

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

The effect of education based on health belief model on self-compassion and self - efficacy of premenopausal women

Protocol summary

Study aim

1.Comparison of self-efficacy of premenopausal women in both intervention and control groups before intervention 2.Comparison of self-efficacy of premenopausal women in both intervention and control groups after intervention 3.Comparison of self-compassion of premenopausal women in both intervention and control groups before intervention 4.Comparison of self-compassion of premenopausal women in both intervention and control groups after intervention

Design

The clinical trial has a control group and one-way blind intervention. Sample size according to review studies and considering the level of confidence 95% and 80% test power were calculated according to the formula 35 people and considering 20% drop of 45 people in each group.

Settings and conduct

All actions will be performed in four sessions of forty-five minutes. The members of the intervention group will receive training based on the health belief model, while the control group will receive routine care. Questionnaires will be provided to participants in both groups three times before the intervention, immediately after the intervention and 1 month after the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. PreMenopausal women 2. Having Iranian nationality Criteria for non-entry: 1. Having known malignant diseases 2. Not having a mobile phone if the training is virtual

Intervention groups

The members of the intervention group will be trained based on the health belief model, while the control group will receive routine cares.questionnaires will be available to participants three times before the intervention, immediately after the intervention and 1 month after the intervention and will completed in both groups.

Main outcome variables

Increasing self-efficacy in premenopausal women
Increasing the quality of life of premenopausal women
Increasing self-efficacy in premenopausal women

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120414009463N66**

Registration date: **2022-04-19, 1401/01/30**

Registration timing: **registered_while_recruiting**

Last update: **2022-04-19, 1401/01/30**

Update count: **0**

Registration date

2022-04-19, 1401/01/30

Registrant information

Name

Zahra Behboodi Moghadam

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6692 7171

Email address

behboodi@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-02-10, 1400/11/21

Expected recruitment end date

2022-05-02, 1401/02/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of education based on health belief model on self-compassion and self - efficacy of premenopausal women

Public title

The effect of self-compassion and self - efficacy of premenopausal women

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Literacy for reading and writing Pre menopausal women Having Iranian nationality Age minimum 40 years and maximum 50 years Lack of chronic psychiatric disorders and known malignant diseases Having a smart mobile phone if the training is virtual

Exclusion criteria:

Reluctance to continue participating in the study
Absence of more than 2 training sessions

Age

From **40 years** old to **50 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Not randomized

Randomization description**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 Tehran University of Medical Sciences

Street address

School of Nursing and Midwifery

City

tehran

Province

Tehran

Postal code

1419733171

Approval date

2022-01-05, 1400/10/15

Ethics committee reference number

IR.TUMS.FNM.REC.1400.144

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

premenopausal disorders

ICD-10 code

N95

ICD-10 code description

Menopausal and other perimenopausal disorders

Primary outcomes**1****Description**

Self-efficacy and self-efficacy of premenopausal women in the intervention group

Timepoint

The effect of self-care and self-efficacy on premenopausal women

Method of measurement

Demographic Questionnaire Self-Sufficiency Questionnaire Self-Efficacy Questionnaire Health Belief Model Questionnaire

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Holding educational classes based on health belief model and education using educational videos and slides and using questionnaires before and after the intervention group

Category

Rehabilitation

2**Description**

Control group: In the control group, which includes premenopausal women with intervention qualities, no intervention was performed.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Comprehensive health centers of Kerman University of Medical Sciences

Full name of responsible person

Zahra Behboodi Moghadam

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Higher_education@tums.ac.ir

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Zahra Behboodi Moghadam

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

Title of funding source

Tehran medical university

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

Tehran University of Medical Sciences

Full name of responsible person

Zahra Behboodi Moghadam

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Dr. Zahra Behboodi Moghadam

Position

PHD of Reproductive Health

Latest degree

Ph.D.

Other areas of specialty/work

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Fax**Email**

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Web page address**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

Participants' information is protected and their names are not required.

When the data will become available and for how long

1400

To whom data/document is available

Reputable journals

Under which criteria data/document could be used

Universities of Medical Sciences

From where data/document is obtainable

Try not to use the documents personally

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

Provide complete information and pay

Comments