Cover Page

Baduanjin Intervention in Clinical Studies After Coronary Revascularization Surgery

Study Type: Interventional Study (Experimental Study)

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Zhejiang Chinese Medical University

Department Responsible: Cardiovascular Department

Date: April 2026

This study will be conducted in accordance with this clinical research protocol and GCP

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Research Background

1.Research Background

Coronary heart disease, as a major non-communicable disease causing death and disability worldwide, severely endangers human health[1]. Percutaneous coronary intervention (PCI) and coronary artery bypass grafting (CABG), as the two core approaches of modern coronary revascularization, mechanically restore blood flow in occluded or stenotic coronary arteries, substantially reducing mortality from acute myocardial infarction and saving countless lives. However, patients after coronary revascularization still face a series of severe clinical challenges, and the issue of poor long-term prognosis is becoming increasingly prominent. Approximately 20%-30% of patients with coronary heart disease may still experience recurrent angina after successful and complete coronary revascularization by PCI[2]. In-stent restenosis occurring 3-6 months after PCI is the primary mechanical cause of angina recurrence and repeat revascularization[3]. Other non-mechanical factors, such as incomplete revascularization due to diffuse coronary lesions or multivessel disease[4], peri-procedural myocardial injury or microembolization induced during PCI[5], myocardial ischemia and cardiac dysfunction caused by coronary microvascular dysfunction[6], and psycho-cardiological factors[7], should not be overlooked. The interaction of these factors significantly increases the risk of cardiovascular events in patients, severely affecting their quality of daily life and long-term survival after revascularization, and constitutes a challenging aspect in post-coronary revascularization management. Therefore, how to identify, predict, and intervene in these complex factors multi-dimensionally and comprehensively to improve the long-term prognosis of patients after coronary revascularization has become an urgent bottleneck in the cardiovascular field.

In addressing this multifactorial syndrome after coronary revascularization, modern medicine often focuses on intervening in a single pathological link, lacking a systematic overall regulatory strategy, which leads to persistent symptoms and suboptimal efficacy in some patients[8]. In contrast, comprehensive Traditional Chinese Medicine (TCM) rehabilitation therapy demonstrates unique advantages in holistic regulation and multi-target intervention, aligning with the post-coronary revascularization pathogenesis characterized by “deficiency in origin and excess in superficiality, complexity and variability.” Among TCM rehabilitation therapies, TCM Daoyin, particularly Baduanjin (Eight-Section Brocade), characterized by gentle movements and the integration of mind, Qi, and body, is suitable for early rehabilitation in patients after coronary revascularization. The Expert Consensus on

Integrated Traditional Chinese and Western Medicine Cardiac Rehabilitation After Percutaneous Coronary Intervention[9] indicates that risk-stratified Baduanjin training can significantly improve patients' cardiopulmonary function (e.g., peak oxygen uptake, left ventricular ejection fraction), increase the 6-minute walk distance, and contribute to emotional regulation and improved treatment adherence, serving as a beneficial supplement to Western medical exercise rehabilitation. However, this field still lacks high-quality, large-sample randomized controlled trial evidence, limiting its standardized promotion and protocol optimization.

The team's previous studies have confirmed that Baduanjin is significantly effective in improving cardiac function, alleviating anxiety and depression, and enhancing quality of life in patients after coronary revascularization. On this basis, a standardized Baduanjin rehabilitation guidance protocol and effectiveness evaluation system has been established, providing a technical foundation for conducting large-scale, high-quality Baduanjin clinical research. Therefore, the 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.Main Research Content, Objectives, Protocol, Timeline, and Key Issues to Be Addressed

2.1 Research Content

Patients after coronary revascularization will be selected as study subjects and divided into an experimental group (standardized Western medical treatment+Baduanjin) and a control group (standardized Western medical treatment+aerobic exercise), with an intervention period of 12 weeks. Follow-up will be conducted 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 (MACE). Secondary efficacy endpoints include TCM syndrome score, echocardiography, dynamic electrocardiography, Minnesota Living with Heart Failure Questionnaire (MLHFQ) score, 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.

