

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

Effect of group counseling versus no counseling on the quality of life in women during the transition to menopause: a randomized clinical trial

Protocol summary

Study aim

To assess the effect of group counseling versus no counseling on the quality of life in women during the transition to menopause

Design

This is a randomized clinical trial, phase II, in which 90 eligible patients will be randomly assigned to the intervention and control groups

Settings and conduct

The eligible premenopausal women will refer to the Comprehensive Health Centers in Javanrood city during the study period will be enrolled in the trial and will be randomly assigned to the intervention and control groups through the drawing of lots.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 40 to 50 years, Premenopausal, Married, Littermate Exclusion criteria: History of hysterectomy or oophorectomy, Menstrual cycle disorder, Hormonotherapy

Intervention groups

Intervention group: Routine premenopausal care plus group counseling (including menopausal symptoms, false beliefs, control methods, and symptom relief) each session for 45 to 90 minutes for four sessions Control group: Just routine premenopausal care

Main outcome variables

Primary outcome: Quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N320**

Registration date: **2019-12-07, 1398/09/16**

Registration timing: **registered_while_recruiting**

Last update: **2019-12-07, 1398/09/16**

Update count: **0**

Registration date

2019-12-07, 1398/09/16

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-23, 1398/08/01

Expected recruitment end date

2020-12-20, 1399/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of group counseling versus no counseling on the quality of life in women during the transition to menopause: a randomized clinical trial

Public title

Effect of group counseling versus no counseling on the quality of life in women during the transition to menopause

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age of 40 to 50 years, Premenopausal, Married, Littermate

Exclusion criteria:

History of hysterectomy or oophorectomy, Menstrual cycle disorder, Hormonotherapy

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)

Randomized

Randomization description

Routine premenopausal care plus group counseling (including menopausal symptoms, false beliefs, control methods, and symptom relief) each session for 45 to 90 minutes for four sessions

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 Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research and Technology,
Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Approval date

2019-10-22, 1398/07/30

Ethics committee reference number

IR.UMSHA.REC.1398.471

Health conditions studied

1

Description of health condition studied

Premenopausal women

ICD-10 code

E28.310

ICD-10 code description

Symptomatic premature menopause

Primary outcomes

1

Description

Quality of life

Timepoint

Before the intervention and one month after that

Method of measurement

Using the standard Quality of Life Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Routine premenopausal care plus group counseling (including menopausal symptoms, false beliefs, control methods, and symptom relief) each session for 45 to 90 minutes for four sessions

Category

Other

2

Description

Control group: Just routine premenopausal care

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Comprehensive Health Centers in Javanrood city

Full name of responsible person

Soraya Mardanpour

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School of Nursing and Midwifery, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Saeid Bashirian

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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

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Soraya Mardanpour

Position

Midwifery Student

Latest degree

Master

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Mansoureh Refaei

Position

Reproductive Health Specialist

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

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Person responsible for updating data

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Jalal Poorolajal

Position

Professor of Epidemiology

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

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

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available