

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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

Country

Iran (Islamic Republic of)

Phone

+98 21 2222 8001

Email address

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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	
<u>1</u>	
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
City	Tehran
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	
<u>1</u>	
Description of health condition studied	Elderly
ICD-10 code	
ICD-10 code description	

Primary outcomes	
<u>1</u>	
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

<u>2</u>	
Description	Myostatin level
Timepoint	Pre and Post-test
Method of measurement	ELYZA kit

Secondary outcomes	
<u>1</u>	
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

Street address

Faculty of Physical Education, Hesari Street, Hassani Square, Mirdamad Boulevard,

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

Alireza Harifi mood

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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

Person responsible for general inquiries

Contact

Name of organization / entity

Kharazmi University

Full name of responsible person

Fatemeh Sadat Zendepour

Position

Student

Latest degree

Master

Other areas of specialty/work

Exercise physiology

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Latest degree

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Other areas of specialty/work

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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