"A COMPARATIVE EVALUATION OF VIRTUAL REALITY DISTRACTION AND THAUMATURGY IN MANAGING UNCOOPERATIVE PEDIATRIC PATIENTS"

BABU BANARASI DAS UNIVERSITY, LUCKNOW

Thesis submitted in partial fulfillment of the requirements for degree of

MASTER OF DENTAL SURGERY

In the subject of

PEDIATRIC AND PREVENTIVE DENTISTRY

DEPARTMENT OF PEDIATRIC AND PREVENTIVE DENTISTRY

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DECLARATION BY THE CANDIDATE

I hereby declare that this dissertation entitled "A COMPARATIVE EVALUATION OF VIRTUAL REALITY DISTRACTION AND THAUMATURGY IN MANAGING UNCOOPERATIVE PEDIATRIC PATIENTS" is a bonafide and genuine research work carried out by me under the guidance of **Dr. Neerja Singh,** PROFESSOR, Department of Pediatric and Preventive Dentistry, Babu Banarasi Das College of Dental Sciences, Babu Banarasi Das University, Lucknow, Uttar Pradesh.

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CERTIFICATE

This is to certify that the dissertation entitled "A COMPARATIVE EVALUATION OF VIRTUAL REALITY DISTRACTION AND THAUMATURGY IN MANAGING UNCOOPERATIVE PEDIATRIC PATIENTS" is an original bonafide research work done by **Dr. Ninapyari Ahanthem,** in partial fulfillment of the requirement for the degree of MASTER OF DENTAL SURGERY (M.D.S) in the speciality of PEDIATRIC AND PREVENTIVE DENTISTRY under my direct supervision and guidance.

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CERTIFICATE

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ACKNOWLEDGEMENT

"Understanding the truth forms the cornerstone of wisdom." The three years following my graduation have been a profound learning experience. Mere words of "thank you" feel inadequate to convey the depth of my appreciation and reverence for those who facilitated this research. I am appreciative of their diverse contributions and unwavering support throughout the crafting of my dissertation, and I feel privileged to seize this moment to acknowledge them.

I express my heartfelt gratitude to **Dr. Neerja Singh**, my advisor and mentor, for her continuous support and guidance throughout this research project. Her valuable insights have been instrumental in helping me overcome various challenges. I am profoundly thankful for her patience, encouragement, and expertise that she generously provided. Above all, I appreciate her consistent support, collaboration, and mentorship over the past three years.

Above all, I would like to thank the head of the family and my co-guide **Dr. Monika Rathore**, Professor and Head of the Department for her unflinching support, advice and brilliant supervision. Her valuable suggestions and her instructions have served as the major contributor towards the completion of this project.

I am extremely thankful to **Dr. Subash Singh** and **Dr. Somya Govil** for their kind cooperation and helping me with the conductance of my dissertation, without their constant support this dissertation would not have been possible.

I am grateful for the love and support of my parents**,** Ahanthem Nishikanta Singh, Ahanthem (O) Nayani Devi, who have been my sources of strength. I would also like to express my gratitude to my elder sister Nirupama Ahanthem, Lizarika Gurumayum, my brother Ahanthem Naresh Singh, Naorem Ratan Singh for their constant support and love.

I would also like to enormously thank to **Dr. Mansi Semwal**, M.D.S Reader, **Dr. Anu Bhatt, M.D.S Senior Lecturer, Dr. Abhimanyu Singh, M.D.S Senior Lecturer, Dr. Bibhav Dubey, M.D.S Senior Lecturer and Dr. Binu Singh, M.D.S Senior Lecturer** for their valuable time, knowledge and guidance throughout these three years. Their incessant encouragement and professional insight have helped me to learn in the right direction by leaps and bounds.

Finally, I will be failing in my duty if I do not thank whose profound help, support and sincerity has helped me in completing my thesis. I deeply appreciate the undying support from my dear collegues**,** Dr. Aayushi Bhardwaj, Dr. Sarwani Mishra, Dr. Ajay Kumar Yadav, Dr. Sadia Salman and my seniors Dr. Saheli Basu, Dr. Bibhav Dubey, Dr. Raunaq Sahu, Dr. Akash Roy Chowdhury and Dr. Needhi Singh and my juniors Dr. Anushka Banerjee, Dr. Shifa Amir, Dr.Sushmita Gupta, Dr. Shreeja Anand and Dr. Spandan Dey for their help and guidance. My journey in this department would be incomplete without their encouragement and patience through the constant highs and lows.

A special thanks to my friends Dr. Parmieka Rawat, Dr. Nandita Barman, Dr. Pratima Ngangom, Johnson Laishangbam, Nonika Loitongbam, Dr. Bibani konjengbm, Dr. Sanjana Laishangbam, Dr. Lintoirani Laishram, Dr. Rojeeta Maisnam, Dr. Chansophy, Dr. Abhijeet Rajkumar, Dr. Bidyananda Yumnam, Dr. Sunayana Rabha, Dr. Priyanka Barman, Dr. Risha Bikomiya, Dr. Shristi Aditi, Dr. Rigzing Lepcha, Dr. Divya Arora, Dr. Prashant Singh and Dr. Premabati Nameirakpam. They have been a pillar of strength through all my ups and downs. They have inspired me to be active and hard working in my academic pursuits who have always been my side and supported me throughout my journey.

I would like to express my heartfelt appreciation to my flatmates, Dr. Minerva Haobam, Dr. Pallavi Goswami, Dr. Sarwani Mishra and Dr. Shalu Shukla whose companionship and understanding have made my academic journey more enjoyable and fulfilling. Their support, encouragement, and camaraderie have been invaluable throughout this experience.

It is a pleasure at this point to thank my principal, **Dr. Puneet Ahuja** for providing me with the opportunity to conduct the research and use the facilities of this college.

I would like to express my heartfelt gratitude to the non-teaching personnel in the Pediatric Department for their compassion and assistance.

This is dedicated to my loved ones, friends, and instructors who have supported me throughout my journey. Without them, this would have remained just a dream.

Dr. Ninapyari Ahanthem

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ABSTRACT

BACKGROUND:

Virtual reality distraction is a newer technique of distraction which is a type of human-computer interaction that allows users to interact with a computer-generated environment in real time. Thaumaturgy is a tool that enables the dentist execute necessary treatment by distracting and relaxing the child.

AIM:

To compare the effectiveness of virtual reality distraction and thaumaturgy in managing pediatric patients.

METHODOLOGY:

The present in-vivo study was carried out in children aged between 3-13 years including both the genders. The participants were randomly divided into two groups on the basis of distraction techniques. They were again subdivided in three age groups i.e 3-6 years, 7-10 years and 11-13 years in both the groups. The behaviour management of group A participants was done by Virtual Reality distraction technique and in group B participants, distraction was done by using thaumaturgic techniques. The anxiety score for each participant was noted at baseline and immediately after the treatment using Visual facial anxiety scale (VFAS). Pulse rate and oxygen saturation were also recorded by using pulse oximeter before, during and after treatment to assess the degree of anxiety.

RESULTS:

VFAS was significantly more reduced in virtual reality group than thaumaturgy group when measured after the treatment, in all the age groups. Pulse rate was found to be lesser in the virtual reality group than the thaumaturgy group which was statistically significant in all the three age groups. And the difference in the oxygen saturation was statistically significant in the age group 3-6 years with more oxygen level in the virtual reality group.

CONCLUSION:

In all the age groups, virtual reality was found to be more effective in managing pediatric patients than thaumaturgy.

INTRODUCTION

Behavior management plays a very important role in the treatment of child patients. Uncooperative conduct can make it difficult to provide quality dental care, resulting in longer delivery times, a higher risk of damage to the child patients, and higher costs.[1] As McEclory (1895) wrote "Although operative dentistry may be perfect, but the appointment is a big failure if a child departs in tears". In literature, this marked the initial acknowledgment of the significant reason for behavior management gaining precedence over technical excellence.[2]

The willingness of a child to undergo dental treatment can be adversely affected by the presence of fear and anxiety. The most common cause of uncooperative behavior in the dental office is anxiety towards dental procedures. Dental anxiety is a widespread psychological and instinctual response that is amplified in pediatric age groups. According to Seligman (2015), dental anxiety is defined as persistent and excessive fear caused due to painful and invasive procedures. It is additionally linked to the noise generated in dental clinics, stemming from unfamiliar surroundings and the impact of parental involvement and prior healthcare interventions.[3] Advancements in dentistry have led to technological progress, enhancing treatment options for all segments of society. However, these more advanced and comprehensive procedures may require increased collaboration and cooperation from children. Globally, the attention towards childhood anxiety has increased due to the substantial challenges it presents for clinicians in delivering successful treatments for children. Consequently, it is critical for dental health practitioners to be able to diagnose children with dental anxiety and employ behavior management approaches at the youngest possible age.[4]

The role of a pediatric dentist is crucial in cultivating a trusting and cooperative relationship between the child and the clinician, leading to positive outcomes in the future. Several behavior modification techniques, such as Tell-Show-Do, Positive

Reinforcement, Modeling, and Voice Control, can be employed for this purpose.

However, because of differences in a child's personality, a behavior technique that is effective for one child may not be suitable for another. Conventional basic behavior guidance technique, may not always be advantageous and effective. Fortunately, emerging techniques such as magic acts, audiovisual distraction through mobile dental apps, video game distraction, and virtual reality-based distraction are opening the door to the implementation of innovative, non-invasive behavior management strategies for children, which can be beneficial for few children and can eliminate the need of pharmacological behavior technique. Such modern distraction techniques offer tremendous immersive, engaging, and innovative qualities, allowing dentists to effectively manage children with behavioral difficulties and provide appropriate treatment in a stress-free environment.[5] The goal of distraction techniques is to reduce the impression of unpleasantness and avoid negative or avoidant behavior.[6] Utilizing magic tricks as a strategy can be an effective approach to manage resistant behavior among pediatric dental patients.

Virtual reality distraction is a newer technique of distraction that is currently experiencing increased popularity. Virtual Reality (VR) is a type of human– computer interaction that allows users to interact with a computer-generated environment in real time. VR as a distraction may be preferable to traditional distraction techniques since it provides more immersive pictures using VR headsets that display images directly in front of the user's eyes.[7] Depending on the model used, it block out real-world (visual, auditory, or both) stimuli. VR even combines the audio, visual, and kinesthetic sensory modalities. Depending on how immersive the presented stimuli are, the person’s attention will be more or less “drained” from the real world, leaving less attention available to real-world processes, including painful stimuli. Immersion is particularly increased during VR because the use of Head Mounted Device prevents patients from seeing what is happening in the real world and directs the focus on what is going on in the virtual world. Therefore, the child’s attention is

focused on what happen in the virtual world rather than on the surrounding environment.[8]

Thaumaturgy is a new strategy that is presently being utilised to manage strong- willed children. Thaumaturgy is a tool that enables the dentist to execute necessary treatment by distracting and relaxing the child. Thaumaturgic procedures have proven to be effective in controlling the conduct of children of all ages. In traditional pediatric care, thaumaturgy is employed as a decisive way of behavior modification.[9] Thaumaturgy, which is also commonly known as magic trick reduced the perception of unpleasantness, thereby alleviating the anxiety. It was found to be useful in patients with psychological issues to enhance self confidence in the patients.[10]

Among various behavior modification techniques, distraction emerges as a safe and cost-effective process that contributes to an effectively relaxed experience during dental procedures. The widespread occurrence of dental anxiety in children, coupled with its harmful consequences, is a significant global concern for dentists striving to deliver effective dental treatment. Thus, the purpose of this in-vivo study is to compare and evaluate the effect of Virtual Reality Distraction technique with Thaumaturgy in managing pediatric patients.

AIM:

- To compare the effectiveness of virtual reality distraction and thaumaturgy in managing uncooperative pediatric patients.

OBJECTIVES:

- To evaluate and compare the effectiveness of thumb and light trick technique with virtual reality distraction device in children aged between 3-6 years in reducing anxiety.

- To evaluate and compare the effectiveness of book trick technique with virtual reality distraction device in reducing anxiety in children between 7-10 years of age.

- To evaluate and compare the effectiveness of item trick technique with virtual reality distraction device in reducing anxiety in children between 11-13 years of age.

REVIEW OF LITERATURE

THAUMATURGY

Peretz B, Gluck G (2005)[6] conducted a study to compare the effectiveness of using a magic trick to persuade strong-willed children who refuse to sit in the dental chair at the first visit with more conventional methods like tell-show-do (TSD). Seventy children aged 3-6 years of age who were identified as manifesting strong-willed behaviour were selected for this study. The children were randomly assigned to be managed either by a magic trick distraction or by TSD. There were 35 subjects in each group. Children who were shown a magic trick (Magic+) sat significantly faster on the dental chair than children who were not shown the magic trick (Magic-) . The study concluded that a magic trick is able to facilitate two types of cooperative behaviour: (1) it expedites the movement of the child into the dental chair and (2) it enables the dentist to take radiographs more easily.

Konde S, Sumaiyya S, Agarwal M, Preetha P (2020)[9] evaluated and compared the effectiveness of Thaumaturgy in alleviation of anxiety in children aged 2–13 years. Two hundred and forty children aged 2–13 years, identified as manifesting strong-willed behavior were selected for this study. The children were randomly assigned to be managed by one of the three thaumaturgic distraction techniques. Anxiety was assessed before and after the local anesthetic procedure using the anxiety facial scale. They concluded that the use of thaumaturgy plays an important role in shaping the behavior of a child in pediatric dentistry. The age and cognitive development of child dictates the technique to be used.

Asokan, Sharath, Priya G, PR, Natchiyar, Nambi S; Elamathe (2020)[11] conducted a study to evaluate and compare the effectiveness of two distraction techniques, magic trick and mobile dental game with tell-show-do (TSD) in the management of anxious children. Two hundred and thirty children aged 4–5 years

were screened for their baseline anxiety using the Chotta Bheem-Chutki scale. A double-blinded randomized control trial was conducted among 60 children with high anxiety scores. They were randomly divided into three groups. Group 1 received a magic trick distraction technique. Group 2 received a mobile dental game distraction technique. Group 3, the control group received TSD. Readiness to accept the dental treatment and postoperative anxiety scores were recorded. Statistically significant reduction in the anxiety level was seen in children who received magic, mobile dental game, and TSD technique . Based on the readiness to accept dental treatment, there was a statistically significant difference between the three groups. The study concluded the children in the mobilegroup were found to accept the treatment faster compared to the magic and TSD groups. All three techniques were equally effective in reducing the anxiety of children. The mobile dental game was superior to magic trick and TSD in terms of children's readiness to accept dental treatment.

Thosar NR, Bane SP, Deulkar PV, Deshpande MA, Gupta S. (2022)[12] conducted a study to compare the impacts of magic tricks on reducing dental anxiety in children. Material and methods Patients aged four to 11 years were eligible for inclusion. The study comprised two groups of 15 children each. During the first visit, children weren't subjected to any behavior management. Behavior management aids (magic tricks and audiovisuals) were used during the second visit. Hemodynamic parameters along with an anxiety scale were used to assess anxiety in children before, during, and after treatment procedures. Venham's picture test and modified visual analog scale were also used to assess the anxiety. A reduction in anxiety was seen in both groups after behavior management was used. The hemodynamic parameters like blood pressure and pulse rate were seen to decrease during the second visit, while the oxygen saturation was seen to increase. The study concluded that magic trick along with audiovisual aids was effective in controlling dental anxiety. Thus, magic tricks can be used in dental practice as a behavior management aid for children to facilitate cooperative behavior.

Kothari P, Mathur A, Chauhan RS, Nankar M, Tirupathi S, Suvarna A (2023)[10] conducted a study to evaluate the effectiveness of Thaumaturgic aid in alleviation of anxiety in 4–6 year-old children during administration of local anesthesia using the inferior alveolar nerve block (IANB) technique. Thirty children aged between 4–6 years with dental anxiety requiring IANB were included in this study. Patients were divided equally into two groups: Group I, thaumaturgic aid group and Group II, conventional non-pharmacological group using randomization. Anxiety was measured before and after using the intervention with Raghavendra Madhuri Sujata-Pictorial scale (RMS-PS), Venham's anxiety rating scale, and pulse rate. Children in thaumaturgy group (Group- I) exhibited significantly lower anxiety during IANB in comparison with children in the conventional group (Group- II) and the difference was statistically significant. It was concluded that Magic tricks are effective in reducing anxiety among young children during IANB; Moreover, it expands the arsenal of behavior guidance techniques for treatment of children with anxiety and plays an important role in shaping the behavior of a child in pediatric dentistry.

VITUAL REALITY DISTRACTION

Van Twillert B, Bremer M, Faber AW (2007)[13] conducted a study to explore whether immersive virtual reality (VR) can reduce the procedural pain and anxiety during an entire wound care session and compared VR to the effects of standard care and other distraction methods. Nineteen in patients ages 8 to 65 years (mean, 30 years) with a mean TBSA of 7.1% (range, 0.5-21.5%) were studied using a within-subject design. Within 1 week of admission, standard care (no distraction), VR, or another self-chosen distraction method was administered during the wound dressing change. Each patient received the normal analgesic regimen. Pain was measured with visual analog thermometer scores, and anxiety was measured with the state-version of the Spielberger State Trait Anxiety Inventory. After comparing different distraction methods, only VR and television showed significant pain reductions during wound dressing changes. The effects of VR were superior, but not statistical significant, to that of television. Thirteen of 19 patients reported clinically

meaningful (33% or greater) reductions in pain during VR distraction. There was no significant reduction of anxiety ratings. This is the first known systematic review to report on the effectiveness of VR, in conjunction with pharmacologic analgesia on reducing pain and anxiety in burn injury patients undergoing wound dressing changes and physiotherapy management compared with pharmacologic analgesia alone or other forms of distraction. Used as an adjunct to the current burn pain management regimens, VR could possibly assist health professionals in making the rehabilitation process for burn patients less excruciating, thereby improving functional outcomes.

Prabhaker AR, Marwah N, Raju OS (2007)[7] conducted a study with an aim to evaluate and compare the two distraction techniques, viz, audio distraction and audiovisual distraction, in management of anxious pediatric dental patients. Sixty children aged between 4-8 years were divided into three groups. Each child had four dental visits-screening visit, prophylaxis visit, cavity preparation and restoration visit, and extraction visit. Child's anxiety level in each visit was assessed using a combination of four measures: Venham's picture test, Venham's rating of clinical anxiety, pulse rate, and oxygen saturation. The values obtained were tabulated and subjected to statistical analysis. It was concluded that audiovisual distraction technique was more effective in managing anxious pediatric dental patient as compared to audio distraction technique.

