Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

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 0mega-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.

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

+98 21 8801 1001

Email address

fhariri@modares.ac.ir

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

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 mentstruation till 2 days after begining 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 mentstruation till 2 days after begining 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
FatemehZahra Hariri
Position
Student
Other areas of specialty/work
Street address
Midwifery Department, Tarbiat Modares University, Jalal Ale Ahmad Expway
City
Tehran
Postal code
Phone
+98 21 8288 3857
Fax
Email
fhariri@modares.ac.ir
fatemehzahra_hariri@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tarbiat Modares university
Full name of responsible person
Lida Moghaddam Banaem
Position
PhD
Other areas of specialty/work
Street address
Midwifery Department, Tarbiat Modares University, Jalal Ale Ahmad Expway
City
Tehran
Postal code
Phone
+98 21 8288 3857
Fax
Email
moghaddamb@modares.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Tarbiat Modares University
Full name of responsible person
FatemehZahra Hariri
Position
Student
Other areas of specialty/work
Street address
Midwifery Department, Tarbiat Modares University, Jalal Ale Ahmad Expway
City
Tehran
Postal code
Phone
Fax
Email
fhariri@modares.ac.ir
fatemehzahra_hariri@yahoo.com
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