

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Survey The Effectiveness of Education on fall care behaviors of the elderly in health centers.

Protocol summary

Study aim

Determining survey the effectiveness of education on fall care behaviors of the elderly in health centers.

Design

Clinical trial with control group, 110 elderly eligible to enter the study, Factorial groups, double-blind, randomized.

Settings and conduct

After the list of health centers in the four districts of the municipality Ardabil, two centers were selected randomly from each region. Then from among the two centers of the municipality district, the first selection was considered as the center of intervention and the second choice of control center. The staff and elderly of the selected centers were unaware of the areas and centers. The researcher, by referring to the center and presenting the letter of introduction, collected the national elderly code list and selected the elderly according to the random sample number. At this stage, the evaluator completed questionnaires without knowledge of the type of group.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Having the satisfaction to participate in the study, age 60 and older, earning a score higher than 6 based on AMTS or above 26 based on MMSE, not using mobility aids, lack of training courses care behaviors fall as Exclusion Criteria: lack of willingness to cooperate at each stage of research implementation and death of the elderly.

Intervention groups

The researcher, based on the "Educational Handbook for fall in the Elderly", trained an intervention group in a 45-minute session on the face of falling behaviors. The elderly of the control group after the completion of the sampling, training of fall care behaviors such as intervention group was given.

Main outcome variables

Using the results of nursing education and management and community health, providing an educational booklet

for use in health centers and nursing care centers that can improve their quality of life by preventing them from falling.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180205038618N1**

Registration date: **2018-06-09, 1397/03/19**

Registration timing: **retrospective**

Last update: **2018-06-09, 1397/03/19**

Update count: **0**

Registration date

2018-06-09, 1397/03/19

Registrant information

Name

Samira Samadzade

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 45 3351 1660

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n.mozaffari@arums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-08-23, 1396/06/01

Expected recruitment end date

2018-02-20, 1396/12/01

Actual recruitment start date

2017-09-02, 1396/06/11

Actual recruitment end date

2018-05-09, 1397/02/19

Trial completion date
empty

Scientific title
Survey The Effectiveness of Education on fall care behaviors of the elderly in health centers.

Public title
Survey The Effectiveness of Education on fall care behaviors of the elderly

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
 Having the satisfaction to participate in the study Age 60 and older Earning a score higher than 6 based on Abbreviated Mental Test Score (AMTS) or above 26 based on Mini-Mental State Examination (MMSE) Not using mobility aids Lack of training courses care behaviors fall
Exclusion criteria:
 Not wanting to get involved in every step of this research Death of the elderly

Age
From **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
 Target sample size: **92**
 Actual sample size reached: **110**

Randomization (investigator's opinion)
Randomized

Randomization description
 The sampling method is stratified random cluster sampling. In this method, sampling units are health centers of Ardabil city that are considered as four clusters of the municipality and a list of health centers of clusters from the health center of Ardabil city and each cluster of 2 centers (A total of 8 centers) were randomly selected using sealed envelopes. The two selected centers in each cluster were randomly with draw divided into the intervention and control groups and then the elderly were classified according to records from the age group of 70-60, 80-71, 81 and above, and from among the categories a random sample of samples was selected.

Blinding (investigator's opinion)
Double blinded

Blinding description
 After the list of health centers in the four districts of the municipality, two centers were selected randomly from each region. Then from among the two centers of the Municipality district, the first selection was considered as the center of intervention and the second choice of control center. The staff and elderly of the selected

centers were unaware of the areas and centers. The researcher, by referring to the center and presenting the letter of introduction, collected the national elderly code list and selected the elderly according to the random sample number and invited them to the center by telephone. At this stage, the evaluator completed questionnaires without knowledge of the type of group. Then, the researcher in the intervention group provided his education according to the booklet and completed one month and three months after the intervention, the questionnaire was completed by the assessor. Data were entered by the researcher without specifying the control group and the intervention, and was provided to the statistician for analysis.

Placebo
Not used

Assignment
Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
 Ethics committee of Ardabil University of Medical Sciences
Street address
 Bakeri Street
City
 Ardabil
Province
 Ardabil
Postal code
 56198-19148
Approval date
 2017-08-21, 1396/05/30
Ethics committee reference number
 IR.ARUMS.REC.1396.89

Health conditions studied

1

Description of health condition studied
 Falling in the elderly
ICD-10 code
ICD-10 code description

2

Description of health condition studied
 education in the elderly
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description

Survey The Effectiveness of Education on fall care behaviors of the elderly

Timepoint

Before the intervention, 1 month and 3 months after the education

Method of measurement

Falls Behavioral scale

Secondary outcomes

1

Description

Effect of fall care behaviors Education on Fear of Falling among Elderly

Timepoint

Before the intervention, 1 month and 3 months after education

Method of measurement

Fall efficacy scale international

Intervention groups

1

Description

Intervention group: Fall care behaviors Education based on the "Educational Handbook on Fall Behaviors in the Elderly" face-to-face in a 45-minute session.

Category

Prevention

2

Description

Control group: Fall care behaviors Education based on the "Educational Handbook on Fall Behaviors in the Elderly" face-to-face in a 45-minute session after completing the sampling

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Ghanadi Emami Health Center

Full name of responsible person

Seyed Farhad Reese

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Hafez Street

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Name of recruitment center
Omid Rayehe Institute
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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
Ardabil 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
Ardabil University of Medical Sciences
Full name of responsible person
Samira Samadzade
Position
Postgraduated Student
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Person responsible for updating data

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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

Undecided - It is not yet known if there will be a plan to make this available