

Original Article

Mobile App versus Tell-Show-Do Technique in Reduction of Anxiety and Pain during Administration of Local Anaesthesia in Children: A Randomized Clinical Trial.

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Abstract

Aim: To evaluate the effectiveness of the mobile app versus the tell-show-do technique in reducing anxiety and pain during the administration of local anaesthesia in children.

Subjects and methods: Eighty children aged from four to six years old were randomly allocated into two groups, forty patients in each group. Group A: children were managed using the mobile dental app (little lovely dentist). Group B: children were managed using Tell-Show-Do technique, then, both groups received the local anaesthesia and the required treatment. During the second visit both groups received the required treatment without behaviour management. The outcomes measured for both groups during the first visit were: preoperative and post-operative anxiety recorded by pulse oximeter and the RMS pictorial scale, post-operative pain was evaluated by the visual analogue scale, and the attitude was recorded by Venham scale and Frankle scale in the first and second visits.

Results: The results of this study showed that, mobile app group showed less anxiety scores, less pain scores and more cooperative behaviour compared to tell-show-do group but the effect size was small.

Conclusion: : the mobile app "little lovely dentist" can be used to reduce levels of dental anxiety, pain, and to acquire cooperative behaviour in pediatric dental patients.

Keywords: child behaviour, dental anxiety, mobile app, tell-show-do, pediatric dentistry.

I. INTRODUCTION

Dental anxiety and fear are very common problems that occur regularly in dental offices, especially when treating a child patient. Anxiety is frequently associated with painful stimuli and enhanced pain perception, and as a result, those individuals feel more pain that lasts longer, as well as exaggerating their pain memory. Treating fearful patients is stressful for the dentist because of the decreased

cooperation, which necessitates extra treatment time and resources, resulting in a negative experience for both the patient and the dentist (Appukuttan, 2016).

Local anaesthesia is the main cause of dental anxiety and pain that result in uncooperative behaviour and avoidance in dental practice. Prevalence of fear of local anaesthesia injection is 19% among children aged 4-6 years, 11% among 10- 11years, and

11% among young adults aged 18 years (Pande et al. 2020).

Decreasing the levels of anxiety and pain during administration of local anaesthesia is a great challenge in paediatric dentistry and there is not sufficient evidence supporting any of the techniques used nowadays as published in a systematic review in Cochrane library (Monteiro et al., 2020).

This study aimed to evaluate the effect of mobile app versus tell-show-do technique in reducing anxiety and pain during the administration of local anaesthesia in children.

II. SUBJECTS AND METHODS

The study was designed to be a randomized clinical trial with parallel-group and allocation ratio (1:1).

Participants were randomly allocated into two groups. Group A: children were managed by using the mobile dental app (little lovely dentist). Group B: children were managed using Tell-Show-Do technique.

Randomization was done by using numbered opaque sealed envelopes contained eight times folded label, 40 envelopes carried mobile app label and the other 40 carried tell-show-do label, then, shuffling the envelopes. Each child selected an envelope upon the enrolment, when the participant selected, his name and telephone number were written on the envelope. Neither the operator nor the patients were blinded because the behaviour management was done at the beginning of the visit, but the statistician was blinded.

A power analysis was designed to have adequate power to apply a two-sided statistical test of the null hypothesis that there is no difference between tested groups. By adopting an alpha level of (0.05) a beta of (0.2) i.e. power=80% and an effect size (d) of (0.645) calculated based on the results of a previous study (Kanzel et al., 2019) and on expert's opinion; the predicted sample size (n) was a total of (78) cases. Sample size calculation was performed using PS software version 3.1.2 (Dupont and Plummer, 1990).

This study was registered on clinical trial.gov with the identifier: NCT04731181

Eighteen patients were selected from the out-patient clinic of Pediatric department, Faculty of dentistry, Cairo University.

All patients were aged 4-6 years old, children without any systemic or mental disorders, without any prior experience with the dental environment or treatment procedures (first dental visit), and they need local anaesthesia for dental treatment during their first dental visit. Children whose behaviour could be rated as positive or negative based on the Frankl behaviour rating scale were accepted in the trial. While, Children seeking dental treatment that did not necessitate local anaesthesia or whose parents were not willing to participate in the study were excluded from the trial.

