Original Article

Association of Whole Grains, Dairy and Dietary Fibre with Neonatal Outcomes in Women with Gestational Diabetes Mellitus: The WINGS Project (WINGS – 12)

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Abstract

Background: Dietary modifications have been shown to lower the risk for gestational diabetes mellitus (GDM). However, there is little evidence whether dietary modifications during pregnancy can improve neonatal outcomes in women with GDM, particularly in low-resource settings. **Aim:** The aim of the study is to assess the effect of a dietary modification delivered through a low-cost model of care (MOC), on neonatal outcomes in women with GDM in India. **Methodology:** Dietary intake was assessed in 133 women with GDM enrolled under the women in India with GDM strategy-MOC (WINGS-MOC), from six maternity centres in Chennai, in South India. The WINGS-MOC dietary intervention included one-on-one monthly antenatal diet counselling, providing a dietary guideline booklet and healthy recipe demonstrations. Dietary intake was assessed using 24-h dietary recall and an open-ended diet questionnaire. A 'healthy diet score' was derived from the reported intake of whole grains, dairy products and dietary fibre. The effect of healthy diet score on neonatal outcomes (macrosomia, hyperbilirubinaemia, congenital anomalies and neonatal intensive care unit admissions) was evaluated. **Results:** A six-fold increase in the intake of whole grains (30 vs. 5.1 g) and 20% increase in consumption of dairy products (265.4 vs. 225 g) and dietary fibre (22.3 vs. 18.2 g) were observed after the MOC intervention. Higher consumption of whole grain, dairy products and dietary fibre was inversely associated with adverse neonatal outcomes. Those with the highest healthy diet score had lower risk for adverse neonatal outcomes (odds ratio: 0.2, [95% confidence interval: 0.04–0.9]; $P = 0.04$) even after adjusting for potential confounders. **Conclusions:** A low-cost dietary intervention helps to improve neonatal outcomes in women with GDM.

Keywords: Dairy, dietary fibre, gestational diabetes mellitus, pregnancy outcomes, whole grains, WINGS India

Introduction

Gestational diabetes mellitus (GDM), also referred to as hyperglycaemia during pregnancy, is strongly linked to several adverse outcomes for both a mother and a baby.[1] According to the current global data, 16.2% live births are affected by hyperglycaemia during pregnancy.[2] A mother with hyperglycaemia during pregnancy is at higher risk for complications including pre-eclampsia and has a greater likelihood of undergoing caesarean section and progression to type 2 diabetes in the future. Conversely, the baby is at increased risk of macrosomia, shoulder dystocia and neonatal hypoglycaemia.[3,4] The prevalence of GDM has been increasing rapidly, especially in developing countries.[5,6] Results from various landmark studies have shown that treating GDM can help to reduce specific adverse maternal and neonatal outcomes.[7-9]

Pregnancy is an opportune time to encourage women to make lifestyle changes. Some studies have shown that

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dietary habits can be improved by interventions during pregnancy.[10] Although dietary counselling is considered an important strategy for GDM management, there is little agreement as to what is the best dietary therapy for women with GDM.[11] Several clinical trials addressing physical activity[12] and diet[13] in pregnancy have been carried out; however, most of them were underpowered to look at clinical outcomes. A recent study from India reported that diet therapy improved pregnancy outcomes, but this was based on a small sample size; further, details of the dietary intervention were not reported.[14] Many studies have assessed the risk of GDM in relation to maternal diet patterns, but there is a little evidence as to whether dietary modifications during pregnancy among women with GDM could improve pregnancy outcomes, especially among Asian Indian women.

As part of the women in India with GDM strategy (WINGS) project, we attempted to determine the dietary intake of women with GDM and to assess the effect of a dietary intervention on neonatal outcomes in women with GDM.

