EFFECTIVENESS OF SMART PHONE APPLICATION IN REDUCING ANXIETY DURING PEDIATRIC DENTAL PROCEDURES: A RANDOMIZED CONTROLLED TRIAL

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ABSTRACT

INTRODUCTION: Numerous dental health programs are directed at reducing the anxiety of children. Smartphone applications may be beneficial in behavior management problems when undergoing dental procedure.
OBJECTIVES: The aim of this research was to determine the effectiveness of smartphone applications (Tell-Play-Do) (TPD) in reduction of preoperative anxiety in children who are undergoing restorative treatment in comparison with the Tell-Show-Do (TSD) technique.
MATERIALS AND METHODS: This research was a randomized controlled clinical trial. A sample of 38 healthy children patients per group (number of groups=2) with age ranging from 6-8 years were assigned from the outpatient clinic of the Department of Pediatric Dentistry and Dental Public Health. All participants were randomly distributed to one of two groups: TPD or TSD. They All required restorative treatment with carious maxillary primary molars (class I only) without-pulpal involvement and infiltration of local anesthesia (LA). Dental anxiety was assessed by using Venham's picture test (VPT) and heart rate (HR) in three steps (baseline, after intervention TPD/TSD and after treatment).
RESULTS: The reduction in dental anxiety scores(VPT) after applying the TPD in comparison with the base line scores for the test group exhibited statistical significance ($P_1<0.0001$), while it was statistically non-significant in the control group (TSD technique). Both groups showed reduction in HR pre-operative and post-operative, however, the reduction was almost doubled in TPD group using dental application.
CONCLUSIONS: In pediatric patients, the Tell-Play-Do technique by using smartphone application is an effective instrument for reducing dental anxiety.
KEY WORDS: Smart phone application, Dental anxiety, Behavior management, heart rate, Venham's picture test
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INTRODUCTION

Despite significant advancements in dental practice in form of technologies, equipment and products, anxiety linked to the dental environment continues to be a serious and common problem for children around the world. As a result, delivering adequate dental treatment becomes difficult (1).

Dental fear (DF) is an emotional response to at least one particular stimulus that is threatening inside the dentist office. Dental anxiety (DA) refers to an extreme and irrational depressive emotional state experienced with a subset of patients with sense of losing control of their situation during dental care (2). Worries and anxiety are often reflected in children through words alone or through acts as shouting, anger and avoiding conversation. Furthermore when making an attempt to conceal from care providers, significant physiological alterations, such as an increased heart rhythm, will also reveal their feelings (3).

Dental anxiety can be triggered by the scent of eugenol, the sound of drilling, the sight of needles and the sensations of high-frequency dental noises (4).

According to studies, children's behaviors or opinions towards dentists and dental care are affected by their first dental visit which is considered the most significant factor. Patients'

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comfort, compliance, and application of oral health care facilities, as well as home care and oral health, will benefit from a supportive dentist-patient partnership. The intensity of a child's dental anxiety has a significant impact on the quality level of dental care services (2, 5, 6).

Various methods can be used to assess a child's dental anxiety, including physiological methods (e.g., heart rate, muscle tension), psychometric assessment (e.g., Venham's Picture Test, Dental Anxiety Scale) (7).

The American Academy of Pediatrics Dentistry (AAPD) has identified a number of non-pharmacological behavior management approaches, ranging from voice control, nonverbal communication, to direct observation in which familiarizing the child patient with the environment in the dentist office as well as the dental fundamentals of any operation by viewing a video or personally observing a cooperative child patient receiving dental care (8).

At a pretreatment appointment, two of the most frequently applied non-pharmacological behavioral management approaches when it comes to the treatment of dental anxiety are Virtual Reality (VR) and Tell, Show and Do technique (TSD) (9).

The TSD method, invented by Addleston (10), has traditionally been used to acquaint patients with dental procedures and instruments in order to alleviate their fear of the unknown. New instruments or techniques were presented to the child using this method by describing, illustrating, then eventually using the instrument or applying a technique (10).The TSD approach depends on the learning philosophy concept, which is implemented in the clinical setting by pediatric dentists. According to Mehrabian and Ferris (11), only 7% of communication comprehension is based on the words used, while visual signals account for 55% of verbal communication content.

Virtual Reality (VR) immersion has recently emerged as a potential method for improving the dental atmosphere, assisting children in adjusting to dental procedures, and encouraging good communication between children and dentists. Smartphones are widely available and accessible, and they serve as private laptops as well as being highly flexible and they are considered an essential part in the world (12).

