Cover Page

Official Title of the Study:
Health Behavior Management Program for Patients with Coronary Heart Disease: A Clinical Study

ClinicalTrials.gov Identifier (NCT Number):
Not yet assigned

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Informed Consent Form

Date:
December 30, 2025

Informed Consent Form

Invitation to Participate

You are invited to participate in a clinical research study conducted by the Department of Cardiovascular Medicine at the First Affiliated Hospital of Bengbu Medical University. The purpose of this study is to evaluate the effectiveness of a health behavior management program for patients with coronary heart disease.

You are being asked to take part in this study because you meet the eligibility criteria for participation.

Please read the following information carefully. You may ask any questions you have before deciding whether or not to participate.

Purpose of the Study

Coronary heart disease is a common condition that may be associated with myocardial ischemia, reduced physical function, frailty, and impaired quality of life. Cardiac rehabilitation and health behavior management are important components of secondary prevention for patients with coronary heart disease.

The purpose of this study is to evaluate the effectiveness of a structured health behavior management program on cardiac rehabilitation outcomes, frailty status, and quality of life in patients with coronary heart disease.

Study Procedures

If you agree to participate in this study, you will take part in a health behavior management program designed according to your individual health condition and physical tolerance.

During the study, researchers may collect information including, but not limited to:

- General health status
- Medical history and disease-related information
- Physical function and rehabilitation-related indicators
- Emotional and psychological status
- Quality of life assessments

Qualified medical staff will monitor relevant clinical indicators, such as heart rate and blood pressure, throughout the study period.

Potential Benefits

You may experience improvements in physical function, exercise capacity, or overall well-being as a result of participating in this study. However, these benefits cannot be guaranteed.

The knowledge gained from this study may help improve health behavior management and cardiac rehabilitation strategies for future patients with coronary heart disease.

Potential Risks and Discomforts

Participation in health behavior management or exercise-related activities may cause temporary discomforts such as fatigue, dizziness, shortness of breath, or muscle soreness. Changes in your health condition may also occur.

Before participation, appropriate assessments will be conducted to reduce potential risks. During the study, trained medical personnel will closely monitor your condition. If any unexpected discomforts or adverse events occur, appropriate medical care will be provided promptly.

Voluntary Participation and Right to Withdraw

Your participation in this study is completely voluntary. You may choose not to participate or may withdraw from the study at any time without penalty or loss of benefits to which you are otherwise entitled.

If you decide to withdraw, your routine medical care, legal rights, and relationship with the medical staff will not be affected.

The investigator may also withdraw you from the study if participation is no longer in your best medical interest, if you experience significant adverse events, or if you do not follow study procedures.

Confidentiality

All personal information and study records will be kept confidential in accordance with applicable laws and regulations. Data collected during this study will be used for research purposes only.

Identifiable personal information will not be disclosed publicly. Study records will be securely stored and retained for the required period after study completion.

Participant Responsibilities

If you choose to participate in this study, you are asked to:

- Provide accurate and complete information about your medical history and current health status
- Inform the research staff promptly of any discomfort, injury, or adverse events
- Inform the investigators if you are currently participating in, or have recently participated in, other research studies

Questions and Contact Information

If you have any questions about this study or about your rights as a research participant, you may contact the study investigator at any time.

Statement of Informed Consent

I have read and understood the information provided in this informed consent form. The study purpose, procedures, potential risks, and possible benefits have been explained to me. I have had the opportunity to ask questions, and all my questions have been answered to my satisfaction.

I voluntarily agree to participate in this study.

Participant Name (Printed):
Participant Signature:
Date:

Investigator Name (Printed):
Investigator Signature:
Date: