# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

13 Jun 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
**Country**
Iran (Islamic Republic of)
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+98 21 7749 2509
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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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shaditorkan@modares.ac.ir

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**
Tarbiat Modares University

**Full name of responsible person**
Dr. Fathollahi Yaghoub

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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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## Person responsible for scientific inquiries

**Contact**

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**Full name of responsible person**

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## Person responsible for updating data

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Shadab Shahali

**Position**

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**Other areas of specialty/work**

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**Email**

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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**