

BMJ Open Subsidy programme for gestational diabetes mellitus screening and lifestyle management in rural areas of western China: a study protocol for a multicentre randomised controlled trial

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ABSTRACT

Introduction Gestational diabetes mellitus (GDM) has become an increasing health problem among pregnant women in western rural China. Insufficient compliance and motivation due to economic factors is one of the major contributors to the currently low GDM screening and management rate. A subsidy program offering GDM screening and lifestyle management might be an effective way to increase pregnant women's awareness of GDM, and further improve maternal and neonatal health in western rural China. This study had two primary purposes: (1) to examine whether the subsidy program would increase the screening and management rates of GDM and reduce adverse complications for mothers and new-born babies and (2) to evaluate whether the subsidy program is cost-effective from a societal perspective.

Methods and analysis This randomised controlled trial will include 3000 pregnant women (at 24–28 weeks of pregnancy) who will be followed up at six hospitals in the provinces of Yunnan, Sichuan and Shaanxi in China. Pregnant women without overt diabetes, with a singleton pregnancy, with telephone access and with written informed consent will be invited. The intervention group will receive subsidies and standard care, and the control group will only receive usual antenatal care. The randomisation sequence will be stratified by study sites with balanced blocks of six patients. Data will be collected using self-report questionnaires and hospital records. Data will be analysed according to the intention-to-treat principle. The primary outcomes are the maternal and neonatal complications. Secondary outcomes are the mother's cognition scores, screening rate, number of re-examinations, weight gain during pregnancy, changes in diet and exercise, and quality of life. Group comparisons will be conducted using χ^2 test for categorical variables, and t-test or the Mann-Whitney-Wilcoxon test for continuous variables where applicable. Multiple logistic regression will also be performed for the primary outcomes.

Ethics and dissemination This study was approved by the Ethics Review Committee of Peking University Health Science Center. Findings will be disseminated through publication in peer-reviewed journals, seminars and national and international conferences.

Trial registration number ChiCTR1800017488.

Strengths and limitations of this study

- The study has a long-term follow-up and will provide knowledge on the effects of economic intervention on gestational diabetes mellitus screening and management.
- The study measured the lifestyle (diet, exercise and glucose) and maternal and neonatal complications as outcomes/effect parameters.
- Pregnant women in western rural China are our participants and the trial's sample size will set up to 3000.
- The nature of the trial interventions prevented blinding of allocation for both medical staff and pregnant women.
- Women in the control group may ask for standard care from providers, which might reduce the effect of this intervention study due to the intention-to-treat principle that will be used for data analyses.

INTRODUCTION

Gestational diabetes mellitus (GDM) is defined as hyperglycaemia diagnosed in the second or third trimester of pregnancy without overt diabetes prior to gestation.¹ GDM has become an increasing public health problem among pregnant women in China. In 2018, over 2 million pregnant women were affected by hyperglycaemia, and half of cases were found in rural areas.^{2,3} As China has abolished The One-children Policy, more middle-aged women will get pregnant in the coming future with the potential to increase the incidence of GDM countrywide. Recent studies have estimated that the prevalence of GDM is as high as 20.9% in several provinces based on the diagnostic criteria of the International Association of Diabetes and Pregnancy Study Groups (IADPSG).^{4,5}

Previous epidemiological studies have reported a significant association between

GDM and adverse maternal and offspring outcomes.^{6–8} Women with GDM are more susceptible to preeclampsia, preterm birth and macrosomia,⁹ as well as type 2 diabetes after childbirth.^{10–11} Exposure to hyperglycaemia during in utero development is also associated with short-term complications such as macrosomia and neonatal hypoglycaemia,¹² and in the longer term, increased risks of developing type 2 diabetes or metabolic syndrome.^{13–15}

An effective intervention is critical for women with GDM. Studies have indicated that most women with GDM (80%–90%) can be successfully treated with strict lifestyle management (dietary and/or exercise), reducing the risk of adverse maternal and new-born health outcomes related to GDM, such as caesarean section, macrosomia, preterm birth and neonatal hypoglycaemia.^{6–16–17} In 2011, the Department of Obstetrics and Gynaecology and the Department of Perinatal Medicine in the Chinese Medical Association developed guideline for the diagnosis and treatment of GDM.¹⁸ This guideline recommended that all pregnant women should receive diagnostic testing with a 75 g oral glucose tolerance test (OGTT) at 24–28 weeks of gestation and that medical institutions should provide health education regarding GDM to pregnant women. For those diagnosed with GDM, a diet and exercise intervention (lifestyle management) for 2 weeks should be provided. If lifestyle management failed, other treatments, such as insulin or metformin, are suggested to be used depending on individual characteristics.

However, the rates of GDM screening and lifestyle management in western rural China are low. In 2018, the GDM incidence rate increased to 14.5% in western China,¹⁹ but the rate of GDM screening and lifestyle management was less than 20.0%.^{20–21} This situation not only caused a heavy disease burden for women living in undeveloped areas but also posed an economic burden on their families. Our previous study showed that the average cost of treatment for GDM complications was Chinese ¥2256 (US\$1 approximately equal to ¥6.23 in 2015), and the annual societal economic burden of GDM was estimated to be ¥19.4 billion in 2015.²² Thus, efforts to improve screening and lifestyle management and control the potential risk of GDM complications are essential in rural areas of China.

Our pilot investigation in western rural areas show that insufficient compliance is an important cause of the currently low GDM screening and management rate.²³ Pregnant women have insufficient motivation to receive GDM screening and lifestyle management (diet and exercise management), and have low levels of compliance with medical staff recommendation. Medical staff also have low motivation to provide GDM screening and management since some GDM services are beyond their routine responsibility. Pregnant women living in rural areas usually have lower socioeconomic status and GDM cognition, and they might be unaware of the adverse consequences of GDM.^{24–25} Studies also show that a large proportion of pregnant women in rural areas are unwilling to receive or pay for GDM screening

and management.^{26–27} The compliance rate with GDM screening and lifestyle management is low in current rural China. Another barrier for the low GDM screening and management rate is the lack of incentives and motivation for medical staff to provide high-quality GDM screening and lifestyle management in rural hospitals since the workload of GDM management usually beyond their routine antenatal services. In contrast, urban hospitals charge extra consulting and/or management fees for providing GDM screening and management, and these hospitals have higher rates of GDM screening and treatment.²⁸

The problem of GDM in rural areas is more than merely clinical, it is multifaceted, and requires an approach that reflects this. The majority of previous intervention studies on improving pregnancy outcomes of GDM women explore clinical interventions, including standard care (health education, diet and exercise, and medicine) and single interventions (health education/diet and exercise/medicine).^{29–30} Few studies consider the effect of economic incentives on managing GDM, which is critical for practices on GDM management. Therefore, we propose that a subsidy programme offering GDM screening and lifestyle management in rural areas might substantially promote people's motivation to receive GDM screening and lifestyle management and therefore improve maternal and neonatal health in rural China.

This paper describes the development of this subsidy programme and study procedures.

METHODS AND ANALYSIS

Study aims

The main aims of the trial include as follows:

1. To evaluate the effects of a subsidy programme on improving the rate of GDM screening and lifestyle management in western rural China.
2. To determine whether the subsidy programme reduces maternal and new-born complications related to GDM in western rural China.
3. To evaluate whether the subsidy for GDM screening and lifestyle management in rural China is cost-effective from a societal perspective.

