Am J Transl Res 2026;18(10):9303-9321
www.ajtr.org /ISSN:1943-8141/AJTR0175385

Original Article

Construction of a management model based on traditional Chinese medicine comprehensive health management for a high-risk gestational diabetes mellitus population and its impact on postpartum diabetes

Yuqin Niu[1,2], Hongmei Liu[3], Dandan Sun[4], Wenxiu Huang[1]

[1]Zhejiang Chinese Medical University, 548 Binwen Road, Binjiang District, Hangzhou 310053, Zhejiang, China; [2]Health Management Center, The First Affiliated Hospital of Shihezi University, North 2nd Road, Shihezi 832000, Xinjiang, China; [3]Department of Gynecology, The First Affiliated Hospital of Shihezi University, North 2nd Road, Shihezi 832000, Xinjiang, China; [4]Department of Obstetrics, The First Affiliated Hospital of Shihezi University, North 2nd Road, Shihezi 832000, Xinjiang, China

Received July 15, 2026; Accepted September 17, 2026; Epub October 15, 2026; Published October 30, 2026

Abstract: Objective: To develop a Traditional Chinese Medicine (TCM) comprehensive health management program for high-risk pregnant women with gestational diabetes and evaluate its impact on postpartum diabetes. Methods: This prospective randomized controlled trial enrolled 248 pregnant women from August 2024 to July 2025 (registration: ITMCTR2026000970). Participants were assigned to a control group (routine management, n=123) or an experimental group (TCM comprehensive health management, n=123). Glycemic parameters, islet function indicators, and lipid parameters, psychological scores, maternal-infant outcomes, and risk factors for postpartum diabetes were compared. Results: At baseline, no significant differences were observed between the groups in any indicator ($P > 0.05$). Repeated-measures ANOVA revealed significant main effects of time and group and significant time × group interaction effects ($P < 0.05$). After the intervention, FPG, 2hPG, and HbA1c significantly decreased in both groups ($P < 0.05$), with greater reductions in the experimental group ($P < 0.05$). Islet function indicators (FINS, C-P, and HOMA-IR) also declined significantly, with larger decrements observed in the experimental group ($P < 0.05$). Concurrently, TC, TG, and LDL-C decreased while HDL-C increased in both groups, all favoring the experimental group ($P < 0.05$). SAS and SDS scores decreased significantly, with more pronounced improvements in the experimental group ($P < 0.05$). Subgroup analyses revealed a significant treatment-by-age interaction ($P=0.034$), with participants aged ≥ 35 years showing more pronounced glycemic improvements than those < 35 years. Among TCM constitution types, the Yin-deficiency subgroup exhibited significant between-group differences in glycemic benefits ($P < 0.001$), although the overall interaction across constitution types did not reach statistical significance ($P=0.416$). The experimental group further exhibited lower rates of cesarean section, pregnancy complications, and perinatal adverse outcomes ($P < 0.05$). At 6-month postpartum follow-up, FPG and 2hPG remained significantly lower in the experimental group ($P < 0.05$). Multivariate analysis identified TCM management as an independent protective factor and family history of diabetes, pre-pregnancy BMI, and prenatal FPG and 2hPG as independent risk factors. Conclusion: TCM comprehensive health management effectively improves glucose and lipid metabolism, enhances islet function, alleviates anxiety and depression, reduces maternal-infant complications, and lowers the risk of postpartum diabetes, with potential greater benefits observed in older pregnant women and those with Yin-deficiency constitution, although the age-related finding requires confirmation in future studies.

Keywords: Gestational diabetes mellitus, high-risk population, TCM comprehensive health management, glucose and lipid metabolism, postpartum diabetes

Introduction

Gestational diabetes mellitus (GDM) is a common metabolic disorder in late pregnancy, which is mainly related to increased insulin resistance during pregnancy and insufficient compensatory function of pancreatic beta cells [1]. Patients' symptoms are often not obvious, but GDM will significantly increase the risk of short-term and long-term complications for

https://doi.org/10.62347/FFLW2564

mothers and babies, especially greatly increase the probability of the mother developing type 2 diabetes in the future [2]. Beyond hyperglycemia, GDM is fundamentally characterized by progressive β-cell dysfunction and aggravated insulin resistance. While clinically convenient, fasting plasma glucose and 2-hour postprandial glucose only reflect instantaneous glycemic status and fail to capture β-cell compensatory capacity. In contrast, fasting insulin (FINS), C-peptide (C-P), and HOMA-IR provide more specific insights into β-cell secretory burden and insulin sensitivity [3], making them essential for evaluating whether an intervention genuinely ameliorates insulin resistance and reduces β-cell workload rather than merely suppressing hyperglycemia.

Current clinical management centers on lifestyle intervention, supplemented by insulin or metformin when glycemic control is inadequate [4]. Although effective during pregnancy, this approach has notable limitations: it concentrates on the gestational period while neglecting the critical postpartum metabolic transition [5]; standardized protocols inadequately address individual variability, compromising long-term adherence; and they fail to integrate Traditional Chinese Medicine (TCM) principles of holistic regulation and preventive care [6]. Therefore, establishing a comprehensive, individualized intervention model that spans pregnancy and postpartum while promoting patient self-management is of great clinical significance.

TCM comprehensive health management emphasizes treatment based on pattern differentiation and individualization, integrating dietary therapy [7], emotional regulation [8], traditional exercises [9], and acupoint therapy to harmonize qi, blood, yin, and yang, thereby improving metabolic stability. This multidimensional approach targets the body's overall state rather than isolated symptoms, potentially yielding synergistic benefits on endocrine function, insulin sensitivity, and inflammatory responses, with advantages in enhancing behavioral compliance and preventing disease progression.

Based on these considerations, we developed a TCM comprehensive health management model incorporating personalized dietary guidance, Baduanjin exercise, and Five-Elements Music Therapy, and applied it to high-risk GDM population to optimize glycemic control during pregnancy. The study evaluated its effect on postpartum glucose metabolism recovery and diabetes incidence through 6-month follow-up. Additionally, prespecified subgroup analyses stratified by pre-pregnancy BMI, family history of diabetes, baseline HbA1c, and TCM constitution types were conducted to clarify differential treatment benefits across high-risk phenotypes, providing evidence for sustained, individualized GDM prevention and management strategies (registration: ITMCTR2026000970).

Materials and methods

General information

This study is a prospective study, which includes 248 pregnant women who were admitted to the obstetrics department of the First Affiliated Hospital of Shihezi University from August 2024 to July 2025 and have regular prenatal examinations. Participants were randomly assigned to a control group and an experimental group by random grouping, with 124 cases in each group. During the intervention and follow-up, one participant in each group withdrew voluntarily for personal reasons; ultimately, 123 participants in each group completed the study. The control group received routine health education and health management, and the experimental group received TCM comprehensive health management, including individualized dietary guidance, Baduanjin exercise and Five-Element Music Therapy. Inclusion criteria: 24 to 28 weeks of singleton pregnancy, and at least one of the following high-risk factors: (1) Age ≥ 35 years old; (2) 5.10 mmol/L ≤ fasting plasma glucose (FPG) < 6.09 mmol/L; (3) Pre-pregnancy body mass index (BMI) ≥ 24 kg/m^2; (4) History of GDM or macrosomia; (5) First-degree relatives with type 2 diabetes; (6) High genetic risk. Exclusion criteria: (1) Multiple pregnancy; (2) History of early pregnancy maintenance therapy; (3) Pre-existing diabetes; (4) Comorbid organ dysfunction; (5) Hypertension during pregnancy; (6) Malignant tumors; (7) Mental illness, intellectual disability, or speech disorder. Withdrawal criteria: (1) The subject voluntarily withdraws; (2) Missed follow-up (failure to contact via the designated method twice consecutively); (3) Missing > 30% of key outcome data and cannot be evaluated effectively; (4) Any serious adverse events occur during the study, or serious pregnancy complications

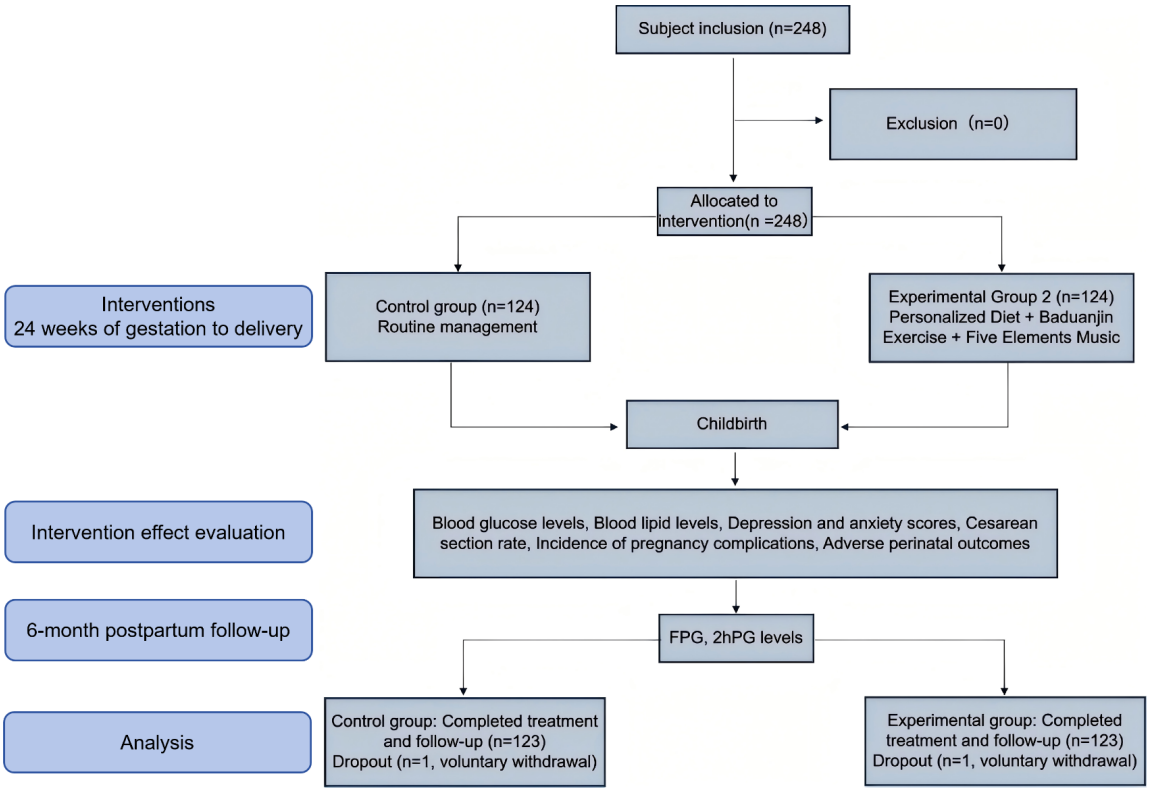


Figure 1. Flowchart of participant recruitment and allocation. Notes: FPG, fasting plasma glucose; 2hPG, 2-hour postprandial plasma glucose.

occur, such as severe preeclampsia, placental abruption, and severe infection; (5) Poor adherence to the intervention protocol, defined as failure to complete the prescribed Baduanjin practice, music listening, or dietary regimen for more than 3 consecutive days without a valid reason, as documented during weekly follow-up visits (**Figure 1**).