2.2 Research Objectives

(1)To evaluate the efficacy and safety of the Baduanjin exercise programme in patients following coronary revascularisation surgery;

(2)To develop a traditional Chinese medicine (TCM) rehabilitation protocol and evaluation system for patients following coronary revascularisation surgery;

(3)To clarify the advantages of TCM rehabilitation in the post-operative management of coronary revascularisation surgery and to provide high-level evidence-based medical evidence for TCM rehabilitation protocols.

2.3 Research Protocol

2.3.1 Sample Size Estimation

Based on previous literature and preliminary experimental results, the effective rate of standardized Western medical treatment combined with aerobic exercise is 72%, and the effective rate of standardized Western medical treatment combined with Baduanjin is 86%. With α=0.05, β=0.20 (power 80%), using the sample size formula for comparison of two proportions, the calculated required sample size is 132 cases per group. Considering a 15% dropout rate, the sample size is expanded to 155 cases per group, for a total recruitment of 310 patients.

$$n_1 = n_2 = \frac{\left[Z_{1-\alpha/2}\cdot\sqrt{2P(1-P)}+Z_{1-\beta}\cdot\sqrt{P_1(1-P_1)+P_2(1-P_2)}\right]^2}{(P_1-P_2)^2}$$

2.3.2 Randomized Controlled Design and Implementation

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, they will be randomly assigned 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. The experimental group receiving standardized Western medical treatment+standardized Baduanjin rehabilitation training and the control group receiving standardized Western medical treatment+aerobic exercise training will be compared. Efficacy endpoint evaluation will be collected and organized by personnel blinded to group assignment, implementing separation among investigators, operators, and statisticians. Study subjects are patients after coronary revascularization in the Cardiovascular Departments of the Third Affiliated Hospital of Zhejiang Chinese Medical University (Zhejiang Zhongshan Hospital), Jinhua Research Institute of Zhejiang Chinese Medical University, Zhejiang Provincial People’s Hospital,

Zhejiang Provincial Hospital of Chinese Medicine, and The First Affiliated Hospital of Zhejiang Chinese Medical University (Zhejiang Dongfang Hospital).

Prior to the start of the study, the investigator will clearly and colloquially explain the study details and its potential risks and benefits to the patient or their authorized representative. After obtaining consent, the patient or their authorized representative and the investigator will sign and date the informed consent form. Patients or their authorized representatives can only enter screening and subsequently participate in the study after signing the informed consent form.

Patients who sign the written informed consent form will then undergo assessment to determine whether they meet the study conditions:

(1)Patient demographic data;

(2)Patient vital signs, medical history, concomitant medications, allergy history;

(3)Patient procedural characteristics: radial/femoral artery approach, target vessel details (number, location), stent data (number, length, diameter), postoperative clinical intervention time.

2.3.3 Diagnostic Criteria

This study adopts the *2025 ACC/AHA/ACEP/NAEMSP/SCAI Guidelines for the Management of Acute Coronary Syndromes* and the *Percutaneous Coronary Intervention Treatment Guidelines (2025)* as the diagnostic criteria for coronary heart disease.

2.3.4 Inclusion Criteria

(1)Participants who meet the diagnostic criteria for coronary heart disease;

(2)Participants who have undergone successful PCI;

(3)Participants aged between 18 and 80;

(4)Participants of any gender;

(5)Participants who have signed an informed consent form.

