Original Article

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Comparative evaluation of the effectiveness of two innovative methods in the management of anxiety in a dental office: a randomized controlled trial

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Background: The first dental experience is vital in molding a child's attitude towards dentistry and dental outcomes. The cooperation of a child during dental treatment is essential to render successful and high-quality treatment. Dental anxiety is common in children undergoing dental treatment. The success of pediatric dental treatments and patient comfort depends on controlling the levels of patient anxiety in clinical settings. This study aimed to compare the effectiveness of the recorded maternal voice and virtual cognitive tool (Roogies application) in the management of pediatric dental patients.

Methods: The study was carried out with children aged of 4-7 years [n = 80, (40 male and 40 female)], without any past dental history, and were randomly allocated into two groups. After informed consent was obtained, the entire procedure was explained to the parents. Anxiety was assessed pre-, during, and post-treatment by measuring pulse rate, and recording Venham Picture Test (VPT) scores. Group A [n = 40; 20 boys and 20 girls)] was provided with a headphone that played a recorded maternal voice. Group B [n = 40; 20 boys and 20 girls)] was administered the virtual cognitive tool. After conditioning the children, oral prophylaxis was performed for both groups. A comparative evaluation was conducted for each treatment session.

Results: The intra-group comparison of VPT scores and heart rate for patients assigned to the recorded maternal voice showed a statistically significant difference in dental anxiety (P-value $\leq$ 0.001).

Conclusion: This study demonstrated that a reduction in dental anxiety with the help of recorded maternal voice forms an important component of non-pharmacological behavior management. Alternatively, the use of a virtual cognitive tool as an anxiety-reducing technique can also be advocated.

Keywords: Anxiety; Behavior Guidance; Dental Visit; Maternal Voice; Roogies Application; Tell-Show-Do.

INTRODUCTION

Dental anxiety in recent generations is a primary concern for dental professionals, as it can significantly prevent a child from looking for dental treatment, which may lead to further complications and for further treatment proceedings [1]. During a child's first dental visit, they tend to experience dental anxiety, which has a major impact on their future dental operatory behavior and can lead to negligence [2,3]. Various cognitive behavioral guidance techniques have been successfully used to control dental anxiety in children [4]. Our generation has been blessed with the latest technologies and advancements.

Research on mobile dental applications has led to the development of promising virtual reality immersion and distraction methods. This technique allows the child to

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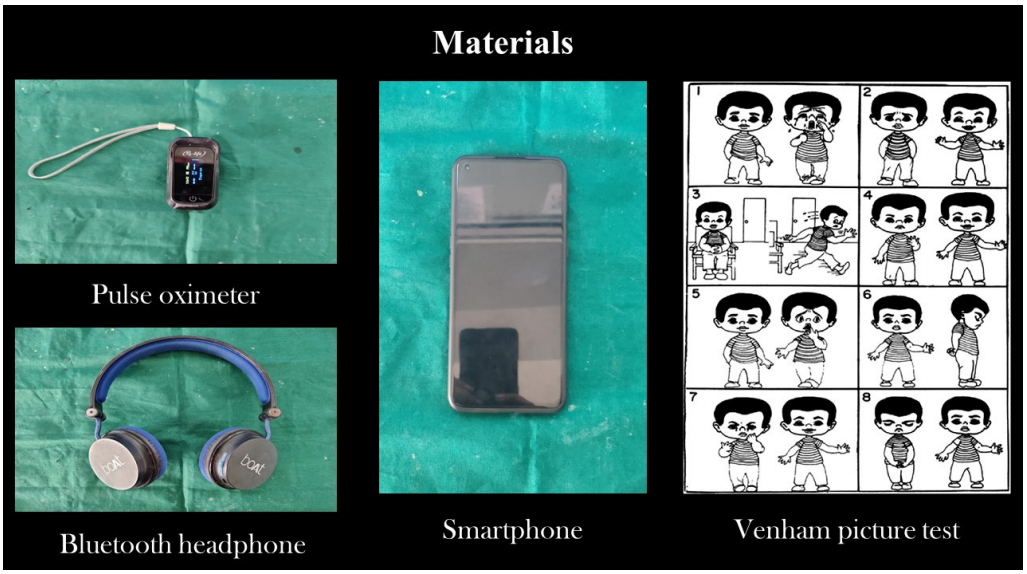

Fig. 1. Materials used in the study.