The trial was done on 2 visits:

a) First visit

For both groups:

1. Verbal assent from participating patients and written consent from their legal guardians were taken.
2. Taking personal data, medical and dental history.
3. Diagnosis and determination of the required treatment.
4. Measuring preoperative anxiety (expressed by heart rate) using a pulse oximeter (figure 1) and using Raghavendra, Madhuri, Sujata - pictorial scale (RMS-pictorial scale) (figure 2).
5. Using the behaviour guidance technique:
 - a. Intervention group (mobile app): Allow the child to play the module simulating the required procedure on little lovely dentist mobile app (figure 3)

- b. Control group: tell-show-do technique is used to explain the procedure to the child.
6. Administration of local anaesthesia.
 7. Evaluation of child behaviour during the administration of local anaesthesia using Venham's behaviour rating scale (figure 4) and Frankl behaviour rating scale (figure 5).
 8. Measuring postoperative anxiety (expressed by heart rate) using the pulse oximeter and RMS pictorial scale.
 9. Evaluation of postoperative pain using the visual analogue scale (figure 6).
 10. The required treatment was done.
 - b) The second visit (after 1 week):

Evaluation of child behaviour during the administration of local anaesthesia was done using Venham's behaviour rating scale (figure 4) and Frankl behaviour rating scale (figure 5), then, the required treatment was done.

The outcomes measured for both groups during the first and second visits are demonstrated in table (1).

The data of the study were monitored by the data monitoring committee that was constituted of trials supervisors.

III. RESULTS

Statistical analysis:

Categorical data were presented as frequency and percentage values and were analyzed using Fisher's exact test. Numerical data were presented as mean and standard deviation values. Parametric data (age) were analyzed using independent t-test. Non-parametric data (all other numerical variables) were analyzed using Mann-Whitney U test for intergroup comparisons and signed rank test for intragroup comparisons. The significance level was set at $p \leq 0.05$ within all tests. Statistical

analysis was performed with R statistical analysis software (Vienna, Austria) version 4.1.3 for Windows (<https://www.R-project.org/>).

Participant flow diagram is shown in (figure 7).

Demographic data of study sample are presented in (table 2).

1. Anxiety recorded by pulse oximeter measuring the heart rate (figure 8):

A- Intergroup comparisons:

Pre-operatively, group (A) had significantly higher value than group (B) ($p=0.021$) and the effect size was small (0.26). While post-operatively, the difference was not statistically significant ($p=0.586$) and the effect size was small too (0.06).

B- Intragroup comparisons:

For both groups, there was no significant difference between values measured preoperative and post-operatively ($p>0.05$) and the effect size was small (<0.3).

2. Anxiety evaluated by RMS pictorial scale (figure 9):

A- Intergroup comparisons:

Pre-operatively, group (B) had significantly higher value than group (A) ($p=0.022$) and the effect size was large (0.62). While for post-operative measurement and the difference, the difference was not statistically significant ($p>0.05$) and the effect size was small (<0.3).

B- Intragroup comparisons:

For both groups, values measured post-operatively were significantly higher than pre-operative values ($p<0.05$) and the effect size was large (>0.5).

3. Postoperative pain evaluated by visual analogue scale (figure 10):

There was no significant difference between both groups ($p=0.272$) and the effect size was small (0.12).

4. Attitude using Venham scale (figure 11):

A- Intergroup comparisons:

Regarding both visits, there was no significant difference between both groups ($p>0.05$) and the effect size was small (<0.3).

B- Intragroup comparisons:

For both groups, values measured in second visit were significantly higher than first visit values ($p<0.05$) and the effect size was large (>0.5).

5. Attitude evaluated by Frankl scale (figure 12):

A- Intergroup comparisons:

Regarding both visits and the difference, there was no significant difference between both groups ($p>0.05$) and the effect size was small (<0.3).

B- Intragroup comparisons:

For group (A), values measured in the first visit were significantly higher than second visit values ($p<0.001$) and the effect size was large (0.67). For group (B) there was no significant difference between values measured at both visits ($p=0.140$) and the effect size was small (0.29).