Intervention methods

Control group: Participants in the control group received standard routine health management and systematic health education. Routine management strictly followed the current clinical guidelines, and the core content includes individualized medical nutrition treatment and exercise guidance. Nutritional treatment calculates the daily total energy requirements according to the pre-pregnancy BMI and weight gain of pregnant women during pregnancy. It adopts the three main meals and three snacks model, supplemented by the food exchange method for accurate meal planning. Exercise guidance is mainly moderate-intensity walking, supplemented by safe resistance training. Health education uses a combination of face-to-face individualized consultation and standardized brochures to systematically explain knowledge, potential risks and basic self-management skills related to gestational diabetes.

Experimental group: Participants in the experimental group received TCM comprehensive health management, including individualized TCM dietary guidance, Baduanjin exercise and Five Elements Music Therapy. (1) Individualized diet of traditional Chinese medicine: After enrollment, two TCM physicians with intermediate or higher professional titles and a registered dietitian jointly formulate an individualized diet guidance plan for them. On the basis of following the principles of medical nutrition treatment and the energy calculation framework, the program provides personalized advice on food selection, selection, flavor pairing, and cooking methods. (2) Baduanjin Exercise: A standard instructional video demonstrated by Professor Deng Tietao, a TCM master, was used as the unified teaching mate-

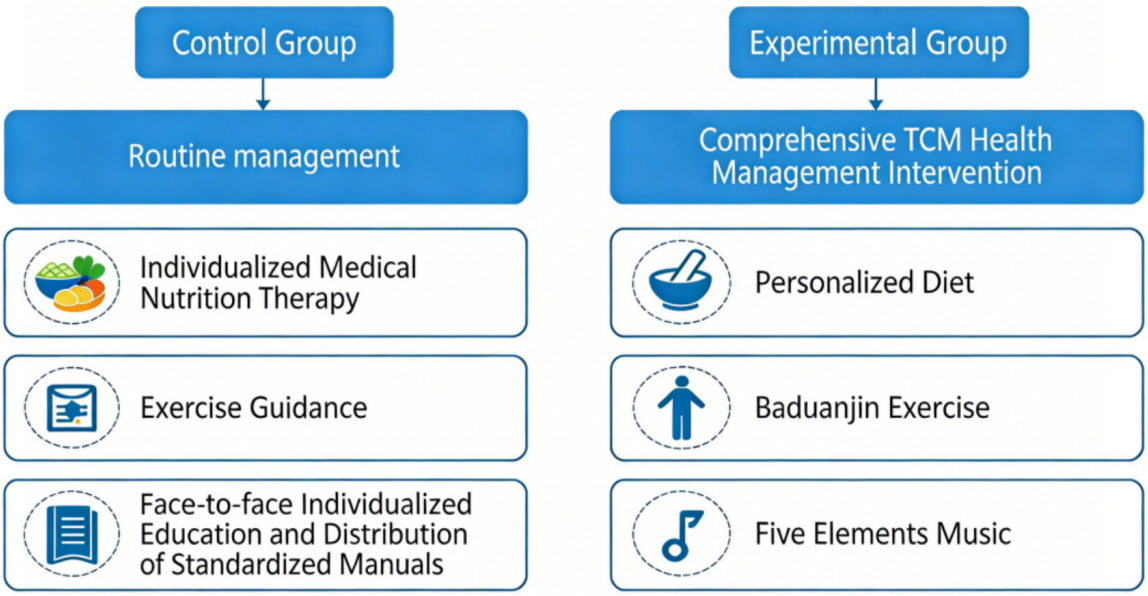


Figure 2. Schematic diagram of grouped interventions. Notes: TCM, Traditional Chinese Medicine.

rial. During the first week after enrollment, professional coaches with a background in TCM-guided exercise conducted two group sessions, 60 minutes each, to ensure that each participant had mastered the essentials of movement, breathing coordination and safety precautions. Exercise content and modifications: complete the eight-section Baduanjin (eight movements). To ensure safety during pregnancy, the two movements that may increase abdominal pressure or place excessive strain on the waist and abdomen were modified or omitted: "Shaking the head and wagging the tail to clear heart fire" was replaced with gentle left - right side bending; "reaching hands to feet to strengthen kidney and waist" was replaced with sitting straight legs or standing with moderate forward bending, while bending/pressing the abdomen was strictly prohibited. The remaining six movements are suitable for practice. Participants were instructed to practice once daily, about 1 hour after breakfast, about 15 minutes each time. Set up a WeChat check-in group, and patients upload practice photos or brief check-in records daily. The research assistant conducted weekly telephone follow-ups to understand the exercises and answer questions. (3) Five Elements Music Therapy: Jiao and Gong audio files with intense rhythms and discordant tones eliminated was used as the background music for Baduanjin exercise; patients could also listen at noon or while lying down before bedtime to promote relaxation and sleep; it can also be played at any time or whenever they felt nervous or anxious. In the process of health education, the basic principle and expected effect of music therapy were explained to patients. Listening frequency, duration, and subjective feelings were monitored and recorded through check-in groups and weekly follow-up visits. Cumulative listening time was required to be at least 30 minutes per day (**Figure 2**).

To ensure adherence to the intervention protocol, several measures were implemented: (1) All participants received standardized face-to-face instruction and a detailed illustrated manual for Baduanjin practice frequency and dietary guidance; (2) Daily WeChat check-in and weekly telephone follow-ups were conducted to monitor compliance and address barriers to adherence; (3) Participants with poor compliance were re-educated and encouraged during weekly follow-up calls. These measures were applied uniformly across all participants in the experimental group, ensuring that adherence was maximized and comparable within the group. The study was designed to evaluate the intention-to-treat efficacy of the TCM comprehensive management model, reflecting the real-world clinical scenario where the intervention is offered as a complete package rather than as individual components.

Observation indicators

(1) Baseline data were collected, including age, weight, gestational age, pre-pregnancy BMI, smoking and alcohol habits, educational level, mode of conception, maternal type, history of adverse pregnancy outcomes, and intervention adherence. Intervention adherence was quantified using a composite adherence score (0-100%) based on three dimensions: (i) Baduanjin practice frequency (proportion of completed sessions relative to prescribed 7 sessions/week); (ii) dietary regimen adherence (nutritionist-rated compliance via weekly follow-up, 0-100%); and (iii) music therapy listening duration (proportion of actual listening time relative to prescribed ≥ 30 min/day). Based on the composite score, participants were classified as high adherence (≥ 80%), moderate adherence (50%-79%), or low adherence (< 50%). Control group adherence was assessed based on adherence to routine nutritional counseling and exercise guidance via the same weekly telephone follow-up protocol.

(2) Glycemic indicators: Fasting and 2-hour postprandial venous blood samples (3 mL) were collected from the antecubital vein at baseline and after the intervention. Serum was separated by centrifugation at 3000 rpm for 10 minutes. Glucose concentrations (fasting plasma glucose, FPG; and 2-hour postprandial plasma glucose, 2hPG) were measured using the glucose oxidase method on a Roche Cobas c 702 automated biochemical analyzer. Additionally, venous blood samples (2 mL) were collected, stored at room temperature without centrifugation, and analyzed within 24 hours using high-performance liquid chromatography (HPLC) on the Bio-Rad D-10 HbA1c analyzer system for glycated hemoglobin (HbA1c) levels.

(3) Islet function assessment: To evaluate pancreatic β-cell function and insulin resistance, FINS and C-P levels were measured at baseline and after the intervention. Venous blood samples (3 mL) were collected after a 12-hour overnight fast, centrifuged at 3000 rpm for 10 minutes, and the separated serum was stored at -80°C until analysis. FINS and C-P concentrations were determined using electrochemiluminescence immunoassay (ECLIA) on a Roche Cobas e 601 analyzer (Roche Diagnostics, Mannheim, Germany). HOMA-IR was calculated using the following formula: HOMA-IR = [FINS (μU/mL) × FPG (mmol/L)]/22.5.

(4) Lipid profiles: Total cholesterol (TC), triglycerides (TG), low-density lipoprotein cholesterol (LDL-C), and high-density lipoprotein cholesterol (HDL-C) were measured before and after the intervention. Participants were instructed to fast for 12-14 hours, and blood samples (5 mL) were drawn from the antecubital vein between 7:00 and 9:00 AM the following morning. Serum was separated by centrifugation at 3000 rpm for 15 minutes, and enzymatic assays were performed using a Mindray BS-2000M automated biochemical analyzer with dedicated reagent kits.

(5) Psychological status assessment: Psychological status was evaluated using the Self-Rating Anxiety Scale (SAS) [10] and Self-Rating Depression Scale (SDS) [11] before and after the intervention. Total scores ranged from 25 to 100, with higher scores indicating poorer psychological well-being.

(6) Pregnancy outcomes: Pregnancy outcomes were compared between the two groups after the intervention, including cesarean section rates and the incidence of pregnancy-related complications such as polyhydramnios, gestational infection, hypertensive disorders of pregnancy, postpartum hemorrhage, and ketoacidosis.

(7) Perinatal adverse outcomes: Adverse neonatal outcomes were documented and compared between the two groups, including macrosomia, neonatal hypoglycemia, neonatal asphyxia, low birth weight, preterm delivery, and respiratory distress syndrome.

