Evaluation of Management Effectiveness of a Traditional Chinese Medicine Three-Level Prevention and Control Model for Patients with Coronary Heart Disease and Stroke: A Single-Center, Prospective Cohort Study Postprint

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Abstract

Background Cardiovascular and cerebrovascular diseases are the leading causes of death and disability worldwide, and their management models still face challenges of insufficient long-term intervention and limited comprehensive prevention and control effects. The Traditional Chinese Medicine (TCM) three-level prevention and control model provides patients with systematic, full-cycle management by constructing a multi-tiered "family-community-hospital" system, combined with health education, lifestyle interventions, and characteristic TCM techniques.

Objective To evaluate the management efficacy of the TCM three-level prevention and control model for patients with coronary heart disease and stroke, and to provide important scientific evidence for optimizing prevention and treatment strategies for cardiovascular and cerebrovascular diseases.

Methods A prospective single-arm cohort study method was adopted. From October to December 2020, 265 patients with non-acute coronary heart disease and stroke from Beichen District, Tianjin were enrolled. Through the TCM three-level prevention and control system of "patient-centered, village/community doctors as the main implementers, and specialists from tertiary TCM hospitals as the leaders", patients were provided with TCM health management measures including health education, lifestyle, risk factors, medication, and appropriate TCM technology management. The management and follow-up period was 1 year, with follow-ups conducted every 6 months. The management effectiveness was evaluated in terms of 1-year recurrence/aggravation rate, incidence of myocardial ischemia, Seattle Angina Questionnaire (SAQ) scores, National

Institutes of Health Stroke Scale (NIHSS) scores, cardiovascular and cerebrovascular disease prevention knowledge questionnaire scores, cardiovascular and cerebrovascular disease risk factor-related indicators, and lifestyle behavior-related indicators.

Results Among the 265 patients, there were 214 patients with coronary heart disease (193 with angina pectoris, 21 with a history of myocardial infarction or in a stable state after percutaneous coronary intervention) and 51 patients with stroke (all ischemic stroke), including 120 males and 145 females. At the end of the management period, 14 patients were lost to follow-up (4 with coronary heart disease and 10 with stroke), and ultimately 251 patients completed the study and were included in the results analysis. After 12 months of management, the recurrence/aggravation rate of patients with coronary heart disease and stroke decreased compared with baseline ($P<0.05$). In terms of coronary heart disease management, the incidence of myocardial ischemia at 12 months of management decreased compared with baseline ($P<0.05$), with the most significant effect observed at 6 months of management ($P<0.05$); the scores of physical activity limitation, angina stability, angina frequency, treatment satisfaction, and disease perception dimensions of the SAQ at 12 months of management all increased compared with baseline ($P<0.05$). In terms of stroke management, the NIHSS score at 12 months of management decreased compared with baseline ($P<0.05$). In terms of disease awareness, the cardiovascular and cerebrovascular disease prevention knowledge questionnaire scores of patients with coronary heart disease and stroke at 12 months of management increased compared with baseline ($P<0.05$). In terms of risk factor control related to coronary heart disease and stroke, the systolic blood pressure at 12 months of management decreased compared with baseline ($P<0.05$); there was no statistically significant difference in other indicators compared with baseline ($P>0.05$). In terms of lifestyle behavior improvement, the rates of sweet food preference, greasy food preference, and PSQI scores at 12 months of management decreased compared with baseline ($P<0.05$); there was no statistically significant difference in other lifestyle behavior indicators compared with baseline ($P>0.05$).

Conclusion The TCM health management based on the three-level prevention and control model demonstrates favorable management efficacy, can reduce the 1-year recurrence/aggravation rate in patients with coronary heart disease and stroke, help patients enhance disease awareness, improve unhealthy lifestyle habits, reduce related risk factors, stabilize patient conditions, and can improve the secondary prevention effect of cardiovascular diseases.

Full Text

Preamble

Evaluation of the Management Efficacy of the Traditional Chinese Medicine Three-Level Prevention and Control Model for Patients with Coronary Heart Disease and Stroke: A Single-Center, Prospec-

tive Cohort Study

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Abstract

Background: Cardiovascular and cerebrovascular diseases are the leading causes of death and disability worldwide. Current management models face challenges of insufficient long-term intervention and limited effectiveness of comprehensive prevention and control. The Traditional Chinese Medicine (TCM) three-level prevention and control model establishes a multi-tiered "family-community-hospital" system, combining health education, lifestyle intervention, and TCM-specific techniques to provide systematic, full-cycle management for patients. **Objective:** To evaluate the management effectiveness of the TCM three-level prevention and control model for patients with coronary heart disease and stroke, providing important scientific evidence for optimizing prevention and treatment strategies for cardiovascular and cerebrovascular diseases. **Methods:** A prospective single-arm cohort study was conducted, enrolling 265 non-acute coronary heart disease and stroke patients from Beichen District, Tianjin, between October and December 2020. Through a TCM three-level prevention and control system "centered on patients, with village/community physicians as the main executors and tertiary hospital specialists as the leaders," patients received comprehensive TCM health management measures including health education, lifestyle modification, risk factor control, medication management, and appropriate TCM techniques. The management and follow-up period was one year, with follow-up visits conducted every six months. Management effectiveness was evaluated in terms of 1-year recurrence and progression rates, myocardial ischemia incidence, Seattle Angina Questionnaire (SAQ) scores, National Institutes of Health Stroke Scale (NIHSS) scores, cardiovascular and cerebrovascular prevention knowledge questionnaire scores, cardiovascular and cerebrovascular disease-related risk factor indicators, and lifestyle behavior indicators. **Results:** Among the 265 patients, there were 214 coronary heart disease patients (193 with angina pectoris, 21 with

