

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

The Effect of Twelve Weeks of Aerobic with Breathing Exercises on Physical-Psychological Symptoms, Functional Capacity (VO₂peak), and Hemodynamic Indicators in Patients with Mitral Valve Prolapse

Protocol summary

Study aim

Effects of aerobic-breathing training on sleep quality, fatigue, functional capacity (VO₂ peak), rest and peak hemodynamic indices in patients with mitral valve prolapse.

Design

Clinical trial with control group, parallel-group trial, single-blinded, randomized, phase 2 clinical trial on 30 patients. Opaque envelopes will be used for randomization.

Settings and conduct

Thirty women with MVP will be selected from Tabriz and randomly assigned to two experimental groups (aerobic plus breathing exercises) and one control group. The outcome assessor and statistical analyst will be blinded to group assignments. Variables will be measured at two-time points: before and after the 12-week exercise protocol.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- A history of more than three years of mitral valve prolapse, 2-mild to moderate Mitral regurgitation, 3- normal ventricular function, 4- no history of stroke, panic attacks, hypertension, mental or cognitive disorders, or valve replacement or repair surgery Exclusion criteria: Other major cardiovascular diseases, respiratory diseases, diabetes, and pregnancy.

Intervention groups

Intervention group: Participated in 12 weeks of aerobics combined with breathing exercises, 3 weekly sessions for 45 to 70 minutes each at a moderate intensity. Control group: will Continue with their usual daily activities

Main outcome variables

Sleep quality, fatigue, functional capacity (VO₂peak), resting and peak blood pressure, resting and peak heart rate, resting and peak RPP

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160523028028N4**

Registration date: **2025-01-06, 1403/10/17**

Registration timing: **prospective**

Last update: **2025-01-06, 1403/10/17**

Update count: **0**

Registration date

2025-01-06, 1403/10/17

Registrant information

Name

Azam Zarneshan

Name of organization / entity

Azərbaycan Şahid Mədanı Universiteti

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-03-02, 1403/12/12

Expected recruitment end date

2025-05-05, 1404/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty	
Scientific title	The Effect of Twelve Weeks of Aerobic with Breathing Exercises on Physical-Psychological Symptoms, Functional Capacity (VO2peak), and Hemodynamic Indicators in Patients with Mitral Valve Prolapse
Public title	The Effect of of Aerobic with Breathing Exercises on Physical-Psychological Symptoms in Patients with Mitral Valve Prolapse
Purpose	Supportive
Inclusion/Exclusion criteria	
Inclusion criteria:	History of mitral valve prolapse for over three years Mild to moderate mitral regurgitation Normal ventricular function
Exclusion criteria:	History of stroke, panic attacks, hypertension, mental or cognitive disorders, or valve replacement or repair surgery. Having other major cardiovascular diseases, respiratory diseases, and diabetes Pregnancy.
Age	From 20 years old to 50 years old
Gender	Female
Phase	N/A
Groups that have been masked	• Outcome assessor • Data analyser
Sample size	Target sample size: 30
Randomization (investigator's opinion)	Randomized
Randomization description	Simple randomization method will be used. Allocation concealment will be conducted by a researcher not involved in the study. Opaque, identical, sealed envelopes will be prepared, containing the type of intervention according to a randomly generated allocation sequence. The envelopes, numbered from 1 to 30, will be distributed based on the order of participants entering the study.
Blinding (investigator's opinion)	Single blinded
Blinding description	The outcome assessor will be blinded to the group differences in both pre-test and post-test phases. The data analyst will also be blinded to the group differences and the groups will be entered into SPSS with codes 1 and 2.
Placebo	Not used
Assignment	Parallel
Other design features	

Secondary Ids	empty
Ethics committees	
1	
Ethics committee	
Name of ethics committee	Ethics committee of Azarbaijan shahidmadani university
Street address	Varzesh Ave
City	Tabriz
Province	East Azarbaijan
Postal code	5541916777
Approval date	2024-07-22, 1403/05/01
Ethics committee reference number	IR.AZARUNIV.REC.1403.005
Health conditions studied	
1	
Description of health condition studied	Mitral Valve Prolapse
ICD-10 code	I34.1
ICD-10 code description	Nonrheumatic mitral (valve) prolapse
Primary outcomes	
1	
Description	Sleep quality
Timepoint	Before and after 12 weeks of training protocol
Method of measurement	Petersburg Sleep Questionnaire (PSQI)
2	
Description	Fatigue
Timepoint	Before and after 12 weeks of training protocol
Method of measurement	Daily fatigue questionnaire (Multidimensional Fatigue Inventory)
3	
Description	Peak VO2
Timepoint	

Before and after 12 weeks of training protocol

Method of measurement

6-minute walk test(6MWT)

4

Description

Resting systolic and diastolic blood pressure

Timepoint

Before and after 12 weeks of training protocol

Method of measurement

Omron M3 digital blood pressure monitor

5

Description

Peak systolic and diastolic blood pressure

Timepoint

Before and after 12 weeks of training protocol
immediately after the 6MWT test

Method of measurement

Omron M3 digital blood pressure monitor

6

Description

Rest Heart rate

Timepoint

Before and after 12 weeks of training protocol

Method of measurement

Omron M3 digital blood pressure monitor

7

Description

Peak Heart Rate

Timepoint

Before and after 12 weeks of training protocol
immediately after the 6MWT test

Method of measurement

Omron M3 digital blood pressure monitor

8

Description

Rest Rate Pressure Product

Timepoint

Before and after 12 weeks of training protocol

Method of measurement

Defined by resting heart rate (RHR) multiplied by systolic blood pressure (SBP)

9

Description

Peak Rate Pressure Product

Timepoint

Before and after 12 weeks of training protocol
immediately after the 6MWT test

Method of measurement

Defined by peak heart rate multiplied by systolic blood pressure (SBP)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Engage in 12 weeks of combined aerobic and breathing exercise training, three days a week for 45 to 70 minutes. The intensity of the workout will be adjusted based on heart rate and Borg's perceived exertion. According to the American College of Sports Medicine guidelines, a heart rate 20 to 30 beats above resting heart rate and a Borg's perceived exertion score of 4 to 6 (relatively mild to slightly intense) would be the target intensity.

Category

Lifestyle

2

Description

Control group: will Continue with their usual daily activities

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Cardiovascular clinic

Full name of responsible person

Babak Zanjani

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Farid Building, Namaz Square

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Azarbaijan Shahid Madani University

Full name of responsible person

Azam Zarneshan

Street address

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Azarbaijan Shahid Madani University

Proportion provided by this source
20

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Azarbaijan Shahid Madani University

Full name of responsible person
Azam Zarneshan

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Cardiovascular and respiratory exercise physiology

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Person responsible for scientific inquiries

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Position
Associate professor

Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Data collection will be done by the researchers and information about the main outcomes of the study will be published.

When the data will become available and for how long

Access to the data will be possible immediately after the results are printed.

To whom data/document is available

The general public, athletic trainers, MVP patients, and researchers

Under which criteria data/document could be used

Reviewers of magazines and Azerbaijan Shahid Madani

university are allowed to send requests to receive non-identifiable personal data or other documents. Until the publication of the results in the form of an article, it is not allowed to perform statistical analysis on the delivered data.

From where data/document is obtainable

Dr. Azam Zarneshan email: zarneshan@azaruniv.ac.ir

What processes are involved for a request to access data/document

via email to the corresponding author: Dr. Azam Zarneshan zarneshan@azaruniv.ac.ir

Comments