Aminabadi NA, Erfanparasi L, Sohrabi A, Oskouel SG, Naghili A (2012)[8] conducted a study to evaluate the influence of using virtual reality eyeglasses on severity of pain and anxiety during dental procedures in pediatric patients. This study included 120 healthy children aged 4-6 years. Children with no previous anxiety disorder were randomly divided into two groups, each consisting of 60 children. The study consisted of 3 consecutive treatment sessions. During the first visit fluoride therapy was carried out in both groups. In the next sessions, the groups received restorative treatment with and without virtual reality eyeglasses in a randomized single-blind-controlled crossover fashion. Then at the end of each session the subjects' 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 (1)]. There was a significant decrease in pain perception and state anxiety scores with the use of virtual reality eyeglasses during dental treatment. The study concluded that virtual reality eyeglasses can successfully decrease pain perception and state anxiety during dental treatment.

Wiederhold MD, Gao K, Wiederhold BK (2014)[14] conducted a study to examine the use of VR as a form of distraction for dental patients using both subjective and objective measures to determine how a VR system affects patients' reported anxiety level, pain level, and physiological factors. As predicted, results of self-evaluation questionnaires showed that patients experienced less anxiety and pain after undergoing VR treatment. Physiological data reported similar trends in decreased anxiety. It was concluded that the favorable subjective and objective responses suggest that VR distraction systems can reduce discomfort and pain for patients with mild to moderate fear and anxiety.

Huang TK, Yang CH, Hsieh YH, Wang JC, Hung CC (2018)[15] conducted a study to estimate the preclinical examination of dental students. They investigated a recently developed in virtual reality (VR) and augmented reality (AR) starting of the dental history to the progress of the dental skill. The development of tracking unit changed the surgical and educational way. Clinical surgery is based on mature education. VR and AR simultaneously affected the skill of the training lesson and navigation system. The study concluded that widely, the VR and AR not only applied in the dental training lesson and surgery, but also improved all field in our life.

Atzori B, Lauro Grotto R, Giugni A, Calabrò M, Alhalabi W, Hoffman HG (2018)[16] conducted a study to evaluate the feasibility and effectiveness of immersive virtual reality as an attention distraction analgesia technique for pain management in children and adolescents undergoing painful dental procedures. Five patients (mean age 13.20 years old, SD 2.39) participated. Patients received tethered immersive interactive virtual reality distraction in an Oculus Rift VR helmet (experimental

condition) during one dental procedure (a single dental filling or tooth extraction). On a different visit to the same dentist (e.g., 1 week later), each patient also received a comparable dental procedure during the control condition treatment as usual‖ (treatment order randomized). Using Oculus Rift VR goggles, patients reported a strong sense of going inside the computer-generated world,‖ without side effects. The dentist preferred having the patients in VR. It was concluded that there were preliminary evidence of the feasibility of using immersive, interactive VR to distract pediatric dental patients and increase fun of children during dental procedures

Niharika P, Reddy NV, Srujana P, Srikanth K, Daneswari V, Geetha KS (2018)[17] conducted a study to evaluate the influence of using virtual reality (VR) eyeglasses on severity of pain and anxiety during pulp therapy in pediatric patients considering childhood anxiety-related disorders as an important confounding factor in the dental setting. A total of 40 children aged between 4 and 8 years with no previous anxiety disorder were randomly divided into two groups. The study consisted of three consecutive treatment sessions. The two groups received pulp therapy with and without VR eyeglasses in a randomized single-blind-controlled crossover fashion. Then, at the end of each session, the 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]. Changes in pulse oximeter and heart rate were recorded in every 10 min. The values obtained were tabulated and subjected to statistical analysis. The study shows a significant decrease in pain perception and state anxiety scores with the use of VR eyeglasses during dental treatment. The results of this study provide an initial encouraging for the use of VR device during dental treatment by pediatric dentists, but additional empirical research is required.

Rajeswari SR, Chandrasekhar R , Vinay C, Uloopi KS , Roja Ramya KS, Ramesh MV(2019)[18] conducted a study to evaluate the effectiveness of cognitive behavioral play therapy and audiovisual distraction for management of preoperative anxiety in children. A total of 45 children of age 6-10 years with moderate-to-severe anxiety were allocated into three groups: group I - cognitive behavioral play therapy (CBT), group II audiovisual (AV) distraction, and group III - tell-show-do technique (control group). Children in the CBT group were allowed to play with building blocks, asked to draw a picture and then showed a modeling video of co- operative child undergoing dental treatment. Children in group II were subjected to passive distraction with audiovisual aids, whereas group III (control) children were managed with the conventional TSD technique. Baseline and postintervention objective and subjective anxiety scores were measured with a pulse oximeter and facial image scale (FIS), respectively. The study concluded that active distraction with cognitive behavioral play therapy is found to be more effective in reducing the preoperative anxiety in children compared to audiovisual distraction and tell-show- do technique. Identification and management of preoperative anxiety in children is most critical for successful dental treatment. Active distraction is an effective psychological approach for behavior management in anxious children.

Rao D.G *et al* (2019)[19] conducted a study to assess the effectiveness of virtual reality distraction on pain perception and state anxiety levels undergoing restorative treatment in children. This was an interventional study with 30 children of age 6–10 years came to the Department of Pedodontics and Preventive Dentistry. And he concluded that virtual reality distraction can be considered as a budding distraction tool in the arena of behavior management that helps adapt the child to dental environment and able to deliver qualitative dental care.

Shetty V, Suresh LR, Hegde AM (2019)[20] conducted a study to assess the impact of Virtual Reality (VR) distraction technique on pain and anxiety in 5–8-year-old children, during short invasive dental procedures. 120 children, aged 5–8 years, scoring less than 25 on the SCARED questionnaire, scheduled to undergo short invasive dental procedures, were randomly divided into a control (without VR distraction) and study group (with VR distraction) of 60 each. State anxiety levels

were assessed in the children from both groups using revised version of Modified Child Dental Anxiety Scale, before and after dental treatment. Pain perceived during treatment was assessed using Wong Baker Faces pain rating scale at the end of treatment. Salivary cortisol levels were also assessed before, during and after the dental procedure, in all children. It was observed a significant reduction in pain perception and state anxiety in children, using VR distraction. The decrease in salivary cortisol levels was significantly greater in children using VR distraction. It was concluded that Virtual Reality distraction can be used as a successful behavior modification method in children undergoing short invasive dental treatments

Koticha P, Katge F, Shetty S, Patil P (2019)[21] conducted a study to evaluate the effectiveness of virtual reality eyeglasses as a distraction aid to reduce anxiety of children undergoing dental extraction procedure. Thirty children of age 6-10 years (n = 60) with bilateral carious primary molars indicated for extraction were randomly selected and divided into two groups of 30 each. The first one was group 1 (VR group) (n = 30) and group II (control group) (n = 30). Anxiety was measured by using Venham's picture test, pulse rate and oxygen saturation. Anxiety level between group I and group II was assessed using paired test. The pulse rate values in intergroup comparison were found statistically significant. The study concluded that the virtual reality used as a distraction technique improves the physiologic parameters of children aged 6-10 years but does not reduce the patient's self-reported anxiety according to Venham's picture test used.

Nunna M, Dasaraju RK, Kamatham R, Mallineni SK (2019)[22] conducted a study to evaluate the efficacy of virtual reality (VR) distraction and counter-stimulation (CS) on dental anxiety and pain perception to local anesthesia in children. A prospective, randomized, single-blinded interventional clinical trial with a parallel design was used. Seventy children 7-11 years old who required local anesthesia (LA) for pulp therapy or tooth extraction were recruited and allocated to two groups with

equal distribution based on the intervention. Group CS (n = 35) received CS and Group VR (n = 35) received VR distraction with ANTVR glasses. Anxiety levels (using pulse rate) were evaluated before, during, and after administration of local anesthesia, while pain perception was assessed immediately after the injection. Wong-Baker faces pain-rating scale (WBFPS), visual analog scale (VAS), and Venham's clinical anxiety rating scale (VCARS) were used for pain evaluation. Student's t-test was used to test the mean difference between groups, and repeated measures ANOVA was used to test the mean difference of pulse rates. Significant differences in mean pulse rates were observed in both groups, while children in the VR group had a higher reduction, and the mean VCARS scores were significant in the VR group. Mean WBFPS scores showed less painperception to LA needle prick in the CS group while the same change was observed in the VR group with VAS scores. The study concluded that VR distraction is better than CS for reducing anxiety to injection in children undergoing extraction and pulpectomy.

Custódio NB, Costa FDS, Cademartori MG, da Costa VPP, Goettems ML (2020)[23] conducted a study to investigate the effect of virtual reality (VR) glasses as an audiovisual distraction technique on dental anxiety, pain perception, and behavior triggered during dental treatment in children up to 12 years old. The research question asked was: Can improvement be seen in the child's behavior, pain perception or anxiety when VR eyeglasses are used during dental treatment. Five databases were searched for studies published until September 2018. Studies were selected by titles and abstracts, followed by full-texts reading. Meta-analysis was performed and combined results were presented as a pooled mean difference for each procedure, using random-effect models. Nine randomized clinical trials assessed the effect of VR glasses on children's behavior during dental care. No differences were observed in anxiety levels during local anesthesia, use of rubber dam, removal of caries and restorative procedures. Similar results were observed in children's behavior when local anesthesia and rubber dam were used. The study concluded that the use of virtual reality glasses is an effective tool for improving behavior and reducing pain perception during the dental treatment of children. Children who used

VR eye-glasses behaved better during removal of caries and showed lower pain perception during restoration.

Ran L, Zhao N, Fan L, Zhou P, Zhang, Cong Yu C (2020)[24] conducted a study to measure the role of VR distraction on behavior management in short-term dental procedures in children. A randomized clinical trial design was carried out on 120 children aged between 4 and 8 years to identify the comparative efficacy of VR and tell-show-do (TSD) to improve behavioral management during dental procedures. The primary outcomes were evaluated anxiety, pain, and compliance scores in perioperative children. The levels of operative anxiety and pain were assessed using the Children's Fear Survey Schedule-Dental Subscale (CFSS-DS) and Wong Baker FACES Pain Rating Scale (WBFS), respectively. The Frankl Behavior Rating Scale (FBRS) was tested before and during dental procedures. The length of the dental procedure was compared between both groups after treatment. The average anxiety and behavioral scores of the VR group significantly reduced compared with the control. The compliance scores of the control group during treatment were 3 (2, 3), and the same in the VR intervention were 3 (3, 4). A significant reduction in pain was observed when using VR distraction. Comparing the length of the dental procedure, the VR group had a shorter treatment time than the control group. The study concluded that the use of VR significantly reduced the anxiety and pain of children and the length of the dental procedure and improved the compliance of children that underwent short-term dental procedures without an adverse reaction.

Rashwan Z.I, Eweida R.S, Hamad N.I, Mohamed A (2020)[25] conducted a study aimed to investigate the effect of VR distraction versus PPVI intervention on children's DFA during LA injection. Design: A quasi-experimental study was conducted at Pedo-dentist Clinic, Dental Centre, Alexandria. A sample of 90 children aged from 4-6 years were observed for their anxious behaviors in the waiting room. The study concluded that both VR distraction and PPVI intervention showed positive effects and had excellent potential as evidence-based interventions for minimizing

children's DFA during LA injection.

López-Valverde N et al (2020)[26] reviewed studies where VR was used for children and adults as a measure against anxiety and pain during dental. VR was defined as a three-dimensional environment that provides patients with a sense of immersion, transporting them to appealing and interactive settings. Anxiety and pain results were assessed during dental treatments where VR was used, and in standard care situations. 31 studies were identified, of which 14 met the inclusion criteria.Pain levels were evaluated in four studies (n = 4), anxiety levels in three (n = 3) and anxiety and pain together in seven (n = 7). Our meta-analysis was based on ten studies (n = 10). The effect of VR was studied mainly in the pediatric population (for pain SMD = −0.82). The findings of the meta-analysis showed that VR was an effective distraction method to reduce pain and anxiety in patients undergoing a variety of dental treatments; however, further research on VR as a tool to prepare patients for dental treatment is required because of the scarcity of studies in this area.

Pande P, Rana V, Srivastava N, Kaushik N. (2020)[27] conducted a study to compare and evaluate the effectiveness of four different behavior guidance techniques in managing uncooperative pediatric patients by measuring pre and post-operative dental fear/anxiety levels using physiological and non physiological parameters. Sixty systemically healthy children aged 5-8 years with negative behavior as per Frankl's Rating Scale, requiring restoration were included in the study and randomly divided into four equal groups (n = 15), based on the guidance techniques used: Tell-Show-Do (TSD) as a control group and audio distraction, audiovisual distraction (AVD) (virtual reality [VR]) and Mobile Phone Game Distraction as test groups. Pre- and post-intervention levels of the child's fear/anxiety were assessed using both physiological (blood pressure and pulse rate) and non physiological (facial image scale) parameters. The data were evaluated using t-test and one-way ANOVA test. A statistically significant difference was observed in both

physiological and non-physiological parameters post-intervention in the groups with a maximum decrease in the AVD (VR) group. AVD (VR) was found to be the most effective while TSD alone as the least effective behavior guidance technique in reducing dental fear/anxiety in uncooperative pediatric dental patients.

Buldur B, Candan M (2020)[28] conducted a study to evaluate the effect of virtual reality (VR) on dental anxiety, pain, and behaviour at different time points among children undergoing dental treatment under local anaesthesia. This randomised, two-armed, within-subject, cross-over, placebo-controlled trial included 76 children. Eligible participants were treated in two dental visits using the following methods: with protective glasses only, without distraction (attention placebo-controlled - APC); and with the treatment condition (i.e., VR). Primary outcomes were dental anxiety and pain; secondary outcome was dental visit behaviour. Heart rate scores were recorded as an objective measure to evaluate dental anxiety and pain. Subjective measurements for each variable were also performed. It was observed that significant reduction in dental pain and anxiety was observed in the VR group, according to the heart rate scores; however, no statistical differences were observed according to the self-reported measures. Decreased dental anxiety and pain were associated with the first visit sequence with VR. Dental pain and anxiety scores were lower during local anaesthesia in the VR group than in the APC group. The study concluded that Virtual reality significantly reduced pain and anxiety during local anaesthesia in children undergoing dental treatment; therefore, it may be recommended during dental treatment in school-age children.

Aditya PVA , Prasad MG, Nagaradhakrishna A , Raju NS , Babu DN (2021)[29] conducted a study with an aim to use a fidget spinner, kaleidoscope, and virtual reality as distraction techniques individually and observe the effects on the anxiety levels of children subjected to inferior alveolar nerve block (IANB). In this parallel-group randomized clinical trial, 102 children aged 6–9 years requiring IANB for various dental treatments were screened and 60 children who met the inclusion criteria were enrolled and randomly assigned into four groups of 15 each; Group 1 fidget spinner (FS), Group 2 kaleidoscope, Group 3 virtual reality (VR) and Group 4 no distraction (Control). The child's self-reported anxiety levels using Venham's

picture test (VPT); the pulse oximeter was used to measure physiological signs of oxygen saturation and pulse rate at three intervals i.e. before, during, and after the IANB procedure. The collected data were statistically analyzed with SPSS 21 software. Paired t-test and One way ANOVA were used to compare the VPT, oxygen saturation, and pulse rate values. It was observed that Groups 1, 2, and 3 showed significantly lower mean VPT scores compared to Group 4. Groups 1 & 3 showed lower mean pulse rates and Group 2 showed comparable mean pulse rates to Group 4 respectively during the IANB procedure. Oxygen saturation levels remained non-significant between all the Groups. The study concluded that Fidget spinner, kaleidoscope, and virtual reality seem to be effective distraction methodsand can be recommended as effective approaches to help alleviate children's dental anxiety during IANB procedures

Sharma Y, Bhatia HP, Sood S, Sharma N, Singh A (2021)[30] The study investigates the effect and compares three techniques-video-eyeglasses earphone system, Digital screens and verbal methods as distracting technique to assess dental pain reaction in children during administration of local anesthesia (LA). Pain or its anticipation can cause fear and anxiety in a child which could complicate further dental treatment. This cross-sectional study consists of 97 children of age-group 4-8 years who required local anesthesia for their dental treatment were selected. Children were randomly allocated into three groups namely- Verbal method (group A), video eyeglass/earphone system (group B) and digital screens (group C). In group A, instructions were given to the patient by the dentist while administering local anesthesia. In group B, VR box was used to show age appropriate videos according to subjects' choice. In group C, digital screens were placed on dental chair for patient to watch while nerve block was administered. Pain was measured using face, legs, activity, cry, consolability (FLACC) scale behavioral anxiety/pain assessment scale. FLACC score was found to be significantly different among three groups. The mean FLACC scale score for pain was less in video eyeglass/earphone than digital screens and highest in Verbal group. Video eyeglasses/earphone method proved to be most effective as a distraction method in children and helped in reducing children's disruptive behavior in the dental setting.

Gómez-Polo C, Vilches AA, Ribas D, Castaño-Séiquer A, Montero J (2021)[31] conducted a study to assess the effectiveness of using a VR headset as a distraction for managing the anxiety and behaviour of paediatric patients during their dental treatment. Eighty patients, aged between five and ten years old and who required dental treatment over three or more appointments, were randomly allocated into two groups. One group used a VR headset during all their appointments, and the other one did not use any distraction technique. The patients were asked to take a Facial Image Scale Test during their first and last appointments to assess their level of anxiety. Additionally, the dentist completed the Frankl Test to quantify the child's behaviour at the beginning and the end of their treatment. The results obtained, both from the group using the VR headset and from the control group, were compared using the chi-square test. The use of a VR headset during dental treatment significantly reduced anxiety (95% of the children were happy) and improved behaviour (100% positive behaviour) as compared with the control group (40% and 57.5%, respectively). A VR headset can effectively distract a paediatric patient, helping to reduce anxiety and manage behaviour during dental treatment.

Halbig A, Latoschik ME (2021)[32] overviewed systematically an extensive state of the art review of the usage of physiological measurements in VR. Weidentified 1,119 works that make use of physiological measurements in VR. Within these, we identified 32 approaches that focus on the classification of characteristics of experience, common in VR applications. The first part of this review categorizes the 1,119 works by field of application i.e. therapy, training, entertainment, and communication and interaction, as well as by the specific target factors and variables measured by the physiological parameters. An additional category summarizes general VR approaches applicable to all specific fields of application since they target typical VR qualities. In the second part of this review, we analyze the target factors and variables regarding the respective methods used for an automatic analysis and, potentially, classification. For example, we highlight which measurement setups have been proven to be sensitive enough to distinguish different levels of arousal, valence, anxiety, stress, or cognitive workload in the virtual realm. This work may prove useful for all researchers wanting to use physiological data in VR and who

want to have a good overview of prior approaches taken, their benefits and potential drawbacks.