2.3.5 Exclusion criteria

(1)Subjects with severe hepatic or renal impairment;

(2)subjects with severe electrolyte disturbances;

(3)subjects with severe haematological disorders or malignant tumours;

(4)pregnant or breastfeeding women;

(5)subjects with psychiatric disorders;

(6)subjects with cognitive impairment (e.g. dementia, post-stroke cognitive impairment) that prevents them from understanding or carrying out exercise instructions;

(7)Subjects scheduled to undergo repeat revascularisation surgery in the near future;

(8)Subjects with other severe cardiovascular diseases such as uncontrolled hypertension, angina pectoris, rapid arrhythmias, high-degree or complete atrioventricular block (without a pacemaker), acute severe aortic stenosis, decompensated heart failure (NYHA Class IV), deep vein thrombosis, obstructive hypertrophic cardiomyopathy, acute pericarditis or myocarditis, acute endocarditis, or acute aortic dissection;

(9)Participants with acute pulmonary embolism or chronic lung disease accompanied by symptoms of dyspnoea (occurring at rest or with minimal exertion);

(10)Subjects with impaired limb mobility or who are unable to move independently;

(11)Subjects with Shy-Drager syndrome;

(12)Subjects who have participated in a clinical trial involving other drugs or exercise interventions within the past month;

(13)Subjects deemed by the investigator to have other conditions rendering them unsuitable for participation in the trial.

2.3.6 Exclusion and Withdrawal Criteria

Exclusion Criteria: (1) Found during the trial not to meet the inclusion and exclusion criteria; (2) Occurrence of significant adverse reactions during treatment; (3) Subjects not treated according to the treatment protocol after enrollment. Note: Excluded cases should be documented, and their original medical records should be retained for reference. They will not be included in the efficacy statistical analysis, but those who received treatment at least once and have records may participate in the adverse reaction analysis.

Withdrawal Criteria: (1) Patient voluntary withdrawal or loss to follow-up; (2) Occurrence of severe adverse reactions or adverse events during treatment.

Note: Implemented in accordance with the Good Clinical Practice regulations (No. 57 Document, 2020).

2.3.7 Discontinuation Criteria

(1)Occurrence of severe adverse reactions during the study, to be evaluated by a specialist physician to determine whether to continue or terminate the study;

(2)Occurrence of severe complications or other serious diseases requiring emergency measures in the subject during the study period;

(3)Subjects with other reasons unable to continue the study.

2.3.8 Adverse Events

Detailed documentation of adverse events and the number of cases withdrawn from the trial and reasons.

2.3.9 Treatment Protocol

This project uses standardized Western medical treatment+aerobic exercise as the control and standardized Western medical treatment+Baduanjin as the experimental group for a randomized controlled design study on rehabilitation after coronary revascularization, to clarify the advantages of TCM rehabilitation in post-coronary revascularization treatment. Planned study duration: January 1, 2026-December 31, 2028. Treatment methods are detailed as follows.

2.3.9.1 Experimental Group (Standardized Western Medical Treatment+Standardized Baduanjin Rehabilitation Training)

Standardized Baduanjin Rehabilitation Training: Under the guidance of professional physicians or rehabilitation therapists, standardized Baduanjin training will be conducted. Training frequency: 4 times per week, following the General Administration of Sport of China Baduanjin standard version video. The standard Baduanjin session lasts 12 minutes, with 2 repetitions per training session. Supervision and guidance will be facilitated through WeChat groups, distribution of video materials, etc.

Subjects will receive online or offline guidance once a week and upload training videos. Throughout the entire study, all sessions will be regularly monitored and feedback will be received to ensure correct guidance.

2.3.9.2 Control Group (Standardized Western Medical Treatment+Aerobic Exercise Training)

Aerobic Exercise Training: Includes stair climbing, jogging, brisk walking, and cycling. The exercise intensity for the aerobic exercise group will be monitored, with maximum heart rate estimated as 208-(0.7*age).

Subjects will receive online or offline guidance once a week and upload training videos. Throughout the entire study, all sessions will be regularly monitored and feedback will be received to ensure correct guidance.

