

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Jul 2026

### Investigating the Effect of a Life Skills Program on Feeling Old and Self-Efficacy in Menopausal women

#### Protocol summary

##### Study aim

Investigating the effect of a Life Skills program on the Feeling Old and self-efficacy of Menopausal women referring to selected centers of Isfahan in 2019

##### Design

A clinical trial with a control group, with parallel, randomized, and outcome assessment

##### Settings and conduct

In this clinical trial study, 208 individuals were selected by convenience sampling method from postmenopausal women referring to the centers and according to the characteristics recorded in the SIB system. Finally, 70 participants were selected based on inclusion criteria. Then they were randomly assigned to the experimental and control groups based on the last number of the national code. The life skills program was held in 5 sessions for 5 weeks at the Navab and Imam Ali centers.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Ability to communicate! Willingness to participate in the study! Having the physical and psychological ability to participate in the study! Lack of mental illness and general health! Minimum literacy skills! Age between 46 and 55 years and at least one year past their last menstruation! Being married and having children! Lack of crisis and stress over the past 6 months! Refusal to participate in other psychotherapy programs. Exclusion criteria of the study: Menopause is followed by surgery and removal of the ovaries! Absent more than two sessions! Physical inability to attend meetings.

##### Intervention groups

Intervention group: Run 5 group sessions with promote Life Skills Program content. Control group: Run 2 group sessions and talk about the experiences and effects of menopause

##### Main outcome variables

Feeling Old and Self-Efficacy

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200227046628N1**

Registration date: **2020-03-10, 1398/12/20**

Registration timing: **retrospective**

Last update: **2020-03-10, 1398/12/20**

Update count: **0**

##### Registration date

2020-03-10, 1398/12/20

##### Registrant information

##### Name

Jahangir Maghsoudi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3792 7566

##### Email address

maghsoudi@nm.mui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-06-13, 1398/03/23

##### Expected recruitment end date

2019-06-21, 1398/03/31

##### Actual recruitment start date

2019-06-13, 1398/03/23

##### Actual recruitment end date

2019-06-13, 1398/03/23

##### Trial completion date

2019-08-19, 1398/05/28

##### Scientific title

Investigating the Effect of a Life Skills Program on  
Feeling Old and Self-Efficacy in Menopausal women

#### Public title

Investigating the Effect of a Life Skills Program on the  
Feeling Old and Self-Efficacy of Menopausal women  
referring to selected centers of Isfahan in 2019

#### Purpose

Supportive

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

They should be able to communicate They should be  
willing to participate in the study They should have the  
physical and mental capacity to participate in the study  
Lack of mental illness and general health of research  
units according to the SIB system Participants should  
have minimum literacy skills Participants between the  
ages of 46 and 55 should be selected and at least one  
year has passed since their last menstruation  
Participants should not participate in Psychotherapy  
programs during the study The specialists should not be  
under the supervision of Menopausal Symptoms  
Participants should not experience crisis and stress  
during the 6 months before the start of the study.  
Participants must be married and had children

##### Exclusion criteria:

Participants do not attend the program for two  
consecutive sessions Participants are unable to attend  
meetings for physical reasons Menopause is followed by  
surgery and removal of the ovaries

#### Age

From **46 years** old to **55 years** old

#### Gender

Female

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **70**

Actual sample size reached: **69**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

Random allocation of samples was done in two groups of  
experimental and control according to the prepared list  
and the last number of National Code of individuals, even  
numbers were assigned to the experimental group and  
odd numbers to the control group

#### 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 Isfahan University Of Medical  
Sciences Faculty Of Nursing and Midwieri

##### Street address

Isfaha University Of Medical Sciences Faculty Of  
Nursing and Midwieri , Hezar Jreb avenue , Isfahan

##### City

Isfahan

##### Province

Isfahan

##### Postal code

81746-73461

#### Approval date

2019-03-13, 1397/12/22

#### Ethics committee reference number

IR.MUI.RESEARCH.REC.1398.042

## Health conditions studied

### 1

#### Description of health condition studied

Feeling Old and Self Efficacy

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Feeling Old

#### Timepoint

Before , immediately after and one month later

#### Method of measurement

Barker's Aging Perception Questionnaire

### 2

#### Description

Self Efficacy

#### Timepoint

Before , immediately after and one month later

#### Method of measurement

Schwartz & Jerusalem Generalized Self-Efficacy  
Questionnaire

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Intervention in the experimental

group was implemented as Life Skills Program in 5 sessions of 60 minutes over a period of 5 weeks (one session per week) in groups of 17-18, using lecture, group discussion, presentation Movies and slideshows and role plays will be held in the classroom. The content of the sessions is the same for all groups and all study groups provide an educational pamphlet based on the subject of each session, and they are asked to practice the homework daily until the next session, and at the beginning of the next meeting, the discussions will be held. It also continually monitors and controls the interval between sessions to ensure that the exercises are carried out

**Category**

Behavior

**2**

**Description**

Control group: In order to eliminate the possible effects of the presence of individuals in a group, 2 sessions will be held on the topic of Menopause and its experiences, effects and challenges, without reference to the Life Skills component.

**Category**

Other

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Imam Ali ibe Abi Talib Health Center

**Full name of responsible person**

Mortaza Ghasemi

**Street address**

west Toosi St, Second 24 Metri St, Isfahan

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8198883982

**Phone**

+98 31 3555 1030

**Fax**

+98 31 3559 3229

**Email**

health-1@mui.ac.ir

**Web page address**

https://hlth1.mui.ac.ir/

**2**

**Recruitment center**

**Name of recruitment center**

Shahid Navaab Safavi Health Center

**Full name of responsible person**

Ali Asghar Sadeghian

**Street address**

Bozorgmehr St, Isfahan

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8156735975

**Phone**

+98 31 3227 5365

**Fax**

+98 31 3227 5288

**Email**

health-1@mui.ac.ir

**Web page address**

https://hlth1.mui.ac.ir/

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Fariba Taleghani

**Street address**

Faculty of Nursing and Midwifery; Isfahan University of Medical Sciences; Azadi Square, Hezar Jirib St; Isfahan

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174673461

**Phone**

+98 31 3792 7565

**Fax**

+98 31 3669 9398

**Email**

taleghani@nm.mui.ac.ir

**Web page address**

http://nm.mui.ac.ir/

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Esfahan 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**

Esfahan University of Medical Sciences

**Full name of responsible person**

Zahra Dibaj

**Position**

MSC student of nursing

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

sfahan University Of Medical Sciences Faculty Of  
Nursing and Midwiery , Hezar Jreb avenue , Isfahan ,  
Iran

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174673461

**Phone**

+98 31 3230 2534

**Email**

zahradibaj96@nm.mui.ac.ir

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Jahangir Maghsoudi

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

**Street address**

Isfahan University Of Medical Sciences Faculty Of  
Nursing and Midwiery , Hezar Jreb avenue , Isfahan ,  
Iran

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174673465

**Phone**

+98 31 3792 7566

**Email**

maghsoudi@nm.mui.ac.ir

## Person responsible for updating data

### Contact

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Zahra Dibaj

**Position**

MSC student of nursing

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

Isfahan University Of Medical Sciences Faculty Of  
Nursing and Midwiery, Hezar Jreb avenue, Isfahan,  
Iran

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174673465

**Phone**

0098 32302534

**Email**

zahradibaj.zd@gmail.com

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

The information obtained during the investigation is the  
responsibility of the author.

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable