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Effectiveness of early cardiac rehabilitation in patients with heart valve surgery

Submission date	Recruitment status	[_] Prospectively registered
27/03/2021	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
16/05/2021	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
14/06/2023	Circulatory System	

Plain English summary of protocol
Background and study aims
Complications of heart valve surgery lead to physical inactivity and produce harmful effects. The present study aimed to investigate the roles of a cardiac rehabilitation programme and its long-term effects in patients with heart valve surgery following the day of post-operation in patients after heart valve surgery in a hospital setting.

Who can participate?
Adults over 18 years, who will undergo heart valve surgery.

What does the study involve?
Patients with heart valve surgery were randomly assigned randomized to the an early cardiac rehabilitation group (intervention) or a usual care group (control).

What are the possible benefits and risks of participating?
Participants could enhance their physical activity level and promote long-term survival. No risks.

Where is the study run from?
The First Affiliated Hospital of An Hui Medical University (China)

When is the study starting and how long is it expected to run for?
January 2018 to December 2019

Who is funding the study?
Investigator-initiated and funded

Who is the main contact?
Dr Wei Xue, weixue20@126.com

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Effectiveness of early cardiac rehabilitation in patients with heart valve surgery: a randomized trial

Study objectives
An early cardiac rehabilitation programme can enhance the physical activity in patients with heart valve surgery and long-term survival.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 04/01/2018, Medical ethics committee of An Hui Medical University (Meishan Road, Hefei City, China; +86 (0)551-65161000; ethicschair@ahmu.edu.cn), ref: none provided

Study design
Single-blind randomized controlled trial

Primary study design
Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied
Cardiac rehabilitation of patients with heart valve surgery

Interventions
A total of 97 consecutive patients who took heart valve surgery were enrolled in the study, after applying inclusion and exclusion criteria, 87 patients were included in this study and met the sample size requirements.

The randomization programme was created using a computer and executed by an investigator who is not involved in the treatment and recruitment of patients. The allocation of patients was screened, applying numbered in the sealed and opaque envelopes. On the first day of treatment after surgery, the envelope that was allocated to the patient was unfolded by the physical therapist.

Patients were randomly assigned to two groups: those who received cardiac rehabilitation or those who received usual care.
Before surgery (baseline), hospital discharge, and after 6 months following up, the physical capacity and psychological status were measured.
This rehabilitation exercise program comprises lower and upper extremity exercise in bed, sitting on the edge of the bed, standing at the bedside, and walking around the bed and for 100 m on the ward. The exercise included 4 sessions and last four days, three times a day, with about 30 minutes each time. After the rehabilitation exercise, patients continued with gait practicing for up to 500 m and carried out endurance training applying a stationary bike in the rehabilitation center of the hospital. The training session took place three times a day with about 30 minutes each time and until they were discharged from the hospital.

Intervention Type
Behavioural

Primary outcome(s)
Physical function was measured using the Short physical performance battery (SPPB) at baseline, the day of hospital discharge, and 6 months later

Key secondary outcome(s))
The mental health was measured with a mental component summary (MCS) from the 12-item Short-Form Health Survey at baseline, the day of hospital discharge, and 6 months later

Completion date
30/12/2019

Eligibility

Key inclusion criteria
1. Elective left-sided or right-sided heart valve surgery, including aortic, mitral, tricuspid, and pulmonary valve replacement
2. Over 18 years of age
3. Able to understand and complete measurements
4. Provide informed written consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
97

Key exclusion criteria
1. Ischaemic heart disease before surgery
2. Diseases in the musculoskeletal system
3. Comorbidity complicating physical activity
4. Expected to not cooperate in the trial instructions

Date of first enrolment
30/01/2018

Date of final enrolment
30/06/2019

Locations

Countries of recruitment
China

Study participating centre
The First Affiliated Hospital of An Hui Medical University
Meishan Road
Hefei City
China
230032

Sponsor information

Organisation

First Affiliated Hospital of Anhui Medical University

ROR
https://ror.org/03t1yn780

Funder(s)

Funder type
Other

Funder Name
investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/07/2022	14/06/2023	Yes	No
Basic results		24/01/2022	24/01/2022	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes