Protocol
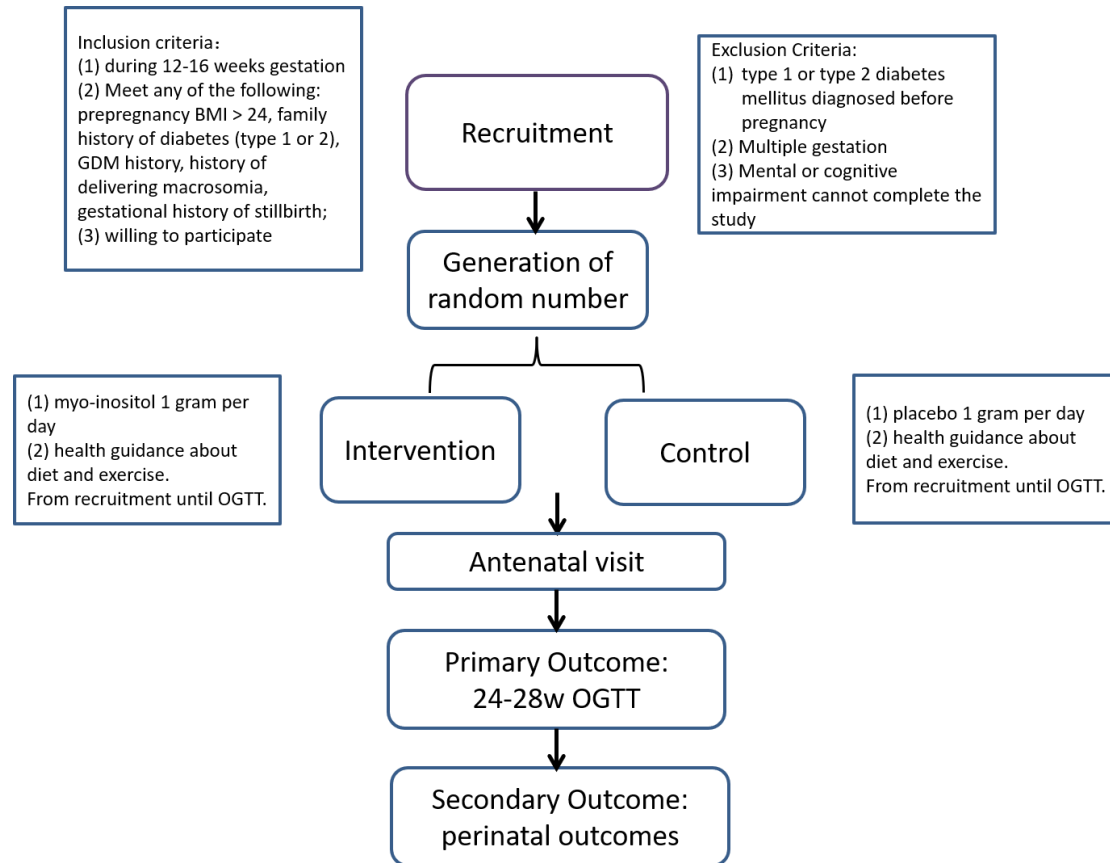
Title: Myo-inositol in prevention of gestational diabetes mellitus in China
RCT Number：
Date：Feb 4th, 2021

Inclusion criteria：
(1) during 12-16 weeks gestation
(2) Meet any of the following: prepregnancy BMI > 24, family history of diabetes (type 1 or 2), GDM history, history of delivering macrosomia, gestational history of stillbirth;
(3) willing to participate

Exclusion Criteria:
(1) type 1 or type 2 diabetes mellitus diagnosed before pregnancy
(2) Multiple gestation
(3) Mental or cognitive impairment cannot complete the study

Recruitment

Generation of random number

(1) myo-inositol 1 gram per day
(2) health guidance about diet and exercise.
From recruitment until OGTT.

Intervention

Control

(1) placebo 1 gram per day
(2) health guidance about diet and exercise.
From recruitment until OGTT.

Antenatal visit

Primary Outcome: 24-28w OGTT

Secondary Outcome: perinatal outcomes

Planned Analysis
1) Chi square test and t test are used to compare the basic information of the subjects.

2) T test is used to compare the results of OGTT between the intervention group and the control group

3) Chi square test is used to analyze the incidences of secondary outcomes (such as cesarean section rate, weight gain, macrosomia etc) between the intervention group and the control group

4) Logistic regression and linear regression analysis were used to calculate the association between inositol intake and other confounding factors (such as age, BMI, etc.).