COMPARATIVE EVALUATION OF EFFECTIVENESS OF SENSORY ADAPTED DENTAL ENVIRONMENT AND REGULAR DENTAL ENVIRONMENT TO ALLEVIATE ANXIETY IN CHILDREN UNDERGOING DENTAL TREATMENT: A RANDOMIZED CONTROL TRIAL

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KAHER'S KLE VISHWANATH KATTI

INSTITUTE OF DENTAL SCIENCES,

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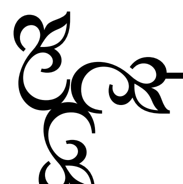

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HOD

Dr. C. M. Badakar M.D.S.
Professor and Head,
Department of Pediatric and
Preventive Dentistry,
KAHER's KLE VK Institute
of Dental Science,
Belagavi -590010.

Professor and Head
Department of Pedodontics
KLE V. K. Institute of Dental Sciences,
Belagavi

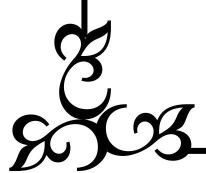
Date: 17/4/25
Place: Belagavi

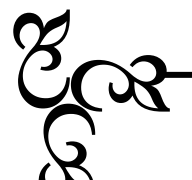
Principal

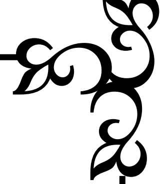
Dr. Alka D. Kale M.D.S, Ph.D.
Principal,
KLE VK Institute of Dental
Sciences,
Belagavi-590010.

PRINCIPAL
KLE V.K. Institute of Dental Sciences
Nehru Nagar BELAGAVI-590010

Date: 17/4/25
Place: Belagavi







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ABSTRACT

AIM: To evaluate and compare the effectiveness of Sensory Adapted Dental Environment (SADE) and Regular Dental Environment (RDE) to alleviate anxiety in children undergoing dental treatment.

MATERIALS AND METHODS: Randomized control trial was conducted on healthy children aged 6 – 12 years. A sample size of 60 was calculated using standard sample size formula. Participants were allocated into 2 groups as Group I: Regular Dental Environment and Group II: Sensory Adapted Dental Environment. Anxiety was measured pre - operative and post - operative using Venham's picture test and Pulse oximeter in both groups. Statistical analysis was carried out and significance was accepted at a confidence level greater than 95% ($p < 0.05$).

RESULTS: A very highly statistically significant reduction of anxiety levels by Venham's picture test was seen postoperatively in Group II: Sensory Adapted Dental Environment group as compared to Group I: Regular Dental Environment with 'p' value of 0.0002 ($p<0.05$). A very highly statistically significant reduction of pulse rate scores was seen postoperatively in Group II: Sensory Adapted Dental Environment as compared to Group I: Regular Dental Environment with 'p' value 0.0007 ($p<0.05$).

CONCLUSION: Thus, our study concluded that treating children in Sensory Adapted Dental Environment (SADE) is highly effective in anxiety reduction and can be used as an effective alternate to Regular Dental Environment (RDE).

KEYWORDS: Behaviour Guidance Technique, Children, Dental anxiety, Dental Treatment, Sensory Adapted Dental Environment,

LIST OF ABBREVIATIONS

Sl. No.	Abbreviation	Expanded form
1.	AAPD	American Academy of Pediatric Dentistry
2.	ADHD	Attention Deficit Hyperactivity Disorder
3.	ANS	Autonomic Nervous System
4.	ASD	Autism Spectrum Disorder
5.	AV	Audio - Visual
6.	BP	Blood Pressure
7.	CFSS-DS	Children’s Fear Survey Schedule-Dental Subscale
8.	CNS	Central Nervous System
9.	CTRI	Clinical Trial Registry of India
10.	DA	Dental Anxiety
11.	DF	Dental Fear
12.	DP	Dental Phobia
13.	DD	Developmental Disabilities
14.	DFS	Dental Fear Scale
15.	FIS	Facial Image Scale
16.	FLACC	Face, Legs, Activity, Cry, Consolability
17.	GABA receptors	Gamma-Aminobutyric Acid Receptors
18.	GSR	Galvanic Skin Response

19.	HR	Heart Rate
20.	SPSS	Statistical Package for the Social Sciences
21.	ID	Intellectual Disabilities
22.	IQR	Interquartile Range
23.	IRB	Institutional Review Board
24.	LA	Local Anesthesia
25.	LLLT	Low-Level Laser Therapy
26.	MCDAS	Modified Child Dental Anxiety Scale
27.	MDAS	Modified Dental Anxiety Scale
28.	MT1 and MT2	Melatonin Receptors 1 and Melatonin Receptors 2
29.	NA	Nor - Adrenaline
30.	PNS	Parasympathetic Nervous System
31.	PI	Principal Investigator
32.	RDE	Regular Dental Environment
33.	SADE	Sensory Adapted Dental Environment
34.	SAD	Seasonal Affective Disorder
35.	SI/SP	Sensory Integration/Sensory Processing
36.	SCN	Supra - Chiasmatic Nucleus
37.	SIA	Sweet Substance– Induced Analgesia
38.	S_PO_2	Peripheral Capillary Oxygen Saturation

39.	TSD	Tell Show Do
40.	VAK	Visual, Auditory and Kinesthetic
41.	VAS	Visual Analogue Scale
42.	VPT	Venham’s Picture Test
43.	VPRS	Venham’s Picture Rating Scale
44.	VR	Virtual Reality
45.	5-HT	5-Hydroxytryptamine

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INTRODUCTION

"Every patient has the right to experience high quality dental care in a relaxing environment where patients can restore their smiles and achieve overall wellness."

-Dr. Ashley Seals

Dental anxiety has negative impact on the mental, physical, emotional and psychological health of the child. Because of this impact, it harmfully affects children's oral health related life quality. Children suffering from dental anxiety, often avoid the dental treatment which in turn impacts the oral and the general health of a child. These children often present with behavioral problems which not only affects the child but also affects the parents, family and the dental team.[1]

Dental anxiety (DA) is a complex phenomenon which involves several factors causing it. A child suffering from anxiety can be easily noticed with some indicators. These features are: increased breathing, facial frowns, increased speed, recurrent changes in sitting position, amplified frequency of urination, excessive talking, enhanced heart rate, sweating and moist palms. Various studies reported pervasiveness of dental anxiety ranging from 5 to 30% in children of different countries.[2] A study on 400 children showed that, anxiety rates were highest in children aged 6-12 years. Where, approximately 61.5% had severe dental anxiety and 23% had mild to moderate anxiety.[3]

Dental anxiety and fear makes a child to escape dental treatment by either avoiding it or postponing it. Their uncooperative behavior leads to prolonged appointment duration which is even more stressful for the child and results in an overall unpleasant experience primarily for the child as well as the dentist. This leads to complete avoidance of dental visits, thus resulting in failed or missed leading to neglected dental care. They may eventually require more complex

treatment with help of conscious sedation or general anesthesia which creates the financial burden on the parents. Thus, dental anxiety negatively impacts the dental treatment quality.[2]

Dental fear and anxiety if left unaddressed may lead to a more severe situation called "phobia". Phobia is characterized by a persistent, irrational and severe aversion of a particular stimuli, leading to complete bypassing of threat. Odontophobia is the term used for fear of dentistry and dental procedures and is marked by overwhelming feelings of anxiety, terror, and unease.[4]

Dental anxiety stems from a complex array of fears such as, fear of pain, injury, betrayal, being ridiculed, unknown, fear of depersonalization and fear of choking or gagging. While the ongoing dental process, the child might feel vulnerable and have a sense of uncontrolled behaviour.[2]

It is very is essential to correctly identify affected individuals suffering from dental anxiety and provide tailored interventions as soon as an individual arrives in the dental clinic. Pediatric dentists should prioritize assuaging dental anxiety in a compassionate and empowering manner. This will cultivate a long lasting positive attitude and inspiration for forthcoming dental visits among patients.

Dental anxiety cannot be managed via a single therapy and hence, Pediatric dentists have executed various techniques to reduce it for enhancement of child's comfort. Behaviour guidance techniques help in anxiety reduction, incorporate positive dental attitude and help deliver excellent quality of dental treatment with complete efficacy and precaution.[2] Depending upon the severity of dental anxiety and a child's behaviour in dental clinic, its management can be done by non-pharmacological or pharmaceutical interventions.

Both non-pharmacological and pharmacological interventions demonstrate comparable efficacy in alleviating dental anxiety. Non pharmacological behaviour guidance techniques are the most fundamental techniques which focuses on improvement of the child's behaviour by utilizing psychological aspects and sometimes multiple sessions may be required to sustain initial treatment response.[5,6]

If Non-Pharmacological behaviour guidance techniques do not show proper results and modification in the behaviour of a child, then the Pediatric Dentist may shift on using pharmacological means to manage such kids. Thus, a Pediatric dentist uses these pharmacological techniques on children showing definitely negative behaviour and children with special health care needs. Premedication, conscious sedation and general anaesthesia are a few techniques of pharmacological interventions. Treatment measures based on these agents does not aim to cope with the child's fear and only aims at carrying out dental treatment in a relatively short time. Thus, pharmacological behaviour guidance techniques for management of a child in dental operatory are less favoured by the parents and patients.[2]

Pharmacological interventions do not address the root cause of dental anxiety. It temporarily supresses the problem which later can become a challenge for Pediatric dentists. Medications used in pharmacological behavior guidance techniques can have adverse effects, such as nausea, vomiting, headaches, and allergic reactions. Moreover, there is a risk of overdose, particularly in pediatric patients. General anesthesia carries even more serious complications, including respiratory and cardiac issues. Furthermore, pharmacological methods can result in significant additional costs, placing a financial burden on families. Due to these drawbacks, Pediatric dentists often prefer non-pharmacological behavior guidance techniques, which offer a safer and more sustainable approach to managing dental anxiety.[2]

Non-Pharmacological behaviour guidance methods bring change in disruptive behaviour by replacing the negative behaviour with more cooperative behaviour. These include techniques like Tell-show-do (TSD), Distraction, Modeling.[2] The practices have demonstrated varying degrees of efficacy in alleviating dental anxiety.

A systematic review and meta-analysis by Kong et al. in 2024 on children aged 4 to 16 years revealed that music therapy was the most effective approach, reducing anxiety in 93.60% of patients. Aromatherapy and game-based interventions followed, with success rates of 78.58% and 70.99%, respectively.[7]

As research continues to evolve, there is a growing emphasis on developing innovative, patient-centred strategies to further optimize anxiety reduction in dental settings. Therefore, Pediatric dentists must efficiently and effectively manage patients by employing modern behaviour guidance techniques.

The ambience of the dental office and operatory plays an important role in aggravating anxiety of a child patient.[8] The visual sights of the operatory specially sight of needle or pungent smell and taste of dental materials and cleaning agents used in the operatory. Sounds and vibrations of the airotor can be inducing factors of anxiety in children.[9]

Conventional behavioral guidance techniques, such as TSD, modeling, distraction and play therapy has shown effective management of children's negative behaviors and anxiety during dental treatment. Even though these approaches are valuable chairside, they often fail to address one of the most critical factors of provoking anxiety in children i.e. the environment of the dental office itself. The physical surroundings, atmosphere, and even the sensory stimuli within the dental setting can significantly influence a child's emotional response. For many children, an

unfamiliar or intimidating environment can exacerbate feelings of anxiety, making it harder to engage with the treatment process. Addressing the dental office environment by creating a more child-friendly, comforting and less intimidating space could play a key role in alleviating anxiety. It helps in ameliorating the complete dental experience for children.[9]

The American Academy of Pediatric dentistry (AAPD) has advocated various newer non pharmacological behavior guidance techniques for management of kids having dental anxiety and kids with special healthcare needs. These techniques are dental treatment of a child in Sensory Adapted Dental Environment (SADE) inspired from Snoezelen Environment. [10]

It is a novel technique to reduce dental anxiety in children. Sensory based treatment aims to enhance sensory processing and self-regulation, upsurge adaptive function and alter responses to external stimuli. In Sensory Adapted Dental Environment (SADE), the child is presented with a controlled multisensory stimuli room which is a combination of specialized dimmed lightings, calming music and pleasant smell addressing the visual, auditory, olfactory, tactile and gustatory stimuli.[11] The Snoezelen therapy activates the preliminary senses of vision, tactile, and aroma, along with patient-centered therapy.[12]

A child suffering from high dental fear and anxiety may react negatively to various visual, smell, taste, sound and touch aspects in a dental clinic. The patient may exhibit unusual responses to dental tools, may get irritated by bright light of dental chair, dental armamentarium noise like suction and airotor and smell or taste of the latex glove.[13] Therefore, masking these unpleasant factors is the main hypothesizes of sensory adapted dental environment. This environment leads to safe

protection of child from harsh stimuli in the surrounding by lowering disconcerting visuo-auditory and tactile intensity while enabling calming responses.[12]

Sensory Adapted Dental Environment (SADE) produces a psychologically optimistic impact on the child. It leads to a tranquil state of mind causing alleviation of anxiety.[14]

Visual stimulation, this is based on the chromotherapy that can treat mental and physical health. The color therapy harmonizes and strengthens body's energy which aids in its natural healing process.[15] Color psychology refers to various emotional, intellectual and behavioral responses and connections attributed to a specific color. A particular spectrum of visible light (blue, pink, green) strikes the photoreceptors of retina which initiates an impulse to the brain. These waves then lead to release of hormone melatonin which is said to be a sleep-inducing hormone thus helps in providing a calming effect.[16] The visual field of the child can be stimulated by using special effects projecting lights called "solar projectors". These lights can be of repetitive colors and have slow motion effects.[14]

Olfactory stimulation, is based on the concept of aromatherapy of using essential oils like lavender to produce an enhanced biological effect through the sensation of smell.[17] Aromatherapy can have both physiological and psychological effects on a person. Sensation of pleasant smell stimuli generates impulses which activates the olfactory nerve cells. These impulses are transformed in the olfactory bulbs into chemical signals. These chemical signals travels to amygdala and activates secretion of hormones such as endorphins, encephalins and serotonin which in turn creates a feeling of pleasure. The GABA receptors (gamma-aminobutyric acid) is affected by essence of essential oil molecules. These receptors are well known for their hypnotic and sedative actions. Thus, they cause a state of

serene and decrease anxiety levels.[18] Mood elevating properties of lavender oil activates parasympathetic nervous system. This causes the pulse rate, saliva cortisol levels and blood pressure to drop.[17]

Auditory stimulation can be done with help of relaxing or calming music. Music therapy is increasingly being integrated into various clinical disciplines, including medicine, dentistry, physiotherapy, speech therapy, and surgery. Stimulation of limbic system of brain by music not only sources the release of endorphin and enkephalin but also PNS activation. This cascade leads to diminution in physiological findings such as heart rate, respiratory rate and blood pressure which in all creates a calm state of mind thus helps in reduction anxiety.[19] The use of white noise (audio analgesia) such as sound of water dripping or nature in the dental clinic can mask the sounds of the dental equipment thus distracting the child.[14]

Tactile stimulation works by stress-relieving play therapy tool, such as a shape-shifting soft rubber ball, which when pressed deviates the child from the procedure that is taking place.[20] The child is presented with attention grabbing task which increases the cognitive load. As a result, diversion of attention of child happens from the pain source which reduces the pain perception and simultaneously anxiety levels.[21]

Gustatory stimulation acts when a pleasant taste stimulus acts on the body's central endogenous system to release endorphin and enkephalin which in turn reduces anxiety.[22]

Although though we have understood the cycle of dental anxiety, yet there remains a prominent gap in the scientific literature of exploring innovative behaviour management techniques in Pediatric Dentistry. In order to acknowledge inimitable

challenges posed by Pediatric Dentists and to over the problem of dental anxiety, this trial was designed to provide insights on efficacy of Sensory adapted dental environment on dental anxiety of young kids undergoing dental procedure. 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.

All the above-mentioned mechanisms help in reduction of anxiety and through literature search found that no studies have been carried out in Indian scenario or worldwide to compare the effectiveness of combined stimuli presented as "Sensory Adapted Dental Environment" on normal children having with dental fear and anxiety. So, we decided to carry out a study which compares the conventional behaviour guidance techniques to a technique which involves utilization of a special effects environment. Hence, an attempt is made to carry out this research to evaluate and compare effectiveness of Sensory Adapted Dental Environment (SADE) and Regular Dental Environment (RDE) on anxiety levels of children undergoing dental treatment.

AIM AND OBJECTIVES

AIM OF THE STUDY:

The aim of the study is to evaluate and compare the effectiveness of Sensory Adaptive Dental Environment (SADE) and Regular Dental Environment (RDE) to alleviate anxiety in children undergoing dental treatment.

OBJECTIVES OF THE STUDY:

- To evaluate the effectiveness of Regular Dental Environment (RDE) to alleviate anxiety in children undergoing dental treatment.
- To evaluate the effectiveness of Sensory Adaptive Dental Environment (SADE) to alleviate anxiety in children undergoing dental treatment.
- To compare the effectiveness of Sensory Adaptive Dental Environment (SADE) and Regular Dental Environment (RDE) to alleviate anxiety in children undergoing dental treatment.

RESEARCH HYPOTHESIS

NULL HYPOTHESIS:

There is no difference in the effectiveness of Sensory Adapted Dental Environment (SADE) and Regular Dental Environment (RDE) to Alleviate Anxiety in Children Undergoing Dental Treatment.

ALTERNATIVE HYPOTHESIS:

There is a difference in the effectiveness of Sensory Adapted Dental Environment (SADE) and Regular Dental Environment (RDE) to Alleviate Anxiety in Children Undergoing Dental Treatment.

REVIEW OF LITERATURE

"To create a special environment is creating a dental heaven, it is about creating a right space for the people who would never want to leave it"

-Dr. Jonathan Levine

It is a well-known fact that dental anxiety is a predominant problem affecting many children during dental procedures. The literature search delves into uncharted territory showing etiological factors, clinical features and seeking to uncover the key elements of management for a calmer, more enjoyable dental experience for young patients using basic behaviour guidance techniques and advanced innovative techniques including specialized environment interventions. This research hopes to revolutionize pediatric dental care, manage their dental anxiety and dental fear while undergoing dental treatment and create a positive dental environment.

The literature review presented herein is structured meticulously to dissect the multifaceted realm of pediatric dental anxiety and its potential improvement through interventions of a special environment addressing the 5 senses of human body called the Sensory Adapted Dental Environment (SADE). Each section of this review represents a distinct facet of this fundamental theme, aiming to unravel the complexities and nuances inherent in interplay between anxiety and visual, auditory, olfactory, tactile and gustatory stimuli presented as Sensory Adapted Dental Environment in the context of Pediatric dental care. The review has delved into the existing literature to explore the following areas:

A. Literature on anxiety and assessment of anxiety in children
B. Literature on prevalence and etiological factors of dental anxiety in children.
C. Literature on relationship between visual stimulation and anxiety (chromotherapy)
D. Literature on relationship between auditory stimulation and anxiety (white noise)
E. Literature on relationship between tactile stimulation and anxiety
F. Literature on relationship between olfactory stimulation and anxiety (aromatherapy)
G. Literature on relationship between gustatory stimuli and anxiety
H. Literature on combination of audio therapy and aromatherapy and anxiety
I. Literature on relationship between SADE and anxiety

A. LITERATURE ON ANXIETY AND ASSESSMENT OF ANXIETY IN CHILDREN

"Dental anxiety refers to a state of apprehension that something dreadful might happen during the course of dental treatment." Dental anxiety ranks 4th among various anxieties and 9th among fears. If dental anxiety is left untreated for a prolonged time, it will lead to postponement the treatment needs and worsen the oral health of such patients.[23]

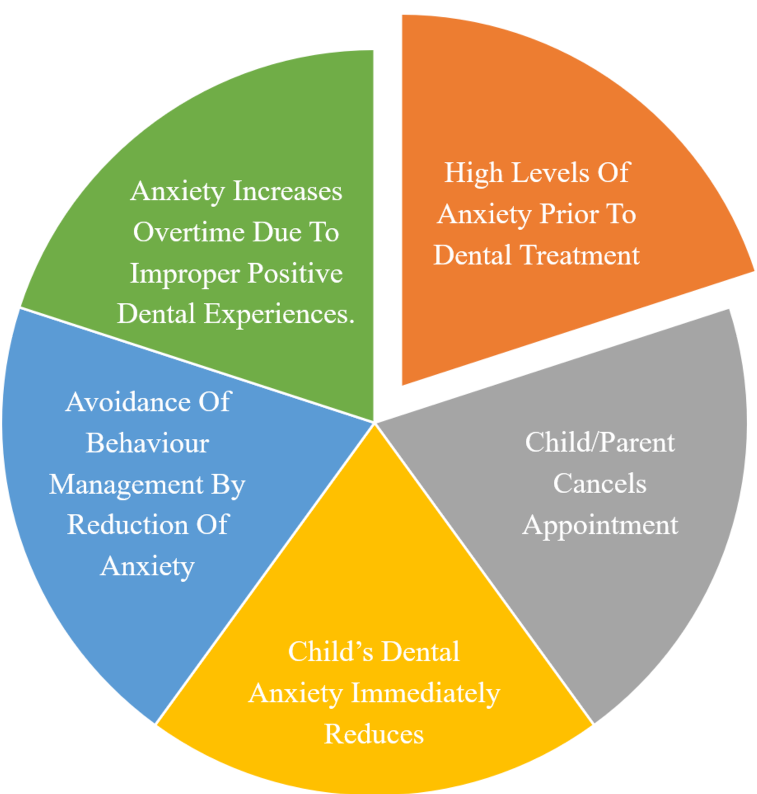


Figure No. 1: Figure Showing Schematic Representation of Cycle of Avoidance

Dental anxiety triggers a self-perpetuating cycle of avoidance, resulting in symptom-driven dental treatments that ultimately exacerbate the child's anxiety. This vicious cycle can lead to a downward spiral, where increasingly complex and traumatic dental experiences reinforce the child's fear, making future dental visits even more challenging.[1] [Figure No. 1]

In order to investigate the hypothesised sequence of the "vicious cycle" of anxiety, a study was performed on 300 children who were 7 to 11 years old. The investigators aimed to evaluate dental anxiety and fear in children and find out connection between dental caries, dental anxiety & fear. A questionnaire was given to the participants in this study and CFSS-DS was used to judge the final results. The study showed a high pervasiveness of dental anxiety in children who were very petrified of injections, followed by airotor, fear of choking, fear of infirmary or clinic, doctor in a white coat, unfamiliar person touch and fear from the dentist. Overall, there was no statistically significant difference in the scores when compared between the 2 genders expect questions like unfamiliar person touch, visiting the hospital, seeing people in white coat and fear of the dentist showed a very highly statistically significant difference with ‘p’ values of 0.00, 0.000, 0.007 and 0.018 respectively. It was seen that children who had previously gone to a dental clinic and were acquainted with the dental environment at an primary stage of life had diminished anxiety than patients who were receiving dental treatment for the first time. This study thus concluded that children are anxious of many things in the dental operatory and as Pediatric Dentist we should try to do proper behaviour guidance and manage the patient in the dental operatory.[24]

Thus, children experiencing higher levels of anxiety do not want to undergo dental treatment. It leads to more severe consequences and pattern of dental visits become symptomatic. This can exacerbate or maintain pre-existing dental anxiety. Patients with anxiety may be subjectively assessed based on their behavioural, emotional, and psychophysiological reactions. The most common clinical features seen in anxious child will be:

- Muscle stiffness, unsteady hands, impatience, increased action of swallowing
- Sweating on the extremities of body, forehead, upper part of lip throbbing pulse in the carotid and temporal arteries, respiration rate increased, rigid posture
- Firmly grabbing things, increased frequency of urination.

On the other hand, certain behavioural and emotional responses include symptoms like

- Hyperactivity, Walking or conversing at increased pace, annoyance
- Alarmed, red-faced, dodging social interaction, panicky habits, unable to remember things
- Confused, hesitant with words, perched on chair's edge, unfocused, undue worrying, forward bending and outburst of emotions.[25]

There are several tools for assessment of a child's psychological or behavioural changes due to dental anxiety. Understanding a child's emotion is of utmost importance as it helps the Pediatric Dentist to manage the child's behaviour and thus reduce their pre and post operative anxiety. A systematic review was conducted to assess whether current research in pediatric dentistry effectively distinguishes between dental fear, dental anxiety and odontophobia. There were 104 papers published between 1986 and 2015. Among them, only 5 studies published employed distinct clinical criterions to discriminate between these 3 features. These studies utilized a variety of assessment tools, including 2 self-assessed tools and 24 recognized scales for dental anxiety, one scale for dental fear, and two scales for injection and blood phobias. The established scales comprised 9 psychometric tests, 10 visual scales and 4 behavioral assessment tools. The most recurrently used scales were: CFSS-DS employed in 40 studies (38%) to assess both dental anxiety and fear.