Aminabadi NA, Golsanamlou O, Halimi Z, Jamali Z (2022)[33] conducted a study to assess the impact of different levels of VR on anxiety, behavior, and oral health status. This study was carried out in the Department of Pediatric Dentistry at the Tabriz University of Medical Sciences from December 2020 to June 2021. We randomly assigned 60 healthy children aged 4 years to 6 years to 4 groups, each consisting of 15 children. The study consisted of 2 consecutive sessions. During the first visit, the plaque index was calculated, and oral health education was carried out in all groups using Immersive VR (group I), Semi-immersive VR (group II), Nonimmersive VR (group III), and tell-show-do (TSD; group IV). In the second session, an amalgam restoration was performed in all groups. Participants' anxiety and behavior were recorded using the face version of the Modified Child Dental Anxiety Scale (MCDAS and Frankl scale. It was concluded that the most positive behavior was observed in the Immersive VR group, followed by the Semi- immersive VR, Nonimmersive VR, and TSD groups. Moreover, oral health education using VR resources can improve oral health status in children.

Torres M.F, Rodriguez LSM, Vivar CG, Ruiz NS, Hernandez PE (2022)[34] conducted a study to analyze and evaluate the effectiveness of the use of Virtual Reality distraction techniques as a measure of pain and anxiety reduction in pediatric patients and their parents. In addition, the effects of two modes of Virtual Reality (passive vs. interactive) were compared. They carried out a quasi experimental study from the 124 patients, 51.6% (n = 64) were girls and 48.4% (n = 60) were boys (p = 0.574). The study concluded that the virtual reality was an effective method to reduce pain and anxiety levels in pediatric patients with the effectiveness of interactive virtual reality and its use in the population aged 7–15 years being greater.

Fahim S et al (2022)[35] conducted a study`to provide an update on the contemporary knowledge, to report on the ongoing progress of AR and VR in various fields of dental medicine and education, and to identify the further research required to achieve their translation into clinical practice. AR and VR have been found to be beneficial tools for clinical practice and for enhancing the learning experiences of students during their pre-clinical education and training sessions. Clinicians can use VR technology to show their patients the expected outcomes before the undergo dental procedures. Hence it was concluded that AR and VR can be implemented to overcome dental phobia, which is commonly experienced by pediatric patients.

Greeshma GS et al. (2022)[36] conducted a study to compare VR distraction with TSD and audio distraction. Children, in the age-group of 6 to 8 years, with moderate level of anxiety, (measured with M-DAS), requiring inferior alveolar nerve block (IANB) for mandibular tooth extraction were selected. Selected children were allocated randomly into 3 groups virtual reality (VR) distraction group, audio distraction group and Tell-show-do (TSD) group. Pre- and post-distraction anxiety level of children was measured subjectively with facial image scale and objectively with pulse rate and oxygen saturation (measured with pulse oximeter). There was a statistically significant decrease in pulse rate after distraction in all the three groups. Post distraction pulse rate was lowest in the VR distraction group when compared to other groups. Oxygen saturation increased in all the three groups which was statistically significant. There was a statistically significant difference in the post distraction oxygen (O2) saturation levels between TSD and audio distraction groups with more O2 saturation in audio distraction group. But while comparing the audio distraction with VR group and TSD with VR group, the difference was not significant. Facial image scale (FIS) scores decreased in all the three groups. The overall results revealed by all the parameters indicate that children were most relaxed in VR group, followed by audio group and were least relaxed in TSD group during dental visits. Hence VR distraction can be considered as a useful technique for behavior management of pediatric patients during a conventional dental treatment.

Addab S, Hamdy R, Thorstad K, Le May S, Tsimicalis A(2022)[37] review aimed to identify, analyse and synthesise studies investigating the clinical efficacy of virtual reality (VR) distraction for children undergoing varying painful and anxiety-inducing medical procedures across different hospital settings and to identify implications for research and clinical practice. Reviewed studies collectively included 2,174 patients aged 6 months-18 years used VR during burn wound care, post-burn physiotherapy, dental, needle-related and other procedures. Additionally, ten studies included samples with adults, for which paediatric data could not be isolated (n = 507). Overall, studies supported the efficacy of VR in managing procedural pain and anxiety in the paediatric setting. The study concluded that Virtual reality is redefining pain management by immersing children in a virtual world, reducing pain and anxiety at the hospital. A notable gap was the neglected use of VR in children with chronic conditions receiving orthopaedic procedures as part of their standard care.

Yan X, Yan Y, Cao M, Xie W, O'Connor S, Lee JJ, Ho MH.(2023)[38] **conducted a study** to analyse the effectiveness of virtual reality (VR) distraction intervention for the management of dental anxiety in pediatric patients. A total of 12 RCTs involving 818 participants were included. The result showed that VR distraction interventions were effective in reducing the dental anxiety of paediatric patients. In meta-analysis, the VR distraction interventions had a significant effect on reducing paediatric patients' anxiety during dental treatment. VR distraction interventions could be an effective approach to alleviatethe dental anxiety of paediatric patients.

Zhao N, Fan L, Zeng J, Ran L, Zhang C, Wang J, Yu C (2023)[39] conducted a study with an aim to identify, analyze, and summarize the clinical efficacy of virtual reality (VR) distraction therapy for oral treatment in different hospital settings in contrast to medical interventions that induce anxiety and pain. Furthermore, this review aimed to determine the implications for research and clinical practice of VR distraction therapy. One thousand five hundred twenty-two patients aged between 0 and 60 years who used VR during dental

treatment were included in this review. Among these studies, 8 and 14 studies comprised adult and pediatric patients. The reviewed studies underscore the efficacy of VR to mitigate pain and anxiety in the context of dental treatment. VR is an innovative pain and anxiety management approach that facilitates dental treatment patients to immerse themselves in a virtual world while using distractions to reduce pain and anxiety. It was concluded that VR is an effective and novel non-pharmacological method of behavioral management that contributes to improving medication safety for dental patients. VR as a distractive approach can reduce the fear associated with medical interventions and prevent severe pain sensitivity, anxiety, and medical avoidance among adults and children.

Zaidman L, Lusky G, Shmueli A, Halperson E, Moskovitz M, Ram D, Fux-Noy A(2023)[40] conducted a study to examine whether screening content through virtual reality (VR) goggles can diminish pain perception during local anaesthesia administered using the inferior alveolar nerve block technique and rubber dam placement in routine paediatric dental treatment. The study included healthy 4- to 12-year-old children who were scheduled to receive local anaesthesia administered using the inferior alveolar nerve block technique and rubber dam placement in 2 visits. The participants were randomly assigned to undergo 1 treatment performed with Oculus GO VR goggles and the other treatment without. Pain was evaluated using the Wong-Baker FACES Pain Rating Scale and the Modified Behavioral Pain Scale (MBPS). Results: The study group included 29 children. Whilst administering local anaesthesia, no significant difference was observed in the Wong-Baker FACES Pain Rating Scale and in MBPS movements between visits with and without the VR goggles. However, significantly lower pain perception was observed in the other parameters of MBPS when using the VR goggles: Face and Cry

During placement of a rubber dam, significantly less pain was reported by the patients and observed by the assessor when the VR goggles were used. It was concluded that VR can decrease pain perception during rubber dam placement in children, but it has limited benefit during administration of local anaesthesia.

Rosa A, Pujia AM, Docimo R, Arcuri C (2023)[41] reviewed studies in which VR was used for children and adults as a measure against anxiety during dental treatments. VR was defined as a three-dimensional place where patients experience a sense of immersion as they find themselves in attractive and interactive environments that detach them from reality. Anxiety and pain were examined and measured during dental treatments in which VR was used by comparing them with standard care situations. Twenty-five studies were identified, of which eleven met the inclusion criteria. The effect of VR was studied mainly in the pediatric population as a distractive method. Only two studies (not significant) on an adult population were considered. This review concluded that VR is an excellent distraction method that is effective in reducing anxiety before dental treatment.

Bagher SM, Felemban OM, Alandijani AA, Tashkandi MM, Bhadila GY, Bagher AM (2023)[42] conducted a study to evaluate the effect of Virtual Reality Distraction (VRD) on dental anxiety among anxious children undergoing prophylactic dental treatment by utilizing both subjective (Venham Anxiety and Behavioral Rating Scale (VABRS) and objective (heart rate (HR) and salivary cortisol level (SCL) measures. This randomized controlled study included 36 (6- to 14-year-old) healthy and anxious children who needed prophylactic dental treatment and had a history of previous dental treatment. The eligible children's anxiety level was evaluated using a modified version of the Abeer Dental Anxiety Scale Arabic version (M-ACDAS) and those who scored at least 14 or more out of 21 were included. Participants were randomly distributed to either the VRD or control group. In the VRD group, participants wore the VRD eyeglasses during prophylactic dental treatment. In the control group, subjects received their treatment while watching a video cartoon on a regular screen. The participants were videotaped during the treatment, and their HR was recorded at four time points. Also, a sample from each

participant's saliva was collected twice, at the baseline and after the procedure. The mean M-ACDAS score at baseline in the VRD and the control groups was not statistically significant. At the end of the treatment, the SCL was significantly lower in the VRD group. Neither the VABRS nor the HR significantly differed between the VRD and control groups. Virtual reality distraction is a non-invasive method that has the potential to significantly reduce anxiety during prophylactic dental treatment among anxious children.

Pathak PD, Lakade LS, Patil KV, Shah PP, Patel AR, Davalbhakta RN (2023)[43] conducted a study to assess the clinical feasibility and effectiveness of the VR device in reducing pain and anxiety in pediatric patients during mandibular primary molar extraction. This research trial had 30 healthy children between the ages of 6 and 12 who required mandibular primary molar extraction. The subjects were divided into two groups using a simple randomization method. In the study group (n = 15), extraction was carried out using a VR device, whereas, in the control group (n = 15), extraction was carried out without the use of a VR device. Pre and post-extraction anxiety levels were measured by Venham's picture test (VPT) and the heart rate. After the procedure, pain and behavior were evaluated by the Wong-Bakers Faces pain rating scale (WBS) and FLACC Scale respectively. The pre-extraction values of the VPT and heart rate showed no statistically significant difference. This indicates that participants of both groups had a similar level of anxiety at baseline. There was a statistically significant increase between pre and post-heart rates in the control group, with no significant change in the study group. The study concluded that the use of a virtual reality device in children can reduce anxiety during primary molar extractions as evaluated by heart rate. Virtual reality devices might be an adjunct to high-quality dental care and to other behavior management methods.

MATERIALS AND METHODS

The present study was conducted in the Department of Pediatric and Preventive Dentistry, Babu Banarasi Das College of Dental Sciences, BBD University, Lucknow. The aim of the study was to compare the effectiveness of virtual reality distraction and thaumaturgy in managing uncooperative pediatric patients. The present in-vivo study was conducted in children of both the genders between the age groups of 3-13 years.

MATERIALS

- Mouth mask
- Kidney tray
- Sterilized gloves
- Diagnostic instruments
- Virtual reality device
- Light and thumb appliance
- Magic book
- Toy items
- Pulse Oximeter

STUDY SUBJECTS:

- The present in-vivo study was carried out in children of both the genders between the age group of 3-13 years.
- The patients were allocated to two distraction technique groups namely virtual reality distraction and thaumaturgy.

STUDY SAMPLE AND SIZE:

- Healthy subjects aged between 3-13 years were included in the study.
- Sample size estimation was done by using nMaster2.0 (CMC, vellore)

A minimum total sample size of 121 was found to be sufficient for an alpha of 0.05, power of 80% Standard deviation in group I = 0.7

Standard deviation in group II = 0.5
Estimated difference between means = 0.1
Desired confidence level (%) = 80
Required sample size = 121
.

Formula

$$n = \frac{Z^2_{1-\alpha/2}\left[2S_p^2\right]}{d^2}$$

Where, $S_p^2 = \frac{S_1^2 + S_2^2}{2}$

S_1^2 : Standard deviation in the first group

S_2^2 : Standard deviation in the second group

S_p^2 : Pooled standard deviation

d : Precision

α : Significance level

ELIGIBILITY CRITERIA:

❖ Inclusion criteria:

- Children aged between 3 to 13 years.
- Children depicting a negative (Score 2) and positive (Score 3) as on Frankel's behavior rating scale.
- Children undergoing dental procedures with or without local anaesthesia.

❖ Exclusion criteria:

- Children depicting definitely positive and definitely negative (Score 4 and 1) as on Frankel's behavior rating scale.
- Medically compromised children.

SAMPLING METHOD: Simple Random Sampling

METHODOLOGY:

The present study was conducted in Department of Pediatric and Preventive Dentistry, Babu Banarasi Das College of Dental Sciences (BBDCODS) after obtaining clearance from institutional ethical committee. The study was done with an aim to determine the anxiety level of uncooperative pediatric patients by evaluating and comparing virtual reality distraction with thaumaturgy. Eligible participants rated as negative (score 2) and positive (Score 3) on the Frankel's Behavior Rating Scale were randomly assigned to one of either techniques. Simple randomization was implemented by utilizing two colors, and patients were blinded to these colors in a single-blinded technique. Ultimately, they were assigned randomly to one of the two distraction techniques.

The preoperative anxiety levels of all children were evaluated prior to the intervention using the Visual facial anxiety scale (VFAS). This scale consists of six stick-figure representations, each portraying various facial expressions ranging from none(1), mild(2), mild-moderate(3), moderate(4), moderate-high (5), and highest anxiety(6).

The present in-vivo study were carried out in children aged between 3-13 years including both the genders. The participants were grouped in two categories, namely group A and group B which consists of 69 participants in each group. Out of this, 23 participants were in the age range of 3-6 years, 23 in 7-10 years and 23 in 11-13 years in both the groups. Considering the fact that patients be favoring one color over the other, a larger number of participants were included to attain the desired symmetrical sample size. Subsequently, a few samples were omitted to achieve the final desired balance.

Group A: The behavior management of group A participants were done by using Virtual reality distraction.

A virtual reality device was utilized to present a pre-recorded cartoon as a method of audiovisual distraction for children undergoing dental procedures. Various popular cartoons were gathered, and the children were given the opportunity to choose their preferred cartoon to be displayed on the virtual reality device. Subsequently, the virtual reality device was tailored to suit the child's preferences, activated, and the chosen video commenced. The child was then prompted to set the volume at a level that felt comfortable, and adjustments were made accordingly. Then, it was observed whether the pediatric patient was fully engaged in the virtual environment, concentrating on the videos, and effectively isolating themselves from their immediate surroundings. Once the treatment was completed, the device was removed.

The anxiety scores for the participants which were noted before starting the dental procedure, was again noted immediately after the treatment procedure using the same Visual Facial Anxiety Scale (VFAS) which comprises of 6 similarly styled stick-figure reflecting different types of facial expressions indicating none, mild, mild-moderate, moderate, moderate-high, highest anxiety.

Oxygen saturation (SpO2) and pulse rate were also recorded before, during and after the procedures by using pulse oximeter to assess the degree of anxiety.

Group B: The behavior management of group B participants were done by thaumaturgy techniques.

The child is deceived using one of three tricks tailored to their age group. The initial category comprised children aged 3 to 6 years, and within this group, the light and thumb tricks were employed to deceive and distract their attention during dental procedures. This trick utilizes the thumb and a light source. The positioning and movement of the thumb control the amount of light visible to the patient. It used to create a visually captivating effect by manipulating the position and angle of the thumb to make light appear and disappear ultimately making the child divert their attention from the treatment.

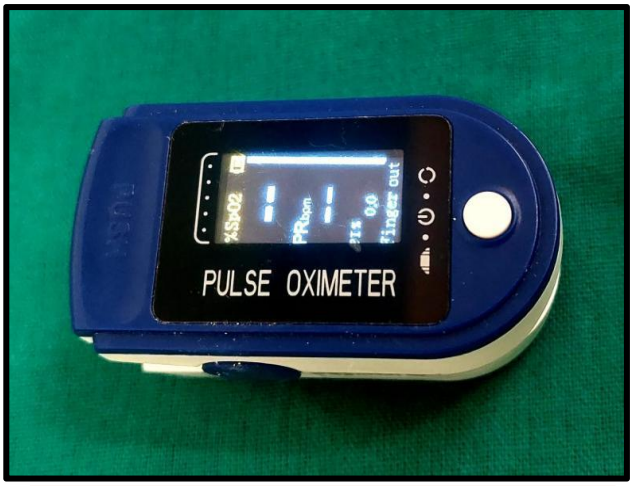
The second cohort consisted of children aged 7 to 10 years. In this group, the book trick, featuring specific cartoon figures, was utilized to deceive and divert the children's attention during dental procedures. In this, we engage the patient in conversation and we present a book in which several well-known cartoon characters were incorporated. We first showed them a black and white version of a certain cartoon character, then in a matter of seconds, we make that same character appear in colour, giving them the impression that we are doing some sort of magic. Finally, we showed them a blank page where that particular cartoon has vanished. In a matter of seconds, it seems as though the animation has mysteriously disappeared or changed colour making their mind wonder about the action and at the same time making them feel distracted and relaxed from the dental procedure going on.

The third group encompassed children aged 11 to 13 years. Within this group, the item trick which consists animal toys were employed to deceive and divert the children's attention during dental procedures. In this technique, animal toys were displayed to the child patients. Before the game, the subject receives a cue card with the name of one of the items. Then, item elimination formula was employed to periodically eliminate one of the items in every round of the game until there is only one item remaining, which is the same item in the cue card.

The anxiety scores for the participants which were noted before starting the dental procedure, were again noted immediately after the treatment procedure using the same scale.

Visual facial anxiety scale (VFAS) which comprises of 6 similarly styled stick- figure reflecting different types of facial expressions indicating none, mild, mild- moderate, moderate, moderate-high, highest anxiety.

