

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

Zhiang Wang*

Shaanxi University of International Trade & Commerce, Xi'an, 712046, China

*Corresponding author: 15592047901@163.com

Abstract: Prediabetes is an early, often asymptomatic stage in the development of type 2 diabetes. Based on the theories of syndrome differentiation and treatment, as well as the properties, flavours and meridian tropisms of the food, traditional Chinese medicine dietary intervention can regulate metabolism and promote the general health of this group of people. Systematically build the theoretical foundation for the dietary intervention of traditional Chinese medicine in prediabetes in this paper and clarify that the main disease locations of "Spleen Impairment" and "Food Stagnation" are phlegm-dampness, damp-heat and qi deficiency. Given that different people have various physical and psychological traits, various meridian tropisms, fluctuations in modern metabolic regulation, etc., this paper will provide some general ideas for personalised formula preparation, a non-linear dose-response model, and compliance optimisation strategies. There are many kinds of assessments; some are time-varying indices of glucose and lipid metabolism, some combine syndrome scores with energy metabolism in analysis, and there are even tiered prediction models for the risk of adverse events. The purpose of this paper is to provide a theoretical basis and quantitative tools for the application of Traditional Chinese Medicine (TCM) diet modification.

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

Introduction

Prediabetes is a state of high blood sugar that can be rectified by making changes to one's lifestyle, so it is an ideal time for intervention. Lifestyle modification and drug therapy in modern medicine have problems of poor long-term adherence and drug resistance. Based on the theory of homology between medicine and food, dietary modification in traditional Chinese medicine can regulate the transformation of visceral qi through properties, flavours and meridian tropism, and it is very safe and convenient for daily life. Most of the research so far has focused on the hypoglycemic effect of individual ingredients or fixed recipes, but there are no personalised plans according to the different types and stages of the syndrome, nor is there an all-encompassing evaluation system. The first part of this paper will present the main pathogenic factors and distribution patterns of prediabetes; next, we will connect the theory of properties, flavors and meridian tropism with modern metabolic regulation mechanisms; then, based on syndrome differentiation and typing, we will put forward principles for formula preparation; after that, we will introduce a nonlinear dose-effect modeling method; finally, we will build a multi-dimensional evaluation framework that includes temporal metabolic indicators, coupling of syndrome patterns and energy metabolism, and prediction of outcome risk.

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

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

The main disease feature of prediabetes is abnormal glucose metabolism, which falls under the categories of "Spleen Deficiency" and "Food Stagnation" in Traditional Chinese Medicine. It is often because of a poor diet and a lack of exercise or rest. The transportation and transformation function of the middle energizer has been reduced; the essential substances in the water and food cannot be

distributed and transported normally, so dampness, turbidity, phlegm and heat are produced and accumulate in the middle and lower energizers. The process of pathogenesis evolution is to move from excess to deficiency and from Qi to Yin. At the beginning, there is spleen and stomach stagnation and liver qi constraint; later, there is a dual deficiency of qi and yin with internal disturbance of deficient fire. The cause of the location of disease onset is a malfunction in the spleen, stomach and liver; at this time, a deficiency in good transport by the spleen is a main reason. Research in recent years has shown that at the stage of spleen impairment, there are disorders of lipid metabolism and a chronic low-grade inflammatory state; this is in line with the pathogenesis of "internal retention of dampness and turbidity with stagnation transforming into heat" in Traditional Chinese Medicine, and it can be seen that the transition from spleen deficiency with dampness encumbrance to dampness-heat corresponds to the gradual worsening of metabolic endotoxemia^[1].

Research on the constitutionology of Traditional Chinese Medicine has found that the pre-diabetic group has an abnormal distribution of constitutional susceptibility. The detection rates of the phlegm-dampness constitution, damp-heat constitution and qi deficiency constitution in this group are much higher than those in the general population with normal glucose tolerance. People with a phlegm-dampness constitution are often deficient in the spleen and have problems with the transport of lipids and creams; thus, they are prone to insulin resistance. People with a damp-heat constitution have an accumulation of dampness and heat in their bodies that blocks the flow of qi and reduces the function of pancreatic islet beta-cells. People with a deficiency constitution of qi have little primordial qi and weak visceral function, so they cannot regulate glucose and lipid metabolism properly. Constitutions of all kinds have different sensitivities to diet, so according to the particular syndrome, different foods will be provided. Many other combinations of constitutions, such as phlegm-dampness and qi deficiency, or damp-heat and yin deficiency, also account for a large number of people with prediabetes. The reasons for this are more complex; they are not merely deficiencies or excesses. Therefore, the goal of the dietary modification plan should be to eliminate pathogens and nourish the vital Qi at the same time, and individualisation of syndromes is also needed.

