SEHAT Trial Study Protocol

Official Title:

Evaluating the Impact of Novel Oral Health Promotion Program "SEHAT" among Adolescents in Pakistan's Resource-Constrained Settings – A Cluster Randomized Trial

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Confidentiality Statement:

This document contains confidential information related to the SEHAT trial. It is intended solely for regulatory review and research purposes. Names of participants are not included.

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Background

Oral diseases remain highly prevalent among adolescents in Pakistan. Digital and school-based interventions may improve oral health literacy and behaviors, particularly in resource-constrained settings.

Objectives

1. To investigate the effectiveness of a Zoom-based oral health promotion intervention among adolescents in improving
    a. Knowledge about oral health
    b. Attitude towards oral health
    c. Behaviour identified as protective for oral health
        i. Toothbrushing twice daily with fluoridated toothpaste
        ii. Dietary habits with reduced consumption of sugary food and drinks
2. To compare the impact of virtual oral health promotion intervention with a conventional in - person (positive control) and no intervention (negative control).

Study Design

Cluster randomized controlled trial with three arms: virtual intervention, conventional intervention, and control.

Study Setting

Public schools in Rawalpindi, Pakistan.

Participants

Adolescents aged 11–15 years enrolled in selected public schools.

Sample Size

A total sample of approximately 1,443 participants accounting for clustering and attrition.

Randomization

Grades will be randomized into three arms using block randomization.

Intervention

SEHAT virtual oral health education sessions delivered via telecommunication technology. Conventional arms will receive face-to-face sessions. Control groups will receive no intervention.

Primary Outcome

Change in plaque score from baseline to follow-up assessments.

Secondary Outcomes

Gingival index, oral health knowledge, attitude and toothbrushing behaviors.

Data Collection

Clinical examinations and structured questionnaires administered at baseline and follow-ups.

Statistical Analysis

Mixed-effects models accounting for clustering will be used to compare outcomes between groups.

Ethical Considerations

Ethical approval obtained from Institutional Review Board. Informed consent will be obtained from participants and guardians.

Timeline

Baseline assessment, intervention delivery, and follow-ups up to 12 months.