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Randomized Control Trials

Effectiveness of carbohydrate counting and Dietary Approach to Stop Hypertension dietary intervention on managing Gestational Diabetes Mellitus among pregnant women who used metformin: A randomized controlled clinical trial

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SUMMARY

Background: Gestational diabetes mellitus (GDM) is one of the most common complication of pregnancy that has significant impacts on both mother and her offspring health. The present study aimed to examine the effect of carbohydrate counting, carbohydrate counting combined with DASH, and control dietary interventions on glycemic control, and maternal and neonatal outcomes.

Methods: A total of 75 pregnant women with GDM at 24th − 30th week of gestation were enrolled and randomized to follow one of the three diets: control or carbohydrate counting, or carbohydrate counting combined with Dietary Approach to Stop Hypertension (DASH). Only 70 of them completed the study until delivery. Fasting blood samples were taken at baseline and the end of the study to measure fasting blood glucose (FBG), fasting insulin, glycated hemoglobin (HbA1c), and fructosamine. Homeostatic model assessment-insulin resistance (HOMA-IR) score was calculated using HOMA2 calculator program. The participants recorded at least four blood glucose readings per day. Maternal and neonatal outcomes were collected from medical records. Dietary intake was assessed by three-day food records at the baseline and the end of the study.

Results: Adherence to the three dietary interventions, resulted in decreased FBG levels significantly among all the participants ($P < 0.05$). Consumption of the carbohydrate counting combined with the DASH diet showed significant reduction in serum insulin levels and HOMA-IR score compared to carbohydrate counting group and control group. Means of fructosamine and HbA1c did not differ significantly among the three intervention diet groups. Overall mean of 1-h postprandial glucose (1 h PG) level was significantly lower in the carbohydrate counting combined with DASH group compared with that in the carbohydrate counting group and the control group ($P < 0.001$). The number of women who were required to commence insulin therapy after dietary intervention was significantly lower in carbohydrate counting group and carbohydrate counting combined with DASH group ($P = 0.026$). There were no significant differences in other maternal and neonatal outcomes among the three dietary intervention groups.

Conclusions: The carbohydrate counting and the carbohydrate counting combined with DASH dietary interventions resulted in beneficial effects on FBG and 1 h PG compared with the control diet. The three dietary interventions produced similar maternal and neonatal outcomes in women with GDM.

Trial registration: This trial was registered on ClinicalTrials.gov under the identification code: NCT 03244579. https://clinicaltrials.gov/ct2/show/NCT03244579.

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1. Introduction

Gestational diabetes mellites (GDM) is one of the most common medical complication and metabolic disorder of pregnancy. GDM is defined as diabetes diagnosed in the second or third trimester of pregnancy that was not obviously overt diabetes prior to gestation [1,2]. Uncontrolled GDM has adverse health consequences for mother and infant [3–5]. GDM is associated with hypoglycemia, large for gestational age, macrosomia, premature birth [3], shoulder dystocia [5], neonatal metabolic disturbances [6], pregnancy-induced hypertension, preeclampsia, antepartum hemorrhage, cesarean delivery [4], and induction of labor [5].

Medical nutrition intervention has been considered the cornerstone of GDM prevention and management and it is recognized as an essential component of an overall healthy lifestyle [7,8]. There is a strong evidence that supports the role of dietary modifications and changes in lifestyle for the treatment of GDM and optimizing maternal and fetal outcomes [9–12]. The American Diabetes Association (ADA) recommended monitoring carbohydrate intake either by carbohydrate counting or experience-based estimation for attaining glycemic control [8]. Carbohydrate counting is a meal planning approach for managing blood glucose levels for patients with diabetes. It has the greatest impact on keeping postprandial blood glucose levels in target range [13]. The actual effect of carbohydrate on blood glucose levels can be exaggerated by the total amount of carbohydrate and the type of carbohydrate [7]. DASH diet is a lifelong approach for healthy eating that is especially recommended for people with hypertension or pre-hypertension [14]. DASH diet is rich in fruits, vegetables, whole grains, and low-fat dairy products. It contains low amounts of saturated fats, cholesterol, and refined grains with a total of 2300 mg/day sodium [14]. Two studies have reported the beneficial effects of using DASH diet on fasting blood glucose, insulin levels, and homeostatic model assessment-insulin resistance (HOMA-IR) score, and is able to reduce insulin use, cesarean rates, and birth weight among patients with GDM [15,16].

To the best of our knowledge, currently there are no studies that examining the effect of carbohydrate counting on glucose control in pregnant women with GDM in Jordan and elsewhere. There are only two studies, involving multi-ethnic women one in Australia [17] and another in United Arab Emirates [18], which examined the levels of nutritional knowledge related to carbohydrate foods among pregnant women with GDM. Therefore, this study aimed to compare the effect of carbohydrate counting, carbohydrate counting combined with DASH dietary interventions, and a general dietary intervention on glycemic control, maternal and neonatal outcomes among pregnant Jordanian women diagnosed with GDM in use of metformin.

2. Methods

2.1. Study design

A randomized controlled clinical trial with three parallel arms was conducted between 1st August 2017 and 15th September 2019. It was carried out on pregnant Jordanian women diagnosed with GDM in use of metformin and followed antenatal clinics at Al-Bashir Hospital and Jordan University Hospital in Amman.

2.2. Ethical approval

The study protocol was approved by the Institutional Review Board of Al-Bashir Hospital and Jordan University Hospital (10/2017/1411). The study protocol was conducted according to ethical guidelines of Declaration of Helsinki. This study was registered at the ClinicalTrials.gov with the identification code: NCT 03244579. Written informed consent was obtained from all participants prior to enrollment in this study.

2.3. Participants

Pregnant women without a previous diagnosis of glucose intolerance were screened for GDM by 75 g oral glucose tolerance test (OGTT) after an overnight fast of 8–10 h between 24th and 28th week gestation. Gestational age was calculated from the date of last menstrual cycle and ultrasound fetal biometrics provided by an obstetrician [19,20].

Diagnosis of GDM was based on the criteria as set by IADPSG Consensus Panel: those whose plasma glucose levels met one of the following criteria were considered as having GDM: fasting $\geq$92 mg/dl, 1-h $\geq$ 180 mg/dl and 2-h $\geq$ 153 mg/dl [21,22].

A total of 95 pregnant women attending antenatal clinics at Al-Bashir Hospital and Jordan University Hospital were assessed for eligibility of the study. Women included in this study were pregnant Jordanian women aged between 20 and 46 years had GD and in use of metformin with singleton pregnancies between 24th and 30th week of gestation. Metformin is safe and effective oral anti-diabetic medication, and it is considered in medical protocol for management GDM in Jordan. The exclusion criteria were women with multiple gestation, personal history of cardiovascular, kidney, liver and autoimmune diseases, type 1 or type 2 diabetes (except previous history of GDM), and a positive OGTT before 24th week of pregnancy consistent with diagnosis of overt diabetes in pregnancy. Women who have contraindications for metformin use, major fetal malformation that was recognized on ultrasound examination or preterm rupture of membrane or placenta abruption at study enrollment, as well as those who take medication that influences glucose metabolism, such as continuous therapy with oral corticosteroids were excluded.

