

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Feb 2026

The Effect of sexual life re-framing interventional program on improving sexual function in postmenopausal women

Protocol summary

Study aim

Determining the effect of sexual life reframing intervention program on improving sexual function in postmenopausal women

Design

The controlled clinical trial study will be conducted on 44 postmenopausal women. Six comprehensive health service centers will be clustered and selected through non-random quota sampling. Three centers will be randomly chosen for the intervention group, and the remaining three will serve as the control group. Postmenopausal women will be selected via convenience sampling at the chosen centers.

Settings and conduct

This study will be conducted in selected urban health service centers affiliated with Isfahan University of Medical Sciences. The educational program will address the physical, psychological, and relational aspects of sexual life, alongside the influence of social and cultural norms on women's perceptions of sexuality during menopause. The program's effectiveness will be assessed by comparing the results of the Women's Sexual Function Index Questionnaire before and after the intervention.

Participants/Inclusion and exclusion criteria

At least 12 months have passed since the onset of menopause
The age range between 40 and 60 years
Being married and living stably with a husband
Not having any diseases affects sexual function
Not using medications that affect sexual function
A score below 28 on the standard Female Sexual Function Index questionnaire

Intervention groups

The intervention group will participate in the educational program through five weekly sessions of 90 minutes each, while the control group will receive their usual care at respective centers. At the end of the study, an educational booklet on improving sexual function will be provided to the control group to ensure ethical

compliance.

Main outcome variables

Improving sexual function in postmenopausal women

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160224026756N8**

Registration date: **2025-01-21, 1403/11/02**

Registration timing: **prospective**

Last update: **2025-01-21, 1403/11/02**

Update count: **0**

Registration date

2025-01-21, 1403/11/02

Registrant information

Name

Mahnaz Noroozi

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-01-24, 1403/11/05

Expected recruitment end date

2025-06-21, 1404/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of sexual life re-framing interventional program on improving sexual function in postmenopausal women

Public title

The Effect of sexual life re-framing interventional program on improving sexual function in postmenopausal women

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Having Iranian nationality for couples Consent to participate in the study Natural menopause At least 12 months have passed since the onset of menopause The age range between 40 and 60 years Having primary and higher education Being married and living stably with a husband At least 1 year has passed since the permanent marriage and the woman is the only wife of her husband Score below 28 on the standard Female Sexual Function Index (FSFI) questionnaire

Exclusion criteria:

A history of diagnosed major psychological problems undergoing drug treatments A history of drug and alcohol abuse in both wife and husband Premature ejaculation or impotence in husband according to the self-reports Prior participation in sex education classes A history of surgery in the participants and their husbands, such as prostatectomy, hysterectomy, oophorectomy, mastectomy, and other breast surgeries Unpleasant events during the last 6 months, such as the death of parents, etc. Any chronic diseases affects sexual function in the participants and their husbands (including systemic diseases such as liver, kidney, and lung failure), cardiovascular diseases, malignant diseases, psychological diseases, mood disorders (depression, anxiety), ulcerative colitis, vasculitis, thyroid and adrenal cortex diseases, diabetes, high blood pressure, central nervous system disorders, infectious, and sexually transmitted diseases Using the most common groups of medications that affect sexual function in the participants and their husbands

AgeFrom **40 years** old to **60 years** old**Gender**

Female

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **44****Randomization (investigator's opinion)**

Randomized

Randomization description

In this study, the selection of comprehensive health

service centers will be clustered and then conducted on a quota basis using non-random methods. In this regard, among the comprehensive health service centers covered by city health center 1 and 2, six centers with appropriate population statistics (three from each city health center) will be selected. Then, among these six centers, three will be randomly selected for the intervention group, and three will be chosen for the control group. Postmenopausal women will be selected using a convenient sampling method at the chosen centers.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

Participants will be randomly assigned to two intervention groups (receiving the training program) and control groups (not receiving the intervention).

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Research Ethics Committees of Nursing, Rehabilitation and Management schools - Isfahan University of

Street address

Isfahan University of Medical Sciences, Faculty of Nursing and Midwifery

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Province

Isfahan

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8174673461

Approval date

2023-02-25, 1401/12/06

Ethics committee reference number

IR.MUI.NUREMA.REC.1401.165

Health conditions studied**1****Description of health condition studied**

Sexual function of postmenopausal women

ICD-10 code

F52

ICD-10 code description

Other sexual dysfunction, not caused by organic disorder or disease

Primary outcomes

1

Description

Sexual function of postmenopausal women

Timepoint

At the beginning of the study (before the intervention) and one month after the program ended.

Method of measurement

Female Sexual Function Index Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this study, participants in the intervention group will participate in an educational program consisting of five 90-minute sessions, held weekly in small groups of 7 to 8 individuals. The program's content has been carefully developed to address the physical, psychological, and relationship aspects of sexual life, as well as the influence of social and cultural norms on women's perceptions of sexuality during menopause. The educational sessions will take place in a private room within the research environment and utilize various teaching methods, including lectures, question-and-answer, group discussions, counseling, role-playing, and the use of photos, slides, and educational booklets. The first few minutes of each session will be dedicated to reviewing background information, assessing participants' awareness, sharing experiences, and addressing any questions or concerns related to the material raised in the previous session. At the end of each session, participants will have the opportunity to ask any questions. If individuals are hesitant to express their opinions or share their issues in front of the group, these concerns can be discussed privately after the session. Additionally, participants in the intervention group will have access to free individual telephone counseling sessions to address private questions and concerns, which will also help enhance their overall cooperation and engagement.

Category

Lifestyle

2

Description

Control group: Control group participants will receive routine care at the relevant centers. To comply with ethical considerations, an educational booklet on improving sexual function will be provided to the subjects in the control group at the end of the study.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Comprehensive Health Service Centers affiliated with Isfahan University of Medical Sciences

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

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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

Esfahan 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

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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