a history of myocardial infarction or in stable condition after percutaneous coronary intervention) and 51 stroke patients (all ischemic stroke), including 120 males and 145 females. By the end of the management period, 14 patients were lost to follow-up (4 coronary heart disease patients and 10 stroke patients), with 251 patients ultimately completing the study and included in the final analysis. After 12 months of management, the recurrence and progression rates of coronary heart disease and stroke patients decreased compared to baseline ($P<0.05$). In terms of coronary heart disease management, the incidence of myocardial ischemia at 12 months decreased compared to baseline ($P<0.05$), with the most significant effect observed at 6 months ($P<0.05$). Patients' scores in the SAQ dimensions of physical limitation, angina stability, angina frequency, treatment satisfaction, and disease perception all increased at 12 months compared to baseline ($P<0.05$). In stroke management, patients' NIHSS scores at 12 months decreased compared to baseline ($P<0.05$). Regarding disease awareness, the cardiovascular and cerebrovascular disease prevention knowledge questionnaire scores of coronary heart disease and stroke patients at 12 months increased compared to baseline ($P<0.05$). In terms of risk factor control for coronary heart disease and stroke, patients' systolic blood pressure at 12 months decreased compared to baseline ($P<0.05$); no statistically significant differences were observed in other indicators compared to baseline ($P>0.05$). In terms of lifestyle behavior improvement, the rates of preference for sweet foods, preference for oily foods, and PSQI scores at 12 months decreased compared to baseline ($P<0.05$); no statistically significant differences were observed in other lifestyle behavior indicators compared to baseline ($P>0.05$). **Conclusion:** TCM health management based on the three-level prevention and control model demonstrates favorable management efficacy, reducing the 1-year recurrence and progression rates of coronary heart disease and stroke patients, helping patients enhance disease awareness, improve unhealthy lifestyle habits, and reduce related risk factors, stabilizing patients' conditions and improving the effectiveness of secondary prevention for cardiovascular diseases. **[Keywords]** Coronary disease; Stroke; TCM three-level prevention and control model; Management effectiveness; Cohort study

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Cardiovascular and cerebrovascular diseases are the leading causes of death and disability worldwide. According to World Health Organization statistics, these diseases cause more than 17 million deaths annually, accounting for 31% of total global mortality [1]. In China, the incidence and mortality of cardiovascular and cerebrovascular diseases are also increasing year by year. According to the "China Cardiovascular Disease Report 2020," the number of patients with cardiovascular and cerebrovascular diseases in China has reached 330 million, imposing a tremendous burden on national medical resources and socioeconomic development [2]. Against this severe backdrop, exploring effective strategies for preventing and managing cardiovascular and cerebrovascular diseases is particularly important. These diseases represent advantageous therapeutic domains for TCM prevention and control. However, current research primarily focuses

on acute-phase interventions and drug therapies, with insufficient investigation into long-term management, recurrence risk control, and comprehensive intervention models, particularly lacking systematic exploration that integrates the advantages of TCM and modern medicine. The TCM concept of "preventing disease before it occurs" aligns highly with modern three-level prevention strategies. Through early intervention and full-cycle management, TCM can effectively reduce or delay the occurrence and progression of cardiovascular and cerebrovascular events [3]. Nevertheless, existing studies mostly evaluate single therapies and lack scientific validation of comprehensive management models. This study aims to evaluate the management effectiveness of the TCM three-level prevention and control model for two major types of cardiovascular and cerebrovascular diseases (coronary heart disease and stroke), thereby providing scientific evidence for the application of TCM in the prevention and treatment of these conditions.

1 Subjects and Methods

This was a single-center, prospective, single-arm cohort study. The study was approved by the Clinical Trial Ethics Committee of the Second Affiliated Hospital of Tianjin University of Traditional Chinese Medicine (ethics approval number: 2020-011-01) and registered with the Chinese Clinical Trial Registry (registration number: ChiCTR2000039187).

1.1 Study Subjects

The study enrolled non-acute coronary heart disease and stroke patients from Beichen District, Tianjin, between October and December 2020. Prior to enrollment, community physicians from various community health service centers conducted initial screening according to coronary heart disease and stroke diagnostic criteria and the study' s inclusion and exclusion standards. Patients who passed the initial screening were scheduled to visit Xititou Community Health Service Center in Beichen District, Tianjin, under unified arrangements by the research team. Tertiary hospital physicians with associate senior or higher professional titles from the research team conducted secondary screening based on patient symptoms and signs, disease descriptions, and relevant medical records. Patients who met the enrollment criteria and signed informed consent forms underwent baseline data collection by research personnel.