Only 75 pregnant women met the inclusion criteria and agreed to participate in this study. Two women were excluded because they were pregnant with twin, 2 women were excluded because they did not use metformin, and 16 pregnant women declined participation in this study. Seventy-five pregnant women with GDM were randomly allocated (ratio1:1:1) into carbohydrate counting or carbohydrate counting combined with DASH or control dietary interventions following an allocation concealment process using a website generated random number table (www.randomization.com). Block size was 9. Randomization was stratified by pre-pregnancy body mass index (BMI) (normal body weight BMI = $\leq$ 24.9 kg/m^2 or overweight BMI = 25–29.9 kg/m^2 or obese BMI = $\geq$ 30 kg/m^2). The random allocation sequence was generated by independent statistician who was not a member of this study team. Due to the nature of dietary intervention study, blinding the participants or study investigator was not possible, but other researchers (obstetricians, pediatricians, and laboratory technicians) were blinded to the assessments of metabolic results and maternal and neonatal outcomes. The study investigator enrolled and assigned participants to their interventions. Seventy pregnant women completed this study (Fig. 1). The duration of intervention extended from 24th –30th week of gestation until delivery, which ranged from 8 to 12 weeks.

2.4. Personal data

Data on maternal age, pre-pregnancy body weight, education level, previous and current health problems, family history of type 2 diabetes, and parity was collected by an interviewer-administered structured questionnaire.

2.5. Physical activity assessment

A semi-quantitative pregnancy physical activity questionnaire (PPAQ) was used in this study to assess physical activity level. PPAQ was originally developed by Chasan -Taber et al. [23] and validated among a sample of 54 pregnant women using 7 days of accelerometer measurement. The participants were asked to recall the amount of time spent on participation in 36 types of activities grouped under the following classifications: household/caregiving, occupational, sports/exercise, transportation, and inactivity in the current trimester. Possible periods range from 0 to 6 or more hours per day and from 0 to 3 or more hours per week. The number of hours expended at each activity was multiplied by its intensity to get a weekly average of metabolic equivalent of activity (MET) units (MET h/week) and summed to derive the total activity score per week. The total number of MET h per week was also computed based on each classification of activity and each intensity level (sedentary activity [< 1.5 METs], (light intensity activity [1.5–3.0 METs], moderate intensity activity [3.0–6.0 METs] or vigorous–intensity activity [> 6.0 METs]) [23].

2.6. Anthropometric measurements

Weight and height were measured for each participant according to standardized techniques as described by Lee and Neiman [24]. The participants were weighed at baseline and end of

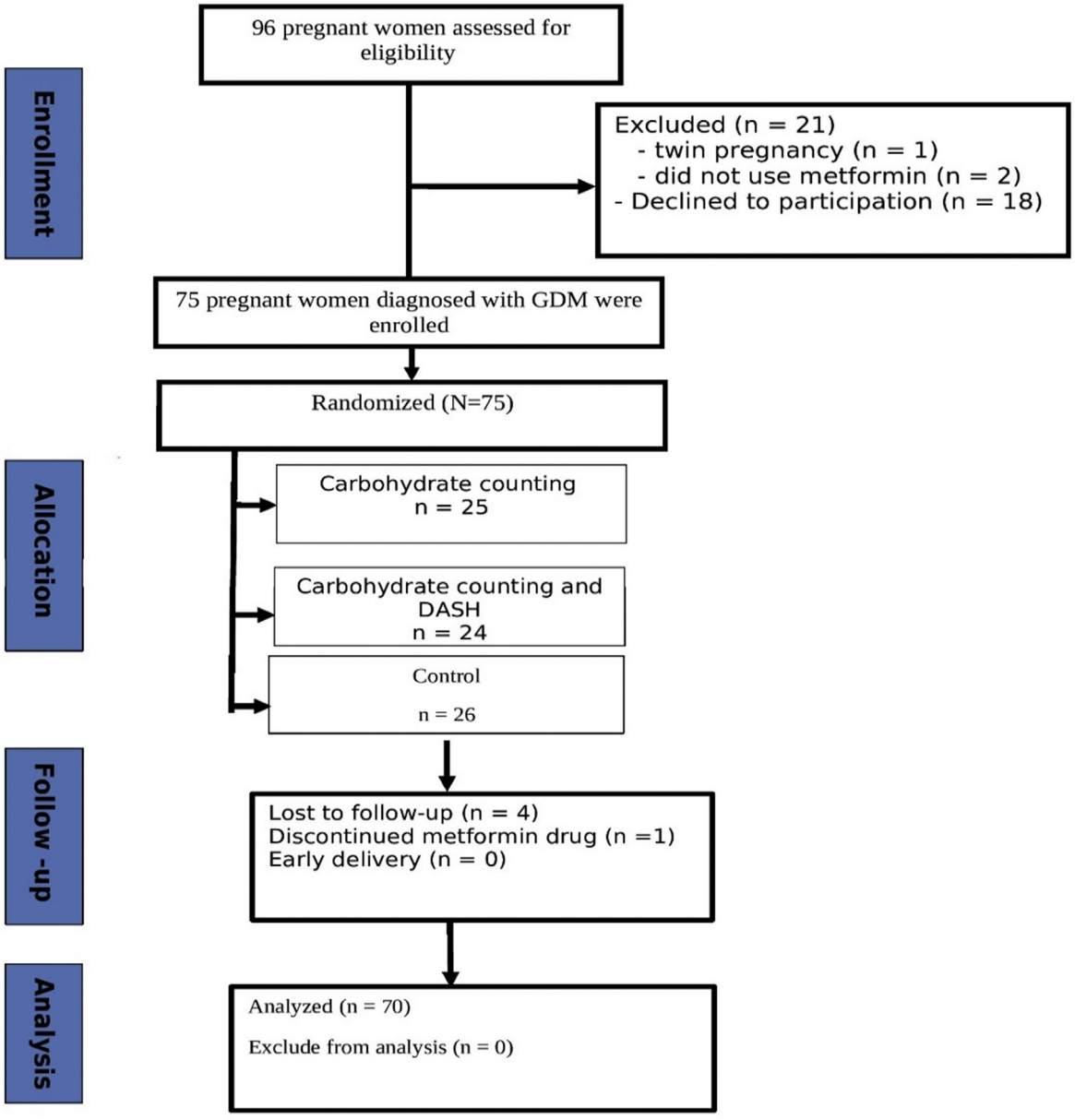

Fig. 1. Flow diagram of participants enrollment.

intervention without shoes and minimal clothing status using a calibrated digital scale to the nearest 0.1 kg (Health O meter Professional, USA). Height was measured without shoes to the nearest 0.1 cm using a wall mounted plastic height rod (Health O meter Professional, USA). The participants were asked to recall their pre-pregnancy body weight. Pre-pregnancy BMI was calculated as weight in kilograms divided by height in meters squared and classified in accordance with WHO guidelines [25].

2.7. Metformin prescription

Starting dose of metformin was 850 mg once a day either at bedtime or before main meal and increased gradually to three times per day as required depending upon the glycemic control of the participants. The maximum dose allowed per study protocol was 2550 mg per day. There was no brand restriction. Glycemic targets of FBG and 1 h PG were set to be < 90 mg/dl < 140 mg/dl, respectively as recommended by American College of Obstetricians and Gynecologist (ACOG) [26]. Insulin was initiated if targets could not be reached on metformin alone at maximum doses [27]. If FBG was higher than 90 mg/dl, long-acting insulin (Novo Nordisk, Levemir, FlexPen, France) would be initiated at bedtime. The basal insulin dose was calculated according to the actual body weight: 0.2 units/kg/day. If the hyperglycemia followed a meal, rapid-acting insulin (Novo Nordisk, NovoRapid, FlexPen, Denmark) would be added before that meal.

