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# Comparison of Effectiveness of Routine Antenatal Care with a Midwife-Managed Clinic Service in Prevention of Gestational Diabetes Mellitus in Early Pregnancy at a Hospital in China

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**Background:** Women with normal fasting glucose (FPG) range ( $5.1 \leq \text{FPG} < 6.09$  mmol/L) in early pregnancy are at high risk of gestational diabetes mellitus (GDM). The aim of this study was to compare the effectiveness of routine antenatal care with a midwife-managed clinic service in the prevention of GDM in early pregnancy at a hospital in China.

**Material/Methods:** We designed a prospective observational clinical study among pregnancy women with normal fasting glucose (FPG) range ( $5.1 \leq \text{FPG} < 6.09$  mmol/L) in early pregnancy. Routine antenatal care was compared with a midwife-managed clinic service providing diet and exercise education before week 16. A 75-g OGTT was performed at weeks 24-28 for both groups. Results of OGTT and gestational weight gain were compared between the 2 groups.

**Results:** Of the 592 eligible women, 296 women received the antenatal nursing clinic service and 296 were enrolled in a control group. Thirty-three women were lost to follow-up during the study, leaving 279 in the intervention group and 280 in the control group. Baseline demographic characteristics were similar between the 2 groups. GDM was diagnosed in 115 participants (41.2%) in the intervention group and 141 (50.4%) in the control group. Subgroup analysis showed a significantly lower rate of GDM in the intervention group among the No-IVF population (37.8% vs. 49.0%,  $P=0.01\%$ ). For pre-pregnancy BMI, significant differences were found in the incidence of GDM and maternal hypertension between the different groups, showing that the overweight group benefited most from the midwife-managed antenatal clinic service.

**Conclusions:** The midwife-managed clinic service was feasible and effective in the prevention of GDM.

**MeSH Keywords:** **Diabetes, Gestational • Life Style • Midwifery • Weight Gain**

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## Background

Gestational diabetes mellitus (GDM), the most common metabolic disorder of pregnancy, is defined as hyperglycemia first detected in pregnancy and not reaching non-pregnant diabetes levels. GDM occurs in 2–19% of all pregnancies, depending on the ethnic background of the study population and the diagnostic criteria. With increased risk of adverse pregnancy outcome, future type 2 diabetes for the mother, and childhood overweight for the baby, GDM is hazardous for both mother and the newborn [1–3].

Universal oral glucose tolerance-based screening is employed to identify pregnant women with GDM, which means GDM cannot be diagnosed until late in the second trimester. However, studies have shown that accelerated fetal growth occurs as early as at 20 weeks' gestation, with increased adiposity in the offspring of women with GDM in early infancy, despite good maternal glycemic control [4]. To mitigate the adverse long-term effects in the offspring of prolonged intrauterine exposure to maternal hyperglycemia, there is a compelling argument for detecting GDM earlier in pregnancy [5]. Detecting women at higher risk for GDM early in pregnancy is a desirable goal, as lifestyle interventions such as diet and exercise may be applied earlier in pregnancy and could reduce later development of GDM or its associated morbidities.

A few studies suggest that first-trimester fasting glucose is a useful biomarker in predicting later development of GDM [6]; however, currently there is no universally accepted definition for safe FPG levels in the early stage of pregnancy [7]. Higher first-trimester fasting glucose levels, even within the normal glycemic range, constitute an independent risk factor for the development of GDM. Riskin-Mashiah et al. reported an approximately 1.5-fold increase in the risk of developing GDM with each 5 mg/dl increase in fasting glucose in the first trimester [8], especially for women with high-risk factors, including mother's age over 30–35 years old, overweight, and progressive history of type 2 diabetes in the family. Fasting plasma glucose cut-off is a valid strategy to determine the need for oral glucose tolerance testing (OGTT) [9]. A study in a Chinese population showed that FPG level over 4.6 mmol/L was the best threshold for predicting GDM, with a sensitivity of 53.89% and specificity of 70.9% [10].

