# COMPARATIVE EVALUATION OF EFFECTIVENESS OF 'TELL SHOW DO' (TSD) AND VIRTUAL REALITY (VR) METHOD OF BEHAVIOUR MANAGEMENT ON ANXIETY LEVELS OF CHILDREN UNDERGOING RESTORATIVE TREATMENT OF CARIOUS TEETH - A RANDOMISED CONTROL STUDY

**By**

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# Dissertation

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This is to certify that the dissertation **"Comparative evaluation of effectiveness of 'Tell Show Do' (TSD) and Virtual Reality (VR) method of Behaviour management on anxiety levels of children undergoing restorative treatment of carious teeth – A Randomised Control Study."** is a bonafide research work done by **REG.NO.IJ0219001.**

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## UNDERTAKING

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# ABSTRACT

**Aim:** To evaluate and compare the effectiveness of 'Tell Show Do' (TSD) And Virtual Reality (VR) Method of Behaviour Management on anxiety levels of Children Undergoing Restorative Treatment of Carious Teeth.

**Materials and Method:** Sixty children belonging to the age group of 6-12 years having their first dental visit with occlusal caries limited to enamel and dentin were included in our study. These children were randomly allocated to Group A (Tell Show Do) and Group B (Virtual Reality). Dental anxiety was assessed by Venham's Picture Test and pulse rate, pre-operative and post-operative to the restorative treatment of primary teeth.

**Results:** There was a statistically significant difference seen in anxiety values pre-operatively and post-operatively within Group A and Group B; whereas intergroup comparison showed no statistically significant difference.

**Conclusion:** It was found that new technological Virtual reality method was as effective as the conventional, non-aversive, Tell Show Do method of behaviour management. Virtual Reality can be considered as a budding tool in the wide arena of behaviour management techniques and can be clinically applied in managing dentally anxious patients and providing qualitative dental care.



**Keywords**: Behaviour management, Dental anxiety, Virtual Reality.

# LIST OF ABBREVIATIONS

| | | |
|---|---|---|
| 1. | 3D | Three Dimensional |
| 2. | AAPD | American Academy of Pediatric Dentistry |
| 3. | ANS | Autonomic Nervous System |
| 4. | AVD | Audio-visual Distraction |
| 5. | AV | Audio-visual |
| 6. | ACC | Anterior cingulate cortex |
| 7. | CFSS-DS | Children's Fear Survey Schedule |
| 8. | CONSORT | CONsolidated Standards of Reporting Trials |
| 9. | CTRI | Clinical Trials Registry of India |
| 10. | d | Mean difference |
| 11. | et al | et alia |
| 12. | etc. | et cetera |
| 13. | FDI | Federation Dentaire Internationale |
| 14. | FLACC | Faces, Legs, Activity, Cry, Consolability |
| 15. | FIS | Facial Image Scale |
| 16. | HMDs | Head mounted displays |
| 17. | GIC | Glass Ionomer Cement |
| 18. | MDAS | Modified Dental Anxiety Scale |
| 19. | MCDAS | Modified Child Dental Anxiety Scale |

| | | |
|---|---|---|
| 20. | MID | Minimum Intervention Dentistry |
| 21. | n | Sample Size |
| 22. | No. | Number |
| 23. | OHrQoL | Oral health related quality of life |
| 24. | PI | Principal Investigator |
| 25. | SCARED | Screen for Child Anxiety Related Disorders |
| 26. | SPSS | Statistical package for the Social Sciences |
| 27. | SD | Standard Deviation |
| 28. | SE | Standard Error |
| 29. | Sl. | Serial |
| 30. | SOP | Standard Operating Protocol |
| 31. | SFP | Smiley Faces Program |
| 32. | TSD | Tell Show Do |
| 33. | VR | Virtual Reality |
| 34. | VPT | Venham's Picture Test |
| 35. | VEES | Video Eyeglasses/Earphones System |
| 36. | Z | Standard Score |
| 37. | α | Alpha |
| 38. | β | Beta |
| 39. | % | Percentage |

# TABLE OF CONTENTS

# LIST OF FIGURES

# LIST OF TABLES

# LIST OF GRAPHS

# LIST OF ANNEXURES

# INTRODUCTION

***"Until you make the unconscious conscious, it will direct your life and call it fate"***

***- Carl Jung***

Oral healthcare for children is an integral component of their general well-being; still it has been the most neglected one due to numerous reasons. The pain and anxiety can be the major confounding factors for hampering the willingness of the patient to seek dental care. Mc Elroy rightly quoted "Operative dentistry may be perfect, but the appointment is a failure if a child departs in tears", thus it may seem that managing a child in the dental operatory is the toughest task to accomplish, but if we try to understand the child's behavior first and try to modify it by various behavior modification techniques then their cooperation can be achieved. Behavior management techniques hold a significant role in reducing anxiety and also in developing a positive dental attitude in the formative years of a Pediatric patient. There are various techniques available in the literature for behavior modification of children experiencing dental anxiety, the gold standard and widely accepted of them is "Tell Show Do" technique given by Addleston in 1959.

The technique involved in the "Tell Show Do" approach is extremely simple. The basic purpose is to contend with a child's fear of new and strange surroundings and people. The child's fear is overcome by telling him about the new situation, showing him what will be done and then doing it while retelling him about it. This process of "Tell, show, and do" should be continued from the child's first entry into the operatory throughout all treatment. Attempts should be made during the first meeting with the child to place and maintain them in a relaxed mood. Friendliness,

empathy, and attempts to make the visit as enjoyable as possible serve to bring about reciprocal inhibition. A hierarchy is established by introducing the child to phases of dental treatment usually associated with low anxiety levels and proceeding to more complex phases of treatment potentially associated with greater anxiety. As each new person, instrument, or procedure is introduced to the child, care is taken to use the "Tell, show, and do" approach to gradually orient the child to the anxiety-provoking stimuli. This is done until they are able to successfully cope with the situation[1].

Another widely accepted method is Distraction; it helps the patients in coping with the anxious and painful stimuli they undergo in various situations. Distraction is an effective, inexpensive, non-invasive method of behavior management which helps the patient in having a relaxed experience in short, painful dental procedure. Literature states that a large psychological component is involved for pain perception, it is also stated that the amount of attention directed to the noxious stimuli modulates the perceived pain. McCaul and Mallet established the current theory that an individual needs to concentrate on the painful stimuli in order to perceive pain; therefore, perception of pain decreases when a person's attention is distracted away from the stimulus[2].

The ways in which distraction principle is applied has also evolved with advancements in technology. Over the last few years, there has been an upsurge in behavioral research in Virtual Reality (VR) and Virtual world. VR denotes to a human–computer interface that allows the user to interact actively with the virtually simulated environment. VR uses head mounted displays (HMDs) and three-dimensional systems in order to make the experience more immersive in nature[3].

Use of VR may prove to be better when compared to traditional distraction because it shows more immersive images due to the HMDs that project the images right in front of the eyes of the user and block out real-world stimuli. Depending on the degree of immersion of the stimuli presented, the attention of the person will be close to "drained" from the real world, causing less attention available to real-world processes, including painful stimuli. Immersion is predominantly amplified during VR because the use of HMDs avoids patients from seeing what is going on in the real world and leads the focus on what is going on in the virtual world. Therefore, the child's attention is focused on what is happening in the virtual world rather than on the environment that surrounds it[3].

VR is especially engaging for children as they become truly captivated by imaginative play and get immersed in virtual presence rather than the surroundings in reality around them[3]. Beyond providing distraction, it is said that VR also helps in alleviating pain and anxiety; but when the literature search was carried out there were very few studies in Indian scenario and worldwide regarding evaluating the effectiveness of Tell Show Do (TSD) and Virtual Reality (VR) method of Behaviour management on anxiety levels of children undergoing restorative treatment of carious teeth. So, an attempt is made to carry out this research to evaluate the effect of Virtual Reality technology on anxiety levels in children during restoration of primary teeth.

# AIM AND OBJECTIVES

**AIM OF THE STUDY:**

The aim of the study was to evaluate and compare the effectiveness of 'Tell Show Do' (TSD) and Virtual Reality (VR) method of Behaviour management on anxiety levels of children undergoing restorative treatment of carious teeth.

**OBJECTIVES OF THE STUDY:**

- To evaluate the effectiveness of 'Tell Show Do' (TSD) and Virtual Reality (VR) Method of Behaviour Management on anxiety levels of Children Undergoing Restorative Treatment of Carious Teeth.
- To compare the effectiveness of 'Tell Show Do' (TSD) and Virtual Reality (VR) Method of Behaviour Management on anxiety levels of Children Undergoing Restorative Treatment of Carious Teeth.

# RESEARCH HYPOTHESIS

**NULL HYPOTHESIS:**

There is no statistically significant difference in the effectiveness of 'Tell Show Do' (TSD) And Virtual Reality (VR) Method of Behaviour Management on anxiety levels of Children Undergoing Restorative Treatment of Carious Teeth.

**ALTERNATIVE HYPOTHESIS:**

There is a statistically significant difference in the effectiveness of 'Tell Show Do' (TSD) And Virtual Reality (VR) Method of Behaviour Management on anxiety levels of Children Undergoing Restorative Treatment of Carious Teeth.

# REVIEW OF LITERATURE

## LITERATURE IN RELATION TO DENTAL ANXIETY:

A behavior based cross sectional study was conducted aiming at estimating the prevalence of dental anxiety and fear among 5–10-year-old children in India. A sum of 523 children and parents were enlisted for this study; Indian parent's version of the Dental Subscale of the Children's Fear Survey Schedule (CFSS-DS) was used to evaluate dental anxiety. Total fear scores were calculated discretely for boys and girls and at different age levels. The projected prevalence of dental anxiety in the study population was 6.3%. The prevalence of dental anxiety was 7.9% in 5 years old, 7.1% in 6 years old, 6.6% in 7 years old, 6.5% in 8 years old, 6.3% in 9-year-old children and 5.8% in children aged 10 years. No statistically significant gender differences were found in the dental anxiety scores[4].

A cross sectional study was conducted to determine the dental anxiety among 6- to 12-year-old children using Modified Dental Anxiety Scale (MDAS) score. The authors collected data from 400 south Indian children. A 5 item MDAS questionnaire was used; the scores for each of the five questions were added to calculate a total dental anxiety score value. The score of 19 or above was considered to be dentally anxious, the score of 12–19 was considered mildly dental anxious, and the score of 5–11 was considered not anxious.61.5% had severe dental anxiety, 23% had mild anxiety, and 17% had no anxiety from the included samples. Females had higher anxiety level compared to males. Dental anxiety was found to be highest in smaller age groups[5].

A randomized clinical trial was done to compare the behavior and dental anxiety of 99 children in the age group of 6-9 years, during preventive care, endodontic treatment and dental extraction. The children were randomly distributed among three groups in which Group 1 (Control group) children were provided with oral prophylaxis and topical fluoride application; Group 2 and 3 (Intervention group) children were provided endodontic therapy and dental extraction respectively. Behavior was measured using the Frankl scale. Dental anxiety was assessed using the modified Venham's Picture Test and measured at three moments: before, during, and after the procedure. Caregivers were asked to complete a questionnaire about the child's past dental experience. The results inferred that neither negative behaviour nor anxiety was associated with the type of procedure. It was found that Dental anxiety was associated with age, previous difficult behaviour and moment of measurement. The study concluded that negative behaviour and dental anxiety in children were not associated with the type of treatment performed[6].

An overview study of behavioural management techniques in the dental scenario was conducted along with a view to prepare guidelines for the treatment of dentally fearful children, focusing on the behavioural management approach. An insight of the literature review showed that many studies focused on behaviour management strategies in general but only few studies have been done on specific strategies like cognitive interventions or desensitisation procedures. Until now, most of the research are comparative or correlational in nature but no wide-ranging randomised control studies have been reported or conducted among pediatric dental patients. Based on the literature review authors gave suggestions for a guideline for behaviour management strategies in Pediatric dentistry; which included adequate assessment of probable pathway of child's dental fear, offering children step by step

exposure in treatment and preventing procedural pain, knowledge about cognitive behaviour management strategies and their application during treatment[7].

A systematic review about dental fear and anxiety was carried out with an aim of finding out the crux theories of dental fear, anxiety and phobia. Studies on fear, anxiety and phobia within dentistry and/or psychiatry, published from 1949 to 2013 were included in this review. Out of 200 articles, 140 were included in this review. Five specific pathways were identified relating to dental fear and anxiety; Cognitive conditioning, Informative, Visual Vicarious, Verbal threat, Parental. This systematic review enumerated currently accepted management techniques to cope dental anxiety and fear; it highlighted that there is a lack of knowledge of the effect of demographics, casual factors, ethnicity and treatment modalities relating to the etiological factors, origin and pathways of dental fear and anxiety. Understanding the patient's fear and anxiety can help dental personnel to manage the Pediatric patient efficiently and effectively, hence it is very important in dental practice[8].

**LITERATURE IN RELATION TO VARIOUS SCALES USED TO MEASURE DENTAL ANXIETY:**

Various scales have been given to assess anxiety. In an effort to develop self-report measure for analyzing situational anxiety in children, a picture selection task which could be easily perceived by children was developed. In this, a stylized male cartoon figure with large head was drawn expressing emotions commonly seen in a pediatric dental clinic. A total of 236 children participated in this study. The final version of this self-report measure consisted of an 8-item picture scale; which was a rapid administered task, understood by children as young as three years old. This picture test was also compared with other anxiety measuring scales and it gave

significant correlation with anxiety indices using human drawings, ratings of anxiety and cooperative behavior, heart rate and basal skin response. The results of this pioneer study indicated that this picture test is simple yet valid and reliable index of a young child's response to situational anxiety and stress[9].