2.8. Diet planning

An individually prescribed diet was planned according to participant's food preference, physical activity level and nutrition assessment with guidance from the Dietary Reference Intakes for each woman. The energy requirement was calculated based on present body weight during pregnancy. For participants who were at ideal body weight, the energy requirement was 30 kcal/kg/day; for women who were overweight, the energy requirement was 22–25 kcal/kg/day; and for severely obese women, the energy requirement was 12–14 kcal/kg/day [28]. The control diet was designed to contain 45–55% carbohydrates, 15–20% protein and 25–30% total fat [29] (Table 1). This was distributed into three moderate-sized meals and two to four snacks. The participants received written dietary guidelines and meal plan. Also, the participants were contacted by telephone at least once a week to verify adherence to the prescribed diet.

2.9. Diet planning for carbohydrate counting diet

Carbohydrate counting diet was planned according to Kulkarni [30]. The amount of carbohydrate in food was estimated in grams using counting carbohydrate exchanges. The carbohydrate counts were distributed into three main meals and 3 snacks.

Carbohydrate counting essentials were delivered to participants based on structured educational activities including education about food portion size estimation, food package labels, managing hyper and hypoglycemia using carbohydrate counting approach, physical activity, glycemic index, and suitable types and amounts of dietary fat. Visual aids such as food models and measuring cups and spoons were used for each participant to become familiar with carbohydrate counting. The calorie, protein, carbohydrate, and fat contents of the carbohydrate counting diet were similar to the control diet (Table 1) [28,29].

2.10. Diet planning for carbohydrate counting combined with DASH diet

The calorie content and protein composition of the DASH diet combined with carbohydrate counting were comparable to the control diet; however, the DASH diet was rich in fruits (3–4 servings/day), vegetables (4–5 servings/day), cereals (at least half of the total servings were whole grain (6–8 servings/day)), low-fat dairy products (2–4 servings/day), low in lean meat (0–2 servings/day), and nuts, seeds and legumes (4–5 servings/week). Adequate intake of sodium (<2400 mg/day) was applied into participants' diet [14] (Table 1). The carbohydrate counts were calculated and distributed like that in carbohydrate counting diet which is mentioned above.

2.11. Evaluation of participants' compliance

Dietary intake was assessed using the completed 3-day food records. Food record collected data by participants' self-record at the time the food was consumed, thus minimizes reliance on a participants' memory. Paper-based forms were used to collect dietary records. The participants were asked to record all foods and beverages consumed over three non-consecutive days, including 2 weekdays and 1 weekend day at baseline and end line of intervention. The participants were requested to record detailed information of each food/beverage that was consumed. This information included preparation methods, ingredients of mixed dishes and recipes, and even the type and brand name of commercial products. Standard measuring tools (cups and spoons) and photograph food model booklet were provided to the participants to facilitate the estimation of portion size. The researcher reviewed and verified all records with the participant and probed for missing details.

2.12. Nutritional analysis

Prescribed diets and dietary data derived from food records were analyzed using food processor nutrition analysis software (Food Processor SQL, Released 2018.Version 11.6.0. Salem, USA) to estimate daily energy, macro-and micronutrients, and food groups intakes. Food composition of specific Jordanian foods (not included in the Food Processor Nutrition software database) was obtained from food composition tables [31]. The estimated intakes of energy, macronutrients, micronutrients, and food groups were exported from the software and imported into Statistical Package for Social Science (SPSS) (IBM Corp. 2019. IBM SPSS Statistics for Windows, Version 26.0. Armonk, NY, USA) to compare differences between study diet groups at both of basline and end of intervention as well as to make sure that participants adhered to prescribed diets and recommended dietary guidelines.

2.13. Maternal biochemical measurements

Venous blood samples were collected from the participants after overnight fasting (10–12 h) by a phlebotomist. Selected biochemical parameters including FBG, fasting insulin, HbA1c and fructosamine levels were quantified for study participants at baseline and at end of the study. The FBG was measured photometrically at a wavelength of 340 nm using automated analyzer (Roche, Cobas C311, Germany). Fasting serum insulin was quantified using a sandwich electrochemiluminescence immunoassay with a commercially available kit (Lot No. 18095304, Roche Diagnostics, Insulin, Germany). The glycated hemoglobin was determined using turbidimetric inhibition immunoassay with commercially available

Table 1
Constituents of the control, carbohydrate counting, and carbohydrate counting combined with DASH diets prescribed in the study (mean ± SD).

Energy/Nutrients	Control	CHO Counting	CHO Counting and DASH
Energy (kcal/day)	1783.1 ± 95.1	1781.8 ± 91.5	1810.0 ± 81.6
Protein (g/day)	86.5 ± 6.5	90.1 ± 8.5	91.3 ± 4.9
Carbohydrate (g/day)	235.2 ± 17.7	237.2 ± 14.5	231.3 ± 13.6
Added sugar (g/day)	11.9 ± 2.4	12.1 ± 3.3	3.9 ± 1.7
Carbohydrate counting (n)	–	15.6 ± 1.0	15.4 ± 0.91
Dietary Fiber (g/day)	22.5 ± 4.7	23.5 ± 3.6	28.8 ± 3.6
Fat (g/day)	61.9 ± 8.7	60.7 ± 7.4	61.6 ± 6.1
Saturated fatty acids (g/day)	17.5 ± 3.2	17.0 ± 2.6	15.4 ± 2.1
Monounsaturated fatty acids (g/day)	17.5 ± 3.3	18.2 ± 4.2	22.1 ± 2.5
Polyunsaturated fatty acids (g/day)	10.5 ± 2.4	11.1 ± 3.4	13.2 ± 1.9
Cholesterol (mg/day)	273.9 ± 137.9	278.0 ± 131.2	209.3 ± 79.6
Vitamin C (mg/day)	188.2 ± 104.1	213.1 ± 69.2	290.5 ± 88.7
Vitamin D (IU/day)	182.3 ± 79.7	165.1 ± 69.0	240.5 ± 63.3
Calcium (mg/day)	1217.2 ± 181.2	1295.7 ± 175.0	1780.5 ± 184.7
Magnesium (mg/day)	241.4 ± 73.5	258.6 ± 90.7	425.4 ± 130.0
Potassium (mg/day)	2799.9 ± 530.3	2927.5 ± 555.3	4330.2 ± 584.0
Sodium (mg/day)	2903.6 ± 671.9	2999.5 ± 886.9	2041.2 ± 630.1
Food Groups			
Grains[a] (ounce/day)	7.0 ± 0.7	7.0 ± 0.7	6.0 ± 0.6
Proteins (ounce/day)	5.0 ± 0.5	5.0 ± 1.0	5.0 ± 0.8
Vegetables (cup/day)	3.0 ± 0.9	3.0 ± 0.8	5.0 ± 0.7
Fruits (cup/day)	2.0 ± 0.5	2.0 ± 0.4	3.0 ± 0.3
Dairy products[b] (cup/day)	3.0 ± 0.5	3.0 ± 0.4	4.0 ± 0.3
Fats and oils (serving/day)	7.0 ± 2.1	7.0 ± 1.8	6.5 ± 1.3

Abbreviation: CHO: Carbohydrate; DASH: Dietary Approaches to Stop Hypertension.
[a] At least half of servings from whole grains in the DASH diet.
[b] Low fat (<2%) in the DASH diet.

kit (Lot No. 620741-01, Roche Diagnostic, HbA1c-3, Germany). Fructosamine in serum samples was quantified by a plate-based colorimetric assay with a commercially available kit (Lot No. 5615-01, Bio Scientific, MaxDiscovery fructosamine Assay Kit, USA). The HOMA-IR was calculated by the following formula: fasting insulin (μU/ml) x fasting glucose (mg/dl)/405 [32]. The HOMA-IR index was obtained by HOMA2 Calculator program (The Oxford Centre for Diabetes, Endocrinology and Metabolism. 2017. Version for Windows, Version 2.2.3. UK).