Additional aims include the following:

1. To determine whether subsidy programmes improve participants' diet and/or exercise.
2. To examine whether subsidised GDM screening and lifestyle management improves pregnant women's understanding of GDM and their quality of life during pregnancy.

Patient and public involvement

The results of the study will be communicated to participants through a popular scientific report. No other patient involvement has been included.

Study setting and ethics approval

This protocol includes the elements elaborated in the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) checklist.³¹ Participants will be recruited from the outpatient pregnancy check-ups at six county-level hospitals in three provinces in western China. They are Ziyang Maternal and Child Health Hospital and Hanyin Maternal and Child Health Hospital (in Shaanxi Province), Pingchang Maternal and Child Health Hospital and Yingshan Maternal and Child Health Hospital (in Sichuan Province), Zhaoyang People's Hospital and Yiliang County People's Hospital (in Yunnan Province).

This study was approved by the Peking University Institutional Review Board (registration number: IRB0001052-18052).

Study participants

Participants will be assessed by asking them whether they are at 24–28 weeks of gestation and whether they will give birth at the study hospital. If the answers to both questions is yes, they will be invited to participate in this project as long as they meet the following inclusion criteria: (1) without overt diabetes before or during pregnancy (ie, type 1 diabetes or type 2 diabetes); (2) with singleton pregnancy; (3) with telephone access from family members, friends or neighbours and (4) with signed informed consent forms (online supplemental file 1).

The exclusion criteria are as follows: (1) fasting blood glucose >7 mmol/L or glycosylated haemoglobin ≥6.5% at the first GDM screening; (2) concomitant severe systemic diseases (ie, essential hypertension, renal disease, thalassemia, systemic lupus erythematosis, coeliac disease and thyroid disease) and (3) physical or cognitive disability.

Participants will receive an explanation of the of the study and what would be involved. Written consent will be obtained from all those who express and interest in taking part. Women who do not meet the inclusion criteria will be thanked for their time, and the reasons for exclusion will be documented.

Study design

Randomisation and blinding

We will perform a stratified multicentre, randomised controlled trial in rural areas of western China. Eligible women who provide consent will undergo an internet-based, computer-generated randomisation procedure incorporating concealed allocation to one of two arms:

1. The intervention group will receive subsidised standard care. The subsidy includes free GDM screening and lifestyle management for women and economic compensation for the medical department. Standard care includes health education, GDM screening and standardised lifestyle management (diet and exercise management).
2. The control group will receive usual care, and pregnant women will receive standard care (health education, GDM screening and standardised lifestyle

management) as indicated for the intervention group. However, due to insufficient motivation and compliance among pregnant women and medical staff, there is a large gap between practices and standard care. Therefore, we will use the usual care group instead of the standard care group as the control group.

The randomisation sequence will be stratified by study sites with balanced blocks of six patients and will be held by the ResMan management platform of the China Clinical Trials Registry. An outpatient nurse will perform the allocation. The nature of the trial interventions will prevent blinding of allocation for both medical staff and pregnant women.

Sample size calculation

The intervention group and usual care group will have the same sample size (1:1). We calculated that a total sample size of 3000 women (allowing for 20% drop-out) would provide at least 80% power to detect a clinically important 25% increase in the rate of GDM screening from 50% (observed in the pilot study of 309 women) to 80%. From a review of published population complications in Chinese women with gestational diabetes, 3000 women provided 80% power to detect a 40% relative risk reduction for caesarean section (from 51.4% to 30.5%)^{19 30} and an 80% relative risk reduction for macrosomia (from 6.2% to 1.2%).^{30 32}

Procedure

Intervention group (subsidised standard care)

The characteristics, knowledge of GDM, diet, physical activities and quality of life of women allocated to the intervention group will be collected with questionnaire 1 (online supplemental file 2), and these women will be required to receive a ≥10 min individual health education session at the beginning of recruitment. This session will provide these women with information on the GDM concept, risk factors, complications, screening procedure, dietary and exercise interventions, recommended foods and recipes, physical activity and treatments. A handbook with the same content will also be provided. Women will be informed and recommended to receive free of charge GDM screening during the sessions. The medical departments that provide the health education sessions will be subsidised with ¥10 per participant they persuaded to attend the session. For women rejecting GDM screening, we will document their reasons.

Participants in the intervention group will receive free GDM screening, and an OGTT (75 g) will be administered to all women between 24 and 28 weeks of gestation using the diagnostic criteria recommended by the IADPSG, namely, fasting venous glucose of 5.1 mmol/L or higher, 1-hour venous glucose of 10.0 mmol/L or higher, 2-hour venous glucose of 8.5 mmol/L or higher or a combination of these.³³

For women diagnosed with GDM in the intervention group, a free of charge 30 min individual session on diet and exercise management and antenatal retest

of glucose will subsequently be provided every 2 weeks until their glucose becomes normal. A nurse or doctor will be required to provide remote consultation and management of diet and exercise to women with GDM to promote the effect of self-monitoring every week by WeChat, and a log book will be used to record their daily diets and exercise (online supplemental file 3), which is useful to help doctors tailor advice for each woman with GDM at retest. If a participant misses her retest, a nurse or doctor will contact and inform her again via telephone or WeChat. Up to three free retests for GDM will be provided according to women's gestational weeks. The medical department was subsidised with ¥20 per participant for the provision of the GDM lifestyle management. For women without GDM, the remote consultation and management of diet and exercise will be provided every week by WeChat in case of abnormal glucose in the last trimester.

Individual recommendations for diet and exercise will be based on the guidelines of diet and exercise for women with GDM,³⁴ and will also be adjusted according to participants' habitual preferences. Dietary recommendations will be based on the following principles: restricting dietary intake of saturated fat and exchanging carbohydrate-rich foods with a medium-to-high glycaemic index for foods with a lower glycaemic index to reduce the glycaemic load. For advice on physical activity,³⁴ we will focus on incremental increases in walking tailored to the woman's pre-existing activities. Moderate-intensity activities will be suggested, and additional options, including aerobics, yoga and swimming, will be encouraged, particularly for women already engaging in some physical activities. A medical record (online supplemental file 4) will also be used to record the effect of subsidised GDM screening and lifestyle management at delivery. After 34 weeks of gestation, all women in the intervention group will be surveyed again. Data on knowledge of GDM, diet, physical activities and quality of life will be collected via questionnaire 2 (online supplemental file 5).

Control group (usual care)

All participants allocated to the control group will receive usual care. Additional services, including health education, screening persuasion, retest information and lifestyle management, will not be required or compensated. We will not provide subsidies for women or medical departments. A medical record will also be used to record the process and results of usual care. At recruitment and after 34 weeks of gestation, all women in this group will be surveyed. Data on the understanding of GDM, diet, physical activities and quality of life will be collected via questionnaires 1 and 2 (online supplemental files 1 and 4).

