

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jul 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

+98 83 4227 2023

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 stratification 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 Kazemini

Street address

Habib Vand village

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6775139177

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Cyrus Jalili

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Email

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

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

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Amir Jalali

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Email

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Person responsible for updating data

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

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Phone

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Email

mkazeminia69@gmail.com

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