Figure 1: iMDK pulse oximeter



Figure 2: RMS- pictorial scale



Figure 3: little lovely dentist mobile app

Rating	Definition
0	Total cooperation, best possible working condition, no crying or physical protest.
1	Mild, soft verbal protest or (quiet) crying as a signal of discomfort, but does not obstruct progress. Appropriate behaviour for procedure, i.e., slight start at injection, "ow" during drilling if hurting, etc.
2	Protest more prominent. Both crying and hand signals. May move head around making it hard to administer treatment. Protest more distracting and troublesome. However, child still complies with request to cooperate.
3	Protest presents real problem to dentist. Complies with demands reluctantly, requiring extra effort by dentist. Body movement.

Figure 4: Venham's behaviour rating scale

Rating	Attitude	Definition
1	Definitely negative	Refusal of treatment, crying forcefully, fearful or any other overt evidence of extreme negativism.
2	Negative	Reluctant to accept treatment, uncooperative, some evidence of negative attitude but not pronounced, i.e. /sullen, withdrawn.
3	Positive	Acceptance of treatment; at times cautious, willingness to comply with the dentist, at times with reservation but patient follows the dentist's directions cooperatively.
4	Definitely positive	Good rapport with the dentist, interested in the dental procedures, laughing and enjoying the situation.