2.14. Home blood glucose monitoring

The participants were advised to perform and record blood glucose monitoring at least four times daily (fasting and post-prandial for breakfast, lunch and dinner meals) using glucometer (Rocha, Accu-Check Performa, Germany) with commercially available test strips (Lot No.06454011, Roche Diagnostic, Germany). Participant's chart was carefully reviewed by researcher and endocrinologist.

2.15. Other maternal outcomes

Total maternal weight gain (kg), dose of metformin and insulin required for optimal glycemic control for each participant, type of delivery (cesarean section or vaginal delivery) and presence or absence of pregnancy-induced hypertension and preeclampsia were retrieved from participants medical records. The need for emergency caesarean section in the study participants was determined by obstetrician based on fetal mal-presentation, fetal distress, dystocia and failure to progress vaginal delivery.

2.16. Newborn outcomes

Data on newborn sex, gestational age at birth, fetal birth weight, length and head circumference, Apgar score, neonatal intensive care unit (NICU) admission, and presence or absence of hypoglycemia and shoulder dystocia were extracted from the medical record. Gestational age was determined based on the last menstrual period and early pregnancy ultrasound. Preterm birth or premature birth is the birth of a baby at fewer than 37th week gestational age was also reported. Birth weight of infants was measured to the nearest 10 g using a pediatric scale (Scale-Tronix, USA). Length and head circumference of babies were measured to the nearest 1 mm during the first 24 h using (Seca 334 Scale, Germany) and Seca girth measuring tape, respectively. The birth weight percentile, length percentile, and head circumference percentile were calculated [33]. The birth weight percentile was used to categorize infant as SGA (birth weight <10th percentile), normal (10th percentile to 90th percentile), or LGA (birth weight >90th percentile) Macrosomia infants were defined as those with birth weight ≥4000 g [34]. Neonatal BMI and ponderal index (PI) were calculated according to the standard equations. The neonatal BMI was computed as birth weight (in kilograms) divided by infant length (in meters) squared, whereas, the PI was calculated as birth weight (in kilograms) divided by infant length (in meters) cubed.

2.17. Statistical analyses

To estimate the required sample size, appropriate formula was used, where the type one (α) and type two errors (β) were set as 0.05 and 0.20 (power = 80%), respectively. In addition, FBG level was defined as the key variable and based on earlier studies [16,35], and the standard deviation (SD) of this variable was 12 mg/d1. 10 mg/d1 was considered as the significant difference in mean FBG level between the control and intervention groups. Therefore, the required sample size was determined to be 23 participants in each group. Statistical analyses were performed using SPSS (IBM Corp. Released 2019. IBM SPSS Statistics for Windows, Version 26.0. Armonk, NY, USA). Mean and SD were calculated for the continuous variables. Frequency and percentage were used to describe categorical variables. The frequency of participants in terms of categorical variables was compared using X^2 test. To ensure the normal distribution of continuous variables, Shapiro–Wilk test was applied. One-way analysis (ANOVA) and Fisher's least significant

difference (LSD) post hoc test were used to detect differences between control and intervention groups in term of continuous variables. A paired t test was used to assess within-group changes in maternal metabolic profile (FBG, HbA1c, fasting insulin, HOMA-IR, and fructosamine) from baseline to end of the study. A P value < 0.05 was considered as statistically significant.

3. Results

3.1. General characteristics of participants

Participant characteristics of the 70 pregnant women who were diagnosed with GDM and took metformin are shown in Table 2. The participants were allocated into carbohydrate counting group, carbohydrate counting combined with DASH group, and control group were well matched for general characteristics. There were no significant differences between participants across the three groups in terms of maternal age, height, pre-pregnancy weight, pre-pregnancy BMI, baseline body weight, baseline gestational age, physical activity level, OGTT results, and daily metformin dose ($P > 0.05$). Educational level, the rate of positive history of GDM and family history of type 2 diabetes, and parity did not differ significantly among women in the three groups (Table 3). Twelve women had been diagnosed with GDM in a previous pregnancy (carbohydrate counting combined with DASH, n = 2; carbohydrate counting, n = 6; control, n = 4; $P = 0.293$). Most of the participants were multiparous (Table 2).

3.2. Dietary intakes of the study participants at baseline and end-of-intervention

Daily dietary intakes of the study participants are presented in Table 3. Based on the 3-day dietary records that participants provided at baseline and end-of intervention, there were no significant differences among the three groups regarding dietary intake of protein, carbohydrate, saturated fatty acids, monounsaturated fatty acids, polyunsaturated fatty acids, and cholesterol at baseline. The number of carbohydrate counting was matched between the carbohydrate counting group and the carbohydrate counting combined with DASH group. There were significant differences in intake of energy and dietary intake of carbohydrates, added sugar, dietary fiber, vitamin C, vitamin D, calcium, magnesium, potassium, and sodium among the three groups ($P < 0.05$). Intake of energy, carbohydrate, dietary fiber, vitamin C, vitamin D, calcium, magnesium, and potassium was significantly higher in the carbohydrate counting combined with DASH group ($P < 0.05$). The participants in the carbohydrate counting group and the control group had significantly higher intake of simple sugar, sodium, grains, fats and oils compared to those in the carbohydrate counting combined with DASH group ($P < 0.05$). The consumption of vegetables, fruits, and dairy products was significantly higher in the carbohydrate counting combined with DASH group as compared to the carbohydrate counting group and the control group ($P < 0.05$) (Table 3).

At the end of intervention, the dietary intakes were like those record at the baseline except intake of carbohydrate, magnesium, and potassium. Intake of carbohydrate and the number of carbohydrate exchanges decreased significantly in the participants of the carbohydrate counting group ($P < 0.05$). The participants in the control group significantly decreased intake of magnesium, and potassium ($P < 0.05$) (Table 3).

3.3. Metabolic profiles of the study participants

Table 4 displays metabolic profile of the study participants. At baseline, biochemical parameters were similar among groups and the differences were not statistically significant. At the end of the intervention, biochemical parameters were different among groups. Adherence to the three dietary interventions, resulted in decreasing FBG levels. Pregnant women in the carbohydrate counting group had significantly the lowest FBG level (78.5 ± 8.2 mg/dl) as compared with that in the carbohydrate counting combined with DASH group (80.9 ± 9.4 mg/dl) and control group (86.7 ± 12.0 mg/dl) ($P = 0.021$). Insulin levels (carbohydrate counting combined with DASH 48.7 ± 16.7 pmol/l vs. carbohydrate counting 79.3 ± 40.2 pmol/l vs. control 86.6 ± 61.4; $P = 0.026$) and HOMA-IR score (carbohydrate counting combined with DASH 0.91 ± 0.32% vs. carbohydrate counting 1.4 ± 0.71% vs. control 1.6 ± 1.1%; $P = 0.038$) decreased significantly among participants who followed carbohydrate counting combined with DASH dietary intervention. Fructosamine and HbA1c values did not differ significantly among the three intervention groups (Table 4).