(8) 6-month postpartum blood glucose follow-up: At the 6-month postpartum follow-up, FPG and 2hPG levels were measured and compared between the two groups using the same methods as described in (2).

Statistical analysis

Statistical analyses were performed using SPSS 27.0 software (IBM Corporation, Armonk, NY, USA). All continuous variables were first tested for normality using the Shapiro-Wilk test and for homogeneity of variance using Levene's

test. Normally distributed continuous variables with homogeneous variances were expressed as mean ± standard deviation ($\bar{x}$±s); non-normally distributed continuous variables were expressed as median (interquartile range) [M (P25, P75)]; categorical variables were expressed as frequency (percentage) [n (%)]. For baseline comparisons between the two groups, independent samples t-test was used for normally distributed continuous variables, the Mann-Whitney *U* test was used for non-normally distributed continuous variables, and the chi-square (χ^2) test was used for categorical variables. To evaluate the intervention effects, a two-way repeated-measures analysis of variance (repeated-measures ANOVA) was conducted, with time (pre-intervention vs. post-intervention) as the within-subject factor and group (control vs. experimental) as the between-subject factor. The main effects of time, main effects of group, and time × group interaction effects were analyzed. When a significant interaction effect was detected, simple effects analysis was further performed to clarify the changes within each group from pre- to post-intervention and the differences between groups at each time point. Multiple comparisons were adjusted using the Bonferroni correction to control for type I error inflation. Subgroup analyses were performed by adding each stratification variable (age, pre-pregnancy BMI, family history of diabetes, baseline HbA1c, and TCM constitution types) as a third factor in the repeated-measures ANOVA model to test the group × time × subgroup interaction effect. To control for family-wise type I error inflation across the five predefined subgroup analyses, the Bonferroni correction was applied, setting the adjusted significance threshold at $\alpha'=0.05/5=0.01$. Within each subgroup, simple effect analyses were further adjusted using the Bonferroni method for multiple pairwise comparisons. All primary tests were two-sided, and a *P*-value < 0.05 was considered statistically significant; for subgroup interaction tests, $P < 0.01$ was considered significant after correction. To assess potential confounding by compliance differences, adherence level was included as a categorical covariate (high/moderate/low). Additionally, a per-protocol (PP) sensitivity analysis was performed, including only participants with high compliance (≥ 80%) in both groups, to evaluate the robustness of the primary ITT findings.

Results

Comparison of baseline characteristics

No significant differences were observed between the two groups in age, weight, gestational week, pre-pregnancy BMI, smoking, drinking, education attainment, method of conception, type of mother, family history of diabetes, adverse pregnancy history, and adherence level (all $P > 0.05$; **Table 1**).

Comparison of glycemic indicators

Before the intervention, there were no significant differences in FPG, 2hPG, and HbA1c levels between the two groups ($P > 0.05$), indicating baseline comparability. Repeated-measures ANOVA revealed significant main effects of time and group and a significant time × group interaction effect for FPG, 2hPG, and HbA1c (all $P < 0.001$). These results indicate that after the intervention, all three glycemic indicators significantly decreased in both groups compared to baseline ($P < 0.05$), and the experimental group showed significantly greater reductions than the control group ($P < 0.05$), indicating an intervention-by-time interaction (**Table 2** and **Figure 3**).

Comparison of islet function indicators

At baseline, there were no significant differences in FINS, C-P, and HOMA-IR levels between the two groups ($P > 0.05$), indicating good baseline comparability. Repeated-measures ANOVA revealed significant main effects of time and group and a significant time × group interaction effects for FINS, C-P, and HOMA-IR (all $P < 0.001$). These results indicate that after the intervention, FINS, C-P, and HOMA-IR levels significantly decreased in both groups compared to baseline ($P < 0.05$), with the experimental group showing significantly greater reductions than the control group ($P < 0.05$), as shown in **Table 3** and **Figure 4**.

Comparison of lipid profile indicators

At baseline, there were no significant differences in TC, TG, LDL-C, and HDL-C levels between the two groups ($P > 0.05$), indicating good baseline comparability. Repeated-measures ANOVA revealed significant main effects of time and group and a significant time × group interaction

Table 1. Comparison of baseline characteristics between the two groups

Indicators		Control Group (n=123)	Experimental Group (n=123)	χ^2/t	*P*
Age (years, $\bar{x}\pm s$)		30.61 ± 3.56	30.39 ± 3.52	0.487	0.627
Weight (kg, $\bar{x}\pm s$)		57.39 ± 5.68	57.45 ± 5.19	-0.541	0.589
Gestational age (weeks, $\bar{x}\pm s$)		26.51 ± 1.54	26.62 ± 1.55	-0.288	0.773
Pre-pregnancy BMI (kg/m^2, $\bar{x}\pm s$)		24.15 ± 4.10	24.28 ± 3.03	-0.082	0.935
Smoking [n (%)]	No	121 (98.37)	122 (99.19)	0.000	1.000
	Yes	2 (1.63)	1 (0.81)		
Alcohol consumption [n (%)]	No	99 (80.49)	100 (81.30)	0.026	0.871
	Yes	24 (19.51)	23 (18.70)		
Educational attainment [n (%)]	Junior high school and below	11 (8.94)	9 (7.23)	1.029	0.905
	High school and technical secondary school	26 (21.14)	22 (17.89)		
	Junior college	20 (16.26)	21 (17.07)		
	Bachelor's degree	62 (50.41)	65 (52.85)		
	Master's degree and above	4 (3.25)	6 (4.88)		
Method of conception [n (%)]	Natural	116 (94.31)	113 (91.87)	0.569	0.451
	In vitro	7 (5.69)	10 (8.13)		
Type of mother [n (%)]	Primiparous	83 (67.48)	88 (71.54)	0.480	0.489
	Multiparous	40 (32.52)	35 (28.46)		
Family history of diabetes [n (%)]	No	94	91	0.196	0.658
	Yes	29	32		
Adverse pregnancy history [n (%)]	No	107 (86.99)	108 (87.80)	0.037	0.848
	Yes	16 (13.01)	15 (12.20)		
Adherence level [n (%)]	High adherence	115 (93.50)	108 (87.80)	2.420	0.298
	Moderate adherence	6 (4.88)	12 (9.76)		
	Low adherence	2 (1.63)	3 (2.44)		

effects for TC, TG, LDL-C, and HDL-C (all $P < 0.001$). These results indicate that after the intervention, TC, TG, and LDL-C levels significantly decreased in both groups compared to baseline ($P < 0.05$), with the experimental group showing significantly greater improvements than the control group ($P < 0.05$). Meanwhile, HDL-C levels significantly increased in both groups after the intervention ($P < 0.05$), and the elevation was more pronounced in the experimental group than in the control group ($P < 0.05$). Details are shown in **Table 4** and **Figure 5**.

Comparison of psychological status

Before intervention, there were no statistically significant differences in SAS and SDS scores between the two groups ($P > 0.05$), indicating good baseline comparability. Repeated-measures ANOVA revealed significant main effects of time and group and a significant time × group interaction effects for SAS and SDS scores (both $P < 0.001$). These results indicate that after the intervention, SAS and SDS scores significantly decreased in both groups compared to baseline ($P < 0.05$), and the scores in the experimental group were significantly lower than those in the control group ($P < 0.05$), demonstrating a synergistic effect between the intervention and time. Details are shown in **Table 5** and **Figure 6**.

Subgroup analysis results

Subgroup analyses showed that the experimental group achieved significantly greater reductions in both ΔFPG and Δ2hPG than the control group across most predefined subgroups (all $P < 0.050$, **Table 6**). In the age subgroup, participants aged ≥ 35 years showed a larger between-group difference in FPG reduction (-1.28 mmol/L) than those < 35 years (-0.68 mmol/L), with an interaction $P=0.034$; however, this value did not reach the Bonferroni-corrected significance threshold ($\alpha'=0.010$) and thus should be interpreted as a suggestive trend rather than a confirmatory finding. Regarding TCM constitution types, patients with Yin-deficiency constitution showed signifi-

Table 2. Comparison of glycemic indicators between the two groups

Indicators		Control Group (n=123)	Experimental Group (n=123)	Between-group Mean Difference (95% CI)	*F*	*P*
FPG	Pre-	5.28 ± 0.93	5.31 ± 0.91	-0.023 (-0.254, 0.208)	0.039	0.884
	Post-	4.90 ± 0.90	4.37 ± 0.76	0.527 (0.318, 0.736)	24.627	< 0.001
	F_{time}=72.886, P_{time} < 0.001, F_{group}=9.820, P_{group}=0.002, $F_{interaction}$=12.523, $P_{interaction}$ < 0.001					
2hPG	Pre-	8.53 ± 1.48	8.57 ± 1.42	-0.040 (-0.405, 0.325)	0.046	0.830
	Post-	7.42 ± 1.27	5.75 ± 0.98	1.670 (1.385, 1.955)	133.128	< 0.001
	F_{time}=261.375, P_{time} < 0.001, F_{group}=51.691, P_{group} < 0.001, $F_{interaction}$=49.475, $P_{interaction}$ < 0.001					
HbA1c	Pre-	6.73 ± 0.93	6.72 ± 0.97	0.000 (-0.238, 0.238)	0.000	0.999
	Post-	6.15 ± 0.88	5.32 ± 0.69	0.830 (0.632, 1.028)	67.854	< 0.001
	F_{time}=173.208, P_{time} < 0.001, F_{group}=25.904, P_{group} < 0.001, $F_{interaction}$=30.128, $P_{interaction}$ < 0.001					

Notes: FPG, fasting plasma glucose; 2hPG, 2-hour postprandial plasma glucose; HbA1c, glycated hemoglobin.

