<p style="text-align:center; color:red;">**Study Protocol**</p>

Official Title: Effectiveness of an Interactive School-Based Oral Health Education Program in Reducing Periodontal Disease Among Palestinian Adolescents: A Double-Blind Intervention Study

NCT Number: Pending

Document Date: March 1, 2024

Sponsor: Al-Quds University

Introduction

Periodontal disease (PD) is a prevalent and preventable oral health issue that has a significant impact on adolescents globally. In Palestine, particularly among school-aged youth, the rates of gingivitis and calculus are concerningly high, compounded by limited access to preventive oral health initiatives. Adolescents are particularly susceptible to PD due to various behavioural, hormonal, and dietary influences. Implementing school-based oral health education is a cost-effective and scalable approach to enhance students' knowledge, attitudes, and practices regarding oral hygiene.

Primary Aim of this study

To evaluate the effectiveness of a two-month interactive school-based oral health education program in reducing periodontal disease among 15-year-old students in Nablus City, Palestine, using clinical indices such as the Community Periodontal Index for Treatment Needs (CPITN) and the Simplified Oral Hygiene Index (S-OHI).

Secondary Aims

To assess the effect of the intervention on students' oral hygiene practices, including brushing frequency, technique, and duration.

To evaluate changes in dietary habits following the intervention, particularly regarding breakfast consumption and intake of nutritious foods.

To examine changes in smoking behaviours, including cigarette and waterpipe use, among students exposed to the educational sessions.

Study design

A pre-test/post-test experimental design was utilised.

The study adopted an interactive educational approach to teach oral health self-care. This method actively engaged participants through two-way communication, practical demonstrations, and hands-on activities.

This study employed a multistage sampling technique to ensure a representative sample of schools and students from Nablus City. Schools and students were selected using a stratified simple random sampling method. This randomness in selection helped create comparable groups, thereby reducing potential biases and confounding factors that could influence the relationship between the intervention and outcomes.

Table 1. Geographical Distribution and Proportional Sample Allocation of Schools in Nablus

Area	Total Schools	Proportion of Total	Sample Size (Proportional)
East Nablus	27	41.5%	6
Central Nablus	25	38.5%	6
West Nablus	13	20.0%	3
Total	65	100%	15

To ensure proportional representation, schools were evenly selected from three geographical areas of Nablus (East, Central, and West), corresponding to the number of schools in each area (Table 1). The Epi Info program was used to calculate the sample size based on schools with 9th-grade classes (East = 27, Central = 25, West = 13). A total of 15 schools were selected: 6 from East Nablus, 6 from Central Nablus, and 3 from West Nablus. The final sample included 10 governmental schools and 5 private schools, ensuring proportional distribution across the city.

Schools were eligible for inclusion if they had 9th-grade classes, were feasible for participation in the study and data collection and implemented an appropriate consent

process for students and their parents. According to the educational directorate's records for 2024, Nablus City had 2832 9th-grade students in governmental schools (males = 1360, females = 1472) and 737 students in private schools (males = 434, females = 303).

The G*Power program was used to estimate the required sample size for the study, following the guidelines of Kang (2015, 2020). The effect size was set at dz = 0.5, with an alpha error probability (α) of 0.05 and a study power of 90% (1 - β).

Based on these calculations, 536 students from intervention schools and 410 students from control schools were required to obtain accurate and meaningful data.

Clinical Screening

In this study, the Community Periodontal Index for Treatment Needs (CPITN) was used to assess the prevalence of periodontal disease (PD) among 9th-grade students before and after the intervention. For adolescents, CPITN scores 0, 1, and 2 are used to assess gingivitis:

- Score 0: Healthy gingiva
- Score 1: Gingival bleeding observed after gentle probing
- Score 2: Presence of supra or sub-gingival calculus

For adults, CPITN includes the following scores for periodontitis:

- Score 3: Pathological pockets measuring 4 to 5.99 mm deep

Score 4: Pathological pockets measuring 6 mm or deeper

Each sextant of the mouth examined was assigned a code number, with the index teeth representing each sextant: 16, 11, 26, 36, 31, and 46 (22).

The Oral Hygiene Index-Simplified (OHI-S) was used to determine the oral hygiene status of the subjects. This index consists of two components: debris and calculus, each with a possible score range of 0 to 3. The amounts of calculus and debris were assessed by examining the facial surfaces of teeth numbers 11, 16, 26, and 31 and the lingual surfaces of teeth 36 and 46. The scores for calculus and debris were added together and divided by the number of examined surfaces to calculate the OHI-S score for each individual.

In the pilot phase of the study, the Interclass Correlation Coefficient (ICC) was calculated to assess the reliability of the clinical measurements. A total of 20 students were examined five times by five data collectors, resulting in ICC values of 0.83 for CPITN and 0.98 for OHI-S, indicating high reliability.

Instrument Development

The questionnaire utilised in this study was adapted from existing literature with modifications to align with the study's primary objective. The secondary aim was to evaluate the impact of the interactive oral education program on students' oral hygiene practices, dietary habits, and smoking behaviours two months after the implementation of the educational sessions. Initially, the questionnaire was developed in English and later translated into Arabic. To ensure accuracy, the translation was validated through a back-translation process from Arabic to English before being administered as a pre-test.