Compared with data at baseline, means of FBG decreased significantly in the participants of the three dietary intervention groups ($P < 0.05$). Great change in FBG was observed in the carbohydrate counting combined with DASH group as compared with carbohydrate counting group and control group (carbohydrate counting combined with DASH -14.2 mg/dl vs. carbohydrate counting −12.5 mg/dl vs. control −7.4 mg/dl). Participants in the control group had significantly higher HOMA2-IR score ($P < 0.001$), fructosamine level ($P = 0.010$), and HbA1c value ($P = 0.010$) than those in the others two groups. The HOMA2-IR score decreased significantly in the carbohydrate counting combined with DASH group compared to the others two groups ($P = 0.048$).

3.4. Home-monitored blood glucose levels

For the remainder of participants, mean capillary blood glucose level was maintained within the target fasting and postprandial ranges. Home-monitored blood glucose levels of participants are given in Table 5. Daily FBG concentrations were significantly lower in the carbohydrate counting group and the carbohydrate counting combined with DASH group compared with those in control group (carbohydrate counting combined with DASH 81.8 ± 5.8 mg/dl vs. carbohydrate counting 81.3 ± 6.8 mg/dl vs. control 88.4 ± 5.8 mg/dl; $P = 0.002$). Overall mean of 1 h PG concentration was significantly lower in the carbohydrate counting combined with DASH group compared with that in the carbohydrate counting group and the control group ($P < 0.001$). When postprandial glucose measures were separated into breakfast, lunch, and dinner meals, 1 h PG levels were lower specifically after breakfast and dinner in the carbohydrate counting combined with DASH group ($P < 0.001$).

3.5. Maternal and neonatal outcomes

Maternal and neonatal outcomes of the study participants are presented in Table 6. There were no significant differences among the three intervention diet groups in any of the maternal outcomes (pregnancy induced hypertension, preeclampsia, labor induction and emergency caesarean-section) and neonatal outcomes (neonatal birth weight, birth weight percentile, neonatal length, head circumference, BMI, PI, Apgar score, and NICU admission), except needing for insulin therapy. The number of women whose condition required insulin therapy was significantly different among the three intervention groups. Sixteen women required insulin therapy (carbohydrate counting combined with DASH, n = 3 vs. carbohydrate counting, n = 3 vs. control, n = 10; $P = 0.026$). Fewer women in the carbohydrate counting group and the carbohydrate counting combined with DASH group needed insulin therapy (Table 6).

Table 2
General characteristics of the study participants.

Continuous Variable	Control n = 24	CHO Counting n = 23	CHO Counting and DASH n = 23	*P* *
	Mean ± SD			
Maternal age (years)	33.6 ± 4.9	34.0 ± 4.3	33.1 ± 5.0	0.839
Height (m)	1.6 ± 0.05	1.6 ± 0.07	1.6 ± 0.07	0.983
Pre-pregnancy body weight (kg)	77.2 ± 19.2	76.5 ± 17.2	75.4 ± 15.6	0.972
Body weight at the baseline (kg)	85.0 ± 17.6	86.0 ± 17.0	84.9 ± 14.0	0.976
Pre-pregnancy BMI (kg/m²)	29.7 ± 6.3	29.3 ± 6.0	29.3 ± 7.2	0.957
Gestational age at entry (week)	27^{+5} ± 2.2	28^{+6} ± 2.1	28^{+5} ± 2.2	0.150
Metformin dose (mg/day)	2252.1 ± 588.6	2039.1 ± 732.2	1921.7 ± 722.7	0.250
Total physical activity (MET-h/week)	111.7 ± 37.2	130.9 ± 54.3	134.3 ± 59.7	0.575
By intensity of activity (MET-h/week)				
Sedentary	29.7 ± 15.3	34.2 ± 17.2	32.7 ± 19.5	0.932
Light	68.9 ± 25.4	72.3 ± 30.7	80.2 ± 32.1	0.362
Moderate	13.1 ± 2.3	24.2 ± 6.3	21.3 ± 6.3	0.861
Vigorous	0	0.31 ± 0.21	0.78 ± 0.07	0.185
By type of activity (MET-h/week)				
Household/caregiving	76.8 ± 35.9	88.7 ± 50.0	89.9 ± 52.6	0.733
Occupational	15.0 ± 4.2	25.8 ± 6.4	30.7 ± 5.8	0.075
Sport/exercise	0.28 ± 0.23	0.44 ± 0.17	0.55 ± 0.28	0.728
Transportation activity	9.8 ± 2.0	11.2 ± 2.0	9.7 ± 1.7	0.990
Inactivity	18.5 ± 3.2	18.9 ± 3.3	19.9 ± 3.5	0.940
75 g OGTT results (mg/dl)				
Fasting	95.5 ± 13.6	90.8 ± 11.4	94.4 ± 13.8	0.444
1 h	172.8 ± 26.9	172.2 ± 15.8	169.6 ± 36.7	0.750
2 h	143.3 ± 17.1	144.9 ± 26.2	143.9 ± 22.4	0.974
Metformin dose (mg/day)	2252.1 ± 588.6	2039.1 ± 732.2	1921.7 ± 722.7	0.250
Categorical Variable n (%)				
Educational Attainment				
High school or less	7 (29.2)	3 (13.0)	3 (13.0)	0.131
Associate degree	8 (33.3)	6 (26.1)	2 (8.7)	
Bachelor's degree	9 (37.5)	12 (52.2)	16 (69.6)	
Master's degree or higher	0 (0)	2 (8.7)	2 (8.7)	
Positive history of GDM	4 (16.7)	6 (26.1)	2 (8.7)	0.293
Family history of type 2diabetes	14 (58.3)	13 (56.5)	12 (52.2)	0.910
Maternal	10 (41.7)	8 (34.8)	9 (39.1)	0.887
Paternal	8 (33.3)	8 (34.8)	7 (30.4)	0.950
Parity				
Nulliparous	5 (20.8)	2 (8.7)	4 (17.4)	0.477
Multiparous	19 (79.2)	21 (91.3)	19 (82.6)	0.502

Abbreviation: BMI: Body Mass Index; OGTT: Oral Glucose Tolerance Test; MET-h/week: Metabolic Equivalent Hours/Week; GDM: Gestational Diabetes Mellitus.
**P* values calculated by one-way ANOVA for continuous variables and Pearson X^2 for categorical variables.
P value < 0.05 was considered statistically significant.

More than 50% of women gained an acceptable amount of weight according to the American IOM guidelines (carbohydrate counting combined with DASH 65.2% vs. carbohydrate counting 52.2% vs. control 58.3%%; $P = 0.688$). Participants in the control group appeared to gain less weight than those in the carbohydrate counting group and the carbohydrate counting combined with DASH group (carbohydrate counting combined with DASH 9.9 ± 5.6 kg vs. carbohydrate counting 9.5 ± 5.4 kg vs. control 8.0 ± 5.7 kg; $P = 0.448$) (Table 6). No incidences of macrosomia and shoulder dystocia were reported among the groups. Episodes of neonatal hypoglycemia were observed in the control group (n = 2) and the carbohydrate counting group (n = 1) (Table 6).

