



The Effect of Training Intervention Based on Health Belief Model on Physical Activity of Pregnant Women at Risk of Gestational Diabetes Mellitus: A Triple-Blind Randomized Controlled Trial

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Abstract

Objectives: This study was aimed at determining the effect of training intervention based on health belief model (HBM) on physical activity (PA) of pregnant women at risk of gestational diabetes mellitus.

Materials and Methods: A total of 104 pregnant women at risk for gestational diabetes mellitus were enrolled in this triple-blind randomized controlled trial. The intervention protocol consisted of six 60-minute educational sessions focused on physical activity, which were theoretically grounded in the HBM. Participants in the control condition received only routine pregnancy care education. Data was conducted using SPSS version 21.

Results: The results showed that the levels of Perceived Susceptibility (28.63 ± 3.79 , $P < 0.001$), Perceived Threat Severity (28.48 ± 1.79 , $p = 0.015$), Perceived Benefits (18.96 ± 1.94 , $P = 0.022$), and Self-Efficacy (17.85 ± 3.40 , $P < 0.001$) in the intervention group significantly increased after the education compared to before the education. In the intervention group, the amount of daily physical activity (18.07 ± 3.66 , $P = 0.011$) and weekly physical activity (74.26 ± 26.99 , $P < 0.001$) was significantly higher than before the intervention.

Conclusions: Sustaining and improving maternal health outcomes, particularly for pregnant individuals at elevated risk for gestational diabetes, mandates the adoption of structured educational models by policymakers and service providers, particularly practicing midwives. In this context, the implementation of the HBM is strongly recommended.

Keywords: Physical activity, Pregnant women, Gestational diabetes mellitus, Education, Health belief model

Introduction

Pregnancy is a physiological condition accompanied by metabolic changes. These changes indicate the growth and development of the fetus. The dysregulation of these physiological processes leads to problems such as gestational diabetes (1,2). Diabetes is one of the most common medical problems during pregnancy, and the growing prevalence of type 2 diabetes generally, and especially in young individuals, has led to an increase in its occurrence during pregnancy (3-5). The association of gestational diabetes with macrosomia, birth trauma, shoulder dystocia, high rates of Cesarean section, as well as metabolic disorders in offspring and an increased risk of developing type 2 diabetes in the mother's future life has been proven in previous studies (6,7).

Therefore, given the importance of the disease and its adverse consequences for affected infants and mothers, and considering that Iran is a developing country with limited economic resources and pro-natalist policies, where about eleven million people in the reproductive age group are exposed to this disease, and considering that

this disease is mostly asymptomatic yet highly morbid for both mother and neonate, the necessity of preventative measures against this disease is quite clear. One of the essential ways to prevent this disease is adequate physical activity in susceptible individuals (8).

Emphasizing the importance of physical activity in maintaining the health of pregnant women, and the inappropriateness of this pattern among women in the country, coupled with the low knowledge and attitude of women in this regard, necessitates interventional measures. Health education is considered one of the most effective health promotion actions. It is a process of teaching health behaviors to individuals or groups to promote, maintain, and restore their health (9). However, some studies show that pregnancy education regarding physical activities is associated with an increase in these activities (10,11). The low physical activity level among pregnant women in the country, despite routine pregnancy education, also suggests that education not designed based on educational models is less effective (12,13).

To succeed in changing and establishing healthy

Received 20 August 2025, Accepted 14 October 2025, Available online 3 November 2025

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Key Messages

- ▶ The HBM-based educational intervention significantly increased physical activity levels.
- ▶ The HBM-based educational intervention promotes health behaviors.

behaviors, health educators need to understand the factors influencing people's learning, and theories help support this process. In health education, the effectiveness of programs improves when there is a solid theoretical foundation along with addressing key health needs, and applying educational theories suitable for the community can be very helpful in this regard (14-16). Research has shown that the health belief model (HBM), as an individual-level model, effectively promotes certain health-related behaviors across different groups. The basis of the HBM is that if individuals are aware of the consequences of a behavior and believe these consequences can be prevented through correct actions, they are more likely to engage in that behavior (17-19).

