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

STUDY PROTOCOL

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

ClinicalTrials NCT Number:

NCT07060963

Study Type:

Interventional Study (Clinical Trial)

Study Design:

Parallel-group clinical trial

Research Center / Institution:

Ankara Yıldırım Beyazıt University Graduate School of Health Sciences

Principal Investigator:

Esra ALTUN

Ethics Approval:

Approved by the Ethics Committee of Ankara Yıldırım Beyazıt University, Graduate School of Health Sciences. NO: 06/791

Document Type:

Study Protocol

Version Number:

Version 1.0

Country:

Türkiye

1. Title

Evaluatıon of the effectıveness of a dıabetes self-management program based on pender's health promotıon model ın pregnant women dıagnosed wıth gestatıonal dıabetes mellıtus

2. Study Summary

This randomized controlled trial aimed to evaluate the effectiveness of a self-management program based on Pender's Health Promotion Model (HPM) in pregnant women diagnosed with gestational diabetes mellitus (GDM). Participants were randomly assigned to intervention and control groups, which were similar in demographic and obstetric characteristics ($p>0.05$). Following the intervention, meal frequency and water intake significantly increased, while physical activity and sleep duration improved in the intervention group ($p<0.05$). Fasting and postprandial blood glucose levels were significantly lower in the intervention group during pregnancy and postpartum, and maternal blood glucose at delivery was reduced compared to controls ($p<0.05$). HbA1c levels remained similar between groups ($p>0.05$). Significant improvements were observed in health beliefs, self-efficacy, and healthy lifestyle behaviors in the intervention group, particularly in diet, physical activity, stress management, and spiritual development domains (η^2 =0.029–0.218). Regarding birth outcomes, the intervention group showed lower rates of preterm birth (2.7% vs 23.5%, $p=0.012$), shorter hospital stays, and reduced macrosomia risk ($p<0.05$). APGAR scores and delivery mode did not significantly differ between groups. These findings suggest that a Pender HPM-based self-management program may improve metabolic control, healthy lifestyle behaviors, and certain perinatal outcomes in women with GDM.

3. Introduction & Objectives

Background: Gestational diabetes mellitus (GDM) is a common metabolic disorder during pregnancy, associated with maternal and neonatal complications, including hyperglycemia, hypoglycemia, hypertension, polyhydramnios, infection, dystocia, cesarean delivery, macrosomia, and neonatal metabolic issues. Despite existing management strategies, optimizing self-management and promoting healthy lifestyle behaviors remain challenging. Pender's Health Promotion Model (HPM) provides a framework to enhance health behaviors and self-efficacy in individuals with chronic conditions, including GDM.

Study Aim: The aim of this study is to evaluate the effectiveness of a self-management program based on Pender's HPM in pregnant women diagnosed with GDM.

Research Hypotheses:

- H01: No difference in mean *Health Belief Model Scale for Patients with Diabetes* scores between groups.
- H02: No difference in mean *Gestational Diabetes Self-Efficacy Scale* scores between groups.
- H03: No difference in mean *Multidimensional Perceived Social Support Scale* scores between groups.
- H04: No difference in mean *Health-Promoting Lifestyle Profile II* scores between groups.
- H05: No difference in incidence of at least one maternal complication between groups.
- H06: No difference in fasting and postprandial blood glucose levels at 24–28, 28–32, 32–38 weeks, delivery, and first 24 hours postpartum between groups.
- H07: No difference in HbA1c levels in the first and third trimesters between groups.
- H08: No difference in neonatal complications frequency between groups.
- H09: No difference in neonatal blood glucose levels at 3, 6, and 9 hours postpartum between groups.

4. Study Population and Sample Size

Population: Pregnant women attending antenatal clinics at a university hospital in Ankara, diagnosed with GDM at 24–28 weeks gestation via OGTT (ICD-10 O24.4).

Sample Size: Using G*Power (v3.1.9.6) with α=0.05, power=80%, and effect size=0.20, minimum 26 participants per group were required. To account for 20% dropout, 36 participants per group (total 64) were enrolled (Intervention: n=32; Control: n=32).

5. Eligibility Criteria and Randomization

Inclusion Criteria: Communication in Turkish, no mental/visual/hearing impairments, ≥secondary education, singleton pregnancy at 24–28 weeks, no prior GDM, not high-risk pregnancy, no contraindications for exercise, no special diet requirements, no psychiatric or endocrine disorders affecting glucose.

Exclusion Criteria: Withdrawal at any stage, missing program sessions, developing high-risk pregnancy during study, incomplete data collection forms.

Randomization: Simple randomization with day-based rotation was performed by an independent dietitian to avoid bias. Groups were balanced with at least 10 participants per educational subgroup.

6. Study Procedures

Enrollment and Group Assignment: Eligible participants were screened, consented, and systematically assigned to intervention or control groups using day-based rotation.

Intervention:

- Intervention group received a structured diabetes self-management program based on Pender's HPM.
- Four face-to-face sessions (40 min each, total 160 min) delivered to groups of 10–15 participants.
- Provided with *Gestational Diabetes Patient Education Booklet* and *Lifestyle Behavior Change Tracking Booklet*.
- Individual motivational interviews conducted at 28–32 weeks and 32–36 weeks, with phone reminders and follow-up.
- Group engagement encouraged through sharing exercise photos/videos; positive behaviors reinforced via telephone counseling.

Postpartum Assessment:

- Intervention group: Maternal and neonatal outcomes collected from hospital records using a *Postpartum Follow-up Form*.
- Control group: Received routine care with dietitian referral, glucose monitoring instructions, and pre/post-test data collection using KBF, DHSİMÖ, GDÖYÖ, SYBDÖ-II, ÇBASDÖ; postpartum outcomes recorded 24–48 hours after delivery.

7. Outcome Measures

Primary Outcomes:

- Maternal fasting and postprandial blood glucose levels, HbA1c, health beliefs, self-efficacy, healthy lifestyle behaviors.

Secondary Outcomes:

- Maternal complications (hyper/hypoglycemia, hypertension, polyhydramnios, cesarean delivery, dystocia, infection).
- Neonatal outcomes (birth weight, APGAR scores, neonatal complications, NICU admission).
- Postpartum maternal and neonatal glucose levels.