THE USE OF VIRTUAL REALITY TECHNOLOGY IN DENTAL MANAGEMENT OF CHILDREN WITH ATTENTION DEFICIT/HYPERACTIVITY DISORDER: A RANDOMIZED CONTROLLED CLINICAL TRIAL

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ABSTRACT

BACKGROUND: There is a limited number of studies addressing behavior management techniques for children with attention-deficit/hyperactivity disorder (ADHD).

AIM: To evaluate and compare the effect of virtual reality (VR) glasses as a distraction method versus conventional behavior management techniques on dental anxiety of children with ADHD and the time during preventive dental management.

MATERIALS AND METHODS: A total of 32 children aged 7-10 years diagnosed with ADHD were enrolled in this study. Participants were randomly divided into two groups, VR glasses (test) and conventional behavior management techniques (control). The intervention was performed in two visits with one-week interval. The preventive procedures included oral examination, prophylaxis, and topical fluoride application on the first visit and fissure sealant application on the second visit. The outcome measures were dental anxiety using the Faces Image Scale (FIS) and Pulse Rate (PR). Length of the procedure was recorded in minutes. Comparisons of age, PR, and procedure time between the two study groups were performed using independent samples t-test, while Mann-Whitney test was used for comparison of FIS scores. Comparisons between different visits within each group were done using Repeated measures ANOVA and Friedman tests.

RESULTS: All children in the VR and control groups showed a significant reduction in FIS scores across the two visits (P=<0.001, 0.005 respectively). However, no significant difference was found between the two groups in the first and second visits (P=0.57, 0.56). The mean PR values didn't differ significantly between the groups during baseline, first, and second visits (P=0.43, 0.14 and 0.68 respectively). Intra-group comparison of mean PR across the visits revealed no significant difference in the VR (P=0.10) and control groups (P=0.44). The length of the procedure didn't differ significantly between the groups in both visits (P=0.13, 0.98).

CONCLUSION: Virtual reality could be a valuable adjunctive method in the dental management of dental anxiety in children with ADHD during preventive dental procedures. Implementing such a technique should be based on the clinical situation, patient's preference, and needs. Future studies are recommended to evaluate the effectiveness of VR distraction during more traumatic dental procedures.

KEYWORDS: Attention Deficit/Hyperactivity Disorder, Dental Anxiety, Virtual Reality

RUNNING TITLE: Virtual reality technology for dental management of children with ADHD.

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INTRODUCTION

Attention-deficit/hyperactivity disorder (ADHD) is one of the most common neurobehavioral disorders of childhood and often lasts into adulthood, thus pediatric dentists are more likely to deal with it (1). The main symptoms of ADHD are inattention, hyperactivity, and impulsivity(2). These symptoms may affect their academic performance and social interactions(1,2). Children with ADHD are exposed to a variety of situations in their daily lives that require adaptation. One such instance is a dental appointment which is connected with dental fear and anxiety(3). Children

with ADHD present more disruptive behavior and behavior management problems than healthy children(4,5). Thus, pediatric dentists may struggle to perform the simplest procedures including examination and oral prophylaxis(6).

Distraction is a non-pharmacological behavior management technique that disrupts the patient's focus away from anxiety-provoking stimuli(7). Traditionally it can be applied in the dental context by counter-stimulation, camouflaging of syringes, asking the patient to move their feet, toys, books, and storytelling. However, advanced distraction techniques may be needed(8). With its combined visual and audible elements, audiovisual distraction could be more effective than conventional distraction techniques as it blocks out visual and auditory stimuli(7). Audiovisual distraction through video eyewear has been reported to be effective in managing dental anxiety and improving the behavior of children with ADHD(9). Virtual Reality (VR) is one of the most recent audiovisual distraction techniques. It has proved to be effective in reducing dental anxiety and improving the behavior of healthy children(8,10,11) and children with autism (6)(12).

