Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the effect of kegel exercise and lubricant gel on the sexual function of menopausal women

Protocol summary

Study aim

To determine and compare the effect of Kegel exercise and lubricant gel on sexual function in menopausal women

Design

The present study is a clinical trial with a control group and parallel groups.The allocation of individuals to each of the three groups is based on a random number table.

Settings and conduct

Postmenopausal women who recruited to health care centers of Dezful and wish to participate in the study will be randomly assigned to one of three study groups if they meet the inclusion criteria. Participants first fill in the DAAS questionnaire to examine psychological criteria and then are examined by the researcher for evaluating their pelvic-floor muscle strength which will be scored based on the Oxford Grading Scale. Participants will enter the study if they achieve a score of 2 or higher and do not have depression, anxiety, and stress based on DAAS. Prior to the intervention, all groups will complete the Sexual Function Questionnaire. The first group will receive intervention based on the Kegel exercise and instruction on how to perform the exercises. The second group will receive lubricant gel and will be instructed on how to use it. No intervention will be for the control group. These interventions will be continued for 12 weeks, and sexual function will be re-evaluated three times, i.e. the end of the first, second, and third months.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Married postmenopausal women who are in their first ten years of menopause, who are not physically and mentally ill and do not use hormone or sexually affecting drugs. Exclusion criteria: Unwillingness to participate in the study and sensitivity and allergy to lubricant gel in the intervention group with gel.

Intervention groups

Fifty women are assigned to the Kegel exercise group, 50 to lubricant gel group

Main outcome variables

Sexual function

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150128020854N7**
Registration date: **2019-09-30, 1398/07/08**
Registration timing: **registered_while_recruiting**

Last update: **2019-09-30, 1398/07/08**
Update count: **0**

Registration date

2019-09-30, 1398/07/08

Registrant information

Name

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Name of organization / entity

Shahid Beheshti University of Medical Science

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-22, 1398/04/01

Expected recruitment end date

2019-10-22, 1398/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of the effect of kegel exercise and lubricant gel on the sexual function of menopausal women

Public title
Effect of kegel exercise and lubricant gel on the sexual function

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Physiologic menopause (not due to surgery or premature menopause before 40 years of age) Being in the first 10 years of menopause Lack of self-reported medical diseases affecting sexual function (respiratory and cardiovascular disease, arthritis, Parkinson's disease, or multiple sclerosis) Lack of any self-reported psychological disease Absence of depression, anxiety, or stress based on the Depression Anxiety Stress Scales (DAAS) Scoring 2 or higher on the Oxford Grading Scale (OGS) for pelvic-floor muscle strength having sexual function Absence of impotence in the spouse (as declared by the participant) Not taking any herbal medicine containing phytoestrogen or any form of hormone replacement therapy Not taking any medicine affecting sexual function Negative history of hysterectomy and mastectomy Maximum five vaginal delivery Lack of self-reported genital infections Using lubricant gel in all the sexual intercourses in lubricant gel intervention group)

Exclusion criteria:
Unwillingness to cooperating in the study. Allergy to lubricant gel.

Age
No age limit

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
From the 7 health care centers in Dezful city, five centers will be randomly selected. Then postmenopausal women covered by these centers will be contacted and invited to participate in the study. Eligible women will be divided into three groups of 50 based on the random number table. In this way, all participants will be given three-digit codes from 001 to 150. Then, using the website www.Randomization.com, the statistical consultant will provide three sets of codes for researcher, the first in the intervention group with kegel, the second in the intervention group with lubricant gel, and the third in the control group.

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
Shahid Beheshti Univercity of Medical Sciences, School of Nursing and Midwifery

Street address
Vali Asr Ave, Niayesh Cross Road, SBMU School of Nursing & Midwifery

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Province
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Approval date
2017-07-18, 1396/04/27

Ethics committee reference number
IR.SBMU.PHMN.1396.777

Health conditions studied

1

Description of health condition studied
sexual function

ICD-10 code
F52.9

ICD-10 code description
Unspecified sexual dysfunction not due to a substance or known physiological condition

Primary outcomes

1

Description
Sexual function

Timepoint
Before intervention, one, two and three months after intervention

Method of measurement
Female Sexual function questionnaire (FSFI)

Secondary outcomes

empty

Intervention groups

1

Description

In the Kegel intervention group, in a 60-minute session, a brief introduction to the anatomy and function of the pelvic floor muscles, an introduction to how the Kegel exercise is performed, its mechanism and function, its benefits, and finally an evaluation of participants to ensure that the exercise is performed properly will be done. PowerPoint, replica pelvis and movies will be used through individually and face-to-face teaching. A daily checklist (three times daily in the morning, noon, night) for 12 weeks as well as a Kegel Exercise Training Guide will be given to the participants as a pamphlet and then weekly follow up by telephone is performed.

Category

Behavior

2

Description

In the intervention group with lubricant gel 45 minutes training session will be held for familiarizing with pelvic anatomy, pelvic floor muscles, vaginal and genitalia changes in menopause, lubricant gel and its benefits and how to use it is performed and finally evaluation of participants for learning materials will be done. Participants will be asked to record the frequency of using lubricant gel in their checklists for 12 weeks and will be followed up weekly by phone for investigation any reaction and side effects of lubricant gel and possible questions.

Category

Behavior

3

Description

Control group: The control group will not receive any intervention and will solely receive general menopausal care. Demographic questionnaire and sexual function questionnaire will be completed with 12 weeks interval.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrat-e Roghayeh healthcare center

Full name of responsible person

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Sponsors / Funding sources

1

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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
Shahid Beheshti 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

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
All the data will be published in tables in the final paper.
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
--
When the data will become available and for how long
--
To whom data/document is available
--
Under which criteria data/document could be used
--
From where data/document is obtainable
--
What processes are involved for a request to access data/document
--
Comments