Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Evaluating the Effectiveness of a Multifaceted Intervention Program Including Activity and Balance Exercises, Nutritional, Biomechanical, Pharmacological, and Psychological Components on Improving Balance in Older Adults

Protocol summary

Study aim
To investigate the effectiveness of a multimodal intervention program (including nutritional modification, physical exercise, biomechanical modification, psychological interventions, and drug management) to improve health in the elderly.

Design
Each of the intervention and the control group will consist of 40 subjects. The intervention group will receive medication counseling for polypharmacy, an exercise program in accordance with international standards, biomechanical correction with orthoses, nutritional correction, and psychological counseling, and the control group will receive only routine medical care.

Settings and conduct
Tehran selected elderly care centers

Participants/Inclusion and exclusion criteria
Inclusion criteria: - Age ≥ 65 years - Ability to walk independently with or without a mobility aid - Score of 21 to 40 on the Berg Balance Scale, indicating moderate balance - Written informed consent to participate in the study Exclusion criteria: - Severe neurological disorders (such as stroke or advanced Parkinson's) - Moderate to severe dementia (MMSE score less than 20) - Severe musculoskeletal problems - Inability to participate in interventions for more than 2 weeks

Intervention groups
The intervention group will undergo a multimodal intervention program that includes the following: 1. Nutritional modification and Supplement prescription 2. Selected physical exercises (strength, balance, functional) 3. Biomechanical modification (posture correction, footwear, mobility aids) 4. Medication management (focusing on polypharmacy) 5. Psychological interventions including CBT) The control group will receive usual care.

Main outcome variables
Balance score of Berg test; Mobility score (TUG); Nutritional status; Polypharmacy index; Depression and anxiety; lower limb strength; Gait speed

General information

Reason for update

Acronym
MFI

IRCT registration information
IRCT registration number: **IRCT20251102067858N1**
Registration date: **2025-11-23, 1404/09/02**
Registration timing: **prospective**

Last update: **2025-11-23, 1404/09/02**
Update count: **0**

Registration date
2025-11-23, 1404/09/02

Registrant information

Name
Farhad Moradi Shahpar

Name of organization / entity

Country
Iran (Islamic Republic of)

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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
Evaluating the Effectiveness of a Multifaceted Intervention Program Including Activity and Balance Exercises, Nutritional, Biomechanical, Pharmacological, and Psychological Components on Improving Balance in Older Adults

Public title
Multifaceted Intervention on Balance in Older Adults
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
- Age ≥ 65 years- Ability to walk independently with or without a mobility aid- Score of 21 to 40 on the Berg Balance Scale, indicating moderate balance- Written informed consent to participate in the study
Exclusion criteria:
- Severe neurological disorders (such as stroke or advanced Parkinson's) Moderate to severe dementia (MMSE score less than 20) Severe musculoskeletal problems Inability to participate in interventions for more than 2 weeks
Age
From **65 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, after assessing the inclusion and exclusion criteria, participants will be randomly assigned to two groups: intervention and control. The randomization method will be performed in four-block randomization using Random Allocation Software (RAS). To avoid bias in allocation, the randomization process will be performed by an individual independent of the research team.
Blinding (investigator's opinion)
Single blinded
Blinding description
For blinding, due to the nature of the intervention, blinding of participants is not possible. However, the outcome assessors and the data analyst will be blinded to the group allocation (single-blind study design). To ensure that blinding is maintained, the groups will be coded and will only be opened after the statistical analysis is completed.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Tehran University of Medical Sciences
Street address
Poorsina ave., Enghelab Sq., Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1461884513
Approval date
2025-07-13, 1404/04/22
Ethics committee reference number
IR.TUMS.NI.REC.1404.022

Health conditions studied

1

Description of health condition studied
balance impairment in elderly
ICD-10 code
R26.81
ICD-10 code description
Unsteadiness on feet

Primary outcomes

1

Description
Berg Balance Scale
Timepoint
Pre-test before intervention and at the end of 12 weeks intervention
Method of measurement
14 items in Berg balance Test

2

Description
Time of Timed Up and Go Test
Timepoint
Pre-test before intervention and at the end of 12 weeks

intervention

Method of measurement

Time taken by the participant to cover the 3-meter distance

3

Description

Nutritional situation in Mini Nutritional Assessment

Timepoint

Pre-test before intervention and at the end of 12 weeks intervention

Method of measurement

Short Form Nutrition Assessment Score

4

Description

Score of the Medication Appropriateness Index

Timepoint

Pre-test before intervention and at the end of 12 weeks intervention

Method of measurement

Score from the quality of medication use assessment for the elderly based on the Medication Appropriateness Index

5

Description

Level of Anxiety and Depression

Timepoint

Pre-test before intervention and at the end of 12 weeks intervention

Method of measurement

The scores of Geriatric Depression Scale and Geriatric Anxiety Inventory tests

6

Description

The strength of lower limbs

Timepoint

Pre-test before intervention and at the end of 12 weeks intervention

Method of measurement

30 -Second Chair Stand Test score

7

Description

The Speed of Gait

Timepoint

Pre-test before intervention and at the end of 12 weeks intervention

Method of measurement

Average gait speed of the participant on the 4-meter path

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group:

Category

Treatment - Other

2

Description

Control group:

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Hashemi Care centers for the elderly in Kahrizak

Full name of responsible person

Mohsen Salman Nedjad

Street address

Hakimzadeh Blvd, Qom road,

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1819117536

Phone

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Email

info@kahrizakcharity.com

Web page address

https://kahrizakcharity.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Ramin Kordi

Street address

Corner of Qods Street, Keshavarz Blvd

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Fax

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Email

vcr@tums.ac.ir

Web page address

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran University of Medical Sciences

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

Tehran University of Medical Sciences

Full name of responsible person

Farhad Moradi Shahpar

Position

Researcher at Sports Medicine Research Center

Latest degree

Medical doctor

Other areas of specialty/work

Sport Medicine

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Person responsible for scientific inquiries

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Position

Reseacher

Latest degree

Ph.D.

Other areas of specialty/work

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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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Information about the main research findings will be published in the form of an article.

When the data will become available and for how

long

After the results are published, up to two years later

To whom data/document is available

Employees at academic institutions and well-known researchers

Under which criteria data/document could be used

For verification by the editor of the journal or journals in which the articles are published and for researchers who wish to conduct further research in this field.

From where data/document is obtainable

Email the principal investigator.

What processes are involved for a request to access data/document

After receiving the email, it is discussed with the research center's research council and, with the center's permission, the information is made available to the researchers by removing the subjects' names and carrying out other legal and ethical considerations.

Comments