

**The Effect of The Health-Promoting Lifestyle Education Program Provided to Women With Gestational Diabetes on Maternal and Neonatal Health: A Randomized Controlled Trial**

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## **The study**

This study has addressed topics of related to healthy lifestyle, in addition to nutrition and exercise. Topics of the Health-Promoting Lifestyle Education Program (**HPLEP**) were self-management of blood glucose, nutrition, physical activity, coping with stress, sleeping, smoking, self-care and breastfeeding. Within the scope of the **HPLEP**, one-to-one applied education and counseling were provided to the women using written and visual materials.

## **Aim**

The aim of the study was to examine the effects of the **HPLEP** on maternal and neonatal health.

Hypotheses of this study;

H<sub>1</sub>: The **HPLEP** is effective for women with GDM in their adoption of a healthy lifestyle.

H<sub>2</sub>: The **HPLEP** is effective in reducing the symptoms of depression in women with GDM.

H<sub>3</sub>: The **HPLEP** is effective in improving the quality of life of women with GDM.

H<sub>4</sub>: The **HPLEP** is effective in reducing postpartum neonatal complications.

## **Desing**

The study was designed and conducted as a two group quasi-experimental study. Intervention group (n=46) and control group (n=42) were administered the data collecting tools in the first assessment. After first assessment, the intervention group were included in the educational program. Data collecting tools were re-administered four weeks after to the intervention group only. Than data collecting tools were re-administered to the both groups in the postpartum 6th week.

## **Sample**

This study was conducted in the perinatology clinic of the Istanbul Zeynep Kamil Hospital, Turkey in 2015. The records show that 350 women with GDM were referred to the perinatology clinic in that period. The sample size was calculated using Power and Sample Size Program, with 80% power and a 0.05 margin of error, and it was

determined that both the intervention and the control group should include at least 30 women with GDM. It was considered appropriate that 50 women with GDM be included in each group.

The inclusion criteria for participation in the study included a gestational period of 24 to 34 weeks, a diagnosis of GDM, an age of 18 years or older, and voluntary consent to participate in the study, while the exclusion criteria included the presence of a psychiatric disease, multiple pregnancy, the risk of preterm labor, placenta previa or premature rupture of the membranes, and failure to obtain voluntary consent to participate in the study.

### **Data collection**

Data were collected by the first author (both control and intervention group). All data were collected with questionnaires conducted through face-to-face structured interviews with the data collector.

#### *Primary outcomes:*

- Primary outcome of women with GDM was their healthy lifestyle behaviours measured on the Health-Promoting Lifestyle Profile II (HPLP-II). This scale, developed by Walker et al. (1987) on the basis of Pender's health promotion model, measures the health-promoting behaviours associated with a health-promoting lifestyle. The scale was revised in 1996 and designated as HPLP-II (Walker et al. 1996). Bahar et al. (2008) tested the scale's validity and reliability in Turkish. The Cronbach's alpha internal consistency coefficient of the scale was found to be 0.92. Higher scores on the scale indicate a higher performance level of the determined health-promoting behaviours. The scale consists of 52 items under the six subscales of spiritual growth, nutrition, physical activity, health responsibility, interpersonal relations and stress management. The lowest and highest possible scores on the scale are 52 and 208, respectively.

- Center for Epidemiologic Studies Depression Scale (CES-D Scale) was used to assess symptoms of depression in women. This short scale, developed by Radloff (1977) to measure depressive symptoms, can be administered to both the general population and specially selected groups. The CES-D consists of 20 items, each item scored between 0 and 3. The total score ranges between 0 and 60, and a score of 16 and higher suggests the risk of depression, while lower scores on the CES-D Scale indicate decreased risks for depression. Yilmaz (2010) tested the scale's validity and reliability in Turkish. The Cronbach's alpha value was found to be 0.85 for the entire scale.
- Quality of life of the women was measured using the Short Form 36 Health Survey (SF-36). This scale, developed by Ware in 1987, is globally referred to as SF-36, as this acronym has been commonly used in all studies since the development of the scale. SF-36 is a self-assessment scale, consisting of 36 questions under eight subscales: physical functioning, physical role limitation, social functioning, mental health, energy-vitality, bodily pain, general health perceptions and emotional role limitation (Ware & Sherbourne 1992). Pınar (1995) tested the scale's validity and reliability in Turkish. The Cronbach's alpha internal consistency value was found to be 0.91.
- Women's level of knowledge about GDM was measured using pre-test and post-test question form. This form, developed by the researcher in accordance with the literature, includes questions about GDM and healthy lifestyle.

