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Effects of dietary fiber on maternal health in pregnant women with metabolic syndrome risk: a randomized controlled trial†

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Metabolic Syndrome (MetS) during pregnancy can lead to complications such as gestational diabetes mellitus (GDM) and hypertensive disorders. In this study, we sought to examine the influence of dietary fiber, from both food sources and soluble fiber supplementation, on the metabolic health and overall pregnancy outcomes of women at high risk of MetS. We conducted a randomized controlled trial involving 376 women between 11 and 13 weeks of gestation. To evaluate dietary fiber intake, we performed an exhaustive dietary component analysis using a food frequency questionnaire. Additionally, the participants in the intervention group received daily soluble fiber supplements until delivery. All participants underwent nutritional consultations and metabolic health assessments at three distinct stages of pregnancy (GW 11–13, GW 24–26, and GW 32–34). Our findings revealed a significant correlation between insufficient dietary fiber intake and an increased risk of GDM, even after adjusting for variables such as maternal age and pre-pregnancy BMI. We also noted that a high total dietary fiber intake was associated with reduced changes in triglyceride levels. In addition, the intervention group showed lower need for constipation medication, and soluble fiber supplementation may offer potential benefits for GDM patients. Importantly, our study verified the safety of long-term soluble fiber supplementation during pregnancy. Our results underscore the importance of adequate fiber intake, particularly from dietary sources, for the metabolic health of pregnant women. Moreover, our findings suggest that early fiber supplementation may benefit pregnant women experiencing constipation or those diagnosed with GDM.

Introduction

As economic growth and improved living standards lead to changes in dietary habits, metabolic syndrome (MetS) emerges as a significant global public health challenge.[1] MetS is commonly defined as a complex set of conditions that increase the risk of cardiovascular disease and diabetes.[2,3] Different parameters are used to define MetS by many international organizations, including the World Health Organization (WHO), the National Cholesterol Education Program Adult Treatment Panel III (NCEP:ATPIII), and the International Diabetes Federation (IDF). It is often characterized by obesity, diabetes, impaired glucose tolerance (IGT), insulin resistance (IR), dyslipidemia, and hypertension.

Pregnancy, with its physiological changes like relative IR, adipose tissue accumulation, hyperlipidemia, and up-regulation of systemic inflammatory responses, predisposes women to metabolic diseases.[3] Gestational diabetes mellitus (GDM) and hypertensive disorders of pregnancy (HDP) share characteristics with MetS, such as IR and hyperlipidemia.[4,5] For instance, an association between MetS and preeclampsia (PE) and GDM was reported in a multiple-center, international, prospective Screening for Pregnancy Endpoints (SCOPE) cohort study, which included 5628 low-risk, nulliparous women.[4] Moreover, these conditions also increase the risk of developing MetS later in life.[6–8] Women with GDM are at an increased risk of developing type 2 diabetes mellitus (T2DM) and cardiovascular disease (CVD),[9] while those with HDP are more likely to develop hypertension and CVD[10] in later life. Thus, managing GDM and HDP during pregnancy could potentially reduce the risk of future MetS.

In non-pregnant MetS patients, a diet low in fat and sugar but high in dietary fiber is generally recommended.[11] However, a low-fat diet during pregnancy could adversely affect

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fetal growth and development, making it unsuitable for pregnant women at high risk of MetS.[12,13] Research supports the metabolic benefits of a low-sugar diet in GDM patients.[14] A *meta*-analysis revealed that fiber interventions in GDM patients significantly improved blood sugar and lipid levels,[15] but these interventions were implemented post-diagnosis, during the mid-to-late stages of pregnancy. Early intervention is known to be crucial for preventing adverse outcomes such as GDM, HDP, and macrosomia. According to a 2020 practice bulletin from the American College of Obstetricians and Gynecologists (ACOG),[16] women with any of the high-risk factors for pre-eclampsia are recommended to receive low-dose aspirin ideally before 16 weeks of gestation. Additionally, research suggests that implementing lifestyle changes before 12 weeks of gestation can help prevent GDM in high-risk pregnant women.[17] Considering the critical importance of early intervention, there is a clear need for further research into fiber interventions. We hypothesize that incorporating dietary fiber into a low-sugar diet early in pregnancy could improve blood lipid and glucose regulation in pregnant women at high risk of MetS, potentially preventing adverse outcomes such as GDM, HDP, and macrosomia.

Dietary fiber, defined as the edible plant components or carbohydrate polymers resistant to digestion and absorption in the human small intestine with complete or partial fermentation in the large intestine,[18] has been linked with lower lipid levels, obesity, T2DM, cancer, and CVD rates.[19] Originally added to diets to prevent constipation and maintain health,[20] dietary fiber could potentially improve constipation in pregnant women at high risk of MetS, a condition common during pregnancy. However, studies on fiber supplements during pregnancy are limited, and the safety of long-term use during pregnancy is yet to be explored.

In this study, our aim is to investigate whether dietary fiber and fiber supplementation during early pregnancy can enhance the metabolic health and overall pregnancy outcomes of women at high risk of MetS. To accomplish this goal, we conducted a randomized controlled trial involving 376 women at 11–13 weeks of gestation for fiber supplementation. Alongside the assessment of their dietary fiber intake, we also evaluated the effects of early fiber supplementation. Our specific outcomes of interest included maternal metabolic indicators (blood glucose and lipids), pregnancy outcomes (the incidence of GDM, HDP, and macrosomia), and the impact on constipation. In addition, to ensure the long-term safety of fiber supplementation, routine check-ups were conducted, involving blood biochemical tests and the documentation of any potential side effects, particularly gastrointestinal adverse reactions.

Materials and methods

Study design

This was a single-center, clinic-based, prospective, randomized controlled trial (RCT) with two parallel groups, targeting all pregnant women followed by the Obstetrics Department of the International Peace Maternity & Child Healthcare Hospital (IPMCHH), Shanghai Jiaotong University, Shanghai, China. It was conducted from March 10, 2020, to April 30, 2021. The first woman was enrolled in the study on March 10, 2020, and the last one was enrolled on Oct 20, 2020. The follow-up until delivery finished on April 30, 2021. The study was approved by the Ethics Committee of the International Peace Maternity & Child Healthcare Hospital (IPMCHH), Shanghai Jiaotong University on Dec 29, 2018 (No. GKLW2018-34) and conducted in accordance with the Helsinki Declaration. This trial was registered on the website of the Chinese Clinical Trial Registry on Jan 19, 2020, with the number ChiCTR2000028964. The authors confirmed that all ongoing and related trials for this intervention have been registered. All women signed informed consent forms.