Data collection

Indexes

To assess the efficacy of subsidised standard care, we have identified 11 effect indexes based on our hypothesis, namely maternal screening rate, cognition for GDM,

Table 1 Maternal and neonatal complications related to GDM

Maternal complication	Fetal/neonatal complication
Spontaneous abortions	Stillbirth
Pre-eclampsia	Neonatal death
Gestational hypertension	Non-chromosomal congenital malformations
Amniotic fluid turbidity	Fetal macrosomia
Polyhydramnios	Low-birth-weight infants
Oligohydramnios	Neonatal asphyxia
Intrauterine infection	Neonatal pneumonia
Fetal growth restriction	Neonatal anaemia
Placenta previa	Neonatal jaundice
Preterm labour	Neonatal hypoglycaemia
Postmature delivery	Neonatal infection
Caesarean delivery	Fetal distress
Premature rupture of membranes	Neonatal thyroid abnormalities
Dystocia	Neonatal cholestasis
Postpartum haemorrhage	

GDM, gestational diabetes mellitus.

number of retests, dietary and physical activity, gestational weight gain, antenatal visits, quality of life, maternal and neonatal outcomes, and costs in both groups. All maternal and neonatal outcomes are defined by standard clinical diagnosis. These indexes are categorised by primary outcomes and second outcomes.

Primary effectiveness outcomes

Primary outcomes are adverse complications in mothers and new-born babies related to GDM. We have identified 12 types of GDM-related adverse complications for mothers and new-born babies in the literature (table 1). Among them, five commonly reported maternal complications included hypertensive disorders, premature delivery, postpartum haemorrhage, premature rupture of membranes and caesarean section. Five reported neonatal complications include macrosomia, neonatal jaundice, neonatal pneumonia, neonatal asphyxia and fetal distress in utero. Caesarean section and macrosomia are the most frequently observed complications according to previous studies.^{19 32}

Primary cost-effectiveness outcomes

The primary cost-effectiveness will be measured by the incremental cost per unit decrease in the maternal and/or new-born complication rate between the intervention and control groups. The costs of the proposed GDM subsidy programme include materials, equipment, labour, time, and transportation from a societal perspective. The effectiveness of the proposed GDM subsidy programme indicates avoidable maternal and new-born complications.

The costs and effectiveness will be compared, and we will examine whether the incremental cost per unit reduction in the complication rate is less than the treatment cost of complications compared with the control group.

Secondary effectiveness outcomes

Secondary outcomes include the maternal screening rate, cognition for GDM, number of retests, dietary and physical activity, gestational weight gain, antenatal visits and the quality of life measured by the WHO Quality of Life Brief Version (WHOQOL-BREF).³⁵

Diet and physical activity will be assessed with the food questionnaire adapted from the Food Frequency Questionnaire (FFQ) of pregnant women in rural China,^{36–39} and the physical activity questionnaire is a simplified version of the self-report physical activity scale from the International Physical Activity Questionnaire (IPAQ).^{40–41} We will exclude participants who are estimated to be underreporting (weight of food intake ≤ 5 kg per time) or overreporting (weight of food intake ≥ 10 kg per time) their food intake.

Questionnaire

To collect the data in this study, we will use two questionnaires that include five types of instruments, a medical record and a cost form.

Questionnaire 1

1. The basic information portion consists of two sections: demographic characteristics and a self-designed cognitive scale of GDM.

Demographic and sociological characteristics include age, height, weight, weeks of pregnancy, blood pressure, parity, family disease history, residence, education level and occupational status, among other factors. Family economic situation refers to household resident population, personal income, family income and medical insurance, among other factors. Transportation comprises transportation time, cost and lost working days, among others, to calculate direct non-medical intervention costs and indirect intervention costs in the health economics evaluation.

The cognition portion is comprised of nine 5-point scale questions. The higher the score is, the better the cognition is. We will calculate a total cognitive score by multiplying the average score of each item by 4 and then converting the score into the percentage system according to the following formula: total score = (total score - 4) * (100/16).

2. Diet and physical activity. Changes in diet and physical activity from baseline to 34–36 weeks of gestation were measured by a modified FFQ and self-reported physical activity scale from the IPAQ.

– FFQ: This part includes 15 categories according to the recommended classification of food and supplements of China's GDM guidelines: rice, wheat flour, cereals, potato flour, fried food, dark vegetables, fresh fruits, poultry/livestock meat, aquatic prod-

ucts, eggs, milk and its products, beans and their products, nuts, snacks and beverages. The nutritional components (energy, carbohydrate, protein, fat, fibre) are measured accordingly.

– Physical activity: This part was designed to investigate the frequency and duration of vigorous exercise, moderate exercise and walking among pregnant women.

3. Quality-of-life scale. Each woman's quality of life will be measured via the WHOQOL-BREF at the beginning of recruitment and at 34–36 weeks of gestation. There are four dimensions, namely, physical health, psychological health, social relationships and the environment, with a total of 26 questions. The WHOQOL-BREF is commonly used to measure quality of life over 2 weeks with great reliability and validity. The score of each dimension is recorded in a positive way and is obtained by calculating the average score of each item and multiplying it by 4 according to the following formula: domain score = (score-4) * (100/16).

Questionnaire 2

Questionnaire 2 adds a section of examination items and the costs for women with GDM. These items include urinalysis, glucose tests, the glycated albumin test, the glycosylated, haemoglobin test, b-mode ultrasonography, liver and kidney function examinations, insulin levels and other. Two questions were added to the section on basic information, which includes antenatal visits, the average cost per visit, the total cost, and the total out-of-pocket cost. The component on cognition, diet and physical activity is the same as in questionnaire 1.

Medical records

Medical records were designed for nurses to record the effect of the intervention on pregnant women, including on the screening rate, blood glucose value, lifestyle management rate, GDM re-examination rate and outcomes of mothers and new-born babies. Maternal and new-born complications will be diagnosed by standard clinical criteria.

► GDM screening: Information on the fasting blood glucose value, 1-hour glucose and 2-hour glucose levels of the 75 g OGTT, screening rate, number of re-examinations, and whether the patient received a diet and exercise session will be collected. The performance of nurses and doctors will also be measured at this stage.

► GDM retests pregnant women with GDM will be required to have one to three re-examinations based on their gestational weeks. Fasting blood glucose and 2-hour glucose levels after a meal will also be recorded.

► Maternal complications include caesarean section, premature delivery (defined as gestational weeks at birth < 37 weeks), gestational hypertension (defined as systolic blood pressure ≥ 140 mm Hg, diastolic blood pressure ≥ 90 mm Hg or both on at least two occasions 4 hours apart, with proteinuria ≥ 300 mg/24 hours,

spot urine protein showing creatinine ratio ≥ 30 mg/mmol creatinine or urine dipstick protein $\geq 2+$), postpartum haemorrhage and premature rupture of membranes, among others.

- ▶ Neonatal complications include fetal macrosomia (birthweight ≥ 4.0 kg), neonatal jaundice, pneumonia of the new-born, pneumonia asphyxia and fetal distress in the uterus.

Form on costs

Information of direct intervention costs and indirect intervention costs will be collected from a social perspective. Direct intervention costs are categorised into direct medical costs and direct non-medical costs.

- ▶ Direct medical costs include the GDM screening cost, consultation and management cost, GDM re-examination cost and additional examination cost. The unit cost of each category will be estimated based on market price. We will not measure the costs of insulin treatment for pregnant women with GDM. Transportation costs will be regarded as direct non-medical costs in this study.
- ▶ Indirect intervention costs include the cost of missed working days for women and their families according to the minimum hour wage in 2018 and garbage disposal cost.

