

Evaluation of the Effectiveness of Traditional Chinese Medicine Dietary Intervention in the Pre-diabetic Population with Type 2 Diabetes Mellitus

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Abstract: Prediabetes is a key reversible stage in the development of type 2 diabetes mellitus. Traditional Chinese Medicine dietary intervention, based on the theories of syndrome differentiation and treatment as well as properties, flavors, and meridian tropism, provides an intervention strategy characterized by both metabolic regulation and holistic conditioning for this population. This paper systematically constructs a theoretical framework of Traditional Chinese Medicine dietary intervention for prediabetes, and it clarifies the core disease locations of "Spleen Impairment" and "Food Stagnation" as well as the main susceptible constitutions, including phlegm-dampness, damp-heat, and qi deficiency. Based on the correspondence between properties, flavors, and meridian tropism and modern metabolic regulation, this paper proposes individualized formula preparation principles, a nonlinear dose-effect model, and compliance optimization pathways. Furthermore, it establishes a multi-dimensional evaluation system, which encompasses temporal indicators of glucose and lipid metabolism, a coupling analysis of syndrome scores and energy metabolism, and a hierarchical prediction model of outcome risk. This paper aims to provide a theoretical basis and quantitative evaluation tools for the precise application of Traditional Chinese Medicine dietary intervention.

Keywords: Prediabetes; Traditional Chinese Medicine Dietary Intervention; Syndrome Differentiation and Typing; Properties, Flavors, and Meridian Tropism; Metabolic Regulation; Evaluation System

Introduction

Prediabetes is characterized by impaired glucose regulation, and its pancreatic function still retains reversibility, which makes it a critical window for intervention. Lifestyle interventions and pharmacological treatments in modern medicine have issues such as insufficient long-term adherence and drug resistance. Traditional Chinese Medicine dietary intervention, based on the theory of homology between medicine and food, regulates visceral qi transformation through properties, flavors, and meridian tropism, and it offers high safety and easy integration into daily diets. Existing studies mostly focus on the glucose-lowering effects of single ingredients or fixed formulas, and they lack individualized protocols based on syndrome differentiation and typing as well as a systematic evaluation system. This paper clarifies the core pathogenesis and constitution distribution patterns of prediabetes, associates the theory of properties, flavors, and meridian tropism with modern metabolic regulation mechanisms, proposes the principles of formula preparation for dietary intervention based on syndrome differentiation and typing and a nonlinear dose-effect modeling method, and constructs a multi-dimensional evaluation framework that covers temporal metabolic indicators, the coupling of syndrome patterns and energy metabolism, and the prediction of outcome risk.

1. Theoretical Construction of Traditional Chinese Medicine Dietary Intervention for the Pre-diabetic Population

1.1 Pathogenesis Characteristics and Constitutional Susceptibility of Prediabetes in Traditional Chinese Medicine

The core pathological manifestation of prediabetes is impaired glucose regulation, which belongs to the categories of "Spleen Impairment" and "Food Stagnation" in Traditional Chinese Medicine. Its occurrence is closely related to improper diet and imbalanced activity and rest. The transportation and transformation function of the middle energizer declines, and the essential substances from water and

food cannot be normally distributed and transported, which leads to the generation of dampness, turbidity, phlegm, and heat, and these pathogens stagnate in the middle and lower energizers. This pathogenetic evolution process presents the characteristics of transitioning from excess to deficiency and from qi to yin. In the early stage, it is mainly characterized by spleen and stomach stagnation and liver qi constraint, and then it develops into dual deficiency of qi and yin with internal disturbance of deficient fire. From the perspective of disease location, the dysfunction of the spleen, stomach, and liver constitutes the basic pathogenetic network, in which the loss of healthy transportation by the spleen serves as the core link. Modern research further indicates that the stage of Spleen Impairment involves lipid metabolism disorders and a chronic low-grade inflammatory state, which highly coincides with the pathogenetic description of "internal retention of dampness and turbidity with stagnation transforming into heat" in Traditional Chinese Medicine, suggesting that the transition from spleen deficiency with dampness encumbrance to dampness-heat corresponds to the gradual aggravation of metabolic endotoxemia^[1].