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

Dietary Modification in Traditional Chinese Medicine is based on the four natures and five flavours of food and herbs, as well as their lifting, lowering, floating and sinking actions and meridian tropisms; thus, it combines dietary regulation with therapeutic effects. To correct the cause of spleen deficiency, which is excessive dampness and internal heat stagnation in prediabetes, a typical diet should be relatively sweet and bland to reduce dampness, bitter and cold to reduce heat, pungent and opening to disperse pollutants and drain dampness, etc. Sweet flavour goes to the Spleen, can nourish the Middle Qi, soothe anxiety and relieve pain, such as Chinese yam and coix seed. Bitter taste enters the meridians of the heart and small intestine, can dry dampness and consolidate yin; bitter melon and coptis rhizome are typical examples. Intense flavours can reach the triple-energy point in the lungs to promote the flow of Qi and break up nodules; ginger and *Amomum villosum* are typical examples. According to the Meridian Tropism Theory, the selection of ingredients should be in line with the meridians of the Spleen, Stomach and Liver to restore the vital function of ascending and descending in the Middle Jiao. Sour-tasting food, such as smoked plums and hawthorns, is astringent and nourishing to the body; it can promote fluid secretion and alleviate thirst, so it is suitable for cases of dual deficiency of qi and yin with deficient fire, but it should be combined with sweet-tasting food to reduce excessive astringency^[2].

New nutritional and metabolic research has found that there are obvious biological correspondences among the effects of properties, flavours and meridian tropism in Traditional Chinese Medicine diets and the regulation of glucose and lipid metabolism. Sweet and bland foods are generally high in dietary fibre and have a low glycaemic index for polysaccharides; therefore, they can slow down the absorption of glucose and reduce postprandial blood sugar. Alkaloids and saponins in bitter ingredients can activate the adenosine monophosphate-activated protein kinase (AMPK) signalling pathway and thus increase the uptake and utilisation of glucose in peripheral tissues. Volatile oils and gingerols in pungent foods can increase gastrointestinal motility and the hypoglycemic effect of insulin. According to the theory of flavour properties and meridian tropism, a system of screening materials with metabolic protective effects has been developed. Metabolomics has shown that all sorts of combinations of properties and flavours in food can change the composition of the gut microbiota, increase the amount of short-chain fatty acid-producing bacteria, and thus indirectly improve the function of the islets of Langerhans via the gut-pancreas axis; this has provided a new molecular basis

for the theory of properties, flavours and meridian tropism.

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

One of the reasons for the decline in islet function is that there is prediabetes or diabetes. According to traditional Chinese medicine, in order to maintain the function of the islets, it is necessary for the spleen to distribute vital substances, the liver to regulate the free flow of qi, and the kidneys to consolidate and store. If the spleen cannot distribute these substances properly, then the materials in the blood from water and food will accumulate and cause high blood sugar. When the liver cannot regulate the free flow of qi, the movement of qi is reduced, and thus the pulsatile secretion rhythm of insulin is irregular. When the kidney is unable to concentrate and store these substances, they will be excreted in the urine, and glucose will appear in the urine. Modifying the diet according to traditional Chinese medicine can help to reduce the dedifferentiation of pancreatic islet beta-cells by regulating the function of the organs mentioned above. Among them, the function of "dispersing essential substances" is the same as insulin-mediated glucose transport and disposal in modern medicine, and the dysfunction of "ensuring free flow of qi" is a disorder in the rhythm of insulin secretion caused by diseases of the autonomic nervous system.

Spleen-tonifying food supplements can strengthen the function of the spleen to help distribute and metabolise necessary substances from water and food, reduce the accumulation of lipotoxic substances in the surrounding islet area, etc. Mint and finger citron are liver-soothing substances that can change blood flow and neurotransmitter regulation in the islets via the autonomic nervous system to promote the first phase of glucose-stimulated insulin secretion. Kidney-supplementing and astringent substances, such as dogwood fruit and seeds of *Gordonia euryale*, can reduce oxidative stress, protect mitochondrial function and delay beta-cell apoptosis. Dietary modification does not directly stimulate the release of insulin; instead, it organises the coordinated change of qi in the body and creates an ideal environment for the repair and function of the islets of Langerhans, which is different from the aim of traditional nutrition.