The second most recurrent tool used for assessment of DFA was Venham Picture Test (VPT) appearing in 13 studies (12.5%). The Modified Child Dental Anxiety Scale Faces Version (MCDASF) was used in 11 studies (10.5%). The participants in this review were divided into three age categories: preschoolers (3-6 years), school-age children (6-12 years), and adolescents (12-18 years).[26]

Pictorial scales were the most commonly used measure type for children aged 3 to 6. 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. CFSS-DS for parents ranked highest in this aspect. 8% of investigations involved behavioral rating measures. DFA was assessed frequently by using psychometric tests (50%) and visual scales (33%) in children aged 6 to 12 years. 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. 38% of studies used psychometric tests while 13% studies employed the utilization of visual scales. 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.[26]

B. LITERATURE ON PREVALENCE AND ETIOLOGY OF DENTAL FEAR, DENTAL ANXIETY AND ODONTOPHOBIA IN CHILDREN

Dental anxiety and fear often go hand in hand where it becomes very challenging for the Pediatric dentists to distinguish between dental fear and anxiety. Dental anxiety is a phenomenon which is predominant among people who had negative dental experiences in past. Children suffering from dental anxiety postpone their dental treatment which causes decline of oral health of child and further degenerates the dental anxiety. Dental anxiety pervasiveness among kids varies from 4 % to 98 %. A systematic review and meta-analysis done on 25 studies aimed to determine the global pooled prevalence of dental anxiety among children of age 2 – 6-year-old. This review stated that the frequency of dental anxiety among kids of this age group approximately 30%.[27]

A systematic review and meta-analysis conducted by Grisolia et al aimed to describe the global prevalence of DA in children and adolescents. The objective was to scrutinize the influence of factors such as age, gender and caries experience and on dental anxiety. This review involved studies published from 1985 to 2020. After going through 1207 records, 224 complete articles were screened. 50 articles were included in the review. The study found an overall occurrence of dental fear and anxiety of 23%, with varying rates across age groups: preschoolers (36.5%), schoolchildren (25.8%), and adolescents (13.3%). Dental anxiety and fear were significantly more prevalent in kindergarten (preschoolers) children and school going children.[28]

A study was conducted on 400 children with the aim to determine the occurrence of dental anxiety among six- to twelve-year-old children. This study was done on children of India with the use of Modified Dental Anxiety Scale (MDAS). The results showed that among 400 participants, 61.5% (n=240) had severe dental anxiety, 23% (n=92) reported mild anxiety and 17% (n=78) exhibited no anxiety. Females exhibited significantly higher anxiety levels than males. Furthermore, the majority of participants identified the administration of local anesthesia (LA) injections as the most fear-inducing aspect of dental treatment. Interestingly, dental anxiety was found to be more pronounced in younger age groups. The pervasiveness of DFA in 6 – 12-year-old children of South India was 84%, while it was 6.3% in children of North India.[3]

Dental anxiety is triggered by multiple etiological factors for instance past undesirable experience of dental treatment (conditioning experiences) or indirectly acquiring it from anxious family members or peers, lack of understanding, fear of unknown, individual personality (neuroticism and self-consciousness), attitude of dental personnel and even the positioning of the dental chair. Other factors such as sight of needle, smell and taste of dental materials used, sound of airotor handpiece and even the sensations of vibrations from dental equipment can elicit anxiety.[29] Among these factors mentioned above, the environment of the dental operatory theaters an vital role in provoking dental anxiety of the patient undergoing dental treatment. The determinants of dental anxiety are patient factors, dentist/staff attitude, dental operatory and dental procedure.[30] [Figure No. 2]

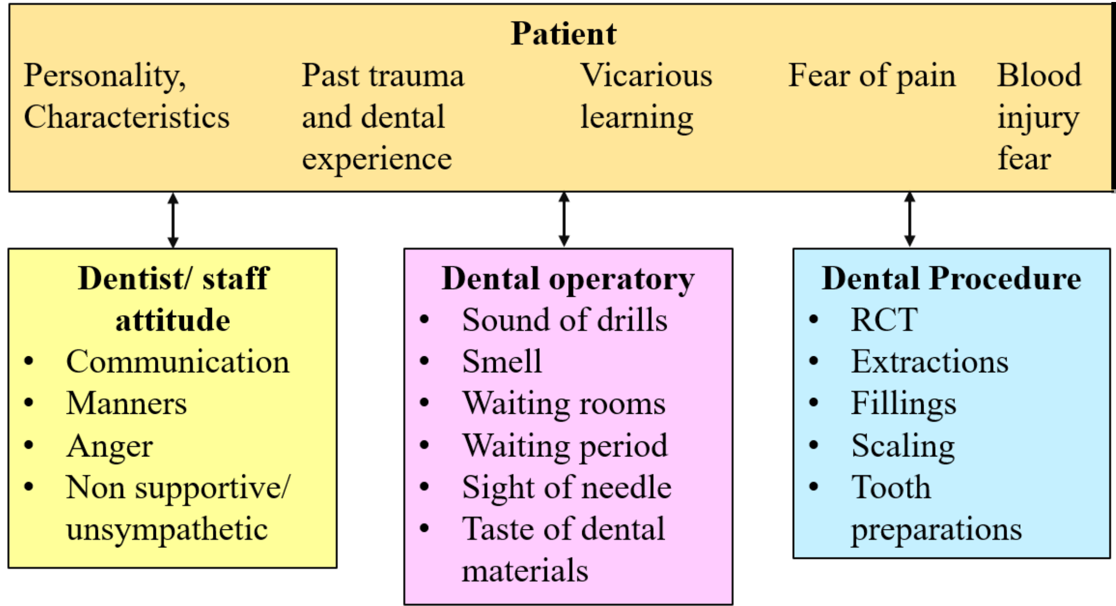


Figure No. 2: Figure Showing Schematic Representation of Determinants of Dental Fear and Anxiety

Review done by Shindova et al on environmental influences, stated that factors of dental environment such as instruments, blood, unpleasant smell and taste, sight of needle, sound and sensations of dental drill are the most provoking factors during dental treatment. The children are afraid of sight of needle and sensations of dental drill. They are bothered by the smell and taste of cut dentin and dental materials. These factors thus become the major factors leading to increased dental fear and anxiety children undergoing dental treatment.[31]

Stein Duker et al in the year 2022 have developed a conceptual model showing the direct affiliation of dental anxiety and sensory over responsivity (including sensory related challenges triggered by tactile, auditory, visual, olfactory and gustatory stimuli) have stated that DA leads to declined quality of life related to oral health and increased behavioral problems of children in the dental clinic. [32] [Figure No. 3]

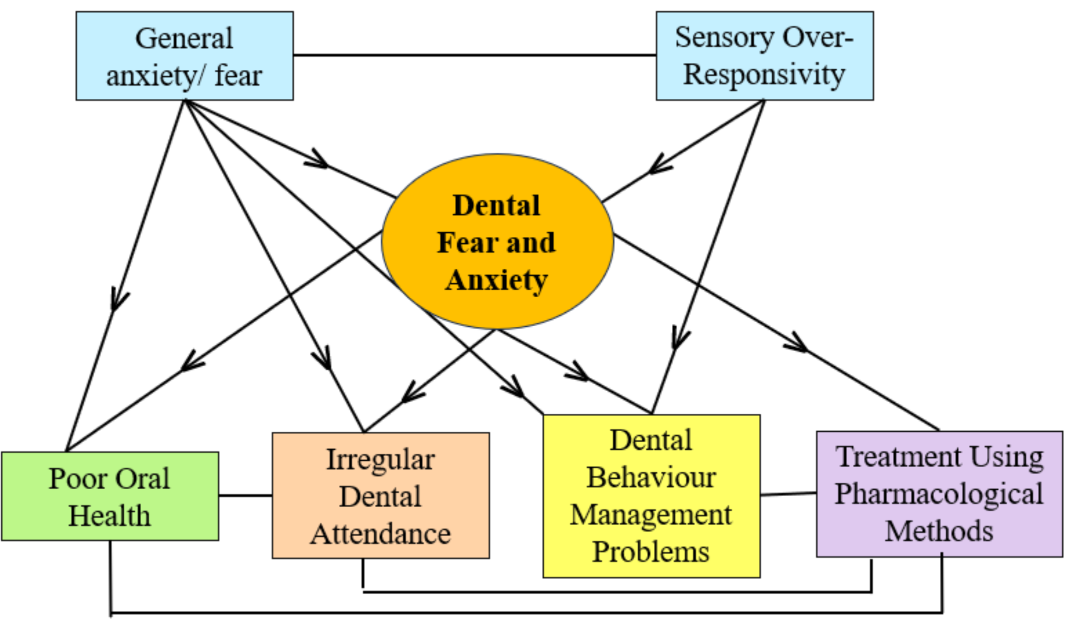


Figure No. 3: Figure Showing Schematic Representation of Conceptual Model of The Relationships of Dental Fear and Its Outcomes

The management of dental fear and dental anxiety can be done various non pharmacological methods like Modeling, Tell Show Do (TSD), Distraction, Hypnosis, Reframing etc. however, these conventional methods do not address one the most important anxiety causing factors i.e. the environment of dental operatory which includes stimulation by 5 sensations and is based on Snoezelen therapy.

C. LITERATURE ON RELATIONSHIP BETWEEN VISUAL STIMULATION AND ANXIETY (CHROMOTHERAPY)

Chromotherapy, also known as color therapy or visible range radiation therapy, is a holistic treatment approach that harnesses the therapeutic potential of visible light wavelengths to alleviate various diseases and medical conditions.[33] Color psychology is a multidisciplinary field that explores the complex emotional, cognitive, and behavioral responses elicited by specific colors.[14] Chromotherapy is one of the primordial therapeutic systems which has been utilized by ancient societies, including India, Egypt and China.

For centuries, chromotherapy has been employed to treat a range of diseases such as psoriasis, rickets, etc. This modality is closely related to light, photo and photobiomodulation therapy. It includes utilization of low-level laser therapy (LLLT). Phototherapy utilizes polychromatic light, with its origins tracing back to the work of Nobel laureate Niels Ryberg Finsen. Chromotherapy on the other hand utilizes only monochromatic light for its therapeutic effects.

Lights and wavelengths in the visible spectrum has demonstrated excellent therapeutic effects in various medical conditions like high BP, insomnia, dengue fever, high sugar levels, psychiatric problems, SAD (Seasonal Affective Disorder) and many more like acidity, joint inflammation and disorders.[33]

Monochromatic light of wavelength 600–750nm has shown light induces biological effects in both in vitro and in vivo studies. In vitro experiments by Lipovsky & authors and Maclean & authors have shown not only bactericidal but also proliferative effects of monochromatic light on bacterial cell. Apart from this, other various effects of chromotherapy as suggested in literature involves its effects on

wound healing, radiation of enzymes, effects on human psychology and psychological disroders.[34]

Chromotherapy is a holistic healing modality that harnesses the unique energy signatures of the seven colors of the visible spectrum i.e VIBGYOR (violet, indigo, blue, green, yellow, orange and red). Each color parallels to a particular wavelength of light, collectively forming vibrant tapestry of the spectrum. Each color depicts different emotion and has different effect on the psychology of the patient. Like the color red and yellow are warmer tone colors and hence are associated with aggression, sadness and feeling of tense. While colors of cooler shades like blue, green, pink is totally opposite of the color yellow and red. Colors like blue, green, pink is associated with relaxing and comfort. Both blue and green are colors of peace, calm and quiet and hence help in decreasing heart rates, blood pressure which in turn helps in relaxing of an individual.[35]

The colors of visible spectrum have a direct effect on the brain and they enter the brain via retina and visual pathways. As soon as the visible light falls on the retina, the impulses are perceived by the retinal cells (photoreceptor cells) and this is transmitted to the optic tract by the optic nerve. These impulses then reach the anterior part of the hypothalamus in the suprachiasmatic nucleus (SCN). This SCN then conveys retinal impulses to the pineal gland. From this gland secretion of melatonin hormone takes place. The SCN also contains melatonin receptors (MT1 and MT2) which enhances secretion of hormone melatonin. Serotonin is also released which in turn affects the mood and behaviour of a person. Balance between the secretion of these hormones maintains the circadian rhythm in the body and regulates the correct sleep cycle. With this, these hormones also produce a calming effect which finally

helps in relaxation of an individual. The following figure shows the visual pathway of the visible light and its effect on brain.[33] [Figure No. 4 and 5]

Thus, these positive emotion colors like blue, green, pink etc not only affects the psychology of a person but also helps in creating a positive environment in the surroundings. Research suggests that environmental elements that evoke positive emotions can significantly alleviate anxiety. By extension, it is plausible that a thoughtfully designed dental environment, incorporating calming colors, can have a thoughtful impact on a child's behavior and comfort levels. This, in turn, may help mitigate dental anxiety, creating a more positive experience for young patients.[36]

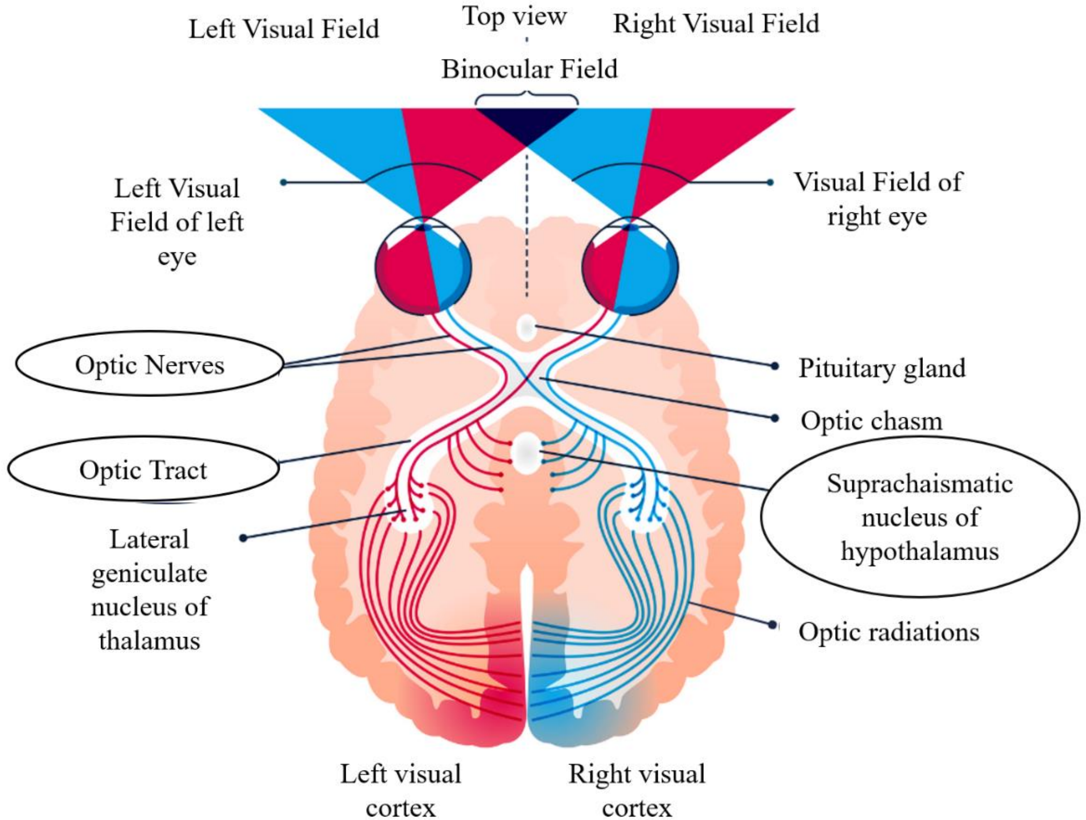


Figure No. 4: Figure Showing Pictorial Representation of Visual Pathway of Visible Spectrum of Light

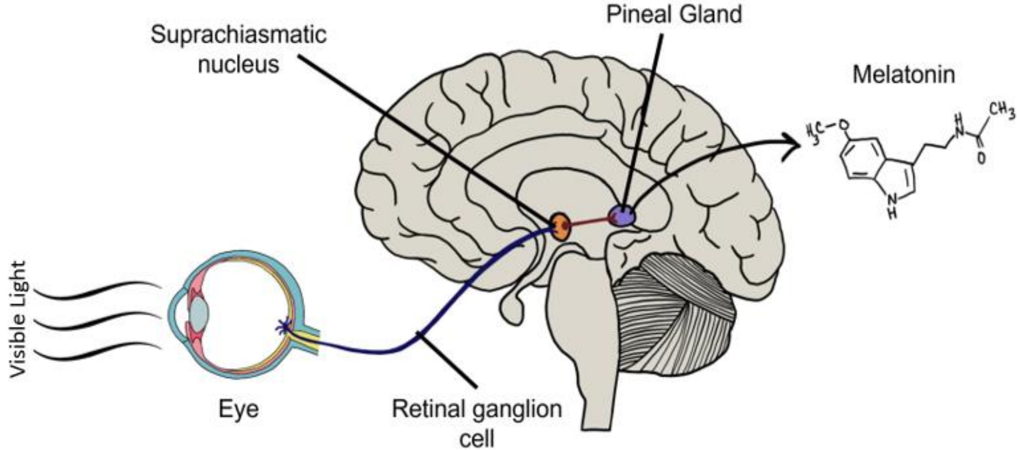


Figure No. 5: Figure Showing Pictorial Representation of Mechanism of Action of Visible Light on Brain

A trial by Saklecha et al aimed at evaluating the efficacy of using color therapy (chromotherapy) on the levels of anxiety of people undergoing endodontic dental treatment. 90 patients were randomly segregated into 3 groups. Each group contained of 30 patients. Group 1 received chromotherapy by using blue color. Group 2 received pink color therapy and group 3 was control group. The results of this study stated that anxiety scores after chromotherapy and after endodontic treatment in between groups was very highly statistically significant ($p = 0.000$) and ($p = 0.000$) respectively. Anxiety levels increased post operatively in control group with a statistically significant difference of 0.006. Hence it was proved that chromotherapy by using blue and pink color reduced anxiety in patients who were undergoing endodontic dental treatment.[16]

A study aimed to assess the relation between emotions of child, color and in turn its correlation with anxiety. 300 young participants aging 6 to 12 years were first divided equally into 2 groups. The division was based on the age group of children. The younger age group comprised to kids from age 6 to 9 years. The older age group

consisted of participants aged from 10 to 12 years. The results stated that, among children from younger age group 66.67% were highly anxious while 33.33% were non anxious. In the other group (older age) only 38.89% of while 61.11% were non anxious. This difference in anxiety was statistically significant 'p' value <0.001. Showing that younger children are more afraid of dental treatment. Children in this age group preferred yellow color and related to it as a "happy emotion" color. Older children like blue color and linked it to "positive emotion". This difference in preference of color was statistically significant 'p' value ($p<0.001$). Hence proving that use of color friendly environment with colors like blue and yellow creates a positive dental attitude in children.[36]

Another study by Hotwani et al aimed at assessing the impact of colors on the anxiety of children. They also assessed the color which was mist preferred by the child for LA injections. 100 pediatric population of age 9 years were included. The results found that male participants were more inclined towards the color blue while female participants liked red color. The color associated with "happy emotion" was blue and yellow by male and female participants respectively. This difference between gender was statistically significant ($p<0.05$). Hence concluding that a child's anxiety can be reduced by remodeling the appearance of dental instruments and use of colors like blue and yellow can be helpful in anxiety reduction.[37]

Cross sectional study by Kattakayam et al sought to seek the association of color to emotions when a child's gender, age and anxiety level was taken into consideration. 382 children participated in this study and the age range was 6 to 12 years. Of the total population in this study, 31.2% kids preferred blue color. Followed by pink, yellow, green and red with 29.2%, 17%, 13% and 1.2% respectively. There was a statistically significant difference between male and female preferring blue

color with ‘p’ value of 0.046, yellow color with ‘p’ value of 0.004, green color with ‘p’ value of 0.001, pink color with ‘p’ value of 0.001 for positive emotions. Hence showcasing that blue and pink color helps in establishing positive emotion and attitude in the dental set up in children.[38]

D. LITERATURE ON RELATIONSHIP BETWEEN AUDITORY STIMULATION AND ANXIETY (WHITE NOISE / AUDIO ANALGESIA)

"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.[39] 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.[40]

White noise was first originated in 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.

Listening to music can improve attention and memory. It helps to connect perception and action also called ‘mirror neuron system’, helps in achieving multisensory integration, emotional processing and social cognition. A study in 1990 stated that ‘white noise’ is a flat frequency, consistent noise which aids in falling asleep of neonates. People exposed to white noise in the background can relax better as white noise masks the other peak noises effectively.[41] White noise, named for its similarity to white light, is a consistent, even mixture of all audible frequencies. This unique sound phenomenon can be found in various natural and soothing environments, such as:

- Ocean waves and beach sounds
- Heart beat noises, often used to mimic the comforting sound of a mother's heart beat
- Instrumental lullabies and calming melodies

These examples of white noise have been shown to create a sense of calm and relaxation, making them ideal for promoting sleep, reducing anxiety, and improving overall well-being.[42]

The therapeutic effects of music can be attributed to its profound impact on various psychological and cognitive processes. Five key factors contribute to the benefits of music therapy:

1. Attention Modulation: Music has the ability to divert attention away from unpleasant stimuli, such as pain and anxiety, thereby reducing their perceived intensity. This explains the observed reduction in anxiety and pain perception during painful dental treatments.
2. Emotional Modulation: Music is a powerful emotional trigger, capable of evoking a wide range of feelings, from joy to sadness. By influencing brain activity, music can effectively regulate and modulate emotional responses.
3. Cognitive Modulation: Music is closely linked to memory and storage processes, with musical experiences often serving as powerful triggers for recollection. This connection highlights the role of music in shaping cognitive function.
4. Behavioral Modulation: Music therapy can also influence behavior, with music affecting patterns such as walking, speaking, and grasping. This underscores the potential of music to shape motor responses and behavioral habits.

5. Communication Modulation: Furthermore, music serves as a means of communication, facilitating expression and connection. By influencing communication patterns, music therapy can foster social bonding and emotional understanding.[43]

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 calm music causes a relaxation, which in turn lowers heart rate (HR) by arousing the parasympathetic nervous system (PNS).[44] Oxytocin is a neurohormone that has calming and bonding properties, making it a potential explanation for the music effect. 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.[45] A systematic review conducted by Ainscough et al in 2019 has states that music has its effects on both ANS and brain's limbic system. Listen to music or music therapy directly affects the limbic system of brain leading to release of hormones like endorphins & enkephalins which helps in anxiety reduction and stress relief.[46]

Apart from anxiolytic actions, music or audio therapy also has analgesic actions which helps in relieving pain of the patient and in turn helps in reducing anxiety. This mechanism of action can be explained by the gate control theory of pain. This theory proposes that pain signals are transmitted from the site of injury to the brain through a complex process involving nerve receptors, synapses, and spinal cord pathways. When pain stimuli are applied to the body, sensory receptors are activated.

