

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jun 2026

Effects of eight weeks flexibility training and supplement vitamin B6 on primary dysmenorrhea in female non-athletes

Protocol summary

Registration timing: **retrospective**

Summary

Primary dysmenorrhea or painful menstruation is one of the most common complaints in gynecology which has physical and psychological symptoms. The aim of this investigation was to study the effects of eight weeks flexibility exercise and use of vitamin B6 on physical and psychological symptoms of primary dysmenorrhea in non-athlete girls. The present research is the study of experimental clinical. Sixty non-athletes suffering from primary dysmenorrhea between ages of 16 to 18 years old which randomly divided into four groups including 15 people (control, exercise, vitamin and exercise with vitamin). Inclusion criteria: suffering from primary dysmenorrhea, not being athlete; not having any previous pelvic inflammatory disease, fibroma, tumor and cyst after doctor check; being single and, not having any chronic diseases. Exclusion criteria: not participate in the training program and chronic diseases. Intervention: group control: no treatment; exercise group engaged in a 8 weeks flexibility training program including stretch of abdomen, back, hamstring, pelvis and hip adductors stretches. They performed 8 movements, each movement with 3 times repetition and each repetition lasted 10 seconds during 4 days per week; the vitamins group used during 8 weeks from 2 weeks before menstruation to 3 days after menstruation daily 2 tablets of 40 milligram vitamin B6 and exercise& vitamin group: 8 weeks flexibility training program and used from 2 weeks before menstruation to 3 days after menstruation daily 2 tablets of 40 milligram B6 vitamin. Primary outcome measure: physical and psychological symptoms and primary dysmenorrhea.

Last update:

Update count: **0**

Registration date

2013-04-29, 1392/02/09

Registrant information

Name

Elham Motesharee

Name of organization / entity

Science and Rsearch Branch, Islamic Azad University fars

Country

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Recruitment status

Recruitment complete

Funding source

Science and Rsearch Branch, Islamic Azad University Fars

Expected recruitment start date

2011-09-23, 1390/07/01

Expected recruitment end date

2011-12-21, 1390/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of eight weeks flexibility training and supplement vitamin B6 on primary dysmenorrhea in female non-athletes

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013011412127N1**

Registration date: **2013-04-29, 1392/02/09**

Public title

Effects of training and t vitamin B6 on primary dysmenorrhea

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: not being athlete; not having have any previous pelvic inflammatory disease, fibroma, tumor and cyst after doctor check; being single and not having any chronic diseases. Exclusion criteria: not participate in the training program- chronic diseases.

Age

From **16 years** old to **18 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **500**

Randomization (investigator's opinion)

Randomized

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

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

Present a study on combining flexibility exercises and consuming vitamin B-6 has been dysmenorrhea Brlaym

Secondary Ids

empty

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

Science and Rsearch Branch, Islamic Azad University fars

Street address

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City

marvdashat

Postal code

73715-181

Approval date

2012-02-05, 1390/11/16

Ethics committee reference number

48121404901001

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

Primary dysmenorrhoea

ICD-10 code

N94.4

ICD-10 code description

Primary dysmenorrhoea

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

Physical and psychological symptoms

Timepoint

Before and after 8 weeks

Method of measurement

Moos menstrual distress questionnaire

Secondary outcomes

empty

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

Group contorol:no intervention.

Category

N/A

2**Description**

Group 2, training: 8 weeks flexibility training.

Category

Prevention

3**Description**

Group3, Vitamin: during 8 weeks; from 2 weeks before menstruation to 3 days after menstruation daily 2 tablets of 40 miligram B6 vitamin

Category

Treatment - Drugs

4**Description**

Group 4, training whit vitamin: 8 weeks fleybility training and used during 8 weeks from 2 weeks before menstruation to 3 days after menstruation daily 2 tablets of 40 miligram B6 vitamin

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Mottahari Hospital

Full name of responsible person

Dr. Nnasrin Asadi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Science and Rsearch Branch, Islamic Azad University
Fars

Full name of responsible person

Dr.mohammad mahdi jabbari

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Science and Rsearch Branch, Islamic Azad University
Fars

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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

Science and Rsearch Branch, Islamic Azad University
Fars

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

Science and Rsearch Branch, Islamic Azad University
Fars

Full name of responsible person

Elham Motesharee

Position

MSc physical Education

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

Assistant professor Department of physical Education

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Person responsible for updating data

Contact

Name of organization / entity

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Other areas of specialty/work

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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