Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Effect of a Health Literacy Based Educational Program on Health Seeking Behaviors among Older Adults: A Randomized Controlled Trial

Protocol summary

Study aim
To determine the effectiveness of the educational program in improving health seeking behaviors among community dwelling older adults.

Design
A randomized controlled clinical trial with a parallel design will be conducted among 80 older adults, with 40 participants allocated to each group. Participants will be randomly allocated using block randomization. The random allocation sequence will be generated using the Randomization.com website.

Settings and conduct
This randomized clinical trial will be conducted at the Akbarabad Comprehensive Health Service Center in South Tehran. A total of 80 older adults will be randomly allocated to two groups, intervention and control. The intervention group will receive a group based educational program focused on improving health literacy over 6 weeks, while the control group will receive usual care. The primary outcome will be assessed before the intervention, immediately after the intervention, and two months after the intervention.

Participants/Inclusion and exclusion criteria
Community dwelling older adults aged 60 years and older, who are attending a Comprehensive Health Service Center in southern Tehran, have experienced an illness within the past 6 months, are Persian speaking, are able to communicate and provide informed consent, and have a score of 24 or higher on the Mini Mental State Examination will be eligible to participate in the study. Individuals with cognitive impairment or communication disorders, or those participating in a similar educational program, will not be eligible for participation.

Intervention groups
Intervention group: Participants will receive a group-based educational program focused on enhancing health literacy. The program will be delivered over 6 weekly sessions in groups of 6 to 8 participants.

Main outcome variables
Health-Seeking Behavior Score

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20260829070827N1**
Registration date: **2026-09-07, 1405/06/16**
Registration timing: **prospective**

Last update: **2026-09-07, 1405/06/16**
Update count: **0**

Registration date
2026-09-07, 1405/06/16

Registrant information
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Zahra Yousefi
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Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-09-19, 1405/06/28

Expected recruitment end date
2026-11-19, 1405/08/28

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Effect of a Health Literacy Based Educational Program on Health Seeking Behaviors among Older Adults: A Randomized Controlled Trial

Public title
Effect of a Health Literacy Based Educational Program on Health Seeking Behaviors among Older Adults

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Age 60 years or older Living in the community and attending Akbarabad Comprehensive Health Service Center in South Tehran Having experienced an illness during the past 6 months Fluency in Persian Having the ability to communicate and participate in the educational sessions A score of 24 or higher on the Mini Mental State Examination Providing written informed consent to participate in the study

Exclusion criteria:
Having a cognitive impairment that affects the ability to understand and participate in the educational program. Having a psychological disorder that affects the ability to communicate and participate in the study. Having a visual or hearing impairment that affects communication and participation in the study. Concurrent participation in a similar educational program on health-seeking behaviors or health literacy.

Age
From **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Data analyser

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
Eligible participants will be individually allocated in a 1:1 ratio to the intervention or control group after obtaining informed consent and completing the baseline assessment. Block randomization with a fixed block size of 4 will be used. The random sequence will be generated using Randomization.com based on the six possible arrangements within blocks of 4 participants: AABB, ABAB, BBAA, BABA, ABBA, and BAAB. No stratified randomization will be used, and the individual participant will be the unit of randomization. To ensure allocation concealment, 80 opaque, non-transparent, sequentially numbered, and sealed envelopes will be prepared, with an allocation card placed inside each envelope. The envelopes will be kept by a person who is not involved in participant recruitment or baseline assessment. After eligibility is confirmed, informed consent is obtained, and the baseline assessment is completed, the envelope corresponding to the participant's study number will be opened.

Blinding (investigator's opinion)
Single blinded

Blinding description
Participants will not be blinded to their group allocation because the intervention involves participation in a group-based educational program. The researcher responsible for delivering the intervention will also not be blinded to group allocation. The researcher responsible for collecting the outcome data will not be blinded if the same researcher administers the questionnaires at post-intervention and follow-up assessments. No healthcare personnel responsible for routine care will be involved in group allocation or delivery of the intervention. Data analysis will be conducted using coded group identifiers only if the analyst is not informed of the meaning of the group codes. No independent Data Safety and Monitoring Committee is planned for this study.

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 (TUMS)

Street address
Tohid Square, Dr. Mirkhani Street (East Nosrat Street), Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1419733171

Approval date
2024-05-08, 1403/02/19

Ethics committee reference number
IR.TUMS.FNM.REC.1403.015

Health conditions studied

1

Description of health condition studied
Health-seeking behavior in older adults

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Health-Seeking Behavior Score: The total score obtained from the Health-Seeking Behavior Scale (HSBS) in the elderly. This variable is measured using the total questionnaire score at specified times before and after the intervention, and the change in score will be compared between the intervention and control groups. A higher score indicates a higher level of health-seeking behaviors.

Timepoint

The score of health-seeking behaviors will be measured at three time points in both the intervention and control groups: (1) at the beginning of the study and before the start of the intervention (pre-test), (2) immediately after the end of the six-week intervention (post-test), and (3) two months after the end of the intervention (follow-up).