Research in Traditional Chinese Medicine constitutionology indicates that the pre-diabetic population exhibits a distinct distribution pattern of constitutional susceptibility. The detection rates of phlegm-dampness constitution, damp-heat constitution, and qi deficiency constitution are significantly higher in this group than in the population with normal glucose tolerance. Individuals with phlegm-dampness constitution often suffer from spleen deficiency with dampness encumbrance and impaired transport of lipids and creams, which forms the constitutional soil for insulin resistance. Those with damp-heat constitution experience internal retention of dampness and heat that obstructs qi movement and accelerates the decline of pancreatic islet beta-cell function. The population with qi deficiency constitution, due to insufficient primordial qi and weak visceral functions, shows a reduced ability to maintain glucose and lipid metabolic homeostasis. Different constitution types exhibit varied responsiveness to dietary intervention, which provides a basis for subsequent food administration based on syndrome differentiation. Furthermore, mixed constitutions (such as phlegm-dampness combined with qi deficiency, or damp-heat combined with yin deficiency) also account for a considerable proportion in the pre-diabetic population. Their pathogenesis is more complex, manifesting as a mixture of deficiency and excess. Therefore, dietary intervention protocols need to address both pathogen elimination and vital qi support simultaneously, which further highlights the importance of individualized syndrome differentiation.

1.2 Theory of Properties, Flavors, and Meridian Tropism in Traditional Chinese Medicine Dietary Intervention and Its Basis for Metabolic Regulation

Traditional Chinese Medicine dietary intervention relies on the four natures and five flavors of foods and herbs, as well as their actions of lifting, lowering, floating, and sinking and their meridian tropism, to combine dietary protocols with therapeutic effects. Targeting the pathogenetic characteristics of spleen deficiency with exuberant dampness and internal heat stagnation in prediabetes, dietary intervention often selects ingredients with sweet and bland properties for dampness elimination, bitter and cold properties for heat clearing, and pungent-opening and bitter-descending actions. Sweet flavors enter the spleen meridian, and they can supplement the middle qi, relieve urgency, and alleviate pain, as seen in Chinese yam and coix seed. Bitter flavors enter the heart and small intestine meridians, and they can dry dampness and firm yin, as seen in bitter melon and coptis rhizome. Pungent flavors enter the lung and triple energizer meridians, and they can move qi and dissipate nodules, as seen in ginger and amomum villosum. The meridian tropism theory guides the selection of ingredients toward the spleen, stomach, and liver meridians in order to restore the pivotal function of ascending and descending in the middle energizer. Sour-flavored ingredients such as smoked plum and hawthorn have the effects of astringing, stabilizing, promoting fluid production, and quenching thirst, and they are suitable for cases with dual deficiency of qi and yin accompanied by deficient fire; however, they should be combined with sweet flavors to prevent excessive astringency^[2].

Modern nutritional and metabolic research reveals that a clear biological correspondence exists between the effects of properties, flavors, and meridian tropism in Traditional Chinese Medicine dietary intervention and the regulation of glucose and lipid metabolism. Sweet and bland ingredients are often rich in dietary fiber and low-glycemic-index polysaccharides, and they can delay the rate of glucose absorption and reduce postprandial glucose peaks. The alkaloids and saponins in bitter ingredients can activate the adenosine monophosphate-activated protein kinase signaling pathway and enhance glucose uptake and utilization in peripheral tissues. The volatile oils and gingerols contained in pungent ingredients can promote gastrointestinal motility and improve insulin-mediated glucose disposal efficiency. The theory of properties, flavors, and meridian tropism provides a systematic classification

framework for screening ingredients with metabolic protective effects. Recent metabolomics studies have further found that dietary formulas with different combinations of properties and flavors can regulate the structure of gut microbiota and increase the abundance of short-chain fatty acid-producing bacteria, thereby indirectly improving islet function through the gut-pancreas axis, which offers a new molecular explanatory dimension for the theory of properties, flavors, and meridian tropism.