Methodology

The WINGS project, a partnership between the International Diabetes Federation (IDF) and the Madras Diabetes Research Foundation (MDRF), Chennai, was conceived by a panel of global experts to address the growing concerns with regard to GDM care in resource-constrained settings.[15] Under the WINGS project, a low-cost model of care (MOC) was developed for the management of GDM. The WINGS-MOC was piloted in Chennai, in Southern India, with the aim of improving maternal and neonatal outcomes in women with GDM. This also included assessing the best screening and diagnostic test for GDM in developing countries.[16,17] The MOC consisted mainly of lifestyle intervention (diet and physical activity), along with pharmacotherapy when indicated (mainly insulin which was needed by about 15% women with GDM). Results from the WINGS project showed that the pregnancy outcomes in women with GDM who were treated using structured MOC were similar to women without GDM.[18] Following delivery, several efforts were undertaken to bring back women with GDM for postpartum testing which resulted in over 95% postpartum follow-up.[19] The project also showed significant improvement in physical activity in women with GDM which was shown to be associated with improved glycaemic control and reduction in adverse neonatal outcomes.[20] This article deals with the diet component of the WINGS study.

Study population

The study included pregnant women booked for antenatal care before 28 weeks of gestation from selected maternity centres in Chennai, recruited between November 2013 and December 2014. The International Association of Diabetes in Pregnancy Study Groups criteria were used for the diagnosis of GDM.[1] Women with pre-existing diabetes, multiple pregnancy or assisted pregnancy were excluded.

Clinical information including obstetric history, family history of diabetes and previous history of GDM was collected from all the study participants using a structured case report form. Physical activity and diet intake were recorded using pre-tested questionnaires which were administered by an interviewer.

Biochemical parameters

Plasma glucose (PG) was estimated by the glucose-oxidase–peroxidase method using autoanalyser AU2700 (Beckman, Fullerton, CA, USA). Glycated haemoglobin was measured using high-performance liquid chromatography using the variant machine (BIO-RAD, Hercules, CA, USA). All samples were processed in a laboratory certified by the College of American Pathologists and by the National Accreditation Board for Testing and Calibration Laboratories, Government of India.

Neonatal outcomes

The neonatal outcomes included the presence of any one of the following conditions – macrosomia (birth weight >3.5 kg), shoulder dystocia, neonatal hypoglycaemia (blood glucose <30 mg/dl in the first 24 h of life), polycythaemia, congenital anomalies, hyperbilirubinaemia and admission to neonatal intensive care unit (NICU). These were retrieved from the obstetric records at the maternity clinics.

Dietary intervention

All pregnant women were screened at their first antenatal appointment. Those who had normal blood glucose at screening underwent oral glucose tolerance test at 24–28 weeks. The baseline visit is referred to as the 'before MOC' visit, during which anthropometric data were collected and dietary assessment was carried out. Diet was assessed using an open-ended diet questionnaire and 24-h diet recall. The open-ended diet questionnaire included data pertaining to the choice of main cereal staple, frequency of fruits and vegetables, fat intake and consumption of dairy products. The food and nutrient intake reported by the participants were estimated using in-house nutrient database EpiNu (Version 1, Madras Diabetes Research Foundation, Chennai, Tamil Nadu, India; 2006).

Following the diagnosis of GDM, women with GDM were enrolled into the WINGS-MOC. As part of the WINGS-MOC, women were educated about GDM and its implications. The dietary intervention included one-on-one dietary counselling with trained nutritionists who advised them on following a proper meal pattern. They were counselled on both short-term and long-term implications of GDM on their pregnancy outcomes and were guided to choose a healthy diet using a visually printed plate model. The health meal pattern advice in the printed plate model including replacing refined grain with whole grains; increasing dairy products (good source of protein and calcium) and increasing dietary fibre-rich foods such as whole grains, pulses, legumes, fruits and vegetables and restricting sugar intake. They were asked to chart down their meal pattern and food choices. Women with GDM were followed up for a mean duration of 20 weeks. Diet counselling/advice was reinforced at every monthly visit, and the dietary intake was again assessed using the open-ended diet questionnaire and 24-h repeat dietary recall at every visit after GDM diagnosis to check compliance to the diet counselling. In addition to diet counselling, women were also counselled about the importance of physical activity. Printed dietary educational material in the form of a booklet called 'having a baby' was provided after GDM diagnosis. The booklet contains facts about GDM, sample meal plans and details about management of GDM. Women were also given pedometers and were encouraged to chart their daily step count in this booklet. This booklet and other intervention materials can be accessed at the IDF website: https://www.idf.org/e-library/guidelines/97-having-a-baby-now-is-the-time-to-learn-more-about-gestational-diabetes.html. The development and implementation of the WINGS-MOC have been explained in detail in the previous publications.[15]

Patient engagement activities through recipe demonstrations and nutrition education activities were conducted in all the maternity centres by nutrition experts. Towards the end of the pregnancy (between 30 and 35 weeks), called the 'after MOC' visit, questionnaires and anthropometry details were recorded again. A 'healthy diet score' was derived as explained below from the reported intake of whole grains, dairy products and dietary fibre, the effect of which was evaluated on neonatal outcomes such as macrosomia, hyperbilirubinaemia, congenital anomalies and admissions to NICU.

