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Original Article

Lifestyle intervention prevents pregnant woman from gestational diabetes mellitus: a Chinese randomized controlled trial

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Abstract: Lifestyle intervention prevents pregnant women with GDM, limits their weight gain and improves their psychological comfort. The objective of the study was to assess the effect of lifestyle intervention prevents GDM during and after pregnancy. This study used a longitudinal interventional design. Between July 2011 and October 2013, 388 pregnant women with GDM were randomized to a control group and intervention group. We found that general characteristics and constituents of selected pregnant patients with GDM were similarity in our study. Meanwhile, dietary intakes of selected pregnant patients with GDM in control group were similar to those of intervention group. Gestational weight gain (GDM) of selected pregnant patients with GDM was significantly decreased in intervention group, compared with the control group. Lifestyle intervention significantly reduced the number of pregnant patients needed for insulin therapy, compared with the total number of control group. Furthermore, in medical record number of cesarean section, macrosomia (birth weight > 4000 g) and polyhydramnios (%), no significant changes between control group and intervention group were observed. No differences in birth size of the newborns outcomes were observed between the two groups. To our knowledge, lifestyle intervention reduces GDM and the number of pregnant patients needed for insulin therapy in obese pregnant women.

Keywords: Lifestyle intervention, pregnant woman, gestational diabetes mellitus

Introduction

Diabetes mellitus (DM) is a set of metabolic disease caused by insulin secretion and (or) effect defects characteristic by chronic increased plasma glucose levels. And there are two situation combine with DM and pregnancy: The first one is pregnancy has a definitive diagnosis of diabetes and postpartum continues to has DM, such people are called GDM mellitus; The other one is gestational diabetes mellitus (GDM), refers to the pregnancy first discovered sugar metabolic abnormalities, about 80%-90% in the crowd of pregnancy blood glucose abnormalities [1, 2]. GDM to pregnant women and fetus, even causes many adverse effects in neonatal, infant, increased the macrosomia, malformation fetus and the incidence of stillbirth, and increase risk of cardiovascular disease in women who had type 2 DM family history [3]. Screening for different ethnic groups found, morbidity of GDM different as different races, and the yellow race is the high risk race of GDM, GDM is the high risk people of the type 2 DM, it has already been an important source of the type 2 DM morbidity increase [4]. So for our country, the study of the GDM should pay full attention [5].

Main interference factors of the DM are diet, exercise, and being overweight, so in the study at home and abroad which prevent DM. The content of lifestyle intervention is mainly intervening to the food and exercise [6]. So in this study, lifestyle intervention means through the method of family and telephone follow-up visits, to the puerperal with GDM and postpartum glucose tolerance proceed planned, systematic guidance and the aspects of diet and exercise, make it gradually form healthy way of life such as a reasonable diet, exercise, quit smoking alcohol, so as to increase insulin sensitivity and

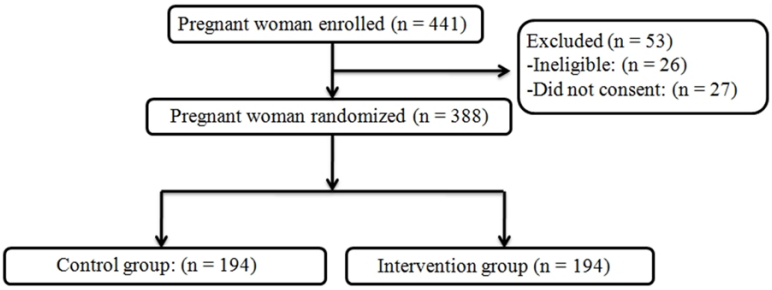

Figure 1. Flowchart of randomization into three study group.

improving islet B cell function, and eventually improve glucose metabolism [7, 8].

