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# Tianjin Gestational Diabetes Mellitus Prevention Program Study design, methods, and 1-year interim report on the feasibility of lifestyle intervention program

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ABSTRACT

*Objective:* To assess whether lifestyle intervention can reduce type 2 diabetes risk in women with prior GDM in the Tianjin Gestational Diabetes Mellitus (GDM) Prevention Program.
*Methods:* 1180 women who were diagnosed with GDM from 2005 to 2009 were randomly assigned to either a lifestyle intervention ($n = 586$) or a control group ($n = 594$). Major elements of the intervention include six face-to-face meetings with study dietitians in the first year, and two additional sessions and two telephone calls in second year.
*Results:* During the first year, average body weight loss in the first 404 subjects was 1.40 kg (2.1%) in the intervention group vs 0.21 kg (0.3%) in the control group ($P = 0.001$), and the decrease was more significant among baseline overweight women (body bass index [BMI] $\geq 24$ kg/m$^2$) in the intervention (2.91 kg/4.2%) compared with that in the control group (0.51 kg/0.7%) ($P < 0.001$). In addition, women in the intervention group, compared with those in the control group, have decreased BMI, body fat, waist circumference, and plasma insulin levels, and have improved behaviors including increased leisure time activity and dietary fiber intake and decreased sedentary time and fat consumptions.
*Conclusion:* The interim results support the efficacy and feasibility of the lifestyle intervention program.



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## 1. Introduction

Gestational diabetes mellitus (GDM) is defined as any degree of glucose intolerance with onset or first recognition during pregnancy [1]. GDM is a common pregnancy outcome affecting about 7% of pregnancies in the U.S. [2]. In general, Asian women compared with other racial/ethnic groups in the U.S. have a very high risk for GDM [3–6]. In 1998, we introduced a universal screening program for GDM to women living in the six urban districts of Tianjin, China and found that the prevalence of GDM had increased from 2.4% in 1999 to 6.8% in 2008 [7]. Women with GDM are likely to develop impaired glucose tolerance (IGT) and type 2 diabetes in the postnatal period [8] or later life [9–11], and children born from a pregnancy complicated by GDM are also at risk of childhood obesity and abnormal glucose metabolism [12,13].

Several randomized clinical trials such as the Chinese Da Qing Diabetes Prevention Study (DQDPS) [14], the Finnish Diabetes Prevention Study (DPS) [15], and the American Diabetes Prevention Program (DPP) [16], have demonstrated that effective lifestyle intervention strategies can prevent or delay the progression to type 2 diabetes among high-risk adults with IGT. In additional analyses of data from the DPP, the intensive lifestyle intervention was highly effective in delaying and preventing type 2 diabetes in 350 women with a history of both IGT and GDM [17]. However, the mean age of women with prior GDM entering DPP was 43 years and the mean interval was 12 years from the index GDM pregnancy [17]. Moreover, the study was limited by small sample size and posthoc analysis. To our knowledge, thus far no study has scientifically tested whether lifestyle management can prevent type 2 diabetes risk among women with GDM in a short period after delivery. The primary aim of the Tianjin Gestational Diabetes Mellitus Prevention Program (TGDMPP) is to assess whether an intensive and individually designed diet and exercise program can prevent or delay the onset of type 2 diabetes in women with a history of GDM. Secondary research aim is to evaluate the effects of the intervention program on cardiovascular risk factors. Third research aim is to test the gene-intervention interactions in relation to type 2 diabetes related metabolic changes among women with prior GDM. This interim report will present the study methods/protocols and the lifestyle intervention, as well as the impact of such an intervention on benchmarks for the risk of diabetes at the end of year 1.

## 2. Subjects and methods

### 2.1. *Tianjin GDM screening project*

Tianjin is the fourth largest city with over 11 million residents in Northern China. Among Tianjin permanent residents, 3.9 million live in six central urban districts. Since 1999, all pregnant women who live in six urban districts have participated in the universal screening for GDM [7]. The average proportion of screened pregnancies was over 91% during 1999 to 2008 [7]. All pregnant women at 26–30 gestational weeks participated in a 1-h oral glucose tolerance test (OGTT) with 50-g glucose load. Women who had a glucose reading $\geq$7.8 mmol/l were invited to undergo a 2-h OGTT with a 75-g glucose load at the Tianjin Women's and Children's Health Center. We have been using the World Health Organization (WHO)'s criteria [18] to define GDM [7]. Women with a 75-g glucose 2-h OGTT result confirming either diabetes (fasting glucose $\geq$7 mmol/l or 2-h glucose $\geq$11.1 mmol/l) or IGT (2-h glucose $\geq$7.8 and $<$11.1 mmol/l) are regarded as having GDM [7]. A total of 128,125 pregnant women took part in the GDM screening program and 6247 were diagnosed with GDM from December 1998 to December 2009.

### 2.2. *Study samples, recruitment, screening visits, run-in, and randomization*

All pregnant women with GDM ($N$ = 4644) in six urban districts from 2005 to 2009 are eligible for the study. The study was approved by the human subjects committee of Tianjin Women's and Children's Health Center. All participants gave written informed consent.

The inclusion criteria were: (1) age 20–49 years at baseline survey, and (2) women diagnosed with GDM between 2005 and 2009. The exclusion criteria were: (1) age $<$20 or $\geq$50 years; (2) at the screening visit: (a) fasting glucose $\geq$7.0 mmol/l or 2-h glucose $\geq$11.1 mmol/l in the OGTT test; and (b) taking medicines known to alter OGTT; (3) presence of any chronic diseases that could seriously reduce the life expectancy or the ability to participate in the trial/study; (4) unable or unwilling to give informed consent or communicate with study staff; (5) currently pregnant, or planning to become pregnant in the next 2 years.

*Pre-screening contact*: Since we have set up a good health care registration system for GDM mothers' health and contact information, we first mailed a letter explaining the study aims and inviting all eligible women to participate in the screening visit. Then we had a telephone call to decide who would participate in the screening visit. Women had been asked to fast for at least 12 h overnight before the screening visit.

*Screening visit*: This included informed consent and completion of a detailed medical eligibility questionnaire. The eligibility screening questionnaire was based on the inclusion/exclusion criteria described above. If eligible, subjects would finish the baseline survey at the same time. A total of 1263 GDM mothers (participation rate 27%) finished the baseline survey during August 2009 to July 2011. At the baseline survey, all women subjects completed a self-administered questionnaire and underwent a physical examination. They also completed the 3-day 24-h food records using methods for dietary record collections taught by a dietician.

*Run-in*: A 2-week ''run-in'' period followed the baseline survey during which 2 classes on general principles of lifestyle intervention for the prevention of type 2 diabetes and obesity were taught. Participants discussed previous experience with lifestyle changes and obstacles encountered. Accumulating evidence showing that lifestyle intervention is effective for the prevention of type 2 diabetes had been presented. The specific lifestyle intervention program did not begin during this period. If a woman had newly diagnosed type 2 diabetes (fasting glucose $\geq$7.0 mmol/l or 2-h glucose $\geq$11.1 mmol/l) in our baseline OGTT test, we excluded her from the present study at this period ($N$ = 83).