1.1.1 Western Diagnostic Criteria Coronary heart disease diagnosis had to meet one or more of the following criteria: (1) previous coronary angiography or coronary CT angiography (CTA) showing single or multiple coronary artery stenosis $ $50%; (2) definite history of old myocardial infarction; (3) having undergone coronary revascularization treatment (stent implantation or coronary artery bypass grafting) [4]. Clinical subtypes of coronary heart disease mainly included stable angina, unstable angina, myocardial infarction, and ischemic cardiomyopathy (coronary heart disease with heart failure). Diagnostic

criteria for relevant diseases referred to the "Guidelines for the Diagnosis and Treatment of Chronic Stable Angina" [4], "Guidelines for the Diagnosis and Treatment of Unstable Angina and Non-ST-segment Elevation Myocardial Infarction" [5], "Guidelines for the Diagnosis and Treatment of Acute Myocardial Infarction with Integrated Traditional Chinese and Western Medicine" [6], and the "Chinese Guidelines for the Diagnosis and Treatment of Heart Failure 2018" [7]. Stroke and its clinical subtypes included ischemic (cerebral infarction) and hemorrhagic (cerebral hemorrhage) types. Diagnostic criteria for cerebral infarction referred to the "Chinese Guidelines for the Diagnosis and Treatment of Cerebral Infarction with Integrated Traditional Chinese and Western Medicine (2017)" [8], and diagnostic criteria for cerebral hemorrhage referred to the "Chinese Guidelines for the Diagnosis and Treatment of Cerebral Hemorrhage (2014)" [9].

1.1.3 Patient Inclusion Criteria

(1) Met diagnostic criteria for coronary heart disease [stable angina, patients with definite history of myocardial infarction or in stable condition for $ $1 month after acute coronary syndrome treatment (post-stent implantation or coronary artery bypass grafting)], or stroke (ischemic or hemorrhagic) related diseases; (2) previously diagnosed with coronary heart disease or stroke by a hospital at or above the secondary level; (3) in stable disease phase or sequelae period, able to cooperate in completing questionnaires, blood tests, physical examinations, and follow-up; (4) age $ $18 years; (5) informed consent and voluntary participation. Patients meeting all five criteria could be included.

1.1.4 Patient Exclusion Criteria

(1) Coronary heart disease or stroke patients in acute/critical condition unable to complete relevant investigations or blood tests; (2) history of mental illness, cognitive dysfunction, communication barriers, or non-cooperation; (3) patients with major diseases such as malignant tumors or life expectancy <1 year; (4) estimated poor compliance during the management period; (5) currently participating in other management programs. Patients meeting any of the above four criteria were excluded.

1.1.5 Patient Withdrawal (Dropout) Criteria

(1) Patients who voluntarily withdrew or were lost to contact; (2) patients unable to continue cooperating in chronic disease management due to disease changes or other reasons; (3) patients who missed two follow-up visits during the management period; (4) other situations deemed appropriate by researchers; (5) deceased patients. Patients meeting any of the above five criteria were considered withdrawn or dropped out.

Sample size calculation was based on references [12-13], targeting a 90% effective

rate after intervention with 80% as the lower acceptable limit. With α=0.025 (one-sided), β=0.20, P_0=0.80, P=0.90, Z_1 α=1.96, Z_1 β=0.84, δ=0.10, the formula n=[(Z_1 $\alpha/_2$×P_0×(1-P_0)+Z_1 β×P_0×(1-P))/δ]^2 yielded n=107. With two disease types included, total sample size n=107$×$2=214. Considering a 20% dropout rate, the total sample should be no less than 257 cases.

1.2 TCM Three-Level Prevention and Control Model

Under the unified guidance of the research team, management was conducted according to the "Service Specifications for TCM Health Management Three-Level Prevention and Control of Cardiovascular and Cerebrovascular Diseases" compiled by the research team and published by the China Association of Chinese Medicine [14], as well as relevant intervention technical standards including the "Guidelines for TCM Health Management of Stable Angina," "Guidelines for TCM Health Management of Myocardial Infarction," "Guidelines for TCM Health Management of Heart Failure," "Guidelines for TCM Health Management of Cerebral Infarction," and "Guidelines for TCM Health Management of Cerebral Hemorrhage" [15]. The TCM three-level prevention and control system emphasizes "patient-centered, community physicians as the main executors, and tertiary hospital specialists as the leaders." At the patient level, daily self-management such as lifestyle adjustment and disease information feedback is emphasized, suitable for stable low-risk patients. Community health service institutions, as the execution level, are mainly responsible for establishing health records, health education, regular follow-up, and basic interventions under the guidance of tertiary hospitals, suitable for medium-risk patients requiring regular management. Tertiary hospitals serve as the leading level, responsible for diagnosis and treatment of complex cases, risk assessment, and formulation of personalized treatment plans, suitable for high-risk or acute-phase patients. Upward referral is primarily due to acute disease exacerbation or poor community management effects, while downward management applies to patients whose conditions have stabilized after treatment and can be transferred from hospital to community or family to reduce medical resource burden. The implementation process is shown in Figure 1 [Figure 1: see original paper], with specific protocols as follows.

1.2.1 Establishing TCM Health Records Content includes: general information, past medical history, allergy history, personal history, marital and menstrual history, family history, present illness, physical examination, laboratory tests, TCM syndrome patterns, pattern elements, TCM constitution, four-season climate information, and disease recurrence or exacerbation conditions (including unstable angina hospitalization, coronary revascularization, acute myocardial infarction, heart failure, ischemic stroke, cardiovascular death, other disease hospitalizations, any death, adverse reactions, etc., recording onset time, duration, precipitating factors, and intervention status).

