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ORIGINAL RESEARCH

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The effect of virtual reality distraction on anxiety level during dental treatment among anxious pediatric patients: a randomized clinical trial

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Abstract

This study evaluated 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 ($p = 0.424$). At the end of the treatment, the SCL was significantly lower in the VRD group ($p < 0.001$). Neither the VABRS ($p = 0.171$) 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.

Keywords

Dental anxiety; Heart rate; Pediatric dentistry; Salivary cortisol; Virtual reality

1. Introduction

Dental fear and anxiety are the most common challenges facing pediatric dentists in the dental operatory [1]. Irregular dental attendance and poor cooperation with care providers are considered the main outcomes of dental anxiety [2]. The American Academy of Pediatric Dentistry (AAPD) recommends a series of non-pharmacological behavior management techniques (BMTs) for managing children during dental care, including distraction [3]. Distraction is defined by AAPD as "the technique of diverting the patient's attention from what may be perceived as an unpleasant procedure" [3]. It is widely used as it provides an effective and relaxing experience during treatment [4].

One of the distraction modalities is the use of Virtual Reality distraction (VRD) in dental clinics. Virtual reality distraction immerses the patient in an environment generated by a computer and works by simulating as many senses as possible: vision, hearing, and touch [5]. In dentistry, VRD has exhibited great results in reducing anxiety and fear among children and adolescents compared to those who received no intervention or more conventional BMTs. VRD allows the dentist to provide more efficient dental treatments, ranging from simple anesthesia to more advanced forms of dental treatment [6].

Generally, anxiety can be assessed by several subjective and objective measures. The subjective measure includes behavioral and self-reported measures. In the self-reported measures, the patient reports his/her anxiety *via* direct report, interview, or inventory [7]. On the other hand, the objective measure includes physiological measures such as breathing, sweating, heart rate (HR), and salivary cortisol level (SCL) [8]. Amid stressful situations, the cortisol hormone is secreted in the body by the hypothalamus-pituitary-adrenal axis. Its level is an accurate, reliable, and non-invasive measure of long-term stress in adults and children [9]. Its low molecular weight and lipophilic nature allows the unbound cortisol to enter cells by passive diffusion. Therefore, measuring the free cortisol fraction in all bodily fluids, including saliva, is feasible [10]. In

dentistry, SCL has been used to assess stress and anxiety during dental treatment and suggests a positive correlation between anxiety-producing events and SCL [11, 12].

Many studies have evaluated the effect of VRD on anxiety among children using different subjective and objective tools to measure dental anxiety among participating children [6, 13–17]. However, none of the previously published studies evaluated the impact of VRD on anxiety among highly anxious children by pre-measuring the anxiety level of the participating children. Thus, the aim of this study was to evaluate the effect of virtual reality distraction among 6- to 14-year-old anxious children undergoing prophylactic dental treatment by utilizing both subjective (Venham Anxiety and Behavioral Rating Scale (VABRS)) and objective (heart rate and salivary cortisol level) measures. We hypothesized that virtual reality would be an effective strategy for reducing anxiety during dental treatments in anxious children by reducing Venham Anxiety and Behavioral Rating Scale scores, heart rate, and salivary cortisol level.

2. Materials and methods

This two-arm parallel randomized controlled study was conducted at the Department of Pediatric Dentistry at King Abdulaziz University Dental Hospital (KAUDH) between January and May 2022, the trial was registered in ClinicalTrials.gov under the identifier NCT05663619. The study is reported according to the protocol established by the Consolidated Standards of Reporting Trials (CONSORT) statement [18].

The inclusion criteria were 6- to 14-year-old, healthy children who were categorized based on the American Society of Anesthesiologist physical status as (ASA I) with a history of previous dental treatment. The included subjects also had to have high dental anxiety (high score on a modified version of the Abeer Children Dental Anxiety Scale (M-ACDAS)). Children with visual or auditory deficits, a history of epilepsy, anxiety disorder (such as specific phobias, social anxiety disorders, or generalized anxiety disorder), or non-Arabic speaking children were excluded.

Records of pediatric patients on the dental treatment waiting list were reviewed and potentially eligible children were contacted *via* the phone. The aim of the study was introduced to the parents/guardians, and upon agreement to participate, an appointment was scheduled.