The available literature on using VR distraction with ADHD children is sparse (6). Thus, this study aimed to evaluate the effect of using VR distraction versus conventional behavior management techniques on dental anxiety of children with ADHD and the time during preventive dental procedures. The null hypothesis was that there would be no significant difference between VR distraction and conventional behavior management techniques on dental anxiety of ADHD children and the time during preventive measures.

MATERIALS AND METHODS

This study was a parallel randomized controlled clinical trial with allocation ratio 1:1. The study was set up in full accordance with Consolidated Standards of Reporting Trials (CONSORT) guidelines(13). The research protocol was approved by the Research Ethical Committee of the Faculty of Dentistry (IRB NO: #0646-03/2023-IORG 0008839) and the Faculty of Medicine, Alexandria University, Egypt (Serial NO: 0107698-IRB NO:00012098-FWA NO: 00018699). Recruitment of participants and data collection were carried out from July 2023 to December 2023. The trial was registered at ClinicalTrials.gov (NCT06071117) on 10/02/2023.

Sample size estimation

Sample size was based on 95% confidence level to detect differences in anxiety between audio and audiovisual distraction methods. Prabhakar et al.(14) reported mean (SD) anxiety (Venham's scale) in the prophylaxis visit = 0.9 (0.6) and 0.7 (0.5) after using audio and audiovisual distraction methods, respectively. The calculated mean

(SD) difference = 0.2 (0.55), 95% CI [-0.24, 0.63]. The minimum sample size was calculated to be 15 per group, increased to 16 to make up for cases lost to follow up. The total required sample size= number of groups × number per group= $2 \times 16=32$ patients(15).

Study Sample

A total of 32 children were recruited for the study from patients attending the Pediatric Neurology Outpatient Clinic at Smouha Specialized Hospital for Children, Faculty of Medicine, Alexandria University. The trial was carried out at the dental clinic of the same hospital. The inclusion criteria included 7-10-year-old children diagnosed with ADHD according to the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria (2). All children were on stimulant medication (Methylphenidate)(9). The children had positive behavior according to the Frankl Behavioral Rating Scale(16) with no previous dental experience, and with at least one fully erupted first permanent molar indicated for fissure sealant(9). Written consent from parents and/or legal guardians was obtained and children's assent to participate in the study was secured. Children with physical disabilities. visual or hearing impairment, intellectual disabilities, or other psychiatric disorders, were excluded from the study.

Recruitment of trial participants

A total of 50 ADHD children were screened for eligibility. Preliminary screening and assessment of preoperative behavior were done. A detailed medical and dental history was obtained. Out of the 50 children, 10 children were excluded due to their comorbid neurodisabilities (autism, epilepsy, intellectual disability), and 5 children were excluded due to their past dental history. Whereas, 3 parents refused their children to participate in the study. The parents of the remaining 32 children were given a detailed explanation of the benefits and risks of the study and a written consent was obtained.

Randomization technique, allocation concealment, and grouping

Randomization was performed using computergenerated random allocation software. Participants were allocated in blocks of four to one of the study groups. Each child was given a serial number written on identical sheets of paper with the group allocation placed inside opaque envelopes carrying the respective names of the children. Trial-independent personnel was assigned to the role of keeping envelopes and unfolding them. The participants were randomly divided into 2 groups where, in group I (test): 16 children were managed by VR glasses and group II (control): 16 children were managed by conventional behavior management techniques. Blinding of the operator, outcome assessor, and participants was not applicable due to different behavior management techniques. Interventions

An early morning dental appointment was set for all participants. For standardization, all procedures were performed by a single trained operator. Parents were allowed to accompany their children as passive observers. The intervention was split into two visits with one-week interval as a washout period(17). The first visit included a thorough dental examination, oral prophylaxis with a rotary brush, and topical fluoride application (Enamel Pro® Varnish, Premier[®] Dental Company, PA, USA). The second visit included fissure sealant application(18). The selected tooth was brushed, washed, dried, and partially isolated using cotton rolls and highvolume evacuation. Light-cured fissure sealant (Fisseal®, Promedica Dental Material GmbH, Neumuenster, Germany) was used and it was applied according to the manufacturer's instructions.