Lifestyle factors in early pregnancy are moving to the forefront as key forces that drive the pathogenesis of GDM [11]. Maternal dietary patterns before and during pregnancy play important roles in the development of GDM. According to a 24-h dietary recall of pregnant women, there are 3 dietary patterns significantly associated with the increase risk for GDM: “high in refined grains, fat, oils, and fruit juice”; “high in nuts, seeds, fat, and soybean; low in milk and cheese”, and “high in added sugar and organ meats; low in fruits, vegetables, and

seafood” [12]. Physical activity before and during pregnancy was associated with a significant 22% reduction and 20% reduction in the relative risk of GDM, respectively [13]. One randomized controlled trial (RCT) has also supported the effectiveness of regular exercise in early pregnancy in preventing GDM among overweight and obese Chinese pregnant women [14]. It is important for women with normal fasting glucose (FPG) range ( $5.1 \leq \text{FPG} < 6.09$  mmol/L) in early pregnancy to engage in dietary and lifestyle modification [15].

In China, maternity health care uses an obstetrician-led model. Pregnant women in China attend antenatal clinics and receive checkups mostly by obstetricians, who cannot devote time to communicate with women for health education [16]. A nurse-led clinic service is an effective way to promote lifestyle change, but it is usually implemented after GDM is diagnosed. Thus, the challenge is to develop a model of nurse-led clinic service in which hyperglycemic pregnant women can receive counseling and information about the harmful effects of GDM and engage in dietary and lifestyle modification to reduce the prevalence of GDM [17]. Therefore, we conducted a randomized control study to compare the effectiveness of routine antenatal care with a midwife-managed antenatal clinic service in prevention of GDM among pregnant women with fasting hyperglycemia in early pregnancy at a hospital in China.

## Material and Methods

### Study design and participants

This was a prospective observational clinical study, using clinical data and samples from the International Peace Maternity and Child Health Hospital of China Welfare Institute (IPMCH). Between January 2016 and December 2016, Chinese women age 18 years and over with a gestational age  $\leq 20$  weeks were recruited using a convenience sampling method at the antenatal clinic. Women were eligible for the study if they met the following inclusion criteria: (1) normal fasting glucose (FPG) range ( $5.1 \leq \text{FPG} < 6.09$  mmol/L) in early pregnancy (11 to 13 weeks) and (2) singleton pregnancy. Those who were participating in any other clinical trial, and/or had pre-gestational diabetes mellitus, and/or any indication of major medical or psychological diseases, or any physical restriction, were excluded. All participants entered the study voluntarily and provided written informed consent. The study was approved by the Clinical Research Ethics Committee of the International Peace Maternity and Child Health Hospital, School of Medicine, Shanghai Jiao Tong University [(GKLW)2017-60]. Eligible participants were randomized in a 1: 1 ratio to either the intervention group or the control group upon recruitment, according to a computer-generated randomization series. Individuals receiving random numbers 0–4 were assigned to the control group, while those

**Table 1.** Recommendations for total and rate of weight gain during pregnancy by pre-pregnancy BMI.

Pre-pregnancy BMI	Total weight gain (Kg)	Rates of weight gain 2 <sup>nd</sup> and 3 <sup>rd</sup> trimester [Mean (Range), kg/week]
<18.5	12.5~18.0	0.51 (0.44~0.58)
18.5~24.9	11.5~16.0	0.42 (0.35~0.50)
≥25	7.0~11.5	0.28 (0.23~0.33)

with random numbers 5–9 were assigned to the intervention group. The list of random numbers and group allocations were kept in sealed opaque envelopes. All participants were provided routine obstetrician-led antenatal care, while the intervention group received midwife-managed antenatal clinic service.

### Routine antenatal care

All women were given general information on diet and physical activity for pregnant women, and were followed up in the prenatal clinic at 1-month intervals according to standard care of the hospital before screening for GDM [18]. They were also offered optional antenatal classes at the pregnant women school in the hospital.

### Midwife-managed antenatal clinic service

The antenatal clinic was managed by a Chinese midwife practitioner who had been working for 14 years in the obstetrical wards and delivery room. The midwife was trained by obstetricians and nutritionists, focusing on the prevention of GDM and lifestyle modification counseling before the clinic service was approved by the hospital. The clinic service was provided before 16 weeks of gestation.

During the 30-min face-to-face counseling, the pregnant women received information about the risk of GDM in pregnant women with fasting hyperglycemia and its potential effects on mother and infant. All women were given written instructions for diet, exercise, and weight gain education. Husbands were also encouraged to participate in the clinic.

