Cover Page

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

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Study Protocol and Statistical Analysis Plan

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Study Protocol and Statistical Analysis Plan

1. Study Overview and Objectives

1.1 Study Background and Rationale

Coronary heart disease (CHD) remains a leading cause of morbidity and mortality worldwide. Despite advances in pharmacological and interventional treatments, secondary prevention and long-term health behavior management remain suboptimal. Patients with CHD often experience reduced exercise capacity, progression of frailty, and impaired quality of life.

Health behavior management programs integrating exercise rehabilitation, lifestyle modification, and self-management support have shown potential benefits. However, existing management models are often fragmented, lack personalization, and demonstrate limited sustainability and patient adherence.

This study aims to evaluate a comprehensive health behavior management program for patients with CHD, focusing on exercise-based secondary prevention and multimodal behavioral interventions, and to assess its clinical effectiveness, feasibility, and applicability.

1.2 Study Objectives

The primary objectives of this study are:

1. To evaluate the effectiveness of a health behavior management program on exercise rehabilitation outcomes, frailty progression, and quality of life in patients with CHD.
2. To develop and validate a risk prediction model for frailty occurrence in patients with CHD based on multiple risk factors.
3. To assess the feasibility, sustainability, and cost-effectiveness of a structured CHD health behavior management model.

2. Study Design and Methods

2.1 Key Scientific and Technical Issues

This study addresses the following key issues:

1. Development of a multi-factor risk prediction model for frailty in patients with CHD.
2. Formulation of a long-term, sustainable secondary prevention management strategy centered on exercise rehabilitation.
3. Integration of digital health tools to support multimodal behavioral interventions.

2.2 Research Plan and Study Phases

Phase 1: Assessment of Current Health Management Practices

A systematic evaluation of existing CHD health management models will be conducted through literature review, field investigation, patient interviews, and expert consultation. Baseline data on patient demographics, clinical characteristics, health behaviors, and management practices will be collected to identify gaps and unmet needs in current secondary prevention strategies.

Phase 2: Risk Factor Analysis and Model Development

Cross-sectional surveys, longitudinal follow-up data, and/or existing databases will be used to analyze factors associated with frailty in patients with CHD. Statistical methods such as factor analysis, cluster analysis, and multivariable modeling will be applied to identify key risk factors and develop a frailty risk prediction model.

Phase 3: Development and Implementation of the Health Behavior Management Program

Based on evidence synthesis and expert consensus, a structured health behavior management program will be developed. The intervention will include modular components such as:

- Exercise and cardiac rehabilitation training
- Relaxation and breathing exercises
- Medication adherence support
- Nutritional and lifestyle guidance

Digital delivery methods (e.g., mobile platforms, short videos, graphical materials) will be used to enhance engagement and adherence. The program will be implemented in a standardized CHD patient cohort, and outcomes will be systematically evaluated.

Phase 4: Effectiveness Evaluation and Health Economic Analysis

Clinical outcomes, patient-reported outcomes, and health service utilization data will be collected to assess intervention effectiveness. Health economic analyses will be

conducted to evaluate cost-effectiveness, feasibility, and scalability of the management model.

3. Statistical Analysis Plan

3.1 General Principles

Statistical analyses will be conducted using appropriate statistical software. All analyses will follow predefined analysis plans. Descriptive statistics will summarize baseline characteristics. Continuous variables will be expressed as mean ± standard deviation or median (interquartile range), and categorical variables as frequencies and percentages.

3.2 Effectiveness Analysis

Comparative analyses will be performed to evaluate changes in exercise capacity, frailty status, and quality of life before and after intervention, and/or between study groups if applicable. Appropriate parametric or non-parametric tests will be used based on data distribution.

3.3 Risk Prediction Model Development

Multivariable regression models will be used to identify independent predictors of frailty. Model performance will be evaluated using discrimination and calibration metrics. Internal validation methods will be applied where appropriate.

3.4 Economic Evaluation

Cost-benefit and cost-effectiveness analyses will be conducted to assess the economic impact of the intervention from a healthcare system perspective.

4. Implementation and Dissemination

If the intervention demonstrates feasibility and effectiveness, implementation strategies based on implementation science frameworks will be applied to facilitate translation into routine clinical practice. Dissemination will include academic publications, conference presentations, and collaboration with healthcare stakeholders to support broader adoption.