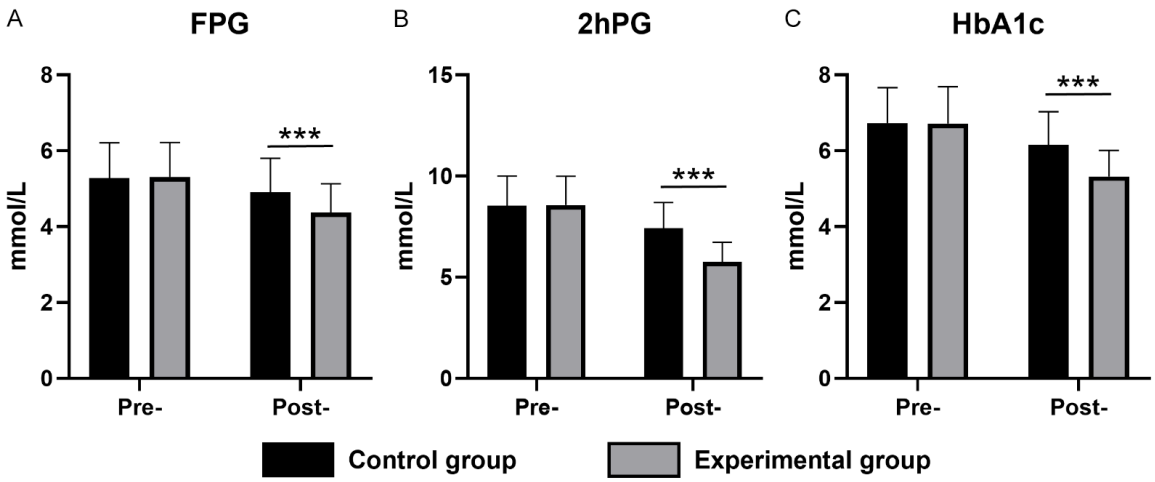


Figure 3. Comparison of Glycemic Indicators. A. FPG; B. 2hPG; C. HbA1c. Notes: FPG, fasting plasma glucose; 2hPG, 2-hour postprandial plasma glucose; HbA1c, glycated hemoglobin; ***P < 0.001.

cant treatment benefits (between-group difference in ΔFPG: -1.01 mmol/L, 95% CI: -1.45 to -0.57), whereas those with Qi-deficiency constitution did not reach statistical significance (ΔFPG: -0.51 mmol/L, 95% CI: -1.15 to 0.13, P=0.115). After multiple comparison correction, no significant interactions were observed for TCM constitution types, pre-pregnancy BMI, family history of diabetes, or baseline HbA1c (all P > 0.010).

Sensitivity analyses

Sensitivity analysis adjusting for adherence level (high/moderate/low) as a covariate in the repeated-measures ANOVA model yielded consistent results for all primary outcomes (glycemic, lipid, islet function, and psychological status), with the experimental group continuing to show significantly greater improvements than the control group (all P < 0.050). In the per-protocol analysis restricted to participants with high adherence (115 in the control group and 108 in the experimental group), the adjusted mean differences between groups for all outcomes were slightly larger than those observed in the intention-to-treat analysis, further confirming the robustness of the primary findings (**Table 7**).

Comparison of cesarean section rates and pregnancy complication incidence

Following the intervention, the cesarean section rate in the experimental group was 13.01%, markedly lower than the 34.15% observed in the control group (P < 0.05). Likewise, the incidence of pregnancy complications in the exper-

Table 3. Comparison of islet function indicators between the two groups

Indicators		Control Group (n=123)	Experimental Group (n=123)	Between-group Mean Difference (95% CI)	*F*	*P*
FINS (μU/mL)	Pre-	15.63 ± 4.21	15.71 ± 4.08	-0.098 (-1.138, 0.942)	0.023	0.880
	Post-	14.34 ± 3.85	10.54 ± 3.12	3.808 (2.928, 4.687)	72.327	< 0.001
	F_{time}=92.009, P_{time} < 0.001, F_{group}=27.477, P_{group} < 0.001, $F_{interaction}$=33.433, $P_{interaction}$ < 0.001					
C-P (ng/mL)	Pre-	3.25 ± 0.72	3.31 ± 0.69	-0.059 (-0.236, 0.118)	0.445	0.505
	Post-	2.98 ± 0.65	2.21 ± 0.58	0.771 (0.617, 0.926)	96.095	< 0.001
	F_{time}=132.902, P_{time} < 0.001, F_{group}=35.540, P_{group} < 0.001, $F_{interaction}$=48.480, $P_{interaction}$ < 0.001					
HOMA-IR	Pre-	3.67 ± 1.21	3.72 ± 1.31	-0.025 (-0.315, 0.265)	0.097	0.756
	Post-	3.13 ± 1.02	2.05 ± 0.76	1.082 (0.859, 1.306)	88.669	< 0.001
	F_{time}=158.616, P_{time} < 0.001, F_{group}=26.460, P_{group} < 0.001, $F_{interaction}$=40.158, $P_{interaction}$ < 0.001					

Notes: FINS, fasting insulin; C-P, C-peptide; HOMA-IR, homeostatic model assessment of insulin resistance.

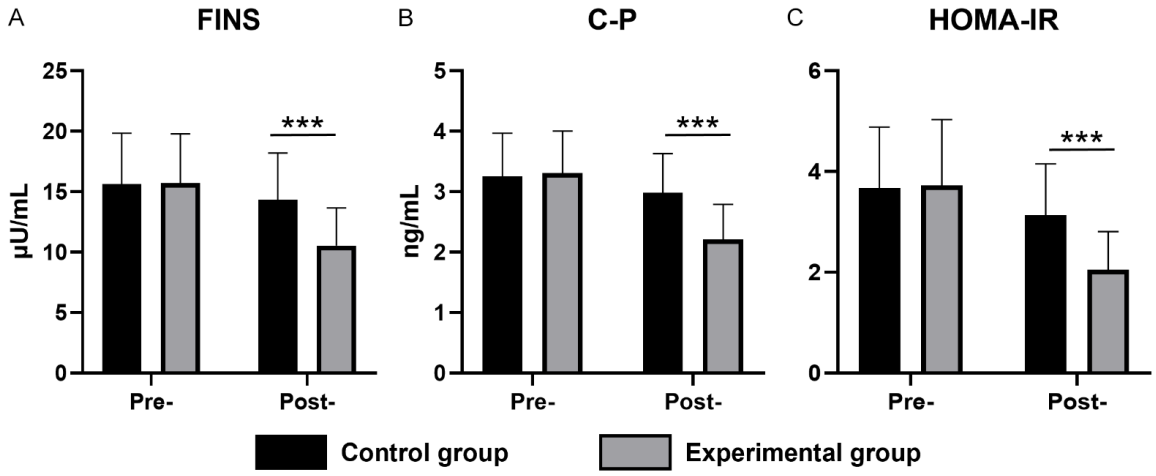


Figure 4. Comparison of islet function indicators. A. FINS; B. C-P; C. HOMA-IR. Notes: FINS, fasting insulin; C-P, C-peptide; HOMA-IR, homeostatic model assessment for insulin resistance; ***P < 0.001.

Table 4. Comparison of lipid profile indicators between the two groups

Indicators		Control Group (n=123)	Experimental Group (n=123)	Between-group Mean Difference (95% CI)	*F*	*P*
TC	Pre-	5.28 ± 0.36	5.27 ± 0.33	0.001 (-0.087, 0.089)	0.001	0.981
	Post-	4.86 ± 0.53	4.02 ± 0.41	0.840 (0.721, 0.959)	193.828	< 0.001
	F_{time}=539.535, P_{time} < 0.001, F_{group}=117.050, P_{group} < 0.001, $F_{interaction}$=134.688, $P_{interaction}$ < 0.001					
TG	Pre-	2.40 ± 0.53	2.41 ± 0.53	-0.010 (-0.143, 0.124)	0.021	0.884
	Post-	1.74 ± 0.41	1.03 ± 0.29	0.710 (0.045, 0.821)	246.984	< 0.001
	F_{time}=600.234, P_{time} < 0.001, F_{group}=75.933, P_{group} < 0.001, $F_{interaction}$=74.770, $P_{interaction}$ < 0.001					
LDL-C	Pre-	3.13 ± 0.62	3.16 ± 0.63	-0.030 (-0.186, 0.126)	0.144	0.705
	Post-	2.55 ± 0.41	1.57 ± 0.25	0.980 (0.896, 1.065)	521.690	< 0.001
	F_{time}=522.811, P_{time} < 0.001, F_{group}=125.741, P_{group} < 0.001, $F_{interaction}$=113.284, $P_{interaction}$ < 0.001					
HDL-C	Pre-	1.36 ± 0.11	1.36 ± 0.15	0.000 (-0.033, 0.033)	0.000	1.000
	Post-	1.48 ± 0.15	1.78 ± 0.25	-0.306 (-0.363, -0.248)	125.564	< 0.001
	F_{time}=274.400, P_{time} < 0.001, F_{group}=97.044, P_{group} < 0.001, $F_{interaction}$=84.691, $P_{interaction}$ < 0.001					

Notes: TC, total cholesterol; TG, triglycerides; LDL-C, low-density lipoprotein cholesterol; HDL-C, high-density lipoprotein cholesterol.

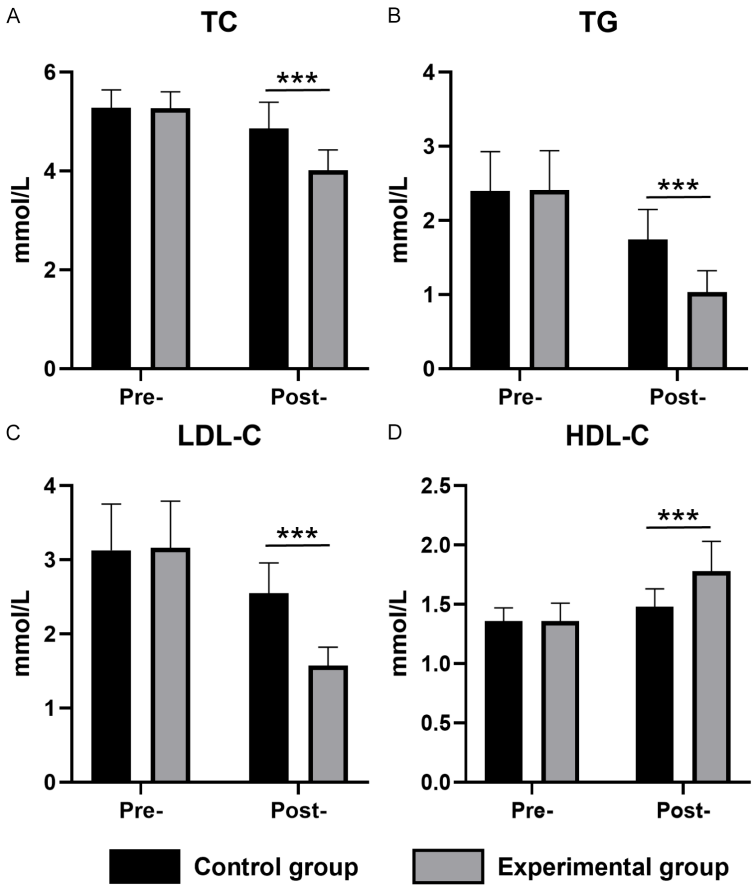


Figure 5. Comparison of lipid profile indicators. A. TC; B. TG; C. LDL-C; D. HDL-C. Notes: TC, total cholesterol; TG, triglycerides; LDL-C, low-density lipoprotein cholesterol; HDL-C, high-density lipoprotein cholesterol; ***P < 0.001.

imental group (5.69%) was significantly reduced compared with that in the control group (30.89%, $P < 0.05$), as shown in **Table 8**.

