Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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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No1 , Dr. Mirkhani St. (Nosrat Sharghi) , Tohid Square ,School of Nursing and Midwifery

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Sponsors / Funding sources

1

Sponsor

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Tehran University of Medical Sciences

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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

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Person responsible for updating data

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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
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