OFFİCİAL TİTLE:

Evaluation of the Effectiveness of a Diabetes Self-Management Program Based on Pender's Health Promotion Model in Pregnant Women Diagnosed with Gestational Diabetes Mellitus

NCT NUMBER:

NCT07060963

DOCUMENT DATE:

15.01.2025

STATISTICAL ANALYSIS PLAN

Official Study Title:

Evaluation of the Effectiveness of a Diabetes Self-Management Program Based on Pender's Health Promotion Model in Pregnant Women Diagnosed with Gestational Diabetes Mellitus

Clinical Trial Registration Number:

NCT07060963

Study Type:

Randomized Controlled Clinical Trial

Principal Investigator:

Esra Altun

Institution:

Ankara Yıldırım Beyazıt University Graduate School of Health Sciences

Ethics Approval:

Approved by the Ethics Committee of Ankara Yıldırım Beyazıt University
Graduate School of Health Sciences
Ethics Approval No: 06/791

Document Type:

Statistical Analysis Plan

Document Date: 15/01/2025

Statistical Analysis Plan

This study is designed as a randomized controlled clinical trial with a parallel group assignment to evaluate the effectiveness of a diabetes self-management program based on Pender's Health Promotion Model in pregnant women diagnosed with gestational diabetes mellitus. The study was conducted at Ankara Yıldırım Beyazıt University, Graduate School of Health Sciences. Ethical approval was obtained from the Ethics Committee of Ankara Yıldırım Beyazıt University, Graduate School of Health Sciences (Ethics Approval No: 06/791). The trial was registered at ClinicalTrials.gov (Identifier: NCT07060963).

Statistical analyses will be performed using R software (version 4.4.1), Minitab (version 14), and Jamovi (version 2.7.6). The normality of continuous variables will be assessed using the Shapiro–Wilk test, and the results of this assessment will guide the selection of appropriate parametric or non-parametric statistical methods.

Descriptive statistics for continuous variables will be presented as mean ± standard deviation for normally distributed data and as median (minimum–maximum) for non-normally distributed data. Categorical variables will be summarized using frequencies and percentages. Between-group comparisons will be conducted using the independent samples t-test for normally distributed continuous variables and the Mann–Whitney U test for non-normally distributed variables. Within-group comparisons for repeated measurements will be performed using appropriate non-parametric tests when normality assumptions are not met.

Categorical variables will be analyzed using Fisher's Exact Test, Monte Carlo–corrected Fisher's Exact Test, or Yates' continuity correction, as appropriate. To control for Type I error in multiple comparisons, Bonferroni-corrected z tests and Holm-corrected robust t-tests will be applied.

Group effects, time effects, and group × time interaction effects will be evaluated using Generalized Linear Models for normally distributed data and Robust ANOVA for non-normally distributed data. In addition to p-values, effect sizes will be reported to assess clinical and practical significance. Partial eta-squared (η^2) values will be interpreted as small (0.01), medium (0.06), or large (≥0.14) effects. All statistical analyses will be two-tailed, and statistical significance will be set at $p < 0.05$.