaxation. Likewise, 93.33% of the cases responded positively to binaural beats by the time of termination of treatment procedure. Also, it was observed that gag reflex was significantly reduced in cases of fluoride application even in hypersensitive patients. The study concluded that Binaural beats can be used effectively as a non-invasive treatment modality to reduce anxiety in apprehensive paediatric patients.[70]

In a study involving 134 university students, researchers conducted a double-blind randomized controlled trial to investigate the impact of superimposed binaural beats on anxiety reduction. They compared the effects of these beats with receptive music listening and relaxation treatment. Through block randomization, participants were assigned to three groups: one receiving binaural beats in the form of Thai Lanna music with superimposed binaural beat tones with 10 Hz difference, another receiving receptive music listening in the form of Thai Lanna music without superimposed binaural beat, and a control group exposed to blank audio. All groups underwent 20-minute daily relaxation sessions for five consecutive days. Anxiety levels were measured using the State-Trait Anxiety Inventory (STAI) before and after treatment, revealing significant reductions in anxiety levels among the superimposed binaural beat group compared to both the music listening and control groups Anxiety was decreased in all subjects in the superimposed binaural beat group, 95.56% in the

music listening group, and 84% in the control group with a statistically significant difference as indicated by the 'p' value= 0.045 ($p<0.05$). Thus, it was concluded that interventions based on superimposed binaural beats might offer more effective anxiety reduction among university students compared to music listening and general relaxation methods.[71]

A randomized clinical trial was conducted by Isik et al. to evaluate the effectiveness of binaural beat in reducing preoperative anxiety in dentistry. Sixty patients who were to undergo impacted third molars extraction were studied. According to randomization, the participants were assigned to two groups, where group 1 included 30 patients listening to binaural beats through stereo earphones with 10 Hz difference (200 Hz for the left ear and 209.3 Hz for the right ear), whereas group 2 included 30 patients whom no special intervention was given (control group). All the participants were informed and their pre operative score was anxiety was recorded using visual analogue scale. In both groups anxiety was then recorded after the tooth was extracted. The difference between the two groups was statistically significant ($p = 0.006$), where the experimental group showed less anxiety. The degree of anxiety in the control group was found unchanged after the second measurement ($p = 0.625$), while that in the experimental group showed a significant reduction in anxiety ($p = 0.001$). Thus, they conclude that binaural beats may be useful in reducing preoperative anxiety in dentistry.[72] [Figure No. 9]

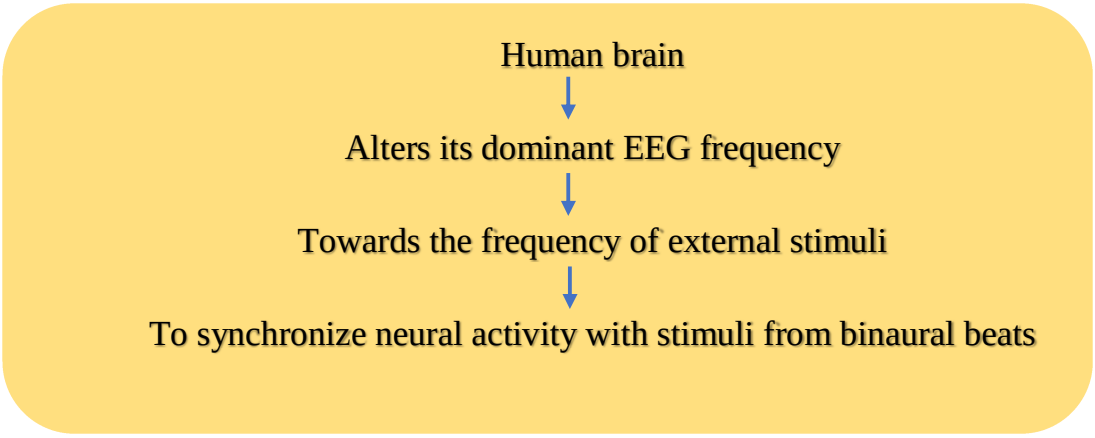

Figure No. 9: Photograph showing human brain alteration and its synchronization with neural activity

A clinical study aimed to assess and compare the effectiveness of binaural beats and music at a frequency of 432 Hz among ninety patients aged between 18-45 years for reducing preoperative dental anxiety in impacted third molar surgery. Visual analog scale was used to evaluate dental anxiety before the local anesthesia in the first measurement. Local anesthesia was administered to the all patients. For ten minutes, patients in the music group wore earphones calibrated to 432 Hz. For ten minutes, patients in the binaural beats group wore headphones (220 Hz for the right ear and 210 Hz for the left) to listen to binaural beats. The patients in the control group did not receive any specific music intervention. Dental anxiety was measured again in each of the three groups during the second assessment. The initial measurement's results showed that all three groups recorded the same amount of anxiety ($p = 0.811$). There was a significant decrease in anxiety in both the binaural beats and music group in the second measurement ($p<0.001$). However, there was no statistical difference between music and binaural beats group ($p=1$). The authors came to the conclusion

that 432 Hz tuned music and binaural beats are effective non-pharmacological adjuvants to lessen dental anxiety during impacted third molar surgery.[73]

Auditory beat stimulation (ABS) is a non-invasive neuro modulatory technique that aims to produce a neural frequency following response using sound waves in the alpha (8–13 Hz), beta (14–30 Hz), theta (4–8 Hz), gamma (30–50 Hz), or delta (1–4 Hz) frequency ranges, A randomized controlled trial aimed to assess anxiety-reducing potential of calm music combined with theta auditory beat stimulation (ABS) among 163 participants taking anxiolytics who were randomly assigned to four groups: combined (music & ABS), music-alone, ABS-alone, or pink noise (control). The study measured pre and post-intervention somatic and cognitive state anxiety levels along with trait anxiety, personality measures, and musical preferences. Participants were divided into moderate and high trait anxiety sub-groups based on their trait anxiety scores. The study found that sound-based treatments effectively reduced somatic and cognitive state anxiety in all participants, with greater reductions observed in the combined and music-alone conditions in the moderate trait anxiety sub-group. Compared to the ABS-alone condition, the music-alone condition significantly reduced somatic cognitive state anxiety in persons with high trait anxiety. They used theta ABS in this investigation and saw a substantial influence of trait anxiety on the effectiveness of our music in reducing anxiety, but no significant effects of arousal with ABS or ABS conditions. The authors concluded that sound-based treatments are effective in reducing anxiety levels, and combined conditions were most effective in participants with moderate trait anxiety.[74]

A randomized, double-blind, placebo-controlled pilot study was conducted to investigate the effectiveness of binaural auditory beat stimulation to alleviate inattention symptoms in a group of 20 children and adolescents diagnosed with

attention-deficit/hyperactivity disorder, aged between 8 and 21 years. The participants were assigned to one of two groups using a randomization process. One group listened to a 20-minute audio program containing binaural auditory beats, while the other group listened to a sham audio program that did not include binaural beats. Both groups listened to their assigned program thrice a week for a duration of three weeks. The Children's Color Trails Test, Test of Variables of Attention (TOVA), and the Homework Problem Checklist were used to measure changes in inattention pre- and postintervention. Time had a notable impact on the Color Trails Test. After the intervention, there was no appreciable group differences on the Color Trails Test or the TOVA scores. Following the session, parents indicated that the study participants had fewer homework issues. Although the binaural auditory beat stimulation did not result in a significant reduction of inattention symptoms in the experimental group, parents and adolescents reported an improvement in homework-related issues due to inattention during the three-week study. Thus, the authors concluded that further investigation was required with a larger sample size over an extended period to assess the effectiveness of this modality in reducing inattention symptoms in individuals diagnosed with attention-deficit/hyperactivity disorder to obtain more comprehensive results.[75]

A prospective, randomized controlled study was conducted to explore the potential for the use of binaural beat audio to decrease acute pre-operative anxiety in 108 adult patients undergoing general anaesthesia for day case surgery. Subjects were allocated to one of three groups according to a predetermined computer-generated random sequence. Participants listened for 30 min to binaural beat audio which generated a progressive slowing of the binaural beat to give a closing 10-min period of delta activity of Binaural group or an identical soundtrack without these added

tones (Audio Group), or received no specific intervention, representing standard practice (No Intervention Group). Anxiety with the State-Trait Anxiety Inventory questionnaire was measured. Results revealed that mean decreases in anxiety scores were 26.3% in the Binaural Group ($p = 0.001$ vs. Audio Group, $p < 0.0001$ vs. No intervention Group), 11.1% in the Audio Group ($p = 0.15$ vs. No intervention Group) and 3.8% in the No intervention Group. Thus, the authors concluded that Binaural beat audio has the potential to decrease acute pre-operative anxiety significantly, which can be used to produce anxiolysis in many preprocedural hospital settings in which pharmacological sedation is undesirable.[76]

An in vivo study compared cortical brain responses to amplitude-modulated acoustic beats at 3 and 6 Hz in 250 and 1000 Hz tones with their binaural beats counterparts in unmodulated tones. Event-related potentials (ERPs) were recorded for 3- and 6-Hz acoustic and binaural beats in 2000 ms duration tones presented at approximately 1 s intervals. ERP components' latency, amplitude, and source current density estimates for beats-evoked oscillations were compared across beat types, frequencies, and base frequencies. Tone-onset components followed by beat frequency oscillations and a subsequent tone-offset complex were observed in all stimuli. Acoustic beats showed higher amplitude oscillations than binaural beats, 250 Hz beats surpassed 1000 Hz, and 3 Hz beats exceeded 6 Hz. The sources of beats-evoked oscillations predominantly localized to left temporal lobe areas. However, differences in estimated sources between acoustic and binaural beats were not significant. These findings suggested that the cortical processing of binaural beats is similar to that of acoustic beats in terms of distribution and the effects of beat- and base frequency.[77]

A study aimed to assess the feasibility of inducing noticeable changes in EEG patterns within the alpha or beta frequency ranges and explored the potential practical applications. Additionally, it sought to understand entrainment effects on EEG throughout the epoch and identify effective strategies. Twenty-two participants were randomly assigned to groups exposed to distinct binaural beat frequencies (10 Hz alpha, 20 Hz beta) for ten 1-minute epochs. EEG recordings from temporal regions during pre-exposure, exposure, and post-exposure phases revealed no significant impact on broad-band and narrow-band amplitudes or frequency changes. In conclusion, interleaved alpha and beta binaural beats failed to demonstrate clear EEG changes, limiting potential applications, particularly in behavioral change assumptions tied to cortical entrainment.[78]

This randomized controlled clinical trial sought to assess the impact of alpha binaural beat music on pain levels following the initial placement of a maxillary fixed orthodontic appliance, comparing it to music without binaural beats (placebo) and no music (control). Sixty patients undergoing this procedure were randomly assigned to the three groups. Using a frequency of 440 Hz in one ear and 450 Hz in the other, an inaudible 10 Hz binaural beat (of the alpha-range) was produced. Pain levels were measured over seven days using the short-form McGill pain questionnaire (SF-MPQ). The binaural beat music (BBM) group exhibited a significant reduction in both sensory and psychological pain aspects compared to the control, particularly after the 5th day. Present Pain Intensity (PPI) showed significantly lower scores in the BBM group from days 3 to 7 and in the placebo group on days 4, 5 and 6 compared to the control. Visual Analog Scale scores were lower for the placebo group on day 4 and the BBM group on days 6 and 7 compared to the control. The authors concluded a noteworthy reduction in pain in the BBM group compared to the control towards the

end of the first week of treatment, with no significant difference in reported pain between the BBM and placebo groups.[79] [Figure No. 10]

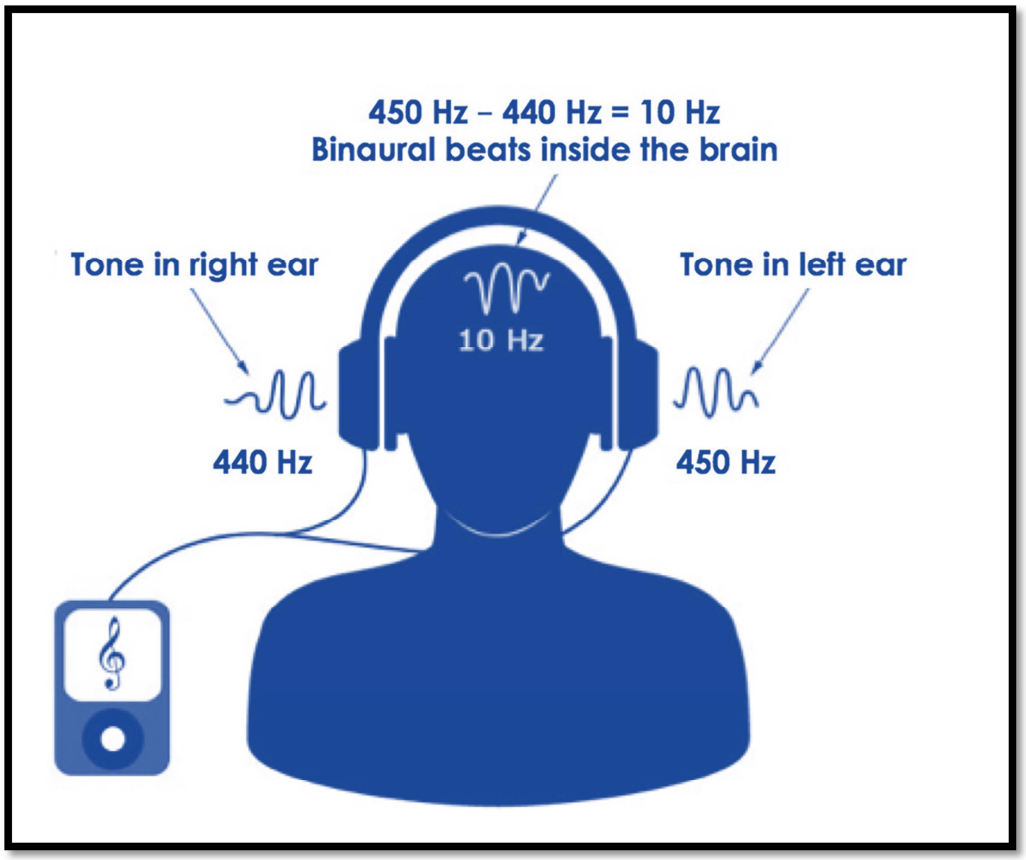

Figure No. 10: Photograph showing illustration of the binaural beats

In a randomized clinical trial, researchers examined how effective binaural beats are in reducing anxiety during dental procedures for children aged 3 to 10. They enrolled 120 pediatric patients undergoing dental treatment and exposed them to either binaural beats (experimental group) or white noise (control group) via wireless headphones for 10 minutes. Throughout the trial, pulse rate and anxiety levels were assessed at three intervals with 5-minute breaks, using a pulse oximeter and Venham's picture test. Significant differences ($p < 0.01$) were observed between the groups for pulse rates and anxiety levels at certain intervals, with higher levels noted in the control group. However, no significant differences ($p > 0.05$) were found at other

intervals. These results suggest that binaural beats are more effective than white noise in reducing dental anxiety in pediatric patients before and during dental procedures.[80]

In this pilot study, the aim was to assess the impact of combining virtual reality and binaural tones on pediatric patients with chronic pain. Psychophysiological responses (heart rate and galvanic skin response) and pain perception were measured using a mixed pre- and post-test experimental design. Data were collected from a sample of n = 13 healthy participants and n = 9 pediatric patients with chronic pain. The results demonstrated a significant difference between baseline and post-application of virtual reality and binaural beats ($p < 0.05$). The authors concluded that the combination of virtual reality and binaural beats has notable effects on chronic pain perception, surpassing the effects of virtual reality alone. This suggests that this technological combination could serve as a valuable tool for managing chronic pain in pediatric patients with rheumatic diseases.[81]

A randomized clinical trial aimed to compare and assess the degree of anxiety experienced by children aged 6 to 12 years throughout restorative treatment utilizing monaural beats and binaural auditory beats. There were 45 participants, divided into 3 groups. Primary and permanent molar teeth with Class I cavities were prepared and restored. Venham's picture scale and a pulse oximeter were used to quantify anxiety both before and after the intervention. When compared to the control group, children who received treatment with binaural beats and monaural beats had lower anxiety ratings on the Venham Picture Test and lower pulse rate values. Thus, the authors came to the conclusion that choosing monaural beats and binaural auditory beats can be an effective non-invasive therapy method for reducing anxiety in young children who are anxious.[82]

XII. LITERATURE ON MUSIC OF CHOICE

A patient's musical preferences and willingness to engage in music-related activities determine the advantages of therapeutic music.[104,105] Taking decisions about their own music therapy helps patients reach full engagement and adds a human element to the process. Choosing music that they enjoy helps children feel more in charge of the situation, creates a familiar environment that lessens feelings of strangeness, represents their personalities, and expresses their emotions.[83]

A clinical study aimed to ascertain if music distraction is an effective means of managing anxiety among forty children aged between 4 and 8 years. The children were randomly divided in to two groups. First group was control group (group A) and the second group was music group. The music group was further divided equally into two subgroups viz. instrumental music group (group B) and Nursery rhymes music group (group C). The choice of the type of music depended upon the patient's selection. Each child had four dental visits, first was the screening visit followed by three treatment visits. Each child had four dental visits, first was the screening visit followed by three treatment visits. The authors concluded that audio distraction did decrease the anxiety level in pediatric dental patients, but not to a very significant level.[84]

Active distraction techniques include elements like using games and toys that need the child to participate directly. The use of music, movies, and other media is the foundation of passive approaches, which don't need the child to actively participate.

