Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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; heahthy; 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
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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