Study setting and ethical considerations

This study was designed as a triple-blinded, two-arm, parallel-group randomized active-controlled trial and conducted at the Department of Pediatric Dentistry, Faculty of Dentistry, Damascus University, Syria, between February 2024 and March 2024. The study was performed in full accordance with the CONSORT statement [8] and the World Medical Association Declaration of Helsinki on experimentation involving human subjects, as revised in 2013 [9]. The legal guardians provided written informed consent before the participants' inclusion in the study, and the participants' anonymity was preserved. The dental procedure was explained in detail. No child was excluded based on their gender, race, and socioeconomic status, and excluded children still received complete treatment. Ethical approval was obtained from the Ethical Committee of Damascus University (N1325/2024), and the trial was approved and registered at the ISRCTN registry () on //2024.

Sample size

Sample size calculation done using G*Power version 3.1.9.4 (G*Power 3.1.9, Heinrich Hein Universität Düsseldorf, Düsseldorf, Germany). A sample size of 60 patients achieved a small effect size f (0.36), 80% Power (1 - β err prob), and a significance level of 0.05.

Participant recruitment and grouping

67 patients who were referred to the Department of Pediatric Dentistry were screened according to the following recruitment criteria:

Inclusion criteria

1. Children aged 6-10 years.
2. Children could be categorized as definitely positive or positive ratings, according to Frankel's behavior rating scale.
3. Children required pulpotomy for a primary molar.
4. Children were familiar with smartphone games.

Exclusion criteria

1. Children with oral, mental, and/or systemic conditions.
2. Children could be categorized as definitely negative or negative ratings, according to Frankel's behavior rating scale.
3. Children with previous dental surgery experience and/or traumatic dental experience.

The CONSORT flow diagram is presented in Figure 1. Based on inclusion criteria, 60 patients were recruited and randomly divided into two groups:

Group 1: control group, TSD technique (n = 30).

Group 2: experimental group, Baby Panda Dental Care game (Baby Panda Dental Care, BabyBus Co., Fuzhou, China) (n = 30).

Randomization and blinding

Participants were randomly assigned into two groups in a ratio of 1:1 according to the randomization online software: https://www.randomizer.org. The number of sets was 2, with 30 patients per set, and the number range was from 1 to 60. It was a triple-blinded trial where the pediatric dentist and the outcome assessors were masked to the group allocation. In addition, participants were not aware of the grouping and the aim of the study.

Primary outcome measures

The following primary outcome measures were considered:

1. Pulse rate

The pulse rate was measured using a finger pulse oximeter (Alpha, Prolinx GmbH, Düsseldorf, Germany) at four time points: (1) at the baseline in the waiting room (t0). (2) After conditioning the child before initiating the treatment (t1). (3) Mean pulse rate during treatment (t2). (4) After putting the final restoration and finishing the treatment (t3) [10]. Pulse rate is an objective measurement of dental anxiety [11].

2. RMS Pictorial Scale.

RMS pictorial scale was recorded at four time points: (1) at the baseline in the waiting room (t0). (2) After conditioning the child before initiating the treatment (t1). (3) Immediately after amputating of the pulp (t2). (4) After putting the final restoration and finishing the treatment (t3). RMS pictorial scale is a subjective measurement of dental anxiety (Figure 2) [12].

3. Face, Legs, Activity, Cry, Consolability (FLACC) behavioral pain scale

FLACC behavioral pain scale was recorded during treatment (t2). FLACC behavioral pain assessment scale is a non-verbal, self-report pain scale (Figure 3) [13].

Procedure

The baseline anxiety level in waiting room was assessed by recording the pulse rate and using the RMS pictorial scale. Children were presented with two sets of five faces (Figure 2) based on their gender and were asked to select the most suitable face that matched their current level of anxiety. For the TSD technique group, children were provided with a verbal explanation followed by a demonstration of the dental treatment in a friendly, non-threatening way. The “do” phase was performed after initiating the dental treatment without deviating from the verbal explanation and demonstration. For the Baby Panda dental care game, Arabic was installed, and children were asked to play for 5 minutes. It includes five dental procedures: restoring chipped teeth, filling cavities, performing root canal therapy, extracting decayed teeth, and performing orthodontic treatment for five little animals: a cat, hippo, mouse, bunny, and monkey. The different stages of the selected procedure are presented in Figure 4. Children were presented with two animals in the waiting room, and then a root canal therapy virtual procedure was selected. Children were instructed to remove the dental calculus using an ultrasonic scaler, clean teeth using a water gun, and then suction dirty water. Children were instructed to perform an intraoral radiograph of the decayed tooth, drill the decayed cavity,

anesthetize the nerve cells using an electric gun, fill the tooth, polish the teeth to fit well with the dental crown, and then put the dental crown. Pulse rate and RMS pictorial scale were recorded after conditioning the child when sitting on a dental chair before initiating the dental treatment. The conventional pulpotomy method was performed according to AAPD guidelines. During treatment, the FLACC behavioral pain scale and pulse rate were recorded by two blinded investigators. After finishing the cavity preparation and amputation of the pulp RMS pictorial scale was recorded. It was recorded during controlling hemorrhage using a wet cotton pellet. After removing the rubber dam and cementing the stainless steel crown, the pulse rate and RMS pictorial scale were recorded [10, 12]. Cohen's Kappa coefficient values of intra-examiner and inter-examiner reliability were > 0.8 [14].

Statistical analysis

Statistical analysis was performed using IBM SPSS software version 24 (IBM SPSS Statistics® version 24, IBM Corp., New York, USA). Descriptive statistics were presented as mean and standard deviation (SD). The normality of data was checked by performing the Kolmogorov–Smirnov test. Fisher's exact test and Mann-Whitney U test were performed to compare baseline demographic and clinical characteristics between groups. Mann-Whitney U test was used for comparing pulse rate, RMS pictorial scale, and FLACC behavioral pain assessment scale scores between control and experimental groups. The statistical significance level was adjusted at 0.5 ($p < 0.5$).