Comparison of perinatal adverse outcomes

Following intervention, the incidence of adverse perinatal outcomes in the experimental group (13.01%) was significantly lower than that in the control group (37.40%), demonstrating a statistically significant difference ($P < 0.05$; **Table 9**).

Comparison of blood glucose levels at 6-month follow-up

Follow-up was conducted at 6 months post-intervention to compare FPG and 2hPG levels between the two groups. The experimental group demonstrated significantly lower FPG and 2hPG levels than the control group ($P < 0.05$). See **Table 10**.

Univariate analysis of poor prognosis

To clarify the impact of various factors on the prognosis of postpartum glucose metabolism, this study defined and coded potential influencing factors, including demographic characteristics, clinical biochemical indicators, and intervention methods. Detailed definitions of each variable, their coding methods, and their roles in subsequent analyses are presented in Supplementary Table 1.

Univariate analysis showed that among demographic and medical history factors, family history of diabetes (OR=4.457, 95% CI: 2.380-8.348) was a strong risk factor. In addition, pre-pregnancy BMI (OR=2.462, 95% CI: 1.926-3.149), 2hPG (OR=3.631, 95% CI: 2.538-5.194), and FPG (OR=2.524, 95% CI: 1.781-3.579) were also significantly positively correlated with the risk of abnormal postpartum glucose metabolism (all $P < 0.001$). In terms of management methods, compared with conventional management, the TCM comprehensive management significantly reduced the risk of postpartum adverse outcomes (OR=0.049, 95% CI: 0.019-0.127; $P < 0.001$). Factors not significantly associated included: age, smoking, alcohol consumption, education level, conception method, maternal type, adverse pregnancy history, gestational age, pre-pregnancy weight, FINS, C-P, HOMA-IR, TC, HbA1c, TG, LDL-C, and HDL-C (all $P > 0.05$). See **Table 11**.

Multivariate analysis of poor prognosis

Multivariate logistic regression analysis revealed that, after adjustment for potential confounders, TCM comprehensive management emerged as an independent protective factor against postpartum glucose metabolism abnormalities (OR=0.114, 95% CI: 0.020-0.659, P=0.015), substantially lowering the risk of adverse outcomes. In contrast, several factors

Table 5. Comparison of psychological status scores between the two groups

Indicators		Control Group (n=123)	Experimental Group (n=123)	Between-group Mean Difference (95% CI)	*F*	*P*
SAS	Pre-	56.32 ± 7.21	56.27 ± 7.39	0.049 (-1.784, 1.881)	0.003	0.958
	Post-	51.41 ± 6.32	40.23 ± 4.56	11.179 (9.794, 12.564)	252.890	< 0.001
	F_{time}=329.103, P_{time} < 0.001, F_{group}=90.957, P_{group} < 0.001, $F_{interaction}$=92.877, $P_{interaction}$ < 0.001					
SDS	Pre-	58.36 ± 7.28	59.00 ± 7.68	-0.650 (-2.529, 1.229)	0.465	0.496
	Post-	51.75 ± 6.94	38.59 ± 4.06	13.154 (11.726, 14.583)	328.903	< 0.001
	F_{time}=478.667, P_{time} < 0.001, F_{group}=116.120, P_{group} < 0.001, $F_{interaction}$=124.907, $P_{interaction}$ < 0.001					

Notes: SAS, Self-Rating Anxiety Scale; SDS, Self-Rating Depression Scale.

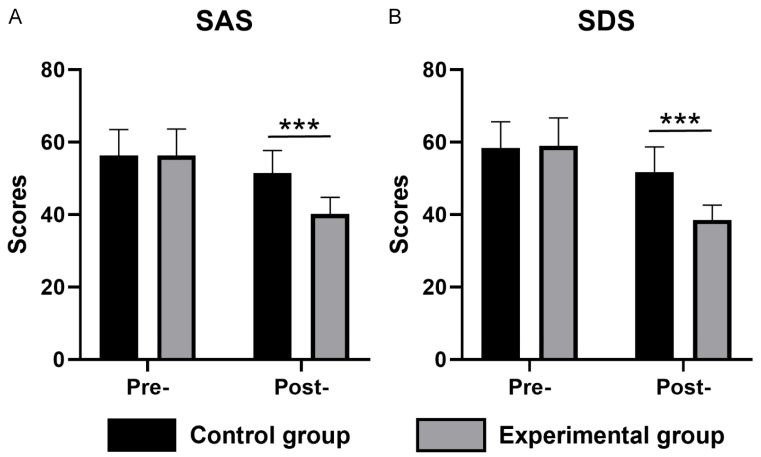


Figure 6. Comparison of psychological status. A. SAS; B. SDS. Notes: SAS, Self-Rating Anxiety Scale; SDS, Self-Rating Depression Scale; ***P < 0.001.

were identified as independent risk factors for poor postpartum outcomes, including family history of diabetes (OR=6.654, 95% CI: 1.330-33.286, P=0.021), pre-pregnancy BMI (OR=4.354, 95% CI: 2.183-8.684, P < 0.001), 2hPG (OR=8.296, 95% CI: 2.335-29.477, P=0.001), and FPG (OR=23.283, 95% CI: 4.286-126.483, P < 0.001), as shown in **Table 12**.

Discussion

GDM is not only a common metabolic disorder during pregnancy but also represents a critical window for predicting long-term postpartum diabetes risk, making early intervention in high-risk populations a significant public health priority [12, 13]. As a single-center exploratory study focusing on high-risk GDM patients diagnosed at 24-28 weeks of gestation, this trial was designed to evaluate the feasibility and preliminary efficacy of a TCM comprehensive management model in a defined population. The findings are intended to generate hypotheses and provide a foundation for future multicenter studies with broader population coverage, rather than to establish generalizability across all settings. Grounded in the TCM principle of "prevention before disease onset", this study integrated personalized dietary therapy, an adapted Baduanjin exercise regimen, and Five-Element Music therapy to establish a comprehensive health management protocol for high-risk pregnant women with GDM. Through a prospective randomized controlled trial, we validated the integrated efficacy of this model in improving glycemic control, psychological well-being, and maternal-infant outcomes during pregnancy, while also demonstrating sustained protective effects on postpartum glucose metabolism. These findings provide new evidence-based support for establishing a continuous management strategy that spans the entire pregnancy and postpartum periods.

Our results demonstrated that, compared with conventional management, the TCM comprehensive health management model significantly reduced fasting plasma glucose, 2-hour postprandial glucose, and HbA1c levels in high-risk pregnant women, with these improvements persisting through the 6-month postpartum follow-up. This sustained effect suggests that the glycemic benefits of this model extend beyond the active intervention period. This finding aligns with the current global trend toward integrative approaches in metabolic disorder

Table 6. Subgroup analysis of intervention effects on glycemic control

Subgroup	n (Experimental/ Control)	Mean Difference in ΔFPG (95% CI)	*P* for ΔFPG	Mean Difference in Δ2hPG (95% CI)	*P* for Δ2hPG	*P* for interaction	Adjusted α'	Significance after correction
Age								
< 35 years	104/86	-0.68 (-0.96, -0.40)	< 0.001	-0.94 (-1.56, -0.32)	0.003	0.034	0.010	No
≥ 35 years	19/37	-1.28 (-1.82, -0.74)	< 0.001	-2.41 (-3.58, -1.24)	< 0.001			
Pre-pregnancy BMI								
< 24 kg/m^2	41/61	-0.79 (-1.14, -0.44)	< 0.001	-1.21 (-1.97, -0.45)	0.002	0.397	0.010	No
≥ 24 kg/m^2	82/62	-0.74 (-1.05, -0.43)	< 0.001	-1.44 (-2.15, -0.73)	< 0.001			
Family history of diabetes								
No	91/94	-0.82 (-1.14, -0.50)	< 0.001	-1.40 (-2.12, -0.68)	< 0.001	0.911	0.010	No
Yes	32/29	-0.78 (-1.16, -0.40)	< 0.001	-1.31 (-2.16, -0.46)	0.003			
Baseline HbA1c								
< 6.5%	59/43	-0.73 (-1.09, -0.37)	< 0.001	-1.46 (-2.30, -0.62)	0.001	0.564	0.010	No
≥ 6.5%	64/80	-0.84 (-1.15, -0.53)	< 0.001	-1.23 (-1.90, -0.56)	< 0.001			
TCM constitution types								
Qi-deficiency	30/20	-0.51 (-1.15, 0.13)	0.115	-0.05 (-1.52, 1.42)	0.946	0.416	0.010	No
Yin-deficiency	43/27	-1.01 (-1.45, -0.57)	< 0.001	-1.52 (-2.41, -0.63)	0.001			
Other constitutions	50/76	-0.79 (-1.13, -0.45)	< 0.001	-1.38 (-2.14, -0.62)	< 0.001			