Dental mobile applications are enjoyable games in which the customer is given the opportunity to implement a variety of procedures in the dental field on cartooned individuals. The whole dental operation can be shown to the child patient by a dental app, which provides more detailed explanations (13, 14). In addition, these applications provide us with a variety of treatment services such as dental hygiene, pulp therapy, tooth removal, teeth restoration and more (15).

With that idea, the TSD strategy was modified to Tell-Play-Do (TPD), a method that is based on the theory of learning where there is a two-way interchange of information by conducting dental treatments on smartphone dentist games by which the child patient is educated on using standard dental devices such as the air motor, scalers, nozzle of the vacuum cleaner, etc. This application was designed to alleviate patient anxiety by teaching them the importance of treating their teeth as well as enticing them to interact with the therapy comfortably in a fun way and developing cooperative behavior (16).

There have been no prior researches in Egypt concerning the usefulness of smartphone applications as a TPD technique to alleviate dental anxiety. Therefore, this study aimed to evaluate the effectiveness of smartphone application (TPD) in reduction of preoperative anxiety in children undergoing restorative treatment with dental local anesthesia.

The null hypothesis of the present study was that smartphones applications (TPD) will provide the same benefit as traditional behavior management technique (TSD) in decreasing dental anxiety.

Materials and Methods

Study design:

This study was a randomized controlled clinical trial. In accordance with the Consolidated Standards of Reporting Trials (CONSORT) statement, this research had been set up and registered (17). The PICO question was: do children patients between the ages of 6 and 8 years (population; P) allocated in tell, play &do technique (TPD) with the use of smartphone application (intervention; I) in comparison with the use of tell, show& do technique (TSD) (control; C) show reduction in their anxiety levels (outcome; O). The Research Ethics Committee, Faculty of Dentistry, Alexandria University gave its approval to our study (# IRB 00010556)-(IORG 0008839) and signed up for ClinicalTrial.gov within the registry number (#NCT04719299).

Eligibility criteria

Seventy-six healthy Children with no prior dental history were enrolled in the research, with ages ranging from 6-8 years. All participants required dental treatment with carious maxillary primary molars without pulpal involvement. Both children with special needs or who are physically ill are omitted. Participants were enrolled in the clinical trial after informing their parents about the study

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protocol and signing their informed consent prior to treatment.

Study setting and location

Groups were selected (from January to March 2020) from the outpatient clinic, Pediatric Dentistry and Dental Public Health Department, Faculty of Dentistry, Alexandria University, Egypt.

Sample size estimation

The minimum sample size was determined depending on an earlier research conducted by Shah et al. (2017) (13). With 80 % power and at a significance level of 0.05 as statistically significant, a sample size of 38 patients per group (n=2) was enough to identify a standardized impact size of 0.685 difference in the primary result (scores of Venham's picture test) (18,19 , 20). GPower version 3.1.9.2 was used to measure the sample size (21).

Randomization technique

Using a computer-generated list, participants that met the inclusion requirements were randomly assigned to one of two groups (Tell, Play &Do smartphone application or Tell, Show &Do technique). The allocation was done by a trial-unrelated personnel, and the allocation ratio was established to be equal.

Allocation concealment

Each participant who took part in the trial was assigned a unique serial number, which was used in the randomization process .These numbers were formed on similar sheets of paper with the name of the group whereby each child was assigned and enclosed in impermeable envelopes with the children's names. The task of holding and opening the envelopes was delegated to a trial independent staff.

Sample grouping

All participants were categorized equally into two groups of 38 member each, at random as follows: Group I: (acted as test group) (TPD) assigned to smart phone application (Tell-Play-Do technique) and Group II: (acted as control group) (TSD) assigned to traditional behavior management technique (Tell-Show-Do technique).

Blinding

The operator was not blinded to the type of intervention. However, the statistic consultant was blinded during analyzing the results.

Intervention

Equipment used : smart phone device (IPhone, Apple), smart phone dental app used as (TPD) modified behavior management technique was (DENTIST OFFICE KIDS), finger pulse oximeter was used to record heart rate (Pulse Oximeter (PULSOX) GRANZIA) and dental syringe with 27-gauge needle (Beehive Solutions Ltd, Ilford, Essex, UK). In addition, Benzocaine 20% (Pharma Research, INC. FL,

USA) topical anesthetic gel and Mepivacaine HCl 2%, 1/20000 Levonordefrin (Alexandria co. for Pharmaceuticals, Alexandria, Egypt) local anesthetic carpools were the materials used.