4. Discussion

Medical Nutritional therapy is the main treatment for GDM and consequently, it has a significant effect on women and newborns. It was found that carbohydrate counting and carbohydrate counting combined with DASH dietary interventions significantly improved FBG and 1 h PG as compared with control dietary intervention in GDM. Large reduction in FBG was observed in the participants who followed carbohydrate counting diet and carbohydrate counting combined with DASH diet compared with control diet. These findings suggest that carbohydrate counting combined with DASH dietary intervention is more effective for improving glycemic control in GDM women. The explanation for these findings is that participants of carbohydrate counting group and carbohydrate counting combined with DASH group distributed their carbohydrate intake throughout the day in three small-to moderate meals and three to four snacks. Some studies revealed that carbohydrate counting can provide better glycemic control and improve quality of life for patients with type 1 diabetes [36–38]. A previous study that explored blood glucose control by a DASH diet compared with the control diet in women with GDM demonstrated that DASH diet improved glucose tolerance in such that plasma glucose levels reduced at 60 min (−1·86 vs. 0·45 mmol/l, $P = 0·02$), 120 min (−2·3 vs. 0·2 mmol/l, $P = 0·001$), and 180 min (−1·7 vs. 0·22 mmol/l, $P = 0·002$) after the glucose load [40]. However, Asemi et al. [39] found a significant difference in mean changes of FPG between DASH diet and control diet. Metformin also reduces hyperglycemia by suppressing hepatic gluconeogenesis, increasing insulin sensitivity, and enhancing peripheral glucose uptake [40].

The carbohydrate counting combined with DASH diet in this study resulted in increase of consumption of fiber and low GI compared to the carbohydrate counting diet and control diet. Dietary fiber intake could delay gastric emptying and slow down the rate of carbohydrate digestion, thus decreasing postprandial glucose levels [41,42]. Previous studies have also reported that low

Table 3
Baseline and end-of-intervention daily dietary intakes of the study participants.

Nutrients	Baseline			*P**	End of intervention			*P**	*P***		
	Control n = 24	CHO Counting n = 23	CHO Counting and DASH n = 23		Control n = 24	CHO Counting n = 23	CHO Counting and DASH n = 23		Control	CHO Counting	CHO Counting and DASH
	Mean ± SD				Mean ± SD						
Energy (kcal)	1802.3 ± 78.4[b]	1805.5 ± 103.4[b]	1891.7 ± 66.8[a]	0.007	1843.4 ± 108.2[b]	1790.3 ± 86.5[b]	1887.5 ± 82.3[a]	0.029	0.271	0.537	0.821
Protein (g)	89.1 ± 8.7	91.1 ± 6.5	95.1 ± 4.7	0.055	91.9 ± 5.1	90.8 ± 4.7	95.5 ± 4.0	0.071	0.504	0.825	0.957
Carbohydrate (g)	226.7 ± 13.4[b]	222.0 ± 18.1[b]	240.9 ± 9.5[a]	0.001	230.6 ± 15.1[a]	220.0 ± 20.0[b]	240.3 ± 15.1[a]	0.008	0.785	0.001	0.941
Added Sugar (g)	10.5 ± 3.8[a]	12.8 ± 9.9[a]	1.7 ± 2.4[b]	0.001	12.3 ± 2.6[a]	10.5 ± 4.0[a]	0.85 ± 1.8[b]	0.001	0.439	0.434	0.129
CHO counting (n)	–	15.0 ± 1.2[b]	16.0 ± 0.6[a]	0.564	–	14.6 ± 1.3[b]	16.0 ± 1.0[a]	0.008	0.785	0.541	0.941
Dietary Fiber (g)	22.2 ± 4.5[b]	23.9 ± 4.5[b]	32.7 ± 2.9[a]	0.001	23.5 ± 4.7[b]	25.0 ± 4.3[b]	32.9 ± 3.8[a]	0.001	0.668	0.356	0.942
Fat (g)	62.3 ± 8.0	67.7 ± 11.0	63.1 ± 6.2	0.201	63.8 ± 8.4	65.7 ± 8.3	63.3 ± 6.9	0.697	0.261	0.414	0.956
SFA (g)	17.9 ± 2.4	19.3 ± 4.4	17.3 ± 2.6	0.23	19.3 ± 3.0	17.6 ± 2.3	17.5 ± 2.3	0.160	0.257	0.166	0.951
MUFA (g)	19.4 ± 3.6	20.0 ± 4.6	20.8 ± 3.4	0.629	16.9 ± 3.2[b]	20.2 ± 4.3[a]	20.2 ± 2.7[a]	0.031	0.090	0.913	0.657
PUFA(g)	12.0 ± 3.3	11.8 ± 2.9	10.3 ± 2.4	0.233	9.6 ± 1.9[b]	11.7 ± 3.0[a]	9.1 ± 2.6[b]	0.026	0.068	0.949	0.217
Cholesterol (mg)	207.1 ± 52.5	243.5 ± 60.9	215.9 ± 60.5	0.234	220.0 ± 59.1	245.5 ± 61.1	196.1 ± 43.4	0.072	0.634	0.932	0.526
Vitamin C (mg)	132.8 ± 42.6[b]	149.1 ± 49.5[b]	210.9 ± 67.9[a]	0.001	150.9 ± 49.4[b]	147.1 ± 45.9[b]	237.3 ± 86.2[a]	0.001	0.252	0.911	0.079
Vitamin D (IU)	168.5 ± 54.95[b]	182.1 ± 56.6[b]	231.3 ± 40.9[a]	0.004	174.7 ± 64.2[b]	192.4 ± 58.3 [ab]	229.4 ± 45.5[a]	0.049	0.786	0.520	0.813
Calcium (mg)	1290.0 ± 200.4[b]	1288.1 ± 140.6[b]	1649.9 ± 215.1[a]	0.001	1252.9 ± 203.0[b]	1246.0 ± 210.4[b]	1578.4 ± 168.5[a]	0.001	0.088	0.490	0.176
Magnesium (mg)	241.5 ± 38.8[b]	223.6 ± 77.7 [ab]	303.1 ± 117.7[a]	0.038	216.9 ± 39.0[b]	216.1 ± 78.0[b]	292.3 ± 117.5[a]	0.040	0.014	0.474	0.660
Potassium (mg)	2926.4 ± 386.8[b]	2640.4 ± 471.5[b]	3702.2 ± 651.7[a]	0.001	2791.9 ± 364.9[b]	2703.1 ± 425.3[b]	3752.5 ± 691.4[a]	0.001	0.021	0.643	0.565
Sodium (mg)	4155.8 ± 560.8[a]	3800.3 ± 808.1[a]	2004.7 ± 437.5[b]	0.001	4434.9 ± 523.0[a]	4002.6 ± 690.7[a]	2071.0 ± 433.3[b]	0.001	0.543	0.526	0.685
Food Groups											
Grains (ounce)	7.2 ± 0.66[a]	7.3 ± 1.2[a]	6.2 ± 1.5[b]	0.040	7.2 ± 1.1[a]	7.3 ± 0.82[a]	6.3 ± 1.3[b]	0.033	0.814	0.893	0.995
Proteins (ounce)	4.9 ± 1.2	4.7 ± 0.79	4.8 ± 1.1	0.929	4.6 ± 0.95	4.8 ± 0.82	4.8 ± 0.70	0.796	0.467	0.803	0.940
Vegetables (cup)	3.9 ± 0.86[b]	3.7 ± 0.95[b]	4.7 ± 0.83[a]	0.010	3.8 ± 0.78[b]	3.6 ± 0.89[b]	4.9 ± 0.64[a]	0.001	0.603	0.519	0.385
Fruits (cup/day)	2.2 ± 0.65[b]	2.2 ± 0.60[b]	3.2 ± 0.45[a]	0.001	2.4 ± 0.47[b]	2.3 ± 0.39[b]	3.3 ± 0.47[a]	0.001	0.815	0.162	0.390
Dairy products (cup)	3.0 ± 0.62[b]	3.1 ± 0.47[b]	3.9 ± 0.33[a]	0.001	3.0 ± 0.65[b]	3.0 ± 0.50[b]	3.9 ± 0.31[a]	0.001	0.711	0.528	0.754
Fats and oils (serving)	8.0 ± 1.5[a]	8.5 ± 1.3[a]	7.0 ± 1.2[b]	0.003	7.7 ± 2.1[a]	8.6 ± 1.5[a]	6.5 ± 1.0[b]	0.005	0.111	0.866	0.761