Statistical analysis

Data will be entered using Epidata software, and statistical analyses will be carried out using STATA V.16.0 (Stata). Bivariate analyses (t-tests or the Mann-Whitney-Wilcoxon test for continuous measures and χ^2 tests for categorical measures) and multivariate analyses (ordinary least

squares regression, logistic regression, generalised linear estimation and others) will be employed to estimate the effects (control for confounding variables) of subsidies for GDM screening and lifestyle treatment in rural China. Repeated data will be examined using difference-in-difference regression models. A general growth mixture model will be used to test a joint trajectory of female characteristics at pregnancy and GDM intervention with maternal and child outcomes. Both parametric and non-parametric econometric analyses will be implemented. The costs (implementing the subsidy programme) and effectiveness/benefits for both women and children will be compared, and the incremental cost-effectiveness and cost-benefit ratios will be studied.

To minimise the loss of information and potential bias caused by missing data, we will use multiple imputation to generate plausible values for each missing value of covariables in our final models. We will generate 50 completed data sets for each set of missing data using STATA.

Ethics and dissemination

Ethics approval and consent to participate

Ethical approval was obtained from the Ethics Review Committee of Peking University Health Science Center in Beijing China (PU IRB reference code: IRB00001052-18052).

Informed consent

Written informed consent will be obtained from pregnant women in the pre- and post-intervention study prior to participant involvement in the study. The consent form

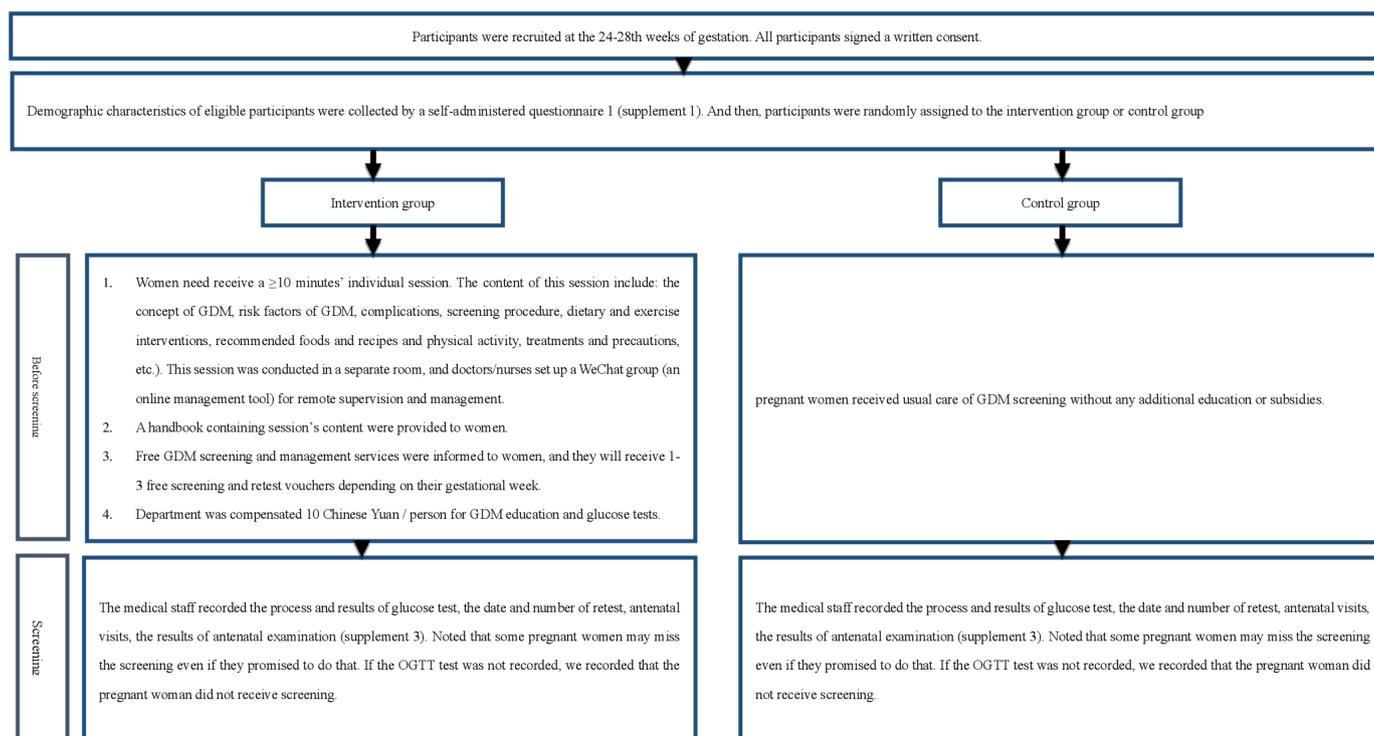


Figure 1 Flow chart of participants' selection. GDM, gestational diabetes mellitus; OGTT, oral glucose tolerance test.

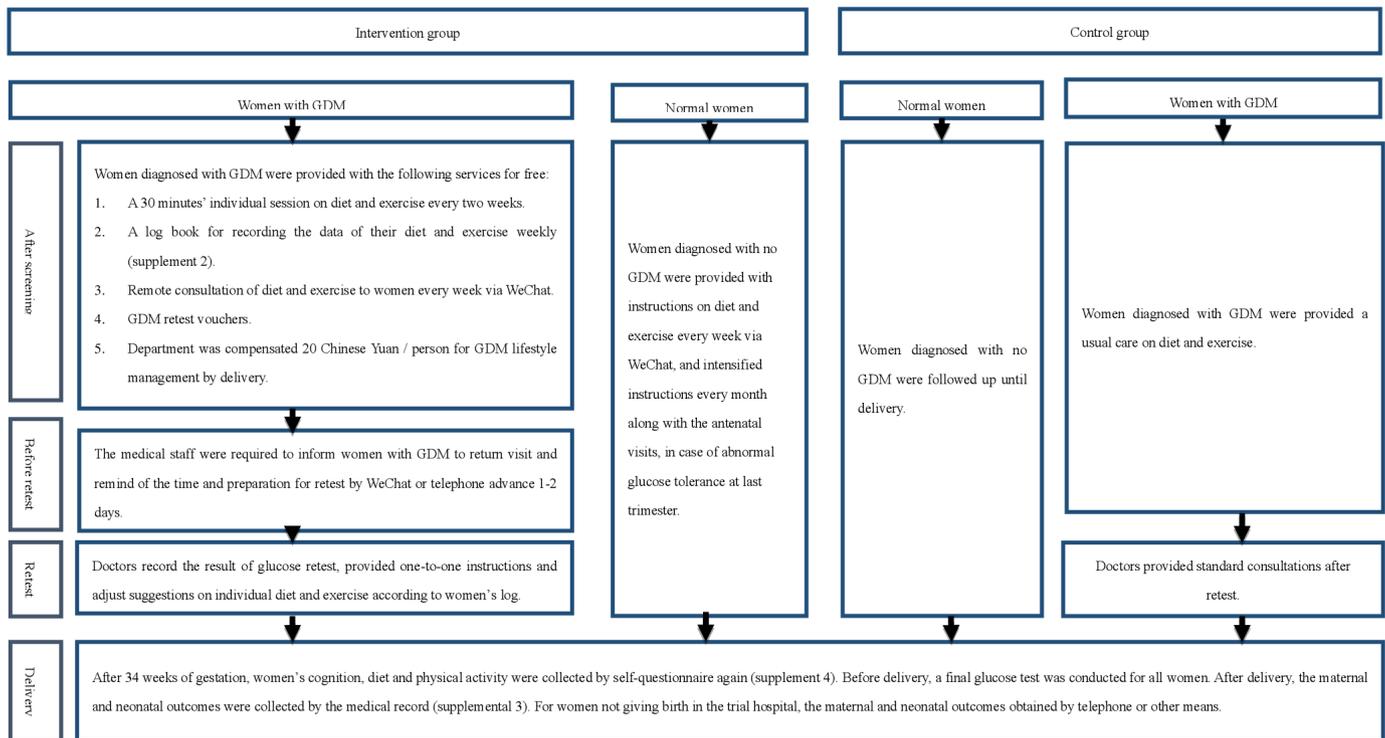


Figure 2 Flow chart (continued). GDM, gestational diabetes mellitus.

is held by institutions (Peking University) and is available for review from the Chief Investigator.