A randomized clinical trial performed on 83 children aimed to determine the effect of music therapy and distraction cards on the anxiety of hospitalized children aged 8-12 years with chronic diseases. The participants were assigned to three groups,

namely cards, music, and cards combined with music groups. The authors concluded that playing with distraction cards decreased anxiety and fear in children to a greater extent as compared to music therapy. Compared to the passive approach (music), playing cards was another distraction strategy used in the current study that had a greater effect on reducing children's fear. This is mostly because children are more engaged and entertained by active tactics. Therefore, the active distraction method can be a practical approach to reduce anxiety and fear in hospitalized children.[85]

A prospective in vivo study was conducted to assess the effectiveness of audio distraction as an intervention for managing anxiety in pediatric dental patients. Sixty children were randomly assigned and equally distributed into two groups, with the first group serving as the control and the second as the music intervention group. Both groups underwent dental extractions. The children in the music group were provided with an audio presentation during the entire treatment procedure. Anxiety levels were assessed using Venham's picture test, as well as monitoring pulse rate, blood pressure, and oxygen saturation. The results demonstrated the efficacy of audio distraction in mitigating anxiety among pediatric dental patients. Consequently, the authors concluded that audio distraction significantly reduced anxiety in this population.[86]

This study aimed to compare the efficacy of Music of choice and Anand Bhairavi raga in alleviating pre-procedural anxiety among adult patients. 30 participants were allocated to each group. Pre-procedural anxiety was assessed before and after music intervention in both groups. Before intervention, 93.3% of Music of choice group and 96.7% of Anand Bhairavi raga group exhibited severe anxiety. Post-intervention, 56.7% in Music of choice group had mild anxiety, and 43.3% had

moderate anxiety, while in Anand Bhairavi raga group, 50% had mild anxiety, and 50% had moderate anxiety. No significant difference in pre-procedural anxiety was observed between the two groups ($p > 0.05$). The authors concluded that both interventions, Music of choice and Anand Bhairavi raga, were equally effective in reducing pre-procedural anxiety.[87]

This in vivo study aimed to assess and compare the efficacy of audio and audiovisual distraction aids in managing anxiety among pediatric dental patients across two age groups (4-6 years and 6-8 years). The research included 30 patients in each age group during their initial dental visit, divided into three subgroups: control, audio distraction, and audiovisual distraction (with 10 patients in each subgroup). Results indicated that the audiovisual distraction group exhibited a statistically highly significant difference from both the audio and control groups. Additionally, the audio group showed a statistically significant difference from the control group. Consequently, the authors concluded that audiovisual distraction is a more effective mode of distraction in managing anxiety among children in both age groups compared to audio distraction.[88]

MATERIALS AND METHOD

The present in vivo study was designed 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.

The study was conducted in the Department of Pediatric and Preventive Dentistry at KLE Academy of Higher Education and Research's KLE VK Institute of Dental Sciences, Belagavi. Ethical clearance for the study was obtained from the Institutional Review Board (IRB) of the KAHER's KLE VK Institute of Dental Sciences Belagavi [Sl.No.: 92]. **(Annexure I)**

CTRI REGISTRATION:

Trial had been registered prospectively with the following CTRI number: CTRI/2024/02/063286 **(Annexure II).**

The following are the armamentarium used for the clinical procedure in the study: [Figure No. 11,12,13,14]

- Dental chair with illumination
- Kidney trays
- Disposable mouth mask (Ramson's Care Plus, Ramson Health Care, Bangalore)
- Disposable head cap (Ramson's Care Plus, Ramson Health Care, Bangalore)
- Disposable gloves (Rakshak, Ramya Impex Pvt. Ltd., Mumbai)
- Mouth mirror

- Straight probe
- Explorer
- Spoon Excavator
- Cotton rolls (Prabhat Surgical Cotton Pvt. Ltd., Tumkur, Karnataka, India)
- Pair of tweezers.
- Airotor (NSK handpiece).
- Diamond burs (Mani diamond burs, SS Dental Supply).
- Rubber dam kit (Hygienic Fiesta Colour Coded clamps and Dental Dam – Coltene Whaledent Inc.)
- Glass Ionomer Cement (GC Gold label H.S. Posterior Extra)
- Composite restorative (Shofu Beautifil Bulk Restorative Composite)
- Articulating paper (Articulating Paper Superior, Deepashree Products G–711 MIDC Ratnagiri).
- Light curing gun. (Woodpecker)
- Wireless Headphone (boAt Rockerz 400 Bluetooth On Ear Headphones)
- Samsung Galaxy M52 Smartphone with Binaural auditory beats application software (Brain Waves Binaural Beats, MynioTech Apps, Chapeco, Santa Catarina, Brazil)
- Finger Pulse oximeter with OLED display

MATERIAL & ARMAMENTARIUM USED IN THE STUDY

Figure No. 11: Photograph Showing Clinical Armamentarium Used In The Study

Figure No. 12: Photograph showing Posterior High strength Glass Ionomer Cement material used in the study

Figure No. 13: Photograph showing Composite used in the study

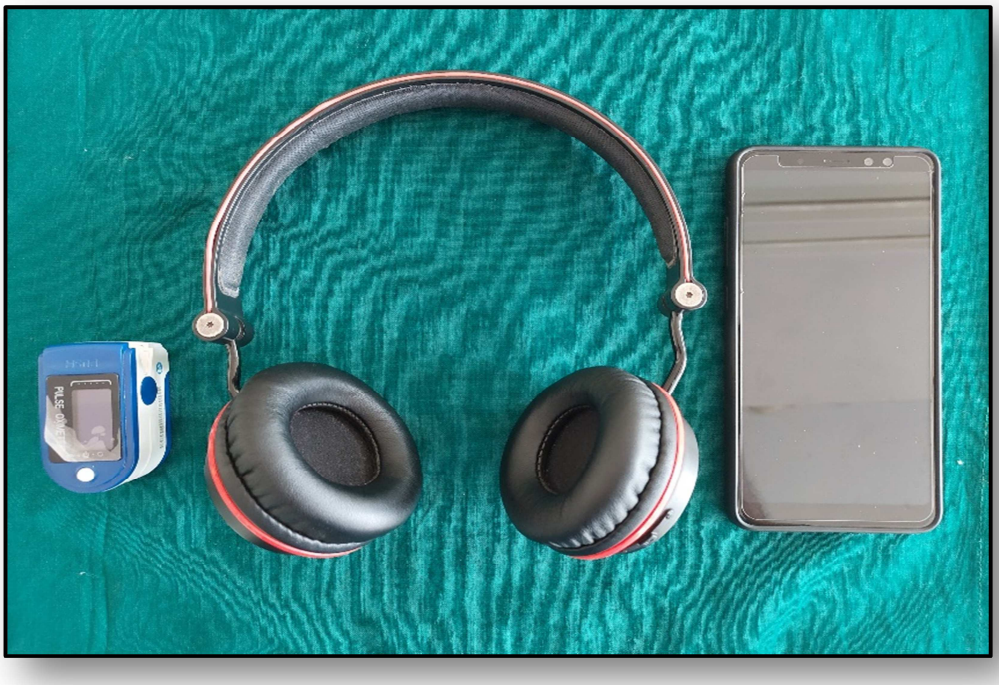

Figure No. 14: Photograph showing Music distraction ear phone used in the study

SOURCE OF DATA:

Patients reporting to the outpatient department of the Department of Pediatric & Preventive Dentistry at KLE Academy and Higher Education and Research's KLE VK Institute of Dental Sciences, Belagavi who met the study's inclusion and exclusion requirements were chosen. Written informed consent was obtained from all the parents of children participating in the study **(Annexure III a, IIIb).** Assent was obtained from all the children participating in the study **(Annexure IV).**

STUDY DESIGN:

This was an In vivo, Randomized control, double blinded, three-arm, parallel group study.

SELECTION OF SUBJECTS:

Subjects for the study were selected according to the following inclusion and exclusion criteria.

INCLUSION CRITERIA USED IN THE STUDY:

- Children between 6-12 years of age.
- Children visiting dental clinic for the first time.
- Children who require restoration for Class 1 cavity in the primary/ permanent molar teeth.
- Children with moderate dental caries involving enamel and dentin.

EXCLUSION CRITERIA USED IN THE STUDY:

- Children with special health care needs.
- Children showing Frankl Behavior rating 1 and II (i.e., Definitely negative and Negative).
- Children having Visual or Auditory impairment.
- Children and/or Parents who are unwilling to participate in the study.

SAMPLE SIZE:

Samples required for the study was selected as per the inclusion and exclusion criteria. The following formula was used to calculate the sample size:[70]

$$n = \frac{2S^2}{d^2}\left[z_{1-\alpha} + z_{1-\beta}\right]^2$$

Where: d = 2.20

α error = 1%,

Z 1-α =2.58 at 1% α error

Z $1-_{\beta}$ = 0.842 at 20% β error or 80% power

S_1 = 2.12 S_2 = 2.42

(α = probability of type I error, Z $1-_{\beta}$ = power of the study, S = standard deviation, d = mean difference.)

So, n = 25 in each group. Total Sample is 75 Children.

So, a total of 75 sample size was selected and divided into three study groups of twenty-five each.

RANDOMIZATION AND STUDY GROUP ALLOCATION:

All the seventy-five samples of the study group were equally divided into three equal groups by simple random sampling using lottery method to ensure standardization. [Figure No. 15]

Figure No. 15: Photograph showing Randomization used in the study using lottery method to ensure standardization.

STUDY GROUPS:

- **Group I (Control Group):** 25 subjects were treated without any music intervention
- **GROUP II (Experimental Group)**: 25 subjects were treated using Music of Choice. Children listened to familiar songs which helped the child gain control over unpleasant stimulus of dental treatment from the sound of airotor or sight of syringe.

- **GROUP III (Experimental Group):** 25 subjects were treated using Binaural auditory beats. The children were presented with beats of frequencies 400 Hz and 412 Hz in the left and right ears, superimposed on soft, relaxing music (to utilize their synergistic effect) by means of over-the-ear headphones using the mobile device. The frequencies were produced by software (Brain Waves Binaural Beats, MynioTech Apps, Chapeco, Santa Catarina, Brazil) as used in the previous studies and the treatment procedure was started thereafter.

BLINDING FOLLOWED IN THE STUDY:

A trained assistant provided beats to participants in groups II and III through over-the-ear headphones, while the principal investigator was blinded. The participants in group I were not introduced to any music intervention, however over-the ear headphones were presented to them as well for blinding of principal investigator. Likewise, the data analysist was blinded from the intervention.

METHOD OF COLLECTION OF DATA:

A. SELECTION OF CASE AND RECORDING OF CASE HISTORY:

- Children who met the inclusion and exclusion criteria were made to settle into the dental chair, and the Principal Investigator (PI) thoroughly described the process to both the children and their parents.
- A case history was recorded for the present study so as to have a systematic and methodological recording of all the observations and information. **(Annexure V)**
- After recording the preliminary information, clinical examination was carried out on a dental chair under standard operating protocol.
- A trained Pediatric dentist was made to assess the anxiety levels before and after dental treatment.

B. RECORDING BEHAVIOR LEVELS BY FRANKL BEHAVIOR RATING SCALE:

- Behaviour of the patient prior to the study was evaluated according to FRANKL Behaviour Rating Scale for selection of the participant in the study.[89]

C. RECORDING ANXIETY LEVELS BY VENHAM'S PICTURE TEST

- Anxiety of the participants was evaluated by a trained Pediatric dentist using Venham's Picture Test, a Self-administered anxiety scale, both pre-operatively and post-operatively.
- There are eight cards in the Venham Picture Test, each containing two figures one "anxious" and one "non-anxious"on it. The children were instructed to indicate which figure, at that precise moment, most resembled them. Every card was displayed in its assigned number. If the child pointed at the 'anxious' figure a score of one was recorded, if the child pointed at the 'non anxious' figure a score of zero was recorded. There was a minimum score of zero and a maximum score of eight based on the total number of times the 'anxious' figure was selected. [Figure No. 16]

Figure No. 16: Photograph showing evaluation of anxiety using Venham Picture Test

Figure No. 17: Photograph showing evaluation of preoperative anxiety using Pulse oximeter

D. RECORDING THE PULSE RATE:

Similarly, the physiological parameter like pulse rate of the participants was recorded using a fingertip pulse oximeter device with an integrated monitor displaying values of pulse rate to evaluate the anxiety subjectively by a Pediatric dentist both pre- and post-operatively. [Figure No. 17]

E. STEP-BY-STEP PROCEDURE OF THE STUDY TO BE CONDUCTED:

- The Principal Investigator performed the procedure under Standard Operating Protocols. The procedure was carried out in 45 min for each patient in all the three groups. Patients allocated to Group I was treated using No music, Group II using Music of Choice and Group III was treated using Binaural auditory beats. [Figure No. 18]

- The tooth selected for the study was isolated using Rubber dam and the tooth preparation for Class I cavity was carried out in primary or permanent molars.

Figure No. 18: Photograph showing patient undergoing dental treatment

- Tooth was restored using Posterior High Strength Glass Ionomer for Primary molars and Resin based Composite filling material for Permanent molars.
- Occlusion was checked with an articulating paper for any occlusal irregularities.

The immediate post-operative evaluation of all the restoration was done by an experienced examiner (Pediatric Dentist) in the Department of Pediatric and Preventive Dentistry and findings were recorded in a master chart.

E. POST OPERATIVE INSTRUCTIONS:

After completion of treatment, patients were made to sit and given post-operative instructions. Post-operative instructions were as follows:

- Not to drink or take water for thirty minutes.
- Not to eat anything for one hour and have a soft diet for next 24 hours.
- Patient were asked to report to the dental clinic if any kind of pain or sensitivity was present or patient had any kind of discomfort during mastication.
- Patient were asked to report to the dental clinic if they noticed any kind of fractured restoration.

STATISTICAL ANALYSIS:

The results were tabulated and entered on the excel sheet. Then the results were subjected to the following statistical tests using IBM SPSS software (version 20.0 Chicago IL, USA) by the statistician.

- Descriptive statistics was used to provide a clear and concise overview of the key characteristics of the study sample, such as means, standard deviations, and frequencies. Also to help in understanding the central tendency and variability of the data.

- One way ANOVA for Intergroup comparison was applied for intergroup comparison, specifically to assess whether there are statistically significant differences in anxiety levels among the three groups (No Music, Music of choice and Binaural Auditory Beats).

- Independent 't' test for Intergroup was used to compare anxiety level reductions between pairs of groups (e.g., Binaural Auditory Beats vs. No Music, Monaural Beats vs. No Music).

- Dependent 't' test for Intragroup comparison was used to assess whether there is a significant difference in anxiety levels within each group before and after the intervention (pre- and post-intervention measurements)

- Level of significance was set at p= 0.05. ($p \leq 0.05$: Statistically significant, $p \leq 0.01$: highly significant, $p \leq 0.001$: very highly significant and $p \geq 0.05$ not significant).