These signals travel to the spinal cord via the posterior nerve root, where fibers from the sensory receptors (posterior column fibers) send branches to the neurons involved in the pain pathway, including the cells of the marginal nucleus and substantia gelatinosa. The impulses associated with the unpleasant sensation traveling through these branches prevent the release of glutamate and substance P from the pain fibers. This process effectively closes the "gate" and blocks the transmission of pain signals. The 'gate' controlling pain perception is opened, allowing auditory stimuli to dominate and reducing pain perception. In essence, the introduction of auditory stimulation 'closes the gate' to pain signals, preventing them from reaching the Central Nervous System (CNS). This mechanism underlies the analgesic effects of music and sound therapy, which can effectively reduce pain perception by modulating the neural pathways involved in pain processing.[47] In the brain, the descending pain pathway is stimulated which is also called as descending inhibitory system for control of pain frequencies and intensities. Several neuro-modulators such as endogenous opioids (endorphin, encephalin, endomorphin, and dynorphin) and serotonin (5-HT) are released which causes the relief of stress or reduced anxiety.[48] [Figure No. 6]

An alternative explanation for pain relief through music is provided by "Robert and Sowray's Cross-Sensory Mechanism". This theory suggests that pain and auditory pathways are closely linked together. These pathways are in the reticular formation in lower thalamus of brain. Interaction between these two systems is vastly inhibitory. The reduction in pain perception occurs due to the activation of another sensory pathway that has an inhibitory effect. In this case, the auditory stimulation effectively masks pain signals, leading to a decrease in dental anxiety. Both the direct suppression of pain and the effects mediated through relaxation, anxiety reduction,

and distraction can be attributed to acoustic stimulation, which lowers the "gain" of pain transmission pathways that system influences.[43] [Figure No. 7]

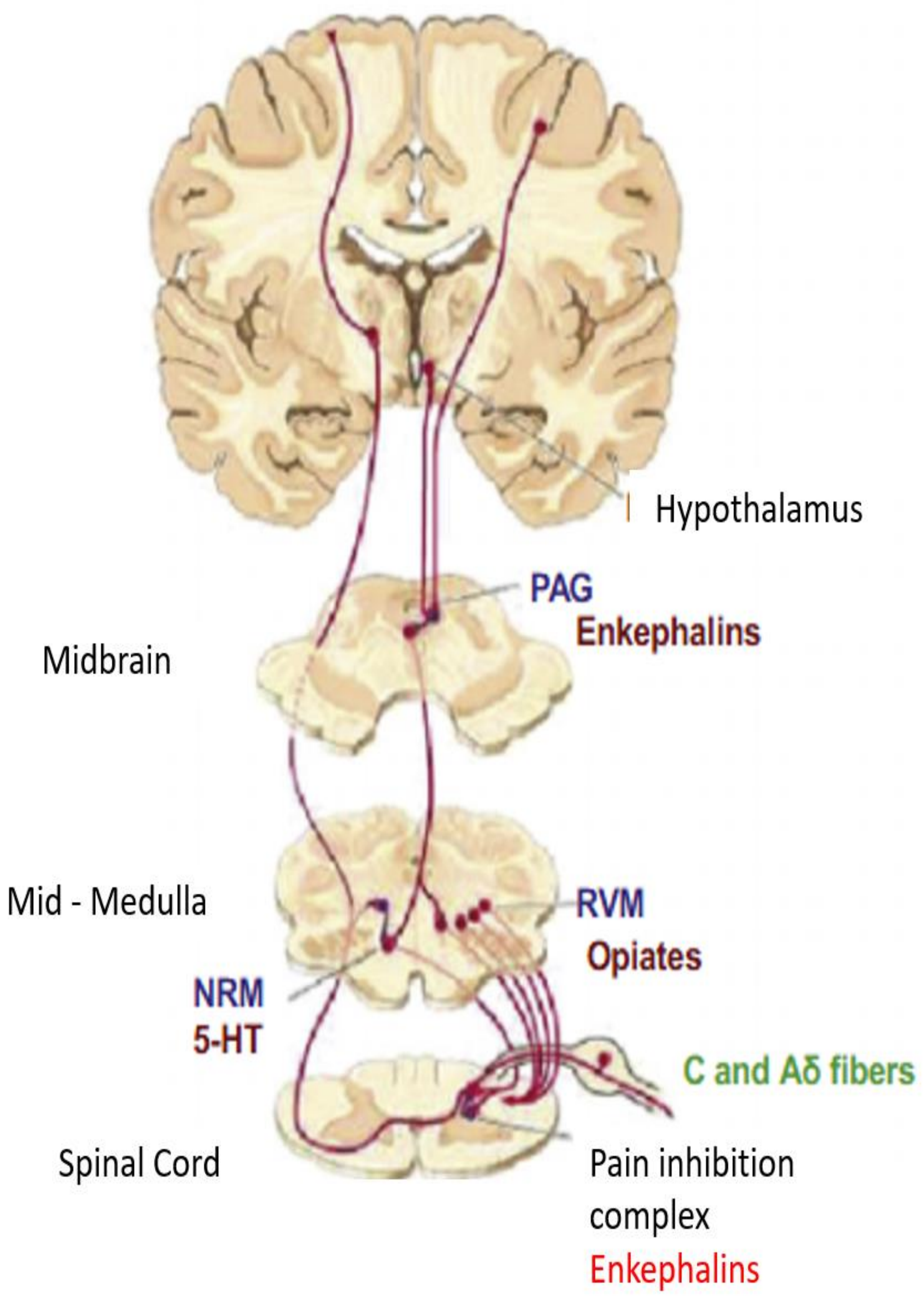


Figure No. 6: Figure Showing Pictorial Representation of Gate Control Theory

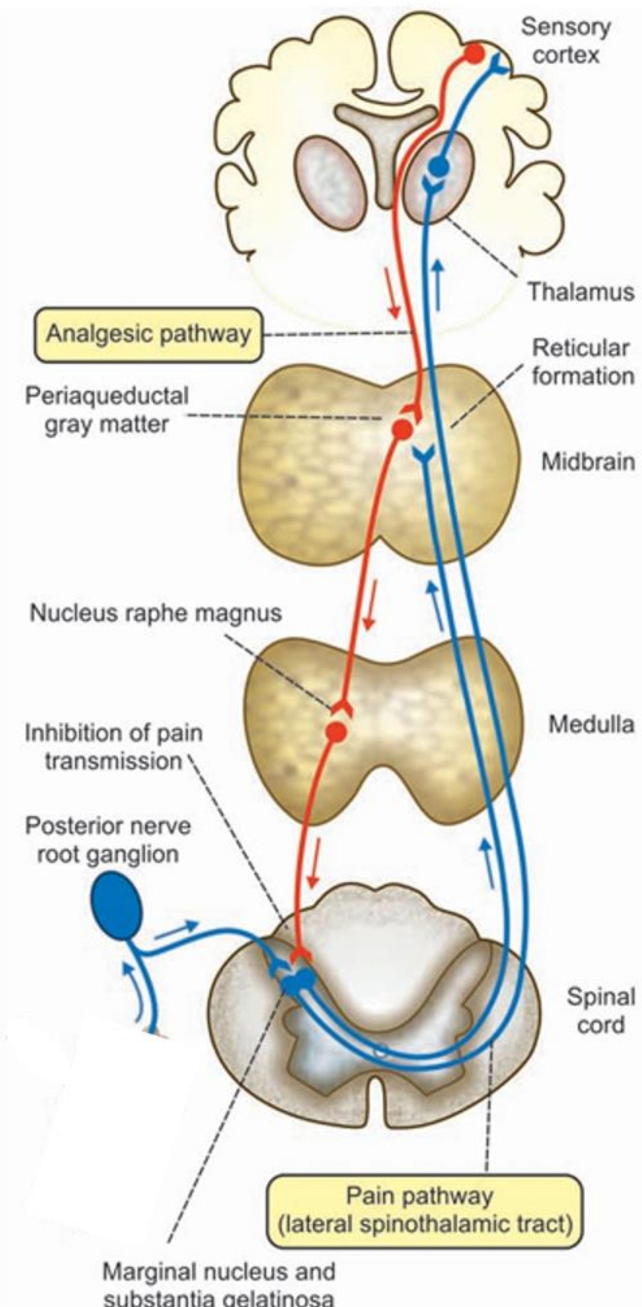


Figure No. 7: Figure Showing Pictorial Representation of Pain and Analgesic Pathway (Cross Sensory Pathway)

A randomized trial by Kolhe in 2024, aimed to check the effectiveness of various types of noise on children undergoing removal of deciduous teeth. These noises were white, pink and brown noise. 40 children participating in the study were randomly divided into 4 groups. The age of the children was 8 to 12 years. Group A

was white noise, group B was pink, group C was brown noise group while group D was control group listening to cartoon music. The change in the pulse rate scores within each group showed statistically significant results with white noise with ‘p’ value of 0.02. Changes in the VAS scores within each group was highly statistically significant results with white noise with ‘p’ value of 0.003. Comparison of Venham’s Picture Test (VPT) scores within each group was highly statistically significant results with white noise with ‘p’ value of 0.002. Pairwise comparison of change of pulse rate with white noise with each group was statistically significant results with ‘p’ value of 0.021. The study thus concluded that audio distraction can effectively reduce anxiety.[41]

A trial performed with aim to seek efficacy of different types of noise in aiding in relaxation of children. 40 children of age range 4 to 8 years were a part of the study. They were randomly allocated into 4 groups. The comparison was done among white, brown and pick noise. Results showed that Face, Legs, Activity, Cry, Consolability (FLACC) scores comparison among different groups was found to be non-significant with 'p' value of 0.188. Comparison of WBFPRS among different groups was also non-significant with ‘p' value of 0.524. Intra-group comparison of heart at different time points revealed a significant value. Ratings of before exposure, at the time of treatment and after treatment were 0.020, 0001. 0.006 respectively for white noise group which was statistically significant. Intergroup comparison of mean scores at various time intervals was significant for white noise group (p=0.022). Thus, this study concluded that no particular shade of sound is better, its audio destruction which is responsible for reduction in anxiety.[49]

Another study by Ramar and authors was designed to evaluate the effectiveness of audio analgesia by white noise in children undergoing tooth extraction procedure. 6 to 12 year old 40 children were a part of this study. They were then saggared into 2 groups. Group 1 underwent tooth extraction procedure without any audio. Group 2 children were made to listen to music while undergoing tooth removal. A very highly statistically significant difference with ‘p’ value 0.000 was seen between control and study group during LA administration. During extraction procedure, a very highly statistically significant difference with ‘p’ value 0.000 was seen between control and study group. This study thus concluded that audio analgesia can be effectively used a behaviour management tool in children aged 6 – 12 years during dental procedures.[50]

E. LITERATURE ON RELATIONSHIP BETWEEN TACTILE STIMULATION AND ANXIETY

Tactile stimulation works like an active distraction for the child while the dental treatment in on going. Tactile stimulation can be achieved by play therapy with the help of using stress ball which the child can easily squeeze during the procedure and this act can aid in distraction of the child away from the unpleasant stimuli.

Grabbing task mechanism works by cognitive refocusing theory which states that pain management technique rooted in the theory that distraction can significantly alter pain perception. By diverting attention towards more engaging and pleasant stimuli, individuals can effectively reduce their pain experience. This method leverages the brain's limited cognitive resources, redirecting mental focus away from pain and towards more enjoyable and captivating attractions.[20]

A review by Chen J et al in year 2024 has mentioned that tactile stimulation can be achieved by both passive and active distraction aids. The active distraction aids by stress ball not only works on cognitive refocusing theory but also on gate control theory of pain. For tactile stimulation, activation of non-painful sensory inputs like senses of touch or vibration takes place which in turn reduced the pain perception and thus reduces the anxiety.[51]

According to Tracey and Mantyh, pain perception is a multifaceted experience that encompasses cognitive-evaluative, motivational-affective, and sensory-discriminative components. Building on this understanding, Legrain et al. proposed a neuro-cognitive model of attention, that contends that raising cognitive load can lessen the perception of pain. Specifically, it postulates that engaging in attention-grabbing tasks can divert attention away from the pain source, thereby reducing pain sensation.[21] [Figure No. 8]

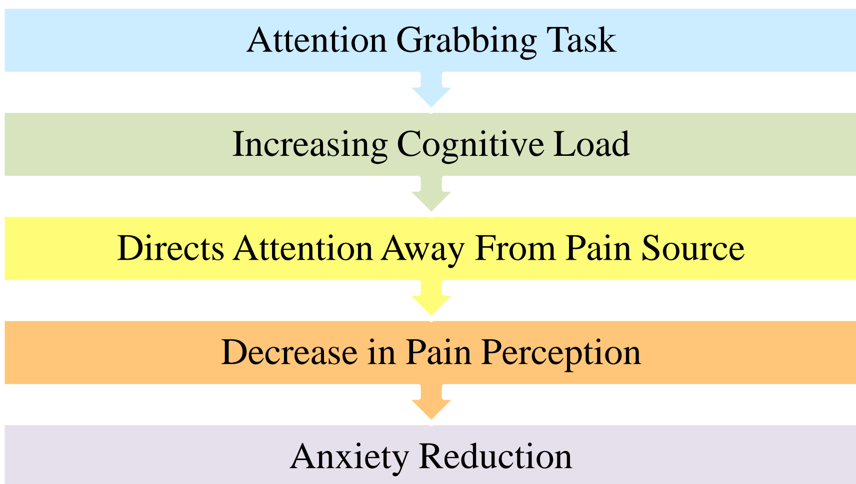


Figure No. 8: Figure Showing Schematic Representation of Neuro - Cognitive Model of Attention

A study with aim of comparison of efficacy of 3 distraction methods was performed for management of DA in children. The methods involved utilization of intellectual color game, AV distraction and stress ball. 108 kids of age 5 – 12 years were divided into 3 Groups. The groups of the study was intellectual color game for group 1, AV distraction for group 2 and stress ball was used in group 3. Group 3 showed significant reduction in the gagging scores after the dental treatment when compared to other groups with ‘p’ value of 0.026. Intragroup comparison of anxiety scores showed highly statistically significant difference in reduction of anxiety in stress ball group with ‘p’ value of 0.001. The conclusion was distraction via use of stress ball can be recommended in children for gagging and anxiety management.[52]

A randomized study aimed at comparing the effectiveness of stress ball and AV glasses on dental anxiety, behaviour and pain perception of children. Children aged 8–12 years 123 in number were assigned arbitrarily into 3 groups. The first group was stress ball group, second group was AV glasses group and third one was control group. Intergroup comparison of the mean anxiety scores did not yield a

statistically significant value at both the time intervals i.e. 'p' values was 0.869 before the procedure and 'p' values was 0.688 after the procedure. The difference in the behaviour rating scores between 3 groups was non-significant with 'p' value of 0.871. The intergroup comparison of mean of pain scores showed no significant difference with 'p' value of 0.072. The study thus concluded that active distraction via stress ball and passive distraction via AV eyeglasses did not show any significant change in anxiety, behaviour and pain of child during dental procedure.[20]

A randomized split mouth trial was done to evaluate the utilization of a stress ball as a distraction method on stress levels of patients undergoing a dental treatment. Study was conducted on 20 subjects requiring dental treatment with or without use of local anaesthesia. Anxiety was assessed using MDAS and galvanic skin response (GSR). The difference in the GSR scores with or without use of stress ball was found to be non-significant (p=0.14). There was no difference in the change of MDAS scores between the 2 groups where the 'p' value was 0.15. This study found that utilization of a stress ball during dental treatment under LA did not result in reduction in stress levels in patients.[21]

F. LITERATURE ON RELATIONSHIP BETWEEN OLFACTORY STIMULATION AND ANXIETY (AROMATHERAPY)

Dental anxiety often develops in childhood and adolescence, with a significant proportion of young individuals experiencing some level of dental fear. Research indicates that approximately 50% of children exhibit low to moderate dental anxiety. 10% to 20% of children experience dental anxiety at severe levels. Thus, early identification and intervention is important in mitigating the development of dental anxiety and promoting positive oral health experiences. Pungent smell in the dental operatory like smell of cut dentin, smell of dental materials like eugenol, smell of the chemicals used in sterilizing the dental clinic can provoke anxiety in children experiencing dental treatment.[17] To overcome these factors, olfactory stimulation via aromatherapy was designed.

The word “aromatherapy” is a combination two words “aroma” which means “smell” or “fragrance” and “therapy” which means “treatment”. It is a holistic healing approach that nurtures the soul, body and mind. It has a rich history spanning over 6,000 years and its ancient practice has been employed by civilizations such as China, Egypt and India. These ancient cultures utilize aromatherapy as a complementary and alternative practice. An extensive range of health conditions can be treated by aromatherapy. A comprehensive literature review reveals that aromatherapy gained significant popularity in 20th century and remains a prevalent wellness approach in the 21st century. Due to its widespread acceptance, aromatherapy has evolved into a recognized discipline, aptly termed 'aroma science therapy' [53]

Aromatherapy utilizes the therapeutic potential of essential oils, which are highly concentrated, bioactive substances extracted from various plant parts, including flowers, leaves, stalks, fruits, roots etc. These complex oils are comprised of

diverse array of chemical constituents, such as saturated and unsaturated hydrocarbons. Other components are esters, alcohols, aldehydes, ethers, ketones, phenols, oxides, and terpenes, which collectively contribute to their distinctive aromas.[54]

Essential oils are characterized by their colorless, fragrant liquid state and high refractive index. Their potency and concentration enable them to interact with pressure points, promoting rejuvenation and well-being. These essences are stored in specialized structures, such as pockets, reservoirs, glandular hairs, and intercellular spaces within plants. The evaporation of these essences from plants serves as a natural defense mechanism, protecting them from bacterial attacks and temperature fluctuations. This intricate process highlights the remarkable role of essential oils in plant biology and their potential applications in aromatherapy.[55]

Lavender (Lavandula officinalis Chaix.) is a member of the Lamiaceae family. A versatile and fragrant herb commonly found in garden. Its essential oil is composed of beta ocimene, camphor, linalool, terpinen-4-ol, linalyl acetate and 1,8-cineole. Linalool has been demonstrated to possess sedative characteristics, while linalyl acetate demonstrates pronounced narcotic activities. These synergistic effects may contribute to lavender's traditional use in alleviating anxiety, promoting relaxation, and improving sleep quality. The following figure shows the mechanism of action of lavender on the limbic system of brain and how it effects in alleviating anxiety. [18] [Figure No. 9]

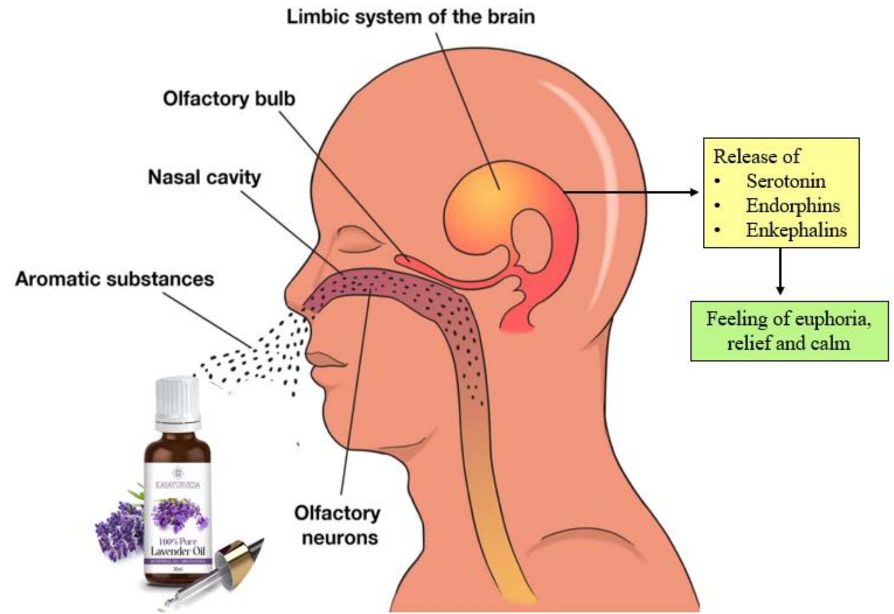


Figure No. 9: Figure Showing Pictorial Representation of Mechanism of Action of Lavender Essential Oil on Brain's Limbic System

A study sought to examine the effects of lavender and patchouli oil in the form of aromatherapy on dental anxiety in children. This was an in vivo study done on 60 children who were 6 to 12 years old. Anxiety was evaluated using 'chota bheem and chutki scale' and pulse rate scores were also evaluated. The intergroup comparison of 2 groups i.e. Lavender oil group and patchouli oil was highly statistically significant with 'p' value of 0.001. The intergroup difference in the pulse rate scores between the 2 groups was statistically non-significant. The intragroup comparison of pulse rate at pre-operative, intraoperative, postoperative and exposure after treatment in both the groups was statistically significant with 'p' value <0.001. Thus, this study concluded that lavender oil can be effectively used in anxiety reduction in children undergoing dental treatment.[55]

Ghaderi et al in the year 2020 conducted a study with the aim to asses that how lavender essential oil affects a child's dental anxiety while undergoing a dental procedure. Trial was conducted on 24 children aged 7 to 9 years. These children were

divided into 2 groups where 12 children in group 1 were given dental treatment without lavender aroma in first session and treatment was provided with lavender aroma in second session. Similarly, 12 children in group 2 were given dental treatment with lavender aroma in first session and treatment was provided without lavender aroma in session. The variance of mean salivary cortisol levels between the treatment with and without lavender aroma was found to be very highly statistically significant with 'p' value of 0.00064. The difference in mean pulse rate between intervention visit and control visit was also very highly statistically significant with 'p' value of 0.00043. Evaluation of pain perception was done by Facial Rating scale in both session and difference was again found to be very highly statistically significant with 'p' value of 0.00083. This study thus concluded that lavender aromatherapy can reduce child's anxiety while undergoing dental treatment.[17]

Arslan et al conducted a randomized clinical trial with the aim to assess the correlations between psychological and physiological outcomes following inhalation of lavender oil in children who are getting their tooth extracted. 126 kids between the ages of 6 and 12 were part of this trial. They were split into two groups namely control and lavender oil group. A statistically significant reduction of pain was seen by FIS between 2 groups with 'p' value of 0.023. However, intergroup comparison of FLACC and WBS scores were not statistically significant. Comparison of vital signs in control and lavender oil group were found to be statistically significant. In control group, the BP and HR values increased and the difference was highly statistically significant with 'p' value of 0.001. In lavender oil group, BP and HR were reduced with highly statistically significant 'p' value of 0.001 and 0.005 respectively. Accordingly, this study found that lavender oil can be used regularly in pediatric dentistry clinical practice as a relaxing agent to reduce anxiety.[56]

G. LITERATURE ON RELATIONSHIP BETWEEN GUSTATORY STIMULATION AND ANXIETY

In the dental operatory, a child might show increased anxiety due to unpleasant taste of dental materials like rubber dam, restorative cements, irrigating solution etc. because of which the child may not cooperate for the dental treatment. To overcome this problem use of flavored dental materials have come into picture.

The basic mechanism of action of how taste is perceived by our mind is related to the taste buds present in the tongue. A taste bud is a cluster of specialized cells embedded in the epithelial lining of the papillae on the tongue. Individual taste bud contains several cell types, including supporting cells (Type I and Type IV) and taste receptor cells (Type III). Type I, II, and III cells have specialized structures called 'microvilli' that protrude in a small opening in the epithelium, known as the 'taste pore'. The cells inside taste bud are interconnected, with their necks attached to one another. Furthermore, epithelial cells surround the taste buds establishing a tight junction with the neck portion of the Type I, II, and III cells. Effective taste perception is made possible by this configuration, which guarantees that only the tips of these cells are in contact with the fluid in the oral cavity. Taste receptor cells are type III cells. About 50 sensory nerve fibres innervate each of these taste buds. Within the medulla oblongata, the primary neurones of the taste pathway are found in the nuclei of three different cranial nerves. These neurones then extend to the taste buds, where they receive sensory information.

The taste sensation from the taste buds is then carried by the axons present here and finally these signals reaches the nuclei of cranial nerve via three specific nerves:

1. The chorda tympani branch of the facial nerve

2. The glossopharyngeal nerve

3. The vagal nerve

These cranial nerves contain the first order neurons which then congregate in the medulla oblongata. They end in the nucleus of the tractus solitarius. The second-order neurons of the taste pathway are located within the nucleus of the tractus solitarius. From here, their axons project via the medial lemniscus, ultimately terminating in the posteroventral nucleus of the thalamus. The thalamic posteroventral nucleus contains third-order neurones. Third-order neurones send axons into the cerebral cortex's parietal lobe. The opercular insular is the centre for flavour perception cortex, that is, in the postcentral gyrus's lower region, which receives facial cutaneous sensations. As a result, the taste fibres lack a separate cerebral projection.[47]

Pleasant taste not only provides good sensation of taste but also antinociceptive effects to pain and is called sweet substance– induced analgesia (SIA). The analgesic effect of sweet taste involves the activation of central regulatory systems, particularly the opioid-related descending inhibitory network. Consumption of sucrose solution upsurges beta-endorphin levels which demonstrates that the endogenous opioid system is activated sucrose. Furthermore, sweet-induced analgesia (SIA) is thought to involve opioid-related neurotransmitters, including serotonin (5-HT) and noradrenaline (NA), within the central nervous system (CNS). Therefore, SIA participates in the descending inhibitory pathway which reduced PNS related symptoms and is not a mere distraction.[57] [Figure No. 10]

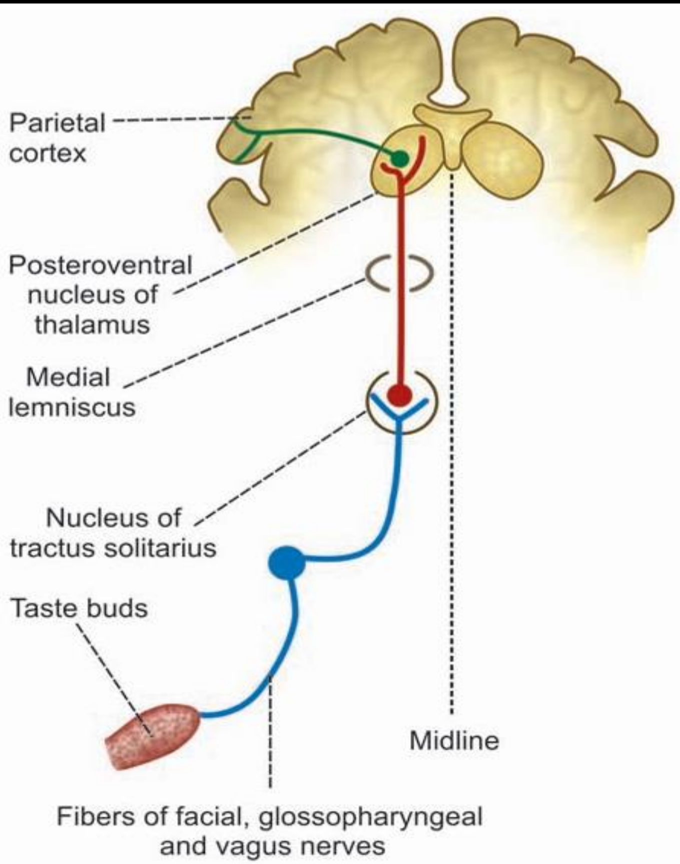


Figure No. 10: Figure Showing Pictorial Representation of Pathway of Taste Sensation

A study by Kumar et al 2020 designed to assess and determine children's preferences towards flavoured dental products. The objective was to check the effectiveness if these products in clinical practice. 60 children aging between 6 to 16 years were a part of this study. The results revealed that both males and females preferred flavored rubber dam with 38.88% and 45% preference respectively. However, the results were non-significant with 'p' value of 0.793. When age wise comparison was done between age groups of 6 to 10, 11 to 13 and 14 to 16 years, all preferred flavored rubber dams the percentage of which amounts to 28.33%, 30% and 25% respectively. The 'p' value was 0.122 which was non-significant. The study concluded that children preferred use of flavored materials and armamentarium and that flavors can be utilized in effective management of a child posed with behaviour and anxiety issues.[58]

A study with aim to determine whether the parents and kids preferred conventional, colored and flavored restorative materials, appliances and the armamentarium. 60 children aging between 6 to 12 years participated in this study. The results showed that all parents (100%) preferred the use of flavored materials. Children also liked flavored materials like rubber dam sheets and topical anaesthesia gel (100%). Thus, this study concluded that flavored materials are preferred by both parents and children as they provide with feelings of freshness and taste benefits.[59]

H. LITERATURE ON COMBINATION OF WHITE NOISE AND AROMATHERAPY AND ANXIETY

The amygdala situated in the brain's limbic system receives signals of the 5 sensations of human body. Here, emotions like fear, anxiety and sadness are formulated. Any unpleasant stimuli or any harm to the sensory system of the human body will lead to release of stress hormones (cortisol) and cause activation of the sympathetic nervous system. The dental operatory has such unpleasant stimuli which can create a stressful situation the patient undergoing dental treatment. Thus, to suppress multiple factors combination therapy (music + aromatherapy) is used to overcome such situations.[60]

A single blinded randomized control study conducted by Abdalhai et al in 2024 aimed to evaluate the effectiveness of aromatherapy in music together on dental anxiety and pain perception of children. In the study, lavender-neroli essential oil was used for aromatherapy. Whtie noise was used for music therapy. 56 children who were 6 to 10 years old were randomly divided into 2 groups. Group 1 was control and group 2 was combination therapy group. In the results of this study, it was found that there was no difference in the dental anxiety when measured by FIS in control group (p=0.916). Group 2 showed a very highly statistically significant reduction in anxiety with 'p' value of 0.000. Dental anxiety increased postoperatively in control with very highly statistically significant 'p' value of 0.000. Vital signs like BP decreased in group with a very highly statistically significant 'p' value of 0.000. There was no difference in pain perception according to FLACC scores with 'p' value of 0.176. Hence concluding that a child's dental anxiety can be effectively managed by combining music and aromatherapy.[61]

A study with the aim to evaluate efficacy of music therapy + aromatherapy on 132 children aging 10 to 12 years old for alleviating dental anxiety and fear. Study had 4 groups i.e i) control, ii) music, iii) aromatherapy and iv) combination of music + aromatherapy groups respectively. The heart rate increased in control group as compared to experimental group with non-significant 'p' value of 0.210. There was a highly statistically significant difference in the heart rate between control group and group receiving combination therapy with 'p' value of 0.003. The difference between in the SpO_2 levels were also highly statistically significant with 'p' value of 0.007. The difference in the FIS and CFSS – DS were statistically significant in all the groups with 'p' value of 0.05. This study thus concluded that combination therapy is effective in reduction of anxiety and fear in school going children.[18]

An in vivo study conducted in 2020 aimed to understand the effectiveness of virtual reality (VR) and white noise + aromatherapy on anxiety and troublesome behaviour of pediatric patients requiring administration of LA. 60 children of 6-to-9-year age were a part of the study. 20 children were equally divided in 3 groups. Group I being VR experience using AV Eyeglasses, Group II was White noise in adjunct with Aromatherapy, Group III was child's music of choice. Intragroup comparison of Group 1 of VPRS and FIS scores were statistically non-significant with 'p' value of 0.102 and 0.083 respectively. For Group 2, VPRS scores were statistically significant with 'p' value of 0.046 and FIS scores were statistically non-significant with 'p' value of 0.317. In group 3, VPRS and FIS scores were statistically non-significant with 'p' value of 0.56 and 0.317 respectively. Intergroup comparison of group 1, 2, 3 or VPRS and FIS scores were also statistically non-significant with 'p' values of 0.410 and 0.410 respectively. Thus, this study suggested that aromatherapy combined with white noise is useful aid in managing patients' dental anxiety.[60]

I. LITERATURE ON RELATIONSHIP BETWEEN SENSORY ADAPTED DENTAL ENVIRONMENT AND ANXIETY

The dental office is frequently perceived by children as an unpleasant, irritating, and anxiety-inducing setting, characterised by loud noises, strong smells, bright lights, intrusive oral contact, and the potential for discomfort.[9] A child's dental attitude and temperament should be carefully examined by pediatric dentist in order to forecast how the youngster will respond to treatment. There are many outmoded behaviour guidance techniques like tell show do, modeling, play therapy, AV distraction etc. but these techniques do not address the two most important things that provoke anxiety: the sensory aspects which increases anxiety and the environment of the dental operatory itself.

A comprehensive approach to behavior guidance is essential, as it acknowledges the unique needs and characteristics of each child. To achieve this, dentists should consider integrating multiple strategies into a personalized behavior guidance plan. A multidisciplinary approach can be developed by incorporating principles of sensory and perceptual processing in children, thereby creating a tailored, multi-sensory integration strategy. The brain's ability to arrange the data gathered from the senses to create a suitable reaction is known as 'sensory integration'. The VAK model (Visual, Auditory and Kinesthetic) was developed by Lisle et al to augment the children's skills. Multi-sensory approach consists of integrating two or more senses in order to enhance the skills of a child. This approach combines pictorial, acoustic, tactile-kinesthetic.

Ayres' sensory integration model identifies vestibular, proprioceptive, and tactile inputs as the foundational components of sensory processing. By incorporating this model into adapting the environment to meet individual needs, healthcare

professionals can develop effective behavior management approaches. This integrated approach enables clinicians to better support children's sensory needs, promoting more adaptive and cooperative behaviors during dental visits.[14]

In 2021, AAPD first presented Sensory Adapted Dental Environment (SADE), one of the most cutting-edge non-pharmacological behaviour guidance methods.[10] The SADE uses the "Snoezelen room" approach that is a room with well-resourced multisensory environment combining excellent lighting, hypnotic sound, good vibrations, smell and tactile sensation. The enactment of sensory adaptions regulates sensory 'flight or fight' responses to reduce allied uncooperative behaviours and decrease dental anxiety.[62]

It has been established that the Snoezelen environment, also known as a multisensory environment, effectively reduces dental anxiety and panic in kids having dental work done. 'Snoezelen' is derived from two Dutch terms for "doezelen," which means "to relax," and "snuffelen," which means "to explore." Originally created in the 1970s to help people with developmental difficulties relax and engage their senses. The Snoezelen environment has since been adapted for various applications, including pediatric dentistry, where it has shown promising results in promoting relaxation and reducing anxiety in young patients.[63] This environment is composed of 5 sensory stimulation including visual, audio, olfactory, tactile and gustatory stimulation. Thus, Sensory Adapted Dental Environment (SADE) addresses all the 5 senses of human beings together and in turn each of these components plays an important role in reducing not only general but also dental anxiety.[14]

In the year 2020, Camrata et al proposed a basic mechanism of action of how sensory integration when used in SADE helps in behaviour modification. They proposed that the "Sensory Integration/Sensory Processing (SI/SP)-based therapy" approach is the intentional incorporation of tactile, proprioceptive, and vestibular activities within a naturalistic, play-based intervention framework. Specifically, this approach integrates sensory experiences related to touch, pressure, movement, balance, and muscle exertion. A key strength of this approach lies in its operational definitions and reliable observational coding methods, which enable precise measurement and evaluation of these sensory events.[64] [Figure No. 11]

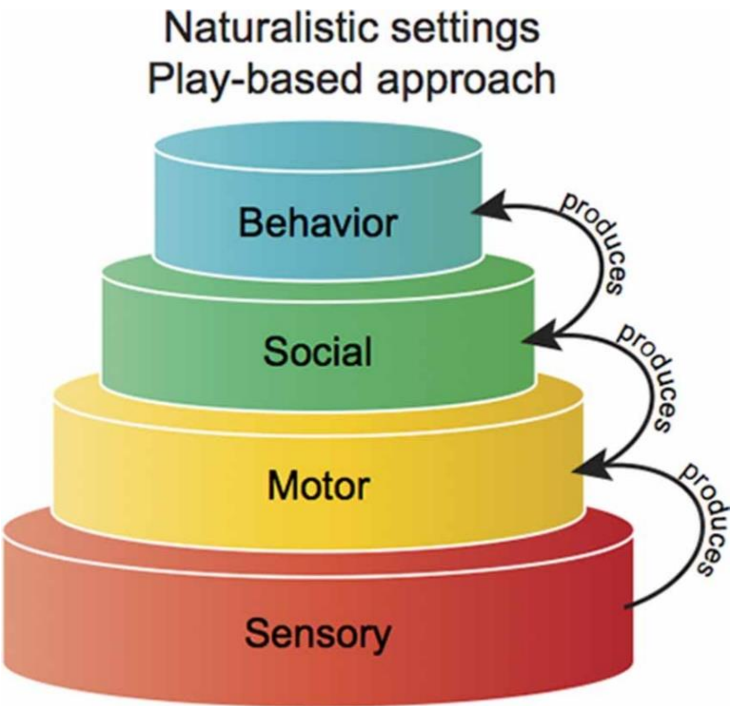


Figure No. 11: Figure Showing Schematic Representation of Concept of Change for Sensory Integration/Sensory Processing (SI/SP) Therapy.

Based on the advantages and mechanism of action of SADE it has now been incorporated in Pediatric dentistry to enhance the behaviour of a child and in turn reduce anxiety.

A randomized control trial aimed to assess how well the snoezelen environment affects the child's anxiousness who were visiting the pediatric dental clinic for the 1st time. The study included children in the age range of six to nine years. Two groups of 126 children were formed. Where, Group 1 was Snoezelen environment group and group 2 was control group. The FIS and CFSS - DS scale showed a very highly statistically significant difference in median scores between the study and control group with 'p' value of 0.000 and 0.000 respectively. Post-treatment anxiety levels showed no significant difference in mean scores between the two groups ($P > 0.05$). Thus, the study came to the conclusion that Snoezelen's method can successfully lessen children's dental anxiety and terror while enhancing their cooperative behaviour and preparing them for future dental treatment.[63]

A randomized control trial aimed to compare interactive virtual games and the Snoezelen environment to traditional Tell - Show - Do in terms of how well they reduced anxiety. 40 children at ages 4 to 6 years were included. 2 groups were formed where group 1 was virtual game group and group 2 was Snoezelen group. Anxiety levels were compared using FIS showed non-statistically significant difference between the two groups ($p=0.419$). Anxiety levels when recorded using VPT also showed non-statistically significant difference between the 2 groups ($p=0.342$). There was a statistically significant difference in the mean scores pre and post operatively in virtual game group with 'p' value of 0.000000183 and in snoezelen environment group with 'p' value of 0.000000498. There was no difference in the SpO_2 between the 2 groups. The study thus concluded that virtual games and snoezelen environment was effective in assuaging the dental anxiety in children attending pediatric dental clinic.[65]

A study aimed on comparing and evaluating the efficacy of Sensory-Adapted Dental Environment (SADE) and Regular Dental Environment (RDE) in alleviating child's anxiety levels. Twenty-four children with mild ID, ages 8 to 13, participated in this study. Control group consisted of 12 children exposed to Regular Dental Environment (RDE) and experimental group consisted of 12 children undergoing treatment in (SADE). The results revealed that in Sensory-Adapted Dental Environment (SADE) group there was a statistically significant decrease in pulse rate at 5 mins with 'p' value of 0.012 and at the end of the procedure a highly statistically significant reduction was seen with 'p' value of 0.004. There was a very highly statistically significant decrease in Venham's anxiety rating scale at 5 mins and at end of procedure with 'p' value of 0.000. Intragroup comparison showed highly statistically significant reduction in pulse and BP with 'p' value of 0.006 and 0.000 respectively from baseline to end of the procedure in SADE group. The study thus concluded that Sensory-Adapted Dental Environment (SADE) is a successful, non-intrusive, cost-effective alternative to induce relaxation and reduce dental anxiety in children suffering from intellectual disabilities.[11]

A case control study designed to assess the differentiation in the efficacy of the waiting room's atmosphere on the child's anxiousness. 2 waiting rooms were created i.e. multisensory and traditional waiting rooms. 102 patients between the ages of 3 and 10 participated in this study. Anxiety levels were recorded with VPT. The results showed no statistically significant difference in mean VPT scores when 2 groups were compared with 'p' value of 0.668. A statistically significant association with 'p' value of 0.019 was seen between the VPT scores and the waiting time. Therefore, the study came to the conclusion that a sensory-adapted waiting room setting is not essential for lowering children's anxiety levels before receiving dental care.[66]

MATERIALS AND METHODS

The current trial was premeditated to evaluate and compare the effectiveness of Sensory Adaptive Dental Environment (SADE) and Regular Dental Environment (RDE) to alleviate anxiety in children undergoing dental treatment.

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 trial was procured from the Institutional Review Board (IRB) of the KAHER's KLE VK Institute of Dental Sciences Belagavi [Sl.No.: 92]. **(Annexure I)**

CLINICAL TRIALS REGISTRY OF INDIA (CTRI) REGISTRATION:

Before starting the trial, it was registered on Clinical Trials Registry of India (CTRI) with the following number: CTRI/2024/04/065178 **(Annexure II).**

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

- 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.)
- Composite restorative (Shofu Beautifil Bulk Restorative Composite)
- Articulating paper (Articulating Paper Superior, Deepashree Products G–711 MIDC Ratnagiri).
- Light curing gun. (Woodpecker)
- Finger Pulse oximeter with OLED display
- Venham's Picture Scale

The following are the armamentarium used for the designing of the Sensory Adapted Dental Room clinical in the study: [Figure No. 14]

- Moving projected ceiling lights (DesiDiya® Astronaut Galaxy Projector, ELAAR Store, India)
- Transportable Bluetooth Speakers (JBL Go 3 Wireless Ultra-Portable Bluetooth Speaker, Clicktech Retail Pvt. Ltd., India)
- Air Diffusers (ASAKUKI Essential Oil Diffuser, ASAKUKI, India)
- Stress Balls (VIPS Flashing Light Puffer Squishy Ball)
- Flavored Rubber Dam Sheets (GDC Rubber Dam Sheet Mint Flavored, GDC Fine Crafted Dental Pvt. Ltd., India)

MATERIAL & ARMAMENTARIUM USED IN THE STUDY

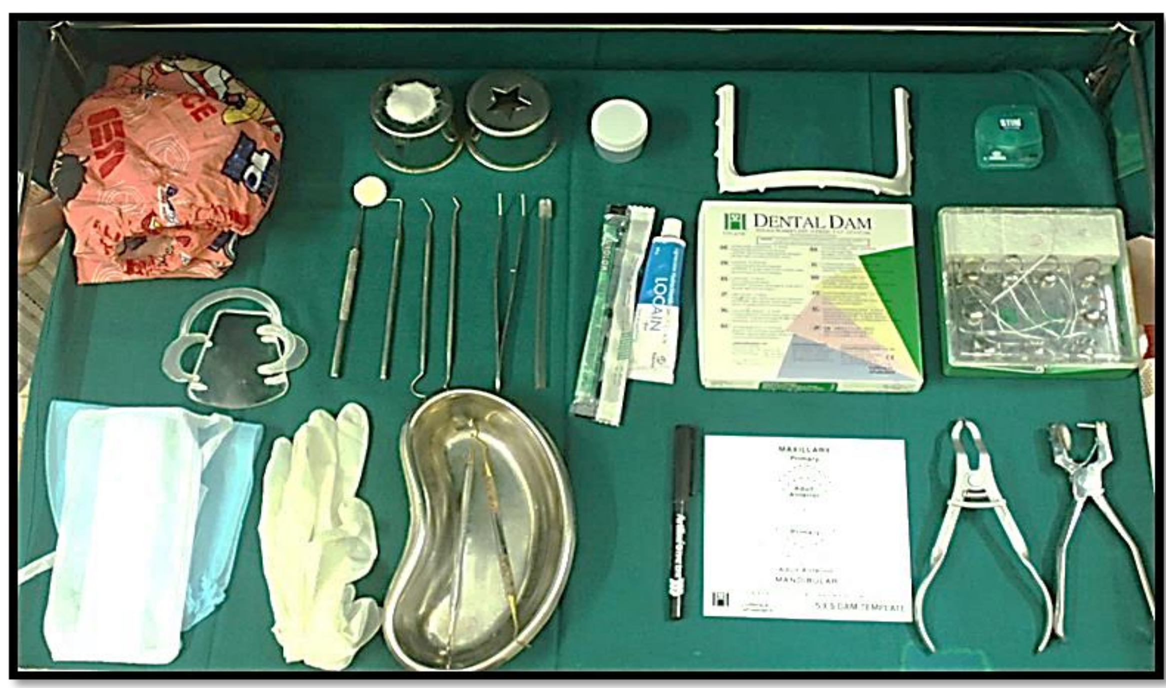


Figure No. 12: Photograph Showing Clinical Armamentarium Used in The Study

Figure No. 13: Photograph Showing Composite Restorative Material Used in The Study

Figure No. 14: Photograph Showing Five Components Used in Sensory Adapted Dental Environment (Group II) in The Study

1. Solar projecting lights: visual stimulation (Chromotherapy)
2. Air diffuser: olfactory stimulation (Aromatherapy)
3. Wireless Bluetooth speaker: audio stimulation (Audio therapy)
4. Flavored rubber dam sheets (Gustatory stimulation)
5. Stress ball (Tactile stimulation)

<u>SOURCE OF DATA</u>:

Patients reporting to OPD of Department of Pediatric & Preventive Dentistry at KAHER'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, III b).** Assent was obtained from all the children participating in the study **(Annexure IV).**

STUDY DESIGN:

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

SELECTION OF SUBJECTS:

The inclusion and exclusion criteria of the trial was:

INCLUSION CRITERIA USED IN THE STUDY:

- Children visiting dental clinic for the first time.
- Children amid 6-12 years of age.
- Children with caries extending up to superficial dentin requiring Class 1 restoration in permanent molar teeth.
- Children and/or parents who are willing to partake in the study.

EXCLUSION CRITERIA USED IN THE STUDY:

- Children with special health care requirements.
- Parents of children who insist on being in the operatory shall be excluded from the study to avoid parental influence on child

SAMPLE SIZE:

Sample required for the study was premeditated using following formula based.[12]:

Standard deviation in first group = S_1 = 3.9

Standard deviation in the second group =S_2 = 1.9

Mean difference between groups d= $(\bar{x}_1 - \bar{x}_2)$ = 2.5000

Effect size = 0.862068965517241

Alpha Error (%) = 5

Power (%) = 85

Sided = 2

Sample size formula

$$n = \frac{2S^2(z_{1-\alpha} + z_{1-\beta})^2}{d^2}$$

Where,

$Z_{1-\alpha}$= Z-value for α level (1.96 at 5% α error or 95% confidence)

$Z_{1-\beta}$ = Z-value for β level (1.0370 at 15% β error or 85% power)

d=Margin of error=2.5000

S=Pooled SD= $(S_1+S_2)/2$

So, Number needed (n) = 27 in each group (approximately = 30) Total Sample is 60 Children.

So, a total of 60 sample size were selected and divided into two study groups of 30 each.

RANDOMIZATION AND STUDY GROUP ALLOCATION:

60 participants were evenly divided into 2 groups by simple random sampling using lottery method to ensure randomization.

STUDY GROUPS:

The following were the study groups:

- **Group I: Control group (Regular Dental Environment):** 30 children were treated in regular dental environment with no special effects. The white tube lights were kept switched on during the procedure. The air diffuser and the Bluetooth speaker were switched off. No toys were provided to the child during the dental treatment and non-flavored rubber dam sheets were used to isolate the teeth requiring class I restoration.
- **GROUP II: Experimental group (Sensory Adapted Dental Environment):** 30 children in group II were treated in a sensory stimulated environment. The Sensory adapted dental environment was designed using special effects light, music and smell.

1. Visual stimulation was provided by using moving projected ceiling lights of colours like blue and green.
2. Auditory stimulation was done by playing calming music like sound of nature or ocean (white noise) was used with help of portable Bluetooth speakers.
3. Olfactory stimulation was provided with the help of air diffusers using lavender essential oil.
4. Tactile stimulation was done by methods of active distraction by using stress ball
5. Gustatory stimulation was provided by using flavoured rubber dam sheets for the teeth which needed class I restoration.

METHODOLOGY:

A. SELECTION OF CASE AND RECORDING OF CASE HISTORY:

A systematic and structured record of all the observations and data was done in case history format for the children who met the above-mentioned requirements. **(Annexure V)**

Following the primary data recording, a clinical examination was conducted in accordance with standard operating procedure (SOP) in a dentist chair. An experienced paediatric dentist was asked to estimate patients' anxiety levels both before and after receiving dental care. For every child taking part in the study, all of the aforementioned tasks were completed.

B. RECORDING BEHAVIOR LEVELS BY FRANKL BEHAVIOR RATING SCALE:

Frankl Behaviour Rating Scale was used evaluate pre and post operative behavior of the child.[67]

C. RECORDING DENTAL ANXIETY LEVELS BY VENHAM'S PICTURE TEST

Anxiety of the child was assessed by a trained Pediatric Dentist with Venham's Picture Test (VPT). This test is a self-administered scale consisting of eight cards in the Venham Picture Test, each containing two figures one "anxious" and one "non-anxious"on it. Each card was indivisually shown to the child. He/she was then requested to indicate the figure that symbolizes how they feel. Every card was displayed in its assigned number. The child received a score of "one" if they pointed at the "anxious" figure, and a score of "zero" if they pointed at the "non-anxious"

figure. According on the total number of times the child selected the "anxious" figure, the score ranged from zero to eight.[68] [Figure No. 15].

The PI documented dental anxiety before and after the procedure.

D. RECORDING THE PULSE RATE:

Assessment of participant's anxiousness was done by pulse oximeter. A Pediatric Dentist used a fingertip pulse oximeter gadget. This machine is integrated with a monitor that displayed the child's subjective parameters, such as pulse rate. The recording of the pulse rate pre and post operatively was done for both the study groups.[69] [Figure No. 16]

Figure No. 15: Photograph Showing Pre – Operative Evaluation of Anxiety Using Venham Picture Test

Figure No. 16: Photograph Showing Pre - Operative Evaluation of Anxiety by Recording Pulse Rate Using Pulse Oximeter

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

The entire procedure was performed under the supervision of experienced Pediatric Dentist. The Principal Investigator (PI) performed dental treatment following the SOP. Before starting the restorative treatment, tell show do was done to explain the child the dental procedure. This protocol was followed in both the study groups.

In Group I (Control Group) children requiring dental treatment were treated in regular dental environment [Figure No. 17] and in Group II (Experimental Group) children requiring dental treatment were treated in sensory adapted dental environment. [Figure No. 18]. Pre operative anxiety scores were recorded using Venham's Picture Test. Heart rate were recorded using gadget called pulse oximeter. The behaviour of the child was assessed by Frankl's Behaviour Rating Scale by a skilled Pediatric Dentist.

After complete recording of case history, anxiety and behaviour scores and obtaining the informed consent, the children were allocated to the control or experimental group.