Data management

Data from this study will be stored on an electronic server (ResMan management system) at the platform of the China Clinical Trials Registry. Written informed consent forms, questionnaires, medical records and cost forms will initially be stored in a locked storeroom at the hospital and then delivered by a nurse to the Department of Public Health at Peking University. Personal data that can identify individuals will be deleted at the beginning of 2021, but anonymous information will be used for follow-up studies, depending on future funding.

Dissemination plan

In our study, we followed the World Medical Association Declaration of Helsinki (<http://www.wma.net>). Women meeting the inclusion criteria will be informed that neither the decision to participate nor decline of participation will influence their care. Participation is voluntary, and women can withdraw whenever they want.

Medical staff have been made aware of this. The intervention is a non-invasive method. The 75g OGTT used in this study has certificate approval.

This study has been considered by the Ethics Review Committee of Peking University Health Science Center and the patient privacy protection boards governing the recruitment sites.

Important modifications to the protocol are updated on the ClinicalTrials.gov website and disseminated to all relevant parties. We have a contractual agreement with

key collaborators determining access to trial data and authorship.

Data services

Sensitive information such as the participant's name, project ID number, phone number, country of birth from the recruitment form and information from the medical records will be stored in a locked cupboard at the hospitals. Every person involved in the recruitment has signed a confidentiality form. The results from the study will be presented in scientific journals and at national and international congresses.

DISCUSSION

GDM is the leading attributable risk factor for some serious complications that occur in women during pregnancy. It is estimated that the incidence rate of GDM has been increasing across China, and by 2019, approximately 3 million pregnant women suffered from GDM in China.⁴⁵ Despite many studies exploring interventions to reduce adverse consequences among women with GDM,^{17 42} few studies have tried to study the features of GDM in rural areas, which are different from those in urban areas. This exploratory research can provide a new direction for improving health quality and equity in rural areas.

At present, various GDM interventions and management strategies focusing on improving women's compliance aimed to attract pregnant women by designing new methods of management. There is a lack of incentive to encourage women to seek GDM screening and treatment

initially. Additionally, health providers' demands are usually ignored, while in practice, a large proportion of personnel in GDM management services are beyond their regular clinical workload. In this study, we propose subsidised GDM screening and management for pregnant women and medical staff. We supposed that standard care together with economic intervention would substantially increase their motivation. In addition, once women are diagnosed with GDM, the expenses of GDM screening and treatment are paid completely out of pocket in China, which is a large obstacle for women with low income in terms of receiving appropriate care. Subsidised GDM care that is provided for women and medical staff is essential for the health improvement of individuals with insufficient initiative.

In this study, we offered subsidies to two types of GDM services: screening and lifestyle management. This study will help us to determine which means of financial intervention has better performance. We are not yet sure who is the largest contributor to the low screening rate in rural areas: pregnant women or healthcare providers. Separate subsidies on GDM screening and management can help make this distinction.

Our outcomes not only evaluate the effectiveness of subsidised standard care intervention for women in western rural China but also show the cost-effectiveness of the intervention. The results of the cost-effectiveness analysis will demonstrate whether our project has economic feasibility in the future for popularisation and application. Another point is that we only provide subsidy to women in the intervention group. There is no contamination between the two groups.

Trial status

Participants are being recruited. The first patient was enrolled in September 2018. The SPIRIT study timeline details are shown in [figures 1 and 2](#).

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Contributors HF conceptualised this study, contributed to the interpretation of the results and reviewed and substantially revised the manuscript. TX conceived the study question and designed the study, conducted the data analyses and wrote the first draft of the manuscript. XL and KH reviewed and edited the manuscript substantially. LM contributed to the interpretation of the results and critically reviewed and edited the manuscript for important intellectual content. All authors approved the final manuscript as submitted and agree to be accountable for all aspects of the work.

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Supplement

Supplement 1

Informed Consent (English version)

We are going to carry out a study on screening management of gestational diabetes mellitus among pregnant women in rural areas of Western China. You are eligible for the study. Therefore, we would like to invite you to participate in the study. The project leader of this study is (Fang Hai, Peking University).

1. Why is this study conducted?

Gestational diabetes mellitus (GDM) is the most common medical complication during pregnancy, which belongs to high-risk pregnancy. Universal screening of pregnant women, timely detection of patients with hyperglycemia and effective intervention can significantly reduce the adverse effects of the disease on maternal and child health.

2. What are the contents of this study?

This study mainly includes four aspects: admission, which is carried out in the outpatient department, and the basic personal and family information of the participants is collected through the questionnaire; The screening link was conducted in the outpatient department, and the compliance and incidence rate of screening were collected through the screening chart. The management process was carried out in outpatient department and at home. Nutritional status, blood glucose control level and management rate were obtained through outpatient questionnaire and WeChat interaction; In the postpartum stage, the maternal and infant complications and the satisfaction and feelings of pregnant women were obtained through the collection of pregnant women research manual. In this study, pregnant women were followed up from 24-28 weeks to 6 weeks postpartum. The frequency of follow-up was the same as that of routine prenatal examination. The research time is expected to be one year.

3. What are the risks of participating in this study?

There was no physical damage to the participants in this study. The screening management measures used in the study are currently being used by the medical institution and recommended by the management guidelines for screening of gestational diabetes mellitus. The follow-up treatment of patients diagnosed with gestational diabetes mellitus is also conducted according to the principles and routine of the guidelines. Therefore, there is no additional medical risk in theory for the two groups of pregnant women. The medical information obtained by you will be kept confidential. When the research results are published in academic journals, they will not reveal any information that can identify you. Peking University will keep all your records in this study as well as the relevant hospital and office records. No one is allowed to access this information without authorization.

4. What are the benefits of participating in this study?

If you participate in this study, you may get more close and detailed follow-up observation and treatment from our research team, which may be more beneficial to the control of blood glucose. At the same time, you can get the pregnancy health education training of our research group.

5. How to deal with research related injuries?

The clinical management in this study was carried out according to the current standard treatment guidelines and conventional clinical treatment, and this study did not interfere with the medical treatment process. There are no related injuries that can be expected.

6. Will my information be confidential?

If you decide to participate in this study, your personal data in the study and in the study are confidential. Without your permission, any information that can identify you will not be disclosed to members outside the research team. All research members and interested parties will keep your identity confidential as required. Your file will be kept for researchers' reference only. When the results of this study are published, no personal information will be disclosed.

Subject statement

I have read this informed consent and agree to participate in this study. I know that I can withdraw from this study at any time during the study period without any reason.

