

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jul 2026

Effect of group counseling on the quality of life among postmenopausal women by surgical method

Protocol summary

Study aim

Determine the effect of group counseling on the quality of life in women with surgical menopause

Design

Clinical trial study phase 2, with control group, based on a specific population (surgical postmenopausal women), with parallel groups, open blind, randomized, sample size: 78 samples

Settings and conduct

This open blind study was conducted in Pasargad Hospital, Tehran, on two groups (intervention and control). In the intervention group, counseling is done on 6 sessions weekly. Each session lasts for 45 minutes. The control group receives routine individual counseling. Before the intervention, after the intervention, one and three months after the end of the intervention, the quality of life score in each group is measured.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Postmenopausal women due to hysterectomy plus bilateral oophorectomy or bilateral oophorectomy that they had experienced menopausal symptoms last month and between the ages of 35-55 years, 2-Married, 3-literate Exclusion criteria: 1-Use of hormone therapy in the last six months 2- -Use of tobacco or alcohol

Intervention groups

In the intervention group, group counseling is done on 6 sessions weekly. Each session lasts for 45 minutes. Group counseling is done based on the GATHER method. Each session has a specific topic. The control group receives routine individual counseling about menopausal symptoms.

Main outcome variables

Quality of life in postmenopausal women

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180110038302N4**

Registration date: **2018-12-30, 1397/10/09**

Registration timing: **retrospective**

Last update: **2018-12-30, 1397/10/09**

Update count: **0**

Registration date

2018-12-30, 1397/10/09

Registrant information

Name

Mansoureh Yazdkhasti

Name of organization / entity

Alborz University medical science

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-21, 1397/03/31

Expected recruitment end date

2018-12-21, 1397/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of group counseling on the quality of life among postmenopausal women by surgical method

Public title

Effect of group counseling on the quality of life among postmenopausal women by surgical method

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Postmenopausal women due to hysterectomy plus bilateral oophorectomy or bilateral Oophorectomy that they had experienced menopausal symptoms last month
Married Literate

Exclusion criteria:

Use of hormone therapy over the past six months use of Tobacco or alcohol

Age

From **35 years** old to **55 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **78**

Randomization (investigator's opinion)

Randomized

Randomization description

Sampling is done simple random, individually, and open blind. First, based on the random number table, the numbers are read from left to right. Then, paired numbers are considered for the intervention group and the singular numbers for the control group. In this way, the random allocation of the two groups is done. In the intervention group, group counseling is performed in 6 sessions (once every week) in 90 minutes. In the control group, individual routine counseling is performed.

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 Alborz University of Medical Sciences

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NO. 5, Kohnavard Blvd, Dadgostari Street

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3149779453

Approval date

2018-03-17, 1396/12/26

Ethics committee reference number

IR.Abzums .REC.1396.214

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

Menopause

ICD-10 code

N95.1

ICD-10 code description

Menopausal and female climacteric states

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

Menopause quality of life

Timepoint

Before intervention, after intervention, one month after intervention, three months after intervention

Method of measurement

Measurement tool is "menopausal quality of life Hildich questionnaire".

Secondary outcomes

empty

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

Intervention group: , 6 sessions per week, they receive group counseling according to the GATHER method. Each session will be 45 minutes. The subject of each session is planned according to menopausal symptoms. Session 1: Preparation for Menopause, Session 2: Vasomotor Signs, Session 3: Psycho social Symptoms, Session 4: Physical Symptoms, Session , 5: Sexual Symptoms, Session Six: Changing life style

Category

Lifestyle

2**Description**

Control group: The control group receives individual routine counseling

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Pasargad hospital

Full name of responsible person

Mansoureh Yazdkhasti

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Alborz University of Medical Sciences

Full name of responsible person

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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

Alborz 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

The Alborz University of Medical Sciences

Full name of responsible person

Mansoureh Yazdkhasti

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

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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