In Group I (Control Group: Regular Dental Environment), children having class I caries in permanent molars were provided with restorative treatment. The tooth requiring class I restoration was isolated with non-flavored rubber dam sheet. Class I cavity preparation was carried out using airotor and round carbide bur. After 15 seconds of etching and water rinsing, the bonding agent was applied, and the tooth was allowed to cure for 20 seconds. Resin based composite filling material was then used to restore the prepared cavity after which the restoration was polished and

occlusion was checked with an articulating paper for any occlusal irregularities. [Figure No. 19]

In Group II (Experimental Group: Sensory Adapted Dental Environment), children having class I caries in permanent molars were provided with restorative treatment. The tooth requiring class I restoration was isolated with flavored rubber dam sheet, class I cavity preparation was carried out using airotor and round carbide bur. After 15 seconds of etching and water rinsing, the bonding agent was applied, and the tooth was allowed to cure for 20 seconds. The resin based composite filling material was then used to restore the prepared cavity after which the restoration was polished and occlusion was checked with an articulating paper for any occlusal irregularities. [Figure No. 20]

Post operative anxiety, pulse rate and behaviour scores were recorded by a qualified Pediatric Dentist.

F. POST OPERATIVE INSTRUCTIONS:

After completion of treatment, patients were made to sit and given post-operative instructions. The following post operative instructions were given:

- Do not consume any water for half an hour.
- For the next 24 hours, follow a soft diet. Refrain from eating anything for an hour.
- Patients who experienced any pain, sensitivity, or discomfort during mastication were advised to report to the clinic.
- Patients who observed any type of broken restoration were asked to come to the dental clinic.

Figure No. 17: Photograph Showing Child Undergoing Dental Treatment in Regular Dental Environment in Group I (Control Group)

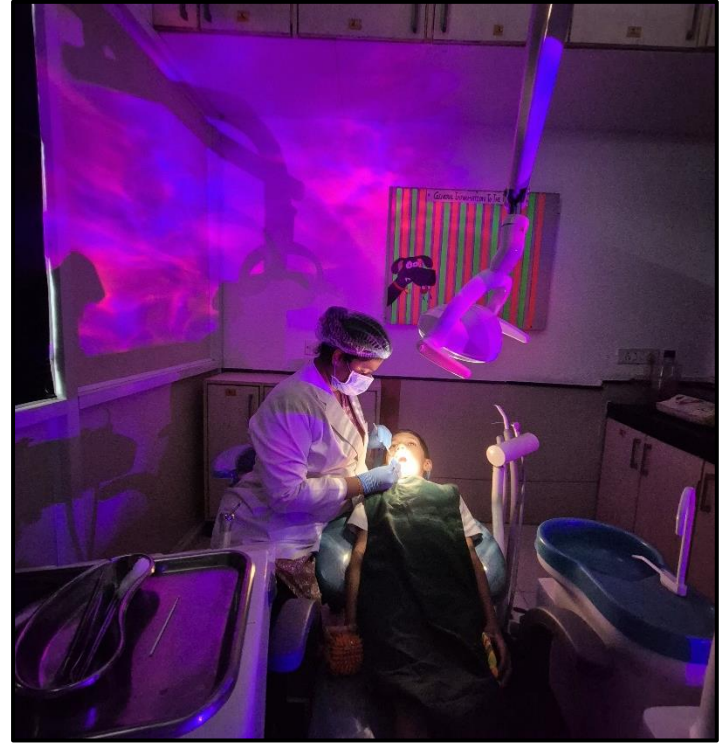
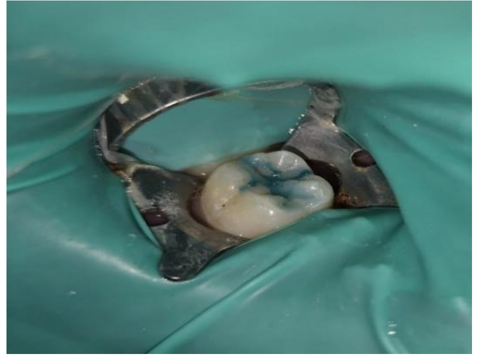


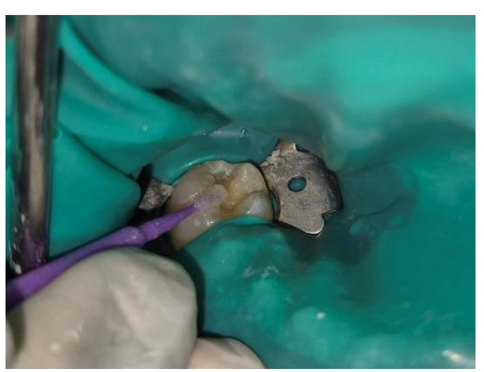
Figure No. 18: Photograph Showing Child Undergoing Dental Treatment in Sensory Adapted Dental Environment in Group II (Experimental Group)

Class I Caries in Permanent Molar Requiring Restoration

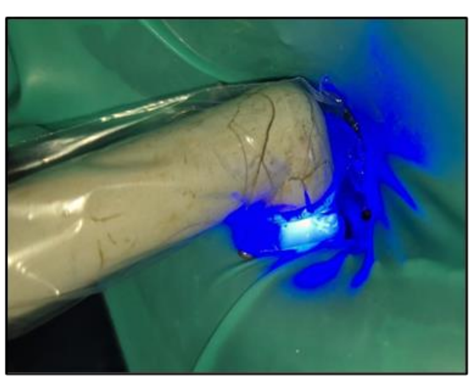
Prepared cavity using airotor and carbide bur



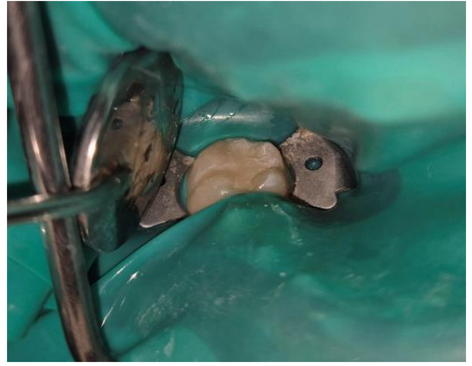
Acid etching of the tooth for 15 seconds



Application of bonding agent to the tooth



Curing of the bonding agent for 20 secs



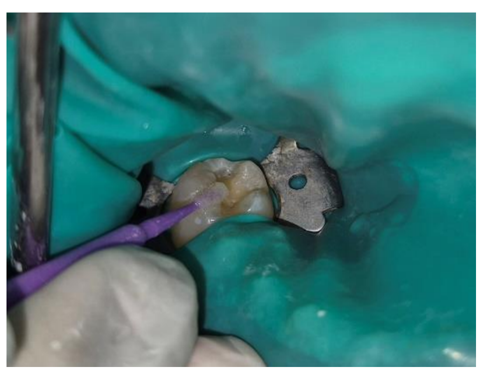
Final restoration with resin based composite material

Figure No. 19: Photograph Showing Steps of Class I Restorative Treatment Provided to Children in Regular Dental Environment in Group I (Control Group)

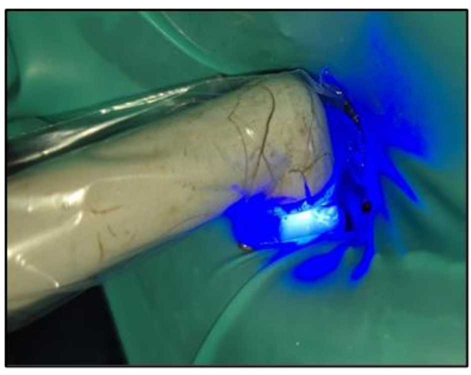
Class I caries in permanent molar requiring restoration

Prepared cavity using airotor and carbide bur

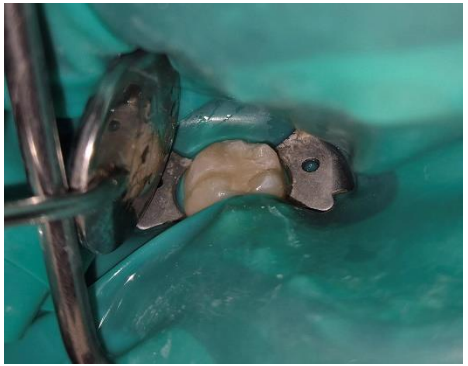
Acid etching of the tooth for 15 seconds



Application of bonding agent to the tooth



Curing of the bonding agent for 20 secs



Final restoration with resin based composite material

Figure No. 20: Photograph Showing Steps of Class I Restorative Treatment Provided to Children in Sensory Adapted Dental Environment in Group II (Experimental Group)

STATISTICAL ANALYSIS:

After tabulating the data, they were entered into the Excel sheet. The statistician then used IBM SPSS software (version 20.0, Chicago, IL, USA) to run the following statistical tests on the results.

- The main features of the study sample, including mean, standard deviations, and frequencies, were succinctly and clearly summarised using descriptive statistics. This aids in comprehending the data's primary tendency and variability.

- Mann Whitney 'U' Test for intergroup association was applied. specifically, to assess whether there are statistically significant differences in anxiety levels among the two study groups.

- To determine whether there is a significant difference in anxiety levels between each group before and after treatment, the Wilcoxon matched pair test was utilised for intragroup comparison.

- Level of significance was set at $p = 0.05$. (where, $p \leq 0.05$: Statistically significant, $p \leq 0.001$: highly significant, $p \leq 0.0001$: very highly significant and $p \geq 0.05$ not significant).

The summary of methodology of the study is explained as in the CONSORT flow diagram. **(Annexure VI)**

RESULTS

TABLES, GRAPHS AND OBSERVATIONS

The data collected was complied, entered and tabulated on the excel sheet. Then the collected data underwent statistical analysis tests using IBM SPSS software (version 20.0 Chicago IL, USA):

1. Descriptive statistics was used to provide a clear and brief outline 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.
2. Paired 't' test used for intragroup association of pulse rate scores to assess whether there is a statistically significant difference in pulse rates within each group in pre-operative and post-operative measurements.
3. Independent 't' test for intergroup comparison was applied, specifically to assess whether there are statistically noteworthy differences in pulse rate scores among the two study groups.
4. Mann-Whitney 'U' test for intergroup association was applied, specifically to assess whether there are statistically noteworthy differences in anxiety levels among the two study groups.
5. Wilcoxon matched pair test for intragroup comparison was used to judge whether there is a statistically noteworthy difference in anxiety levels within each group in pre-operative and post-operative measurements.

TABLES

Table No. 1: Master Chart of Anxiety Scores Measured Pre–Operatively and Post-Operatively Using Venham Picture Test and Pulse Rate Scores in Regular Dental Environment in Group I (Control Group)

SI. No.	Allotment no.	Age	Sex	Venham Picture Test		Pulse rate	
				Pre op	Post op	Pre op	Post op
1.	C1	10	M	2	0	82	86
2.	C2	9	M	4	2	87	87
3.	C3	6	M	3	2	103	97
4.	C4	6	M	6	4	107	110
5.	C5	11	F	4	1	95	97
6.	C6	6	M	2	0	83	89
7.	C7	8	M	3	1	93	85
8.	C8	7	M	3	2	100	98
9.	C9	10	M	4	3	83	85
10.	C10	6	M	2	0	114	110
11.	C11	11	F	6	6	118	120
12.	C12	7	M	5	4	103	103
13.	C13	7	M	3	2	106	105
14.	C14	11	F	4	2	111	108
15.	C15	6	M	2	2	108	103
16.	C16	9	M	2	0	81	85
17.	C17	8	F	3	1	104	102
18.	C18	11	F	1	0	100	102
19.	C19	6	M	3	4	82	90
20.	C20	6	M	4	4	136	138
21.	C21	7	F	3	2	101	106
22.	C22	6	M	3	3	101	102
23.	C23	9	M	2	1	69	73
24.	C24	11	F	4	1	100	102
25.	C25	6	F	2	0	69	75
26.	C26	8	M	2	2	111	109
27.	C27	12	M	0	0	62	67
28.	C28	12	F	0	0	97	108
29.	C29	9	M	3	1	70	68
30.	C30	8	M	5	3	103	109

Table No. 2: Master Chart of Anxiety Measured Pre– Operatively and Post-Operatively Venham Picture Test and Pulse Rate Scores in Sensory Adapted Dental Environment in Group II (Experimental Group)

SI. No.	Allotment No.	Age	Sex	Venham Picture Test		Pulse rate	
				Pre op	Post op	Pre op	Post op
1.	E1	7	M	3	0	90	85
2.	E2	9	M	2	0	65	68
3.	E3	12	F	2	1	97	85
4.	E4	11	F	2	0	82	76
5.	E5	10	F	2	1	89	83
6.	E6	12	F	5	1	103	98
7.	E7	7	M	3	1	93	89
8.	E8	11	F	2	0	88	80
9.	E9	8	F	3	1	75	73
10.	E10	6	F	2	0	108	97
11.	E11	10	M	2	0	88	87
12.	E12	12	M	3	0	118	102
13.	E13	6	F	4	2	97	94
14.	E14	7	M	3	0	94	85
15.	E15	8	F	2	0	85	78
16.	E16	10	F	2	1	82	80
17.	E17	6	F	1	0	83	81
18.	E18	8	M	4	3	104	98
19.	E19	11	M	2	0	93	85
20.	E20	7	M	4	2	108	105
21.	E21	8	M	1	0	82	76
22.	E22	9	M	2	0	87	80
23.	E23	6	F	3	0	95	90
24.	E24	12	M	1	0	87	83
25.	E25	9	M	4	2	80	84
26.	E26	10	M	2	0	97	85
27.	E27	11	F	2	0	98	92
28.	E28	10	F	1	0	88	82
29.	E29	7	F	0	0	97	88
30.	E30	7	M	0	0	86	82

Table No. 3: Master Chart of Behaviour Ratings Measured Pre– Operatively and Post-Operatively Using Frankl's Behaviour Rating Scale in Regular Dental Environment in Group I (Control Group)

SI. No.	Allotment No.	Age	Sex	Frankl's Behaviour Rating Scale	
				Pre operative	Post operative
1.	C1	10	M	Negative	Positive
2.	C2	9	M	Negative	Negative
3.	C3	6	M	Negative	Positive
4.	C4	6	M	Negative	Positive
5.	C5	11	F	Positive	Negative
6.	C6	6	M	Positive	Positive
7.	C7	8	M	Positive	Positive
8.	C8	7	M	Positive	Positive
9.	C9	10	M	Positive	Positive
10.	C10	6	M	Negative	Positive
11.	C11	11	F	Negative	Negative
12.	C12	7	M	Definitely Negative	Negative
13.	C13	7	M	Positive	Positive
14.	C14	11	F	Positive	Positive
15.	C15	6	M	Negative	Positive
16.	C16	9	M	Definitely Negative	Negative
17.	C17	8	F	Negative	Negative
18.	C18	11	F	Negative	Negative
19.	C19	6	M	Negative	Positive
20.	C20	6	M	Positive	Definitely Positive
21.	C21	7	F	Positive	Positive
22.	C22	6	M	Definitely Negative	Definitely Negative
23.	C23	9	M	Positive	Negative
24.	C24	11	F	Positive	Definitely Positive
25.	C25	6	F	Negative	Positive
26.	C26	8	M	Negative	Positive
27.	C27	12	M	Negative	Negative
28.	C28	12	F	Negative	Negative
29.	C29	9	M	Negative	Positive
30.	C30	8	M	Definitely Negative	Negative

Table No. 4: Master Chart of Behaviour Ratings Measured Pre– Operatively and Post-Operatively Frankl's Behaviour Rating Scale in Sensory Adapted Dental Environment in Group II (Experimental Group)

SI. No.	Allotment No.	Age	Sex	Frankl's Behaviour Rating Scale	
				Pre operative	Post operative
1.	E1	7	M	Negative	Positive
2.	E2	9	M	Positive	Positive
3.	E3	12	F	Negative	Positive
4.	E4	11	F	Positive	Definitely Positive
5.	E5	10	F	Negative	Negative
6.	E6	12	F	Positive	Positive
7.	E7	7	M	Definitely Negative	Negative
8.	E8	11	F	Negative	Positive
9.	E9	8	F	Positive	Positive
10.	E10	6	F	Negative	Positive
11.	E11	10	M	Positive	Definitely Positive
12.	E12	12	M	Positive	Definitely Positive
13.	E13	6	F	Negative	Positive
14.	E14	7	M	Negative	Negative
15.	E15	8	F	Negative	Positive
16.	E16	10	F	Positive	Positive
17.	E17	6	F	Definitely Negative	Negative
18.	E18	8	M	Positive	Positive
19.	E19	11	M	Positive	Positive
20.	E20	7	M	Negative	Positive
21.	E21	8	M	Positive	Definitely Positive
22.	E22	9	M	Positive	Definitely Positive
23.	E23	6	F	Definitely Negative	Negative
24.	E24	12	M	Positive	Positive
25.	E25	9	M	Negative	Positive
26.	E26	10	M	Negative	Positive
27.	E27	11	F	Positive	Positive
28.	E28	10	F	Positive	Positive
29.	E29	7	F	Negative	Negative
30.	E30	7	M	Definitely Positive	Definitely Positive

Table No. 1 and 2 showing master chart of evaluation of anxiety through recording of pre-operative and post-operative findings using Venham picture test and Pulse rate in Regular Dental Environment [Group I] and Sensory Adapted Dental Environment [Group II] respectively. Table No. 3 and 4 showing master chart of evaluation of behaviour pre-operative and post-operative using Frankl's behaviour rating scale in Regular Dental Environment [Group I] and Sensory Adapted Dental Environment [Group II] respectively. A total of 60 children aged 6-12 years were included in our study and were equally divided into two groups of 30 each i.e. Regular Dental Environment in Group I (Control Group) and Sensory Adapted Dental Environment in Group II (Experimental Group).

Table No. 5: Table Showing Age Wise Distribution of Children Undergoing Dental Treatment Under Regular Dental Environment in Group I (Control Group) and Sensory Adapted Dental Environment in Group II (Experimental Group)

Age group	Group I	%	Group II	%	Total	%
6-7yrs	13	43.33	10	33.33	23	38.33
8-9yrs	8	26.67	7	23.33	15	25.00
10-12yrs	9	30.00	13	43.33	22	36.67
Total	30	100.00	30	100.00	60	100.00
Mean	8.30		8.90		8.60	
SD	2.09		2.04		2.07	
Chi-square=1.1850, p=0.5530						

Graph No. 1: Graphical Representation of Age Wise Distribution of Children Undergoing Dental Treatment Under Regular Dental Environment in Group I (Control Group) and Sensory Adapted Dental Environment in Group II (Experimental Group)

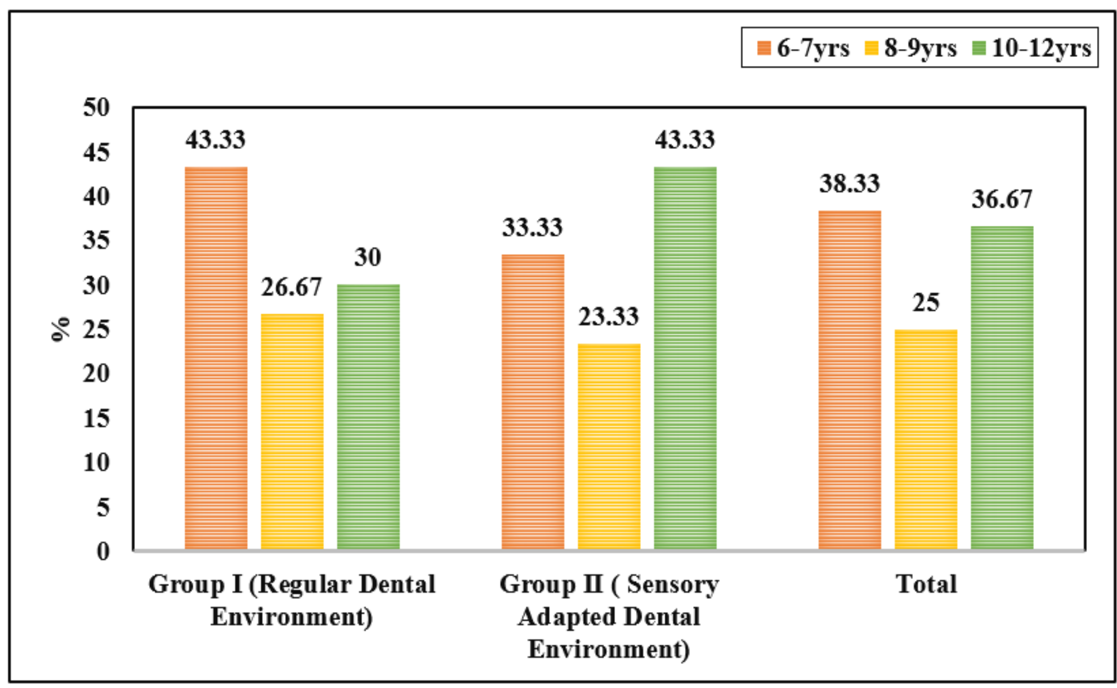


Table No. 5 and Graph No. 1 shows the demographic profile of the participants by showing age wise distribution of patients in Group I: Control Group (Regular Dental Environment) and Group II: Experimental Group (Sensory Adapted Dental Environment). In group I, 30 children were included among which 13 children were 6 – 7 years old (43.33%), 8 children were 8 – 9 years old (26.27%) and 9 children were 10 – 12 years old (30%). The mean ± standard deviation of age in Group I was 8.30 ± 2.09.

In Group II, 30 children were included among which 10 children were 6 – 7 years old (33.33%), 7 children were 8 – 9 years old (23.33%) and 13 children were 10 – 12 years old (43.33%). The mean ± standard deviation of age in group II was 8.90 ± 2.04. Finally in both the groups, 23 children (38.33%) were in the age group of 6 – 7 years, 15 children (25%) were in the age group of 8 – 9 years and 22 children

(36.67%) were in the age group of 10 – 12 years. The mean ± standard deviation of age in both the groups was 8.60 ± 2.07 with chi square value of 1.1850. The 'p' value was 0.5530 ($p<0.05$) which was non-significant indicating equal age wise distribution of children in both the groups.

Table No. 6: Table Showing Gender Wise Distribution of Children Undergoing Dental Treatment Under Regular Dental Environment in Group I (Control Group) and Sensory Adapted Dental Environment in Group II (Experimental Group)

Gender	Group I	%	Group II	%	Total	%
Male	21	70.00	15	50.00	36	60.00
Female	9	30.00	15	50.00	24	40.00
Total	30	100.00	30	100.00	60	100.00
Chi-square=2.5000, p=0.1140						

Graph No. 2: Graphical representation of Gender Wise Distribution of Children Undergoing Dental Treatment Under Regular Dental Environment in Group I (Control Group) and Sensory Adapted Dental Environment in Group II (Experimental Group)

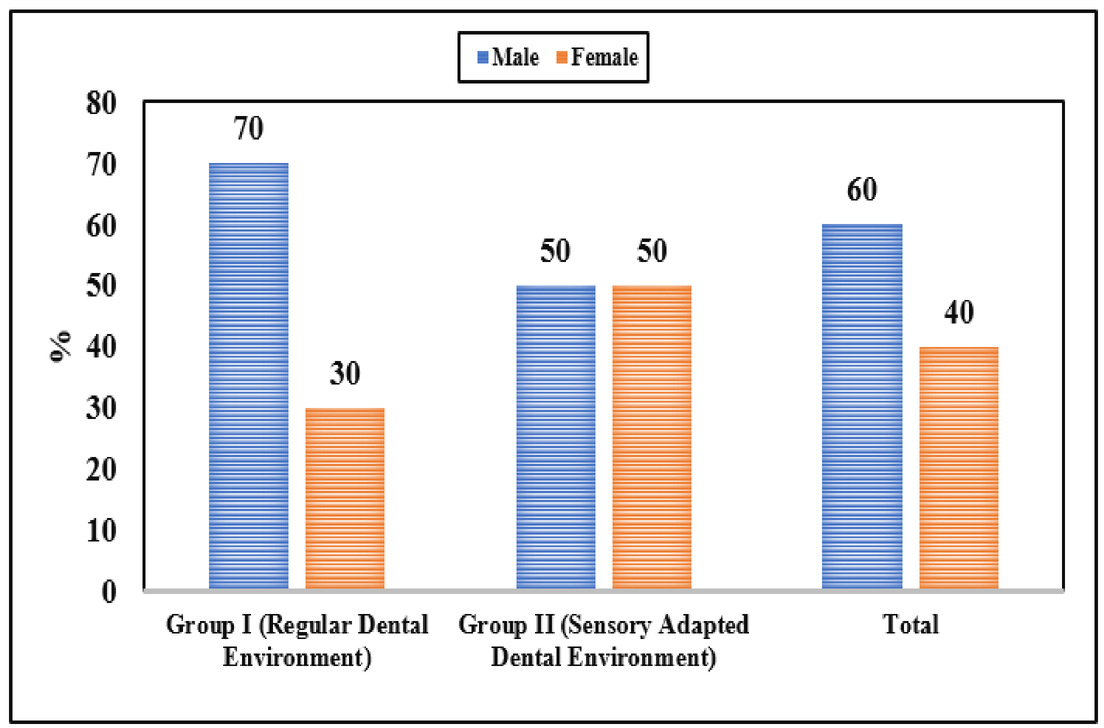


Table No. 6 and Graph No. 2 shows demographic profile of the participants by gender wise distribution of patients in Group I: Control Group (Regular Dental Environment) and Group II: Experimental Group (Sensory Adapted Dental Environment). In group I, among 30 children 21 children (70%) were male and 9 children (30%) were female. In group II, among 30 children 15 children (50%) were male and 15 children (50%) were female. Thus, among 60 children 36 children (60%) were males and 24 children (40%) were females. The chi square value was 2.5000 and the 'p' value was 0.1140 ($p<0.05$) which was non-significant indicating equal gender wise distribution of children in both the groups.

