

# 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

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 81 1838 0090

###### Email address

poorolajal@umsha.ac.ir

##### 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**

Hamadan

**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

**Street address**

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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Hamadan University of Medical Sciences, Shahid Fahmideh Ave

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info.research@umsha.ac.ir

**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**

Narges Alavipoor

**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**

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Zahra Massomi

**Position**

Fertility Health Specialist

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Ph.D.

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Midwifery

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Zahramid2001@yahoo.com

## 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