ISRCTN16443494 https://doi.org/10.1186/ISRCTN16443494

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

Submission date 23/05/2023	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 30/05/2023	**Overall study status** Completed	
Last Edited 21/05/2026	**Condition category** Circulatory System	

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

Contact details
Kunming Puji Hospital
Yunye Living Area
Wuhua District
Kunming City, Yunnan Province
China
650011
+8613888835781
lrawow@163.com

Additional identifiers

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)
Current primary outcomes as of 21/05/2026:
1. Exercise endurance measured using the 6-minute walk test at baseline, and 6-week post-intervention
2. Cardiorespiratory function: peak oxygen uptake (peakVO_2) and anaerobic threshold (AT) measured using the Cardiorespiratory Exercise Test (CPET), and the Cortex META CONTROL 3000 system at baseline, and 6-week post-intervention

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

Key secondary outcome(s))
Current key secondary outcome:
1. Physical Function Performance: balance, gait and chair-stand tests, measured using the Short-Time Physical Fitness Scale (SPPB) at baseline, and 6-week post-intervention
2. Quality of Life: physical and emotional dimension scoring and total score, measured using the Minnesota Heart Failure Quality of Life Questionnaire (MLHFQ) at baseline, and 6 weeks after intervention

Previous key secondary outcome:
1. Peak VO2 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 ≥65 to 80 years old
3. Meet the indications for cardiac rehabilitation

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Senior

Lower age limit
65 years

Upper age limit
80 years

Sex
All

Total final enrolment
40

Key exclusion criteria
1. Aged65 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

IPD sharing plan summary

Data sharing statement to be made available at a later date