Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The Effect of Practical Training Based on Sensory Evaluation Using Artificial Intelligence on Fear of Falling Among Community-Dwelling Older Adults

Protocol summary

Study aim

determine the effect of practical exercises based on sensory assessment (vision and hearing) using artificial intelligence on fear of falling in older adults.

Design

A randomized controlled clinical trial with parallel groups and no blinding will be conducted on 62 older adults. Participants will be allocated 1:1 to intervention and control groups using block randomization with block sizes of 4 and 6.

Settings and conduct

This study will be conducted among eligible older adults at comprehensive health centers affiliated with Tehran University of Medical Sciences. After screening and informed consent, participants will be randomly assigned to intervention and control groups. The intervention group will receive two face to face training and assessment sessions, followed by eight weeks of home use of the artificial intelligence platform, three times per week, for sensory assessment, feedback, and practical exercises. The control group will receive baseline assessment only. No blinding will be performed.

Participants/Inclusion and exclusion criteria

Participants will include older adults aged 60 years and older with stable physical and cognitive status, ability to move, walk, and communicate, adequate sensory function for assessments, basic literacy or caregiver support, and smartphone access. Individuals with severe physical, sensory, or cognitive limitations preventing participation will be excluded.

Intervention groups

Intervention group: Participants will receive two face to face training and assessment sessions, followed by eight weeks of using the artificial intelligence platform at home, three times per week, for sensory assessment, feedback, and practical exercises. Control group: Participants will receive only baseline assessment without artificial intelligence based intervention, training, or feedback.

Main outcome variables

Level of fear of falling among older adults

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260801070487N1**
Registration date: **2026-08-08, 1405/05/17**
Registration timing: **prospective**

Last update: **2026-08-08, 1405/05/17**
Update count: **0**

Registration date

2026-08-08, 1405/05/17

Registrant information

Name

Shiva Zamani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3776 6906

Email address

sh-zamani@razi.tums.ac.ir

Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-11-05, 1405/08/14

Expected recruitment end date

2027-03-19, 1405/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Practical Training Based on Sensory Evaluation Using Artificial Intelligence on Fear of Falling Among Community-Dwelling Older Adults

Public title

The Effect of Practical Training Based on Sensory Evaluation Using Artificial Intelligence on Fear of Falling Among Community-Dwelling Older Adults

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Age 60 years or older Stable general physical condition Ability to move and change body position (sitting, standing, and lying down) without severe medical limitations Ability to walk independently or with an assistive device Correctable vision with eyeglasses or contact lenses (minimum visual acuity required to read the digital Snellen chart) Adequate hearing to understand standard verbal instructions (with or without hearing aids), assessed using a simple word repetition test Ability to communicate Stable psychological and cognitive status with sufficient cognitive ability to understand instructions and respond to the assessments (Mini-Cog score ≥ 3) Ability to read and write at a basic level or availability of a caregiver to assist with understanding the questionnaires and instructions Access to a smartphone and the ability to use it

Exclusion criteria:

Age

From **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **62**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method and description: In this study, participants will be allocated to the intervention and control groups using block randomization. The block sizes will include blocks of 4 and 6 participants (including eight blocks of 4 participants and five blocks of 6 participants). Participants will be equally allocated to the intervention group (31 participants) and the control group (31 participants) with an allocation ratio of 1:1. Randomization unit: The unit of randomization in this study is the individual. Each eligible older adult will be independently allocated to one of the two study groups. Randomization strata: Stratified randomization will not be used in this study. Randomization tool: The random allocation sequence will be generated using the online randomization service provided by Sealed Envelope Ltd. Generation of random allocation sequence: The random allocation sequence will be generated using block randomization with block sizes of 4 and 6 participants and an allocation ratio of 1:1 by the online randomization service of Sealed Envelope Ltd. Eligible participants will be assigned to either the intervention or control group according to this sequence. Allocation concealment: Allocation concealment will be performed using opaque and sealed envelopes containing the random allocation sequence (Sequentially Numbered, Opaque, Sealed Envelopes; SNOSE).

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of School of Nursing and Midwifery & Rehabilitation - Tehran University o

Street address

School of Nursing and Midwifery, Dr. Mirkhani St. (Nosrat Sharghi), Towhid Sq., Tehran University of Medical Sciences, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1419733171

Approval date

2026-04-05, 1405/01/16

Ethics committee reference number

IR.TUMS.FNM.REC.1405.002

Health conditions studied

1

Description of health condition studied

Fear of falling in older adults

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Fear of falling score based on the total score of the 16-item Falls Efficacy Scale International questionnaire (score range: 16–64).

Timepoint
Fear of falling score will be measured using the Falls Efficacy Scale International questionnaire at two time points: at the beginning of the study (baseline) and after completion of the 8-week intervention (post-intervention).

Method of measurement
Standard 16-item Falls Efficacy Scale International questionnaire for assessing concerns about the possibility of falling during daily activities.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The intervention will be implemented in two phases. In the first phase, participants will attend two face-to-face sessions at comprehensive health centers in a controlled environment. During these sessions, sensory assessment, including vision and hearing, will be performed in three body positions (standing, sitting, and supine) using an artificial intelligence platform. The platform will assess visual and auditory performance using a digital vision chart and standardized auditory commands. After analyzing the collected data, it will provide targeted feedback, including alerts, notification to the participant and caregiver, and, if necessary, recommendation for specialist evaluation. Participants and their caregivers will also receive training on using the platform, viewing the educational video, responding to platform feedback, and performing practical exercises. The educational content will be tailored according to the initial assessment results and will cover three components: sensory awareness (vision and hearing), environmental and behavioral safety, and cognitive-behavioral training related to fear of falling. At the end of each session, participants' learning will be evaluated using the Teach-Back method, and additional training will be provided if needed. In the second phase, the platform will be installed on the participants' smartphones. Participants will use it at home for eight weeks, three sessions per week, with each session lasting 30–45 minutes, to perform sensory assessment, receive feedback, and complete practical exercises based on the assessment results. During each session, all three body positions will be assessed, and feedback and training will be provided as needed. Throughout the intervention period, the researcher will monitor the correct implementation of the intervention through telephone or video calls, and participants' adherence will be monitored through the platform's automatic data recording system.

Category
Behavior

2

Description
Control group: Participants will receive only baseline and post-intervention assessments. During the study, they will not receive any artificial intelligence-based intervention, training, practical exercises, or feedback

Category
Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center
Comprehensive Health Centers Affiliated with Tehran University of Medical Sciences

Full name of responsible person
shiva zamani

Street address
No. 252, First Floor, Intersection of Hafez St. and Jomhouri St., Tehran

City
Tehran

Province
Tehran

Postal code
1134845764

Phone
+98 21 6670 5068

Email
health-deputy@sina.tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Vice-Chancellor for Research and Technology of Tehran University of Medical Sciences

Street address
6th Floor, Vice-Chancellor for Research and Technology Office, Central Building of Tehran University of Medical Sciences, Corner of Ghods Street, Keshavarz Boulevard, Tehran

City
Tehran

Province
Tehran

Postal code
141765383761

Phone
+98 21 8163 3698

Fax

Email

vcr@tums.ac.ir

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

shiva zamani

Position

Master's Student in Geriatric Nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

School of Nursing and Midwifery, Dr. Mirkhani St. (Nosrat-e Sharghi), Towhid Sq., Tehran University of Medical Sciences, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1419733171

Phone

+98 21 6692 7171

Email

shiiivazamani@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

shiva zamani

Position

Master's Student in Geriatric Nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

School of Nursing and Midwifery, Dr. Mirkhani St. (Nosrat-e Sharghi), Towhid Sq., Tehran University of Medical Sciences, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1419733171

Phone

+98 21 6692 7171

Email

shiiivazamani@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

shiva zamani

Position

Master's Student in Geriatric Nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

School of Nursing and Midwifery, Dr. Mirkhani St. (Nosrat-e Sharghi), Towhid Sq., Tehran University of Medical Sciences, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1419733171

Phone

+98 21 6692 7171

Email

shiiivazamani@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

No - There is not 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	Undecided - It is not yet known if there will be a plan to make this available