Research Protocol

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Dentistry Section

Comparative Evaluation of Active Noise Cancellation Headphones, 8D Audio and White Noise for Reducing Dental Anxiety Among Children Aged 6-9 Years: A Research Protocol

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ABSTRACT

Introduction: Dental anxiety is a significant challenge in paediatric dentistry, commonly triggered by unfamiliar environments, invasive procedures, and distressing sounds from dental equipment. Non-pharmacological techniques, such as auditory distraction, have gained interest for their ability to shift a child's focus away from anxiety-inducing stimuli. ANC (ANC) headphones, Eight-dimensional (8D) audio, and white noise are emerging tools that may help alleviate dental fear by masking or modulating unpleasant auditory experiences during treatment.

Need of the study: Despite the widespread application of auditory distraction methods, limited evidence exists on the comparative effectiveness of ANC headphones, especially when used with different sound types such as 8D audio and white noise. With increasing demand for child-friendly and non-invasive anxiety management techniques, this study aims to identify the most effective auditory approach to improve behaviour and reduce anxiety in children.

Aim: To compare and evaluate the efficacy of ANC Headphones with 8D audio and white noise for reducing dental anxiety in children aged 6-9 years.

Materials and Methods: A randomised controlled trial will be conducted on paediatric patients aged 6-9 years at Sharad Pawar Dental College and Hospital, Wardha, Maharashtra, India, from June 2025 to December 2026. Participants will be randomly divided into three groups: Group 1 will receive ANC headphones with 8D Audio, Group 2 will receive ANC headphones with White Noise, and Group 3 will receive ANC headphones only. Anxiety levels will be assessed pre, during, and post-treatment using the Modified Child's Dental Anxiety Scale (MCDAS) and Venham's Anxiety and Behaviour Rating Scale (VABRS). Physiological markers such as pulse rate, blood pressure, and oxygen saturation will also be recorded. Data will be analysed using appropriate statistical tests, including Analysis of Variance (ANOVA), t-tests, and Pearson's correlation.

Keywords: Binaural beats, Distraction techniques, Eight dimensional audio, Paediatric dentistry

INTRODUCTION

One of the most frequent challenges in paediatric dentistry is handling children who experience fear and dental anxiety. Dental anxiety (DA) is described as a condition of uneasiness or nervous anticipation, often accompanied by a perceived loss of control and an expectation that something unpleasant or distressing will occur during dental treatment [1]. Approximately 6-42% of children experience dental anxiety, which can be influenced by many contributing factors [2]. Dental treatment involves invasive procedures utilising sharp, high-speed rotary instruments, often necessitating multiple clinical sessions [3]. A variety of non-pharmacological behaviour management strategies have been suggested for paediatric patients, including voice modulation, the Tell-Show-Do (TSD) technique, positive reinforcement, distraction using auditory and visual stimuli, protective stabilisation, observational learning (modelling), and guided relaxation or hypnosis [4]. Distraction with the help of audio is an easy, simple, and effective technique among the non-pharmacological techniques that concentrates on redirecting a child's focus away from unpleasant stimuli, thereby reducing fear and anxiety during dental procedures [5]. In 1959, Gardner and Licklider were the first to introduce the concept of auditory analgesia in dental procedures. They reported that in approximately 90% of 5,000 cases, auditory stimulation served as the sole method of pain relief required [6].

8D audio is a form of sound engineering that creates an immersive, multidirectional audio experience, making it appear as though the sound is moving around the listener's head. This dynamic auditory engagement can serve as an effective distraction, drawing the child's attention away from the dental procedure [7]. White noise, on the other hand, consists of a steady, consistent sound that masks sudden or loud noises, providing a soothing background effect that can promote relaxation [8].

