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CGM-guided personalized diet enhances glycemic and metabolic outcomes in Chinese adults with prediabetes and T2DM: A randomized trial

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ABSTRACT: This 24-week randomized controlled trial compared a continuous glucose monitoring (CGM)-guided personalized postprandial-targeting (PPT) diet with the standardized Chinese Diabetic Diet (CDD) in 175 Chinese adults with prediabetes or unmedicated type 2 diabetes (T2DM). The PPT diet dynamically adjusted macronutrients composition based on individualized glucose responses, whereas the CDD followed national guidelines. Compared with the CDD group, the PPT group achieved significantly greater reductions in HbA1c [-0.46% *vs.* 0.06%; between-group difference: -0.4% (-0.55, -0.25)%, $P < 0.001$], fasting plasma glucose [-1.12 *vs.* -0.74 mmol/L; -0.37 (-0.64, -0.11) mmol/L, $p = 0.007$], and 2-h oral glucose tolerance test [-3.52 *vs.* -2.47 mmol/L; -1.04 (-2.13, -0.04) mmol/L, $p = 0.028$]. PPT also reduced postprandial glucose exposure [incremental area under the curve: -101.24 *vs.* -59.39 mmol/L ꞏmin; between-group difference: -42.86 (-70.4, -16.08) mmol/L ꞏmin, $P < 0.003$], accompanied by a greater reduction in carbohydrate consumption (244.0→148 g/day *vs.* 240→181.4 g/day for CDD), improved lipid profiles (LDL-C: -1.02 *vs.* -0.23 mmol/L; triglycerides: -0.67 *vs.* -0.1 mmol/L; HDL-C: + 0.31 *vs.* + 0.13 mmol/L; all $P < 0.001$), and more pronounced weight loss [-6.83 *vs.* -0.55 kg; -5.97 (-7.2, -4.74) kg, $P < 0.001$]. Liver enzymes improved significantly in the PPT group (ALT: -6.23 *vs.* -0.97 U/L, $p = 0.004$; GGT: -8.41 *vs.* -1.04 U/L, $P < 0.001$), as did self-management scores. These findings demonstrate that CGM-guided personalized nutrition can substantially improve glycemic control, lipid metabolism, and overall metabolic health, providing a promising and potentially scalable strategy for high-risk populations. However, the long-term sustainability and cost-effectiveness of this approach warrant further study.

Keywords: Personalized nutrition; continuous glucose monitoring; prediabetes; type 2 diabetes mellitus; glycemic control; randomized controlled trial

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1. Introduction

The prevalence of diabetes in China has surged over the past four decades, increasing from less than 1.0% in 1980, 12.4% in 2018 and to 13.8% in 2024 [1]. In 2021, approximately 140.9 million Chinese adults aged 20-79 were living with diabetes, making China home to the world's largest diabetic population [2]. However, Type 2 diabetes mellitus (T2DM) rarely develops abruptly; it is rather typically preceded by a prolonged phase of dysglycemia known as prediabetes. Prediabetes is defined by blood glucose levels elevated above normal but below the diagnostic threshold for T2DM, and is pathophysiologically marked by a combination of insulin resistance (IR) and varying degrees of impaired glucose regulation (IGR) such as the impaired fasting glucose (IFG) and/or impaired glucose tolerance (IGT) [3]. Recent estimates suggest that more than 170 million Chinese adults, over 20% of the population, currently are prediabetes, with an annual progression rate to diabetes of 5-10% [1, 4].

Addressing the escalating diabetes epidemic requires coordinated, multisectoral efforts and a paradigm shift toward comprehensive, prevention-centered public health strategies. Recognizing this imperative, the Chinese government launched the Healthy China 2030 initiative and its subsequent Action Plan. These programs collectively signal a strategic transition from a disease-centered to a health-centered model of care [1]. However, translating national policy into sustained individual behavior change remains a formidable challenge, especially in the domain of dietary modification, as the adherence to healthy eating patterns is influenced by a complex interplay of individual preferences, sociocultural norms, and environmental constraints (i.e., regional food availability and affordability). In this context, the internationally promoted diets such as mediterranean diet (MED) and carbohydrate-restricted regimens often face limited acceptance in China's carbohydrate-dominant food culture. For example, aggressive carbohydrate restriction is difficult to implement sustainably, as it conflicts with ingrained culinary practices and social norms around staple consumption [5, 6]. In China, the Jiangnan diet, traditionally followed by populations residing south of the Yangtze River, has garnered attention for its health-promoting properties. This dietary pattern is characterized by a high intake of seasonal vegetables and fruits, freshwater fish and shrimp, soy-based products, and a moderate consumption of plant oils and unrefined carbohydrates such as brown rice. Recent studies have reported that the Jiangnan diet offers metabolic benefits comparable to those of MED, including reductions in body weight and improvements in glucose homeostasis [7]. Aligned with these principles, the updated Chinese Dietary Guidelines (CDG) similarly advocate for dietary patterns emphasizing food diversity (http://dg.cnsoc.org/index.html). These culturally rooted dietary frameworks underscore the importance of leveraging local food systems and preferences in designing effective, population-specific strategies for metabolic health and diabetes prevention.

Despite these advances, a critical gap remains: current dietary guidelines and culturally rooted models such as the Jiangnan diet are inherently static, offering generalized recommendations that fail to account for the substantial inter-individual variability in glycemic responses, along with poor long-term compliance. For instance, identical meals may produce markedly different postprandial glucose excursions across individuals,

driven by differences in gut microbiota, insulin sensitivity, lifestyle, and meal timing [8]. This inter-individual heterogeneity underscores a critical gap in current dietary guidance: the lack of culturally adapted, personalized nutrition strategies capable of effectively addressing postprandial glycemic excursions [9, 10].

Postprandial glucose (PPG) excursions, shaped by meal composition, timing, and individual metabolic variability, have emerged as strong, independent predictors of long-term glycemic status and diabetes-related complications [8, 11-13]. In response, emerging evidence suggests that equipping individuals with tools to manage their glycemic responses based on personalized predictions of their postprandial blood glucose response (PPGR) can significantly enhance glycemic stability and metabolic outcomes [13, 14]. An algorithm-based personalized postprandial-targeting (PPT) diet aimed at lowering PPGR with real-time feedback through a smartphone application have demonstrated superior efficacy in reducing hyperglycemia compared to conventional MED diet, with a significantly greater reduction in glycated hemoglobin (HbA1c) with a between-group difference of -0.14% to -0.02% (95% CI) (p = 0.007) [15]. Despite promising evidence, a critical next step in developing effective PPT diets for glycemic control is to determine whether the PPGR can be accurately predicted at the individual level, and to identify the key modulators such as food choices, meal timing, and individual metabolic traits that best capture a person's vulnerability to glycemic spikes. Equally important is to establish the relationships between PPGR and meals with identical macronutrient compositions, which can guide the personalized design of PPT interventions beyond standard nutritional metrics.

To address this gap, we conducted a 24-week randomized controlled trial to test the hypothesis that whether continuous glucose monitoring (CGM)-guided personalized nutrition, dynamically tailored to individual PPGR and cultural preferences, would outperform standardized dietary guidelines in improving glycemic control and metabolic health in Chinese adults with prediabetes or early-stage T2DM. The CGM technology provided participants with real-time feedback on current glucose levels, as well as the direction and rate of change, enabling timely, data-driven adjustments to dietary choices and lifestyle behaviors to mitigate or prevent acute glycemic excursion [16-19].

In the intervention group, a PPT dietary strategy was implemented, integrating real-time CGM feedback with a culturally tailored food library to optimize individual dietary decisions. The trial aimed to evaluate the effectiveness of this CGM-guided PPT approach compared with the standardized Chinese Diabetes Diet (CDD) in enhancing glycemic control and metabolic health. We hypothesized that the CGM-guided PPT intervention would produce greater improvements in HbA_1c, and glycemic variability, as well as in broader metabolic outcomes, including lipid profiles, liver function, and body composition, than the CDD over the 24-week intervention period. The findings from this trial have the potential not only to advance diabetes prevention strategies but also to provide a framework for integrating artificial intelligence and digital health tools into culturally tailored interventions, ultimately contributing to the global effort to reduce the diabetes burden.

2. Materials and methods

2.1 Participants recruitment

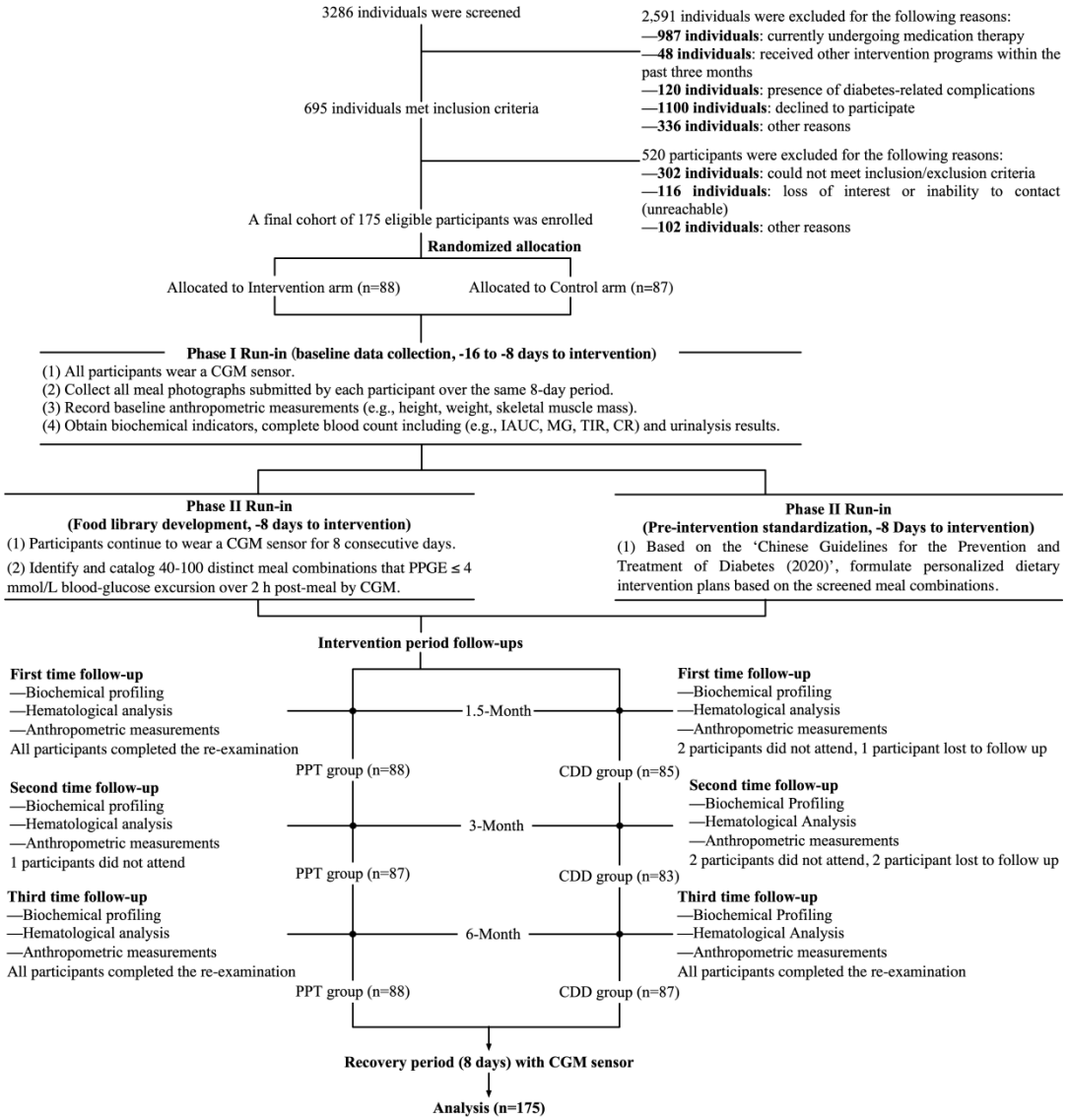

Figure. 1 Methodological framework of the dietary intervention cohort study. The diagram outlines participant recruitment, randomization, dietary intervention protocols for the PPT and CDD groups, CGM assessment periods, and outcome measurements.

