Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

An optimized protocol for reducing risk of fall in older adults

Protocol summary

Study aim
The aim of this study is to examine the effectiveness of a protocol based on the principles of the OPTIMAL theory as a fall-prevention program specifically designed for older adults.

Design
After initial assessments, participants will be randomly assigned to the OPTIMAL or control group. All older adults will then complete eight weeks of Short Stick Exercises, with instructional cues provided according to group assignment. The OPTIMAL group will train under OPTIMAL conditions, while the control group will perform the exercises without these motivational and attentional cues.

Settings and conduct
The study was conducted at the Mohammad Amin Charity Center, with sessions three days per week. Both groups performed the same exercises in terms of type, intensity, number, and duration. The intervention group received additional OPTIMAL theory–based attentional and motivational instructions, while the control group did not. Instructors were not blinded; however, participants were blinded to the study objectives and instructional role, and outcome assessors and the data analyst were blinded to group assignments.

Participants/Inclusion and exclusion criteria
Age range: 75 to 85 years Ability to walk independently without assistive devices No visual impairments

Intervention groups
Intervention group: Participants in this group will take part in an exercise program conducted under conditions based on the OPTIMAL theory. Control group: Participants in this group will receive the same exercise program in terms of type and intensity, as well as the number and duration of sessions; however, they will not receive instructional cues based on the OPTIMAL theory.

Main outcome variables
Static and dynamic balance, walking speed, depressive, postural sway, quality of life, intrinsic motivation, mental and physical effort, movement automaticity, positive affect, and fear of falling

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20240709062370N3**
Registration date: **2026-02-02, 1404/11/13**
Registration timing: **retrospective**

Last update: **2026-02-02, 1404/11/13**
Update count: **0**

Registration date
2026-02-02, 1404/11/13

Registrant information

Name
Hamid Salehi
Name of organization / entity
The university of Isfahan
Country
Iran (Islamic Republic of)
Phone
+98 31 3793 2577
Email address
salehi@spr.ui.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-08-30, 1404/06/08
Expected recruitment end date
2025-09-06, 1404/06/15
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
An optimized protocol for reducing risk of fall in older adults

Public title
An optimized protocol for reducing risk of fall in older adults

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Age range: 65 to 80 years No visual impairments

Exclusion criteria:
Diagnosis of depression Use of walking aids

Age
From **75 years** old to **85 years** old

Gender
Female

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization method. For this purpose, participants are first listed in alphabetical order, and the numbers one and two are assigned to each participant on the list. The unit of randomization is the individual. Randomization is generated and implemented using Microsoft Excel by combining the SORTBY and ARRAYRAND functions. Using this method, each participant is allocated through simple randomization to either the control group or the OPTIMAL group, and the influence of all relevant and irrelevant variables on group allocation is neutralized through random assignment.

Blinding (investigator's opinion)
Double blinded

Blinding description
Given that the type of exercise, duration, intensity, and implementation conditions are identical in both groups, participants will not be aware of the differences in the instructional cues provided or their role as the main intervention of the study. Accordingly, participants will be blinded to the study objectives and group allocation. In addition, the outcome assessor and the data analyst will be blinded to participants' group assignments.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research ethics committees of University of Isfahan

Street address
The university of Isfahan, Hezar Jarib Ave

City
Isfahan

Province
Isfehan

Postal code
8174673444

Approval date
2025-08-16, 1404/05/25

Ethics committee reference number
IR.UI.REC.1404.106

Health conditions studied

1

Description of health condition studied
Fall

ICD-10 code
W01

ICD-10 code description
Fall on same level from slipping, tripping and stumbling

Primary outcomes

1

Description
Postural sway

Timepoint
Pre-test, post-test

Method of measurement
Foot scanner device

Secondary outcomes

1

Description
Static and dynamic balance

Timepoint
Pre test, Post test

Method of measurement
Timed Up and Go test (TUG)

2

Description
Quality of life

Timepoint
Pre test, Post test

Method of measurement
Older Adults' Quality of Life Questionnaire

3

Description
Fear of falling
Timepoint
Pre test, Post test
Method of measurement
Geriatric Fear of Falling Measure

4

Description
Intrinsic Motivation
Timepoint
Pre test, Post test
Method of measurement
Intrinsic Motivation Questionnaire

5

Description
Falls Self-Efficacy
Timepoint
Pre test, Post test
Method of measurement
Falls Self-Efficacy Scale

Intervention groups

1

Description
Intervention group: Short stick exercises with motivational and attentional instructions based on Optimal theory; The intervention consists of eight weeks and three sessions per week. Short stick exercises include six consecutive warm-up phases, one-handed stick throwing, two-handed throwing, balance exercises, swinging and releasing the stick, and cool-down exercises. Participants in the Optimal group will receive motivational instructions during exercise, including positive feedback, “You are doing great” and the choice of stick color, as well as attentional instructions, “Pay attention to the color mark on the stick.” Exercises are performed while sitting on a chair and using a light stick (21.5 inches long, one inch in diameter, and 200 grams in weight).
Category
Prevention

2

Description
Control group: Exercises completely similar to the experimental group (same number of sessions and duration) but without motivational and attentional instructions based on optimal theory.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Mohammad Amin Charity, Isfahan
Full name of responsible person
Ms. Abbasi
Street address
33, Sina Alley, 13 (Shahid Hadi) Alley, Hosseinabad St., Hakim Nezami St., Isfahan, Iran
City
Isfahan
Province
Isfehan
Postal code
0000
Phone
+98 31 3624 9595
Fax
Email
info@mohammadamin.org
Web page address
https://www.mohamadamin.org/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
The university of Isfahan
Full name of responsible person
Dr. Amir Rahimi
Street address
The University of Isfahan, Azadi square, Isfahan, Iran
City
Isfahan
Province
Isfehan
Postal code
8174673441
Phone
+98 31 3793 2003
Email
info@ui.ac.ir
Web page address
https://favic.ui.ac.ir/
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
The university of Isfahan
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
The university of Isfahan
Full name of responsible person
Dr. Hamid Salehi
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Motor behavior
Street address
The University of Isfahan, Azadi square, Isfahan, Iran
City
Isfahan
Province
Isfehan
Postal code
8174673444
Phone
+98 31 3793 2577
Email
salehi.hamid@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
The university of Isfahan
Full name of responsible person
Dr. Hamid Salehi
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Motor behavior
Street address
The University of Isfahan, Azadi square, Isfahan, Iran
City
Isfahan
Province
Isfehan
Postal code
8174673444
Phone
+98 31 3793 2577
Email
salehi.hamid@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
The university of Isfahan
Full name of responsible person
Dr. Hamid Salehi
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Motor behavior
Street address
The University of Isfahan, Azadi square, Isfahan, Iran
City
Isfahan
Province
Isfehan
Postal code
8174673444
Phone
+98 31 3793 2577
Email
salehi.hamid@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Not applicable