Subject recruitment

Women between 11^{+0} and 13^{+6} gestational weeks (GWs) and at a high risk of MetS with a single fetus were eligible for the study. Women were recruited if they had at least one of the following risk factors:[21–25] age ≥35 years, a pre-pregnancy body mass index (BMI) ≥25 kg m^{-2}, a first-degree relative with diabetes mellitus (DM) or hypertension, a history of GDM or HDP, a history of polycystic ovary syndrome (PCOS), or a pregnancy resulting from *in vitro* fertilization-embryo transfer (IVF-ET). Those with age <18 years, a BMI <18.5 kg m^{-2}, pre-existing diabetes, chronic hypertension, chronic kidney disease (CKD), auto-immune disease, or multiple pregnancies were excluded from this study. The recruitment process took place at the antenatal clinic during the fetal Nuchal Skinfold Thickness scanning in the first trimester. A total of 376 women formally consented to participate in the study.

Randomized grouping

All participants were randomly divided into two groups: the intervention group and the control group. Both groups were advised to follow a diet with a relatively low glycemic index. However, the participants in the intervention group were further guided to incorporate daily soluble fiber supplementation into their diet. The random number table was generated by Professor Zhijie Zhang, a statistician of Fudan University, using the block randomization method in the Software and Systems (SaS) 9.4. The intervention group and the control group each consisted of 188 participants. Due to the nature of the RCT design, participants, obstetricians, and dieticians were aware of the allocation assignment.

Intervention

In this study, dietitians played a crucial role in analyzing dietary intake questionnaires, providing comprehensive nutritional counseling, which included recommendations for a diet with a relatively low glycemic index, and conducting follow-up sessions focused on dietary fiber intake. Obstetricians were responsible for carrying out routine prenatal check-ups, documenting clinical data for both the expectant mothers and their

fetuses, closely monitoring the implementation and progress of dietary fiber supplementation in the intervention group, and evaluating its influence on the specified test parameters.

The intervention group was given additional daily soluble fiber supplements (10g of inulin and 2g of xylooligosaccharide per pack), supplied by Nutrasumma Inc in China, provided from the point of recruitment during the first trimester (GW 11–13) and continued until delivery. Organic inulin was extracted from natural Jerusalem artichoke crops, and xylooligosaccharide was extracted from corn cobs through physical enzymatic hydrolysis, both of which were certified to be organic. This formula contains relatively low amounts of inulin, supplemented with oligoxylose. Inulin, being a moderately fermentable fiber, can potentially lead to bloating when consumed in high doses. To address this concern, the amount of inulin was reduced in the formula. Oligoxylose, another type of dietary fiber, promotes the improvement of intestinal flora and helps alleviate discomfort, including bloating.[26] Importantly, this formula is completely soluble with a mild sweetness, and is well-tolerated among pregnant women. It is recommended to take fiber supplements during lunch or dinner, alongside meals, to optimize their effectiveness. Importantly, it is advised not to take them in the morning before breakfast on an empty stomach. Researchers provided supplemental fiber at each antenatal visit and documented the consumption situation and adverse reactions. According to the Preconception and Prenatal Care guidelines in China, regular antenatal visits in our hospital were defined as the first visit before GW 13, every 4 weeks before GW 32, every 2 weeks before GW 36, every week before GW 40, and every 3 days before GW 41. If complications occur, extra visits were recommended.

Nutritional consultations

Three nutritional consultations were arranged for both groups during pregnancy (enrollment time in the first trimester: GW 11–13, GW 24–26, and GW 32–34), and a 24-hour dietary retrospective survey method was used to investigate the diet of the respondents in the first and third trimesters. Dietary data were entered into Zhending Women's Insurance version 2.0 software to calculate each person's daily intake of various nutrients. During the second trimester, a modified version of the food frequency questionnaire (FFQ) used in the 2010 Chinese residents' nutrition and health status survey[27] was employed to collect data on the frequency and quantity of food intake over the past three months. The frequency of food consumption was classified into times per day, per week, and per month. The FFQ, modified according to the specific dietary needs of pregnant women, was composed of 12 modules with a total of 118 food items. The modules were: 1 Staple food; 2 Beans; 3 Vegetables; 4 Bacteria and algae; 5 Fruits; 6 Milk; 7 Meat; 8 Aquatic products; 9 Eggs; 10 Snacks; 11 Beverage and seasoning category; and 12 Cooking oils. The investigators used verbal expressions, food pictures, and food models to help respondents estimate food intake. The "average daily intake of food" was calculated and cross-referenced with the "Chinese food composition table Volume 1, version 2" using the Visual Basic programming language, which allowed for the computation of the daily intake of various nutrients per person.

Both the intervention and control groups were prescribed a relatively low glycemic index diet. Based on standard weight calculations (kg) using the formula "height – 105", the participants were advised to consume energy equivalent to 25–30 kcal kg^{-1} of body weight in the first trimester. An additional 200–300 kcal per day could be added in the second and third trimesters, adjusted according to weight gain. Carbohydrates were recommended to contribute to about 55% of the total energy intake, with the following guidance: (1) minimize the consumption of sweets; (2) prioritize whole grains as the main source, comprising at least one-quarter to one-fifth of the total intake; (3) consume approximately 200g of fruit per day. In cases of high and unstable blood sugar levels, temporarily replacing fruits with vegetables; and (4) consume over 500 g of vegetables per day, while avoiding high-carbohydrate varieties. Additionally, the participants were encouraged to engage in appropriate postprandial exercise.

Outcomes and data collection

We compared the effects of fiber supplementation between the intervention and control groups. The primary outcomes were blood lipid and glucose levels, as well as the incidence of GDM and HDP. The secondary outcome involved assessing the impact on the incidence of constipation.

During the first prenatal visit, the following information was collected through questionnaire inquiries, including age, pre-pregnancy BMI (kg m^{-2}), pre-pregnancy weight (kg), educational status, gravidity, parity, smoking, family history of diabetes, family history of hypertension, history of GDM in previous pregnancies, history of HDP in previous pregnancies, history of PCOS and IVF-ET pregnancy, constipation at enrollment, Euthyrox for hypothyroidism, and treatment with aspirin or heparin.