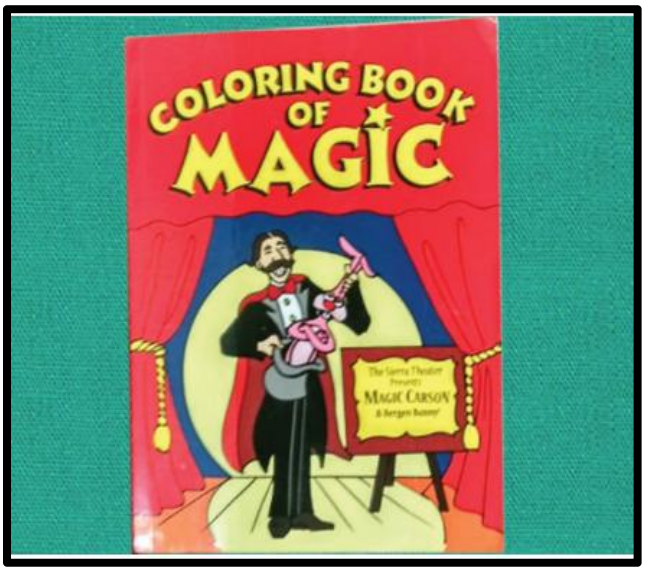
Oxygen saturation (SpO2) and pulse rate were also recorded before, during and after the procedures by using pulse oximeter to assess the degree of anxiety.



Pulse oximeter

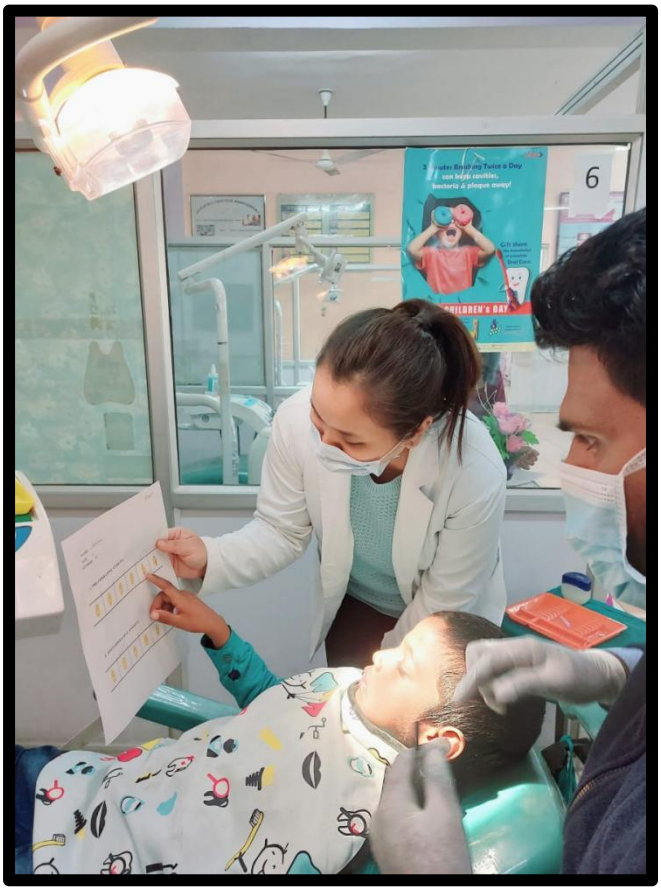
Virtual reality device

Thumb and light trick



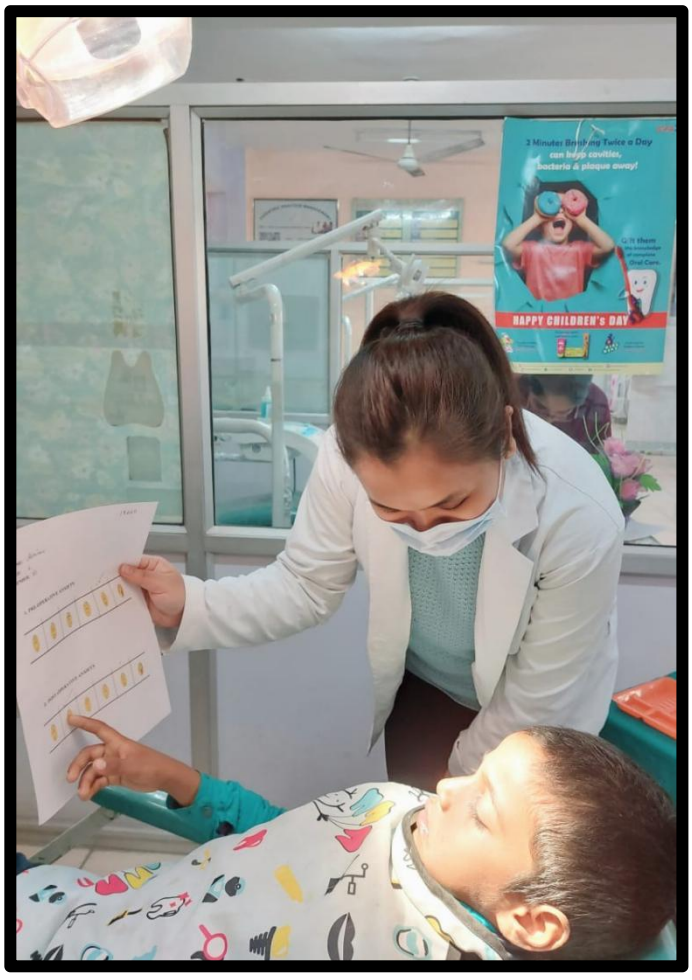
Book trick

Item trick



Pre-operative anxiety assessment

Post-operative anxiety assessment



Behavior Management using Virtual Reality Device

Dental Procedure using Virtual Reality Device

Behavior Management by Thumb and Light trick

Behavior Management by Book trick

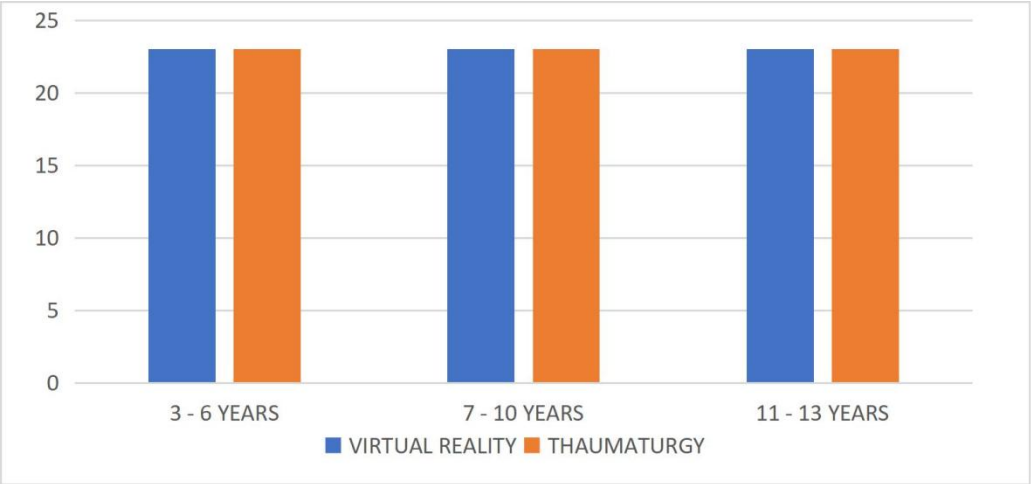
Behavior Management by Item trick

RESULTS AND OBSERVATIONS

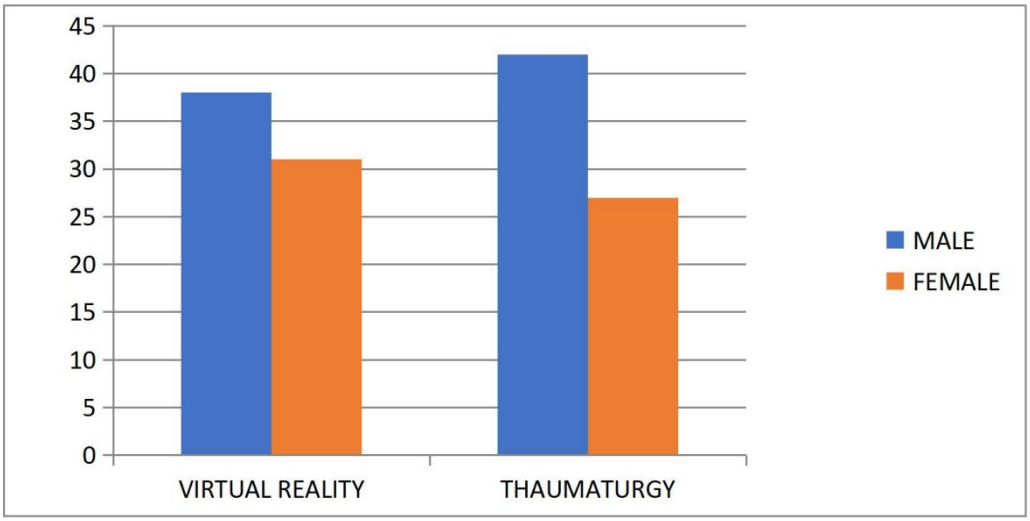
Table 1: Distribution of the study subjects according to age, gender, and frankl rating

Variables		Virtual Reality (Group I)	Thaumaturgy (Group II)
Age	**3 – 6 years**	23 (33.3%)	23 (33.3%)
	7 – 10 years	23 (33.3%)	23 (33.3%)
	11 – 13 years	23 (33.3%)	23 (33.3%)
Gender	**Male**	38 (55.1%)	42 (60.9%)
	Female	31 (44.9%	27 (39.1%)
Frankl rating	**Rating 2**	50 (72.5%)	45 (65.2%)
	Rating 3	19 (27.5%)	24 (34.8%)

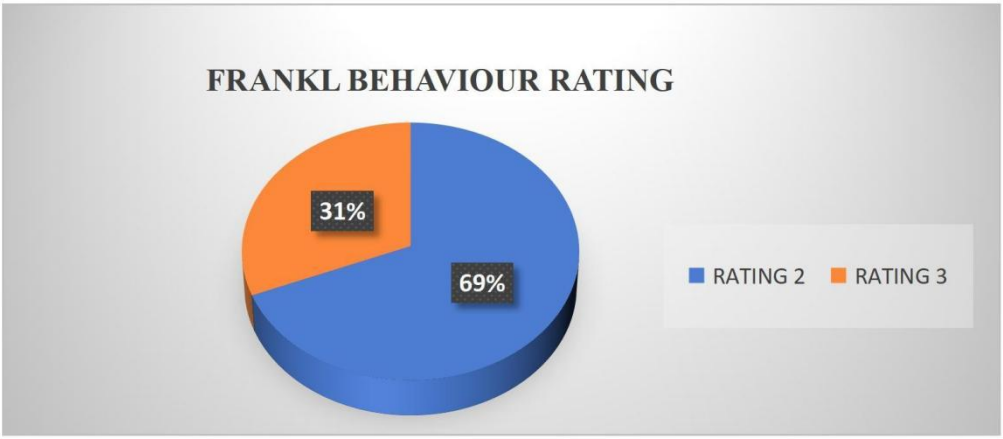
The observation table depicts that in Group I (Virtual Reality) and Group II (Thaumaturgy), out of 69 subjects in each group, 23 were in between age 3 to 6 years, 23 in 7 to 10 years and 23 in 11 to 13 years. Out of this 69 subjects, 38(55.1%) were male and 31(44.9%) were females in Group I while 42(60.9%) were male and 27(39.1%) were females in Group II. There were 50(72.5%) of Frankl rating 2 and 19(27.5%) from Frankl rating 3 in Group I and 45(65.2%) in Frankl rating 2 and 24(34.8%) from Frankl 3 in Group II.



Graph 1: Distribution of the study subjects according to age



Graph 2: Distribution of the study subjects according to gender



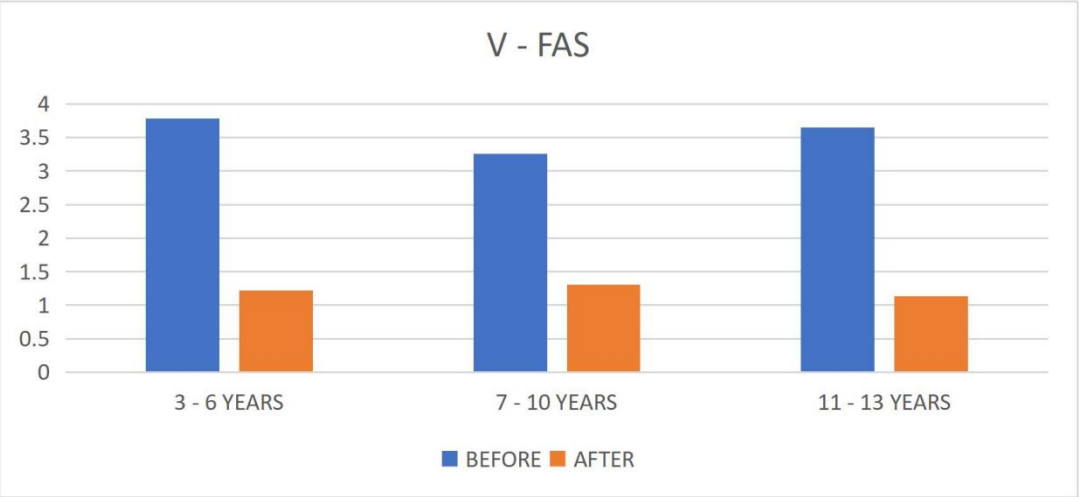
Graph 3: Distribution of the study subjects according to Frankl rating

Table 2– Comparison of Visual facial anxiety score (VFAS) In Virtual reality group

	BEFORE	AFTER	P -VALUE
3 - 6 YEARS	3.78± 0.902	1.22 ± 0.422	0.001*
7 - 10 YEARS	3.26± 1.096	1.30 ± 0.470	0.000*
11 - 13 YEARS	3.65± 0.832	1.13 ± 0.344	0.000*

*t - test. p- value statistically significant ≤ 0.05.

Table 2 and graph 4 shows comparison of VFAS before and after treatment among different age groups in subjects from Virtual reality group. In age group 3-6 years, before treatment the mean score was 3.78± 0.902 and after treatment it was found to be 1.22 ± 0.422 and this was found to be statistically significant (p value = 0.001). In age group 7-10 years, before treatment the mean score was 3.26± 1.096 and after treatment it was found to be 1.30 ± 0.470 and this was found to be statistically significant (p value = 0.000). In age group 11-13 years, before treatment the mean score was 3.65± 0.832 and after treatment it was found to be 1.13 ± 0.344 and this was found to be statistically significant (p value = 0.000).



Graph 4: Comparison of VFAS (1-6) before and after in Virtual reality group

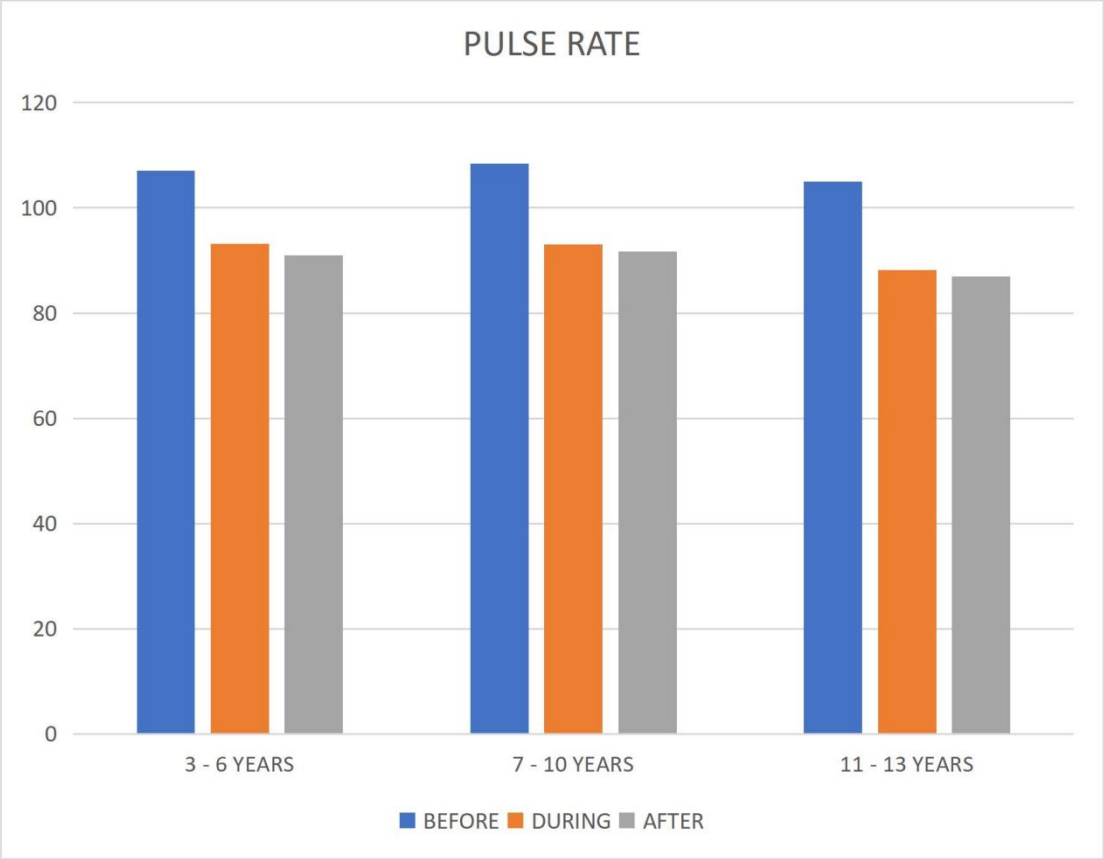
Table 3 - Comparison of pulse rate before, during and after treatment in Virtual reality group

		Mean	P - value
3 – 6 years	**Before**	107.04 ± 12.627	**0.000***
	During	93.22 ± 11.817	
	During	93.22 ± 11.817	**0.000***
	After	93.22 ± 11.817	
	Before	107.04 ± 12.627	**0.000***
	After	93.22 ± 11.817	
7 – 10 years	**Before**	108.43 ± 5.534	**0.001***
	During	93.09 ± 7.064	
	During	93.09 ± 7.064	0.514
	After	91.65 ± 7.786	
	Before	108.43 ± 5.534	**0.000***
	After	91.65 ± 7.786	
11 – 13 years	**Before**	105.04 ± 6.350	**0.001***
	During	88.13 ± 7.40	
	During	88.13 ± 7.40	0.597
	After	86.96 ± 7.535	
	Before	105.04 ± 6.350	**0.001***
	After	86.96 ± 7.535	

Post hoc test. p - value statistically significant ≤ 0.05.

