

# Effects of cardiac rehabilitation among elderly patients with heart failure preserved ejection fraction

<b>Submission date</b> 23/05/2023	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 30/05/2023	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 25/11/2024	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

The main clinical manifestations of heart failure with preserved ejection fraction (HFpEF) are exercise intolerance and decreased quality of life, which are more common in patients who also suffer from dyspnea and fatigue during physical activity. These symptoms are also the main determinants of the decreased quality of life of such patients. With the progress of society, cardiac rehabilitation (CR) was born. CR is a comprehensive secondary prevention plan, which includes exercise, drugs, nutrition, psychological intervention, smoking cessation and alcohol restriction. Among them, the prescription of exercise is the most important and has the same effects as traditional drugs for secondary prevention. The American College of Cardiology and the American Heart Association regard cardiac rehabilitation as an indication of heart failure. Early exercise prescription and cardiac rehabilitation can greatly improve the health of the elderly. Physical activity function can reduce the mortality rate of elderly patients with heart failure and improve the quality of life. However, at present, there is no unified prescription for exercise for heart failure with preserved ejection fraction (HFpEF) in China, and even in the world. This project aims to formulate exercise prescription standards for the future and provide a theoretical basis for their use.

### Who can participate?

Patients aged 65 to 80 years old who meet the diagnostic criteria for HFpEF

### What does the study involve?

The study will last 6 months and will end with a telephone follow-up. Enrolled personnel strictly follow the standard indications and contraindications. The entire research process will be guaranteed by experienced physicians.

### What are the possible benefits and risks of participating?

Participants benefit from inclusion as they can improve their exercise tolerance and quality of life. The risks are major cardiovascular adverse events.

Where is the study run from?  
Kunming Puji Hospital (China)

When is the study starting and how long is it expected to run for?  
March 2023 to December 2024

Who is funding the study?  
Kunming Municipal Health and Family Planning Commission (China)

Who is the main contact?  
Mr Rui Li, lrawow@163.com

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Mr Rui Li

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## Additional identifiers

**Clinical Trials Information System (CTIS)**  
Nil known

**Protocol serial number**  
Nil known

## Study information

**Scientific Title**  
Effects of cardiac rehabilitation among elderly patients with heart failure preserved ejection fraction

**Study objectives**  
The purpose of this study was to investigate the effects of cardiac rehabilitation (CR) on elderly patients with chronic heart failure (CHF)

**Ethics approval required**  
Old ethics approval format

## **Ethics approval(s)**

1. Approved 22/05/2023, Kunming Puji Hospital Research Ethics Committee (WuHua District, Kunming City, Yunnan Province, China; +8613888835781, 59528425@qq.com), ref: not provided
2. Approved 12/11/2023, Kunming Puji Hospital Medical Ethics Review Form (puji Road Wuhua district Kunming city Yunnan province China, Yunnan Kunming, 650011, China; +8613888835781; lrawow@163.com), ref: 2023001

## **Study design**

Single-center single-blind cohort study

## **Primary study design**

Observational

## **Study type(s)**

Safety, Efficacy

## **Health condition(s) or problem(s) studied**

Effects of cardiac rehabilitation (CR) on elderly patients with chronic heart failure (CHF)

## **Interventions**

Participants will enter a prospective cohort study researching cardiac rehabilitation training. The training length is divided into 3 stages in total, the first stage is 4 weeks, the second stage is 16 weeks, and the third stage is more than 26 weeks. The initial time of exercise starts from 5-10 minutes (METs<3), gradually increasing the training time to 20-30 minutes, and the maximum training time is mainly 60 minutes. The control group did not receive cardiac rehabilitation treatment (mainly based on daily activities, and did not intentionally inform patients about the content of daily activities). The cardiac rehabilitation training exercise prescription is issued by a doctor. The doctor is a professional rehabilitation doctor, and the exercise prescription is mainly based on the principle of frequency, intensity, time, type, volume, and progression (FITT-VP). During the patient intervention period, cardiologists and rehabilitation physicians will conduct follow-up registration to ensure patient safety

## **Intervention Type**

Behavioural

## **Primary outcome(s)**

Exercise endurance measured using the 6-minute walk test at 6 months (study finish)

## **Key secondary outcome(s)**

1. Peak VO<sub>2</sub> measured using cardiopulmonary exercise testing (CPET) at 6 months (study finish)
2. B-type natriuretic peptide (BNP) measured using biochemical testing equipment and standard techniques at 6 months (study finish)

## **Completion date**

01/12/2024

## **Eligibility**

### **Key inclusion criteria**

1. Meet the diagnostic criteria for heart failure with preserved ejection fraction (HFpEF)
2. Age  $\geq$ 65 to 80 years old
3. Meet the indications for cardiac rehabilitation

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Mixed

**Lower age limit**

65 years

**Upper age limit**

80 years

**Sex**

All

**Total final enrolment**

40

**Key exclusion criteria**

1. Aged  $\geq$ 65 years old
2. Does not meet the indications for cardiac rehabilitation
3. Contraindications to cardiac rehabilitation

**Date of first enrolment**

01/06/2023

**Date of final enrolment**

01/08/2023

**Locations****Countries of recruitment**

China

**Study participating centre**

**Kunming Puji Hospital**

Yunye Living Area

Wuhua District

Kunming City, Yunnan Province

China

650011

# Sponsor information

## Organisation

Kunming Puji Hospital

## Funder(s)

### Funder type

Government

### Funder Name

Kunming Municipal Health and Family Planning Commission

### Alternative Name(s)

### Funding Body Type

Government organisation

### Funding Body Subtype

Local government

### Location

China

# Results and Publications

## Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date

## IPD sharing plan summary

Data sharing statement to be made available at a later date