Pregnancy outcomes included gestational weight gain, incidence of GDM, incidence of HDP, occurrence of constipation requiring drug treatment, gestational week of delivery, birth weight, gestational length, gender, incidence of macrosomia (birth weight ≥4000 g), small for gestational age (SGA) neonates (birth weight <10 percentile), type of birth and the mean amount of postpartum hemorrhage and pre-term delivery (<GW 37). GDM was diagnosed with a one-step approach, a 2-hour, 75g OGTT at GW 24–26 for the study women. GDM was diagnosed when 1 or more glucose indexes met or exceeded the following cut-offs: fasting, ≥5.1 mmol L^{-1}; 1 hour, 10.0 mmol L^{-1}; and 2 hours, 8.5 mmol L^{-1}. If the OGTT result was normal and fasting glucose at GW 32–34 ≥5.1 mmol L^{-1}, GDM was diagnosed. Hypertensive disorders of pregnancy included gestational hypertension and preeclampsia, blood pressure ≥140 mm Hg systolic or 90 mm Hg diastolic on at least two occasions 4–6 hours apart, with or without proteinuria (24-hour urine protein ≥300 mg or + on a urine dipstick).

Routine check-ups at our antenatal clinic included three blood tests (first trimester, oral glucose tolerance test (OGTT) in the second trimester, and GW 32–34). Fasting blood glucose, glycosylated hemoglobin (HbA1C), and lipid profiles were detected for the above three times. Blood was drawn at 7:30–8:30 a.m. after an overnight fast. Blood biochemical tests (including FG, TG, TC, LDL, and HDL) were performed on a Hitachi type 7180 automatic biochemical analyzer (Japan, Hitachi High-Tech Science Systems Corporation). HbA1c test was performed on a Tosoh automated glycohemoglobin analyzer HLC-723G8. Blood biochemical data were collected three times at GW 11–13, GW 24–26, and GW 32–34. Changes in lipids also were compared between the two groups.

Differences in dietary components (excluding dietary fiber supplementation) obtained from the first/second/third-trimester nutritional surveys were analyzed between the two groups. Dietary components included energy (kal), protein (g), fat (g), carbohydrates (g), and fiber (g).

Sample size

For sample size calculation, the primary end-point was changed in TGs. In our previous work[28] it was found that controlling weight gain in GDM women, all of whom were advised to follow a low-glycemic index diet, can blunt the elevation of TG during pregnancy, and a study showed that a high-fiber diet can achieve the same effect on lipids as a low-glycemic index diet in GDM women.[29] The estimated mean change in TG after the intervention was 0.5 and 0.7 mmol L^{-1}, respectively, and the standard deviation (SD) was 0.7 and 0.6 mmol L^{-1}, respectively. Bilateral examination was performed and α = 0.05, confidence level (CL) $1 - \beta$ = 80%. The final calculated sample size was 376.

Statistical analysis

We applied an intention-to-treat (ITT) analysis to evaluate the primary outcomes like blood glucose and lipid levels. Given that blood glucose and lipid levels physiologically increase during pregnancy, the values in early and mid-pregnancy cannot serve as substitutes for those in late pregnancy. Therefore, to compensate for missing data, we adopted the average values from the corresponding gestational weeks within the group to which the missing cases belonged. Categorical variables were expressed numerically (percentage of the population involved), and numerical variables were expressed as mean ± SD. The chi-squared test was applied for categorical variables, and two independent sample t-tests were used for continuous variables obeying Gaussian distribution, otherwise the Wilcoxon rank sum test was used instead. Multivariate logistic regression analysis was applied to analyze dietary fiber intake risk on GDM/HDP and lipid changes in the control group. Confounding variables were maternal age and pre-pregnancy body-mass index (BMI), which were selected based on both clinical knowledge and existing literature reports.[30–32] All the statistical analysis was performed using SPSS19.0 software. P < 0.05 was considered statistically significant.

Results

Participant recruitment, characteristics, and dietary intake across pregnancy

The 376 women who agreed to participate were randomly divided into either the intervention or control group. Both groups were advised to follow a low glycemic index diet, but the intervention group also received guidance on daily soluble fiber supplements, containing 10 g of inulin and 2 g of xylooligosaccharide per pack, provided by Nutrasumma Inc. in China. Initially, each group consisted of 188 women in the first trimester (GW 11–13). However, these numbers reduced to 178 and 168 for the control and intervention groups, respectively, in the second trimester (GW 24–26), and further decreased to 171 and 167 in the third trimester (GW 32–34). By the end of the study, 174 women from the control group and 168 from the intervention group remained, totaling 342 participants. The study experienced a dropout rate of 9.04%, mainly due to abortion, premature delivery, transfers to other hospitals, and withdrawals from the intervention group (Fig. 1).

Upon enrollment in the first trimester, we found no significant differences between the intervention and control groups in terms of demographic and clinical characteristics, including maternal age, pre-pregnancy BMI, pre-pregnancy weight, educational status, gravidity, parity, family history of diabetes or hypertension, previous GDM or HDP, PCOS, aspirin or heparin usage, and incidence of constipation (Table 1). Excluding the contribution of the fiber supplementation, we assessed the baseline dietary intake of participants. Across all three trimesters, we observed no significant differences in the consumption of key dietary components such as protein, fat, carbohydrates, and dietary fiber between the two groups (Table 2).

Effects of dietary fiber intake on metabolic health during pregnancy

We first investigated the potential impact of dietary fiber intake on key metabolic parameters. Notably, using Food Frequency Questionnaire data from the control group (n = 171) at GW 24–26, which recorded dietary fiber intake over the previous three months, we found that insufficient dietary fiber intake (<25 percentile, <11.28 g day^{-1}) correlated with an increased risk of GDM (OR = 2.17, P = 0.048). This association remained significant even after adjusting for maternal age and pre-pregnancy BMI (aOR = 2.37, P = 0.031) (Table 3). We further divided dietary fiber into specific categories, including grains, vegetables, fruits, and other sources. No specific type of fiber intake showed a statistically significant correlation with GDM (Table 3), suggesting that the fiber–GDM relationship is not dependent on the fiber's source.