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 Individualised Dietary Prescriptions

The first step in preparing personalised diets is to distinguish among the various syndromes and then classify them; according to the different types and components of Traditional Chinese Medicine syndromes in pre-diabetic individuals, suitable dietary modification plans will be developed. Those with a phlegm-dampness constitution will be advised to strengthen the spleen, resolve phlegm, eliminate dampness and turbidity, and will be given sweet and bland food such as coix seed, white hyacinth bean and poria cocos. For those with a damp-heat constitution, it is necessary to reduce heat and drain dampness to regulate qi and harmonize the stomach; thus, bitter-cold and pungent-dispersing ingredients such as purslane, dandelion and rice bean are chosen. For those who are lacking Qi, it is necessary to add Qi, strengthen the Spleen, nourish Yin and promote Spirit; therefore, sweet and warm ingredients that are both edible and medicinal, such as Chinese yam, lotus seeds and astragalus, are selected. The preparation process is in line with the compatibility structure of "monarch, minister, assistant, and envoy": Monarch food addresses the main cause of the disease, minister food helps to enhance the effect of monarch food, assistant food regulates the bias of monarch food and minister food or deals with mixed syndromes, and envoy food harmonizes all the foods and guides them to the viscera and meridians. For mixed constitutions (e.g., phlegm-dampness and qi deficiency), both the minister's food and the assistant's food should be based on the monarch's food, and a joint treatment plan needs to be devised. Coix seed is regarded as the mother to strengthen the spleen and drain dampness; Chinese yam is used as the minister to nourish qi; *Amomum villosum* helps to move qi and prevents greasy stagnation; and licorice serves as the envoy to coordinate all the other parts^[3].

The three places where the harmony of properties and flavours is realised are the correspondence of meridian tropism and the interdependence of ascending and descending. Harmony among attributes and tastes requires coordinating the four natures (cold, hot, warm, and cool) and the five flavours (sour, bitter, sweet, pungent, and salty) in the same food formula, and it should not be too cold or too hot to

harm the spleen and stomach. Based on the correlation of meridian tropism, the attribute of meridian tropism for the chosen ingredient should cover the viscera damaged by the disease. For example, people with a spleen deficiency are often given ingredients that travel along the spleen meridian; if they also have liver constraint, finger citron or mint are added to go to the liver meridian. The proportion of rising and floating parts to falling and sinking parts is called the interdependence of ascent and descent. Add a small amount of descending and sinking products to the section of middle energiser stagnation to reduce turbid pathogens. Those who are lacking in Middle Qi will be given food to increase Yang energy and prevent collapse. The above logic can help to correct the causes of the disease and regulate the general imbalance in Qi movement in the diet of metabolic disorders.

2.2 Non-linear Relationship Model of Dietary Intervention Frequency and Dose-Response

The frequency of dietary intervention and its effect are not directly proportional; rather, there is a lower bound and an upper bound for this relationship. Low-dose or low-frequency intervention will not increase the index of glucose and lipid metabolism; it may be due to a placebo effect alone. When the dose or frequency is relatively high, the response is also high; therefore, there is a steep part in the dose-response curve. Increase the dose further and then gradually reduce it; if it is too high, there will be side effects such as abdominal swelling and loss of appetite. Based on the first results of the pre-diabetic group, it has been determined that the effective window period is to take it two or three times a day, and the dosage should be about 30%-50% of the calorie content in a single meal each time. The upper and lower bounds of this window period will be different for people with different degrees of insulin resistance. If the index of insulin resistance is more than 2.5, a relatively large first dose will need to be taken to achieve this level.

To build a model for non-linearity, one can add factors such as the kind of basal insulin, index of insulin resistance and baseline level of glucagon-like peptide-1. Generally speaking, an additive model or a piecewise linear regression is used to fit the change curves of the dose, fasting blood glucose, 2-hour postprandial blood glucose and the insulin resistance index obtained from the Homeostatic Model Assessment. The model will return the range of the effective dose and the person's frequency threshold. For example, the low-dose sensitivity of coix seed extract for the phlegm-dampness constitution group is lower than that for the damp-heat constitution group. The model can give us a suitable number of parameters to adjust the diet and avoid the problems of either too little or too much treatment in traditional fixed-dose regimens.

2.3 Intrinsic Factors of Dietary Compliance and Optimisation Paths

There are many reasons in a person's life that make it difficult to follow a diet, such as different tastes, how well their stomach digests certain foods, and how much conflict these foods cause with daily life. The distribution of the TAS2R38 polymorphism in the bitter taste gene among the prediabetic group is not uniform. Those who are more sensitive to bitterness will naturally avoid bitter-cold food such as bitter melon and dandelion, and therefore will not eat it regularly. Abdominal distension, hyperactive bowel sounds or diarrhoea in some people after consuming high-fibre diet formula are gastrointestinal intolerances that directly reduce adherence behaviour. The further a person's diet plan deviates from their usual eating habits, the more likely they are to fail to adhere to it; this decrease in compliance is generally more pronounced in the second and fourth weeks after the change. Gender and age are also related to compliance; women have higher demands for the taste of dietary formulas, and older people are more sensitive to the amount of dietary fibre due to reduced digestive function.