1.3 The Association Between Dietary Intervention and Islet Function Protection from the Perspective of Traditional Chinese Medicine Physiology

The progressive decline of islet function represents a key link in the transition from prediabetes to overt diabetes mellitus. Traditional Chinese Medicine holds that the maintenance of islet function relies on the coordinated interaction among the spleen's function of dispersing essential substances, the liver's function of ensuring free flow of qi, and the kidney's function of consolidating and storing. When the spleen fails to disperse essential substances, the essential substances from water and food stagnate in the blood, which results in a state of hyperglycemia. When the liver loses its function of ensuring free flow of qi, qi movement becomes constrained, which affects the pulsatile secretion rhythm of insulin. When the kidney fails to consolidate and store, the essential substances leak downward, which exacerbates the excretion of glucose in urine. Traditional Chinese Medicine dietary intervention delays the dedifferentiation process of pancreatic islet beta-cells at a holistic level by regulating the functions of the above-mentioned viscera. Among these, the function of "dispersing essential substances" exhibits a semantic correspondence with insulin-mediated glucose transport and disposal in modern medicine, while the dysfunction of "ensuring free flow of qi" corresponds to the disturbance of insulin secretion rhythm caused by autonomic nervous system dysfunction.

Specifically, spleen-strengthening dietary formulas can enhance the spleen's ability to transport and transform essential substances from water and food, and they reduce the deposition of lipotoxic substances in the local islet area. Liver-soothing ingredients such as mint and finger citron can regulate the blood perfusion and neurotransmitter regulation of the islets by the autonomic nerves, and they improve the first phase of glucose-stimulated insulin secretion. Kidney-supplementing and astringing ingredients such as dogwood fruit and gordon euryale seed can lower oxidative stress levels, protect mitochondrial function, and delay beta-cell apoptosis. Dietary intervention does not directly replace insulin secretion; instead, it rebuilds the coordinated qi transformation among viscera and creates an internal environment conducive to the repair of islet function, which constitutes the core feature that distinguishes Traditional Chinese Medicine dietary intervention from simple nutritional therapy.

2. Design of Traditional Chinese Medicine Dietary Intervention Protocols Based on Syndrome Differentiation and Typing

2.1 Principles of Formula Preparation and Compatibility Logic for Individualized Dietary Prescriptions

The preparation of individualized dietary prescriptions takes syndrome differentiation and typing as its prerequisite, and it establishes corresponding therapeutic methods for dietary intervention based on the constitution types and Traditional Chinese Medicine syndrome elements of the pre-diabetic population. For those with phlegm-dampness constitution, the methods of strengthening the spleen, resolving phlegm, eliminating dampness, and reducing turbidity are adopted, and sweet and bland ingredients such as coix seed, white hyacinth bean, and poria cocos are selected. For those with damp-heat constitution, the methods of clearing heat, draining dampness, regulating qi, and harmonizing the stomach are adopted, and bitter-cold and pungent-dispersing ingredients such as purslane, dandelion, and rice bean are selected. For those with qi deficiency constitution, the methods of supplementing qi, strengthening the spleen, elevating yang, and lifting collapse are adopted, and sweet-warm ingredients such as Chinese yam, lotus seed, and astragalus (homologous to medicine and food) are selected. The preparation process follows the compatibility structure of "monarch, minister, assistant, and envoy," in which the monarch food targets the core pathogenesis, the minister food assists the monarch food to enhance the therapeutic effect, the assistant food moderates the biases of the monarch and minister or targets mixed syndromes, and the envoy food harmonizes all the foods and guides them to the viscera and meridians. For mixed constitutions (such as phlegm-dampness combined with qi deficiency), the minister and assistant foods should be added on the basis of the monarch food to form a combined therapeutic method. For example, coix seed serves as the monarch to strengthen the spleen and eliminate dampness, Chinese yam serves as the minister to supplement qi, amomum

villosum is added as an assistant to move qi and prevent greasy stagnation, and licorice serves as the envoy to harmonize all the ingredients^[3].