A preliminary cross-sectional study was conducted on 200 participants in the age group of 8-10 years old to determine whether a relationship exists between the past dental experience and dental anxiety. Children were divided in two groups consisting of 100 in each group who had and did not have previous dental experience. Venham's Picture Test was used to measure situational anxiety. Each child was asked about how would they feel to visit the dentist the next day and to select a picture from the two; scoring was done when the child selected a picture with high fear and summed up and a total score for each child was noted. No statistically significant result was found between the two groups; which signified that previous dental experience did not affect the child's dental anxiety using Venham's Picture Test[10].

Another study assessed the comparative effectiveness of Facial Image Scale (FIS) and Venham's Picture Test. The aim of this study was to assess the reliability of Facial Image Scale in children's anxiety. In this experiment, 103 children between the ages of 3-18 years were chosen. Both the scales were shown to children in the waiting room. The correlation of the two scales was found to be high. Both the scales showed strong correlation which meant to high validity for FIS. The Venham's scale finding showed that children showed anxious behavior toward dentistry[11].

In a study aimed at evaluating two anxiety rating scales, Faces Image Scale and Venham's picture test, 52 Indian children in the age group of 6-12 years were included. The children were assessed for their anxiety while they were sitting in the waiting area of the clinic. The results of the study did not reveal any statistically significant difference in the two anxiety scales to be compared. This experiment proved that Venham's Picture Test and Faces Image Scale both were comparable as far as situational anxiety testing was involved[12].

To assess the physiological changes due to anxiety in children, pulse oximeter has been used in many studies. The effectiveness of this technique has been aptly given in a study conducted to assess finger pulse volume as a measure of anxiety. In this experiment, 32 males and 32 females were subjected to threatening and non-threatening stimuli and assessed using pulse oximeter. Finger volume pulse was noted, whereas self-reported anxiety was collected using a questionnaire. The experiment yielded a statistically significant difference in pulse rate on subjecting the patients to threatening and non-threatening stimuli which in turn affected the subject's anxiety. This experiment proves that changes in anxiety will affect the pulse rate which can be assessed using pulse oximeter[13].

**LITERATURE IN RELATION TO DISTRACTION USED FOR DENTALLY ANXIOUS CHILDREN:**

As the use of non-aversive behavior management techniques are more acceptable to parents, patients and practitioners as well, a study was conducted to compare and evaluate the efficacy of audio-distraction in reduction of anxiety in pediatric patients undergoing non-invasive to invasive dental procedures in consecutive appointments. 150 children in the age group of 6-12 years were selected for the study according to the inclusion criteria, they were divided in 5 groups of 30 each, viz. the control group, the instrumental music group, musical-nursery rhymes group, movie-songs group, audio-stories group. Each child had 4 visits, first visit was the screening visit, second was the oral prophylaxis visit followed by restorative visit and finally a visit for treatment procedure done under local anesthesia like pulpotomy, pulpectomy or extraction. After completion of each visit the child's anxiety was assessed by using a combination of Venham's picture test, Venham's Clinical Rating scale and pulse rate. A significant difference was seen in mean pulse rate for all the groups, with an increase in subsequent visits. However, no significant difference was seen in Venham's Picture Test and Venham's clinical rating scale values in all the groups. This study showed that audio-distraction in general helped in reducing anxiety, but of them, audio-stories group showed the most significant reduction in dental anxiety in Pediatric patients[14].

A research was conducted to evaluate the effectiveness of distraction method of passive television watching while undergoing dental procedures. 55 children with no previous history of dental treatment in the age group of 2-6 years were included in this study. The control group had 30 children, who underwent the dental treatment routinely without any distraction methods; whereas the experimental group had 25 children, who

watched the popular television programs while undergoing the dental treatment in 4 consequent visits. The child's response to dental care was assessed by Behaviour rating scale, Venham's Picture Test and heart rate. This study stated that there was no evidence supporting to reduction of dental anxiety on passive watching of popular television programs, but there were significant differences found in age and visit type on dental anxiety. This study concluded that more distraction methods must be developed which will include an active participation of the pediatric patient[15].

A systematic review of 21 randomized controlled trials was conducted to assess the efficacy and effectiveness of distraction methods to manage dental anxiety in children aged from 4-16 years. There were no limits put on language and publication dates. An intensive search was done on PubMed, Web of Science, Scopus, Cochrane Library, Latin American and Caribbean Health Sciences Literature (Lilacs), US National Library of Medicine and Google Scholar. Two independent reviewers extracted data using standardised data tables. Risk of bias was assessed using Cochrane Collaboration's Risk of Bias Tool. There was heterogeneity found which precluded meta-analysis. Qualitative analyses were performed. Distraction techniques included ranged from using audio and audio-visual techniques, instrument camouflage, biofeedback therapy to dental operating microscope and toys. Data were collected pre- and post-dental procedures including: dental examination; prophylaxis; local anaesthetic administration; restoration placement; exodontia; and placement of rubber dam. Within studies, between one and six instruments were used to measure children's anxiety and dental fear. Objective measures with pulse oximeters and blood pressure cuffs were used most frequently. The studies included in this systematic review propose that distraction techniques might be useful to control children's anxiety and fear during dental appointments, however, the certainty of evidence is very low, but also there are

no contraindications for the use of distraction techniques during children's and adolescents' dental appointments, so they can be easily used in dental practice effectively[16].

**LITERATURE IN RELATION TO TELL SHOW DO (TSD) USED FOR DISTRACTION:**

Although widely used, the ability of TSD technique to prepare, acclimatize and reduce child anxiety remains an area for research[17]. Data was collected from two hundred children referred in pain for general anesthetic extractions. They were randomly divided into intervention and control groups. Anticipatory anxiety was assessed using an observational schedule and by monitoring heart rate prior to and during treatment. The children in the intervention group, were advocated TSD, had lower observed anxiety and lower heart rate prior to treatment, compared with the control children. However, the study concluded that TSD was unable to reduce heart rate in children who had previous experience of general anesthesia but reduced anxiety in children who had their first dental experience[18].

As world has progressed with digitalization so did our behavior management techniques. Many new distraction techniques like television distraction, audio-visual distraction (AVD) came into play. A study was conducted to evaluate and compare reduction in anxiety level in 69 children undergoing restorative dental treatment at first dental visit using TSD and Audio-visual distraction methods. Anxiety was recorded using Facial Image Scale (FIS), Venham's picture test (VPT), blood pressure, pulse rate, and oxygen saturation at different stages of the visit. AVD was found to be more capable in reducing anxiety than TSD. Combination of TSD and

AVD had an additive effect in reduction of anxiety level and it proved to be more beneficiary[19].

Another study was conducted to evaluate and compare TSD with Audio-visual distraction in which they collected data from 69 children belonging to the age group of 5-12 years underwent restorative dental treatment. Anxiety was assessed by Facial Image Scale (FIS) and co-operation was assessed by Frankl's Behavior rating scale. Reduced anxiety, decreased pulse rate and increased co-operation was observed by authors while using Audio-visual distraction as compared to TSD[20].

**LITERATURE IN RELATION TO VIRTUAL REALITY USED FOR DISTRACTION:**

A study was conducted to assess the effect of distraction using Virtual Reality technology on pain perception and anxiety levels in children during pulp therapy of primary molars. The study was carried out on 40 children aged between 4 and 8 years not having any anxiety disorders at their first visit according to SCARED questionnaire and presence of at least two carious mandibular primary molars requiring pulp therapy; falling under the category of Frankl's behaviour rating 2 were included in this study. These children were further divided into 2 groups using the stratified random selection method. In first visit all children were introduced to VR by Tell-Show-Do and were made accustomed to its use. In second visit children in Group 1 underwent pulp therapy with VR; children in Group 2 without VR and vice versa in third visit. Changes in pulse oximeter readings were recorded every ten minutes. Patients' pain severity was assessed using Wong–Baker FACES Pain Rating Scale and state anxiety was measured by Faces version of the Modified Child Dental Anxiety Scale (MCDAS). Results showed a significant decrease in pain perception

and state anxiety scores with the use of VR during the treatment. The study concluded that usage of VR had a positive effect during dental treatment for a paediatric patient[2].

Another study was conducted to evaluate the influence of Virtual Reality eyeglasses on severity of pain and anxiety during dental procedures in paediatric patients. This study included 120 healthy children belonging to the age group of 4-6 years. Children with no previous history of anxiety disorders according to SCARED questionnaire were included. The other inclusion criteria were first visit and presence of at least two primary molars requiring restorative treatment. These children were randomly divided into 2 equal groups. In first session all children underwent fluoride therapy without any intervention. In second session children belonging to the group 1 underwent restorative treatment using VR. Topical anaesthesia was applied and Inferior alveolar nerve block was administered following restoration of primary mandibular molar. In third session similar procedure was followed for children in group 2 and without VR in group 1. Pain severity was assessed using Wong Baker FACES Pain Rating Scale and anxiety was measured by Faces version of the MCDAS. The study concluded that virtual reality eyeglasses can successfully decrease pain perception and state anxiety during dental treatment[3].

A study was conducted to evaluate the effectiveness of a Video Eyeglasses/Earphones System (VEES) as distracting device in reducing anxiety in children during dental procedures carried out under local anaesthesia. 36 children aged 5-8 years received different dental treatment with and without the VEES system in this randomised crossover clinical trial. Children belonging to Frankl II and III were included in this study. Pain was assessed by FLACC scale. Pulse rate and oxygen saturation were recorded to evaluate the state of anxiety. These were

evaluated on four occasions viz. procedure explanation and instrument exhibition, local anesthesia administration, rubber dam placement and first 10 mins with high-speed handpiece. Results showed no statistically significant difference with the use of VEES. The study concluded that VEES method was not more effective than traditional non-aversive behavioural techniques for reducing anxiety and pain perception in children undergoing dental treatment[21].

A study was conducted to assess the effectiveness of video eyewear and Computerised delivery system- intrasulcular anaesthesia (CDS-IS) during pulp therapy of primary molars. This study was a randomized, crossover clinical trial on 15 hearing impaired children in the age group of 5-7 years. The treatment was completed in 3 sessions. In first session oral prophylaxis was performed on patients showing them cartoon movie with sign language interpretations, projected on the ceiling above dental chair. To assess the level of anxiety, children were asked to answer questions by selecting appropriate faces as set response in the "Smiley Faces Program (SFP)" with the help of their parents. In second session, children in Group A underwent endodontic therapy using video eyewear and Group B children were shown cartoon movie as previous. In session three Group children were treated using video eyewear. Pain was assessed by Wong Bakers' faces pain scale after the treatment. Patients were anesthetized using CDS-IS machine. During Session II and III, blood oxygen saturation and pulse rate were monitored and recorded throughout the procedure in every 5 min using pulse oximeter for approximately 30 min of pulp treatment. There was a significant change in heart rate observed in children who underwent treatment using video eyewear. Also, there was an increase in pain scores seen in children undergoing pulp therapy with video eyewear in second session and without video eyewear in third session. The study concluded that use of audiovisual distraction with

video eyewear and the use of Computerised delivery system- intrasulcular anaesthesia was effective in improving children's cooperation, than routine psychological methods[22].

An interventional study was conducted on 30 children of age 6–10 years to assess the effectiveness of Virtual Reality distraction on pain perception and state anxiety levels undergoing restorative treatment in children. Pain perception was analysed subjectively by Wong Baker FACES pain rating scale and objectively by FLACC scale; anxiety was analysed physiologically by measuring pulse rate and oxygen saturation levels using pulse oximeter. The parameters were recorded before the treatment, during and after the restorative treatment procedure. The mean scores were compared baseline to during treatment and baseline to after treatment. The study exhibited a very high statistical significance in reduction of pain perception and anxiety levels. The study concluded that Virtual Reality distraction can be considered as a potential distraction tool in the field of behaviour management that helps adapt the child to dental environment and able to deliver qualitative dental care[23].

A study was carried out to assess the impact of Virtual reality distraction technique on pain and anxiety in 120 children belonging to the age group of 5-8 years during short invasive dental procedures. In the initial visit clinical and radiographic examination was performed and parents were given parent version of SCARED questionnaire, children scoring less than 25 in this questionnaire were randomly divided into two equal groups of 60 each. On the second visit, single-visit pulpotomy was performed for all children in the study. State anxiety was assessed using revised version of MCDAS before and after the dental treatment. Pain perceived was assessed using Wong Baker FACES pain rating scale after the treatment. Salivary cortisol

levels were also assessed before, during and after the treatment using ELISA Kit. The results showed a significant decrease in anxiety, pain perception and salivary cortisol levels with the use of Virtual Reality distraction during the treatment; concluding that Virtual Reality can be used as an effective behaviour modification technique for children undergoing short invasive dental procedures[24].

A study was done to determine the effect of Virtual Reality distraction on pain perception during dental treatment in children. Thirty children in the age group of 6-8 years requiring pulp therapy in primary mandibular molars were randomly divided in two equal groups consisting of 15 children in each group. Children in experimental group were shown VR videos during administration of local anesthesia (Inferior alveolar nerve block) following pulp therapy. Pain was assessed at the end of the treatment using revised version of Faces pain scale. Less pain perception was found in children using Virtual Reality eyewear, the reduction in pain was found statistically significant. The study concluded that VR eyewear can be successfully used to distract children and decrease the amount of pain perceived by them during dental procedures[25].

