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Effectiveness of a dental simulation game on children behavior during pulp treatments in primary molars: a randomized controlled trial

Submission date
19/04/2024

Recruitment status
No longer recruiting

Registration date
19/04/2024

Overall study status
Completed

Last Edited
23/08/2024

Condition category
Oral Health

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Dental anxiety is considered a vicious cycle, where avoidance of attending the clinic and lack of cooperation during treatment are common consequences. Thus, dental anxiety leads to poor oral health and painful dental experiences, which escalate over time. According to Grisolia et al., the global prevalence of dental anxiety is 25.8%.
Primary molars pulpotomy is the most common dental procedure among pediatric patients, which consists of several distressing steps. Tell-show-do (TSD) is a basic guidance technique that includes a verbal explanation of the dental procedure, followed by a demonstration of different sensory aspects of the treatment, and then completion of the treatment in correspondence with explanation and demonstration. Dental simulation games are virtual educational games that help children get familiar with different dental procedures and tools and increase acceptance towards treatment. Baby Panda Dental Care is a mobile app that lets children enjoy the experience of being a dentist and perform different dental procedures such as extraction, scaling, drilling, filling, aligning brackets, and much more. This study aimed to evaluate the pre-treatment exposure to the Baby Panda Dental Care game in reducing pain and anxiety in comparison with TSD technique during primary molars pulpotomy in pediatric patients aged 6-10 years.

Who can participate?
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.

What does the study involve?
This study was designed as a triple-blinded, two-arm, parallel-group randomized active-controlled trial. 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).

What are the possible benefits and risks of participating?
Possible benefit: Performing pulpotomy treatment.
Possible risk: receiving painful injection.

Where is the study run from?
Damascus University (Syria)

When is the study starting and how long is it expected to run for?
January 2024 to March 2024.

Who is funding the study?
Damascus University (Syria)

Who is the main contact?
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Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers

Nil known

Study information

Scientific Title
Effectiveness of a dental simulation game on children behavior during pulp treatments in primary molars

Study objectives
The null hypothesis is that no statistically significant difference would be noted between the pre-treatment exposure to the Baby Panda Dental Care game in reducing pain and anxiety in comparison with the TSD technique during primary molars pulpotomy in pediatric patients aged 6-10 years.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 05/02/2024, The Ethical Committee of Damascus University (Al Mazzeh Street, Damascus, -, Syria; +963 1133926091; dean.dent@damascusuniversity.edu.sy), ref: 1325/2024

Study design
Triple-blinded two-arm parallel-group randomized active-controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Dental clinic

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Pain and anxiety during primary molars pulpotomy in pediatric patients aged 6-10 years.

Interventions
This study was designed as a triple-blinded, two-arm, parallel-group randomized active-controlled trial. 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).
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.
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 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. 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. Cohen’s Kappa coefficient values of intra-examiner and inter-examiner reliability were > 0.8.

Intervention Type
Behavioural

Primary outcome measure
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 completing the final restoration and finishing the treatment (t3). Pulse rate is an objective measurement of dental anxiety.
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 completing the final restoration and finishing the treatment (t3). RMS pictorial scale is a subjective measurement of dental anxiety.
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.

Secondary outcome measures
There are no secondary outcome measures

Overall study start date

11/01/2024

Completion date
13/03/2024

Eligibility

Key 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.

Participant type(s)
Healthy volunteer

Age group
Child

Lower age limit
6 Years

Upper age limit
10 Years

Sex
Both

Target number of participants
60

Total final enrolment
60

Key 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.

Date of first enrolment
09/02/2024

Date of final enrolment
05/03/2024

Locations

Countries of recruitment

Syria

Study participating centre
Department of Pediatric Dentistry, Faculty of Dentistry, Damascus University
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Nill

Sponsor information

Organisation
Damascus University

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University/education

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https://ror.org/03m098d13

Funder(s)

Funder type
University/education

Funder Name
Damascus University

Alternative Name(s)
University of Damascus, , DU

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Syria

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
01/08/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Mawiamaherkarkoutly@hotmail.com

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file			19/04/2024	No	No
Results article		22/08/2024	23/08/2024	Yes	No