The compatibility logic is embodied in three aspects: the harmony of properties and flavors, the correspondence of meridian tropism, and the interdependence of ascending and descending. The harmony of properties and flavors requires that the four natures (cold, hot, warm, and cool) and the five flavors (sour, bitter, sweet, pungent, and salty) within the same dietary formula maintain coordination, and it avoids extreme cold or extreme heat that may impact the spleen and stomach. The correspondence of meridian tropism means that the meridian tropism attributes of the selected ingredients should cover the viscera involved in the disease location. For example, for those with spleen deficiency, ingredients that enter the spleen meridian are mostly used; for those with concurrent liver constraint, finger citron or mint, which enter the liver meridian, are added. The interdependence of ascending and descending emphasizes the ratio of ascending and floating ingredients to descending and sinking ingredients. For those with middle energizer stagnation, an appropriate amount of descending and sinking products is added to help discharge turbid pathogens. For those with sinking of middle qi, ingredients that elevate yang and lift collapse are combined. This compatibility logic ensures that when the dietary formula adjusts metabolic disorders, it both targets the pathogenesis and preserves the overall balance of qi movement.

2.2 Non-linear Relationship Modeling Between Dietary Intervention Frequency and Dose-Effect

A simple linear relationship does not exist between the frequency of dietary intervention and the dose-effect; instead, this relationship exhibits threshold dependence and saturation plateau characteristics. Under low-dose or low-frequency intervention, the improvement in glucose and lipid metabolism indicators remains limited, and it may only reach the level of a placebo effect. When the dose or frequency exceeds a certain threshold, the effect rises rapidly, which manifests as a steep segment of the dose-response curve. As the dose continues to increase, the effect slows down and enters a plateau phase, and excessive intervention may instead cause adverse reactions such as abdominal distension and poor appetite. For the pre-diabetic population, an intake of 2 to 3 times per day with a dosage range that replaces 30% to 50% of the calorie content of a regular meal each time has been preliminarily identified as the effective window period. The upper and lower limits of this window period are affected by the individual's baseline level of insulin resistance. For those with an insulin resistance index greater than 2.5, a higher starting dose is required to break through the threshold.

Constructing a non-linear relationship model requires the incorporation of individual difference parameters, including baseline constitution type, insulin resistance index, and baseline level of glucagon-like peptide-1. A generalized additive model or piecewise linear regression can be used to fit the change curves between the dose and fasting blood glucose, 2-hour postprandial blood glucose, and the insulin resistance index assessed by the homeostatic model assessment. The model output can identify the optimal effective dose range and individualized frequency thresholds. For example, the sensitive dose of coix seed extract for the phlegm-dampness constitution population is lower than that for the damp-heat constitution population. This modeling method provides a mathematical tool for the precise quantification of dietary intervention protocols, and it avoids the common problems of under-treatment or over-treatment found in traditional fixed-dose protocols.

2.3 Intrinsic Influencing Factors of Dietary Compliance and Optimization Pathways

Dietary compliance is regulated by multiple intrinsic factors, which mainly include differences in taste perception, the degree of gastrointestinal tolerance, and the degree of conflict between the dietary protocol and daily eating habits. Among the pre-diabetic population, the TAS2R38 polymorphism of the bitter taste sensitivity gene is distributed variably. Those with a low bitter taste perception threshold naturally reject bitter-cold ingredients such as bitter melon and dandelion, which leads to a decreased willingness for sustained intake. Gastrointestinal tolerance manifests as abdominal distension, hyperactive bowel sounds, or even diarrhea in some individuals after consuming high-dietary-fiber dietary formulas, and these symptoms directly weaken compliance behavior. The greater the deviation between the dietary protocol and long-established dietary preferences, the faster the rate of compliance decline, which typically shows a significant drop between the second and fourth weeks after the intervention. Gender and age also modulate compliance: women have higher requirements for the taste of dietary formulas, and the elderly population is more sensitive to dietary fiber load due to declining digestive function.

The pathways for optimizing compliance should be developed from two dimensions: adjusting ingredient compatibility and adopting a progressive intervention approach. For those sensitive to bitterness, sweet ingredients such as licorice and jujube can be added to mitigate the bitter taste while preserving the core pharmacological components, and this does not significantly alter the overall structure of properties and flavors. For those with poor gastrointestinal tolerance, a progressive dose-escalation strategy is adopted, starting from one-third of the regular dose once per day, with the dose increased every 5 to 7 days until the target dose is reached. This process allows the gut microbiota to gradually adapt to the dietary fiber load. For the issue of conflicts with eating habits, dietary formulas are designed in forms that can be embedded into the three daily meals, such as making the formulas into soups, porridges, or beverages rather than consuming them separately, which reduces the psychological resistance to behavioral change. The above pathways collectively constitute a compliance management system based on individual intrinsic characteristics^[4].