Abbreviation: CHO: Carbohydrate; DASH: Dietary Approach to Stop Hypertension; MUFA: Monounsaturated Fatty Acids; PUFA: Poly unsaturated Fatty Acids; SAF: Saturated Fatty Acids.
**P* values obtained from one-way NOVA to test for difference between groups and *Fisher's* LSD post hoc test was used and means within the same row with different superscript letters are significantly different.
***P* values obtained from paired sample t test to examine difference between baseline and end of intervention.
P value < 0.05 was indicated statistically significant.

glycemic diets are effective for controlling the level of postprandial glucose [43,44] and FBG [45] in pregnant diabetic women.

The advantage for glycemic control in the present study was observed despite a lack of significant differences in HbA1c and fructosamine among the three groups after 10–12 weeks of dietary intervention compared with baseline. In contrast, Asemi et al. [39] found that consumed DASH diet for 4 weeks decreased HbA1c levels compared with control diet among pregnant women with GDM (- 0·2 vs. 0·05%, $P = 0·001$).

The combination of carbohydrate counting with DASH diet in pregnant women with GDM reduced insulin levels and HOMA-IR score. The effect of DASH diet on insulin levels and HOMA-IR score have previously been studied in Iranian pregnant women with GDM [15]. Asemi et al. [15] also documented that DASH diet reduced insulin levels and HOMA-IR score. Numerous studies demonstrated the effects of the DASH diet on serum insulin levels and HOMA-IR score in adults [46,47]. Hinderliter et al. [48] found that the consumption of the DASH diet improved insulin sensitivity of overweight people. It appears that the DASH diet could be recommended as a healthy dietary pattern to all individuals including pregnant women with metabolic abnormalities.

The valuable effects of the carbohydrate counting combined with DASH diet on insulin resistance could be explained by several mechanisms. Firstly, the dietary intake of simple sugar in the carbohydrate counting combined with DASH diet group in the current study was very low as compared with the carbohydrate counting diet and the control diet, whereas its dietary fiber content was higher than the carbohydrate counting diet and the control diet. Previous studies have revealed that high simple sugar diet could increase insulin resistance and impair insulin sensitivity [49,50]. Asemi et al. [15] reported that higher dietary fiber content of the DASH diet was also responsible for improvement in insulin sensitivity among Iranian pregnant women with GDM. Secondly, the DASH diet is also a rich source of dietary magnesium and calcium which ameliorate insulin resistance [51–53]. Thirdly, low dietary sodium intake reduces insulin secretion [54] and improves insulin sensitivity in humans [55]. High sodium intake may aggravate insulin resistance through increasing circulating free fatty acids [56] and activation of sympathetic nervous system and the renin–angiotensin–aldosterone system [57]. Excess dietary salt increases signaling by the mineralocorticoid receptor, results in increased production of reactive oxygen species and oxidative stress. The excess reactive oxygen species and oxidative stress trigger insulin resistance [58]. Finally, further beneficial effect of the carbohydrate counting combined with DASH diet could contribute to high potassium intake. It was reported that dietary potassium can improve insulin resistance by inhibition of central sympathetic nerve, suppression of salt-induced insulin resistance, and decreasing generation of reactive oxygen species [59].

There was no significant difference in weight gain during pregnancy among the pregnant women who followed carbohydrate counting, carbohydrate counting combined with DASH diet,

Table 4
Biochemical parameters at baseline and end-of-intervention of the study participants.

Biochemical Parameters	Baseline			P*	End of intervention			P*	Change P**		
	Control n = 24	CHO Counting n = 23	CHO Counting and DASH n = 23		Control n = 24	CHO Counting n = 23	CHO Counting and DASH n = 23		Control	CHO Counting	CHO Counting and DASH
	Mean ± SD				Mean ± SD						
Fasting BG (mg/dl)	94.1 ± 15.7	91.0 ± 11.0	95.0 ± 14.1	0.650	86.7 ± 12.0[a]	78.5 ± 8.2[b]	80.9 ± 9.4[ab]	0.021	−7.4 0.012	−12.5 < 0.001	−14.1 < 0.001
Insulin (pmol/L)	66.4 ± 53.0	75.5 ± 39.0	62.9 ± 27.8	0.358	86.6 ± 61.4[a]	79.3 ± 40.2[a]	48.7 ± 16.7[b]	0.026	20.2 0.109	3.8 0.495	−14.2 0.051
HOMA2-IR (%)	1.2 ± 0.98	1.4 ± 0.74	1.2 ± 0.52	0.384	1.6 ± 1.1[a]	1.4 ± 0.71[a]	0.91 ± 0.32[b]	0.038	0.4 < 0.001	0 0.823	−0.2 0.048
Fructosamine (mmol/L)	205.5 ± 28.3	210.7 ± 22.1	206.1 ± 21.7	0.687	219.2 ± 27.2	219.6 ± 24.9	210.4 ± 19.3	0.364	13.7 0.010	8.9 0.165	4.3 0.354
HbA1c (%)	5.1 ± 0.48	5.2 ± 0.38	5.1 ± 0.37	0.702	5.3 ± 0.46	5.3 ± 0.42	5.2 ± 0.33	0.364	0.2 0.010	0.1 0.165	0.1 0.354

Abbreviation: FBG: Fasting Blood Glucose; HOMA2-IR: Homeostasis Model Assessment of Insulin Resistance; HbA1c: Glycated Hemoglobin.
*P values obtained from one-way ANOVA to test for difference between groups and *Fisher's* LSD post hoc test was used and means within the same row with different superscript letters are significantly different.
**P values obtained from paired sample *t* test to examine difference between baseline and end of intervention.
P value < 0.05 was indicated statistically significant.

Table 5
Home-monitored blood glucose levels of participants.

Blood glucose mg/dl	Control n = 24	CHO Counting n = 23	CHO Counting and DASH n = 23	P*
	Mean ± SD			
Fasting	88.4 ± 5.8[a]	81.3 ± 6.8[b]	81.8 ± 5.8[b]	0.002
Breakfast (1 h PG)	129.6 ± 4.9[a]	116.3 ± 11.1[b]	111.8 ± 8.1[b]	<0.001
Lunch (1 h PG)	129.1 ± 5.5[a]	119.5 ± 8.5[b]	115.9 ± 6.9[b]	<0.001
Dinner (1 h PG)	123.7 ± 7.5[a]	117.5 ± 10.0[b]	110.8 ± 8.4[c]	<0.001
Pooled post-meal	127.5 ± 5.2[a]	117.8 ± 8.2[b]	112.8 ± 5.7[c]	<0.001

Abbreviation: 1 h PG: One Hour Postprandial Glucose.
*P values calculated by one-way ANOVA to test for difference between groups and *Fisher's* LSD post hoc test was used and means within the same row with different superscript letters are significantly different.
P value < 0.05 was considered statistically significant.

and control diet. The average weight gain during pregnancy was calculated and ranged from 8 to 10 kg with a proposed target weight gain for overweight women [60]. Healthy women should not gain more than 16 kg during pregnancy, and obese women not more than 9 kg [60]. More than half of women gained an acceptable amount of weight according to the American IOM guidelines [60].