Table 7. Sensitivity analyses for outcomes: ITT vs. PP

Outcome	Analysis	Experimental/ Control	Adjusted Mean Difference (Experimental vs. Control)	95% CI	P	Consistency with ITT
ΔFPG (mmol/L)	ITT	123/123	-0.76	(-0.98, -0.54)	< 0.001	-
	Adjusted for adherence	123/123	-0.79	(-1.02, -0.56)	< 0.001	Consistent
	Per-protocol	108/115	-0.91	(-1.12, -0.700)	< 0.001	Consistent
Δ2hPG (mmol/L)	ITT	123/123	-1.38	(-1.78, -0.98)	< 0.001	-
	Adjusted for adherence	123/123	-1.42	(-1.85, -0.99)	< 0.001	Consistent
	Per-protocol	108/115	-1.98	(-2.45, -1.51)	< 0.001	Consistent
ΔHbA1c (%)	ITT	123/123	-0.72	(-0.92, -0.52)	< 0.001	-
	Adjusted for adherence	123/123	-0.75	(-0.96, -0.54)	< 0.001	Consistent
	Per-protocol	108/115	-0.89	(-1.12, -0.66)	< 0.001	Consistent
ΔTC (mmol/L)	ITT	123/123	-0.84	(-0.95, -0.72)	< 0.001	-
	Adjusted for adherence	123/123	-0.86	(-0.98, -0.73)	< 0.001	Consistent
	Per-protocol	108/115	-0.92	(-1.04, -0.79)	< 0.001	Consistent
ΔFINS (μU/mL)	ITT	123/123	-3.80	(-4.68, -2.91)	< 0.001	-
	Adjusted for adherence	123/123	-3.92	(-4.85, -2.99)	< 0.001	Consistent
	Per-protocol	108/115	-4.21	(-5.16, -3.26)	< 0.001	Consistent
ΔHOMA-IR	ITT	123/123	-1.08	(-1.30, -0.85)	< 0.001	-
	Adjusted for adherence	123/123	-1.12	(-1.35, -0.88)	< 0.001	Consistent
	Per-protocol	108/115	-1.25	(-1.49, -1.01)	< 0.001	Consistent
ΔSAS	ITT	123/123	-11.17	(-12.56, -9.79)	< 0.001	-
	Adjusted for adherence	123/123	-11.45	(-12.87, -10.03)	< 0.001	Consistent
	Per-protocol		-12.10	(-13.56, -10.64)	< 0.001	Consistent
ΔSDS	ITT	123/123	-13.154	(-14.58, -11.72)	< 0.001	-
	Adjusted for adherence	123/123	-13.48	(-14.96, -12.00)	< 0.001	Consistent
	Per-protocol	108/115	-14.21	(-15.74, -12.68)	< 0.001	Consistent

Note: ITT, intention-to-treat; PP, per-protocol; FPG, fasting plasma glucose; 2hPG, 2-hour postprandial plasma glucose; HbA1c, glycated hemoglobin; TC, total cholesterol; TG, triglycerides; LDL-C, low-density lipoprotein cholesterol; HDL-C, high-density lipoprotein cholesterol; FINS, fasting insulin; HOMA-IR, homeostatic model assessment of insulin resistance; SAS, Self-Rating Anxiety Scale; SDS, Self-Rating Depression Scale; CI, confidence interval. PP analysis included participants with high adherence only (108 in the experimental group and 115 in the control group; for adherence classification, see **Table 1**).

Table 8. Comparison of cesarean section rates and pregnancy complication incidence between the two groups [n (%)]

Group	Cesarean section	Pregnancy Complications					
		Polyhydramnios	Pregnancy-related infection	HDP	Postpartum hemorrhage	Ketoacidosis	Total
Control group (n=123)	42 (34.15)	10 (8.13)	8 (6.50)	10 (8.13)	8 (6.50)	2 (1.63)	38 (30.89)
Experimental Group (n=123)	16 (13.01)	3 (2.44)	2 (1.63)	1 (0.81)	1 (0.81)	0 (0.00)	7 (5.69)
χ^2	15.251						26.137
P	< 0.001						< 0.001

Note: HDP, hypertensive disorders of pregnancy.

management [14]. Previous studies have also indicated that comprehensive interventions during pregnancy and the postpartum period contribute not only to immediate glycemic control but also, through cumulative effects on insulin resistance, reduce the risk of postpartum glucose metabolism abnormalities [15]. The efficacy of our protocol likely stems from its integration of TCM principles with modern nutritional science. Standard medical nutrition therapy, while foundational to individualized intervention, primarily emphasizes standardized energy and macronutrient distribution, with limited attention to the correspondence between food properties (the "four natures and five flavors") and individual physiological states (yin-yang, qi, and blood) [16, 17]. By incorporating TCM pattern differentiation into daily dietary guidance, we added a layer of personalized modulation to nutritional intervention, which may contribute to the stabilization of metabolic homeostasis [18, 19]. For the exercise component, we selected Baduanjin, a classical qigong form characterized by gentle move-

Table 9. Comparison of perinatal adverse outcomes between the two groups [n (%)]

Group	Macrosomia	Neonatal hypoglycemia	Neonatal asphyxia	Low birth weight	Preterm birth	Respiratory distress	Total
Control group (n=123)	10 (8.13)	6 (4.88)	8 (6.50)	4 (3.25)	12 (9.76)	6 (4.88)	46 (37.40)
Experimental Group (n=123)	3 (2.44)	1 (0.81)	3 (2.44)	0 (0.00)	8 (6.50)	1 (0.81)	16 (13.01)
χ^2							19.407
P							< 0.001

Table 10. Comparison of blood glucose levels at 6-month follow-up between the two groups (mmol/L, $\bar{x} \pm s$)

Blood glucose levels	Control group (n=123)	Experimental Group (n=123)	Between-group Mean Difference (95% CI)	*t*	*P*
FPG	5.38 ± 0.96	4.92 ± 0.85	0.457 (0.230, 0,685)	3.954	< 0.001
2hPG	7.52 ± 1.28	6.31 ± 1.05	1.212 (0.918, 1.506)	8.123	< 0.001

Note: FPG, fasting plasma glucose; 2hPG, 2-hour postprandial plasma glucose.

ments and coordinated mind-breath regulation, which is suitable for pregnant women [20]. To ensure safety in late pregnancy, we modified or simplified two movements - "Shaking the Head and Wagging the Tail to Clear Heart Fire" and "Reaching Hands to Feet to Strengthen Kidneys and Waist" - to avoid increased abdominal pressure or excessive lumbar strain, thereby enabling the safe application of this traditional practice in a modern clinical setting [9]. The marked glycemic improvement observed in the intervention group supports the effectiveness of this modified Baduanjin regimen. Thus, the glycemic benefits conferred by the TCM comprehensive health management model do not derive from any single measure, but rather from the synergistic effects of precision nutrition and safe exercise. At its core, this model embeds TCM holistic principles throughout lifestyle intervention, thereby complementing and refining conventional metabolic management approaches. Notably, the concurrent and more pronounced reductions in fasting insulin, C-peptide, and HOMA-IR in the experimental group indicate that this model not only lowers glucose levels but also improves insulin sensitivity and reduces β-cell secretory burden. This deeper metabolic effect, which goes beyond simple glucose reduction, further underscores the comprehensive action of this intervention on multiple metabolic regulatory targets.

Regarding lipid metabolism and psychological status, the experimental group showed greater reductions in total cholesterol, triglycerides, and low-density lipoprotein cholesterol, along with a more pronounced increase in high-density lipoprotein cholesterol, compared with the control group. Concurrently, the experimental group exhibited significantly greater decreases in both Self-Rating Anxiety Scale and Self-Rating Depression Scale scores. These observations are consistent with earlier studies on psychosomatic interventions for metabolic syndrome, in which integrated approaches improved core metabolic markers while simultaneously enhancing mood, thereby initiating a positive feedback loop [21, 22]. Women at high risk for GDM frequently present with multiple concurrent metabolic disturbances. Dyslipidemia and anxiety or depression are bidirectionally associated, and heightened inflammation may serve as a shared underlying pathway [23]. The Five-Element Music therapy incorporated in this study - specifically the Jiao and Gong modes, selected according to TCM theory - may have played a unique role in interrupting this vicious cycle. The Jiao mode is believed to enter the Liver channel, soothe the liver and regulate qi, thereby helping to stabilize emotions; the Gong mode is believed to enter the Spleen channel, strengthen the spleen and harmonize the stomach, and nourish qi and blood. Both modes are therefore relevant to common pregnancy-related disturbances such as excessive worry and liver qi stagnation [24]. Research assistants used WeChat check-in groups and weekly telephone follow-ups to monitor adherence to the music therapy schedule and, equally importantly, to provide participants with channels for emotional expression and psychological support. This form of human-

Table 11. Univariate analysis of factors associated with poor prognosis

Variables	*β*	*S.E*	*Z*	*P*	*OR* (95% *CI*)
Management approach					
0					1.000 (Reference)
1	-3.024	0.491	-6.161	< .001	0.049 (0.019-0.127)
Smoking					
0					1.000 (Reference)
1	0.378	1.234	0.307	0.759	1.460 (0.130-16.378)
Educational attainment					
0					1.000 (Reference)
1	-0.000	0.615	-0.000	1.000	1.000 (0.300-3.336)
2	-0.033	0.632	-0.052	0.959	0.968 (0.281-3.337)
3	0.021	0.555	0.038	0.970	1.021 (0.344-3.034)
4	0.539	0.812	0.664	0.507	1.714 (0.349-8.421)
Method of conception					
0					1.000 (Reference)
1	0.206	0.554	0.372	0.710	1.228 (0.415-3.635)
Types of mothers					
0					1.000 (Reference)
1	0.079	0.315	0.251	0.801	1.082 (0.584-2.007)
Family history of diabetes					
0					1.000 (Reference)
1	1.495	0.320	4.669	< .001	4.457 (2.380-8.348)
Drinking alcohol					
0					1.000 (Reference)
1	-0.005	0.372	-0.014	0.989	0.995 (0.480-2.062)
Adverse pregnancy history					
0					1.000 (Reference)
1	0.012	0.439	0.027	0.979	1.012 (0.428-2.393)
Age	0.025	0.042	0.600	0.548	1.025 (0.945-1.112)
Gestational age	-0.033	0.096	-0.344	0.731	0.968 (0.802-1.167)
Pre-pregnancy BMI	0.901	0.125	7.181	< 0.001	2.462 (1.926-3.149)
Pre-pregnancy weight	0.034	0.027	1.253	0.210	1.035 (0.981-1.091)
2hPG	1.289	0.183	7.058	< 0.001	3.631 (2.538-5.194)
FPG	0.926	0.178	5.200	< 0.001	2.524 (1.781-3.579)
FINS	-0.006	0.035	-0.177	0.860	0.994 (0.927-1.065)
C-P	0.092	0.208	0.444	0.657	1.097 (0.730-1.649)
HOMA-IR	-0.026	0.127	-0.205	0.837	0.974 (0.759-1.251)
TC	-0.003	0.419	-0.006	0.995	0.998 (0.439-2.267)
HbA1c	-0.082	0.155	-0.529	0.597	0.922 (0.681-1.248)
TG	-0.229	0.276	-0.829	0.407	0.796 (0.463-1.366)
LDL-C	-0.114	0.236	-0.482	0.630	0.892 (0.561-1.418)
HDL-C	0.154	1.121	0.137	0.891	1.166 (0.130-10.500)