A study was carried out to evaluate the effectiveness of Virtual Reality eyeglasses as a distraction aid to reduce anxiety of children undergoing dental extraction procedure. Thirty children in the age group of 6-8 years having bilateral non-restorable primary molars were included in the study. A split mouth design was followed in this study. Extractions with the help of VR were randomly assigned to left or right dentition sites. Experimental group children underwent extraction procedure with the help of VR eyeglasses. In first visit, oral prophylaxis was done in both groups and they were introduced to VR eyeglasses by using Tell-Show-Do technique.

In second visit, children were given time to get accustomed to VR eyeglasses and were made to wear them during extraction procedure. Application of topical anesthetic was done followed by administration of local anesthesia and extraction. Anxiety was assessed by Venham's Picture Test; pulse rate and oxygen saturation levels were measured by using finger pulse oximeter. The pulse rate values in intergroup comparison were found statistically significant. The study concluded that virtual reality when used as a distraction technique improves the physiologic anxiety parameters of children but does not reduce the patient's self-reported anxiety according to Venham's picture test[26].

A study was conducted to assess the effectiveness of audiovisual distraction using Virtual reality and Tablet device in managing anxious pediatric patients during inferior alveolar nerve block (IAN) administration. 120 children were randomly divided into 3 equal groups in which Group 1 underwent IAN administration using basic behaviour guidance techniques without AV aids, in Group 2 AV eyeglasses 'VR box' and wireless headphones were used whereas in Group 3 a tablet device with wireless headphones was used. Pain perceived was assessed using Wong Baker FACES pain rating scale after IAN administration. Pulse rate was recorded for the first time when patients were seated on the dental chair and immediately after IAN block was finished. For each patient all the body responses during the whole procedure were video recorded and then evaluated by an external evaluator according to FLACC scale. No statistically significant differences were seen in Wong Bakers FACES pain rating scale and FLACC scale, however there were significant differences in pulse rates of children in three groups. The study also reported a limitation regarding the size of VR box being too large for some children. The study concluded that video shown on tablet device gave the best results; VR acceptance was

seen more in age group of 8-10 years than the younger children and it gave children some exciting experiences which can further strengthen a positive dental attitude in children for future dental visits[27].

A systematic review (reference CRD42019155570) was conducted to identify and evaluate the effectiveness of studies applying Virtual Reality or bespoke smartphone applications to dentistry, either pre-operatively or peri-operatively for decreasing patient anxiety. The focused question was "can the use of virtual reality or smartphone applications decrease dental anxiety in paediatric patients attending for dental examination or treatment, compared with no intervention or more conventional behavioural management techniques?". Studies assessing children below 18 years of age undergoing dental examination or treatment with the use of Virtual Reality element in intervention and reporting their anxiety as primary or secondary outcome were included. The final search was carried out on 31st August 2019. A total of 1287 studies were found from database search and 16 studies were found from other sources. At the end 4 studies were included for qualitative synthesis after full text screening. The quality of these studies was found to be low; all demonstrating a high risk of bias in allocation concealment, blinding of personnel and blinding of outcome assessment. The results showed that till date VR has only been applied in dentistry only in a very limited number of studies. This systematic review concluded that VR till date has been under-utilised for its potential in reducing dental anxiety in children. High quality randomised clinical trials using Virtual Reality and smartphone applications are needed to be carried out to for more concrete results[28].

During the past decade, Virtual Reality has gained popularity in attenuating the pain during medical and dental procedures; thus, a review was conducted on

simplifying the neurobiology of pain when using Virtual Reality during procedures. This study suggests that VR mainly helps in reducing anxiety and pain perception due to its highly immersive nature. The presentation of VR through a headset limits the user from unwanted visual and auditory impulses. This review states that VR may produce analgesia by directly acting on C fibers signalling, VR may change the activity of body's intricate pain modulation system, thus altering pain perception. Anterior cingulate cortex (ACC) acts as the critical component in VR mediated pain modulation pathway, it exerts its effects on structures known to modulate pain, peri-aqueductalgray (PAG). In a nutshell, VR acts through ACC to divert attention from pain and produce analgesia[29].

# MATERIALS AND METHOD

The present randomized control study was designed to compare and evaluate the anxiety using Tell Show Do and Virtual Reality behavior management techniques in children of 6-12 years of age during restorative treatment.

The study was conducted in the Department of Pediatric and Preventive Dentistry, KLE Academy of Higher Education and Research, KLE VK Institute of Dental Sciences, Belagavi. Ethical clearance for the study was obtained from the Institutional review board **(Annexure I)**. The study has been registered prospectively under Clinical Trials Registry – India (CTRI) with the CTRI number of CTRI/2020/12/029531**(Annexure II).**

The study has intended to improve the reporting of parallel group randomized controlled trial by following CONsolidated Standards of Reporting Trials (CONSORT) guidelines.

## SOURCE OF DATA

The study was conducted on patients reporting to the outpatient department of the Department of Pediatric & Preventive Dentistry at KLE Academy of Higher Education and Research's KLE VK Institute of Dental Sciences, Belagavi.

## SAMPLE SIZE

- The required sample size for the study was calculated according to the following formula[2], $n = \frac{2S^2(Z_{1-\alpha/2} + Z_{1-\beta})^2}{d^2}$

- Where: d = 2.987, α error = 5%, $Z_{\alpha}$ =1.96, $Z_{\beta}$ = 0.84, $S_1$ = 3.787 $S_2$ = 3.417 to achieve 80% power.

$$S=\frac{S_1+S_2}{2}$$

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

So, **n =23**, which is adjusted to **30** samples in each group.

## SELECTION OF SUBJECTS

60 children were selected for our study according to following inclusion and exclusion criteria

**Inclusion criteria:**

- Children between 6-12 years of age.
- Children with Occlusal caries limited to enamel and dentin.
- Children who are willing to participate in the study.

**Exclusion criteria:**

- Children with special health care needs.
- Children requiring invasive procedures.
- Children with deep carious lesion requiring pulp therapy.
- Children who are not willing to participate in the study.

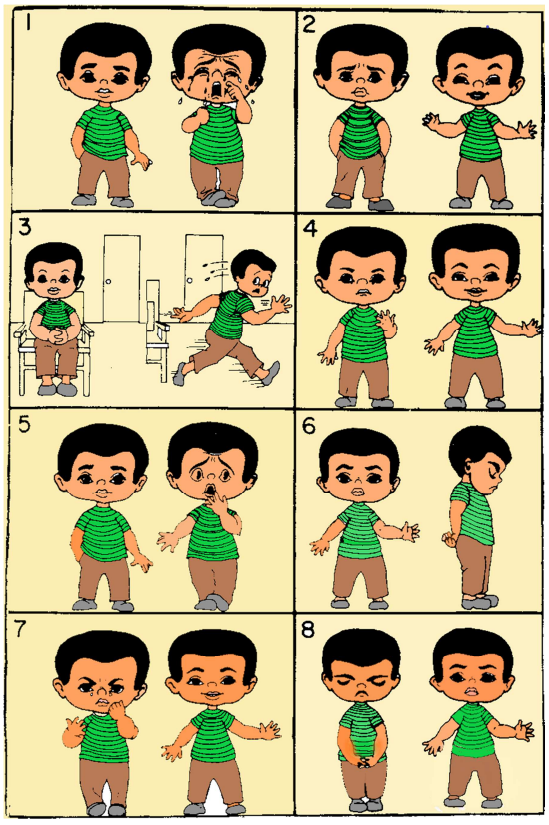
**The following armamentarium was used in the study [Figure 1a, 1b, 1c]**

- Rubber dam kit
- Virtual Reality gadget [Samsung Gear VR SM-R322NZWAINU, Samsung Electronics Vietnam Co., Ltd.]
- Pulse oximeter [CONTEC $^{TM}$ CMS50dl IP22]
- Venham's Picture Test cards

**Figure 1a: Clinical Armamentarium used in the study**

**Figure 1b: Virtual Reality gadget.**

**Figure 1c: Venham's Picture Test cards.**



## METHOD OF DATA COLLECTION

### A) CASE SELECTION:

After comfortably seating the patient on the dental chair, the procedure was completely explained to the parents as well as the child by the principal investigator. Consent forms and Assent forms were given to the parent/Guardian and Patient to be filled and duly signed (**Annexure IIIa, IIIb, IIIc, IV).** Case history was recorded in a special format in which the preliminary information and clinical findings were recorded. (**Annexure V)**.

### B) ALLOCATION:

Patients were allocated to two different groups by lottery method. Chits were prepared before the start of the experiment. The principal investigator asked the patient to pick up one chit containing the printed name of the interventional behavior management technique, Tell Show Do or Virtual Reality. In accordance to this, the patient would belong to one of the following groups.

1. Group A (Tell Show Do)
2. Group B (Virtual Reality)

**C) ASSESSMENT OF DENTAL ANXIETY:**

Anxiety of the patient was evaluated using Venham's Picture Test pre-operatively (**Figure 2a**). Eight cards containing one anxious and one non-anxious picture in each was showed to the child and was asked to point the picture they feel most like at that moment. Score 'zero' was given to the non-anxious picture and score 'one' for anxious picture. The sum of eight cards was recorded.

The pre-operative pulse rate was recorded by the principal investigator using pulse oximeter on right index finger of children (**Figure 2b**).

**Figure 2a: Assessment of anxiety using Venham's Picture Test**

**Figure 2b: Assessment of anxiety using Pulse oximeter**

**D) PROCEDURE OF TOOTH RESTORATION:**

The Principal Investigator performed the procedure under Standard Operating Protocols. The behaviours of the patients in Group A and Group B were managed by Tell Show Do and Virtual Reality method respectively (**Figure 3,4**). The teeth were isolated using rubber dam and the tooth preparation was carried out to receive the restoration using high speed round diamond point burs according to Minimally Invasive Dentistry principles. The prepared tooth was restored using Type IX Glass ionomer cement (GC Gold label H.S. Posterior Extra, Lot no:1905201) and post-operative instructions were given.

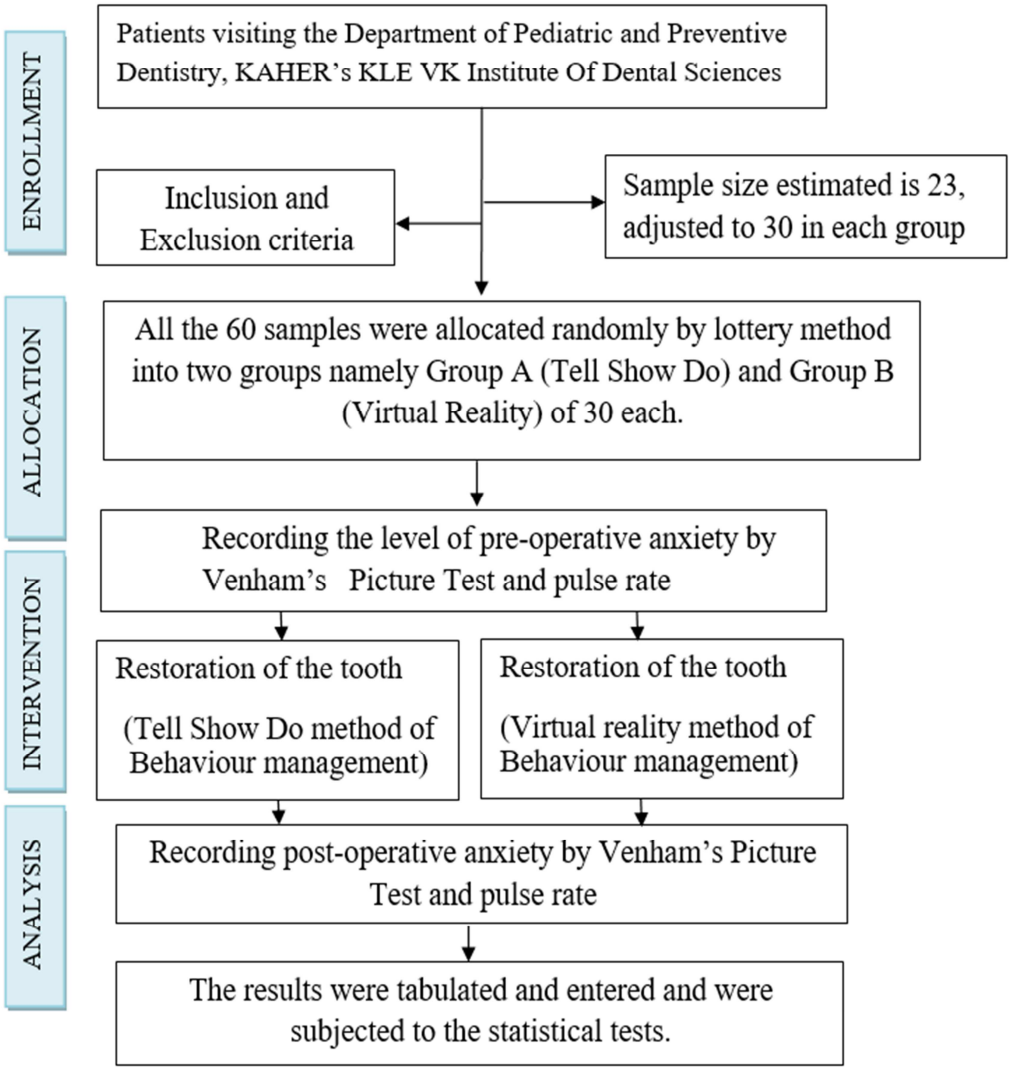
**Figure 3: Behaviour of patients in Group A managed using Tell Show Do**

**Figure 4: Behaviour of patients in Group B managed using Virtual Reality**

**E) ASSESSMENT OF DENTAL ANXIETY AFTER TREATMENT:**

The post-operative anxiety was assessed by Venham's Picture Test and Pulse oximeter as mentioned earlier.