The carbohydrate counting diet and the carbohydrate combined with DASH diet could significantly reduce the number of women who are required to initiate insulin therapy. One explanation for this finding is that the carbohydrate counting diet and the carbohydrate combined with DASH diet were effective in achieving glycemic control. Similar finding was reported by Asemi et al. [16]. Asemi et al. [16] found that percentage of GDM participants who are needed to initiate insulin therapy after intervention was also significantly different between the DASH diet and control diet (23% for DASH vs.73% for control group, $P < 0$ .0001). Previous studies have shown that participants needed supplemental insulin therapy beside metformin to attain euglycemia and reduce the incidence of maternal and fetal complications [19,61]. On the other hand, some studies reported that no supplemental insulin was required in GDM patients who are treated with metformin and control diet [62,63].

Gestational diabetes is associated with several adverse pregnancy and neonatal outcomes [3,4]. The current study showed no significant differences in the rate of emergency caesarean-section, and incidence of pregnancy induced hypertension and pre-eclampsia. However, Asemi et al. [16] indicated that consumption of DASH eating pattern for 4 weeks among pregnant women with GDM reduced rate of cesarean-section compared with control diet.

There were no significant differences in the incidence of maternal–fetal outcomes, including preterm delivery, macrosomia, neonatal hypoglycemia, shoulder dystocia and NICU admission among the carbohydrate counting, the carbohydrate counting combined with DASH, and control groups. Average infant birth weight, birth weight centile, infant birth length, infant birth head circumference, BMI and PI were within healthy norms in all groups. In contrast, Asemi et al. [16] reported that infant birth weight, head circumference, and PI in offspring were significantly lower among women who followed the DASH diet versus control diet. Yamamoto et al. [12] showed that modified dietary interventions were associated with lower infant birth weight and less macrosomia in pregnant women with GDM compared with control dietary intervention.

The main strength of the current study is that the allocation of participants in the study groups was randomized. Randomization balanced known and unknown confounders and enhances similarity of baseline features of all study groups. Moreover, sample size of participants was adequately powered to avoid both type 1 error and type 2 error.

Several limitations must be considered when interpreting findings of this study. Firstly, the current study was a behavioral intervention study rather than a double-blinded randomized controlled trial. Both researcher and the participants could not be

Table 6
Maternal and neonatal outcomes of the study participants.

Variable	Control n = 24	CHO Counting n = 23	CHO Counting and DASH n = 23	*P* *
Body weight at end of the study (kg)	85.0 ± 17.1	86.3 ± 15.6	84.6 ± 14.2	0.925
Total maternal weight gain (kg)	8.0 ± 5.7	9.5 ± 5.4	9.9 ± 5.6	0.448
Below target n (%)[a]	6 (25.0)	6 (26.1)	4 (17.4)	0.745
Within target n (%)[a]	14 (58.3)	12 (52.2)	15 (65.2)	0.688
Above target n (%)[a]	4 (16.7)	5 (21.7)	4 (17.4)	0.891
Required insulin (n (%))	10 (41.7)	3 (13.0)	3 (13.0)	0.026
Labour induction (n (%))	11 (45.8)	8 (34.8)	7 (30.4)	0.529
Emergency caesarean-section (n (%))	4 (16.7)	1 (4.3)	3 (13.0)	0.607
Pregnancy induced hypertension (n (%))	0 (0)	0 (0)	0 (0)	–––––
Preeclampsia (n (%))	0 (0)	0 (0)	0 (0)	–––––
Gestational age at birth (week)	37^{+5} ± 0.89	37^{+4} ± 0.86	37^{+1} ± 1.4	0.395
Preterm birth (n (%))	5 (20.8)	4 (17.4)	8 (34.8)	0.345
Birth weight (kg)	3.1 ± 0.39	3.0 ± 0.35	2.9 ± 0.44	0.210
Birth weight percentile (%)	49.0 ± 29.0	44.4 ± 22.0	42.6 ± 21.9	0.660
Neonatal length (cm)	49.1 ± 2.8	49.1 ± 2.1	48.4 ± 2.6	0.551
Neonatal head circumference (cm)	34.4 ± 0.94	34.3 ± 1.3	34.0 ± 1.6	0.588
Neonatal PI (kg/m^3)	26.3 ± 4.4	25.5 ± 4.0	25.5 ± 3.3	0.760
Neonatal BMI (kg/m^2)	12.9 ± 1.7	12.6 ± 1.8	12.4 ± 1.5	0.630
LGA (n (%))	1 (4.2)	0 (0)	0 (0)	0.378
SGA (n (%))	2 (8.3)	0 (0)	2 (8.7)	0.354
Macrosomia (n (%))	0 (0)	0 (0)	0 (0)	–––––
Apgar score at 1 min	8.0 ± 0.20	7.9 ± 0.29	8.0 ± 0.21	0.762
NICU admission (n (%))	4 (16.7)	8 (33.3)	5 (21.7)	0.409
Neonatal hypoglycaemia (n (%))	2 (8.3)	1 (4.3)	0 (0)	0.139
Shoulder dystocia (n (%))	0 (0)	0 (0)	0 (0)	–––––––

Abbreviation: BMI: Body Mass Index; PI: Ponderal Index; Large for Gestational Age; SGA: Small for Gestational Age.
Data are presented as mean ± SD or number of participants (percent).
*P values calculated by one-way ANOVA for continuous variables and Pearson X^2 for categorical variables.
$P < 0.05$ was considered statistically significant.
[a] Weight gain during pregnancy was classified below or within or above target based on Institute of Medicine [60].

blinded to the group status. Secondly, the assessment of compliance to the diets by comparing dietary nutrients intake with their relevant concentration in plasma and urine was not conducted in this study. Thirdly, examining the effects of carbohydrate counting diet and carbohydrate counting combined with DASH diet on other neonatal outcomes including respiratory distress syndrome, hypocalcemia, and hyperbilirubinemia was not carried out in the current study.

5. Conclusion

In conclusion, the carbohydrate counting and the carbohydrate counting combined with DASH dietary interventions among pregnant women with GDM resulted in beneficial effects on FBG and 1 h PG compared with a control diet. The number of women that required insulin therapy was significantly lower in the carbohydrate counting group and the carbohydrate counting combined with DASH group. The three intervention diets produced comparable maternal and neonatal outcomes in women with GDM. The carbohydrate counting combined with DASH diet appears to be a safe alternative to the conventional pregnancy diet for women with GDM and enlarges the range of dietary strategies that can be recommended to GDM pregnant women.

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Author contributions

Allehdan carried out the conception, developed the methodology, performed the experiment, and wrote the manuscript. Tayyem collaborated on the design of the study. Tayyem and Basha supervised the dissertation project. Basha, Nabhan, Hyasat, and Qasrawi provided access to the patients. Tayyem and Basha critically reviewed the manuscript. All authors have read and approved the final manuscript.

Conflict of interest

The authors declare that they have no competing interest.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.clnu.2021.11.039.

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