Table 3 and graph 5 shows the post hoc comparisons of pulse rate before, during and after treatment among various age group subjects from Virtual reality group. The comparisons of pulse rate among 3–6 aged group between baseline and during treatment, during treatment and after treatment and for baseline and after treatment were found to be statistically significant (p= 0.000 each) for 7–10 age group the comparisons of pulse rate between baseline and during treatment (p=0.001) and for baseline and after treatment (p=0.000) were found to be statistically significant but for during treatment and after treatment (p=0.514) it was found to be statistically non-

significant. Whereas among 11–13 years aged subjects the comparisons of pulse rate between baseline and during treatment (p=0.001) and for baseline and after treatment (p=0.001) were found to be statistically significant but for during treatment and after treatment (p=0.597) it was found to be statistically non-significant.



Graph 5: Comparison of pulse rate before, during and after treatment in Virtual reality group

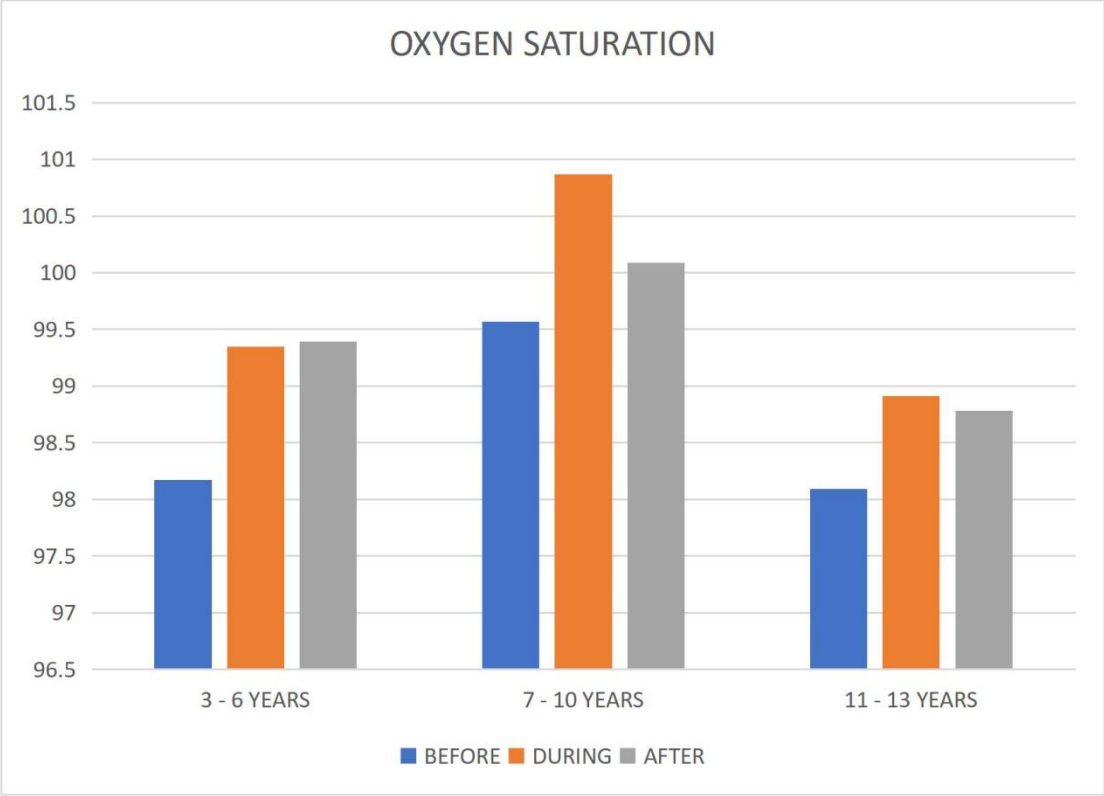
Table 4 - Comparison of oxygen saturation before, during and after treatment in Virtual reality group

		Mean	P - value
3 – 6 years	**Before**	98.17 ±1.696	0.074
	During	99.35 ±2.587	
	During	99.35 ±2.587	0.957
	After	99.39 ±2.407	
	Before	98.17 ±1.696	0.053
	After	99.39 ± 2.407	
7 – 10 years	**Before**	99.57 ± 3.752	0.364
	During	100.87 ±5.675	
	During	100.87 ±5.675	0.604
	After	100.09 ±4.389	
	Before	99.57 ± 3.752	0.6679
	After	100.09 ±4.389	
11 – 13 years	**Before**	98.09 ± 1.998	0.205
	During	98.91 ±2.314	
	During	98.91 ±2.314	0.844
	After	98.78 ±2.131	
	Before	98.09 ± 1.998	0.263
	After	98.78 ±2.131	

Post hoc test. p - value statistically significant ≤ 0.05.

Table 4 and graph 6 shows the post hoc comparisons of oxygen saturation before, during and after treatment among various age group subjects from Virtual reality group. Among 3-6 age group subjects, the comparisons of oxygen saturations between baseline and during treatment (p=0.074), during treatment and after treatment (p= 0.957) and for baseline and after treatment (p=0.053) were found to be statistically non-significant. Among 7-10 years age group subjects, comparisons of oxygen saturations between baseline and during treatment (p=0.364), during treatment and after treatment (p=0.604) and for baseline and after treatment (p=0.667)

were found to be statistically non-significant. Whereas among 11-13 years aged subjects, comparisons of oxygen saturations between baseline and during treatment (p=0.205), during treatment and after treatment (p=0.844) and for baseline and after treatment (p = 0.263) were found to be statistically non-significant.



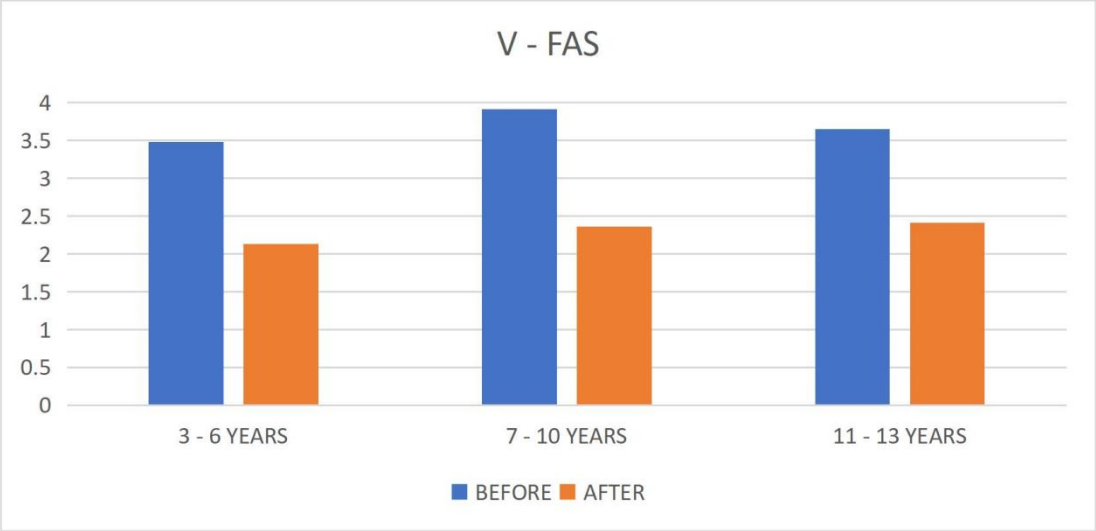
Graph 6: Comparison of oxygen saturation before, during and after treatment in Virtual reality group

Table 5– Comparison of VFAS (1-6) before and after treatment in thaumaturgy group

	BEFORE	AFTER	P – VALUE
3 - 6 YEARS	3.48 ±0.846	2.13 ± 0.920	0.000*
7 - 10 YEARS	3.91± 0.811	2.36 ± 0.790	0.000*
t11 - 13 YEARS	3.65± 0.714	2.41± 0.915	0.000*

*t - test. p- value statistically significant ≤ 0.05.

Table 5 and graph 7 shows comparison of VFAS before and after treatment among different age groups in subjects from thaumaturgy group. In age group 3-6 years, before treatment the mean score was 3.48 ±0.846 and after treatment it was found to be 2.13 ± 0.920 and this was found to be statistically significant (p value = 0.001). In age group 7-10 years, before treatment the mean score was 3.91± 0.811 and after treatment it was found to be 2.36 ± 0.790 and this was found to be statistically significant (p value = 0.000). In age group 11-13 years, before treatment the mean score was 3.65± 0.714 and after treatment it was found to be 2.41± 0.915 and this was found to be statistically significant (p value = 0.000).



Graph 7: Comparison of VFAS (1-6) before and after treatment in Thaumaturgy group

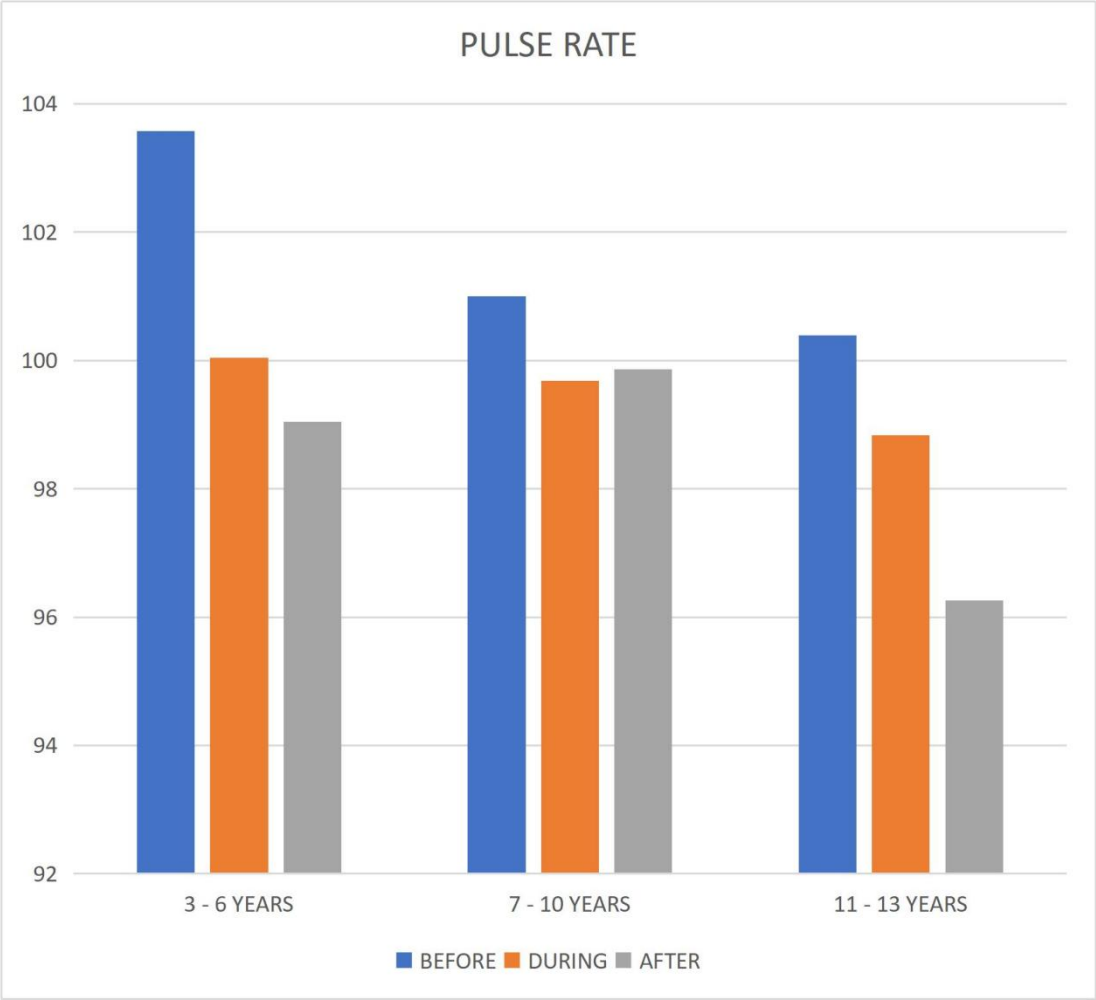
Table 6 - Comparison of pulse rate before, during and after treatment in Thaumaturgy group

		Mean	P - value
3 – 6 years	**Before**	103.57±9.624	0.219
	During	100.04±9.613	
	During	100.04±9.613	0.739
	After	99.04±10.632	
	Before	103.57±9.624	0.137
	After	99.04±10.632	
7 – 10 years	**Before**	101.00 ± 13.119	0.734
	During	99.68 ± 13.091	
	During	99.68 ± 13.091	0.926
	After	99.86 ± 12.800	
	Before	101.00 ± 13.119	0.766
	After	99.86 ± 12.800	
11 – 13 years	**Before**	100.39 ± 11.048	0.636
	During	98.83 ± 11.175	
	During	98.83 ± 11.175	0.426
	After	96.26 ± 10.562	
	Before	100.39 ± 11.048	0.201
	After	96.26 ± 10.562	

Post hoc test. p - value statistically significant ≤ 0.05.

Table 6 and graph 8 shows the post hoc comparisons of pulse rate before, during and after treatment among various age group subjects from thaumaturgy group. Among 3-6 years aged subjects from thaumaturgy group, comparisons of pulse rate between baseline and during treatment (p=0.219), during treatment and after treatment (p= 0.739) and for baseline and after treatment (0.137) were found to be statistically non-significant. Among 7-10 years aged subjects, comparisons of pulse

rate between baseline and during treatment (p=0.734), during treatment and after treatment (p= 0.926) and for baseline and after treatment (0.766) were found to be statistically non-significant. Whereas among 11–13 years aged subjects, comparisons of pulse rate between baseline and during treatment (p=0.636), during treatment and after treatment (p=0.426) and for baseline and after treatment (0.201) were found to be statistically non–significant.



Graph 8: Comparison of pulse rate before, during and after treatment in Thaumaturgy group

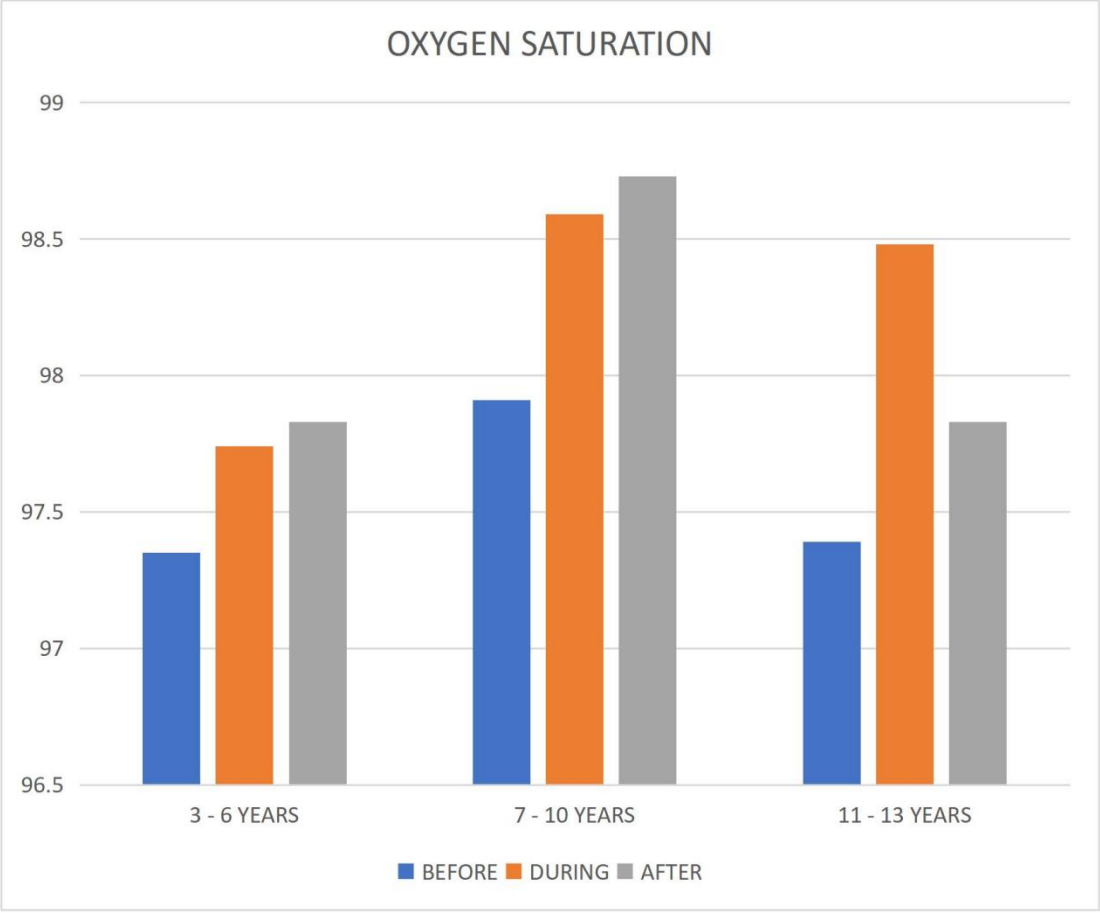
Table 7 - Comparison of oxygen saturation before, during and after treatment in Thaumaturgy group

		Mean	P - value
3 – 6 years	**Before**	97.35 ± 1.774	0.494
	During	97.74 ± 2.050	
	During	97.74 ± 2.050	0.879
	After	97.83 ± 1.946	
	Before	97.35 ± 1.774	0.386
	After	97.83 ± 1.946	
7 – 10 years	**Before**	97.91 ± 1.477	**0.050***
	During	98.59 ± 0.666	
	During	98.59 ± 0.666	0.441
	After	98.73 ± 0.550	
	Before	97.91 ± 1.477	**0.016***
	After	98.73 ± 0.550	
11 – 13 years	**Before**	97.39 ± 1.751	**0.011***
	During	98.48 ± 0.898	
	During	98.48 ± 0.898	0.208
	After	97.83 ± 2.269	
	Before	97.39 ± 1.751	0.465
	After	97.83 ± 2.269	

Post hoc test. p - value statistically significant ≤ 0.05.

Table 7 and graph 9 shows the post hoc comparisons of oxygen saturation before, during and after treatment among various age group subjects from thaumaturgy group. Among 3-6 age group subjects, the comparisons of oxygen saturations between baseline and during treatment (p=0.494), during treatment and after treatment (p= 0.879) and for baseline and after treatment (0.386) were found to be

statistically non –significant. For subjects of 7–10 years age group, the comparisons of oxygen saturations between baseline and during treatment (p=0.050) and for baseline and after treatment (p=0.016) were found to be statistically significant but for during treatment and after treatment (p=0.441) it was found to be statistically non–significant. For the subjects from 11–13 years age group the comparisons of oxygen saturations between baseline and during treatment (p=0.011) was found to be statistically significant whereas comparisons during treatment and after treatment (p=0.208) and for baseline and after treatment (p=0.465) were found to be statistically non–significant.