Different types of diabetes at all ages leave short-term and long-term complications for the patient, which can lead to a decrease in quality of life, stress, diabetic foot ulcers, etc (20-22). For this reason, this study was conducted.

Materials and Methods

Study Type and Statistical Population

This triple-blind randomized controlled trial conducted on 104 pregnant women at risk of gestational diabetes, divided into two groups: $n = 52$ For each group.

Sample Size and Calculation Method

The sample size was determined based on the formula $n = \frac{(z_1 + z_2)^2 (2s^2)}{d^2}$, yielding a minimum of 52 participants in each group.

- z_1 is the 95% confidence coefficient, which is 1.96.
- z_2 is the 80% power of the test coefficient, which is 0.84.
- s is the estimated standard deviation of the score for each variable in the two groups.
- d is the minimum mean difference score for each variable between the two groups that indicates a significant difference, which was considered $0.5s$.

Sampling and Randomization

This study adopted a cluster random sampling approach. Initially, the city of Ilam was stratified into five distinct regions which were randomly assigned labels. Subsequently, one health center from each region was randomly selected, resulting in a total of five health centers included in the sampling framework. The randomization was performed by a coin toss conducted by an independent research colleague. To generate the randomization list, the coin was tossed 104 times. When the first side of the coin

landed face up, it signified assignment to the intervention group, and when the second side landed face up, it signified assignment to the control group. Subsequently, the results of the randomization, ranging from 1 to 104, were recorded in a list. To blind the results from the researcher, each outcome was recorded on a separate sheet according to the list, sealed in an envelope, and the corresponding list number was written on the envelope. Finally, after each sample was enrolled in the study, the envelopes were opened sequentially, from 1 to the last, to determine the assignment of patients to either the intervention or control group. All data were recorded without disclosing the nature of the group to ensure that the researcher, the interviewer, and the statistical analyst remained unaware of the samples' group categorization (Figure 1).

Inclusion/Exclusion Criteria

Inclusion Criteria

- Presence of risk for gestational diabetes according to previously published articles (23-25), including body mass index (BMI) ≥ 25 kg/m², age over 35 years, history of glucose intolerance, history of gestational diabetes, history of macrosomia, and also using the Gestational Diabetes Risk Assessment Scale (GEDRISK) guideline (26)
- Informed consent to participate in the study
- Residency in Ilam city
- No pre-existing or developing chronic diseases during the intervention (such as cardiovascular diseases, pulmonary diseases, seizures, type 1 and 2 diabetes).

Exclusion Criteria

- Withdrawal from continued participation,
- Absence from more than one session of the taught interventions,
- Migration,
- Inaccessibility of the patient and 5-Incomplete questionnaires.

Data Collection Tools

In this study, data were collected using a demographic information form, the Standard Physical Activity Questionnaire (METs), a researcher-made Health Belief Model questionnaire (HBQ).

Standard Physical Activity Questionnaire (Metabolic Equilibrium of Task)

To assess the duration of PA, a Physical Activity Questionnaire based on metabolic equivalent of tasks (METs) was employed. This questionnaire included the total duration of household and occupational activities categorized as Work Activity, the total duration of walking and exercises categorized as Leisure Time Activity, and the time spent commuting, recorded separately. The intensity of each activity is specified in metabolic equivalent of