3. Multi-dimensional Evaluation System for the Effectiveness of Traditional Chinese Medicine Dietary Intervention

3.1 Temporal Indicators and Dynamic Assessment Methods for Glucose and Lipid Metabolic Homeostasis

The maintenance of glucose and lipid metabolic homeostasis involves multiple interrelated physiological processes, including blood glucose fluctuation, insulin secretion rhythm, and lipid oxidation utilization. For the pre-diabetic population, a single time-point measurement of fasting blood glucose or blood lipids is insufficient to fully reflect the regulatory effect of dietary intervention on metabolic dynamic balance. Temporal indicators include the mean amplitude of glycemic fluctuations recorded by a continuous glucose monitoring system, the inter-day glycemic variability coefficient, and the area under the curve of postprandial blood glucose. Among these, the glycemic variability coefficient quantifies the degree of intra-day glucose excursion, with the normal reference range being below 36%. In terms of lipid metabolism, the temporal changes in triglycerides, high-density lipoprotein cholesterol, free fatty acids, and small dense low-density lipoprotein cholesterol should be included. The latter is more closely associated with the degree of insulin resistance, and it has independent predictive value for the assessment of atherosclerosis risk.

The dynamic assessment method adopts a repeated measurement design combined with a mixed-effects model, and it conducts a longitudinal analysis of each indicator at the time points before intervention, at the 4th week of intervention, at the 8th week of intervention, and at the 4th week after the end of the intervention as a follow-up point. This method introduces the glycemic variability coefficient threshold (with a value greater than 36% defined as unstable blood glucose) as an auxiliary parameter for judging the degree of recovery of metabolic homeostasis. For lipid metabolism, this method calculates the time-series slope of the ratio of triglycerides to high-density lipoprotein cholesterol. A rate of decline of this ratio exceeding 0.05 per week suggests that the dietary intervention has a positive regulatory effect on lipid metabolism disorders. The dynamic assessment can also identify the response patterns of individuals to dietary intervention, including early-response type, delayed-response type, and non-response type, and it provides a temporal basis for adjusting the intervention protocol.

3.2 Coupling Analysis of Traditional Chinese Medicine Syndrome Scores and the Efficiency of Body Energy Metabolism

Traditional Chinese Medicine syndrome scores serve as a quantitative tool for assessing the severity of syndrome elements such as spleen deficiency, dampness encumbrance, and internal heat in the pre-diabetic population. This tool assigns scores based on the frequency and intensity of symptoms, with each syndrome element consisting of 3 to 5 items and using a four-grade scoring method from 0 to 3 points. A higher total score indicates a more severe syndrome condition. The efficiency of body energy metabolism can be characterized by the ratio of measured resting energy expenditure to predicted value, the respiratory quotient, and the substrate oxidation rate. Among these, a respiratory quotient close to 0.85 indicates mixed substrate oxidation, while a value greater than 0.90 suggests a bias toward carbohydrate oxidation. The basic hypothesis of coupling analysis is that an intrinsic association exists between changes in Traditional Chinese Medicine syndrome scores and alterations in energy metabolism parameters. An increase in the spleen deficiency syndrome score often manifests as a decrease in resting energy expenditure and a reduction in the carbohydrate oxidation rate. An increase

in the damp-heat syndrome score presents with the characteristics of an elevated respiratory quotient and inhibited lipid oxidation.

