Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The Effect of Neuromuscular Exercises with Respiratory Control on Total Oxidant and Antioxidant Capacity, Mental and Motor Performance in Elderly Stroke Patients

Protocol summary

Study aim

The Effect of Neuromuscular Exercises with Respiratory Control on Total Oxidant and Antioxidant Capacity, Mental and Motor Performance in Elderly Stroke Patients

Design

Clinical trial with a 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 men and women with an ischaemic stroke will be selected from Hashtrood and randomly assigned to two experimental groups and a 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 8-week exercise protocol

Participants/Inclusion and exclusion criteria

Age range 61 to 75 years, both male and female, experiencing their first ischemic stroke. Cognitive status score of 23 or higher, Berg Balance Scale score between 30 and 44, the ability to stand unassisted, and the ability to walk without a cane. Education level of middle school or higher. No dizziness or balance disorders during testing and training. No other chronic conditions affect balance and movement during testing and training.

Intervention groups

Intervention group: Participants will undergo eight weeks of neuromuscular training combined with breath control, with three sessions per week, each lasting 60 to 90 minutes, in addition to a routine rehabilitation programme. Control group: only the routine rehabilitation programme.

Main outcome variables

Total oxidative capacity, total antioxidant capacity, balance, Mental performance, isometric strength, VO2peak

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160523028028N5**
Registration date: **2025-11-15, 1404/08/24**
Registration timing: **prospective**

Last update: **2025-11-15, 1404/08/24**
Update count: **0**

Registration date

2025-11-15, 1404/08/24

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

Email address

zarneshan@azaruniv.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-12-06, 1404/09/15

Expected recruitment end date

2026-01-05, 1404/10/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The Effect of Neuromuscular Exercises with Respiratory Control on Total Oxidant and Antioxidant Capacity, Mental and Motor Performance in Elderly Stroke Patients

Public title
The Effect of physical activity with Respiratory Control on, Mental and Motor health of Elderly Stroke Patients

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Achieving a score of 23 or higher on the cognitive status test and 30 to 44 on the Berg Balance Scale , the ability to stand unassisted for at least eight minutes, walk without a cane having at least a middle school education. Patients with ischemic stroke

Exclusion criteria:
Experiencing dizziness and difficulty standing during tests and exercises. Uncontrolled epileptic seizures Having Parkinson’s or other chronic diseases that cause balance and movement disorders during tests and exercises.

Age
From **61 years** old to **75 years** old

Gender
Both

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
کمیته اخلاق دانشگاه شهید مدنی آذربایجان

Street address
خیابان ورزش

City
تبریز

Province
East Azarbaijan

Postal code
5541916777

Approval date
2025-11-04, 1404/08/13

Ethics committee reference number
IR.AZARUNIV.REC.1404.028

Health conditions studied

1

Description of health condition studied
stroke

ICD-10 code
I63

ICD-10 code description
Cerebral infarction

Primary outcomes

1

Description
balance performance

Timepoint
Before and after 8 weeks of training protocol

Method of measurement
Berg Balance Scale

2

Description
Total Oxidant Status (TOS)

Timepoint
Before and after 8 weeks of training protocol

Method of measurement
ELISA (TOS kit -Navan Salamat)

3

Description
Total Antioxidant Capacity (TAC)

Timepoint
Before and after 8 weeks of training protocol

Method of measurement

ELISA (Naxifer™-Total Antioxidant Capacity Assay Kit-TAC)

4

Description
Vo2peak
Timepoint
Before and after 8 weeks of training protocol
Method of measurement
6-Minute Walk Test

5

Description
Isometric strength
Timepoint
Before and after 8 weeks of training protocol
Method of measurement
Dynamometer

6

Description
Mental performance
Timepoint
Before and after 8 weeks of training protocol
Method of measurement
Mini-Mental State Examination

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In addition to routine rehabilitation, participants performed combined exercises for 8 weeks, with three sessions per week, each lasting 60 to 90 minutes. Each session included a warm-up with stretching exercises (10 minutes), continuous walking on a line (10 to 15 minutes), fall-resistance training (15 to 20 minutes), PNF exercises for motor function (15 to 20 minutes), and a cool-down with breathing exercises during the final 15 to 20 minutes.
Category
Lifestyle

2

Description
Control group: Routine rehabilitation program (including initial assessment to check physical condition, Common physical exercises at the rehabilitation center, education and lifestyle changes, including nutrition modification, smoking cessation, and stress management)
Category
Lifestyle

Recruitment centers

1

Recruitment center
Name of recruitment center
Sanateb Corrective Exercise Center
Full name of responsible person
Ismael Khairzadeh
Street address
Hashtrood, Imam Street, next to Mellat Bank
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5571963311
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Azarbaijan Shahid Madani University
Full name of responsible person
Azam Zarneshan
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Varzesh Ave
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5375171379
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zarneshan@azaruniv.ac.ir
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 Ĩ

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Cardiovascular and respiratory exercise physiology

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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, Stroke patients, and researchers

Under which criteria data/document could be used
Reviewers of magazines and the Azarbaijan 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