

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

Evaluation of the effect of self-management strategies training on life management skills and resilience in community-dwelling older adults

Protocol summary

Study aim

Evaluation of the effect of self-management strategies training on life management skills and resilience in community-dwelling older adults

Design

Elders aged 60 and older eligible to participate, will randomly be assigned to one of the two intervention and control groups using the random numbers table. The sample size is estimated 60. The study will be double blind. Sampling in both intervention and control groups and interventions are carried out simultaneously and in parallel.

Settings and conduct

Setting of the study is Fatemeh College of Nursing. Participants in the intervention group participate in 16 sessions of the 90-minute self management education program. Participants in the control group do not receive intervention. The outcome assessor, data analyzer, and participants will be blinded to the randomization status.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Aged 60 year-old and older; Willingness to participate in the study. Exclusion criteria: Having reading and writing skills in Persian.

Intervention groups

Intervention group: Participants in the experimental group will participate in 8 90_minute sessions of self management education program that will be held twice a week. The first session will be devoted to the introduction and completion of questionnaires and the purpose of the study and the rules of the group. Next sessions are dedicated to self management education components. Control group: There is no intervention to participants in control group. The data from this group will be collected only for comparison with the intervention group.

Main outcome variables

Life management score; Resilience

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120312009267N6**

Registration date: **2018-12-01, 1397/09/10**

Registration timing: **prospective**

Last update: **2018-12-01, 1397/09/10**

Update count: **0**

Registration date

2018-12-01, 1397/09/10

Registrant information

Name

Giti Setoodeh

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 3647 4254

Email address

setoodeh@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-20, 1398/01/31

Expected recruitment end date

2019-07-22, 1398/04/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of self-management strategies training on life management skills and resilience in community-dwelling older adults

Public title

Effect of self-management strategies training on life management skills and resilience

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Aged 60 year-old and older Willingness to participate in the study Having reading and writing skills in Persian

Exclusion criteria:

Mental and cognitive impairment

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: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Individuals will randomly assign to one of the two intervention and control groups with the help of a random number table.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants are unaware of which groups they are allocated to. The research assistant will randomly divide the participants into the two groups; therefore, he is aware of the status of the participants. But the outcome assessor and data analyser are blinded to the randomization status.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Shiraz University of Medical Sciences

Street address

Ethics Committee of Shiraz University of Medical Sciences, 7th floor, Shiraz University of Medical Sciences, Zand street

City

Shiraz

Province

Fars

Postal code

7193613119

Approval date

2018-09-11, 1397/06/20

Ethics committee reference number

IR.SUMS.REC.1397.656

Health conditions studied**1****Description of health condition studied**

Life management

ICD-10 code**ICD-10 code description****2****Description of health condition studied**

Resilience

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Life management score in the Baltes' Selection, Optimization and Compensation questionnaire

Timepoint

Before intervention and 1 month after intervention

Method of measurement

Baltes' Selection, Optimization and Compensation questionnaire

2**Description**

Resilience score on the Cannar-Davidson Resilience Scale

Timepoint

Before intervention and 1 month after intervention

Method of measurement

Cannar-Davidson Resilience Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Participants in the experimental group will participate in 8 90_minute sessions of self management education program that will be held twice a week. The first session will be devoted to the introduction and completion of questionnaires and the purpose of the study and the rules of the group. Next sessions will be focused on self management components.

Category

N/A

2

Description

Control group: There is no intervention to participants in control group. The data from this group will be collected only for comparison with the intervention group.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Shiraz Senior Centers

Full name of responsible person

Giti Setoodeh

Street address

Shiraz Senior Centers, Kholdebarin Park, Besat Blvd.

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7174775741

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+98 71 3647 5010

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site@halyzendegy.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Yunes Ghasemi

Street address

Research Deputy of Shiraz University of Medical Sciences, 7th floor, Shiraz University of Medical Sciences, Zand Avenue

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Shiraz

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7134814336

Phone

+98 71 3230 5410

Email

ghasemiy@sums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Giti Setoodeh

Position

Instructor

Latest degree

Master

Other areas of specialty/work

Nursery

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7193666877

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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setoodeh@sums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
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Full name of responsible person
Giti Setoodeh
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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

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Only the main outcome data can be published.

When the data will become available and for how long

Access since 2021

To whom data/document is available

All health care researchers

Under which criteria data/document could be used

Use of data is permitted exclusively in scientific research.

From where data/document is obtainable

The responsible for the project must send an application to setoodeh@sums.ac.ir.

What processes are involved for a request to access data/document

The data will be submitted no later than 2 weeks after receiving the email.

Comments