Subject signature:

contact number:

Date:

A1. Birth date		A2. Age	_____years	A3. Blood pressure	_____ / _____mmHg
A4. Height	_____cm	A5. Weight before pregnancy	_____Kg	A6. Current weight	_____Kg
A7. Parities	_____ (Natural birth_____ Cesarean section_____)				
A8. Disease history	1.No 2. History of hereditary diseases 3. Chronic history of diabetes / hypertension / coronary heart disease 4. Others _____				
A9. Living areas	1.City 2. County and town 3. Village				
A10.How long you took to hospital		hours	A11.how much you spent on traveling to hospital		YUAN
A12.How long you take in hospital for prenatal care	_____hour				
A13. How many family members company you to the hospital ?	_____				
A14.Education	1. No schooling 2. Primary school 3. Junior middle school 4. Senior high school 5. Technical secondary school 6. Junior college 7. Bachelor degree or above				
A15.Occupation	1. Farmers 2. Workers 3. Service industry personnel 4. Individual or private 5. Civil servants 6. Students 7. Professional and technical workers 8. No work 9. Others _____				
A16. Number of permanent residents		A17. Total annual household income last year	Ten thousand	A18. Monthly household income	Yuan
A19. Types of medical insurance	1. None; 3. Medical insurance for urban employees; 4. Medical insurance for urban and rural residents; 5. Commercial medical insurance; 6. Public medical insurance				

B Maternal Cognition

B1. Do you know well on GDM?	1. Very Well 2. Well 3. General 4.Not Quite 5.Not At All (answer 4 or 5, jump to next question)
B2. Which way do you obtain these information ?	1.Doctors or Nurse 2. Books or Media 3. Friends or Other Pregnant Women 4. Other
B3. Do you know GDM screening including specific process?	1. Very Well 2. Well 3. General 4.Not well 5.Not At All
B4. Do you know the complications due to GDM ?	1. Very Well 2. Well 3. General 4.Not well 5.Not At All
B5. Do you know well the reasons on GDM?	1. Very Well 2. Well 3. General 4.Not well 5.Not At All

B6. Do you know how to treat GDM?	1. Very Well 2. Well 3. General 4. Not well 5. Not At All
b7. Do you think there is necessary to control food intakes in pregnancy?	1. Very Necessary 2. well Necessary 3. General 4. Not Quite Necessary 5. Not At All
b8. Will you be careful to select your food to control glucose in pregnancy?	1. Very Careful 2. Careful 3. General 4. Not Quite Careful 5. Not At All
b9. Do you think there is necessary to take exercise in pregnancy?	1. Very Necessary 2. Necessary 3. General 4. Not Quite Necessary 5. Not At All
b10. Will you be careful to take exercise to control glucose in pregnancy?	1. Very Careful 2 Careful 3. General 4. Not Quite Careful 5. Not At All
b11. Did you receive any education in your prenatal care hospital?	1. Very Frequent 2. Sometimes 3. Never 4. I Don't Know
b12. Will you agree if doctors suggest you to take screening in pregnancy?	1. Totally Agree 2. Agree 3. Not Quite 4. Reject

C Diet and Nutrition

C1 Please recall whether you have eaten the following food in last seven days, and then estimate the average intakes' weight accordingly.				
FOOD	YES/NO	FREQUENCY		Consumption per time (Liang/g)
	1. Yes 2. No	Every day	Every week	
C1.1. Rice				
C1.2. Wheat flour				
C1.3. Coarse cereals (millet / corn / purple rice / sorghum / Buckwheat / wheat bran, etc.)				
C1.4. Potato flour (sweet potato / potato / taro / yam, etc.)				
C1.5. Fried food (fried dough sticks / pancakes / French fries / fried chicken, etc.)				
C1.6. Vegetables (spinach / water spinach / broccoli / tomato / carrot, etc.)				
C1.7. Fruits				
C1.8. Poultry/livestock meat (Chicken / duck / goose / pork / beef /				

mutton, etc.)					
C1.9. Aquatic products (fish / shrimp / shellfish / sea fish, etc.)					
C1.10. Eggs					
C1.11. Dairy products (liquid milk / yogurt / cheese, etc.)					
C1.12. Beans products (tofu / shredded tofu / Sufu / Douchi / soymilk, etc.)					
C1.13. Nuts (Walnut / almond / peanut / pistachio / melon seed / cashew / chestnut, etc.)					
C1.14. Snacks (cream / cake / biscuit, etc.)					
C1.15. Beverages (coke / Iced Tea / coffee / fruit juice, etc.)					
C1.16. What are the types of edible oil you used in the past month, and estimate the consumption? (multi options)	1. Soybean oil 2. Rapeseed oil 3. Peanut oil 4. Sunflower oil 5. Corn oil 6. Salad oil 7. Linseed oil 8. Olive oil, tea oil 9. Others				_____kg
C2 Did you have taken the following dietary supplements in the past month					
C2.1 Folic Acid	1. No	2. Yes			
C2.2 Multivitamins	1. No	2. Yes			
C2.3 Vitamin D	1. No	2. Yes			
C2.4 Calcium	1. No	2. Yes			
C2.5 Iron	1. No	2. Yes			
C2.6 Fish Oil	1. No	2. Yes			
C2.7 Others	_____				

D Exercise

D1 Did you take any types of the following exercise in the past seven days, and estimated your exercise time				
TYEPES	YES/NO	Frequently		How long per time (minutes)
	1.YES 2.NO	Every day	Every week	
D1 Strenuous activities (moving or lifting weights / running / swimming / playing tennis / rope skipping, etc.)				

D2 Moderate activities (carrying (lifting) light objects / cycling / Taiji / Aquan / table tennis, etc.)				
D3 Walk for at least 10 minutes at a time (walking for work / home / transportation and walking for exercise)				
D4 Sitting in the past 7 days (at work / at home / on the bus, etc.)	_____hours (if you don't know, please fill out I don't know)			

F Quality of life

F1 How would you rate your quality of life ?	1.very poor 2 poor 3. Neither poor nor good 4. Good 5. Very good.
F2 How satisfied are you with your health?	1. Very dissatisfied 2. Dissatisfied 3. Neither satisfied nor dissatisfied 4. Satisfied 5. Very satisfied
The following questions ask about how much you have experienced certain things in the last four weeks.	
F3 To what extent do you feel that physical pain prevents you from doing what you need to do?	1.Not at all 2. A little 3. A moderate amount 4.very much 5. An extreme amount
F4 How much do you need any medical treatment to function in your daily life?	1.Not at all 2. A little 3. A moderate amount 4.very much 5. An extreme amount
F5 How much do you enjoy life?	1.Not at all 2. A little 3. A moderate amount 4.very much 5. An extreme amount
F6 To what extent do you feel your life to be meaningful?	1.Not at all 2. A little 3. A moderate amount 4.very much 5. An extreme amount
F7 How well are you able to concentrate?	1.Not at all 2. A little 3. A moderate amount 4.very much 5. extremely
F8 How safe do you feel in your daily life?	1.Not at all 2. A little 3. A moderate amount 4.very much 5. extremely
F9 How healthy is your physical environment?	1.Not at all 2. A little 3. A moderate amount 4.very much 5. extremely
The following questions ask about how completely you experience or were able to do certain things in the last four weeks.	
F10 Do you have enough energy for everyday life?	1.Not at all 2. A little 3. Moderately 4.mostly 5. completely
F11 Are you able to accept your bodily appearance?	1.Not at all 2. A little 3. Moderately 4.mostly 5. completely
F12 Have you enough money to meet your needs?	1.Not at all 2. A little 3. Moderately 4.mostly 5. completely
F13 How available to you is the information that you need in your day-to-day life?	1.Not at all 2. A little 3. Moderately 4.mostly 5. completely
F14 To what extent do you have the opportunity for	1.Not at all 2. A little 3. Moderately 4.mostly 5. completely

