Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The Effect of an Educational Program on the Adoption of Foot Care Behaviors among Older Adults: A Quasi-Experimental Trial

Protocol summary

Study aim

The aim of this study is to determine the effect of an educational program on the adoption of foot self-care behaviors among older adults.

Design

Controlled clinical trial, with parallel groups, open-label, cluster-randomized, on 120 elderly participants. The unit of randomization was the health center, and allocation of centers to the intervention and control groups was performed via lottery.

Settings and conduct

The study will be conducted among older adults attending four selected urban health centers. After screening based on inclusion and exclusion criteria, participants will be randomly assigned to the intervention or control group. The study is designed as open-label.

Participants/Inclusion and exclusion criteria

Older adults aged over 65 years, with functional independence and the ability to perform activities of daily living, without cognitive impairment (score of 6 or higher on the Persian version of the Abbreviated Mental Test), and willing to participate in the study were eligible for inclusion. Exclusion criteria: Older adults with diabetes or those taking medications that cause dizziness or drowsiness

Intervention groups

The intervention group will receive six 60–90-minute sessions over three weeks on foot hygiene and inspection, proper footwear, exercises, self-efficacy, and home safety, with telephone follow-up, while the control group will receive routine care only and complete the questionnaires at the scheduled time points.

Main outcome variables

Foot care behavior; Quality of life; Social support; Fall risk.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250428065506N1**
Registration date: **2026-06-03, 1405/03/13**
Registration timing: **registered_while_recruiting**

Last update: **2026-06-03, 1405/03/13**
Update count: **0**

Registration date

2026-06-03, 1405/03/13

Registrant information

Name
avatef savari
Name of organization / entity
Tarbiat Modares University
Country
Iran (Islamic Republic of)
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+98 61 3623 0992
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-05-22, 1405/03/01

Expected recruitment end date

2026-07-22, 1405/04/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The Effect of an Educational Program on the Adoption of Foot Care Behaviors among Older Adults: A Quasi-Experimental Trial

Public title
Investigating the Effect of an Educational Intervention on Foot Care in Older Adults.

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Age 65 years or older Functional independence and ability to perform activities of daily living Absence of cognitive impairment (defined as obtaining a score of 6 or above on the Persian version of the Mini-Mental State Examination) Informed consent to participate in the study

Exclusion criteria:
Individuals with diabetes Use of specific medications that cause dizziness or drowsiness in older adults

Age
From **65 years** old to **90 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **120**

Randomization (investigator's opinion)
Randomized

Randomization description
Cluster randomization will be used in this study, with the health center considered as the unit of randomization. Two comparable urban health centers will be selected from those covered by the health network. The centers will then be allocated to the intervention and control groups using simple randomization. For this purpose, the names of the two centers will be written on identical pieces of paper, and through drawing lots, one center will be assigned to the intervention group and the other to the control group. After the group assignment of each center, older adults attending each center will be recruited using convenience sampling following assessment of the inclusion and exclusion criteria. The objectives of the study will be explained to eligible individuals, and written informed consent will be obtained from those who agree to participate. Participant recruitment in each group will continue until the required sample size is reached, and if the sample size is not initially achieved, enrollment of eligible participants will continue until the target number is completed. Since randomization is conducted at the cluster level, stratification will not be performed. Due to the nature of the educational intervention, allocation concealment and participant blinding will not be feasible.

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
Ethics Committee of Tarbiat Modares University

Street address
Tarbiat Modares University, Nasr Bridge, Jalal Al-Ahmad Street, Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1411713116

Approval date
2024-10-02, 1403/07/11

Ethics committee reference number
IR.MODARES.REC.1403.092

Health conditions studied

1

Description of health condition studied
Foot care

ICD-10 code
Z71.9

ICD-10 code description
Counseling, unspecified

Primary outcomes

1

Description
Foot self-care behavior among older adults

Timepoint
Foot self-care behavior among older adults will be assessed at five time points: before the intervention, immediately after, and at 1, 3, and 6 months following the completion of the educational program.

Method of measurement
Foot care behavior as a composite primary outcome, including daily foot inspection, regular washing, use of appropriate footwear, and checking water temperature before washing, measured using a self-developed Foot Care Behavior Questionnaire.