Lifestyle intervention refers to patients with glucose tolerance reduce stage for planned, systems guidance and control such as diet and exercise, and to establish and maintain healthy lifestyle such as reasonable diet, appropriate exercise, smoking cessation and restrain alcohol, increase insulin sensitivity, and improve the function of islet B cell, to improve glucose metabolism, ultimately prevent or delay the occurrence of diabetes [9, 10]. Lifestyle intervention is also applied to the prevention of DM in women with GDM and who have postpartum glucose tolerance [11]. Therefore, the main aim of the current research was to examine that lifestyle intervention prevents GDM during and after pregnancy.

Materials and methods

Participants

The size of the sample was worked out by supposing a GDM incidence of 30% in the control arm and an incidence of 20% in the intervention arm. Making use of a two-sided significance level of 0.05 and a power of 80%, and presuming a rate of dropout at 30%, it was estimated that a sample size of 1000 subjects would suffice to achieve the intended goal. Calculation of the sample size was performed with NQuery Advisor (6.0) by using a continuity corrected chi-square test. Randomization was conducted by making use of randomly permuted blocks (**Figure 1**). Each and every subject was randomized by distributing the next sequentially numbered code and opening the corresponding code envelope which showed the study arm to be given to the participant under consideration. The intervention and control arms were made at random in a balanced fashion one by one within each site of the study.

Study design and recruitment

Women who had a previous history of GDM or a prepregnancy BMI ≥ 30 kg/m^2, either planning pregnancy or pregnant for less than 20 + 0 weeks, were qualified for participating in the study. The subjects were enlisted by taking advantage of newspaper and targeted social media notices, at primary health care centers and antenatal clinics as well as by personal invitation letters distributed grounded upon records at the hospital.

Women with the following items were excluded from the study: aged below 18, diabetes diagnosed prior to pregnancy, drugs that make an influence upon glucose metabolism (e.g. oral corticosteroids and metformin), multiple pregnancies, physical disability, substance abuse at the present time, severe psychiatric disorders and considerable difficulties in socializing with other people (e.g. inadequate Finnish language skills). In case of a miscarriage or fetal death after 22 + 0 weeks' gestation, it was not a dropout criterion but an outcome of pregnancy; the mother was permitted to proceed with the follow-up.

Three overweight pregnant women at the very most who were brought together in a 1.5-2 h session were assisted by the same midwife (AB) at all times. There were four scheduled sessions: (1) prior to 15 weeks of gestation, (2) between 18 and 22 weeks, (3) between 24 and 28 weeks and (4) between 30 and 34 weeks of gestation. Those sessions zeroed in on the relationship between energy intake and energy output grounded upon the active and wholesome food pyramid for women who were pregnant. Advice on a wholesome and balanced diet was founded upon the official National Dietary Recommendations and included intake of 50-55% carbohydrates, 30-35% fat and 9-11% protein energy. What was already deliberated about was theoretical considerations in relation to the women's own lifestyle and eating habits by keeping a diary of their 7 day food; exercises in reading food labels and shopping methods were also performed. Ways to increase their amount of physical activity were also debated. The rationale behind this lifestyle intervention programme for overweight preg-

nant women was grounded upon the stages of the behavioural change model of Prochaska and coworkers, as well as upon the notion of motivational interviewing. This means has been proved to work properly in diet and exercise advice in a population with normal weight and among overweight pregnant women. Motivational interviewing is founded upon a directive method of communication highlighting intrinsic motivation. Motivational items are aimed at developing discrepancy and probing and finding a solution to ambivalence with regard to making changes, with moderate pressure. Following each session, the women were required to discover behaviors that called for change and to set small attainable goals with a view to cultivating an acceptable behavior. Explorations were conducted into personal barriers to behavioural change, together with positive verbal reinforcement to any extent aiming at raising self-confidence and self-efficacy of every pregnant woman. Much as the main consideration was advice on nutrition and physical activity, the women's anxiety and personal scruples in relation to their pregnancy were dealt with to boot.

Outcomes

Measurements of maternal anthropometry were taken at baseline and following a month's intervention by qualified midwives respectively. The weight and height of the women prior to pregnancy were obtained from the registry of patients in the clinic. The measurement of the body weight was taken twice at baseline and subsequent to a month's of intervention respectively, on an empty stomach with the minimum clothing but without any shoes on, by means of a digital scale (Seca, Hamburg, Germany) to the nearest 0.1 kg. The measurement of height was taken by way of a non-stretched tape measure (Seca) to the nearest 0.1 cm. BMI was worked out as weight expressed in kg divided by height in meters squared.