In examining the effects on blood lipids, a high total dietary fiber intake (>75 percentile, >18.09 g day^{-1}) was linked with a reduced change in triglycerides (TG) between the first and second trimesters (OR = 3.34, P = 0.009; aOR = 3.33, P = 0.01) (Table 4). However, no correlation was found between total dietary fiber intake and TG changes between the first and
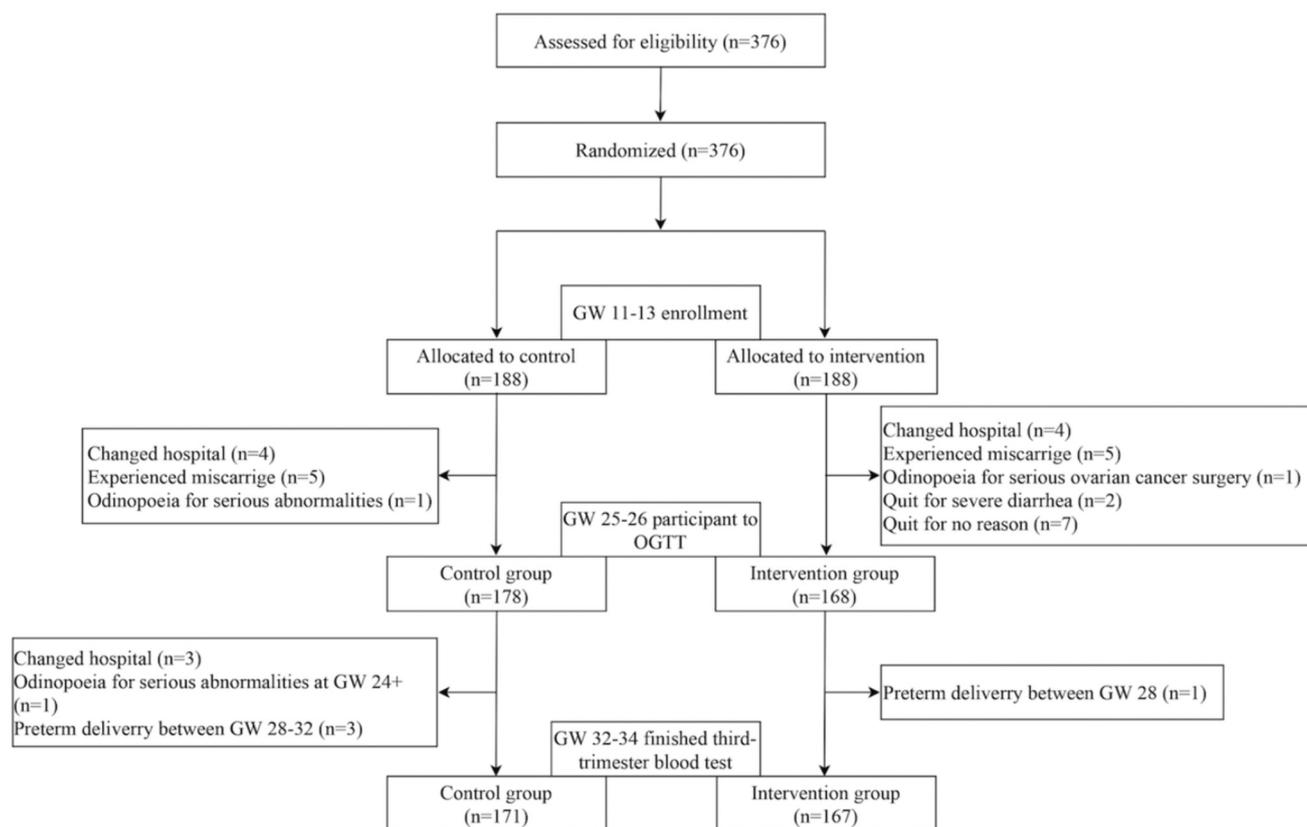
Fig. 1 The flowchart of patient selection. GW: gestational week and OGTT: oral glucose tolerance test.

third trimesters (Table S1†). This may be due to TG changes later in pregnancy being more influenced by fetus-related factors.

Regarding HDP, no correlation was found with total fiber intake or fiber from grains, vegetables, or fruits. Interestingly, a high intake of fiber from other sources (>75 percentile, >4.85 g day^{-1}) showed a significant correlation with HDP incidence (OR = 3.08, P = 0.016; aOR = 3.26, P = 0.020), while low and mid-level intake did not show such correlation (Table 3).

Our findings suggest that inadequate dietary fiber intake during pregnancy increases the risk of GDM, while high fiber intake can moderate early pregnancy TG changes.

Fiber supplementation's impact on metabolic health and pregnancy outcomes

Next, we examined the effects of fiber supplementation in the intervention and control groups. At enrollment, and throughout the pregnancy, there were no significant differences in blood glucose, HbA1C (Table 5), and lipid levels (Table 6) between the groups. Pregnancy outcomes, including weight gain, gestational age at delivery, birth weight, cesarean section rate, and postpartum bleeding, also showed no significant differences. The incidence of HDP, GDM, macrosomia, SGA neonates, and preterm birth were similar. However, fewer women in the intervention group needed medication for gestational constipation (3.0% *vs.* 12.6%, P = 0.001) (Table 7).

We then shifted our focus to GDM patients, comparing their blood glucose, HbA1c, and lipid profiles at early, mid, and late pregnancy stages across both groups. Despite similar baseline levels among all participants, GDM patients in the intervention group exhibited significantly higher blood glucose levels in early pregnancy (P = 0.013) and elevated HbA1c levels in mid-pregnancy (P = 0.021) compared to the control group. However, these levels aligned between the intervention and control groups in late pregnancy (Table 8). Nonetheless, no significant differences were observed in lipid profiles at any pregnancy stage (Table S2†). This result suggested that soluble fiber supplementation might have potentially benefits for GDM patients.

All the data above were analyzed using the ITT approach, which accounts for missing data through compensation methods. Additionally, we conducted the Per-Protocol (PP) analysis using only the data from participants who completed the entire trial. Consistent results were obtained between the PP analysis and the ITT analysis, as illustrated in Tables S3–S6.†

In addition, our study verifies the safety of fiber supplementation during pregnancy. Our intervention spanned a significant duration, from initial recruitment in the first trimester (GW 11–13) through to delivery. The most common side effects in the intervention group were bloating and excessive gas at the onset of fiber supplementation, but these were gen-

Table 1 Baseline characteristics of the pregnant women and neonates

	Intervention group (n = 188)	Control group (n = 188)	P
Maternal age, years, mean ± SD	34.30 ± 4.14	34.78 ± 4.76	0.29
Prepregnancy BMI, kg m^{-2}, Mean ± SD	25.31 ± 3.8	24.95 ± 3.32	0.33
Prepregnancy weight, kg, Mean ± SD	66.4 ± 10.82	65.61 ± 9.92	0.46
Educational status, n (%), university degree	89.67	89.25	0.98
Gravidity (unigravida), n (%)	65 (38.69)	67 (38.51)	0.87
Parity (primipara), n (%)	103 (61.31)	97 (55.75)	0.16
Family history of diabetes, n (%)	56 (29.8)	49 (26.1)	0.421
Family history of hypertension, n (%)	95 (50.5)	99 (52.7)	0.680
IVF-ET, n (%)	41 (21.8)	51 (27.1)	0.230
History of diabetes in previous pregnancy, n (%)	10 (5.3)	13 (6.9)	0.519
History of hypertension in previous pregnancy, n (%)	4 (2.1)	11 (5.8)	0.065
PCOS, n (%)	19 (10.1)	20 (10.6)	0.866
Taking aspirin in pregnancy, n (%)	34 /168(20.2)	33/174 (19.0)	0.767
Using heparin in pregnancy, n (%)	7/168 (4.2)	7/174 (4.0)	0.947
Using Euthyrox for hypothyroidism, n (%)	18 (9.6)	18 (9.6)	1.000
Constipation at enrollment, n (%)	26 (13.8)	24 (12.8)	0.761

SD: standard deviation; BMI, body mass index; IVF-ET: *in vitro* fertilization-embryo transfer; and PCOS: polycystic ovary syndrome.