Abeer Children Dental Anxiety Scale (ACDAS), a cognitive dental anxiety scale, is the first Arabic-validated cognitive dental anxiety scale developed to measure anxiety in children and adolescents. It consists of 19 self-reported questions arranged in a logical order to assess dental anxiety in children [19]. In this study, the ACDAS was modified (M-ACDAS), and only seven of the 19 self-reported questions were included to avoid a lengthy questionnaire with the children (Fig. 1). Each question can be scored 1, 2 or 3 by choosing between three faces with different expressions. The first face is a smiley face and reflects the feeling of being relaxed, happy, and not scared, while the second face represents a neutral feeling, and the third face is a sad face and represents an anxious and scared feeling. The children were asked to circle the face that best represented his/her response to the question. Therefore, the total values ranged from 7 to 21. The M-ACDAS was used at the beginning of the scheduled appointment in the waiting area to assess the pre-treatment anxiety level of the potentially eligible children. Those who scored 14 (66.7% of the maximum score) or more were considered anxious and were included in the study. Those who scored less than 14 in the M-ACDAS were excluded from the study.

An Arabic consent form was obtained from the parents/guardians, and verbal assent was obtained from the child before participation. The participants' age, gender, the timing, type of treatment provided, and behavior during their most recent dental visit were also recorded.

A stratified block randomization process was used to randomize the 36 participants into either a VRD or a control group. The participants were stratified into two strata based on gender: males and females. Within each stratum, a random number generator was used to fill the sequence of assignments in a block. Each block contained six assignments to guarantee a balanced number within each group after six participants were added. To ensure allocation concealment, the allocation assignment and sequence were kept with a dental assistant not involved in the study. Each time a new subject was included, the dental assistant was asked to provide the assignment sequence based on the participant's gender. In the VRD group, participants wore a light weighted VRD eyeglasses (Lucky Goldstar (LG) 360 virtual reality (VR) headset, LG Electronics) and watched a previously selected favorite cartoon during the prophylactic dental treatment. The VRD eyeglasses was introduced to the participants using the Tell-Show-Do technique at the beginning of the appointment. In the control group, participants received their treatment while watching a previously selected favorite cartoon on a regular screen. For both groups, only speakers with no headphones were used.

The subjects underwent a dental prophylactic treatment performed by a single trained dental intern using a low-speed handpiece and a rubber cup with prophy paste. The dental treatment was conducted in the same order, the upper right, upper left, lower left, and lower right quadrants, with all the participants. The participants were allowed to choose the prophy paste flavor (Bubble Gum, Cherry Tart, Concord grape, Mint Parfait, Raspberry Jam and Valencia Orange). During the treatment, the HR was recorded using a pulse oximeter (TECNO-GAZ pulse oximeter-Vital Test-Parm, Italia) at four-time points: (1) in the waiting area as a baseline; (2) in the dental chair before starting the procedure and after the VRD eyeglasses or the regular screen were turned on; (3) during prophylactic dental treatment (after prophy of the two quadrants in the upper arch was completed); (4) after the procedure was completed and before taking off the VRD eyeglasses in the VRD group or turning off the regular screen in the control group.

During the treatment, participants were videotaped using a high-resolution camera. Later, two trained and calibrated evaluators assessed the participant's anxiety using the VABRS independently. The scale consists of five defined behavioral categories ranging from zero to five. A higher score indicates a greater level of anxiety as shown in Table 1 [20].

Two saliva samples were collected from each participant: the first sample was collected as a baseline in the waiting area,

A modified version of Abeer Dental Anxiety Scale – English version

Date: **Child age:** **Gender: M/F** **Operator's name:**

The child self-report part

I would like you to please tell me how relaxed or scared you feel at the dentist. Please use the below from 1 to 3, and tick () under the face that shows how you feel now.

How do you feel about:	**1** 	**2** 	**3** 
1. Sittng in the waittng room?			
2. A dentist wearing a mask on his face?			
3. Laying flat on the dental chair?			
4. A dentist checking your teeth with a mirror?			
5. Having a strange state in your mouth?			
6. The sounds that you hear at the den□st?			
7. The smell at the dentist?			

FIGURE 1. A modified version of Abeer's Dental Anxiety Scale-English version (M-ACDAS).

TABLE 1. The scores of the Venham anxiety behavior rating scale.

