Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

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

Protocol summary

Summary

Primary dysmenorrrhea 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 dysmenorrheal, 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 dysmenorrheal.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013011412127N1**
Registration date: **2013-04-29, 1392/02/09**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2013-04-29, 1392/02/09

Registrant information

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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

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
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Postal code
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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 miligaram 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 miligaram 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
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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

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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