The total study duration is 48 weeks. The treatment period is 12 weeks, and the follow-up period is 48 weeks. Observation time points are: pretreatment baseline, Week 6, Week 12, Week 24, Week 36, and Week 48 (follow-up).

2.3.9.3 Efficacy Endpoints and Evaluation

(1)Primary Outcome Endpoint

Incidence of 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).

(2)Secondary Efficacy Endpoints

①TCM Syndrome Score: Compiled with reference to the *2021 Guidelines for Integrated Traditional Chinese and Western Medicine Diagnosis and Treatment of Angina Pectoris (Post-Coronary Revascularization)*. Scoring: None=0 points, Mild=1 point, Moderate=2 points, Severe=3 points. See table below.

Symptom/Sign Name	**None**	**Mild**	**Moderate**	**Severe**
Mental fatigue and lack of strength				
Shortness of breath				
Disinclination to speak				
Spontaneous sweating				
Palpitations				
Chest pain	□ Distending pain □ Stabbing pain □ Dull pain□ Other _____			
Dark purplish complexion/lips				
Scaly dry skin				
Chest oppression				
Epigastric fullness and poor appetite				
Body obesity				
Expectoration/phlegm rales in throat	□ Profuse sputum □ Scanty sputum Sputum color/quality _____ □ Other _____			
Heavy sensation in head as if swathed				
Aversion to cold and cold limbs				
Tidal fever and night sweating				
Dry mouth and throat				
Pale conjunctiva				
Severe bitter taste in				

mouth				
Emotional depression / tendency to sigh				
Urination and defecation				
Tongue body quality				
Tongue body shape				
Tongue body motility				
Tongue coating				
Sublingual collateral vessels				
Pulse condition	□ Deep pulse □ Wiry pulse □ Slippery pulse □ Thready pulse □ Choppy pulse □ Other _____			
Other symptoms				
Basic syndromes: □ Qi deficiency □ Yang deficiency □ Yin deficiency □ Blood deficiency □ Phlegm obstruction □ Blood stasis □ Heat toxin □ Qi stagnation □ Cold congealing □ Other _____				

②Echocardiography;

③Dynamic Electrocardiography;

④Minnesota Living with Heart Failure Questionnaire (MLHFQ);

⑤Myocardial Enzymes;

⑥Blood Lipids;

⑦Blood Glucose.

(3)General Information:

①Demographic Data: Including age, sex, marital status, height, weight, ethnicity;

②General Clinical Data: Vital signs, medical history, concomitant medications, allergy history;

③Procedural Characteristics: Radial/femoral artery approach, target vessel details (number, location), stent data (number, length, diameter), postoperative clinical intervention time;

(4)Safety Endpoints: Vital signs, complete blood count, hepatic and renal function, other adverse reactions and adverse events.

2.3.10 Emergency Management

During the trial, under the guidance of a specialist physician, if a patient experiences

disease exacerbation that cannot be relieved by existing treatment, severely affecting daily work and life, emergency treatment plan adjustments may be made after specialist physician evaluation and diagnosis, and the specialist physician will evaluate whether to discontinue the study. The date, time, and dosage of all emergency medications or other treatment measures used must be recorded promptly.

2.4 Research Timeline

(1)January 2026-June 2026: Finalize the research protocol and related inclusion/exclusion criteria, develop clinical information collection forms, complete standardized training for research personnel, undergo ethical review and clinical study registration.

(2)July 2026-June 2027: Complete enrollment of all subjects for the randomized controlled study and collect clinical data. Publish 1 paper and complete the interim report.

(3)July 2027-June 2028: Complete follow-up of the randomized controlled study, conduct clinical validation of the prognostic risk assessment model for post-revascularization patients in at least 3 medical institutions, with predictive accuracy reaching>85%.

(4)July 2028-December 2028: Based on the randomized controlled study results, develop at least 1 set of TCM rehabilitation treatment protocol and evaluation system; form at least 1 expert consensus. Publish 1 paper.