Score	Criteria of the score
0	Relaxed, smiling, willing, and able to converse.
1	Uneasy, concerned. During stressful procedure, may protest briefly and quietly to indicate discomfort. Hands remain down or partially raised to signal discomfort. Child willing and able to interpret experience as requested. Tense facial expression, may have tears in eyes.
2	Child appears scared. Tone of voice, questions and answers reflect anxiety. During stressful procedure, verbal protest, (quiet) crying, hands tense and raised, (not interfering much—may touch dentist's hand or instrument, but not pull at it). Child interprets situation with reasonable accuracy and continues to work to cope with his/her anxiety.
3	Shows reluctance to enter the situation, difficulty in correctly assessing situational threat. Pronounced verbal protest, crying. Using hands to try to stop procedure. Protest out of proportion to threat. Copes with situation with great reluctance.
4	Anxiety interferes with the ability to assess the situation. General crying is not related to treatment. More prominent body movement. Child can be reached through verbal communication, and eventually with reluctance and great effort he or she begins the work of coping with the threat.
5	Child out of contact with the reality of the threat. Genera1 loud crying, unable to listen to verbal communication, and makes no effort to cope with threats. Actively involved in escape behavior. Physical restraint required.

and the second sample was collected after the dental procedure was completed. Saliva (2.0 mL) was collected using cotton Salivette® collection methods. The samples were immediately stored at −20 °C until evaluation. To minimize the effects of the diurnal cortisol cycle, all study procedures and saliva sample collection were performed between 10:00 AM and 2:00 PM. The cortisol levels were measured using the Cortisol Saliva Enzyme-Linked Immunosorbent Assay (ELISA) Assay Kit (ab 154996- cortisol ELISA kit, Abcam, Cambridge, UK) following the manufacturer's instructions.

2.1 Sample size

A sample size of 18 in each group will have 80% power to detect a difference in means of −1.5, assuming that the common standard deviation is 1.5 with a 5% two-sided significance level.

2.2 Statistical analysis

The Statistical Package for Social Science software for Windows was used for the statistical analysis (BM SPSS Statistics for Windows, Version 28.0. IBM Corp, Armonk, NY, USA). Shapiro-Wilk test and visual inspection of histograms and Q-Q plots were utilized to examine the normality of the data. It was determined that the data are not normally distributed, prompting the use of non-parametric tests for data analysis. The participants' baseline characteristics were compared using the Mann-Whitney U test, chi-square test, or Fisher exact test. The Mann-Whitney U test was used to compare the three outcomes of the research (HR, SCL and VABRS) between the VRD and control groups. The significance threshold was set at 0.05.

3. Results

Between January and May 2022, a total of 40 healthy, 6- to 14-year-old, Arabic-speaking children with a history of previous dental treatment and who require prophylactic dental treatment were potentially eligible for the study. The guardians/parents of these children were contacted by phone and asked to participate in the study. At the scheduled appointment, three of the children scored less than 14 on the M-ACDAS, and one parent/guardian refused participation. A total of 36 children participated in the study (18 in the VRD, and 18 in the control group). The study flow chart is presented in Fig. 2.

Table 2 shows the demographic data and dental history of the participants. The participants' mean age was 9.1 ± 2.6 years in the VRD and 10.1 ± 2.8 years in the control group (p = 0.252). Males and females were equally distributed across both groups (p = 1.00). There was no statistically significant difference between both groups in timing (p = 0.74), the kind of treatment delivered (p = 0.13), and their behavior in the most recent dental visit (p = 0.72). The mean M-ACDAS score at baseline in the VRD group was 18.0 ± 1.8 and 17.3 ± 1.6 in the control group, with no statistically significant difference (p = 0.42).

Although the total mean HR in the VRD group was slightly higher at each of the four measurement intervals (baseline = 99.0 ± 12.0, before = 97.4 ± 9.7, during = 96.4 ± 13.3, and after = 91.7 ± 8.2) compared to the mean HR in the control group (baseline = 93.8 ± 12.9, before = 96.6 ± 12.8, during = 93.6 ± 10.8, and after = 91.0 ± 8.8), the differences were not statistically significant (Fig. 3).

Fig. 4 compares the mean SCL in ng/mL before and after the prophylactic dental treatment in the VRD and control groups. Salivary cortisol levels in the VRD group (12.8 ± 1.2 ng/mL) were not significantly different (p = 0.913) from the control group (12.7 ± 1.6 ng/mL) before prophylactic dental treatment. However, after the dental procedure, the participants in the VRD group had a significantly ($p < 0.001$) lower mean SCL (16.0 ± 1.3 ng/mL) compared to the control group (19.0 ± 1.6 ng/mL). Finally, there was no significant change in the VABRS values distribution between the VRD and control groups (p = 0.171), with both groups scoring between 1 and 3 (Fig. 5).

4. Discussion

This randomized controlled study aimed to evaluate the effect of VRD among 6- to 14-year-old anxious children undergoing prophylactic dental treatment by utilizing both subjective and objective measures. When compared to the control group, children wearing VRD eyeglasses had significantly lower levels of SCL after treatment.

