Informed Consent Form

Polygonatum Sibiricum for Visceral Obesity and Related Metabolic Abnormalities: A Randomized Controlled Trial and Mechanistic Exploration

Research Center Name: Zhejiang Provincial Tongde Hospital

Registration number: NCT

Protocol Version and Date: V3.0, 2026.07.07

Name of the subject: _____

Subject screening number: _____

Principal Investigator: Wang Xiaoli

Consensual Form · Notification page

Dear madam/Sir:

We sincerely invite you to participate in the clinical study titled "Polygonatum Sibiricum for Visceral Obesity and Related Metabolic Abnormalities: A Randomized Controlled Trial and Mechanistic Exploration." Before you decide whether to participate, please read the following information carefully. You may ask the research staff questions at any time, and you may discuss with your family or friends before making your own decision. If you are currently participating in another clinical study, please inform us in advance.

1. Why is this study being conducted?

Visceral obesity is a major contributor to type 2 diabetes, fatty liver disease, and cardiovascular and cerebrovascular diseases. Simple diet and exercise interventions often have limited effects, and Western weight-loss drugs have disadvantages such as multiple side effects, high costs, and poor adherence. Polygonatum sibiricum (Huangjing) is a traditional Chinese medicinal and edible herb. Modern research has confirmed that its active components can regulate glucose and lipid metabolism and modulate gut microbiota, with high safety and suitability for long-term use.

Based on our previous animal studies, this clinical randomized controlled trial aims to verify the effects of Polygonatum on visceral fat accumulation and glucolipid metabolic abnormalities, and to explore its mechanisms. The ultimate goal is to provide a safe and effective traditional Chinese medicine intervention for people with obesity and metabolic disorders, and to provide scientific evidence for clinical application.

2. Who will be invited to participate?

You are eligible to participate if you meet ALL of the following criteria:

1.Age 18–65 years, male or female;

2.Diagnosed with visceral obesity: BMI ≥ 24 kg/m² or body fat percentage ≥25% (male) / ≥30% (female), and visceral fat area ≥100 cm²;

3.Weight has been stable in the last 3 months (fluctuation ≤5%);

4.Fully understand the study content, voluntarily participate, and sign the informed consent form. If you are illiterate, a witness may accompany you to sign.

3. Who should NOT participate?

You cannot participate if you have any of the following conditions:

1.Secondary obesity caused by thyroid disorders, polycystic ovary syndrome, or other endocrine diseases;

2.Prior metabolic/bariatric surgery, or current use of any weight-loss medications;

3.Severe glucolipid metabolic disorders requiring immediate intensive drug therapy;

4.Severe cardiovascular, cerebrovascular, or other unstable chronic diseases;

5.Significant liver or kidney dysfunction;

6.Malignancy, active infection, or autoimmune disease;

7.Use of antibiotics, probiotics, or other agents affecting gut microbiota within the last 1 month;

8.Pregnancy, lactation, or planned pregnancy during the study period;

9.Allergy or intolerance to Polygonatum or its preparations;

10.Any other condition deemed unsuitable by the investigator.

4. If you participate, what will you need to do?

You will participate in a 12-week prospective randomized controlled clinical study. First, you will complete a baseline assessment (including physical measurements, body composition analysis, and

collection of blood and stool samples). Then you will be randomly assigned (1:1 ratio) to either the Polygonatum intervention group or the control group. Both groups will receive a uniform lifestyle intervention program, including: An individualized calorie-restricted diet formulated by a dietitian, based on the principles of "total calorie control, reduced sugar and fat, and regular meals"; An exercise prescription consisting of at least 150 minutes per week of moderate-intensity aerobic exercise combined with resistance training; Traditional Chinese Medicine "preventive treatment" behavioral guidance, covering sleep management, stress management, and lifestyle education. The intervention group will additionally take 15 g/day of Polygonatum water decoction orally after meals. During the study, you will be required to: Attend scheduled follow-up visits (for physical measurements, body composition reassessment, and glucolipid metabolic tests); Record medication adherence, adverse events, and diet/exercise logs; Provide blood and stool samples again at the end of the intervention for mechanistic analyses.

5. What are the risks?

The main risks include: Possible gastrointestinal discomfort, allergic reactions, or other unknown adverse effects from Polygonatum;

Possible exercise-related injuries or discomfort from calorie restriction during the lifestyle intervention; Repeated blood sampling and stool collection may cause temporary discomfort; Although Polygonatum is a food-drug homology substance and has shown good safety in animal studies, long-term safety data in the visceral obesity population are still limited; Bioelectrical impedance analysis for visceral fat area has certain technical limitations; The open-label design means you may know your group assignment; There is a possibility of study discontinuation due to dropout. If you experience a serious adverse event or your adherence falls below 80%, you will be asked to withdraw from the study.