Virtual reality glasses group (Group I)

Children in this group were distracted for the entire duration of the visit using virtual reality glasses with headphones and adjustable interpupillary distance (Shinecon[®], Dongguan, China). It included a slot for a smartphone with suitable dimensions. Age-appropriate cartoons and movies were played through the device(19). The VR glasses were introduced gradually to the children and they were given some time to accommodate the device before starting the procedure(12). The children were allowed to make their own choice of the cartoon movie. Frequent breaks were provided for the children to explain the procedure and to decrease the likelihood of developing cybersickness(10). Control group (Group II)

Children in this group were managed by the conventional behavior guidance techniques that include TSD, communication, positive reinforcement, and voice control with no adjunctive distraction tools(8).

Outcome assessment and data recording

Dental anxiety measured subjectively using Faces Image Scale (FIS)(20) and objectively using the pulse rate (PR) was considered as the primary outcome. The length of the procedure in minutes was considered as the secondary outcome(20). The FIS is a valid scale with five faces ranging from an extremely sad to an extremely smiley face. The FIS was explained to the children by the operator and they were asked to choose which of the faces they felt like at baseline (preoperatively) and the end of the 1st and 2nd visits.

The pulse rate was measured using a small fingertip pulse oximeter (Beurer GmbH, Ulm, Germany). The readings were taken at the baseline (preoperatively) and every 5 minutes until the end of the 1st and 2nd visits(19). The length of the procedure was recorded by a trained dental assistant using a digital stopwatch. The time was measured from the moment the child entered the

dental clinic to the end of the procedure and recorded in minutes.

Statistical methods

Normality was tested using descriptive statistics, plots (Q-Q plots, boxplots, and histograms), and normality tests. Descriptive statistics were calculated as means and standard deviation (SD) for quantitative normally distributed variables, in addition to medians and interquartile range (IQR) for non-normally distributed variables. Frequencies and percentages were calculated for qualitative variables. Comparisons of age, PR, and procedure time between the two study groups were performed using independent samples t-test, while Mann-Whitney test was used for comparison of FIS scores. Comparisons between different visits within each group were done using Repeated measures ANOVA and Friedman tests. In case of significant results, these tests were followed by multiple pairwise comparisons using Bonferroni adjusted significance level. The significance level was set at p value <0.05. Data were analyzed using IBM SPSS for Windows (Version 26.0, IBM Corp.)

RESULTS

All participants completed the trial with no loss to follow-up (Figure 1). There was no significant difference in the distribution of age and gender in the two groups (P = 0.95 and 1.00 respectively). (Table 1)

The inter-group comparison revealed no statistically significant difference in FIS scores between the two groups at the baseline, first, and second visits (P =0.92, 0.57, and 0.56 respectively). (Figure 2) However, the mean FIS scores for children in the VR group were lower than those in the control group. In the intra-group comparison, children in the VR and control groups showed a significant reduction in the mean FIS scores across the two visits (P=<0.001 and 0.005 respectively). Post-hoc comparison revealed that the children in the VR group showed a statistically significant reduction in the mean FIS scores in the first (1.69 ± 1.08) and second visits (1.31 ± 0.48) compared to the baseline values (3.25 ± 1.53) , (P =0.01, 0.004). Whereas, in the control group, the mean FIS scores decreased significantly only in the second visit (1.69 ± 1.14) compared to the baseline (3.33 ± 1.40) , (P = 0.02). (Figure 2)

Regarding the PR values, the mean PR values were (100.44 ± 9.58) for the VR group at the baseline and (103.56 ± 12.34) for the control group with no statistically significant difference between the two groups (P= 0.43). The mean PR of the children in the VR group was (96.38\pm 6.59) and (100.30\pm 10.53) for the control group during the first visit with no statistically significant difference between the two groups (P=0.14). Whereas, in the second visit the mean PR was (96.72 ± 7.23) for the VR group and (98.08 ±11.01) for the control group.

