ISRCTN18094960 https://doi.org/10.1186/ISRCTN18094960

The effect of early rehabilitation nursing

Submission date 24/12/2025	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 30/12/2025	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 29/12/2025	**Condition category** Circulatory System	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims
Acute myocardial infarction (AMI) is a common life-threatening cardiovascular disease characterised by rapid onset, severe clinical manifestations and poor prognosis.Percutaneous coronary intervention (PCI)is currently a key treatment for AMI, as it can rapidly restore myocardial blood supply, reduce myocardial damage and improve survival rates. Early rehabilitation nursing is an evidence-based approach that promotes rapid recovery and improves long-term prognosis.This study aimed to investigate the effect of implementing early rehabilitation nursing on the recovery of cardiac function indices and prognosis after PCI treatment in patients with AMI.

Who can participate?
Patients diagnosed with AMI and treated with PCI.

What does the study involve?
The control group received routine nursing after surgery, whereas the observation group received structured early rehabilitation nursing.

What are the possible benefits and risks of participating?
Early rehabilitation nursing for patients with AMI can effectively improve patients' cardiac function indices and reduce the risk of MACE, thereby improving their quality of life.
The main risks are the occurrence of major adverse cardiovascular events and their impact on quality of life.

Where is the study run from?
Henan Provincial People's Hospital, China.

When is the study starting and how long is it expected to run for?
February 2020 to June 2025.

Who is funding the study?
Henan Provincial People's Hospital, China.

Who is the main contact?
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Contact information

Type(s)
Principal investigator, Scientific, Public

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Additional identifiers

Research on Multidisciplinary Digital Health Management Model for Post PCI Patients in the Metaverse Perspective grant number
LHGJ20230059

Construction and Empirical Study of Pre hospital Emergency Training Program for Family Members of High Risk Sudden Cardiac Death Patients Based on Action Promotion Theory grant number
HNSYHLKT202209

Study information

Scientific Title
The effect of early rehabilitation nursing on the recovery of cardiac function in patients with acute myocardial infarction

Study objectives

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 01/04/2024, Medical Ethics Committee of Henan Provincial People's Hospital (No. 7 Weiwu Road, Jinshui District, , Henan Province,China, Zhengzhou City, 450000, China; +86-037165580014; fengzwmmnn9@21cn.com), ref: (2024) Ethical Approval No. (59)

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Active

Assignment
Parallel

Purpose
Supportive care

Study type(s)

Health condition(s) or problem(s) studied
Patients diagnosed with acute myocardial infarction and treated with percutaneous coronary intervention

Interventions
A structured, phase-specific protocol was implemented by trained cardiac nurses, starting within 24 hours after PCI (initiation criteria: stable vital signs, no active bleeding at the puncture site and absence of severe chest pain/dyspnoea).

The protocol was divided into three phases, as described below
Phase 1 Postoperative day 1
- Bedside care: assist with bed rest, urination/defecation; turn every 2 hours to prevent pressure ulcers.
- Passive exercises: range-of-motion (ROM) training for non-operative limbs.
- Breathing exercises: deep breathing and coughing exercises.
- Psychological support: explain the rehabilitation plan and address concerns.
- Turning: every 2 hours
- Breathing exercises: 2 times/d, 10–15 min/time
- ROM training: 1 time/d, 5–10 min/time Cardiac nurses

Phase 2 Postoperative days 2–3
- Active exercises: active ROM training for all limbs; semi-recumbent/sitting position exercises (12 hours after puncture site haemostasis).
- Bedside standing: 5–10 min/ session.
- Daily living training: brushing teeth, washing face (assisted).
- Health education: emphasise adherence to rehabilitation. - Active exercises: 2 times/d, 10–15 min/time
- Standing: 2 times/d Cardiac nurses + family caregivers (trained by nurses)

Phase 3 Postoperative days 4–7
- Ambulation: ward/hallway walking (tolerated by patients: 75–100 m on day 4; 200–350 m on day 5; progressive increase on days 6–7).
- Strength training: supine leg extension, arm raising and squatting (avoiding Valsalva manoeuvre).
- Diet guidance: low-salt, low-fat, high-fibre diet.
- Walking: 1–2 times/d, duration based on tolerance
- Strength training: 1 time/d, 10–15 min/time Cardiac nurses

Discharge and post-discharge Postoperative day 7 to 6 months
- Discharge planning: individualised home exercise programme (10–15 min/d walking, target heart rate 85–90 beats/min).
- Follow-up: monthly telephone calls + 3-month outpatient visits to monitor compliance and adjust the plan.
- Emergency guidance: advise reducing/stopping exercise if chest tightness/sweating occurs.
- Home exercise: daily
- Follow-up: monthly (telephone) + 3-month (outpatient) Cardiac nurses

Randomisation was performed by an independent statistician, and group allocation was concealed using sequentially numbered, opaque envelopes.

Intervention Type
Behavioural

Primary outcome(s)
1. Cardiac function indices measured using Stroke volume (SV): measured by echocardiography (unit: mL; higher = better cardiac output). Left ventricular ejection fraction (LVEF): measured by echocardiography (unit: %; higher = better left ventricular systolic function). Left ventricular end-diastolic volume (LVEDV): measured by echocardiography (unit: mL; lower = better left ventricular remodelling). Six-minute walking distance (6MWD): measured by standard protocol (unit: m; higher = better exercise tolerance). at at baseline (1 day before PCI) and 6 months after PCI (follow-up endpoint)

2. Major adverse cardiovascular events (MACE), defined as composite events including angina pectoris, arrhythmia (documented by electrocardiogram) and coronary restenosis (confirmed by coronary angiography) measured using data collection from hospital records, outpatient visits and monthly telephone follow-up at 6 months after PCI

3. Quality of life measured using the World Health Organization Quality of Life Measurement Brief Form (WHO-QOL-BREF) questionnaire at at baseline (1 day before PCI) and 6 months after PCI (follow-up endpoint)

Key secondary outcome(s))

Completion date
28/02/2025

Eligibility

Key inclusion criteria
1. Meeting the diagnostic criteria in the Diagnostic and Therapeutic Guidelines for Acute Myocardial Infarction
2. Complete clinical data
3. New York Heart Association (NYHA) classification II–IV
4. No serious complications (e.g. severe infection, organ failure) or contraindications to rehabilitation
5. Patients and their families provided informed consent

Healthy volunteers allowed

No

Age group
Mixed

Lower age limit
35 years

Upper age limit
72 years

Sex
All

Total final enrolment
314

Key exclusion criteria
1. Comorbidity with other major diseases (e.g. malignant tumours, end-stage renal disease)
2. Contraindications to PCI or rehabilitation (e.g. severe arrhythmia, haemodynamic instability)
3. Poor compliance (refusal to participate in rehabilitation or follow-up)
4. Comorbid psychiatric disorders, audio-visual impairment or speech disorders

Date of first enrolment
20/02/2020

Date of final enrolment
01/06/2024

Locations

Countries of recruitment
China

Sponsor information

Organisation
Henan Provincial People's Hospital

ROR
https://ror.org/03f72zw41

Funder(s)

Funder type

Funder Name
Henan Provincial People's Hospital

Alternative Name(s)

Funding Body Type
Government organisation

Funding Body Subtype
Other non-profit organizations

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