This randomized controlled trial was conducted at Quzhou Hospital of Traditional Chinese Medicine between September 2023 and December 2024. The study protocol complied with the Declaration of Helsinki and was approved by the Ethics Committee of Quzhou Hospital of Traditional Chinese Medicine (Approval No: ChiCTR2400085589). The trial was registered at ClinicalTrials.gov.

Participants were recruited through flyers distributed at Quzhou Hospital of Traditional Chinese Medicine and nearby communities. Interested individuals contacted the research team via the phone number provided and underwent initial screening, which included FPG, HbA1c, and oral glucose tolerance test (OGTT) assessments. Individuals meeting the preliminary eligibility criteria were invited to the Nutrition Department of Quzhou Hospital of Traditional Chinese Medicine, where they received a detailed explanation of the study protocol and provided written informed consent prior to enrollment. Ultimately, participants were deemed eligible according to the diagnostic criteria specified in the Guideline for the Prevention and Treatment of

Type 2 Diabetes Mellitus in China (2020 edition) for diabetes [20], and in the Intervention for Adults with Prediabetes: Chinese Expert Consensus (2023 edition) for prediabetes [21], as follows:

Prediabetes: HbA1c ranges between 5.7%-6.4%, or FPG ranges between 5.6-6.9 mmol/L, or 11.1 mmol/L > 2-h OGTT ≥ 7.8mmol/L. The OGTT was conducted according to World Health Organization guidelines, using a glucose load equivalent to 75 g anhydrous glucose dissolved in water. Participants were required to refrain from taking any glucose-lowering medications prior to testing.

Untreated T2DM: $HbA_{1}c \geq 6.5\%$, or FPG ≥ 7.0 mmol/L (126 mg/dL), and/or 2-h OGTT ≥ 11.1 mmol/L (200 mg/dL).

A detailed flowchart of participant recruitment and the dietary intervention design is presented in Fig. 1 and eventually all 175 qualified participants were employed for intervention.

2.2 Participants randomization

For group assignment, an unpredictable random allocation sequence was generated using the *blockrand* package (version 1.5) in *R*. Block sizes of 4 or 6 were employed, with a fixed allocation ratio of 1:1. As descried in detail in Table S2. A total of 30 to 44 blocks were pre-generated to cover the intended sample size (N = 175). The randomization sequence was generated by an independent statistician and sealed in consecutively numbered, opaque envelopes. Allocation concealment was ensured by having a study coordinator open the envelopes sequentially based on the order of participant enrollment. Ultimately, 88 participants were assigned to the intervention group and 87 to the control group, with no deviations from the randomization sequence.

2.3 Structured dietary intervention protocol: Development and implementation for experimental and control cohorts

2.3.1 Definition of hypoglycemic events

Hypoglycemic episodes were defined based on patient-reported symptoms consistent with hypoglycemia, regardless of measured plasma blood glucose concentrations levels ≤ 3.9 mmol/L (70 mg/dl). All clinically significant hypoglycemic events were included, categorized as follows: severe hypoglycemia, documented symptomatic hypoglycemia, asymptomatic hypoglycemia, probable symptomatic hypoglycemia, and relative hypoglycemia (i.e., symptoms without glucose measurement). These event were assessed to evaluate potential risks of harm [22].

2.3.2 Dietary intervention

PPT group

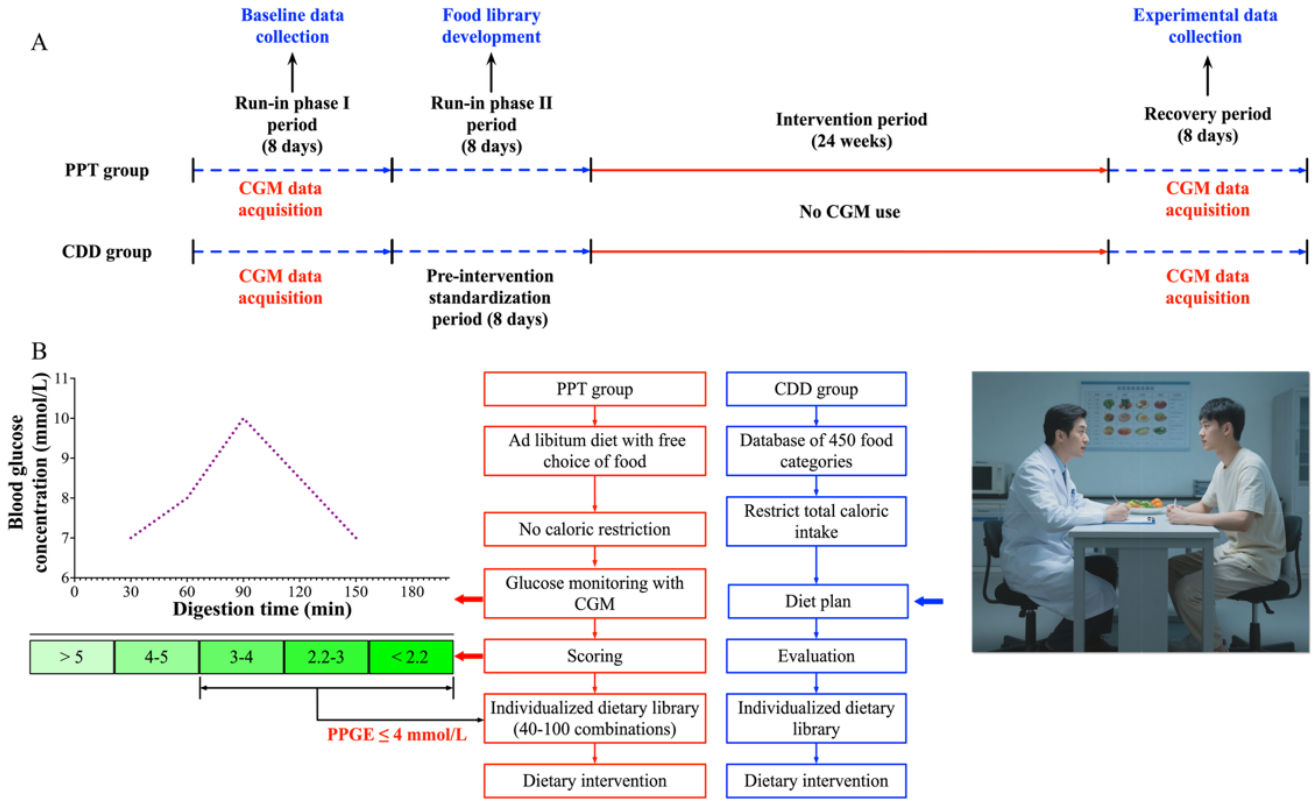

Figure. 2 Overview of intervention protocol. (A) Study timeline including baseline data collection, food library development, the 24-week intervention period and post-intervention follow-up. (B) Workflow for CGM in the PPT group, coupled with the food categorization and scoring system used to develop individualized dietary libraries. Participants in both groups consumed ad libitum diets without caloric restriction. The PPT group received personalized dietary guidance based on PPGE scores.

Run-in phase I (Screening period, 8 days): as shown in **Fig. 2A**, during pre-intervention (days -16 to -8), participants wore a CGM device for 8 days while maintaining their usual dietary patterns and lifestyle habits. They consumed meals using the meal kits provided by the dietitians (Fig.S1) and uploaded photos of each meal to the app. The weight of each food item (cooked weight) was recorded to calculate baseline daily energy intake and the proportions of macronutrients. Dietitians accessed the backend of the app using individual accounts to retrieve CGM-derived data and scored each meal based on the PPGE levels. Here, PPGE refers to the difference between the peak postprandial glucose level and the pre-meal (baseline) glucose level, reflecting the magnitude of glycemic fluctuation in response to a specific meal:

$$\text{PPGE (mmol/L)} = \text{postprandial glucose peak (2 h)} - \text{pre-meal glucose level}$$

A smaller value of PPGE indicated a lower glycemic impact of the food combination. Only food combinations $\leq$ 4 mmol/L were included in each participant's personalized food library. Regarding the selection of the PPGE $\leq$ 4 mmol/L threshold, while current CGM-based guidelines for diabetes management, outlined in both Chinese expert consensus and international recommendations [18], do not designate PPGE as a primary outcome measure, our study deliberately prioritized PPGE as a key endpoint. This decision reflects the fact that PPGE provides a direct and sensitive measure of postprandial glycemic excursions, which are particularly relevant in individuals with prediabetes or early-stage T2DM who are not receiving medication and have no complications. A threshold of 4 mmol/L was chosen to enable timely and clinically meaningful

dietary adjustments while avoiding overly restrictive modifications that could compromise long-term adherence.

Run-in phase 2 (Standardization period, 8 days): from Day -8 to intervention commencement. Participants continued to wear a CGM device. Dietitians provided comprehensive guidance on CGM usage, including information on safe glycemic ranges, data interpretation, and dietary strategies to improve postprandial glucose control. During this period, dietitians re-evaluated food combinations from the first stage that had received PPGE ≥ 4 mmol/L, identifying key items likely responsible for glycemic excursions. These items were then substituted with similar alternatives to optimize the combination and reduce the PPGE (≤ 4 mmol/L). In addition to PPGE, dietitians also monitored peak postprandial glucose levels at 2 h. If this peak exceeded 10 mmol/L, further dietary adjustments were made to ensure the 2-3 h postprandial glucose remained below this threshold (this criterion applied only to combinations with PPGE ≥ 4 mmol/L). All optimized combinations were added to each participant's personalized food library. Ultimately, 40-100 individualized meal combinations were developed per participant. In constructing these food libraries, dietitians also considered personal dietary preferences, nutritional balance, ingredient accessibility, and overall feasibility to ensure high adherence.

Intervention phase (24 weeks): throughout the intervention period, participants selected all meals from their personalized food libraries. Before each meal, participants photographed their food and sent the images to the assigned dietitian via WeChat. If a participant's actual meal deviated substantially from the prescribed combinations in their food library, the dietitian the promptly provided feedback and recommended appropriate substitutions.

CDD group

The CDD group's dietary regimen was formulated based on the Chinese Guidelines for the Prevention and Treatment of Type 2 Diabetes (2020 edition). This protocol emphasizes individualized energy intake and macronutrient distribution (carbohydrates: 45%-60% of total energy; fats: 20%-30%; proteins: 15%-20%).

Run-in phase 1 (screening phase, 8 Days): participants wore CGM devices for 8 days while adhering to their habitual dietary patterns and lifestyles. Similarly, they consumed meals using the meal kits provided by the dietitians (Fig.S1). All meals were photographed and uploaded to a dedicated mobile application (APP) for blinded nutrient quantification (participants had no access to real-time glucose data). Nutritional parameters including cooked food weights (grams) and daily energy intake were recorded to calculate baseline macronutrient ratios (carbohydrate/fat/protein distribution).

Run-in phase 2 (pre-intervention standardization, 16 Days): from Day -8 to intervention commencement. Dietary plans were designed in strict accordance with the guidelines. Dietitians calculated total daily energy requirements and macronutrient ratios using standardized formulae (e.g., 25-30 kcal/kg of ideal body weight). Participants were instructed to follow food exchange portions to meet carbohydrate, fat, protein, and vegetable intake targets. Food selections prioritized low- GI whole grains (e.g., oats, quinoa), legumes, and non-starchy vegetables, as recommended by the guidelines.

For both the two groups, at the end of intervention period, all participants continued wear a CMG sensor while maintaining their usual dietary patterns and lifestyle habits. During this period, all data such as blood glucose indicators were collected and measured, as shown in Fig. 1 and Fig. 2A.

To enhance adherence and enable continuous monitoring, dietitians provided individualized support through multiple channels during the 24-week intervention. Scheduled one-on-one counseling sessions were conducted at 1.5, 3, and 4.5 months, each lasting approximately 30 min, to reinforce dietary compliance, evaluate progress, and make timely adjustments. In addition, participants attended three face-to-face dietary follow-up meetings with a dietitian (30 min each) and completed a follow-up questionnaire at the following time points: 1) one week before the intervention, 2) four weeks after the intervention, and 3) eight weeks after the intervention.