Table No. 7: Table Showing Intragroup Comparison of Pre-Operative and Post-Operative Anxiety Scores by Venham's Picture Test of Children Undergoing Dental Treatment Under Regular Dental Environment in Group I (Control Group) and Sensory Adapted Dental Environment in Group II (Experimental Group) by Wilcoxon Matched Pair Test

Groups	Time	Mean	SD	Mean Diff.	SD Diff.	% of effect	Z-value	p-value
Group I	Pre Op	2.47	1.31	0.77	0.73	31.08	3.7017	0.0002***
	Post Op	1.70	1.51					
Group II	Pre Op	2.20	1.21	1.70	0.88	77.27	4.6226	0.0001***
	Post Op	0.50	0.82					

*p<0.05

Graph No. 3: Graphical Representation of Intragroup Comparison of Pre-Operative and Post-Operative Anxiety Scores by Venham's Picture Test of Children Undergoing Dental Treatment Under Regular Dental Environment in Group I (Control Group) and Sensory Adapted Dental Environment in Group II (Experimental Group) by Wilcoxon Matched Pair Test

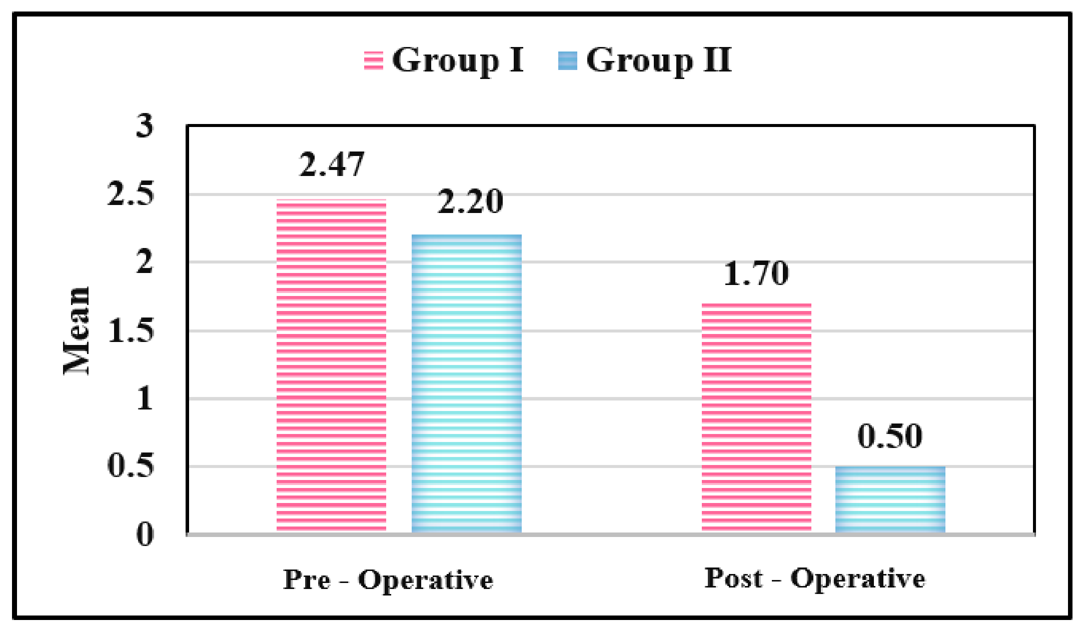


Table No. 7 and Graph no. 3 shows intragroup comparison of pre-operative and post-operative Venham's Picture Test Scores in Group I: Control Group (Regular Dental Environment) and Group II: Experimental Group (Sensory Adapted Dental Environment) by Wilcoxon matched pair test.

In Group I (Control Group) the mean ± standard deviation of anxiety scores pre-operatively was 2.47±1.31 and post-operatively the mean ± standard deviation was 1.70±1.51. In Group I (Control Group) pre-operative and post-operative scores were compared, the mean ± standard deviation was 0.77±0.73. The percentage of effect was 31.08% and 'Z' value was 3.7017 resulting in a very highly statistically significant 'p' value of 0.0002 ($p<0.05$).

In Group II (Experimental Group) the mean ± standard deviation of anxiety scores pre-operatively was 2.20±1.21 and post-operatively the mean ± standard deviation was 0.50±0.82. In Group II (Experimental Group) pre-operative and post-operative scores were compared, the mean ± standard deviation was 1.70±0.88. The percentage of effect was 77.27% and 'Z' value was 4.6226 resulting in a very highly statistically 'p' value of 0.0001 ($p<0.05$). Thus, post-operative anxiety reduction was seen in both the groups with very highly statistically significant 'p' values of 0.0002 ($p<0.05$) in Group I (Control Group) and 0.0001 ($p<0.05$) in Group II (Experimental Group). Thus, anxiety reduction was more in Group II (Experimental Group) as compared to Group I (Control Group).

Table No. 8: Table Showing Intergroup Comparison of Pre-operative and Post-operative Anxiety Scores by Venham's Picture Test of Children Undergoing Dental Treatment Under Regular Dental Environment in Group I (Control Group) and Sensory Adapted Dental Environment in Group II (Experimental Group) by Mann-Whitney 'U' test

Times	Group I			Group II			U-value	Z-value	p-value
	Mean	SD	Mean rank	Mean	SD	Mean rank			
Pre op	2.47	1.31	32.35	2.20	1.21	28.65	394.50	0.8131	0.4161
Post op	1.70	1.51	37.97	0.50	0.82	23.03	226.00	3.3043	0.0010**
Difference	0.77	0.73	22.07	1.70	0.88	38.93	197.00	-3.7331	0.0002***

*p<0.05

Graph No. 4: Graphical representation of Intergroup Comparison of Pre-operative and Post-operative Anxiety Scores by Venham's Picture Test of Children Undergoing Dental Treatment Under Regular Dental Environment in Group I (Control Group) and Sensory Adapted Dental Environment in Group II (Experimental Group) by Mann-Whitney 'U' test

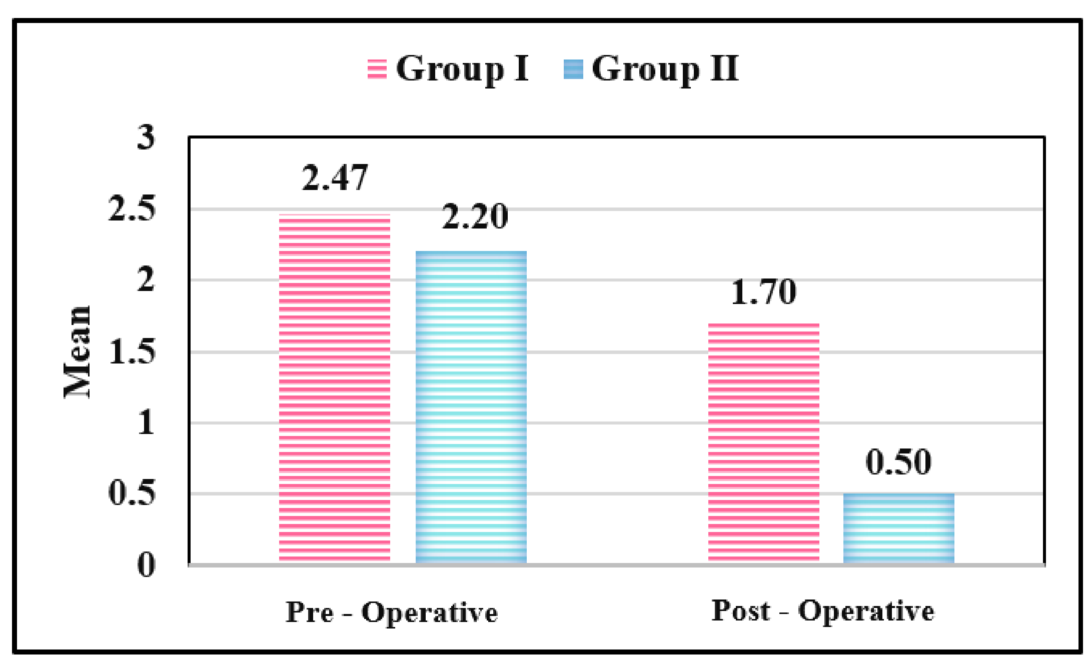


Table No. 8 and Graph No. 4 showing intergroup comparison of Group I: Control Group (Regular Dental Environment) and Group II: Experimental Group (Sensory Adapted Dental Environment) with pre-operative and post-operative Venham's picture test scores by Mann-Whitney 'U' test. In Group I (Control Group) the mean ± standard deviation of anxiety scores pre-operatively was 2.47±1.31 and the mean rank was 32.35. While, in Group II (Experimental Group) the mean standard deviation of anxiety scores pre-operatively was 2.20±1.21 and the mean rank was 28.65. When both groups were compared for anxiety scores using Mann-Whitney 'U' test, it gave a 'U' value of 394.50 at baseline. The 'Z' value at baseline was 0.8131 resulting in a non-statistically significant 'p' value of 0.4161 ($p<0.05$).

In Group I (Control Group) the post-operative mean ± standard deviation of anxiety scores was 1.70±1.51 and the mean rank was 37.97. While, in Group II (Experimental Group) the post-operative mean ± standard deviation of anxiety scores was 0.50±0.82 and the mean rank was 23.03. When both groups were compared for anxiety scores using Mann-Whitney 'U' test, it gave a 'U' value 226.00 post-operatively. The 'Z' value post-operatively was 3.3043 resulting in a highly statistically significant 'p' value of 0.0010 ($p<0.05$).

In Group I (Control Group), the difference in the mean ± standard deviation of anxiety scores was 0.77±0.73 and the mean rank was 22.07. While in Group II (Experimental Group), the difference in the mean standard deviation of anxiety scores was 1.70±0.88 and the mean rank was 38.93. The 'U' value was 197.00 and 'Z' value was -3.7331 resulting in a very highly statistically 'p' value of 0.0002 ($p<0.05$). Thus, maximum reduction of anxiety was seen in Group II (Experimental Group) as compared to Group I (Control Group).

Table No. 9: Table Showing Intragroup Comparison of Pre-Operative and Post-Operative Pulse Rate Scores of Children Undergoing Dental Treatment Under Regular Dental Environment in Group I (Control Group) And Sensory Adapted Dental Environment in Group II (Experimental Group) By Paired 't' Test

Groups	Time	Mean	SD	Mean Diff.	SD Diff.	% of effect	t-value	p-value
Group I	Pre Op	95.97	16.47	-1.33	4.31	-1.39	3.7017	0.0002***
	Post Op	97.30	15.49					
Group II	Pre Op	91.30	10.71	5.60	4.18	6.13	4.6226	0.0001***
	Post Op	85.70	8.51					

*p<0.05

Graph No. 5: Graph Showing Intragroup Comparison of Pre-Operative and Post -Operative Pulse Rate Scores of Children Undergoing Dental Treatment Under Regular Dental Environment in Group I (Control Group) And Sensory Adapted Dental Environment in Group II (Experimental Group) By Paired 't' Test

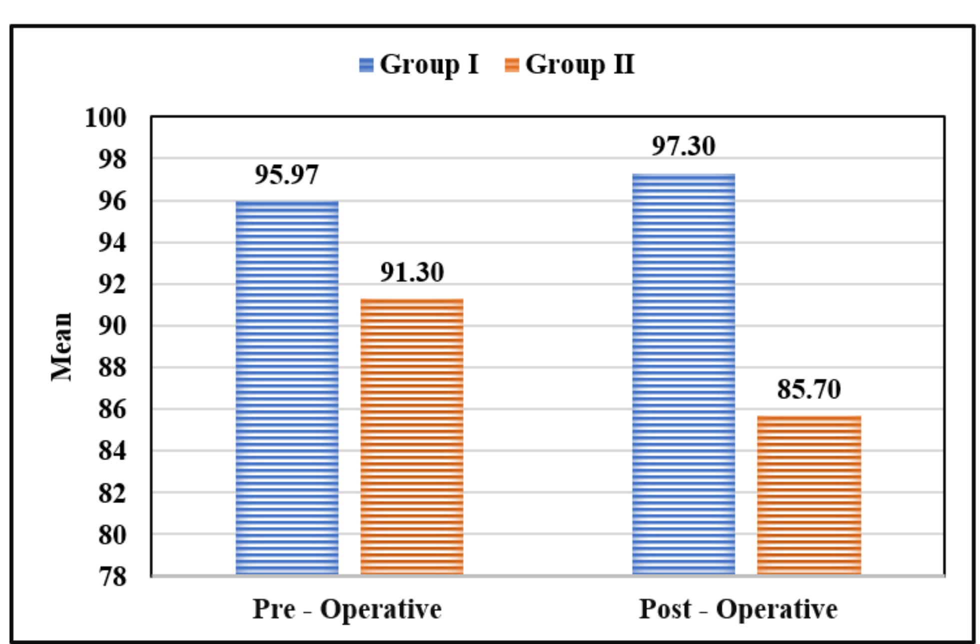


Table no. 9 and Graph no. 5 shows the intragroup comparison of pre-operative and post-operative pulse rate scores in two groups namely Group I: Control Group (Regular Dental Environment) and Group II: Experimental Group (Sensory Adapted Dental Environment) by paired ‘t’ test.

In Group I (Control Group) the mean ± standard deviation of pulse rate scores pre-operatively was 95.97±16.47 and post-operatively the mean ± standard deviation was 97.30±15.49. In Group I (Control Group) pre-operative and post-operative scores were compared, the mean ± standard deviation was -1.33±4.31. The percentage of effect was -1.39% and ‘t’ value was 3.7017 resulting in a very highly statistically significant ‘p’ value of 0.0002 ($p<0.05$).

In Group II (Experimental Group) the mean ± standard deviation of pulse rate scores pre-operatively was 91.30±10.71 and post-operatively the mean ± standard deviation was 85.70±8.51. In Group II (Experimental Group) when pre-operative and post-operative scores were compared, the mean ± standard deviation was 5.06±4.18. The percentage of effect was 6.13% and ‘t’ value was 4.6226 resulting in a very highly statistically ‘p’ value of 0.0001 ($p<0.05$). Thus, post-operative anxiety reduction was seen in both the groups with very highly statistically significant ‘p’ values of 0.0002 ($p<0.05$) in Group I (Control Group) and 0.0001 ($p<0.05$) in Group II (Experimental Group). Thus, anxiety reduction was more in Group II (Experimental Group) as compared to Group I (Control Group).

Table No. 10: Table Showing Intergroup Comparison of Pre-Operative and Post -Operative Pulse Rate Scores of Children Undergoing Dental Treatment Under Regular Dental Environment in Group I (Control Group) And Sensory Adapted Dental Environment in Group II (Experimental Group) by Independent 't' Test

Times	Group I		Group II		t-value	p-value
	Mean	SD	Mean	SD		
Pre op	95.97	16.47	91.30	10.71	1.3008	0.1985
Post op	97.30	15.49	85.70	8.51	3.5941	0.0007***
Difference	1.33	4.31	-5.60	4.18	6.3236	0.0001***

*p<0.05

Graph No. 6: Graph Showing Intergroup Comparison of Pre-Operative and Post -Operative Pulse Rate Scores of Children Undergoing Dental Treatment Under Regular Dental Environment in Group I (Control Group) And Sensory Adapted Dental Environment in Group II (Experimental Group) by Independent 't' Test

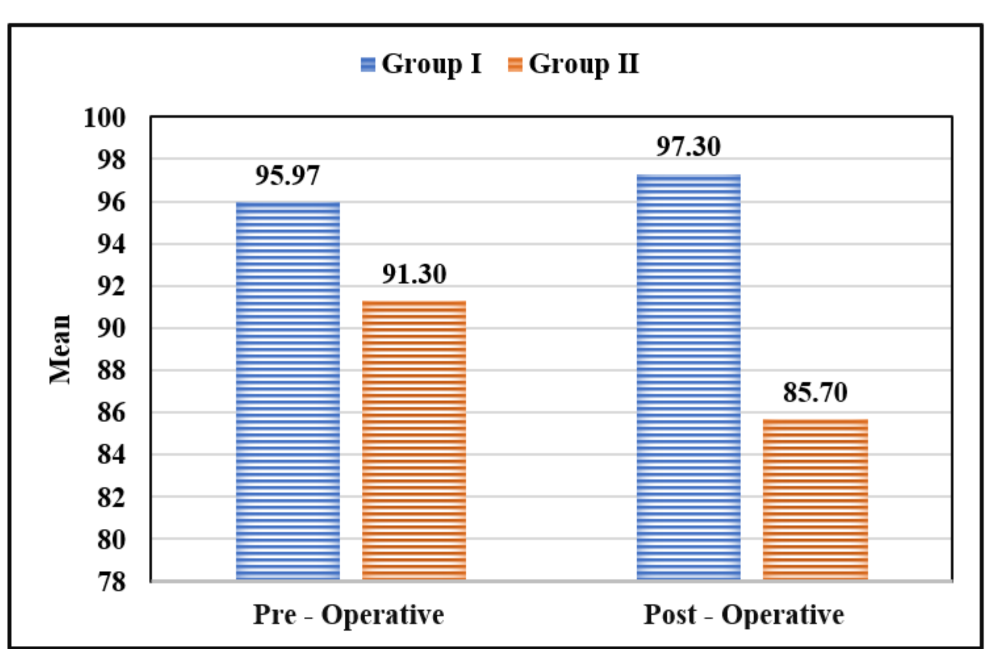


Table No. 10 and Graph No. 6 shows intergroup comparison of pre-operative and post-operative pulse rate scores in Group I: Control Group (Regular Dental Environment) and Group II: Experimental Group (Sensory Adapted Dental Environment) by Independent 't' test.

In Group I (Control Group), the mean ± standard deviation of pulse rate scores pre-operatively was 95.97±16.47. While, in Group II (Experimental Group) the mean ± standard deviation of pulse rate scores at pre-operatively was 91.30±10.71. When both groups were compared for pulse rate scores pre-operatively using Independent 't' test, it resulted in a 't' value of 1.3008. The 'p' value at pre-operatively was 01985 ($p<0.05$) which was non-significant.

In Group I (Control Group), the post-operative mean ± standard deviation of pulse rate scores was 97.30±15.49. While, in Group II (Experimental Group) the post-operative mean ± standard deviation of pulse rate scores was 85.70±8.51. When both groups were compared for pulse rate scores post-operatively using Independent 't' test, it resulted in a 't' value of 3.5941. The 'p' value post-operatively was 0.0007 ($p<0.05$) which was very highly statistically significant.

In Group I (Control Group), the difference in the mean ± standard deviation of pulse rate scores was 1.33±4.31. While in Group II (Experimental Group), the difference in the mean standard deviation of pulse rate scores was -5.60±4.18. The 't' value was 6.3236 resulting in a very highly statistically 'p' value of 0.0001 ($p<0.05$). Thus, anxiety reduction was more in Group II (Experimental Group) as compared to Group I (Control Group).

Table No. 11: Table Showing Intergroup Comparison of Pre-Operative and Post -Operative Behaviour Scores Using Frankl's Behaviour Rating Scale of Children Undergoing Dental Treatment Under Regular Dental Environment in Group I (Control Group) And Sensory Adapted Dental Environment in Group II (Experimental Group) by Mann – Whitney 'U' Test

Times	**Group I**			**Group II**			**U-value**	**Z-value**	**p-value**
	Median	IQR	Mean rank	Median	IQR	Mean rank			
Pre op	3.00	0.00	29.57	3.00	1.00	31.43	422.0	-0.4066	0.6843
Post op	3.00	0.00	26.40	3.00	0.00	34.60	327.0	-1.8111	0.0701

*p<0.05

Table No. 11 shows comparison of pre-operative and post-operative behaviour scores using Frankl's Behaviour Rating Scale in Group I: Control Group (Regular Dental Environment) and Group II: Experimental Group (Sensory Adapted Dental Environment) by Mann – Whitney 'U' test.

In Group I (Control Group) the median pre-operatively was 3.00, interquartile range (IQR) was 0.00 and the mean rank was 29.57. While, in Group II (Experimental Group) the median pre-operatively was 3.00, interquartile range (IQR) was 1.00 and the mean rank was 31.43. When both groups were compared for behaviour scores using Mann-Whitney 'U' test, it resulted in a 'U' value of 422.00 at pre-operatively. The 'Z' value pre-operatively was -0.4066. The 'p' value was 0.6843 ($p<0.05$) which was non–significant.

In Group I (Control Group) post-operatively, the median was 3.00, interquartile range (IQR) was 0.00 and the mean rank was 26.40. While, in Group II (experimental group) post-operatively, the median was 3.00, interquartile range (IQR)

was 0.00 and the mean rank was 34.60. When both groups were compared for behaviour scores using Mann-Whitney 'U' test, it resulted in a 'U' value of 327.00 post-operatively. The 'Z' value post-operatively was -1.8111. The 'p' value was 0.0701 ($p<0.05$) which was non–significant.

Table No. 12: Table Showing Intragroup Comparison of Pre-Operative and Post -Operative Behaviour Scores Using Frankl's Behaviour Rating Scale of Children Undergoing Dental Treatment Under Regular Dental Environment in Group I (Control Group) And Sensory Adapted Dental Environment in Group II (Experimental Group) By Wilcoxon Matched Pair Test

Groups	Changes from	% of effect	Z-value	p-value
Group 1	Pre op to Post Op	3.66	0.7338	0.4631
Group 2	Pre op to Post Op	-5.88	1.3337	0.1823

*p<0.05

Table No. 12 shows comparison of pre-operative and post-operative behaviour scores using Frankl's Behaviour Rating Scale in Group I: Control Group (Regular Dental Environment) and Group II: Experimental Group (Sensory Adapted Dental Environment) by Wilcoxon matched pair test.

In Group I (Control Group) the changes of behaviour scores from pre-operative to post-operative was 3.66%. The 'Z' value pre-operatively was 0.7338 and the 'p' value was 0.4631 ($p<0.05$) which was non-significant. In Group II the changes of behaviour scores from pre-operative to post-operative was -5.88%. The 'Z' value post-operatively was 1.337 and the 'p' value was 0.1823 ($p<0.05$) which was non-significant.

DISCUSSION

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

-Dr. Jones

Dental anxiety can be particularly pronounced in children. 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 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.

Anxiety is one of the primary emotions acquired soon after birth. The type of anxiety seen in the child plays a very important role in determining the child’s behaviour during the dental treatment. The types of anxiety commonly seen in children can be trait, state, free-floating, situational and general anxiety. It is a character trait and is a feeling of trepidation, tension or uneasiness that originates from anticipation of peril, the source of which is largely unidentified or unrecognized.[1]

Dental restorations provoke anxiety due to the auditory and tactile sensations of the dental drill and anticipation of receiving local anaesthesia injections.

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 use of local anaesthesia or sedation to manage pain. Patients may experience anxiety about the outcome of the treatment and how it will affect their self-confidence and social interactions.

Anxious patients showing symptoms are addressed by "4 S" rule or so-called “4 S principle”. The philosophy aims to conceal the four primary sensory inputs that contribute to dental anxiety in the dentist's office: sounds (like airotor sound), sensations (like airotor vibrations), sight (injection/needle) as well as smells.[70]

Dental anxiety is characterized by distinct pathophysiological features, including muscle tension, tremors, restlessness, excessive sweating, rapid heartbeat, and altered respiratory patterns. These physical manifestations can have a profound impact on the child, parents, and dental team, ultimately compromising the child's oral health and in-turn the general body health.[25]

The consequences of untreated dental anxiety can be severe, leading to increased incidence of dental caries, which in turn can cause pain, infection, and malnutrition. Furthermore, dental caries can result in emotional and psychological distress, including poor appetite, sleep disturbances, and reduced ability to concentrate. The financial burden on parents also increases as more complex and costly treatments become necessary. The presence of dental anxiety can make it challenging for dentists to manage the child's behavior, leading to prolonged and difficult treatment sessions. In some cases, dentists may even hesitate to provide necessary treatment due to concerns about exacerbating the child's anxiety.[1]

There are many conventional behaviour guidance techniques such as TSD, Modeling, Reframing, Distraction via dental applications, mobile phones, Audio Distraction, Audio-Visual Distraction etc. These are one of the most common behaviour guidance techniques used by Pediatric Dentists.[30]

Although the conventional methods may be one of the most commonly used behaviour guidance techniques, yet they are unable to completely mask certain anxiety provoking stimuli in a dental operatory. For example, audio distraction can help mask the unpleasant sound of the dental drill but cannot distract the child from the sight of needle or unpleasant taste sensation of dental materials or uneasy feeling of the dental drill. Thus, these conventional behaviour guidance techniques fail to cope with the anxiety provoking sensory stimuli present in the environment of the dental operatory.[31]

Regular dental settings often evoke feelings of unease, characterized by an unfamiliar atmosphere, harsh lighting, and unpleasant sounds of dental equipment. For children, these components of the dental operatory acts as a sensory sensitive and thus induce anxiety. These environments can be particularly distressing, triggering increased anxiety, reluctance to seek dental care, and even delays in receiving necessary treatments. This can lead to a cycle of avoidance, exacerbating existing oral health issues and creating a negative association with dental care.[71] Regular dental settings are characterized by monochromatic color schemes and subdued lighting, creating an austere atmosphere that can exacerbate patient anxiety and apprehension about upcoming treatments and appointments. These dental settings are often designed according to the dentist’s preference and convenience, which does not bring any freshness to the operating room. These rooms are gloomy and monotonous which in turn causes a undesirable effect on the psychology of the pediatric patient.

