Original Article

Effect of caring intervention on preeclampsia in pregnant women with metabolic syndrome: A randomized controlled trial

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Abstract

Context: There are many studies on the health effects of dietary advice and physical activity in pregnancy, with only a few describing the effects of the simultaneous use of a combined intervention on preeclampsia in pregnant women with metabolic syndrome (MetS).

Aims: This study was designed to examine the effects of motivational interviews, dietary advice, and physical activity on the incidence and symptoms of preeclampsia in pregnant women with MetS.

Setting and Design: This randomized, single-blind, controlled clinical trial was performed in two hospitals in Babol, Iran, in 2018.

Materials and Methods: The participants included 120 pregnant women with a gestational age of 15–20 weeks with the diagnosis of MetS. The patients were block randomization allocated to two groups of 60 mothers. From the 20th week of pregnancy edema, blood pressure, proteinuria, and preeclampsia were evaluated and compared between the two groups. The intervention group had one motivational interview, two consultation sessions, and three training sessions for physical activity. The tools used for data collection included demographic fertility characteristics, anthropometric measurements, and a biochemical pregnancy outcomes checklist.

Statistical Analyses Used: The data were analyzed using descriptive statistics, independent *t*-test, ANOVA and logistic regression.

Results: The intervention group showed a significant decrease in edema (20.4% and 47.3%), proteinuria (5.6% and 30.9%), BP ≥140/90 mmHg (3.7% and 14.5%), and preeclampsia (1.9% and 12%) compared to the control group.

Conclusion: Dietary recommendations and physical activity by pregnant women with MetS in prenatal care can be safe and practical interventions to avoid preeclampsia.

Keywords: Dietary advice, Metabolic syndrome, Physical activity, Preeclampsia, Pregnant women

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Received: 04 April 2021; **Accepted:** 02 August 2021; **Published:** 16 February 2022.

Access this article online	
Quick Response Code:	**Website:** www.jnmsjournal.org
	DOI: 10.4103/jnms.jnms_49_21

How to cite this article: Mohsenzadeh-Ledari F, Taghizadeh Z, Motaghi Z, Keramat A, Moosazadeh M, Yazdani S, *et al*. Effect of caring intervention on preeclampsia in pregnant women with metabolic syndrome: A randomized controlled trial. J Nurs Midwifery Sci 2022;9:8-15.

INTRODUCTION

Metabolic syndrome (MetS) is a cluster of risk factors that encompasses metabolic, vascular, and inflammatory indicators.[1] MetS with its various features involving all body organs in the pathological process is a major public health problem. The main concern regarding MetS is that each of its individual components is associated with the increased risk of cardiovascular disease (CVD), and the presence of MetS greatly augments CVD morbidity and mortality.[2] Meanwhile, the existing data suggest that the incidence of MetS is rising at an alarming rate worldwide.[3,4] The prevalence of MetS has been reported to be higher in Iran compared to other Asian and European countries.[2-4] According to the definition of the International Diabetes Federation (IDF), 36.9% of the population have MetS in Iran, and its prevalence in women is higher than in men.[5-7] A study showed the prevalence of MetS to be 12.4% in pregnant women and 29% in puerperal women.[8] The metabolic disturbances underpinning MetS are consistent and include atherogenic dyslipidemia, raised blood pressure (BP), insulin resistance, obesity, and pro-thrombotic and pro-inflammatory states. Pregnancy is linked to some components of MetS. Normal pregnancy is pro-inflammatory, pro-thrombotic, highly insulin resistant,[9] and hyperlipidemia state.[10] Pregnant women with metabolic risk factors such as increased adiposity and dyslipidemia are at high risk for adverse pregnancy outcomes.[11] High levels of triglycerides (TGs) and cholesterol are independent risk factors for preeclampsia[12] and gestational diabetes.[13,14]

Given the established links between MetS and chronic diseases in adulthood[15,16] and between preeclampsia and CVD in later stages of life,[17] pregnancy may offer a window of opportunity to identify women with MetS, elevated risk of adverse pregnancy outcomes, and later life chronic diseases.