Fig. 2. Roogies mobile application.

adjust to the dental office and also enables positive and promising conversations between professionals and patients [5,6]. Panchal [7] described the use of such virtual reality apps for discrete risk as well as prevention of caries by exponentially improving oral hygiene and dietary habits.

One such technological application is Roogies, which was created by considering the cognitive-behavioral principles for children, such as systematic desensitization, modeling, distraction, guidance, imagery, and cognitive restructuring. The use of the maternal voice as a tool for a child's well-being has been investigated in infants and children in the literature. This study aimed to evaluate the effectiveness of two innovative techniques for managing dental anxiety in children.

METHODS

Materials: materials used in the study were a portable finger pulse oximeter, smartphone, Bluetooth headphones, and the Venham picture test (VPT) (Fig. 1), and

Fig. 3. Conditioning the child using a recorded maternal voice.

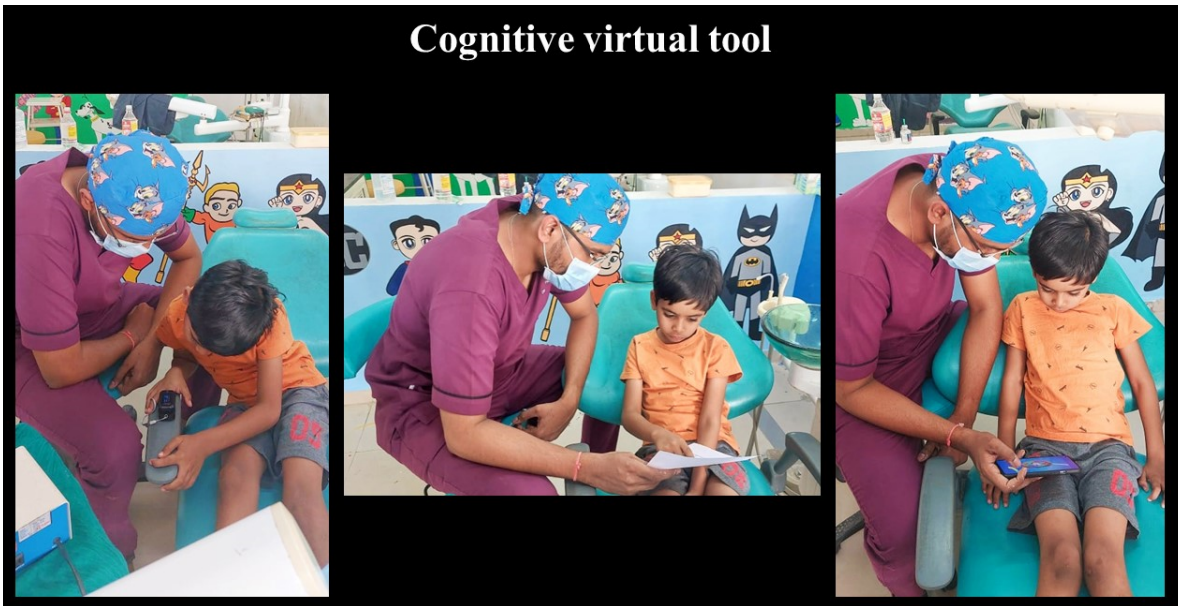

Fig. 4. Conditioning the child using a cognitive virtual tool (Roogies mobile application).

Roogies mobile application (Fig. 2).

Methods: This was a parallel-arm-type study design, and the allocation ratio was 1:1. The study was approved by the institutional ethical committee (CDSRC/IEC/20200803/27). Initially, 100 children aged between 4-7 years who reported to the Department at the College with their parents for dental treatments were assessed. The sample size was calculated using the following formula:

$$n = \frac{z2 \times P \times (1-P)}{E2}$$

With a confidence level of 95% and probability of 0.05, the obtained sample size was 80.

The study was carried out on 80 children (n = 80) between the ages of 4-7 years according to our inclusion and exclusion criteria, as they tend to have their first dental visit at that age. The study was conducted over a two-month period (January and February 2022).