Throughout the study, participants in either group could contact a dietitian at any time for temporary advice. All scheduled meetings, unscheduled contacts, and questionnaires were intended to maximize retention, support adherence to the intervention protocol, and identify potential adverse events. To further strengthen monitoring, all participants were required to send daily real-time photographs of their complete dietary intake (including snacks and fruits) to dietitians via WeChat.

2.4 Dietary adherence assessment

2.4.1 Photographic documentation

During intervention, all participants consumed meals using the standardized meal kits (Fig. S1) distributed uniformly across the cohort and photographed their meals prior to consumption. These images were transmitted to dietitians via a secured digital platform for adherence evaluation. Adherence was quantified as the proportion of compliant meals (e.g., alignment with prescribed macronutrient ratios and portion sizes) relative to the total expected submissions. Deviations in image quality (e.g., missing components, unapproved substitutions) or submission frequency were systematically categorized as non-adherence.

2.4.2 Adherence scoring system with dual-evaluator validation

Dietitians conducted monthly adherence assessments using a validated 5-point Likert scale (1: non-adherent; 5: fully adherent). Scoring criteria included compliance with meal timing, portion control, and macronutrient targets. To minimize bias, two independent dietitians performed blinded evaluations. Discordant scores (defined as a $\geq$ 2-point discrepancy) triggered re-evaluation using a consensus protocol.

2.5 Assessment of biochemical and hematological parameters

All participants maintained their usual diet and exercise routines for 3 consecutive days prior to blood sampling and fasted overnight for 8-12 h before sample collection. Blood samples were drawn at baseline, 3 months, and 6 months, and all samples were analyzed in the same laboratory. The test was approved by the Ethics Committee of Quzhou Hospital of Traditional Chinese Medicine (Approval No. 202402097), and comply with the Declaration of Helsinki.

2.5.1 Blood glucose measurements

FPG was measured using a Siemens ADVIA 2400 biochemical analyzer, employing the glucose oxidase method.

HbA_1c levels were using a Huizhong MQ-8000 glycated hemoglobin analyzer and an HbA_1c assay kit (high-performance liquid chromatography method), with a normal reference range of 3.6%-6.0%.

Fasting insulin (FINS) levels were measured on a Siemens Atellica IM 1600 automated chemiluminescence immunoassay analyzer using the acridinium ester direct chemiluminescence method.

2.5.2 Blood lipid measurements

Blood lipids indicators, including total cholesterol (TC), triglycerides (TG), low-density lipoprotein cholesterol (LDL-C), high-density lipoprotein cholesterol (HDL-C), apolipoprotein B (ApoB), and apolipoprotein A (ApoA-I), were analyzed using standard laboratory methods.

TC was measured using the cholesterol oxidase-peroxidase method, with a normal reference of 1.70-5.20 mmol/L.

TG was measured using the glycerol phosphate oxidase method, with a normal reference range of 0.38-1.77 mmol/L.

LDL-C was determined using the catalase clearance method, with a normal reference range of 1.55-3.36 mmol/L.

HDL-C was directly measured using the catalase clearance method.

ApoA-I was determined using the immunoturbidimetric assay, with normal reference ranges of 0.90-1.63 g/L for male, and 0.97-1.73 g/L for female).

ApoB was also determined using the immunoturbidimetric assay, with normal reference ranges of 0.60-1.25 g/L for male, and 0.57-1.22 g/L for female.

2.5.3 Liver functions

Serum levels of aspartate aminotransferase (AST), glutamic-pyruvic transaminase (ALT), alkaline phosphatase (ALP) and γ-glutamyl transferase (GGT) were measured using kinetic spectrophotometric assays.

ALT activity was measured by monitoring the transamination of L-alanine and α-ketoglutarate at 37 ℃, without the addition of pyridoxal 5'-phosphate, via NADH oxidation at 340 nm.

AST activity was assayed analogously using L-aspartate and α-ketoglutarate under identical conditions.

ALP activity was determined by the kinetic hydrolysis of p-nitrophenyl phosphate at pH 10.4 (AMP buffer), with the generation of p-nitrophenol monitored at 405 nm.

GGT activity was assessed by measuring the cleavage of L-γ-glutamyl-3-carboxy-4-nitroanilide in a dual-reagent system designed to minimize bilirubin interference, with 5-amino-2-nitrobenzoate formation recorded at 405 nm.

The reference intervals were defined according to clinical laboratory standards:

ALT: 9.0-50.0 U/L (males), 7.0-40.0 U/L (females).

AST: 15.0-40.0 U/L (males), 13.0-35.0 U/L (females).

ALP: 45.0-125.0 U/L (males，> 18 years old), 35.0-100.0 U/L (females, > 18 years old).

GGT: 10.0-60.0 U/L (males), 7.0-45.0 U/L (females).

2.5.4 Renal function tests

Blood urea (Urea), creatinine (Crea), and uric acid (UA) were measured in venous serum using automated enzymatic methods.

Urea was quantified using the coupled urease-glutamate dehydrogenase technique. Urease hydrolyzes urea into ammonia and carbonate, which then reacts with glutamate dehydrogenase to catalyze the reductive amination of α-ketoglutarate using NADH, the rate of NADH oxidation, measured at 340 nm, is directly proportional to the urea concentration.

Crea was determined by an IDMS-traceable enzymatic assay based on creatininase/creatine amidinohydrolase/sarcosine oxidase pathway. This method exhibits no significant interference from ascorbic-acid up to 500 mg/L and can tolerate bilirubin levels up to 342 μmol/L without bias.

UA was quantified using the uricase-peroxidase coupling method. Uricase oxidizes uric acid to allantoin and hydrogen peroxide, which is then used by peroxidase to oxidize a chromogen to a colored dye. The intensity of the color, measured at 515 nm, is proportional to the uric acid concentration.

The reference intervals for these biomarkers were defined as:

Urea: 1.70-8.30 mmol/L.

Crea: 57.0-101.0 μmol/L (males), 41.0-81.0 μmol/L (females).

UA: 208.0-428.0 μmol/L (males), 155.0-357.0 μmol/L(female).

2.5.5 Other blood indicators

After a fasting period of 8-12 h, venous blood was collected from all participants using Jierui serum tubes. The samples were centrifuged at 3000 × g for 10 min and serum was separated. Total bilirubin, direct bilirubin, indirect bilirubin, total protein, albumin, globulin, lipoprotein, white blood cell (WBC) count, neutrophil count, lymphocyte count, monocyte count, eosinophil count, basophil count and other relevant blood markers were analyzed using a using a Siemens ADVIA 2400 biochemical analyzer within 2 h of sample collection.

2.5.6 Urinalysis

Morning urine samples were collected after a fasting period of 8-12 h, avoiding strenuous exercise and excessive fluid intake. Urine samples were collected at baseline, 3 months and 6 months. Following parameters were analyzed using a fully automated urine particle analyzer (Sysmex UF-5000TM, TOA Electric Co., Ltd, Bornbarch 1, Norderstedt, Germany): color, turbidity, specific gravity, pH, protein, occult blood, ketones, glucose, nitrites, bilirubin and leukocyte esterase.

2.5.7 Anthropometric measurements

Anthropometric measurements, including body mass index (BMI), were recorded as: BM= weight / height² (kg/m²), as recommended by the WHO's 2002 guidelines and the People's Republic of China standard WS/T 428-2013. Additional measurements included body weight, fat mass, fat-free mass, skeletal muscle, body fat percentage, total body water, protein content, visceral fat level and area, waist circumference, hip circumference, waist-hip ratio, blood pressure and heart rate. All measurements were performed using a Body Composition Analyzer (ioi-353) (Jawon Medical Co., Ltd. Seoul, Korea) following with producer's instructions.

2.5.8 CGM-Monitored data

Sinocare (iCanH3/h3) is an ultra-lightweight (≈ 6 g), water-resistant CGM device. It features a subcutaneous sensor that automatically measures interstitial glucose every 3 min, providing approximately 480 readings per day. The device wirelessly transmits the data to a receiver or smartphone for real-time monitoring. The following key parameters are recorded:

Time in Range (TIR): the percentage of readings between 3.9-10.0 mmol/L (70-180 mg/dL), which is an emerging target in clinical practice alongside HbA1c [23].

Incremental AUC (IAUC): the area under the post-prandial (2 h) glucose curve above baseline, typically calculated using the trapezoidal rule.

Coefficient of variation (CV): a measure of glycemic variability, defined as (SD of glucose/mean glucose)×100 %.

Mean glucose (MG): the arithmetic average of all sensor glucose readings, reported in mg/dL.

2.6 Sleep quality assessment using the Pittsburgh sleep quality index

Pittsburgh sleep quality index (PSQI) is a validated self-report questionnaire developed by Buysse, Reynolds [24] to assess the sleep quality of participants. It consists of 19 self-reported items that evaluate seven dimensions of sleep, including: subjective sleep quality, sleep latency, sleep duration, sleep efficiency, sleep disturbances, use of hypnotic medications, and daytime dysfunction. Each dimension is scored on a 0-3 scale, and the sum of all component scores yields the total PSQI score, which ranges from 0 to 21, with higher scores reflecting poorer sleep quality.

2.7 Diabetes management self-efficacy scale

The Chinese version of the diabetes management self-efficacy scale (C-DMSES) is an instrument designed to assess the self-management ability of individuals with diabetes by measuring their confidence in performing daily management tasks. The scale consists of 15 specific items, such as blood glucose monitoring, dietary management, and exercise planning. For each item, participants rate their level of confidence on a scale from 0 to 10 (1: no confidence; 10: full confidence). Higher scores indicate greater self-management ability.

2.8 Glucose monitoring satisfaction survey for type 2 diabetes

The glucose monitoring system satisfaction survey for T2DM (GMSS-T2DM) is a multidimensional tool used to evaluate patient satisfaction with glucose monitoring systems [25, 26]. The Chinese version of

the GMSS-T2DM consists of 15 items, scored using a mix of positively and negatively worded items. Responses are rated on a 5-point Likert scale: 'Strongly disagree' = 1 point, 'Disagree' = 2 points, 'Neutral' = 3 points, 'Agree' = 4 points, and 'Strongly agree' = 5 points. The total score ranges up to 75 points and is categorized into four factors: openness, emotional burden, behavioral burden, and perceived value. A higher total score indicates greater patient satisfaction with glucose monitoring.

2.9 Statistical analysis

Statistical analyses were performed using SPSS 27.0 (IBM Corp.) and R 4.4.2 (R Foundation). Continuous variables are presented as mean ± standard deviation (SD) if normally distributed (assessed via Shapiro-Wilk test) or median (interquartile range [IQR], Q1, Q3) for non-normal distributions. For group comparisons, independent or paired t-tests were applied for normally distributed independent or paired samples, respectively. Mann-Whitney U (independent) or Wilcoxon signed-rank (paired) tests were used for non-parametric data. Categorical variables are expressed as frequencies (percentages), and were analyzed via Pearson's χ^2 test or Fisher's exact test when > 20% of cells had expected counts < 5. The food similarity analysis was conducted based on Euclidean distance, which quantifies the degree of similarity between food items by calculating the square root of the sum of squared differences across selected nutritional or compositional variables. All analysis were two-tailed, with $P < 0.05$ considered statistically significant.

3. Results

3.1 Participant characteristics

A total of 175 participants were enrolled and randomly assigned to PPT (n = 88; 50%) or the CDD group (n = 87; 50%), respectively. As detailed in Table S1, at the baseline, no statistically significant differences were observed between the two groups across a wide range of demographic, clinical, and biochemical variables, including age, sex, education level, occupation, alcohol use, smoking status, physical activity, presence of chronic disease, duration of diabetes, number of diabetic patients, body weight, BMI, skeletal muscle mass, body fat mass, visceral fat area, visceral fat grade, waist-to-hip ratio, FPG, HbA1c, OGTT, FINS, HOMA-IR, TIR, CV, MG, IAUC, TC, TG, HDL-C, LDL-C, ApoA-I, ApoB, ALT, AST, ALP, GGT, Urea, Crea, UA and among others.

All 175 participants have completed the full 6-month intervention period.