The summary of methodology of the study is explained as a Consort flow diagram that summarizes the study on how the trial was conducted, reporting enrolment, allocation, follow-up and analysis of patients involved in the randomized controlled trial. **(Annexure VI)**

TABLES, GRAPHS AND OBSERVATIONS

The data collected were tabulated and entered on the excel sheet. Then the collected data were subjected to the following statistical tests using IBM SPSS software (version 20.0 Chicago IL, USA) by the statistician:

1. Descriptive statistics
2. Independent 't' test
3. Dependent 't' test
4. Kolmogorov Smirnov test
5. One way ANOVA
6. Kruskal Wallis ANOVA
7. Mann-Whitney U test
8. Wilcoxon matched pairs test
9. Tukeys multiple posthoc analysis

Table No. 3: Table showing master chart of evaluation of anxiety through recording of pre and post operative findings using Venham picture test and Pulse rate scores using No music [Group I]

Allotment no.	Age	Sex	Venham picture test		Pulse rate	
			Baseline	Post op	Baseline	Post op
C1	9	M	2	2	84	96
C2	**7**	F	3	2	96	94
C3	8	M	4	4	110	111
C4	7	M	2	3	102	104
C5	11	F	3	3	96	94
C6	7	F	6	5	114	106
C7	8	F	4	3	112	108
C8	11	F	2	2	96	104
C9	6	F	7	6	124	118
C10	6	F	4	5	108	112
C11	6	M	5	5	114	122
C12	9	M	3	3	84	92
C13	12	F	6	5	82	76
C14	7	F	1	2	96	92
C15	11	M	1	1	82	78
C16	12	M	0	0	80	76
C17	8	F	4	3	102	96
C18	7	F	3	4	97	94
C19	12	M	2	2	82	87
C20	11	M	2	1	86	84
C21	8	M	4	3	92	83
C22	9	M	2	4	88	102
C23	8	M	3	4	94	97
C24	10	M	2	4	78	86
C25	10	F	3	3	90	94

Table No. 4: Table Showing Master Chart of Evaluation of Anxiety Through Recording of Pre and Post Operative Findings Using Venham Picture Test and Pulse Rate Scores Using Music Of Choice [Group II]

Allotment no.	Age	Sex	Venham Picture Test		Pulse Rate	
			Baseline	Post op	Baseline	Post op
E1.1	12	F	3	1	92	84
E1.2	10	F	2	0	90	82
E1.3	8	M	4	3	104	94
E1.4	12	F	3	2	86	82
E1.5	8	F	2	0	98	84
E1.6	9	M	3	1	104	96
E1.7	7	M	5	3	114	104
E1.8	11	M	3	0	84	72
E1.9	7	F	5	2	102	92
E1.10	12	M	4	2	88	76
E1.11	7	F	5	3	96	90
E1.12	12	F	2	0	84	76
E1.13	12	F	4	1	88	78
E1.14	9	M	3	1	92	84
E1.15	8	M	6	4	100	92
E1.16	7	F	3	2	102	106
E1.17	12	M	2	0	78	72
E1.18	6	F	3	1	96	90
E1.19	8	F	2	0	86	78
E1.20	7	F	4	2	112	102
E1.21	8	M	4	2	108	92
E1.22	10	M	3	2	93	82
E1.23	8	F	3	1	109	94
E1.24	9	F	4	2	97	86
E1.25	9	M	3	1	107	96

Table No. 5: Table Showing Master Chart of Evaluation of Anxiety Through Recording of Pre and Post Operative Findings Using Venham Picture Test And Pulse Rate Scores Using Binaural Auditory Beats [Group III]

Allotment no.	Age	Sex	Venham picture test		Pulse rate	
			Baseline	Post op	Baseline	Post op
E2.1	11	M	2	0	86	78
E2.2	7	M	1	0	92	86
E2.3	8	F	1	0	96	84
E2.4	11	M	4	2	92	88
E2.5	12	F	3	1	98	90
E2.6	12	F	4	2	94	86
E2.7	6	F	7	5	112	102
E2.8	11	F	5	2	82	74
E2.9	7	M	4	2	108	96
E2.10	12	M	3	1	78	72
E2.11	6	M	4	2	102	94
E2.12	12	F	3	1	104	96
E2.13	12	M	2	0	84	76
E2.14	10	M	3	1	86	74
E2.15	7	M	3	1	92	80
E2.16	10	M	5	3	84	76
E2.17	12	M	2	1	78	78
E2.18	9	F	1	0	94	82
E2.19	11	F	4	1	96	84
E2.20	12	F	4	2	110	96
E2.21	12	M	2	0	86	80
E2.22	10	F	3	1	94	82
E2.23	10	M	2	0	88	80
E2.24	9	F	4	2	113	94
E2.25	7	F	3	1	104	90

Table No. 3, 4 and 5 showing master chart of evaluation of anxiety through recording of pre and post operative findings using Venham picture test and Pulse rate using No music [Group I], Music of choice [Group II] and Binaural auditory beats [Group III] respectively. A total of 75 patients among 6-12 years of age were included in our study and were equally divided into the aforementioned three groups.

Table No. 6: Table showing age wise distribution of patients in three groups namely No music [Group I], Music of choice [Group II] and Binaural auditory beats [Group III]

Age groups	No music	%	Music of choice	%	Binaural auditory beats	%	Total	%	χ^2	p-value
6-7yrs	8	32.00	6	24.00	6	24.00	20	26.67	8.5850	0.1980
8-9yrs	8	32.00	10	40.00	3	12.00	21	28.00		
10-11yrs	6	24.00	3	12.00	8	32.00	17	22.67		
12yrs	3	12.00	6	24.00	8	32.00	17	22.67		
Mean age	8.80		9.12		9.84		9.25			
SD age	9.20		1.99		2.13		2.06			
Total	25	100.0	25	100.00	25	100.00	75	100.0		

Graph No. 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]

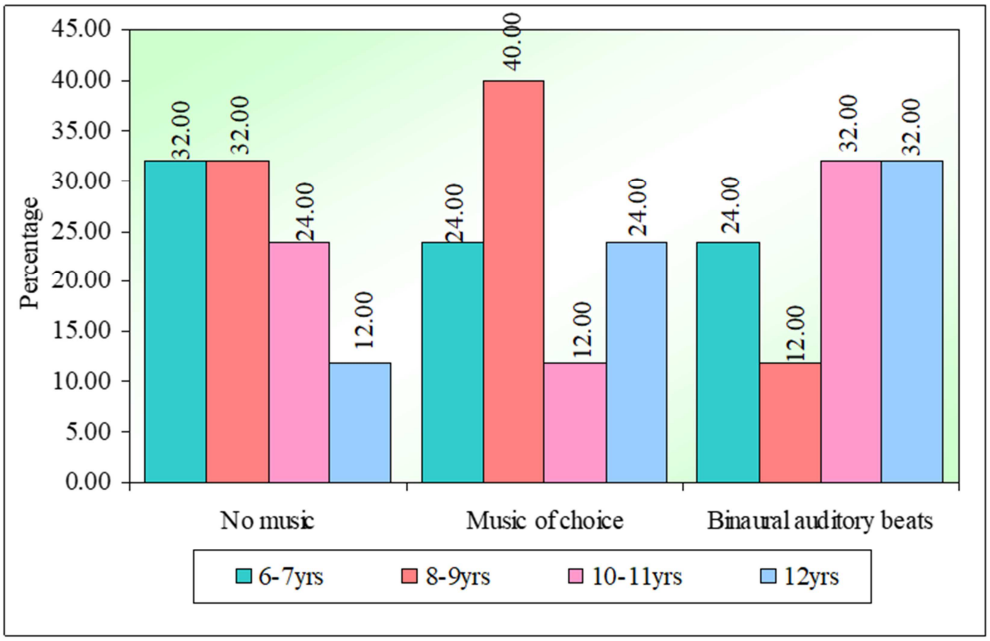

Table No. 6 and Graph No. 1 showing demographic profile of the participants by showing age wise distribution of patients in three groups namely No music [Group I], Music of choice [Group II] and Binaural auditory beats [Group III]. Seventy-five patients with mean age of 9.25 ± 2.06 were included. Twenty children (26.67%) were 6-7 years of age, twenty-one children (28%) were 8-9 years of age, seventeen children (22.67%) were 10-11 years of age and seventeen children (22.67%) were 12 years of age.

Table No. 7: Table showing gender wise distribution of patients in three groups namely No music [Group I], Music of choice [Group II] and Binaural auditory beats [Group III]

Gender	No music	%	Music of choice	%	Binaural auditory beats	%	Total	%	χ^2	p-value
Male	13	52	11	44	13	52	37	49.33	0.427	0.908
Female	12	48	14	56	12	48	38	50.67		
Total	25	100	25	100	25	100	75	100.00		

Graph No. 2: Graphical representation of gender wise distribution of patients in three groups namely No music [Group I], Music of choice [Group II] and Binaural auditory beats [Group III]

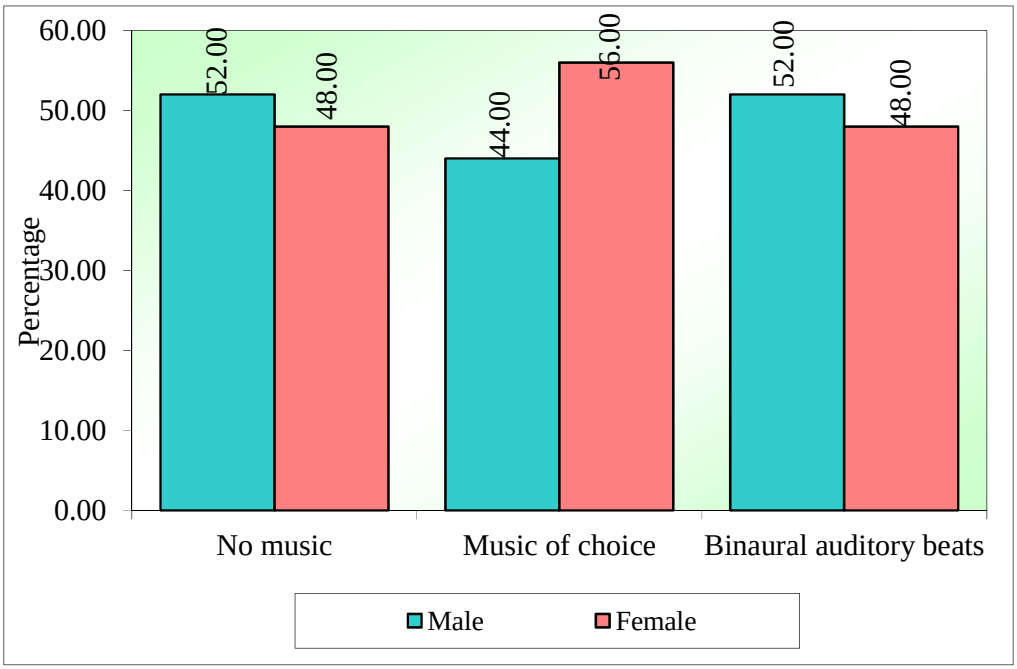

Table No. 7 and Graph No. 2 showing gender wise distribution of patients in three groups namely No music [Group I], Music of choice [Group II] and Binaural auditory beats [Group III]. 37 out of 75 (49.33%) were male and 38 (50.67%) of the participants were female. All the groups showed equitable distribution of participants which maintained standardization of selection criteria in our study.

Table No. 8: 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 I], 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

Note that, the baseline and post-test Venham's picture test scores in three groups did not follow a normal distribution. Therefore, the non-parametric tests were applied. baseline and post-test Pulse rate scores in three groups follow a normal distribution. Therefore, the parametric tests were applied.

Table No. 8: 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 I], Music of choice [Group II] and Binaural auditory beats [Group III] by Kolmogorov Smirnov test. When comparison of baseline and post-operative Venham's picture test scores was carried out in three groups using Kolmogorov Smirnov test, a very highly statistically significant difference was found in Binaural auditory beats group with a 'p' value of 0.0001 ($p < 0.05$) indicating it to be the most efficient in reduction of anxiety. This was closely followed by Music of choice group with a 'p' value of 0.0020 ($p < 0.05$) which also showed a statistically significant difference between baseline and post-operative Venham picture scores. On the contrary, no significant difference was observed in Control group. However, when Pulse rate scores were assessed, no significant difference was observed in all the three groups.

Table No. 9: Table showing 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 test scores by Kruskal Wallis ANOVA

Interval	Groups	Mean	SD	Median	IQR	Mean rank	H-value	P-value
Baseline	No music	3.12	1.67	3.00	2.00	35.5	0.9900	0.6090
	Music of choice	3.40	1.08	3.00	1.00	41.3		
	Binaural auditory beats	3.16	1.40	3.00	2.00	37.2		
Post operative	No music	3.16	1.46	3.00	2.00	54.74	23.5460	0.0001*
	Music of choice	1.44	1.12	1.00	1.00	31.6		
	Binaural auditory beats	1.24	1.16	1.00	2.00	27.66		
Difference	No music	-0.04	0.93	0.00	2.00	14.28	51.2310	0.0001*
	Music of choice	1.96	0.54	2.00	0.00	50.28		
	Binaural auditory beats	1.92	0.49	2.00	0.00	49.44		

*p <0.05

Graph No. 3: Graphical representation of 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 test scores

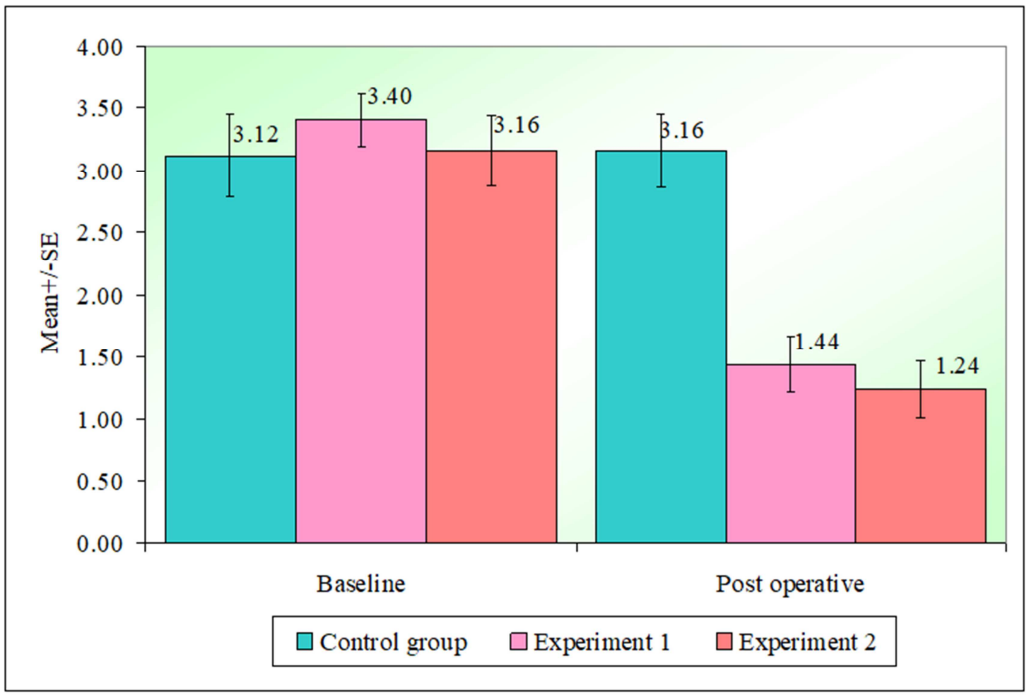

Table No. 9 and Graph No. 3 showing comparison of three groups namely No music [Group I], Music of choice [Group II] and Binaural auditory beats [Group III] with baseline and post operative Venham's picture test scores by Kruskal Wallis ANOVA. When comparison of baseline and post-operative Venham's picture test score was done among three groups using Kruskal Wallis ANOVA, maximum reduction in anxiety was observed in Music of choice and Binaural auditory beats group as the difference between the baseline and post-operative scores were highest with a 'p' value of 0.0001. No music group showed a slight decrease in Venham's picture test score but the difference was statistically non-significant.

Table No. 10: 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 No. 10 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. When pair wise comparison was done using Mann-Whitney U test between Control group and Music of choice & Binaural auditory beats group, a statistically significant difference was observed as indicated by a 'p' value of 0.0001 ($p<0.05$) which indicated the efficacy of both the modalities in reducing the anxiety among children during restorative treatment. However. when pair wise comparison was done between Music of choice & Binaural auditory beats group no significant difference was observed as indicated by a 'p' value of 0.8462 ($p> 0.05$).

Table No. 11: Table showing comparison of baseline and post operative Venham's picture scale scores in three groups namely No music [Group I], Music of choice [Group II] and Binaural auditory beats [Group III] by Wilcoxon matched pairs test

Groups	Interval	Mean	SD	Mean Diff.	SD Diff.	% of change	Z-value	p-value
No music	Baseline	3.12	1.67					
	Post operative	3.16	1.46	-0.04	0.93	-1.28	0.2272	0.8203
Music of choice	Baseline	3.40	1.08					
	Post operative	1.44	1.12	1.96	0.54	57.65	4.3724	0.0001*
Binaural auditory beats	Baseline	3.16	1.40					
	Post operative	1.24	1.16	1.92	0.49	60.76	4.3724	0.0001*

*p <0.05

Graph No. 4: Graphical representation of comparison of baseline and post operative Venham's picture scale scores in three groups namely No musi[Group I], Music of choice [Group II] and Binaural auditory beats [Group III]

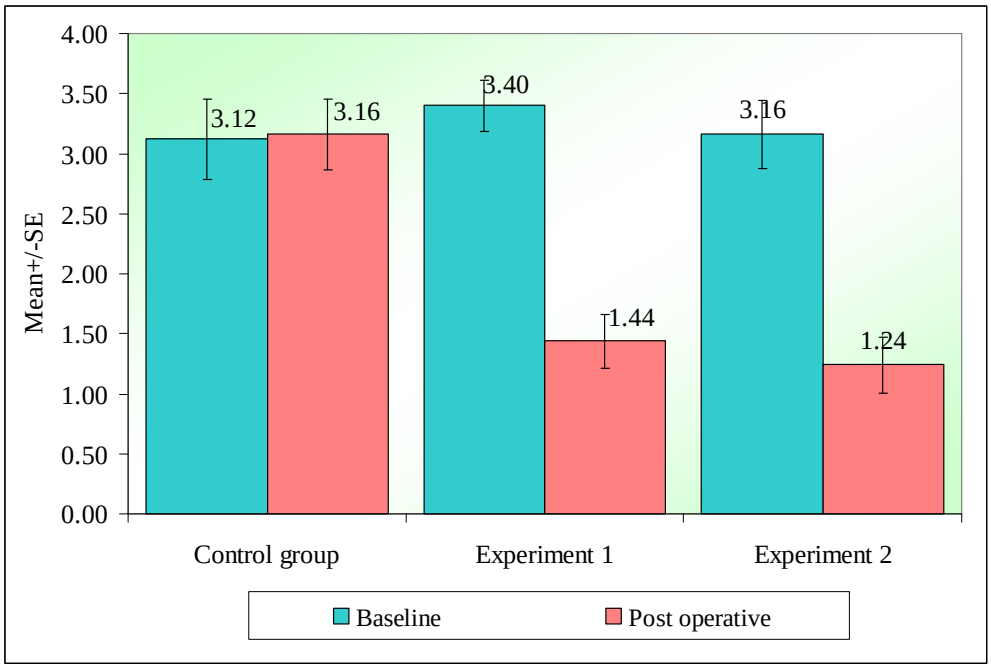

Table No. 11 and Graph No. 4 showing comparison of baseline and post operative Venham's picture scale scores in three groups namely No music [Group I], Music of choice [Group II] and Binaural auditory beats [Group III]. When pair-wise data was considered among the three groups, Music of choice and Binaural auditory beats group showed a statistically significant difference between baseline and postl operative scores with a 'p'value of 0.0001.