**Figure 5: CONSORT Flowchart showing methodology followed in the study**



**STATISTICAL ANALYSIS:**

The obtained values were tabulated in master charts and subjected to the following statistical tests.

- Chi-square test – for comparison of gender distribution.
- Independent t-test – for comparison of age among the two groups.
- Kolmogorov Smirnov test – for evaluating the distribution of Venham's Picture Test and Pulse rate values in both groups.
- Mann-Whitney U test – for intergroup comparison of anxiety.
- Wilcoxon matched-pairs test – for intragroup comparison of anxiety.
- Spearman's correlation test – to check the correlation between Venham's Picture Test and Pulse rate values in both groups.

## RESULT TABLES, GRAPHS AND OBSERVATIONS

**Table1: Master chart of the Venham's Picture test and Pulse rate values in Tell Show Do group [Group A].**

| Sl. no | Tooth no. (FDI System) | Age (Years) | Sex | Venham's picture scale rating | | Pulse rate (per minute) | |
|---|---|---|---|---|---|---|---|
| | | | | Pre-operative | Post-operative | Pre-operative | Post-operative |
| 1 | 74 | 10 | F | 0 | 0 | 85 | 99 |
| 2 | 54 | 6 | F | 6 | 3 | 93 | 99 |
| 3 | 75 | 10 | F | 3 | 1 | 88 | 88 |
| 4 | 55 | 6 | F | 1 | 0 | 99 | 97 |
| 5 | 54 | 9 | F | 3 | 1 | 99 | 98 |
| 6 | 54 | 6 | M | 1 | 0 | 99 | 98 |
| 7 | 74 | 9 | F | 4 | 0 | 99 | 98 |
| 8 | 85 | 6 | M | 2 | 0 | 97 | 98 |
| 9 | 84 | 8 | M | 1 | 0 | 99 | 98 |
| 10 | 75 | 8 | F | 1 | 0 | 117 | 114 |
| 11 | 74 | 6 | M | 3 | 1 | 119 | 115 |
| 12 | 75 | 12 | F | 1 | 0 | 116 | 114 |
| 13 | 63 | 6 | F | 3 | 1 | 120 | 117 |
| 14 | 65 | 12 | M | 1 | 0 | 97 | 95 |
| 15 | 75 | 6 | F | 1 | 0 | 99 | 98 |

| Sl. no | Tooth no. (FDI System) | Age (Years) | Sex | Venham's picture scale rating | | Pulse rate (per minute) | |
|---|---|---|---|---|---|---|---|
| | | | | Pre-operative | Post-operative | Pre-operative | Post-operative |
| 16 | 65 | 9 | M | 1 | 0 | 95 | 94 |
| 17 | 75 | 8 | F | 1 | 1 | 99 | 98 |
| 18 | 65 | 9 | M | 2 | 0 | 97 | 95 |
| 19 | 55 | 8 | M | 1 | 1 | 98 | 99 |
| 20 | 75 | 10 | F | 1 | 1 | 98 | 98 |
| 21 | 83 | 6 | M | 4 | 2 | 99 | 98 |
| 22 | 53 | 6 | M | 2 | 1 | 99 | 97 |
| 23 | 84 | 12 | M | 4 | 2 | 99 | 98 |
| 24 | 85 | 10 | M | 1 | 0 | 106 | 95 |
| 25 | 85 | 9 | M | 1 | 0 | 112 | 98 |
| 26 | 55 | 8 | F | 6 | 1 | 113 | 63 |
| 27 | 75 | 7 | M | 3 | 1 | 111 | 90 |
| 28 | 63 | 10 | F | 3 | 1 | 139 | 124 |
| 29 | 85 | 9 | F | 3 | 2 | 73 | 88 |
| 30 | 85 | 6 | M | 2 | 0 | 104 | 95 |

**Table 2: Master chart of the Venham's Picture test and Pulse rate values in Virtual Reality group [Group B].**

| Sl. no | Tooth no. (FDI System) | Age (Years) | Sex | Venham's picture scale rating | | Pulse rate (per minute) | |
|---|---|---|---|---|---|---|---|
| | | | | Pre-operative | Post-operative | Pre-operative | Post-operative |
| 1 | 55 | 8 | M | 2 | 1 | 99 | 99 |
| 2 | 74 | 8 | M | 1 | 1 | 98 | 95 |
| 3 | 64 | 6 | F | 1 | 0 | 98 | 97 |
| 4 | 65 | 6 | M | 0 | 0 | 98 | 97 |
| 5 | 84 | 10 | M | 1 | 0 | 99 | 96 |
| 6 | 83 | 6 | F | 1 | 1 | 114 | 116 |
| 7 | 85 | 6 | M | 2 | 1 | 112 | 111 |
| 8 | 75 | 12 | F | 3 | 1 | 120 | 110 |
| 9 | 63 | 9 | F | 1 | 0 | 98 | 97 |
| 10 | 65 | 6 | M | 4 | 3 | 116 | 111 |
| 11 | 75 | 7 | F | 1 | 0 | 110 | 112 |
| 12 | 74 | 6 | F | 4 | 2 | 121 | 119 |
| 13 | 55 | 10 | M | 3 | 1 | 99 | 97 |
| 14 | 65 | 9 | M | 1 | 0 | 98 | 95 |
| 15 | 85 | 8 | F | 1 | 1 | 112 | 99 |

| Sl. no | Tooth no. (FDI System) | Age (Years) | Sex | Venham's picture scale rating | | Pulse rate (per minute) | |
|---|---|---|---|---|---|---|---|
| | | | | Pre-operative | Post-operative | Pre-operative | Post-operative |
| 16 | 75 | 9 | M | 2 | 1 | 98 | 96 |
| 17 | 55 | 6 | F | 2 | 0 | 99 | 99 |
| 18 | 75 | 11 | M | 1 | 1 | 99 | 98 |
| 19 | 65 | 9 | M | 1 | 0 | 97 | 97 |
| 20 | 85 | 8 | M | 1 | 1 | 101 | 99 |
| 21 | 85 | 8 | M | 1 | 0 | 112 | 109 |
| 22 | 85 | 9 | M | 1 | 0 | 98 | 95 |
| 23 | 53 | 8 | M | 1 | 0 | 101 | 99 |
| 24 | 85 | 6 | F | 1 | 1 | 111 | 105 |
| 25 | 55 | 7 | M | 2 | 0 | 124 | 117 |
| 26 | 54 | 8 | M | 3 | 1 | 112 | 102 |
| 27 | 75 | 7 | M | 2 | 1 | 104 | 89 |
| 28 | 85 | 7 | M | 3 | 1 | 71 | 89 |
| 29 | 65 | 8 | M | 4 | 2 | 139 | 122 |
| 30 | 74 | 10 | M | 3 | 0 | 130 | 110 |

**Table3: Comparison of gender distribution among Group A and Group B by Chi- square test.**

| Sex | Group A | % | Group B | % | Total | % |
|---|---|---|---|---|---|---|
| Male | 15 | 50.00 | 21 | 70.00 | 36 | 60.00 |
| Female | 15 | 50.00 | 9 | 30.00 | 24 | 40.00 |
| Total | 30 | 100.00 | 30 | 100.00 | 60 | 100.00 |
| Chi-square=2.5000, p=0.1150 | | | | | | |

*p<0.05

**Graph 1: Comparison of gender distribution among Group A and Group B.**

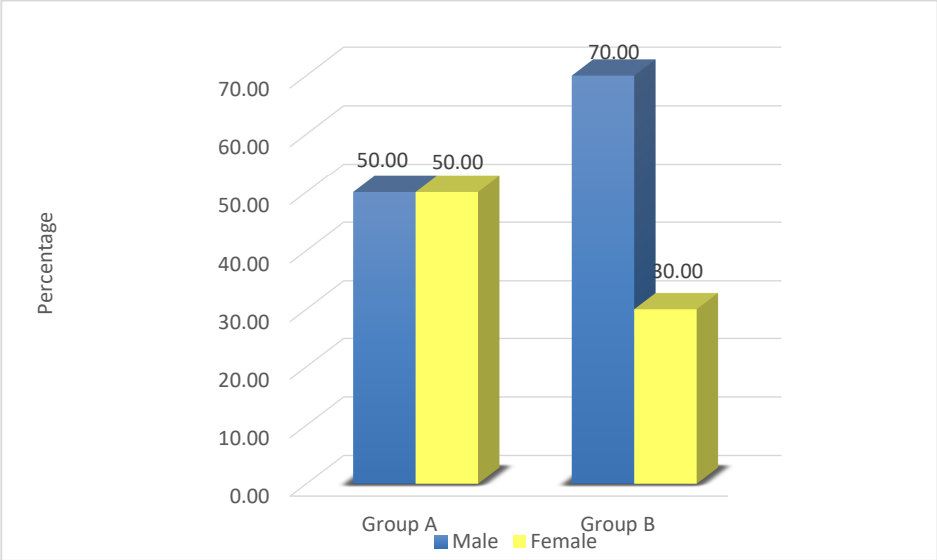



Table 3 and Graph 1 shows comparison of gender distribution in Group A and Group B by using Chi-square test. A total of 60 patients were included in the study, of them 60% were males and 40% were females. In Group A, males and females were 50% each and in Group B they were 70% and 30% respectively. The intergroup comparisonby Chi square test showed no statistically significant difference in the gender distribution. (p=0.1150)

**Table 4: Comparison of mean age among Group A and Group B by Independent t test.**

| Group | Mean | SD | SE | t-value | p-value |
|---|---|---|---|---|---|
| Group A | 8.23 | 1.98 | 0.36 | 0.6399 | 0.5248 |
| Group B | 7.93 | 1.64 | 0.30 | | |

*p<0.05 Independent t test

**Graph 2: Comparison of mean age among Group A and Group B.**

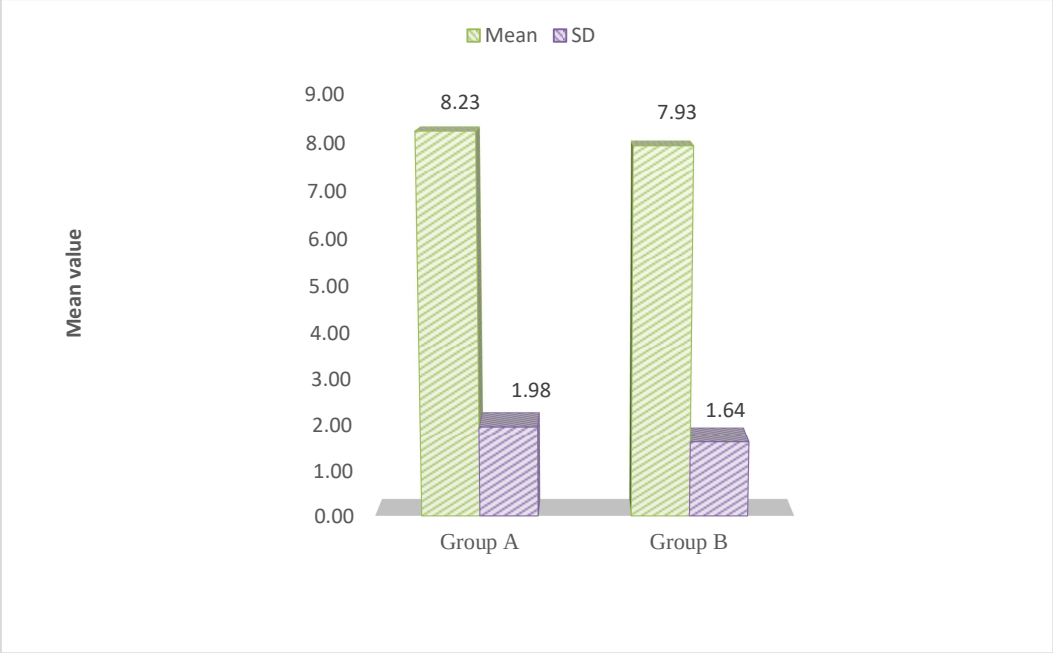



Table 4 and Graph 2 shows comparison of mean age in Group A and Group B by Independent t test. The mean age of Group A and Group B were 8.23 and 7.93 respectively, showing no statistically significant difference among two groups (p=0.5248).

**Table 5: Distribution of pre-operative and post-operative Venham's Picture test and Pulse rate values in Group A and Group B by Kolmogorov Smirnov test.**

| Variables | Treatment times | Group A | | Group B | |
|---|---|---|---|---|---|
| | | Z-value | p-value | Z-value | p-value |
| Venham's picture test | Pre-operative | 1.3810 | 0.0440* | 1.6470 | 0.0090* |
| | Post-operative | 1.6270 | 0.0100* | 1.4140 | 0.0370* |
| | Difference | 1.2950 | 0.0700 | 1.3670 | 0.0480* |
| Pulse rate | Pre-operative | 1.3690 | 0.0470* | 1.1160 | 0.1660 |
| | Post-operative | 1.5890 | 0.0130* | 1.3920 | 0.0420* |
| | Difference | 1.4590 | 0.0280* | 1.3160 | 0.0620 |

*p<0.05 indicates skewed distribution Kolmogorov Smirnov test

Table 5 shows the distribution of pre-operative and post-operative Venham's Picture test and Pulse rate values in Group A and Group B. The Kolmogorov Smirnov test showed that the values of Group A and Group B do not follow normal distribution, hence the non-parametric tests, Mann-Whitney U test and Wilcoxon matched pairs test were used for Inter-group and Intra-group comparison respectively ($p<0.05$).