BMI prior to pregnancy was grounded upon weight and height prior to pregnancy reported by themselves upon participation in the study. GDM as the principal variable was interpreted by weight in labor minus weight prior to pregnancy. GDM for the first, second and third trimester was interpreted as the difference between the weight at about the 14^{th}, 22^{nd} and 34^{th} week of gestation and the weight prior to pregnancy.

Much as the intervention continued for 4 weeks, each and every participant was followed up until labor. Once a week all of the women were called to inquire if they have begun injections of insulin following the intervention in relation to diet. As far as all participants were concerned, their way of delivery (cesarean section or vaginal delivery) was also registered. Diagnosis of polyhydramnios was made according to sonographic estimation method. Measurement of the length and weight of each newborn baby was taken by making use of standard methods (Seca 155 Scale) in the course of the first 24 h following birth and was registered to the nearest 1 mm and 10 g, respectively. Newborn babies weighing no less than 44000 g were deemed macrosomic. Measurement of the circumference of each infant's head was made to the nearest 1 mm with the help of a Seca girth measuring tape. In addition, 5 min Apgar score of the infants was determined as another assessment of the outcome of pregnancy. The ponderal index (kg/m^3) of the infant was worked out. In case of the need of any woman participant for a cesarean section, the study obstetrician would make a decision grounded upon evaluated fetal weight, pelvic examination and such relevant indications as malpresentation, fetal distress, dystocia and failure to progress of labor.

Statistical analysis

In order to make a description of continuous data which was normally distributed, means, range and/or standard deviation (SD) were made use of. Description of skewed continuous statistics was made by means of median and range. Tests of differences in means and in medians between the independent groups were performed by using Student's t-test and Mann-Whitney u-test respectively. Pearson's chi-square test was used for analysis of data which was cross-tabulated. The limit for significance was determined as equal to 0.05. And SPSS 19.0 was made use of to analyze the data.

Results

General characteristics of selected pregnant patients with GDM

Between July 2011 and October 2013, 388 women were recruited into the study. In our

Table 1. General characteristics of selected pregnant patients with gestational diabetes

	Control group (n = 194)	Intervention group (n = 194)	*P*-value
Maternal age (years)	29.2 ± 4.7	28.9 ± 4.2	0.41
Height (cm)	156.8 ± 4.6	155.7 ± 5.9	0.56
Prepregnancy weight (kg)	71.5 ± 7.8	71.9 ± 7.2	0.71
Weight at study baseline (kg)	77.3 ± 7.2	78.9 ± 7.4	0.21
Weight at end of trial (kg)	79.7 ± 7.4	80.2 ± 6.7	0.74
Prepregnancy BMI (kg/m^2)	28.9 ± 4.1	29.2 ± 4.4	0.33
BMI at study baseline (kg/m^2)	29.9 ± 4.8	30.3 ± 4.5	0.70
BMI at end of trial (kg/m^2)	31.1 ± 4.1	31.8 ± 4.8	0.51
FPG (mg/dl)	97.5 ± 14.7	98.1 ± 14.1	0.24
Gestational age (weeks)	27.1 ± 1.7	27.3 ± 1.6	0.93

Table 2. Constituents of selected pregnant patients with gestational diabetes

Food group	Control group (n = 194)	Intervention group (n = 194)	*P*-value
Grains	159/194 (82.0)	162/194 (83.5)	0.85
Vegetables	21/194 (10.8)	23/194 (11.9)	0.89
Fruits	12/194 (6.2)	9/194 (4.6)	0.71
Else	1/194 (0.05)	2/194 (1.0)	0.66