leisure activities?	
F15 How well are you able to get around?	1.very poor 2 poor 3. Neither poor nor good 4. Good 5. Very good.
The following questions ask about how completely you experience or were able to do certain things in the last four weeks.	
F16 How satisfied are you with your sleep?	1. Very dissatisfied 2. Dissatisfied 3. Neither satisfied nor dissatisfied 4. Satisfied 5. Very satisfied
F17 How satisfied are you with your ability to perform your daily living activities?	1. Very dissatisfied 2. Dissatisfied 3. Neither satisfied nor dissatisfied 4. Satisfied 5. Very satisfied
F18 How satisfied are you with your capacity for work?	1. Very dissatisfied 2. Dissatisfied 3. Neither satisfied nor dissatisfied 4. Satisfied 5. Very satisfied
F19 How satisfied are you with yourself?	1. Very dissatisfied 2. Dissatisfied 3. Neither satisfied nor dissatisfied 4. Satisfied 5. Very satisfied
F20 How satisfied are you with your personal relationships?	1. Very dissatisfied 2. Dissatisfied 3. Neither satisfied nor dissatisfied 4. Satisfied 5. Very satisfied
F21 How satisfied are you with your sex life?	1. Very dissatisfied 2. Dissatisfied 3. Neither satisfied nor dissatisfied 4. Satisfied 5. Very satisfied
F22 How satisfied are you with the support you get from your friends?	1. Very dissatisfied 2. Dissatisfied 3. Neither satisfied nor dissatisfied 4. Satisfied 5. Very satisfied
F23 How satisfied are you with the conditions of your living place?	1. Very dissatisfied 2. Dissatisfied 3. Neither satisfied nor dissatisfied 4. Satisfied 5. Very satisfied
F24 How satisfied are you with your access to health services?	1. Very dissatisfied 2. Dissatisfied 3. Neither satisfied nor dissatisfied 4. Satisfied 5. Very satisfied
F25 How satisfied are you with your transport?	1. Very dissatisfied 2. Dissatisfied 3. Neither satisfied nor dissatisfied 4. Satisfied 5. Very satisfied
The following question refers to how often you have felt or experienced certain things in the last four weeks.	
F26 How often do you have negative feelings such as blue mood, despair, anxiety, depression?	1.Never 2.Seldom 3.Quite Often 4.Very often 5.Always

Supplement 3

Diet and Exercise Log

Date	Breakfast(7:00-8:00)	Extral meal (9:30-10:30)	Lunch (11:00-13:00)	Extral meal (14:30-15:30)	Dinner (18:00-19:00)	Extral meal (21:00-22:30)	Exercise time	Doctor's score
FOR EXAMPLE 2018.08.26	Oatmeal porridge: 100g Milk: 250ml Egg: 1 Chinese cabbage: 100g	Green cucumber: 100g Soybean milk: 250ml	Coarse cereals: 50g Fish: 50g Tenderloin: 50g Sauerkraut: 100g Mushroom: 20g Celery: 200g Tofu: 50g	Walnut: 2 Apple: half	Coarse cereals: 50g Tomatoes: 2 Eggplant: 100g Chicken: 100g Auricularia auricula: 50g Spinach: 200g	Strawberry: 100g Milk: 250ml Oatmeal porridge: 100g	Walking: one hour	1-10 SCORES

Supplement 4

Medical Records

											75gOGTT	
Group	Name	Cellphone	Nationality	The date of enrollment	Weeks of pregnancy	Education	Screening voucher	Screening	Fasting	1h	2h	
Continued medical records												
											First retest	
GDM	The number of needing retests	Instruction of diet and exercise	Log and	Retest voucher	The date of first retest	Instruction via WeChat or phone	Fasting	2h after meal	Intensive intervention of diet and exercise	Additional inspection items	The date of second retest	Instruction via WeChat or phone
Continued medical records												
Second retest						Third retest						
Fasting	2h after meal	Intensive intervention of diet and exercise	Additional inspection items	The date of third retest	Instruction via WeChat or phone	Fasting	2h after meal	Intensive intervention of diet and exercise	Additional inspection items			
Continued medical records												
											Delivery	
Insulin	Inpatient number	Fasting blood glucose at admission	2h after meal	Additional inspection items	Gestational weeks of delivery	Hospital of transfer	Mode of delivery	Weight before birth	Maternal complications	Neonatal complications	Neonatal birth weight	

A. Characteristics

A1. Gestational weeks at birth	_____week	A2. Birth weight	_____Kg	A3. Blood pressure	_____/____mmHg
A4. The number of antenatal visits	_____time	A5. The costs of per antenatal visits		_____YUAN	
A6. The total costs of antenatal visits	_____YUAN	A7. The costs of out-pocket for antenatal visits		_____YUAN	
A8. Do you need additional tests during pregnancy due to gestational diabetes mellitus				1.No (jump to B section) 2. Yes	
Category	Do or not 1.Yes 2.No	Increased times			Costs per time (Chinese Yuan)
		Every two weeks	Every month	Entire pregnancy	
Urinalysis					
Glucose tests					
Glycated Albumin Test					
Glycosylated Hemoglobin Test					
B-Mode Ultrasonography					
Liver and Kidney Function Examination					
Insulin					
Other	_____				

B Maternal Cognition

B1. Do you know well on GDM?	1. Very Well 2. Well 3. General 4. Not Quite 5. Not At All (answer 4 or 5, jump to next question)
B2. Which way do you obtain these information ?	1. Doctors or Nurse 2. Books or Media 3. Friends or Other Pregnant Women 4. Other
B3. Do you know GDM screening including specific process?	1. Very Well 2. Well 3. General 4. Not well 5. Not At All
B4. Do you know the complications due to GDM ?	1. Very Well 2. Well 3. General 4. Not well 5. Not At All
B5. Do you know well the reasons on GDM?	1. Very Well 2. Well 3. General 4. Not well 5. Not At All

B6. Do you know how to treat GDM?	1. Very Well 2. Well 3. General 4. Not well 5. Not At All
b7. Do you think there is necessary to control food intakes in pregnancy?	1. Very Necessary 2. well Necessary 3. General 4. Not Quite Necessary 5. Not At All
b8. Will you be careful to select your food to control glucose in pregnancy?	1. Very Careful 2. Careful 3. General 4. Not Quite Careful 5. Not At All
b9. Do you think there is necessary to take exercise in pregnancy?	1. Very Necessary 2. Necessary 3. General 4. Not Quite Necessary 5. Not At All
b10. Will you be careful to take exercise to control glucose in pregnancy?	1. Very Careful 2 Careful 3. General 4. Not Quite Careful 5. Not At All
b11. Did you revive any education in your prenatal care hospital?	1. Very Frequent 2. Sometimes 3. Never 4. I Don't Know
b12. Will you agree if doctors suggest you to take screening in pregnancy?	1. Totally Agree 2. Agree 3. Not Quite 4. Reject