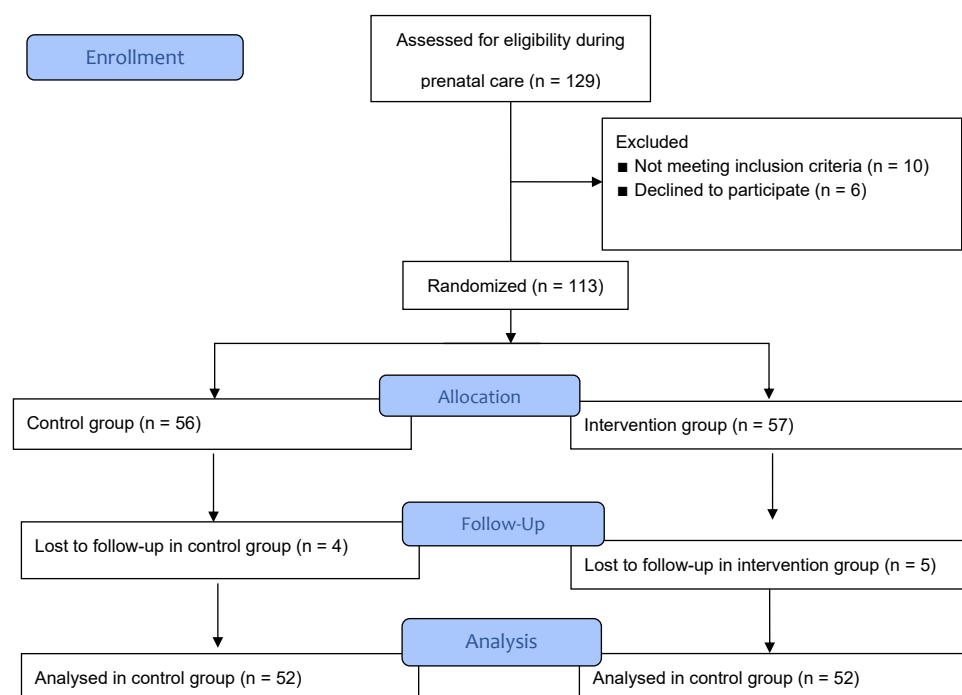


Figure 1. CONSORT Flow Diagram of Study Selection.

task (MET) units. Physical activities are classified as: light intensity with 1.5-3 METs, moderate intensity with 3-6 METs, and vigorous intensity with more than 6 METs. The total duration of activities with an intensity less than 1.5METs was considered as the duration of sedentary time. Sleep duration is not included in the activity assessment (27-30).

Health Belief Questionnaire

The researcher-made HBQ consisted of 6 items measuring Perceived Susceptibility, 6 items measuring Perceived Severity, 4 items measuring Perceived Benefits, 4 items measuring Perceived Barriers, and 4 items measuring Perceived Self-Efficacy. The construct questionnaire of the HBM comprised 24 items (4 items per construct), which were developed using a review of existing literature and expert consultation, rated on a 5-point Likert scale (1 to 5).

Validity and Reliability HBQ Questionnaire

The HBM constructs questionnaire, sourced from reliable literature, underwent validation by 10 experts (including specialists in health promotion, reproductive health, and nursing). Following expert input, the questionnaire was amended. Reliability was then tested on 20 pregnant women at risk for gestational diabetes, with Cronbach's alpha calculated for each dimension: perceived susceptibility ($\alpha=0.77$) perceived severity ($\alpha=0.75$) perceived benefit ($\alpha=0.79$) and perceived barriers ($\alpha=0.78$).

Methodology

Following the approval of the research proposal and

receipt of ethical clearance from the Ethics Committees of Ilam University of Medical Sciences, the researcher, with an introduction letter from the Ethics Committees, was introduced to the Health Deputy of Ilam City. Written permission was then obtained from the officials of the Health Deputy for the health centers in Ilam City. After the necessary coordination with the officials of the health centers, pregnant women at risk of developing diabetes were contacted by telephone. They were invited to provide informed consent, complete the pre-test questionnaires, and participate in the study. Individuals who met the inclusion criteria were then enrolled in the study.

Interventions

The educational interventions, aligned with the HBM, were delivered to pregnant women in classes of 8–12 participants over six 60-minute sessions, spaced one week apart, focusing on PA.

The training content, based on the HBM and utilizing existing scientific literature (30-34) while considering the specific requirements for HBM-based education, was initially drafted. This draft was then presented to an expert panel consisting of three reproductive health specialists, one master's level midwife, and one health promotion specialist, and was approved after necessary revisions (Table 1).

