

## **Statistical Analysis Plan (SAP)**

**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:**

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## **Overview**

This Statistical Analysis Plan outlines the statistical methods and procedures used to analyse data for the intervention study assessing the effect of a school-based oral health education program on periodontal conditions and related behaviours among 9th-grade students in Nablus City, Palestine.

## **Study Objectives**

- Primary: To evaluate the effectiveness of the intervention on CPITN and S-OHI scores.
- Secondary: To assess changes in oral hygiene practices, dietary habits, and smoking behaviours.

## **Data Preparation and Management**

Data were entered into IBM SPSS Statistics version 25.0.

All data were reviewed for completeness and consistency prior to analysis.

Normality testing was conducted using Shapiro-Wilk tests.

Missing data was minimal and handled by complete case analysis.

## **Statistical Analyses**

Descriptive statistics will be used to summarise baseline characteristics by group (mean  $\pm$  SD, frequencies, percentages).

- Paired t-tests will be used to assess within-group differences from baseline to post-intervention.
- Independent t-tests were used to compare mean differences between the intervention and control groups.
- Statistical significance was set at  $p < 0.05$ .
- Confidence intervals were calculated at the 95% level for all primary outcomes.

## **Study Questions VS Analysis Plan**

1. Can interactive educational sessions reduce **Community Periodontal Diseases Index** scores among 9th-grade students in Nablus City for two months?

### **1. Data Type and Variables**

**Dependent Variable:** Community Periodontal Index for Treatment Needs (CPITN) **score** → Continuous quantitative variable

**Independent Variable:** Group type (Intervention vs. Control) → Binary categorical variable

**Time Points:** Pre-intervention (baseline)

Post-intervention (after two months) → true experimental design (pre-post measurements)

### **2. Statistical Design**

Since there are two time points and two groups, the analysis includes:

#### **A. Within-Group Analysis (Intervention group and control group):**

Purpose: To assess whether there is a significant reduction in CPITN scores after the interactive educational sessions within the two groups themselves.

Test to use: Paired t-test, as the data is normally distributed.

#### **B. Between-Group Analysis (Post-intervention comparison):**

Purpose: To compare the post-intervention CPITN scores between the intervention and control groups.

Test to use: Independent T-test as the data is normally distributed

**Note:** The two groups were examined for their differences in baseline measurement.

2. Can interactive educational sessions reduce S-Oral hygiene index scores among 9th-grade students in Nablus City within two months?

### **1. Data Type and Variables**

**Dependent Variable:** Simplified Oral Hygiene Index (S-OHI) score → Continuous quantitative variable

**Independent Variable:** Group type (Intervention vs. Control) → Binary categorical variable

**Time Points:** Pre-intervention (baseline)

Post-intervention (after two months) → true experimental design

### **2. Statistical Design**

Since there are two time points and two groups, the analysis includes:

#### **A. Within-Group Analysis (Intervention group only):**

**Purpose:** To assess whether there is a significant improvement (reduction) in S-OHI scores after the interactive educational sessions.

**Test to use:** *Paired t-test*, as the data is normally distributed.

#### **B. Between-Group Analysis (Post-intervention comparison):**

**Purpose:** To compare the post-intervention S-OHI scores between the intervention and control groups.

**Test to use:** *Independent t-test*, as the data is normally distributed

3. Will oral hygiene practices, smoking habits, and dietary habits improve among 9th-grade students after interactive educational sessions are applied in Nablus City?

Questionnaire responses related to oral hygiene practices, dietary habits, and smoking behaviour were recoded into scale variables to facilitate the computation of mean scores pre-and post-intervention. Correct answers reflecting preventive behaviours, in line with American Dental Association (2023) guidelines, were assigned the highest scores, while incorrect responses received the lowest scores, for example:

- "Do you clean your teeth?": Yes = 1, No = 0
- "How often do you clean your teeth?": Once/day = 1, Twice/day = 2, Three times/day = 3
- "How long does it take to clean your teeth?": One minute = 1, Two minutes = 2, More than two minutes = 3, Don't know = 0
- "Brushing technique": Scrubbing = 1, Bass = 2, Modified Bass = 3
- "Toothbrush type": Hard bristle = 1, Soft bristle = 2, Medium bristle = 3

"Toothbrush replacement frequency": Every three months = 1, Two months = 2, Monthly = 3

Additional coding schemes are provided at the end of this document. The overall mean differences in oral hygiene practices, dietary habits, and smoking behaviour scores were then compared between groups using independent sample t-tests, with sub-analyses conducted for each behavioural domain separately. Statistical significance was set at  $p < 0.05$ .