In the present study, children were asked to choose their favorite cartoon, wear the VRD eyeglasses during the dental treatment, provide saliva samples, and answer both the M-ACDAS and VABRS, all of which require some degree of maturation, cognitive development, complexity, and experience to report and react accurately [7]. Also, children younger than six years are more likely to develop dental anxiety and behave negatively [21]. Therefore, children between the age of 6 and 14 were included in the study. Despite the fact that the children's age was not a confounder in the current study, dental anxiety and behavioral issues are reportedly related to the child's age [22, 23]. Future research should therefore take into account subdividing the children according to their cognitive developmental stage.

The participants in the control group watched their video on a regular screen while the VRD eyeglasses were provided to the VRD group participants. The complete blockage of the participants' visual field in the VRD group made them more engaged and concentrated on the content of the VRD eyeglasses rather than on their surroundings. As a result, the dentist was able to provide efficient dental treatment without trying to distract the child from the dental procedure provided. None of the groups used headphones; therefore, the participants could still hear the handpiece and suction sounds around them, which might justify the comparable HR records between the two groups. Future studies should consider sound isolation in assessing the effectiveness of VRD, especially among anxious children.

Salivary cortisol level is a non-invasive measure of stress in adult and pediatric patients [9]. A previous study by Furlan *et al.* [12], reported higher SCL before dental prophylactic procedures than after the events in children aged 7 to 8 years without any history of dental treatment. We speculate that the absence of both previous dental treatment and the utilization of distraction techniques during the prophylactic treatment in