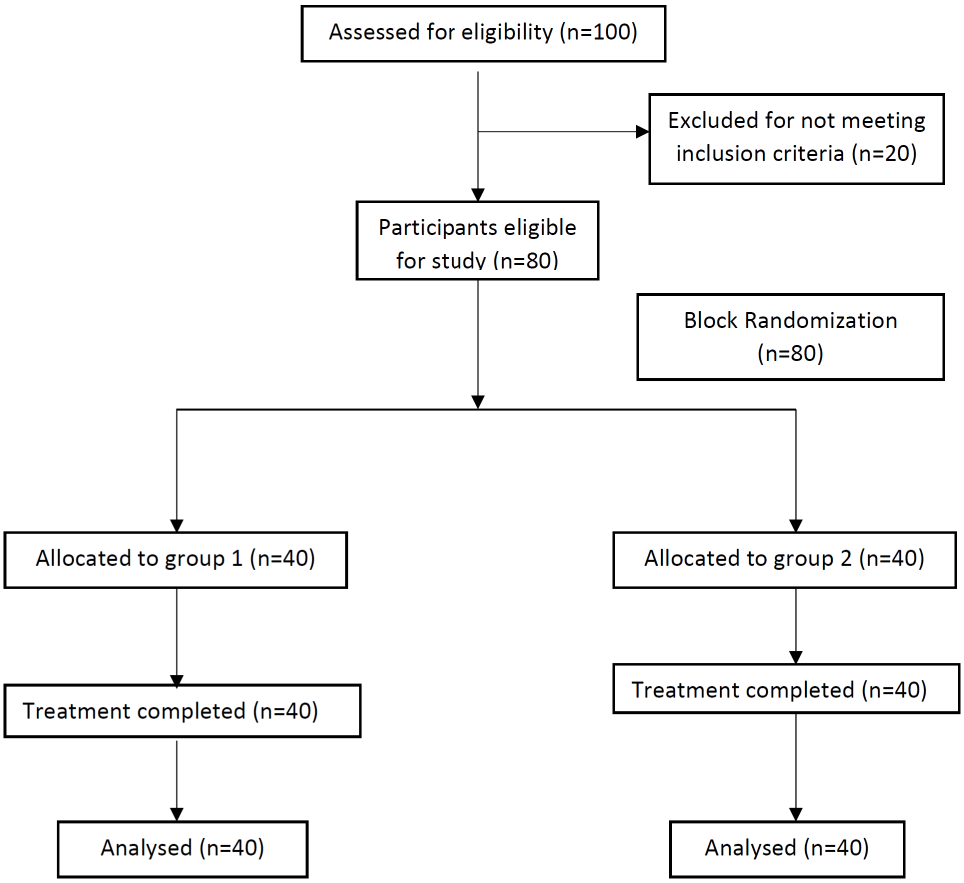

Fig. 5. CONSORT flow diagram of the study design.

The criteria for inclusion were:

- Child who had no occurrence of dental operatory environment.
- Child without any systemic disorders.
- Child without mental disorders.
- Behaviors were rated as positive (+) or negative (-) based on the Frankl behavior rating scale. (Wright's modification).
- Child who showed willingness for participation.

The exclusion criteria were:

- Child or parents who didn't agree to participate.
- Behavior was rated as definitely positive (++) or definitely negative (--) based on the Frankl behavior rating scale. (Wright's modification).

After informed consent was obtained, the entire procedure was explained to the parents. Anxiety was assessed pre- during, and post-treatment using the VPT. The pulse rate was also estimated before, during, and after completing the procedure. The 40 children allotted to group A (Fig. 3) were provided with recorded maternal voices using headphones. Another group of 40 children allotted to Group B (Fig. 4) was provided with digital dental education through a smartphone during the treatment. The participants included in the trial proceedings were unaware of any kind of procedure they were undergoing.

"Roogies" is an application available on the Google Play Store. It can be utilized to joyfully educate the child about the whole procedure (for example, oral prophylaxis, various restorations, etc.) (Fig. 2, 4).

The recorded maternal voice was recorded using a smartphone before the procedure. The child was provided with headphones to listen to the voice during the procedure (Fig. 3). After conditioning the child, an oral prophylaxis procedure was performed in both groups (Fig 5).

Table 1. Male and female participants (Demographic distribution)

Group	Male	Female	Total participants
Group A - recorded maternal voice	20	20	40
Group B - cognitive virtual tool	20	20	40

Table 2. Age-wise demographic distribution of participants

Age	Total participants
4 years	22
5 years	16
6 years	18
7 years	24

Table 3. Intra-group comparison of heart rate in both the groups

Group	Time period	Numbers	Heart rate		P-value
			Mean	SD	
Group A	Pre-operative	40	87.00	4.81	≤ 0.001***
	During procedure	40	82.70	3.77	
	Post-operative	40	78.35	2.89	
Group B	Pre-operative	40	87.80	4.61	≤ 0.05*
	During procedure	40	85.10	4.43	
	Post-operative	40	81.50	3.53	

Levels of significance: P ≤ 0.05, *significant, **highly significant, ***very highly significant.