### Diet

The midwife used models and pictures of food to explain dietary nutrient distribution and the glycemic index. The total energy in an optimal diet contains carbohydrate (about 50%), fat (less than 30%), and protein (10–20%) [19]. Total calories were advised to be distributed in 3 small-to-moderate-sized meals and 2–3 snacks [20]. Pregnant women were encouraged to have a healthy dietary pattern, avoiding high consumption of fried food, animal fat, dietary cholesterol, and highly refined grains, and to increase consumption of high-fiber foods [21].

### Exercise

All pregnant women were encouraged to perform daily aerobic exercise, which uses large-muscle groups rhythmically and continuously for a sustained period of 15–20 min or longer while maintaining 60–80% of the maximum heart rate, except when they have contraindications (e.g., threatened abortion, colporrhagia, severe heart disease), and the length and intensiveness of exercise were determined by the pregnant women's pre-pregnancy BMI and physical activity. The pregnant women were advised to perform over 30 min of moderate-intensity aerobic exercise 3–4 times a week. If the BMI of a pregnant woman was over 30 kg/m<sup>2</sup> or if she had not been physically active before pregnancy, the exercise was started at 15 min per day 3 times a week [22]. Recommended types of exercise were walking, cycling, and gymnastics for pregnant women.

### Body weight gain

Based on the recommendations of the Diagnosis and Therapy Guideline of Pregnancy with Diabetes Mellitus for the Chinese Population, the midwife explained proper bodyweight gain during different stages of pregnancy based on pre-pregnancy BMI (Table 1) [23]. The pregnant women were advised to monitor bodyweight weekly.

### Outcomes and data collection

Clinical data were collected through a retrospective review of medical records. Data on demographics and medical and obstetric history were obtained from the patients' medical history record database. Pre-pregnancy weight was self-reported. Body mass index (BMI) was calculated using the standard formula (weight divided by height squared, kg/m<sup>2</sup>). Gestational bodyweight gain (GWG) in the second trimester was calculated as the difference between the pregnant women's body weight at week 28 and week 13. Data on maternal weight, height, blood pressure, perinatal and obstetric outcomes, neonatal outcomes, and complications were retrieved from the hospital records. A 75-g OGTT was performed at weeks 24–28 for both groups to diagnose GDM. The diagnosing obstetricians were unaware of whether the participant had attended the midwife-managed clinical service. Perinatal and obstetric

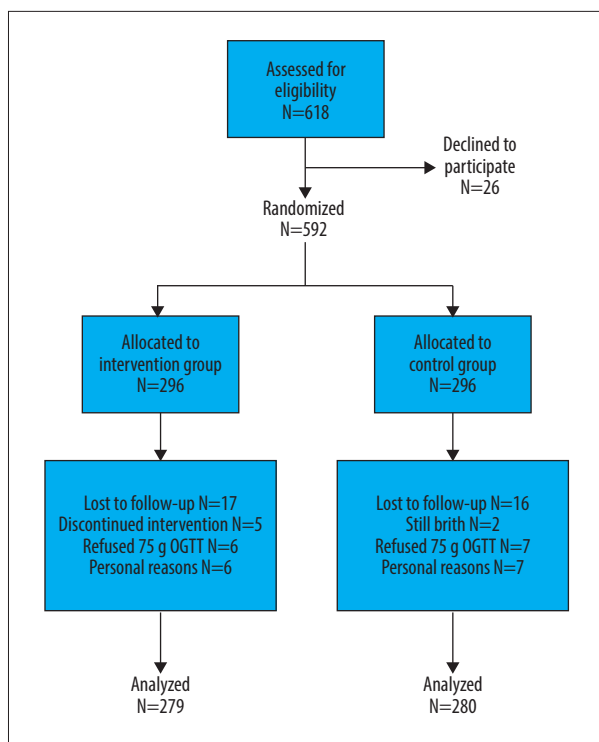


Figure 1. Flow chart of the prospective parallel group study.

outcomes and complications included hypertensive diseases, type of delivery, premature rupture of membranes (PROM), preterm birth, and gestation at delivery. Fetal and neonatal outcomes included neonatal weight, large for gestational age (LGA), macrosomia, and fetal distress.