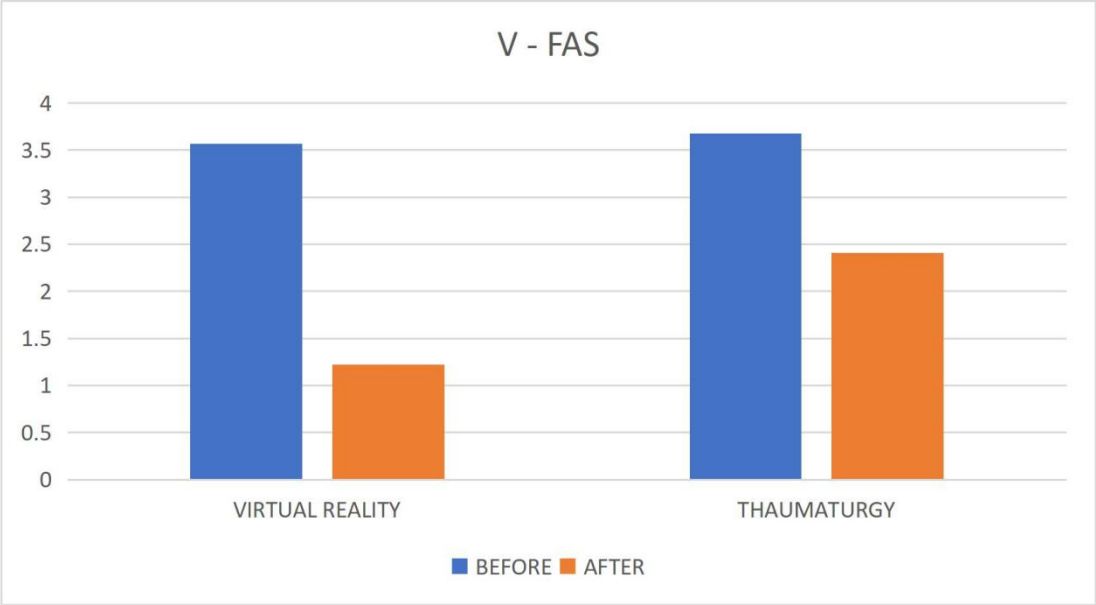
Graph 9: Comparison of oxygen saturation before, during and after treatment in Thaumaturgy group

Table 8– Comparison of VFAS (1-6) before and after treatment in Virtual reality group and Thaumaturgy group

		VIRTUAL REALITY	THAUMATURGY	P – VALUE
BEFORE	**3 - 6 YEARS**	3.78 ± 0.902	3.48 ± 0.846	0.250
	7 - 10 YEARS	3.26 ± 1.096	3.91 ± 0.811	**0.0271***
	11- 13 YEARS	3.65 ± 0.832	3.65 ± 0.714	1.000
AFTER	**3 - 6 YEARS**	1.22 ± 0.422	2.13 ± 0.920	**0.001***
	7 - 10 YEARS	1.30 ± 0.470	2.36 ± 0.790	**0.000***
	11- 13 YEARS	1.13 ± 0.344	2.41 ± 0.915	**0.000***

*t - test. p- value statistically significant ≤ 0.05.

Table 8 and graph 10 shows comparison of VFAS before and after treatment among different age groups in subjects from Virtual reality and thaumaturgy group. In age group 3-6 years, before treatment the mean score was 3.78 ± 0.902 and 3.48 ± 0.846 for Virtual reality group and thaumaturgy group respectively, which is non significant (p value = 0.250) and after treatment it was found to be 1.22 ± 0.422 and 2.13 ± 0.920 in Virtual reality group and thaumaturgy group respectively and this was found to be statistically significant (p value = 0.001). In age group 7-10 years, before treatment the mean score was 3.26 ± 1.096 and 3.91 ± 0.811 for Virtual reality group and thaumaturgy group respectively which is statistically significant (p value = 0.0271), and after treatment it was found to be 1.30 ± 0.470 and 2.36 ± 0.790 and this was also found to be statistically significant (p value = 0.000). In age group 11-13 years, before treatment the mean score was 3.65 ± 0.832 and 3.65 ± 0.714 in Virtual reality group and thaumaturgy group respectively which is statistically non significant (p value = 1.000) and after treatment it was found to be 1.13 ± 0.344 and 2.41 ± 0.915 for Virtual reality group and thaumaturgy group respectively and this was found to be statistically significant (p value = 0.000).



Graph 10: Comparison of VFAS (1-6) before and after treatment in Virtual reality group and Thaumaturgy group

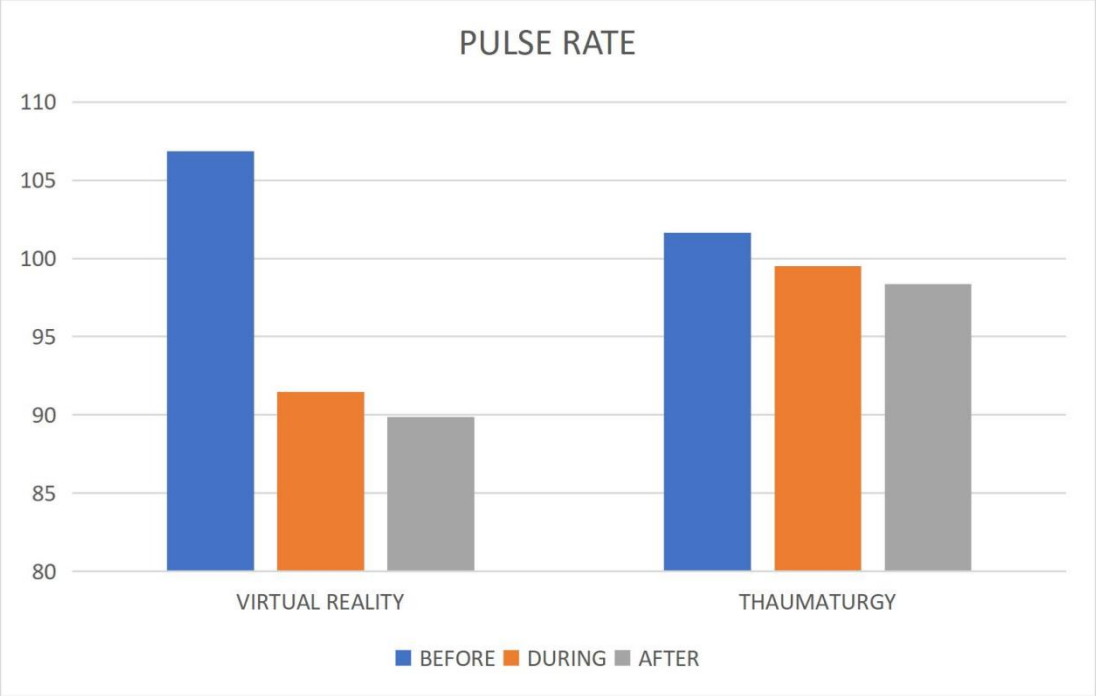
Table 9 – Comparison of pulse rate before and after treatment in Virtual reality group and Thaumaturgy group

		VIRTUAL REALITY	THAUMATURGY	P – VALUE
BEFORE	**3 - 6 YEARS**	107.04 ± 12.627	103.57 ± 9.624	0.3003
	7 - 10 YEARS	108.43 ± 5.534	101.00 ± 13.119	**0.0161***
	11 - 13 YEARS	105.04 ± 6.350	100.39 ± 11.048	0.087
DURING	**3 - 6 YEARS**	93.22 ± 11.817	100.04 ± 9.613	**0.0373***
	7 - 10 YEARS	93.09 ± 7.064	99.68 ± 13.091	**0.039***
	11 - 13 YEARS	88.13 ± 7.40	98.83 ± 11.175	**0.004***
AFTER	**3 - 6 YEARS**	90.96 ± 11.356	99.04 ± 10.632	**0.0166***
	7 - 10 YEARS	91.65 ± 7.786	99.86 ± 12.800	**0.011***
	11 - 13 YEARS	86.96 ± 7.535	96.26 ± 10.562	**0.0013***

*t- test. p- value statistically significant ≤ 0.05.

Table 9 and graph 11 shows comparison of pulse rate before and after treatment among different age groups in subjects from Virtual realityand thaumaturgy group. In age group 3-6 years, before treatment the mean score was 107.04 ± 12.627 and 103.57 ± 9.624 for Virtual reality group and thaumaturgy group respectively, which is non significant (p value= 0.3003); during treatment the mean score was 93.22 ± 11.817 and 100.04 ± 9.613 for Virtual reality group and thaumaturgy group respectively and this was found to be statistically significant (p value = 0.0373) and after treatment it was found to be 90.96 ± 11.356 and 99.04 ± 10.632 in Virtual reality group and thaumaturgy group respectively and this was found to be statistically significant (p value = 0.0166). In age group 7-10 years, before treatment

the mean score was 108.43 ± 5.534 and 101.00 ± 13.119 for Virtual reality group and thaumaturgy group respectively which is statistically significant (p value = 0.0161); during treatment the mean value was 93.09 ± 7.064 and 99.68 ± 13.091 for Virtual reality group and thaumaturgy group respectively which is statistically significant (p value = 0.039); and after treatment it was found to be 91.65 ± 7.786 and 99.86 ± 12.800, this was also found to be statistically significant (p value = 0.011). In age group 11-13 years, before treatment the mean score was 105.04 ± 6.350 and 100.39 ± 11.048 in Virtual reality group and thaumaturgy group respectively which is statistically non significant (p value = 0.087); during treatment the mean score was 88.13 ± 7.40 and 98.83 ± 11.175 respectively for Virtual reality and thaumaturgy which was found to be statistically significant (p value= 0.004) and after treatment it was found to be 86.96 ± 7.535 and 96.26 ± 10.562 for Virtual reality group and thaumaturgy group respectively and this was found to be statistically significant (p value = 0.0013)



Graph 11: – Comparison of pulse rate before and after treatment in Virtual reality group and Thaumaturgy group

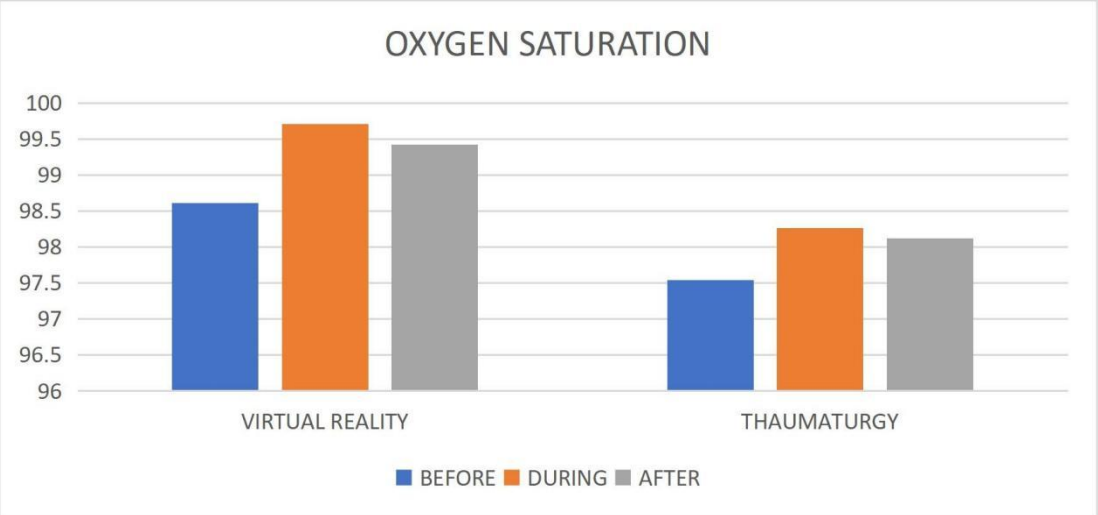
Table 10 – Comparison of oxygen saturation before, during and after treatment in Virtual reality group and Thaumaturgy group

		VIRTUAL REALITY	THAUMATURGY	P – VALUE
BEFORE	**3 - 6 YEARS**	98.17 ± 1.696	97.35 ± 1.774	0.116
	7 - 10 YEARS	99.57 ± 3.752	97.91 ± 1.477	0.054
	11-13 YEARS	98.09 ± 1.998	97.39 ± 1.751	0.213
DURING	**3 - 6 YEARS**	99.35 ± 2.587	97.74 ± 2.050	**0.024***
	7 - 10 YEARS	100.87 ± 5.675	98.59 ± 0.666	0.062
	11-13 YEARS	98.91 ± 2.314	98.48 ± 0.898	0.411
AFTER	**3 - 6 YEARS**	99.39 ± 2.407	97.83 ± 1.946	**0.019***
	7 - 10 YEARS	100.09 ± 4.389	98.73 ± 0.550	0.147
	11 - 13 YEARS	98.78 ± 2.131	97.83 ± 2.269	0.150

*t - test. p- value statistically significant ≤ 0.05.

Table 10 and graph 12 shows comparison of oxygen saturation before and after treatment among different age groups in subjects from Virtual reality and thaumaturgy group. In age group 3-6 years, before treatment the mean score was 98.17 ± 1.696 and 97.35 ± 1.774 for Virtual reality group and thaumaturgy group respectively, which is non significant (p value= 0.116); during treatment the mean score was 99.35 ± 2.587 and 97.74 ± 2.050 for Virtual reality group and thaumaturgy group respectively and this was found to be statistically significant (p value=0.024) and after treatment it was found to be 99.39 ± 2.407 and 97.83 ± 1.946 in Virtual reality group and thaumaturgy group respectively and this was found to be statistically significant (p value = 0.019). In age group 7-10 years, before treatment

the mean score was 99.57 ± 3.752 and 97.91 ± 1.477 for Virtual reality group and thaumaturgy group respectively which is statistically non significant (p value = 0.054); during treatment the mean value was 100.87 ± 5.675 and 98.59 ± 0.666 for Virtual reality group and thaumaturgy group respectively which is statistically non significant (p value = 0.062); and after treatment it was found to be 100.09 ± 4.389 and 98.73 ± 0.550 , this was also found to be statistically non significant (p value = 0.147). In age group 11-13 years, before treatment the mean score was 98.09 ± 1.998 and 97.39 ± 1.751 in Virtual reality group and thaumaturgy group respectively which is statistically non significant (p value =0.213); during treatment the mean score was 98.91 ± 2.314 and 98.48 ± 0.898 respectively for Virtual reality and thaumaturgy which was found to be statistically non significant (p value=0.411) and after treatment it was found to be 98.78 ± 2.131 and 97.83 ± 2.269 for Virtual reality group and thaumaturgy group respectively and this was found to be statistically non significant (p value = 0.150).



Graph 12: Comparison of oxygen saturation before, during and after treatment in Virtual reality group and Thaumaturgy

DISCUSSION

In the field of paediatric dentistry, dental anxiety is a frequent occurrence that can profoundly affect a child's perception and attitude towards dental care. This pertains to the anxiety or uneasiness that child could experience after dental procedure, examinations, or even simple dental appointments. Recognising and treating dental anxiety is essential to encouraging good oral hygiene practices from a young age. Dental anxiety is defined as "an abnormal fear or dread of visiting the dentist for preventive care or therapy and unwarranted anxiety over dental procedures.[44] Pediatric dentists have received specialised training in treating dental anxiety in child and fostering a calm, happy atmosphere. They employ various strategies to alleviate fear and make the dental experience more enjoyable.

Management techniques have been provided to alleviate distress during dental treatment in children and are largely split into two broad categories. Non pharmacological behavioral strategies such as the tell-show-do method, distraction, inspiration, modelling, and hypnotism are covered in the first category. Pharmacologic methods comes in the second category.[8] Of these, children's anxiety can be effectively reduced by using the distraction technique.[45] Distraction is a psychobehavioral method employed in medical and dental settings, involves employing non-aversive techniques to alleviate a child's discomfort by redirecting their focus away from the primary task. This approach aims to ensure successful and high-quality treatment.[46,47]

The present study was conducted to evaluate and compare the effectiveness of distraction using virtual reality device and thaumaturgy on anxiety levels in children undergoing the invasive and non invasive dental procedures.

There are various distraction techniques, with virtual reality devices proving more effective than traditional methods. When a child uses a virtual reality device, they immerse themselves in a lifelike environment, experiencing multisensory

distractions. By staying focused on the screen, the child effectively blocks out the sights of dental treatment. Additionally, the accompanying audio from the virtual reality program helps the child overcome the unpleasant sounds associated with dental tools such as the handpiece and airotor.[7] Virtual reality is the most immersive medium, and the level of immersion in the presented stimuli directly influences the extent to which an individual's attention is diverted from the real world. This diversion results in a reduced capacity to process other real-world elements, including painful stimuli.[48,49] Therefore, virtual reality was selected as one of the modalities for behavior management in this study.

Thaumaturgy is an innovative technique employed for handling strong-willed children, aiming to distract and relax the child, facilitating dentists in carrying out essential treatments.[6] **Bonewits** defined thaumaturgy as “the use of the magic for non-religious purposes, the art and science of wonderworking”.[50] Hence, thaumaturgy was chosen as one of the modalities for behavior management in this study.

The present in vivo study was planned to evaluate and compare the virtual reality distraction(Group I) and thaumaturgy(Group II) in managing anxious pediatric patients. This was a simple randomized trial in which total of 138 participants, 69 in each group were treated under virtual reality and thaumaturgy distraction techniques. Three age groups (3–6 years, 7–10 years, and 11–13 years) were categorized based on the cognitive development of the children in which 23 participants were taken in each age group for both the groups (Table 1 and Graph 1). The children's cognitive development had a major impact on the technique used for the thaumaturgic group.[9] The brain consists of two hemispheres, namely the left and the right, each assigned specific functions. In right-handed individuals, the left hemisphere is associated with verbal and voluntary skills, playing a role in language, speech analysis, and problem-solving. Conversely, the right hemisphere is linked to non-verbal skills and emotions, overseeing activities like art and music. Additionally, imagination is believed to be associated with the right hemisphere.[51] Hence, while using thaumaturgic procedures, the right hemisphere of the brain

plays a major role. In this group, three types of magic trick were employed for different age groups. The virtual reality group also comprises individuals of the same age group, taking into account the similarity in brain and cognitive development within this particular age.