Table 4. Levels of significance of heart rate in both the groups

Group	Time period		P-value
Group A	Pre-operative	During procedure	≤ 0.001***
		Post-operative	≤ 0.001***
	During procedure	Post-operative	≤ 0.001***
Group B	Pre-operative	During procedure	≤ 0.05*
		Post-operative	≤ 0.05*
	During procedure	Post-operative	≤ 0.05*

Levels of significance: P ≤ 0.05, *significant, **highly significant, ***very highly significant.

As a primary outcome, the anxiety levels pre- during, and post-procedure were assessed by recording the heart rate (physiological measurement) and as a secondary outcome, the subjective measures of anxiety in the treatment duration were recorded and justified using a portable finger pulse oximeter and the VPT, respectively. (Fig. 3, 4)

Statistical Package for Social Sciences software (SPSS 21.0) for Windows was used to perform all statistical analyses. The statistical tests used were repeated measures ANOVA, Bonferroni test, Friedman test, Wilcoxon signed ranks test, unpaired t-test, and Mann Whitney test. Statistical significance was set at $P < 0.05$.

RESULTS

Forty boys and 40 girls were randomly recruited and allocated to two groups. There was a symmetrical distribution of participants in both groups (20 male and 20 female participants in each group) (Tables 1, 2).

Intragroup comparison of heart rate in Group A (recorded Maternal voice) showed a mean heart rate of 87.00 ± 4.81 at the preoperative period, 82.70 ± 3.77 during the procedure, and 78.35 ± 2.89 at the post-operative period (Table 3). Statistically, a significant difference was present in the change in heart rate from preoperative to during the procedure, from preoperative to post-operative, and from the procedure to the post-operative period in Group A (Table 4).

Intragroup comparison of heart rate in Group B (Roogies application) showed that the mean heart rate was 87.80 ± 4.61 at the preoperative period, 85.10 ± 4.43 during the procedure, and 81.50 ± 3.53 at the post-operative period (Table 3). Statistically, a significant difference was present in the change in heart rate from

Table 5. Intragroup comparison of VPT scores in both the groups

Group	Time period	Numbers	Heart rate		P-value
			Mean	SD	
Group A	Pre-operative	40	1.60	1.08	≤ 0.001***
	During procedure	40	1.03	0.15	
	Post-operative	40	0.25	0.43	
Group B	Pre-operative	40	1.65	0.77	≤ 0.05*
	During procedure	40	1.58	0.54	
	Post-operative	40	0.52	0.54	

Levels of significance: P ≤ 0.05, *significant, **highly significant, ***very highly significant.

Table 6. Levels of significance of VPT scores in both the groups

Group	Time period		P-value
Group A	Pre-operative	During procedure	≤ 0.001***
		Post-operative	≤ 0.001***
	During procedure	Post-operative	≤ 0.001***
Group B	Pre-operative	During procedure	≤ 0.05*
		Post-operative	≤ 0.05*
	During procedure	Post-operative	≤ 0.05*

Levels of significance: P ≤ 0.05, *significant, **highly significant, ***very highly significant.

Table 7. Inter-group comparison of heart rates between group A and group B

Time period	Numbers of participants	Group A (Maternal recorded voice)		Group B (Roogies application)		P-value
		Mean	SD	Mean	SD	
Pre-operative	40	87.00	4.81	87.80	4.61	0.235
During procedure	40	82.70	3.77	85.10	4.43	≤ 0.001***
Post-operative	40	78.35	2.89	81.50	3.53	≤ 0.001***

Levels of significance: P ≤ 0.05, *significant, **highly significant, ***very highly significant.

preoperative to during the procedure, from preoperative to post-operative, and from the procedure to the post-operative period in Group B (Table 4).

Intragroup comparison of the VPT scores in Group A showed mean VPT score was 1.60 ± 1.08 at the preoperative time period, 1.03 ± 0.15 during the procedure and 0.25 ± 0.43 at the post-operative period (Table 5). Statistically, a significant difference was present in the change in VPT score from preoperative to during the procedure, from preoperative to post-operative, and from during the procedure to the post-operative period in Group A (Table 6).