2.5 Key Issues to Be Addressed

(1)To verify the definitive efficacy and overall safety of Baduanjin in reducing the incidence of major adverse cardiovascular events in patients after coronary revascularization;

(2)To establish a standardized treatment protocol and comprehensive evaluation system for Baduanjin cardiac rehabilitation that integrates TCM syndrome assessment and modern objective indicators;

(3)To elucidate the relative advantages of Baduanjin compared to conventional aerobic exercise in improving patients' quality of life and regulating psycho-cardiological health, providing high-level evidence-based evidence for its TCM rehabilitation value.

3.Adverse Events

3.1 Definitions of Adverse Events and Serious Adverse Events

(1)Adverse Event: Any untoward medical event occurring in a subject from the time the informed consent form is signed until the last visit, regardless of whether it has a causal relationship with the trial intervention, shall be determined as an adverse event. Adverse events can be any unfavorable and unintended signs (including abnormal laboratory test

results), symptoms, or diseases temporally associated with the use of the treatment, regardless of whether they are causally related to the treatment.

Adverse events include the following:

-- All suspected adverse reactions;

-- All reactions resulting from overdose, abuse, withdrawal, allergy, toxicity, or “failure of expected pharmacological action of the drug”;

-- Unrelated illnesses, including exacerbation of pre-existing conditions;

-- Injuries or accidents. Note: If a medical condition is known to be capable of causing an injury or accident (e.g., a fall due to dizziness), then the medical condition (dizziness) and the accident (fall) should be reported as two distinct adverse events. The outcome of this accident (e.g., hip fracture caused by the fall) should be recorded in the remarks section.

-- Abnormalities in physical examination or laboratory tests necessitating further investigation (excluding repeat tests).

(2)Serious Adverse Event refers to an adverse event occurring during the study phase that meets one or more of the following criteria: Death; Life-threatening; Requires inpatient hospitalization or prolongation of existing hospitalization; Permanent or severe disability; Results in congenital anomaly/birth defect.

Some medical events that have not yet resulted in death, been life-threatening, or required hospitalization may, after appropriate medical judgment, be considered serious adverse events if they may jeopardize the subject or require drug or surgical treatment to prevent the occurrence of the above situations.

3.2 Collection of Adverse Event Information

The study physician shall report all adverse events directly observed by the physician or spontaneously reported by the subjects using concise medical terminology. Additionally, at each subsequent visit after treatment initiation when inquiring about the subject's condition to collect trial data, the subject must be asked about adverse events. A suitable question could be: “Have you had any health problems or discomfort since you started receiving XX treatment?”

3.3 Observation and Documentation of Adverse Events

This includes any symptoms, signs, and laboratory test abnormalities occurring from the signing of the informed consent form to the end of the last visit. Detailed descriptions of the adverse event occurrence, including time of occurrence, severity, duration, measures taken, and outcome, must be recorded. All adverse events should be documented in the designated adverse event form in the Case Report Form.

3.4 Management of Adverse Events and Serious Adverse Events

(1)Severity: The physician may use the following definitions to judge the severity of all adverse events and serious adverse events as study endpoints/data cutoff points.

Mild adverse events are transient and easily tolerated by the patient.

Moderate adverse events cause discomfort to the subject and interfere with the subject's normal activities.

Severe adverse events cause a considerable impact on the subject's daily activities and may result in functional impairment or be life-threatening.

(2)Management of Adverse Events: In the event of any adverse event during the clinical trial, regardless of whether there is a causal relationship with the treatment method used, the investigator shall take necessary measures to provide treatment and rescue. For adverse events occurring during the trial, their type, severity, time of occurrence, duration, management measures, and management process should be recorded in the inpatient medical records and Case Report Form, and a comprehensive analysis should be conducted to determine whether they are related to the trial intervention. After an adverse event, the investigator may decide whether the subject should terminate the clinical trial based on the condition. Cases terminated from the trial due to serious adverse events should be followed up, and their outcomes should be recorded.