Following the completion of the demographic information, the PA Questionnaire, and the Health Belief Questionnaire, the study participants were introduced by the interviewing midwife to the educating midwife. The interviewing midwife then randomly allocated the participants to either the intervention or the control

group. Subsequently, the educating midwife provided the intervention group with physical activity education based on the HBM, while the control group received routine education.

The sessions were conducted in-person, face-to-face, utilizing lectures, question-and-answer sessions, group discussions, and the provision of educational pamphlets and brochures.

The intervention group was provided with an illustrated educational pamphlet detailing appropriate exercises during pregnancy and recommendations for physical activity. Routine training was provided to both groups. The health center personnel administered the standard training for the control group as part of their routine duties. This training was structured as individual pre-pregnancy care education, and its method and content were entirely different from and had no overlap with the education provided based on the HBM.

Furthermore, the competency of the trainers within the framework of the HBM model was validated by the team supervisor, who holds the academic rank of Assistant Professor of Reproductive Health.

The Physical Activity Questionnaire and the assessment for the HBM constructs were administered by the interviewing midwife six weeks later—when the pregnant mothers returned for their next appointment in the second trimester—and were completed by the participants. The pamphlets and brochures given to the test group during the research were provided to the health centers at the end of the study so they could be distributed to the control group samples if they wished.

Data Analysis

All patients cooperated with the researcher until the end of the study, and none of them dropped out during the study. Therefore, data analysis was conducted with a sample size of 104 patients. Research data were analyzed using SPSS software version 21.

Results

In this research, demographic characteristics included: the woman's education level, the husband's education level, the woman's occupation, the husband's occupation, housing

status, and economic status. Also, the mean (SD) BMI for the intervention and control groups was 27.32 ± 4.53 and 26.52 ± 5.04 , respectively (Table 2). According to Table 2, 31 (59.6%) of the women and 33 (63.5%) of their husbands in the intervention group, and 30 (57.7%) of the women and 29 (55.8%) of their husbands in the control group had a diploma or lower education. Furthermore, 44 (84.6%) of the women in both the intervention and control groups were homemakers (Table 2).

When examining the effects of routine training within the control group, paired t-tests found no significant pre- to post-test changes in any HBM (Table 3).

The results showed that there was no significant difference in the PA control group before (39.74 ± 18.10) and after (38.05 ± 17.85) the intervention ($P = 0.34$), which was not expected to change since the group had merely received routine training related to PA (Table 3).

Discussion

The main objective of this research was to determine the effect of education based on the HBM on engaging in appropriate physical activities in pregnant women at risk for GDM who attended health centers in Ilam city. In line with this objective, the constructs of the HBM and the duration of daily and weekly PA were compared in two stages in both intervention and control groups.

Various studies have been conducted on the impact of the HBM. For instance, in the survey by Ritchie et al, articles published between 1974 and 2020 were reviewed. According to the results, 673 articles regarding the impact of HBM were extracted, of which 43 ultimately met the final inclusion criteria for the study. The findings indicated that while the implementation of the HBM did not affect patient health promotion in some studies, it resulted in the improvement of the examined variables in the majority of them (35). Furthermore, in the study by Jones et al, which systematically reviewed the effect of the HBM on improving adherence, it was shown that the implementation of the HBM led to enhanced patient adherence to treatment in 14 out of the 18 articles reviewed (36). The results of this study are consistent with the findings of the conducted review studies.