Table 3. Dietary intakes of study participants throughout the study

	Control group (n = 194)	Intervention group (n = 194)	*P*-value
Energy (kcal/d)	2409 ± 166	2398 ± 159	0.91
Fat (g/d)	74.6 ± 12.9	75.4 ± 11.6	0.63
Protein (g/d)	102.3 ± 16.5	103.5 ± 12.3	0.21
Carbohydrate (g/d)	322.8 ± 36.8	318.7 ± 40.8	0.86
Saturated fatty acids	18.9 ± 4.1	19.2 ± 3.7	0.74
Polyunsaturated fatty acids	25.9 ± 0.77	26.2 ± 0.82	0.79
Cholesterol (mg/d)	266.1 ± 155.4	271.3 ± 151.7	0.69
Dietary fiber (g/d)	17.8 ± 1.7	17.3 ± 1.8	0.62
Simple sucrose (g/d)	21.5 ± 11.8	20.4 ± 12.2	0.25
Sodium (g/d)	3.651 ± 0.399	3.771 ± 0.405	0.19
Potassium (g/d)	2.784 ± 0.311	2.849 ± 0.289	0.75
Magnesium (mg/d)	248.2 ± 44.6	252.7 ± 43.6	0.81
Calcium (g/d)	9.97 ± 0.221	9.89 ± 0.236	0.64
Fruits (servings/d)	4.3 ± 1.1	4.5 ± 0.9	0.91
Vegetables (servings/d)	4.8 ± 0.7	5.0 ± 0.6	0.93
Nuts (servings/d)	0.4 ± 0.1	0.3 ± 0.2	0.88

study, no differences regarding general baseline characteristics were demonstrated between the two study groups (**Table 1**).

Constituents of selected pregnant patients with GDM

Table 2 showed that diet constituents of 159/194 (82.0%) selected pregnant patients were grains, that of 21/194 (10.8%) selected pregnant patients were vegetables, that of 12/194 (6.2%) selected pregnant patients were fruits and that of 1/194 (0.05%) selected pregnant patients were else in control group. Meanwhile, diet constituents of 162/194 (83.5%) selected pregnant patients were grains, that of 23/194 (11.9%) selected pregnant patients were vegetables, that of 9/194 (4.6%) selected pregnant patients were fruits and that of 2/194 (1.0%) selected pregnant patients were else in intervention group. No differences regarding constituents of selected pregnant patients with GDM were demonstrated between the two study groups.

Dietary intakes of selected pregnant patients with GDM

Table 3 showed that there was no significant difference the dietary intakes of selected pregnant patients with GDM between control group and intervention group.

Lifestyle intervention on GDM

To analyze that the effect lifestyle intervention on GDM, gestational weight of selected pregnant patients with GDM was tested in our study. GDM was 13.7 ± 6.9 kg and 10.4 ± 5.8 kg in control group and intervention group, respectively (**Table 4**). Lifestyle intervention could reduce GDM of selected pregnant patients with GDM. 14/194 (7.2%) pregnant patients appear GDM < 5 kg in control group and 58/194 (29.9%) pregnant patients appear GDM < 5 kg in intervention

Table 4. Lifestyle intervention on gestational weight gain

	Control group (n = 194)	Intervention group (n = 194)	*P* value
GWG (kg)	13.7 ± 6.9	10.4 ± 5.8	< 0.01
GWG, categorical (n%)			0.036
< 5 kg	14 (7.2)	58 (29.9)	
5-8.9 kg	47 (24.2)	36 (18.5)	
≥ 9 kg	133 (68.5)	100 (51.5)	

GWG, gestational weight gain.

group (**Table 4**). Meanwhile, 47/194 (24.2%) pregnant patients appear GDM 5-8.9 kg in control group and 36/194 (18.5%) pregnant patients appear GDM 5-8.9 kg in intervention group (**Table 4**). However, 133/194 (68.5%) and 100/194 (51.5%) pregnant patients appear GDM ≥ 9 kg in control group and intervention group, respectively (**Table 4**).