Notes: OR, Odds Ratio; CI, Confidence Interval; FPG, fasting plasma glucose; 2hPG, 2-hour postprandial plasma glucose; TC, total cholesterol; HbA1c, glycated hemoglobin; TG, triglycerides; LDL-C, low-density lipoprotein cholesterol; HDL-C, high-density lipoprotein cholesterol.

istic care, delivered through familiar communication platforms, naturally carries a counseling function. When participants practiced Baduanjin with Five-Element Music as background

Table 12. Multivariate analysis of independent risk factors for poor prognosis

Variables	*β*	*S.E*	*Z*	*P*	*OR* (95% *CI*)
Intercept	75.858	18.452	-4.111	< .001	-
Management approach					
0					1.000 (Reference)
1	-2.174	0.896	-2.425	0.015	0.114 (0.020-0.659)
Family history of diabetes					
0					1.000 (Reference)
1	1.895	0.821	2.307	0.021	6.654 (1.330-33.286)
Pre-pregnancy BMI	1.471	0.352	4.176	< 0.001	4.354 (2.183-8.684)
2hPG	2.116	0.647	3.271	0.001	8.296 (2.335-29.477)
FPG	3.148	0.863	3.645	< 0.001	23.283 (4.286-126.483)

Note: OR, Odds Ratio; CI, Confidence Interval; FPG, fasting plasma glucose; 2hPG, 2-hour postprandial plasma glucose; BMI, body mass index. Management approach: 0, control group, 1 = experimental group; Family history of diabetes: 0 = no, 1 = yes.

accompaniment, or listened to it quietly at noon or before bedtime, exercise therapy, music therapy, and psychological support merged into a cohesive intervention that synergistically induced a relaxation response [8]. This would be expected to reduce sympathetic nervous system activity and decrease the release of stress hormones such as cortisol, thereby improving lipid metabolism and alleviating anxiety and depression [25]. The superior improvements in lipid profiles and psychological scores observed in the intervention group provide robust evidence for the value of this multidimensional mind-body approach. Its benefits are not merely additive; rather, they exemplify how the TCM concept of "unity of body and mind" can be operationalized in contemporary health management.

Subgroup analyses revealed heterogeneous treatment responses across different participant characteristics. An exploratory interaction between age and treatment effect was observed (P=0.034), suggesting a potential trend toward greater glycemic improvements in participants aged ≥ 35 years, which may reflect greater baseline metabolic vulnerability. However, given that this interaction did not reach the Bonferroni-corrected significance threshold (α'=0.010), this finding should be interpreted with caution as hypothesis-generating rather than confirmatory. Notably, TCM constitution types moderated treatment outcomes: participants with Yin-deficiency constitution showed significant benefits (ΔFPG: -1.01 mmol/L, 95% CI: -1.45 to -0.57), whereas those with Qi-deficiency constitution did not reach statistical significance (P=0.115), suggesting that cooling and nourishing interventions may yield more rapid effects than tonifying approaches in this population. No significant interactions were observed for pre-pregnancy BMI, family history of diabetes, or baseline HbA1c (P > 0.05), indicating broad applicability of this protocol across conventional risk strata. These findings support the integration of TCM constitution identification into individualized GDM management strategies.

In terms of maternal and neonatal clinical outcomes, the TCM comprehensive management model established in this study also demonstrated significant advantages. The experimental group had significantly lower rates of cesarean section, pregnancy complications (including polyhydramnios, pregnancy-related infections, hypertensive disorders of pregnancy, postpartum hemorrhage, and ketoacidosis), and perinatal adverse outcomes (including macrosomia, neonatal hypoglycemia, neonatal asphyxia, low birth weight, preterm delivery, and respiratory distress syndrome) compared with the control group. These results strongly indicate that optimization of metabolic management during pregnancy can ultimately translate into tangible clinical benefits. Pregnancy complications are often closely associated with poor maternal glycemic and lipid control, excessive weight gain, and systemic inflammation [26]. Through comprehensive TCM management that achieves stable glycemic and lipid control, the maternal metabolic burden is alleviated, thereby naturally reducing the risk of the aforementioned compli-

cations. Good glycemic control can significantly reduce polyhydramnios caused by increased osmotic pressure from hyperglycemia, and also lower the risks of neonatal hypoglycemia and other adverse outcomes associated with maternal-fetal hyperinsulinemia [27]. The improved neonatal outcomes in the intervention group suggest that effective intervention during this critical pregnancy window can directly benefit the newborn and may have far-reaching effects on both short- and long-term health. Therefore, this model is not merely a management protocol but also a preventive strategy grounded in the concept of life-course health. Data from the 6-month postpartum follow-up showed that fasting plasma glucose and 2-hour postprandial glucose remained significantly lower in the experimental group than in the control group, indicating that the metabolic protective effects of this model did not dissipate with the cessation of the intervention but rather exhibited a certain degree of persistence.

Multivariate logistic regression analysis further identified independent factors influencing postpartum glucose metabolism outcomes and highlighted the core value of the TCM comprehensive management model as a protective factor. After adjusting for traditional risk factors including family history of diabetes, pre-pregnancy BMI, and prenatal fasting and 2-hour postprandial glucose levels, TCM comprehensive management remained a significant independent protective factor, reducing the risk of postpartum glucose metabolism abnormalities by approximately 89% (OR=0.114, 95% CI: 0.020-0.659, *P*=0.015). This finding carries substantial clinical significance: regardless of how many inherent or baseline risk factors a pregnant woman carries, receiving TCM comprehensive management is itself a powerful intervention that can independently improve long-term metabolic outcomes. In this study, family history of diabetes was confirmed as one of the strongest inherent risk factors (OR=6.654, 95% CI: 1.330-33.286), which is highly consistent with findings from large-scale epidemiological surveys demonstrating the decisive role of genetic factors in the development of type 2 diabetes [28, 29]. The relatively high odds ratios for prenatal glucose levels (particularly fasting plasma glucose, OR=23.283, 95% CI: 4.286-126.483) indicate that glycemic control in late pregnancy is the most direct and sensitive predictor of postpartum outcomes, further emphasizing the critical importance of achieving glycemic targets during pregnancy [30]. Pre-pregnancy BMI, as a reflection of long-term energy metabolic status, was also identified as an independent risk factor (OR=4.354, 95% CI: 2.183-8.684), suggesting that pre-pregnancy weight management should be incorporated into primary prevention strategies [31]. However, the wide confidence intervals for FPG and 2hPG estimates warrant caution in interpreting the magnitude of these associations, and the exact effect sizes should be confirmed in larger samples. The prominent protective effect of our protocol as an independent factor may stem from the diversity and synergy of its multiple intervention components: personalized dietary guidance directly modulates energy intake and nutritional balance, Baduanjin exercise continuously enhances insulin sensitivity, and Five-Element Music therapy combined with humanistic care jointly regulates the neuroendocrine axis. The combined effects of these three components may simultaneously target multiple pathophysiological pathways involved in the development of postpartum diabetes from various dimensions, producing a synergistic protective effect that exceeds the sum of individual measures.

Limitations

This study has several limitations. First, the follow-up duration was only 6 months postpartum, which precludes assessment of the intervention's effect on progression to diabetes at 1-year, 3-year, or longer intervals. Second, as a single-center study, the generalizability of the results is limited and requires validation in larger, multicenter populations. Future studies should enroll participants from early pregnancy and extend follow-up to longer postpartum periods. Third, the absence of cellular or animal experiments prevents elucidation of the molecular mechanisms underlying insulin resistance and HPA-axis modulation, leaving the current evidence at a phenomenological level; mechanistic investigations are therefore warranted. Despite these limitations, this study provides a relatively solid theoretical foundation and practical framework for establishing a GDM prevention and control system tailored to the Chinese

context. Pending confirmation in larger, multicenter studies, this model holds promise for further implementation and evaluation in primary healthcare and community settings.

Conclusion

In summary, this single-center exploratory study demonstrates that the TCM comprehensive health management model effectively improves metabolic indicators, optimizes maternal-infant outcomes, and reduces postpartum diabetes risk in high-risk GDM populations. Despite its limitations, including a short follow-up period, single-center design, and lack of mechanistic investigations, this study provides a robust theoretical and practical foundation for establishing a GDM prevention and control system in China. Further validation through multicenter studies is needed, and upon confirmation, this model holds promise for implementation in primary healthcare facilities and community settings.

Acknowledgements

We gratefully acknowledge all participants for their involvement in this study.

All eligible participants signed written informed consent forms prior to study participation.

Disclosure of conflict of interest

None.

Address correspondence to: Wenxiu Huang, Zhejiang Chinese Medical University, 548 Binwen Road, Binjiang District, Hangzhou 310053, Zhejiang, China. E-mail: hwx@zcmu.edu.cn

References

[1] Lu W and Hu C. Molecular biomarkers for gestational diabetes mellitus and postpartum diabetes. Chin Med J (Engl) 2022; 135: 1940-1951.

[2] Mohan S and Egan AM. Diagnosis and treatment of hyperglycemia in pregnancy: type 2 diabetes mellitus and gestational diabetes. Endocrinol Metab Clin North Am 2024; 53: 335-347.