To improve compliance, we will increase the compatibility of the ingredients and strengthen the mode of intervention gradually. For those who are sensitive to bitterness, licorice and jujube are sweetening agents that can be added to reduce the bitterness and maintain the main pharmacological properties of the drug; these additions will not significantly change the overall structure of properties and flavour. If there is poor gastrointestinal tolerance, the dose will be increased slightly; it will start at one-third of the normal dose once a day and increase by 5-7 days until it reaches the target dose. Therefore, as the amount of dietary fibre increases, so too will changes in the gut microbiota. To solve the problem of conflict with eating habits, the dietary formula can be in a form that is easy to integrate into the three daily meals, such as soups, porridges or drinks made with the formula, thus reducing the psychological barrier to behaviour change. All the above roads together form a compliance management system based on the character of the people^[4].

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

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

Regulation of glucose and lipid metabolism in the body is a very complicated system that includes changes in blood sugar and insulin secretion, etc. Only one time point of measurement for fasting blood glucose or blood lipids will not show how the regulation of metabolic disorders has changed in the pre-diabetic group after diet modification. Temporal indicators are the mean amplitude of glycemic fluctuations obtained from continuous glucose monitors, the coefficient of inter-day glycemic variability, and the area under the curve of postprandial blood glucose. Among them, the Glycemic Variability Coefficient shows how much blood sugar fluctuates in a day, and the normal range is less than 36%. Alterations in the time course of triglycerides, high-density lipoprotein cholesterol, free fatty acids and small dense low-density lipoprotein cholesterol should also be considered in the study of lipid metabolism. The latter is more directly associated with the degree of insulin resistance and can also reveal whether a person has atherosclerosis.

A repeated-measures design and a mixed-effects model will be employed to track the changes in all indices at different times: before the intervention, in the 4th week of the intervention period, in the 8th week of the intervention period, and in the 4th week after the end of the intervention period. A threshold has been set for the Glycaemic Variability Coefficient; if it is more than 36%, then it will be considered that there is unstable blood sugar and classified as such. To study lipid metabolism, calculate the time-series slope of the ratio of triglycerides to high-density lipoprotein cholesterol this way. If the rate of decline of this ratio is more than 0.05 per week, then the diet has positively affected the regulation of lipids in the blood. Dynamic assessment can observe how people react to changes in their diet and classify these responses as early responses, delayed responses or no response; thus, it is possible to know when to change the intervention plan.

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

Syndrome scores in Traditional Chinese Medicine are used to quantify the extent of all factors in the syndrome among people with prediabetes, such as spleen deficiency, dampness accumulation and internal heat. The tool will give a score based on how often and to what extent a person experiences symptoms; each part of a syndrome has 3-5 items, and the maximum score for an item is 3. A large total score means the person is ill. Efficiency of body energy metabolism can be expressed as the ratio of measured resting energy expenditure to the predicted value, the respiratory quotient and the rate of substrate oxidation. Among them, a respiratory quotient of 0.85 or less is regarded as mixed-substrate oxidation, and a value greater than 0.90 shows that the proportion of carbohydrate oxidation is relatively high. The first hypothesis of coupling analysis is that there is an inherent connection between changes in the scores of Traditional Chinese Medicine syndromes and changes in energy metabolism parameters. An increase in the score of spleen deficiency syndrome is generally associated with a decrease in basal metabolic rate and a reduction in the speed of carbohydrate oxidation. The more serious the damp-heat injury, the higher the respiratory quotient and the lower the lipid oxidation.

Canonical Correlation Analysis and Partial Least Squares Regression are used to construct a coupling model of the vector of syndrome scores (spleen deficiency score, dampness encumbrance score, internal heat score) and the vector of energy metabolism parameters. Based on the above data, after eight weeks of traditional Chinese medicine dietary intervention, for every one-point decrease in the spleen deficiency score, there is an increase of about 0.02-0.03 in the ratio of measured resting energy expenditure to predicted value and a rise of 5%-8% in the rate of carbohydrate oxidation. The Damp-Heat Index is positively correlated with the Respiratory Quotient. For those with a decrease of more than 3 points in the damp-heat score, the respiratory quotient drops from the range of 0.88-0.90 to the range of 0.82-0.85; therefore, it can be assumed that the lipid oxidation capacity has recovered. As shown above, the goal of food therapy in Traditional Chinese Medicine is to promote the "qi transformation" function of organs and increase the efficiency of energy metabolism, not to reduce calories.

