Informed Consent Form·Information Page

Dear Sir/Madam:

We would like to invite you to participate in a clinical trial study titled “Clinical Study of Baduanjin Intervention After Coronary Revascularization.” This study has been reviewed and approved by the Medical Ethics Committee of the Third Affiliated Hospital of Zhejiang Chinese Medical University and complies with relevant Chinese regulations, the Declaration of Helsinki, and other ethical principles for the protection of subjects’ rights and interests.

Before you decide whether to participate in this study, please read the following information as carefully as possible. It will help you understand the content of the study, why it is being conducted, and the possible benefits, risks, and discomforts it may bring to you. If you have any questions, please ask the doctor or researcher responsible for the study.

1. Why is this study being conducted?

(1) Background information on this clinical study

Coronary heart disease seriously endangers human health. Currently, percutaneous coronary intervention and coronary artery bypass grafting are the main surgical methods used clinically to restore blood flow in occluded or stenotic coronary arteries. However, patients often have a poor long-term prognosis after surgery, such as recurrent angina and in-stent restenosis, which significantly increases their risk of cardiovascular events.

Modern medicine often focuses on intervening in a single pathological link and lacks a systematic, holistic regulatory strategy. In contrast, Traditional Chinese Medicine (TCM) rehabilitation therapy demonstrates unique advantages in terms of holism. In particular, the Baduanjin training in TCM Daoyin can significantly improve patients' cardiopulmonary function and increase the 6-minute walk distance, making it suitable for early rehabilitation of patients after coronary revascularization. Currently, this field lacks high-quality, large-sample randomized controlled trial evidence. Therefore, our team plans to conduct a high-standard randomized controlled clinical study to verify and optimize the Baduanjin protocol in TCM rehabilitation, establish a scientific and systematic TCM rehabilitation evaluation system, and ultimately achieve the goal of improving patients' long-term prognosis and enhancing their quality of survival.

(2) Study purpose

Focusing on the post-coronary revascularization period, this study evaluates the clinical efficacy and safety of a TCM rehabilitation treatment protocol combining standardized Western medical treatment with Baduanjin.

(3) Main study content

The management center for this study is located in the Cardiovascular Department of the Third Affiliated Hospital of Zhejiang Chinese Medical University (Zhejiang Zhongshan

Hospital). It is expected that 310 subjects will voluntarily participate. Patients who meet the enrollment criteria and participate in this study will be randomly assigned by a doctor to either the experimental group or the control group. The experimental group will receive standardized Baduanjin rehabilitation training on top of standardized Western medical treatment, while the control group will receive aerobic exercise training on top of standardized Western medical treatment. The intervention period is 12 weeks. Follow-up will occur at baseline (enrollment day), Week 6, Week 12, Week 24, Week 36, and Week 48. The primary efficacy endpoint is the incidence of major adverse cardiovascular events. Secondary efficacy endpoints include TCM syndrome score, echocardiography, dynamic electrocardiography, Minnesota Living with Heart Failure Questionnaire, myocardial enzymes, blood lipids, and blood glucose. Safety endpoints include vital signs, complete blood count, hepatic and renal function, and other adverse reactions and adverse events. Through a rigorous multicenter, randomized controlled trial, this study will evaluate the effectiveness and safety of Baduanjin intervention for patients after coronary revascularization, develop a TCM rehabilitation treatment protocol and evaluation system for Baduanjin intervention after coronary revascularization, clarify the advantages of TCM rehabilitation in post-coronary revascularization treatment, and provide high-level evidence-based medical evidence for the TCM rehabilitation protocol.

2. Who are the main subjects of this study?

① Meeting the diagnostic criteria for coronary heart disease;

② Having undergone effective PCI;

③ Aged 18-80 years;

④ Sex not limited;

⑤ Signed informed consent form.