Table 2 Comparison of the dietary intake components at different GWs between the intervention and control groups (excluding fiber supplementation)

	Variable	Intervention group Mean ± SD	Control group Mean ± SD	P
First trimester (n = 188/intervention group, 188/control group)	Energy, KJ	1524.65 ± 451.35	1538.03 ± 456.92	0.775
	Protein, g	58.76 ± 19.44	59.02 ± 19.36	0.894
	Fat, g	50.63 ± 22.02	51.43 ± 20.47	0.716
	Carbohydrates, g	215.10 ± 71.40	217.00 ± 85.62	0.815
	Dietary fiber, g	10.11 ± 5.03	10.66 ± 5.11	0.293
Second trimester (n = 168/intervention group, 178/control group)	Energy, KJ	2218.26 ± 562.99	2211.96 ± 533.56	0.916
	Protein, g	104.16 ± 36.78	103.45 ± 32.34	0.853
	Fat, g	84.93 ± 25.84	85.31 ± 23.95	0.889
	Carbohydrates, g	265.76 ± 76.79	264.15 ± 77.84	0.849
	Dietary fiber, g	14.72 ± 6.41	15.50 ± 6.45	0.267
Third trimester (n = 167/intervention group, 171/control group)	Energy, KJ	1841.47 ± 381.31	1774.50 ± 330.02	0.119
	Protein, g	75.04 ± 18.91	74.00 ± 16.98	0.657
	Fat, g	68.26 ± 22.60	63.58 ± 18.00	0.063
	Carbohydrates, g	240.48 ± 62.01	233.38 ± 56.51	0.360
	Dietary fiber, g	11.94 ± 5.20	11.95 ± 5.50	0.987

GWs: gestational weeks and SD: standard deviation.

erally tolerable. Only two women opted to discontinue due to initial episodes of diarrhea, and no serious adverse reactions were reported.

Discussion

In this study, we found that insufficient dietary fiber intake was associated with an increased risk of GDM, while high fiber intake was linked to reduced changes in TG. The source of fiber intake did not significantly correlate with GDM or HDP, except for a high intake of fiber from other sources, which was correlated with HDP. Supplementation with soluble fiber did not significantly affect metabolic parameters or pregnancy outcomes, but it did reduce the need for constipation medication. Notably, in GDM patients, the intervention group showed higher blood glucose or HbA1c levels in early or mid-preg-

nancy, but these levels equalized by late pregnancy. The study also confirmed the safety of long-term fiber supplementation during pregnancy, with the most common side effects being tolerable bloating and gas production. No serious adverse reactions were reported.

High-fiber diets have been shown to suppress appetite and decrease overall energy intake, potentially mitigating obesity and enhancing insulin sensitivity.[33] Moreover, fiber intake could potentially slow gastric emptying,[34] which in turn decelerates glucose absorption, leading to a moderate increase in insulin levels.[35] Indeed, numerous studies have underscored the beneficial impact of fiber intake on blood glucose regulation. For example, an increase of 10 g per day in total fiber intake was shown to result in a 26% reduction in the risk of gestational diabetes mellitus (GDM).[35] Similarly, another study revealed that women in the highest three quartiles of dietary fiber intake before and during pregnancy had an 11%,

Table 3 Logistic regression analysis of the correlation between dietary fiber and HDP/GDM in the control group

Variety	Quartile	g day^{-1}	GDM				HDP			
			OR	P	aOR	P	OR	P	aOR	P
Total fiber	<25 percentile	8.95 (3.13–11.28)	2.17 (1.01–4.67)	0.048	2.37 (1.08–5.21)	0.031	1.05 (0.38–2.85)	0.928	1.30 (0.43–3.87)	0.643
	25–75 percentile	14.53 (11.39–17.97)	1		1		1		1	
	>75 percentile	24.02 (>18.09)	1.09 (0.48–2.49)	0.828	1.09 (0.47–2.51)	0.839	1.51 (0.59–3.91)	0.390	2.23 (0.79–6.31)	0.132
Cereal fiber	< 25 percentile	1.78 (0.87–2.24)	1.29 (0.59–2.81)	0.529	1.54 (0.68–3.48)	0.303	1.17 (0.42–3.23)	0.766	1.89 (0.60–5.97)	0.279
	25–75 percentile	3.22 (2.28–4.25)	1		1		1		1	
	>75 percentile	6.14 (4.29–11.9)	1.16 (0.53–2.55)	0.715	1.18 (0.53–2.63)	0.686	1.77 (0.69–4.50)	0.233	2.56 (0.89–7.34)	0.080
Vegetable fiber	< 25 percentile	1.95 (0.58–2.70)	1.11 (0.51–2.40)	0.792	1.16 (0.53–2.54)	0.713	1.06 (0.39–2.89)	0.906	1.05 (0.36–3.05)	0.927
	25–75 percentile	4.14 (2.74–6.13)	1		1		1		1	
	>75 percentile	9.28 (6.23–21.20)	0.74 (0.32–1.67)	0.463	0.73 (0.32–1.68)	0.464	1.59 (0.61–4.10)	0.341	1.65 (0.59–4.60)	0.342
Fruit fiber	< 25 percentile	1.03 (0.05–1.54)	1.57 (0.73–3.88)	0.251	1.66 (0.76–3.62)	0.204	1.17 (0.45–3.03)	0.752	1.31 (0.46–3.69)	0.612
	25–75 percentile	2.55 (1.54–3.88)	1		1		1		1	
	>75 percentile	5.69 (3.90–11.69)	0.79 (0.35–1.81)	0.582	0.81 (0.35–1.88)	0.626	0.78 (0.28–2.18)	0.632	1.09 (0.36–3.31)	0.879
Other fiber	< 25 percentile	1.14 (0.12–2.01)	1.94 (0.90–4.20)	0.092	1.90 (0.87–4.16)	0.106	0.897 (0.29–2.77)	0.850	0.74 (0.22–2.51)	0.632
	25–75 percentile	3.24 (2.08–4.82)	1		1		1		1	
	>75 percentile	8.69 (>4.85)	1.17 (0.52–2.62)	0.706	1.14 (0.50–2.57)	0.756	3.08 (1.24–7.68)	0.016	3.26 (1.21–8.83)	0.020

HDP: hypertensive disorders of pregnancy; GDM: gestational diabetes mellitus; adjusted for maternal age and pre-pregnancy body mass index.