Figure 5: Frankl behaviour rating scale

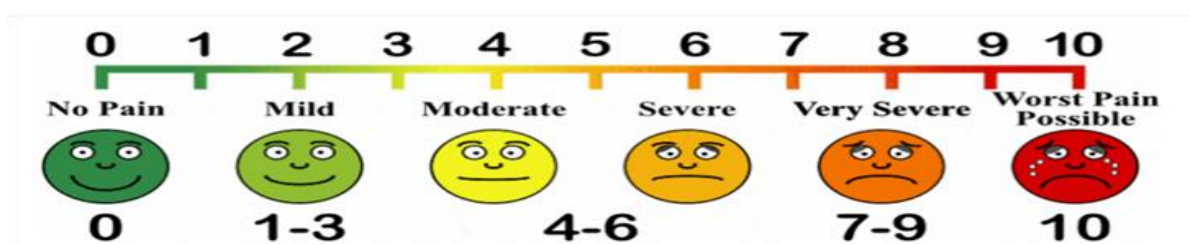


Figure 6: visual analogue scale

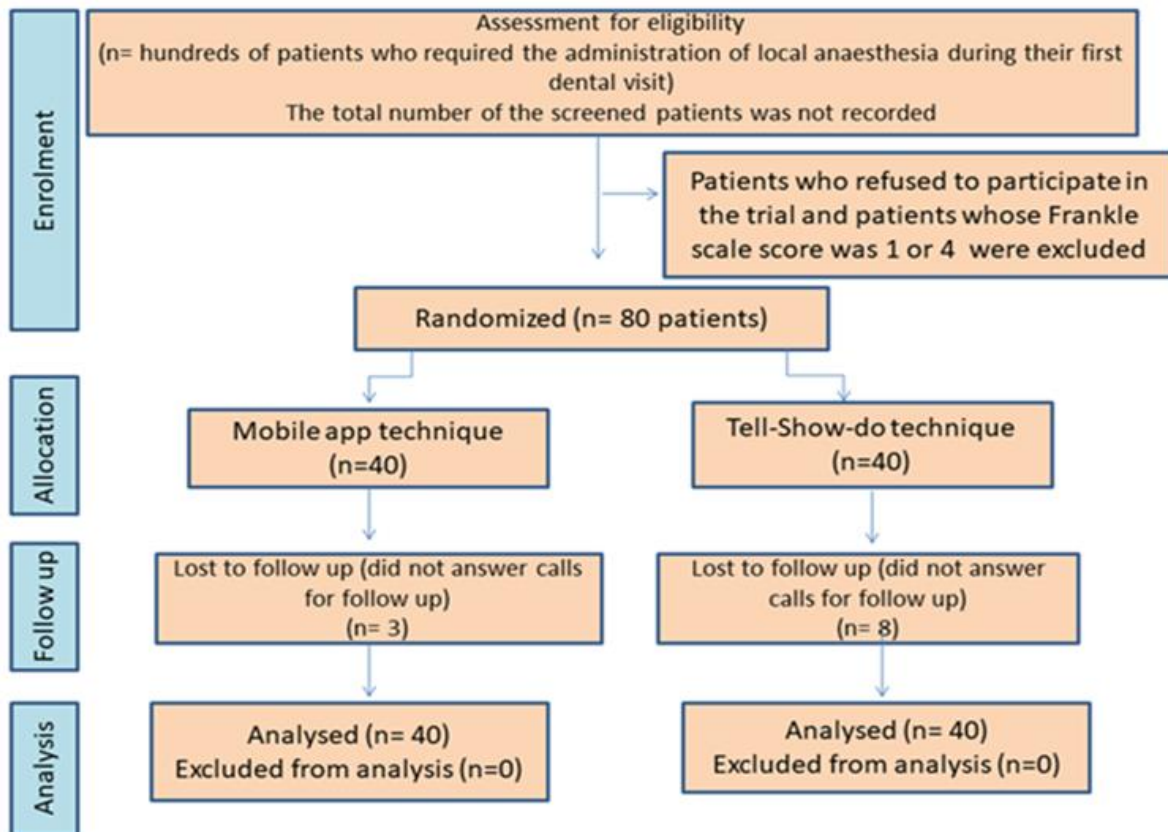


Figure 7: Participants flow diagram

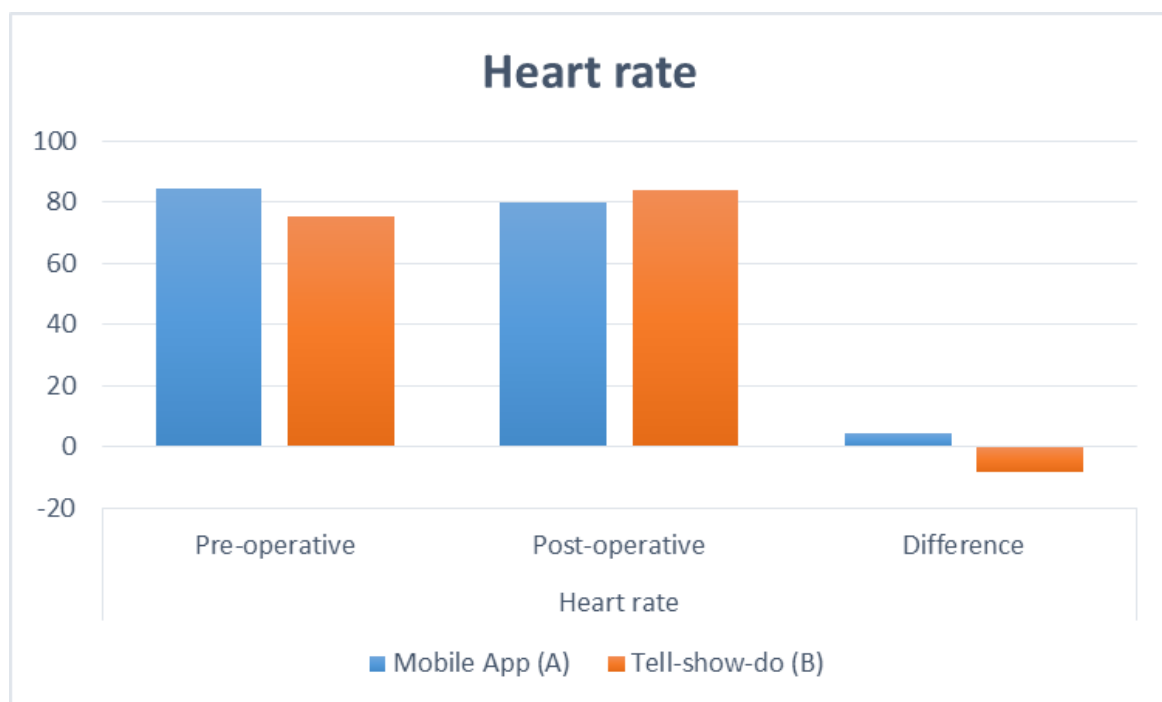


Figure 8: Bar chart showing average heart rate in different groups

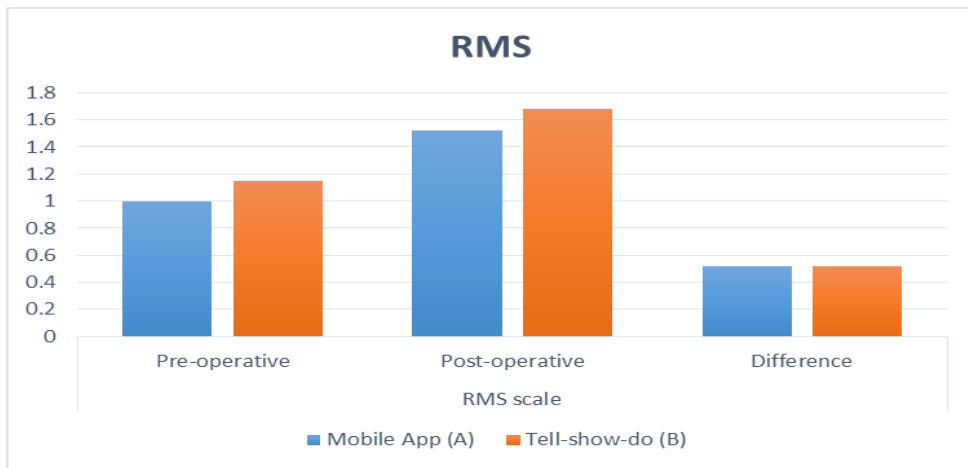


Figure 9: Bar chart showing average RMS scale in different groups

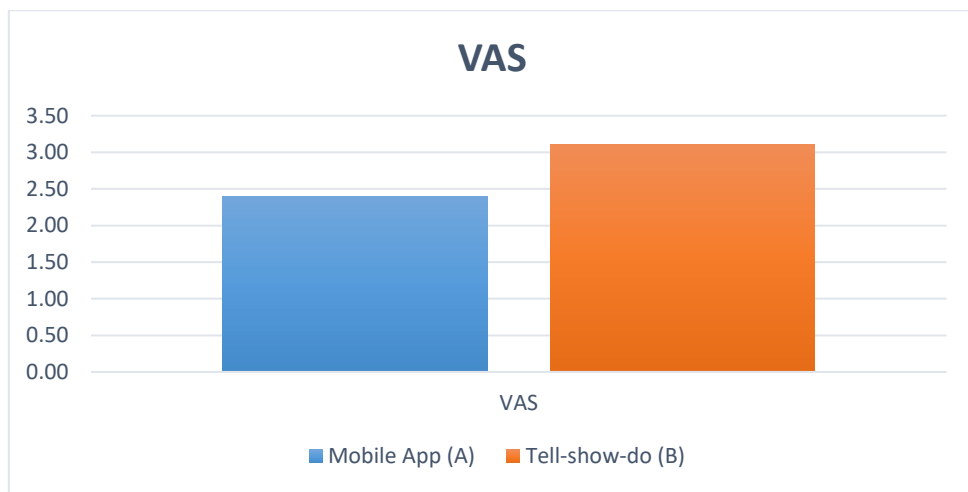


Figure 10: Bar chart showing average VAS in different groups

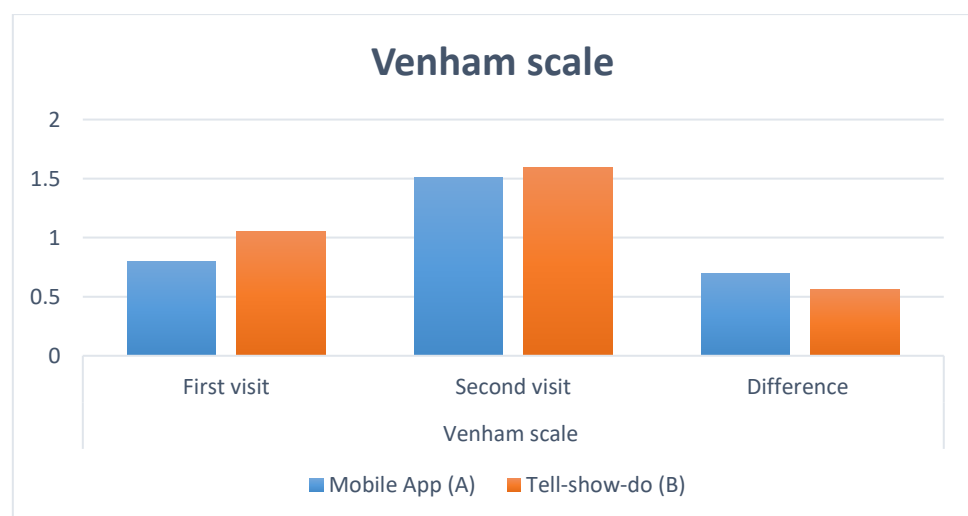


Figure 11: Bar chart showing average Venham scale in different groups