Derivation of healthy diet score

Regression analysis was used to identify the dietary determinants that are significantly associated with the neonatal outcomes. Three dietary factors (whole grains, dairy products and dietary fibre) that were found to be strongly associated with neonatal outcomes were considered while developing the 'healthy diet score.' Whole grains included whole wheat flour and its products, brown rice and unpolished millets. Dairy products included milk and milk products. Dietary fibre for healthy diet score includes dietary fibre from whole grains, fruits, vegetables, pulses and legumes. Each dietary factor was given a score of 1 for less than median and 2 for greater than median reported intake. The total score was calculated and then categorised into tertiles. The highest tertile (T3) indicates a healthy dietary score (median score = 6), while the lower two tertiles (T1 and T2) were grouped as the risk group (median score = 4) and was considered as a reference. Logistic regression analysis was used to determine the association between the diet score and neonatal outcomes such as macrosomia, hyperbilirubinaemia, congenital anomalies and admission to NICU after adjusting for potential confounders.

Statistical analysis

Statistical analysis was performed using SPSS software (version 22.0; SPSS, Inc., Chicago, IL, USA). Data were expressed as median (interquartile range) or proportions as the data were not normally distributed. Significance of differences between groups was tested using the Mann–Whitney test. Chi-square test was used to test differences in proportions. The association of dietary factors and neonatal outcomes was examined using logistic regression analysis and odds ratio (ORs) were calculated. Covariates included in the model were family history of diabetes, previous history of diabetes, gestational age at delivery, medication during pregnancy (yes/no), total weight gain during pregnancy (kg), physical activity (active/inactive), body mass index (BMI) (kg/m^2), maternal complications, full-term birth (yes/no), energy (kcal/d), carbohydrates (%E), fat (%E), saturated fatty acids (SFA) (g/d), monounsaturated fatty acids (MUFAs) (g/d), polyunsaturated fatty acids (g/d), milk and its products, fruits and vegetables (g/d), egg (g/d) and added sugar (g/d).

Results

A total of 1086 women were screened for GDM in the WINGS study and data on dietary patterns were available in 881 women. Figure 1 shows the study design. Of those screened, women with GDM (n = 133) were enrolled for the intervention under the WINGS-MOC. The prevalence of neonatal outcome was 22.6% (n = 30). Table 1 shows the baseline clinical characteristics of women with and without GDM screened, for whom dietary information was available. The mean gestational age of women with GDM was 19 weeks. There was no difference in weight (60.0 kg vs. 60.0 kg, P = 0.95) and BMI (25.0 vs. 24.4, P = 0.12) of women with GDM and those without GDM. About 6% of women with GDM reported the previous history of GDM and 43% had a family history of diabetes. There was a significant difference in the gestation age at delivery (38.0 weeks vs. 39.0 weeks, P < 0.001) of women with GDM and without GDM, whereas there was no difference in the birth weight of the babies.

Table 2 shows the nutritional profile of women with GDM before and after the implementation of the MOC. After the MOC intervention, there was a six-fold increase in the intake of whole grains (30 vs. 5.1 g, P < 0.001) and the consumption of dairy products was increased by 20% (265.4 vs., 225 g,