Table No. 12: Table showing 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 one way ANOVA

Interval	Groups	Mean	SD	SE	F-value	P-value
Baseline	No music	95.56	12.54	2.51	0.2802	0.7564
	Music of choice	96.40	9.68	1.94		
	Binaural auditory beats	94.12	10.25	2.05		
Post operative	No music	96.24	12.44	2.49	8.7004	0.0004*
	Music of choice	87.36	9.53	1.91		
	Binaural auditory beats	84.72	8.26	1.65		
Difference	No music	-0.68	6.43	1.29	34.2553	0.0001*
	Music of choice	9.04	3.94	0.79		
	Binaural auditory beats	9.40	3.83	0.77		

*p<0.05

Graph No. 5: Graphical representation of 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

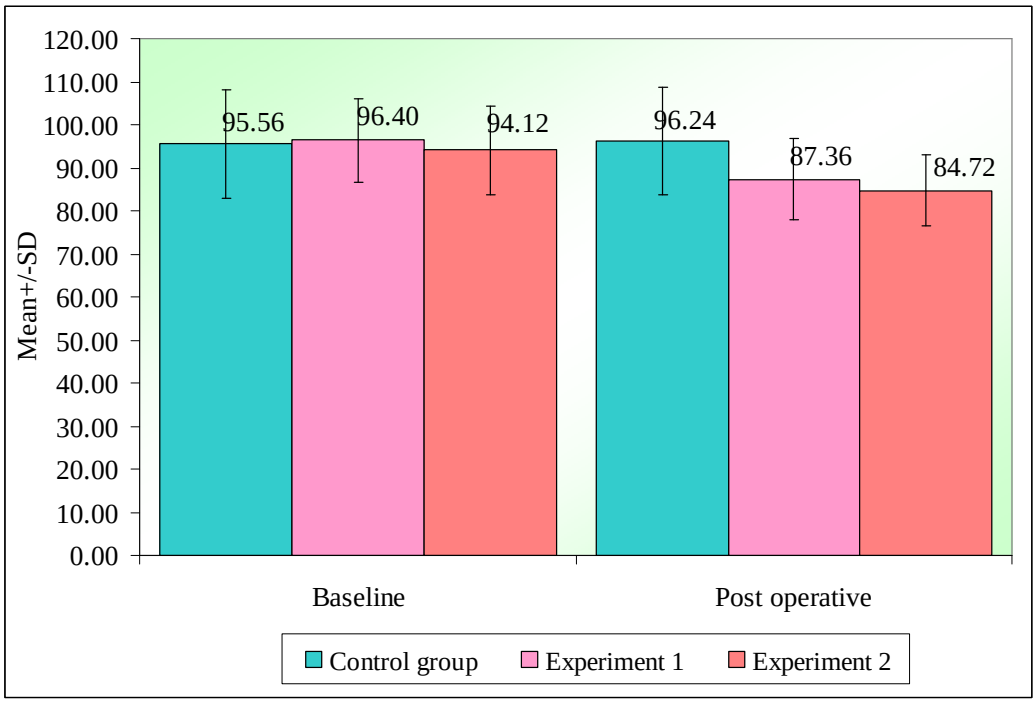

Table No. 12 and Graph No. 5 showing comparison of three groups namely No music [Group I], Music of choice [Group II] and Binaural auditory beats [Group III] with baseline and post operative Pulse rate scores by one way ANOVA. When comparison of baseline and post-operative Pulse rate scores was done among three groups using One way ANOVA, a statistically significant difference was observed with the three grouos with a ‘p’ value of 0.0001 which indicated that the pulse rate scores varied significantly among the groups.

Table No. 13: 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 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 auditory beats	P=0.8868	P=0.7406	-
Post operative	Mean	96.24	87.36	84.72
	SD	12.44	9.53	8.26
	No music	-		
	Music of choice	P=0.0085*	-	
	Binaural auditory beats	P=0.0006*	P=0.6344	-
Difference	Mean	-0.68	9.04	9.40
	SD	6.43	3.94	3.83
	No music	-		
	Music of choice	P=0.0001*	-	
	Binaural auditory beats	P=0.0001*	P=0.9634	-

*$p<0.05$

Table No. 13 showing pair wise comparison of three groups namely No music [Group I], Music of choice [Group II] and Binaural auditory beats [Group III] to evaluate the anxiety in children by measuring pulse rate scores at baseline and post operative procedures by Tukey's multiple posthoc test.

At baseline, there was no difference found between No music and Music of choice nor between Music of choice and Binaural auditory beats group. Post-operatively, a significant difference was found in children undergoing dental treatment without listening to music as compared to children who were listening to Music of choice with a 'p' value of 0.0085 ($p<0.05$).

Children undergoing dental treatment using Binaural auditory beats showed statistically significant difference with a 'p' value of 0.0006 ($p<0.05$) when compared to children undergoing dental treatment with No music. Thus, children undergoing dental treatment using Music of choice ($p=0.0001$) and Binaural auditory beats ($p=0.0001$) showed statistically significant results when compared to children undergoing dental treatment without music. Among the Binaural auditory beats and Music of choice there was no statistically significant difference as indicated by 'p' value ($p= 0.06344$).

DISCUSSION

"By introducing novel audio distraction techniques, we aim to turn fear into curiosity and tears into smiles"

-Dr. Jones

Dental anxiety can be particularly pronounced among children, especially during certain dental procedures that are commonly perceived as uncomfortable or frightening. Common procedures eliciting dental anxiety include tooth extractions, wherein the prospect of tooth removal is fear-inducing, especially if associated with pain or discomfort. Dental restorations provoke anxiety due to the auditory and tactile sensations of the dental drill and anticipation of receiving local anaesthesia injections. Pulpectomy or root canal treatment is anxiety-provoking due to its procedural complexity, duration, and utilization of specialized instruments. Similarly, dental crown placement induces anxiety during the process of fitting, cementing, and undergoing dental impressions. Orthodontic procedures, such as bracket placement or adjustments, evoke anxiety in children due to perceived discomfort and alterations to their physical appearance.

Among these minimizing dental anxiety during restorative dental treatment is particularly necessary due to its complexity of procedures compared to routine check-ups, potential pain and discomfort from deep cavities which may necessitate local anaesthesia or sedation to manage pain and discomfort, also they may often require longer treatment durations compared to routine appointments and the emotional impact associated with it, especially if they involve the restoration of visible teeth or the improvement of the child’s smile. Patients may experience

anxiety about the aesthetic outcome of the treatment and how it will affect their self-confidence and social interactions.

Patients experiencing anxiety before undergoing restorative procedures are commonly addressed using the "4 S" rule or the so-called 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), feels (such as high-frequency vibrations), and olfactory sensations.[90]

In recent years, there has been a notable surge in the exploration of non-pharmacological methods for managing anxiety, particularly in dental settings. These methods, including animal-assisted therapy, aroma therapy, Snoezelen sensory-adapted dental environments, virtual reality, guided imagery, and auditory beat stimulation, have shown promising results in reducing anxiety levels among patients. However, despite their potential benefits, several limitations exist which warrant their consideration in the context of their implementation.

For instance, many non-pharmacological interventions, such as animal-assisted therapy and Snoezelen sensory environments, require dedicated spaces or specialized equipment to achieve optimal results. Establishing and maintaining these resources can significantly increase the costs for dental practices. For instance, setting up a designated area for animal-assisted therapy or investing in sensory equipment may pose financial challenges for smaller practices.

Space Constraints is another limitation within dental clinics. For instance, creating a separate area for activities like animal-assisted therapy or Snoezelen sensory environments may not be feasible in smaller clinics with limited square footage. This limitation could hinder the widespread adoption of these interventions,

particularly in urban areas where space is a limitation. Likewise, conducting animal-assisted therapy sessions necessitates the involvement of trained handlers and ensuring the well-being of both patients and animals. Similarly, guiding patients through virtual reality experiences or utilizing guided imagery techniques requires proficiency in using the technology. The need for ongoing training and education can pose challenges for dental professionals, particularly in busy clinical settings where time is limited. Also, some patients may be hesitant to participate in interventions like animal-assisted therapy or virtual reality due to personal preferences or discomfort with the unfamiliar techniques. Dentists must consider the preferences and comfort levels of their patients when implementing these interventions to ensure their effectiveness and avoid potential resistance or non-compliance.

In light of these limitations, auditory beat stimulation emerges as a potential economical alternative for anxiety management in dental settings. Unlike many other non-pharmacological interventions, auditory beat stimulation 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.

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. Active music distraction involves the intentional engagement of the listener with the music, where they actively participate by choosing the music, adjusting the volume, or focusing on specific elements of the music. This type of

distraction can be highly personalized, allowing individuals to select music that resonates with their preferences and emotional state. Active music distraction may involve activities such as singing along, tapping to the rhythm, or mentally analyzing the music, thereby diverting attention away from discomfort or stressors.

On the other hand, passive music distraction entails the listener being passively exposed to music without active engagement or control over the musical stimuli. In passive music distraction, individuals may simply listen to background music provided by the environment or by others, without actively selecting or manipulating the music. This type of distraction can still be effective in diverting attention and reducing anxiety, as the rhythmic and melodic elements of music can evoke emotional responses and draw focus away from unpleasant stimuli. [Figure No. 19]

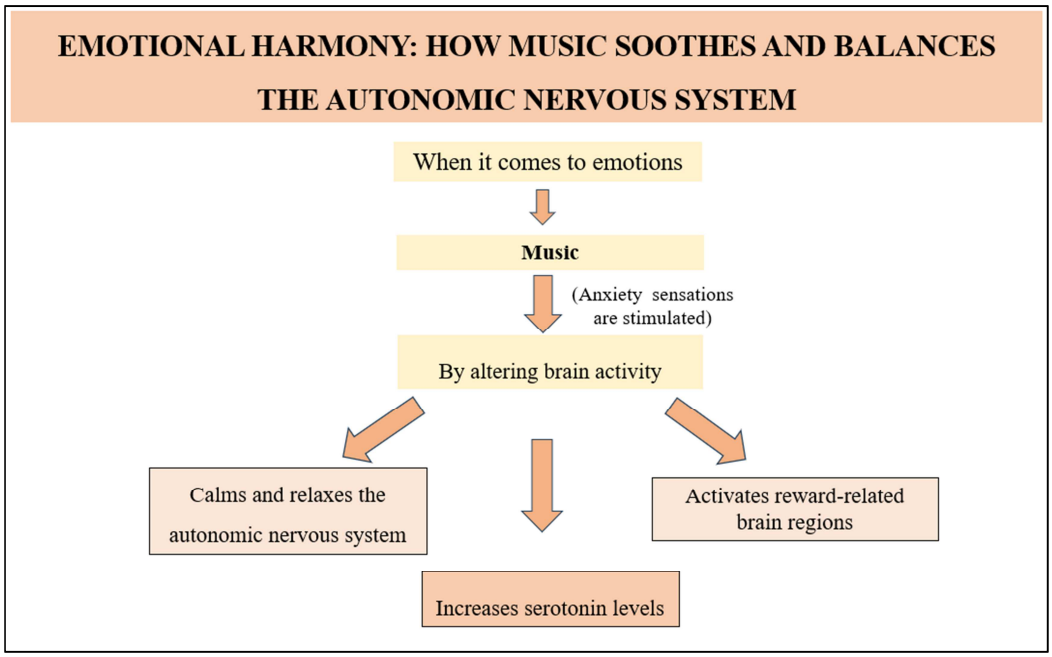

Figure No. 19: Photograph demonstrating how Music balances the ANS by altering the brain activity.

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 Isik et al[72], Singh et al[70], Chairinkam et al[71], Menziletoglu et al[73], Padmanabhan et al[78], Mallik and Russo[74], Aly et al[79], Perales et al[92,] Padawe et al[80], and Bhusari et al[82] all corroborate the effectiveness of binaural beats in reducing anxiety across various contexts, ranging from dental procedures to virtual reality environments.

Singh et al proposed a mechanism involving the stimulation of theta brainwaves leading to the release of endorphins, contributing to relaxation and reduced anxiety.[70] Chairinkam et al demonstrated that binaural beat interventions were more effective in reducing anxiety compared to other relaxation methods.[71] Additionally, studies by Isik et al and Menziletoglu et al specifically focused on dental anxiety and concluded that binaural beats could be beneficial in such contexts.[72,73] Moreover, Mallik and Russo observed significant reductions in both somatic and cognitive anxiety, particularly when theta auditory beat stimulation was combined with calming music.[74] Perales et al highlighted the superiority of binaural beats over non-binaural beats in inducing relaxation, especially when incorporated into virtual reality environments.[92] Similarly, Padmanabhan et al suggested the utility of binaural beats in producing anxiolysis in preprocedural settings, where pharmacological sedation might be undesirable.[78] Furthermore, Aly et al and Padawe et al specifically examined the effects of binaural beats in the context of orthodontic

treatment and pediatric dental procedures, respectively, both concluding that binaural beats effectively reduced anxiety.[79,80] Riera et al also found promising results when combining binaural beats with virtual reality to alleviate chronic pain in pediatric patients.[81]

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 these 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.[78] These different binaural beat ranges can produce stimulus waves that can synchronize a listener's brainwave activity and have associated psychophysiological consequences. [Figure No. 20]

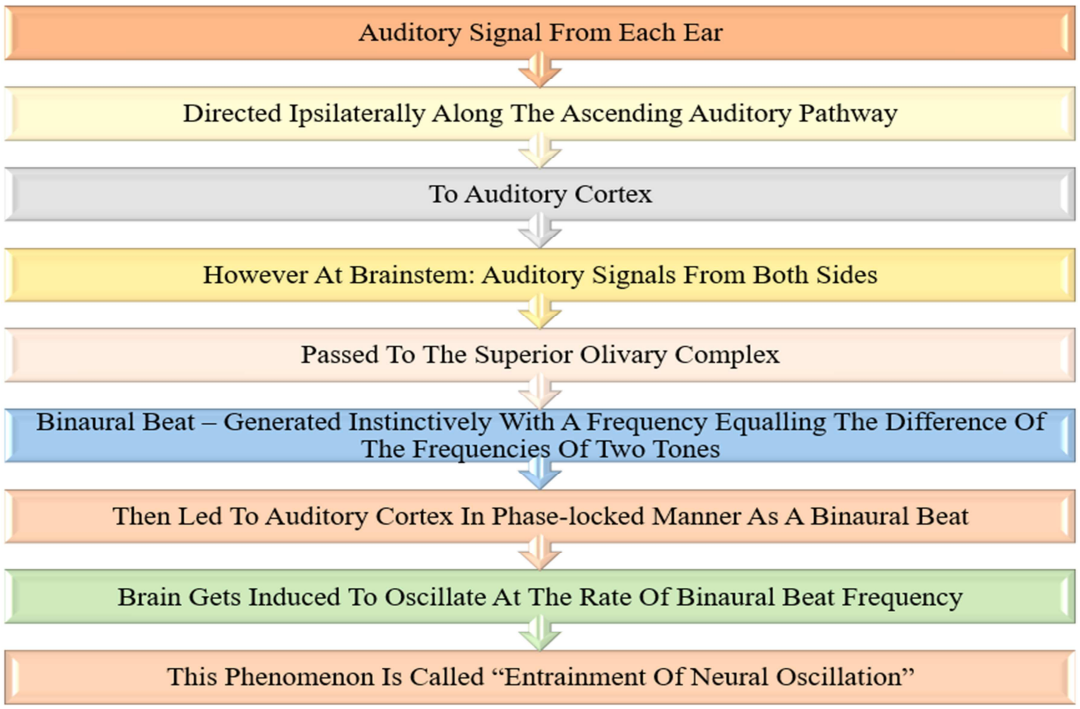

Figure No. 20: Photograph showing pathway of action of Binaural auditory beats in the brain.

However, it's important to acknowledge the contrasting findings from studies conducted by Kennel et al[75], Pratt et al[77], and Vernon et al[78]. 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.

