Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of oral evening primrose oil capsule on sexual function and sexual quality of life of married women in reproductive ages: A double-blinded randomized placebo-controlled trial.

Protocol summary

Study aim
Exploring and determining the effects of oral evening primrose oil capsule on sexual function and sexual quality of life of married women in reproductive ages

Design
A double-blinded randomized placebo-controlled trial.

Settings and conduct
It will be a double-blind phase 1 of clinical trial. Research units will be 60 women referring to tehran Health Centers which are in reproductive age and eligible for inclusion in this study. Participants will be randomly assigned into two groups of 30 with homogeneity of age and number of deliveries. And will be assigned randomly by block randomization. The control group will receive placebo capsules and the intervention group will receive evening primrose oil capsule orally for 8 weeks. The tutorial will provide to participants including how to use tablets. In the control group, placebo capsules containing 1000 mg of edible paraffin which will be administered orally daily for 8 weeks. Participants' contact numbers and addresses will be recorded for access to the samples and follow-up assessments, and the researcher's contact number will also be available to answer participants' questions.

Participants/Inclusion and exclusion criteria
Iranian reproductive aged women (18-49 years old) who have no allergy to evening primrose oil capsule.

Intervention groups
Intervention group:30 women who will receive 1 tablets of evening primrose oil capsule 1000 mg daily for 8 weeks orally. Control group: 30 women who will receive 1tablets of evening primrose oil capsule 1000 mg daily for 8 weeks orally.

Main outcome variables
Sexual function; Sexual quality of life

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20191127045517N1**
Registration date: **2020-09-18, 1399/06/28**
Registration timing: **retrospective**

Last update: **2020-09-18, 1399/06/28**
Update count: **0**

Registration date
2020-09-18, 1399/06/28

Registrant information

Name
Shadi Torkan

Name of organization / entity
The University of Tarbiat Modares

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-02-09, 1398/11/20

Expected recruitment end date
2020-05-09, 1399/02/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
The effect of oral evening primrose oil capsule on sexual function and sexual quality of life of married women in reproductive ages: A double-blinded randomized placebo-controlled trial.

Public title
The effect of oral evening primrose oil capsule on sexual function of women

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Women over the age of 18 (age 18 is considered a good time for marriage) and before the age of pre-menopause (49 years). Being Iranian and living in Tehran Reading and Writing Persian Language participants who had a monogamous husband during the study and at the beginning of it Having sex in the last two months

Exclusion criteria:
Having a known underlying disease Couples are addicted to drugs and alcohol Having a history of pelvic surgery pregnancy or breastfeeding Having a mental illness Sensitive to evening primrose oil Taking drugs that affect sexual function Have a stressful accident over the past month Have a urinary tract infection Having vaginitis, cervicitis, pelvic genital pain disorders, active sores or genital lesions that interfere with sexual intercourse (penetration) Victims of rape having the history of infertility

Age
From **18 years** old to **49 years** old

Gender
Female

Phase
1

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Block randomization will be use for randomizing participants within blocks such that an equal number will assigned to treatment. we will give a block size of 4, which there are 6 possible ways to equally assign participants to a block. Allocation proceeds by randomly selecting one of the orderings and assigning the next block of participants to study groups according to the specified sequence.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, the researcher and the study participants will not aware of the drug or placebo.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Tarbiat Modarres University

Street address
Faculty of Medicine, Tarbiat Modares University, Jalal al Ahmad high way

City
Tehran

Province
Tehran

Postal code
1411713116

Approval date
2019-07-17, 1398/04/26

Ethics committee reference number
IR.MODARES.REC.1398.141

Health conditions studied

1

Description of health condition studied
Sexual dysfunction

ICD-10 code
F52

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

Primary outcomes

1

Description
Female sexual function

Timepoint
Evaluation of research units will be done 4 and 8 weeks after the intervention.

Method of measurement
Female sexual function index

2

Description
Sexual Quality of Life

Timepoint
Evaluation of research unitswill be don 4 and 8 weeks after the intervention

Method of measurement
Sexual Quality of Life-Female (SQOL-F) questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 30 women who will be included in the study according to inclusion criteria. They will consume 1 capsule of 1000 mg oral evening primrose oil daily prepared by barij esans Company for 8 weeks. Following the intervention, the researcher will contact the research units in the intervention group each week to ensure proper use of the evening primrose oil capsule. Evaluation of the research units will be done 4 weeks after the intervention using the questionnaires completed by the research units in person.

Category

Treatment - Drugs

2

Description

Control group: 30 women who will be included in the study according to inclusion criteria. They will consume 1placebo capsule of 30 mg daily prepared by barij esans Company for 8 weeks. Following the intervention, the researcher will contact the research units in the intervention group each week to ensure proper use of the placebo capsule. Evaluation of the research units will be done 4 weeks after the intervention using the questionnaires completed by the research units in person.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Tehran Health Centers

Full name of responsible person
Shadab Shahali

Street address
Faculty of Medical Sciences, Tarbiat Modares University, Jalal al Ahmad St.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tarbiat Modares University

Full name of responsible person
Dr. Fathollahi Yaghoub

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Faculty of Medical Sciences, Tarbiat Modares University, Jalal al Ahmad

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http://www.modares.ac.ir/en

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Tarbiat Modares University

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
Tarbiat Modares University

Full name of responsible person
Shadab Shahali

Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Reproductive Health

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Faculty of Medical Sciences, Tarbiat Modares University, Jalal al Ahmad St.

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tarbiat modares university

Full name of responsible person

Shadab Shahali

Position

Assistant Professor

Latest degree

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Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Shadab Shahali

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

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Web page address

http://www.modares.ac.ir/en

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

No more information

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Only the main outcome will be published.

When the data will become available and for how long

The main outcome will be available after 2021

To whom data/document is available

The data will be available for college researchers

Under which criteria data/document could be used

For more research, researchers could send their request letter to the co respond anther.

From where data/document is obtainable

Correspondence Author. Department of Reproductive Health and Midwifery, Faculty of Medical Sciences, Tarbiat Modares University.

What processes are involved for a request to access data/document

Upon receiving the request letter by the coresponding author, the request will be forwarded to Tarbiat Modarres University Research Unit, and the analyzed data will be send to researchers if applicable.

Comments