Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparing the Effects of Two Training approaches: Low-Intensity Steady-State Training versus Functional Training on Cognitive Function, Dual Task Performance and Quality of Life in Elderly Men

Protocol summary

Study aim

Comparing the effects of eight weeks of low-intensity steady-state and functional training on cognitive function, dual-task performance, and quality of life in elderly men aged 60-75 years.

Design

Randomized controlled trial, single-blind (outcome assessors), parallel three-group, pre-test/post-test, sample size 45, simple randomization by lottery, phase not applicable.

Settings and conduct

Tarbiat Modares University. After screening and consent, randomization and 8-week intervention in standard hall under trainer and physician supervision. Assessments by blinded assessors at pre-test and post-test.

Participants/Inclusion and exclusion criteria

Inclusion: men 60-75 years; independent walking; no active cardiovascular, neurological or muscular disorders; no uncontrolled diabetes; controlled blood pressure; no stroke or seizures in the past year; no regular exercise in last 3 months; signed consent; negative PAR-Q; fewer than 4 steps in turn test. Exclusion: spinal or joint surgery in last 12 months; open foot wound; plantar fasciitis; foot deformity; serious mental illness; severe visual or hearing impairment; cardiorespiratory limiting diseases.

Intervention groups

Group 1: 8 weeks, three 45-min sessions/week, low-intensity aerobic exercise (walking, stationary cycling, stair stepper) at 40-65% HRmax. Group 2: 8 weeks, three 45-min sessions/week, functional training (balance, strength, coordination, daily activities). Group 3: control with no training.

Main outcome variables

Cognitive function (MMSE, Digit Span, Stroop, CVLT, WCST); dual-task performance (dual-task gait speed and dual-task throwing accuracy); quality of life (SF-36).

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260624069940N1**
Registration date: **2026-07-23, 1405/05/01**
Registration timing: **prospective**

Last update: **2026-07-23, 1405/05/01**
Update count: **0**

Registration date

2026-07-23, 1405/05/01

Registrant information

Name

Atiye Gholizadeh

Name of organization / entity

Tarbiat modares university

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-08-06, 1405/05/15

Expected recruitment end date

2026-10-07, 1405/07/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the Effects of Two Training approaches: Low-Intensity Steady-State Training versus Functional Training on Cognitive Function, Dual Task Performance and Quality of Life in Elderly Men

Public title

Comparison of the Effects of Two Training Methods on Brain Function, Dual-Task Performance, and Quality of Life in Elderly Men

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Elderly men aged between 60 and 75 years Ability to walk independently without using assistive devices No active or uncontrolled cardiovascular diseases (confirmed by medical examination) No severe neurological or muscular disorders that prevent performing exercises (e.g., Parkinson's disease or stroke) No uncontrolled diabetes (confirmed by a physician) Systolic blood pressure less than 140 mmHg and diastolic blood pressure less than 90 mmHg (controlled) No history of stroke or seizures in the past year No participation in regular exercise programs (more than 150 minutes per week) in the last three months Ability to understand and cooperate in performing tests and exercises Signed written informed consent to participate in the study Negative answers to all questions on the Physical Activity Readiness Questionnaire (PAR-Q) Taking fewer than 4 steps in the 180-degree turn test No use of anti-inflammatory or steroidal drugs that affect physiological indicators (confirmed by a physician)

Exclusion criteria:

History of spinal or other joint surgery within the last 12 months Presence of open wound on the foot Plantar fasciitis Fixed foot deformity (acquired or congenital) History of serious mental illness Severe visual impairment that prevents performing exercises Severe hearing impairment that prevents performing exercises Cardiorespiratory diseases that limit exercise tolerance

Age

From **60 years** old to **75 years** old

Gender

Male

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **45**

Randomization (investigator's opinion)

Randomized

Randomization description

After initial screening and confirmation of participants' eligibility, the names of eligible individuals are written on separate pieces of paper. Then, through a lottery method, each participant is randomly allocated to one of three groups (Low-Intensity Steady-State Training, Functional Training, and Control Group). Randomization method: Simple Randomization Randomization unit: Individual Stratification factors: None (no stratified randomization) Randomization tool: Lottery (using separate paper slips) Sequence generation method: Using lottery method without using software or random number tables Allocation concealment: Since allocation is performed through lottery and the slips are prepared by an independent person and placed in a sealed container before selection, the allocation cannot be predicted by the researcher or participants, thus allocation concealment is ensured.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, due to the nature of the exercise intervention, complete blinding for all groups is not possible. However, to reduce bias in outcome assessment, the Outcome Assessors, who are responsible for administering the cognitive tests, dual-task assessments, and quality of life questionnaires, will be blinded to the group allocation of participants. Detailed explanation by role: Participants: Not blinded. Participants are aware of the type of exercise they are performing (Low-Intensity Steady-State Training, Functional Training, or Control). Principal Investigator and Exercise Trainers: Not blinded. The researcher and exercise trainers who are responsible for conducting the training sessions are aware of the type of intervention each group receives. Personnel (Center Physician): Not blinded. The physician who monitors participants' health and conducts initial examinations is aware of the intervention type. Medical supervision is essential for participant safety. Outcome Assessors: Blinded. Individuals who administer and score the cognitive tests (MMSE, Digit Span, Stroop, CVLT, WCST), dual-task assessments, and quality of life questionnaire (SF-36) will be unaware of the participants' group allocation. These individuals are not involved in the exercise intervention process and only interact with participants during pre-test and post-test assessments. Data Analyst: Not blinded. The person analyzing the data is aware of the group allocation. Data Safety and Monitoring Committee (DSMB): Not applicable in this study. Method of blinding for Outcome Assessors: Outcome assessors will be kept blinded through participant coding and lack of access to group allocation information. After randomization, each participant receives a unique code, and the assessors only work with these codes, without knowing which code belongs to which group.