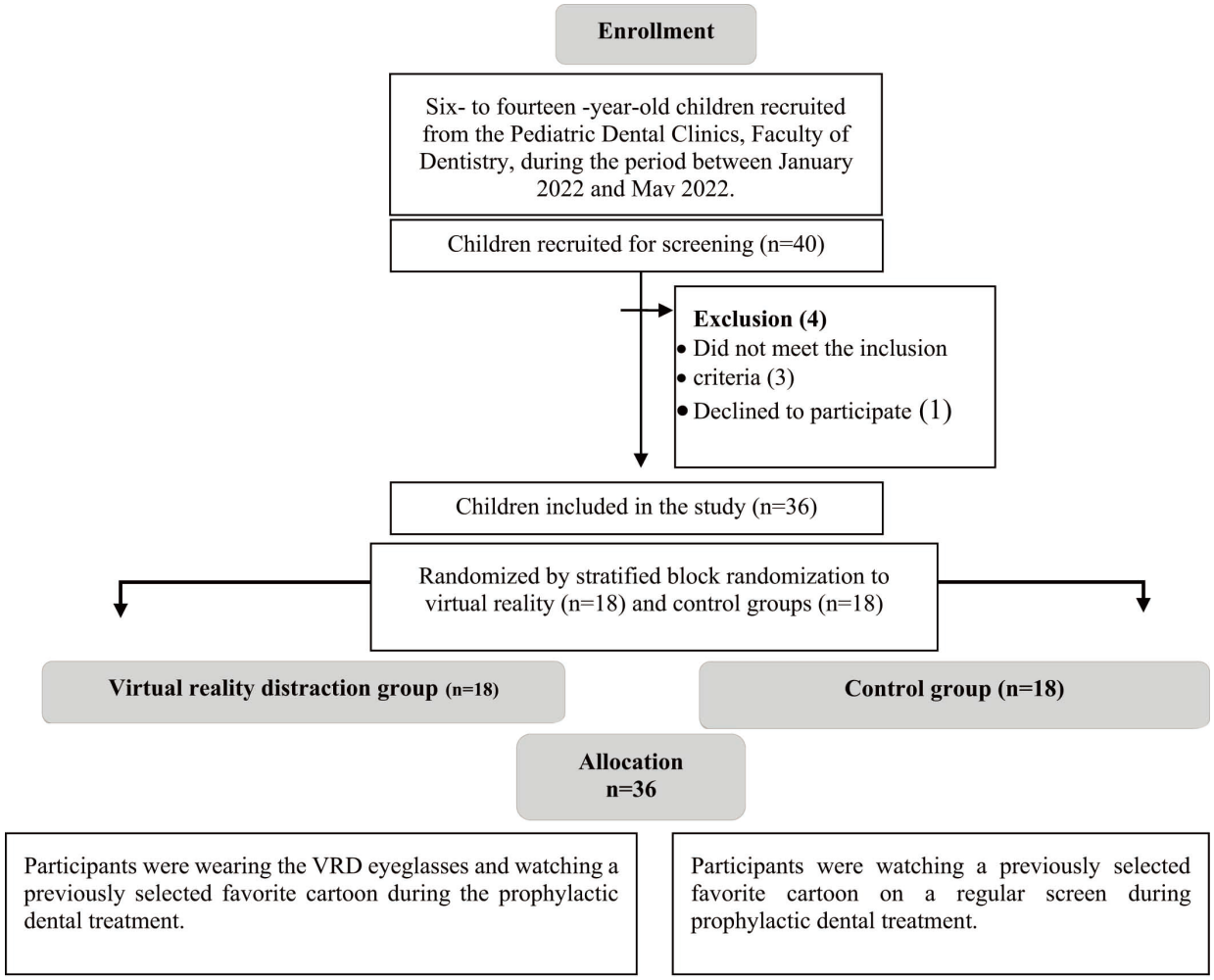

FIGURE 2. Study flow diagram.

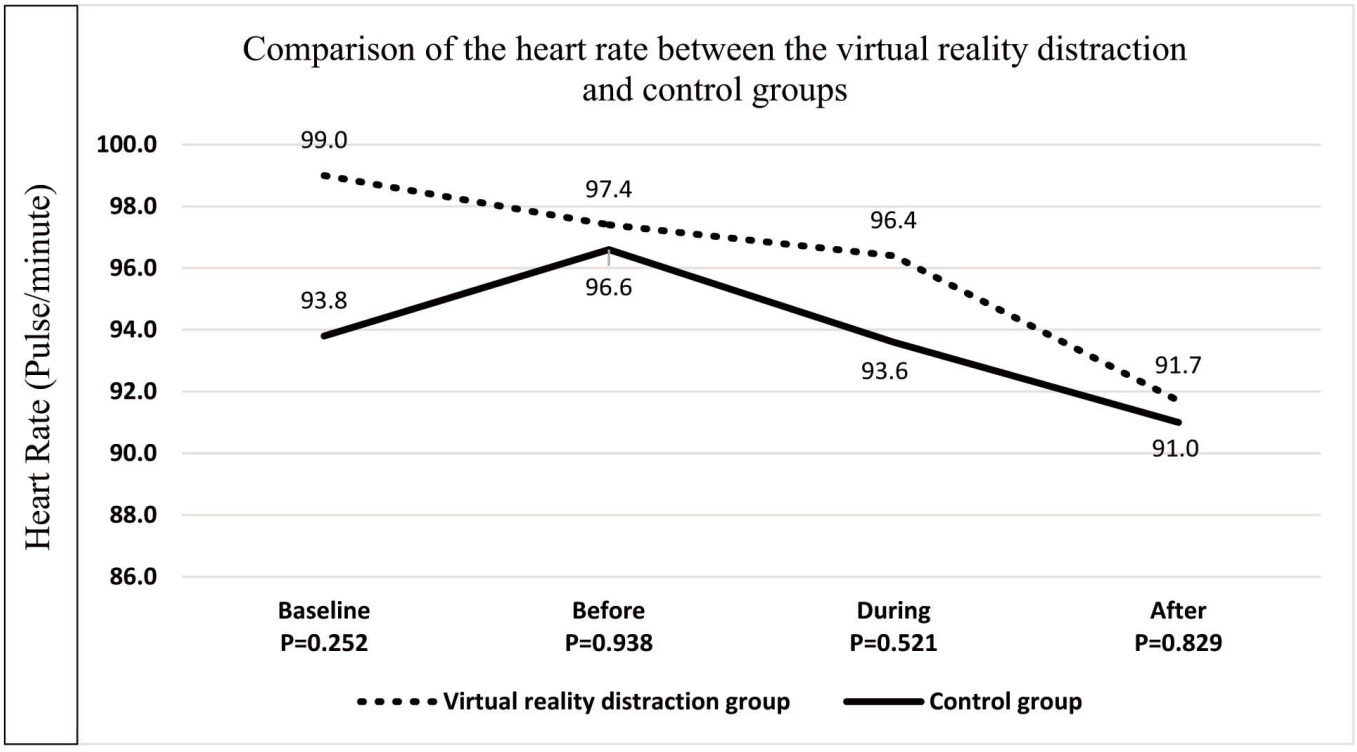

FIGURE 3. Heart rate of virtual reality distraction *vs.* control groups at baseline, before, during, and after prophylactic dental treatment (n = 36).

TABLE 2. Demographic characteristics and dental history of the participants (n = 36).

