

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison the effects of 2 month of regular Aerobic exercise and vitamin B6 intake on the Symptoms of premenstrual syndrome in Non-Athlete student girls

Protocol summary

Summary

The main objective of this project is to Comparison the effects exercise of aerobic and vitamin B6 intake on the symptoms of premenstrual-syndrome in Non-athlete girls. 60 girl university students in Khorasgan University with inclusion and exclusion criteria: aged between 18-25 years old; single; healthy; with regular menstrual periods and Non-Athlete were chosen by the use of complementary questionnaires including dairy symptoms recording table, (DMS-IV) Premenstrual syndrome, General Health (GHQ28), Beck depression and anxiety questionnaire and were divided in three Aerobic exercise and vitamin B6 and control groups randomly. The activities lasted for 2 months, 3 sessions in a week, and each session 60 minutes. The experimental group vitamins B6 were used a pill every day for 2 months. After 1 months the PMS questionnaire was distributed among the 3 groups again (mid-test) and after 2 months the posttest was conducted. The results show that physical and psychological symptoms reduced after 1 and 2 months exercise and vitamin B6 intake. Also the results indicate that the mean score in decreasing physical, psychological symptoms and total score in Aerobic was more than vitamins B6 and control group.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013082614428N2**

Registration date: **2013-10-27, 1392/08/05**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-10-27, 1392/08/05

Registrant information

Name

Zeinab Samadi

Name of organization / entity

Islamic Azad University, Khorasgan (Isfahan) Branch

Country

Iran (Islamic Republic of)

Phone

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Email address

samadi1404@yahoo.com

Recruitment status

Recruitment complete

Funding source

IslamiIslamic Azad University, Khorasgan

Expected recruitment start date

2011-06-26, 1390/04/05

Expected recruitment end date

2013-04-21, 1392/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effects of 2 month of regular Aerobic exercise and vitamin B6 intake on the Symptoms of premenstrual syndrome in Non-Athlete student girls

Public title

Comparison the effects of 2 month of regular Aerobic exercise and vitamin B6 intake on the Symptoms of premenstrual syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: aged between 18-25 years old; single; with regular menstrual periods; bleeding between menstrual cycle length of 22-35 days ,for 3-8 days.
Exclusion criteria : history of regular physical activity for 3 months before starting the study and during the study;history of diseases such as asthma, diabetes, renal, cardiac, psychiatric, thyroid, epilepsy;medication or being on a special diet.

Age

From **18 years** old to **25 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **25**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Isfahan

City

Isfahan

Postal code**Approval date**

2011-06-26, 1390/04/05

Ethics committee reference number

290064

Health conditions studied**1****Description of health condition studied**

Premenstrual Syndrome

ICD-10 code

N94.3

ICD-10 code description

Premenstrual tension syndrome

Primary outcomes**1****Description**

Physical symptoms premenstrual syndrome

Timepoint

After, 1 months the PMS and after 2 months the posttest

Method of measurement

Questionnaires including dairy symptoms recording table, (DMS-IV) PMS, General Health (GHQ28), Beck depression and anxiety questionnaire

2**Description**

Psychological symptoms premenstrual syndrome

Timepoint

After, 1 months and after 2 months the posttest

Method of measurement

Questionnaires including dairy symptoms recording table, (DMS-IV) PMS, General Health (GHQ28), Beck depression and anxiety questionnaire

Secondary outcomes

empty

Intervention groups**1****Description**

The experimental group vitamins B6 were used a pill every day for 2 months.

Category

Treatment - Drugs

2**Description**

The activities lasted for 8 weeks, 3 sessions in a week, and each session 60 minutes.

Category

Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

, IslamiIslamic Azad University, Khorasgan (Isfahan)

Branch

Full name of responsible person**Street address****City**

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

School of Nursing and Midwifery, Isfahan University of Medical Sciences

Full name of responsible person

Muosavi

Street address

Isfahan University of Medical Sciences

City

Isfahan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

School of Nursing and Midwifery, Isfahan University of Medical Sciences

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

Islamic Azad University, Khorasgan (Isfahan) Branch

Full name of responsible person

zeinab samadi

Position

MSC

Other areas of specialty/work

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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