6. What are the benefits?

You may receive the following health benefits: Potential reduction in visceral fat accumulation and improvement in glucolipid metabolism from Polygonatum; 12 weeks of free professional nutritional guidance, exercise prescription, and TCM behavioral management, which may improve weight and metabolism; Free systematic body composition assessments (visceral fat area, body fat percentage, etc.) and glucolipid metabolic tests, with a personal metabolic health profile established for you. In addition, your participation will

provide important human evidence for translating Polygonatum from basic research to clinical practice, promoting the application of food-drug homology Chinese medicines in the prevention and treatment of metabolic diseases, and benefiting more patients with obesity and related metabolic disorders.

7. What are the costs?

The Polygonatum decoction used in this study, study-related tests, and biosample analyses are all covered by the research grant – you do not need to pay for them. You will receive a transportation subsidy of 100 RMB per month. If you complete the 12-week observation, you will receive a total of 300 RMB. Costs for medications for your underlying conditions and routine medical care are your own responsibility. If any study-related injury occurs, it will be handled according to relevant national laws and regulations.

8. Is my personal information confidential?

All your medical records, examination data, biospecimens, and personal identifying information will be kept strictly confidential. Only the study researchers and the hospital ethics committee will have access. When the study results are published or presented at academic conferences, all information that could identify you will be

removed to protect your privacy.

9. Must I participate?

Participation in this study is entirely voluntary. You may refuse to participate, or you may withdraw at any time during the study, without any effect on your medical care. If you decide to withdraw, please contact your study doctor. You may be asked to undergo relevant examinations, which is beneficial for your health.

10. If I do not participate, are there other treatment options?

If you do not participate, your other options include:

Receiving routine observation without study intervention;

Participating in another clinical study;

Receiving no intervention at all.

Before deciding whether to participate, you may discuss the risks and benefits of different treatment options with your doctor.

11. Ethics Committee Information

If you have any complaints or concerns during the study, please contact the Ethics Committee of Zhejiang Provincial Tongde Hospital:

Address: Building 6, No. 234 Gucui Road, Xihu District, Hangzhou, Zhejiang, China

Tel: +86-0571-89975971

Email: tongdelunli@163.com

Contact person: Zhu Yuqing

After carefully reading the above information, if all your questions have been answered and you voluntarily agree to participate, please sign below.

Informed Consent Form – Signature Page

Participant's Statement:

I have read the above introduction to this study, and I have had the opportunity to discuss it with the doctor and ask questions. All my questions have been answered satisfactorily. I understand the potential risks and benefits of participating in this study. I am aware that participation is voluntary, and I confirm that I have had sufficient time to consider this. I also understand that:

1.This study has been approved by the Ethics Committee of Zhejiang Provincial Tongde Hospital.

2.My privacy rights, medical care, and compensation are safeguarded.

3.I may choose not to participate, or I may withdraw from the study at any time, without discrimination or retaliation, and my medical treatment and rights will not be affected.

4.I agree that representatives from the research sponsor, the ethics committee, or the conducting institution may review my research records.

5.The study physician may terminate my participation if I do not follow the study plan, if I experience a study-related injury, or for any other reason.

6.If my condition changes and I need any other treatment, I will

consult the doctor in advance.

7.I will receive a signed and dated copy of this informed consent form.

Finally, I have decided to voluntarily participate in this study and will try my best to comply with the study procedures.

Participant's signature: _____

Date: _____ (Year) _____ (Month) _____ (Day)

Participant's contact phone number: _____

Legal guardian's signature (if applicable): _____

Date: _____ (Year) _____ (Month) _____ (Day)

Relationship to participant: _____

Legal guardian's contact phone number: _____

Witness's signature (if applicable): _____

Date: _____ (Year) _____ (Month) _____ (Day)

Relationship to participant: _____

Witness's contact phone number: _____

Investigator's Statement:

I confirm that I have explained the details of this study to the participant, including their rights, potential benefits, and risks, and I have answered their questions. The participant voluntarily agreed to participate in this study and has been given a signed copy of the informed consent form.

Investigator (the doctor who conducted the informed consent discussion) signature: _____

Date: _____ (Year) _____ (Month) _____ (Day)

Contact phone number: _____