Method of measurement

Health-seeking behavior will be measured using the Health Seeking Behavior Scale developed by Kıraç and Öztürk. The final version of the scale consists of 12 items across three dimensions: online health-seeking behavior (6 items), professional health-seeking behavior (3 items), and traditional health-seeking behavior (3 items). The items are rated using a Likert-type response scale, with higher scores indicating a higher level of health-seeking behavior. In the present study, the Persian version of the scale will be used following translation and cultural adaptation and assessment of its validity and reliability.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Participants in the intervention group will receive a group-based educational program aimed at improving health-seeking behaviors through the enhancement of health literacy. The program is designed based on Nutbeam's three-level model of health literacy, including functional, interactive, and critical health literacy. The content of the program was developed based on the findings of the qualitative study, the results of the scoping review, and the prioritization of modifiable challenges identified in the Delphi study.The intervention will be delivered over **six weekly group sessions for groups of 6–8 participants . Each session will generally last 60–75 minutes, while the fourth session, depending on the educational content, may last up to 100 minutes. The sessions will be conducted at a Comprehensive Health Service Center by the researcher.The content of the sessions will include education on concepts and skills related to health-seeking behaviors, improving the ability to obtain and understand health information, strengthening communication skills and the ability to ask questions of healthcare providers, using the teach-back method, recognizing the appropriate time and way to seek healthcare services, evaluating and comparing health information and recommendations, strengthening informed decision-making skills, identifying and addressing barriers to health-seeking behaviors, goal setting and action planning, self-monitoring, and strengthening the continuation of desirable behaviors.Active and participatory educational methods, including group discussion, scenario-based learning, role-play, practical exercises, teach-back, action planning, self-monitoring, problem-solving, and peer learning, will be used to conduct the sessions. The educational content will be tailored to the participants' health literacy levels and needs as older adults. Participants in the intervention group will attend all six educational sessions, and the implementation of the sessions and participants' engagement will be documented using an intervention fidelity checklist.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Akbarabad Comprehensive Health Services Center

Full name of responsible person

Seyed Mehdi Mahdavi

Street address

South Tehran, Tehran, District 10, Navab Highway, Mahboob Mojaz (Sina) Street, before reaching Nahid Street, next to the former District 10 Education Department

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Ramin Kordi

Street address

Keshavarz Boulevard, corner of Ghods Street, Central Organization of the University, 6th floor, Deputy of Research and Technology

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Web page address
https://vcr.tums.ac.ir/about

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
Zahra Yousefi
Position
PhD student in nursing
Latest degree
Master
Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
Given the nature of the collected data and the requirements related to maintaining the confidentiality and privacy of the participants, there is no plan to share individual participants' data in this study. The research data will be used solely for the specified research purposes and will be kept in accordance with ethical

requirements and regulations related to information confidentiality.

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

No - There is not 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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Study Protocol: The complete study protocol will be made available for sharing after completion of the study. The protocol will include information on the study objectives and design, eligibility criteria, sampling and participant allocation procedures, intervention description, study outcomes, data collection methods, and statistical analysis plan. The shared protocol will not contain any personally identifiable or confidential participant information. Access will be provided in accordance with applicable ethical requirements and regulations governing the use and dissemination of research documents.

When the data will become available and for how long

Access to the documents will begin 6 months after the completion of the study, and thereafter, upon request by eligible researchers and in compliance with ethical and confidentiality requirements, access to the documents will be provided.

To whom data/document is available

Researchers and faculty members employed at universities and eligible research and scientific institutions can apply to receive study documents. Requests will be reviewed and approved by the principal investigator of the study, and in compliance with ethical requirements, confidentiality, and regulations related to the use of research documents. Upon approval, access to the documents will be granted.

Under which criteria data/document could be used

Access to the study documents will be permitted solely for scientific and research purposes and within the scope of topics related to the study. Applicants must submit a request including their name and institutional affiliation, the purpose of the request, the intended use of the documents, and, where applicable, the intended manner of publication or use of the results derived from them. The use of the documents for commercial purposes, their transfer to third parties, or any use that is inconsistent with ethical requirements and regulations concerning the confidentiality of research information will not be permitted. Requests will be reviewed by the principal investigator of the study, and access to the documents will be provided upon approval.

From where data/document is obtainable

Applicants may initially contact the principal investigator to submit a request for access. Requests should be submitted in writing by email and should include the applicant’s full name, institutional affiliation, purpose of the request, and intended use of the requested documents. Each request will be reviewed by the principal investigator. Upon approval, the requested documents will be made available to eligible applicants. Name of the responsible contact person: Zahra Yousefi Position: PhD Student in Nursing, Tehran University of Medical Sciences and Health Services Institutional affiliation: School of Nursing and Midwifery, Tehran University of Medical Sciences and Health Services Postal address: Tohid Square, Dr. Mirkhani Street (East Nosrat Street), Tehran, Iran Email: stu.yousefi@yahoo.com Telephone:+98 910 905 9966

What processes are involved for a request to access data/document

The applicant submits their request in writing via the responsible researcher's email. The request will be reviewed for completeness of information and compliance of the intended use with the conditions set for access to the documents. The result of the review will be communicated to the applicant within a maximum of 30 working days. If the request is approved, the requested documents will be sent to the applicant via email after coordination and completion of the necessary procedures. If additional information is required, the review process will continue upon receipt of the needed information.

Comments