1.2.2 Disease Status Monitoring Disease status monitoring for coronary heart disease and stroke patients includes regular monitoring and daily monitoring. (1) Regular monitoring content includes lifestyle improvement in personal history, medication/non-pharmacological treatment status, present illness, past medical history, physical examination (cardiac examination, neurological examination), laboratory tests (blood/urine/stool routine, liver and kidney function, blood glucose/lipids, coagulation indicators, electrolytes), electrocardiogram, TCM syndrome patterns, TCM constitution, and disease recurrence or exacerbation. Monitoring is conducted once every six months. (2) Daily monitoring refers to patients being able to contact community physicians for diagnosis and treatment whenever they experience discomfort during the management period. Community physicians assess patient conditions, record sudden changes in symptoms and signs, conduct risk assessments (Tables 1, 2), provide targeted interventions (basic treatment/referral/consultation, etc.), with monitoring content including blood pressure, heart rate, electrocardiogram, cardiac enzymes, carotid ultrasound, and TCM syndrome elements.

1.2.3 TCM Health Management Intervention The TCM health management protocol for coronary heart disease and stroke patients embodies the TCM "preventing disease progression" and "preventing recurrence after recovery" concepts of preventive treatment. In terms of regular management, tertiary hospital physicians conduct systematic assessments every six months and provide individualized treatment prescriptions, supervising community physicians' implementation of chronic disease management. For daily management, community physicians, under the guidance of tertiary hospital specialists, conduct routine health management based on established TCM three-level prevention and control service specifications and intervention technical standards, focusing primarily on medication therapy supplemented by exercise, psychological, dietary, smoking cessation, and other lifestyle interventions and risk factor control.

(1) **Lifestyle Intervention.** Individualized lifestyle guidance is provided based on patient conditions, including smoking cessation, alcohol limitation, weight control, emotional regulation, dietary adjustment (low-salt, low-sugar, low-fat diet, advocating medicinal food therapy), daily routine regulation, TCM exercise health care (Tai Chi, Baduanjin, etc.), and music therapy (five-element music). Building upon Western interventions for smoking cessation, alcohol limitation, and weight control, TCM-specific interventions are emphasized, including emotional regulation, diet, daily routine, and TCM health exercises. Key emphases include: **Exercise Management:** Develop individualized treatment goals and progressive exercise plans, incorporating traditional TCM exercises such as Tai Chi and Baduanjin. During exercise, intensity should be closely monitored. TCM methods such as "knocking teeth" and "guiding and swallowing saliva" may also be selected. **Emotional Management:** Emotional management for coronary heart disease and stroke should run through

the entire disease management process. Assess patients' mental and psychological status, understand their concerns about the disease, living environment, economic status, and social support, and provide targeted treatment measures. Conduct health education and counseling through one-on-one or group interventions, encouraging participation of patients' partners, family members, and friends. Identify and address patients' mental and psychological problems. **Sleep Management:** Maintain regular daily routines and adequate sleep. Advocate adjusting the body according to the waxing and waning patterns of the four seasons, arranging sleep time appropriately to harmonize the body with natural changes. **Dietary Management:** Assess patients' dietary habits and nutritional structure, daily energy intake, and proportions of saturated fat, salt, and other nutrients in the diet, guiding patients and families to develop healthy eating habits. The "spleen and stomach" are considered the foundation of postnatal health, requiring protection. Maintain spleen and stomach health through dietary adjustment. TCM dietary therapy recommendations should combine TCM constitution identification results to provide individualized syndrome-based dietary plans. For example, balanced qi and blood regulation for balanced constitution, qi supplementation and spleen strengthening for qi deficiency constitution, and warming spleen and kidney for yang deficiency constitution.

(2) **Risk Factor Control.** The development of coronary heart disease and stroke is inseparable from risk factors such as hypertension, diabetes, and dyslipidemia, which have mutual influencing relationships. For blood pressure management, guidance focuses on rational use of five major classes of antihypertensive drugs [angiotensin-converting enzyme inhibitors (ACEI), angiotensin receptor blockers (ARB), β-blockers, calcium channel blockers (CCB), diuretics]. ACEI and ARB can delay myocardial and renal damage and are recommended for patients with proteinuria or diabetic nephropathy; CCB drugs are suitable for elderly patients with isolated systolic hypertension, while β-blockers are suitable for post-myocardial infarction patients with heart failure but contraindicated in bradycardia or sick sinus syndrome. Blood pressure control targets are adjusted based on coronary heart disease/stroke recurrence risk stratification and age: <140/90 mmHg for high-risk populations (1 mmHg=0.133 kPa), stepwise reduction to <140/90 mmHg for elderly aged 65-79 (if tolerated), and <150/90 mmHg for those $ $80 years. For glucose management, strict control of glycated hemoglobin (HbA1c) levels is required, with a target of <7% but individualized adjustment to avoid hypoglycemia risk; insulin or oral hypoglycemic therapy must be combined with dietary intervention and self-monitoring of blood glucose (SMBG), ensuring fasting glucose control within 4.4-7.0 mmol/L to reduce recurrence and complication risks. Lipid management is stringent for coronary heart disease and stroke patients, with dietary therapy and lifestyle improvement as fundamental measures. Regardless of whether drug lipid-lowering therapy is

selected, dietary control and lifestyle improvement must be maintained. Daily physical exercise and weight control are recommended, along with low-fat diets. Drug therapy primarily recommends statins, with ezetimibe added if targets are not met, and proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitors added if still not 达标. Low-density lipoprotein cholesterol (LDL-C) should be reduced to $ $1.80 mmol/L. For those with high baseline LDL-C who cannot reach targets, consider reducing LDL-C by at least 50% as an alternative goal; for very high-risk patients with 达标 baseline LDL-C, still reduce by approximately 30% from baseline.