Most studies to date, however, have only assessed individual metabolic components in pregnancy including raised TGs and low-density lipoprotein cholesterol, and reduced high-density lipoprotein cholesterol (HDL-C) has been found to be associated with the increased risk of hypertensive disorders of pregnancy and preeclampsia.[13,18] Poor dietary habits, sedentary lifestyle, and underlying genetic predisposition all contribute to this phenomenon. Dietary advice and physical activity have demonstrated a beneficial effect in reducing metabolic risk factors, such as adiposity, hypertension, dyslipidemia, and pregnancy complications.[14] Diet and physical activity have shown a beneficial effect on gestational weight gain, with varied effects on pregnancy outcomes such as preeclampsia.[8] Various studies have reported the association of MetS with adverse maternal, fetal, and neonatal outcomes.[19] In pregnant individuals with metabolic risk factors, dietary advice intervention and physical activity were found to reduce adverse pregnancy outcomes.[20] There are few studies on MetS in pregnancy,[21,22] and there is a lack of studies addressing MetS and the effects of caring interventions on pregnancy complications including preeclampsia in pregnant women. Thus, there is a need for an adequately powered pragmatic randomized trial to evaluate the beneficial effects of diet and physical activity in pregnancy while targeting women at the highest risk of complications. The current study aimed at assessing the effects of motivational interview, dietary advice, and physical activity on preeclampsia in pregnant women with MetS.

MATERIALS AND METHODS

The current study was a single-blind, randomized controlled trial with a parallel-group design, which was approved by Shahroud University of Medical Sciences. The study has been registered in the Iranian Clinical Trials Registry (code of IRCT2017042333070 N1). The study samples included pregnant women with MetS referred to the Rouhani and Shahid Yahya Nejad Hospitals of Babol city in the North of Iran during 2018.

The inclusion criteria were Iranian nationality, gestational age 15–20 weeks, age of 15–45 years, singleton pregnancy, waist circumference ≥80 cm, BP 130/85 mmHg, fasting blood sugar ≥100 mg/dL, serum HDL-C ≤50 mg/dL, TG ≥150 mg/dL, diagnosis of MetS based on IDF criteria,[23] and no pregnancy complications (e.g., rheumatoid arthritis and depression). The exclusion criteria included contraindication for exercise, abortion, and fetal death during the study, missing more than two sessions by the pregnant women, unwillingness to continue the study, congenital malformation, vaginal bleeding, cervical insufficiency, and participating in similar counseling programs in other centers.

The required sample size was estimated based on a study by Bo *et al*.,[24] considering 95% confidence interval and 90% study power. MetS with $P1 = 0.3490$ and $P2 = 0.6570$ and $n2/n1 = 1.00$ and using the comparison formula between the two ratios in G Power software, the sample size was calculated to be 106 women (53 women in the intervention group and 53 in the control group). Considering 15% attrition, the sample size was increased to 120 pregnant women (60 in the intervention group and 60 in the control group).