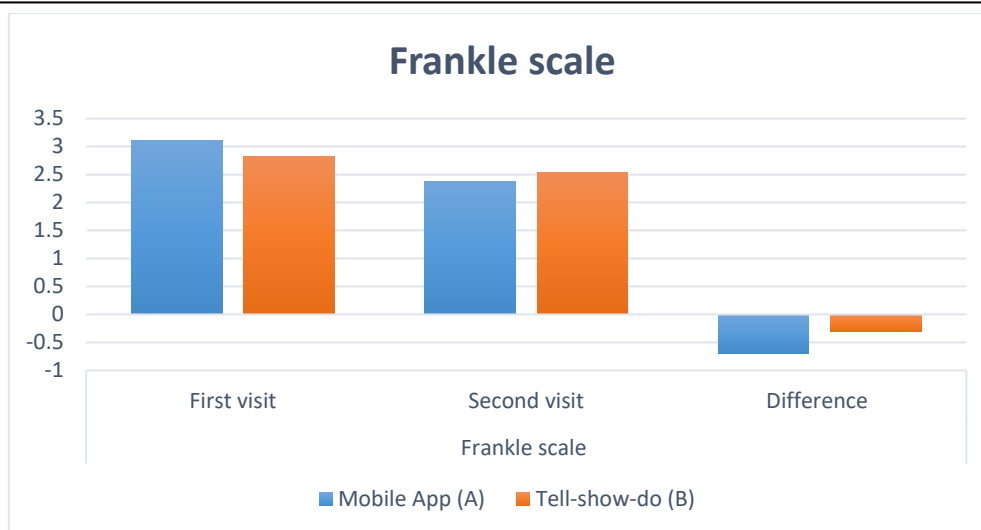


Figure 12: Bar chart showing average Frankle scale in different groups

Table (1): outcomes of the study

	outcome	Method of measurement	unit
primary	Preoperative and postoperative anxiety	Pulse oximeter (heart rate) RMS-pictorial scale ¹	Continuous Numerical
	Postoperative pain	Visual analogue scale	Numerical
secondary	Attitude during the administration of local anaesthesia in first and second dental visits	-Venham's behaviour rating scale -Frankl behaviour rating scale	Numerical Numerical

Table (2): Demographic data of study sample

Parameter		Mobile App (A)	Tell-show-do (B)	P-value	
Sex	Male	n	20	24	00.500
		%	50.0%	60.0%	
	Female	n	20	16	
		%	50.0%	40.0%	
Age (years)	Mean±SD	5.00±0.68	5.12±0.79	00.450	
DMF or dmf	Mean± SD	6.45±3.12	5.95±2.70	00.614	

¹ RMS-pictorial scale: Raghavendra, Madhuri, Sujata - pictorial scale

IV. DISCUSSION

Child anxiety is one of the most challenging situations to the paediatric dentist, controlling and limiting anxiety is a cornerstone in behaviour management which allows the dentist to deliver a high-quality service to the child. Moreover, it reduces the possibility of future need to more invasive approaches such as the conscious sedation or general anaesthesia (AAPD, 2021).