**Table 6: Intergroup comparison of Venham's picture test between Group A and Group B by Mann-Whitney U test.**

| Treatment times | Group A | | | | Group B | | | | U-value | Z-value | P-value |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | Mean | SD | Median | IQR | Mean | SD | Median | IQR | | | |
| Pre-operative | 2.20 | 1.52 | 2.00 | 1.0 | 1.80 | 1.10 | 1.00 | 1.00 | 396.0 | 0.791 | 0.429 |
| Post-operative | 0.67 | 0.80 | 0.50 | 0.5 | 0.70 | 0.75 | 1.00 | 0.50 | 431.0 | 0.273 | 0.784 |
| Difference | 1.53 | 1.11 | 1.00 | 0.5 | 1.10 | 0.80 | 1.00 | 0.63 | 353.5 | 1.419 | 0.155 |

*p<0.05 Mann-Whitney U test

**Graph 3: Intergroup comparison of Venham's picture test between Group A and Group B.**

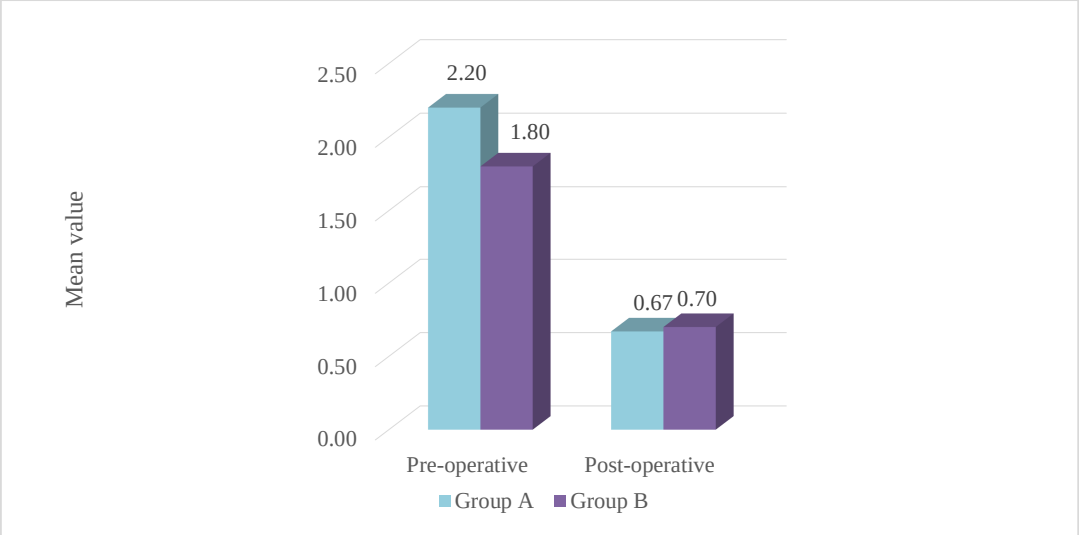



Table 6 and Graph 3 shows the Intergroup comparison of the Venham's Picture test by Mann- Whitney U test, showing no statistically significant difference. The 'p'-value of pre-operative anxiety is 0.4290, for post-operative anxiety is 0.7845 and difference between pre-operative and post-operative is 0.1558 (p<0.05).

**Table 7: Intragroup comparison of Venham's picture test values within Group A and Group B by Wilcoxon matched pairs test.**

| Groups | Time points | Mean | SD | Mean Diff. | SD Diff. | % of change | Z-value | P-value | Effect size |
|---|---|---|---|---|---|---|---|---|---|
| Group A | Pre-operative | 2.20 | 1.52 | 1.53 | 1.11 | 69.70 | 4.4573 | 0.0001* | 0.6650 |
| | Post-operative | 0.67 | 0.80 | | | | | | |
| Group B | Pre-operative | 1.80 | 1.10 | 1.10 | 0.80 | 61.11 | 4.1973 | 0.0001* | 0.6600 |
| | Post-operative | 0.70 | 0.75 | | | | | | |

*p<0.05 Wilcoxon matched pairs test

**Graph 4: Intragroup comparison of Venham's picture test values within Group A and Group B**

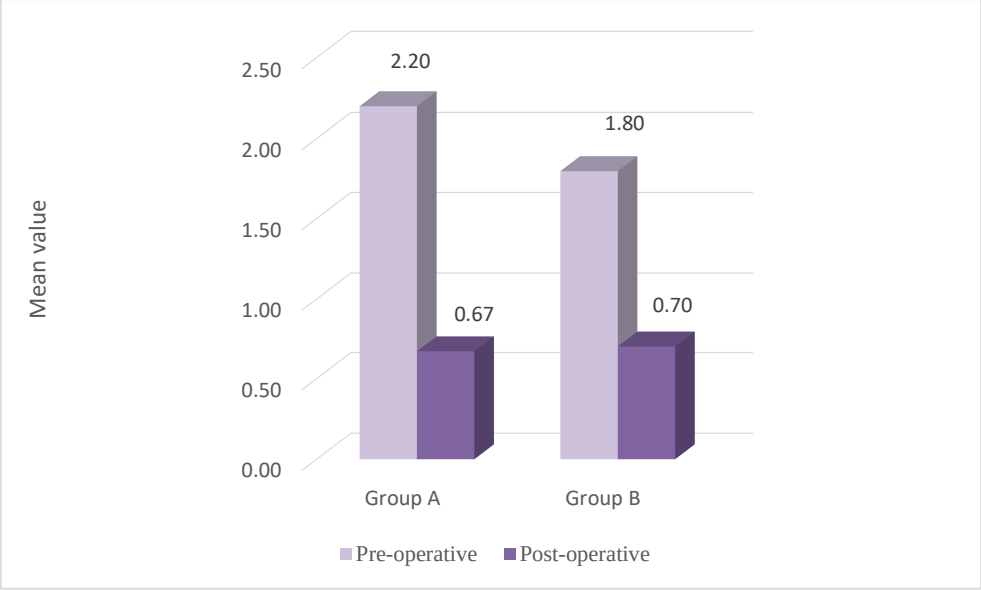



Table 7 and Graph 4 shows Intragroup comparison of Venham's Picture test values in Group A and Group B by Wilcoxon matched pairs test, is found to be statistically significant (p=0.0001*).

**Table 8: Intergroup comparison of Pulse rate between Group A and Group B by Mann-Whitney U test.**

| Treatment times | Group A | | | | Group B | | | | U-value | Z-value | P-value |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | Mean | SD | Median | IQR | Mean | SD | Median | IQR | | | |
| Pre-operative | 102.67 | 12.3 | 99.00 | 7.1 | 106.2 | 12.9 | 101.00 | 7.2 | 370.5 | -1.168 | 0.242 |
| Post-operative | 98.73 | 10.8 | 98.00 | 2.0 | 102.5 | 8.91 | 99.00 | 7.1 | 362.0 | -1.293 | 0.195 |
| Difference | 3.93 | 11.2 | 2.00 | 1.8 | 3.70 | 6.91 | 2.00 | 2.6 | 403.5 | -0.680 | 0.496 |

*p<0.05 Mann-Whitney U test

**Graph 5: Intergroup comparison of Pulse rate between Group A and Group B**

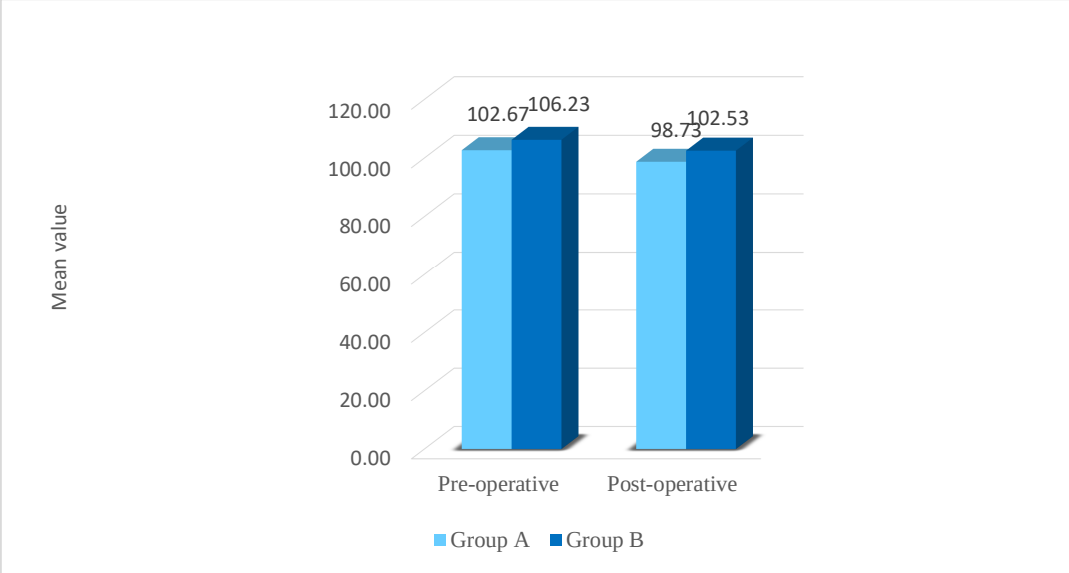



Table 8 and Graph 5 shows the intergroup comparison of pulse rate between Group A and Group B, is found to be not significant by Mann-Whitney U test (p=0.4965).

**Table 9: Intra group comparison of Pulse rate within Group A and Group B by Wilcoxon matched pairs test**

| Groups | Time points | Mean | SD | Mean Diff. | SD Diff. | % of change | Z-value | P-value | Effect size |
|---|---|---|---|---|---|---|---|---|---|
| Group A | Pre-operative | 102.67 | 12.37 | 3.93 | 11.23 | 3.83 | 2.8350 | 0.0046* | 0.1130 |
| | Post-operative | 98.73 | 10.86 | | | | | | |
| Group B | Pre-operative | 106.23 | 12.90 | 3.70 | 6.91 | 3.48 | 3.4836 | 0.0005* | 0.2290 |
| | Pre-operative | 102.53 | 8.91 | | | | | | |

*p<0.05 Wilcoxon matched pairs test

**Graph 6: Intragroup comparison of Pulse rate within Group A and Group B**

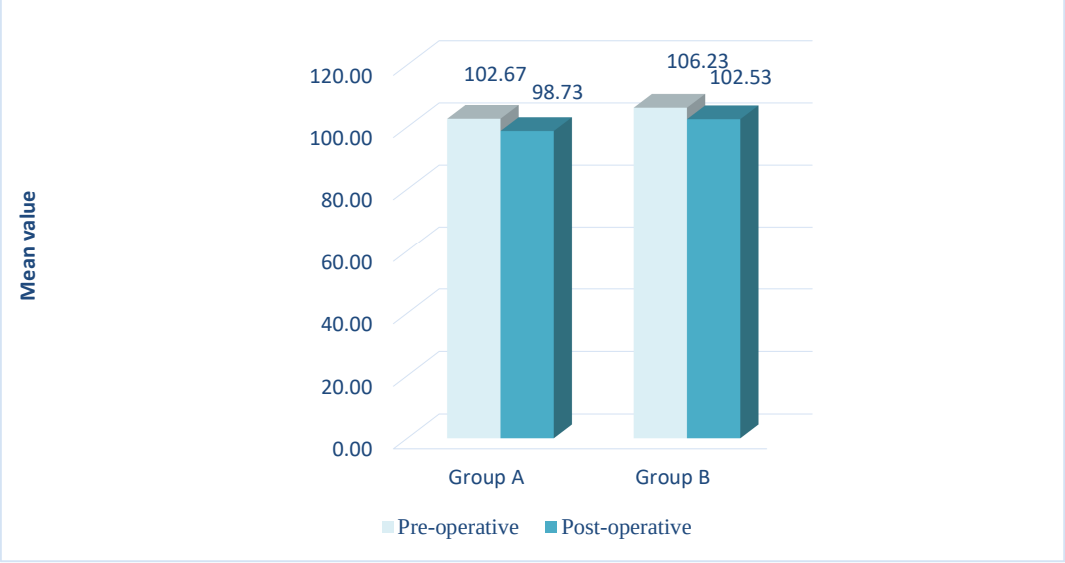



Table 9 and Graph 6 shows intragroup comparison of pulse rate within Group A and Group B by Wilcoxon matched pairs test is found to be statistically significant in Group A (p=0.0046*) and Group B (p=0.0005*).

**Table 10: Correlation between the changes in Venham's picture test and Pulse rate in Group A and Group B by Spearman's rank correlation test.**

| Groups | Variable | R-value | p-value |
|---|---|---|---|
| Group A | Venham's Picture Scale | 0.3612 | 0.498* |
| | Pulse Oximeter | | |
| Group B | Venham's Picture Scale | 0.2075 | 0.2716 |
| | Pulse Oximeter | | |

*p<0.05 Spearman's rank correlation test

Table 10 shows correlation between the changes in Venham's picture test and Pulse rate in Group A and Group B by Spearman's rank correlation test; a positive correlation was found in Group A and Group B. The 'p'-value for Group A was found to be statistically significant (p=0.498*).