Active Noise-cancelling headphones are advanced audio devices designed to reduce unwanted ambient sounds, providing a quieter and more focused listening experience. The headphones generate a sound wave that is the exact opposite (antiphase) of the incoming noise. This process, known as destructive interference, effectively cancels out the external sounds, creating a quieter environment for the listener. Unlike traditional headphones that rely solely on physical barriers to block noise, ANC headphones use sophisticated electronic technology to cancel out external sounds actively [9]. By minimising exposure to distressing dental sounds, ANC headphones can potentially help children feel more relaxed and less anxious during dental procedures [10]. The advantages of ANC headphones are that they are easy and efficient in use, have adaptive ANC modes for different environmental noise frequencies, Bluetooth support for wireless use, touch-sensitive panels or physical buttons for easy control of volume, voice control and foldable or compact designs for easy storage and travel [10].

Despite the growing interest in these auditory interventions, there is limited research on their comparative effectiveness in paediatric dental settings. The present study aims to evaluate the efficacy of ANC headphones with 8D Audio and white noise for reducing dental anxiety in children aged 6-9 years.

REVIEW OF LITERATURE

Dental anxiety is a common issue in paediatric patients, as excessive noise from dental equipment acts as a significant contributor to heightened stress and fear in children. The high-pitched sounds of dental drills, suction devices, and other instruments can be particularly distressing for children, evoking negative associations and contributing to their reluctance to cooperate during procedures. Therefore, the use of ANC can be advantageous in distracting the child from traumatic dental procedures and can be helpful for the operator in achieving cooperation from the child.

Karuppiah M et al., (2024) [10] evaluated and compared the effectiveness of two distraction techniques, virtual reality (VR) and 8D audio analgesia, in reducing pain perception and anxiety levels in children during restorative dental procedures. A total of 120 children aged 4-10 years were randomly assigned to three groups: a control group with a conventional TSD technique, a group using 8D audio distraction, and a group using VR glasses. Pain and anxiety were assessed using subjective (Chotta Bheem-Chutki pictorial scale), objective (FLACC scale), and physiological (pulse rate and oxygen saturation) parameters. The results showed that both 8D audio and VR methods significantly reduced pain and anxiety compared to the control group, with no significant difference between them. Another study by Rathi N et al., (2024) [11] concluded that AV distraction with binaural beats is an effective, non-invasive anxiolytic intervention in paediatric dental practice.

Han S et al., (2024) [12] conducted a study to assess the effectiveness of ANC in reducing fear and anxiety during professional dental cleaning among children and adolescents aged 7 to 16 years and concluded that ANC is a valuable tool for reducing dental anxiety in paediatric patients, particularly those with high dental fear or difficulty attending dental visits. Padawe D et al., (2023) [13] investigated the effectiveness of binaural beats as a non-pharmacological method for reducing dental anxiety in children aged 3-10 years. The results showed a significant reduction in anxiety and pulse rate in the binaural beat group compared to the control group. The study concluded that binaural beats are effective, non-invasive, and practical for managing paediatric dental anxiety and can be easily incorporated into routine dental practice.

Aim: To compare and evaluate the efficacy of ANC headphones with 8D Audio and white noise for reducing dental anxiety in children aged 6-9 years.

Objectives:

- To evaluate the effectiveness of ANC headphones with 8D audio in reducing dental anxiety among paediatric patients aged 6-9 years.
- To evaluate the effectiveness of ANC headphones with white noise in reducing dental anxiety among paediatric patients aged 6-9 years
- To evaluate the effectiveness of ANC headphones in reducing dental anxiety among paediatric patients aged 6-9 years
- To compare the effectiveness of ANC headphones and their efficacy with 8D audio and white noise in reducing dental anxiety among paediatric patients aged 6-9 years

Null hypothesis (H_0): There is no significant difference in the effectiveness of ANC headphones, ANC with 8D Audio, and ANC with White Noise in reducing dental anxiety among children aged 6-9 years.

Alternative hypothesis (H_1): There is a significant difference in the effectiveness of ANC headphones, ANC with 8D Audio, and ANC with White Noise in reducing dental anxiety among children aged 6-9 years.