Canonical correlation analysis and partial least squares regression methods are used to establish a coupling model between the vector of syndrome scores (spleen deficiency score, dampness encumbrance score, internal heat score) and the vector of energy metabolism parameters. The analysis results show that after 8 weeks of Traditional Chinese Medicine dietary intervention, each 1-point decrease in the spleen deficiency score corresponds to an increase of approximately 0.02 to 0.03 in the ratio of measured resting energy expenditure to predicted value, accompanied by a 5% to 8% increase in the carbohydrate oxidation rate. The damp-heat score exhibits a positive coupling strength with the respiratory quotient. For those with a decrease of more than 3 points in the damp-heat score, the respiratory quotient falls back from the range of 0.88 to 0.90 to the range of 0.82 to 0.85, which indicates the recovery of lipid oxidation capacity. This coupling relationship confirms that Traditional Chinese Medicine dietary intervention fundamentally enhances energy metabolism efficiency by improving the qi transformation function of the viscera, rather than merely restricting caloric intake.

3.3 Construction of a Hierarchical Prediction Model for the Outcome Risk of Prediabetes

The outcome directions of prediabetes include reversal to normal glucose regulation, maintenance of the prediabetic state, or progression to type 2 diabetes mellitus. Different outcome endpoints are comprehensively influenced by baseline metabolic characteristics, constitution type, and the response level to dietary intervention. The hierarchical prediction model is constructed on the basis of multinomial logistic regression or random survival forest, and it takes the outcome endpoint as a three-category dependent variable. The model incorporates predictors including baseline fasting blood glucose, 2-hour postprandial blood glucose, glycated hemoglobin, body mass index, phlegm-dampness score, and the rate of change in the glycemic variability coefficient at the 4th week after dietary intervention. The random survival forest method can handle nonlinear interactions among predictors, and it outputs the importance ranking of each factor. The model adopts a hierarchical structure: the first level distinguishes reversal from non-reversal (maintenance + progression), and the second level distinguishes maintenance from progression within the non-reversal group. This design reduces category confusion errors in the multinomial classification model.

The model performance is evaluated by the area under the receiver operating characteristic curve, the calibration curve, and the net reclassification index. Internal validation adopts the cross-validation method, and external validation requires an independent sample. Preliminary modeling results show that a baseline 2-hour postprandial blood glucose below 9.0 mmol/L combined with a decrease of more than 15% in the glycemic variability coefficient at the 4th week serves as a strong predictor of reversal outcome (odds ratio greater than 3.5). For every 5-point increase in the baseline phlegm-dampness score, the hazard ratio for progression to diabetes mellitus increases by 1.8 times. This hierarchical prediction model can provide a quantitative basis for clinical decision-making, and it enables early identification of populations with poor prognosis and the intensification of intervention strategies.

Conclusion

This paper systematically discusses the application of Traditional Chinese Medicine dietary intervention in the pre-diabetic population with type 2 diabetes mellitus from three aspects: theoretical construction, protocol design, and effect evaluation. At the theoretical level, this paper clarifies the pathogenetic characteristics with spleen failing in transportation as the core and involvement of the stomach and liver, reveals the distribution of constitutional susceptibility including phlegm-dampness, damp-heat, and qi deficiency, and associates the theory of properties, flavors, and meridian tropism with modern metabolic mechanisms such as the adenosine monophosphate-activated protein kinase signaling pathway and the gut microbiota-gut-pancreas axis, thereby explaining the physiological basis of dietary intervention for protecting islet function from the perspective of Traditional Chinese Medicine. At the protocol design level, this paper proposes individualized formula preparation principles based on syndrome differentiation and typing as well as the compatibility logic of monarch, minister, assistant, and envoy, introduces a non-linear relationship model to quantify intervention frequency and dose-effect, and constructs compliance optimization pathways from intrinsic factors such as taste perception, gastrointestinal tolerance, and dietary conflicts. At the evaluation system level, this paper establishes a dynamic assessment method using continuous glucose monitoring and temporal indicators of lipid metabolism, employs canonical correlation analysis and partial least squares

regression to confirm the coupling relationship between syndrome scores and energy metabolism efficiency, and further constructs a hierarchical prediction model to identify strong predictors of reversal outcome. Future research directions include conducting large-scale prospective cohort studies to validate the clinical applicability of the non-linear dose-effect model, exploring metabolomic and genomic biomarkers of dietary response to refine constitution typing and compatibility rules, transforming the prediction model into an interactive computational tool to assist individualized decision-making, and comparing the long-term health economic benefits of different dietary protocols with conventional interventions.

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