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Management strategies for Chinese women with gestational diabetes

Submission date
13/06/2024

Recruitment status
No longer recruiting

Registration date
17/06/2024

Overall study status
Completed

Last Edited
06/12/2024

Condition category
Pregnancy and Childbirth

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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?
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Efficacy

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
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 measure
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

Secondary outcome measures
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

Overall study start date
15/08/2019

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 ≥5.1 mmol/L, 1 hour ≥10.0 mmol/L, 2 hours ≥8.5 mmol/L)
2. Single pregnancy
3. Body mass index (BMI) <40 kg/m2
4. Muscle strength at level IV or above

Participant type(s)
Patient

Age group
Adult

Lower age limit
20 Years

Upper age limit
50 Years

Sex
Female

Target number of participants
200

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
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Sponsor information

Organisation
Guangxi Natural Science Foundation

Sponsor details
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Sponsor type
Government

Website
http://kjt.gxzf.gov.cn/zwfw/bsxx/xmtzgg/index_1.shtml

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

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

Intention to publish date
16/06/2024

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?
Results article		19/09/2024	06/12/2024	Yes	No