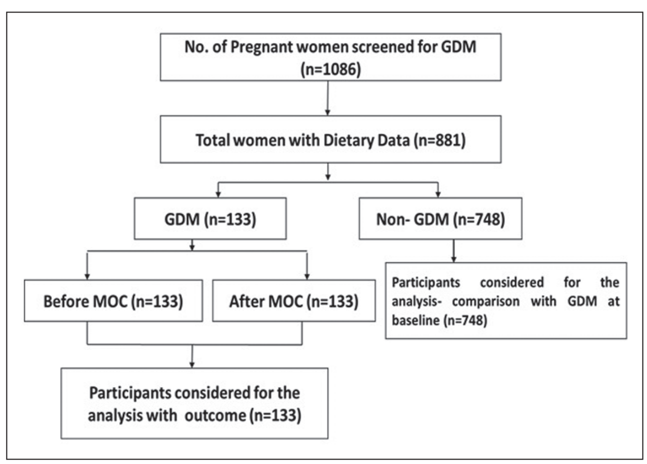

Figure 1: Flowchart depicting the study design

Table 1: Baseline characteristics of women with and without gestational diabetes mellitus

Parameters	Median (IQR)		P*
	Women with GDM (n=133)	Women without GDM (n=748)	
Age (years)	28.0 (7.0)	27.0 (5.0)	0.207
Gestation age at the recruitment (weeks)	19.0 (12.0)	18.5 (12.0)	0.434
Height (cm)	154.0 (8.0)	156.0 (8.0)	<0.001
Weight (kg)	60.0 (18.0)	60.0 (17.0)	0.955
BMI (kg/m²)	25.0 (6.0)	24.4 (6.1)	0.117
Primi mothers, *n* (%)	50 (39.4)	364 (51.6)	<0.001
Previous history of GDM, *n* (%)	8 (6.3)	16 (2.3)	0.020
Family history of DM, *n* (%)	55 (43.3)	247 (35.0)	0.046
Gestation age at delivery (weeks)	38.0 (2.0)	39.0 (2.0)	<0.001
Birth weight (kg)	3.0 (0)	3.0 (0)	0.341

**P*<0.050 is considered as significant. Tested using Mann–Whitney. BMI: Body mass index, GDM: Gestational DM, DM: Diabetes mellitus, IQR: Interquartile range

Table 2: Nutritional profile of gestational diabetes mellitus women before and after model of care (n=133)

Description	Median (IQR)		P*
	Before MOC (n=133)	After MOC (n=133)	
Energy (kcal)	1546.0 (701.6)	1586.8 (590.2)	0.523
Protein g (g/d)	42.8 (22.1)	47.8 (19.0)	0.226
Protein (%E)	11.1 (1.9)	11.5 (1.6)	0.084
Fat (g/d)	42.0 (30.8)	46.0 (24.9)	0.596
Fat (%E)	25.5 (7.4)	25.9 (6.7)	0.410
Carbohydrate (g/d)	236.6 (111.8)	246.0 (86.9)	0.704
Carbohydrate (%E)	63.9 (8.8)	63.1 (6.4)	0.189
Dietary fibre (g/d)	18.2 (12.9)	22.3 (13.2)	0.007
Weighted glycaemic index	63.1 (7.2)	62.9 (5.8)	0.582
Glycaemic load (g/d)	135.0 (59.5)	138.6 (50.7)	0.738
Total SFA (g/d)	12.5 (10.8)	13.1 (8.4)	0.625
Total SFA (%E)	7.5 (3.7)	7.6 (2.6)	0.440
Total MUFA (g/d)	11.3 (8.0)	11.3 (6.9)	0.856
Total MUFA (%E)	6.7 (2.4)	6.6 (2.4)	0.936
Total PUFA (g/d)	15.9 (12.5)	17.9 (9.9)	0.496
Total PUFA (%E)	9.5 (4.3)	10.0 (3.0)	0.769
Refined cereals (g/d)	171.0 (98.6)	166.2 (81.5)	0.965
Whole grains (g/d)	5.1 (34.9)	30.0 (75.2)	<0.001
Pulses legume (g/d)	41.0 (32.4)	42.7 (28.8)	0.303
Fats and edible oils (g/d)	23.0 (21.1)	23.0 (13.6)	0.661
Dairy products (g/d)	225.0 (233.0)	265.4 (205.3)	0.043
Fruits and vegetables (g/d)	211.0 (243.3)	196.8 (226.9)	0.371
Vegetables (g/d)	80.3 (97.6)	85.6 (81.7)	0.944
Fruits and fruit juice (g/d)	100.0 (203.0)	95.7 (213.1)	0.188
Tubers (g/d)	16.0 (42.0)	22.0 (31.1)	0.141
Nuts and oil seeds (g/d)	5.0 (11.2)	7.3 (15.1)	0.021
Meat, fish, egg and poultry (g/d)	21.6 (48.0)	27.6 (49.5)	0.643
Added salt (g/d)	6.0 (3.9)	6.0 (3.3)	0.575
Added sugar (g/d)	7.0 (15.0)	3.7 (11.9)	0.015