The questionnaire consisted of pretested standardised closed-ended questions that were assessed for face and content validity by three experts in the field. It was divided into five sections:

1. **Student Background**: This section included questions about the type of school (governmental or private) and the school system.
2. **Family Background**: The questions covered family size, parents' educational and occupational status, and the family's economic status.
3. **Oral Hygiene Practices**: This section addresses the frequency and technique of tooth brushing.
4. **Dietary Habits**: Questions focused on the frequency of breakfast consumption per week and the daily intake of nutritious versus non-nutritious foods.
5. **Smoking Behaviours**: This section assessed the frequency of cigarette and water pipe smoking and the number of cigarettes consumed.

The questionnaire's internal consistency was also evaluated using Cronbach's alpha, yielding a reliability coefficient of 0.967 for the 47 items tested.

The questionnaire was administered through direct interviews with individual students. All participants completed the questionnaire and underwent clinical examinations, resulting in

a 100% response rate. The questions in the questionnaire were designed to align with the topics covered in the educational program.

Data Collection Processes

The Al-Quds Committee for Ethical Considerations approved this study (REF.13/24). Consent forms were distributed to students, and their approval was sought before data collection began.

The researcher trained five dentists to conduct interviews and dental examinations, ensuring the data collection process was standardised and calibrated. Training sessions for the data collectors were held every 15 days throughout the research period to maintain consistency and accuracy in data collection.

During the baseline phase, all participants were provided with a comprehensive explanation of the study. Baseline data were collected in March 2024. The selected participants were randomly divided into intervention and control groups, ensuring that both groups were matched by age and gender. The control group received one oral educational session, while the intervention group participated in six sessions. The educational sessions were held every 10 days over two months.

After two months of interactive education, participants were re-examined and interviewed. Follow-up data were collected in the same schools using the same dental examination measures and questionnaires used during the baseline phase.

Intervention Description

The oral education program in this study focused on (PD). It aimed to equip participants with the knowledge and skills to understand, manage, and prevent complications associated with periodontal conditions. The program was adapted from previous studies, with modifications made to suit the specific objectives of this research.

The educational content was based on the standard guidelines set by the World Health Organization. The oral education sessions lasted between 30 and 45 minutes and employed an interactive approach, incorporating various audio-visual aids such as dental forms,

models, charts, posters, and plaster models (Table 2). These materials were designed to engage participants actively, fostering a deeper understanding of oral health practices

Table (2): Educational Sessions Program

Session No.	Session Title	Duration & Group Size	Learning Objectives & Content	Teaching Methods	Instructional Tools	Evaluation Strategy
1	Anatomy & Physiology of the Oral Cavity and Clinical Presentation of Periodontal Disease	45–60 minutes, 30–35 participants	Objectives: Identify the major anatomical structures of the oral cavity; Explain the normal function of periodontal tissues Content: Overview of teeth, gingiva, periodontal ligament, alveolar bone; Signs and clinical presentation of periodontal disease (PD)	Interactive lecture & Q&A	Smartboard, photographs, PowerPoint, dental models	Prepare a brief report on a family member's oral condition
2	Prevention and Treatment of Periodontal Disease	45–60 minutes, 30–35 participants	Objectives: Describe primary preventive measures against PD; Compare non-surgical treatment options	Group discussion & live demonstration under supervision	Whiteboard & markers, photographs, PowerPoint	Compile a list of barriers to effective oral hygiene

			Content: Oral hygiene techniques: brushing, flossing, mouthwash; Professional measures: scaling, polishing, fluoride application			
3	Maintenance and Follow-Up of Preventive Measures	45–60 minutes, 30–35 participants	Objectives: Outline a maintenance schedule for periodontal health; Apply problem-solving strategies to common barriers Content: Recall intervals and re-evaluation protocols; Strategies for overcoming patient-identified maintenance barriers	Brainstorming & group discussion	Photos, preventive devices (toothbrush, floss, mouthwash), posters, puzzles	Develop a list of solutions to overcome identified barriers
4	Daily Preventive Practices	45–60 minutes, 30–35 participants	Objectives: Practice correct brushing and interproximal cleaning techniques;	Live demonstration under supervision	Whiteboard, PowerPoint, tooth models, preventive	Create a resource list for daily oral-health information

			Reinforce daily oral-care routines Content: Live demonstrations of toothbrush and floss use; Hands-on practice with models and peer feedback	& mini-lecture	devices (brush, floss, mouthwash)	
5	Smoking and Its Harmful Effects on Periodontal Tissues	45–60 minutes, 30–35 participants	Objectives: Explain how tobacco smoking damages periodontal tissues; List short- and long-term oral health effects of smoking Content: Chemical effects of nicotine and tar; Epidemiology of PD in smokers vs. non-smokers	Live demonstration under supervision & lecture	Colorful PowerPoint slides with photos	Compile a resource list on the oral-health impacts of smoking
6	Nutrition and Its Impact on Supportive Periodontal Tissues	45–60 minutes, 30–35 participants	Objectives: Analyze how different foods affect periodontal health; Recommend dietary adjustments to support	Group discussion & live demonstration	Colorful PowerPoint slides with photos	Prepare a list of dietary guidelines and resources on nutrition and oral health

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periodontal tissues
Content: Role of
sugars, acids, and
antioxidants;
Nutritional
guidelines and
examples of tooth-
friendly diets