

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of effect of two interventional methods including of kegel excersice and sexual education on sexual function in postmenopausal women

Protocol summary

Summary

This study will be a randomized clinical trial. A total of 150 women, aged 40 to 60 years, who have reached menopause no longer than 3 years prior to the study, and are willing to cooperate, will participate in the study. After giving informed consent, the subjects will complete the Female Sexual Function Index (FSFI) questionnaire, the World Health Organization Quality of Life-BREF (WHOQOL-BREF) questionnaire, the Menopause Rating Scale (MRS), and a researcher-made questionnaire about personal and marital relationship. Blood samples will, also, be taken to check the sex hormones (total testosterone, DHEAS, SHBG, and estradiol) of the subjects. To encourage the subjects to participate, their blood sugar, triglycerides, total cholesterol, LDL, and HDL, will be measured. The subjects, then, will be randomly divided into three groups of 50 members: a group performing Kegel exercises (intervention group), a group being trained on sex issues related to menopause (intervention group), and a group being trained on general issues related to menopause (control group). These three groups will participate in their respective training sessions. Apart from receiving the necessary trainings, the subjects will be given educational booklets. The members of the group performing Kegel exercises will receive a daily exercise checklist. The intervention groups will be monitored weekly by phone calls. After 12 weeks, all participants will complete the questionnaires again and blood samples will be taken from them for hormone testing. The data acquired before and after the intervention in the three groups will be analyzed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014120320201N1**

Registration date: **2015-01-26, 1393/11/06**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-01-26, 1393/11/06

Registrant information

Name

Soheila Nazarpour

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8865 5366

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Recruitment status

Recruitment complete

Funding source

Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2014-12-14, 1393/09/23

Expected recruitment end date

2015-04-09, 1394/01/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of effect of two interventional methods including of kegel excersice and sexual education on

sexual function in postmenopausal women

Public title
Comparison of effect of pelvic floor exercise and sex education on sexual function in postmenopausal women

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion Criteria: Natural menopause (neither surgical nor premature menopause); age 40-60, not having been more than 3 years since the onset of menopause; lack of acute heart diseases; lack of any serious mental illness; absence of severe psychological stress such as an accident or loss of a family member in the past 3 months; having sexual intercourse with husband; the absence of sexual dysfunction in husband; not using herbal medicines containing phytoestrogens or supplements of sexual hormones in any form; not having a drug abuser spouse; having the willingness to participate in interventions to improve sexual function
Exclusion criteria: Being unwilling to cooperate in the ongoing investigation; having debilitating diseases (such as cancer) which prevent the person from participating in interventions; having a surgery during the intervention; having marital discord, divorce, death or illness of spouse during the intervention

Age
From **40 years** old to **60 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **150**

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
Ethics committee of Research Institute for Endocrine Sciences, Shahid Beheshti University of Medical
Street address
Velenjak St. , Shahid Chamran Highway, Tehran, Iran

City
Tehran
Postal code
Approval date
2015-01-13, 1393/10/23
Ethics committee reference number
4ERCIES93/10/23

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
Rate of sexual function
Timepoint
Before Intervention, 3 months after intervention
Method of measurement
Female Sexual Function Index (FSFI) questionnaire

2

Description
Life Quality
Timepoint
Before Intervention, 3 months after intervention
Method of measurement
WHO Quality of Life-BREF (WHOQOL-BREF) questionnaire

3

Description
severity of menopausal symptoms
Timepoint
Before Intervention, 3 months after intervention
Method of measurement
Menopause Rating Scale (MRS) questionnaire

4

Description
Total Testosterone
Timepoint
Before Intervention, 3 months after intervention
Method of measurement
Enzyme immunoassay (EIA)

5

Description
Dehydroepiandrosterone Sulfate (DHEAS)

Timepoint

Before Intervention, 3 months after intervention

Method of measurement

Enzyme immunoassay (EIA)

6**Description**

SHBG

Timepoint

Before Intervention, 3 months after intervention

Method of measurement

Enzymo-immunometric assay (EIMA)

7**Description**

EStradiol

Timepoint

Before Intervention, 3 months after intervention

Method of measurement

Enzyme-Linked Fluorescent Immunoassay (FLFA)

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention 1: Education on sex issues and how to deal with problems of sexual dysfunction including disorders in desire, arousal, orgasm, and pain; and education using PowerPoint presentation and speech in groups of 10-15 members in a session; and delivery of training booklets and weekly follow-ups for three months.

Category

Behavior

2**Description**

Intervention 2: Pelvic floor muscles training (Kegel exercises) by PowerPoint presentations and videos in groups of 10-15 members in a session; and delivery of training booklets, checklists of daily exercise, and weekly follow-ups for regular exercise for three months.

Category

Behavior

3**Description**

Control: Education on general issues related to menopause such as complaints, nutrition, etc. by PowerPoint presentations and speech in groups of 10-15 members in a session; and delivery of training booklets.

Category

Behavior

Recruitment centers**1****Recruitment center****Name of recruitment center**

Islamic Azad University, Chaloos Branch

Full name of responsible person

Soheila Nazarpour

Street address**City**

17 Shahrivar street, Opposite the mosque of Imam Hussain (AS), Islamic Azad University, Chaloos Br

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Masome Simbar (Vice chancellor for research of Nursing and Midwifery Department), Fahimeh Ramezani T

Street address

Velenjak Street , Shahid Chamran Highway, Tehran, Iran

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences, Midwifery and Nursing Department

Full name of responsible person

Soheila Nazarpour

Position

PhD student in the field of Reproductive Health

Other areas of specialty/work**Street address**

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o.comsn_9547@yahoo.com

Web page address

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