Variables	Mean ± SD or n (%)	Virtual Reality n = 18	Control n = 18	*p*-value
Age in years	Mean ± SD	9.1 ± 2.6	10.1 ± 2.8	0.252†
	6–9	11 (61.1)	8 (44.4)	0.317§
	10–14	7 (38.9)	10 (55.6)	
Gender				
	Male	9 (50.0)	9 (50.0)	1.000§
	Female	9 (50.0)	9 (50.0)	
Timing of the last dental visit (in months)				
	1–3	15 (83.3)	13 (72.2)	0.735¥
	4–6	1 (5.6)	2 (11.1)	
	7–12	2 (11.1)	3 (16.7)	
Type of treatment provided during the last dental visit				
	Dental checkup	8 (44.4)	6 (33.3)	0.125¥
	Restorative treatment	2 (11.1)	8 (44.4)	
	Stainless steel crown	4 (22.2)	3 (16.7)	
	Extraction	4 (22.1)	1 (5.6)	
Behavior during the last dental visit				
	Cooperative	5 (27.8)	6 (33.3)	0.717§
	Uncooperative	13 (72.2)	12 (66.7)	
M-ACDAS (before the procedure)	Mean ± SD	18.0 ± 1.8	17.3 ± 1.6	0.424†

†: *Mann Whitney U test;* §: *chi-square test;* ¥: *Fisher Exact test. SD: Standard deviation; M-ACDAS: Modified version of the Abeer Dental Anxiety Scale-Arabic version.*

the Furlan *et al.* [12], study can explain the reversed findings observed in the current study.

A recent study published by Shetty *et al.* [17], (2019) evaluated the effect of VRD on pain and anxiety among 5- to 8-year-old children with no previous dental treatment experience. The SCLs were measured before, during, and after dental treatment to assess the participant's anxiety level. Although the SCL among all the participants decreased post-treatment when compared to the pre-treatment levels, the difference was more substantial among participants in the VRD group (20.9 ng/mL) when compared to the control group (16.22 ng/mL). In the current study, an increase in SCL was observed after prophylactic dental treatment in both groups; however, the increase was higher among the control group participants (6.3 ng/mL) compared to the VRD group participants (3.2 ng/mL). The discrepancy between the study by Shetty *et al.* [17], (2019) and the current study might be due to the fact that all the children included in our study were anxious, had previous dental experience within the last year, and most of them were uncooperative. Therefore, it was expected that even the simplest dental procedure would trigger their anxiety and cause an increase in their SCL, which was significantly less among the children who were distracted by VRD eyeglasses during the treatment. Additionally, the treatment used in our study (prophylaxis) was short and non-invasive in contrast to the lengthy and invasive procedure used in Shetty's study (pulpotomy).

The effect of VRD in decreasing pain and anxiety among children receiving different types of dental treatment was evaluated by many studies using various objective [13, 14, 16] and subjective measures [6, 14]. Heart rate is one of the main objective physiological tools utilized to assess the effect of VRD on anxiety levels [6, 13, 14, 16]. A gradual and significant decrease in HR was observed from the baseline toward the end of the treatment among children distracted by VRD devices [14, 16]. In the current study, a decrease in HR from the baseline toward the end of the treatment was observed in both groups; however, the difference was not significant.

The VABRS was utilized to measure the anxiety level among participants after the treatment. Slightly higher but not significant anxiety scores post-treatment were found among the VRD group compared to the control group participants, indicating a higher anxiety level among children distracted by the VRD eyeglasses. We speculate that complete visibility blockage provided by the VRD stimulated the participants' fear of the unknown/unseen resulting in a slight increase in their anxiety