The inter-group comparison revealed no statistically significant difference in the mean PR between the two groups during the second visit (P=0.68) (Figure 3). However, the mean PR values for children in the VR group were lower than those in the control group. Regarding intragroup comparison, the mean

PR values didn't differ significantly and remained stable across the visits in both VR (P=0.10) and control groups (P=0.44). The total length of the first and second visits didn't differ significantly between the two groups (P=0.13 and 0.98). (Table 2)

Table 1 Sample characteristics

			VR (n= 16)	Control (n=16)	P value
Age ^a		Mean (SD)	8.75 (0.91)	8.78 (1.96)	0.95
Gender ^b	Male	n (%)	12 (75%)	11 (68.8%)	1.00
	Female		4 (25%)	5 (31.3%)	1.00

^a: independent samples t-test was used, ^b: Fisher exact test was used

Table 2 Comparison of the mean	procedure time in minutes	s between the two stud	ly groups
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	VR (n= 16)	Control (n= 16)	P value
	Mean (SD)	P value	
1 st visit	7.30 (0.99)	7.95 (1.37)	0.13
2 nd visit	21.14 (3.25)	21.09 (5.60)	0.98

Independent samples t-test was used

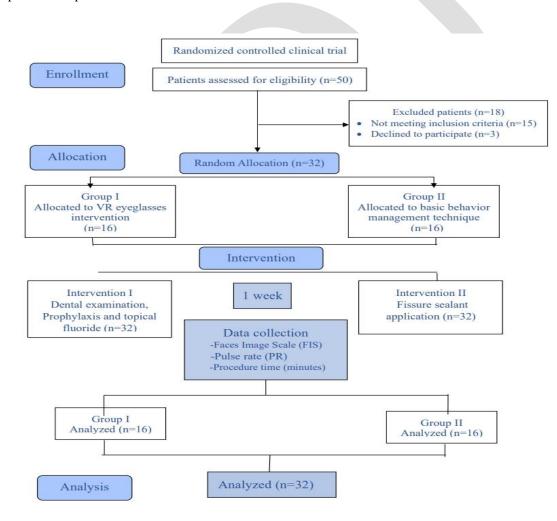


Figure 1 CONSORT flow diagram

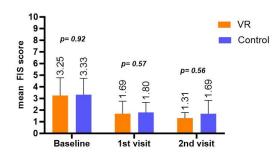


Figure 2 Comparison of FIS scores between the two study **groups at different visits**, error bars represent standard deviation

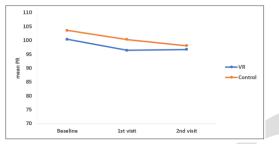


Figure 3 Comparison of mean PR between the two study groups at different visits

DISCUSSION

The current study showed a significant effect of VR as well as conventional behavior management techniques in the reduction of dental anxiety during preventive dental procedures with no significant difference between the two groups, accepting the null hypothesis.

Children and adolescents with ADHD are at higher risk of dental caries as compared to their neurotypical peers(21). Moreover, they may experience a greater level of dental anxiety than healthy children, which may negatively affect the frequency of dental visits and, subsequently, oral health(6) Thus, children with ADHD should necessarily maintain regular appointments with the pediatric dentist. That's why preventive measures were the chosen intervention for the current study. Exposure to multiple painless appointments is less likely to develop dental anxiety than exposure to a traumatic dental experience early in life. (22) That's why the intervention was split into two consecutive dental visits.

