informed consent

Project name: The effect of quinoa functional dietary combined standard treatment on the prognosis of early type 2 diabetes patients and the intestinal-pancreatic glucose regulation cycle	
Research unit: Qilu Hospital, Shandong University	
Research office/department: Geriatric Endocrinology Department	Tel: 0531-82166641
Project host: Tang Kuanxiao	Title: Chief Physician
Co-sponsors/participants: Sun Lei et al. 6	Profession: Chief physician/ attending physician/postgraduate/ associate chief nurse
Emergency contact: Zhang Jianbo	Emergency contact: 18560083053

Name of voluntary subject: ID number: Name of voluntary subject: ID number:

Gender: Age: Gender: Age:

Mailing address: Tel: Mailing address: Tel:

Medical record number:

(I) Research Objectives:

We cordially invite you to participate in a medical research program involving 120 patients in China. Building upon previous studies, this initiative explores the impact of quinoa-based functional diets combined with standard treatment on prognosis and intestinal-galactose regulation cycle in early-stage type 2 diabetes patients. The implementation of this study will contribute to developing innovative foundational therapies for early-stage type 2 diabetes, providing theoretical support for establishing new clinical intervention strategies to reverse the condition.

(II) Research methods: (including the criteria and number of subjects enrolled; the design and steps of the trial; the trial Timeframes and progress; follow-up or rehabilitation plans; assessment and statistical methods)

(1) Criteria and number of subjects enrolled

All the following conditions must be met for a subject to participate in this trial

1) Newly diagnosed T2DM patients diagnosed according to the 1999 World Health Organization diagnostic criteria for type 2 diabetes mellitus (T2DM), with a disease course of ≤2 years; 2)7.0mmol/l ≤ fasting blood glucose (FBG) ≤ 11.1mmol/L; 3) have not been treated with hypoglycemic drugs; 4) All subjects must sign an informed consent form before entering the trial.

You cannot participate in this study ifyou have any of the following conditions:

1) Acute diabetic complications such as type 1 diabetes and ketoacidosis; 2)FBG(16.7mmol/l; 3) Positive results for glutamic acid decarboxylase (GAD) antibody, islet cell antibody (ICA), or insulin antibody (IAA); 4) Severe acute or chronic complications involving the liver, kidneys, heart, cerebrovascular system, gastrointestinal tract, or acute infectious diseases; 5) Pregnancy, planned pregnancy in the near future, or breastfeeding.

(2) Experimental design and main steps

Case Grouping: Selected patients were randomly assigned to two groups: (1) Intervention Group: Standard treatment combined with 12 weeks of quinoa functional dietary intervention, followed by standard treatment alone; (2) Control Group: Standard treatment only. The study

observed the effects of quinoa functional dietary intervention combined with standard treatment on early-stage diabetes patients' glucose homeostasis at 0, 4, 12,26, and 52 weeks. It also examined the metabolic memory effects and macrovascular impacts in early-stage diabetes patients, as well as the effects on their enterospancreatic glucose regulation cycle and clinical outcomes (including potential clinical reversal).

Blood glucose monitoring: Participants were given free supplies related to blood glucose monitoring, and the researchers were responsible for training them on how to use them. Participants should actively cooperate and provide complete and truthful monitoring data for the researchers' analysis to help adjust the treatment plan.

(3) Trial period and schedule

The trial will be conducted from June 2019, with an estimated 120 patients participating.

(4) Tracking plan

Clinical constitution data were collected during each follow-up visit, and relevant clinical efficacy and safety indicators were tested. Blood glucose level changes were monitored by fingertip micro blood glucose test on a daily basis. Dynamic blood glucose monitoring was conducted before and after the study.

(5) Evaluation and statistical methods

Based on the fluctuation of blood glucose, carotid ultrasound, islet function test and blood glucose level assessment, the effects of quinoa functional diet combined with standard treatment on blood glucose stability, metabolic memory effect, macrovascular lesions, intestinal-pancreatic glucose regulation cycle and clinical outcome (can be clinically reversed) in early diabetic patients were evaluated.

(III) Description of participation cost: You will not need to pay any additional fees for participating in this trial.

(IV) Possible benefits from participation in the trial: The medical staff will provide you with complete medical care during the trial.

V. Possible Adverse Reactions and Risks: This study will not interfere with the subject's regular medical treatment regimen. The potential side effects and risks associated with this trial are within clinically manageable safety parameters. Emergency Procedures: In case of any emergency or unusual physical condition, contact your attending physician or nursing staff immediately.

(6) Current Therapeutic Options and Their Mechanisms: The current treatment protocol for type 2 diabetes involves a stepwise approach where oral hypoglycemic agents are gradually increased in dosage and variety after lifestyle modifications fail to achieve target levels. However, this strategy carries significant drawbacks: accelerated decline of pancreatic islet function, increased blood glucose fluctuations, and prolonged suboptimal glycemic control may accelerate the development of both microvascular and macrovascular complications. These complications severely compromise patients' quality of life and lifespan. Therefore, there is an urgent need to establish innovative therapeutic interventions for type 2 diabetes.

(7) Your rights and responsibilities:

Your personal rights and interests will be protected by the following conditions:

If any injury is caused by the execution of the test in accordance with the test plan, the test commissioning party shall be liable for damages according to law.

1. The implementing agency of this clinical trial plan (the drug of this trial plan has been marketed in China) will safeguard your rights and interests during the trial.

2. Your privacy protection

(1) The research doctors and staff will keep your medical records confidential. The data collected,

examination results and diagnosis will be kept confidential, and there will be an code to protect your name from being disclosed. In addition to the investigation by relevant institutions according to law, we will maintain your privacy.

(2) The data obtained from the experiment may be published for academic purposes, but your privacy (such as name, medical record number, etc.) will not be disclosed and will be kept strictly confidential.

3. If you are injured or have any questions about your rights during the trial, please contact Tang Kuanxiao at 18560082261.

(8) You have the right to refuse to participate in the trial without giving any reason and may withdraw your consent to withdraw from the trial at any time. This decision will not cause any unpleasantness or affect your future medical care.

Signature of study sponsor: Date: Signature of study sponsor: Date:

(9) I have read the above information in detail, and have been thoroughly explained by the experiment leader about the questions related to this clinical research plan. After understanding the overall situation of the study and after full consideration, I agree to be a voluntary participant in this clinical research.

Name of voluntary participant: ID number: Name of voluntary participant: ID number:

Gender: Age: Gender: Age:

Mailing address: Tel: Mailing address: Tel:

Medical record number:

Voluntary participant signature:

Date:June 8, 2025