3.2 Dietary adherence outcomes

Throughout the 6-month intervention, participants in both the PPT and CDD groups demonstrated high and comparable levels of dietary adherence. The median number of dietary images submitted was 432.5 (409.25, 460.25) in the PPT group and 429.5 (401.00, 449.25) in the CDD group, with no statistically significant difference between groups ($p = 0.083$) (Table 1, Fig. S2). This suggests that both groups maintained high and comparable adherence. Noted that although a downward trend in image submissions was observed over time, adherence remained stable overall, with minimal fluctuations. Notably, both groups reached their lowest submission counts in the fifth month: 63 (58.75, 66) images for the PPT group and 64

(59.75, 68) for the CDD group. Submission numbers rebounded in the final month, with no significant between-group differences in the magnitude of increase, further supporting comparable adherence across both dietary protocols.

Table 1. Number of dietary images sent, median (Q1, Q3) [1].

Month	PPT Group	CDD Group	*p*	All participants
1	78 (75, 82)	78 (74, 80)	0.187	78 (74.75, 81)
2	76 (68.75, 79.25)	73.5 (68, 78)	0.147	75 (68, 78)
3	74 (66.75, 80)	72 (67.75, 78)	0.363	72.5 (67, 79)
4	77 (71, 80)	75 (70.75, 80)	0.493	76.5 (71, 80)
5	63 (58.75, 66)	64 (59.75, 68)	0.057	64 (59, 67)
6	70.5 (66, 75)	69 (63, 72.25)	0.013*	70 (66, 74)
Total	432.5 (409.25, 460.25)	429.5 (401, 449.25)	0.083	430.5 (406.75, 454.25)

[1] The between-group comparisons were conducted using the Mann-Whitney U test. * $P < 0.05$.

3.3 Food category similarity analysis

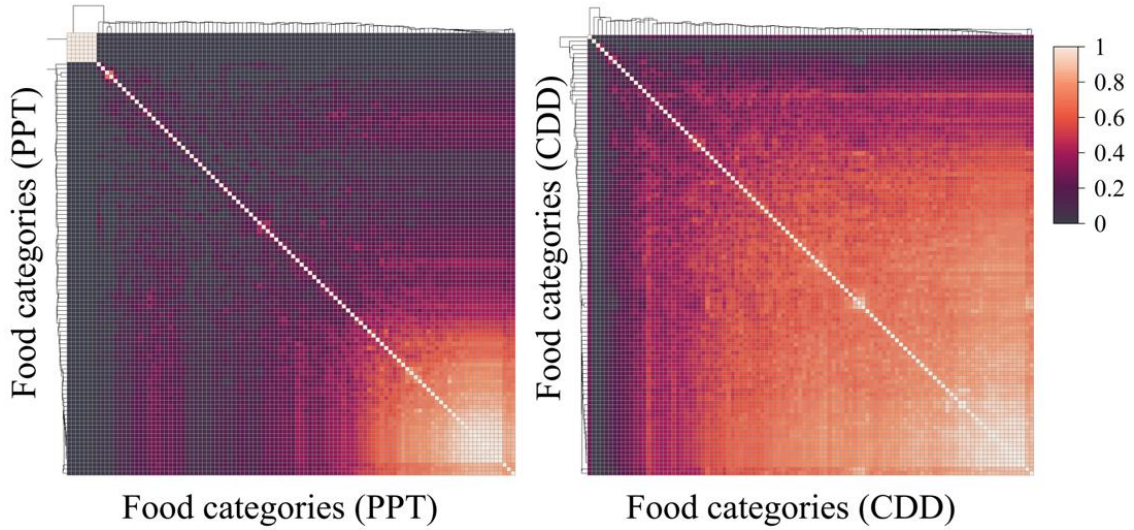

Figure. 3 Food category similarity analysis of the PPT and CDD groups. Darker colors denote lower similarity between individuals, while lighter colors reflect higher similarity.

To further evaluate intra-group dietary similarity, all dietary images submitted by participants throughout the 6-month intervention were annotated and analyzed. Each image was reviewed by trained nutritionists, who categorized food items into predefined food groups and recorded their presence or absence using a binary scheme (1 = consumed, 0 = not consumed). It was noted that while the participants in the PPT group predominantly consumed low-GI, high-fiber and plant-based proteins, participants in the CDD group were adhered more closely to guideline-recommended staples and conventional vegetables, with common foods. The frequency of each food category was then aggregated for each individual and used to calculate pairwise Bray-Curtis dissimilarity indices.

As shown in Fig. 3, the resulting heatmaps demonstrate markedly different patterns between groups. The PPT group exhibited significantly lower intra-group similarity, reflected by a higher mean dissimilarity score (0.68 ± 0.12), whereas the CDD group showed greater dietary convergence with a lower mean dissimilarity (0.32 ± 0.08; $P < 0.001$). This suggests that participants in the PPT group demonstrated a higher degree of dietary individualization, consistent with the personalized, CGM-guided nature of the intervention. In

contrast, the CDD group displayed marked dietary homogeneity, reflecting adherence to standardized dietary guidelines rather than personalized glycemic responses. Additionally, the 20 most commonly consumed food items in each group were as follows:

PPT group: Chinese yam, cauliflower, skim milk, green pepper, tomato, dried bean curd, broccoli, asparagus lettuce, lettuce, celery, pork, carrot, tofu, plum, fish, shrimp, millet, egg, black rice, and oats.

CDD group: cauliflower, cucumber, green pepper, tomato, tofu, broccoli, asparagus lettuce, lettuce, banana, celery, rice, wheat noodles, pork, carrot, mung bean sprouts, orange, dumplings, and rice flour.

These food choices align with the respective dietary principles of PPT and standardized CDD, and provide further context for the observed differences in dietary composition and similarity across groups.

3.4 Biochemical and hematological parameters

3.4.1 Blood glucose indicators

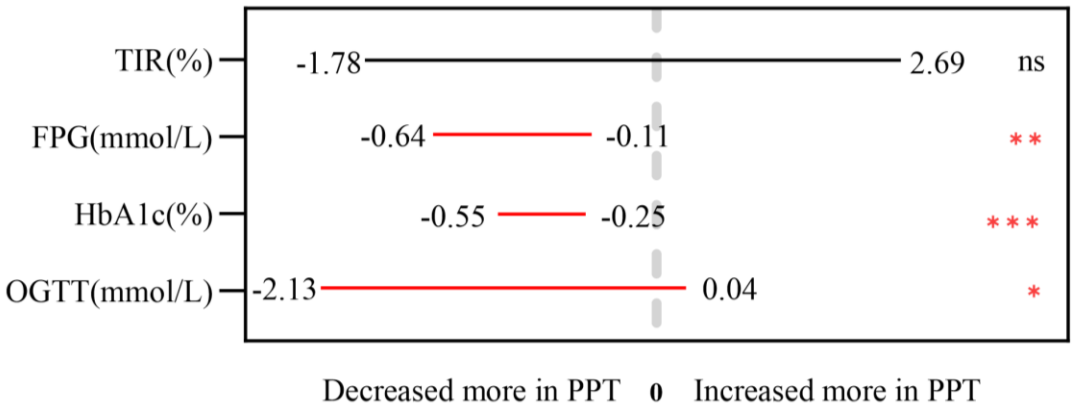

Figure. 4 Blood glucose outcomes including HbA1c, FPG, OGTT and TIR. For continuous variables with a normal distribution, 95% confidence intervals (CI) and between-group comparisons were calculated using Student's t-test. For non-normally distributed variables, 95% CI were estimated using the Hodges-Lehmann method, and between-group comparisons were performed using the Mann-Whitney U test. The red line indicates a significant difference between the two dietary groups ($P < 0.05$), while the black line denotes no significant difference. * $P < 0.05$; ** $P < 0.01$; *** $P < 0.001$, ns = not significant.

At baseline, no significant differences were observed between the PPT and CDD groups in FPG, HbA1c, or OGTT levels ($P > 0.05$ for all, Table S1). Following the 6-month intervention, the CDD group exhibited a significant increase in TIR, along with reductions in FPG and OGTT levels, while HbA1c remained unchanged ($p = 0.602$, Table 2). These findings suggest a modest yet favorable metabolic effect of the standardized CDD intervention in individuals with prediabetes or early-stage T2DM. In comparison, as shown in Fig. 4, the PPT group demonstrated not only a significant increase in TIR but also more pronounced reductions in FPG, HbA1c, and OGTT levels, indicating superior glycemic improvements under the personalized dietary approach.

For FPG: the between-group difference in change ranged from -0.64 to -0.11 mmol/L (95 % CI; $p = 0.007$), with a greater reduction in the PPT group -1.12 (-1.3, -0.93) mmol/L) compared to the CDD group -0.74 (-0.93, -0.55) mmol/L.

For HbA₁c: the between-group difference ranged between -0.55% and -0.25 % (95 % CI; $P < 0.001$), with a median (Q1, Q3) change of -0.46 (-0.57, -0.35) % in the PPT group, versus 0.06 (-0.16, 0.04) % in the CDD group.

For OGTT: the between-group difference was -2.13 to 0.04 mmol/L (95 % CI; $p = 0.028$), with the PPT group showing a larger median reduction -3.52 (-4.2, -2.83) mmol/L than the CDD group -2.47 (-3.31, -1.63) mmol/L.

For TIR: although both groups experienced significant improvements in TIR, the between-group difference in TIR was not significantly changed.

These findings suggest that although both the PPT and CDD dietary interventions yielded improvements in glycemic control over the 6-month period, the PPT regimen elicited significantly greater reductions in FPG, HbA₁c and 2-h OGTT glucose compared to the standardized CDD diet. Additionally, while improvements in the TIR were comparable between the two groups, the more substantial reductions in key glycemic biomarkers observed in the PPT group underscore its superior efficacy in modulating glucose homeostasis among individuals with prediabetes. Collectively, these results support our hypothesis that precision-tailored dietary strategies, guided by real-time glycemic feedback, may offer a more effective approach than conventional dietary guidelines for mitigating early dysglycemia and preventing progression to overt T2DM.

Moreover, as recommended by one of the reviewers, we also have conducted a quantitative comparison of HbA1c effect sizes between our PPT intervention and other PPGR-guided dietary trials. Our 6-month intervention resulted in a between-group HbA1c reduction of -0.55% to -0.35% (95% CI, $P < 0.001$), which notably exceeds the effect observed in a previous study, where a PPT diet outperformed the MED diet by -0.14% to -0.02% ($p = 0.007$) [15]. Additionally, in our study, the between-group difference in OGTT glucose levels reached -2.13 to 0.04 mmol/L (95% CI, $p = 0.028$), whereas no significant change in OGTT was reported in their trial. Taken together, these findings position our intervention at the higher end of efficacy among existing CGM-informed dietary strategies, despite differences in study population, duration, and baseline metabolic characteristics.

3.4.2 Secondary outcomes

The secondary outcomes of the dietary intervention including mean glucose (MG), coefficient of variation (CV), and incremental area under the curve (IAUC) were shown in Table 2.

(1) Blood glucose indictors

MG, CV and IAUC were directly derived from the CGM data.

At baseline, no significant differences were observed between the two groups across these indicators. After the 6-month intervention, the CDD group showed a significant reduction in IAUC compared to baseline, while MG and CV remained statistically unchanged. In contrast, the PPT group demonstrated significant reductions across all three CGM-derived metrics including MG, CV, and IAUC, with changes of a greater magnitude than those observed in the CDD group.

For MG: the between-group difference in change ranged from -1.26 to -0.66 mmol/L (95% CI), with a reduction of -0.06 (-0.3, 0.19) mmol/L in the CDD group versus -1.01 (-1.19, -0.84) mmol/L in the PPT group ($P < 0.001$).

For IAUC: the between-group difference in change ranged from -90.97 to -30.95 mmol·min/L (95% CI), with median (interquartile range) reductions of -59.17 (-82.48, -35.86) mmol·min/L in the CDD group and -120.13 (-139.03, -101.23) mmol·min/L in the PPT group ($P < 0.001$).

Table 2. Metabolic and physiological outcomes between- and within-group changes.