#### *Secondary outcomes*

- Postpartum diabetes control of women with GDM was assessed through the postpartum 6th week information form that developed by the researchers on the basis of the literature.
- Postpartum characteristics of neonates were assessed through the neonate's information form that developed by the researchers on the basis of the literature.

The flowchart of this study is shown in Figure 1. The patients followed up in the perinatology clinic were assigned to groups through randomization (drawing lots by the clinic nurse). Data collector checked patients in the perinatology clinic daily. If there were more than one patient who met the inclusion criteria, it was determined which group to take with the lottery method. When there was only one woman with GDM in the clinic, it was determined which group to take with the lot but the next patient was taken directly to the opposite group. When two patients were in the same room, they were taken into the same group in order not to have any ethical problems. The women in the both group were administered the introductory information form, the HPLP-II, the CES-D and the SF-36 in the first assessment.

The education program and also usual care applied to the intervention group. The education program consisted of three 45-min sessions, which included a face-to-face lecture with the dissemination and presentation of written and visual materials. Also each participant in the intervention group was given the *Health-Promoting Lifestyle Booklet* and the *Diary of a Woman with GDM* card. The booklet features all of the health-promoting practices (self-monitoring of blood glucose, nutrition, physical activity, stress, sleeping, smoking, self-care and breastfeeding). The *Diary of a Woman with GDM* card features the daily program that women should follow (the hours for main meals and snacks, insulin hours, etc.). The education and counseling were maintained through follow-up via phone for intervention group.

The women in the control group which receiving only usual care were followed according to the institution's routine diabetes follow-up protocol (monitoring blood glucose levels as frequently as indicated by the doctor, and patients are referred to dietitian and to diabetes nurse). To assess the effectiveness of the educational program, the HPLP-II, CES-D and SF-36 were re-administered to the intervention group four weeks after the first assessment (second assessment). The HPLP-II, CES-D and SF-36 were re-administered to the both groups in the postpartum 6th week (third assessment).

### **Validity and reliability**

Women with GDM in the intervention and control group were divided into groups by randomization method. Women with GDM who were followed up in the perinatology clinic were divided into groups by means of a lottery method. In the clinic, women in

the same room were not taken to different groups to avoid problems among GDM women.

In this study reliability of the instruments was measured with Cronbach's alpha. The Cronbach's alpha value of the HPLP II was 0.90; the CES-D was 0.85 and the SF-36 was 0.85.

### **Ethical considerations**

The required permissions were obtained from the Clinic Research Ethics Committee of Zeynep Kamil Women and Children Diseases Education and Research Hospital. All participants gave informed consent prior to inclusion in the study. Participants were informed that they could leave the study if they wanted. All contact numbers were given to the participants for any inquiries.

### **Data analysis**

The data were analysed using the SPSS 21 package. The introductory information derived from the introductory form administered to the participants in the intervention and the control group were analysed using descriptive statistical methods and compared using the Chi-square ( $\chi^2$ ) test and Mann-Whitney test. Pre-post test results of women in the intervention group were compared using the Wilcoxon Signed Rank Test. The first, second and third assessments of the intervention group were compared using the Wilcoxon Signed Rank Test, while the first and third (postpartum 6th month) assessments of the intervention and the control groups were compared using the Mann-Whitney test. Postpartum characteristics of the neonates were analysed using the Chi-square ( $\chi^2$ ) test and Mann-Whitney test. Lastly, the postpartum diabetes controls of the intervention and control groups were compared using Fisher's exact chi-square test.