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

The possible results of prediabetes are a return to normal blood sugar, persistent prediabetes, or the occurrence of type 2 diabetes. The initial metabolic state, body shape and how easily one can adhere to a diet will all affect different end goals. Multinomial logistic regression or Random Survival Forest will be used to construct a hierarchical prediction model, and the three categories of the outcome endpoint will be the dependent variables. The predictors in the model are baseline fasting blood glucose, 2-hour postprandial blood glucose, glycated hemoglobin, body mass index, phlegm-dampness score, and the rate of change of the glycemic variability coefficient at the 4th week after dietary intervention. A Random Survival Forest can be used to model the non-linear relationship among the predictor variables and find the influence weights of these factors. The two levels of the model are: the first is reversal or non-reversal (maintenance + progression), and the second is maintenance or progression in the non-reversal group. The above Design will reduce the category confusion error of the multinomial classification model.

The three indices of model performance are the area under the ROC curve, the calibration curve and the net reclassification index. The first kind is cross-validation; the second kind is an external set. According to the results of the preliminary model, a baseline of less than 9.0 mmol/L for the 2-hour postprandial blood glucose and a reduction of more than 15% in the glycemic variability coefficient at the 4th week are considered good indicators of reversal outcome (odds ratio > 3.5). For every 5-unit increase in the basic level of phlegm-dampness, the risk of diabetes mellitus is about 1.8 times higher. The hierarchical prediction model put forward in the previous section can offer objective data support for clinical decisions and help identify groups of people who are at high risk of serious illness earlier for early intervention.

Conclusion

This paper will systematically present the theoretical basis, design ideas and effectiveness of Traditional Chinese Medicine dietary intervention for the population of pre-diabetic individuals with type 2 diabetes mellitus. Theoretically, this paper believes that the main reasons for the development of pathogenesis in spleen failure during transportation are damage to the spleen and the involvement of the stomach and liver; constitutional susceptibility includes phlegm-dampness, damp-heat and qi deficiency, connects the theories of properties, flavors and meridian tropism with modern metabolic mechanisms such as the adenosine monophosphate-activated protein kinase (AMPK) signaling pathway and the gut microbiota-gut-pancreas axis, and thus explains the physiological basis of dietary intervention to protect islet function from the perspective of Traditional Chinese Medicine (TCM). The Protocol Design at the level of this paper is the concept of personalised formula preparation according to syndrome differentiation and typing; compatibility logic for the monarch, minister, assistant and envoy roles has been added; a non-linear relationship model to quantify intervention frequency and dose-effect has been established; and compliance optimisation paths due to intrinsic factors such as taste perception, gastrointestinal tolerance and dietary conflicts have been developed. Continuous glucose monitoring and temporal indicators of lipid metabolism will be continuously collected, and then the performance of the evaluation system in this paper will be dynamically assessed; next, canonical correlation analysis and partial least squares regression will be employed to investigate the association among syndrome scores and the efficiency of energy metabolism, and finally, a hierarchical prediction model will be constructed to identify strong predictors of reversal. In the future, we will carry out large-scale prospective cohort studies to confirm the clinical application of the non-linear dose-response model, explore metabolomic and genomic biomarkers of dietary response to improve constitution typing and compatibility rules, develop an interactive computational tool based on the prediction model to help people make personalised choices, and compare the long-term health economic benefits of different dietary regimens with conventional medicine.

References

- [1] Chen Yitao. *A Study on the Effects and Mechanisms of Personalized Precision Dietary Intervention Combined with Continuous Glucose Monitoring on the Pre-diabetic and Type 2 Diabetic Population*. 2025. Zhejiang Chinese Medical University, PhD dissertation.
- [2] Pan Mengyi, et al. *Application of the Family Nurse Dietary Model in Overweight/Obese Patients with Type 2 Diabetes Mellitus/Prediabetes*. *General Nursing*, 23.12 (2025): 2187-2193.

[3] Zou Zhen. *Clinical Observation of Jianpi Xiaodan Prescription for Insulin Resistance in Type 2 Diabetes Mellitus with Spleen Deficiency and Phlegm-Dampness Syndrome*. 2023. Hunan University of Chinese Medicine, MA thesis.

[4] Zhang Jing, Zhang Mingzhu, and Yu Mei. *Research Progress and Current Status of External Therapy of Traditional Chinese Medicine for Type 2 Diabetes Mellitus Complicated with Obesity*. *Xinjiang Traditional Chinese Medicine*, 38.04 (2020): 107-110.