Placebo

Not used

Assignment

Parallel

Other design features

None

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committee of Tarbiat Modares University

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Tarbiat Modares University, Shahid Chamran Blvd., Tehran, Iran

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Approval date
2026-05-25, 1405/03/04

Ethics committee reference number
IR.MODARES.REC.1405.040

Health conditions studied

1

Description of health condition studied
Age-related cognitive decline

ICD-10 code
R41.81

ICD-10 code description
Age-related cognitive decline (کاهش شناختی مرتبط با سن)

Primary outcomes

1

Description
Cognitive Function

Timepoint
Before the intervention and after 8 weeks of intervention

Method of measurement
Mini Mental State Examination for global mental status; Digit Span test for working memory; Stroop test for information processing speed; California Verbal Learning Test for long-term memory; Wisconsin Card Sorting Test for executive functions

2

Description
Dual-Task Performance

Timepoint
Before the intervention and after 8 weeks of intervention

Method of measurement
Measuring gait speed in single-task and dual-task conditions (while counting backwards); measuring throwing accuracy in single-task and dual-task conditions (while naming words)

3

Description
Quality of Life

Timepoint
Before the intervention and after 8 weeks of intervention

Method of measurement
SF-36 Quality of Life Questionnaire (36 items in eight domains: physical functioning, role limitations due to physical health, bodily pain, general health, vitality, social functioning, role limitations due to emotional health, and mental health)

Secondary outcomes

1

Description
Global Mental Status

Timepoint
Before the intervention and after 8 weeks of intervention

Method of measurement
Mini Mental State Examination (30 items in five domains: orientation to time and place, short-term memory registration, attention and calculation, memory recall, and language and visuospatial skills)

2

Description
Working Memory

Timepoint
Before the intervention and after 8 weeks of intervention

Method of measurement
Digit Span Test (including forward and backward digit repetition, administered aurally)

3

Description
Information Processing Speed

Timepoint
Before the intervention and after 8 weeks of intervention

Method of measurement
Stroop Test (including four cards, measuring reaction time and number of errors)

4

Description
Long-Term Memory

Timepoint
Before the intervention and after 8 weeks of intervention

Method of measurement
California Verbal Learning Test (including word list presentation, immediate recall, short-term recall, cued recall, and delayed recall)

5

Description
Executive Functions

Timepoint

Before the intervention and after 8 weeks of intervention

Method of measurement

Wisconsin Card Sorting Test (including 128 cards, measuring correct responses, completed categories, perseverative errors, and failure to maintain set)

Intervention groups

1

Description

Intervention group: Low-intensity steady-state training for 8 weeks, three sessions per week, each session lasting 45 minutes. Each session includes 10 minutes of warm-up with light walking and dynamic stretching, 30 minutes of main exercise including treadmill walking, stationary cycling, and stair stepper at an intensity of 40-65% of maximum heart rate (increasing by 5% every two weeks), and 5 minutes of cool-down with light walking and static stretching. In case of physical weakness, the intensity is maintained at 40-50% of maximum heart rate.

Category

Behavior

2

Description

Intervention group: Functional training for 8 weeks, three sessions per week, each session lasting 45 minutes. Each session includes 10 minutes of warm-up with light walking and dynamic stretching, 30 minutes of functional exercises including balance exercises (single-leg stance, heel-toe walking, side walking), strength exercises (squats, lunges, sit-to-stand, core and spinal extensor strengthening), coordination exercises (throwing and catching a ball, walking between obstacles), and simulation of daily activities (picking up an object from the floor, 180-degree turn) with progressive overload across different weeks, and 5 minutes of cool-down with light walking and static stretching.

Category

Behavior

3

Description

Control group: Participants in this group receive no structured training intervention and are asked to continue their normal daily activities throughout the 8-week study period. After the study completion, if the interventions prove effective, the beneficial training program will be offered to this group as well.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Tarbiat Modares University

Full name of responsible person

Jaafar Jameel Abdolkaadim

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Sponsors / Funding sources

1

Sponsor

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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

Tarbiat Modares 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

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Tarbiat Modares University

Full name of responsible person
Jaafar Jameel Abdolkaadim

Position
PhD Candidate in Exercise Physiology

Latest degree
Master

Other areas of specialty/work
Exercise Physiology

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Person responsible for scientific inquiries

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Full name of responsible person
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Postdoctoral

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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
No - There is not 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 Dictionary and Variable Coding System: Includes variable names, data types, value ranges, measurement methods, and operational definitions of all primary and secondary outcome variables (cognitive function, dual-task performance, and quality of life).

When the data will become available and for how long
Six months after publication of study results

To whom data/document is available
Researchers affiliated with reputable academic and scientific institutions who have an approved research proposal by their institutional ethics committee.

Under which criteria data/document could be used
Data may be used solely for research purposes and secondary analyses related to aging and exercise physiology. Commercial use of the data is not permitted. All users must adhere to ethical requirements and maintain data confidentiality, and must report any findings from their analyses to the primary authors.

From where data/document is obtainable
To request data, please contact the corresponding author, Mr. Jaafar Jameel Abdolkaadim, via email at jameel.jaafar@modares.ac.ir. Requests may also be submitted through the Department of Exercise Sciences at Tarbiat Modares University.

What processes are involved for a request to access data/document
Upon submission of a request via email, the corresponding author will review the application. After

approval by the university ethics committee, the request will be forwarded to the research team. If finally approved, de-identified data will be provided within two to four weeks via email or a secure data-sharing platform.

Comments

Data will be provided solely for non-commercial purposes, with full adherence to ethical principles and confidentiality of participant information.