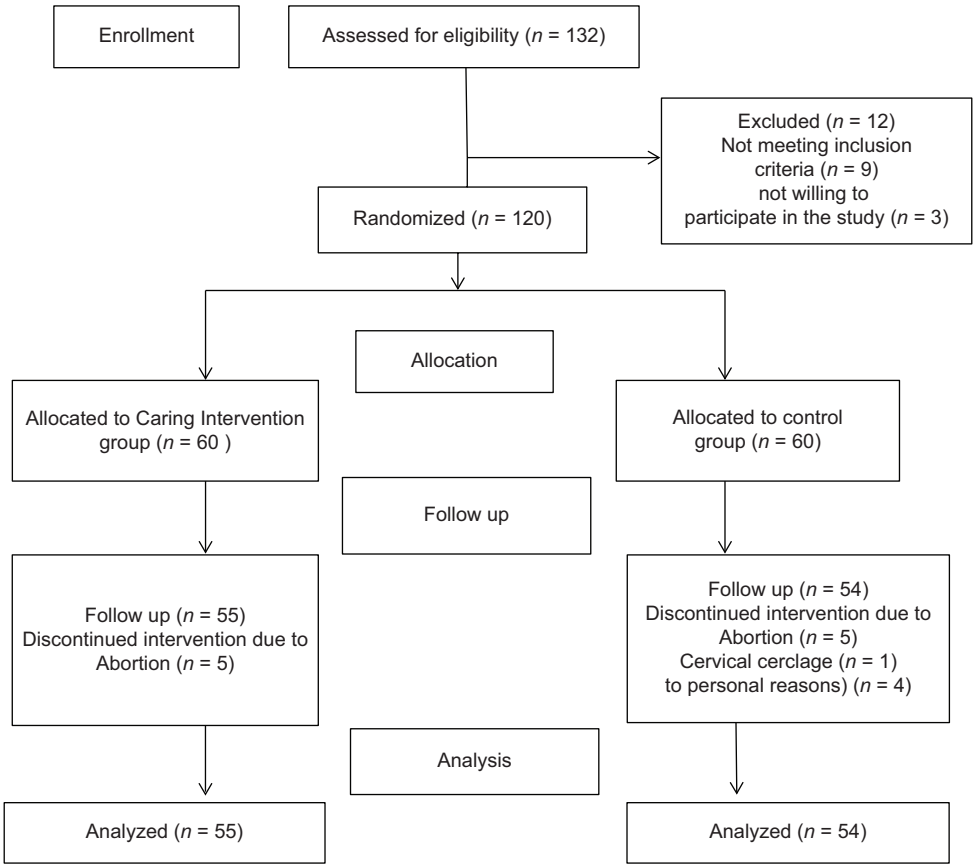

Figure 1: Screening, enrollment, random assignment, and follow-up of the study participants

The participants were then randomly allocated to the intervention and control groups (60 per group) through block randomization (20 block size of 6). For blinding, central randomization was applied, for which a randomized sequence of numbers was prepared by a person outside the research team based on codes assigned to the participants at the registration step.

The tools used for data collection included demographic and fertility characteristics checklist (consisting of items on age, gestational age, body mass index [BMI], occupation, economic status, level of education, weight [kg], eating habits [vegetarian], physical exercise prior to pregnancy, gravidity, parity, abortion, preterm labor, postterm labor, particular disease, gestational diabetes, history of preeclampsia, and history of gestational hypertension), anthropometric measurements and biochemical indices checklist (waist [cm], systolic BP [mmHg] and diastolic BP [mmHg], fasting glucose [mg/dL], HDL, cholesterol [mg/dL], and TGs [mg/dL]), and pregnancy outcomes (edema, proteinuria, BP above 140/190, preeclampsia, and gestational weight gain).

Before the initiation of the study, pregnant women referred to our prenatal clinic meeting the inclusion criteria were selected. The checklists (demographic, anthropometric, and biochemical measures) were then completed by each group.

In the intervention group, at first, all the participants enrolled in a 2-h individualized motivational interview session. The women were asked to identify behaviors that needed to change and to set small stepwise goals to develop a healthy behavior. Personal barriers to behavioral change were explored and as much as possible positive verbal reinforcement was provided to boost each pregnant woman's self-confidence and self-efficacy. Although the main focus was on nutritional advice and physical activity, concerns and personal questions regarding pregnancy were also addressed by a midwife trained in motivational interviews. Two individual counseling sessions with a nutrition expert in the 15–20 weeks of pregnancy and 20–24 weeks of pregnancy and three individual training sessions for physical activity by a midwife in the 15th, 20th, and 32th weeks of gestation were held.

