Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effect of Evening Primrose Oil supplementation on menstrual pain, mastalgia, menstrual distress, fatigue and anaerobic capacity in physically active women with primary dysmenorrhea: A single-center, randomized, double-blind, placebo-controlled trial

Protocol summary

Study aim
To determine the effects of evening primrose oil supplementation on menstrual pain, mastalgia, menstrual distress, fatigue, and anaerobic capacity in physically active women with primary dysmenorrhea.

Design
A single-center, randomized, double blind, parallel, placebo-controlled clinical trial with repeated measurements will include 28 women allocated equally to intervention and control groups using simple randomization and a random number table.

Settings and conduct
The study will be conducted at Alzahra University, Tehran, Iran. Eligible participants will provide informed consent and be randomly allocated to the two groups. Outcome assessments will be performed at predefined time points according to the menstrual cycle. Participants and outcome assessors will be blinded to group allocation.

Participants/Inclusion and exclusion criteria
Physically active women aged 18 to 35 years with primary dysmenorrhea, regular menstrual cycles of 21 to 35 days, a menstrual pain score of at least 4 on the Visual Analogue Scale in two consecutive cycles, regular moderate to vigorous physical activity, and normal pelvic ultrasonography will be included. Major pelvic or systemic diseases, recent use of hormonal or relevant medications or supplements, allergy to evening primrose oil, and unwillingness to participate are exclusion criteria.

Intervention groups
The intervention group will receive one 1000 mg evening primrose oil capsule daily for 8 weeks from day 5 of the menstrual cycle. The control group will receive one identical 1000 mg soybean oil placebo capsule daily for 8 weeks from day 5. Capsules will be taken with food and water.

Main outcome variables
Menstrual pain; mastalgia; menstrual distress; fatigue; anaerobic capacity

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20181125041749N2**
Registration date: **2026-08-11, 1405/05/20**
Registration timing: **prospective**

Last update: **2026-08-11, 1405/05/20**
Update count: **0**

Registration date
2026-08-11, 1405/05/20

Registrant information
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Recruitment status
Not yet recruiting

Funding source

Expected recruitment start date
2026-11-21, 1405/08/30

Expected recruitment end date
2027-02-19, 1405/11/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of Evening Primrose Oil supplementation on menstrual pain, mastalgia, menstrual distress, fatigue and anaerobic capacity in physically active women with primary dysmenorrhea: A single-center, randomized, double-blind, placebo-controlled trial

Public title
Effect of Evening Primrose Oil supplementation on menstrual pain, mastalgia, menstrual distress, fatigue and anaerobic capacity in physically active women with primary dysmenorrhea: A single-center, randomized, double-blind, placebo-controlled trial
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age 18–35 years Regular menstrual cycles (21–35 days) Menstrual pain score ≥4 based on the Visual Analog Scale (VAS) in two consecutive menstrual cycles, according to the DSM-IV-TR criteria for primary dysmenorrhea Regular physical activity, defined as at least three sessions per week of ≥30 minutes of moderate-to-vigorous intensity physical activity during the previous 6 months Provision of a normal pelvic ultrasonography report obtained within the previous 6 months to rule out secondary causes of dysmenorrhea and confirm the absence of structural abnormalities of the uterus and ovaries, including endometriosis, adenomyosis, uterine fibroids, endometrial polyps, and pathological ovarian cysts No use of hormonal medications, including oral contraceptive pills (OCPs), during the 3 months preceding the study No use of nonsteroidal anti-inflammatory drugs (NSAIDs), antioxidants, other oil-based supplements, or herbal medicines affecting menstruation during the 4 weeks preceding the study Willingness to participate in the study and provision of written informed consent
Exclusion criteria:
Presence of secondary dysmenorrhea or a known structural pelvic disorder, including endometriosis, adenomyosis, uterine fibroids, endometrial polyps, or pathological ovarian cysts Presence of systemic diseases, including diabetes, thyroid disorders, liver or kidney diseases, or severe psychiatric disorders Current use of hormonal medications, including oral contraceptive pills (OCPs) Current use of medications or supplements that may affect menstrual symptoms, including nonsteroidal anti-inflammatory drugs (NSAIDs), antioxidants, oil-based supplements, or herbal medicines Known allergy or hypersensitivity to evening primrose oil (EPO) or any of its components Pregnancy or breastfeeding at the time of enrollmentAny medical condition that contraindicates participation in moderate-to-vigorous physical activity
Age
From **18 years** old to **35 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **28**
Randomization (investigator's opinion)
Randomized
Randomization description
After assessing the inclusion and exclusion criteria, completing the Physical Activity Readiness Questionnaire (PAR-Q), and obtaining written informed consent, eligible participants will be randomly allocated using simple randomization to two equal groups: an intervention group receiving evening primrose oil (EPO) and a control group receiving placebo. The unit of randomization will be the individual participant, and randomization will be performed at the individual level. To generate the randomization sequence, each participant will be assigned a unique identification code, and participants will be allocated to the two groups using a random number table. Fourteen participants will be allocated to each group. No stratified or cluster randomization will be used in this study. To ensure allocation concealment, the group codes will be generated and maintained by a third party who will not be involved in participant assessment, intervention delivery, or data analysis. The EPO and placebo capsules will be identical in appearance, size, color, packaging, and administration procedure and will be packaged using identical, non-identifiable codes. The participants and researchers responsible for conducting the assessments will remain unaware of group assignments. The allocation codes will remain confidential until completion of data collection and statistical analysis and will then be unblinded.
Blinding (investigator's opinion)
Double blinded
Blinding description
After random allocation, the group codes will be generated and maintained by a third party who will not be involved in participant assessment, intervention delivery, or data analysis. The evening primrose oil and placebo capsules will be identical in appearance, size, color, packaging, and administration procedure and will be provided using non-identifiable codes. Participants will be blinded to the intervention they receive. Researchers and outcome assessors will also remain unaware of the participants' group assignments throughout data collection. The allocation codes will remain confidential until completion of the statistical analysis and will then be unblinded. If data analysis is performed using coded group assignments, the data analyst will also remain

