Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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

Azarbaijan Shahid Madani University

Country

Iran (Islamic Republic of)

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+98 41 3432 7505

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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

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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
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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 Zarnashan zarneshan@azaruniv.ac.ir

Comments