Table 1. Content of Educational Interventions

Session	Description of Educational Intervention Sessions
1	Study objectives, the HBM and its constructs, and a Q&A session focused on participants' awareness of the importance and level of physical activity.
2	Providing explanations regarding the physiological changes during pregnancy, familiarization with the stages of natural childbirth, the importance of physical activity in facilitating labor, and a Q&A session with participants
3	Providing explanations regarding physical activity, its importance, its impact on body physiology, and permissible physical activities throughout pregnancy, followed by a Q&A session with participants
4	The session focused on musculoskeletal adaptations associated with pregnancy, as well as the influence of physical activity, and concluded with a participant Q&A segment.
5	Instruction on how to perform permitted physical activities during pregnancy, followed by a Q&A session with participants.
6	Training on the safe execution and implementation of stretching and strengthening exercises during pregnancy, followed by a Q&A session with participants

The results showed that educating pregnant women susceptible to gestational diabetes was associated with an increase in Perceived Susceptibility, Perceived Severity, and Self-Efficacy. Furthermore, this educational approach was practical in perceiving the benefits of an active lifestyle and led to a reduction in Perceived Barriers to physical activity. The findings of the current study are consistent with the study by Taheri et al, which was conducted on healthy, nulliparous pregnant women (37). That study also showed that educating first-time pregnant women was associated with an increase in Perceived Susceptibility, Perceived Severity, and Self-Efficacy, and a decrease in Perceived Barriers to physical activity. An increase in the constructs of Perceived Severity, Perceived Benefits, Self-Efficacy, and a decrease in Perceived Barriers were also reported in the study by Shafieian and Kazemi among healthy pregnant women with first and multiple pregnancies. Still, an increase in Perceived Susceptibility was not observed (38). This difference might be attributed

to the differing items related to Perceived Susceptibility and the variation in the target groups studied (focus on at-risk women).

Women moving past a stage of pregnancy where anxiety about pregnancy loss and general lethargy and malaise associated with pregnancy have relatively improved (39,40) could explain this change in PA. Studies by Shafieian and Kazemi and Taheri et al also observed an increase in PA (37,38). An increase in physical activity to an optimal level among first-time pregnant women was also observed in the study by Shakeri et al (41). However, that study did not utilize education based on HBMs.

In the study by Karimipour et al, a lifestyle intervention to prevent gestational diabetes resulted in a significant increase in PA among pregnant women (42). Yang et al conducted an educational intervention for high-risk pregnant women for gestational diabetes using the Self-Efficacy Theory (43). They reported the effect of education on physical activity in the intervention group

Table 2. Individual and Demographic Variables in the Control and Intervention Groups

Variable	Group	Intervention group	Control group	P value (between-group comparisons)
Education, No. (%)	Diploma or less	31 (59.6%)	30 (57.7%)	0.999
	University	21 (40.4%)	22 (42.3%)	
Spouse's education, No. (%)	Diploma or less	33 (63.5%)	29 (55.8%)	0.549
	University	19 (36.5%)	23 (44.2%)	
Occupation, No. (%)	Housewife	44 (84.6%)	44 (84.6%)	0.999
	Other	8 (15.4%)	8 (15.4%)	
Spouse's occupation, No. (%)	Employee	8 (15.4%)	10 (19.2%)	0.746
	Freelance/Other	44 (84.6%)	42 (80.8%)	
Housing status, No. (%)	Rental	44 (84.6%)	21 (40.4%)	0.011*
	Personal/Owned	18 (34.6%)	31 (59.6%)	
Economic status, No. (%)	Poor	13 (25.0%)	7 (13.5%)	0.052
	Medium	31 (59.6%)	27 (51.9%)	
	Good	8 (15.4%)	18 (34.6%)	
Age (y), mean \pm SD		31.37 \pm 7.51	29.88 \pm 6.63	0.289
Spouse's age (y), mean \pm SD		36.40 \pm 7.66	36.51 \pm 6.93	0.862
BMI, mean \pm SD		27.32 \pm 4.53	26.52 \pm 5.04	0.394