The sessions were held in the conference room in a hospital in Babol city. The six sessions of the intervention program were designed based on guidelines of the Ministry of Health for Pregnant Women emphasizing the use of the five main nutrient groups including fruits, vegetables,

grains, meat, dairy, and water based on the Pregnant Mothers' food pyramid, which comprises 15–20 kcal/kg daily for body mass above 30, 25 kcal/kg daily for body mass 25–30, and 30 kcal/kg daily for body mass between 20 and 25.[23] The diets contain 20% protein, 30% fat, and 50% carbohydrate, and physical activity three times a week such as pelvic floor muscle training, bodybuilding, muscle strengthening, stretching, and 30 min a day walking. A pamphlet, an educational booklet, and educational CDs prepared by the Ministry of Health and Medical Education, Maternal Health Department for Pregnant and Postpartum Women's Health, were provided.[24] To follow-up on the caring intervention, the researcher contacted the intervention group through a phone call every 10–14 days.

Women in the control group, on the other hand, received no education or counseling during the study, and instead, they were given routine prenatal care. Post intervention, follow-up was performed from week 20 of pregnancy, and signs of edema, hypertension, proteinuria, and preeclampsia were assessed by a midwife at references for prenatal care in both groups until the end of pregnancy.

Statistical analyses

Primary and secondary outcomes of the study were preeclampsia and gestational weight gain, respectively. Data analysis was performed in SPSS, version 16 (SPSS Inc., Chicago, IL). Descriptive statistics including mean, standard deviation, and frequency were used for presenting the data. Inferential statistical tests including logistic regression and odds ratio for the impact of the intervention were applied.

To compare quantitative variables (i.e., gestational weight gain, age, weight, BMI, waist circumference, fasting glucose, HDL, cholesterol, TGs, and gestational age) between the two groups, independent samples Student's *t*-test was used. For comparing qualitative variables (i.e., level of education, income, and occupation) between the two groups, Chi-square test was run. Variables of weight, level of education, and BMI that differ in basic characteristics were adjusted due to the potential confounding effect. $P < 0.05$ was considered significant.

Ethical considerations

After obtaining the required permissions from authorized organizations, the study received code of ethics (IR.SHMU.REC.2016.123) from the Ethics Committee of the Deputy of Research and Technology of Shahroud University of Medical Sciences and the code of ethics IR.BAMU.REC.2017.102 from the Ethics Committee of the Deputy of Research and Technology of Babol University of Medical Sciences. Furthermore, after explaining the aims and methods of the study, written informed consents were obtained from the participants. The participants were ensured that their responses will be merely used toward the aims of the study and their information will remain confidential. They were also informed that they can leave the study at any time, and their decisions will not affect the health services presented to them.

RESULTS

Based on the convenience sampling method, 132 pregnant women with MetS were initially enrolled, from whom 12 pregnant women were excluded for not meeting the inclusion criteria and unwillingness to participate in the study.

Eleven pregnant women from each of the intervention and control groups were excluded due to abortion and cervical insufficiency, and the final analysis was performed among 109 pregnant women in two groups [Figure 1].

The demographic information and baseline characteristics of the pregnant women in both intervention and control groups, except for weight, level of education, and BMI, were not significantly different between the two groups [Table 1].

Furthermore, the two groups were not significantly different in terms of preterm delivery, postpartum delivery, specific disease, gestational diabetes, history of preeclampsia, and history of gestational hypertension. Postintervention analyses showed that edema ($P \leq 0.003$), proteinuria ($P \leq 0.002$), BP ≥140/190 ($P \leq 0.06$), and preeclampsia were significantly lower in the intervention group than the control group at the end of pregnancy. After adjusting the two groups for the variables of BMI, weight, waist circumference, and level of education, the frequencies of edema ($P \leq 0.01$), proteinuria ($P \leq 0.002$), hypertension ≥140/190 mmHg ($P \leq 0.01$), and preeclampsia ($P \leq 0.02$) were less in the intervention group than the control group [Table 2].

Finally, postintervention analyses showed that gestational weight gain was significantly lower in the intervention group compared to the control group at the end of pregnancy (caring group 9.07 ± 4.85, control group 11.83 ± 5.50, $P \leq 0.007$).

