

# Effectiveness of early cardiac rehabilitation in patients with heart valve surgery

<b>Submission date</b> 27/03/2021	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 16/05/2021	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 14/06/2023	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data

## 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

**Contact name**

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## **Additional identifiers**

**EudraCT/CTIS number**

Nil known

**IRAS number****ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

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

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

**Participant information sheet**

Not available in web format, please use the contact details to request a patient information sheet.

**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 measure**

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

**Secondary outcome measures**

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

**Overall study start date**

04/01/2018

**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

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

80

**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

**Sponsor details**  
Meishan Road  
Hefei  
China  
230032  
+86 (0)551-65161000  
lql@ahmu.edu.cn

**Sponsor type**  
Hospital/treatment centre

**Website**  
<http://www.ayfy.com/>

**ROR**  
<https://ror.org/03t1yn780>

## **Funder(s)**

**Funder type**  
Other

**Funder Name**  
investigator initiated and funded

## **Results and Publications**

**Publication and dissemination plan**

Planned publication in a high-impact peer-reviewed journal.

### **Intention to publish date**

30/12/2022

### **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?
<a href="#">Basic results</a>		24/01/2022	24/01/2022	No	No
<a href="#">Results article</a>		01/07/2022	14/06/2023	Yes	No