(3) **Medication Intervention.** Coronary heart disease treatment drugs mainly include those improving prognosis (such as antiplatelet, lipid-lowering, β-blockers, ACEI or angiotensin II receptor antagonists) and anti-myocardial ischemia drugs (nitrates, calcium channel blockers, potassium channel openers, If current blockers, cardiac metabolic drugs). Standardized Western medicine treatment for stroke mainly includes antithrombotic therapy (antiplatelet aggregation for non-cardiogenic cerebral infarction, anticoagulation for cardiogenic cerebral infarction), statins for lipid regulation, improvement of cerebral blood circulation, neuroprotection, and complication management.

(4) **TCM Syndrome-Based Intervention.** For coronary heart disease: Xuefu Zhuyu Decoction, Xuefu Zhuyu Capsules, Compound Danshen Dripping Pills, or Xin Ke Shu Tablets may be recommended for qi stagnation and blood stasis syndrome; Gualou Xiebai Banxia Decoction or Danlou Tablets for phlegm turbidity obstruction syndrome; Danggui Sini Decoction or Guanxin Suhe Pills for cold congealing in the heart meridian syndrome; Qishen Yiqi Dripping Pills or Yangxinshi Tablets for qi deficiency and blood stasis syndrome; Shengmai Powder or Shensong Yangxin Capsules for qi and yin deficiency syndrome. For stroke patients: Banxia Baizhu Tianma Decoction combined with Taoren Honghua Decoction modifications for wind-phlegm obstructing the collaterals syndrome; Huatan Tongluo Decoction modifications for phlegm-stasis obstructing the collaterals syndrome; Buyang Huanwu Decoction modifications for qi deficiency and blood stasis syndrome. Specific treatment may refer to syndrome differentiation and treatment protocols recommended in the "Guidelines for Prevention and Treatment of Cardiovascular and Cerebrovascular Diseases" [15]. Actively promote the use of appropriate TCM techniques. For coronary heart disease patients, commonly used acupuncture points include Neiguan (PC6), Danzhong (CV17), Taiyuan (LU9), and Kongzui (LU6); commonly used moxibustion points include Xinshu (BL15), Jueyinshu (BL14), Danzhong (CV17), and Neiguan (PC6); commonly used acupoint plaster points include Neiguan (PC6), Danzhong (CV17), and Xinshu (BL15), with blood-activating and pain-relieving TCM plasters as the medication. For stroke patients, commonly used acupuncture points include Neiguan (PC6), Shuigou (GV26), Yintang (EX-HN3), Sanyinjiao (SP6), Xiajiquan, Chize (LU5),

Weizhong (BL40), Renying (ST9), Hegu (LI4), Taichong (LR3), Zusanli (ST36), and Quchi (LI11); auricular point pressure mainly selects blood pressure-lowering points, Shenmen, heart points, cardiovascular subcortex, and liver points.

1.2.4 Health Education Health education for coronary heart disease and stroke patients primarily involves community physicians, under the guidance of tertiary hospitals, disseminating disease management knowledge to patients and families, including lifestyle intervention, rational medication use, and appropriate TCM techniques, aiming to improve patients' self-management abilities and treatment compliance to achieve effective risk factor control and improved quality of life. Educational methods include providing health education materials, setting up health education bulletin boards, conducting public health consultation activities, organizing health knowledge lectures, and implementing individualized health education. Meanwhile, tertiary hospitals are responsible for developing health education content and annual plans, and training and supervising community physicians to ensure the scientific validity and standardization of educational content.

1.2.5 Two-Way Referral Patients with worsening or acute onset of coronary heart disease or stroke-related clinical manifestations, or those with poor community management effects—such as increased angina frequency, worsening chest pain, prolonged duration, recurrent episodes, poor nitroglycerin relief effect, reduced exercise tolerance, with or without ECG ST-segment depression; or acute onset presenting as chest pain with new left or right bundle branch block, dynamic ST-segment changes, obvious heart failure symptoms, or combined severe arrhythmia, unexplained syncope, or hemodynamic instability; or suspected cerebral infarction using the "Stroke 1-2-0" method—should be immediately referred to higher-level hospitals. When patients' conditions remain continuously stable after treatment and recurrence risk assessment is low-risk, management can be transferred from community to family. Family management conditions include: patients and families possess basic disease monitoring and self-management abilities, can contact community physicians as needed through electronic platforms or phone; regular assessments show lifestyle intervention goals are achieved (such as blood pressure, glucose, and lipid targets). At this point, family management focuses primarily on daily lifestyle maintenance and health behavior consolidation, while community physicians provide regular follow-up and remote support.

1.2.6 Quality Control 1.2.6.1 Strengthening Infrastructure. To better conduct the application research of the TCM three-level prevention and control model for coronary heart disease and stroke, ensure and promote the construction of TCM three-level prevention and control demonstration bases, hardware and software facilities such as filing cabinets, health education bulletin boards, cardiovascular and cerebrovascular disease TCM health education

manuals, TCM constitution identification forms, TCM syndrome scoring scales, and coronary heart disease and stroke integrated Chinese-Western medicine screening models and risk assessment forms were configured based on existing community equipment (such as sphygmomanometers and ECG machines) and actual work requirements of base construction.