To select patients who fulfilled the inclusion criteria, an initial evaluation and a complete medical and dental history were performed. The participants were examined clinically and radiographically to ensure that they matched the inclusion criteria. Patients were randomly allocated into two groups.

Identical clinical procedures were performed for both groups. Preoperative instructions had been given for all participants, then prior to dental treatment, the parent was informed about the study's goals, consequences, and advantages, and a written consent was signed. After obtaining approval, subjects were randomly allocated into one of the two groups. At least one of the children's parents observed the session passively. The intervention of test and control group had been applied. The anesthesia administration process was explained to all participants in terminology that can be easily understood on both groups. Topical anesthetic gel was applied for one minute followed by infiltration LA administration (22). All dental procedures steps were done in one visit. Each carious lesion was removed followed by the proper restorative material. The whole treatment procedure was completed within 20-30 minutes. In order to prevent bias, children were handled by a single operator. The researcher passively observed and recorded HR & VPT scores based on the scoring criteria.

Intervention for Group I: test group (smart phone application group) (Tell-Play-Do) patients' behavior was influenced by displaying a mobile dental app game to them. The 'tell' phase was demonstrating the usage of standard dental instruments such as mirror, excavator, hand piece and nozzle of the vacuum cleaner etc. in the shape of animations with graphical and sounding effects in the mobile app. The operator was a participant in the activity by playing the game with children patient for 5-10 minutes to educate them about dental treatment procedures such as restorations that will be performed on them later this was the 'play' phase (Fig.1). Group II: control group, conventional behavior modification methods (Tell-Show-Do) were used prior to the application of LA. The 'tell' phase includes a verbal description about treatment suitable for child's growth stage. During the 'show' phase, they became acquainted with the procedure tool kit and then a presentation of the technique in a properly

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described, non-aggressive way (Fig. 2). Finally, in the 'do' phase, for both study groups, the LA was administrated and the dentist started the treatment for the rest of the operation without distraction from the description and demonstration.

Behavioral evaluation method

For both groups all parameters (VPT and HR) were recorded at three steps, first baseline (preoperatively), second after-intervention (TPD/ TSD) technique and third after treatment was done (postoperatively).

First Dental anxiety had been evaluated using VPT as a subjective assessment (23).It is self-measure test that permits the child to respond non-verbally, minimizing the distortion produced by the subject's attempt to give socially desirable responses. It comprises of eight cards, with two pictures in each card, one "anxious" figure and one "non-anxious" figure. The child was asked to point the picture they felt most like at that moment. All the cards were shown in their numbered order. If the child pointed at the "anxious" figure, a score of one was recorded, if the child pointed at the "non-anxious" figure, a score of zero was recorded (Fig. 3) (24). Therefore, the scale has a range of zero (minimum score) to eight (maximum score). It is quick to administer in 2 to 3 minutes. Second, pulse rate had been recorded by using a finger pulse oximeter which had been inserted on the participant's index finger of right hand after he or she was seated in an upright posture. Registering HR as a potential secondary measure of anxiety as objective assessment (Fig.4). Study flow chart provides an overview of the current research methods (Fig. 5).

Statistical analysis

IBM SPSS statistical software (version 25) has been used to interpret the data. The significance level for this study was set at 0.05. Dental anxiety scores and heart rate values were not normally distributed so it was decided to use non-parametric tests. The Mann Whitney U test was used to measure the two parameters across groups. Discrepancies within each group were assessed using Friedman test followed by post hoc test.
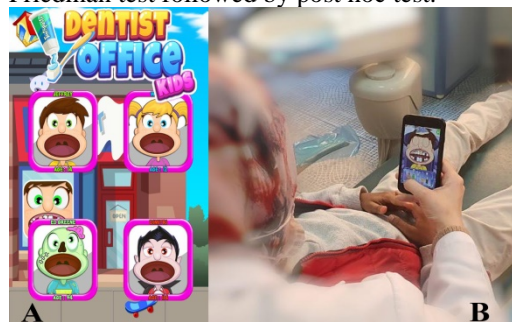
Figure 1: Educating a child about the procedour using smartphone app as the TPD tech.