17%, or 18% reduced risk of GDM, respectively.[36] Furthermore, causal evidence from animal studies demonstrates that high-fiber diets or supplementation with short-chain fatty acids (SCFAs) protect against kidney disease development in diabetic mice by restoring gut microbial balance. This restoration is mediated by metabolite-sensing G protein–coupled receptors.[37] Additionally, inflammation-driven insulin resistance was shown to play a crucial role in GDM, with high fermentable dietary fiber (HFDF) reducing GDM development in mice by modulating the gut flora–short-chain fatty acid–placental inflammation axis.[38] In line with these findings, our study also indicated that inadequate dietary fiber intake increased the risk of GDM. This correlation remained significant even after adjusting for maternal age and pre-pregnancy BMI in the control group. However, when considering the entire participant group, there was no significant difference in GDM incidence between the control group and the group supplemented with soluble fiber. This suggests that the beneficial effects observed may be more attributable to dietary fiber intake rather than externally supplemented fiber. Meanwhile, it is important to acknowledge that factors unrelated to diet, such as healthy lifestyle habits, may also contribute to the improved blood glucose control observed in women with high fiber diets.

Our study shows the potential benefits of dietary fiber supplementation in improving blood sugar metabolism in GDM patients. We enrolled pregnant women during early pregnancy and randomly assigned them to intervention and control groups. The diagnosis of GDM was made in the second trimester; thus the baseline prevalence of GDM in both groups remained unknown. Following completion of the trial, we conducted a retrospective analysis focusing on pregnant women diagnosed with GDM. Unexpectedly, we observed that among the GDM population, fasting blood glucose levels were higher in the intervention group during the first trimester compared to the control group, yet this discrepancy vanished by the second and third trimesters. HbA1C, reflecting the average blood sugar level over the past 8 to 12 weeks, mirrored these findings, showing higher levels in the intervention group during the second trimester among GDM patients compared to the control group, with no difference by the third trimester. These findings suggest a beneficial effect of dietary fiber supplementation on blood sugar metabolism in GDM patients. Importantly, this effect is unlikely attributed to grouping bias, as pregnant women were not diagnosed with GDM at enrollment, and there were no significant differences in the aforementioned blood sugar indicators between the two groups at the baseline. Consequently, we hypothesize that early dietary

Table 4 Logistic regression analysis of the correlation between dietary fiber and the TG change from the first trimester to second trimester in the control group

Variety	Quartile	g day⁻¹	TG change <25 percentile				TG change (25–75)	TG change >75 percentile			
			OR	P	aOR	P		OR	P	aOR	P
Total fiber	< 25 percentile	8.95 (3.13–11.28)	1.05 (0.38–2.85)	0.927	1.08 (0.39–2.96)	0.878		0.56 (0.22–1.44)	0.230	0.59 (0.23–1.51)	0.270
	25–75 percentile	14.53 (11.39–17.97)	1		1		1	1		1	
	>75 percentile	24.02 (>18.09)	3.34 (1.34–8.29)	0.009	3.33 (1.33–8.32)	0.01		0.74 (0.27–2.04)	0.560	0.76 (0.27–2.11)	0.603
Cereal fiber	< 25 percentile	1.78 (0.87–2.24)	1.58 (0.62–4.01)	0.334	1.81 (0.69–4.75)	0.227		1.97 (0.79–4.87)	0.143	2.29 (0.89–5.92)	0.086
	25–75 percentile	3.22 (2.28–4.25)	1		1		1	1		1	
	>75 percentile	6.14 (4.29–11.9)	0.84 (0.32–2.19)	0.717	0.82 (0.31–2.16)	0.683		0.99 (0.39–2.54)	0.984	1.02 (0.40–2.65)	0.962
Vegetable fiber	< 25 percentile	1.95 (0.58–2.70)	1.22 (0.47–3.14)	0.684	1.24 (0.48–3.23)	0.654		0.61 (0.24–1.57)	0.305	0.59 (0.23–1.54)	0.283
	25–75 percentile	4.14 (2.74–6.13)	1		1		1	1		1	
	>75 percentile	9.28 (6.23–21.20)	2.06 (0.83–5.11)	0.118	2.09 (0.84–5.21)	0.115		0.83 (0.32–2.12)	0.695	0.79 (0.31–2.04)	0.629
Fruit fiber	< 25 percentile	1.03 (0.05–1.54)	0.76 (0.30–1.94)	0.572	0.78 (0.31–1.99)	0.601		0.57 (0.21–1.53)	0.263	0.56 (0.21–1.53)	0.258
	25–75 percentile	2.55 (1.54–3.88)	1		1		1	1		1	
	>75 percentile	5.69 (3.90–11.69)	0.88 (0.34–2.26)	0.789	0.88 (0.34–2.29)	0.800		1.12 (0.46–2.71)	0.804	1.18 (0.48–2.89)	0.711
Other fiber	< 25 percentile	1.14 (0.12–2.01)	0.47 (0.17–1.32)	0.152	0.44 (0.16–1.26)	0.128		0.61 (0.24–1.52)	0.284	0.57 (0.22–1.44)	0.230
	25–75 percentile	3.24 (2.08–4.82)	1		1		1	1		1	
	>75 percentile	8.69 (>4.85)	1.73 (0.71–4.24)	0.227	1.69 (0.69–4.17)	0.254		1.07 (0.42–2.73)	0.888	1.00 (0.39–2.59)	0.996

TG: triglyceride. Adjusted maternal age and pre-pregnancy body mass index.

