

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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  $\geq$  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

##### 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

##### Email address

f\_moradishahpar@sbu.ac.ir

##### 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 analyst

**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,

**City**

تهران

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Tehran

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1819117536

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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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**Province**

Tehran

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1417653761

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+98 21 8163 3047

**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**

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**Other areas of specialty/work**

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Farhad Moradi Shahpar

**Position**

Researcher

**Latest degree**

Ph.D.

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Sport Medicine

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**Email**

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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**