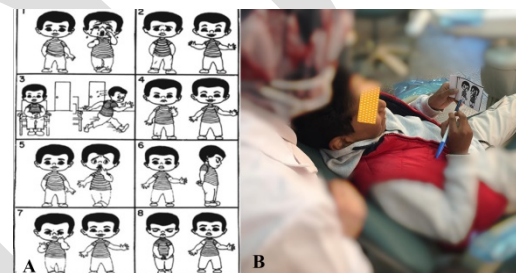**Figure 2:** Conditioning a child using Tell-Show-Do technique.

Figure 3: Patient selecting how he felt from VPT**.**

Figure 4: A finger pulse oximeter for monitor heart rate on a child.

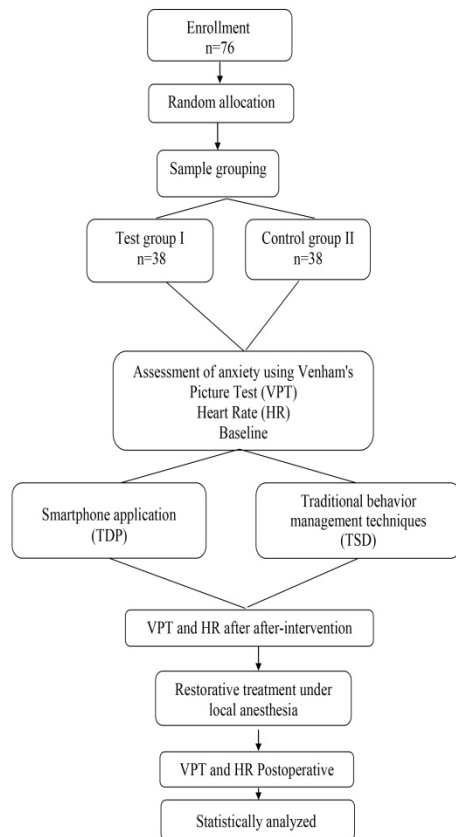Alexandria Dental Journal. Volume 47 Issue 2 Section C

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Figure 5: A CONSORT diagram showing the study protocol.

RESULTS

The sample involved 76 children who met the inclusion criteria, were aged 6 to 8 years old. They were categorized equally into two groups of 38member each, at random, either the TPD group or the TSD group.

Table (1) shows a comparison of the dental anxiety scores through Venham's picture test between study groups. Mean baseline dental anxiety score of the test group was 3.21 (2.42) while it was 3.18 (2.29) for the control one, there was no statistically significant difference between the two groups (P= 0.962). Mean value of dental anxiety scores after TPD/TSD for test group was 1.08 (1.15) and it was 2.24 (1.62) for the control one, there was a statistically significant difference between both groups (P=0.002). Mean value of dental anxiety scores after the procedure for test group was 0.76 (1.02) and it was 1.34 (1.55) for the control one, there was no statistically significant difference between the two groups (P=0.125). Friedman test was applied to compare the 3 values in each group (baseline, after TPD/TSD, and after the procedure), there was a statistically significant difference between both test and control groups (P<0.0001 in both groups). Difference between the baseline scores and after applying the TPD for the test group was statistically significant (P_1<0.0001), conversely the difference between the baseline scores and after applying the TSD in the control group was statistically non-significant (P_1=0.175). Difference between baseline scores and after the procedure in the test group was statistically significant (P_2<0.0001), and the difference between the baseline scores and after the procedure in the control group was statistically significant (P_2<0.0001). Difference between the after TPD/TSD and after the procedure was statistically non-significant in both test and control groups (P_3=1.00, 0.076 respectively).

Table (2) shows a comparison of the heart rate between the study groups. Mean baseline heart rate of the test group was 118.71 (15.542) while it was 118.37 (17.52) for the control group, there was no statistically significant difference between the two groups (P= 0.888). Mean value of heart rate after TPD/TSD for test group was 89.29 (12.25) and it was 106.16 (16.69) for the control group, there was a statistically significant difference between both groups (P<0.0001). Mean value of heart rate after the procedure for test group was 87.05 (10.44) and it was 98.66 (18.98) for the control group, the difference was statistically significant (P<0.0001). Friedman test was applied to compare the 3 values in each group (baseline, after TPD/TSD, and after the procedure), the difference was statistically significant in both test and control groups (P<0.0001 in both groups). Difference between the baseline heart rate and after applying the TPD in the test group was statistically significant (P_1<0.0001), and the difference between the baseline heart rate and after applying the TSD in the control group was also statistically significant (P_1<0.0001). Difference between baseline heart rate and after the procedure in the test group was statistically significant (P_2<0.0001), and the difference between the baseline heart rate and after the procedure in the control group was statistically significant (P_2<0.0001). Difference between the after TPD/TSD and after the procedure was statistically non-significant in both test and control groups (P_3=1.00, 0.408 respectively).

