Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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

Country
Iran (Islamic Republic of)

Phone
+98 21 4401 8856

Email address
m.yazdkhasti@abzums.ac.ir

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
Street address
NO. 5, Kohnavard Blvd, Dadgostari Street
City
Karaj
Province
Alborz
Postal code
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
Street address
No. 132,Shariati Ave, Taleghani Blvd,Tehran
City
Karaj
Province
Alborz
Postal code
1423586541
Phone
+98 26 3433 6422
Email
Mansoyazd@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Alborz University of Medical Sciences
Full name of responsible person
Mohamad NoriSepehr
Street address
No.65, Safarian Ave, Shams Blvd, Karaj Town
City
Karaj
Province
Alborz
Postal code
1414557975
Phone
+98 26 3464 4720
Email
M.Norisepehr@abzums.ac.ir

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
Reproductive Health
Street address
No. 47, Baghestan Ave, Hassanabad Blvd, Karaj Town
City
Karaj
Province
Alborz
Postal code
1412556885
Phone
+98 26 3433 2720
Email
Mansoyazd@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Alborz University of Medical Sciences
Full name of responsible person
Mansoureh Yazdkhasti
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Reproductive Health
Street address
No.47, Baghestan Ave, Hassanabad Blvd, Karaj Town
City
Karaj
Province
Alborz
Postal code
3149779453
Phone
+98 26 3430 1616
Email
Mansoyazd@yahoo.com

Person responsible for updating data

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
Reproductive Health
Street address
NO.47, OOge Ave, HassanAbad Blvd, Karaj Town
City
Karaj
Province
Alborz
Postal code
3131614171
Phone
+98 26 3432 3008
Email
Mansoyazd@yahoo.com

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