

A Study of the Intervention of Time-restricted Eating in High-risk Populations of GDM

NCT06431997

Status	RECRUITING
Phase	Not Applicable
Sponsor	Fudan University
Enrollment	240 participants

Key Eligibility Criteria

Inclusion (5)

- Aged 18-50 years;
- The risk for GDM includes overweight or obesity (BMI \geq 24 kg/m² before pregnancy), first-degree relative with diabetes, history of cardiovascular disease, hypertension (\geq 130/80 mmHg or on therapy for hypertension), HDL cholesterol level $<$ 1 mmol/L and/or a triglyceride level $>$ 2.8 mmol/L, history of GDM, history of macrosomia delivery, individuals with polycystic ovary syndrome, repeated positive fasting urine glucose in the first trimester, or age $>$ 45 years according to Guideline of Diagnosis and Treatment of Hyperglycemia in Pregnancy (2022);
- Less than 14 weeks of gestation;
- Able to read and complete questionnaires in Chinese;
- singleton pregnancy.

Exclusion (17)

- Pregestational diabetes (including diabetes diagnosed before conception; fasting blood glucose \geq 7.0 mmol/L or HbA1c \geq 6.5% in the first trimester; typical symptoms of hyperglycemia or hyperglycemic crisis with optional blood glucose \geq 11.1 mmol/L);
- Impaired glucose tolerance (including fasting blood glucose \geq 5.6 mmol/L or two fasting blood glucose \geq 5.1 mmol/L in the first trimester);
- Current or recent use of drugs that affect glucose metabolism such as metformin, glucocorticoids and Orlistat;
- Severe comorbidities (including cardiac diseases, kidney diseases, hepatopathy, autoimmune diseases, uncontrolled thyroid disease, previous or current malignant tumors, etc.);
- Fetal malformations or chromosomal abnormalities;
- ... and 12 more (see full listing online)

Locations (1 total)

Obstetrics and Gynecology Hospital of Fudan University, Shanghai, Shanghai Municipality, China