The FIS was chosen for assessing dental anxiety subjectively as it has been developed for children with limited cognitive skills so it would be suitable for children with ADHD(20). Children in the two groups showed significantly reduced dental anxiety across the two visits. However, no statistically significant difference was found between the two groups. This could be due to the fact that conventional behavior management techniques were applied for children in both groups while performing non-invasive dental procedures(23). Perhaps the anxiolytic effect of VR distraction is more noticeable if it was used during more painful dental procedures. Additionally, the parental presence might have had a relaxing effect on the children in both groups confounding the results as reported by Al-Khotani et al(7).

Although the self-reported measures of dental anxiety didn't differ significantly between the VR and the control groups, the mean FIS scores were lower for children in the VR group. This might be due to the immersive nature of the VR headset blocking the visual and auditory noxious stimuli in the dental environment resulting in a pleasurable experience.(7,8,19) Distraction through VR glasses has proved to be effective in reducing dental anxiety of children with mild intellectual disability, similar to our results(12). Additionally, VR distraction has shown positive results in managing autistic children(24).

Assessing physiological parameters such as pulse rate allows objective evaluation of anxiety Improvement of mood reduction(23). and enjoyment through distraction influences the autonomic nervous system's activity and prevents the raise of PR during dental procedures(23). The mean pulse rate did not differ significantly between the VR and control groups. The reason for the null findings could be attributed to the VR might have increased anxiety for some children as it completely blocks out the vision (25). The child is not fully aware of the surroundings and a threatening situation may be anticipated. Another reason could be that the pulse rate may reflect the degree of arousal and engagement with the cartoon movie played through the VR glasses(12).

The effective application of distraction techniques requires a significant amount of time for the introduction of the distraction tool and accommodation of the child to the tool (10,23). This could explain why the length of the procedure didn't differ significantly between the test and the control. This is in agreement with Bagattoni et al(26) who reported no significant difference in the length of the appointment with or without audiovisual distraction. Children with ADHD are successfully managed when given an appropriate introduction and explanation of the treatment rather than being forced (5). The length of the procedures didn't exceed 30 minutes (7) due to the short attention span of children with ADHD(27)

Conventional behavior management techniques can reduce dental anxiety and improve patient's behavior allowing safe delivery of highquality dental care. This could explain the anxiety reduction in the control group(8). Additionally, splitting the dental treatment into short visits could have contributed to anxiety reduction. Familiarization of a child with the dental environment and the dental staff through multiple dental visits can positively impact the dental anxiety of the children as reported by previous studies on healthy children(7,17,28), children with autism spectrum disorder(29), and children with ADHD(9).

Based on the findings of this study, the virtual reality distraction technique could be a beneficial adjunctive method in managing children with ADHD(23). However, as VR eyewear blocks vision, it has been clinically observed that some children found it uncomfortable(19). Thus, breaks were provided during VR use between different dental procedures to increase the child's awareness of the dental treatment steps. Breaks are necessary when dealing with children with ADHD due to their short attention span(2). Additionally, breaks help to minimize the likelihood of cybersickness(8)(10). No one of the children in the VR group experienced any nausea, dizziness, or any other harmful side effects.

The current study encountered some limitations, blinding the operator and as participants was not applicable due to different technologies of the distraction methods. More evidence is needed to assess the effectiveness of VR distraction in managing dental anxiety of children with ADHD during traumatic dental procedures such as dental injections. Future studies are needed to further investigate the effect of VR glasses on dental anxiety of children with ADHD of different ages and genders. Additionally, studies on ADHD children with negative behavior or past dental history are recommended. It can be concluded from the current study that the VR distraction technique is beneficial in managing dental anxiety in children with ADHD and could be used as an adjunctive distraction method to conventional behavior management techniques. Virtual reality could be integrated into daily dental practice to manage dental anxiety and help ADHD children to accept treatment on dental chair. Implementing such a technique should be based on the clinical situation, patient's preference, and needs. Future studies are recommended to evaluate the effectiveness of VR distraction during more traumatic dental procedures."

DECLARATION

CONFLICT OF INTEREST:

The authors declare they have no conflict of interest.

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