According to the current study, the brainwave entrainment brought about by alpha wave stimulation may cause the hormone endorphin to be released, which would have the therapeutic effect of calming the patients. According to a recent meta-analysis of research on binaural beats, waves in the alpha/beta range have been linked to increased attentiveness, creativity, and vigilance, whereas waves in the delta/theta region are more likely to cause hypnosis and relaxation.[93] According to a different study, the highest levels of anxiety are conferred by binaural beat audio that is strong in delta brain-wave entrainment.[94]

Since music has also been implicated in reducing anxiety in general, various sources offer binaural beats conjugated with light music for added beneficial effects. In our study, we explored the efficacy of superimposed binaural beats, a novel technique involving the synthesis of additional binaural beats based on frequency shifting of sound waves from traditional musical instruments, alongside the original binaural beats generated by pure-tone sine wave-frequency differentiation. The literature has shown that there was no significant difference between original binaural auditory beats and superimposed binaural auditory beats.[79] It is expected that

superimposed binaural beat's quality and efficiency will be better than that of original binaural beat. Theoretically, an audio embedded with binaural beats can induce a predictable alteration in brainwave activity.[95]

Wiwatwongwana et al incorporated musical arrangements with relaxing components of melodies, tones and rhythms of 60-minute duration were embedded with the binaural beats. Natural sounds such as waterfall, bird chirping, ocean, river and forest sounds were also inserted and suggested that binaural beat embedded musical intervention may have additional anxiolytic effects over music without binaural beats.[80] Singh et al used superimposed beats on soft, relaxing music and found that 93.33% of the cases responded positively to binaural beats by the time of termination of treatment procedure.[96]

Chairinkam employed superimposed binaural beats, which are binaural beats created by synthesising additional beats based on frequency shifting of sound waves from traditional Thai musical instruments, except for drum sounds, which are produced by their extremely low frequency. Chairinkam also found that these superimposed binaural beats were more effective in reducing anxiety than other relaxation techniques.[71]

Weiland et al compared anxiety reduction effects of different original sound compositions (electroacoustic music, audio field recordings obtained from natural and constructed settings and audio field recordings with embedded binaural beat) with reconstructed ambient noise simulating an emergency department environment and headphones only without music in emergency department patients. They reported that musical interventions including binaural beat embedded compositions significantly

reduced anxiety compared with headphones only or simulated emergency department noise.[97]

Mallik et al used sound waves to produce combination tones, binaural beats, or monoaural beats in the alpha (8–13 Hz), beta (14–30 Hz), theta (4–8 Hz), gamma (30–50 Hz) or delta (1–4 Hz) frequency ranges with the intention of producing a neural frequency following response and found that combined and music-alone conditions had greater somatic state anxiety reduction than the pink-noise control.[74]

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.

The recent study's findings regarding the influence of music selection on children's anxiety levels resonate with several prior research endeavors, including those conducted by Marwah et al, Singh et al, and Jomon et al. These studies collectively support the notion that allowing children to choose their preferred music can contribute positively to anxiety reduction. Marwah et al's investigation, focusing on pediatric dental patients, revealed a decrease in anxiety levels, though not at a statistically significant level.[84] Singh et al's research corroborated the effectiveness of music choice in significantly reducing anxiety among pediatric dental patients.[86] Furthermore, Jomon et al's study compared the efficacy of different musical interventions and concluded that both music of choice and the Anandabhairavi raga were equally effective in alleviating pre-procedural anxiety.[87]

However, it's crucial to acknowledge the divergent findings from studies conducted by Karbandi et al and Kaur et al. Karbandi et al's research, which explored

the impact of music therapy and distraction cards on hospitalized children with chronic diseases, concluded that distraction cards were more effective in reducing anxiety and fear compared to music therapy.[85] Similarly, Kaur et al's study, which evaluated the efficacy of audio versus audiovisual distraction aids in managing anxiety among pediatric dental patients, found that audiovisual distraction was more effective than music of choice.[88]

Our study included children aged between 6 and 12 years as children in this age group are typically demonstrate significant advancements in cognitive abilities compared to younger age groups. They are better able to understand abstract concepts such as pain and anxiety and can articulate their experiences more effectively. This cognitive development allows for more reliable self-reporting of anxiety levels using standardized scales. Unlike younger children, they can comprehend the questions asked in the scales and provide more accurate responses. Also, by the age of 6, most children have developed sufficient language skills to express their thoughts and feelings, including sensations of anxiety or discomfort. This linguistic competence enables them to communicate their experiences during dental procedures, allowing for more nuanced and detailed data collection. Furthermore, between the ages of 6 and 12, children begin to develop coping mechanisms to deal with stressful situations. They may actively seek out strategies to manage their anxiety, such as listening to music or employing relaxation techniques. Understanding how different audio distraction techniques impact anxiety levels in this age group can provide valuable insights into the efficacy of these interventions. Thus, including children aged 6 to 12 years allowed for more reliable assessment of anxiety levels during restorative treatments due to their cognitive development, language skills, development of coping mechanisms and clinical relevance to the pediatric dental setting.

In the present study, we included restorative treatment as a standard treatment modality for several reasons. Firstly, restorations and extractions are common clinical procedures in pediatric dentistry, reflecting a typical scenario encountered in dental practice. These procedures often evoke anxiety and fear in children, attributed to factors such as fear of needles, discomfort, and unfamiliarity with the dental environment. Restorative treatments, in particular, involve the use of dental instruments like drills and needles, which are known to provoke anxiety in pediatric patients. This anxiety can manifest as behavioral problems, increased heart rate, or physiological symptoms such as sweating and restlessness. Effective management of anxiety in pediatric patients is crucial for successful dental treatment outcomes, as unmanaged anxiety may lead to the avoidance of dental care, thereby exacerbating dental problems and resulting in poor oral health outcomes in the long term. Moreover, in a clinical trial setting, it is essential to have standardized and objective measures for evaluating anxiety levels before, during, and after the intervention. Restorative treatments provide a tangible and measurable stimulus for assessing anxiety levels, enabling researchers to quantify the effectiveness of interventions such as music distraction as anxiety management techniques. Furthermore, ethical considerations play a significant role in conducting clinical trials involving pediatric patients. By incorporating routine restorative procedures into the trial protocol, researchers can minimize the risk of harm to participants while still evaluating interventions aimed at improving their dental experience.Therefore, selecting restorative treatment as a standard modality for anxiety evaluation in pediatric dental clinical trials involving music distraction is justified due to its common occurrence, potential to induce anxiety, need for anxiety management, relevance to distraction techniques, ability to provide objective measurements, and ethical considerations.

In our study, we utilized Venham's Picture Test as a method to subjectively evaluate anxiety levels in children. This test is chosen for its projective, psychometric, and self-measure characteristics, which have been demonstrated as valid means of assessing dental anxiety in clinical contexts. The Venham Picture Test offers several advantages, making it a widely used tool in clinical trials for assessing anxiety among children. Firstly, its ease of use makes it suitable for children of varying ages and cognitive abilities, ensuring broad applicability. The test involves presenting children with a series of pictures depicting different scenarios, allowing them to express their feelings about each image. This subjective evaluation is particularly valuable for capturing the nuanced experiences of anxiety, especially in children who may struggle to articulate their emotions.

Additionally, the child-friendly approach of using pictures enhances engagement and reduces potential stress associated with traditional assessment methods, fostering more accurate responses. The reliability and validity of the Venham Picture Test have been extensively validated, ensuring consistency and meaningfulness of results. Its self-measure aspect empowers children to assess and express their anxiety levels, providing valuable insights into their subjective experiences. Incorporating such a comprehensive and validated assessment tool strengthens the credibility and reliability of our study findings, enhancing the overall scientific validity of our research on pediatric dental anxiety. Overall, the Venham Picture Test offers a practical and effective means of assessing anxiety in children within the context of clinical trials, providing researchers with valuable data to inform treatment strategies and improve outcomes for pediatric patients.

In our study, we utilized a pulse oximeter to objectively assess anxiety levels in children, focusing on changes in heart rate as a physiological marker of anxiety. While an increase in heart rate is a direct outcome of sympathetic activation brought on by anxiety, employing a Finger Pulse Oximeter in clinical trials offers several advantages for objective evaluation. Firstly, it provides an objective physiological measure of anxiety, allowing researchers to accurately quantify anxiety levels in children by tracking changes in heart rate. This non-invasive method is safe and well-tolerated by children, involving the simple placement of a sensor on the fingertip to measure pulse rate. Real-time monitoring capabilities enable researchers to assess the impact of interventions on anxiety-related physiological responses dynamically throughout the trial, providing valuable insights into intervention effectiveness. The quantitative data produced by finger pulse oximeters facilitates statistical analysis and comparison across participants and time points, enhancing the robustness of study results. Moreover, their portability and affordability make them suitable for use in diverse clinical and research settings, including those with limited resources, thus increasing the accessibility and generalizability of study findings. Overall, employing finger pulse oximeters in clinical trials offers a reliable and versatile method for objectively evaluating anxiety in pediatric populations. Therefore, it can be useful to combine psychometric and physiological methods of assessment in order to provide both quantitative and qualitative estimates of anxiety. Aitken et al[100], Marwah et al.[84], Singh et al.[86], Navit et al.[38], Nuvvula et al.[101], Ozkalayci et al.[52], Gupta et al.[102], and Ghadimi et al.[103] have also documented the use of heart rate to quantify anxiety during dental treatment.

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.[104] It has been proposed that tones in the 200–900 Hz range are more effective for evoking binaural beats.[94] In dental settings, a brief 10-minute period has been shown to be effective in considerably lowering pre-operative anxiety.[72]

In our study evaluating anxiety during restorative dental procedures among children, the decision to utilize headphones instead of speakers for the intervention group, which involved binaural auditory beats and music of choice, is rooted in several key considerations. Firstly, headphones offer a controlled audio environment, ensuring consistent sound quality and volume levels for all participants regardless of their position in the room, thus maintaining experimental consistency. Additionally, headphones aid in noise reduction, effectively minimizing external disturbances such as equipment noise or conversations in the dental setting, thereby enhancing the focus on the intervention stimuli. Binaural beats, a critical component of the intervention, rely on the brain's ability to process distinct frequency differences presented separately to each ear. Consequently, over-the-head headphones are preferred for delivering binaural beats due to their superior isolation, consistency, spatial separation, and comfort compared to other audio delivery methods like speakers or in-ear headphones. These features ensure optimal delivery of the intervention, potentially mitigating anxiety levels and enhancing the overall experience of dental procedures for pediatric patients.

The inclusion criteria employed in the present study have been thoughtfully selected to ensure the investigation captures a specific subset of the population and dental condition relevant to pediatric dentistry. By including children who are visiting the dental clinic for the first time, the study aims to minimize potential biases associated with prior treatment experiences. Focusing on children requiring

restoration for Class 1 cavity in primary or permanent molar teeth allows the research to concentrate on a well-defined dental condition commonly encountered in pediatric practice, offering insights into the efficacy of restorative treatments for this prevalent issue. Additionally, by selecting children with moderate dental caries involving enamel and dentin, ensures that the study focuses on cases where dental caries have progressed beyond the enamel layer but have not yet reached a depth where pulp therapy (such as pulpotomy or pulpectomy) is indicated.

Similarly, the exclusion criteria employed in this study have been carefully chosen. By excluding children with special health care needs, the study aims to streamline its focus on a more homogeneous sample, thereby reducing potential variability in treatment responses and outcomes that could arise from underlying health conditions. Similarly, excluding children exhibiting Frankl Behavior ratings of 1 and II (Definitely negative and Negative) helps to eliminate cases where behavioral factors may significantly impact treatment outcomes, ensuring that the study's findings are more indicative of typical patient responses to dental interventions. By excluding children with visual or auditory impairments, the study ensures that participants can fully engage with the assessment tools and intervention techniques utilized. This decision promotes the accuracy and reliability of subjective anxiety assessments conducted through the Venham Picture Test, which relies on visual cues for evaluation. Additionally, by excluding children with auditory impairments, the study safeguards the integrity of the music distraction intervention, which relies on auditory stimuli to divert attention during restorative dental treatment. Finally, excluding children and/or parents who are unwilling to participate ensures that the study's sample comprises individuals fully engaged in the research process, thereby

enhancing data quality and minimizing potential biases associated with non-participation.

The results of our study have led to the rejection of the null hypothesis. Through rigorous analysis, it has been determined that there is indeed a statistically significant difference in anxiety levels during restorative treatment among children aged 6–12 years when utilizing different audio distraction techniques. Consequently, our alternate hypothesis, asserting such a distinction, has been accepted. This finding underscores the importance of considering alternative audio modalities, such as music of choice and binaural auditory beats, in mitigating anxiety during dental procedures for this age group.

The clinical significance within the field of dentistry gleaned from our study's findings is multi-faceted and impactful. Firstly, our investigation into various audio distraction techniques stands to significantly enhance the patient experience during restorative dental procedures for children. Identifying effective strategies to alleviate anxiety can markedly improve young patients' comfort levels and cooperation, ultimately enhancing greater satisfaction with dental visits. Moreover, this knowledge empowers clinicians to tailor anxiety management approaches according to individual patient preferences and requirements, thereby optimizing treatment outcomes. Additionally, our randomized clinical trial enhance the existing evidence base supporting the efficacy of audio distraction techniques in pediatric dentistry. By rigorously demonstrating the effectiveness of these interventions through scientific research, our study promotes evidence-based practice and encourages the adoption of innovative anxiety management strategies in clinical settings. Notably, non-pharmacological alternatives like binaural auditory beats offer promising avenues for

anxiety reduction, potentially reducing the reliance on sedation or pharmacological interventions in pediatric dental care. Integrating such techniques into routine practice not only mitigates associated risks but also fosters a more holistic approach to pediatric dental treatment.

Furthermore, our study's focus on addressing anxiety and cultivating positive dental experiences in childhood carries broader implications for long-term oral health. Children who undergo positive dental encounters are more inclined to maintain regular dental care into adulthood, thereby enhancing overall oral health outcomes over time. Moreover, effective anxiety management techniques can streamline dental procedures, potentially reducing treatment time and associated costs. By minimizing the need for sedation or additional interventions, audio distraction methods may contribute to overall cost savings in pediatric dental care, underscoring the far-reaching benefits of our research findings.

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.

The following would be the futuristic ideas of our study:

1. Multisensory Integration of Binaural Auditory Beats with Visual Stimuli: To investigate the synergistic effects of combining binaural auditory beats with visual relaxing stimuli to enhance anxiety reduction in pediatric dental patients. Develop a multimedia intervention that synchronizes binaural beats with visually calming

images or videos, such as nature scenes, underwater footage, or abstract patterns. Conduct a randomized controlled trial to assess the comparative efficacy of audio-visual interventions versus auditory-only interventions in reducing apprehensiveness during dental procedures among children. Utilize advanced technology, such as virtual reality (VR) or augmented reality (AR) to create immersive and personalized relaxation experiences tailored to individual patient preferences.

2. To perform a systematic review and meta-analysis of existing trials investigating the effects of specific binaural beat frequencies regarding the efficacy of different frequency ranges on relaxation and anxiety reduction. Analyze the neurophysiological mechanisms underlying the effects of binaural beats on brainwave activity, focusing on frequency-specific modulations of alpha, beta, theta, and delta waves. Utilize advanced statistical techniques, such as network meta-analysis, to compare the relative effectiveness of different binaural beat frequencies and generate evidence-based recommendations for optimal frequency selection in clinical practice.

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.

The following conclusions are drawn from the present study:

1. When comparison of pre- and post-operative Venham's picture test score and Pulse rate score were done among the three groups, maximum reduction in anxiety was observed in both Music of choice and Binaural auditory beats groups.

2. When pair wise comparison was done between Control group and Music of choice & Binaural auditory beats group, a statistically significant difference was observed which indicated the efficacy of both the modalities in reducing the anxiety among children during restorative treatment. However. when pair wise comparison was done between Music of choice and Binaural auditory beats group no significant difference was observed, showing their equi-efficiency in reduction of anxiety.

Thus, the present study concludes that binaural auditory beat and music of choice were found to be highly effective in reduction of anxiety during dental treatment. Both are novel methods that can efficiently serve as a safer and effective adjunct for the behaviour management of children.

SUMMARY

"Exploring the depths of science is akin to embarking on a voyage through the cosmos, where each discovery is a star illuminating the path of knowledge."

- Martin

Dental anxiety, particularly prevalent among children, can heighten during procedures perceived as uncomfortable or frightening. Recent years have seen increased interest in non-pharmacological anxiety management in dental settings, with auditory beat stimulation emerging as a promising and cost-effective alternative. This method offers potential for effectively alleviating anxiety during dental procedures, presenting a valuable option for enhancing patient comfort and overall dental experience.

The present study was conducted on children aged 6-12 years with the aim to evaluate and compare no music, music of choice and binaural auditory beats as audio distraction behaviour guidance technique during restorative treatment. Seventy-five children were selected according to the inclusion criteria. The teeth with Class I cavity in primary and permanent molars were prepared and restored. Anxiety was measured pre- and post-intervention using Pulse oximeter and Venham's picture test. Children were randomly divided into three groups namely Group I as No music group, Group II as Music of choice group and Group III as Binaural auditory beats group.

Our study showed 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.