Table (1): Comparison of the dental anxiety scores through VPT between the study groups.

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		Test group (n=38)	Control group (n=38)	Mann Whitney Test	P value
Baseline	Mean (SD)	3.21 (2.42)	3.18 (2.29)	0.047	0.962
	Median	3.00	4.00		
	Min-Max	0 – 8	0 – 8		
After TPD/TSD	Mean (SD)	1.08 (1.15)	2.24 (1.62)	3.173	0.002*
	Median	1.00	3.00		
	Min-Max	0 – 4	0 – 5		
After the procedure	Mean (SD)	0.76 (1.02)	1.34 (1.55)	1.536	0.125
	Median	0.00	1.00		
	Min-Max	0 – 3	0 – 5		
Friedman test		46.892	24.509		
P value		<0.0001*	<0.0001*		
P_1		<0.0001*	0.175		
P_2		<0.0001*	0.0001*		
P_3		1.00	0.076		

*Statistically significant different at *p* value≤0.05
P1: Differences between the baseline scores and after applying the techniques. P2: Difference between the baseline scores and after the procedures. P3: difference between the after TPD/TSD and after the procedure.

Table (2): Comparison of the heart rate between the study groups.

		Test group (n=38)	Control group (n=38)	Mann Whitney Test	P value
Baseline	Mean (SD)	118.71 (15.542)	118.37 (17.52)	0.140	0.888
	Median	125.00	121.00		
	Min-Max	77 – 143	77 – 144		
After TPD/TSD	Mean (SD)	89.29 (12.25)	106.16 (16.69)	4.018	<0.0001*
	Median	90.00	108.50		
	Min-Max	64 – 125	69 – 130		
After the procedure	Mean (SD)	87.05 (10.44)	98.66 (18.98)	3.557	<0.0001*
	Median	88.00	100.00		
	Min-Max	69-120	54-123		
Friedman test		51.368	38.00		
P value		<0.0001*	<0.0001*		
P_1		<0.0001*	<0.0001*		
P_2		<0.0001*	<0.0001*		

P_3	1.00	0.408		

*Statistically significant different at *p* value≤0.05
P1: Differences between the baseline scores and after applying the techniques. P2: Difference between the baseline scores and after the procedures. P3: difference between the after TPD/TSD and after the procedure.

DISCUSSION

Dental anxiety is a common issue that can influence the management of the patient. There are different techniques used for reduction of preoperative anxiety. The most widely used approach is TSD (25). Smartphone application is one of the newly developed tools and has shown significant effects on children's behaviour and in reducing anxiety (13).

The purpose of this work was to assess and compare the effectiveness of the TPD, using smartphone applications, and the TSD techniques in reducing preoperative anxiety in children who are undergoing restorative treatment, as measured by HR and VPT.

For the study, we included children aged from 6 to 8 years old. Dental treatment is more likely to be tolerated by children over the age of five than it is by younger ones, according to Davidovich et al (26), since their cognitions, emotions, and even mental understanding become more evolved as they grow older.

In this research, there was no distinction between boys and girls because it was hypothesized that gender was less important for behavioral changes in this younger age group (27,28,29).

Children with prior dental experiences were excluded from the study sample, as this could have an effect on dental anxiety thus affecting the outcome of the study so it was their first visit (30).

Only patients who needed simple restoration of their carious upper primary molars (class I only) without -pulpal involvement and infiltration of LA were included in the study to ensure that the duration and level of anxiety experienced during the whole procedure are consistent and comparable for standardization purposes. As the type of dental procedure and its duration were discovered to be the factors that had the greatest impact towards patients' attitudes at dentist's clinic for various age groups (31).

Physiological measures like heart rate were used to properly evaluate dental anxiety. HR measurement is considered a harmless method to be used throughout dental work (32). For this reason in present study, a pulse

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oximeter was used to monitor all the patients as it has been used as an objective measure of anxiety in many recent studies (9). To prevent any postural shift impact, HR meas urements were taken in a seated posture on the dental chair (33).

