

Effect of adding guided deep breathing to conventional behavior guidance on dental anxiety, pain, behavior, and heart rate in anxious children: a randomized controlled trial

Submission date 20/07/2026	Recruitment status No longer recruiting	☐ Prospectively registered ☒ Protocol
Registration date 20/07/2026	Overall study status Ongoing	☐ Statistical analysis plan ☐ Results
Last Edited 04/09/2026	Condition category Oral Health	☐ Individual participant data ☒ Record updated in last year

Plain English summary of protocol

Background and study aims

Many children feel worried or scared when visiting the dentist. Dental anxiety can make treatment more difficult and may lead some children to avoid dental care in the future. Deep breathing is a simple technique that may help people feel calmer by slowing their breathing and lowering their heart rate.

This study looked at whether teaching children a guided deep breathing exercise before and during dental treatment could reduce anxiety, pain, and stress. The researchers compared standard behaviour guidance used by dentists with the same guidance plus guided deep breathing. They also measured how children behaved during treatment and monitored their heart rate.

Who can participate?

Children can take part if they:

Are aged 5 to 8 years

Are generally healthy

Have moderate to high levels of dental anxiety

Need a dental procedure called a pulpotomy on a baby tooth using local anaesthetic

Have consent from a parent or guardian and agree to take part themselves

What does the study involve?

Participants attend a dental appointment for treatment of a baby tooth.

Children are randomly assigned to one of two groups:

Standard behaviour guidance only, including techniques such as explaining procedures, showing equipment, giving encouragement, and using appropriate verbal guidance

Standard behaviour guidance plus a guided deep breathing exercise. Children are taught how to take slow, deep breaths and practise the technique before receiving local anaesthetic. They are encouraged to continue the breathing exercise during treatment.

Children are asked about their anxiety and pain at different stages of the appointment. Their behaviour during treatment is recorded, and their heart rate is measured using a small sensor placed on a finger.

What are the possible benefits and risks of participating?

Children who learn the deep breathing technique may feel less anxious, calmer, and more comfortable during dental treatment. The study may also help dentists find simple ways to improve the experience of dental care for children.

The deep breathing exercise is considered low risk and does not require any equipment or medication. Participants receive routine dental treatment that they would need regardless of the study. As with any dental procedure involving local anaesthetic, children may experience some temporary discomfort during treatment.

Where is the study run from?

The study is run from the paediatric dentistry clinic at the University Clinics of Syrian Private University in Damascus, Syria.

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

April 2026 to December 2026.

Who is funding the study?

The study is investigator-initiated and funded by the researchers. No specific grant was received from a public, commercial, or charitable funding organisation.

Who is the main contact?

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Contact information

Type(s)

Public, Scientific, Principal investigator

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Study information

Scientific Title

Effect of adding guided deep breathing to conventional behavior guidance on dental anxiety, pain, behavior, and heart rate in anxious children: a randomized controlled trial

Study objectives

1. To evaluate and compare the changes in dental anxiety levels between children receiving the combined protocol (guided deep breathing and conventional behavior guidance) and those receiving conventional behavior guidance alone
2. To determine the effect of the integrated intervention on children's self-reported procedural pain
3. To assess the impact of guided deep breathing on objective clinical behavior ratings during the dental procedure
4. To measure and analyze real-time physiological stress responses by monitoring heart rate fluctuations across critical procedural milestones

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 30/03/2026, The institutional research ethics committee of Syrian Private University (Syrian Private University, Damascus, 0100, Syria; +963 116990251; Info@spu.edu.sy), ref: -

Primary study design

Interventional

Allocation

Randomized controlled trial

Masking

Blinded (masking used)

Control

Active

Assignment

Parallel

Purpose

Treatment

Study type(s)

Health condition(s) or problem(s) studied

Dental anxiety, pain, behavior, and heart rate in anxious children

Interventions

Eligible children were randomly allocated to the control or intervention group in a 1:1 ratio using a computer-generated random sequence.

1. Control arm

Children receive conventional behavior guidance throughout the appointment: tell-show-do, positive reinforcement, and voice control, applied consistently by the researcher, followed by local anesthesia and completion of the required dental procedure.

2. Intervention arm

Children receive the same conventional behavior guidance plus a guided deep breathing exercise. This diaphragmatic technique is used because slow, deep breathing augments parasympathetic (vagal) tone and reduces sympathetic arousal, thereby lowering heart rate and subjective anxiety and pain (Jerath et al., 2006; Levi et al., 2022). It requires no device, application, or timer and is delivered through verbal instruction and live modelling alone, which keeps it applicable in resource-limited settings (Levi et al., 2022).