Secondary outcomes

1

Description
Quality of life
Timepoint
Before intervention (Day 0), immediately after intervention (Day 0), 1 month after intervention , 3 months after intervention, and 6 months after intervention .
Method of measurement
Quality of life will be measured using the LEIPAD Quality of Life Questionnaire for older adults. This instrument consists of 31 items covering seven domains: physical functioning, self-care, depression and anxiety, cognitive functioning, social functioning, sexual functioning, and life satisfaction. The items are rated on a four-point Likert scale ranging from 0 (worst condition) to 3 (best condition). The total score is calculated by summing the item scores, with a possible range from 0 to 93. Higher scores indicate a better quality of life among older adults.

2

Description
risk of falling
Timepoint
Before intervention (Day 0), immediately after intervention (Day 0), 1 month after intervention , 3 months after intervention, and 6 months after intervention .
Method of measurement
Risk of falling will be assessed using the Comprehensive Fall Risk Assessment Questionnaire developed by Fabre et al. (2010). This instrument includes five subscales: fall history, medication use, physical function, vision, and environmental factors. Each domain is scored based on its respective items, and the total score is calculated by summing the scores of all subscales. Higher scores indicate a greater risk of falling among older adults.

3

Description
Social support
Timepoint
Before intervention (Day 0), immediately after intervention (Day 0), 1 month after intervention , 3 months after intervention, and 6 months after intervention .
Method of measurement
Social support will be assessed using the Duke Social Support Index (DSSI), which consists of 19 items across two domains: emotional support and social interaction. The instrument is specifically designed for older populations. Items are rated on a multi-point Likert scale, and the total score is obtained by summing the item scores. Higher scores represent greater perceived social support among older adults.

Intervention groups

1

Description
Intervention group: This structured educational intervention, designed based on the Protection Motivation Theory (PMT), will be implemented with the aim of improving foot-care behaviors among older adults. Participants will take part in a three-week program consisting of six in-person educational sessions (two sessions per week), with each session lasting between 60 and 120 minutes and delivered by the researcher at the Comprehensive Health Services Center. The session content includes education on common foot disorders in older adults, risk factors for foot problems, proper foot-care practices (including daily inspection, foot hygiene, appropriate washing and drying techniques, and proper toenail trimming), guidance on selecting appropriate footwear and socks, identification of warning signs of foot complications, and strategies for fall prevention. The sessions will be delivered through lectures, group discussions, question-and-answer activities, and the use of educational materials and images. In addition, home safety will be assessed using a standardized home-safety checklist, and tailored recommendations will be provided to reduce the risk of falls. Family members and relevant healthcare providers will also receive the necessary training to support foot-care behaviors and fall-prevention practices among older adults.
Category
Behavior

2

Description
Control group: Participants in the control group will not receive any educational intervention. They will only complete the study questionnaires at the same five time points as the intervention group: baseline, immediately after the intervention, one month, three months, and six months post-intervention.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Health Center No. 5, Shushtar County
Full name of responsible person
Dr. Roxana Gholami
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2

Recruitment center

Name of recruitment center

Health Center No. 4, Shushtar County

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tarbiat Modares University

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

Tarbiat Modares University

Full name of responsible person

Dr. Alireza Heydarnia

Position

professor

Latest degree

Ph.D.

Other areas of specialty/work

Health Promotion

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data

Contact

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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
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
Only a portion of the dataset—such as information related to the primary outcome—will be available for data sharing.
When the data will become available and for how long
The data access period will begin six months after the publication of the study results.
To whom data/document is available
The de-identified data from this study will be accessible only to researchers affiliated with academic and scientific institutions
Under which criteria data/document could be used
Access to the de-identified data from this study will be available only to researchers affiliated with recognized academic or research institutions. A formal request outlining the research objective and proposed statistical analysis plan is required. Data may be used solely for non-commercial, research purposes and only after signing a confidentiality agreement. All requests will be reviewed and approved by the study's scientific committee prior to data release.
From where data/document is obtainable
Dr. Alireza Heydarnia Tarbiat Modares University
hidarnia@modares.ac.ir
What processes are involved for a request to access data/document
Researchers who are interested in accessing the study documents or datasets may submit a formal request to the principal investigator via email. The request should include the purpose of the study, the intended use of the data, and relevant institutional affiliation. All requests will be reviewed by the research team to ensure that the proposed use is consistent with ethical standards and participant confidentiality. After approval, the requested documents or de-identified datasets will be shared with the applicant. The review and response process is expected to take approximately 2 to 4 weeks from the time the request is received.
Comments