

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 be 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

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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

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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