Intragroup comparison of VPT scores in Group B showed that the mean VPT score was 1.65 ± 0.77 at the preoperative period, 1.58 ± 0.54 during the procedure and 0.52 ± 0.54 at the post-operative period (Table 5). Statistically, a significant difference was present in the change in VPT scores from preoperative to during the procedure, from preoperative to post-operative, and from during the procedure to the post-operative period in Group B (Table 6).

Statistically, no significant difference was present in the heart rate between groups A and B during the pre-operative period. The mean heart rate was lower in group A (82.70 ± 3.77) than in group B (85.10 ± 4.43) during the procedure. Statistically, a significant difference was present in heart rate between groups A and B during the procedure. The mean heart rate was lower in Group A (78.35 ± 2.89) than in Group B (81.50 ± 3.53) during the postoperative period. Statistically, a significant difference was present in the heart rate between Group A and Group B during the postoperative period (Table 7) (Fig. 6).

Statistically, no significant difference was present in

Table 8. Inter-group comparison of VPT scores in group A and group B

Time period	Numbers of participants	Group A (maternal recorded voice)		Group B (roogies application)		P-value
		Mean	SD	Mean	SD	
Pre-operative	40	1.60	1.08	1.65	0.77	0.976
During procedure	40	1.03	0.15	1.58	0.54	≤ 0.001***
Post-operative	40	0.25	0.43	0.52	0.54	≤ 0.05*

Levels of significance: P ≤ 0.05, *significant, **highly significant, ***very highly significant.

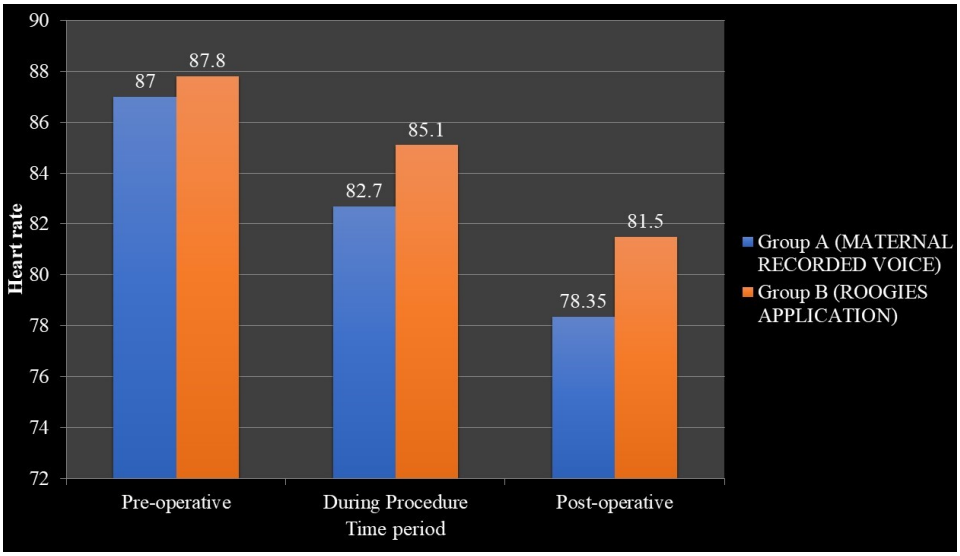

Fig. 6. Graph showing Inter-group comparison of Heart Rates between Group A and Group B.

