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# Observation on the effects of group pregnancy care combined with nutritional guidance in patients with gestational diabetes mellitus

**Submission date**
20/11/2024

**Recruitment status**
No longer recruiting

**Registration date**
05/12/2024

**Overall study status**
Completed

**Last Edited**
11/12/2024

**Condition category**
Pregnancy and Childbirth

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

## Plain English summary of protocol

Background and study aims
The increasing prevalence of gestational diabetes mellitus (GDM) in China highlights the growing importance of effective management and prevention strategies. This upward trend has been associated with modern lifestyle changes and dietary habits, underscoring the need for early intervention and effective management of GDM. Recent statistics indicate that GDM affects about 1.78 million women in China, making it one of the most common pregnancy-related complications. GDM not only compromises maternal and neonatal health but also elevates the risk of type 2 diabetes and cardiovascular disease for both mothers and their offspring. The current management strategies for GDM generally include individualized nutritional intervention, blood glucose monitoring, and weight management. However, these traditional approaches often encounter challenges such as inadequate patient adherence and limited professional support. In response, the combined approach of group prenatal care with nutritional guidance has emerged as a promising alternative. This model seeks to enhance patient self-management and improve pregnancy outcomes by integrating standardized professional lifestyle management with individualized nutritional counseling and systematic blood glucose monitoring.

Who can participate?
Female patients aged between 20 and 45 years old with a single pregnancy (gestational age 24 to 28 weeks)

What does the study involve?
The control group received routine prenatal care. In addition to the routine care provided to the control group, the observation group used a WeChat platform for enhanced management through the group prenatal care model. This approach included internet-based self-management, group activities, and social support.

What are the possible benefits and risks of participating?
Patients can enhance their self-management and improve pregnancy outcomes by integrating standardized professional lifestyle management (group prenatal care) with individualized

nutritional counseling and systematic blood glucose monitoring.
As for the potential side effects of the treatment, if there are any, they may include symptoms such as gastrointestinal disturbances. This could manifest as nausea, vomiting, or diarrhea, particularly if dietary changes are significant.
Patients may experience low blood sugar levels, leading to symptoms such as dizziness, sweating, tremors, or confusion, especially if they are not adequately monitored. Some patients may experience anxiety or stress related to dietary restrictions or managing their condition. Depending on the nutritional guidance, some patients might experience unintended weight loss or gain.

Where is the study run from?
The Second Affiliated Hospital of Fujian Medical University (China)

When is the study starting and how long is it expected to run for?
July 2023 to December 2024

Who is funding the study?
Provincial clinical key specialty construction project (China) (Grant No. HLZDZK202302).

Who is the main contact?
Huifen Zhao, zhaohuifeng21102@163.com

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## Additional identifiers

### EudraCT/CTIS number
Nil known

### IRAS number

### ClinicalTrials.gov number
Nil known

### Secondary identifying numbers
HLZDZK202302

## Study information

### Scientific Title
Group pregnancy care and nutritional guidance in gestational diabetes mellitus management

### Study objectives
Following the guidelines of the American Diabetes Association, this study developed a tailored maternal nutritional assessment and management program aimed at stabilizing blood glucose levels. By employing group prenatal care alongside nutritional guidance, the study aims to empower pregnant women and enhance their self-management abilities. This research evaluates the practical application of this combined approach and aims to support the development of more effective gestational diabetes mellitus (GDM) management strategies.

### Ethics approval required
Ethics approval required

### Ethics approval(s)
Approved 14/07/2023, Ethics Committee of the Second Affiliated Hospital of Fujian Medical University (No. 950 Donghai Street, Quanzhou, 326000, China; +86 (0)595 26655161; fyeykj@163.com), ref: 2023-254

### Study design

Randomized controlled trial

## Primary study design
Interventional

## Secondary study design
Randomised controlled trial

## Study setting(s)
Hospital

## Study type(s)
Quality of life

## Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

## Health condition(s) or problem(s) studied
Gestational diabetes mellitus

## Interventions
Convenience sampling was used to retrospectively identify pregnant women who registered for and received regular prenatal care at our hospital's obstetrics and gynecology department from February 2023 to February 2024. Participants who registered between February 2023 and July 2023 were assigned to the control group, while those who registered from August 2023 to February 2024 were assigned to the observation group, with 46 participants in each group. The control group received routine prenatal care, whereas the observation group received group prenatal care supplemented with nutritional guidance. Their dietary compliance, knowledge of GDM, self-management ability and perception of social support between the two groups were assessed and compared.