3. Who should not participate in the study?

① Complicated with severe hepatic or renal insufficiency;

② Complicated with severe electrolyte disturbances;

③ Complicated with severe hematological diseases or malignant tumors;

④ Pregnant or lactating women;

⑤ Patients with psychiatric disorders;

⑥ Cognitive impairment (e.g., dementia, post-stroke cognitive impairment) rendering the patient unable to understand or execute exercise instructions;

⑦ Planned repeat revascularization surgery in the near future;

⑧ Complicated with other severe cardiovascular diseases such as uncontrolled hypertension, angina, tachyarrhythmia, high-degree or complete atrioventricular block

(without pacemaker implantation), acute severe aortic stenosis, decompensated heart failure (NYHA Class IV), deep vein thrombosis, obstructive hypertrophic cardiomyopathy, acute pericarditis or myocarditis, acute endocarditis, acute aortic dissection, etc.;

⑨ Acute pulmonary embolism and chronic pulmonary diseases accompanied by dyspnea symptoms (at rest or upon slight activity);

⑩ Limb mobility impairment or inability to move autonomously;

⑪ Complicated with Shy-Drager syndrome;

⑫ Participation in other drug or exercise intervention clinical trials within the past 1 month;

⑬ Other conditions deemed unsuitable for trial participation by the investigator.

4. Are there any alternative treatments?

Other treatment methods, such as resistance/strength training, can effectively increase muscle strength and improve insulin sensitivity, which is particularly important for patients with sarcopenia or diabetes. When combined with aerobic exercise, it can more comprehensively improve physical function and quality of life. However, improper execution may cause a sudden rise in blood pressure or stress on the stent area, requiring implementation under professional monitoring and making it unsuitable for early-stage/high-risk patients. Additionally, acupuncture treatment can help alleviate angina and anxiety; however, high-quality clinical studies are relatively few, efficacy quantification standards are inconsistent, it must be performed by a professional TCM practitioner, cannot be self-administered, and has high professional requirements.

5. What do I need to do if I participate in the study?

This study adopts a randomized controlled study design. A random number table will be generated by computer. Cases will be strictly screened according to diagnostic criteria, inclusion criteria, and exclusion criteria. After enrollment, researchers will randomly assign you to a group according to the random number table until the total number of observed cases is completed. Personnel involved in group assignment will not participate in data statistical analysis. Because this study uses a double-blind design, the doctors, statisticians, and you will not know the group assignment. If you are willing to participate in this study, during the treatment period you will need to, on the basis of standardized Western medical treatment, perform Baduanjin training 4 times per week, with each session consisting of 2 repetitions of the 12-minute standard Baduanjin, or perform aerobic exercise such as stair climbing, jogging, brisk walking, cycling, etc., per week. You will receive online or offline guidance once a week and upload training videos. You will also undergo clinical condition assessment and information collection at 6 time points: at enrollment and at Week 6, Week 12, Week 24, Week 36, and Week 48 after enrollment. The specific content includes: ① TCM syndrome

scale based on the Four Diagnostic Methods of TCM; ② Minnesota Living with Heart Failure Questionnaire; ③ Clinical laboratory indicators: venous blood drawn under fasting conditions in the morning for testing complete blood count, hepatic and renal function, myocardial enzymes, blood lipids, glycated hemoglobin, etc.; fingertip blood collection for blood glucose measurement; ④ Echocardiography and dynamic electrocardiography examinations; ⑤ Recording of basic vital signs (respiration, heart rate, temperature, blood pressure after 5 minutes of rest), new major adverse cardiovascular events (all-cause death, subacute stent thrombosis, peri-procedural myocardial infarction, recurrent myocardial infarction, recurrent unstable angina, repeat revascularization, rehospitalization due to angina or heart failure, if any), and other adverse reactions; ⑥ Recording of demographic data, medical history, comorbidities, medication use, etc.

6. What are the benefits of participating in the study?

You and society may benefit from this study. Such benefits include timely identification of existing problems, possible improvement in your cardiac function, exercise capacity, quality of life, and mental health, and enhanced communication with your doctor. Additionally, through the internet and telephone, we will provide you with consultation services related to post-coronary revascularization rehabilitation, allowing you to obtain scientific and personalized information.

7. What risks and inconveniences might there be from participating in the study?

Common adverse reactions in this study include knee discomfort, muscle soreness, joint sprains, muscle strains, and plantar fasciitis caused by non-standard movements. Transient dizziness, shortness of breath, palpitations, slightly elevated blood pressure, and post-exercise hypotension may occur initially after exercise. Excessive sweating, dehydration, and post-exercise fatigue may also occur. If adverse events occur during the study period, you will receive full treatment, consultation, and scale assessments throughout the entire experimental process (including the follow-up period). You will need to come to the hospital on time or receive follow-up by phone during the study period, which may cause you trouble or inconvenience.

