Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Jun 2026

Effect of group counseling versus no counseling on the sexual function in postmenopausal women: a randomized clinical trial

Protocol summary

Study aim
To assess the effect group counseling versus no counseling on the sexual function in postmenopausal women

Design
This is a randomized clinical trial, in which 90 eligible postmenopausal women will be randomly assigned to the intervention and control groups

Settings and conduct
The eligible postmenopausal women who will refer to Health Centers of Hamadan City during the study period will be enrolled in the trial

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age 40 to 65 years; Natural menopause; Poor sexual function with a score of less than 28; Married; Being literate Exclusion criteria: Previous history of group counseling; Early ejaculation or impotence of her spouse; Cardiovascular and Cancer Diseases; Mental illnesses; Opioid addiction; Family disputes; Using hormonal drugs; A history of infertility

Intervention groups
Intervention group: Routine care plus group counseling for 60 minutes once a week for 4 weeks Control group: Just routine care

Main outcome variables
Primary outcome: Assessing sexual function

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120215009014N236**
Registration date: **2018-09-26, 1397/07/04**
Registration timing: **registered_while_recruiting**

Last update: **2018-09-26, 1397/07/04**
Update count: **0**

Registration date
2018-09-26, 1397/07/04

Registrant information
Name
Jalal Poorolajal
Name of organization / entity
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
1990-10-21, 1369/07/29

Expected recruitment end date
2019-03-20, 1397/12/29

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 sexual function in postmenopausal women: a randomized clinical trial

Public title
Effect of group counseling versus no counseling on the sexual function in postmenopausal women

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age 40 to 65 years; Natural menopause; Poor sexual function with a score of less than 28; Married; Being literate
Exclusion criteria:
Previous history of group counseling; Early ejaculation or impotence of her spouse; Cardiovascular and Cancer Diseases; Mental illnesses; Opioid addiction; Family disputes; Using hormonal drugs; A history of infertility

Age
From **40 years** old to **65 years** old

Gender
Female

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
The patients will be randomly assigned to intervention and control groups using block randomization

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
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Postal code
6517838695

Approval date
2018-09-01, 1397/06/10

Ethics committee reference number
IR.UMSHA.REC.1397.399

Health conditions studied

1

Description of health condition studied
Sexual dysfunction

ICD-10 code
F52

ICD-10 code description
Sexual dysfunction not due to a substance or known physiological condition

Primary outcomes

1

Description
Assessing sexual function

Timepoint
Before intervention and 4 weeks after intervention

Method of measurement
Using the standard FSFI questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Routine care plus group counseling for 60 minutes once a week for 4 weeks

Category
N/A

2

Description
Control group: Just routine care

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Health Centers of Hamadan City

Full name of responsible person
Narges Alavipoor

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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
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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
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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