**Statistical analysis**

All analyses were performed with a statistical significance level of 0.05, using SPSS 16.0 (SPSS, Inc., Chicago, IL). Differences between the 2 groups were analyzed using the *t* test for continuous variables, and the chi-square test and Fisher’s exact test were used for categorical variables. Logistic regression analyzes were performed to evaluate the independent association of pregnancy outcomes with the pre-pregnancy BMI and the use of assisted-reproductive technologies for conception.

**Results**

**Characteristics of the participants**

In total, 618 women met the study inclusion criteria and 592 pregnant women were included in the study. Figure 1 shows

Table 2. Demographic characteristics of participants (N=559).

Variable	Intervention (N=279)	Control (N=280)	P
Maternal age, years [mean (SD)]	31.9 (3.9)	32.4 (4.2)	0.18
BMI, kg/m <sup>2</sup> [mean (SD)]	22.6 (3.7)	23.0 (3.3)	0.18
Weight before pregnancy, kg [mean (SD)]	59.6 (10.0)	60.4 (9.7)	0.33
FPG, nmol/L [mean (SD)]	5.3 (0.3)	5.3 (0.2)	0.16
BMI categories [n (%)]			0.24
Underweight	31 (11.1)	19 (6.8)	
Normal weight	169 (60.6)	167 (59.6)	
Overweight	60 (21.5)	71 (25.4)	
Obese	19 (6.8)	23 (8.2)	
Education [n (%)]			0.92
Year 12 or below	102 (36.7)	103 (36.8)	
Bachelor	130 (46.8)	134 (47.9)	
Undergraduate	46 (16.5)	43 (15.4)	
Parity [n (%)]			0.09
None	171 (61.3)	152 (54.3)	
≥1	108 (38.7)	128 (45.7)	
IVF [n (%)]			0.34
No	254 (91.0)	261 (93.2)	
Yes	25 (9.0)	19 (6.8)	

**Table 3.** Effect of control on GDM and other pregnancy outcomes in all participants.

Variable	Intervention (N=279)	Control (N=280)	P
<b>Maternity</b>			
GWG in early pregnancy, g [mean (SD)]	2152.5 (213.3)	3194.7 (200.9)	<0.0001*
GDM [n (%)]	115 (41.2)	141 (50.4)	0.03*
Maternal hypertension [n (%)]	24 (8.6)	33 (11.8)	0.21
Gestational age, w [mean (SD)]	38.6 (1.3)	38.8 (1.5)	0.39
Preterm delivery (<37 weeks) [n (%)]	17 (6.1)	11 (3.9)	0.24
Type of delivery [n (%)]			0.03*
Vaginal delivery	149 (53.4)	123 (44.1)	
C-section	130 (46.6)	156 (55.9)	
PROM [n (%)]	65 (23.3)	54 (19.3)	0.35
GBS [n (%)]	13 (4.6)	18 (6.5)	0.43
Thyroid disease [n (%)]	25 (9.0)	15 (5.4)	0.10
<b>Newborn</b>			
Birthweight, g [mean (SD)]	3383.3 (465.4)	3390.1 (457.5)	0.86
Birthweight categories(g) [n (%)]			0.78
Adequate 2500–4000	251 (90.0)	256 (91.4)	
Low <2500	8 (2.9)	8 (2.9)	
Macrosomia >4000	20 (7.2)	16 (5.7)	
Birth length, cm [mean (SD)]	49.9 (1.3)	49.9 (1.5)	0.76
Fetal distress [n (%)]	64 (22.9)	60 (21.4)	0.67

the number of participants at different study stages, leaving 279 women in the intervention group and 280 in the control group. Baseline characteristics were compared between the 2 groups (Table 2).

### Study outcomes

Significant differences were found in gestational weight gain in early pregnancy and the incidence of GDM between the 2 groups. GDM was diagnosed in 115 participants (41.2%) in the intervention group and 141 (50.4%) in the control group, and the vaginal birth rate was significantly higher in the intervention group (53.4% vs. 44.1%,  $P=0.03$ ). However, there were no differences in the other maternity and newborn complications or outcomes between the 2 groups (Table 3).