# DISCUSSION

***"Although the operative Dentistry may be perfect, the appointment is a failure if the child departs in tears"*** ***- Mc Elroy***

The strength of a building lies in its strong foundation, similarly, the roots of Pediatric Dentistry are formed by effective Behaviour management of the child. It is implicated to be the key to successful dental treatment of child. Dental anxiety has been ranked fifth among the most commonly feared situations[29]. Anxiety is a reaction to a perceived danger. It can be defined as a state of unpleasantness with an associated fear of danger from within or a learned process of one's own environment[30]. In a cross-sectional study conducted by Kumar et al., 61.5% children have showed severe dental anxiety[5]. Given its high prevalence, it is not unexpected that children with high dental anxiety often avoid dental care and may have high DMFT scores as projected in a systematic review and meta-analysis conducted by Janakiram et al, the mean prevalence of dental caries in 5–12-year-old Indian children was 49%[31]. We have come a long way from neem sticks to smart toothbrush; despite these gains there are certain aspects in oral healthcare which still needs improvement. The major roadblock to these improvements is supposedly the anxiety related to dental environment and procedures carried out.

It should be documented that the nature of a child's dental anxiety can vary significantly[29]. Dental anxiety is a multi-dimensional concept and there exists no solitary variable which can solely account for its development. There have been numerous factors which have been consistently linked with a greater incidence of dental anxiety. All these factors are enlisted in the following figure as follows: (**Figure 6**)

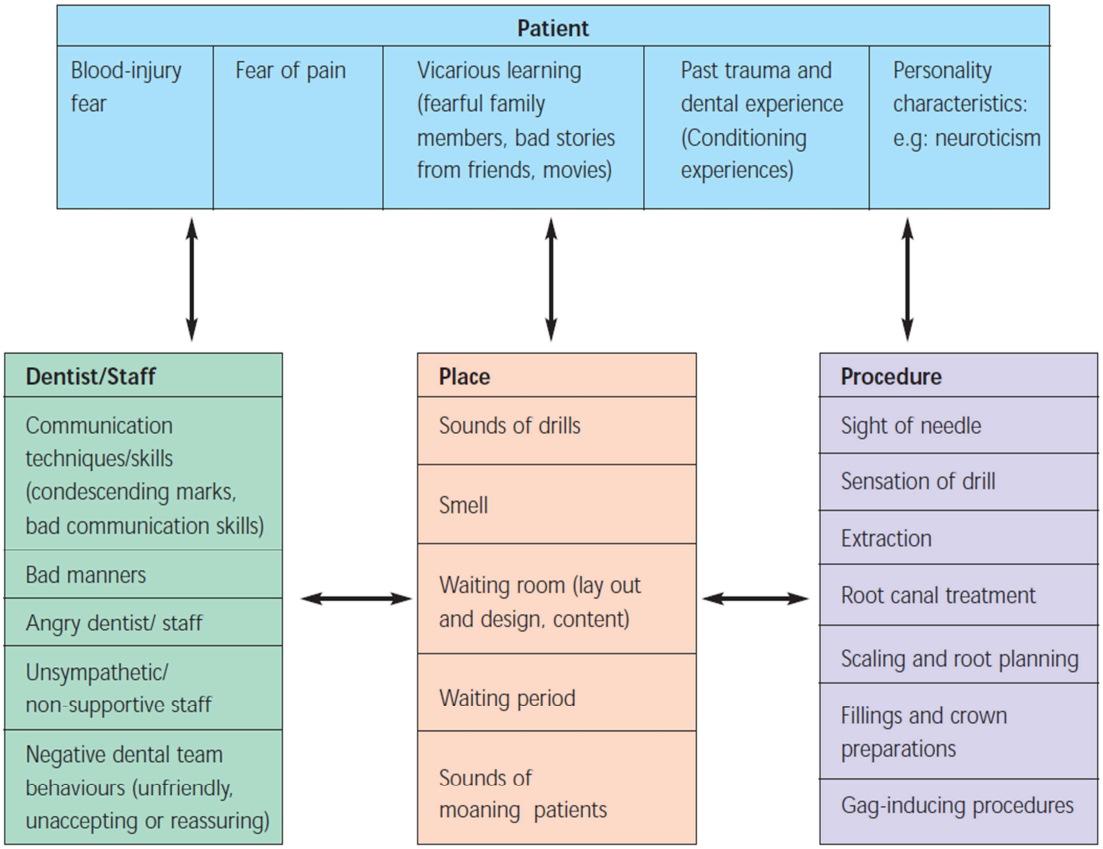
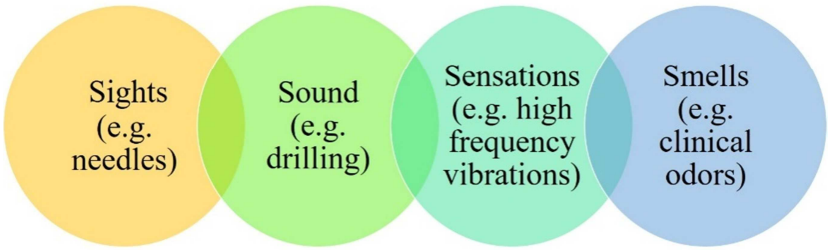



**Figure 6: Interactions which lead to and modify dental anxiety**[29]

Several studies have been conducted to assess the relationship of dental anxiety and patient satisfaction with the treatment provided, of them some have noted that highly anxious patients are more likely to be dissatisfied with the appearance of their teeth[32,33]. Also the patient's attitude towards the dentist has revealed an inverse linear relationship with dental anxiety, i.e., more the anxious patient, less positive they would be about their dentist[34]. Several studies have quoted that restorative treatment procedures deliver the most potent triggers responsible for dental anxiety, as "4 S"-




On identifying a dentally anxious patients, we can put forward an array of measures that should be followed for their appointments[34], for example

- Allowing sufficient time for the appointment.
- Minimizing triggers, following not to trigger the 4S principle.
- Introducing relaxation methods
- Provision of extra control during the procedure
- Use of distraction methods
- Referral to cognitive or behavioural specialists for behaviour therapy and anxiety management
- Conscious sedation using pharmacological agents

The management of an anxious patient diverges on several factors like the age, estimated degree of cooperation and their medical/dental history; to add to this, if we use a multi-layered approach rather than relying on a single method helps us to improve the management of the anxious patient[34]. Desensitization, modeling and contingency management in combination has been found to be very rewarding in managing the dentally anxious children in initial and subsequent visits[35]. The widely used behaviour management technique especially for the first visit of a child is the "Tell Show Do" first advocated by Addleston in 1959.

Tell Show Do (TSD) is a method of introducing child patients to a procedure in a stepwise fashion. Each hierarchy of stimuli is first told to the patient, then shown, then done; to allow the child to assimilate the procedure in a graduated manner: the procedure is first described in words and phrases appropriate to the child's understanding, then demonstrated in a way that involves the appropriate senses, and when acceptance has been obtained, the child's behavior can be rewarded, and the technique then becomes part of behavior shaping. According to American Academy of Pediatric Dentistry (AAPD), the objectives of TSD are to teach the patient important aspects of dental visit and familiarize them with the dental setting so as to shape their response to procedures through desensitization. This is a very simple technique and can be used with children to deal with pre-existing anxieties and fears, or with patients having their first dental visit[35]. Thus, in our study we used Tell-Show-Do method for the children included in control group (Group A).

Distraction is another such simple method of managing a child in the dental chair. These are the techniques which overload the patient's limited attention capacity to concentrate over the noxious stimuli by diverting their attention away from it. It can be classified into active or passive, depending on the participation of the child [36]. Many studies have evaluated and compared various distraction techniques during dental treatment of children. The most popular distraction technique – Audio distraction or audio-analgesia, was given by Gardner and Licklider in 1959[37]. Several studies conducted on comparison of audio-distraction with other behaviour management techniques showed varying results[17,19].

Another most widely used distraction method which came into play is the audio-visual distraction. Audio-visual distraction (AVD) is a simple and effective

method for easing the anxious children through their dental experience. There are various ways in which AVD has been put into use, viz. computer screens, television screens attached to ceiling, 3D-eyeglasses and Virtual Reality eyeglasses.The AVD used conventionally did not use kinesthetic stimuli between the user and stimuli they are exposed to; to bridge this gap Virtual Reality technology came into use. Virtual Reality (VR) is a computer-generated user interface, it allows the user to interact with the virtually created environment. VR uses a wide screened, 3D displays which are head-mounted and easy to use. Use of VR combines audio, visual as well as kinesthetic stimulations, thus being the most immersive of all, it is expected to be more superior than less technologically advanced audio-visual distraction methods[38]. Therefore, we used Virtual Reality method in our study and compared it with Tell Show Do method of behaviour management.

**The 6-12 age group:**

In our study we evaluated dental anxiety of children belonging to the age group of 6-12 years of age. As stated by Piaget, this is approximately the third major developmental stage of cognition, i.e., the stage for concrete operations. During these years, mental representations of actions become a part of child's cognitive abilities. Thus, these children can easily understand Tell Show Do method of behaviour management. Piaget also specified that, children in this age group acquire the abilities to understand constancies between length, mass, number and weight despite their external differences. Relativity also emerges in the child's evaluation system during this age[39]. Taking all these facts into consideration, children between the age group of 6-12 years were selected for our studyas they would also understand the immersive nature of Virtual Reality.

**Venham's Picture Test and Pulse rate:**

Dental anxiety was assessed by using both subjective and objective measures, i.e., the Venham's Picture Test and Pulse rate respectively in our study.Venham's Picture Test (VPT) is a self-reporting, pictorial scale used to measure situational anxiety for young children. Advantages of using VPT are it is very simple, easily understood and rapidly administered[9]. A systematic review revealed that VPT was the second most used measure for assessing anxiety among their included studies. The review also stated that for the age group of 6-12 years, pictorial scales were the second most used after the psychometric tests for assessment of dental anxiety and fear. The time of assessment of dental anxiety also holds an important role which can affect the outcomes. Importance should also be given to the time frame of assessment in order to evaluate the dynamic process of change of anxiety. The review revealed that dental anxiety was most widely assessed prior and after the dental treatment[40]. Pulse rate is governed by the Autonomic Nervous System (ANS). Physiological responses like heart rate, body temperature, respirations vary in presence of negative emotions. Thus, physiological responses of ANS are good indicators to evaluate whether the person is in stress or relaxation[25]. Hence, pulse rate was also measured in conjunction with self-reported anxiety scale.

**First dental visit:**

To rule out the effect of confounding variables to dental anxiety we included patients having their first appointment for their dental care. With a view on dental anxiety, there can be a feeling of apprehension of possible pain, discomfort or danger during the course of treatment even when there is no prior experience[40]. A study showed that there is a negative relationship between frequency of dental visits and

dental fear and anxiety, also higher dental anxiety has been shown in patients having no preceding dental visits[41]. In contrast, another study has also shown a strong association between dental anxiety and fear with past negative dental experiences[23,24,38,42].

According to Critchley et al., cingulate gyrus gets activated during pain, and anxiety[43]. Studies found that increased fast wave (Beta) and decreased slow wave (Alpha) activity was seen in periods of stress and anxiety on EEG[44,45]. Extreme Beta activity in Anterior cingulate or midline cortex in cases of anxiety were found[46]. Another study disclosed a significant decrease of Beta activity in Anterior cingulate cortex (ACC) region in VR group, this also implicated that ACC as one specific region likely to be affected with the use of VR in individuals[47].

Researchers have concluded that VR produces a deep illusion which makes the user feel the 'presence' in the virtual world produced by computer through a variety of sensory stimuli which includes vision, hearing and sometimes touch[24]. Numerous studies have demonstrated that cortical areas which are associated with attentional processes and pain modulation are more active during distraction technique, whereas the less attentive areas are those associated with painful stimuli[3,48,49]. They also say that the more a child is absorbed into VR world, the less it gives attention to the painful stimuli.

Riva et al. stated that in order to achieve the profits of VR therapy, presence alone is necessary but not sufficient[50]. Riva discussed that VR being so unique in its technology, works on the same basic mechanism of the brain: embodied simulations[51,52]. According to neuroscience, the brain creates an embodied simulation of the body in the world; this body is used to represent and predict emotions and

actions based on the concepts and emotions learned throughout life[53]. Thus, in this view, VR can be defined as an "embodied technology" since it has the likelihood of altering the embodiment experience of the users[54,55,56,57].

There are certain additional advantages on use of VR which include ease of use, greater control and its frequent application does not affect its positive efficacy. Apart from these advantages, there are certain considerations that should be noted into VR applications; Hoffman et al. reported that many patients undergo emotional and nervous states during the first few minutes of VR device use, to aid in this, adequate time should be given to adjust and adapt themselves to the device[58]. We also faced some difficulties during the use of VR in our study, like some children were not as accepting towards its use as other children and hence they were excluded from our study. The size of the VR also posed to be an issue for some younger children, who could not accommodate it properly even with the help of head straps.

In our study, we found that Tell Show Do and the Virtual Reality methods are equally efficacious in reducing anxiety of children during restorative treatment. Both groups showed statistically significant differences in anxiety pre-operatively and post-operatively. VR gadget blocked out the clinical setting which may be anxiety-provoking for some and instead gave them a pleasant scene on VR screen, this may lead to the reduction in anxiety levels[59]; but some children may feel blinded by the VR gadget thus adding on to the child's anxiety by increasing the fear of the unknown[24].

**LIMITATIONS:**

The study was conducted among children from 6-12 years of age, however children belonging to different age groups may portray different cognitive behaviours towards the use of VR. Thus, in future studies can be conducted assessing different age groups. Another limitation is the smaller sample size, studies with a larger sample size would be beneficial for generalizing the use of VR in effective behaviour management of anxious children.