In children aged between 3-6 years, light and thumb trick was used, book trick in age between 7-10 years and item trick employed at the age range of 11-13 years. According to the study by **Konde S et al.**[9] among children aged 2 to 7 years, there is more advanced development of the right hemisphere of the brain in children within this age range. Children in this group perceived the appearance and disappearance of light as a magical phenomenon. The enchanting effect prompted the child to contemplate the trick during the local anesthetic procedure, fostering cooperative behavior in the subjects. In the 7 to 11 year-old age group, the left hemisphere of the brain begins to develop which is responsible for semi-logical reasoning, analytical thinking, and verbal skills. Subjects in this age group were interested to know the logic behind the trick performed but they were still unable to reason it. The inability to reason out the trick kept the subjects occupied and fascinated during the dental procedure. In the 11 to 13 year-old age group, with both the right and left hemispheres of the brain fully developed, individuals have attained hypothetical reasoning skills that can be applied to any presented situation. Consequently, only the item tick proved effective in anxiety reduction. The cognitive level and the associated diversionary trick played a significant role in fostering a positive attitude and eliciting cooperative behavior in the subjects.

In the present study, anxiety was assessed using both objective and subjective measures. The subjective measure was carried out using the visual facial anxiety scale (VFAS). The new VFAS is quick and easy to administer, and therefore easy to incorporate into routine clinical practice. The preoperative anxiety levels of all children were evaluated prior to the intervention using this scale. VFAS is a pictorial presentation of different facial expressions as a relatable measure of the patient‟s levels of acute [state] anxiety. The dentists merely had to ask the patient to select one of the six facial expressions which most accurately reflects their level

of anxiety at that precise moment in time. The score in the scale was again noted immediately after the treatment procedure using the same VFAS for evaluating the post operative anxiety levels. This tool appears to be a valid tool for assessing the severity of acute anxiety, and could be easily implemented in routine clinical practice without adding significant additional work for the clinical staff.[52] And the objective measure of anxiety was assessed by measuring pulse rate and oxygen saturation with the help of a pulse oximeter. The nervous system, particularly the autonomic nervous system (ANS), regulates the pulse rate, which mirrors negative emotions through physiological parameters like heart rate, respiration, and body temperature. Consequently, the physiological responses of the ANS serve as indicators to discern whether an individual is experiencing stress or anxiety.[53,54] Recognizing pulse rate as a crucial parameter for evaluating anxiety in children, its significance as a physiological indicator of anxiety in children was initially reported by **McCarthy**.[55] Studies by **Messer et al.,**[56] confirmed that the physiological changes occur in the body as a result of dental anxiety. Physiological alterations such as changes in pulse rate or oxygen saturation prove highly valuable in managing the level of anxiety in a patient.

In the present study, pulse oximeter was employed for the measurement of pulse rate and oxygen saturation as it requires no calibration or tissue preparation. The pulse oximeter, a widely accepted method for assessing physiological changes, provides continuous measurements of both the patient's arterial hemoglobin oxygenation and heart rate. Oxygen saturation (SpO2) and pulse rate were recorded before, at the mid and after the treatment by using pulse oximeter to assess the degree of anxiety.

In this study, the anxiety level was measured before and after the treatment in virtual reality group according to the Visual facial anxiety scale (VFAS) in the three different age group and it was found that the anxiety level reduced significantly when measured after the treatment in all the three age groups (Table 2, Graph 4). Similarly, there was also significantly decrease in the anxiety level according to VFAS in all these age groups in Thaumaturgy group since the score

decrease from "before to after the treatment"(Table 5, Graph 7)**.** But in intergroup comparison between virtual reality group and thaumaturgy group, there was a significant difference in the reduction in anxiety score, with the virtual reality group displaying lower post-treatment anxiety levels across all three age groups compared to the thaumaturgy group (Table 8, Graph 10**).**

On comparing pulse rate before, during and after among various age group, subjects from virtual reality group, the comparisons of pulse rate among 3-6 aged group between baseline and during treatment, during treatment and after treatment and for baseline and after treatment, it was found to be statistically significant for 7-10 age group, the comparisons between pulse rate for baseline and during treatment; for baseline and after treatment both were found to be statistically significant. Also, among 11-13 years aged subjects, the comparisons of pulse rate between baseline and during treatment and for baseline and after treatment, the difference were found to be statistically significant (Table 3, Graph 5), which means that the pulse rate in all the age group decline from baseline to after treatment which is an indication that the child were more relaxed and less anxious after the completion of the procedure. In a similar study by **Greeshma SG et al.,**[36] there was significant decrease in pulse rate in VR distraction group. This study and other studies done by **Welderhold et al.**[14] and **Sullivan et al.**[48] show similar results and concluded that the application of virtual reality device is an effective way of distraction in decreasing anxiety level of children. In thaumaturgy, among all the age groups, the difference in pulse rate from baseline to during treatment and after treatment were all observed to be non significant(Table 6, Graph 8). In intergroup comparison between virtual reality group and thaumaturgy group, in all the three age groups 3-6 years, 7-10 years and 11-13 years, it was found that there was statistically significantly difference in the pulse rate between the two groups in which virtual reality group has lesser pulse rate compared to thaumaturgy group while during treatment and after completion of the treatment (Table 9, Graph 11). To the best of our knowledge, there is currently no published data between virtual reality distraction and thaumaturgy distraction till date. However, according to a study **Bansal et al.**[57] there was a

statistically significant difference in pulse rate between a Virtual reality headset (VRH) group and a control group. Also, in a study by **Khandelwar et al.**[58] the post distraction pulse rate scores was declined to a minimum in audio-visual distraction group when compared to the other distraction group. Similar studies were also conducted by **Prabhakar et al.,**[7] **Hoffman et al.**[59] **and Nilson et al.**[60] in which the results were in accordance with this study and brought to the conclusion that the use of audiovisual distraction during dental treatment was more effective in managing anxious children than using audio distraction solely.

On comparison of oxygen saturation before, during and after treatment in virtual reality group, the difference in the rise of oxygen saturation was found to be statistically non-significant in all the three age groups (Table 4, Graph 6). In thaumaturgy group, oxygen saturation before, during and after treatment in subjects of 7-10 years age group, the comparisons of oxygen saturations between baseline and during treatment and for baseline and after treatment, the difference were found to be statistically significant but for during treatment and after treatment, it was found to be statistically non-significant. For the subjects from 11-13 years age group the comparisons of oxygen saturations between baseline and during treatment, it was found to be statistically significant (Table 7, Graph 9)**.** In intergroup comparison of oxygen saturation of both the groups, the difference were found to be statistically significant in the age group of 3-6 years with more oxygen saturation level in the virtual reality group (Table 10, Graph 12)**.** This result can bring to the conclusion that the oxygen saturation is significantly increase in the Virtual reality group of in age group 3-6 years, while during treatment and after treatment which means that the child were more relaxed and were less anxious. Anxiety due to pain releases corticosteroids, glucagon and catecholamines. This increases the heart rate, constricts the blood vessels and affects the tissue perfusion and oxygenation. Therefore, a reduction in anxiety reverses these processes, leading to an improvement in oxygen saturation. According to study conducted by **Bansal et al.**[57] the distraction group exhibited higher levels of oxygen saturation in comparison to the non-distraction group. Results were similar to a study conducted by **Khandelwal et al.,**[58] in which post

distraction oxygen saturation was highest in audio video distraction (AVD) than tell show do(TSD) technique and concluded that the AVD was found to be more capable in reducing anxiety than TSD. **Aminabadi et al.**[8] reported that virtual reality eyeglasses successfully decreased pain perception and the anxiety state during dental treatment in 4–6-year-old children .Similarly, **Shetty et al.**[20] observed that virtual reality distraction could be used as a successful behavior modification method in 5–8-year-old children.

The findings from this study showed that the utilization of VR distraction effectively reduced anxiety in children during dental procedures. Some other studies have shown that VR distraction has positive effect on pain, anxiety and behavior during medical procedures such as treatment of traumatic injuries, burn care, dental procedures, chemotherapy, injection or blood sampling, and physiotherapy.[7,57,61] The result of the present study was in accordance to **Shetty et al.,**[20] **Chaturvedi et al.,**[62] **Asl Aminabadi et al.**[8] **Wiederhold et al.**[14] and **Sullivan et al.,**[48] where both the pain perception and anxiety were reduced. The impact of Virtual Reality Distraction (VRD) can extend beyond the treatment session, as suggested by a comparison of oxygen saturation levels during and after the treatment. However, these differences were not found to be statistically significant. Moreover, the observed lower pulse rate during the procedure aligns with the notion that the child was in a relaxed state, which is beneficial for the pediatric dentist. The benefits of VR distraction encompass its user-friendly nature, widespread acceptance, safety, economic efficiency, and simplified comprehension of procedures. However, a notable drawback of VR distraction is the challenge of communication with the child while it is in use.[8,17] Moreover, VR distraction has the potential to diminish recollections of the procedure, ensuring that any unpleasant stimuli during the treatment do not influence future appointments. Additionally, it contributes to fostering a positive attitude towards dentists and dental treatments, with lasting effects from adolescence into adulthood.[63]

In conclusion, the present study explored two techniques for managing the behavior and reducing anxiety in pediatric patients across different age groups.

Both virtual reality distraction and thaumaturgic techniques proved effective overall. Virtual reality distraction emerged as particularly successful, demonstrating superiority in anxiety reduction compared to the thaumaturgic techniques. The findings suggest that virtual reality distraction holds promise as a versatile and impactful intervention across various pediatric age ranges.

CONCLUSIONS

The present study was conducted in the Department of Pedodontics and Preventive Dentistry, BBDCODS, Lucknow Uttar Pradesh on 138 children to compare and evaluate the effectiveness of virtual reality distraction and thaumaturgy in managing uncooperative pediatric patients.

Based on the results obtained from the present study, following conclusions have been drawn:

1. Both virtual reality distraction and thaumaturgic technique were effective in managing pediatric patients.

2. Virtual reality distraction was more effective than the light and thumb trick technique in reducing anxiety in children aged between 3-6 years.

3. In 7-10 years group, virtual reality distraction was more effective in reducing the anxiety than that of the book trick technique.

4. Virtual reality distraction was more effective in children aged between 11-13 years than that of item trick technique in reducing anxiety.

5. In all the age groups, virtual reality was more effective in managing pediatric patients than thaumaturgy.

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ANNEXURE-I

BABU BANARASI DAS UNIVERSITY
BBD COLLEGE OF DENTAL SCIENCES, LUCKNOW

INSTITUTIONAL RESEARCH COMMITTEE APPROVAL

The project titled **"A Comparative Evaluation Of Virtual Reality Distraction And Thaumaturgy In Managing Uncooperative Pediatric Patients"** submitted by **Dr Ninapyari Ahanthem** Postgraduate student in the **Department of Pediatric & Preventive Dentistry** for the Thesis Dissertation as part of MDS Curriculum for the academic year 2021-2024 with the accompanying proforma was reviewed by the Institutional Research Committee in its meeting held on **14th September, 2022** at BBDCODS.

The Committee has granted approval on the scientific content of the project. The proposal may now be reviewed by the Institutional Ethics Committee for granting ethical approval.

Prof. Dr. Puneet Ahuja
Chairperson

Dr. Mona Sharma
Co-Chairperson

ANNEXURE-II

BABU BANARASI DAS UNIVERSITY
BBD COLLEGE OF DENTAL SCIENCES, LUCKNOW

BBDCODS/IEC/09/2022 **Dated: 16th September, 2022**

Communication of the Decision of the Xth Institutional Ethics Sub-Committee Meeting

IEC Code: 27

Title of the Project: A Comparative Evaluation Of Virtual Reality Distraction And Thaumaturgy In Managing Uncooperative Pediatric Patients.

Principal Investigator: Dr Ninapyari Ahanthem **Department:** Pediatric & Preventive Dentistry

Name and Address of the Institution: BBD College of Dental Sciences Lucknow.

Type of Submission: New, MDS Project Protocol

Dear Dr Ninapyari Ahanthem,

The Institutional Ethics Sub-Committee meeting comprising following members was held on 15th September, 2022.

1.	Dr. Lakshmi Bala Member Secretary	Prof. and Head, Department of Biochemistry
2.	Dr. Praveen Singh Samant Member	Prof. & Head, Department of Conservative Dentistry & Endodontics
3.	Dr. Jiji George Member	Prof. & Head, Department of Oral Pathology & Microbilogy
4.	Dr. Amrit Tandan Member	Professor, Department of Prosthodontics and Crown & Bridge
5.	Dr. Rana Pratap Maurya Member	Reader, Department of Orthodontics & Dentofacial Orthopaedics

The committee reviewed and discussed your submitted documents of the current MDS Project Protocol in the meeting.
The comments were communicated to PI, thereafter it was revised.

Decisions: The committee approved the above protocol from ethics point of view.

Forwarded by:

Lakshmi Bala 16/09/22

Prof. Dr. Puneet Ahuja
Principal
BBD College of Dental Sciences
BBD University, Lucknow

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Dr. Lakshmi Bala
Member-Secretary
Institutional Ethics Sub-Committee (IEC)
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ANNEXURE-III

Babu Banarasi Das College of Dental Sciences

(Babu Banarasi Das University)
BBD City, Faizabad Road, Lucknow – 226028 (INDIA)

Consent Form (English)

Title of the Study- " A Comparative Evaluation Of Virtual Reality Distraction And Thaumaturgy In Managing Pediatric Patients "

Study Number…….
Subject's Full Name…….
Date of Birth/Age ……
Address of the Subject…….
Phone no. and e-mail address……
Qualification ……
Occupation: Student / Self Employed / Service / Housewife/Other (Please tick as appropriate) Annual income of the Subject……
Name and of the nominees(s) and his relation to the subject (For the purpose of compensation in case of trial related death).

1. I confirm that I have read and understood the Participant Information Document dated……for the above study and have had the opportunity to ask questions. **OR** I have been explained the nature of the study by the Investigator and had the opportunity to ask questions.
2. I understand that my participation in the study is voluntary and given with free will without any duress and that I am free to withdraw at any time, without giving any reason and without my medical care or legal rights being affected.
3. I understand that the sponsor of the project, others working on the Sponsor 's behalf, the Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial. However, I understand that my Identity will not be revealed in any information released to third parties or published.
4. I agree not to restrict the use of any data or results that arise from this study provided sucha use is only for scientific purpose(s).
5. I permit the use of stored sample (tooth/tissue/blood) for future research. **Yes [✓]No [ ]**

I agree to participate in the above study. I have been explained about the complications andside effects, if any, and have fully understood them. I have also read and understood the participant/volunteer's Information document given to me.

Signature (or Thumb impression) of the
Subject/LegallyAcceptable
Representative: …….
Signatory 's Name…….
Date …….
Signature of the Investigator……
Date…….
Study Investigator 's Name.....
Date…….
Signature of the witness……
Date…….
Name of the witness……

Received a signed copy of the PID and duly filled consentform Signature/thumb impression of the subject or legallyacceptable representative Date…….

बाबू बनारसी दास कॉलेज ऑफ डेंटल साइंसेज
(बाबू बनारसी दास विश्वविद्यालय)
बीबीडी सिटी, फैजाबाद रोड, लखनऊ – 226028 (भारत)

सहमति प्रपत्र (हिंदी)

अध्ययन का शीर्षक- "बाल रोगियों के प्रबंधन में आभासी वास्तविकता व्याकुलता और थुमाटुर्जी का तुलनात्मक मूल्यांकन"

अध्ययन संख्या.....
विषय का पूरा नाम.....
जन्म तिथि/आयु .....
विषय का पता.....
फोन नं. और ई-मेल पता.....
योग्यता……..
व्यवसाय: छात्र / स्व नियोजित / सेवा / गृहिणी / अन्य (कृपया उपयुक्त के रूप में टिक करें)
विषय की वार्षिक आय.....
नाम और नामितियों (ओं) और विषय से उनका संबंध (के लिए
परीक्षण से संबंधित मौत के मामले में मुआवजे का उद्देश्य)।

1. मैं पुष्टि करता हूं कि मैंने प्रतिभागी सूचना दस्तावेज दिनांकित पढ़ और समझ लिया है ..... उपरोक्त अध्ययन के लिए और प्रश्न पूछने का अवसर मिला है। या मुझे अन्वेषक द्वारा अध्ययन की प्रकृति के बारे में बताया गया है और प्रश्न पूछने का अवसर मिला है।

2. मैं समझता हूं कि अध्ययन में मेरी भागीदारी स्वैच्छिक है और बिना किसी दबाव के स्वतंत्र इच्छा के साथ दी गई है और मैं किसी भी समय बिना कोई कारण बताए और मेरी चिकित्सा देखभाल या कानूनी अधिकारों को प्रभावित किए बिना वापस लेने के लिए स्वतंत्र हूं।

3. मैं समझता हूं कि परियोजना के प्रायोजक, प्रायोजक की ओर से काम करने वाले अन्य, आचार समिति और नियामक अधिकारियों को वर्तमान अध्ययन और किसी भी आगे के शोध के संबंध में मेरे स्वास्थ्य रिकॉर्ड को देखने के लिए मेरी अनुमति की आवश्यकता नहीं होगी, भले ही मैं परीक्षण से वापस ले लूं। हालांकि, मैं समझता हूं कि मेरी पहचान तीसरे पक्ष को जारी या प्रकाशित किसी भी जानकारी में प्रकट नहीं की जाएगी

4. मैं इस अध्ययन से उत्पन्न होने वाले किसी भी डेटा या परिणामों के उपयोग को प्रतिबंधित नहीं करने के लिए सहमत हूं, बशर्ते कि ऐसा उपयोग केवल वैज्ञानिक उद्देश्य (ओं) के लिए हो।

5.मैं भविष्य के अनुसंधान के लिए संग्रहीत नमूने (दांत / ऊतक / रक्त) के उपयोग की अनुमति देता हूं। हाँ [ ] नहीं [ ]

मैं उपरोक्त अध्ययन में भाग लेने के लिए सहमत हूं। मुझे जटिलताओं और दुष्प्रभावों के बारे में

समझाया गया है, यदि कोई हो, और उन्हें पूरी तरह से समझ लिया है। मैंने मुझे दिए गए प्रतिभागी/स्वयंसेवक के सूचना दस्तावेज को भी पढ़ा और समझा है

विषय / कानूनी रूप से स्वीकार्य प्रतिनिधि के हस्ताक्षर (या अंगूठे का निशान): .....

हस्ताक्षरकर्ता का नाम.....
खजूर……..
अन्वेषक के हस्ताक्षर.....
खजूर……..
अध्ययन अन्वेषक का नाम.....
खजूर……..
गवाह के हस्ताक्षर.....
खजूर……..
गवाह का नाम.....

