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Early bedside personalized rehabilitation for elderly patients with acute decompensated heart failure

Submission date	Recruitment status	[_] Prospectively registered
22/09/2026	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
23/09/2026	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
23/09/2026	Circulatory System	[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Acute decompensated heart failure (ADHF) is a sudden worsening of heart failure symptoms and is a common cause of hospitalisation among older adults. Patients with ADHF often experience reduced physical function, muscle weakness, and difficulty returning to normal activities after hospitalisation. Although rehabilitation is beneficial for patients with stable heart failure, the feasibility and safety of starting personalised bedside rehabilitation during the acute phase of ADHF remain unclear.
This study aims to evaluate the feasibility and safety of early bedside personalised rehabilitation in elderly patients with ADHF. The study also aims to explore the potential effects of this rehabilitation strategy on functional capacity and congestion-related conditions before hospital discharge.

Who can participate?
Patients aged 65 years or older who are admitted to the cardiac intensive care unit due to ADHF with severe symptoms

What does the study involve?
Participants will be randomly allocated to either an early bedside personalised rehabilitation group or a usual care group. Participants in the rehabilitation group will receive an individualised bedside rehabilitation programme based on daily functional assessment. The programme includes early mobilisation training, respiratory rehabilitation, progressive sitting and standing exercises, resistance exercises, and walking training according to each participant’s clinical condition and functional capacity. Participants in the usual care group will receive standard medical treatment and routine nursing care according to clinical practice. The intervention will be provided during hospitalisation until discharge under the supervision of trained healthcare professionals.

What are the possible benefits and risks of participating?
Participants may benefit from receiving structured rehabilitation support that may help maintain or improve physical function during hospitalisation. However, individual benefits

cannot be guaranteed.
Potential risks include temporary fatigue, shortness of breath, dizziness, changes in heart rate or blood pressure, or other discomfort related to physical activity. The rehabilitation programme will be adjusted according to each participant's clinical condition, and exercise will be stopped if safety concerns occur.

Where is the study run from?
The Affiliated Hospital of Jiujiang University (China)

When is the study starting and how long is it expected to run for?
January 2024 to August 2025

Who is funding the study?
The Science and Technology Research Project of Jiangxi Provincial Department of Education (GJJ2401806) (China)

Who is the main contact?
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Study information

Scientific Title
Effects of early bedside personalized rehabilitation on functional capacity and congestion relief in acute decompensated heart failure patients prior to discharge: a pilot randomized controlled trial in elderly heart failure patients

Study objectives
The primary objective of this pilot randomized controlled trial was to evaluate the feasibility and safety of early bedside personalized rehabilitation in elderly patients with acute decompensated heart failure.

The secondary objective was to explore the potential effects of this intervention on pre-discharge functional capacity and congestion status.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 20/12/2023, Medical Ethics Committee of the Affiliated Hospital of Jiujiang University (Jiujiang University Affiliated Hospital, Xunyang District, Jiujiang, 332000, China; +86 (0) 7922180161; jjxysyjyk@163.com), ref: jjuhmer-b-2023-12003

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Active

Assignment
Parallel

Purpose
Health services research, Treatment

Study type(s)

Health condition(s) or problem(s) studied
Acute decompensated heart failure in elderly patients requiring intensive care management

Interventions
Participants were randomly assigned in a 1:1 ratio using a random sequence generated by independent statisticians. Allocation was concealed using sequentially numbered opaque envelopes.

Participants in the intervention group received an individualized bedside rehabilitation program based on daily functional assessment. The rehabilitation protocol included early mobilization training, respiratory rehabilitation, progressive sitting and standing exercises, and walking training according to patients' clinical condition and functional capacity.

The control group received usual care, including standard medical treatment and routine nursing management according to clinical practice.

The intervention was conducted during hospitalization until discharge under the supervision of trained healthcare professionals.

Intervention Type
Behavioural

Primary outcome(s)
1. Feasibility and safety of early bedside personalized rehabilitation, measured using recruitment rate, protocol adherence, completion rate, and the incidence of rehabilitation-related adverse events, including symptomatic hypotension, arrhythmia, oxygen desaturation, falls, and rehabilitation interruption, at randomization until hospital discharge

Key secondary outcome(s)

Completion date
01/08/2025

Eligibility

Key inclusion criteria
1. Age ≥65 years
2. Hospitalized in the cardiac intensive care unit (CICU) due to acute decompensated heart failure (ADHF) with New York Heart Association (NYHA) functional class III–IV
3. Symptoms worsening, including dyspnea, fluid retention, or hypoperfusion, requiring mechanical ventilation or non-invasive ventilation
4. Clinically stabilized and suitable for early bedside rehabilitation

Healthy volunteers allowed
No

Age group
Senior

Lower age limit

65 Years

Upper age limit
90 Years

Sex
All

Total final enrolment
60

Key exclusion criteria
1. Acute coronary syndrome within 2 days or chest pain within 8 hours
2. Malignant arrhythmias
3. Severe aortic stenosis
4. Aortic dissection
5. Acute myocarditis, acute pericarditis, or acute infective endocarditis
6. Recent embolism or cardiac/venous thrombosis
7. Long-term hemodialysis
8. Previous cognitive impairment
9. Inability to walk independently

Date of first enrolment
09/01/2024

Date of final enrolment
31/01/2025

Locations

Countries of recruitment
China

Sponsor information

Organisation
The Affiliated Hospital of Jiujiang University

Funder(s)

Funder type

Funder Name
Science and Technology Research Project of Jiangxi Provincial Department of Education (GJJ2401806)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available