MATERIALS AND METHODS

A single-blinded randomised controlled trial will be conducted in the Department of Paediatric and Preventive Dentistry at Sharad Pawar Dental College and Hospital, Wardha, Maharashtra, India, from June 2025 to December 2026 on paediatric patients aged 6-9 years, where informed consent will be taken from the parents or guardians. The study has been cleared by the Ethics Committee with Ref No. DMIHER(DU)/IEC/2025/553 and has been registered with the Clinical Trials Registry-India CTRI/2025/05/086137.

Inclusion criteria:

- paediatric patients aged between 6 and 9 years who exhibit dental anxiety.
- Children categorised as fearful yet cooperative will be considered eligible. Additionally, participation will require informed consent from the parents or guardians.

Exclusion criteria:

- Children below 6 years of age and those with severe cognitive or developmental disabilities that could interfere with the study procedures.
- Paediatric patients with hearing impairments will also excluded, along with those who were uncooperative during dental visits.

Sample size calculation:

$Z\alpha$ = The standard normal deviate for $\alpha = 1.96$

= Threshold probability for rejecting the null hypothesis. Type I error rate.

$Z\beta$ = The standard normal deviate for $\beta = 0.84$

= Probability of failing to reject the null hypothesis under the alternative hypothesis.

Type II error rate.

r = The expected correlation coefficient. = 0.872 between SPO_2 before and SPO_2 after

Sample Size = N= $[(Z\alpha + Z\beta)/C]$ 2

C = 0.5 * ln[(1+0.872)/(1-0.872)] =

= 0.5* ln[(1+0.872)/(1-0.872)] = 0.5825

N =[(1.96+0.84)/0.5825)] 2

= 27.78 and 10% drop rate

= 30 participants needed in each group [11] [14]

Study Procedure

Children with a score range ≤3 on the VABRS Scale [15] and 19-31 on the MCDAS scale [16] will be assigned randomly to either of the three groups using the lottery method for randomisation, where each child will have to pick up a chit from a glass jar consisting of 90 chits with 30 chits for each group in the jar. Each group would consist of 30 participants.

Group 1: Use of ANC headphones with 8D audio before, during and after restorative procedure (ANC HP + 8D).

Group 2: Use of ANC headphones with white noise before, during and after restorative procedure (ANC HP + WN).

Group 3: Use of only ANC headphones before, during and after restorative procedure (ANC HP).

The patients will be familiarised with the JBL Tour One M2 Wireless ANC headphones using the tell-show-do technique before the start of the restorative procedures. The dental anxiety as well as the biological markers of the patients will be assessed during the restorative procedure.

Children satisfying the criteria as mentioned above will be included in this study. The procedure will be explained in detail to both the child and their parents, and written informed consent will be obtained from the parents.

Outcomes

Preoperative biological markers such as blood oxygen saturation level (SpO_2), pulse rate and blood pressure will be measured using an OMRON HEM 7120 digital sphygmomanometer and pulse oximeter, respectively.

A pre and post operative assessment will be conducted, measuring dental anxiety using the MCDAS scale and VABRS scale, in all three groups.

Venham's Anxiety and Behaviours Rating Scale (VABRS) [15]: These two scales assess the anxiety and uncooperative behaviour of children in the dental setting. Both scales consist of five behaviourally defined categories ranging from 0 to 5, with higher scores indicating a greater level of anxiety or lack of cooperation

Faces version of the Modified Child's Dental Anxiety Scale (MCDAS-f) [16]: This index is a self-reported tool designed to assess dental anxiety in children aged 5-12 years. It comprises 8 questions, each with 5 pictorial answer options. Scores on the MCDAS(f) scale range from 8 to 40: scores below 19 suggest no state anxiety, scores above 19 indicate the presence of anxiety, and scores over 31 signify severe phobic disorder.

STATISTICAL ANALYSIS

The statistical analysis will be done utilising the One Way ANOVA and Tukey multiple comparison test. The data will be analysed using SPSS version 27.0 and GraphPad Prism version 7.0 software, with a significance level set at $p<0.05$.

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