### Subgroup analysis

Additional statistical analyses were performed to confirm the effectiveness of the lifestyle change intervention among women using different methods of conception (Table 4) and pre-pregnancy BMI categories (Table 5). A lower rate of GDM was found in the intervention group among the No-IVF population,

but other maternity and newborn complications or outcomes were similar. For pre-pregnancy BMI, a significant difference was found in the incidence of GDM and maternal hypertension, suggesting that the overweight group benefited most from the midwife-managed antenatal clinic service.

### Discussion

It has been widely demonstrated that women with fasting hyperglycemia in early pregnancy are at high risk for GDM. The present study is, to the best of our knowledge, the first prospective randomized control trial aiming to reduce the overall incidence of GDM in a large sample of women in the early stage of pregnancy in China.

Early assessment and intervention have been considered to be important in terms of limiting maternal and infant complications [24,25]. Early pregnancy is a period of significant behavior change. A qualitative study demonstrated that women's diet and physical activity behavior do not develop gradually during early pregnancy, but instead are triggered by the confirmation of conception, particularly referencing the

**Table 4.** Effect of intervention on GDM and other pregnancy outcomes by IVF.

Variable	Intervention (N=279)	Control (N=280)	P
GDM [n (%)]			
No-IVF	96 (37.8)	128 (49.0)	0.01*
IVF	19 (76.0)	13 (68.4)	0.58
Maternal hypertension [n (%)]			
No-IVF	21 (8.3)	32 (12.3)	0.14
IVF	3 (12.0)	1 (5.3)	0.44
Preterm delivery (<37 weeks) [n (%)]			
No-IVF	12 (4.7)	10 (3.8)	0.62
IVF	5 (20.0)	1 (5.3)	0.16
PROM [n (%)]			
No-IVF	58 (22.8)	53 (20.3)	0.49
IVF	7 (28.0)	1 (5.3)	0.06
GBS [n (%)]			
No-IVF	15 (5.9)	12 (4.6)	0.51
IVF	3 (12.0)	1 (5.3)	0.44
Thyroid disease [n (%)]			
No-IVF	23 (9.1)	14 (5.4)	0.11
IVF	2 (8.0)	1 (5.3)	0.72

\* Odds ratio 0.68; 95% confidence interval, 0.47–0.86; adjusted age, BMI, parity.

risk to the fetus, which provides an exciting “window of opportunity” for motivating healthy behaviors [26]. An observational study demonstrated that a healthy lifestyle, including physical activity, dietary patterns, smoking and stress, during early pregnancy was associated with substantially lower GDM risk after adjustment for maternal age, race, and parity [27]. The combined approach of diet modification with lifestyle and behavior changes we used in this study is an important method for GDM prevention [28].

The results of this midwife-managed antenatal clinic service intervention were encouraging, and were consistent with the findings of the Finnish GDM prevention study, which decreased the overall incidence of GDM by 39% through combined moderate physical activity and diet intervention [29].

One of the possible explanations for the encouraging results in GDM prevention in this study might be the targeted population. The intervention was conducted among women with fasting hyperglycemia ( $5.1 \leq \text{FPG} < 6.09$  mmol/L) in early pregnancy. These women are a high-risk population, as 50.4% of the control group were diagnosed GDM based on the 75-g OGTT, and the rate was even higher than in a previous report (an incidence of 39.80% of 1959 women) among the Chinese population [30]. A study by Chan et al., mainly targeting pregnant women over

35 years old and/or pre-pregnancy BMI/BMI at the 1<sup>st</sup> trimester  $\geq 25$  kg/m<sup>2</sup> and/or family history of diabetes at the first-degree relatives, found that the effectiveness of lifestyle intervention in GDM prevention was unclear [31], as these women were considered to be at modest risk for the development of GDM [29].

In the subgroup analysis, we found that a significant difference in the incidence of GDM in the non-IVF group, but in the pregnant women who underwent IVF, the rate was similar, which was consistent with the findings that pregnancies resulting from assisted-reproductive techniques are associated with increased risk of GDM, and the risk is 2-fold higher in women with singleton pregnancies compared with women who conceived spontaneously [32]. However, in most studies that focused on GDM prevention through lifestyle change in early pregnancy, the method of conception was not considered a risk factor [31,33,34].