BIBLIOGRAPHY

1. Gatchell RJ, Ingersoll BD, Bowman L, Robertson MC, Walker C. The prevalence of dental fear and avoidance: a recent survey study. J Am Dent Assoc. 1983;107(4):609–610
2. Agras S, Sylvester D, Oliveau D. The epidemiology of common fears and phobia. Compr Psychiatry. 1969;10(2):151–156.
3. Appukuttan DP. Strategies to manage patients with dental anxiety and dental phobia: Literature review. Clin Cosmet Investig Dent 2016;8:35-50.
4. Berggren U, Hakeberg M, Carlsson SG. No differences could be demonstrated between relaxation therapy and cognitive therapy for dental fear. J Evid Based Dent Pract. 2001;1(2):117–118.
5. Weisenberg M, Aviram O, Wolf Y, Raphaeli N. Relevant and irrelevant anxiety in the reaction to pain. Pain. 1984;20(4):371–383.
6. Al Absi M, Rokke PD. Can anxiety help us tolerate pain? Pain. 1991; 46(1):43–51.
7. Al-Khotani A, Bello LA, Christidis N. Effects of audiovisual distraction on children's behaviour during dental treatment: A randomized controlled clinical trial. Acta Odontol Scand 2016;74:494-501.
8. Armfield JM, Stewart JF, Spencer AJ. The vicious cycle of dental fear: exploring the interplay between oral health, service utilization and dental fear. BMC Oral Health. 2007;7:1.
9. Cohen SM, Fiske J, Newton JT. The impact of dental anxiety on daily living. Br Dent J. 2000;189(7):385–390.

10. Locker D, Shapiro D, Liddell A. Overlap between dental anxiety and blood-injury fears: psychological characteristics and response to dental treatment. *Behav Res Ther*. 1997;35(7):583–590.
11. Seeman K, Molin C. Psychopathology, feelings of confinement and helplessness in the dental chair, and the relationship to the dentist in patients with disproportionate dental anxiety (DDA). *Acta Psychiatry Scand*. 1976;54(2):81–91.
12. Ost LG, Hugdahl K. Acquisition of blood and dental phobia and anxiety response in clinical patients. *Behav Res Ther*. 1985;23(1):27–34.
13. Oosterink FM, de Jongh A, Aartman IH. What are people afraid of during dental treatment? Anxiety-provoking capacity of 67 stimuli characteristic of the dental setting. *Eur J Oral Sci*. 2008;116(1):44–51.
14. Walsh LJ. Anxiety prevention: implementing the 4 S principle in conservative dentistry. *Auxiliary*. 2007;17(5):24–26.
15. Hmud R, Walsh LJ. Dental anxiety: causes, complications and management approaches. *J Minim Interv Dent*. 2009;2(1):67–78.
16. Milgrom P, Weinstein P, Getz T. *Treating Fearful Dental Patients: A Patient Management Handbook*. Seattle: Reston Prentice Hall; 1995
17. Willumsen T, Vassend O. Effects of cognitive therapy, applied relaxation and nitrous oxide sedation: a five-year follow-up study of patients treated for dental fear. Acta Odontol Scand. 2003;61(2):93–99.
18. Thom A, Sartory G, Jöhren P, Deecke L. Comparison between one-session psychological treatment and benzodiazepine in dental phobia. J Consult Clin Psychol. 2000;68(3):378–387.
19. Forbes MD, Boyle CA, Newton T. Acceptability of behaviour therapy for dental phobia. Community Dent Oral Epidemiol. 2012; 40(1):1–7.

20. Newton JT, Naidu R, Sturmey P. The acceptability of the use of sedation in the management of dental anxiety in children: views of dental students. Eur J Dent Educ. 2003;7(2):72–76.
21. White JM. State of the science of music interventions: critical care and perioperative practice. Crit Care Nurs Clin North Am. 2000; 12(2):219–225.
22. Moola S, Pearson A, Hagger C. Effectiveness of music interventions on dental anxiety in paediatric and adult patients: a systematic review. JBI Database System Rev Implement Rep. 2011;9(18):588–630.
23. Asl AN, Shokravi M, Jamali Z, Shirazi S. Barriers and Drawbacks of the Assessment of Dental Fear, Dental Anxiety and Dental Phobia in Children: A Critical Literature Review. J Clin Pediatr Dent. 2017;41(6):399-423.
24. Gardner, WJ; Licklider JC (1959). "Auditory analgesia in dental operations". J Am Dent Assoc. 59 (6): 1144–1149.
25. August RV. Hypnosis in obstetrics: varying approaches. American Journal of Clinical Hypnosis. 1965 Jul 1;8(1):47-51.
26. Essentials of Medical Physiology, Sembulingam, 6th edition, JAYPEE Publishers (P). Ltd. New Delhi. 2012:1013-1021.
27. Textbook of Medical Physiology, Guyton and Hall, 13th Edition, ELSEVIER (P) Ltd. Philadelphia. 2016.
28. Robinson PD, Pitt Ford TR, McDonald F. Local Anaesthesia in Dentistry. 7th ed. Oxford: Butterworth-Heinemann Ltd.; 2000.
29. Howitt, Jack W., "An evaluation of audio-analgesia effects," Journal of Dentistry for Children, 34:406-411, September 1967.

30. Petrie, Asenath, Taffy Holland, and Irene Wolk, "Sensory stimulation causing subdued experience: audio-analgesia and perceptual augmentation and reduction," Journal of Nervous and Mental Disease, 137:312-321, October 1963.
31. Liu Y, Petrini MA. Effects of music therapy on pain, anxiety, and vital signs in patients after thoracic surgery. Complement Ther Med. 2015;23(5):714-718.
32. Carlin, Sidney, et al., "Sound stimulation and its effects on dental sensation threshold," Science, 138:1258-1259,1962.
33. Melzack, R., "Perception of pain," Scientific American, 204:41-49, 1961.
34. Alkahtani ZM, Zakirulla M, Alshehri ES, Alqahtani, Alshehri MM. The Effect of Music on Children's Anxiety During Dental Treatment. J. Res. Med. Dent. Sci. 2020;8(3):39-43
35. Tshiswaka SK, Pinheiro SL. Effect of music on reducing anxiety in children during dental treatment. RGO, Rev Gaúch Odontol. 2020;68:e20200033
36. Buranavichetkul O, Klinklai S, Teparat-Burana T. Effect of Music Intervention on Anxiety in Patients Undergoing Periodontal Surgery: A Pilot Study. SOJ Den Oral Disor.2021;1(1):1–6. 000503
37. Packyanathan JS, Lakshmanan R, Jayashri P. Effect of music therapy on anxiety levels on patient undergoing dental extractions. J Family Med Prim Care 2019;8:3854-60.
38. Navit S, Johri N, Khan SA, Singh RK, Chadha D, Navit P, Sharma A, Bahuguna R. Effectiveness and Comparison of Various Audio Distraction Aids in Management of Anxious Dental Paediatric Patients. J Clin Diagn Res. 2015 Dec;9(12):ZC05-9.

39. Chen LC, Wang TF, Shih YN, Wu LJ. Fifteen-minute music intervention reduces pre-radiotherapy anxiety in oncology patients. Eur J Oncol Nurs. 2013 Aug;17(4):436-41.
40. Rao A, Raju A, Kashyap RS, Vijaya K, Boloor V, Patil S. Impact of passive music intervention in subjects with self-reported moderate to high dental anxiety undergoing ultrasonic scaling procedure. J Oral Health Oral Epidemiol 2021; 10(1): 23-8.
41. Naithani M, Viswanath D. Child's dental anxiety: Management by audio and audio-Visual distraction technique - A comparative study. Univ Res J Dent 2014;4:101-7.
42. Goshvarpour A, Abbasi A, Goshvarpour A, Karamloo N, Ghorbani F. Effects of music on cardiac functioning in young women and men. Applied Medical Informatics. 2013;33(4):40.
43. White JM. Effects of relaxing music on cardiac autonomic balance and anxiety after acute myocardial infarction. American Journal of Critical Care. 1999;8(4):220.
44. Gebauer L, Witek M, Hansen NC, Thomas J, Konvalinka I, Vuust P, editors. The influence of oxytocin on interpersonal rhythmic synchronization and social bonding. The Neurosciences and Music-V; 2014.
45. Halbert JD, Van Tuyll DR, Purdy C, Hao G, Cauthron S, Crookall C, et al. Low Frequency Music Slows Heart Rate and Decreases Sympathetic Activity. Music Med. 2018;10(4):180.
46. Steelman VM: Intraoperative music therapy. Effects on anxiety, blood pressure. AORN J, 1990; 52: 1026–34.

47. Salamon E, Kim M, Beaulieu J, Stefano GB: Sound therapy induced relaxation: down regulating stress processes and pathologies. Med Sci Monit, 2003; 9: RA96–RA101
48. Stefano GB, Goumon Y, Casares F et al: Endogenous morphine. Trends in Neurosciences, 2000; 9: 436–42
49. Mejía-Rubalcava C, Alanís-Tavira J, Mendieta-Zerón H, Sánchez-Pérez L. Changes induced by music therapy to physiologic parameters in patients with dental anxiety. Complement Ther Clin Pract. 2015 Nov;21(4):282-6.
50. Yamashita K, Kibe T, Ohno S, Kohjitani A, Sugimura M. The Effects of Music Listening During Extraction of the Impacted Mandibular Third Molar on the Autonomic Nervous System and Psychological State. J Oral Maxillofac Surg. 2019 Jun;77(6):1153.e1-1153.e8.
51. Koch ME, Kain ZN, Ayoub C, Rosenbaum SH. The sedative and analgesic sparing effect of music. Anesthesiology. 1998 Aug;89(2):300-6.
52. Ozkalayci O, Araz C, Cehreli SB, Tirali RE, Kayhan Z. Effects of music on sedation depth and sedative use during pediatric dental procedures. J Clin Anesth. 2016 Nov;34:647-53.
53. Chaieb L, Wilpert EC, Hoppe C, Axmacher N, Fell J. The Impact of Monaural Beat Stimulation on Anxiety and Cognition. Front Hum Neurosci. 2017;11:251.
54. International Organization for Standardization. ISO/TC 43 Acoustics. Acoustic measurements and noise abatement in general: Acoustics — Standard tuning frequency (Standard musical pitch) [Internet]. ISO 16:1975.
55. Calamassi D, Pomponi GP. Music Tuned to 440 Hz Versus 432 Hz and the Health Effects: A Double-blind Cross-over Pilot Study. Explore (NY). 2019;15(4):283-290.

56. Grey JM, Gordon JW. Perceptual effects of spectral modifications on musical timbres. J Acoust Soc Am. 1978;63(5):1493-500.
57. Padmanabhan, V.; Islam, M.S.; Habib, M.; Abdulaziz, Z.; Goud, M.; Chaitanya, N.C.S.K.; Haridas, S.; Rahman, M.M. Association between Salivary Cortisol Levels, Dental Anxiety, and Dental Caries in Children: A Cross-Sectional Study. Dent. J. 2023, 11, 205.
58. Aravena PC, Almonacid C, Mancilla MI. Effect of music at 432 Hz and 440 Hz on dental anxiety and salivary cortisol levels in patients undergoing tooth extraction: a randomized clinical trial. J Appl Oral Sci. 2020;28:e20190601.
59. Di Nasso L, Nizzardo A, Pace R, Pierleoni F, Pagavino G, Giuliani V. Influences of 432 Hz Music on the Perception of Anxiety during Endodontic Treatment: A Randomized Controlled Clinical Trial. J Endod. 2016 Sep;42(9):1338-43.
60. Joshi, G.N. (1977) Understanding Indian Classical Music. Bombay: Taraporevala.
61. Seaward, B.L. (1999) Managing Stress: Principles and Strategies for Health and Wellbeing. Sadbury, MA: Jones and Bartlet.
62. Balan R, Bavdekar SB, Jadhav S. Can Indian classical instrumental music reduce pain felt during venepuncture? Indian J Pediatr. 2009 May;76(5):469-73.
63. Gowdham G, Shetty AA, Hegde A, et al. Impact of Music Distraction on Dental Anxiety in Children Having Intellectual Disability. Int J Clin Pediatr Dent 2021;14(1):170–174.
64. Gupta U, Gupta BS. Psychophysiological responsivity to Indian instrumental music. Psychol Music. 2005;33(4):363-372.
65. Bach E. Heal Thyself: An Explanation of the Real Cause and Cure of Disease. Saffron Walden, Essex, UK: C.W. Daniel; 1931.

66. Dixit UB, Jasani RR. Comparison of the effectiveness of Bach flower therapy and music therapy on dental anxiety in pediatric patients: A randomized controlled study. J Indian Soc Pedod Prev Dent 2020;38:71-8.
67. Oster G. Auditory beats in the brain. Sci Am 1973;229:94–102.
68. Lavallee CF, Koren SA, Persinger MA. A quantitative electroencephalographic study of meditation and binaural beat entrainment. J Altern Complement Med. 2011;**17**(4):351–5.
69. Grose, J. H., and Mamo, S. K. Electrophysiological measurement of binaural beats: effects of primary tone frequency and observer age. Ear Hear.2012; 33:187–194.
70. Singh SS, Yadav T, Rodricks K, Patel D. Effectivity of binaural beats in reduction of anxiety during dental treatment in pediatric patients. IOSR J Dent Med Sci 2021;22:1338-43.
71. Chairinkam W, Thaikruea L, Klaphajone J, Lerttrakarnnon P. Effects of newly-developed superimposed binaural beat on anxiety in university students in Thailand: A randomised controlled trial. Chiang Mai Univ J Nat Sci 2019;18:122-30.
72. Isik BK, Esen A, Büyükerkmen B, Kilinç A, Menziletoglu D. Effectiveness of binaural beats in reducing preoperative dental anxiety. British Journal of Oral and Maxillofacial Surgery. 2017;55:571–4.
73. Menziletoglu D, Guler AY, Cayır T, Isik BK. Binaural beats or 432 Hz music? Which method is more effective for reducing preoperative dental anxiety? Med Oral Patol Oral Cir Bucal. 2021;26:97–101.

74. Mallik A, Russo FA (2022) The effects of music & auditory beat stimulation on anxiety: A randomized clinical trial. PLoS ONE 17(3): e0259312
75. Kennel S, Taylor AG, Lyon D, Bourguignon C. Pilot feasibility study of binaural auditory beats for reducing symptoms of inattention in children and adolescents with attention-deficit/hyperactivity disorder. J Pediatr Nurs. 2010 Feb;25(1):3-11.
76. Padmanabhan R, Hildreth AJ, Laws D. A prospective, randomised, controlled study examining binaural beat audio and pre-operative anxiety in patients undergoing general anaesthesia for day case surgery. *Anaesthesia*. 2005;60(9):874-877
77. Pratt H, Starr A, Michalewski HJ, Dimitrijevic A, Bleich N, Mit¬telman N. A comparison of auditory evoked potentials to acoustic beats and to binaural beats. Hear Res. 2010;262:34-44.
78. Vernon D, Peryer G, Louch J, Shaw M. Tracking EEG changes in response to alpha and beta binaural beats. Int J Psychophysiol. 2014 Jul;93(1):134-9.
79. Aly AE, Hansa I, Ferguson DJ, Vaid NR. The effect of alpha binaural beat music on orthodontic pain after initial archwire placement: A randomized controlled trial. Dental Press J Orthod. 2023 Feb 13;27(6):e2221150.
80. Padawe D, Chettiankandy TJ, Rathi GV, Sachdev SS, Takate VS, Yadav T. Effectivity of binaural beats in reduction of anxiety during dental treatment in pediatric patients. Glob J Med Pharm Biomed Update 2023;18:3.
81. Riera L, Verger S, Montoya PJ, Perales FJ. Advances in the Cognitive Management of Chronic Pain in Children through the Use of Virtual Reality Combined with Binaural Beats: A Pilot Study. Genet Res (Camb). 2022;2022.
82. Bhusari BN, Hugar SM, Kohli N, Karmarkar S, Gokhale N, Saxena N. Comparative evaluation of anxiety level during restorative treatment using no

music, monaural beats, and binaural auditory beats as audio distraction behavior guidance technique in children aged 6-12 years: A randomized clinical trial. J Indian Soc Pedod Prev Dent. 2023;41(2):156-162.

83. Klein SA, Winkelstein ML. Enhancing pediatric health care with music. J Pediatr Health Care. 1996 Mar-Apr;10(2):74-81.
84. Marwah N, Prabhakar AR, Raju OS. Music distraction--its efficacy in management of anxious pediatric dental patients. J Indian Soc Pedod Prev Dent. 2005 Oct-Dec;23(4):168-70.
85. Karbandi, S., Soltanifar, A., Salari, M., Asgharinekah, S. M., Izie, E. Effect of Music Therapy and Distraction Cards on Anxiety among Hospitalized Children with Chronic Diseases. Evidence Based Care, 2020; 9(4): 15-22.
86. Singh D, Samadi F, Jaiswal J, Tripathi AM. Stress Reduction through Audio Distraction in Anxious Pediatric Dental Patients: An Adjunctive Clinical Study. Int J Clin Pediatr Dent. 2014 Sep-Dec;7(3):149-52.
87. Cu J. Jomon CU, et al: Effectiveness of Choice music and Anandabhairavi Raga on adult patients' pre-procedural anxiety. 2015;1(1):34–8.
88. Kaur R, Jindal R, Dua R, Mahajan S, Sethi K, Garg S. Comparative evaluation of the effectiveness of audio and audiovisual distraction aids in the management of anxious pediatric dental patients. J Indian Soc Pedod Prev Dent 2015;33:192-203.
89. Arthur J. Nowak. Pediatric Dentistry: Infancy Through Adolescence. 6th edition. ELSEVIER Ltd. 2019.
90. Walsh LJ. Anxiety prevention: implementing the 4 S principle in conservative dentistry. *Auxiliary*. 2007;17(5):24–26.
91. Piaget, J., & Inhelder, B. (1969). The psychology of the child. New York: Basic Books.