1.2.6.2 Improving Operational Mechanisms. (1) A working group for coronary heart disease and stroke TCM three-level prevention and control was established, including cardiovascular and cerebrovascular specialists, general practitioners from community health service centers and stations, public health physicians, and chronic disease management nurses, primarily responsible for daily management, health education, and organizing physical examinations of cardiovascular and cerebrovascular patients. (2) Clarifying responsibilities at three levels: For patients: actively participate in cardiovascular and cerebrovascular disease knowledge lectures regularly organized by village doctors, community physicians, and specialists; complete regular physical examinations and follow-up; proactively inform village doctors/specialists of disease changes; seek medical attention for any discomfort. For community physicians: actively participate in diagnosis and treatment technical training organized by tertiary hospital specialists (including TCM constitution identification, syndrome determination, and appropriate TCM techniques such as moxibustion, auricular points, massage, and cupping); assist specialists in daily follow-up, diagnosis, and management of patients under their jurisdiction; complete health education and consultation tasks; conduct follow-up including phone follow-up (at least once monthly) and home/outpatient appointment follow-up (at least once every three months), maintaining follow-up records. For tertiary hospital specialists: actively participate in technical training classes and academic exchanges organized by higher-level units to further improve their own specialized diagnosis and treatment levels; promote the 下沉 of high-quality medical resources; regularly visit community health service centers to conduct diagnosis and treatment technical training for community physicians to further improve their service capabilities for chronic disease patients; conduct physical examinations for managed populations every six months, inquire about disease changes, adjust patient medication plans, and supervise community physicians' chronic disease management implementation. (3) Scientific and reasonable training: cardiology specialists provide training on the "Service Specifications for TCM Health Management Three-Level Prevention and Control of Cardiovascular and Cerebrovascular Diseases" [14] to community physicians and medical staff assisting in management. Training content is demand-oriented and combined with urgent needs of community physicians in frontline work, mainly including Chinese-Western medicine diagnosis and treatment techniques, guidelines, chronic disease management service processes, and coronary heart disease and stroke risk assessment and high-risk factor identification mentioned in the specifications.

1.3 Observation Indicators

All observation indicators were evaluated at enrollment, 6 months, and 12 months of management.

1.3.1 Primary Efficacy Indicators

(1) **Recurrence and Progression Rate.** Coronary heart disease recurrence and progression were defined by clinical manifestations of angina symptoms and ischemic ST-T changes on ECG during chest pain episodes, including patients who died due to coronary heart disease recurrence during follow-up. Stroke recurrence and progression referred to the Sacco criteria: patients develop new neurological deficit symptoms and signs on the same or opposite side after improvement or disappearance of original deficits; recurrent stroke also includes patients who died due to stroke recurrence during follow-up; new lesions found on cranial CT or MRI (same or opposite side) [16-19]. Recurrence and progression rate = (number of recurrence and progression cases / total number of cases) × 100%.

(2) **Myocardial Ischemia Incidence.** Myocardial ischemia was defined as: resting ECG showing flat or inverted T waves with horizontal ST-segment depression $ $0.05 mV, or pathological Q waves [20].

(3) **Seattle Angina Questionnaire (SAQ)** [21]: SAQ is a standardized tool for quantitatively assessing angina symptoms and their impact on quality of life in coronary heart disease patients, with high sensitivity and reliability/validity. The questionnaire contains five independent dimensions: physical limitation, angina stability, angina frequency, treatment satisfaction, and disease perception, with 19 items total. Each dimension is scored separately from 0-100, with higher scores indicating milder symptoms, less life limitation, or greater treatment satisfaction. SAQ is widely used in clinical trials and chronic coronary heart disease management as an indicator for evaluating disease management effectiveness and quality of life.

(4) **National Institutes of Health Stroke Scale (NIHSS)** [22]: NIHSS is an internationally recognized tool for assessing neurological functional deficits in stroke patients, widely used for functional impairment evaluation and prognosis judgment in acute stroke patients. The scale includes 15 assessment items covering level of consciousness, visual fields, facial palsy, motor arm and leg, aphasia, dysarthria, and inattention/neglect, with total scores ranging from 0-42: 1-4 indicates mild, 5-15 moderate, 16-20 moderate-severe, and >20 severe. NIHSS can dynamically reflect disease changes and provides important basis for clinical management and treatment effect evaluation.

1.3.2 Secondary Efficacy Indicators

(1) **Cardiovascular and Cerebrovascular Disease Prevention Knowledge Score:** The questionnaire was developed by the research team based on preliminary surveys, the "Guidelines for Prevention and Treatment of Cardiovascular and Cerebrovascular Diseases," and practical problems in chronic disease management, aiming to evaluate patients' understanding of cardiovascular and cerebrovascular disease prevention knowledge and mastery of chronic disease-related health behaviors and medication principles. The questionnaire includes 21 questions covering risk factors, unhealthy lifestyles, diagnostic criteria for hypertension and diabetes, monitoring principles for blood lipids and pressure, emergency knowledge, and appropriate TCM techniques. Question types include single-choice and multiple-choice questions, with 1 point for each correct single-choice answer and 1 point for each correct option in multiple-choice questions, 0 points for incorrect or "don' t know" responses. Higher total scores indicate better knowledge mastery.

(2) **Cardiovascular and Cerebrovascular Disease-Related Risk Factors**, including blood pressure, blood lipid, and blood glucose indicators.