Combined lifestyle interventions including diet control plus moderate but continuous physical activity have shown better efficacy in preventing the development of GDM [35]. Our intervention was individualized by the midwife-managed antenatal clinic service. The experienced midwife provided different diet and exercise instructions according to the women's personal preferences and pre-pregnancy BMI to ensure

**Table 5.** Effect of intervention on GDM and other pregnancy outcomes by pre-pregnancy body mass index categories.

	Normal weight		Underweight		Overweight		Obese		P
	Interven- tion	Control	Interven- tion	Control	Interven- tion	Control	Interven- tion	Control	
	(n=169)	(n=167)	(n=31)	(n=19)	(n=60)	(n=71)	(n=19)	(n=23)	
Maternal outcomes [n (%)]									
GDM	57 (33.7)	71 (42.5)	9 (29.0)	2 (10.5)	35 (58.3)	53 (74.6)	14 (73.7)	15 (65.2)	<0.001
Maternal hypertension	10 (5.9)	14 (8.4)	0 (0.0)	0 (0.0)	10 (16.7)	13 (18.3)	4 (21.1)	6 (26.1)	<0.001
Preterm delivery (<37 w)	14 (8.3)	6 (3.6)	1 (3.2)	0 (0.0)	2 (3.3)	5 (7.0)	0 (0.0)	0 (0.0)	0.12
PROM	44 (26.0)	39 (23.4)	8 (25.8)	2 (10.5)	11 (18.3)	11 (15.5)	2 (10.5)	2 (8.7)	0.16
GBS	12 (7.1)	7 (4.2)	0 (0.0)	2 (10.5)	5 (8.3)	3 (4.2)	1 (5.3)	1 (4.3)	0.46
Thyroid disease	18 (10.7)	7 (4.2)	1 (3.2)	1 (5.3)	6 (10.0)	6 (8.5)	0 (0.0)	1 (4.3)	0.17
Newborn birthweight categories [n (%)]									
Adequate 2500–4000	155 (91.7)	153 (91.6)	27 (87.1)	19 (100.0)	54 (90.0)	63 (88.7)	15 (78.9)	21 (91.3)	0.43
Low <2500	6 (3.6)	6 (3.6)	0 (0.0)	0 (0.0)	1 (1.7)	2 (2.8)	3 (15.8)	2 (8.7)	
Macrosomia >4000	9 (5.3)	8 (4.8)	1 (3.2)	0 (0.0)	6 (10.0)	6 (8.5)	3 (15.7)	2 (8.7)	

safety [36]. The face-to-face consulting by midwives also increased vaginal birth rate, which could be associated with the fact that midwives could increase women's confidence in vaginal birth [37]. We also advised the mothers to monitor bodyweight gain weekly, as excessive weight gain above the upper limits of the IOM guideline during pregnancy is associated with multiple maternal and neonatal complications. Weight gain over 7 kg in the second trimester independently increased the risk of GDM [38]. The present study showed significantly lower gestational weight gain in the intervention group, which might also contribute to the lower GDM rates.

Effect of exercise intervention in preventing GDM depends on compliance and intensity, especially the adherence to the exercise program [39]. Compliance to aerobic exercise programs studies that involved women diagnosed with GDM were high for the supervised program [40]. One of the limitations of the present study is the lack of supervision and assessment of adherence of dietary advice and physical activity [41,42]. In addition, short-term results like incidence of GDM and gestational weight gain in the second trimester were limited, and long-term observation focusing on delivery mode, birthweight, insulin requirement might be more useful to determine the effectiveness of the study.

The strength of this study is that the intervention was performed in a midwife-managed antenatal clinical service targeting a high-risk population in the early stage of pregnancy, which also expands midwives' working scope and job roles. The results proved to be feasible and encouraging. The midwifery clinical service is a new approach for providing health advice and integrating education for GDM prevention and management in a high-risk population.

## Conclusions

Early intervention with diet and exercise consultation from the midwife-managed clinic service is feasible among fasting hyperglycemia pregnant women in the early stage of pregnancy. The study provided clear evidence of prevention of GDM, and it can be of benefit for pregnant women at high risk of GDM in gestational weight management.

## Conflicts of interest

None.

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