

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

Country

Iran (Islamic Republic of)

Phone

+98 21 7749 2509

Email address

shaditorkan@modares.ac.ir

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 1 placebo 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.

City

Tehran

Province

Tehran

Postal code

1411713116

Phone

+98 21 8288 3811

Email

shaditorkan@modares.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tarbiat Modares University

Full name of responsible person

Dr. Fathollahi Yaghoub

Street address

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

City

Tehran

Province

Tehran

Postal code

1411713116

Phone

+98 21 8288 4230

Fax

+98 21 8288 4230

Email

shaditorkan@modares.ac.ir

Web page address

<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

Street address

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

City

Tehran
Province
Tehran
Postal code
1411713116
Phone
+98 21 8288 3811
Email
shadab.shahali@modares.ac.ir

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
Ph.D.
Other areas of specialty/work
Reproductive Health
Street address
Faculty of Medical Sciences, Tarbiat Modares University, Jalal al Ahmad St.
City
Tehran
Province
Tehran
Postal code
1411713116
Phone
+98 21 8288 3811
Email
shadab.shahali@modares.ac.ir

Person responsible for updating data

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
Street address
Faculty of Medical Sciences, Tarbiat Modares

University, Jalal al Ahmad St.
City
Tehran
Province
Tehran
Postal code
1411713116
Phone
+98 21 8288 3811
Email
shadab.shahali@modares.ac.ir
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 corresponding author, the request will be forwarded to Tarbiat Modarres University Research Unit, and the analyzed data will be send to researchers if applicable.

Comments