

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Omega-3 consumption in premenstrual syndrome: measuring its effects on the quality of life using the Premenstrual Symptoms Screening Tool (PSST) and SF12 questionnaire

#### Protocol summary

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##### Summary

The purpose of this study is to evaluate Omega-3 consumption on quality of life of people with premenstrual syndrome using PSST and SF-12 questionnaires. In this double blind placebo controlled study, 90 students living in dormitories who meet eligibility criteria will be randomly into omega-3 or placebo group. Participants will take 2 capsules of Omega-3 or placebo daily in the first month. They will take capsules in the second and third months since 8 days before menstruation until 2 days after onset of menstrual bleeding. PSST and SF-12 questionnaires will be filled by participants every month.

##### Recruitment status

**Recruitment complete**

##### Funding source

Tarbiat Modares University

##### Expected recruitment start date

2009-05-22, 1388/03/01

##### Expected recruitment end date

2010-03-20, 1388/12/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT138809212843N1**

Registration date: **2010-04-24, 1389/02/04**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2010-04-24, 1389/02/04

##### Registrant information

###### Name

Fatemeh Zahra Hariri

###### Name of organization / entity

Tarbiat Modares University

###### Country

Iran (Islamic Republic of)

###### Phone

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###### Email address

##### Scientific title

Omega-3 consumption in premenstrual syndrome: measuring its effects on the quality of life using the Premenstrual Symptoms Screening Tool (PSST) and SF12 questionnaire

##### Public title

Omega-3 consumption in premenstrual syndrome: measuring its effects on the quality of life using the Premenstrual Symptoms Screening Tool (PSST) and SF12 questionnaire

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: Age 20-35 years, single girls, normal cycle (duration of cycle 22-35, bleeding 3-7 days), normal BMI (18.5-25), PMS according to PSST questionnaire Exclusion criteria: any history of disease such as hepatic, renal, or respiratory cardiac, diabetes, or respiratory diseases, presence of secondary dysmenorrheal, sea food allergy, use of alcohol, smoking, presence of chronic diseases such as like migraine, use

of any drug affecting PMS such as OCP or B6, stressful condition like death of family members

### Age

From **20 years** old to **35 years** old

### Gender

Female

### Phase

N/A

### Groups that have been masked

*No information*

### Sample size

Target sample size: **90**

### Randomization (investigator's opinion)

Randomized

### Randomization description

### Blinding (investigator's opinion)

Double blinded

### Blinding description

### Placebo

Used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Tarbiat Modares University

##### Street address

Faculty of Medicine, Tarbiat Modares University, Jalal Ale Ahmad EXP way

##### City

Tehran

##### Postal code

#### Approval date

2009-01-18, 1387/10/29

#### Ethics committee reference number

15070878

## Health conditions studied

### 1

#### Description of health condition studied

Premenstrual syndrome

#### ICD-10 code

N94.3

#### ICD-10 code description

Pain and other conditions associated with female genital organs and menstrual cycle

## Primary outcomes

### 1

#### Description

premenstrual syndrome (existing symptoms in PSST questionnaire)

#### Timepoint

before intervention, 1, 2, and 3 months after intervention

#### Method of measurement

PSST questionnaire

### 2

#### Description

quality of life

#### Timepoint

before intervention, 1, 2, and 3 month after intervention

#### Method of measurement

SF-12 questionnaire

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Omega-3, one gram capsule, twice daily, everyday in the first month and since 8 days before menstruation till 2 days after beginning of bleeding in the second and third months

#### Category

Treatment - Drugs

### 2

#### Description

Placebo, one gram capsule, twice daily, everyday in the first month and since 8 days before menstruation till 2 days after beginning of bleeding in the second and third months

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Tehran & Tarbiat Modares University

##### Full name of responsible person

##### Street address

##### City

Tehran

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Tarbiat Modares University

**Full name of responsible person**

Fateme Zahra Hariri

**Street address**

Tarbiat Modares University, Jalal EXP way

**City**

Tehran

**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***empty***Domestic or foreign origin***empty***Category of foreign source of funding***empty***Country of origin****Type of organization providing the funding***empty***Person responsible for general inquiries****Contact****Name of organization / entity**

Tarbiat Modares University

**Full name of responsible person**

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**Position**

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**Web page address****Sharing plan****Deidentified Individual Participant Data Set (IPD)***empty***Study Protocol***empty***Statistical Analysis Plan***empty***Informed Consent Form***empty***Clinical Study Report***empty***Analytic Code***empty***Data Dictionary***empty*