पीआईडी की एक हस्ताक्षरित प्रति प्राप्त की और विधिवत भरा सहमति फॉर्म विषय के हस्ताक्षर/अंगूठे का निशान या कानूनी रूप से स्वीकार्य प्रतिनिधि तिथि…….

ANNEXURE-IV

Babu Banarasi Das College of Dental Sciences

(Babu Banarasi Das University)

BBD City, Faizabad Road, Lucknow 226028 (INDIA)

PARTICIPANT INFORMATION DOCUMENT

1. Study Title

A comparative evaluation of virtual reality distraction and thaumaturgy in managing uncooperative pediatric patients. Virtual reality distraction is a type of human–computer interaction that allows users to interact with a computer-generated environment in real time. Thaumaturgy is a tool that enables the dentist execute necessary treatment by distracting and relaxing the child.

2. Invitation Paragraph

To participate in this research study, you will be interviewed/ examined and if found to fulfil the criteria, you will be eligible to be enrolled in this research study. Since you are in the age group of 3-13 years we ask your accompanying parent / guardian will also sign a similar form called as the Parent Informed Consent Form.

You are being invited to take part in a research/trial study. Before you decide it is important for you to understand why the research/study is being done and what it will involve. Please take time to read the following information carefully and discuss it with friends, relatives and your treating physician/family doctor if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

3.What is the purpose of the study?

To compare the effectiveness of virtual reality distraction and thaumaturgy in managing pediatric patients.

4. Why have I been chosen?

121 Healthy subjects aged between 3-13 years will be included in the study. Children depicting a negative (Score 2) as on Frankel's behaviour rating scale and children undergoing dental procedures under local anaesthesia are included in the study. Children depicting the positive, definitely positive and definitely negative (Score 3, 4 and 1) as on Frankel's behaviour rating scale and medically compromised children are excluded in the study.

5..Do I have to take part?

You should explain that taking part in the research is entirely voluntary. It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still are free to withdraw at any time and without giving a reason

6.What will happen to me if I take part?

The patient/volunteer will be involved in the research till the treatment procedure ends. It will last for approximately one hour. The patient/volunteer will need to visit the centre for minimumof 1 to maximum of 3 visits.

7. What do I have to do?

There is no lifestyle or dietary restrictions for the patient/volunteer. Patient can continue to take his/her regular medication.

8. What is the procedure that is being tested?

The patients will be allocated to two distraction technique groups namely virtual reality distraction andthaumaturgy. The study will be carried to evaluate and compare the effectiveness of the two techniquesin reducing anxiety.

9.What are the interventions for the study?

Restorative and minimum invasive procedures will be carried out on the participants

10.What are the side effects of taking part?

There is no reports of serious side effects to the patients/volunteer. If anything happens during the procedure, we have skilled personnel and specialized equipment to manage any emergency.

11.What are the possible benefits of taking part?

The participant will be benefited as the required dental treatment will be carried out once the participant goes into non-pharmacological patient distraction technique. This will also help thepatients to get the treatment done with less fear and anxiety.

12. What if new information becomes available?

Sometimes during the course of a research project, new information becomes available about the research being studied. If this happens, your researcher will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw, your researcher/investigator will make arrangements for your withdrawal. If you decide to continue in the study, you may be asked to sign an updated consent form.

13.What happens when the research study stops?

Nothing will happen to the participants.

14. What if something goes wrong?

The problems/complaint will be handled by the HOD or the IRC. If something serious happensthe institute will take care of the problems

15. Will my taking part in this study be kept confidential?

Yes it will be kept confidential.

17.What will happen to the results of the research study?

The results of the study will be used to evaluate and compare the effectiveness of the two techniques in reducing anxiety. The identity of the patient/volunteer will be kept confidential in case of any report/publications.

18.Who is organizing the research?

The research is done in the DEPARTMENT OF PEDIATRIC AND PREVENTIVE DENTISTRY, BBDCODS. The research is self-funded. The participants will have to pay for procedural charges as given by the institution.

19. Will the results of the study be made available after study is over?

Yes

20. Who has reviewed the study?

The HOD and the members of IRC/IEC of the institution has reviewed and approved the study.

21. Contact for further information

You should give the patient a contact address for further information. This can be your name or that of another scientist/investigator involved in the study. **Name of the PI, Address, e-mail address, Telephone Numbers and name , Member Secretary of Ethics Committee of the institution (Dr.Lakshmi Bala, Member Secretary, bbdcods.iec@gmail.com) with address, e-mail address with telephone numbers (ext. no.1291).**

Remember to thank your patient for taking part in thestudy!

The patient information sheet should be dated
The Participant Information document should state that the participant will be given a copy of the information sheet and the signed consent form.

Signature of PI……

Name……..

Date……..

बाबू बनारसी दास कॉलेज ऑफ डेंटल साइंसेज

(बाबू बनारसी दास विश्वविद्यालय)
बीबीडी वसटी, फै जाबाद रोड,
लखनऊ - 226028 (भारत)

प्रवतभागी सूचना दस्ताि जे

1.अध्ययन शीर्षक

"असहयोगी बाल रोगियों के प्रबंधन में आभासी वास्तविकता व्याकुलता और थुमाटुर्जी का तुलनात्मक मूल्यांकन"। आभासी वास्तविकता व्याकुलता एक प्रकार का मानव-कंप्यूटर इंटरैक्शन है जो उपयोगकर्ताओं को वास्तविक समय में कंप्यूटर जनित वातावरण के साथ बातचीत करने की अनुमति देता है। थुमातुर्गी एक ऐसा उपकरण है जो दंत चिकित्सक को बच्चे को विचलित और आराम करके आवश्यक उपचार निष्पादित करने में सक्षम बनाता है।

2.आमंत्रण अनुच्छेद

इस शोध अध्ययन में भाग लेने के लिए, आपको साक्षात्कार / जांच की जाएगी और यदि मानदंडों को पूरा करने के लिए पाया जाता है, तो आप इस शोध अध्ययन में नामांकित होने के पात्र होंगे। चूंकि आप 3-13 वर्ष के आयु वर्ग में हैं, इसलिए हम आपके साथ आने वाले माता-पिता / अभिभावक से भी एक समान फॉर्म पर हस्ताक्षर करेंगे जिसे माता-पिता सूचित सहमति फॉर्म कहा जाता इस शोध अध्ययन में भाग लेने के लिए, आपको साक्षात्कार / जांच की जाएगी और यदि मानदंडों को पूरा करने के लिए पाया जाता है, तो आप इस शोध अध्ययन में नामांकित होने के पात्र होंगे। चूंकि आप 3-13 वर्ष के आयु वर्ग में हैं, इसलिए हम आपके साथ आने वाले माता-पिता / अभिभावक से भी एक समान फॉर्म पर हस्ताक्षर करेंगे जिसे माता-पिता सूचित सहमति फॉर्म कहा जाता है।

3. अध्ययन का उद्देश्य क्या है?

बाल रोगियों के प्रबंधन में आभासी वास्तविकता व्याकुलता और थुमाटुर्जी की प्रभावशीलता की तुलना करने के लिए।

4. मुझे क्यों चुना गया है?

अध्ययन में 3-13 वर्ष की आयु के 121 स्वस्थ विषयों को शामिल किया जाएगा। फ्रैंकेल

के व्यवहार रेटिंग पैमाने के अनुसार नकारात्मक (स्कोर 2) का चित्रण करने वाले बच्चे और स्थानीय संज्ञाहरण के तहत दंत प्रक्रियाओं से गुजरने वाले बच्चों को अध्ययन में शामिल किया गया है। फ्रैंकेल के व्यवहार रेटिंग पैमाने और चिकित्सकीय रूप से समझौता किए गए बच्चों के अनुसार सकारात्मक, निश्चित रूप से सकारात्मक और निश्चित रूप से नकारात्मक (स्कोर 3, 4 और 1) का चित्रण करने वाले बच्चों को अध्ययन में बाहर रखा गया है।

5. क्या मुझे भाग लेना है?

आपको समझाना चाहिए कि अनुसंधान में भाग लेना पूरी तरह से स्वैच्छिक है। यह आपको तय करना है कि भाग लेना है या नहीं। यदि आप भाग लेने का निर्णय लेते हैं तो आपको यह सूचना पत्र रखने के लिए दिया जाएगा और सहमति फॉर्म पर हस्ताक्षर करने के लिए कहा जाएगा। यदि आप भाग लेने का निर्णय लेते हैं तो आप अभी भी किसी भी समय और बिना कारण बताए वापस लेने के लिए स्वतंत्र हैं

6. अगर मैं भाग लेता हूं तो मेरा क्या होगा?

रोगी/स्वयंसेवक उपचार प्रक्रिया समाप्त होने तक अनुसंधान में शामिल रहेंगे। यह लगभग एक घंटे तक चलेगा। रोगी/स्वयंसेवक को न्यूनतम 1 से अधिकतम 3 यात्राओं के लिए केंद्र का दौरा करना होगा।

7. मुझे क्या करना होगा?

रोगी/स्वयंसेवक के लिए कोई जीवनशैली या आहार प्रतिबंध नहीं है। रोगी अपनी नियमित दवा लेना जारी रख सकता है

8. परीक्षण की जा रही प्रक्रिया क्या है?

रोगियों को दो व्याकुलता तकनीक समूहों को आवंटित किया जाएगा, अर्थात् आभासी वास्तविकता व्याकुलता और थुमाटुर्जी। चिंता को कम करने में दो तकनीकों की प्रभावशीलता का मूल्यांकन और तुलना करने के लिए अध्ययन किया जाएगा।

9. अध्ययन के लिए हस्तक्षेप क्या हैं?

प्रतिभागियों पर पुनर्स्थापनात्मक और न्यूनतम इनवेसिव प्रक्रियाएं की जाएंगी

10. भाग लेने के दुष्प्रभाव क्या हैं?

रोगियों/स्वयंसेवकों को गंभीर दुष्प्रभावों की कोई रिपोर्ट नहीं है। यदि प्रक्रिया के दौरान कुछ भी होता है, तो हमारे पास किसी भी आपात स्थिति का प्रबंधन करने के लिए कुशल कर्मी और विशेष उपकरण हैं

11. भाग लेने के संभावित नुकसान और जोखिम क्या हैं?

इस अध्ययन में भाग लेने के कोई नुकसान और जोखिम नहीं हैं

12. क्या होगा यदि नई जानकारी उपलब्ध हो जाए?

कभी-कभी एक शोध परियोजना के दौरान, अध्ययन किए जा रहे शोध के बारे में नई जानकारी उपलब्ध हो जाती है। यदि ऐसा होता है, तो आपका शोधकर्ता आपको इसके बारे में बताएगा और आपके साथ चर्चा करेगा कि क्या आप अध्ययन में जारी रखना चाहते हैं। यदि आप वापस लेने का निर्णय लेते हैं, तो आपका शोधकर्ता/अन्वेषक आपकी वापसी की व्यवस्था करेगा। यदि आप अध्ययन जारी रखने का निर्णय लेते हैं, तो आपको एक अद्यतन सहमति फॉर्म पर हस्ताक्षर करने के लिए कहा जा सकता है।

13. जब शोध अध्ययन बंद हो जाता है तो क्या होता है?

प्रतिभागियों को कुछ नहीं होगा

14. अगर कुछ गलत हो जाए तो क्या होगा?

समस्याओं/शिकायत को विभागाध्यक्ष या आईआरसी द्वारा निपटाया जाएगा। अगर कुछ

गंभीर होता है संस्थान समस्याओं का ध्यान रखेगा

15. क्या इस अध्ययन में मेरा भाग लेना गोपनीय रखा जाएगा?
हां, इसे गोपनीय रखा जाएगा।

16. क्ा इस अध्ययन में मेरे भाग लेने को गोपनीय रखा जाएगा?हां इसे गोपनीय रखा

जाएगा।

17. शोध अध्ययन के परिणामों का क्या होगा?
अध्ययन के परिणामों का उपयोग चिंता को कम करने में दो तकनीकों की प्रभावशीलता का मूल्यांकन और तुलना करने के लिए किया जाएगा। किसी भी रिपोर्ट/प्रकाशन के मामले में रोगी/स्वयंसेवक की पहचान गोपनीय रखी जाएगी।

18 अनुसंधान का आयोजन कौन कर रहा है?

यह शोध बाल चिकित्सा और निवारक दंत चिकित्सा विभाग, बीबीडीसीओडी में किया जाता है। अनुसंधान स्व-वित्त पोषित है। प्रतिभागियों को संस्था द्वारा दिए गए प्रक्रियात्मक शुल्क के लिए भुगतान करना होगा।

19. क्या अध्ययन समाप्त होने के बाद अध्ययन के परिणाम उपलब्ध कराए जाएंगे?
हाँ

20. अध्ययन की समीक्षा किसने की है?
एचओडी और संस्था के आईआरसी/आईईसी के सदस्यों ने अध्ययन की समीक्षा की और उसे मंजूरी दे दी है

21.अधिक जानकारी के लिए संपर्क करें

अधिक जानकारी के लिए आपको रोगी को संपर्क पता देना चाहिए। यह आपका या अध्ययन में शामिल किसी अन्य वैज्ञानिक / अन्वेषक का नाम हो सकता है। पीआई का नाम, पता, ईमेल पता, टेलीफोन नंबर और नाम, संस्था की आचार समिति के सदस्य सचिव (डॉ. लक्ष्मी बाला, सदस्य सचिव, bbdcods.iec@gmail.com) पता, टेलीफोन नंबर के साथ ई-मेल पता (एक्सटेंशन नंबर 1291)

अध्ययन में भाग लेने के लिए अपने मरीज को धन्यवाद देना याद रखें!

रोगी सूचना पत्र दिनांकित होना चाहिए

प्रतिभागी सूचना दस्तावेज में यह बताया जाना चाहिए कि प्रतिभागी को सूचना पत्र और हस्ताक्षरित सहमति फॉर्म की एक प्रति दी जाएगी।

पीआई के हस्ताक्षर.....

नाम.....

खजूर.....

ANNEXURE - V

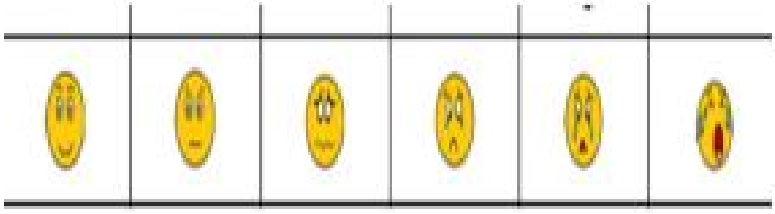
VISUAL FACIAL ANXIETY SCORE (VFAS)

NAME:

AGE:

GENDER:

1. PRE-OPERATIVE ANXIETY



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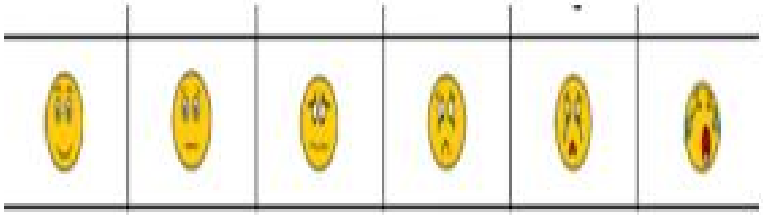

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Paper/Submission ID	1416284
Submitted by	amarpal.singh056@bbdu.ac.in
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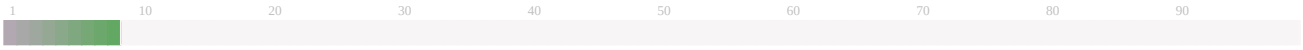

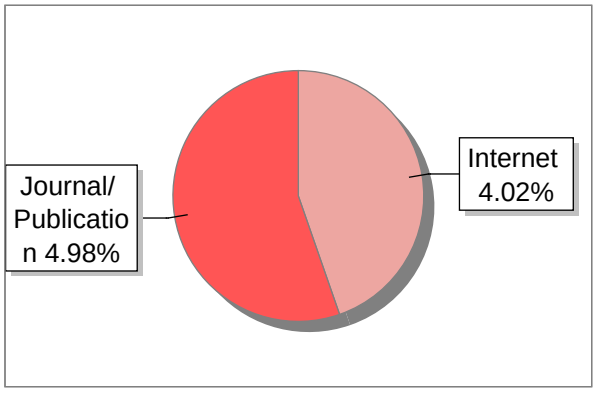

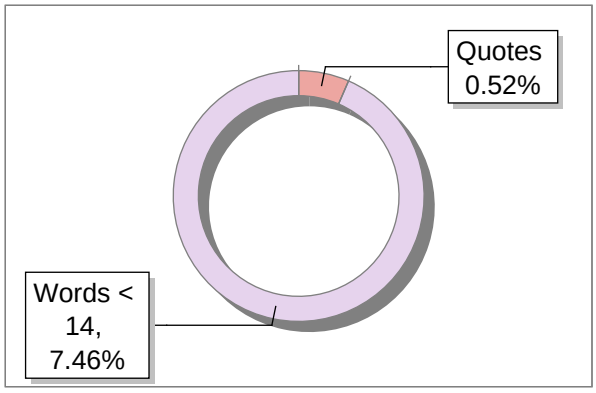

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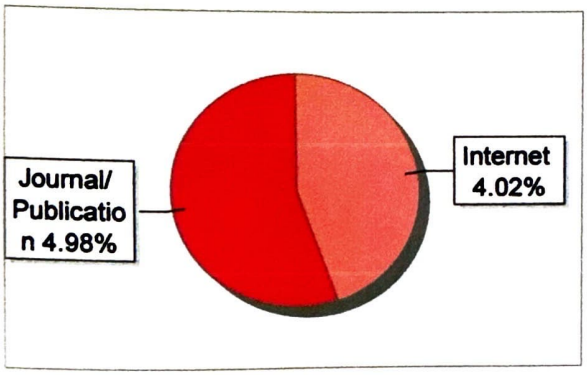

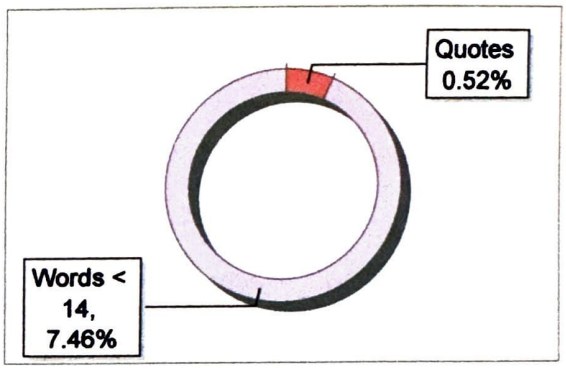

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