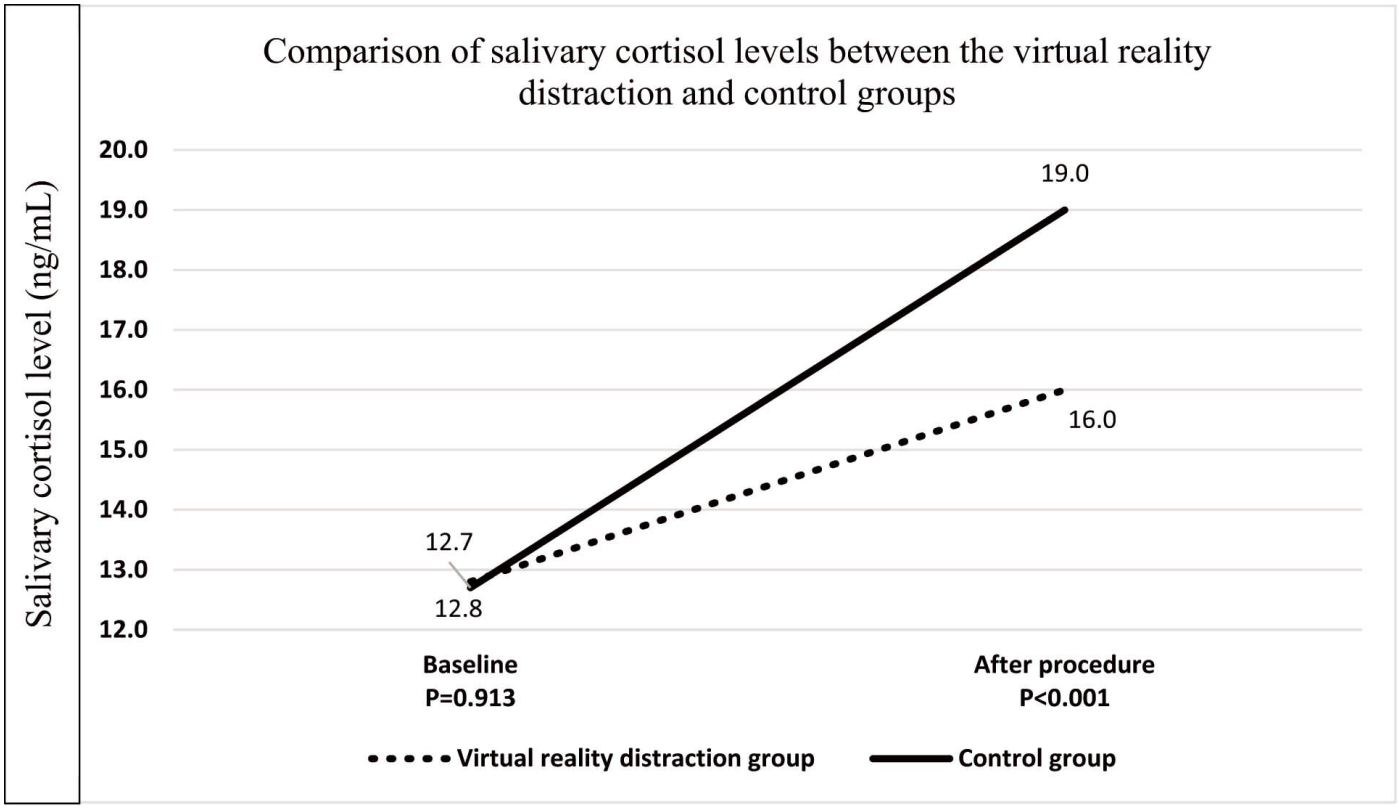

FIGURE 4. The salivary cortisol level in ng/mL of virtual reality distraction *vs.* control groups at baseline and after prophylactic dental treatment (n = 36).

