Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The Effect of Empowerment Based on 5A Model on Fall Self-Efficacy, Self-Care and Quality of Life in Older Adults: A Parallel Randomized Clinical Trial

Protocol summary

Study aim

Determining the Effect of the 5A Empowerment Model on Fall Self-efficacy, Self-Care and Quality of Life in Older Adults: A Parallel Randomized Clinical Trial

Design

A clinical trial with a control group with parallel groups, randomized by a block method with a volume of 4 is used to create a random allocation sequence because the elderly are gradually included in the study. The sample size is 110 people.

Settings and conduct

The research population includes all elderly people over 65 living in Gorgan city. The research environment is the health centers of Gorgan city. The elderly will be selected by sequential sampling. In this way, the city of Gorgan will be classified into three regions one, two and three in terms of municipal divisions and two centers will be randomly selected from each region and a sample will be taken according to the population of the elderly covered by the health centers of that region.

Participants/Inclusion and exclusion criteria

Inclusion criteria: being 65 years of age and over, understanding educational materials, independence in performing activities in daily life. Exclusion criteria: physical or psychiatric disorder, participation in similar educational programs at the same time, unwillingness to participate in the study

Intervention groups

In the intervention group, the individual program will be conducted based on the 5A self-management model. Each person will receive the intervention within 3 months (12 weeks). Face-to-face meetings will be in a classroom and non-face-to-face meetings will be through phone calls. Individual empowerment based on the 5A model has 5 steps: Assessment, Advice, Agreement, Assistance, and Arrangement. The control group will receive routine care and counseling.

Main outcome variables

Fall self-efficacy, Self-care, Quality of life

General information

Reason for update

editing the english translation of title and the fall self-efficacy In the primary outcome variable field. In these parts, fall self-efficacy was translated as falls self-efficacy, which is correct fall self-efficacy.

Acronym

IRCT registration information

IRCT registration number: **IRCT20221231057000N2**
Registration date: **2023-12-11, 1402/09/20**
Registration timing: **prospective**

Last update: **2024-08-23, 1403/06/02**
Update count: **1**

Registration date

2023-12-11, 1402/09/20

Registrant information

Name
Ermia Maghsoodloo
Name of organization / entity
Country
Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-01-21, 1402/11/01

Expected recruitment end date

2024-09-21, 1403/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Empowerment Based on 5A Model on Fall Self-Efficacy, Self-Care and Quality of Life in Older Adults: A Parallel Randomized Clinical Trial

Public title

The Effect of Empowerment Based on 5A Model on Fall Self-Efficacy, Self-Care and Quality of Life in Older Adults

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

Being 65 years old and above All seniors should be aware of the time, place and person and have the ability to understand educational materials. Having independence in activities of daily living

Exclusion criteria:

The participant suffering from an known physical or psychiatric disorder. The participant suffering participated in similar educational programs at the same time. The participant is not willing to participate in the study.

Age

From **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **110**

Randomization (investigator's opinion)

Randomized

Randomization description

A block method with a volume of 4 will be used to create a random allocation sequence because the elderly will gradually enter the study and also to ensure that the number of people assigned to each group is equal. By referring to any health center and finding eligible people and according to the order of their entry into the study, the individual will be assigned to the intervention or control group using the allocation sequence hidden in opaque envelopes. The way to hide the sequence is to use opaque envelopes, which will be prepared in 110 pieces and each sequence is placed inside an opaque envelope and numbered on the envelopes. The random allocation sequence was obtained with the cooperation of the methodological consultant. Example: 1,4,1 group A and 1,4,2 group B.

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 Shahroud University of Medical Sciences

Street address

Shahroud University of Medical Sciences and Health Care Services, Haftam Tir Square, Shahroud

City

Shahroud

Province

Semnan

Postal code

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Approval date

2023-11-28, 1402/09/07

Ethics committee reference number

IR.SHMU.REC.1402.137

Health conditions studied

1

Description of health condition studied

Fall self-efficacy

ICD-10 code

ICD-10 code description

2

Description of health condition studied

Self-care

ICD-10 code

ICD-10 code description

3

Description of health condition studied

Quality of life

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Fall self-efficacy score in Activities-specific Balance Confidence Scale

Timepoint

Measuring fall self-efficacy before the start of the intervention and random allocation and after the twelfth week and completion of the intervention

Method of measurement

Activities-specific Balance Confidence Scale questionnaire

2

Description

Self-care score in the Self-Care Questionnaire for the Elderly

Timepoint

Measuring self-care before the start of the intervention and random allocation and after the twelfth week and completion of the intervention

Method of measurement

Self-Care Questionnaire for the Elderly

3

Description

Quality of life score in WHO-5 Well-being questionnaire

Timepoint

Measuring Quality of life before the start of the intervention and random allocation and after the twelfth week and completion of the intervention

Method of measurement

WHO-5 Well-being questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: in this group individual empowerment will be done based on the 5A self-management model. The intervention will be done within 3 months (12 weeks) for each person. The content of the sessions is about falls and self-care. Face-to-face meetings will be in a classroom and non-face-to-face meetings will be through phone calls. Individual empowerment based on the 5A model has 5 steps as follows: 1- The first step is assessment. At this stage, the patient's records and history, including having a history of falls, family history, medications, nutrition, rest and sleep status, co-morbidity, activity, symptoms, risk factors and causes of problems with the help of questionnaires, history forms and evaluation methods, will be assess. 2- The second step is advice. In this step, abnormal cases, problems and risks of health deviation identified from the first step are individually informed to the patients. The risks of not performing self-care, having low self-efficacy of falling and the consequences of not taking the necessary measures to prevent falling and the benefits of changing behavior in preventing complications of falling and fear of falling are informed to the patient. At this stage, the patient is informed about the factors influencing the creation or exacerbation of the fear of falling, its consequences, complications, its nature, and the benefits of performing behaviors to prevent falls and reduce the fear of falling, and the benefits of performing self-care behaviors and improving the quality of life. 3- The third step is agreement, according to the identified problems of the elderly, goals are determined based on the patient's interest and satisfaction, and an operational plan (action) is designed for each of the goals. In order to ensure that the agreed program is carried out by the elderly, he is asked to record his functional status at the end of the study in a self-report form for each of the goals. 4- The fourth step is assist education about falling and fear of falling will be done based on the prepared booklet. During the meeting, the elderly are provided with training such as methods of preventing the risk of falling, the nature, causes, complications and factors affecting falling and fear of falling, and balance maintenance activities. Also, trainings on self-care such as physical self-care (adherence to medication and food regimens, personal hygiene, etc.) are provided to the elderly. Training will be carried out by individual method, questions and answers, presentation of booklets, pamphlets and telephone consultations. 5- The fifth step is arrange. In this step, the previous four steps and the plan agreed with the elderly are reviewed and modified if there are any changes. The follow-up for 3 months will be done in absentia through a phone call or in person if necessary.

Category

N/A

2

Description

Control group: The control group received routine care and counseling.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

health centers of gorgan

Full name of responsible person

Ermia Maghsoodloo

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Sponsors / Funding sources

1

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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
Shahroud 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
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Position
Master's student in geriatric nursing _ Shahroud University of Medical Sciences
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is 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
Still undecided - no release schedule yet
When the data will become available and for how long
Still undecided - no release schedule yet
To whom data/document is available
Researchers and students of academic and scientific institutions
Under which criteria data/document could be used
Still undecided - no release schedule yet
From where data/document is obtainable
ermiamaghsoodloo@gmail.com
What processes are involved for a request to access data/document
A clear explanation of why data access is needed
Comments