# CONCLUSION

Oral health awareness has been increased by leaps and bounds in recent years in all age groups but a neglect is still seen towards oral care for younger children. The main confounding factor behind this could be dental anxiety. Thus, in order to help the child cope up with dental anxiety during the procedures various behaviour management techniques have been described in literature. The key to successful clinical Pediatric dentistry is definitely the effective behaviour management of the child.

In our study we compared Tell Show Do and Virtual Reality method of behaviour management among children undergoing restorative treatment. Our study concluded that Virtual Reality was as effective as Tell Show Do method of behaviour management. Both TSD as well as VR showed statistically significant decrease in anxiety levels pre-operatively as well as post-operatively.

VR is the new addition in distraction techniques described in literature, thus we conclude that more studies should be conducted to discover the unexplored potential of this new immersive technology. This will help in managing the dental anxiety of children and also help in increasing the oral health related quality of life from childhood to adult life.

# SUMMARY

Children having high dental anxiety and fear, are sometimes difficult to treat, require more time and present with behavioural problems which can result in a stressful and unpleasant experience for both, the patient as well as the dental practitioner. In this situation, behaviour management comes into play with which we can help a child with their dental experience by guiding them through their anxiousness to a positive dental experience.

The present randomized control study was conducted to compare and evaluate the effectiveness of Tell Show Do and Virtual Reality method of behaviour management on anxiety levels of children undergoing restorative treatment of carious primary teeth. Sixty children were selected according to the inclusion criteria and allocated in Group A and Group B. Behaviour of children in Group A and Group B were managed by Tell Show Do method and Virtual Reality respectively.

Anxiety was assessed pre-operatively and post-operatively by Venham's Picture Test and Pulse rate. There was a statistically significant difference seen in anxiety values pre-operatively and post-operatively within Group A and Group B; whereas on intergroup comparison, no statistically significant difference was found.

It was found that new technological Virtual reality method was as effective as the conventional, non-aversive, Tell Show Do method of behaviour management. Virtual Reality can be considered as a budding tool in the wide arena of behaviour management techniques and can be clinically applied in managing dentally anxious patients and providing qualitative dental care.

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# ANNEXURE I
# ETHICAL CLEARANCE CERTIFICATE

**Research and Ethics Committee**
**KLE V K INSTITUTE OF DENTAL SCIENCES**
**KLE University**
Accredited 'A' Grade by NAAC  Placed in Category 'A' by MHRD (GoI)
Nehru Nagar, Belagavi - 590 010, Karnataka State
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Web: http://www.kledental-bgm.edu.in
E-mail:principal@kledental-bgm.edu.in

Sl. No. : 1394

## CERTIFICATE

*This is to Certify that the synopsis titled*

Comparative evaluation of effectiveness of "Tell show do" (TSD) and virtual reality (VR) method of behaviour management of anxiety levels of children undergoing restorative treatment of carious teeth - A Randomised Control study *Submitted by*

*Dr.* _____ *P. G. Student /*

*Staff, Guided by* _____ *from Department of* Pediatrics & Preventive Dentistry *has been critically evaluated by committee members and granted ethical clearance to conduct the above mentioned study*

**Date :**

**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

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

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

**Clinical Trial Details (PDF Generation Date :- Mon, 01 Nov 2021 07:45:38 GMT)**

| | |
|---|---|
| **CTRI Number** | CTRI/2020/12/029531 [Registered on: 03/12/2020] - **Trial Registered Prospectively** |
| **Last Modified On** | 01/11/2021 |
| **Post Graduate Thesis** | Yes |
| **Type of Trial** | Interventional |
| **Type of Study** | Dentistry |
| **Study Design** | Randomized, Parallel Group Trial |
| **Public Title of Study** | Comparing the Effectiveness of Tell Show Do and Virtual Reality method in reducing Anxiety in children undergoing filling for decayed teeth |
| **Scientific Title of Study** | COMPARATIVE EVALUATION OF EFFECTIVENESS OF "TELL SHOW DO" (TSD) AND VIRTUAL REALITY (VR) METHOD OF BEHAVIOUR MANAGEMENT ON ANXIETY LEVELS OF CHILDREN UNDERGOING RESTORATIVE TREATMENT OF CARIOUS TEETH– A RANDOMISED CONTROL STUDY. |

**Secondary IDs if Any**

| Secondary ID | Identifier |
|---|---|
| NIL | NIL |

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

| Details of Principal Investigator | |
|---|---|
| **Name** | Dr |
| **Designation** | Post Graduate Student |
| **Affiliation** | KLE VK Institute of Dental Sciences |
| **Address** | Department of Pediatric and Preventive Dentistry, KLE V. K. Institute of Dental Sciences, KLE Academy of Higher Education And Research (KAHER), Nehru Nagar, Belagavi. JNMC Campus Nehru Nagar, Belagavi<br>Belgaum<br>KARNATAKA<br>590010<br>India |
| **Phone** | |
| **Fax** | |
| **Email** | |

**Details Contact Person (Scientific Query)**

| Details Contact Person (Scientific Query) | |
|---|---|
| **Name** | Dr |
| **Designation** | Reader |
| **Affiliation** | KLE VK Institute of Dental Sciences |
| **Address** | Department of Pediatric and Preventive Dentistry, KLE V. K. Institute of Dental Sciences, KLE Academy of Higher Education And Research (KAHER), Nehru Nagar, Belagavi. JNMC Campus Nehru Nagar, Belagavi<br>Belgaum<br>KARNATAKA<br>590010<br>India |
| **Phone** | |
| **Fax** | |
| **Email** | |

**Details Contact Person (Public Query)**

| Details Contact Person (Public Query) | |
|---|---|
| **Name** | D |
| **Designation** | Post Graduate Student |
| **Affiliation** | KLE VK Institute of Dental Sciences |
| **Address** | Department of Pediatric and Preventive Dentistry, KLE V. K. Institute |

| | | |
|---|---|---|
| | | of Dental Sciences, KLE Academy of Higher Education And Research (KAHER), Nehru Nagar, Belagavi. JNMC Campus Nehru Nagar, Belagavi<br>Belgaum<br>KARNATAKA<br>590010<br>India |
| | **Phone** | |
| | **Fax** | |
| | **Email** | |

**Source of Monetary or Material Support**

| Source of Monetary or Material Support |
|---|
| > KAHERS KLE V.K. Institute of Dental Sciences, Nehru Nagar, Belagavi - 590010 |

**Primary Sponsor**

| Primary Sponsor Details | |
|---|---|
| **Name** | KLE V K Institute of Dental Sciences |
| **Address** | Department of Pediatric and Preventive Dentistry, KLE V. K. Institute of Dental Sciences, KLE Academy of Higher Education And Research (KAHER), Nehru Nagar, Belagavi. |
| **Type of Sponsor** | Research institution and hospital |

**Details of Secondary Sponsor**

| Name | Address |
|---|---|
| NIL | NIL |

**Countries of Recruitment**

| List of Countries |
|---|
| India |

**Sites of Study**

| Name of Principal Investigator | Name of Site | Site Address | Phone/Fax/Email |
|---|---|---|---|
| Dr | KAHERS KLE VK Institute Of Dental Sciences, Nehru Nagar, Belagavi | Department of Pediatric and Preventive Dentistry<br>Belgaum<br>KARNATAKA | |

**Details of Ethics Committee**

| Name of Committee | Approval Status | Date of Approval | Is Independent Ethics Committee? |
|---|---|---|---|
| Research and Ethics Committee KLE VK Institute of Dental Sciences | Approved | 01/09/2020 | No |

**Regulatory Clearance Status from DCGI**

| Status | Date |
|---|---|
| Not Applicable | No Date Specified |

**Health Condition / Problems Studied**

| Health Type | Condition |
|---|---|
| Patients | Dental caries, unspecified |

**Intervention / Comparator Agent**

| Type | Name | Details |
|---|---|---|
| Comparator Agent | Tell Show Do Technique | Patients allocated to Group A will be treated using 'Tell Show Do' (TSD) where the procedure will be told shown and the procedure will be then performed |
| Intervention | Virtual Reality | Patients allocated to Group B will be treated using 'Virtual Reality Glasses |

**Inclusion Criteria**

| Inclusion Criteria | |
|---|---|
| **Age From** | 6.00 Year(s) |

| | | |
|---|---|---|
| | **Age To** | 12.00 Year(s) |
| | **Gender** | Both |
| | **Details** | 1 Children with 6-12 years of age.<br/> 2 Children with Frankl Behavior rating scale of negative (-)<br/> 3 Children who are anxious for receiving dental treatment (According to Venham's Picture Scale)<br/> 4 Children with Occlusal caries limited to enamel and dentin.<br/> 5 Children who are willing to participate in the study.<br/> |

**Exclusion Criteria**

| **Exclusion Criteria** | |
|---|---|
| **Details** | 1 Children with special health care needs.<br>2 Children requiring invasive procedures.<br>3 Children with deep carious lesion requiring pulp therapy.<br>4 Children who are not willing to participate in the study. |

| | |
|---|---|
| **Method of Generating Random Sequence** | Coin toss, Lottery, toss of dice, shuffling cards etc |
| **Method of Concealment** | Not Applicable |
| **Blinding/Masking** | Not Applicable |

**Primary Outcome**

| **Outcome** | **Timepoints** |
|---|---|
| Effectiveness of 'Tell Show Do' (TSD) And Virtual Reality (VR) method of Behavior Management on anxiety levels of Children Undergoing Restorative Treatment of Carious Teeth | Before the procedure and after completion of the procedure |

**Secondary Outcome**

| **Outcome** | **Timepoints** |
|---|---|
| Effectiveness in reducing the pulse rate | Baseline, at end of the procedure |

| | |
|---|---|
| **Target Sample Size** | **Total Sample Size**=60<br>**Sample Size from India**=60<br>**Final Enrollment numbers achieved (Total)**=60<br>**Final Enrollment numbers achieved (India)**=60 |
| **Phase of Trial** | N/A |
| **Date of First Enrollment (India)** | 15/12/2020 |
| **Date of First Enrollment (Global)** | No Date Specified |
| **Estimated Duration of Trial** | **Years**=0<br>**Months**=8<br>**Days**=0 |
| **Recruitment Status of Trial (Global)** | Not Applicable |
| **Recruitment Status of Trial (India)** | Completed |
| **Publication Details** | None |
| **Brief Summary** | Children and adults with high dental anxiety and fear, may prove difficult to treat, require more time and present with behavioural problems which can result in a stressful and unpleasant experience for both, the patient as well as dental practitioner.[1]In order to overcome this Pediatric dentist has to manage the patient efficiently and effectively by adopting newer behaviour management techniques so that the dental treatment of the child leaves a positive psychological impact towards Dentistry and Oral health.<br><br>Behaviour management techniques are significant in alleviating anxiety, nurture a positive dental attitude, and help perform a high quality oral health care safely and efficiently So a technique |



which has more acceptances of the parents and children and free from invasion and negative sights must be used.[1]

'Tell Show Do' method of behaviour management is most commonly used in the management of children in Pediatric dentistry. But, currently we are living in a world that is largely influenced by Digitalization. Digital world has reached widespread and is deeply rooted in our day today life. Even children are becoming parasitic on watching cartoons to that extent that their parents make them watch cartoon while having food. The child in a dental operatory is anxious and this behaviour can be effectively modified by the use of cartoons[2].VR uses sophisticated systems such as head-mounted, wide field-of-view; three-dimensional displays and motion sensing systems.[3]

VR engages the conscious attention of the patient, resulting in less pain perception by diverting attention from an unpleasant medical setting to a pleasant and absorbing virtual world, while also engaging higher cognitive and emotional centres of the nervous system.[3]

VR technique produces a deep illusion of entering a virtual world produced by a computer through coordination of sensory perceptions (vision, hearing and sometimes touch), which is referred to as "presence". Studies have demonstrated that cortical areas associated with attention processes and pain modulations are more active during distraction, whereas areas associated with pain perception are less active.

When the literature search was carried out by me in last three months, there were very few studies in Indian scenario and worldwide regarding the use of virtual reality technology on evaluation of anxiety level in children during restoration of primary teeth.

So an attempt is made to carry out this research to evaluate the effect of virtual reality technology on anxiety levels in children during restoration of primary teeth.

## ANNEXURE III a
## CONSENT FORM (ENGLISH)

**KLE Academy of Higher Education and Research.**

**KLE V.K. Institute of Dental Sciences, Belagavi.**

**Department of Pediatric and Preventive Dentistry**

**"Comparative Evaluation of Effectiveness of 'Tell Show Do' (TSD) And Virtual Reality (VR) Method of Behaviour Management on anxiety levels of Children Undergoing Restorative Treatment of Carious Teeth –A Randomised Control Study."**

**Date :**

- I, the undersigned, authorize the performance upon my son/ daughter, Mst. / Miss …… the advised treatment to be performed under the direction of Dr. _____and by Dr._____
- I consent to the use of Virtual Reality method of Behaviour management for my son/daughter during the treatment to be performed.
- I consent to the photographing or video recording of the operation or procedures to be performed for medical, scientific or educational purposes provided his/ her identity is not revealed by the pictures or by the descriptive texts accompanying them.
- For the purpose of advancing dental education, I consent to the admittance of observers to the operating room.
- At any time if I don't like I will quit from the study without any guarantee.
- I give my consent to publications and presentations of this study.
- The nature and purpose of the operation, possible alternative methods of treatment, the risk involved and the possibility of complications have been fully explained to me in my vernacular language. No guarantee or assurance has been given by anyone as to the results that may be obtained.