Lifestyle intervention on pregnancy outcomes

To explore that the effect lifestyle intervention affect on pregnancy outcomes, pregnancy outcomes was observed after intervention treatment. 152/194 (78.4%) pregnant patients needed for insulin therapy in control group after intervention and 121/194 (62.4%) pregnant patients needed for insulin therapy in intervention group (**Table 5**). However, in medical record number of cesarean section, macrosomia (birth weight > 4000 g) and polyhydramnios (%), no significant changes amongst between control group and intervention group were seen (**Table 5**).

Lifestyle intervention on birth size of the newborns

To probe that the effect lifestyle intervention affect on birth size of the newborns, birth size of the newborns was inspected after intervention treatment. We found that there was no significant difference between control group and intervention group (**Table 6**).

Discussion

GDM refers to the occurrence or discovery of diabetes during pregnancy, the incidence has obvious rising trend in recent years [12]. GDM is a kind of high-risk pregnancy, if their condition can't be controlled, pregnant women prone to miscarriage, premature delivery, fetal abnormalities macrosomia, pregnancy-induced hypertension syndrome, infection, neonatal hypoglycemia, high bilirubin concentration and respiratory distress syndrome, even maternal and infant death [13, 14]. At present, the domestic incidence of GDM is 1.32-3.75%, and has a rising trend. GDM has important effect on maternal and fetal health, and easy cause obstetric complications, increase the case fatality rate of perinatal infant [15]. In our study, general characteristics, constituents and dietary intakes of selected pregnant patients with GDM were very similar in lifestyle intervention group and control group.

Diet, exercise and insulin therapy is the main treating method of GDM, the diet treatment is the basis for effective treatment [16]. In diet treatment scheme of GDM patients, the total caloric intake is related to the blood glucose control, and involves the patient's age, weight, pregnancy, activity level and other factors. Exercise can increase muscle glucose intake, still can make the number of insulin receptor or binding force rising, post-receptor effect enhanced [17]. Exercise makes the muscle glucose transporters and content of ribonucleic acid of transport protein increase which determine its transfer rate, so as to improve insulin resistance [18]. The study included that lifestyle intervention could reduce GDM of selected pregnant patients with GDM.

After patients with GDM get lifestyle intervention, in addition to the incidence of pregnancy-induced hypertension syndrome and polyhydramnios is still higher than the control group, other pregnancy complications and the incidence of perinatal infant complications have no significant difference with the control group, prove the good control of blood glucose, and has important significance in improving outcome of GDM (especially the health of perinatal infant) [19]. Therefore, to strengthen the early screening and diagnosis of GDM, to effectively control blood sugar is important measure to reduce maternal and infant complication and to improve the prognosis [20]. The targeted health education and lifestyle intervention, it is one of the effective methods to control the GDM patients' blood sugar [21]. In our study population, there are significantly lower regnant patients needed for insulin therapy in intervention group than in control group. But,

Table 5. Lifestyle intervention on pregnancy outcomes

	Control group (n = 194)	Intervention group (n = 194)	*P*-value
Cesarean section (%)	165 (85.1)	154 (79.4)	0.13
Need for insulin therapy after intervention (%)	152 (78.4)	121 (62.4)	0.02
Macrosomia (birth weight > 4000 g) (%)	5 (2.6)	3 (1.5)	0.21
Polyhydramnios (%)	12 (6.2)	10 (5.2)	0.73

Table 6. Lifestyle intervention on birth size of the newborns

	Control group (n = 194)	Intervention group (n = 194)	*P*-value
Apgar score	9.89 ± 0.03	9.92 ± 0.04	0.62
Newborn length (cm)	50.6 ± 0.6	51.1 ± 0.5	0.56
Newborn weight (kg)	3.7 ± 0.2	3.6 ± 0.2	0.79
Newborn head (cm)	36.2 ± 0.3	36.5 ± 0.2	0.82
Ponderal index (kg/m^3)	2.89 ± 0.06	2.95 ± 0.05	0.32

lifestyle intervention could not influence birth size of the newborns in pregnant woman with GDM. In conclusion, lifestyle intervention reduces GDM and the number of pregnant patients needed for insulin therapy in obese pregnant women.

Disclosure of conflict of interest

None.

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