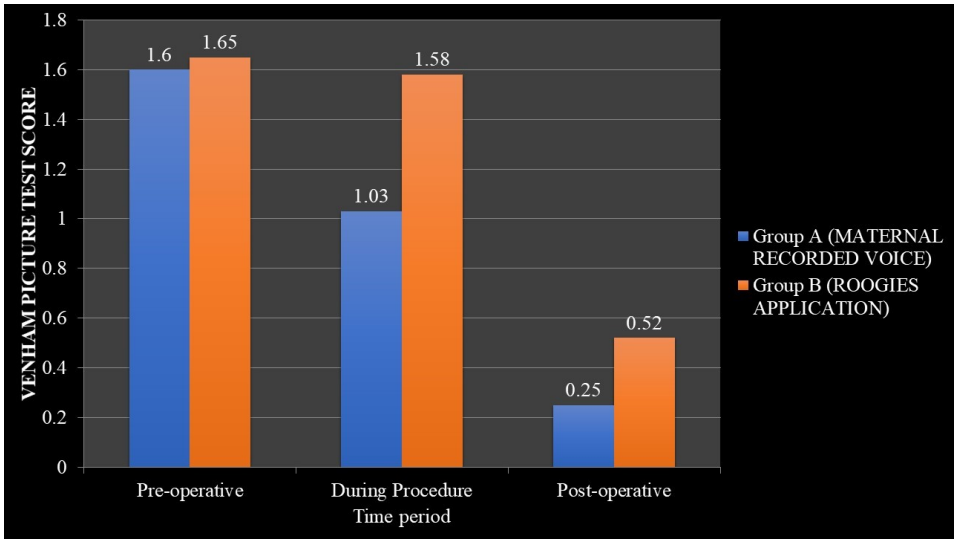

Fig. 7. Graph showing Inter-group comparison of Venham picture test scores in Group A and Group B.

the VPT scores between groups A and B at the pre-operative period. The mean VPT score was lower in group A (1.03 ± 0.15) than in group B (1.58 ± 0.54) during the procedure. Statistically, a significant difference was present in the VPT score between groups A and B during the procedure. The mean VPT score was lower in Group A (0.25 ± 0.43) than in Group B (0.52 ± 0.54) during the postoperative period. Statistically, a significant difference was observed in the VPT scores between Group A and Group B during the postoperative period

(Table 8) (Fig. 7).

DISCUSSION

For several years, dental fear and anxiety have been recognized as crucial sources of trouble in managing children during dental procedures [8,9]. Anxiety and fear during simple dental procedures in children have been recognized as major health problems. Moreover, it has been ed that the effects of dental fear and anxiety may persist until adolescence and become a major cause of negligence and avoidance of dental treatments. This kind of fear and dental anxiety have also been recorded as a root cause of disruptive behavior in children in dental offices. In order to prevent such health-negligent behavior of the children in the dental office, a major emphasis has been placed on appropriate pediatric management techniques and modalities.

The noise of cutting the dentin, sight of needles, sounds of drills, and smell of various filling and sealing materials can aggravate dental anxiety and fear. Treating such anxious children often results in stressful conditions for dentists as well. Therefore, it is important to study the imperativeness and intensity of dental anxiety in children. With ongoing research, several new techniques for assessing dental anxiety in children have emerged. [10] With all due respect to old techniques such as observation, measuring characteristics using various scales, and pictorial presentations, we have entered an era of utilizing digital technologies to assess dental anxiety in children. Earlier, in the assessment of dental anxiety, the methods were mainly divided into two types: one that relied on the observations of reactions of children, and the other was measurement techniques. Owing to several contraindications and limitations of these early methods, we have stepped ahead in an era where we have started utilizing digital technologies to assess dental anxiety and fear. [10]

The conclusion of the study conducted by Brand et al. correlated the increase in heart rate in several dental phobic and anxious children before treatment [11].
For a few years, the recorded maternal voice has been utilized as one of the finest weapons to reduce dental fear and anxiety in children. Various areas of a child's brain are engaged by their mother's voice, which is claimed in the latest study conducted by the Stanford University of Medicine. As per the study, it is claimed that different areas of the brain respond more powerfully to the mother's voice, which is involved in producing a number of emotions in various situations [12].

A study published in the National Academy of Sciences found that children's social communication skills can be predicted from the brain region activated by the child's own mother's voice [12].

One study included evidential data regarding increased screen time and mobile usage in preschool children [13]. This significant depletion of awaiting anxiety can be accredited to the reduction of anticipatory anxiety and can be attributed to exposure to the treatment in a joyful method by this dental educational application called "Roogies." The cognitive pediatric dentistry paradigm has recently played a vital role in behavior management, which aids in well-formed and structured dental treatment. The results of the present study are similar to those of other studies, in which smartphone applications showed better results [14-16].

A possible limitation of the study is the small sample size and study period, and the use of non-invasive procedures alone. Future studies are required to confirm the efficacy of both methods using invasive procedures. In conclusion, from the above study, behavioral remodeling utilizing a recorded maternal voice has proven to be more promising than the virtual cognitive tool technique. Alternatively, a virtual cognitive tool can also be used to educate children about various dental treatments.

Thus, the recorded maternal voice was more effective in controlling the child's anxiety without any dental history.

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Deepika Chari: Data curation, Methodology
Rushita Shah: Investigation, Writing - review & editing
Binny Parmar: Investigation, Writing - review & editing

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