

CLINICAL STUDY PROTOCOL

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

Short title	Deep breathing in pediatric behavior guidance
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Design of study	Two-arm, parallel-group, randomized controlled trial (1:1)
Population	Anxious children aged 5–8 years undergoing pulpotomy under local anesthesia
Setting	Pediatric dentistry clinic, University Clinics of Syrian Private University, Damascus, Syria
Registration	ID to be assigned
Recruitment status	Recruiting
Reporting standard	CONSORT extension for non-pharmacologic treatments; SPIRIT-informed

1. Background and Rationale

Dental anxiety is one of the most frequent challenges in pediatric dentistry. It is associated with disruptive and uncooperative behavior, longer and more difficult appointments, and a heightened risk of dental avoidance that can persist into adulthood (Klingberg & Broberg, 2007). Practical strategies that reduce anxiety during treatment are therefore an important goal of behavior guidance in children.

Guided deep breathing has attracted growing interest as a non-pharmacological method for managing anxiety. Slow, diaphragmatic breathing enhances parasympathetic (vagal) activity and reduces sympathetic arousal, which is reflected physiologically in a lower heart rate and, subjectively, in reduced tension and distress (Jerath et al., 2006). Because it requires no equipment and can be taught within minutes, deep breathing is particularly attractive for routine clinical use, including in resource-limited settings.

Most existing studies have evaluated deep breathing either in isolation or against basic behavior guidance, rather than as an adjunct integrated into a complete, conventional behavior-guidance protocol as it would be applied in everyday practice. Relatively few trials have simultaneously assessed anxiety, behavior, self-reported pain, and an objective physiological marker within the same design. This trial addresses that gap by testing guided deep breathing as an add-on to a full conventional protocol, with a multi-domain outcome set.

2. Objectives and Hypothesis

2.1 Primary objective

To evaluate whether adding guided deep breathing to conventional behavior guidance reduces self-reported pain and dental anxiety in anxious children aged 5–8 years undergoing dental treatment with local anesthesia.

2.2 Secondary objectives

- To assess the effect on cooperative behavior during treatment (Frankl scale).
- To assess the effect on heart rate at predefined timepoints, and the immediate within-group change following the breathing exercise.

2.3 Null hypothesis

Adding guided deep breathing to conventional behavior guidance produces no significant difference in dental anxiety, self-reported pain, behavior, or heart rate compared with conventional behavior guidance alone.

3. Trial Design

This is a two-arm, parallel-group randomized controlled trial with a 1:1 allocation ratio. It is designed and reported in accordance with the CONSORT extension for non-pharmacologic treatments. Participants are individually randomized to a control arm (conventional behavior guidance) or an intervention arm (conventional behavior guidance plus guided deep breathing).

4. Methods: Participants

4.1 Setting and recruitment

The trial is carried out in the pediatric dentistry clinic at the University Clinics of Syrian Private University, Damascus, Syria. Children are recruited consecutively from those attending the clinic and requiring dental treatment under local anesthesia -specifically pulpotomy of primary molars (first or second upper molars, or first lower molars). Planned recruitment runs from April 2026 to November 2026.

4.2 Eligibility criteria

Inclusion

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

Exclusion

- Any systemic, neurological, developmental, or respiratory condition that could affect cooperation or breathing.
- A History of severe or disabling dental anxiety requiring pharmacological management.
- Refusal to participate by the parent or the child.
- Presence of any contraindication to local anesthesia or the specific anesthetic agent used.

5. Interventions

5.1 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.

5.2 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).

5.3 Local anesthesia (both arms)

Local anesthesia is achieved by local infiltration using 4% articaine hydrochloride with 1:100,000 epinephrine. The maximum dose is calibrated to each child’s body weight and kept below the conservative threshold of 5 mg/kg. Adequate anesthesia is verified clinically by the absence of a pain response on probing before the pulpotomy begins. All operators follow a standardized clinical protocol to minimize variability.

6. Outcomes and Instruments

6.1 Co-primary outcomes

- **Self-reported pain:** Wong-Baker FACES Pain Rating Scale (ordinal, 0–10).
- **Dental anxiety:** Children’s Fear Survey Schedule–Dental Subscale (CFSS-DS; 15–75).

6.2 Secondary outcomes

- **Behavior** — Frankl Behavior Rating Scale (1–2 negative; 3–4 positive).
- **Heart rate**— recorded with 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.

6.3 Timepoints

Dental anxiety (CFSS-DS) is assessed before the intervention and after the session. Self-reported pain and heart rate are recorded at four points: baseline; after the breathing exercise (intervention arm); after local anesthesia; and at the end of the session. Frankl behavior is recorded during treatment. This scheme allows between-group comparison at each timepoint and, for heart rate, a within-group comparison of the immediate effect of the breathing exercise in the intervention arm.