**P*<0.050 is considered as significant. Tested using Mann–Whitney. MOC: Model of care, IQR: Interquartile range, MUFAs: Monounsaturated fatty acids, SFAs: Saturated fatty acids, PUFAs: Polyunsaturated fatty acids

$P < 0.005$). Dietary fibre intake also significantly increased from 18.2 g to 22.3 g (20% increases). There were a significant increase in the consumption of nuts and oil seeds (15.1 vs. 5.0 g, $P < 0.005$) and a significant decrease in the consumption of added sugar (3.7 vs. 7.0 g, $P < 0.005$) after the intervention.

Increased consumption of whole grains was associated with reduced risk of adverse neonatal outcomes (OR: 0.3, [95% confidence interval [CI]: 0.7–0.9], $P = 0.043$) [Figure 2a]. Dairy products (OR: 0.14, [95% CI: 0.02–0.8], $P = 0.03$) and dietary fibre (OR: 0.2, [95% CI: 0.05–0.9], $P = 0.038$) also showed protection against adverse neonatal outcomes [Figure 2b and c].

Women in the highest tertile of the healthy diet score had a lower risk of adverse neonatal outcomes even after adjusting for potential confounders such as gestational age, medication during pregnancy, physical activity, weighted glycaemic index, glycaemic load, and intake of total energy, fat, SFA, MUFA, fruits and vegetable, added salt and added sugar [Figure 3].

Discussion

To our knowledge, this is the first study from South Asia to test the effect of a cost-effective MOC on the changes in the dietary intake of women with GDM and their association with neonatal outcomes among women with GDM. Some South Asians have very high prevalence rates of GDM and have unique sociocultural features, especially with respect to high carbohydrates consumptions; the findings are of great significance.

Several studies in the past have focussed on assessing the impact of diet on risk of developing GDM and have therefore utilised food frequency questionnaires to assess the frequently consumed foods by the pregnant women in the year preceding her pregnancy.[21] Since diet modification during pregnancy is often the first line of treatment for GDM, it is important to understand how food choices made during pregnancy affect the risk of adverse neonatal outcomes. Following diet counselling, these women consumed higher amounts of whole grains, dairy products, dietary fibre and less added sugar. Our results showed that whole grain intake was inversely associated with fasting hyperglycaemia and neonatal outcomes. Women with a higher healthy dietary score (derived from higher intake of whole grains, dairy and dietary fibre) also had beneficial neonatal outcomes.

