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Effectiveness of pink noise on reducing pain and anxiety during primary molars pulpotomy

Submission date
02/08/2025

Recruitment status
No longer recruiting

Registration date
04/08/2025

Overall study status
Completed

Last Edited
04/08/2025

Condition category
Oral Health

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Pink noise has more energy in lower frequencies, making it sound deeper and more balanced, similar to natural sounds. Examples include the sound of crashing waves, falling rain, and rustling leaves. Pink noise improves sleep quality, aids relaxation, treats tinnitus, reduces stress, enhances comfort in office environments, boosts productivity, and decreases anxiety during dental procedures.
Another type of auditory stimulus used in clinical settings is children's songs, which serve as preferred music. These songs modulate pain-related activity in the brain's anterior cingulate cortex, and effectively raise pain thresholds by increasing endorphin production. Listening to music for 10 minutes is a sufficient duration to allow its anxiety-reducing effects to take hold. Studies suggest that waiting in dental clinics while listening to music is equally effective in lowering anxiety levels compared to taking benzodiazepines. The current study aimed to evaluate and compare the effects of pink noise and children's songs on anxiety and pain in children aged 6–9 years during pulpotomy procedures. The null hypothesis is that there is no significant difference in the reduction of anxiety and pain levels during pulpotomy procedures in children aged 6–9 years when exposed to pink noise compared to children’s songs.

Who can participate?
1. Children aged 6–9 years.
2. Classified as "definitely positive" or "positive" on Frankel’s behavior rating scale.
3. Requiring pulpotomy treatment in mandibular primary molars.

What does the study involve?
Following screening against inclusion criteria, 75 eligible patients were enrolled and randomly allocated into three study groups:
• Group 1: Pink noise (n = 25).
• Group 2: Children’s songs (n = 25).
• Group 3: Control group, tell-show-do (TSD) technique (n = 25).

What are the possible benefits and risks of participating?
Possible benefits are: Performing non-urgent dental treatment in the mandibular arch.
Possible risk is: Injection will be painful if the device is not effective.

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

When is the study starting and how long is it expected to run for?
October 2024 and December 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

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Effectiveness of pink noise on reducing pain and anxiety during primary molars pulpotomy compared with music: a randomized clinical trial

Study objectives
The current study aimed to evaluate and compare the effects of pink noise and children's songs on anxiety and pain in children aged 6–9 years during pulpotomy procedures.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 27/05/2024, The Biomedical Research Ethics Committee (BMREC) of Damascus University (Mazzeh, Damascus, -, Syria; +963 992647528; info@damascusuniversity.edu.sy), ref: N3551/2024

Study design
Randomized controlled trial with a double-blinded three-arm parallel-group

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Dental pain and anxiety

Interventions
Baseline anxiety levels were evaluated by measuring pulse rate and administering the FI scale. Children were shown two sets of five facial expressions and instructed to choose the image that best represented their current anxiety state. Children in the pink noise group listened using headphones. In the children's songs group, the child was asked to choose one of the songs from their favorite program and cartoon movies on YouTube, so that it would be familiar to them to listen to. The music or pink sound continued throughout the session through headphones. In the TSD technique group, the procedure was first explained verbally and then demonstrated in a child-friendly manner before treatment initiation. The "Do" phase was implemented during actual treatment without altering the initial explanation. Pulse rate was recorded after conditioning the child using the TSD technique or after listening to the songs or pink noise for 10 minutes.
The conventional pulpotomy procedure is based on AAPD guidelines. Following IANB administration, pulse rate, FLACC behavioral pain scores, and FI scale ratings were documented. Pulse rate and FLACC behavioral pain scores were repeated after rubber dam placement and again following cavity preparation and pulp amputation, including during hemorrhage control with a moist cotton pellet. Final pulse rate and FI scale assessments were conducted upon completion.

Intervention Type
Other

Primary outcome(s)
1. Pulse rate was objectively measured as an indicator of dental anxiety using a finger pulse oximeter (Alpha, Prolinx GmbH, Düsseldorf, Germany). Measurements were recorded at six critical time points: Baseline (t0). Following patient conditioning before treatment initiation (t1). Immediately after IANB administration (t2). Post rubber dam placement (t3). Following pulp

amputation (t4). Upon treatment completion (t5)
2. The Face, Legs, Activity, Cry, and Consolability (FLACC) Behavioral Pain Assessment Scale (FLACC) behavioral pain scale, a nonverbal pain assessment tool, was recorded at three critical time points: Immediately after IANB administration (t2). Post rubber dam placement (t3). Following pulp amputation (t4)

Key secondary outcome(s))
Subjective anxiety levels were assessed using a 5-point pictorial scale (Facial Image (FI) Scale) with facial expressions ranging from very happy (score = 1) to very fearful (score = 5). The children were asked to choose the face that best matched their emotional state at three-time points: Baseline (t0), immediately after IANB administration (t2), and following pulp amputation (t4)

Completion date
17/12/2024

Eligibility

Key inclusion criteria
1. Children aged 6–9 years.
2. Classified as "definitely positive" or "positive" on Frankel’s behavior rating scale.
3. Requiring pulpotomy treatment in mandibular primary molars.

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Child

Lower age limit
6 years

Upper age limit
9 years

Sex
All

Total final enrolment
75

Key exclusion criteria
1. Children with oral, mental, and/or systemic conditions that could affect treatment outcomes.
2. Children who had taken sedative or analgesic medications within the 24 hours preceding the dental examination.

Date of first enrolment

03/10/2024

Date of final enrolment
28/11/2024

Locations

Countries of recruitment
Syria

Study participating centre
Damascus University
Mazzeh
Damascus
Syria
-

Sponsor information

Organisation
Damascus University

ROR
https://ror.org/03m098d13

Funder(s)

Funder type
Not defined

Funder Name
Damascus University

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from mawia95.karkoutly@damascusuniversity.edu.sy, mawiamaherkarkoutly@hotmail.com

The type of data that will be shared: Not currently known
Timing for availability: Upon a reasonable request
Whether consent from participants was required and obtained: Informed consent was obtained

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes