Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Investigating the effect of empowerment interventions based on Pender's health promotion model in adopting a healthy lifestyle and self-efficacy of the elderly

Protocol summary

Study aim
Determining the effect of empowerment interventions based on the Pender health promotion model in adopting a healthy lifestyle and self-efficacy of the elderly

Design
A randomized controlled clinical trial on 70 elderly people

Settings and conduct
The study will be conducted on the elderly of Kermanshah city, and first two centers will be selected among the available health centers of Kermanshah city. After reviewing the case of the elderly, the elderly will be contacted and 70 people will be randomly selected. The intervention sessions will be conducted in the form of 6 group discussion sessions and 2 training sessions on their families in selected health centers.

Participants/Inclusion and exclusion criteria
The Inclusion criteria of the research include: having the ability to perform daily life activities, not suffering from severe diseases, interest in participating in the intervention. Exclusion criteria include: admission to hospital, withdrawal from intervention and emigration from Kermanshah city

Intervention groups
The intervention group includes elderly people over 60 years old who receive the educational intervention. The comparison group includes elderly people over 60 years old who do not receive any intervention.

Main outcome variables
Healthy lifestyle and self-efficacy

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230715058786N1**
Registration date: **2023-11-17, 1402/08/26**
Registration timing: **registered_while_recruiting**

Last update: **2023-11-17, 1402/08/26**
Update count: **0**

Registration date
2023-11-17, 1402/08/26

Registrant information

Name
Mohsen Kazeminia

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
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Email address
mkazeminia69@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-07-23, 1402/05/01

Expected recruitment end date
2024-01-20, 1402/10/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the effect of empowerment interventions based on Pender's health promotion model in adopting a healthy lifestyle and self-efficacy of the elderly

Public title
Empowering the elderly to adopt a healthy lifestyle and

self-efficacy

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Interested in participating in the study Full consciousness Having the ability to perform activities of daily living Not suffering from severe psychiatric diseases (such as Alzheimer's and dementia) Not having serious emergency conditions Not having hearing, vision and movement limitations Living in Kermanshah for more than five years

Exclusion criteria:

being admitted to the hospital Absence of more than three sessions in intervention sessions Refusal to continue the intervention Migration from Kermanshah city

Age

From **60 years** old to **100 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization To apply randomization, the method of random blocks will be used with blocks of size four. The randomization unit will be individual. According to the sample size of 60 people, 24 quadruple blocks according to the statification factors including gender (male and female), age (less than 75 and 75 years and more) and literacy level (below diploma, diploma and above) using An online site (www.sealedenvelope.com) will be developed. Each sample is assigned a number that the researchers do not know about.For concealment, random allocation concealment will be used, which refers to the method used to implement a random sequence in the participants, so that the participant is unaware of his allocation in the study groups. For this purpose, based on the sequence created in the randomization software, each of the created sequences is recorded on a card, and the cards are placed inside sealed opaque envelopes, and to maintain the sequence on the outer surface of the envelopes, no. Placement is done in the same order. The lids of the envelopes are glued and placed in a box. Based on the order of entry of eligible participants to the study, the envelopes will be opened in order and the participant group will be revealed.

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 Kermanshah University of Medical Sciences

Street address

Shahid Beheshti Blvd., Medical Sciences Building No. 2

City

kermanshah

Province

Kermanshah

Postal code

6714673159

Approval date

2023-07-16, 1402/04/25

Ethics committee reference number

IR.KUMS.REC.1402.145

Health conditions studied

1

Description of health condition studied

the old age

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Healthy lifestyle

Timepoint

Before and after the intervention

Method of measurement

Healthy lifestyle questionnaire

2

Description

Efficacy

Timepoint

Before and after the intervention

Method of measurement

Sharr self-efficacy questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The interventions will be focused on disease prevention behaviors, healthy nutritional behaviors, physical activity, stress management, and building healthy relationships with family, friends, and neighbors, and in the form of six educational intervention sessions for the elderly and the use of self-efficacy strategies, including taking steps to The behavior step and mastering the behavior, the use of verbal encouragement after the development of the desired behavior and the use of successful models of the elderly for behavioral modeling will be done. In addition, two educational intervention sessions will be held with their families. Pamphlets and educational videos will be used for training. Therefore, the content of the interventions is as follows: six training sessions based on Pender's health promotion model (one 2-hour session per week); The first session: teaching the patterns and behaviors of appropriate and adequate nutrition for the elderly, trying to change attitudes and health beliefs and convincing the people of the test group in terms of unhealthy nutritional habits in life, the second session: teaching the patterns and physical and sports activities appropriate for the elderly, increasing the sense of Self-efficacy, trying to change attitudes and health beliefs and convincing the people of the test group to physical activities suitable for the elderly, the third session: teaching the concept of communication, verbal and non-verbal communication methods, teaching problem solving style and conflict in social interactions and personal life of the elderly, session Fourth: Defining self-efficacy, teaching concepts and ways to increase the growth of self-efficacy in the elderly, helping the elderly in identifying and distinguishing between primary and secondary basic needs and valuing personal life priorities and goals, fifth session: Teaching concepts and ways to increase support in interpersonal relationships , paying attention to the present time and using 24 hours of daily life, teaching concepts and ways to increase responsibility in the field of healthy lifestyle in old age and the sixth session: teaching concepts of stress and ways to deal with it, identifying stressful life factors and learning emotional management techniques , the implementation of the post-exam stage. Also, two group discussion sessions with the families of the elderly (the first session: training on the effectiveness of implementing healthy lifestyle programs for the elderly at low risk of disease and the second session: training on increasing self-care of the elderly and having an active and healthy elderly) as well as presenting educational videos and pamphlets for the benefits It is understood that healthy behaviors are performed in the elderly.

Category

Lifestyle

2

Description

Control group: They did not receive any intervention.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Kermanshah University of Medical Sciences

Full name of responsible person
Mohsen Kazeminia

Street address
Habib Vand village

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kermanshah University of Medical Sciences

Full name of responsible person
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research_it@kums.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Kermanshah 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
Kermanshah University of Medical Sciences

Full name of responsible person
Mohsen Kaziminia

Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Nursery

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Person responsible for scientific inquiries

Contact

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Full name of responsible person
Amir Jalali

Position
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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
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
Only a part of the data, such as the information related to the main outcome or the like, can be shared.

When the data will become available and for how long
The access period starts 6 months after the results are published

To whom data/document is available
All people

Under which criteria data/document could be used
For health research purposes

From where data/document is obtainable
Mohsen Kaziminia

What processes are involved for a request to access data/document
send mail: mkazeminia69@gmail.com

Comments