

Official Title:

Effectiveness of Artificial Intelligence Supported Mobile Education Compared with Face-to-Face and Brochure-Based Education on Dysmenorrhea Self-Care and Genital Hygiene Behaviors in Adolescent Girls: A Randomized Controlled Trial

NCT Number: NCTXXXXXXXX (Not yet assigned)

Document Date: Sep 18, 2025

Study Protocol

This study is designed as a three-arm, parallel-group randomized controlled trial with a pretest-posttest design to compare the effectiveness of artificial intelligence supported mobile education, face-to-face education, and brochure-based education on dysmenorrhea self-care and genital hygiene behaviors among adolescent girls.

Participants aged 14-17 years who have experienced menarche and reported dysmenorrhea within the past six months will be randomly assigned to one of three groups using a computer-generated simple randomization method. The intervention will be conducted over four weeks.

The AI-supported mobile education group will receive individualized and interactive education through structured and researcher-guided artificial intelligence prompts focusing on dysmenorrhea self-care and genital hygiene behaviors. The face-to-face education group will receive the same educational content delivered directly by the researcher in a structured format. The brochure-based group will receive written educational materials covering the same topics without interactive components.

Outcome measures will be collected at baseline (pretest), 4 weeks after baseline, and 8 weeks after baseline using validated and reliable instruments assessing dysmenorrhea self-care behaviors and genital hygiene practices. The primary outcomes are changes in dysmenorrhea self-care and genital hygiene behavior scores.

Due to the nature of the intervention, blinding of participants and educators will not be possible; however, data analysis will be performed using coded group assignments to minimize bias.

Statistical Analysis Plan

Data will be analyzed using a statistical software package. Descriptive statistics will be used to summarize participant characteristics, including mean, standard deviation, frequency, and percentage.

Baseline differences among the three groups will be assessed using one-way ANOVA or Kruskal-Wallis tests for continuous variables and chi-square tests for categorical variables.

The primary effectiveness analysis will be conducted using a mixed-design repeated measures analysis of variance or a linear mixed-effects model to examine the effects of group, time, and group-by-time interaction on dysmenorrhea self-care and genital hygiene behavior scores. Time will include three measurement points: baseline, 4 weeks after baseline, and 8 weeks after baseline. Group allocation will include the artificial intelligence–supported mobile education group, face-to-face education group, and brochure-based control group.

If baseline differences are detected, baseline scores and relevant covariates will be included in the model. Post-hoc pairwise comparisons will be performed with Bonferroni correction. Within-group changes over time and between-group differences at each time point will be examined as secondary analyses.

Effect sizes will be reported using partial eta squared for repeated measures analyses and Cohen's *d* for pairwise comparisons. The level of statistical significance will be set at $p < 0.05$. Missing data will be assessed prior to analysis, and appropriate methods such as complete case analysis or multiple imputation will be applied when necessary.