Specially for a child patient, the dentist or Pediatric dentist should create an environment which has a calming effect on the psychology of the child.[72]

There has been a noteworthy escalation in the exploration of non-pharmacological methods for managing anxiety in the recent years. These methods, including animal-assisted therapy, aroma therapy, virtual reality, guided imagery, and auditory beat stimulation, have shown promising results in reducing anxiety levels among patients.

Among these recent advancements in dental care, the development of the 'Sensory Adapted Dental Environment (SADE)' has taken place which incorporates principles from 'Snoezelen therapy'. This innovative approach has demonstrated promising results in reducing anxiety and has been successfully utilized in medical settings to support patients with dementia, ADHD, autism and other conditions.[73] It is a more personalized approach to pediatric healthcare which involves designing specialized environments that accommodates the unique needs and likings of children, with the goal of reducing anxiety, promoting relaxation, and enhancing their overall experience in dental settings. By incorporating elements that address the sensory preferences of children, Sensory Adapted Dental Environments (SADE) enables dental offices to create a calming and supportive atmosphere, ultimately leading to more positive and stress-free dental visits.[71]

Given the limitations of traditional approaches, which often fail to address the anxiety-provoking stimuli inherent to dental settings, Sensory Adapted Dental Environments (SADE) offer a promising alternative for anxiety management. Unlike many other non-pharmacological interventions, Sensory Adapted Dental Environments (SADE) provides a uniquely supportive environment that cushions

children from anxiety-provoking stimuli, promoting overall relaxation and reducing stress during dental treatment.

The Sensory Adapted Dental Environment (SADE) is characterized by multisensory integrated behaviour guidance methods which involves combination of 5 sensory stimuli combined together in a single environment. This involves chromotherapy for visual stimulation, audio therapy for auditory stimulation, grabbing task or using of butterfly blankets for 'hugging' effect for tactile stimulation, aromatherapy for auditory stimulation and use of flavored dental materials for gustatory stimulation. A carefully designed sensory environment is thought to provide a comforting shield against overwhelming stimuli, gently reducing the intensity of distressing visual, auditory, and tactile cues. By creating a soothing atmosphere, this environment aims to facilitate calming responses, promoting relaxation and reducing anxiety. [14] [Figure No. 21]

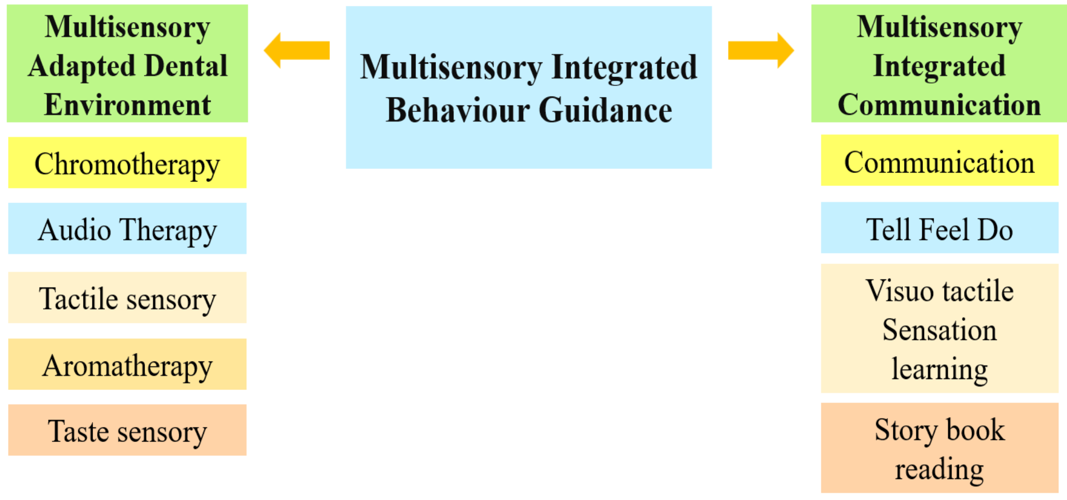


Figure No. 21: Figure Showing Schematic Representation of Multisensory Integrated Behaviour Guidance

Dental treatment within Sensory Adapted Dental Environment (SADE) is created to improve adaptive functioning, ease self-regulation and sensory processing and adjust reactions to outside stimuli. By diverting the child's attention away from

noxious stimuli, SADE leverages the brain's neuroplasticity to promote a more positive experience. Each of the five sensory modifications incorporated into the dental operatory has a distinct impact on brain function, collectively contributing to a more calming experience and thus helping in reduction of anxiety.[14]

In the current study, we have modified the dental environment by using blue, green and pink colored projected lights for visual stimulation (chromotherapy), sound of ocean waves i.e. white noise via Bluetooth speakers for auditory stimulation (audio therapy), providing the child with stress ball (squeezy toys) for tactile stimulation, lavender essential oil for olfactory stimulation (aromatherapy) and flavored rubber dam sheets for gustatory stimulation.

According to Logan-Clarke and Appleby, chromotherapy is a holistic, non-invasive, and potent therapeutic approach which can elicit distinct emotional and psychological responses. The colors blue and green are colors of cooler shades and hence are known to cause calming effects and relief a person.[14]

Blue color is the color of warmth and peace. It is often associated with feelings of calmness, serenity and tranquility which in turn evokes sensation of peacefulness, safety and order. This color not only affects the psychological aspects but also physiological aspects in a person. Blue color causes reduction in body temperature, blood pressure and pulse rate. This color can be used in children’s rooms especially in nurseries, as it benefits the child with relaxed and peaceful changeover into sleep. It can also be comfortably used for children who are highly spirited and dynamic due to its calming effect.[35]

Green holds a profound psychological significance, embodying the essence of health and peace. It’s calming effect on the nervous system is deeply soothing,

evoking feelings of peace, quiet, and stillness. Notably, green is the most relaxing color to the human eye, as the lens focuses green light precisely on the retina. Green color represents the vibrant power of nature and life, earning its reputation as the most natural, calming, and balanced color.[35]

Pink color is a color of warmer tone. Although the tone is warm, the color pink helps in calming a person and hence can be used for anxiety reduction. Pink is a harmonious blend of red and white, has a profoundly positive impact on our physical and emotional well-being. This soothing hue exudes warmth and relaxation, making it an exceptional color for promoting serenity. Notably, pink is the only pastel shade of red with its own distinct name, underscoring its unique properties. Psychologically, pink is a powerful color, symbolizing the continuity of life and femininity. A softer, less vibrant pink can be an excellent choice for energetic and active children, evoking feelings of warmth and tranquility.[35]

Saklecha & authors performed a trial to check the efficiency of chromotherapy using blue and pink colored lights on anxiousness of patients experiencing dental treatment. The results of this study favored the utilization of these colors in the dental operatory and showed that they can be used for effective reduction of anxiety.[16] Another study conducted by Umamasheshwari aimed to evaluate the link of colors and emotions. They stated that children recognized colors like blue, green, pink and yellow as color of happy emotions.[36] Study conducted by Kattakayam et al also aimed to check the association of colors and human emotion. Among the 4 colors blue, pink, yellow and green used in this study children favored and preferred green color and called it as happy emotions.[38] Research on children's color preferences has consistently shown a strong inclination towards the colors blue, green and pink and

given the high impact of these colors on human psychology, we selected these colors for visual stimulation via chromotherapy in the current study.

The success observed in our study with experimental group (Group II), children undergoing dental treatment under Sensory Adapted Dental Environment (SADE) is because the color of visible spectrum hits the photoreceptors in retina. These signals are taken up by suprachiasmatic nuclei in the anterior hypothalamus. The melatonin receptors (MT1 and MT2) present in this area then leads to secretion of melatonin and serotonin which in turn regulates the mood of an individual.[33] [Figure No. 22]

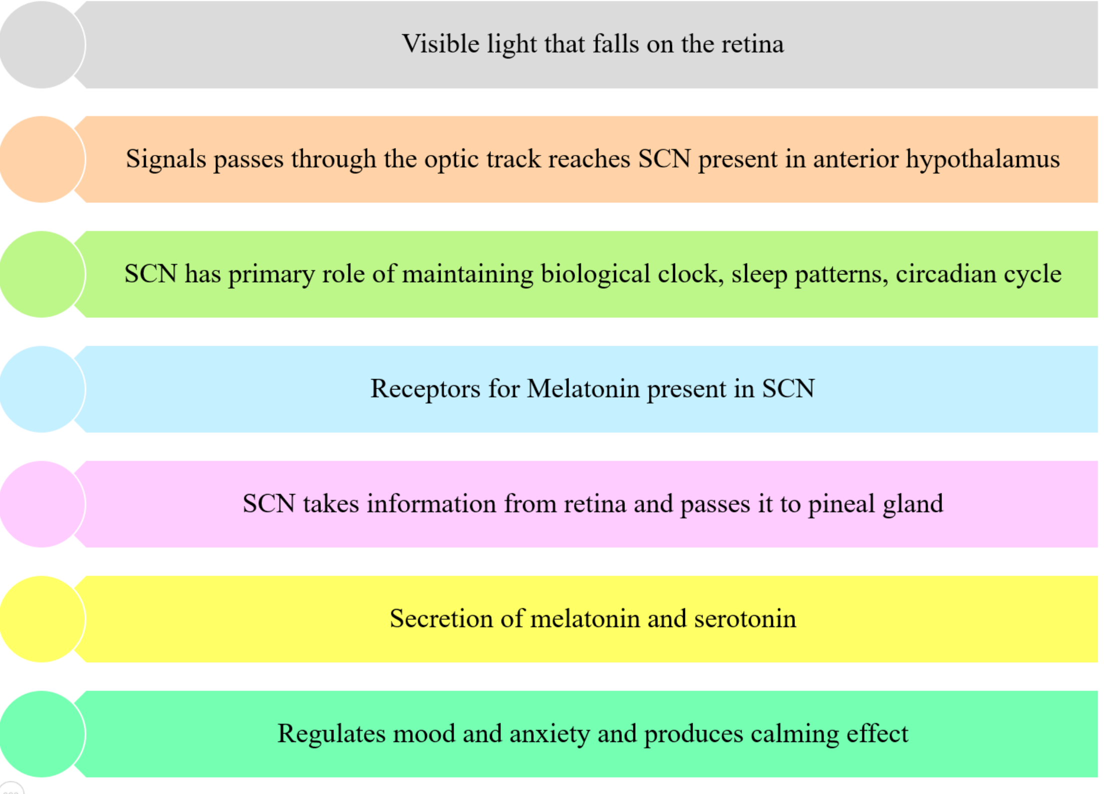


Figure No. 22: Figure Showing Schematic Representation of Mechanism of Action of Visible Light

White noise is a unique type of sound characterized by an equal distribution of energy across all frequency bands, which is a combination of unaltered frequencies or amplitude and masks the unpleasant noise in the surroundings. Its spectral density is

flat and its intensity remains constant within the perceptible frequency ranging from 20 Hz to 20,000 Hz. White noise is culmination of all audible sounds, yielding an unlimited bandwidth and a linear spectrum. As a fundamental example of white noise is ubiquitous in everyday life, with familiar manifestations including the soothing sounds of ocean waves, rainfall, air conditioners, fans, static television etc.

"Ronald Melzack and Patrick Wall's 1965 gate control theory of pain" is the first and most significant mechanism. According to this idea, pain signals are transmitted from the site of injury through spinal cord nerve receptors.
synapses for the brain to receive pain information. When there are two sensory stimuli, the gate is opened for audio stimuli and the audio sensation are increased as a result of which pain sensations reduce and are masked by these audio sensations. Therefore, the auditory stimulation prevents transmission of pain sensation to Central Nervous System (CNS). In the lower thalamus and reticular formation, pain and auditory pathways are physically tightly related, according to Robert and Sowray's cross-sensory mechanism. These two interactions are extremely inhibiting. The stimulation of another inhibitory sensory pathway results in the suppression of pain perception. This is because the audio stimulation reduces oral anxiety by concealing pain impulses.[74] Therefore, introducing white noise in the dental operatory masks the sound of drill and mirrors human speech frequencies, thereby rendering distracting sounds less perceptible and causing reduction of anxiety due to noxious auditory stimuli. [Figure No. 23]

Obnoxious stimuli in dental operatory (unpleasant noise)

Increased stress in the child (cortisol hormone or stress hormone secreted)

Music (played via loudspeaker or headphones)

Blocking of obnoxious stimuli in the dental operatory

Music activates limbic system of brain

Leads to secretion of hormones like endorphins and enkephalins

These hormones blocks the action of cortisol

Relieves the child from stress and reduces anxiety

Figure No. 23: Figure Showing Schematic Representation of Effect of Music on Limbic System of Brain

Thus, white noise can be effectively used a part of the Sensory Adapted Dental Environment (SADE).

Kolhe & authors compared various types of noises like white, pink and brown noises and evaluating their efficacy on children undergoing dental treatment. In this study it was stated that audio distraction via white noise in highly efficacious anxiety reduction of children undergoing dental treatment.[41] Study by Singh et al checked the efficacy of white, pink and brown noises on anxiety levels and pain perception of young patients undergoing dental procedure. However, this study stated that all types of noises are equally effective.[49] Ramar et al stated that audio analgesia via white noise can be useful in anxiety reduction and behaviour management of children undergoing dental procedures.[50]

Research has demonstrated the efficacy of white noise in significantly reducing dental anxiety. Additionally, its masking properties effectively conceal

unpleasant sounds commonly associated with dental procedures, creating a more comfortable environment for children. Based on these findings, white noise was selected as the optimal auditory stimulus for providing audio therapy in the Sensory Adapted Dental Environment (SADE).

Existing research on Sensory Adapted Dental Environment (SADE) has primarily focused on children with special healthcare needs. To order provide tactile stimulation to these children, a friendly immobilization wrap was employed, which generates a soothing "hugging" effect. This wrap not only provides a sense of security but also ensures the children's safety through the application of deep pressure, a technique known to be calming and organizing.[13]

The AAPD explicitly advises against practice of restraints or protective stabilization for children with normal development or cooperative behavior.[75] Given that the partakers in this study were typically developing young indiviuals, we adhered to these guidelines and refrained from using butterfly wraps. Instead, we employed active distraction techniques using stress balls to provide tactile stimulation, promoting a positive and non-invasive dental experience.

The rationale of using stress balls for tactile stimulation was the ability of the child to squeeze these balls during the dental treatment and thus distracting the focus the child away from the on-going dental procedure. Squeezing of the ball works on the grabbing task mechanism and cognitive refocusing theory. It also works on the principles of gate control theory which states that pain signals are carried by nerve receptors from site of injury reaches spinal cord through synapses and finally to brain. When there are 2 sensory stimuli the gate opens for tactile stimulus. Squeezing the stress ball enhances the tactile stimuli and decreases pain perception. Thus, the tactile stimulation averts the travelling of pain sensation to CNS.[51]

Studies on using stress ball for play therapy, have concluded that active distraction via stress balls can help in anxiety reduction of the child undergoing dental treatment.[20,21,52]

Aromatherapy works on the principal of inhalation of essential oils. It is a therapeutic approach that harnesses the potent benefits of scent. Through simple inhalation, individuals can experience state of calmness, relaxation and rejuvenation. The mind and body respond to the soothing properties of essential oils and promotes emotional wellness. Moreover, the release of stress and anxiety is intricately linked to the pleasurable sensations evoked by these fragrances, which can unlock odor memories and evoke feelings of serenity and tranquility.[53]

Lavender essential oils contain linalool and linalyl acetate having sedative properties. Aromatherapy via use of lavender oil has both physiological and psychological effects of on human body. Through the sense of smell, the psychological stimulus produces a physiological effect. It is believed that the physiological effects operate in the amygdala and hippocampus via the limbic system of the brain. The biological mechanism of action is that, like benzodiazepines, which have sedative effects, lavender may also stimulate gamma-aminobutyric acid activity in the amygdala. When lavender is inhaled, linalool causes acetylcholine release to be inhibited and ion channel function at the neuromuscular junction to change.[17]

The cellular mechanism of action is that lavender may increase the activity of GABA receptors in amygdala similar to benzodiazepines which in turn has sedative properties. Lavender contains linalool which leads to inhibition of release of acetylcholine and alters the ion channel function at neuromuscular junction. Lavender oil has linalyl acetate which has narcotic actions. When the lavender aroma is inhaled, the molecules bind with the receptors of the olfactory bulb present in the nasal cavity.

The signals are transmitted from the olfactory bulb to the limbic system of the brain which in turn causes the release of certain hormones like serotonin, endorphins, enkephalins. These hormones are mood elevating hormones and thus the lavender aromatherapy helps in reduction of anxiety.[17] [Figure No. 24]

Essential oils contains aroma molecules

These molecules have good penetration potential into the subcutaneous tissue

When inhaled, binds with receptor cells in nose and is transmitted as biological signal via olfactory bulb

Signal is transmitted to limbic and hypothalamus parts of the brain via olfactory bulb

These signals cause brain to release neuro messengers like serotonin, endorphin, noradrenaline

Providing feeling of relief, calm and euphoria

Figure No. 24: Figure Showing Schematic Representation of Mechanism of Action of Aromatherapy

Studies by various authors have concluded that lavender essential oil has stress relieving properties and aromatherapy via usage of lavender essential oil can reduce anxiety in children undergoing dental procedure and thus can be used regularly to mask the unpleasant olfactory stimuli present in the dental operatory.[17,55,56]

A comprehensive review by Kajjari S et al highlights the pronounced anxiolytic properties of lavender essential oil, which have been consistently supported by existing literature. This review has demonstrated the high efficacy of lavender oil in mitigating anxiety in children undergoing dental procedures.[76] Building on this evidence, the current study incorporated the use of lavender essential oil for olfactory

stimulation, leveraging its calming effects to enhance the dental experience for children.

The unpleasant taste of certain dental materials, such as rubber dams, restorative cements, irrigating solutions and intracanal medicaments can be a significant source of anxiety for children during dental procedures. Studies by Kumar & authors and Dalal & authors have suggested that children preferred use of flavored dental materials over conventional dental materials.[58,59] Pediatric Dentists can minimize exposure to restorative materials by using a rubber dam, the latex taste of traditional rubber dams can still be irritating for young patients. To enhance the dental experience and reduce anxiety, we opted to replace non-flavored rubber dams with flavored alternatives, providing a more comfortable and pleasant treatment environment.

Pleasant taste sensations trigger a cascade of neurological responses, activating the central nervous system (CNS) and influencing the body's endogenous opioid system. This stimulation leads to the release of neurotransmitters and hormones, including serotonin, noradrenaline, endorphins, and encephalins. These hormones collectively modulate the parasympathetic nervous system (PNS). As a result, stress-related clinical symptoms, HR, BP and SPO_2 are mitigated, promoting a state of relaxation and reduced anxiety.[22] [Figure No.25]

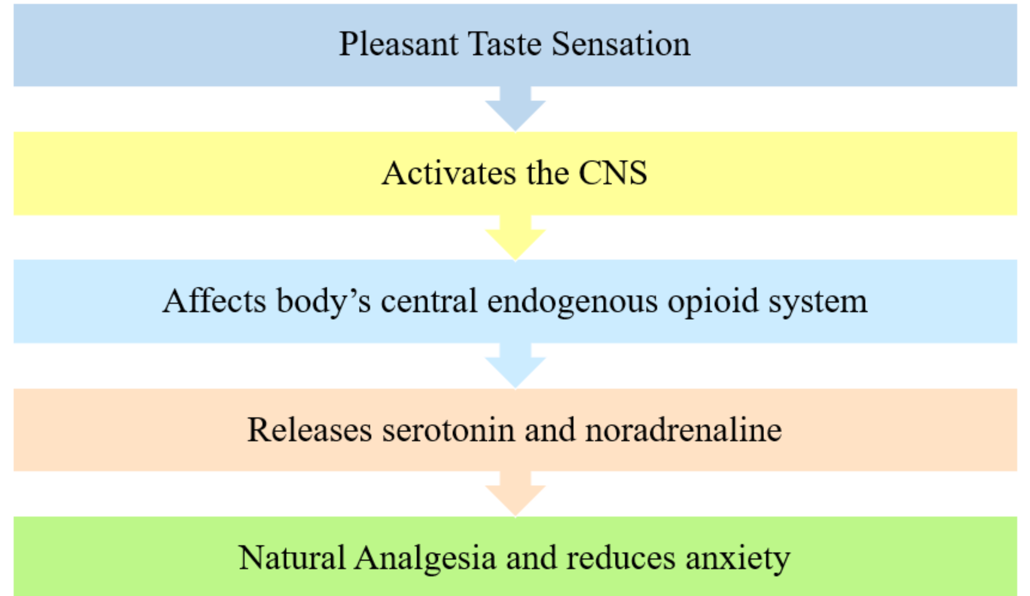


Figure No. 25: Figure Showing Schematic Representation of Mechanism of Action of Taste Sensation on Central Nervous System

The integration of these five sensory stimulations within a multisensory environment creates a relaxing and pleasurable space which is referred to 'Snoezelen room' or 'Sensory Adapted Dental Environment' (SADE). Initially, Sensory Adapted Dental Environment (SADE) was designed to cater to children with special healthcare needs, such as intellectual disabilities (ID), Autism Spectrum Disorder (ASD) and developmental disabilities (DD). These children often exhibit sensory over-responsivity and hence the use of Sensory Adapted Dental Environment (SADE) was recommended.[77] However, given the remarkable success of SADE in this population, AAPD in 2021 suggested its application for typically developing children who experience dental anxiety, recognizing its potential to provide a more comforting and stress-free dental experience.[10]

In the current study we included typically developing children between age range of 6 to 12 years old suffering from DFA. Our study centered participants of this age group as they possess sufficient cognitive maturity to comprehend and articulate

their experiences of pain and anxiety. This also enabled use of self-reporting scales, which were deemed more reliable due to the children's ability to provide accurate and informed responses. To assess anxiety in our pediatric population, we employed the Venham's Picture Test (VPT), a well-established psychometric tool. This self-measure test has demonstrated validity in evaluating child dental anxiety within clinical settings. A pulse oximeter was used to objectively measure anxiety since worry-induced features increases heart rate and are directly caused by sympathetic activation. Therefore, utilising both physiological and psychometric techniques for evaluation can have a crucial part in offering both a qualitative and quantitative assessment of anxiety.

In present study it was found that children receiving dental treatment in Sensory Adapted Dental Environment (SADE) showed significant reduction in anxiety as compared to children receiving dental treatment in Regular Dental Environment (RDE). These results of our study were highly statistically significant with both psychological and physiological parameters.

A study conducted by Kittur et at in 2022 stated that SADE significantly reduced anxiety in children suffering from mild ID.[11]

Similar results were seen in another study performed on children suffering from autism. 68% of children having autism underwent dental treatment successfully in SADE as compared to RDE where only 20% children were treated successfully.[78]

Another randomized controlled study on 22 children with autism and 22 typically developing children was performed. The findings of this study suggested that SADE were beneficial for children with autism, whereas typically developing children did not exhibit significant changes in anxiety levels.[12]

Notably, the results of study by Cermak et al diverged from our own findings, where dental treatment under SADE was found highly efficacious for children having dental anxiety.

A pilot study aimed to evaluate the efficiency of SADE on behaviour and anxiety of children having DD. The results of this study showed that the anxiety levels reduced significantly in SADE and 80% children preferred dental treatment in the SADE.[9]

Although the results from the aforementioned studies were in agreement with our study but these studies were conducted on children with special health care needs.

