Education-Based Oral Health Promotion Intervention During Pregnancy: Implementation Protocol in Bangladesh

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In Bangladesh, over 95% of pregnant women suffer from gum disease, yet oral health is rarely part of regular pregnancy check-ups. This study tests a new "Integrated Oral Health Promotion Package" to see if adding dental education to existing ANC (Upazila Health Complexes) improves the health and habits of expectant mothers.

Objectives

To assess the effect of the education-based oral health promotion intervention, compared with usual care, on oral health behaviours and knowledge among pregnant women at 12 weeks.

Design, and methods

This study is designed as a cluster randomized controlled implementation trial evaluating an education-based oral health promotion model for pregnant women in Bangladesh. The study is conducted in eight Upazila Health Complexes (UHCs) across eight administrative divisions. This protocol and all recruitment materials have been approved by the IRB of Bangladesh Medical University. Any future amendments to the protocol or study sites will be submitted for board approval before implementation. To prevent treatment contamination, staff at intervention sites will not rotate to control sites, and clinical examiners remain blinded to the 1:1 cluster allocation throughout the 12-week follow-up.

Participant Enrollment and Power

A total of 688 pregnant women (86 per cluster) with a gestational age ≤24 weeks will be recruited. The sample size provides 80% power at a 5% significance level to detect a 20% improvement in the primary outcome, assuming a 1.5 design effect (ICC = 0.05) and a 20% attrition rate.

Statistical Analysis Plan (SAP) and Assumption Verification

Analysis follows the Intention-to-Treat (ITT) principle using Mixed-Effects Linear Regression for clinical scores (OHI-S) and Mixed-Effects Logistic Regression for binary behavioral outcomes. The UHC is included as a random effect to account for clustering.

- Verification of Assumptions: To meet PRS requirements for statistical transparency, the normality of continuous outcomes will be verified using Shapiro-Wilk tests and Q-Q plots. If assumptions are violated, non-parametric methods or log-transformations will be employed.
- Multiple Testing: To account for testing multiple variables (OHI-S, Knowledge Score, and Behavior), a Bonferroni correction will be applied to the p-values.
- Missing Data: If missingness exceeds 5%, Multiple Imputation (m=20) will be used to handle incomplete data.

Outcome Measures

The primary clinical endpoint is the Oral Hygiene Index–Simplified (OHI-S), measuring debris and calculus on six tooth surfaces (score 0–6). Secondary endpoints include a 10-item validated Knowledge Score and self-reported behavioral changes in twice-daily brushing frequency from baseline to 12 weeks.