DISCUSSION

The present study demonstrated that adding dietary advice, physical activity, and motivational interview to prenatal care reduced edema, proteinuria, BP ≥140/190 mmHg,

Table 1: Baseline demographic characteristics, blood pressure, and laboratory tests of pregnant women with metabolic syndrome in the caring and control groups

Variables	Mean±SD		*P*
	Caring group (*n*=55), *n* (%)	Control group (*n*=54), *n* (%)	
Age (years)	31.00±6.01	31.36±5.22	0.72
Gestational age week	15.1±2.5	15.3±2.3	0.74
BMI (kg/m^2)	31.30±6.33	28.49±4.38	0.006
Weight (5)	80.36±16.28	73.35±12.80	0.01
Waist (cm)	99.76±12.15	96.23±10.42	0.09
Fasting glucose (mg/dL)	98.88±32.08	90.80±11.93	0.07
HDL-C (mg/dL)	39.68±5.32	40.58±5.91	0.38
TG (mg/dL)	176.16±49.18	177.71±31.16	0.83
Occupation			
Housewife	49 (89.01)	46 (85.0)	0.59
Employed	6 (10.90)	8 (15.0)	
Economic situation			
Low	11 (20.0)	18 (33.0)	0.17
Middle	39 (70.90)	31 (57.4)	
High	5 (9.09)	5 (9.6)	
Education level			
University	9 (15.0)	24 (40.0)	0.009
Secondary school	24 (40.0)	18 (30.0)	
Primary school	27 (45.0)	18 (30.0)	
Gravid			
1	14 (25.45)	9 (16.7)	0.19
2	19 (34.54)	31 (57.4)	
≥3	22 (40.00)	20 (37.03)	
Parity			
0	18 (32.72)	13 (24.07)	−0.16
1	25 (45.45)	34 (62.96)	
≥2	12 (21.8)	8 (14.81)	
Abortion			
0	41 (74.54)	38 (70.37)	0.67
1	10 (18.18)	12 (22.22)	
≥2	4 (7.27)	4 (7.40)	
Systolic pressure ≥130 mmHg	1 (1.7)	2 (3.3)	0.55
Diastolic pressure ≥85 mmHg	0	1 (1.7)	0.31
Eating habits vegetarian			
Yes	1 (1.81)	0	0.31
No	54 (98.1)	54 (100)	
Physical exercise prior to pregnancy			
Yes	21 (38.18)	17 (31.48)	0.33
No	34 (61.81)	37 (68.52)	

BMI: Body mass index, SD: Standard deviation, HDL-C: High-density lipoprotein cholesterol, TG: Triglycerides

Table 2: Comparison of the incidence of preeclampsia and related signs between the caring and control groups

Variables	Group					
	Intervention (*n*=54), *n* (%)	Control (*n*=55), *n* (%)	Nonadjusted		Adjusted	
			OR (95% CI)	*P*	OR (95% CI)	*P*
Edema	11 (20.4)	26 (47.3)	3.50 (1.50–8.18)	0.003	3.54 (1.33–9.40)	0.01
Proteinuria	3 (5.6)	17 (30.9)	7.60 (20.7–17.82)	0.002	10.62 (2044–46.19)	0.002
Blood pressure above 140/190	2 (3.7)	8 (14.5)	4.43 (0.89–21.89)	0.06	15.83 (1.74–143.36)	0.01
Preeclampsia	1 (1.9)	7 (12.7)	7.72 (0.91–65.12)	0.06	7.84 (1.36–234.03)	0.02

OR: Odds ratio, CI: Confidence interval

preeclampsia, and reduction gestational weight gain in pregnant women with MetS. No complications were observed during physical exercise sessions that demanded interruption of the exercise.

