Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Jun 2026

Study and comparison of the effect of a combined oral capsule containing lemon balm and fennel on sexual function and sexual satisfaction in postmenopausal women

Protocol summary

Study aim

General Objective: To determine and investigate the effect of a combined oral capsule containing lemon balm and fennel on sexual function and sexual satisfaction in menopausal women.

Design

A controlled, parallel-group, triple-blind, phase 3 clinical trial randomized by simple random number table on 88 postmenopausal women. R software is used for randomization.

Settings and conduct

Study location: Shahid Beheshti Traditional Medicine School and one of the comprehensive health service centers in North Tehran How to conduct: The researcher, by visiting the mentioned places and finding the samples he needs according to the criteria, invites the samples to a meeting and after giving full and comprehensive explanations and with the informed consent of the samples, starts sampling and first delivers the questionnaires and then the sealed medicine packets to the samples and monitors them for 2 months. The researcher, the sample and the statistical consultant; all 3 are blind in this study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1) At least one year has passed since their menstrual cycle stopped. 2) The postmenopausal woman and her husband are sexually active. 3) The postmenopausal woman's husband does not have sexual dysfunction. Exclusion criteria: 1) Possible side effects of the capsules 2) Unwillingness to continue treatment, such as stopping taking the capsules for 3 consecutive days or a non-consecutive week

Intervention groups

The study was designed to investigate the effectiveness of a combined oral capsule of fennel and lemon balm on sexual function and satisfaction in menopausal women. 88 menopausal women were divided into two groups: intervention and control. They used this capsule for 2 months. The results and observations were analyzed based on questionnaires filled out by the samples.

Main outcome variables

Sexual function; sexual satisfaction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250417065363N1**
Registration date: **2025-05-15, 1404/02/25**
Registration timing: **registered_while_recruiting**

Last update: **2025-05-15, 1404/02/25**
Update count: **0**

Registration date

2025-05-15, 1404/02/25

Registrant information

Name

Shamim Naghibinezhad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2670 2259

Email address

sh.naghibinezhad@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-05-05, 1404/02/15

Expected recruitment end date

2025-07-23, 1404/05/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Study and comparison of the effect of a combined oral capsule containing lemon balm and fennel on sexual function and sexual satisfaction in postmenopausal women

Public title
The effect of Phenalis oral capsules on sexual function and satisfaction in postmenopausal women.
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Be Iranian. Must be at least literate. Not have hearing, speech, or mental disorders that prevent communication with the researcher. At least one year has passed since their menstruation stopped. Do not use herbal teas while taking the medication. Not wanting or needing to use hormone replacement therapy. she doesnt use chemical or herbal medicine for their treatment. Postmenopausal women and their partners should be sexually active. The husband of a menopausal woman, according to her statements, does not have sexual dysfunction (erectile dysfunction, ejaculation). she has not undergone hysterectomy, oophorectomy, cystocele, rectocele, or mastectomy. Postmenopausal women and their spouses (self-reported spouses) should not have a known mental illness. Not be addicted to cigarettes or drugs. Have not recently used antidepressants or anti-anxiety medications. They should not have a history of known chronic diseases such as diabetes, high blood pressure, asthma, immune system disorders, etc. There should be no specific event or incident that constitutes a crisis in their lives, such as the death of a loved one, a terminal illness in a family member, or a change of residence. Have no history of allergy to medicinal plants.
Exclusion criteria:
Possible side effects of the capsules Unwillingness to continue treatment, such as stopping taking the capsule for 3 consecutive days or a non-consecutive week.
Age
From **45 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size
Target sample size: **88**
Randomization (investigator's opinion)
Randomized
Randomization description
Sampling is done conveniently based on the study entry criteria and the samples are assigned to the control and intervention groups by simple randomization method based on a randomization list. The randomization list is prepared using R software and will be given confidentially by the statistical consultant to the pharmacist.
Blinding (investigator's opinion)
Triple blinded
Blinding description
After grouping the samples into the sample and control groups, assigning a code to each individual, and coding the medication packets, the pharmacist will hand over the coded medication packets to the researcher and the intervention will begin. Coding will be done by the pharmacist in the laboratory of Shahid Beheshti Faculty of Medicine. Therefore, the researcher, the research samples, and the statistical consultant will not know the contents of the packets.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committee of the Faculties of Pharmacy, Nursing and Midwifery, Shahid Beheshti Unive
Street address
Faculty of Nursing and Midwifery,Ayatollah Hashemi Rafsanjani Highway Intersection,Vali Asr Street.Tehran Town.
City
Tehran
Province
Tehran
Postal code
1996835119
Approval date
2024-05-27, 1403/03/07
Ethics committee reference number
IR.SBMU.PHARMACY.REC.1403.017