Table 5 Comparison of blood glucose and HbA1c at different time points between the intervention and control groups

Variable	Intervention group (n = 188) Mean ± SD	Control group (n = 188) Mean ± SD	t	P
Fasting blood glucose at first trimester	4.86 ± 0.46	4.83 ± 0.35	0.67	0.51
HbA1C at first trimester	5.44 ± 0.66	5.41 ± 0.49	0.50	0.62
OGTT-0H at second trimester	4.43 ± 0.46	4.38 ± 0.45	1.05	0.29
OGTT-1H at second trimester	8.57 ± 1.67	8.65 ± 1.58	−0.47	0.64
OGTT-2H at second trimester	7.26 ± 1.44	7.27 ± 1.42	−0.08	0.94
HbA1C at second trimester	5.14 ± 0.33	5.08 ± 0.30	1.91	0.06
Fasting blood glucose at third trimester	4.69 ± 0.46	4.70 ± 0.44	−0.08	0.93
HbA1C at third trimester	5.44 ± 0.34	5.39 ± 0.33	1.44	0.15

HbA1C: glycosylated hemoglobin; SD: standard deviation; and OGTT: oral glucose tolerance test.

fiber intervention may not only partially improve blood sugar metabolism in GDM patients but also potentially exert a preventive effect, reducing the progression of subclinical abnormalities in glucose metabolism to full-fledged GDM. Supporting this hypothesis, the intervention group exhibited fewer cases of GDM (49 cases) compared to the control group (57 cases). However, due to the limited sample size, this difference did not reach statistical significance. Therefore, further studies with larger cohorts are warranted to explore whether early dietary intervention can effectively reduce the incidence of GDM.

The viscosity of fiber supplements plays a crucial role in controlling blood glucose levels.[39,40] These supplements increase the viscosity of chyme in a dose-dependent manner, slowing the conversion of complex nutrients. This process stimulates the release of glucagon-like peptide-1, which aids in appetite reduction, pancreatic β-cell growth promotion, insulin sensitivity increase, and glucagon secretion decrease. Additionally, the nutrient present at the distal ileum triggers ileal braking, which curbs food intake and boosts satiety. Evidence supporting this concept comes from a previous study

Table 6 Comparison of lipid profiles between the intervention and control groups

Variable		Intervention group (*n* = 188) Mean ± SD	Control group (*n* = 188) Mean ± SD	*t*	*P*
CHOL	First trimester	4.74 ± 0.81	4.79 ± 0.72	−0.62	0.54
	Second trimester	5.85 ± 0.89	5.81 ± 0.84	0.36	0.72
	Third trimester	6.11 ± 0.95	6.14 ± 0.96	−0.29	0.78
	Changes in pregnancy[a]	1.39 ± 0.85	1.35 ± 0.80	0.43	0.67
TG	First trimester	1.67 ± 0.68	1.67 ± 0.65	0.07	0.94
	Second trimester	2.58 ± 0.94	2.51 ± 0.79	0.67	0.51
	Third trimester	3.28 ± 1.33	3.27 ± 1.18	0.03	0.97
	Changes in pregnancy[a]	1.61 ± 1.08	1.58 ± 0.94	0.24	0.81
HDL	First trimester	1.79 ± 0.39	1.82 ± 0.35	−0.76	0.45
	Second trimester	2.09 ± 0.43	2.06 ± 0.39	0.73	0.46
	Third trimester	2.01 ± 0.38	2.01 ± 0.40	0.05	0.96
	Changes in pregnancy[a]	0.22 ± 0.29	0.19 ± 0.30	1.13	0.26
LDL	First trimester	2.61 ± 0.68	2.63 ± 0.63	−0.34	0.73
	Second trimester	3.22 ± 0.72	3.24 ± 0.74	−0.16	0.87
	Third trimester	3.46 ± 0.82	3.49 ± 0.94	−0.32	0.75
	Changes in pregnancy[a]	0.87 ± 0.78	0.86 ± 0.80	0.09	0.92

SD: standard deviation; CHOL: cholesterol; TG: triglyceride; HDL: high-density lipoprotein; and LDL: low-density lipoprotein. [a] "Changes in pregnancy" was calculated as the difference between lipid levels in the third trimester and those in the first trimester.

showing that high-viscosity fibers, forming a gel-like substance, lowered blood glucose and serum insulin concentrations during a 50 g glucose tolerance test.[41] Interestingly, the beneficial effect on blood glucose concentration was lost when guar gum was altered into a non-viscous form.[42] Further research comparing gel fibers of different viscosities suggested a positive correlation between fiber viscosity and reduction in peak blood glucose concentration.[42] Another study demonstrated that a viscous fiber supplement (plantain) improved blood glucose control in type 2 diabetes patients, as indicated by lower fasting blood glucose and HbA1C levels.[43] However, our current study used a fiber supplement composed of inulin and xylooligosaccharides, which are soluble, fermentable fibers but lack viscosity. This could account for the observed limited effects on blood glucose control.

The effects of dietary fiber on blood lipid levels remain a subject of debate. Some studies suggest that an increase in dietary fiber can lower cholesterol levels, while others yield inconsistent results. A *meta*-analysis demonstrated that the consumption of 2–10 g day^{-1} of soluble fiber significantly reduced serum total TC and LDL-C.[44] However, other studies reported no changes in HDL-C or TG upon the addition of soluble dietary fiber.[45] The viscosity of fiber also plays a crucial role in controlling blood lipid levels. A study reported a positive correlation between the degree of LDL-C reduction and the viscosity of fibers in a North American population.[46] High-viscosity fibers significantly reduced LDL-C compared to low-viscosity fibers. Additionally, it was found that plantain and β-glucan (found in oatmeal) could reduce the risk of cardiovascular disease by lowering serum cholesterol,[47] a finding endorsed by the US Food and Drug Administration. Contrastingly, McRorie JW Jr reviewed 17 randomized, well-controlled clinical studies evaluating the effects of soluble, non-viscous, fermentable fibers on blood lipid concentration.[48] None of these studies showed significant differences

in TC and LDL-C compared to the placebo control group.[48] In our study, we observed that a high intake of dietary fiber led to a decrease in the change of TG in the control group from the first to the second trimester. This suggests that it is not the supplementation of soluble fiber but rather the habit of high dietary fiber consumption that is associated with improved blood lipid control.

Constipation, affecting 11% to 38% of pregnant women, is a common issue during pregnancy. It can be caused by hormonal changes, physical modifications such as uterine enlargement, the use of iron and calcium supplements, insufficient dietary fiber intake, and decreased physical activity. Dietary fiber, particularly fermentable types classified as prebiotics, can help alleviate these symptoms.[49,50] These prebiotics foster the growth of beneficial bacteria like Bifidobacterium and Lactobacillus, which in turn produce short-chain fatty acids (SCFAs).[51] SCFAs play a crucial role in the gastrointestinal tract by stimulating colonic contractile activity and exerting anti-inflammatory effects, thereby aiding in the relief of constipation.[52] However, it is important to note that certain types of fibers can cause gastrointestinal symptoms. Therefore, while dietary fiber is beneficial for gastrointestinal health, its selection and use, especially in pregnant women, should be approached with caution. In our research, we found that fiber supplementation significantly improved constipation symptoms during pregnancy. Furthermore, our data confirmed the safety of long-term fiber supplementation in pregnancy, with side effects being well-tolerated. This underlines the potential of dietary fiber as a safe and effective strategy for managing constipation in pregnancy.