Indicators	PPT		CDD		PPT vs. CDD	
	Compared with baseline (95% CI)	*p*	Compared with baseline (95% CI)	*p*	95% CI	*p*
FPG, mmol/L	-1.12 (-1.3, -0.93)	<0.001***	-0.74 (-0.93, -0.55)	<0.001***	-0.37 (-0.64, -0.11)	0.007**
HbA1c, %	-0.46 (-0.57, -0.35)	<0.001***	-0.06 (-0.16, 0.04)	0.602	-0.4 (-0.55, -0.25)	<0.001***
OGTT, mmol/L	-3.52 (-4.2, -2.83)	<0.001***	-2.47 (-3.31, -1.63)	<0.001***	-1.04 (-2.13, 0.04)	0.028*
TIR, %	4.45 (2.84, 6.06)	<0.001***	4 (2.45, 5.54)	0.002**	0.45 (-1.78, 2.69)	0.395
CV, %	-3.1 (-4.09, -2.11)	<0.001***	-1.63 (-3, -0.26)	0.052	-1.46 (-3.15, 0.23)	0.073
MG, mmol/L	-1.01 (-1.19, -0.84)	<0.001***	-0.06 (-0.3, 0.19)	0.809	-0.96 (-1.26, -0.66)	<0.001***
IAUC, mmol·min/L	-101.24 (-118.13, -83.54)	<0.001***	-59.39 (-82.73, -37.1)	<0.001***	-42.86 (-70.4, -16.08)	0.003**
FIN, μIU/mL	-4.82 (-5.83, -3.81)	<0.001***	-3.03 (-4.94, -1.12)	<0.001***	-1.79 (-3.95, 0.37)	0.034*
HOMA-IR	-1.68 (-2.01, -1.34)	<0.001***	-1.2 (-1.79, -0.61)	<0.001***	-0.48 (-1.16, 0.2)	0.078
TC, mmol/L	-1.19 (-1.43, -0.96)	<0.001***	-0.3 (-0.52, -0.07)	0.09	-0.89 (-1.22, -0.57)	<0.001***
TG, mmol/L	-0.67 (-0.83, -0.51)	<0.001***	-0.1 (-0.44, 0.23)	0.067	-0.56 (-0.94, -0.19)	<0.001***
HDL-C, mmol/L	0.31 (0.23, 0.39)	<0.001***	0.13 (0.07, 0.19)	0.011*	0.18 (0.07, 0.28)	<0.001***
LDL-C, mmol/L	-1.02 (-1.21, -0.84)	<0.001***	-0.23 (-0.4, -0.05)	0.016*	-0.8 (-1.06, -0.54)	<0.001***
Carrier protein A, g/L	0.3 (0.23, 0.36)	<0.001***	0.32 (0.07, 0.57)	<0.001***	-0.02 (-0.28, 0.23)	0.003**
Carrier protein B, g/L	-0.29 (-0.35, -0.23)	<0.001***	-0.14 (-0.21, -0.07)	0.003**	-0.15 (-0.24, -0.06)	<0.001***
ALT, U/L	-6.23 (-8.21, -4.24)	<0.001***	-0.97 (-3.28, 1.33)	0.111	-5.25 (-8.3, -2.21)	0.004**
AST, U/L	-5.92 (-8.31, -3.53)	<0.001***	-3.62 (-5.83, -1.41)	0.008**	-2.3 (-5.56, 0.96)	0.116
ALP, U/L	-13.06 (-16.13, -9.98)	<0.001***	-1.79 (-4.98, 1.4)	0.74	-11.26 (-15.69, -6.83)	<0.001***
GGT, U/L	-8.41 (-10.95, -5.87)	<0.001***	-1.04 (-6.57, 4.49)	0.638	-7.37 (-13.46, -1.29)	<0.001***
Urea, mmol/L	-0.16 (-0.47, 0.15)	0.93	-0.25 (-0.49, -0.02)	0.097	0.09 (-0.3, 0.48)	0.64
Cre, μmol/L	-3.52 (-14.9, 7.86)	<0.001***	-6.15 (-7.78, -4.52)	0.011*	2.63 (-8.87, 14.13)	0.125
UA, μmol/L	-44.38 (-61.23, -27.52)	0.001**	-8.2 (-21.73, 5.34)	0.458	-36.18 (-57.79, -14.57)	0.001**
SBP, mmHg	-16.39 (-19.35, -13.42)	<0.001***	-3.03 (-6.1, 0.03)	0.229	-13.35 (-17.62, -9.09)	<0.001***
DBP, mmHg	-8.44 (-10.58, -6.3)	<0.001***	-1.1 (-2.9, 0.69)	0.483	-7.34 (-10.13, -4.55)	<0.001***
HR, bpm	-1.9 (-3.61, -0.19)	0.171	-2.37 (-4.25, -0.49)	0.127	0.47 (-2.07, 3.01)	0.81
Body weight, kg	-6.83 (-7.89, -5.78)	<0.001***	-0.55 (-1.15, 0)	0.042*	-5.97 (-7.2, -4.74)	<0.001***
BMI, kg/m^2	-2.54 (-2.93, -2.16)	<0.001***	-0.22 (-0.46, -0.02)	0.030*	-2.21(-2.65, -1.75)	<0.001***
Skeletal	-1.05 (-1.42, -0.68)	0.218	-0.05 (-0.3, 0.2)	0.644	-0.03 (-1.55, -0.51)	<0.001***

muscle, %						
Fat mass, %	-5.18 (-5.87, -4.5)	<0.001***	-0.5 (-1.2, -0.1)	0.015*	-4.33 (-5.21, -3.44)	<0.001***
Visceral fat area, cm^2	-17.12 (-33.67, -0.58)	<0.001***	-5.5 (-9.5, -2)	0.003**	-10.53 (-27.61, 6.55)	<0.001***
Visceral fat level	-2.89 (-3.33, -2.44)	<0.001***	-0.47 (-1, 0)	0.047*	-2.42 (-3.05, -1.78)	<0.001***
Waist-to-hip ratio	-0.07 (-0.09, -0.05)	<0.001***	-0.01 (-0.03, -0.01)	<0.001***	-0.05 (-0.07, -0.03)	<0.001***

All abbreviations used in this study are listed and defined in the abbreviation page located at the beginning of the manuscript. CI, confidence interval.

* $P < 0.05$. ** $P < 0.01$. *** $P < 0.001$.

(2) Blood lipid indicators

As summarized in Table 2, both dietary interventions influenced lipid metabolism, but with markedly different outcomes. In the PPT group, significant reductions were observed in TC, TG, LDL-C, and ApoB, alongside significant increases in HDL-C and ApoA-I. In the CDD group, HDL-C and ApoA-I also increased significantly, and LDL-C and ApoB levels were significantly reduced; however, no significant changes were observed in TC or TG levels. Following 6-month intervention, the PPT group demonstrated significantly greater improvements in lipid profiles across multiple markers, particularly:

For TC: the between-group difference in change ranged from -1.22 to -0.57 mmol/L (95% CI). The median (interquartile range) changes were -0.3 (-0.52, 0.07) mmol/L in the CDD group and -1.19 (-1.43, -0.96) mmol/L in the PPT group ($P < 0.001$).

For TG: the between-group difference ranged from -0.94 to -0.19 mmol/L (95% CI). The median (interquartile range) changes were -0.11 (-0.44, 0.23) mmol/L in the CDD group and -0.67 (-0.83, -0.51) mmol/L in the PPT group ($P < 0.001$).

For HDL-C: the between-group difference ranged from 0.07 to 0.28 mmol/L (95% CI). The median (interquartile range) change was 0.13 (0.07, 0.19) mmol/L in the CDD group versus 0.31 (0.23, 0.39) mmol/L in the PPT group ($P < 0.001$).

For LDL-C: the between-group difference ranged from -1.06 to -0.54 mmol/L (95% CI). The median (interquartile range) change was -0.23 (-0.4, -0.05) mmol/L in the CDD group and -1.02 (-1.21, -0.84) mmol/L in the PPT group ($P < 0.001$).

For ApoA-I: The between-group difference ranged from -0.28 to 0.23 g/L (95% CI). The median (interquartile range) change was 0.32 (-0.07, 0.57) g/L in the CDD group and 0.3 (0.23, 0.36) g/L in the PPT group ($P < 0.001$).

For ApoB: the between-group difference ranged from -0.24 to -0.06 g/L (95% CI). The median (IQR) change was -0.14 (-0.21, 0.07) g/L in the CDD group and -0.29 (-0.35, -0.23) g/L in the PPT group ($P > 0.05$).

3.5 Macronutrients intake adjustment and correlation analysis

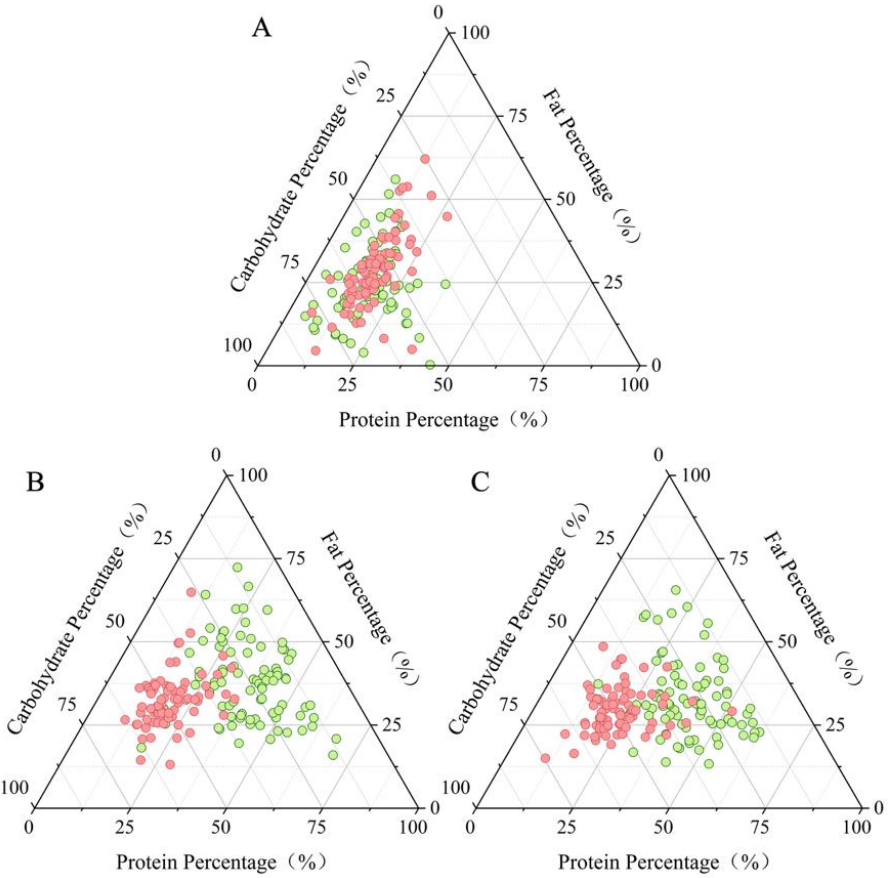

Figure. 5 Longitudinal changes in macronutrient composition (carbohydrates, fats, and proteins) during the dietary intervention period in the PPT and CDD groups. Each point represents an individual meal, with green denoting meals from the PPT group and red from the CDD group. Macronutrient percentages were calculated based on energy contribution from carbohydrate, protein, and fat for each meal and plotted in a ternary coordinate system (A) Baseline (pre-intervention) macronutrient composition; (B) and (C) the macronutrient composition at 3 and 6 months of intervention, respectively.

As shown in **Fig. 5**, over the 6-month intervention, the PPT group exhibited a statistically significant increase in total protein intake, reflected by a rightward trajectory of green markers, accompanied by a notable reduction in the proportion of carbohydrate intake, indicated by an upward shift. In contrast, the CDD group showed no clinically meaningful shifts in macronutrient composition, aside from a modest reduction in carbohydrate intake (upward shift of red markers).