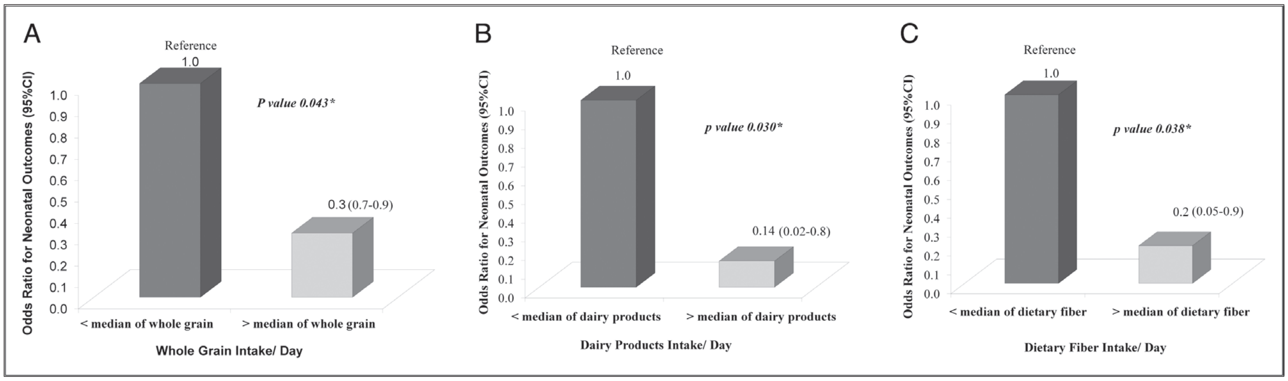

Figure 2: Dietary pattern and risk of neonatal outcomes (odds ratio [95% confidence interval]). (a) Whole grain intake vs risk of neonatal outcomes (OR: 95% CI), $n=103$. (b) Dairy product intake vs risk of neonatal outcomes (OR: 95% CI), $n=105$. (c) Dietary fiber intake vs risk of neonatal outcomes (OR: 95% CI), $n=133$. Less than median intake of whole grain, dairy products and dietary fiber was taken as the reference $^*P$ value< 0.050 is considered as significant. Model for whole grains adjusted for family history of diabetes, gestational age at delivery, physical activity(active/ inactive), body mass index (kg/m^2), energy (kcal/d), SFA (g/d), MUFA(g/d), PUFA (g/d), fruits & vegetables (g/d), added sugar (g/d). Model for dairy product adjusted for family history of diabetes, previous history of GDM, gestational age at delivery, medication during pregnancy (yes/no), total weight gain during pregnancy (kg), physical activity (active/ inactive), energy (kcal/d), SFA (g/d), fruits & vegetables (g/d) & egg (g/d). Model for dietary fiber adjusted for gestational age at delivery, medication during pregnancy (yes/no), physical activity (active/ inactive), maternal complications, full term birth (yes/ no), carbohydrates (%E), fat (%E), SFA (g/d), MUFA (g/d), milk & its product (g/d), fruits & vegetables(g/d) and added sugar (g/d)

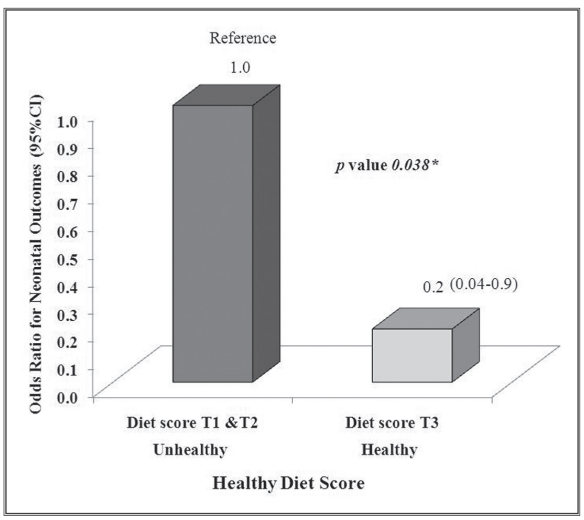

Figure 3: Healthy diet score and risk for neonatal outcomes (odds ratio [95% confidence interval]) $n = 133$

Despite the vast literature on maternal diet during pregnancy, very few studies have looked at the impact of specific foods such as whole grains, dietary fibre and dairy products on neonatal outcomes in the offspring born to women with GDM. A meta-analysis of five studies involving 302 participants showed that low glycaemic index (LGI) diet, with an increased level of dietary fibre, reduced the risk of macrosomia compared to an LGI diet alone (relative risk: 0.17 vs. 0.47, respectively).[22] In contrast, a randomised clinical trial (RCT) that studied 99 women with GDM showed that pregnancy outcomes such as birth weight (LGI 3.3 ± 0.1 kg vs. high fibre [HF] 3.3 ± 0.1 kg; $P=0.619$) and macrosomia (LGI 2.1% vs. HF 6.7%; $P=0.157$) did not differ between women on a LGI diet and HF diet.[23]

Our results also showed that consumption of dairy products was inversely associated with adverse pregnancy outcomes. The dietary approaches to stop hypertension (DASH) study recommend a diet rich in fruits, vegetables, whole grains and low-fat dairy products. The DASH diet, originally developed for control of hypertension,[24] has been shown to be protective against diabetes also.[25] Subsequently, an RCT among 52 women with GDM randomly assigned to consume control diet (45%–55% carbohydrates, 15%–20% protein and 25%–30% fat) or the DASH diet for 4 weeks showed an improved pregnancy outcomes in the latter group.[26]