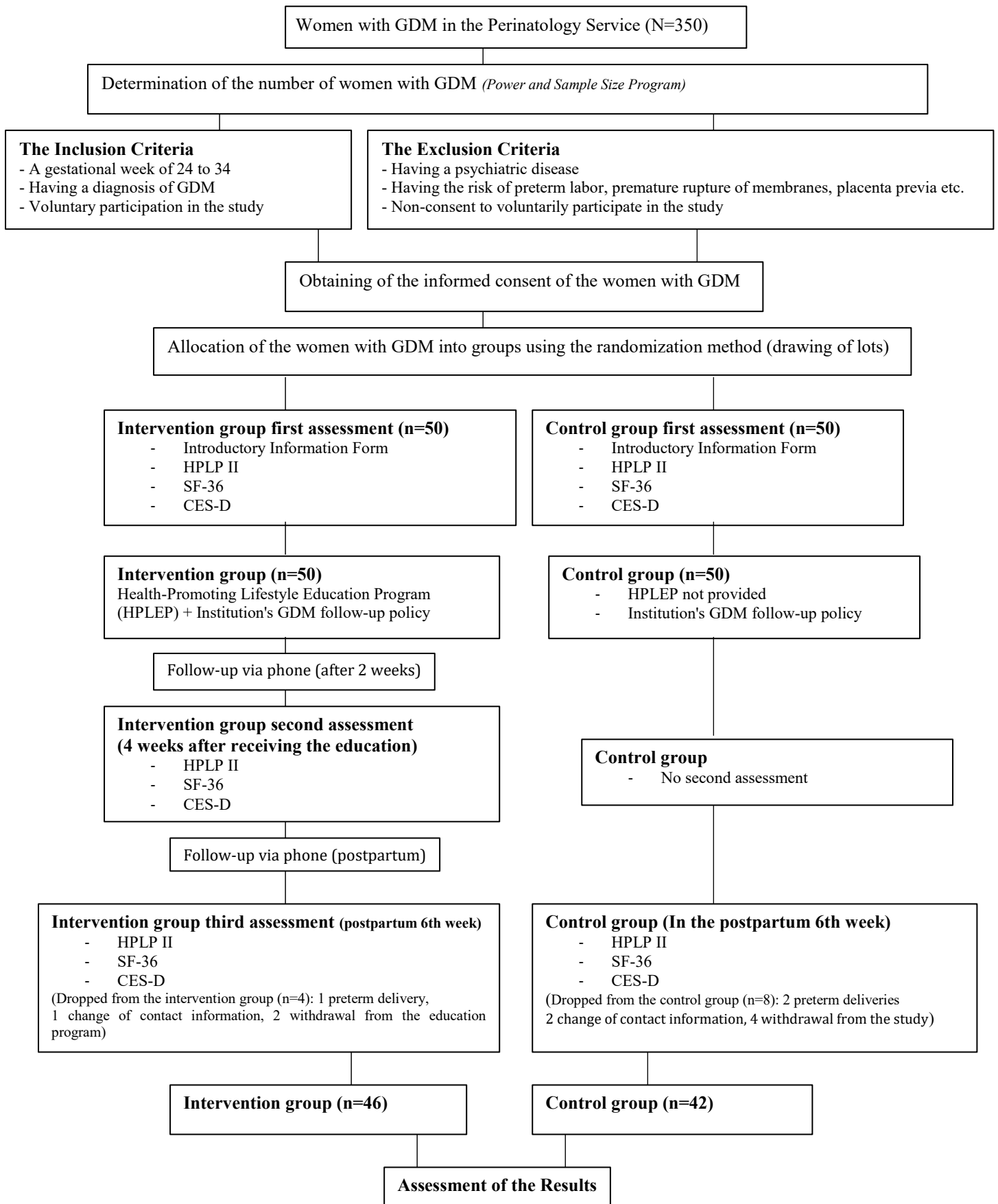


Figure 1. Flowchart of this study