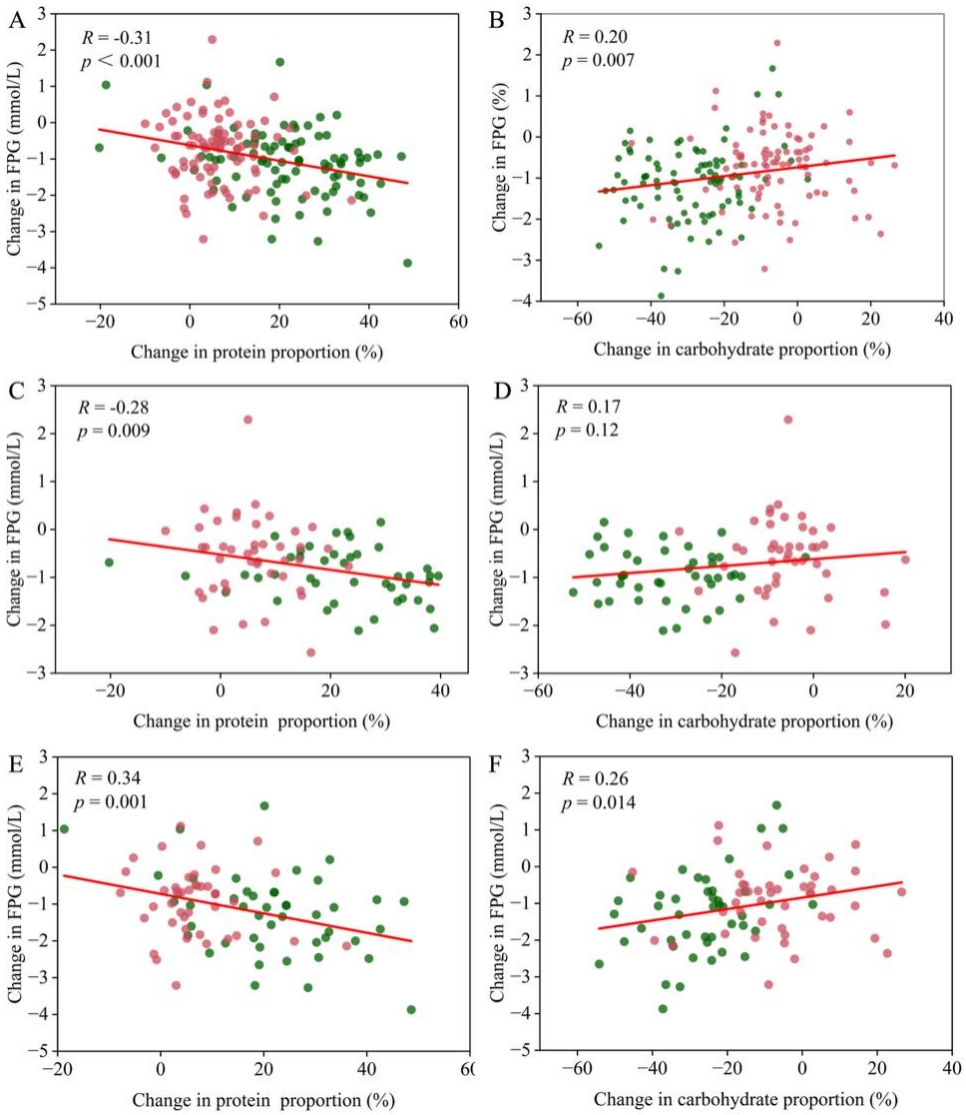

Figure. 6 Correlations between changes in macronutrient proportions (protein: A, C, E; carbohydrate: B, D, F) and changes in FPG levels across different participant subgroups. Panels A and B include all participants (both prediabetes and T2DM); panels C and D include only prediabetes participants; panels E and F include only T2DM participants. Each point represents an individual participant's change in nutrient proportion versus change in FPG. Red dots indicate participants in the CDD group; green dots indicate participants in the PPT group. Pearson's correlation coefficients (R) and corresponding p values are shown for each plot, with regression lines representing the overall trend.

To further elucidate the dietary factors underlying glycemic improvements, we assessed correlation analysis between changes in macronutrient proportions and two primary glycemic endpoints, FPG and HbA1c, in the entire cohort and within prediabetes and T2DM subgroups.

For the whole cohort, increased protein proportion was significantly and negatively correlated with greater reductions in both FPG (R = -0.31, P < 0.001; Fig.6A) and HbA1c (R = -0.38, P < 0.001; Fig. 7A), whereas increased carbohydrate proportion showed positive correlations with changes in FPG (R = 0.20, p = 0.007; Fig. 6B) and HbA1c (R = 0.36, P < 0.001; Fig. 7B).

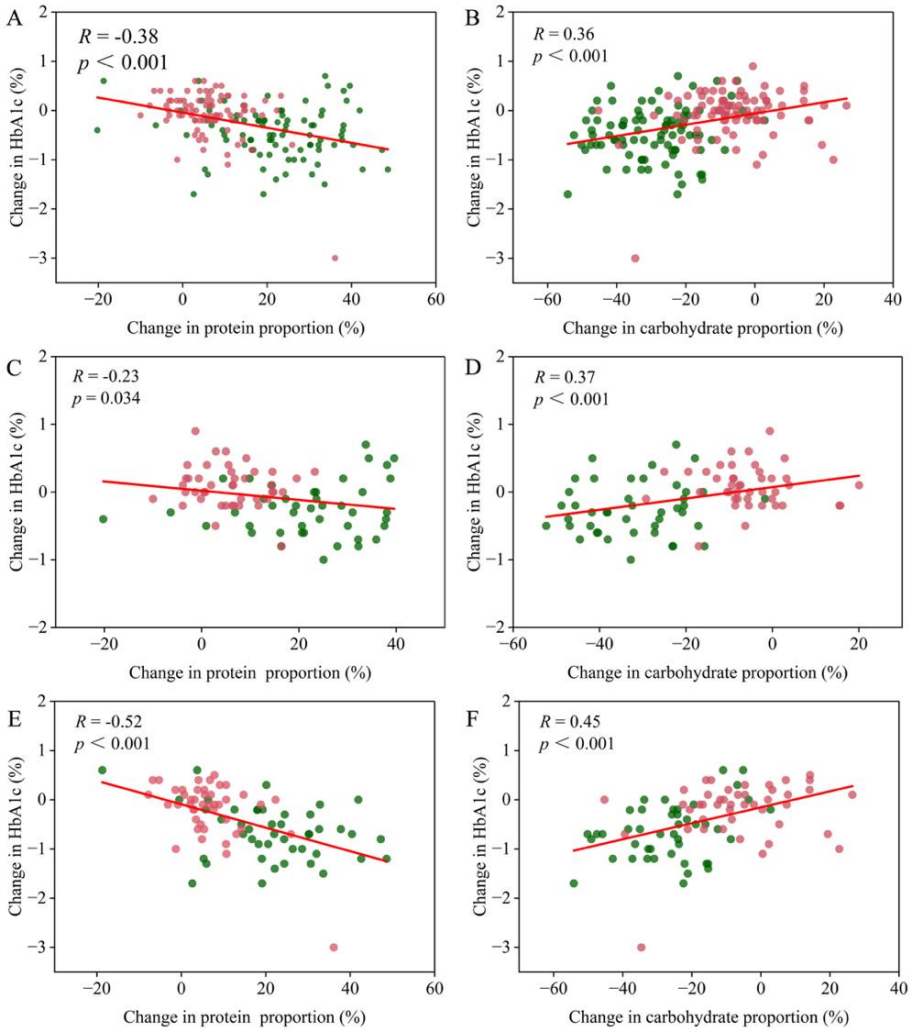

Figure. 7 Correlations between changes in macronutrient proportions (protein: A, C, E; carbohydrate: B, D, F) and changes in HbA1c across different participant subgroups. Panels A and B include all participants (both prediabetes and T2DM); panels C and D include only prediabetes participants; panels E and F include only T2DM participants. Each point represents an individual participant's change in nutrient proportion versus change in FPG. Red dots indicate participants in the CDD group; green dots indicate participants in the PPT group. Pearson's correlation coefficients (R) and corresponding p values are shown for each plot, with regression lines representing the overall trend.

In only prediabetes participants, higher protein proportion remained inversely associated with FPG (R = -0.28, p = 0.009; Fig. 6C) and HbA1c (R = -0.23, p = 0.034; Fig. 7C), while higher carbohydrate proportion tended to correlate positively with these outcomes (FPG: R = 0.17, p = 0.12; Fig. 6D; HbA1c: R= 0.37, P < 0.001; Fig. 7D), though the strength of association was modest. In contrast, T2DM participants exhibited stronger relationships, with protein proportion showing robust inverse associations with both FPG (R = -0.34, p = 0.001; Fig. 6E) and HbA1c (R = -0.52, P < 0.001; Fig. 7E), and carbohydrate proportion displaying significant positive associations (FPG: R = 0.26, p = 0.014; Fig. 6F; HbA1c: R = 0.45, P < 0.001; Fig. 7F).

Together, these findings indicate that shifting macronutrient composition, specifically increasing protein intake at the expense of carbohydrates, was consistently linked to improved glycemic control, with effect sizes more pronounced in individuals with established T2DM. These patterns complement the between-group intervention results, reinforcing that targeted macronutrient modification within the PPT framework not only improves average glycemic metrics but also exerts a gradient of benefit depending on baseline metabolic status.

3.6 Correlation analysis of IAUC changes and carbohydrate intake adjustment

Carbohydrate intake, particularly from high-GI carbohydrates food such as starch-based staples, is a primary determinant of postprandial hyperglycemia. To objectively quantify this relationship, we utilized the IAUC, which is defined as the postprandial glucose excursion above the fasting baseline. IAUC serves as a standardized and sensitive metric for evaluating the glycemic impact of specific dietary patterns and food compositions. By correlating changes in IAUC with adjustments in carbohydrate intake during the intervention, we aimed to elucidate how macronutrient shifts influence dynamic glycemic responses across individuals and dietary strategies.

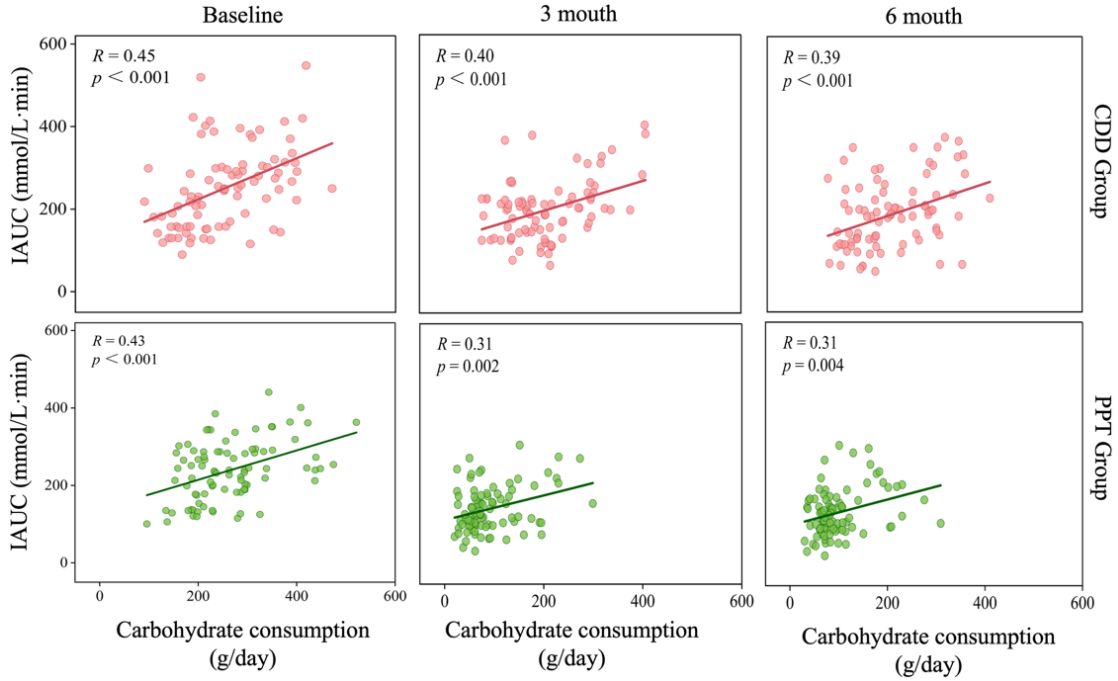

Figure. 8 Relationship between daily carbohydrate consumption (g/day) and postprandial glycemic response (IAUC; mmol·min/L) for all participants (prediabetes and T2DM combined) at baseline, after 3 months and 6 months of intervention. Data are shown separately for the CDD (red) and PPT (green) groups. Each point represents an individual participant's dietary intake and IAUC value. Solid lines represent linear regression fits with Pearson's correlation coefficients (*R*) and *p* values indicated in each panel.