Few studies have focused on the effects of dietary advice and physical activity on pregnant women with MetS, and the published results are mostly related to MetS indices such as obesity and diabetes in pregnant women.[25-27] There are many studies on the health effects of diet or physical activity planning on pregnancy outcomes.[28-35] To the best of our knowledge, this is the first attempt to study the effects of dietary advice, motivational interview, and physical activity planning on preeclampsia in pregnant women with MetS, and the extant literature on the effects of motivational interview, physical activity,

or diet on pregnancy outcomes of pregnant women with MetS have yielded discrepant results.[5,21,31,32]

Our study showed that receiving three types of interventions for 20 weeks during pregnancy resulted in a significant reduction in the incidence rate of preeclampsia compared to the control group. The results of this intervention are consistent with the results of several comprehensive reviews on the impacts of diet and physical activity planning on preeclampsia and related sign.[35-37] One former study found no significant differences in gestational hypertension and preeclampsia between the two groups of standard antenatal care (control) and serial self-weighing and simple dietary advice (intervention).[31] This discrepancy in results may be due to the type of physical activity and diet. A study reported that a physical activity designed with 35–40 min of aerobic exercise performed at least twice a week for a minimum of 12 weeks in pregnant women could effectively decrease BP,[32] while in another study, physical exercise with a stationary bicycle once a week between 12 and 20 weeks of gestation did not show any significant effects on maternal complications in pregnant women with chronic hypertension.[38] In addition, a study showed that three 40–45-min sessions per week, beginning at the start of pregnancy (weeks 6–9) until the end of the third trimester (weeks 38–39), had no significant effects on pregnant women's BP (diastolic or systolic).[39] This difference with the results of our study may be due to the fact that samples were healthy pregnant women in that study. Further, there were no observed effects on other pregnancy outcomes in the intervention group.[37] Exercise in overweight and obese pregnant women caused the least weight gain during pregnancy.

Furthermore, our study showed that receiving three types of interventions during pregnancy resulted in a significant reduction in gestational weight gain compared to the control group. One other study showed that women receiving nutritional advice from a trained dietitian showed significant differences in total maternal weight gain during pregnancy.[34] A previous study found that there were significant reductions in gestational weight gain in a lifestyle intervention group (recommendations for a healthy and balanced diet were based on the official National Dietary Recommendations and consisted of 50%–55% carbohydrate intake, 30%–35% fat intake, and 9%–11% protein–energy intake) compared to a normal care group.[36]

The strengths of this study include using multiple studies and guidelines to extract the data needed to design the care intervention, using a panel of different experts to modify and design the care intervention program, and performing a clinical trial study to determine the effectiveness of the care intervention program.

The most important limitation of this study was the lack of direct supervision over the implementation of physical training exercises, as they were performed at home by the mothers. This obstacle was tried to overcome by making telephone calls to encourage the mothers to follow the recommendations accurately and regularly.

CONCLUSION

The results of this study suggest that exercise, diet, and motivational interview can be used as an alternative therapeutic intervention for women with MetS, and it may be particularly relevant for those women who have a BP of >130/85 mmHg. The incorporation of a dietary advice and physical activity program into the management of pregnant woman with BP ≥130/85 mmHg may lower the prevalence of preeclampsia and maternal and neonatal morbidities associated with preeclampsia in these women. Furthermore, the results of this study can be used as a practical way to reduce the need for medical treatment of preeclampsia in pregnant women with MetS and prevent preeclampsia through the simultaneous improvement of pregnancy outcomes and health of pregnant women.

Conflicts of interest

There are no conflicts of interest.

Authors' contributions

F. Mohsenzadeh Ledari contributed with study conception, data collection, and drafting the manuscript. Z. Taghizadeh, Z. Motaghi supervised the study design and helped with conducting this study. A. Keramat, M. Moosazadeh, S. Yazdani, A. Najafi, M. Ghorbani were the study advisors. All the authors critically evaluated the paper and provided the final draft.

Financial support and sponsorship

Nil.

Acknowledgments

We thank the deputy of research and technology of Shahroud University of Medical Sciences. We also express our gratitude to the management team and staff of Rouhani and Shahid Yahya Nejad Hospital of Babol, as well as all the pregnant women who assisted us on this project.

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