8. Circumstances and/or reasons under which the trial may be terminated:

① Found during the trial not to meet the inclusion or exclusion criteria;

② Occurrence of severe adverse reactions or adverse events during treatment;

③ Subjects not treated according to the treatment protocol after enrollment.

Patients who cannot continue for non-efficacy reasons or voluntarily request withdrawal may have their clinical trial case terminated.

9. Do I need to pay any related fees for participating in the study?

① This study will cover the costs of complete blood count, hepatic and renal function, myocardial enzymes, blood lipids, blood glucose tests, and echocardiography and dynamic electrocardiography examinations at enrollment and at Week 6, Week 12, Week 24, Week 36, and Week 48 after enrollment. It will also provide free online or offline standardized Baduanjin rehabilitation training or aerobic exercise training guidance.

② During the study, the Minnesota Living with Heart Failure Questionnaire and TCM Syndrome Score assessments will be provided to you free of charge.

③ If you experience an adverse event during the study that is confirmed by the medical institution to be related to this study, the Third Affiliated Hospital of Zhejiang Chinese Medical University (Zhejiang Zhongshan Hospital) will bear the treatment costs and provide corresponding economic compensation.

④ You are responsible for the costs of the conventional Western medical treatment you receive in this study.

⑤ The project will not cover the costs of treatment and examinations required due to the natural progression of your illness or concurrent other diseases during the course of this study.

⑥ The team will provide you with a transportation and nutrition subsidy of 40 RMB per visit, for a total of 6 visits. Upon completing all visits, you will receive a total of 240 RMB. Compensation will be distributed based on the number of visits attended.

10. Is my personal information kept confidential?

Your participation in the study and your personal data in the study are confidential. All information from your participation in this study will be recorded in the study medical records / Case Report Forms. All test results appearing in the original medical records (including personal data, laboratory test reports, etc.) will be kept completely confidential within the limits permitted by law. Your name will not appear on the CRF; only your initials in Pinyin and the subject number assigned when you participate in the trial will appear. In related study summaries, articles, and public publications, if necessary, only your initials in Pinyin and subject number will appear. We will make every effort to protect the privacy of your personal medical data within the limits permitted by law.

11. Must I participate in the study?

Whether or not to participate in this study is entirely your voluntary decision. You may refuse to participate in this study or withdraw from the trial at any time without facing any penalty or loss of benefits to which you are otherwise entitled.

12. Other information

If information becomes available that may affect your continued participation in the trial,

you or your legal representative will be promptly informed. If you have any medical questions related to this study or wish to obtain more information, please contact Dr. Wang Yanfei at phone number: 15869195971.

If you wish to express any dissatisfaction or concerns arising from your participation in this study, or if your personal rights and interests have been compromised, you may contact the Ethics Committee of the Third Affiliated Hospital of Zhejiang Chinese Medical University at phone number: 0571-87238255.

Informed Consent Form • Consent Signature Page

Statement of Consent

1.I have read this Informed Consent Form, and the relevant project leader has provided me with a detailed explanation of the purpose, content, risks, and benefits of this trial.
2.I have discussed and asked questions related to this study, and the answers to these questions are satisfactory to me.
3.I have had sufficient time to make a decision.
4.I voluntarily agree to participate in the clinical study introduced in this document.
5.If I withdraw midway due to unavoidable circumstances, I will promptly inform the doctor of any changes in my condition.
6.If I need to undergo any other treatment due to changes in my condition, I will consult the doctor in advance or truthfully inform the doctor afterward.
7.I agree that representatives of the drug regulatory authority, ethics committee, or project funding body may review my research data.
8.I will receive a signed and dated copy of the Informed Consent Form.

Finally, I have decided to agree to participate in this trial study and promise to follow the doctor’s instructions.

Subject’s Signature:
Date:
Subject’s Contact Phone Number:

I confirm that I have explained the details of this study to the subject, including their rights as well as the possible benefits and risks, and have provided them with a signed copy of the Informed Consent Form.

Doctor’s Signature:
Date:
Study Doctor’s Contact Information:

(This page is an essential part of the Subject Informed Consent Form. Every “Subject Informed Consent Form” must bear the signatures of the subject or their legal representative and the study doctor, along with the date, to be considered valid.)