## Intervention Type
Mixed

## Primary outcome measure
1. Diet compliance measured using the self-developed diet compliance scale (encompassing three dimensions: diet treatment attitude, motivation, and behavior regulation) for GDM patients before the intervention and 10 months after the intervention.
2. GDM knowledge level measured using the GDM Knowledge Level Questionnaire (consisting of three dimensions: knowledge of gestational diabetes, diet during pregnancy, and exercise) before the intervention and 10 months after the intervention
3. Self-management ability is measured using the Self-Management Ability Questionnaire (including four dimensions: daily life behavior, fetal monitoring behavior, compliance behavior, and self-protection behavior) before the intervention and 10 months after the intervention

## Secondary outcome measures
Perceived social support level is measured using the fear of missing out (FoMO) scale (including three dimensions: family support, friend support, and other support) before the intervention and 10 months after the intervention

### Overall study start date
01/07/2023

### Completion date
31/12/2024

## Eligibility

### Key inclusion criteria
1. Participants met the diagnostic criteria: undergoing a 75-g oral glucose tolerance test (OGTT) during pregnancy: fasting blood glucose ≥5.1 mmol/l (or 92 mg/dl); 1-hour blood glucose ≥10.0 mmol/l (or 180 mg/dl); 2-hour blood glucose ≥8.5 mmol/l (or 153 mg/dl). If any of the above criteria are met, a diagnosis of gestational diabetes mellitus can be made
2. Participants had a singleton cephalic pregnancy
3. The patient is between the ages of 20 and 45 years
4. Participants were at a gestational age of 24 to 28 weeks
5. Participants had family support available

### Participant type(s)
Patient

### Age group
Adult

### Sex
Female

### Target number of participants
94

### Total final enrolment
94

### Key exclusion criteria
Severe pregnancy complications or communication disorders due to various diseases

### Date of first enrolment
01/02/2023

### Date of final enrolment
01/02/2024

## Locations

### Countries of recruitment
China

### Study participating centre

**The Second Affiliated Hospital of Fujian Medical University**
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# Sponsor information

**Organisation**
Provincial clinical key specialty construction project

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**Sponsor type**
Government

# Funder(s)

**Funder type**
Government

**Funder Name**
Provincial clinical key specialty construction project

# Results and Publications

**Publication and dissemination plan**
Planned publication in a high-impact peer-reviewed journal

**Intention to publish date**
01/02/2025

**Individual participant data (IPD) sharing plan**
The authors declare that all data supporting the findings of this study are available within the paper and any raw data can be obtained from the corresponding author upon request: Huifeng

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The type of data that will be shared:
1. Clinical data:
Basic information of the patient (such as age, gender, race, etc)
Clinical examination results (such as physical examination results and imaging examinations)
2. Biomarker data:
Chemical composition analysis of biological samples such as blood and urine (such as fasting blood glucose levels).
3. Treatment intervention data
Intervention methods: The control group received routine prenatal care, whereas the observation group received group prenatal care supplemented with nutritional guidance.
Duration and frequency of treatment: The intervention spanned from 24 to 28 weeks of gestation to 42 days postpartum, with a total of seven sessions, each lasting 2 hours.
4. Outcome data:
Efficacy evaluation (such as diet compliance, GDM knowledge level, self-management ability, perceived social support level)
5. Statistics and analysis of data:
Statistical significance test results
The authors declare that all data supporting the findings of this study are available within the paper and any raw data can be obtained from the corresponding author upon request.
Written informed consent was obtained from a legally authorized representative(s) for anonymized patient information to be published in this article.

## IPD sharing plan summary

Available on request