

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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)

Phone

+98 21 8863 0228

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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 $\geq$ 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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Province
Tehran
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1819117536
Phone
+98 21 5652 5804
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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1417653761
Phone
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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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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