

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jul 2026

Investigating the Effectiveness of Midwifery Counseling with Meaningful Approach to the Early Complications of Menopause and the General Health of Menopausal Women

Protocol summary

Study aim

Determining the effectiveness of midwifery counseling with meaningful approach to early menopausal complications and general health of postmenopausal women

Design

The clinical trial has a control and intervention group, with parallel groups that are randomly performed, phase 2 on 60 patients. Random number table is used for randomization and Excel software rand function is used for sequencing.

Settings and conduct

This study is performed randomly in Miami clinic and counseling sessions are held for 5 weeks for the intervention group.

Participants/Inclusion and exclusion criteria

Menopausal women aged 45-60 with conditions: menstrual cessation for at least 12 months and lack of physical and mental illness and not using traditional medicine and herbal medicines and not using a relaxation therapy and not participating in yoga and having at least 5-class literacy . No willingness to continue cooperation and migration of the city is a component of exclusion criteria

Intervention groups

A training program for the intervention group (postmenopausal women) in 5 sessions for 60 minutes are provided based on midwifery counseling with the meaningful approach. There is no consultation in the control group.

Main outcome variables

Early symptoms of menopause / General health of postmenopausal women

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200518047493N1**

Registration date: **2020-08-08, 1399/05/18**

Registration timing: **registered_while_recruiting**

Last update: **2020-08-08, 1399/05/18**

Update count: **0**

Registration date

2020-08-08, 1399/05/18

Registrant information

Name

Mobina Rezaei

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-08-05, 1399/05/15

Expected recruitment end date

2020-09-05, 1399/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the Effectiveness of Midwifery Counseling

with Meaningful Approach to the Early Complications of Menopause and the General Health of Menopausal Women

Public title

Investigating the Effectiveness of Midwifery Counseling on the Early Complications of Menopause and General Health

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Stop Menstruation for at least 12 Months Menopausal Women Aged 45-60 Years Lack of Physical and Mental Illness Lack of Use Traditional Medicine and Herbal Medicines Lack of Use of Relaxation Do not Participate In Yoga Having at Least 5 Classes of Literacy (Reading and Writing)

Exclusion criteria:

Lack of Desire to Continue Cooperation Migration from Miami

Age

From **45 years** old to **60 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

To create randomization, we put 30 balls for intervention group A and 30 balls for group B inside a lottery container and then the balls are randomly brought out from container and the related group are recorded.

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

Shahroud University of Medical Sciences Ethics Committee

Street address

7 Tir Square, Shahroud University of Medical Sciences

City

Shahroud

Province

Semnan

Postal code

3614773955

Approval date

2020-05-12, 1399/02/23

Ethics committee reference number

IR.SHMU.REC.1399.041

Health conditions studied

1

Description of health condition studied

Early complications of menopause

ICD-10 code

ICD-10 code description

2

Description of health condition studied

General health

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Improving the early effects of menopause

Timepoint

before the intervention and immediately after the intervention and two months after the intervention

Method of measurement

Menopausal Complications Questionnaire or (MRS)

Secondary outcomes

1

Description

general health

Timepoint

Before the intervention and immediately after the intervention and two months after the intervention

Method of measurement

General Health Questionnaire

Intervention groups

1

Description

Intervention group: The training program for the intervention group in the form of 5 sessions in groups of 10 people with emphasis on meaning therapy for one hour and once a week with one hour of homework is performed at the end of each session. Lectures, face-to-face training, and group discussion will be used.

Mineralogy worked on the intervention group to gain the ability to reach the real self and broaden vision of oneself and the world around and clarify things that are present and future life. One gives meaning. This method emphasizes 4 important interests that are rooted in human existence: death, freedom, loneliness and meaninglessness. In the first session, introduction and explanation of menopausal physiology, in the second session, determination of treatment goals and discussion of members about the complications they experience and explanation of the existential roots of problems (existential crisis and lack of meaning). Selection and mental health in menopause Session 4: Discovering meaning through personal desires and strengthening members in lovemaking and accepting a sense of responsibility Session 5: Summarizing and evaluating sessions to achieve the desired goals.

Category

Prevention

2**Description**

Control group: The control group does not receive counseling, they only receive routine care at the health center.

Category

Prevention

Recruitment centers**1****Recruitment center****Name of recruitment center**

Mayamey City Health Center

Full name of responsible person

Mobina Rezaei

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Imam Reza St.

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shahrood University of Medical Sciences

Full name of responsible person

Mohammad Hassan Emamian

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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

Shahrood 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**

Shahrood University of Medical Sciences

Full name of responsible person

Mobina Rezaei

Position

Master's student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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Position

Reproductive Health PhD

Latest degree

Ph.D.

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

Shahroud University of Medical Sciences

Full name of responsible person

Mobina Rezaei

Position

Master Student

Latest degree

Bachelor

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 study is not over yet

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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available