As shown in Fig. 8, both dietary interventions led to clinically meaningful reductions in daily carbohydrate intake over the 6-months period. In the CDD group, total carbohydrate consumption decreased from 240.0 g at baseline to 189.4 g at 3 months (Δ-21.1%) and 181.4 g at 6 months (Δ-24.4%). In contrast, the PPT group exhibited more substantial reductions, from 244.0 g at baseline to 147.0 g (Δ-39.8%) and 148.0 g (Δ-39.3%) at 3 and 6 months, respectively.

Correlation analysis further shows that at baseline, higher daily carbohydrate intake was positively correlated with IAUC in both the CDD group ($R = 0.45$, $P < 0.001$) and the PPT group ($R = 0.43$, $P < 0.001$). This positive association persisted at 3 months ($R = 0.40$, $P < 0.001$ for CDD; $R = 0.31$, $p = 0.002$ for PPT) and 6 months ($R = 0.39$, $P < 0.001$ for CDD; $R = 0.31$, $p = 0.004$ for PPT), although the strength of correlation was modestly attenuated over time.

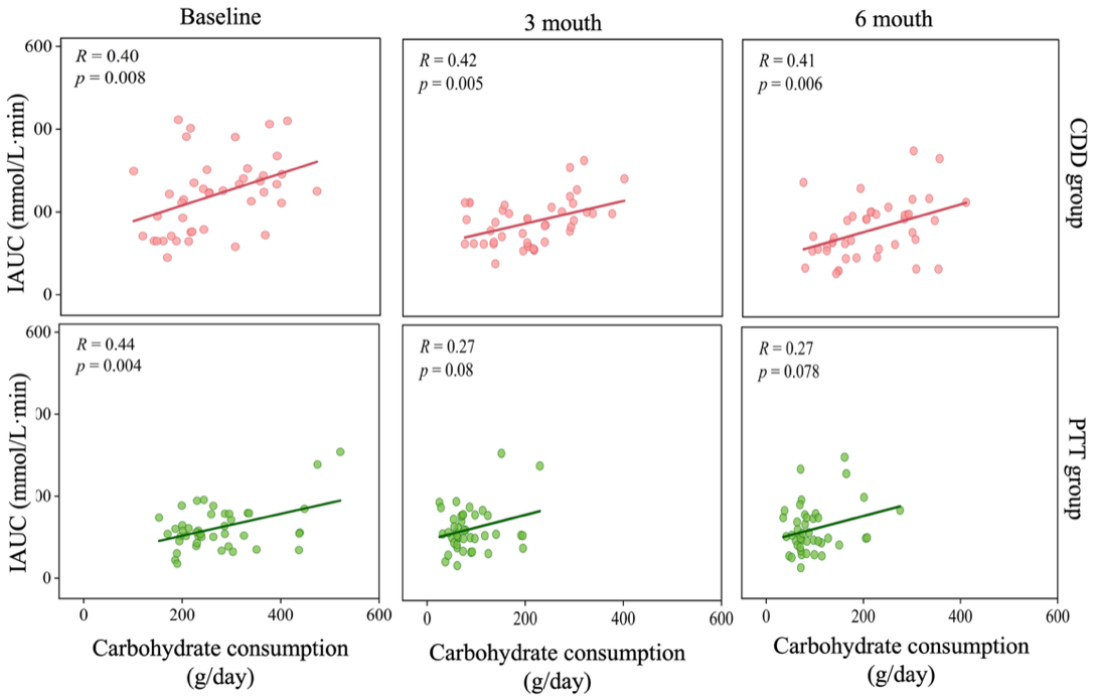

Figure. 9 Relationship between daily carbohydrate consumption (g/day) and postprandial glycemic response (IAUC; mmol ·min/L) for only prediabetes at baseline, after 3 months and 6 months of intervention. Data are shown separately for the CDD (red) and PPT (green) groups. Each point represents an individual participant's dietary intake and IAUC value. Solid lines represent linear regression fits with Pearson's correlation coefficients (*R*) and *p* values indicated in each panel.

In participants with prediabetes, as shown in Fig. 9, carbohydrate intake remained significantly associated with IAUC at baseline ($R = 0.40$, $p = 0.008$ for CDD; $R = 0.44$, $p = 0.004$ for PPT) and at 3 months ($R = 0.42$, $p = 0.005$ for CDD; $R = 0.27$, $p = 0.080$ for PPT). By 6 months, the association persisted for CDD ($R = 0.41$, $p = 0.006$) but was no longer statistically significant for PPT ($R = 0.27$, $p = 0.078$), suggesting a potential attenuation of carbohydrate-IAUC coupling with personalized dietary guidance in this subgroup.

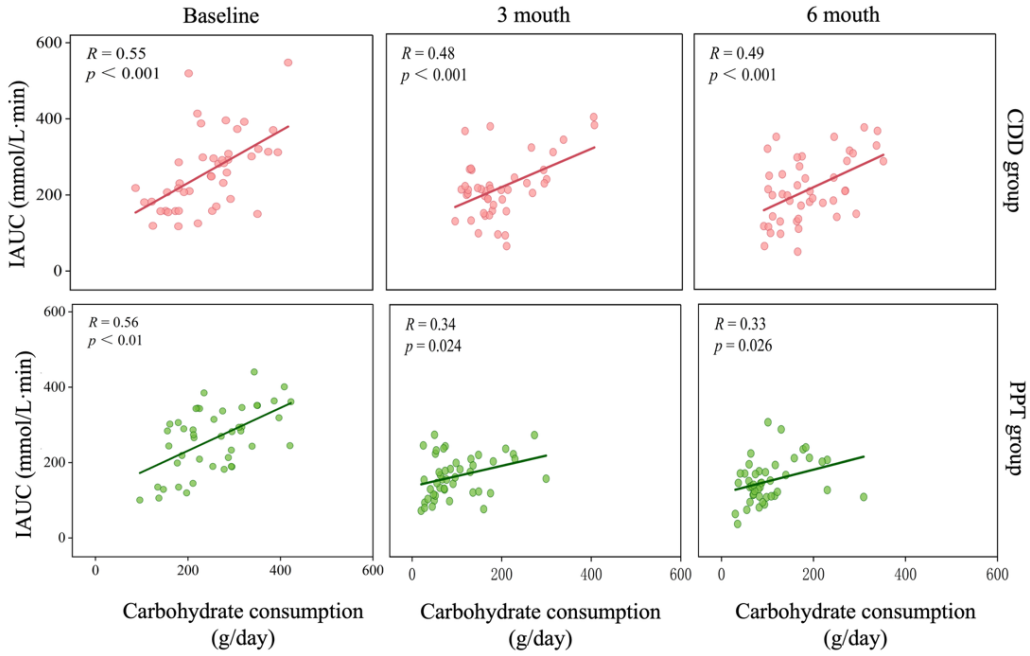

Figure. 10 Relationship between daily carbohydrate consumption (g/day) and postprandial glycemic response (IAUC; mmol ·min/L) for only diabetes at baseline, after 3 months and 6 months of intervention. Data are shown separately for the CDD (red) and PPT (green) groups. Each point represents an individual participant's dietary intake and IAUC value. Solid lines represent linear regression fits with Pearson's correlation coefficients (*R*) and *p* values indicated in each panel.

In contrast, as shown in Fig. 10, among participants with T2DM, correlations between carbohydrate intake and IAUC were consistently stronger and more persistent associations across all time points. At baseline, $R = 0.55$ ($P < 0.001$) for CDD and $R = 0.56$ ($P < 0.01$) for PPT; at 3 months, $R = 0.48$ ($P < 0.001$) for CDD and $R = 0.34$ ($p = 0.024$) for PPT; and at 6 months, $R = 0.49$ ($P < 0.001$) for CDD and $R = 0.33$ ($p = 0.026$) for PPT.

In the PPT group, the intervention strategy focused on identifying foods with a lower glycemic impact to reduce postprandial glucose fluctuations and improve overall glycemic control. Following the intervention, the correlation between carbohydrate intake and IAUC decreased markedly in the PPT group, with a reduction significantly greater than in the CDD group, suggesting that the PPT diet was more conducive to stabilizing postprandial glucose levels. Stratified analyses further revealed that this attenuation was most persistent and pronounced in participants with type 2 diabetes, whereas it diminished over time in those with prediabetes. The weaker association in the prediabetes group may reflect preserved insulin sensitivity and compensatory capacity such as increased insulin secretion, that dietary intervention could further optimize, potentially through partial restoration of β-cell function. In the PPT group, individualized dietary recommendations based on real-time postprandial glucose profiles may have enhanced these compensatory mechanisms or exerted a stronger restorative effect on β-cells, thereby weakening the link between carbohydrate intake and postprandial glucose excursions.

Taken together, analyses of fasting glucose, HbA_1c, and incremental insulin AUC consistently showed that higher protein and lower carbohydrate intake were associated with better glycemic outcomes, with stronger effects in type 2 diabetes due to greater insulin resistance and β-cell dysfunction. Importantly, the PPT approach appeared to blunt the impact of carbohydrate intake on postprandial glucose, particularly in prediabetes, underscoring the potential of personalized macronutrient adjustments to improve early-stage insulin resistance and stabilize glycemic responses.

3.7 Sleep quality outcomes

The sleep quality was assessed using the PSQI form, and the results are summarized in Table 3. At baseline, there were no statistically significant differences in overall PSQI scores or any of the seven individual domains between the PPT and CDD groups ($P > 0.05$ for all comparisons). Following intervention, both groups similarly showed no significant changes across all PSQI domains, including subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleep medications, and daytime dysfunction ($P > 0.05$ for all), suggesting that neither the CGM-guided PPT nor the CDD intervention had a measurable impact on sleep quality over the 6-month intervention period.

Table 3. Sleep quality outcomes of individuals in the two intervention groups across time periods.

Time	Sleep quality	PPT group		CDD group		*p*
		N	Proportion (%)	N	Proportion (%)	
Basiline	Good	10	11.36%	3	3.45%	0.136
	Moderate	26	29.55%	28	32.18%	
	Poor	52	59.09%	56	64.37%	
3-month	Good	10	11.36%	13	14.94%	0.78

	Moderate	30	34.09%	28	32.18%	
	Poor	48	54.55%	46	52.87%	
	Good	6	6.82%	6	6.90%	
6-month	Moderate	41	46.59%	33	37.93%	0.494
	Poor	41	46.59%	48	55.17%	

N, number of participants. Scoring criteria: ≤ 4 = Good sleep quality; 5-7 = Moderate sleep disturbance; ≥8 = Clinically significant poor sleep. The intergroup comparisons were performed using χ^2 tests (Chi-square tests) with Yates' continuity correction.

3.8 Diabetes self-efficacy

As presented in Table 4, following 6-month intervention, the PPT group achieved more substantial improvements in dietary management (Δ+32.4% *vs.* Δ+18.7%), blood glucose monitoring (Δ+28.1% *vs.* Δ+15.9%), and total self-management scores (Δ+25.6% *vs.* Δ+12.3%) compared to the CDD group. In contrast, after the intervention, neither group showed notable improvements in adherence to exercise or medication use, suggesting that the potential influence of these factors on the study outcomes can be ruled out. This pattern of results also highlights the enhanced efficacy of the PPT group in promoting diabetes self-management, particularly in the areas of dietary optimization and glucose monitoring.

The observed differential effects may be attributed to the real-time, individualized feedback mechanisms and CGM-guided decision support embedded within the PPT protocol, which were absent in the standardized CDD approach. These findings suggest that while both dietary interventions contributed to improved behavioral awareness, the PPT protocol elicited significantly greater and behaviorally targeted modifications, supporting its potential utility in empowering patients to take an active role in early-stage diabetes care.

Table 4. Self-efficacy scores expressed as median (first quartile, third quartile) [*M* (Q1, Q3)].