* Significant; BMI: Body Mass Index; SD: standard deviation

Table 3. Mean (SD) of Primary Outcome Scores Before and After the Intervention

Variable	Group	Before	After	Score change	P value (Within-group)
Perceived Susceptibility	Intervention	24.85 \pm 4.06	28.63 \pm 1.78	3.79 \pm 2.96	<0.001*
	Control	24.12 \pm 3.23	24.21 \pm 3.18	0.01 \pm 1.76	0.84
Perceived Severity	Intervention	26.50 \pm 11.35	28.48 \pm 1.81	1.98 \pm 10.79	0.015
	Control	23.87 \pm 3.02	23.65 \pm 3.23	0.21 \pm 1.66	0.76
Perceived Benefits	Intervention	17.10 \pm 6.18	18.96 \pm 1.56	1.87 \pm 5.94	0.022
	Control	15.77 \pm 2.53	15.67 \pm 2.51	0.01 \pm 1.29	0.66
Perceived Barriers	Intervention	10.71 \pm 3.26	7.27 \pm 3.11	3.44 \pm 2.32	<0.001*
	Control	9.67 \pm 2.89	9.81 \pm 2.96	0.13 \pm 1.14	0.77
Perceived Self-Efficacy	Intervention	14.44 \pm 3.40	17.85 \pm 1.74	3.4 \pm 2.31	<0.001*
	Control	14.63 \pm 3.00	14.48 \pm 2.49	0.15 \pm 1.38	0.79
Physical Activity (min-daily)	Intervention	14.76 \pm 12.17	18.07 \pm 12.75	3.31 \pm 3.66	0.011
	Control	12.25 \pm 6.56	11.36 \pm 5.09	0.88 \pm 1.65	0.52
Physical Activity (min-weekly)	Intervention	48.13 \pm 26.08	74.26 \pm 23.57	26.07 \pm 13.99	<0.001*
	Control	39.74 \pm 18.10	38.05 \pm 17.85	1.24 \pm 3.95	0.34

* Significant; The values presented are expressed as mean \pm standard deviation (SD).

women. The results of these two studies, despite using theories other than the HBM, still emphasized the role of education in increasing physical activity, which is similar to the findings of the present study.

Limitations and Recommendations

Limitations of this study include the inability to generalize the findings to non-Iranian populations, the reliance on subjective measures (questionnaires) rather than objective metrics for assessing physical activity, and the presence of potential confounding factors such as the effects of time of day and different seasons on physical activity levels. It is recommended that future studies be conducted with larger sample sizes, longer follow-up periods, and by involving higher-level participants, such as spouses and other family members, in the intervention.

Conclusions

Sustaining and improving maternal health outcomes, particularly for pregnant individuals at elevated risk for gestational diabetes, mandates the adoption of structured educational models by policymakers and service providers, particularly practicing midwives. In this context, the implementation of the HBM is strongly recommended.

Authors' Contribution

Conceptualization: Safoura Taheri, Reihaneh Ghorbani, Mahnaz Shafieian.

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Investigation: Safoura Taheri, Reihaneh Ghorbani, Mahnaz Shafieian, Shiva Heydari.

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Software: Safoura Taheri, Reihaneh Ghorbani, Mahnaz Shafieian.

Supervision: Safoura Taheri, Reihaneh Ghorbani, Mahnaz Shafieian.

Validation: Safoura Taheri, Reihaneh Ghorbani, Mahnaz Shafieian, Bahareh Mosleh.

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Writing—review & editing: Safoura Taheri, Reihaneh Ghorbani, Mahnaz Shafieian, Shiva Heydari, Bahareh Mosleh.

Conflict of Interests

Authors declare that they have no conflict of interests.

Data Availability Statement

The dataset presented in the study is available on request from the corresponding author during submission or after its publication. The data are not publicly available due to privacy.

Ethical Issues

Ethical approval for conducting the study was obtained from the Ethics Committee of Ilam University of Medical Sciences (IR.MEDILAM.REC.1401.183). All research participants were provided with clear and understandable explanations regarding the purpose and methodology of the study. Subsequently, upon their willingness and consent to participate, participants completed the informed consent form. They were assured that all information collected from them would remain

confidential. All questionnaires were anonymous, and the data extracted from them would be published in aggregate form without names. The study was registered in the Iranian Registry of Clinical Trials (IRCT) under the clinical trial code [IRCT20250525065881N1](https://www.irct.ir/clinical-trials/IRCT20250525065881N1).

Acknowledgments

We thank all of the participants in this study.

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