

STUDY PROTOCOL

Title: Comparison Of Model Demonstration And Video-Based Education Methods On Oral Hygiene Practices And Caries Incidence In 3–5-Year-Old Children: A Randomized Controlled Trial

Protocol Version and Date: Version 1.0 – October 2022

Investigator : Elif Ayşe Tamtekin Erdoğan

Current Affiliation: Uskudar University, Faculty of Dentistry, Department of Pediatric Dentistry, İstanbul, Türkiye

Study Conducted Under: Altınbaş University, Faculty of Dentistry, Department of Pediatric Dentistry, İstanbul, Türkiye (The study was performed while the researcher was affiliated with Altınbaş University.)

Ethics Approval: Approved by the Non-Interventional Clinical Research Ethics Committee of Altınbaş University Approval number: 2022/140

Approval date: 2.09.2022

1. Background and Rationale This study was designed to evaluate the impact of toothbrushing education using a demonstrative model and an animation video on oral hygiene habits, plaque index, gingival index, and caries status (ICDAS II) in 3-5 year-old children.

Primary Objective: To compare the effectiveness of three different approaches (model education, video education, and no education control) on oral health outcomes after 6 months.

2. Trial Design This is a parallel-group, cluster-randomized controlled trial with three arms: Model group, Video group, and Control group. Randomization was performed at the school level using sealed envelopes to minimize contamination.

3. Participants

Inclusion Criteria:

- Children aged 3-5 years attending the selected kindergartens whose parents provided written informed consent
- Children with at least one literate parent
- Children with whom cooperation could be established
- Children without any auditory or visual impairment
- Systemically healthy children
- Children who did not undergo any dental treatment during the study period
- Children who remained enrolled in the school throughout the study

Exclusion Criteria:

- Children whose parents did not provide consent
- Children with no literate parent
- Children with whom cooperation could not be established
- Children with visual or auditory impairments
- Children who are not systemically healthy
- Children who underwent any dental procedure during the study
- Children who left the school during the research period

4. Study Setting and Timeline The study was conducted in 6 private kindergartens located in Kartal, Pendik, and Tuzla districts of Istanbul, Türkiye. Timeline:

- Preparation and ethics approval: March – October 2022
- Recruitment and baseline assessments: November 2022
- Intervention and follow-up: November 2022 – June 2023
- Final assessments: June 2023

5. Interventions

Model Group (n=94): Children received hands-on toothbrushing training using an educational demonstrative model. The model demonstrated brushing all tooth surfaces twice daily with fluoridated toothpaste, flossing, tongue brushing, reducing unhealthy snacks, and regular dental visits. The model remained in the classroom and was used weekly under teacher supervision with monthly monitoring by the researcher.

Video Group (n=94): Children watched the 3-minute-21-second animation video “Kıpırdak ile Şıpırdak (İnci Dişler)”, approved by a clinical psychologist. The video covered proper brushing technique, pea-sized toothpaste amount, not wetting the brush, not swallowing toothpaste, flossing, and other oral hygiene topics. The video remained in the classroom and was shown weekly with monthly checks.

Control Group (n=94): No structured oral health education was provided. Children continued with the standard kindergarten curriculum.

6. Outcomes Primary outcomes: Plaque index (Silness & Loe), Gingival index (Silness & Loe), Caries status (ICDAS II)

Secondary outcomes: Changes in oral hygiene behaviors assessed by parent questionnaires. Assessments were performed at baseline and at 6 months.

7. Data Collection

- Two parent questionnaires (26 items at baseline, 14 items at follow-up)

- Standardized clinical examination form recording ICDAS II, plaque, and gingival indices

Examinations were conducted in the classroom under natural light by a single calibrated pediatric dentist.

8. Randomization and Allocation Schools were randomly assigned to groups using the sealed envelope method (cluster randomization).

9. Blinding The examiner and data analyst were blinded to group allocation as much as possible. Due to the nature of the interventions, participants and teachers could not be blinded.

10. Sample Size Sample size was calculated using G*Power 3.1.9.4 and PASS 2022 with 80% power, 5% significance level, and Cohen's $w = 0.30$. The minimum required sample size was 216 (72 per group). Final enrolment was 282 children (94 per group).

11. Statistical Analysis Data were analyzed using IBM SPSS Statistics 25. Chi-square, Fisher's exact, McNemar, and Bonferroni-corrected tests were used as appropriate. Significance level was set at $p < 0.05$.

12. Ethical Considerations The study was approved by the Altınbaş University Non-Interventional Clinical Research Ethics Committee (Approval no: 2022/140). Written informed consent was obtained from all parents. Permission was obtained from Colgate-Palmolive for the use of the toothbrushing model and toothbrush. The study was conducted in accordance with the Declaration of Helsinki.

13. Data Management All data were stored securely on a password-protected computer and anonymized.

14. Funding and Conflicts of Interest This study did not receive any external funding. The authors declare no conflicts of interest.