A Randomized Controlled Trial was conducted in this research, because it is regarded as the gold standard research design to demonstrate a cause-and-effect link between an intervention and an outcome (Salmond 2008).

A random sample has been applied to children who met the eligibility criteria from the outpatient clinic to avoid the selection bias. Upon acceptance to participate in the study, the child was allowed to choose an envelope to allocate the child in a group.

The allocation was concealed in the current study by using an eight times folded paper that was included in closed white envelopes, not to show their contents. The allocation was concealed to avoid selection bias and performance bias. In this study performance bias could not be avoided as behaviour management was done at the beginning of the treatment so the dentist was aware in which group the patient was allocated, however, performance bias was minimized by standardization of the procedure.

The children enrolled in this study were selected in the age group between four to six years old, according to (Sharma and Tyagi, 2011), the 5 years old child is characterized by his/her ability to follow the rules, independence, having the ability to tell what is real and what is not real and shifting between being demanding and being very cooperative. All of these characteristics give the practitioner the ability to explain the dental procedure to this age group, and the child to be able to understand what is going to happen, leading to decrease in fear of unknown and fear of new people.

The first dental visit was chosen as an inclusion criterion to be sure that the children included in this study were not exposed to any previous psychologically traumatic dental situation and their anxiety is related to their own fear not to any subjective fear (Anthonappa et al., 2017).

Accordingly, chronically ill children were excluded from this study to avoid any fear of the medical personnel (AAPD, 2021).

Dental injection is the most commonly reported cause of anxiety and pain during the dental visit followed by extraction and tooth drilling. Therefore, the administration of local anaesthesia was the chosen procedure during which behaviour management techniques were tested (Shetty et al., 2015).

Tell-Show-Do technique was used as a control in this study as it is considered the most commonly used basic behaviour management technique. It is almost considered the gold standard for behaviour management techniques (Vishwakarma et al., 2017; AAPD, 2021).

The majority of homes in the modern world have numerous electronic devices; According to (Radesky et al., 2020), 35% of children aged from three to five years old have their own mobile phones with a daily average usage time of 115.3 minute /day.

Accordingly, mobile app was used as an intervention because of its ease of use, accessibility, child-friendliness, playfulness, and lack of the need for supplementary virtual reality equipment. (Radhakrishna et al., 2019).

Pulse oximeter was used in this study to assess the anxiety level as it measures pulse rate. High anxiety is associated with an increase in heart rate due to sympathetic stimulation. The pulse oximeter is an easy device to use, cost effective, reliable, and relatively small (Hegde et al., 2019; Salih et al., 2021).

RMS Pictorial Scale (RMS-PS) is a recent anxiety rating scale, it consists of a row of faces that range from extremely pleasant to extremely

upset. Boys and girls each had their own set of images. The children were instructed to select the expression they felt most about themselves at the time (Shetty et al., 2015).

Visual analogue scale was used in this study because it is easy to use and quick to administer. (Alinejhad et al., 2018).

Frankl Rating Scale was utilized in this study as it is the most frequently used behaviour rating scale. It is easily used and doesn't consume much time (Narayan and Samuel, 2020).

Venham Behaviour Rating Scale gives additional information about paediatric patients who exhibit negative and disruptive behaviour and characterises children's behaviour in depth (Silva et al., 2020).

Both behaviour rating scales were used to complement each other and give more reliable results.

Anxiety evaluated by pulse oximeter:

The results of the study showed reduction in mean postoperative heart rate in mobile app group by (4.55 ± 25.61) . This may be due to the attractive visual presentation of the treatment that featured a variety of engaging and enjoyable tasks for the patient to complete on the mobile phone. The mobile app also simulates the environment and noises of numerous dental treatments that the young patient will eventually experience. For the Tell-Show-Do (TSD) group the results showed an increase in mean postoperative heart rate by (8.32 ± 28.24) , this may be due to lack of enjoyable time of playing, and non-attractive presentation of the dental instrument compared to virtual ones in the mobile app.