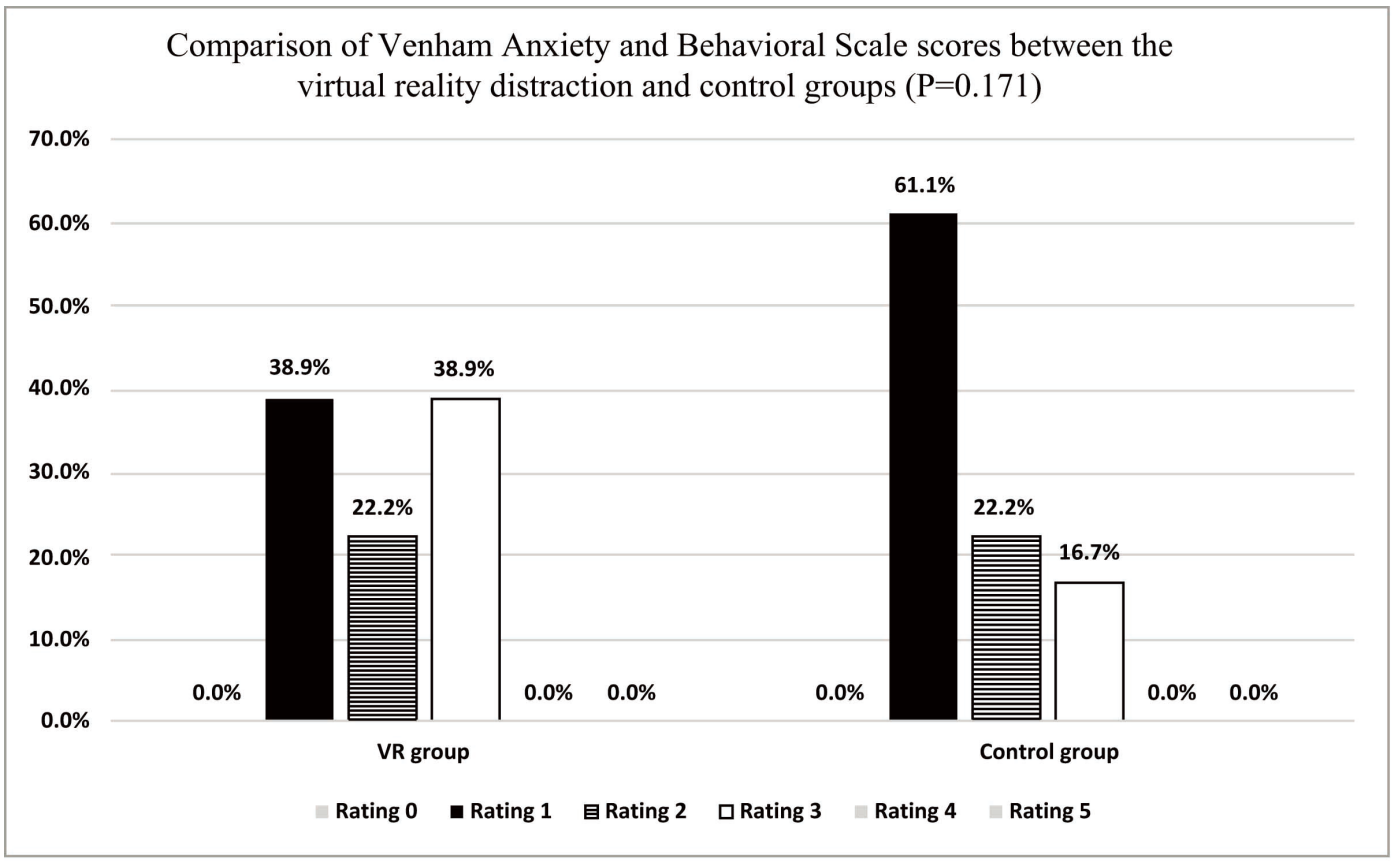

FIGURE 5. Venham Anxiety and Behavioral Rating Scale scores of virtual reality distraction *vs.* control groups (n = 36).

level.

One of the limitations of the current study includes the sample size. A larger sample size might bring out more significant differences between the groups. Also, other variables such as complete medical history, were not evaluated, which might be a limitation since it can influence anxiety and cooperation levels. In addition, the effect of the watched cartoons' content (*e.g.*, calm, fast, action-packed) on the measured outcomes were not investigated. Finally, the addition of a negative control group in which participants received treatment without watching anything could have provided more accurate and valid outcomes.

Despite the study's limitations, it postulates an insight into the clinical implementation of distraction as a non-pharmacological behavioral modification technique in dental settings. Future studies should consider distraction during a more invasive procedure or a procedure that requires dental anesthesia to further explore the VRD's ability to reduce anxiety.

5. Conclusions

The VRD significantly reduced the SCL of 6- to 14-year-old children during dental prophylaxis treatment. However, there was no statistically significant difference in HR and VABRS between the VRD and the regular screen groups. Virtual reality distraction is a non-invasive method that has the potential to significantly reduce anxiety during prophylactic dental treatment among anxious children. Further studies using different dental procedures are warranted to support the findings of this study.

AVAILABILITY OF DATA AND MATERIALS

The corresponding author will consider providing the datasets used and/or analyzed during the current work upon reasonable request.

AUTHOR CONTRIBUTIONS

SMB—contributed to the study design, interpretation of the data and critically drafting and reviewing the manuscript. OMF—contributed to the study design, statistical analysis, interpretation of the data and critically drafting and reviewing the manuscript. AAA—contributed to the data collection and writing the manuscript. MMT—contributed to the data collection and writing the manuscript. GB—contributed to the interpretation of the data, critically drafting and reviewing the manuscript. AMB—contributed to performing the saliva analysis and reviewing the manuscript.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

Throughout the research procedure, ethical issues were adhered to in accordance with the Declaration of Helsinki. The King Abdulaziz University, Faculty of Dentistry Research Ethics Committee granted its approval for the study to be carried out (Number: 341-11-21). Additionally, parents had to sign a paper granting permission for their child's participation (including any images).

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

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