92. F. J. Perales, M. Sanchez, L. Riera and S. Ramis, "A Pilot Study: VR and Binaural Sounds for Mood Management," 2018 22nd International Conference Information Visualisation (IV), Fisciano, Italy, 2018, pp. 442-447

93. Garcia-Argibay M, Santed MA, Reales JM. Efficacy of binaural auditory beats in cognition, anxiety, and pain perception: A meta-analysis. Psych Res 2019;83:357-72.

94. Poggio, G . F., and Mountcastle, V. B. A study of the functional contributions of the lemniscal ana spinothalamic systems to somatic sensibility. Bull. Johns Hopkins Hosp. I960;106:266

95. Doherty C. A comparison of alpha brainwave entrainment, with and without musical accompaniment. Bachelors Final Year Project [Internet]. Dublin: Dublin Business School; 2014.

96. Wiwatwongwana D, Vichitvejpaisal P, Thaikruea L, Klaphajone J, Tantong A, Wiwatwongwana A; Medscape. The effect of music with and without binaural beat audio on operative anxiety in patients undergoing cataract surgery: a randomized controlled trial. Eye (Lond). 2016 Nov;30(11):1407-1414.

97. Weiland TJ, Jelinek GA, Macarow KE, Samartzis P, Brown DM, Grierson EM, Winter C. Original sound compositions reduce anxiety in emergency department patients: a randomised controlled trial. Med J Aust. 2011 Dec 19;195(11-12):694-8.

98. Efficacy of binaural auditory beats in cognition, anxiety, and pain perception: A meta-analysis. Psych Res 2019;83:357-72.

99. Le Scouarnec RP, Poirier RM, Owens JE, Gauthier J, Taylor AG, Foresman PA. Use of binaural beat tapes for treatment of anxiety: a pilot study of tape preference and outcomes. Alternative Therapies in Health and Medicine 2001; 7: 58–63.

100. Aitken JC, Wilson S, Coury D, Moursi AM. The effect of music distraction on pain, anxiety and behavior in pediatric dental patients. Pediatr Dent. 2002;24(2):114-8.

101. Nuvvula S, Alahari S, Kamatham R, Challa RR. Effect of audiovisual distraction with 3D video glasses on dental anxiety of children experiencing administration of local analgesia: a randomised clinical trial. Eur Arch Paediatr Dent. 2015;16(1):43-50.

102. Gupta N, Gupta H, Gupta P, Gupta N. Evaluation of the role of music as a nonpharmacological technique in management of child patients. J Contemp Dent Pract. 2017;18(3):194-197.

103. Ghadimi S, Estaki Z, Rahbar P, Shamshiri AR. Effect of visual distraction on children's anxiety during dental treatment: a crossover randomized clinical trial. Eur Arch Paediatr Dent. 2018;19(4):239-44. http://dx.doi.org/10.1007/s40368-018- 0352-x

104. Becher AK, Höhne M, Axmacher N, Chaieb L, Elger CE, Fell J. Intracranial electroencephalography power and phase synchronization changes during monaural and binaural beat stimulation. Eur J Neurosci 2015;41:254-63.

ANNEXURE I:

ETHICAL CLEARANCE CERTIFICATE

KLE V.K. Institute of Dental Sciences

(A Constituent unit of KLE Academy of Higher Education & Research
Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Nehru Nagar, Belagavi-590 010 INDIA
Accredited 'A' grade by NAAC (3rd Cycle) & Placed in Category 'A' by MHRD (GoI)
☎: 0831-2470362
FAX: 0831-2470640
Web: http://www.kledental-bgm.edu.in
E-mail: principal@kledental-bgm.edu.in

Sl. No. 92

Approval Letter

INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE KLE VKIDS

Ref: IEC/KLE VKIDS/2022/ **Date:**

To.....

Sub: Review of your application for conduct of study

The Institutional Ethics Committee of KLE VKIDS, Belagavi has reviewed and discussed your application to conduct the research:-

Protocol Title: Comparative evaluation of anxiety levels during..... restorative treatment using no music, music of choice and binaural auditory beats as audio distraction behaviour guidance technique in children aged 6-12yrs - A Randomized clinical trial -)

The following documents were reviewed:

1. **Study Protocol synopsis**
2. **Consent form**

Discussion Points:

IEC of KLE VKIDS meeting was held on 19/3/22 at ..... in college council hall, KLE VKIDS, Belagavi. IEC considered your application letter dated: 19/3/22 IEC reviewed and discussed the above submitted study related documents. IEC has decided to approve the study & study related documents. The decision on the protocol is as under:

1.	Approved - [We approve the trial to be conducted in its present form]	✓
2.	Approved with suggestions/conditions	
3.	Minor modification/ Amendments	
4.	Major modification for full board review	
5.	Disapproved	

The study is approved for the duration: 6 months/1 year/ more than 1 year

Conflict of Interest: ~~Yes~~/ No

Note: *It is to be noted that neither PI nor any of the proposed study team members were present during the decision-making procedures of the Ethics Committee and members who are independent of the Investigator and the Sponsor of the trial have voted/provided opinion on the trial. The Institutional Ethical Committee follows procedures that are in compliance with the requirements of ICMR(Indian Council of Medical Research) guidance related to GCP (Good Clinical Practice) and New Drugs and Clinical Trial Rules, 2019.*

Yours truly,

Dr. Anil V Ankola
Member Secretary, IEC KLE VKIDS

ANNEXURE II:

CTRI REGISTRATION CERTIFICATE

CLINICAL TRIALS REGISTRY - INDIA
ICMR - National Institute of Medical Statistics

PDF of Trial
CTRI Website URL - http://ctri.nic.in

Clinical Trial Details (PDF Generation Date :- Sun, 07 Apr 2024 04:41:11 GMT)

CTRI Number	CTRI/2024/02/063286 [Registered on: 29/02/2024] - **Trial Registered Prospectively**
Last Modified On	07/04/2024
Post Graduate Thesis	Yes
Type of Trial	Interventional
Type of Study	Dentistry Behavioral
Study Design	Randomized, Parallel Group, Multiple Arm Trial
Public Title of Study	Audio distraction for behaviour guidance technique during dental treatment in children
Scientific Title of Study	Comparative evaluation of anxiety levels 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: A Randomized clinical trial

Secondary IDs if Any

Secondary ID	Identifier
NIL	NIL

Details of Principal Investigator or overall Trial Coordinator (multi-center study)

Details of Principal Investigator	
Name	
Designation	Post graduate student
Affiliation	KLE VK Institute Of Dental Sciences, Belagavi
Address	Department of Pediatric and Preventive dentistry, KAHERs KLE VK Institute of dental sciences, Nehru Nagar, Belagavi Belgaum KARNATAKA 590010 India
Phone	
Fax	
Email	

Details Contact Person (Scientific Query)

Details Contact Person (Scientific Query)	
Name	
Designation	Professor and Head
Affiliation	KLE VK Institute Of Dental Sciences, Belagavi
Address	Department of Pediatric and Preventive dentistry, KAHERs KLE VK Institute of dental sciences, Nehru Nagar, Belagavi, Karnataka. Belgaum KARNATAKA 590010 India
Phone	
Fax	
Email	

Details Contact Person (Public Query)

Details Contact Person (Public Query)	
Name	
Designation	Professor and Head
Affiliation	KLE VK Institute Of Dental Sciences, Belagavi
Address	Department of Pediatric and Preventive dentistry, KAHERs KLE VK Institute of dental sciences, Nehru Nagar, Belagavi, Karnataka. Belgaum KARNATAKA 590010 India

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Phone	
Fax	
Email	

Source of Monetary or Material Support

Source of Monetary or Material Support
> KLE VK Institute of Dental Sciences, Belagavi

Primary Sponsor

Primary Sponsor Details	
Name	
Address	KLE VK Institute of Dental Sciences, Belagavi
Type of Sponsor	Other [Self]

Details of Secondary Sponsor

Name	Address
NIL	NIL

Countries of Recruitment

List of Countries
India

Sites of Study

Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email
	KAHERs KLE VK Institute of Dental Sciences	Department no. 6, Department of Pediatric and Preventive Dentistry, Nehru Nagar, Belagavi Belgaum KARNATAKA	

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
Institutional Research and Ethics Committee KLE VKIDS	Approved	21/02/2024	No

Regulatory Clearance Status from DCGI

Status	Date
Not Applicable	No Date Specified

Health Condition / Problems Studied

Health Type	Condition
Patients	Other specified disorders of nervous system in diseases classified elsewhere

Intervention / Comparator Agent

Type	Name	Details
Intervention	Binaural auditory beats	After selection of the case and explaining the treatment procedure pre operative anxiety will be measured using Venham picture scale and Pulse oximeter. This will be followed by performing restorative procedure with patient listening to Binaural auditory beats. The patients in Binaural auditory beats group will be presented with beats of frequencies 400 Hz and 412 Hz in the left and right ears respectively superimposed on soft, relaxing music by means of over-the-ear headphones using the mobile device. At the end of the restorative procedure, anxiety

			will be again assessed using Venham's Picture Scale and Pulse oximeter and the post-operative recordings will be noted for further analysis. Binaural auditory beat is an auditory illusion perceived by our brain when two sinusoidal waves (tones) at a different frequency enters through the right and left ear respectively, the brain perceives a third illusory tone with a frequency that equals the difference of the other two. The procedure will be carried out in 45 min for each patient.
	Intervention	Music of choice	After selection of the case and explaining the treatment procedure pre operative anxiety will be measures using Venham picture scale and Pulse oximeter. This will be followed by performing restorative procedure with patient listening to Music of choice. At the end of the restorative procedure, anxiety will be again assessed using Venham's Picture Scale and Pulse oximeter and the post-operative recordings will be noted for further analysis.
	Comparator Agent	No music	After selection of the case and explaining the treatment procedure pre operative anxiety will be measures using Venham picture scale and Pulse oximeter. This will be followed by performing restorative procedure without music intervention. At the end of the restorative procedure, anxiety will be again assessed using Venham's Picture Scale and Pulse oximeter and the post-operative recordings will be noted for further analysis. The procedure will be carried out in 45 min for each patient.

Inclusion Criteria

Inclusion Criteria	
Age From	6.00 Year(s)
Age To	12.00 Year(s)
Gender	Both
Details	1. Children between 6-12 years of age. 2. Children visiting dental clinic for the first time. 3. Children who require restoration for Class 1 cavity in the primary/ permanent molar teeth. 4. Children with moderate dental caries involving enamel and dentin.

Exclusion Criteria

Exclusion Criteria	
Details	1. Children with special health care needs. 2. Children showing Frankl Behavior rating 1 and II (i.e., Definitely negative and Negative). 3. Children having Visual or Auditory impairment. 4. Children and/or Parents who are unwilling to participate in the study.

Method of Generating Random Sequence	Coin toss, Lottery, toss of dice, shuffling cards etc
Method of Concealment	Sequentially numbered, sealed, opaque envelopes
Blinding/Masking	Participant, Investigator and Outcome Assessor Blinded

Primary Outcome

Outcome	Timepoints
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.	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.

Secondary Outcome

Outcome	Timepoints
Not applicable	Not applicable

Target Sample Size	**Total Sample Size**=75 **Sample Size from India**=75 **Final Enrollment numbers achieved (Total)**=75 **Final Enrollment numbers achieved (India)**=75
Phase of Trial	N/A
Date of First Enrollment (India)	01/04/2024
Date of First Enrollment (Global)	No Date Specified
Estimated Duration of Trial	**Years**=1 **Months**=0 **Days**=0
Recruitment Status of Trial (Global)	Completed
Recruitment Status of Trial (India)	Completed
Publication Details	None yet

Brief Summary

Binaural beats are an auditory illusion perceived when two different pure-tone sine waves are presented one to each ear at a steady intensity and frequency. When we want to induce a relaxed state, we simply need a binaural tone with a frequency that matches the alpha brainwaves (8- 12 Hz). Binaural auditory beat was first described by Dove in 1939. Later it was described in detail by Oster in 1973. Tones with a frequency from 200-900 Hz are more effective in provoking Binaural auditory beat than those which exceed 1000 Hz. The difference in frequency between the two sounds must be less than 30 Hz for the beats to occur, otherwise the two tones are captured independently and no beats are perceived. The binaural beats are able to alter the functional connectivity between the brain region and have been reported to have significant brainwave entrainment effects. This brainwave entrainment achieved due to theta wave stimulation could possibly lead to the release of the hormone endorphin which would result in the clinical effect of relaxation of the patients. According to report by Mountcastle, pain-evoked neural activity is suppressed by auditory stimuli in the posterior group nuclei of the thalamus and in the cerebral cortex.

In Music of choice, child listens to familiar songs which help the child gain control over unpleasant stimulus of dental treatment from the sound of airotor or sight of syringe. Thus, giving the child a feeling of being in familiar environment which ultimately helps in reducing anxiety of the child.

Hence, this study aims 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.

ANNEXURE III a:

INFORMED PARENTAL CONSENT FORM FOR CLINICAL TRIAL (ENGLISH)

K L E
VISHWANATH KATTI
INSTITUTE OF DENTAL SCIENCES,
Constituent college of
K.L.E. Academy of Higher Education and Research
J.N.M.C. Campus, Nehru Nagar Belagavi -590010 Karnataka, India.
Department of Pediatric & Preventive Dentistry

This informed consent form is for children between 6-12 years of age, with deciduous or permanent tooth decay, attending the Department of Pediatric Dentistry, KLE VK Institute of Dental Sciences, Nehru Nagar, Belagavi.

The title of our research project is **"Comparative evaluation of anxiety levels 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: A Randomized clinical trial."**

Name of Principal investigator: Dr.

Post-graduate student, Dept. of Pediatric & Preventive Dentistry
KLE ACADEMY OF HIGHER EDUCATION AND RESEARCH
KLE VK INSTITUTE OF DENTAL SCIENCES, NEHRU NAGAR, BELAGAVI

Telephone number:

Name of co-investigator 1: Dr.

(Research guide)
Professor and Head of Department, Dept. of Pediatric & Preventive Dentistry
KLE ACADEMY OF HIGHER EDUCATION AND RESEARCH
KLE VK INSTITUTE OF DENTAL SCIENCES, NEHRU NAGAR, BELAGAVI

Telephone number:

Name of Organization: KLE ACADEMY OF HIGHER EDUCATION AND RESEARCH
KLE VK INSTITUTE OF DENTAL SCIENCES, NEHRU NAGAR, BELAGAVI

This Informed Consent Form has two parts:

- **PART I: Information Sheet (to share information about the research with you)**
- **PART II: Certificate of Consent (for signatures if you agree to take part) You will be given a copy of the full Informed Consent Form**

PART I: INFORMATION SHEET

Introduction

I am Dr._____, Postgraduate student, from the Department of Pediatric and Preventive Dentistry, KAHER's KLE VK Institute of Dental Sciences, Nehru Nagar, Belagavi. I am inviting your son/daughter to participate in this research. If there are words you don't understand I will explain. I am doing research to guide the behavior of anxious children during dental treatment. There may be some words that you do not understand. Please ask me to stop as we go through the information and I will take time to explain. If you have questions later, you can ask them of me, the study doctor or the staff.

Purpose of the research

When it comes to dental treatment, it's normal for children to feel anxious. This type of anxiety makes good treatment difficult and puts pressure on children and dentists. In this case, the purpose of this research is whether music can reduce anxiety.

Type of Research Intervention

In this research, while treating children, mentoring behavior methods using Binaural auditory beats or Music of choice will be used in experimental groups to reduce children's anxiety.

Participant selection

Among children visiting the Department of Pediatric and Preventive Dentistry, KAHER's KLE VK Institute of Dental Sciences, who require treatment for caries will be included in this research.

Voluntary Participation

Your child's participation in this research is completely voluntary. Whether or not your child participates in this research is our choice. Whether or not your child participates in this research, all services available at this institution will be provided to your child accordingly. If you change your mind during the research, you can stop participating. The

behavioral guidance technique we are using is called audio distraction. Audio distraction is an accepted method for reducing anxiety and its use has been proven.

Procedures and Protocol

We currently do not know which behavioral guidance method of audio distraction among without music, Music of choice or Binaural auditory beats, is better in children with dental anxiety, so these three methods are to be compared. Children participating in this research will be divided into three groups by lottery method.

The first group of children will be implemented to conventional restorative technique without any music intervention. In the second and third group of children, the audio distraction behavior was followed by listening to Music of choice and Binaural auditory beats through headphones. There is complete transparency in this method. If you have any doubts about this, you can discuss with me or other researchers. Your child's treatment will be done under the best guidance.