(3) **Lifestyle Behavior Indicators**, including smoking, alcohol consumption, preference for salty foods, preference for sweet foods, preference for oily foods within six months, and Pittsburgh Sleep Quality Index (PSQI) [23]. Preference for salty foods defined as salt intake >6 g/d, preference for sweet foods as sugar intake >50 g/d, and preference for oily foods as cooking oil intake $ $30 g/d. PSQI is a standardized tool for assessing individual sleep quality, comprehensively quantifying patients' sleep status over the past month across seven dimensions: subjective sleep quality, sleep latency, sleep duration, sleep efficiency, sleep disturbances, use of sleep medication, and daytime dysfunction. Scores range from 0-21, with higher scores indicating worse sleep quality and >5 suggesting possible sleep disorders.

1.4 Statistical Methods

SPSS 26.0 statistical software was used for data analysis, with a two-sided test significance level set at $P<0.05$. Count data are expressed as relative numbers. For measurement data, normally distributed data are expressed as ($\bar{x}\pm s$), while non-normally distributed data are expressed as $M(P_{25}, P_{75})$. For repeated measurement data, generalized estimating equations (GEE) were used for analysis. The study primarily analyzed the final follow-up results after 12 months of management, with 6-month interim visit results as supplementary reference to comprehensively evaluate short-term and long-term intervention effects.

2 Results

2.1 Patient Enrollment and Completion

A total of 265 patients were ultimately enrolled, including 214 coronary heart disease patients [193 with angina pectoris, 21 with history of myocardial infarction or in stable condition after percutaneous coronary intervention (PCI)] and 51 stroke patients (all ischemic stroke). By the end of the management period, 14 patients were lost to follow-up (4 coronary heart disease patients and 10 stroke patients), with 251 patients completing the study and included in the final analysis.

Among the 265 patients, 120 (45.28%) were male and 145 (54.72%) were female; mean age was (65.4\$±12.5)$years; medianBMIwas25.2(22.8, 27.6)kg/m^{2}$; 98.87% (262/265) were Han Chinese; 90.57% (240/265) were married; 60.0% (159/265) had primary school education; 35.09% (93/265) were retired/unemployed; 72.45% (192/265) had annual family income <30,000 RMB; 81.13% (215/265) had new rural cooperative medical insurance; 74.72% (198/265) regularly visited township health centers/community health service institutions; 80.00% (196/265) had hypertension, 51.43% (126/265) had diabetes, and 18.37% (45/265) had hyperlipidemia. For TCM syndrome patterns, coronary heart disease patients were mainly qi and yin deficiency syndrome [34.58% (74/241)], while stroke patients were mainly qi deficiency and blood stasis syndrome [56.86% (29/51)], as shown in Table 3 .

2.3.1 Primary Efficacy Indicators

(1) **Recurrence and Progression Rate.** The 12-month recurrence and progression rate of coronary heart disease and stroke patients was lower than baseline, with statistically significant difference (P<0.05), as shown in Table 4 .

(2) **Myocardial Ischemia Incidence.** The incidence of myocardial ischemia in coronary heart disease and stroke patients decreased at 12 months of management, with the most significant effect observed at 6 months (P<0.05), as shown in Table 5 .

(3) **SAQ Scores.** The scores of physical limitation, angina stability, angina frequency, treatment satisfaction, and disease perception dimensions of SAQ in coronary heart disease patients increased at 12 months compared to baseline, with statistically significant differences (P<0.05), as shown in Table 6 .

(4) **NIHSS Scores.** The NIHSS scores of stroke patients decreased at 12 months compared to baseline, with statistically significant difference (P<0.05), as shown in Table 7 .

2.3.2 Secondary Efficacy Indicators

(1) **Cardiovascular and Cerebrovascular Disease Prevention Knowledge.** The knowledge questionnaire scores of coronary heart disease and stroke patients increased at 12 months compared to baseline, with statistically significant difference (P<0.05), as shown in Table 8 .

(2) **Risk Factors.** Systolic blood pressure of coronary heart disease and stroke patients decreased at 12 months compared to baseline, with statistically significant difference (P<0.05). No statistically significant differences were observed in other blood pressure, blood glucose, or blood lipid indicators compared to baseline (P>0.05), as shown in Table 9 .

(3) **Lifestyle Behaviors.** The rates of preference for sweet foods, preference for oily foods, and PSQI scores of coronary heart disease and stroke patients decreased at 12 months compared to baseline, with statistically significant differences (P<0.05). No statistically significant differences were observed in other lifestyle behavior indicators compared to baseline (P>0.05), as shown in Table 10 .

Cardiovascular diseases are characterized by high incidence, high mortality, and heavy economic burden, representing major chronic diseases that seriously threaten human health and have become urgent public health problems requiring solutions in China and globally. Over the past 30 years, clinical technical service capabilities in Chinese hospitals have rapidly improved, with significant progress in in-hospital treatment of cardiovascular diseases. However, hospital-based technological advances have not changed the epidemiological status or disease burden of cardiovascular diseases in China. With continuous population growth, accelerated aging and urbanization, and rising prevalence of cardiovascular disease-related risk factors (such as hypertension, diabetes, dyslipidemia, and overweight/obesity), cardiovascular disease prevention and control in China is facing increasingly severe challenges, with no inflection point in disease burden decline yet observed [1-2]. Developed countries have achieved an inflection point in reducing cardiovascular disease mortality through continuous exploration and improvement of chronic disease prevention and control models. Since China launched the "Shougang Model" in 1972, certain achievements have been made in cardiovascular disease prevention and control, but problems remain, including insufficient emphasis on primary prevention and inadequate secondary prevention [3]. With the strategic policy of "focusing on prevention and emphasizing the grassroots," China' s cardiovascular disease prevention and control should shift from past emphasis on scale growth to high-quality development at strategic and key technical levels, aiming to achieve "center of gravity 下沉" and "gateway forward movement" in cardiovascular disease prevention and control, thereby curbing the growth of cardiovascular disease incidence and mortality.