blinded to group allocation.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committees of Alzahra University

Street address
Alzahra University, Deh-e-Vanak St.

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Province
Tehran

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Approval date
2026-06-30, 1405/04/09

Ethics committee reference number
IR.ALZAHRA.REC.1405.059

Health conditions studied

1

Description of health condition studied
Primary dysmenorrhea

ICD-10 code
N94.4

ICD-10 code description
Primary dysmenorrhea

Primary outcomes

1

Description
Menstrual pain intensity

Timepoint
On the second day of the menstrual cycle at baseline before initiation of the intervention, on the second day of the subsequent menstrual cycle after initiation of the intervention, and on the second day of the following menstrual cycle

Method of measurement
A 10-cm Visual Analogue Scale for pain intensity, ranging from 0 indicating no pain to 10 indicating the most severe pain imaginable.

Secondary outcomes

1

Description
Menstrual-related mastalgia intensity

Timepoint
During the luteal phase of the menstrual cycle at baseline before initiation of the intervention, during the luteal phase of the subsequent menstrual cycle after initiation of the intervention, and during the luteal phase of the following menstrual cycle

Method of measurement
A Numerical Rating Scale for pain intensity ranging from 0 indicating no pain to 10 indicating the most severe pain imaginable.

2

Description
Menstrual distress severity

Timepoint
At the end of the menstrual cycle at baseline, at the end of the subsequent menstrual cycle after initiation of the intervention, and at the end of the following menstrual cycle

Method of measurement
The 42-item Moos Menstrual Distress Questionnaire, with a total score ranging from 0 to 168

3

Description
Mental fatigue score

Timepoint
At the end of the menstrual cycle at baseline, at the end of the subsequent menstrual cycle after initiation of the intervention, and at the end of the following menstrual cycle

Method of measurement
The 20-item Multidimensional Fatigue Inventory assessing general fatigue, physical fatigue, mental fatigue, reduced motivation, and reduced activity

4

Description
Anaerobic capacity

Timepoint
On days 7 to 10 of the follicular phase at baseline, on days 7 to 10 of the follicular phase of the subsequent menstrual cycle after initiation of the intervention, and on days 7 to 10 of the follicular phase of the following menstrual cycle

Method of measurement
The Running-Based Anaerobic Sprint Test consisting of six 35-meter maximal sprints with 10 seconds of rest between sprints; peak power, mean power, and fatigue index are calculated.

Intervention groups

1

Description

Intervention group: Participants will receive one capsule of evening primrose oil (EPO) containing 1000 mg (containing 8%–14% gamma-linolenic acid (GLA)) daily. The capsule will be taken for 8 weeks, starting on the fifth day of the menstrual cycle, with food and a glass of water. The product will be obtained from a reputable pharmaceutical company licensed by the Food and Drug Administration. The composition and specifications of the product will be in accordance with the information provided by the manufacturer.

Category

Treatment - Other

2

Description

Control group: articipants will receive one placebo capsule containing 1000 mg of soybean oil daily. The placebo capsules will be identical to the evening primrose oil capsules in appearance, size, color, packaging, and administration procedure and will contain no gamma-linolenic acid (GLA). The capsules will be taken for 8 weeks, starting on the fifth day of the menstrual cycle, with food and a glass of water.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra University, Faculty of Sport Sciences

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Alzahra 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

Alzahra University

Full name of responsible person

Fahimeh Kazemi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
Data relating to subjects will be shared as unidentified.
When the data will become available and for how long
Six months after the publication of the article.
To whom data/document is available
All researchers
Under which criteria data/document could be used
The data may be used for citation purposes, provided that the source is acknowledged.
From where data/document is obtainable
Fahimeh Kazemi
What processes are involved for a request to access data/document
By an Email
Comments