(3)Recording and Reporting of Serious Adverse Events: In the event of a serious adverse event during the trial, regardless of whether it is related to the trial intervention, immediate emergency measures should be taken, and the principal investigator and ethics committee should be notified by telephone within 24 hours. A Serious Adverse Event Report Form should then be completed and promptly submitted to the above-mentioned departments.

4.Ethics and Quality

Approval from the ethics committee will be obtained prior to the initiation of this study.

Before enrolling patients, their authorized consent for the use and/or disclosure of personal and/or health data must be obtained. To protect patient privacy, patients' initials will be recorded on the CRF.

The consistency of case report form data collected from each research center will be checked, and data query forms will be issued for inconsistent data, requiring physicians to provide clarification.

5.Data Management

5.1 Completion and Transfer of Case Report Forms (CRF)

Completed case report forms will be reviewed by the clinical investigator and monitor, then submitted to the data statistics unit for data entry and management. All processes must be documented in the protocol.

5.2 Data Entry and Modification

Data entry and management will be the responsibility of the data manager from the statistics unit. Two data managers will independently perform double entry and verification.

For any queries regarding the case report forms, the data manager will complete a Data Query Form (DQF) and send inquiries to the investigator through the clinical monitor. The investigator should respond as soon as possible and return it. The data manager will then make data modifications, confirmations, and entries based on the investigator's responses, and may re-issue DQFs if necessary.

5.3 Database Locking

After a blinded review confirming the database is error-free, the principal investigator and statistical analysts will lock the database. If issues are discovered after database locking and confirmed, they can be corrected during the statistical analysis process, with documentation and explanation.

5.4 Unblinding

After all study data have been checked and the database locked, unblinding will occur, followed by statistical analysis according to the statistical analysis plan and the production of a statistical analysis report.

6.Statistical Analysis

6.1 Statistical Software

Statistical analysis of data will be performed by a third-party statistician not involved in the earlier stages of the trial, using statistical software such as SPSS 25.0.

6.2 Data Description

Measurement data will be described using mean ± standard deviation, median, maximum, minimum, and quartiles. Enumeration data will be expressed as percentages (%).

6.3 Statistical Methods

Unless otherwise specified, all statistical tests will use two-sided tests, and $P<0.05$ will be considered statistically significant for the tested differences. Comparisons of general characteristics among groups will be analyzed using appropriate methods based on the data type and distribution. For example: intergroup comparison of quantitative variables will use one-way analysis of variance (if homogeneity of variance and normal distribution are met) or

the Kruskal-Wallis rank sum test (if not normally distributed); qualitative variables will use the Chi-squared test or Fisher's exact test (if the Chi-squared test is not applicable); ordinal variables will use the Kruskal-Wallis rank sum test or the CMH test.

6.4 Statistical Analysis Plan

To be completed by professional statistical personnel. After all data are entered and reviewed, statistical personnel should complete the statistical analysis work in a timely manner and issue a written statistical analysis report.

7.Final Report and Publication

After the completion of the study, the research report will include a description of the research objectives, the methods used in the study, and the results and conclusions.

8.Quality Control

(1)A unified testing SOP will be developed by the research team.

(2)A dedicated training session will be held one month before the official commencement of the clinical trial to provide unified training for all researchers involved in the project. Training will primarily focus on the project implementation plan and various standard operating procedures (SOPs), ensuring each clinical researcher is familiar with the research processes and specific implementation rules, guaranteeing the reliability of the clinical research conclusions.

(3)All observations and findings in the clinical study should be verified and repeatedly confirmed to ensure data reliability and originality, ensuring that all results and conclusions in the clinical study are derived from original data.

(4)Dedicated personnel will be assigned for trial data collection and statistics to control trial bias. A professional data management company will be commissioned for clinical data management.

(5)Strictly implement monthly clinical research quality inspections.

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