

## **STUDY PROTOCOL**

**Title:** Effect of a Visual Pedagogical Intervention on Anticipatory Dental Anxiety in Children: A Randomized Controlled Trial

NCT: Not yet assigned

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## **Sponsor**

Istanbul University Scientific Research Projects Unit (BAP)

## **Background**

Dental anxiety is a common condition in children, characterized by emotional distress, behavioral resistance, and physiological responses such as increased heart rate. It negatively affects cooperation, treatment outcomes, and long-term oral health.

During the COVID-19 pandemic, changes in the dental clinical environment, particularly the use of personal protective equipment (PPE), altered the appearance of dental professionals and reduced nonverbal communication, potentially increasing anticipatory anxiety in pediatric patients.

Visual pedagogy provides age-appropriate information using images and simplified materials to prepare children for clinical procedures. However, limited studies have evaluated such interventions in pandemic-related dental environments.

## **Objectives**

Primary Objective:

To evaluate the effect of a structured visual educational intervention on anticipatory dental anxiety in children.

Secondary Objectives:

- To assess physiological responses using pulse rate
- To evaluate differences across age groups
- To assess sex-related differences

## **Study Design**

This is a single-center, randomized, single-blind, parallel-group clinical trial conducted at the Department of Pediatric Dentistry, Istanbul University Faculty of Dentistry.

Participants (n=70, aged 5–14 years) are randomly assigned (1:1) into two groups:

Group 1: Visual Educational Intervention Group

Group 2: Control Group

Randomization is computer-generated, with allocation concealment using sealed opaque envelopes. Outcome assessment is performed by a blinded pediatric dentist.

### **Study Population**

Inclusion Criteria:

- Children aged 5–14 years
- Requiring restorative dental treatment
- No systemic disease
- No mental or physical disabilities
- Not using medications affecting anxiety
- Previous dental visit experience

Exclusion Criteria:

- First dental visit
- Frankl behavior score 1–2
- Incomplete data
- Withdrawal of consent

### **Intervention Procedure**

A visual educational leaflet was developed based on visual pedagogy principles. The material included images of dental professionals with and without PPE, dental

instruments, and the clinical environment. Children reviewed the leaflet for approximately 10 minutes with their parents prior to treatment.

### **Study Procedure**

All participants completed baseline assessments prior to treatment.

In the intervention group, children reviewed the visual material before being seated in the dental chair. Anxiety scales were administered, followed by pulse rate measurement.

In the control group, standard procedures were followed, and measurements were performed identically.

Outcome assessment was conducted by a blinded pediatric dentist.

### **Outcome Measures**

Primary Outcome:

- Self-reported dental anxiety (MCDASf and FIS)

Secondary Outcomes:

- Pulse rate
- Age subgroup analysis
- Sex subgroup analysis

### **Risk and Safety**

**Potential Risks:**

- Dental anxiety
- Mild discomfort during measurements

**Risk Mitigation:**

- Behavior guidance techniques
- Non-invasive procedures
- Standardized clinical protocols

**Ethical Considerations**

Approved by the Clinical Research Ethics Committee of Istanbul University Faculty of Dentistry (Approval No: 2021/53). Conducted in accordance with the Declaration of Helsinki. Informed consent obtained from parents and assent from children. Participation was voluntary.