

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 Jun 2026

### Comparing the effect of two methods of group and peer education on sexual dysfunction in menopausal women

#### Protocol summary

##### Summary

The present study is a clinical trial to compare the effect of two methods of group and peer education on sexual dysfunction in menopausal women. Participants include 108 menopausal women that would randomly be allocated into three groups of peer education, group education and control (each containing 36 women). Inclusion criteria: being a menopausal woman with sexual dysfunction and having a husband, being younger than 65 years, not having a history of surgery for the participants and their husbands, not having any sexual diseases and other diagnosed diseases that affect sexual function, not consuming drugs that affect sexual function, and not being addicted to alcohol, cigarettes and opioids for the participants and their husbands. The exclusion criteria: occurrence of mental or physical problems, receiving information about sexual function from any source during the study, not fully participating in conducted sessions and having interrupted sexual activity at the time of the study. In the peer education group, first 8 participants would be selected as the peers; after receiving education from the researcher, 4 of them would selected each would educate a group of 9 during two 2-hour sessions. In the group education group, the researcher would provide the education during two 2-hour sessions for 4 groups of 9. The control group would receive no intervention. The educational content for both groups would be similar. Information would be collected from all groups before and one month after the intervention.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016102926756N3**

Registration date: **2017-11-19, 1396/08/28**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2017-11-19, 1396/08/28

##### Registrant information

###### Name

Mahnaz Noroozi

###### Name of organization / entity

Isfahan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 31 3441 1421

###### Email address

noroozi@nm.mui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Isfahan University of Medical Sciences

##### Expected recruitment start date

2016-10-26, 1395/08/05

##### Expected recruitment end date

2017-04-25, 1396/02/05

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparing the effect of two methods of group and peer education on sexual dysfunction in menopausal women

##### Public title

Comparing the effect of two methods of group and peer education on sexual dysfunction in menopausal women

##### Purpose

Supportive

## Inclusion/Exclusion criteria

Inclusion criteria: being a menopausal woman with sexual dysfunction and having a husband and gaining a score of less than 28 from the Female Sexual Function Index (FSFI); being younger than 65 years; not having a history of surgical procedures for the participants and their husbands such as prostatectomy, hysterectomy, oophorectomy, mastectomy and other breast surgeries; having physical and mental health based on the participants' statements and their medical files; not having premature menopause; having an educational level of elementary school or higher; being of Iranian nationality for the couples; not having any diagnosed sexual problems that could influence sexual function such as premature ejaculation and impotence; not living separately from the husband at the time of the study; not having any diagnosed diseases for the participants and their husbands that could affect sexual function such as cancers, mood disorders (depression and anxiety), vasculitis, thyroid disorders, adrenal glands (cortex part) diseases, diabetes, high blood pressure, cardiovascular, pulmonary, liver and renal diseases, central nervous system disorders, infectious and sexually transmitted diseases; not consuming drugs for the participants and their husbands that would affect sexual function including psychotropic drugs, H2 receptor blockers, cardiovascular and antihypertensive drugs, anticonvulsants, opiates, anticholinergic and antihistamines, anticancer drugs, hypnotics and hormonal drugs; not being remarried during the menopause period; not being addicted to alcohol, cigarettes and opioids for the participants and their husbands; not having participated in educational classes about menopause with focus on sexual education; not being a physician, dentist, paramedic and psychologists. Exclusion criteria: occurrence of mental or physical problems for the participants during the study; receiving any information about sexual function from any source during the study; unwillingness to continue the study; not fully participating in the conducted sessions for both groups; having interrupted sexual activity at the time of the study.

### Age

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

### Gender

Female

### Phase

N/A

### Groups that have been masked

*No information*

### Sample size

Target sample size: **108**

### Randomization (investigator's opinion)

Randomized

### Randomization description

### 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

Isfahan University of Medical Sciences

##### Street address

Isfahan University of Medical Sciences, Thousand Acres street, Azadi square, Isfahan, Iran.

##### City

Isfahan

##### Postal code

##### Approval date

2016-09-26, 1395/07/05

##### Ethics committee reference number

IR. MUI. REC. 1395.3.543

## Health conditions studied

### 1

#### Description of health condition studied

Sexual dysfunction

#### ICD-10 code

F52

#### ICD-10 code description

Sexual dysfunction, not caused by organic disorder or disease

## Primary outcomes

### 1

#### Description

Women sexual dysfunction

#### Timepoint

Before the intervention, one month after the intervention

#### Method of measurement

FSFI Questionnaire

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Education through peer menopausal women: conducting two educational sessions (with a one-week interval) by a peer participant for 4 groups of 9 menopausal women with sexual dysfunction

#### Category

Lifestyle

**2**

**Description**

Group education: conducting two educational sessions by the researcher (for 4 groups of 9) with a one-week interval

**Category**

Lifestyle

**3**

**Description**

Control group: receiving no educational intervention and only the routine cares

**Category**

Lifestyle

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Community health centers of Isfahan city

**Full name of responsible person**

Dr Reza Khadivi

**Street address**

**City**

Isfahan

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Isfahan University of Medical Sciences

**Full name of responsible person**

Dr Mehdi Nematbakhsh

**Street address**

Vice-chancellor for Research, Isfahan University of Medical Sciences, St. thousand acres, Azadi Square, Isfahan, Iran.

**City**

Isfahan

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Isfahan University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

*empty*

**Person responsible for general inquiries**

**Contact**

**Name of organization / entity**

Isfahan University of Medical Sciences

**Full name of responsible person**

Dr Mahnaz Noroozi

**Position**

Ph.D in Reproductive Health

**Other areas of specialty/work**

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**Sharing plan**

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

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*