Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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)

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+98 45 3351 1660

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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 Reesee
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4

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5

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6

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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
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Full name of responsible person
Samira Samadzade
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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