7. Sample Size

The sample size was calculated with G*Power. Self-reported pain (Wong-Baker) and dental anxiety (CFSS-DS) were designated co-primary outcomes, and the calculation was anchored to pain because it yielded the more conservative estimate. A between-group difference of 2 points on the 0–10 scale was regarded as the smallest clinically meaningful difference, with an assumed standard deviation of 2.8 points (a moderate-to-large effect, Cohen's $d \approx 0.72$). For a two-tailed independent-samples comparison with $\alpha = 0.05$ and power = 0.80, a minimum of 32 children per group was required, giving 64 participants in total. Accordingly, 64 children are recruited and randomized, 32 per arm.

8. Randomization, Allocation Concealment, and Blinding

8.1 Sequence generation and concealment

Eligible children are randomly allocated to the control or intervention arm in a 1:1 ratio using a computer-generated random sequence. Allocation is concealed using sequentially numbered, opaque, sealed envelopes opened only after a child has been enrolled and a baseline assessment completed.

8.2 Blinding

Because of the behavioral nature of the intervention, blinding of the researcher is not feasible. A structured segregation of roles is therefore used. All dental treatments (including local anesthesia and the clinical procedure) are performed by independent undergraduate operators under continuous supervision by experienced faculty. The researcher provides breathing training and records the Children's Fear Survey Schedule–Dental Subscale (CFSS-DS), Frankl scores, pain, and heart rate readings. All tabulated data are anonymized and coded before transfer to an independent statistician who remains fully blinded to allocation throughout.

9. Statistical Methods

All analyses are performed in IBM SPSS Statistics (version 25 or later). The primary analysis population are all randomised participants, analysed in the groups to which they are allocated (intention-to-treat). Continuous variables are summarised as mean $\pm$ standard deviation and ordinal scores as median [interquartile range]; categorical variables are summarised as frequencies and percentages. The distribution of each continuous outcome is examined with the Shapiro–Wilk test, supported by inspection of skewness and Q–Q plots, and this assessment governs the choice between parametric and non-parametric procedures according to the rules pre-specified below.

Dental anxiety (CFSS-DS total score, range 15–75) and self-reported pain (Wong-Baker FACES) are designated as co-primary outcomes; heart rate and behaviour (Frankl scale) are secondary outcomes. Unless stated otherwise, the primary between-group comparison is the pre-to-post change for dental anxiety and the difference immediately after administration of local anaesthesia for pain.

Heart rate, recorded at four timepoints, is analysed with a linear mixed-effects model (equivalently, a mixed-design repeated-measures ANOVA) entering group, time, and the group $\times$ time interaction as fixed effects and the participant as a random effect; the group $\times$ time interaction is the pre-specified effect of primary interest for this outcome. The model uses all available observations under a missing-at-random assumption, and no imputation is therefore planned. If the interaction is statistically significant, pre-specified between-group contrasts at each timepoint and the within-group change from baseline -including

the immediate change after the breathing exercise- is examined as post-hoc comparisons with Bonferroni adjustment. For every contrast, the adjusted mean difference is reported with its 95% confidence interval and a standardized effect size (Cohen's d for pairwise contrasts and partial η^2 for omnibus effects).

Dental anxiety (CFSS-DS total) is treated as a continuous variable, and its pre-to-post change is compared between groups by analysis of covariance with the baseline score as covariate, reporting the adjusted mean difference, its 95% confidence interval, and Cohen's d . Because the score is derived from ordinal items, the normality assumption is verified as above; if it is not met, the comparison instead uses the Mann–Whitney U test on the change scores, which in any case is reported as a pre-specified sensitivity analysis.

Because Wong-Baker FACES pain is ordinal, it is summarised as median [IQR] and analysed with rank-based methods: between-group differences at each timepoint will use the Mann–Whitney U test with Bonferroni adjustment across timepoints; the within-group trajectory is assessed with the Friedman test and Wilcoxon signed-rank post-hoc comparisons; and the rank-biserial correlation (r) is reported as the effect size.

Behaviour on the Frankl scale is dichotomised as positive versus negative, with Fisher's exact test.

All tests are two-sided. The nominal significance threshold is $p < 0.05$, with a Bonferroni-adjusted threshold applied to the multiple per-timepoint and post-hoc comparisons described above. To control the family-wise error rate across the two co-primary outcomes, each is tested against a Bonferroni-adjusted level of 0.025. Exact p -values are reported throughout.

10. Data Management and Monitoring

- Clinical data are recorded on standardized forms, anonymized, and coded before analysis.
- Heart-rate data are captured automatically by the pulse oximeter's internal logger, minimizing manual-entry and observer effects.
- Data are stored securely with access restricted to the researcher; the analyst receives only de-identified, coded data.
- Given the single-session, low-risk, non-pharmacological nature of the intervention, no formal interim analysis or independent data monitoring committee is planned; adverse events, if any, are recorded and reported.

11. Ethics and Dissemination

The protocol adheres to the principles of the Declaration of Helsinki and receives approval from the institutional research ethics committee of Syrian Private University before commencement (Approval No: DS-30032026-129). Written informed consent is obtained from a parent or legal guardian of every child, and verbal assent from each child, before enrollment.

12. Declarations

- **Funding.** No specific grant from any public, commercial, or not-for-profit agency.
- **Competing interests.** The authors declare none.
- **Data availability.** Available from the corresponding author on reasonable request.

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