The children who took part in this research were anxious towards dental treatment, and revealed high level of anxiety and heart rate for both groups with no significant difference demonstrating that all patients had comparable levels of anxiety prior to treatment.

In the current study's results, when opposed to the TSD group, the TPD group at after-intervention step and after-treatment step had a lower heart rate, suggesting reduced anxiety levels. This corresponded to the findings of Radhakrishna et al.'s research (34) which showed in comparison with the traditional Tell-Show-Do group, the mobile dentist game group had lower mean heart rates. From the results of present study, heart rate levels after-intervention step and after-treatment step were significantly lower than heart rate levels at baseline step for both the TPD and the TSD groups, however, the reduction was higher for TPD group which is in accordance with results of Shah et al. (13) and Khandelwal et al (35) that reflect a decrease in HR as an indicator of anxiety. The significant decline in HR in the TSD group may be attributed to the theoretically positive impact of a detailed pre-treatment description of dental procedures.

The Venham's picture test was used as a subjective measure to evaluate the level of dental anxiety. It is simple to use, quick, dependable, and accurate. Moreover, VPT was the preferred scale when children were given a choice among all self-reported anxiety scales (24).

When anxiety was measured with VPT, the findings of this research revealed that TPD group after-intervention step had statistically significant lower child anxiety levels than TSD group. This reduction of patient's anxiety in TPD group may be attributed to the therapy being presented in an engaging, cheerful, and playful way by the use of smartphone application. In the dental game, access to the practice, the effects and the sounds of the operation could be another significant factor which might have assisted in reducing anxiety. Significant reduction in anxiety levels in the TPD group when evaluated by VPT between baseline to after-intervention steps and also between baseline to after-treatment steps. Researches of Elicherla et al. (14), Vishwakarma et al. (16) and Shah et al. (13) produced identical outcomes, which used different anxiety scales, and their results revealed that TPD has been shown to be more beneficial at relieving anxiety.

Conversely, between baseline and after-intervention steps, there was no statistically significant decline in anxiety in the TSD group. Similar results found by Khandelwal et al. (35). Despite the fact that the participants in the TSD group were handled in a non-threatening manner using acceptable words, it is possible that the lack of play and interaction led to this result.

According the outcomes of this research, among the three steps (baseline, after TPD/TSD and after-treatment steps) there was a statistically significant difference, when evaluated by HR and VPT score for both groups. Even so, the use of the TPD technique has achieved a greater decrease in anxiety compared to the TSD technique. The Tell-Show-Do technique has been changed and modified to the Tell-Play-Do technique by using smart phone application and it becomes significantly more successful in lowering pulse rates and changing behavior than the traditional Tell-Show-Do approach. These observations are close to those of Patil et al. (36), Shah et al. (13) and Vishwakarma et al. (16) whom hypothesized that TPD may be a substitute for behavioral therapy in pediatric dentistry.

The results of this research matched those of Lee et al. (37), whom reported that it can be a diversion in the behavioral guidance strategy to involve a child with mobile apps and stated that applications were helpful in minimizing their anxiety before operation.

The study of Elicherla et al. (14) showed the same conclusion of this study in which it was reported that using a smartphone application to educate a child prior to a dental operation will greatly reduce dental anxiety through their first visit and involve children in treatment. Although the treatment of our study was expected to produce more anxiety levels as it was invasive procedures (restorative with LA administration) but the conclusion was similar to Elicherla's study (14), where the therapy was restricted to a non-invasive method (prophylactic cleaning).

The null hypothesis of the present study was rejected and the use of the smartphones applications (TPD) was found to be effective in reducing children's dental anxiety when receiving restorative treatment. A drawback of this research was that participants and operator could not be blinded due to the use of study smartphone application. Because the care in this trial was confined to the first dental visit for the child patient, it is recommended to confirm the effect of using smartphone application as a TPD technique, in subsequent

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visits, on children's dental anxiety as a method of behavior modification.

CONCLUSIONS

It is possible to draw the following conclusions based on the methods and the findings of this study:

Both TSD and TPD techniques could decrease dental anxiety levels in children aged 6-8 years.

Greater anxiety reduction was accomplished by using 'Smartphone Application' intervention as a TPD technique when compared to TSD technique.

Using dental game application in TPD technique is worth practicing in pediatric dentistry, as it achieves cooperative behavior in the children's first visit.

Conflict of Interest

The authors declare that they have no conflict of interest.

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