

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

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2

Recruitment center

Name of recruitment center

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Full name of responsible person

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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

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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

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Zahra Dibaj

Position

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Latest degree

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Other areas of specialty/work

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Person responsible for scientific inquiries

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Position

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Other areas of specialty/work

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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