Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The effect of dual-task (Cognitive-Functional) training on the biomarkers Cathepsin B and Myostatin in elderly individuals

Protocol summary

Study aim
Effects of 8-week cognitive-functional dual-task training on serum Cathepsin-B, myostatin levels, cognitive performance and physical fitness in elderly adults

Design
A double-blind, randomized block, parallel-group controlled clinical trial will be conducted on 24 elderly individuals.

Settings and conduct
Location: "Zendegi" Elderly Care Center, Tehran Procedure:Session duration: 30-50 minutes (10-minute warm-up, 5-minute cool-down), Training format: Group sessions with 2-4 participants Assessors and statistical analysts were blinded to group allocation and outcomes.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: 1.Aged 60-80 years 2.No participation in regular exercise programs or physiotherapy during the study period 3.No use of specific sports or pharmaceutical supplements. 4.Absence of acute, chronic cardiovascular and metabolic diseases 5. No open surgery within the past 6-12 months Exclusion Criteria: 1.Unwillingness to continue participation at any stage of the study 2.Missing more than 3 training sessions 3.Failure to participate in post-tests 4.Physician's recommendation for study withdrawal

Intervention groups
The intervention training group: this group will perform 8 weeks of dual-task (cognitive-physical) training following progressive overload principles. The control group: this group will not perform any regular physical activity during this period.

Main outcome variables
We anticipate observing: Increased Cathepsin B levels; Decreased myostatin levels; Enhanced cognitive control; Improved physical performance

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250415065336N1**
Registration date: **2025-10-08, 1404/07/16**
Registration timing: **retrospective**

Last update: **2025-10-08, 1404/07/16**
Update count: **0**

Registration date
2025-10-08, 1404/07/16

Registrant information

Name
Fatemeh Zendehpour

Name of organization / entity
Kharazmi university

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-07-11, 1404/04/20

Expected recruitment end date
2025-08-11, 1404/05/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of dual-task (Cognitive-Functional) training on the biomarkers Cathepsin B and Myostatin in elderly

individuals

Public title
Effect of dual training on cathepsin B and mayostatin
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Age 60–80 years No participation in exercise training or physiotherapy during the intervention No use of specific sports or medicinal supplements No history of acute chronic cardiovascular or metabolic diseases No open surgery in the past 6 months to 1 year
Exclusion criteria:
Participant's unwillingness or lack of interest to continue in the study Physician's recommendation for withdrawal from the study Non-participation in 3 consecutive training sessions Non-participation in the post-test
Age
From **60 years** old to **80 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **20**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization was performed using block stratified randomization based on age (60–74 and ≥75 years) at the individual level. The random sequence was generated in blocks of four with a 1:1 ratio by an independent statistician using random number software. Allocation concealment was ensured with sequentially numbered, opaque, sealed envelopes (SNOSE).
Blinding (investigator's opinion)
Double blinded
Blinding description
The examiner will be an experienced individual external to the research team, and only the data (with groups labeled as 1 and 2) will be provided to the statistical analyst. Thus, both individuals remain blinded to the study results.
Placebo
Not used
Assignment
Parallel
Other design features
This study in the field of sports and health aims to examine the effects of a dual-task (physical-cognitive) training program on cognitive and physical performance in elderly participants.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
"The Research Ethics Committee of Kharazmi University"
Street address
Kharazmi University No.43 South Mofateh St Tehran, 15719-14911 Iran
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Province
Tehran
Postal code
15719-14911
Approval date
2024-05-05, 1403/02/16
Ethics committee reference number
IR.KHU.REC.1403.021

Health conditions studied

1

Description of health condition studied
Elderly
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Serum Cathepsin B level
Timepoint
Pre and Post- Test (48 hours before and after 8 weeks of dual training)
Method of measurement
Abcam Human Cathepsin B ELISA Kit

2

Description
Myostatin level
Timepoint
Pre and Post-test
Method of measurement
ELYZA kit

Secondary outcomes

1

Description
Cognitive performance
Timepoint
Pre and Post-test (72 hours before and after 8 weeks of dual training)

Method of measurement
Stroop test

2

Description
Functional-cognitive test
Timepoint
Pre and Post-test (72 hours before and after 8 weeks of dual training
Method of measurement
Timed Up and Go test

3

Description
Aerobic fitness
Timepoint
Pre and Post-test (72 hours before and after 8 weeks of dual training
Method of measurement
6-minute walk test

4

Description
Fat profile
Timepoint
Pre and Post-test (48 hours before and after 8 weeks of dual training
Method of measurement
Elyza kit

Intervention groups

1

Description
Intervention group: Participants: 12 individuals (male/female) /"Participants will complete an 8-week dual-task (functional-cognitive) training program consisting of:• Frequency: 2 sessions/week• Duration: 30-50 minutes/session / Component : Functional training: Aerobic, resistance, and balance exercises / Cognitive tasks: Memory recall and arithmetic exercises / Training load will be progressively modified through: Increased session duration Greater movement repetitions / Exercise intensity will be monitored using the Borg RPE scale:• Weeks 1-2: Moderate intensity (RPE 8-10)• Subsequent weeks: Vigorous intensity (RPE 10-14).
Category
Rehabilitation

2

Description
Control group :12 participants (male/female) / Control participants will be asked to maintain their normal lifestyle patterns and will not participate in structured exercise. They will complete pre-test and post-tests at the same time as the intervention group.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Kharazmi University
Full name of responsible person
Fatemeh Sadat Zendepour
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Kharazmi University
Proportion provided by this source
100
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

Persons

Person responsible for general inquiries

Contact

Name of organization / entity
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Full name of responsible person
Fatemeh Sadat Zendepour

Position
Student

Latest degree
Master

Other areas of specialty/work
Exercise physiology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
There is no further information

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
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
Data will be presented as mean

When the data will become available and for how long
After publishing article

To whom data/document is available
Researchers working in academic and scientific institutions

Under which criteria data/document could be used
The data will be presented to them as mean values.

From where data/document is obtainable
For data acquisition, contact the corresponding author via email.

What processes are involved for a request to access data/document
Approximately 1-2 weeks

Comments