[3] Li R, Zhang B, Zhang Y, Yang Y, Lu Y and Li J. Mitochondrial homeostasis in pancreatic β cell function: mechanisms and therapeutic targets for diabetes. J Diabetes 2026; 18: e70228.

[4] Chiefari E, Arcidiacono B, Foti D and Brunetti A. Gestational diabetes mellitus: an updated overview. J Endocrinol Invest 2017; 40: 899-909.

[5] Brown J, Alwan NA, West J, Brown S, McKinlay CJ, Farrar D and Crowther CA. Lifestyle interventions for the treatment of women with gestational diabetes. Cochrane Database Syst Rev 2017; 5: CD011970.

[6] Huang S, Magny-Normilus C, McMahon E and Whittemore R. Systematic review of lifestyle interventions for gestational diabetes mellitus in pregnancy and the postpartum period. J Obstet Gynecol Neonatal Nurs 2022; 51: 115-125.

[7] McIntosh N, Billingsley H, Hummel SL and Mills WL. Medically tailored meals in heart failure: a systematic review of the literature, 2013-2023. J Card Fail 2025; 31: 939-950.

[8] Wu Q, Liu Z, Pang X and Cheng L. Efficacy of five-element music interventions in perinatal mental health and labor pain: a meta-analysis. Complement Ther Clin Pract 2020; 40: 101217.

[9] Wang F, Zeng W, Zhou T, Yun F, Li X, Li Y, Li H, Huang Y, Yu D, Guo S, Liu X, Hu C, Zhou J, Fan L, Ma L, Yu G, Xie D, Xu X and Qu F. The adjunctive effect of a qigong (Baduanjin) intervention program on maternal and child health outcomes: a multicenter randomized controlled trial protocol. BMC Pregnancy Childbirth 2026; 26: 218.

[10] van der Zee-van den Berg AI, Boere-Boonekamp MM, Groothuis-Oudshoorn CGM and Reijneveld SA. Postpartum depression and anxiety: a community-based study on risk factors before, during and after pregnancy. J Affect Disord 2021; 286: 158-165.

[11] Chen X, Hu W, Hu Y, Xia X and Li X. Discrimination and structural validity evaluation of Zung self-rating depression scale for pregnant women in China. J Psychosom Obstet Gynaecol 2022; 43: 26-34.

[12] Johns EC, Denison FC, Norman JE and Reynolds RM. Gestational diabetes mellitus: mechanisms, treatment, and complications. Trends Endocrinol Metab 2018; 29: 743-754.

[13] Gao C, Sun X, Lu L, Liu F and Yuan J. Prevalence of gestational diabetes mellitus in mainland China: a systematic review and meta-analysis. J Diabetes Investig 2019; 10: 154-162.

[14] García-Moreno RM, Benítez-Valderrama P, Barquiel B, Hillman N, Herranz L and Pérez-de-Villar NG. Predictors of postpartum glucose metabolism disorders in women with gestational diabetes mellitus. Diabetes Metab Syndr 2022; 16: 102629.

[15] Xu J, Lin X, Fang Y, Cui J, Li Z, Yu F, Tian L, Guo H, Lu X, Ding J, Ke L and Wu J. Lifestyle interventions to prevent adverse pregnancy outcomes in women at high risk for gestational

diabetes mellitus: a randomized controlled trial. Front Immunol 2023; 14: 1191184.
[16] Yuan K, Wang H, Chen Y, Li S, Wang Q, Cao Y, Gao S, Xu X and Xie Q. A 12-hour comprehensive nutrition care benefits blood glucose level and weight gain and improves outcomes in pregnant women with gestational diabetes mellitus. Ann Palliat Med 2020; 9: 661-670.
[17] Metzger BE. Diet and medical therapy in the optimal management of gestational diabetes mellitus. Nestle Nutr Workshop Ser Clin Perform Programme 2006; 11: 155-169.
[18] Zhang R, Gao X, Sun T, Li H, Yang Q, Li B, Zhu D and Wang R. Longer physical exercise duration prevents abnormal fasting plasma glucose occurrences in the third trimester: findings from a cohort of women with gestational diabetes mellitus in Shanghai. Front Endocrinol (Lausanne) 2023; 14: 1054153.
[19] Xie Y, Zhao H, Zhao M, Huang H, Liu C, Huang F and Wu J. Effects of resistance exercise on blood glucose level and pregnancy outcome in patients with gestational diabetes mellitus: a randomized controlled trial. BMJ Open Diabetes Res Care 2022; 10: e002622.
[20] Rasmussen L, Poulsen CW, Kampmann U, Smedegaard SB, Ovesen PG and Fuglsang J. Diet and healthy lifestyle in the management of gestational diabetes mellitus. Nutrients 2020; 12: 3050.
[21] Liu M, Chen T, Wang S, Li N and Liu D. To assess the impact of individualized strategy and continuous glucose monitoring on glycemic control and mental health in pregnant women with diabetes. Front Endocrinol (Lausanne) 2025; 16: 1470473.
[22] Zhu GH, Xu Y, Zou L, Zhou Q and Zhou LJ. The effect of interdisciplinary and diversified health education combined with personalized nutrition intervention on FPG, 2hPG, SDS, SAS scores and the pregnancy outcomes of gestational diabetes mellitus. Ginekol Pol 2025; 96: 304-307.
[23] Wu S, Jin J, Hu KL, Wu Y and Zhang D. Prevention of gestational diabetes mellitus and gestational weight gain restriction in overweight/obese pregnant women: a systematic review and network meta-analysis. Nutrients 2022; 14: 2383.
[24] Kwon CY, Kim H and Kim SH. The modernization of oriental music therapy: five-element music therapy combined with artificial intelligence. Healthcare (Basel) 2024; 12: 411.
[25] Zhang Y and Gao SH. Chinese traditional five-tone music therapy. Zhonghua Yi Shi Za Zhi 2022; 52: 323-327.
[26] Chen Y, Qiu C, Chen J, Li L, Xu J and Sheng Z. Effect of the internet combined with exercise-based individualized nursing intervention in patients with gestational diabetes mellitus. Diabetol Metab Syndr 2021; 13: 125.
[27] Guo Y, Zhou L, Sun B, Wang C and Zhang J. Application of online-offline integrated medical care management in patients with gestational diabetes. Ginekol Pol 2021; 92: 720-725.
[28] Moosazadeh M, Asemi Z, Lankarani KB, Tabrizi R, Maharlouei N, Naghibzadeh-Tahami A, Yousefzadeh G, Sadeghi R, Khatibi SR, Afshari M, Khodadost M and Akbari M. Family history of diabetes and the risk of gestational diabetes mellitus in Iran: a systematic review and meta-analysis. Diabetes Metab Syndr 2017; 11 Suppl 1: S99-S104.
[29] Syngelaki A, Wright A, Gomez Fernandez C, Mitsigiorgi R and Nicolaides KH. First-trimester prediction of gestational diabetes mellitus based on maternal risk factors. BJOG 2025; 132: 972-982.
[30] Lyu Y, Cui M, Zhang L, Zheng G, Zuo H, Xiu Q and Shah PS. Pre-pregnancy body mass index, gestational diabetes mellitus, and gestational weight gain: individual and combined effects on fetal growth. Front Public Health 2024; 12: 1354355.
[31] Teshome AA, Li Q, Garoma W, Chen X, Wu M, Zhang Y, Zhang X, Lin L, Wang H, Yang X, Hao L, Sun G, Han W, Chen X, Xiong G and Yang N. Gestational diabetes mellitus, pre-pregnancy body mass index and gestational weight gain predicts fetal growth and neonatal outcomes. Clin Nutr ESPEN 2021; 42: 307-312.

Supplementary Table 1. Variable definitions and coding specifications

Variable	Variable Type	Analysis Type	Code/Unit	Code Meaning
Management Approach	Binary Classification	Single-factor, multi-factor	0	Routine Management (Reference Group)
			1	TCM Comprehensive Health Management
Smoking	Binary Classification	Single-factor analysis only	0	Non-smokers (control group)
			1	Smoking
Drinking alcohol	Binary Classification	Single-factor analysis only	0	No alcohol consumption (control group)
			1	Drinking alcohol
Educational attainment	Multi-category	Single-factor analysis only	0	Junior high school and below (reference group)
			1	High School/Vocational School
			2	Junior college
			3	Bachelor's degree
			4	Graduate students and above
Method of conception	Binary Classification	Single-factor analysis only	0	Natural conception (control group)
			1	Assisted Reproductive Technology (IVF)
Types of Mothers	Binary Classification	Single-factor analysis only	0	First-time birth (reference group)
			1	Postpartum
Family history of diabetes	Binary Classification	Single-factor, multi-factor	0	No family history of diabetes (reference group) No family history of diabetes (reference group)
			1	Family history of diabetes
Adverse pregnancy history	Binary Classification	Single-factor analysis only	0	No adverse pregnancy history (control group)
			1	History of adverse pregnancy outcomes
Age	Continuous variable	Single-factor, multi-factor	year	Change in OR value corresponding to each additional year of age
Gestational age	Continuous variable	Single-factor analysis only	week	Change in OR value for each additional week
Pre-pregnancy BMI	Continuous variable	Single-factor, multi-factor	kg/m^2	The OR value corresponding to each 1 kg/m^2 increase
Pre-pregnancy weight	Continuous variable	Single-factor analysis only	kg	Change in OR value per 1 kg increase
2hPG	Continuous variable	Single-factor, multi-factor	mmol/L	Change in OR value corresponding to each 1 mmol/L increase
FPG	Continuous variable	Single-factor, multi-factor	mmol/L	Change in OR value corresponding to each 1 mmol/L increase
TC	Continuous variable	Single-factor analysis only	mmol/L	Change in OR value corresponding to each 1 mmol/L increase
HbA1c	Continuous variable	Single-factor analysis only	%	The corresponding OR value change for each 1% increase
TG	Continuous variable	Single-factor analysis only	mmol/L	Change in OR value corresponding to each 1 mmol/L increase
LDL-C	Continuous variable	Single-factor analysis only	mmol/L	Change in OR value corresponding to each 1 mmol/L increase
HDL-C	Continuous variable	Single-factor analysis only	mmol/L	Change in OR value corresponding to each 1 mmol/L increase