C Diet and Nutrition

C1 Please recall whether you have eaten the following food in last seven days, and then estimate the average intakes' weight accordingly.				
FOOD	YES/NO	Frequency		Consumption per time (Liang/g)
	1. Yes 2. No	Every day	Every week	
C1.1. Rice				
C1.2. Wheat flour				
C1.3. Coarse cereals (millet / corn / purple rice / sorghum / Buckwheat / wheat bran, etc.)				
C1.4. Potato flour (sweet potato / potato / taro / yam, etc.)				
C1.5. Fried food (fried dough sticks / pancakes / French fries / fried chicken, etc.)				
C1.6. Vegetables (spinach / water spinach / broccoli / tomato / carrot, etc.)				
C1.7 Fruits				
C1.8. Poultry/livestock meat (Chicken / duck / goose / pork / beef /				

mutton, etc.)					
C1.9. Aquatic products (fish / shrimp / shellfish / sea fish, etc.)					
C1.10. Eggs					
C1.11. Dairy products (liquid milk / yogurt / cheese, etc.)					
C1.12. Beans products (tofu / shredded tofu / Sufu / Douchi / soymilk, etc.)					
C1.13. Nuts (Walnut / almond / peanut / pistachio / melon seed / cashew / chestnut, etc.)					
C1.14. Snacks (cream / cake / biscuit, etc.)					
C1.15. Beverages (coke / Iced Tea / coffee / fruit juice, etc.)					
C1.16. What are the types of edible oil you used in the past month, and estimate the consumption? (multi options)	1. Soybean oil 2. Rapeseed oil 3. Peanut oil 4. Sunflower oil 5. Corn oil 6. Salad oil 7. Linseed oil 8. Olive oil, tea oil 9. Others				_____kg
C2 Did you have taken the following dietary supplements in the past month					
C2.1 Folic Acid	1. No		2. Yes		
C2.2 Multivitamins	1. No		2. Yes		
C2.3 Vitamin D	1. No		2. Yes		
C2.4 Calcium	1. No		2. Yes		
C2.5 Iron	1. No		2. Yes		
C2.6 Fish Oil	1. No		2. Yes		
C2.7 Others	_____				

D Exercise

D1 Did you take any types of the following exercise in the past seven days, and estimated your exercise time				
TYEPES	YES/NO	FREQUENTLY		How long per time (minutes)
	1.YES 2.NO	Every day	Every week	
D1 Strenuous activities (moving or lifting weights / running / swimming / playing tennis / rope skipping, etc.)				

D2 Moderate activities (carrying (lifting) light objects / cycling / Taijiquan / table tennis, etc.)				
D3 Walk for at least 10 minutes at a time (walking for work / home / transportation and walking for exercise)				
D4 Sitting in the past 7 days (at work / at home / on the bus, etc.)	_____hours (if you don't know, please fill out I don't know)			

E Satisfaction with medical care during pregnancy

E1 Are you satisfied with the screening of gestational diabetes mellitus?	1. Very dissatisfied 2. Dissatisfied 3. Neither satisfied nor dissatisfied 4. Satisfied 5. Very satisfied
E2. Are you satisfied with the management of gestational diabetes mellitus?	1. Very dissatisfied 2. Dissatisfied 3. Neither satisfied nor dissatisfied 4. Satisfied 5. Very satisfied

F Quality of life

F1 How would you rate your quality of life ?	1. very poor 2 poor 3. Neither poor nor good 4. Good 5. Very good.
F2 How satisfied are you with your health?	1. Very dissatisfied 2. Dissatisfied 3. Neither satisfied nor dissatisfied 4. Satisfied 5. Very satisfied
The following questions ask about how much you have experienced certain things in the last four weeks.	
F3 To what extent do you feel that physical pain prevents you from doing what you need to do ?	1. Not at all 2. A little 3. A moderate amount 4. very much 5. An extreme amount
F4 How much do you need any medical treatment to function in your daily life?	1. Not at all 2. A little 3. A moderate amount 4. very much 5. An extreme amount
F5 How much do you enjoy life?	1. Not at all 2. A little 3. A moderate amount 4. very much 5. An extreme amount
F6 To what extent do you feel your life to be meaningful?	1. Not at all 2. A little 3. A moderate amount 4. very much 5. An extreme amount
F7 How well are you able to concentrate?	1. Not at all 2. A little 3. A moderate amount 4. very much 5. extremely
F8 How safe do you feel in your daily life?	1. Not at all 2. A little 3. A moderate amount 4. very much 5. extremely
F9 How healthy is your physical environment?	1. Not at all 2. A little 3. A moderate amount 4. very much 5. extremely
The following questions ask about how completely you experience or were able to do certain things in the last four weeks.	

F10 Do you have enough energy for everyday life?	1. Not at all 2. A little 3. Moderately 4. mostly 5. completely
F11 Are you able to accept your bodily appearance?	1. Not at all 2. A little 3. Moderately 4. mostly 5. completely
F12 Have you enough money to meet your needs?	1. Not at all 2. A little 3. Moderately 4. mostly 5. completely
F13 How available to you is the information that you need in your day-to-day life?	1. Not at all 2. A little 3. Moderately 4. mostly 5. completely
F14 To what extent do you have the opportunity for leisure activities?	1. Not at all 2. A little 3. Moderately 4. mostly 5. completely
F15 How well are you able to get around?	1. very poor 2. poor 3. Neither poor nor good 4. Good 5. Very good.
The following questions ask about how completely you experience or were able to do certain things in the last four weeks.	
F16 How satisfied are you with your sleep?	1. Very dissatisfied 2. Dissatisfied 3. Neither satisfied nor dissatisfied 4. Satisfied 5. Very satisfied
F17 How satisfied are you with your ability to perform your daily living activities?	1. Very dissatisfied 2. Dissatisfied 3. Neither satisfied nor dissatisfied 4. Satisfied 5. Very satisfied
F18 How satisfied are you with your capacity for work?	1. Very dissatisfied 2. Dissatisfied 3. Neither satisfied nor dissatisfied 4. Satisfied 5. Very satisfied
F19 How satisfied are you with yourself?	1. Very dissatisfied 2. Dissatisfied 3. Neither satisfied nor dissatisfied 4. Satisfied 5. Very satisfied
F20 How satisfied are you with your personal relationships?	1. Very dissatisfied 2. Dissatisfied 3. Neither satisfied nor dissatisfied 4. Satisfied 5. Very satisfied
F21 How satisfied are you with your sex life?	1. Very dissatisfied 2. Dissatisfied 3. Neither satisfied nor dissatisfied 4. Satisfied 5. Very satisfied
F22 How satisfied are you with the support you get from your friends?	1. Very dissatisfied 2. Dissatisfied 3. Neither satisfied nor dissatisfied 4. Satisfied 5. Very satisfied
F23 How satisfied are you with the conditions of your living place?	1. Very dissatisfied 2. Dissatisfied 3. Neither satisfied nor dissatisfied 4. Satisfied 5. Very satisfied
F24 How satisfied are you with your access to health services?	1. Very dissatisfied 2. Dissatisfied 3. Neither satisfied nor dissatisfied 4. Satisfied 5. Very satisfied
F25 How satisfied are you with your transport?	1. Very dissatisfied 2. Dissatisfied 3. Neither satisfied nor dissatisfied 4. Satisfied 5. Very satisfied
The following question refers to how often you have felt or experienced certain things in the last four weeks.	

F26 How often do you have negative feelings such as blue mood, despair, anxiety, depression?	1.Never 2.Seldom 3.Quite Often 4.Very often 5.Always
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