Despite the intriguing findings mentioned above, we did not observe a significant impact of soluble fiber supplementation on either metabolic parameters or pregnancy outcomes. This lack of significance may be attributed to the fact that all participants were at high risk of MetS, leading to metabolic

Table 7 Comparison of pregnancy outcomes between the intervention and control groups

	Intervention group (n = 168)	Control group (n = 174)	P
Weight gain during pregnancy, kg, mean ± SD	13.11 ± 5.16	13.23 ± 5.08	0.82
Prepartum weight, kg, mean ± SD	79.47 ± 11.28	79.11 ± 10.46	0.76
Gestation week of delivery, mean ± SD	38.45 ± 1.62	38.44 ± 1.73	0.97
Fetal birth weight, g, mean ± SD	3396.85 ± 520.22	3376.01 ± 515.48	0.71
Fetal birth length, cm, mean ± SD	49.72 ± 1.78	49.76 ± 1.74	0.84
Gender of the infants, boy, n (%)	86 (51.19%)	85 (48.85%)	0.75
Cesarean rate, n (%)	115 (68.45%)	106 (60.92%)	0.145
Postpartum bleeding, ml, mean ± SD	298.05 ± 374.39	310.64 ± 228.55	0.71
Hypertension, n (%)	25 (14.9%)	30 (17.2%)	0.552
GDM, n (%)	49 (29.2%)	57 (32.7%)	0.473
Macrosomia, n (%)	12 (7.1%)	18 (10.3%)	0.295
SGA, n (%)	6 (3.6%)	7 (4.0%)	0.827
Preterm delivery (<37 GWs), n (%)	12 (7.1%)	15 (8.6%)	0.612
Medication for gestational constipation, n (%)	5 (3.0%)	22 (12.6%)	0.001

SD: standard deviation; GDM, gestational diabetes mellitus; SGA: small for gestational age; and GWs: gestational weeks.

Table 8 Comparison of blood glucose and HbA1c at different time points between GDM women in the intervention and control groups

Variable	GDM from intervention group (n = 49) Mean ± SD	GDM from control group (n = 57) Mean ± SD	t	P
Fasting blood glucose at first trimester	5.20 ± 0.48	4.98 ± 0.39	2.520	0.013
HbA1C at first trimester	5.56 ± 0.91	5.53 ± 0.30	0.229	0.820
OGTT-0H at second trimester	4.88 ± 0.49	4.70 ± 0.50	1.813	0.073
OGTT-1H at second trimester	10.44 ± 1.50	10.21 ± 1.31	0.817	0.416
OGTT-2H at second trimester	8.78 ± 1.60	8.65 ± 1.52	0.424	0.672
HbA1C at second trimester	5.34 ± 0.38	5.18 ± 0.33	2.343	0.021
Fasting blood glucose at third trimester	5.00 ± 0.54	4.91 ± 0.49	0.855	0.395
HbA1C at third trimester	5.54 ± 0.41	5.47 ± 0.38	0.842	0.402

HbA1C: glycosylated hemoglobin; SD: standard deviation; and OGTT: oral glucose tolerance test.

profiles influenced by potential pathological factors alongside the natural physiological changes of pregnancy. Detecting statistical significance for non-medical interventions like dietary fiber supplementation presents a challenge due to the relatively mild therapeutic effect and high data variability. To overcome this challenge, a larger sample size with improved control over confounding factors is necessary. Additionally, since our study detected no long-term side effects at the current dosage, consideration of dosage adjustment is warranted, though caution is required due to the potential for increased risks of side effects. Furthermore, extending the timing of supplementation to before pregnancy, especially for women at high risk of MetS or those already diagnosed with related conditions, could be beneficial. In future studies, we suggest that incorporating lifestyle modifications, adhering to a higher fiber diet, and introducing fiber supplementation under medical supervision during the preconception period could synergistically improve overall pregnancy health for women at high risk of MetS.

Conclusion and future perspective

In this study, we found that inadequate dietary fiber intake, below 11.28g, is associated with a 2.37-fold increase in the relative risk of developing GDM. Additionally, incorporating fiber supplementation intervention may potentially benefit GDM patients and reduce the incidence of constipation. Therefore, we recommend ensuring adequate intake of dietary fiber during pregnancy, especially for individuals at high risk of MetS. A high-fiber diet includes vegetables (such as leafy greens, eggplant, radish, okra, konjac, and edamame), fruits (such as kiwi and plums), and whole grains (such as buckwheat and oats). In cases of inadequate dietary fiber intake, we suggest fiber supplementation, particularly for pregnant women experiencing constipation. Our study underscores the important role of sufficient dietary fiber intake, particularly from food sources, in maintaining the metabolic health of pregnant women, and additional fiber supplementation may provide further beneficial effects. With a relatively large sample size and a randomized controlled design, our study offers a reliable data source on the influence of dietary fiber on maternal health during pregnancy.

Despite our diligent efforts, our study has some limitations. Firstly, the data were collected from a single hospital, which may limit the generalizability of our findings. Increasing the sample size and conducting future randomized trials involving multiple centers would offer more robust statistical support and enhance the applicability of our results. Secondly, the role of viscosity in fiber supplements warrants further exploration,

as modifications in this aspect could potentially enhance their metabolic impact during pregnancy. Additionally, extending the intervention time before pregnancy may provide insights into the long-term effects of dietary fiber supplementation on metabolic parameters and pregnancy outcomes. Furthermore, we recommend incorporating dietary changes alongside fiber supplementation to optimize health outcomes during pregnancy. A well-balanced diet rich in fruits, vegetables, whole grains, lean proteins, and healthy fats can complement the effects of fiber supplementation, promoting overall metabolic health and mitigating pregnancy-related complications. Lastly, the hormonal changes that naturally occur in pregnant women, especially in those at high risk of MetS, can complicate pregnancy, particularly concerning blood sugar and lipid levels in the third trimester. These complex factors could potentially obscure the beneficial effects of dietary fiber. Future research should aim to control these confounding factors when selecting the study population. By focusing on relatively specific single factors, such as obesity, for interventional studies, we could potentially enhance the sensitivity of detecting the beneficial effects of dietary fiber. This approach will pave the way for more targeted and effective dietary interventions in the future.

Author contributions

WC contributed to conceptualization. HS, DC and YJ contributed to investigation, data curation, formal analysis and methodology. SW contributed to investigation. HS and DC contributed to writing the original draft, and all authors contributed to writing – review and editing.

Data availability

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Conflicts of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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