6. **Process description:**

During the research a case history will be taken and treatment will be done which will include filling the decayed tooth using standard operating protocol.

During this treatment anxiety scores will be recorded pre- and post-treatment using the Venham's Picture Scale and Pulse oximeter.

7. **Risks:**

This new method of audio distraction may not be as effective as the conventional method.

8**. Will this research harm my child?**

This research will not harm your child in any way.

9. **Benefits**

There will be no immediate or direct benefit to you or your child from participating in this research. But your child's behavior can help us learn more about the most effective behavior guidance methods for reducing anxiety in children.

10. **Confidentiality:** Your participation in this research will be kept confidential.

11. **Sharing Results:** The knowledge we gain from doing this research will be shared with you before it becomes widely available to the public. Confidential information is not shared. Results are shared with the scientific community through presentation at research forums and publication in scientific journals. And others interested can learn from our research.

12. **Power of Departure**

You always have the right to withdraw from research. We respect this decision. If you do not wish to participate in the research, your son/daughter will be treated accordingly.

13. **Discussion/ Bargaining**

This research was approved by the Institutional Ethics Committee of KLE VK Institute of Dental Sciences, Nehru Nagar, Belagavi, Karnataka that has official recognition. The proposal was reviewed and approved by the Institutional Ethical Clearance Committee to ensure that research participants will be protected from harm.

Who to Contact

If you have any questions you may ask them now or later, even after the study has started. If you wish to ask questions later, you may contact any of the following doctors:

Name	Mobile number
Principal Investigator: Dr. _____, Postgraduate student, Department of Pediatric and Preventive Dentistry	
Guide Name: Dr. _____, Professor and Head of Department, Department of Pediatric and Preventive Dentistry	

This proposal has been reviewed and approved by Ethical Clearance Committee, KAHER, Belagavi, which is a committee whose task it is to make sure that research participants are protected from harm.

You can ask me any more questions about any part of the research study, if you wish to. Do you have any questions?

PART II: CERTIFICATE OF CONSENT

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research.

Name & Signature of Participant _____

Date _____

If illiterate

A literate witness must sign (if possible, this person should be selected by the participant and should have no connection to the research team). Participants who are illiterate should include their thumb-print as well.

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness _____ **AND Thumb print of participant**

Signature of witness _____

Date _____

STATEMENT BY THE RESEARCHER/PERSON TAKING CONSENT

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands that the following will be done:

1.

2.

3.

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this informed consent form has been provided to the participant.

Name and Signature of Researcher /person taking the consent:

Date:

ANNEXURE III b:

CONSENT FORM (KANNADA)

ಸಮ್ಮತಿ ಪತ್ರ

ಚಿಕ್ಕಮಕ್ಕಳ ದಂತ ಚಿಕಿತ್ಸಾ ವಿಭಾಗ

ಕೆಎಲ್ಇ ವಿ. ಕ. ದಂತ ಮಹವಿದ್ಯಾಲಯ ಬೆಳಗಾವಿ–10

ನಾನು ಶ್ರೀ/ಶ್ರೀಮತಿ---------- ಎಲ್ಲ ಮಾಹಿತಿಯನ್ನು

ಪಡೆದುಕೊಂಡಿದ್ದೇನೆ ಮತ್ತು ನನ್ನ ಮಗ/ಮಗಳು----------

ವಯಸ್ಸು---------- ಈ ಸಂಶೋಧನೆಯಲ್ಲಿ ಭಾಗವಹಿಸಲು ಅನುಮತಿಯನ್ನು ನೀಡಿ ಸಹಕರಿಸುತ್ತೇನೆ.

1. ನನ್ನ ಮಗ/ಮಗಳ ಬಗ್ಗೆ ಎಲ್ಲ ಮಾಹಿತಿ ಕೊಡಲು ಒಪ್ಪುತ್ತೇನೆ.
2. ನನ್ನ ಮಗ/ಮಗಳ ಬಯಿಯ ಹುಳುಕು ಹಲ್ಲುಗಳನ್ನು ಸ್ವಚ್ಚಗೋಳಿಸಲು/ಬೇರು ನಾಳನ ಚಿಕಿತ್ಸೆ ಮಾಡಲು ಸಹಮತಿಯನ್ನು ನಿಡುತ್ತೇನೆ.
3. ನಾನು ವೈದ್ಯರು ಕೊಟ್ಟೀರುವ ಸುಚನೆಗಳನ್ನು ಪಾಲಿಸುತ್ತೇನೆ.
4. ಈ ಸಂಶೋಧನೆಯನ್ನು ಪ್ರಕಟಿಸಲು ಅನುಮತಿಯನ್ನು ಕೊಡುತ್ತೇನೆ.
5. ನನ್ನ ಮಗ/ಮಗಳು ಭಾಗವಹಿಸಿದ್ದಕ್ಕೆ ಪ್ರತಿಯಾಗಿ ಏನು ಕೇಳುವುದಿಲ್ಲ.
6. ಯಾವುದೇ ಕಾರಣಕ್ಕಾಗಿ ನನ್ನ ಮಗ/ಮಗಳು ಭಾಗವಹಿಸಿದ್ದಲ್ಲಿ ಹಿಂತೆಗೆದುಕೊಳ್ಳಬಹುದು.
7. ನನ್ನ ಮಗ/ಮಗಳ ಏಲ್ಲ ಮಾಹಿತಿಯನ್ನು ಗುಪ್ತವಾಗಿಡಲಾಗುವದು.
8. ಬೇರೆ ಚಿಕಿತ್ಸೆ ಬಗ್ಗೆ ಮಾಹಿತಿ ಕೊಡಲಾಗುವುದು.

ನಾನು ಮೇಲೆ ತಿಳಿಸಿದ ಎಲ್ಲ ವಿಷಯವನ್ನು ಓದಿದ್ದೇನೆ ಹಾಗು ಅರ್ಥಮಾಡಿಕೊಂಡು ಸಹಿ ಮಾಡಿದ್ದೇನೆ.

ದಂತ ವೈದ್ಯರ ಹೆಸರು:ಃ

ವಿಳಾಸ: ಚಿಕ್ಕಮಕ್ಕಳ ದಂತ ಚಿಕಿತ್ಸಾ ವಿಭಾಗ

ಕೆಎಲ್ಇ ವಿ '

ಬೆಳಗಾವಿ–10

ಪಾಲಕರ ಹೆಸರು: ಪಾಲಕರ ಸಹಿ:

ದಿನಾಂಕ:

ANNEXURE IV:

ASSENT FORM

KLE Academy of Higher Education and Research. K.L.E. V.K. Institute of Dental Sciences, Belagavi.

Department of Pediatric and Preventive Dentistry

My name is Dr. _____. I am a dentist. I am doing a study to learn about a new behavior guidance technique. I am going to fill your teeth with tooth colored cement when you will be listening music. The music is totally painless and will not cause any harm to you.

You can ask questions at any time that you might have about this study. Also, if you decide at any time not to finish, you may stop whenever you want. Signing this paper means that you have read this or had it read to you and that you want to be in the study. If you don't want to be in the study, don't sign the paper. Your parent(s) know that I am asking you to do these things. Remember, being in the study is up to you, and no one will be angry if you don't sign this paper or even if you change your mind later.

Signature of participant _____ Date _____

Signature of investigator _____ Date _____

ANNEXURE V:

CASE-HISTORY FORM

KLE Academy of Higher Education and Research. K.L.E. V.K. Institute of Dental Sciences, Belagavi.

Department of Pediatric and Preventive Dentistry

Name: Sex:

Age: Parent/Guardian:

Address: Contact Number:

HISTORY:

Chief Complaint:

History of Present Illness:

Relevant Medical History:

Previous Dental History:

GENERAL EXAMINATION:

INTRA-ORAL EXAMINATION

Soft Tissue Examination:

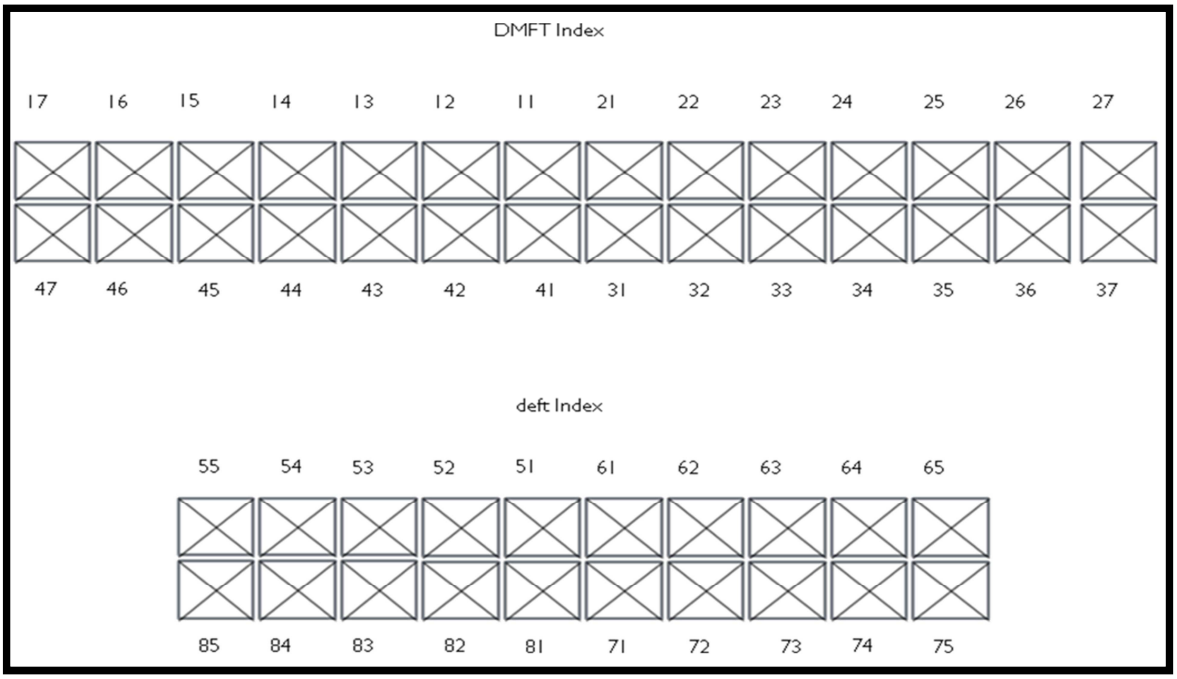
Hard Tissue Examination:

PROVISIONAL DIAGNOSIS:

INVESTIGATION:

FINAL DIAGNOSIS:

TREATMENT PLANNING: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47 46 45 44 43 42 41 31 32 33 34 35 36 37
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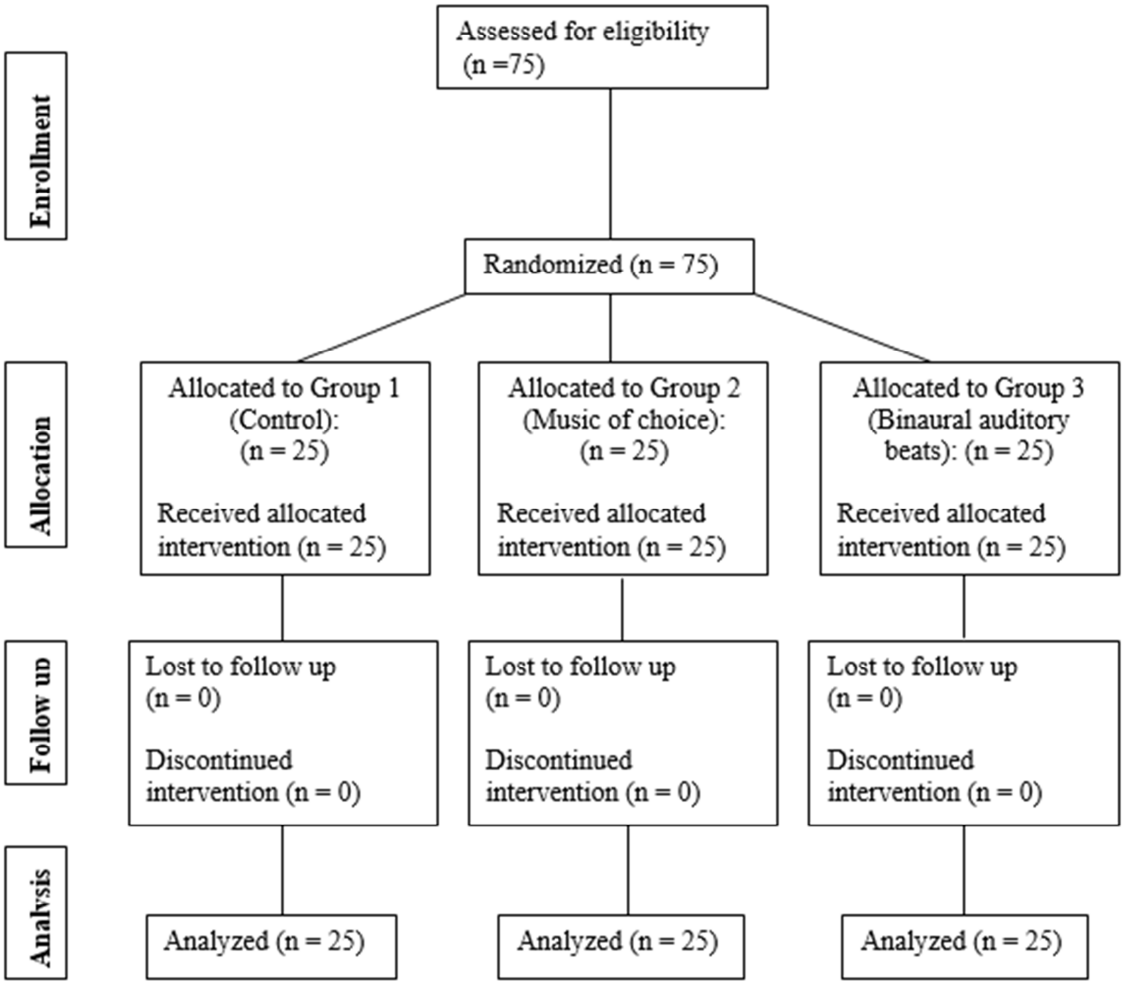
85 84 83 82 81 71 72 73 74 75

ANNEXURE VI:

CONSORT FLOW DIAGRAM OF METHODOLOGY FOLLOWED IN THE STUDY



ANNEXURE VII:

BIOSTATISTICS CERTIFICATE

K L E
VISHWANATH KATTI
INSTITUTE OF DENTAL SCIENCES
A Constituent college of
K:L.E Academy of Higher Education and Research
J.N.M.C Campus, Nehru Nagar, Belagavi – 590010 Karnataka, India
Department of Pediatric and Preventive Dentistry

BIOSTATISTICS CLEARANCE CERTIFICATE

This is to certify that the Biostatistics art of Dissertation/ Research work of **Dr.** **Postgraduate student** under the guidance of **Dr.**

Professor and Head, Department of Pediatric and Preventive Dentistry entitled **"Comparative evaluation of 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: A Randomized clinical trial"** has been done under my guidance and considered satisfactory.

Dr. S. B. JAVALI Ph.D.
Sr. Associate Professor in Statistics
Department of Community Medicine
USM KLE International Medical Programme
BELAGAVI-590010

Name and Signature of Biostatistician

Place: Belagavi
Date: 01.02.2024

ANNEXURE VII:
PLAGARISM CERTIFICATE

Scientific Correspondence and Review Committee

KLE VK Institute of Dental Sciences
A Constituent Unit of KLE Academy of Higher Education and Research
(Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Nehru Nagar, Belagavi - 590 010, Karnataka State
Accredited 'A' Grade by NAAC (2nd Cycle) Placed in Category 'A' by MHRD (GoI)
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FAX: 0831-2470640 E-mail:principal@kledental-bgm.edu.in

Date : 8.04.2024 Serial No. : 171

PLAGIARISM CHECK REPORT

Name of the Applicant : Dr.
UG / PG / Ph.D / Staff : POST GRADUATE
Batch & Year : 2021 – 2024
Department : PEDIATRIC AND PREVENTIVE DENTISTRY

The soft copy of Research Work / Manuscript by ..... entitled "TREATMENT USING NO MUSIC, MUSIC OF CHOICE AND BINAURAL AUDITORY BEATS AS AUDIO DISTRACTION BEHAVIOUR GUIDANCE TECHNIQUE IN CHILDREN AGED 6-12 YEARS: A RANDOMIZED CLINICAL TRIAL" under the guidance of ..... has been submitted for Anti-Plagiarism check to the Scientific Correspondence & Review Committee of KLE VK Institute of Dental Sciences using "Turn-it-in" software.

The scan has been carried out and the scanned output reveals a Similarity Index of .....6.....%, which is **within / not within** the acceptable limits of 10% as per the UGC guidelines.

8/04/2024

Member Secretary
Scientific Correspondence and Review Committee
KLEVK Institute of Dental Sciences
KAHER-Belagavi

Chairman
Scientific Correspondence and Review Committee
KLEVK Institute of Dental Sciences
KAHER - Belagavi