**(Relation to the patient)**

## ANNEXURE III b
## CONSENT FORM (KANNADA)

ಸಮ್ಮತಿ ಪತ್ರ
ಚಿಕ್ಕ ಮಕ್ಕಳ ದಂತ ವಿಭಾಗ
ಕೆ.ಎಲ. ಇ. ವಿಶ್ವನಾಥ ಕತ್ತಿ ದಂತ ಮಹಾವಿದ್ಯಾಲಯ
ಕೆ .ಎಲ. ಇ. ವಿಶ್ವವಿದ್ಯಾಲಯ ಬೆಳಗಾವಿ

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

1. ನನ್ನ ಮಗ / ಮಗಳ ಬಗ್ಗೆ ಎಲ್ಲಾ ಮಾಹಿತಿ ಹೆಸರು ವಯಸ್ಸು, ಆರೋಗ್ಯದ ಬಗ್ಗೆ ಮಾಹಿತಿ ಕೊಡಲು ಒಪ್ಪುತ್ತೇನೆ.
2. ನನ್ನ ಮಗ / ಮಗಳ ಬಾಯಿಯ ತಪಾಸಣೆ ಹಾಗೂ ಚಿಕತ್ಸೆ ಮಾಡಲು ಸಹಕರಿಸುತ್ತೇನೆ.
3. ನನ್ನ ಮಗ / ಮಗಳ ಬಾಯಿಯ ಹುಳುಕು ಹಲ್ಲುಗಳನ್ನು ಸ್ವಚಗೊಳಿಸಿ ಬೇರು ನಾಳಿನ ಚಿಕತ್ಸೆ ಮಾಡಲು ಸಹಮತಿ ನೀಡುತ್ತನೆ.
4. ನನ್ನ ಮಗ / ಮಗಳ ನಡವಳಿಕೆ ನಿರ್ವಹನೆಗೆ ವಾಸ್ತವ ತಂತ್ರ ವನ್ನೂ ಉಪಯೋಗಿಸಲು ಅನುಮತಿಯನ್ನು ನೀಡಿ ಸಹಕರಿಸುತ್ತೇನೆ.
5. ನಾನು ತಜ್ಞರು ಕೊಟ್ಟಿರುವ ಸೂಚನೆಗಳನ್ನು ಪಾಲಿಸುತ್ತೇನೆ.
6. ಈ ಸಂಶೋಧನೆ ಯನ್ನು ಪ್ರಕಟಿಸಲು ಅನುಮತಿ ಕೊಡುತ್ತೇನೆ.
7. ನನ್ನ ಮಗ /ಮಗಳು ಭಾಗವಹಿಸಿದ್ದಕ್ಕೆ ಪ್ರತಿಯಾಗಿ ಏನೂ ಕೇಳುದಿಲ್ಲ.
8. ಈ ಚಿಕತ್ಸೆಯಲ್ಲಿ ಏನಾದರೂ ತೊಂದರೆಯಾದಲ್ಲಿ ತಜ್ಞರು ಎಲ್ಲಾ ಜವಾಬ್ದಾರಿಯನ್ನು ತೆಗೆದುಕೊಳ್ಳುತ್ತಾರೆ.
9. ಯಾವುದೇ ಕಾರಣಕ್ಕಾಗಿ ನನ್ನ ಮಗ /ಮಗಳು ಭಾಗವಹಿಸಿದ್ದಲ್ಲಿ ಹಿಂತೆಗೆದುಕೊಳ್ಳಬಹುದು.
10. ಎಲ್ಲಾ ಮಾಹಿತಿಯನ್ನು ಗುಪ್ತವಾಗಿಡಲಾಗುವುದು.
11. ಈ ಸಂಶೋಧನೆ ಯಲ್ಲಿ ಭಾಗವಹಿಸಿರುವುದರಿಂದ ಯಾವ ಹಾನಿ/ ಅಪಾಯ ಇಲ್ಲ.
12. ಬೇರೆ ಚಿಕೆತ್ಸೆ ಬಗ್ಗೆ ಮಾಹಿತಿ ಕೊಡಲಾಗುವುದು.

ನಾನು ಮೇಲೆ ತಿಳಿಸಿದ ಎಲ್ಲಾ ವಿಷಯವನ್ನು ಓದಿದ್ದೇನೆ ಮತ್ತು ಅರ್ಥಮಾಡಿಕೊಂಡು ಸಹಿ ಮಾಡಿದ್ದೇನೆ
ದಂತ ವೈದ್ಯರ ಹೆಸರು: ಡಾ॥
ಮಾರ್ಗದರ್ಶಕರು: ಡಾ॥
ವಿಳಾಸ : ಚಿಕ್ಕ ಮಕ್ಕಳ ದಂತ ಚಿಕೆತ್ಸೆ ವಿಭಾಗ, ಬೆಳಗಾವಿ -10

| | |
|---|---|
| ಪಾಲಕರ ಹೆಸರು : | ಪಾಲಕರ ಸಹಿ : |
| ಸಾಕ್ಷಿ ಹೆಸರು : | ಸಾಕ್ಷಿ ಸಹಿ : |
| ದಿನಾಂಕ : | ಊರು : |

## ANNEXURE IIIc

## CONSENT FORM (MARATHI)

### छोट्या मुलांचा दंतउपचार विभाग

### क□. एल. ई. वि. क□ □न्स्टिटयूट ऑफ डेंटल सायन्सस□ बळ□गावी

### सम्मती पत्र

- मी श्री/श्रीमती_____, ह□मान्य करत आह□की मला माझ्या मुलाचा / मुलीचा (नाव _____, वय_____ वर्ष ) उपचारांबद्दल माहिती दिली आह□आणि मी डॉ. _____ ह्यांचा □ भ्यासाला पूर्ण सम्मती दत आह□
- मी माझा मुलाची/ मुलीची वय्यक्तिक माहिती जस□की, नाव, वय, लिंग, पत्ता, मागील व सध्याची दंत उपचाराची माहिती व □ न्य तपशील द□ण्यास सहमत आह□
- मी दंतचिकित्सक ह्यांना त्यांच्या □ भ्यासासाठी पुर्ण सहकार्य द□ईन.
- दंतचिकित्सक ह्यांचा □ भ्यास चालू □ सताना, मी त्यांनी दिलल्या सर्व सुचनांच□पालन करीन.
- मी दंतचिकित्सक ह्यांनी सांगितलल्या व□ळ□ला व तारखल□ा त्यांच्या □ भ्यासासाठी हजर राहीन

### पष्ठांट चा माहिती साठी:-

- दंतचिकित्सक ह्यांच्या □ भ्यासा दरम्यान त्यांनी प्राप्त कलली माझी सर्व माहिती व □ भ्यासाच□परिणाम माझी ओळख न उघडता कुठल्याही प्रकाशनात सादर करायला माझी परवानगी आह□
- मी दंतचिकित्सक ह्यांच्या □ भ्यासाच□स्वरूप समजल□आह□व मी त्यांना आवश्यक □ सल□ त□उपयोग करण्यास परवानगी दत आह□
- मी दंतचिकित्सक ह्यांच्या □ भ्यासात माझ□सहकार्य दिल्या बद्धल कोणत्याही परताव्याचा दावा करणार नाही, त्यांचा □ भ्यास कोणत्याही एजन्सि मार्फत प्रायोजित कला □ सल□ तरीही मी परताव्याचा दावा करणार नाही. मी माझ्या स्वतः च्या □च्छ□ह्या □ भ्यासात सहभागी होत आह□
- मी कोणत्याही कारणास्तव □ भ्यासात भाग घ□ शकत नसीन, तर मी ह्या □ भ्यासातुन बाहर□ पडु शकतो/शकत□
- मी पुर्ण शुद्धीत व माझ्या मनाच्या उपस्थितीत, सर्व प्रक्रिया व त्यांच□कचित होऊ शकणार□दुष्परिणाम समजुन, माझ्या मातृभाषत ह्या □ भ्यासात सहभागी होण्यास सम्मती दतो/दत□

तारीख :

दंतवैद्य नाव : स्वाक्षरी :

रुग्णाचा नाव : स्वाक्षरी :

फोन नंबर : पालक नाव :

## ANNEXURE IV

## ASSENT FORM

**KLE Academy of Higher Education and Research.**
**KLE VK 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 management technique. I am going to fill your teeth with tooth colored cement when you will be watching videos in Virtual Reality. Virtual reality is totally painless and will not cause any harm to you.

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

Signature of participant _____

Signature of investigator_____

Date _____

## ANNEXURE V

## CASE HISTORY FORMAT

**KAHER's KLE VK INSTITUTE OF DENTAL SCIENCE**

**DEPARTMENT OF PEDIATRIC AND PREVENTIVE DENTISTRY**

**CASE-HISTORY**

PATIENT INFORMATION:

NAME:

AGE:

SEX:

PARENT/GUARDIAN:

HISTORY:

Chief Complaint:

History Of Present Illness:

Relevant Medical History:

Previous Dental History:

GENERAL EXAMINATION:

INTRA-ORAL EXAMINATION

Soft Tissue Examination:

Hard Tissue Examination:

No of Teeth:

Decayed Teeth:

Filled Teeth:

Missing Teeth:

Root Stumps:

Mobility:

PROVISIONAL DIAGNOSIS:

INVESTIGATION:

INTRA ORAL PERIAPICAL RADIOGRAPH:

FINAL DIAGNOSIS:

TREATMENT PLANNING:

## ANNEXURE VI

## PATIENT INFORMATION SHEET

**"Comparative Evaluation of Effectiveness of 'Tell Show Do' (TSD) And Virtual Reality (VR) Method of Behaviour Management on anxiety levels of Children Undergoing Restorative Treatment of Carious Teeth–A Randomised Control Study."**

Date:

- We are doing a study to compare a conventional method with a new distraction method of behaviour management.
- We will be using conventional behaviour method ('Tell Show Do') in one Group and in another Group we will be giving a virtual reality video headset while performing treatment.
- We assure you that the child will be comfortable and enjoy throughout the treatment.
- During the study anxiety will be assessed by Venham's picture scale and Pulse oximeter.

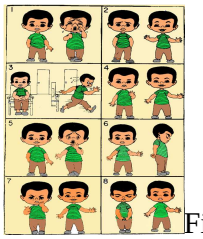

Fig. 1- Venham's Picture Scale.

- Identity of the patient will not be revealed in any condition for educational, publication and scientific research. Results of our study will be used for educational, publication and scientific research.
- I consent to the photographing or video recording of the operation or procedures to be performed for medical, scientific or educational purposes provided his/ her identity is not revealed by the pictures or by the descriptive texts accompanying them.

| Signature | Signature | Signature | Signature |
|---|---|---|---|
| (Parent/Guardian) | Dr.<br>(Principal Investigator) | **Dr.**<br>Reader,<br>Department of Pediatric and Preventive Dentistry<br>KAHER's KLE VKIDS | **Dr.**<br>Prof & HOD<br>Department of Pediatric and Preventive Dentistry<br>KAHER's KLE VKIDS |

## ANNEXURE VII

## BIOSTATISTICS CERTIFICATE

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

### BIOSTATISTICS CLEARANCE CERTIFICATE

This is to certify that the Biostatistics part of Dissertation / Research work of **Dr.** **Postgraduate student** under the guidance of **Dr.** **Reader, Department of Pediatric and Preventive Dentistry** entitled, **"Comparative Evaluation of Effectiveness of Tell Show Do (TSD) and Virtual Reality (VR) method of Behaviour Management on Anxiety levels of Children undergoing restorative treatment of carious teeth – A randomised control study"** has been done under my guidance and considered satisfactory.

**Place:** Belagavi

**Date:** 15.09.2021

Name & Signature of Biostatistician
(Dr. S.B. Javali)
USM KLE IMP
Belagavi.

## ANNEXURE VIII

## PLAGIARISM REPORT

**Scientific Correspondence and Review Committee**

**KLE VK Institute of Dental Sciences**
**A Constituent Unit of KLE Academy of Higher Education and Research**
**(Deemed-to-be-University u/s 3 of the UGC Act, 1956)**
Nehru Nagar, Belagavi - 590 010, Karnataka State
**Accredited 'A' Grade by NAAC (2nd Cycle)** **Placed in Category 'A' by MHRD (GoI)**
☎: 0831-2470362 **Web: http://www.kledental-bgm.edu.in**
FAX: 0831-2470640 **E-mail:principal@kledental-bgm.edu.in**

**Date :** 2.12.2021 **Serial No. :** 067

**PLAGIARISM CHECK REPORT**

Name of the Applicant : DR.
UG / PG / Ph.D / Staff : POST GRADUATE STUDENT
Batch & Year : 2019-22
Department : PEDIATRIC AND PREVENTIVE DENTISTRY

The soft copy of Research Work / Manuscript by DR:..... entitled "COMPARATIVE EVALUATION OF EFFECTIVENESS OF 'TELL SHOW DO' (TSD) AND VIRTUAL REALITY (VR) METHOD OF BEHAVIOUR MANAGEMENT ON ANXIETY LEVELS OF CHILDREN UNDERGOING RESTORATIVE TREATMENT OF CARIOUS TEETH - A RANDOMISED CONTROL STUDY"

under the guidance of D.R:..... ...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 .....8.....%, which is **within** / ~~**not within**~~ the acceptable limits of 10% as per the UGC guidelines.

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

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