## **1. Data Type and Variables**

### **Dependent Variables (Behavioural Scores):**

- **Oral hygiene practices score** → Continuous quantitative
- **Smoking habits score** → Continuous quantitative
- **Dietary habits score** → Continuous quantitative

**Independent Variable:** Group type (Intervention vs. Control) → Binary categorical

**Time Points:** Pre-intervention (baseline)

Post-intervention (after two months) → True experiment design (pre-post)

## **2. Statistical Design**

Since the question involves **multiple behaviours** and **two time points**, the analysis will be conducted separately for each behavioural domain:

### **A. Within-Group Analysis (Intervention Group Only)**

- **Purpose:** To evaluate if there was a significant improvement in each behaviour **after the intervention**.
- **Test to use:** Paired t-test for:
  - Oral hygiene practices score

- Dietary habits score
  - Smoking habits score
- (Assumes normal distribution)*

#### B. Between-Group Analysis (Post-Intervention Comparison)

- **Purpose:** To compare post-intervention behavioural scores between intervention and control groups.
- **Test to use:**
  - **Independent t-test** for:
    - Oral hygiene practices
    - Dietary habits
    - Smoking behavior

*(Assumes normal distribution)*

# Appendix A

## Section 2: Oral Hygiene Practices

| The question   | Responses             | Old codes | New scores |
|--|-----------------------|-----------|------------|
| <b>B.1 – Do you brush your teeth?</b>  | Yes                   | 1         | 1          |
|  | No.                   | 2         | 0          |
| <b>B1.1 How often do you usually brush your teeth?</b>                                 | Once a day            | 1         | 1          |
|  | Twice a day or more   | 2         | 2          |
|  | Sometimes             | 3         | 3          |
| <b>B.1.3 - How long do you spend brushing your teeth?</b>                              | A minute or less      | 1         | 1          |
|  | Two minutes           | 2         | 2          |
|  | More than two minutes | 3         | 3          |
| <b>B.1.4 - How do you brush your teeth?</b>  | Bass method           | 1         | 2          |
|  | Scrubbing method      | 2         | 1          |
|  | Modified Bass method  | 3         | 3          |
|  | Other                 | 4         | 0          |
| <b>B.1.5 - What kind of bristles does your toothbrush have?</b>                        | Soft bristles         | 1         | 2          |
|  | Medium bristles       | 2         | 3          |
|  | Hard bristles         | 3         | 1          |
|  | I am not sure         | 4         | 0          |
| <b>B.1.6 - How often do you change your toothbrush?</b>                                | Every month           | 1         | 3          |
|  | Every two months      | 2         | 2          |
|  | Every three months    | 3         | 1          |
|  | Other                 | 4         | 0          |
| <b>B.1.7 - Do you use other oral and dental cleaning tools besides the toothbrush?</b> | Dental floss          | 1         | 3          |
|  | Interdental brush     | 2         | 2          |
|  | Mouthwash             | 3         | 1          |
|  | Do not use            | 4         | 0          |
| <b>B.1.8 - Do you visit the dentist in your life?</b>                                  | Yes.                  | 1         | 1          |
|  | No.                   | 2         | 0          |
| <b>B.1.9- How did you visit the dentist?</b>   | Regularly             | 1         | 3          |
|  | Sometime              | 2         | 2          |
|  | Pain                  | 3         | 1          |
|  | Before 6 months       | 1         | 3          |
|  | Before 6-12 months    | 2         | 2          |

|   |  |   |   |
|---|--|---|---|
| <b>B.1.10 - When was the last time you visited the dentist?</b>                 | Before 1-2 years                         | 3 | 1 |
|   | Before 3-5 years                         | 4 | 0 |
|   |  |   |   |
| <b>B.1.11 - If you visited the dentist, what was the purpose of your visit?</b> | Pain                                     | 1 | 0 |
|   | Recommendation from a friend or relative | 2 | 1 |
|   | Recommendation from another dentist      | 3 | 2 |
|   | Routine dental check-up                  | 4 | 3 |
|   | Teeth and gum cleaning                   | 5 | 4 |
| <b>Section 3: Diet Habits</b>   |  |   |   |
| <b>C.1.1 - Do you eat breakfast on weekdays?</b>                                | Never                                    | 1 | 0 |
|   | Once a week                              | 2 | 1 |
|   | Twice a week                             | 3 | 2 |
|   | Three times a week                       | 4 | 3 |
|   | Four times a week                        | 5 | 4 |
|   | Every day                                | 6 | 5 |
| <b>C.2.1-Do you have breakfast on weekends?</b>                                 | Never                                    | 1 | 0 |
|   | Once a week                              | 2 | 1 |
|   | Every weekend                            | 3 | 2 |