Indicators	**Groups**	**Basiline**	**3 months**	p_3	**6 months**	p_6
Dietary management	PPT	75 (49.5, 89.8)	82.5 (75, 92.5)	<0.001***	93 (83.8, 98)	<0.001***
	CDD	74 (51.5, 86)	77 (65.5, 87)	0.211	83 (68.5, 94)	0.005**
Physical activity	PPT	16 (13, 20)	16.5 (13, 18)	0.748	17 (12, 18)	0.479
	CDD	16 (13, 19)	16 (13.5, 18)	0.769	16 (12, 18)	0.694
Mediation	PPT	16.5 (14, 20)	18 (12, 20)	0.939	17 (16, 20)	0.234
	CDD	16 (13.5, 20)	16 (14, 18)	0.788	17 (14, 20)	0.21
Blood glucose monitoring	PPT	40 (20, 46)	40 (30, 46)	0.406	45 (39.8, 47)	0.003**
	CDD	31 (25, 43)	34 (26, 40.5)	0.692	38 (28.5, 44.5)	0.049*
Total scores	PPT	141 (102.8, 167.8)	153.5 (133.8, 168)	0.04*	172 (150, 177)	<0.001***
	CDD	130 (104, 156.5)	139 (122, 158)	0.207	147 (119, 170)	0.014*

Continuous variables with non-normal distributions are presented as median (interquartile range) [M (Q1, Q3)]. The 95% confidence intervals was estimated using the Hodges-Lehmann median-difference estimator with corresponding distribution-free methods. The between-group comparisons were performed using the Mann-Whitney U test. p_3 and p_6 denote the p-values for within-group changes from baseline in dietary score, exercise score, medication-adherence score, and total self-management score at 3 months and 6 months, respectively. Statistical significance is indicated as follows: * $P < 0.05$; ** $P < 0.01$; *** $P < 0.001$.

3.9 Glucose monitoring satisfaction survey for type 2 diabetes (GMSS-T2DM)

As shown in Table 5, no statistically significant differences were observed between the PPT and CDD groups across the four individual dimensions of the GMSS-T2DM, including device openness ($p = 0.32$), emotional burden ($p = 0.21$), behavioral burden ($p = 0.18$), and perceived value ($p = 0.45$). However, the PPT

group exhibited significantly higher total satisfaction scores compared to the CDD group, reflecting greater overall acceptance and perceived benefit of the CGM system. continuous glucose monitoring.

These results suggest that while both groups reported similar device-specific experiences, the PPT intervention conferred an enhanced sense of utility and engagement, likely attributable to its personalized feedback and real-time application of CGM data. This enhanced satisfaction may contribute to better adherence and long-term sustainability of CGM-guided lifestyle modifications.

Table 5. Domain-specific satisfaction scores of continuous glucose monitoring (CGM) systems in the PPT and CDD groups, expressed as median (first quartile, third quartile) [*M* (Q1, Q3)].

Dimensions	PPT diet	CDD diet	*p*
Openness	9 (8, 11)	10 (9, 11)	0.078
Emotional burden	11 (9, 12)	11 (10, 13)	0.129
Behavioral burden	10 (8, 11)	10 (9, 11)	0.183
Perceived value	8 (7, 11)	8 (8, 9)	0.337
Overall	3.1 (2.8, 3.3)	3 (2.9, 3.1)	0.014*

Non-normally distributed variables were summarized as median [interquartile range] and compared using Mann-Whitney U tests. Statistical significance threshold: Between-group differences were considered statistically significant at $P < 0.05$ (two-tailed).

4. Discussions

This prospective, randomized controlled trial systematically evaluated the effects of a CGM-guided PPT diet versus a guideline-based standardized CDD diet on multiple metabolic endpoints in individuals with prediabetes and early T2DM. Our findings demonstrate that the PPT intervention significantly outperformed the CDD approach in glycemic control, lipid regulation, weight management, and liver function, without compromising safety or adherence.

(1) Superiority of PPT for glycemic control

The core advantage of the PPT regimen lies in its real-time CGM-based feedback and individualized dietary adjustments tailored to each participant's PPGR. Unlike static glycemic markers such as FPG and HbA_1c, CGM captures minute-by-minute glucose fluctuations and provides a dynamic metabolic profile. After 6-month intervention, the PPT group demonstrated significantly greater reductions in HbA_1c, FPG, and OGTT compared to the CDD group, with a mean HbA1c decrease of 0.46% (Fig. 4, Table 2). In addition, the PPT group also achieved a 101.124 mmol·min/L reduction in IAUC, nearly double the reduction observed in the CDD group (59.39 mmol·min/L) (Table 2). These effects may stem from the targeted exclusion of high–GI foods or the implementation of nutrient substitution strategies, thereby achieving effective control of glycemic fluctuations. In addition, the optimized dietary intervention may exert its benefits by improving the body's glucose metabolic function.

(2) Lipid improvements and cardiovascular risk mitigation

Beyond glycemic endpoints, the PPT diet elicited comprehensive improvements in lipid profiles, including significant reductions in TC, TG, and LDL-C, along with increases in HDL-C levels (Table 2). These favorable changes are consistent with dietary shifts away from high-glycemic-load carbohydrates toward increased consumption of high-quality proteins (Fig. 5). In the meantime, the observed reduction in

ApoB and elevation of ApoA-I levels in the PPT group suggest beneficial remodeling of lipoprotein particles, reflecting a shift toward less atherogenic profile. ApoB is a marker of atherogenic lipoprotein particle concentration, while ApoA-I reflects the anti-atherogenic capacity of HDL particles. Together, a lower ApoB/ApoA-I ratio has been independently associated with decreased risk of cardiovascular disease [27].

(3) Efficacy of weight loss in PPT

Effective weight management is central to diabetes prevention and care. Despite comparable caloric intake across groups, participants in the PPT group experienced a mean weight loss of 6.83 kg, far exceeding the 0.55 kg reduction observed in the CDD group. CGM data revealed attenuated glycemic variability in the PPT group, which may reduce insulin secretion and enhance lipolysis. Moreover, the altered macronutrient profile of the PPT diet, characterized by high protein content and reduced levels of rapidly digestible carbohydrates (Fig. 5), likely enhanced diet-induced thermogenesis and supported the preservation of lean body mass. Previous studies have reported that replacing dietary carbohydrates with protein, while keeping fat intake constant, leads to greater weight loss and metabolic improvements [28]. These effects are thought to be mediated, at least in part, by the stimulation of satiety-related hormones such as GLP-1 and PYY, which contribute to reductions in spontaneous energy intake [29]. It was also noted that many of the top twenty foods consumed in the PPT group were traditionally low-GI items, which may have supported long-term glycemic control. The concurrent reductions in waist-to-hip ratio and visceral fat area further highlight the PPT diet's efficacy in reducing central adiposity.

(4) Hepatic and metabolic health benefit

Significant improvements in liver function markers including ALT, GGT, and ALP were observed in the PPT group, suggesting enhanced hepatic function. These improvements may result from reductions in hepatic fat content, weight loss, and increased antioxidant intake. Enhanced hepatic insulin sensitivity and reduced de novo lipogenesis likely contribute to the observed benefits. Additionally, reductions in serum uric acid suggest potential benefits for hyperuricemia, possibly via decreased purine intake or improved renal clearance. The modest reductions in blood pressure in the PPT group may also be attributed to concurrent weight loss and reduced sodium intake.

(5) From carbohydrate quantity to quality: a dual-level strategy

Although reductions in total carbohydrate intake were correlated with HbA_1c improvements ($R = 0.36$, $P < 0.001$) (Fig. 7B), the superior performance of the PPT intervention underscores the importance of carbohydrate quality, including GI and dietary fiber content. The PPT group maintained a relatively low carbohydrate intake (~ 82 g/day), yet compliance remained high (87.5%) due to personalized meal planning and the inclusion of culturally familiar low-GI foods. Fiber intake increased substantially from 13.3 g to 23.0 g/day, likely contributing to postprandial glycemic attenuation. Unlike previous meta-analyses suggesting no long-term advantage of low-carb diets over high-carb diets in HbA_1c reduction, the PPT

strategy leverages continuous metabolic feedback and dynamic food adjustment, conferring distinct glycemic benefits.

(6) Safety, tolerability, and adherence

Over the 6-month study, the PPT intervention was safe and well-tolerated. Only two asymptomatic hypoglycemic events were recorded, with no adverse effects on renal function or nutrient adequacy. Adherence rates in the PPT group (87.5%) were comparable to those in the CDD group, although a gradual decline in photo-logging frequency was noted over time (Fig. S1). At present, numerous brands of CGM devices are available on the market at relatively controllable costs; however, their clinical effectiveness remains constrained by the lack of scientifically designed intervention protocols. The present study demonstrates that an intervention based on the PPT dietary strategy not only significantly improves glycemic control but also offers excellent clinical accessibility and ease of implementation. These findings provide evidence-based support for the deeper clinical integration of CGM technology, highlighting its substantial translational value and market potential.

(7) Clinical applications and future directions

The PPT model represents a promising paradigm shift by integrating CGM technology with precision nutrition to move beyond one-size-fits-all dietary recommendations. Its key advantages include real-time feedback, increased patient engagement through mobile applications, and simultaneous improvements across multiple metabolic domains. Challenges remain, such as the need for CGM interpretation literacy, and compatibility with regional dietary patterns. Future research should focus on developing AI-powered meal recommendation systems, evaluating the effectiveness of intermittent CGM use, and testing the generalizability of the PPT model in diverse populations (e.g., elderly, obese, rural). Larger multicenter trials with extended follow-up durations will be essential to validate the long-term sustainability, safety, and clinical impact of this approach.

5. Conclusions

This randomized controlled trial demonstrates that a CGM-guided PPT diet significantly outperforms the standardized CDD diet in improving glycemic control and metabolic health among Chinese adults with prediabetes or early-stage T2DM. Over 24 weeks, the PPT group achieved greater reductions in HbA1c (-0.46% *vs.* -0.06%), fasting plasma glucose (-1.12 *vs.* -0.74 mmol/L), and 2-h oral glucose tolerance test results (-3.52 *vs.* -2.47 mmol/L), alongside enhanced lipid profiles, weight loss (-6.83 kg *vs.* -0.55 kg), and reduced liver enzyme levels. Metabolomic shifts in amino acid, carbohydrate, and lipid pathways further underscored the PPT diet's systemic metabolic benefits. The integration of real-time CGM feedback with culturally tailored dietary strategies enabled dynamic adjustments to individual postprandial glucose responses, fostering high adherence (87.5%) and improved self-management scores.

Our results also confirmed that real-time CGM feedback could significantly enhance participants' awareness of glucose regulation, and directly improves the dietary adherence. The implementation of the 'Three Early' principle - early screening, early evaluation, and early intervention-established a closed-loop

management model of continuous screening, assessment, and adjustment, which increased participant engagement and proactivity. Personalized food libraries were created using locally sourced ingredients based on individual preferences and economic capacity, allowing the intervention to integrate naturally into daily life without adding financial burden. Regular feedback from dietitians, including comparisons with previous test results, provided encouragement and boosted participant confidence. Constructive criticism, when necessary, also helped participants recognize mistakes and appreciate the ongoing support, further motivating behavior change. Dietitians offered timely emotional support regardless of whether participants' glycemic outcomes improved, fostering a sense of trust and reassurance. Additionally, the dynamic identification of high-performing individuals as role models served to inspire others, creating a motivational environment that emphasized the attainability of better health through continued effort.

Nonetheless, this study still has several limitations. First, the 24-week duration limits assessment of long-term sustainability and clinical outcomes such as diabetes progression or cardiovascular events. Second, the single-center design and homogeneous cohort may restrict generalizability to broader populations. Third, while dietary adherence was rigorously monitored via photographic documentation, self-reported data may introduce bias. Finally, a slight decline in skeletal muscle mass (-1.1%) in the PPT group suggests the need for optimized protein intake strategies in future protocols.

Future research should prioritize multi-center trials with extended follow-up periods, cost-effectiveness analyses of CGM-driven interventions, and exploration of intermittent CGM use to enhance feasibility. Integrating artificial intelligence for dynamic meal recommendations and validating these strategies in diverse cultural contexts will further advance personalized diabetes management.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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