

# Management strategies for Chinese women with gestational diabetes

<b>Submission date</b> 13/06/2024	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 17/06/2024	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 06/12/2024	<b>Condition category</b> Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

This study aims to examine the effects of three modes of exercise interventions on blood sugar and pregnancy outcomes and explore the most effective exercise patterns for women with gestational diabetes mellitus (GDM). Gestational diabetes is high blood sugar that develops during pregnancy and usually disappears after giving birth.

### Who can participate?

Chinese pregnant women with GDM at 24–28 weeks of gestation

### What does the study involve?

The study lasted for a total of 24 weeks, including initial assessments, the exercise intervention period, and follow-up assessments.

The participants were assigned into four groups:

1. The aerobic exercise group took an exercise intervention of moderate-intensity walking at a speed of 3–6 km/h or 100–200 steps/min. Exercise was recommended every other day, 3–4 times per week. Participants were advised to start exercising 1 hour after a meal and continue for 40 minutes, with a family member to ensure safety, provide motivation, and increase adherence to the exercise routine
2. The resistance training group received an exercise intervention involving seated bicep curls with a 1-kg dumbbell. This was also performed once every other day, 3 to 4 times per week, 1 hour after a meal. The exercise duration was 40 minutes. The specific movements included elbow flexion, double arm abduction (timed for 30 seconds), swinging arms back and forth, chest expansion exercises, and raising both arms overhead. Each movement was repeated 10 times, with five movements making up one set. A total of three sets were performed, with a 15-second rest period between each movement and a 1-minute rest period between each set.
3. The aerobic exercise combined with resistance training group undertook a 20-minute moderate-intensity walk followed by seated bicep curls with a 1-kg dumbbell. This routine was performed once every other day, 3 to 4 times per week, with the exercise session taking place 1 hour after a meal. The walking duration was 40 minutes, and the resistance exercises consisted of five repetitions for each of the five different exercises, totaling three sets. A 15-second rest period was given between each exercise and a 1-minute rest period between each set.
4. The control group received only routine prenatal care, personalized diabetes diet guidance,

and online education guidance on weight control, blood glucose monitoring, and using a food diary.

What are the possible benefits and risks of participating?

Possible benefits include improvement in blood sugar control, enhanced overall physical fitness, and reduction in the risk of complications associated with GDM. As with any physical activity, there is a small risk of injury. However, the exercise program is designed to be safe and appropriate for pregnant women.

Where is the study run from?

The Second Affiliated Hospital of Guangxi Medical University (China)

When is the study starting and how long is it expected to run for?

August 2019 to March 2021

Who is funding the study?

1. Joint Project on Regional High-Incidence Diseases Research of Guangxi Natural Science Foundation (#2023GXNSFAA026241) (China)
2. Guangxi Medical and Health Appropriate Technology Development and Application Project (#S2022095) (China)
3. Guangxi Medical and Health Appropriate Technology Development and Application Project (#S2019101) (China)

Who is the main contact?

Ms Qihong Huang, ssqy13977197819@163.com

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## Additional identifiers

**Clinical Trials Information System (CTIS)**

Nil known

**Protocol serial number**

Nil known

## Study information

**Scientific Title**

Effect of three modes of exercise intervention on glycemic control and pregnancy outcomes among Chinese women with gestational diabetes mellitus

**Study objectives**

Aerobic exercise in combination with resistance training has better effects in reducing FBG, 2h-PBG, HbA1c levels and postpartum bleeding compared to the aerobic exercise, resistance training, and no exercise groups.

**Ethics approval required**

Ethics approval required

**Ethics approval(s)**

approved 01/08/2019, The Second Affiliated Hospital of Guangxi Medical University (166 East Daxue Road, Nanning, 530000, China; +86 (0)771 5356557; gxydkyb@163.com), ref: 2020-KY-E-117

## **Study design**

Non-randomized study

## **Primary study design**

Interventional

## **Study type(s)**

Efficacy

## **Health condition(s) or problem(s) studied**

Gestational diabetes mellitus

## **Interventions**

The participants were assigned into four groups based on their willingness:

1. The aerobic exercise group took an exercise intervention of moderate-intensity walking at a speed of 3–6 km/h or 100–200 steps/min. Exercise was recommended every other day, 3–4 times per week. Participants were advised to start exercising 1 hour after a meal and continue for 40 minutes, with a family member to ensure safety, provide motivation, and increase adherence to the exercise routine
2. The resistance training group received an exercise intervention involving seated bicep curls with a 1-kg dumbbell. This was also performed once every other day, 3 to 4 times per week, 1 hour after a meal. The exercise duration was 40 minutes. The specific movements included elbow flexion, double arm abduction (timed for 30 seconds), swinging arms back and forth, chest expansion exercises, and raising both arms overhead. Each movement was repeated 10 times, with five movements making up one set. A total of three sets were performed, with a 15-second rest period between each movement and a 1-minute rest period between each set.
3. The aerobic exercise combined with resistance training group undertook a 20-minute moderate-intensity walk followed by seated bicep curls with a 1-kg dumbbell. This routine was performed once every other day, 3 to 4 times per week, with the exercise session taking place 1 hour after a meal. The walking duration was 40 minutes, and the resistance exercises consisted of five repetitions for each of the five different exercises, totaling three sets. A 15-second rest period was given between each exercise and a 1-minute rest period between each set.
4. The control group received only routine prenatal care, personalized diabetes diet guidance, and online education guidance on weight control, blood glucose monitoring, and using a food diary.

## **Intervention Type**

Behavioural

## **Primary outcome(s)**

1. Fasting blood glucose (FBG) measured using glucose oxidase method
2. 2-hour postprandial blood glucose (2h-PBG) measured using glucose oxidase method
3. Glycated hemoglobin (HbA1c) measured using high-performance liquid chromatography (HPLC)

Data collection was conducted at the baseline before the intervention, 1 and 3 months after the intervention, and 2 hours after the delivery

## **Key secondary outcome(s)**

1. Maternal pregnancy outcomes: gestational age, preterm birth, mode of delivery, gestational hypertension syndrome, insulin use, late pregnancy weight gain, postpartum hemorrhage

measured using patients' medical records

2. Neonatal birth outcomes: birth weight, length at birth, 1-minute Apgar score, and incidence of neonatal complications such as respiratory distress syndrome measured using patients' medical records

Data collection was conducted at the baseline before the intervention, 1 and 3 months after the intervention, and 2 hours after the delivery

**Completion date**

15/03/2021

## **Eligibility**

**Key inclusion criteria**

1. Pregnant women with GDM at 24–28 weeks of gestation. A diagnosis of GDM is made using the one-step approach of a 75-g oral glucose tolerance test if the plasma glucose value is abnormal (i.e., fasting blood glucose  $\geq 5.1$  mmol/L, 1 hour  $\geq 10.0$  mmol/L, 2 hours  $\geq 8.5$  mmol/L)
2. Single pregnancy
3. Body mass index (BMI)  $< 40$  kg/m<sup>2</sup>
4. Muscle strength at level IV or above

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

20 years

**Upper age limit**

50 years

**Sex**

Female

**Total final enrolment**

184

**Key exclusion criteria**

1. Severe obstetric complications and contraindications listed in the public health guidelines for physical activity during pregnancy
2. Severe heart, liver, lung, or kidney damage
3. Acute or chronic complications caused by diabetes, such as ketoacidosis or diabetic foot

**Date of first enrolment**

25/09/2020

**Date of final enrolment**

30/12/2020

## Locations

**Countries of recruitment**

China

**Study participating centre**

The Second Affiliated Hospital of Guangxi Medical University

166 East Daxue Road

Nanning

China

530000

## Sponsor information

**Organisation**

Guangxi Natural Science Foundation

## Funder(s)

**Funder type**

Government

**Funder Name**

Natural Science Foundation of Guangxi Province

**Alternative Name(s)**

Guangxi Natural Science Foundation

**Funding Body Type**

Government organisation

**Funding Body Subtype**

Local government

**Location**

China

## Funder Name

Guangxi Medical and Health Appropriate Technology Development and Application Project

## Results and Publications

### Individual participant data (IPD) sharing plan

The datasets generated during the current study will be available upon request from Dr Yingchun Zeng (chloezengyc@qq.com)

### IPD sharing plan summary

Available on request

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		19/09/2024	06/12/2024	Yes	No