C.2 - How often do you eat or drink the following items? (Tick one box for each item by marking an "X" under the option that applies to you in each row):

| Item  | Never | Less than once a week | Once a week | 2-4 times a week | 6 times a week | Once a day | More than once a day |
|---|-------|-----------------------|-------------|------------------|----------------|------------|----------------------|
| Fruits  | 0     | 1                     | 2           | 3                | 4              | 5          | 6                    |
| New code                                      | 0     | 1                     | 2           | 3                | 4              | 5          | 6                    |
| Vegetables                                    | 0     | 1                     | 2           | 3                | 4              | 5          | 6                    |
| New code                                      | 0     | 1                     | 2           | 3                | 4              | 5          | 6                    |
| Sweets (e.g., candy or chocolate)             | 0     | 1                     | 2           | 3                | 4              | 5          | 6                    |
| New code                                      | 6     | 5                     | 4           | 3                | 2              | 1          | 0                    |
| Soft drinks or any sugar-containing beverages | 0     | 1                     | 2           | 3                | 4              | 5          | 6                    |
| New code                                      | 6     | 5                     | 4           | 3                | 2              | 1          | 0                    |
| Milk and dairy products                       | 0     | 1                     | 2           | 3                | 4              | 5          | 6                    |



|          |   |   |   |   |   |   |   |
|----------|---|---|---|---|---|---|---|
| New code | 0 | 1 | 2 | 3 | 4 | 5 | 6 |
| Red meat | 0 | 1 | 2 | 3 | 4 | 5 | 6 |
| New code | 0 | 1 | 2 | 3 | 4 | 5 | 6 |
| Fish     | 0 | 1 | 2 | 3 | 4 | 5 | 6 |
| New code | 0 | 1 | 2 | 3 | 4 | 5 | 6 |
| Water    | 0 | 1 | 2 | 3 | 4 | 5 | 6 |
| New code | 0 | 1 | 2 | 3 | 4 | 5 | 6 |
| Nuts     | 0 | 1 | 2 | 3 | 4 | 5 | 6 |
| New code | 0 | 1 | 2 | 3 | 4 | 5 | 6 |
| Pastries | 0 | 1 | 2 | 3 | 4 | 5 | 6 |
| New code | 6 | 5 | 4 | 3 | 2 | 1 | 0 |

#### Section 4: Smoking behaviours

| The question   | Responses                              | Old codes | New scores |
|--|--|-----------|------------|
| <b>D.1- Do you currently smoke (at least one cigarette)?</b>                               | Yes                                    | 1         | 2          |
|  | No                                     | 2         | 0          |
| <b>D.2 - How frequently do you smoke cigarettes or use other tobacco products?</b>         | Every day                              | 1         | 1          |
|  | At least once a week but not every day | 2         | 2          |
|  | Less than once a week                  | 3         | 3          |
|  | I don't smoke                          | 4         | 4          |
| <b>D.2.2 - If you smoke cigarettes, how many cigarettes do you usually smoke per week?</b> | 26 and over                            |           | 0          |
|  | 21-25 cigarettes                       |           | 1          |
|  | 16-20cigarettes                        |           | 2          |
|  | 11-15cigarettes                        |           | 3          |
|  | 6-10cigarettes                         |           | 4          |
|  | 0-5cigarettes                          |           | 5          |
| <b>D.3 - Have you ever smoked a waterpipe (hookah)?</b>                                    | Yes                                    | 1         | 2          |
|  | No                                     | 2         | 0          |
| <b>D.4 - How often do you currently smoke a water pipe?</b>                                | Every day                              | 1         | 1          |
|  | At least once a week but not every day | 2         | 2          |
|  | Less than once a week                  | 3         | 3          |
|  | I don't smoke waterpipe                | 4         | 4          |