Only 7% of communication comprehension is based on the words used, whereas visual elements make up 55% of communication content (Derbala et al., 2022) so, the attractive presentation of tools plays a role in communication and relief of anxiety.

This finding met the conclusion of (Elicherla et al., 2019) and (Abbasi et al., 2021) who studied the mobile app versus TSD

technique in children and found that mobile app was more effective than TSD in reduction of anxiety expressed by the heart rate. In (Elicherla et al., 2019) study the results showed reduction of mean postoperative heart rate in mobile app group by (10.8 ± 0.5) and increase in mean postoperative heart rate in TSD by (1.3 ± 2.3) , while (Abbasi et al., 2021) found reduction of mean postoperative heart rate in mobile app by (3 ± 1.4) and increase in postoperative heart rate in TSD by (6.8 ± 8.4) .

Anxiety evaluated by RMS-Pictorial Scale:

For mobile app group, the mean postoperative scores increased by (0.52 ± 0.99) which means that the anxiety level increased. Although the difference was not large, but it was the contrary to the pulse oximeter readings which revealed that the postoperative anxiety scores were less than the preoperative ones. This may be due to the small age range of children in this trial who could not express their feelings accurately and the invasive nature of the procedure performed i.e. the administration of local anaesthesia. For TSD, the mean postoperative anxiety scores increased by (0.52 ± 0.85) .

The results of this study were in contrast to the results of (Elicherla et al., 2019) who studied the mobile app versus the TSD and evaluated the anxiety using RMS-Pictorial Scale. They found that, the anxiety scores decreased from the preoperative to the postoperative ones by (1.88 ± 0.54) in mobile app group and (1.1 ± 0.2) in TSD group, this contrast may be due to the older age range of children participating in (Elicherla et al) study which was 7-11 years old. With age the children are more able to express their feelings properly. Also, the procedure in (Elicherla et al) study is another factor, it was oral prophylaxis which is simple and less fearful procedure than a dental treatment with the administration of local anaesthesia.

Postoperative pain evaluated by Visual analogue scale:

The mean pain score in mobile app was (2.40±2.53) while in TSD was (3.10±2.68). This may be due to the joyful method of illustration of the dental procedures using the mobile app which helped in reducing the dental anxiety and subsequently the postoperative pain. Anxious children report more pain according to (Mustafa et. al., 2013).

Behaviour rating using Venham behaviour rating scale:

Mobile app group showed more cooperative behaviour during the first (mean score was 0.80±0.88) and second visit (mean score was 1.51±0.90) than TSD group (mean score was 1.05±0.93 and 1.59±1.13 in the first and second visits respectively). This may be due to the interesting display of the dental procedures by the mobile app.

This result coincide with (Tahersoltani et al., 2021) who studied the mobile app versus TSD during class II amalgam restoration for children and tested the behaviour using Venham scale. They found that, children in mobile app group were more cooperative (mean score was 1.25) than TSD group (mean score was 1.98).

Behaviour rating using Frankl behaviour rating scale:

During the first dental visit mobile app group showed more cooperative behaviour (mean score was 3.10±0.87) than TSD group (mean score was 2.83±0.90). This finding met the results of (Radhakrishna et al., 2019) who studied mobile app versus TSD and evaluated the behaviour using Frankl behaviour rating scale. It was found that children in mobile app group showed more cooperative behaviour (mean score was 3.85) than their peers in TSD group (mean score was 3.35). While in the second visit TSD group showed more cooperative attitude than mobile app which is the contrary to the behaviour evaluated by Venham behaviour rating scale during the second visit. This may be due to the grey area

between score 2 (negative) and score 3 (positive) in Frankle scale (Riba et al., 2017).

V. CONCLUSION

Behaviour modification strategies like the mobile app "little lovely dentist" can be used to reduce levels of dental anxiety, pain, and to acquire cooperative behaviour in pediatric dental patients.

Conflict of Interest:

The authors declare no conflict of interest.

Funding:

This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

Ethics:

This study protocol was approved by the ethical committee of the Faculty of Dentistry-Cairo University on: 27/7/2021, approval number (5721).

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