Cardiovascular diseases are advantageous therapeutic domains for TCM prevention and treatment. TCM has a complete theoretical and therapeutic system and possesses certain advantages in chronic disease prevention and control. How-

ever, TCM has not been widely popularized in chronic disease prevention and control, and its advantages have not been fully demonstrated. The "Healthy China Action (2019-2030)" emphasizes strengthening research on TCM prevention and treatment of advantageous diseases, enhancing integrated Chinese and Western medicine, and improving clinical efficacy for major difficult diseases and critical conditions. By 2030, TCM's leading role in "preventing disease," its synergistic role in major disease treatment, and its core role in disease rehabilitation should be fully realized [24]. Based on this, this study summarized previous cardiovascular disease management experience and established a "family-community-hospital" three-level prevention and control system "centered on patients, with community physicians as executors and tertiary hospital specialists as leaders" to implement TCM health management for non-acute coronary heart disease and stroke patients and evaluate management efficacy, providing reference for establishing TCM health management models for major chronic non-communicable diseases.

This single-arm cohort study of 265 coronary heart disease and stroke patients evaluated the effectiveness of the TCM three-level prevention and control model. Results demonstrated that the TCM three-level prevention and control model has definite effects in reducing cardiovascular event recurrence rates and improving quality of life. However, several issues warrant further discussion. First, the study showed that TCM chronic disease management significantly reduced the 1-year cardiovascular event recurrence and progression rates and improved patients' mastery of cardiovascular and cerebrovascular disease prevention knowledge. However, improvements in lifestyle behaviors such as smoking and alcohol consumption were not significant, possibly related to patients' long-standing habits and dependencies that are difficult to change completely even after intervention. Second, although TCM chronic disease management reduced blood pressure levels to some extent, no significant effects were observed on blood glucose and lipid indicators, possibly because TCM treatment effects require longer time to manifest while this study's follow-up period was relatively short. Additionally, individual differences may lead to varying treatment effects. Future research should consider extending follow-up duration and expanding sample size for more comprehensive evaluation of long-term TCM effects. Third, regarding dietary habit improvement, although the proportions of patients preferring sweet and oily foods decreased significantly compared to baseline, preference for salty foods showed little change, possibly related to patients' dietary preferences and regional eating habits, requiring more personalized interventions.

The unique advantages of TCM in coronary heart disease and stroke prevention and treatment lie in its "preventing disease before it occurs" concept, which can effectively reduce first-time and recurrent cardiovascular events through early intervention and full-cycle management. TCM emphasizes holistic concepts and syndrome differentiation and treatment, improving patients' self-management abilities and quality of life through individualized comprehensive regulation [3]. For example, this study's comprehensive TCM intervention significantly improved patients' sleep quality, demonstrating TCM's positive role in enhanc-

ing quality of life. Additionally, TCM non-pharmacological therapies such as acupuncture, massage, and health exercises play important roles in improving patients' psychological status and lifestyle habits. These therapies can not only relieve anxiety and depression but also regulate the internal environment and reduce cardiovascular disease risk factors. For instance, acupuncture can regulate the autonomic nervous system and improve blood circulation by stimulating specific acupoints, thereby reducing blood pressure and lipids.

The TCM health management based on three-level prevention and control demonstrates favorable management efficacy, reducing 1-year recurrence and progression rates of coronary heart disease and stroke, helping patients enhance disease awareness, improve unhealthy lifestyle habits, reduce risk factor levels, stabilize disease conditions, and improve secondary prevention effectiveness for cardiovascular diseases. Future research should further explore this model' s applicability in different populations and optimize implementation strategies for broader promotion and application.

This study has several limitations: (1) The single-arm study design, while able to preliminarily evaluate the TCM three-level prevention and control model' s effectiveness, lacks a control group and cannot completely exclude other factors' influence on results, potentially affecting reliability and generalizability. (2) The relatively small sample size and concentration in a specific region may introduce geographic and population bias, and the relatively short follow-up duration is insufficient to observe long-term prognosis effects of the TCM three-level prevention and control model. (3) Primary outcome indicators rely on patient self-report and questionnaires, introducing some subjective bias. Additionally, individualized TCM treatment poses operational challenges. Due to large individual differences in patient conditions and constitutions, TCM treatment requires adjustment based on specific situations. Therefore, future research should consider larger sample sizes, multi-center randomized controlled trial designs, extended follow-up duration, and studies using objective biomarker detection and clinical endpoint observation as primary outcomes to improve scientific credibility. Simultaneously, further exploration of individualized TCM treatment protocols combined with modern diagnostic technologies should be pursued to enhance treatment precision and effectiveness.

Author Contributions: YANG Ji conceived the research idea, designed the study protocol, organized data, performed statistical analysis, and wrote the manuscript; ZHANG Yao organized data and created figures; ZHANG Qiuyue performed secondary verification of statistical results; ZHAO Yingqiang conducted quality control and manuscript review.

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Note: Figure translations are in progress. See original paper for figures.