A trial proved that there was a notable change in the anxiety levels and behaviour postoperatively for children undergoing dental treatment in SADE.[71] The results of this study were in accordance with our study where the anxiety levels reduced significantly in Sensory Adapted Dental Environment (SADE) group and the behaviour changes was not significant. Another study conducted by Ganapathy in 2024 revealed that snoezelen's approach works well in managing a child's dental anxiety and fear.[63]

For evaluation of effect of desensitization by snoezelen in pediatric patients, Anjali N & authors conducted a study in 2023. The results of this study stated that there was no significant difference in anxiety levels of children when virtual game was compared with snoezelen environment.[65] Fox - Noy et al concluded that the multisensory waiting environment has no significant effect on anxiety of children.[66] However, the results of these studies contradicted the findings of our study, which highlighted the significant benefits of snoezelen therapy in Sensory Adapted Dental Environment (SADE).

In the present study, the null hypothesis was rejected and alternative hypothesis was accepted. There is a statistically significant difference in reduction of anxiety levels in children aged 6 to 12 years during restorative treatment under snoezelen therapy in Sensory Adapted Dental Environment (SADE). The research outcomes show the importance of considering utilization of Sensory Adapted Dental Environment (SADE) in management of uncooperative children by Pediatric Dentists for reduction of 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 of Sensory Adapted Dental Environment (SADE) stands to significantly enhance the patient’s experience during restorative dental procedures. 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 control trial enhances the existing evidence base supporting the efficacy of Sensory Adapted Dental Environment (SADE) 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 dental treatment in Sensory Adapted Dental Environment (SADE) offers promising avenues for anxiety reduction and thus reducing the reliance on sedation or pharmacological interventions. 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, Sensory Adapted Dental Environment (SADE) may contribute to overall cost savings in pediatric dental care, underscoring the far-reaching benefits of our research findings.

This study had limitations, just like any other technique, but they were all solvable. Our study had a small sample size, so the results cannot be extrapolated to a broader population. Additionally, the results of the study may not be consistent with those of other age groups because it was done on youngsters.

The futuristic ideas of our study are: Sensory Adapted Dental Environment (SADE) for pain perception that is to investigate the effects of SADE on pain perception of children undergoing more complex treatments like pulpectomies, root canal treatments and extraction. Conduct a randomized controlled trial to assess the comparative efficacy of SADE versus RDE on pain perception of children undergoing dental treatment. A multi centric study done on a larger sample size.

CONCLUSION

To sum up, dental anxiety is still a major issue in the field of dentistry. One promising approach to reducing anxiety is the multisensory integration of different stimuli in a sensory-adapted dental environment.

The following conclusions are drawn from the present study:

1. When comparison of pre- operaive and post-operative Venham's picture test score were done among the two groups, reduction of anxiety was observed in both the groups, however the reduction was more statistically significant in Sensory Adapted Dental Environment (SADE) group as compared to Regular Dental Environment (RDE) group.

2. When comparison of pre - operative and post – operative pulse rate scores was done among the two groups, reduction of pulse rate was seen in Sensory Adapted Dental Environment (SADE) group which was very highly statistically significant while an increase in the pulse rate was seen in the Regular Dental Environment (RDE) group which was statistically significant.

3. When comparison of pre and post operative changes in behaviour was evaluated, Sensory Adapted Dental Environment (SADE) group showed that children had more positive behaviour postoperatively as compared to Regular Dental Environment (RDE) group however the changes were non-significant.

Therefore, the current study comes to a conclusion that sensory-adapted dentistry environment is quite helpful at lowering anxiety levels during dental procedures. This is a new approach that can effectively be used as a less dangerous and more successful supplement to help regulate children's behaviour in dental operatory.

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 by modifying the environment of the dental operatory. 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 to evaluate and compare the effectiveness of Sensory Adaptive Dental Environment (SADE) and Regular Dental Environment (RDE) to alleviate anxiety in children undergoing dental treatment. Sixty children were selected according to the inclusion criteria. The cavity preparation was performed for tooth having Class I caries in permanent molars. Composite restoration was done for it. Anxiety was measured pre- and post-intervention using Pulse oximeter and Venham's picture test. Children were randomly divided into two groups namely Group I as Regular Dental Environment (RDE) group and Group II as Sensory Adaptive Dental Environment (SADE) group.

Our study showed children who were treated in Sensory Adaptive Dental Environment (SADE) showed reduction in anxiety levels as indicated by lower anxiety scores in Venham picture test and pulse rate values as compared to Regular Dental Environment (RDE) group.

.

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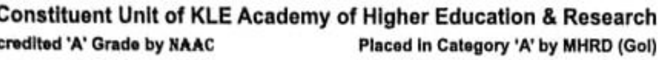
ANNEXURE I: ETHICAL CLEARANCE CERTIFICATE

Research and Ethics Committee

KLE VK INSTITUTE OF DENTAL SCIENCES

A Constituent Unit of KLE Academy of Higher Education & Research



Accredited 'A' Grade by NAAC — Placed in Category 'A' by MHRD (GoI)

Nehru Nagar, Belagavi - 590 010, Karnataka State

☎: 0831-2470362 — Web: http://www.kledental-bgm.edu.in
FAX: 0831-2470640 — E-mail:principal@kledental-bgm.edu.in

Sl. No. : 1634

CERTIFICATE

This is to Certify that the synopsis titled COMPARATIVE EVALUATION of EFFECTIVENESS OF SENSORY ADAPTED DENTAL ENVIRONMENT and REGULAR DENTAL ENVIRONMENT TO ALLEVIATE ANXIETY in CHILDREN UNDERGOING DENTAL TREATMENT - A RANDOMIZED CONTROL TRIAL *Submitted by Dr.* **IJ0222002** ______ *P. G. Student / Staff, Guided by* ______ *from Department of* Pedodontics and Preventive Dentistry *has been critically evaluated by committee members and granted ethical clearance to conduct the above mentioned study*

Date : 27/3/25

Member Secretary
Research and Ethical Committee
KLEVK Institute of Dental Sciences
Belagavi

Chairman
Research and Ethical Committee
KLEVK Institute of Dental Sciences
Belagavi

ANNEXURE II: CTRI REGISTRATION CERTIFICATE

FULL DETAILS (Read-only) -> Click Here to Create PDF for Current Dataset of Trial

CTRI No	**CTRI/2024/04/065178** [Registered on: 03/04/2024] **Trial Registered Prospectively**
Acknowledgement Number	REF/2024/02/079604
Last Modified On:	16/09/2024
Post Graduate Thesis	Yes
Type of Trial	Interventional
Type of Study	Dentistry
Study Design	Randomized, Parallel Group Trial
Public Title of Study Clarification(s) with Reply Modification(s)	Effect of Normal Dental Environment and Special Dental Environment on Anxiety of Children Undergoing Restorative Dental Treatment
Scientific Title of Study Clarification(s) with Reply Modification(s)	Comparative Evaluation of Effectiveness of Sensory Adapted Dental Environment and Regular Dental Environment to Alleviate Anxiety in Children Undergoing Dental Treatment: A Randomized Control Trial
Trial Acronym	NIL
Secondary IDs if Any	Secondary ID: NIL; Identifier: NIL

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

Name	
Designation	Post Graduate Student
Affliation	KAHERs KLE VK Institute of Dental Sciences, Belagavi
Address	Department of Pediatric and Preventive Dentistry KAHERs KLE VK Institute of Dental Sciences, JNMC Campus, Nehru Nagar, Belagavi KARNATAKA 590010 India Belgaum KARNATAKA 590010 India
Phone	
Fax	
Email	

Details Contact Person Scientific Query

Name	
Designation	Professor and Head
Affliation	KAHERs KLE VK Institute of Dental Sciences, Belagavi
Address	Department of Pediatric and Preventive Dentistry KAHERs KLE VK Institute of Dental Sciences, JNMC Campus, Nehru Nagar, Belagavi KARNATAKA 590010 India Belgaum KARNATAKA 590010 India
Phone	
Fax	
Email	

Details Contact Person Public Query

Name	
Designation	Post Graduate Student
Affliation	KAHERs KLE VK Institute of Dental Sciences, Belagavi
Address	Department of Pediatric and Preventive Dentistry KAHERs KLE VK Institute of Dental Sciences, JNMC Campus, Nehru Nagar, Belagavi KARNATAKA 590010 India

		Belgaum KARNATAKA 590010 India
	Phone	
	Fax	
	Email	
Source of Monetary or Material Support	Department of Pediatric and Preventive Dentistry, KAHERs KLE VK Institute of Dental Sciences, Nehru Nagar, Belagavi	
Primary Sponsor	**Name**	
	Address	Department of Pediatric and Preventive Dentistry, KAHERs KLE VK Institute of Dental Sciences, Nehru Nagar, Belagavi
	Type of Sponsor	Other [Self]

Details of Secondary Sponsor

Name	Address
NIL	NIL

Countries of Recruitment: India

Sites of Study

No of Sites = 1

Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email
	KLE VK Institute of Dental Sciences, Belagavi	Department Number 6, Department of Pediatric and Preventive Dentistry, KAHERs KLE VK Institute of Dental Sciences, JNMC Campus, Nehru Nagar, Belagavi KARNATAKA Belgaum KARNATAKA	

Details of Ethics Committee
Clarification(s) with Reply
Modification(s)

No of Ethics Committees= 1

Name of Committee	Ethics Committee registered with DHR /CDSCO or not	Ethics Committee Registration No.	Approval Status	Date of Approval	Approval Document	Is IEC?
Research and Ethics Committee, KLE VK Institute of Dental Sciences, Belagavi	Yes	EC/NEW/INST/2021/2435	Approved	16/11/2023	Approval File	No

Regulatory Clearance Status from DCGI

Status	Date	Aproval Document
Not Applicable	No Date Specified	No File Uploaded

Health Condition / Problems Studied

Health Type	Condition
Patients	**(1) ICD-10 Condition:** K029||Dental caries, unspecified,

Intervention / Comparator Agent
Clarification(s) with

Type	Name	Details
Comparator Agent	Regular Dental Environment	Evaluation of pre and post operative dental anxiety in children undergoing restorative dental treatment in regular

Reply Modification(s)			dental environment. Treatment will be done in 45 minutes
	Intervention	Sensory Adapted Dental Environment	Evaluation of pre and post operative anxiety in children undergoing restorative dental treatment in sensory adapted dental environment. Treatment will be done in 45 minutes

Inclusion Criteria Clarification(s) with Reply Modification(s)	**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 with caries extending up to superficial dentin requiring Class 1 restoration in primary/ permanent molar teeth. 4. Children and/or parents who are willing to participate in the study.
Exclusion Criteria	**Details**	1. Children with special health care needs. 2. Children and/or Parents who are unwilling to participate in the study. 3. Parents of children who insist on being in the operatory shall be excluded from the study to avoid parental influence on child.

Method of Generating Random Sequence	Coin toss, Lottery, toss of dice, shuffling cards etc
Method of Concealment	Sequentially numbered, sealed, opaque envelopes
Blinding/Masking	Not Applicable

	Outcome	TimePoints
Primary Outcome Clarification(s) with Reply Modification(s)	Measurement of preoperative and postoperative anxiety using Venhams Picture Scale and Pulse rate	Baseline and Post operative
Secondary Outcome	NIL	NIL

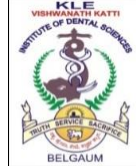
Target Sample Size	**Total Sample Size=**"48" **Sample Size from India=**"48" **Final Enrollment numbers achieved (Total)=** "0" **Final Enrollment numbers achieved (India)=**"60"
Phase of Trial Clarification(s) with Reply Modification(s)	N/A
Date of First Enrollment (India) Clarification(s) with Reply Modification(s)	02/05/2024
Date of Study Completion (India)	27/01/2025
Date of First Enrollment (Global)	If country of recruitment is only India, global date would be not applicable.
Date of Study Completion (Global)	If country of recruitment is only India, global date would be not applicable.
Estimated Duration of Trial	**Years=**"0" **Months=**"6" **Days=**"0"

Recruitment Status of Trial (Global) Modification(s)	If country of recruitment is only India, global status would be not applicable.
Recruitment Status of Trial (India)	Completed
Publication Details	N/A
Individual Participant Data (IPD) Sharing Statement	**Will individual participant data (IPD) be shared publicly (including data dictionaries)?** **Response** - NO
Result Disclosure	**Do you wish to upload results?** **Response** - Summary results will not be disclosed.
Brief Summary	The Principal Investigator will perform the procedure under Standard Operating Protocols. The procedure will be carried out in 45 min for each patient in all the two groups. Parental consent and patient assent will be obtained. The patient will be first asked to sit comfortably on the dental chair. Case History of the patient and preoperative anxiety scores will be noted using Venhamâ€™s Picture Scale and Pulse Oximeter. The operator (principal investigator) will be then perform restorative treatment in sensory adapted and regular dental environment. Selected tooth will be isolated with rubber dam and class I cavity preparation using appropriate armamentarium will be done. After which the cavity will be restored using a suitable material. Post restorative instructions will be given. The sensory adapted dental environment is a specialized environment which will aim to activate all the 5 senses of human body to reduce dental anxiety. The setup will consist of moving ceiling light (visual stimulation), portable speaker with soothing music (auditory stimulation), air diffusers with aromatic oils (olfactory stimulation), stress balls or hugging toys (tactile stimulation) and flavoured runner dam sheets (gustatory stimulation). The regular setup will consist of no such specifications.

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 Effectiveness of Sensory Adapted Dental Environment and Regular Dental Environment to Alleviate Anxiety in Children Undergoing Dental Treatment: A Randomized Control Trial"**

Name of Principal investigator:
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:
Professor, 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 Sensory Adapted Dental Environment 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 Sensory Adapted Dental Environment.

Procedures and Protocol: We currently do not know what type of environment of dental clinic that is: Regular set up or Sensory Adapted Dental Environment, is better in children with dental anxiety, so these two methods are to be compared. Children participating in this research will be divided into two groups by lottery method.

The first group of children will be implemented to conventional restorative technique without any intervention in Regular Dental Environment. In the second of children, the dental treatment will be provided in Sensory Adapted Dental Environment. 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.

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.

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

Will this research harm my child? This research will not harm your child in any way.

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.

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

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.

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.

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, 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)

KLE Academy of Higher Education and Research.

K.L.E. V.K. Institute of Dental Sciences, Belagavi.

Department of Pediatric and Preventive Dentistry

"Comparative Evaluation of Effectiveness of Sensory Adapted Dental Environment and Regular Dental Environment to Alleviate Anxiety in Children Undergoing Dental Treatment: A Randomized Control Trial"

ಸಮ್ಮತಿ ಪತ್ರ

ಸಂಶೋಧಕರು:

ಚಿಕ್ಕಮಕ್ಕಳ ದಂತ ಚಿಕಿತ್ಸಾ ವಿಭಾಗ

ಕೆಎಲ್ಇ ವಿ. ಕ. ದಂತ ಮಹವಿದ್ಯಾಲಯ

ಬೆಳಗಾವಿ–10

ನಾನು ಶ್ರೀ/ಶ್ರೀಮತಿ------------------------------ ಎಲ್ಲ ಮಾಹಿತಿಯನ್ನು ಪಡೆದುಕೊಂಡಿದ್ದೇನೆ ಮತ್ತು ನನ್ನ ಮಗ/ಮಗಳು------------------------ವಯಸ್ಸು---- ಈಸಂಶೋಧನೆಯಲ್ಲಿ ಭಾಗವಹಿಸಲು ಅನುಮತಿಯನ್ನು ನೀಡಿ ಸಹಕರಿಸುತ್ತೇನೆ.

1. ನನ್ನ ಮಗ/ಮಗಳ ಬಗ್ಗೆ ಎಲ್ಲ ಮಾಹಿತಿ ಕೊಡಲು ಒಪ್ಪುತ್ತೇನೆ.
2. ನನ್ನ ಮಗ/ಮಗಳ ಬಯಿಯ ಹುಳುಕು ಹಲ್ಲುಗಳನ್ನು ಸ್ವಚ್ಚಗೋಳಿಸಲು ಸಹಮತಿಯನ್ನು ನಿಡುತ್ತೇನೆ.
3. ನಾನು ವೈದ್ಯರು ಕೊತ್ತೀರುವ 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.

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 seated in a Sensory Adapted Dental Environment. This environment 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:

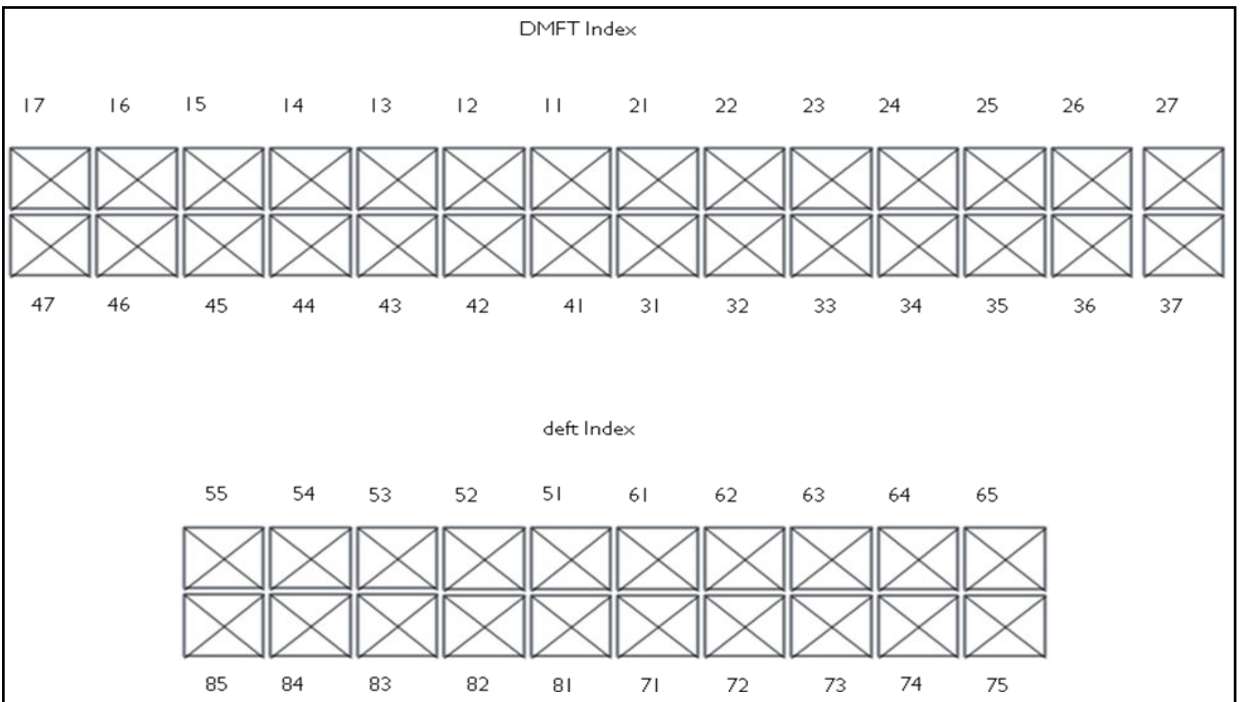
Hard Tissue Examination:

PROVISIONAL DIAGNOSIS:

INVESTIGATION:

FINAL DIAGNOSIS:

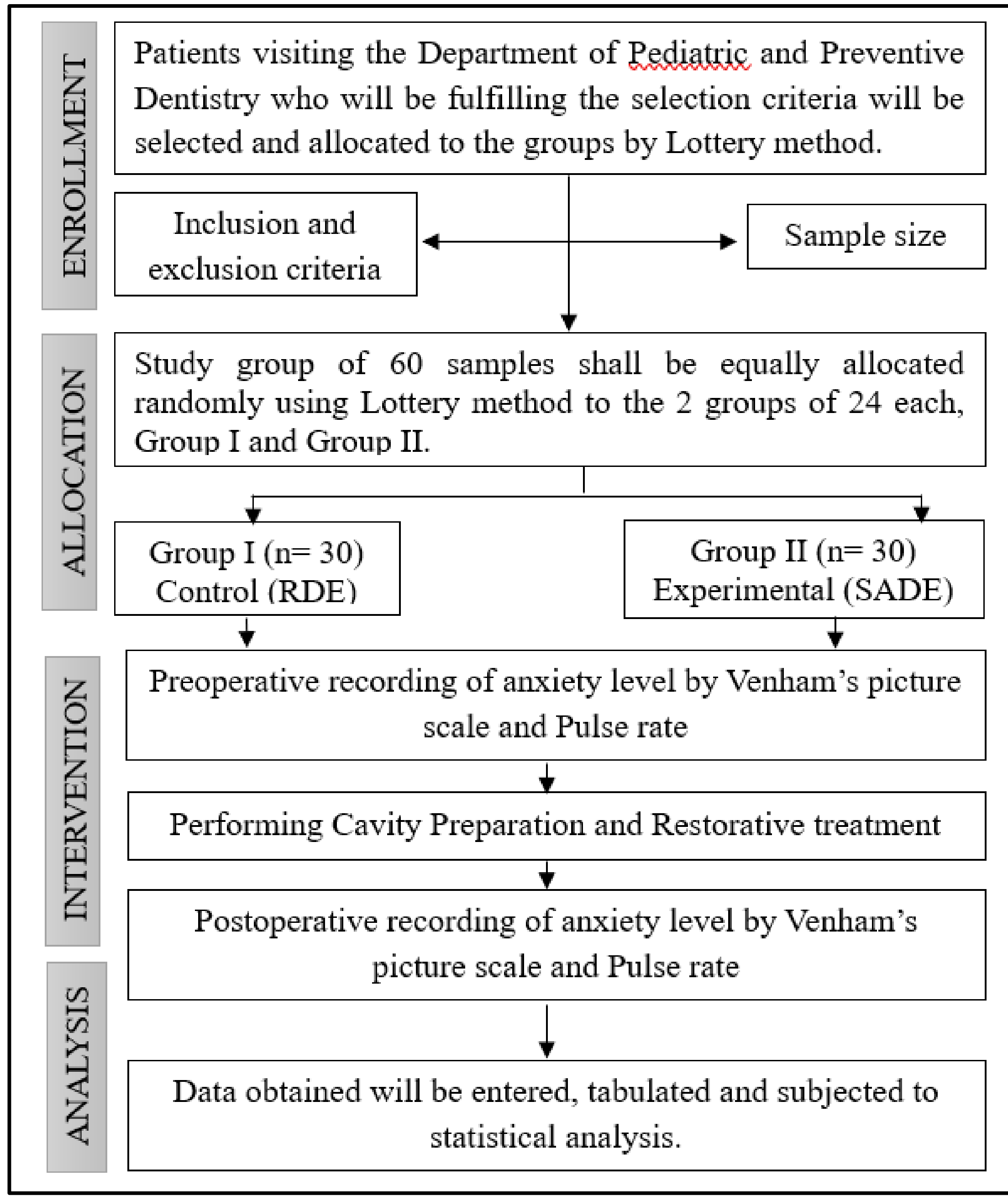
TREATMENT PLANNING:



Preoperative and postoperative anxiety recording:

Name	Opd No.	Age/Sex	Tooth No.	Venham's Picture Test		Pulse Rate	
				Pre Op	PostOp	Pre Op	Post Op

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.

BIOSTATISTICS CLEARANCE CERTIFICATE

This is to certify that the Biostatistics part of Dissertation/ Research work of **Dr.** **IJ0222002** **Postgraduate student** under the guidance of **Professor, Department of Pediatric and Preventive Dentistry** entitled **"Comparative Evaluation of Effectiveness of Sensory Adapted Dental Environment and Regular Dental Environment to Alleviate Anxiety in Children Undergoing Dental Treatment: A Randomized Control Trial"** has been done under my guidance and considered satisfactory.

Name and signature of Biostatistician

Dr. S. B. Javali. Ph.D.
Professor in Statistics
Department of Community Medic
USM KLE International Medical Progr
BELAGAVI-590010.

Place: Belagavi
Date: 10. 02. 2025

ANNEXURE VIII: 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 (3rd Cycle) Placed in Category 'A' by MHRD (GoI)
☎: 0831-2470362 Web: http://www.kledental-bgm.edu.in
FAX: 0831-2470640 E-mail:principal@kledental-bgm.edu.in

Date : 15/04/2025 Serial No. : 402

PLAGIARISM CHECK REPORT

Name of the Applicant : IJ0222002
UG / PG / Ph.D / Staff : PG
Batch & Year : 2022 - 2025
Department : Pediatric & Preventive Dentistry

The soft copy of Research Work / Manuscript by IJ0222002 entitled "comparative evaluation of effectiveness of sensory adapted dental environment & regular dental environment to alleviate anxiety in children undergoing dental treatment : a randomized controlled 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 …………9………%, which is **within / not within** the acceptable limits of 10% as per the UGC guidelines.

15/04/2025
Member Secretary
Scientific Correspondence and Review Committee
KLEVK Institute of Dental Sciences
KAHER-Belagavi

15/4/25
Chairman
Scientific Correspondence and Review Committee
KLEVK Institute of Dental Sciences
KAHER - Belagavi