# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

19 Sep 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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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

**Province**
Fars

**Postal code**
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

**Street address**
Room 57, Fatemeh College of Nursing & Midwifery, Namazi Square

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Shiraz

**Province**
Fars

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## Person responsible for scientific inquiries

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**Position**
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**Latest degree**

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

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**Position**

Instructor

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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**