Before local anesthesia, each child is taught a simple, slow diaphragmatic breathing technique: inhale slowly and deeply through the nose, hold briefly, and exhale slowly through the mouth. Each cycle comprises an approximately 4-second nasal inhalation, an approximately 2-second breath-hold, and an approximately 6-second oral exhalation (about five breaths per minute); the child places one hand on the abdomen to feel it rise and fall so that a diaphragmatic (belly-breathing) pattern is reinforced (Levi et al., 2022; Bahrololoomi et al., 2022).

The exercise is demonstrated by the investigator, a dentist trained in guiding paediatric breathing exercises, and rehearsed with the child until it can be performed correctly. While modelling, the operator breathes audibly in phase with the child and progressively lengthens the exhalation (Levi et al., 2022). Once the child performs the pattern correctly (about 3 minutes of teaching and rehearsal), a focused block of eight guided cycles (approximately two minutes) is completed immediately before needle insertion.

The child is then guided to continue slow breathing during administration of local anesthesia and at intervals during the procedure. The intervention is delivered face-to-face, individually, in a single session. Instructions are standardised for all children; only the imagery used to elicit belly-breathing (for example, “inflate a balloon in your tummy”) is tailored to the individual child (Levi et al., 2022). No modifications are made to the procedure during the trial.

Fidelity is assessed at two levels. First, before the procedure begins, each child must reproduce the target pattern correctly against a brief checklist (a visible abdominal rise on inhalation and a clearly prolonged exhalation); the procedure starts only once this criterion is met. Second, respiratory rate (breaths per minute) is counted by direct observation of thoraco-abdominal excursions over 60 seconds at baseline and again during the procedure, and a reduction during the procedure relative to baseline confirms continued slow diaphragmatic breathing, mirroring the respiration-rate manipulation check of Levi et al. (2022).

Because the finger pulse-oximeter used for heart rate (Masimo Rad-G, Masimo Corporation, Irvine, CA, USA) itself records respiratory rate, this count is obtained automatically, which ensures accurate measurement.

This description follows the TIDieR checklist for intervention reporting (Hoffmann et al., 2014).

Total duration of treatment: The intervention consists of a single-session pulpotomy on a primary molar per a participant.

Follow-up period: This is a single-session study. All assessments is completed within this single treatment session, and there is not subsequent follow-up periods or review visits.

Intervention Type

Behavioural

Primary outcome(s)

1. Dental Anxiety measured using Children's Fear Survey Schedule–Dental Subscale (CFSS-DS; 15–75) at Before procedure, After breathing exercise, After anesthesia, End of session
2. Self-reported pain measured using Wong-Baker FACES Pain Rating Scale (ordinal, 0–10) at Before intervention, After breathing exercise, After anesthesia, End of session

Key secondary outcome(s)

1. Behavior measured using Frankl Behavior Rating Scale at during treatment
2. Heart rate measured using a portable, motion-tolerant, medical-grade pulse oximeter (Masimo Rad-G, Masimo SET® Measure-through Motion technology; Masimo Corporation, Irvine, CA, USA), which reports oxygen saturation, pulse rate and respiration rate from the photoplethysmogram (RRp) from a single fingertip pediatric sensor; parameters are logged automatically by the device's internal data logger at Before procedure, After breathing exercise, After anesthesia, End of session

Completion date

01/12/2026

Eligibility**Key inclusion criteria**

1. Aged 5-8 years
2. Good general health (ASA physical status I)
3. Moderate-to-high dental anxiety (CFSS-DS total score ≥ 32 ; range 15–75)
4. Requiring a dental procedure involving local anesthesia (pulpotomy of a primary molar)
5. Written parental/guardian consent and child assent

Healthy volunteers allowed

No

Age group

Child

Lower age limit

5 Years

Upper age limit

8 Years

Sex

All

Total final enrolment

64

Key exclusion criteria

1. Any systemic, neurological, developmental, or respiratory condition that could affect cooperation or breathing
2. A History of severe or disabling dental anxiety requiring pharmacological management

3. Refusal to participate by the parent or the child
4. Presence of any contraindication to local anesthesia or the specific anesthetic agent used

Date of first enrolment

01/04/2026

Date of final enrolment

03/09/2026

Locations

Countries of recruitment

Syria

Sponsor information

Organisation

Syrian Private University

ROR

<https://ror.org/01h8c9041>

Funder(s)

Funder type**Funder Name**

Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan**IPD sharing plan summary**

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file			20/07/2026	No	No