Our findings on the impact of a low-cost MOC on favourable pregnancy outcomes in women with GDM, explained in previous publications,[18-20] are broadly comparable to the results from the DASH study for the following reasons. First, results from the WINGS-MOC showed that women with GDM were managed on medical nutrition therapy (84.4%) with very few women needing insulin therapy (15.6%).[18] The DASH study also reported that only 23% of women with GDM required insulin when compared to 73% on the control diet.[26] Second, rates of macrosomia in WINGS-MOC were similar between women with GDM and those without (7.5% vs. 8.0%, respectively).[18] In the DASH study, rates of macrosomia were significantly lower (3.8%) and comparable to WINGS but much higher on the control diet (38.5%).[26] Third, rates of caesarean section among women with GDM in WINGS were similar compared to women without GDM (40.7% vs. 47.2%, respectively) and similar to rates of caesarean section in those on the DASH diet (46.2%). An RCT by Asemi *et al*. evaluated the effects of DASH diet consisting of higher amounts of whole grains, low-fat dairy products, lower amount of refined grains and higher in fruits and vegetables with the daily sodium of 2400 mg/day on lipid and glycaemic variables in GDM women and found decreased fasting PG, serum insulin levels and homoeostasis model of assessment insulin resistance.[27]

However, there are also several differences between the two studies. The DASH study was an RCT, with clearly defined diet for both groups under the study. The WINGS study was planned as an implementation program that sought to improve the health outcomes of women with GDM and their new-born. An implementation study examines strategies that are specially designed to improve health intervention in real-world settings, rather than trying to control for these conditions or to remove their influence, like in an RCT. Second, participants in the DASH trial were not asked to alter their routine physical activity, whereas women with GDM under the WINGS-MOC were encouraged to monitor their step count and were advised about proper physical activity.[20] Third, the DASH diet was tested for 4 weeks during pregnancy, while the mean follow-up of women under the WINGS-MOC was 20 weeks. Despite these differences, it is gratifying that a low-cost WINGS-MOC, obtained broadly similar pregnancy outcomes as the DASH study.

A recently published systematic review and meta-analysis pooled results from 18 studies, involving 1151 women, and showed lower birth weight and less macrosomia in those who received advice on diet modification (LGI diet, DASH diet, low carbohydrate diet, fat modification, soy protein enrichment, energy restriction and HF). The authors concluded that there is an urgent need for well-designed dietary intervention studies, especially in low- and middle-income countries where the impact of GDM is greater.[28] WINGS is one of the first studies to show that the beneficial effect of such a dietary intervention on neonatal outcomes and this has huge potential public health applications in low-resource settings.

Assessing lifestyle changes is challenging and determining the adherence to protocol is more difficult. However, the relatively large sample size and a well-structured MOC applied in a real-world setting with positive results are the strengths of the study. There are, however, some limitations that need to be mentioned. The 24-h recall and questionnaire used in our study may not have been comprehensive enough to capture all relevant foods. Moreover, the number of times the 24-h recall was administered varied between participants, depending on the number of antenatal visits for each woman. Longer follow-up and the use of other methods of diet assessment could have yielded better results. Finally, one cannot separate out the effects of diet and physical activity in this study. In spite of these limitations, our study highlights the potential benefit of integrating lifestyle counselling through diet and physical activity during pregnancy. Although making behavioural or lifestyle modification can be difficult outside of pregnancy, during pregnancy, the motivation levels are usually high and this might translate to greater adherence to such modifications during pregnancy.

Conclusions

A low-cost dietary intervention as utilised in the WINGS-MOC can be used as a tool to motivate women with GDM make appropriate food choices that can positively influence their pregnancy outcomes.

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Ethical standard

This study was approved by the Institutional Ethics Committee of the Madras Diabetes Research Foundation, Chennai, India (dated 7th November 2012).

Human and animal rights disclosure

All human rights were observed in keeping with Declaration of Helsinki 2008 (ICH GCP) and the Indian Council of Medical Research (ICMR) guidelines. There are no animal rights issues as this is a clinical study.

Informed consent disclosure

Written informed consent was obtained from all participants before inclusion in the study.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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