Health conditions studied

1

Description of health condition studied
Sexual function and sexual satisfaction
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Sexual function score in Female Sexual Function Index questionnaire
Timepoint
At the beginning of the study, 2 and 3 months after the end of the intervention
Method of measurement
Women's Sexual Function Index Questionnaire

2

Description
Sexual satisfaction score on the Larson Sexual Satisfaction Questionnaire
Timepoint
At the beginning of the study, 2 and 3 months after the end of the intervention
Method of measurement
Larson Sexual Satisfaction Questionnaire(LSSQ)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Oral capsule containing fennel and lemon balm. Manufactured by the Traditional Medicine and Medical Supplies Research Center of Shahid Beheshti University of Medical Sciences. The capsule contains 2 grams of fennel extract (in powder form) and 2 grams of lemon balm extract (in powder form). The samples should take 2 capsules daily, one on an empty stomach and the other before bedtime, for two consecutive months.
Category
Treatment - Drugs

2

Description
Control group: Control group: Oral capsule containing starch powder. (The control capsule package has the same color,smell and shape as the medicine) Manufactured by the Traditional Medicine and Medical Supplies Research Center, Shahid Beheshti University of Medical Sciences. The method and duration of placebo consumption is also similar to the original drug. (Two capsules daily, one on an empty stomach and one before bedtime for 2 consecutive months)
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
سلامتکده طب سنتی وابسته به دانشگاه علوم پزشکی شهید بهشتی
Full name of responsible person
Dr. Sajjad Sadeghi
Street address
Vali Asr Street
City
Tehran
Province
Tehran
Postal code
1516745811
Phone
+98 21 8877 3521
Email
sitm@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dr.sepide hajian
Street address
Shahid Beheshti School of Nursing and Midwifery,In front of Shahid Rajaee Heart Hospital,Ayatollah Hashemi Rafsanjani Highway Intersection,Vali asr street,Tehran town.
City
Tehran
Province
Tehran
Postal code
1996835119
Phone
+98 21 8820 2512
Email
s.hajian@sbmu.ac.ir
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

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Shamim Naghibinezhad

Position

Student

Latest degree

Master

Other areas of specialty/work

Midwifery

Street address

NO. 61 ,North ABOUZAR GHAFARI Ave, SEYYED KHANDAN Blvd

City

Tehran

Province

Tehran

Postal code

1661746665

Phone

+98 21 2670 2259

Fax

Email

sh.naghibinezhad@sbmu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Shamim Naghibinezhad

Position

Student

Latest degree

Master

Other areas of specialty/work

Midwifery

Street address

NO. 61 ,North ABOUZAR GHAFARI Ave, SEYYED KHANDAN Blvd

City

Tehran

Province

Tehran

Postal code

1661746665

Phone

+98 21 2670 2259

Fax

Email

sh.naghibinezhad@sbmu.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Shamim Naghibinezhad

Position

Student

Latest degree

Master

Other areas of specialty/work

Midwifery

Street address

NO. 61 ,North ABOUZAR GHAFARI Ave, SEYYED KHANDAN Blvd

City

Tehran

Province

Tehran

Postal code

1661746665

Phone

+98 21 2670 2259

Fax

Email

sh.naghibinezhad@sbmu.ac.ir

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

Because the data was collected under specific conditions for the thesis, it cannot be used in other studies.

Study Protocol

No - There is not 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

No - There is not 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

No - There is not a plan to make this available