

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 2026

Interactive effect of Plyometric (Elastic) Exercises with Fennel Extract and Calcium-vitamin D supplementation on Premenstrual Syndrome in non-athletic girls

Protocol summary

Study aim

Determination of interactive effect of Plyometric (Elastic) Exercises with Fennel Extract and Calcium-vitamin D supplementation on Premenstrual Syndrome in non-athletic girls

Design

The practical and randomized study with pre-test/post-test six groups and control design is conducted on 70 non-athletic girls for 8 weeks. Random number table will be used in this study for tasks such as selected random samples in groups.

Settings and conduct

This study is conducted on 70 non-athlete female students who has been diagnosed with premenstrual syndrome for 8 weeks. After necessary explanations, they are assigned into seven experimental groups. Participants are investigated pre and post-intervention, using a premenstrual symptoms screening tool, Data analysis is performed by SPSS-20 software, One way ANOVA, ANCOVA and post hoc Tukey test are used to compare the obtained data ($p \leq 0.05$).

Participants/Inclusion and exclusion criteria

1. The non-athlete female students who are inclined participation and had been diagnosed with premenstrual syndrome by Premenstrual Symptoms Screening Tool (PSST), they will be inter in this study. 2. The female students who have had chronic and pelvic inflammatory disease, used special drugs and influenced stress factors, they won't be inter in this study.

Intervention groups

The effect of Elastic exercise, Fennel extract, calcium-vitamin D supplementation, interaction effects of exercise and Fennel extract, exercise and calcium-vitamin D supplementation, exercise, Fennel extract and calcium-vitamin D supplementation with control group (without intervention) are studied on Premenstrual Syndrome in non-athletic girls for 8 weeks.

Main outcome variables

Mean scores of mood; behavioral and physical symptoms of premenstrual syndrome by using premenstrual symptoms screening tool (PSST)

General information

Reason for update

Acronym

PMSS

IRCT registration information

IRCT registration number: **IRCT20201116049412N1**

Registration date: **2020-12-20, 1399/09/30**

Registration timing: **prospective**

Last update: **2020-12-20, 1399/09/30**

Update count: **0**

Registration date

2020-12-20, 1399/09/30

Registrant information

Name

Forouzan Esmaelzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-12-21, 1399/10/01

Expected recruitment end date

2021-02-19, 1399/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Interactive effect of Plyometric (Elastic) Exercises with Fennel Extract and Calcium-vitamin D supplementation on Premenstrual Syndrome in non-athletic girls

Public title

The effect of Elastic Exercises, Fennel Extract and Calcium-vitamin D supplementation in treatment of Premenstrual Syndrome

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

The female students who aren't athletic. The female students who be inclined participation in this study. The non-athlete female students who had been diagnosed with premenstrual syndrome by Premenstrual Symptoms Screening Tool (PSST) .

Exclusion criteria:

The female students who have had chronic and pelvic inflammatory disease in previous record. The female students who have used special drugs. The female students who have influenced stress factors.

Age

From **15 years** old to **20 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Random number table will be used in this study for tasks such as selected random samples in groups.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Factorial

Other design features**Secondary Ids**

empty

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

Ethics committee of Shiraz University of Medical Sciences

Street address

7th floor, Vice Chancellor for Research and Technology, Shiraz University of Medical Sciences, Zand St.

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Shiraz

Province

Fars

Postal code

7176684895

Approval date

2020-11-02, 1399/08/12

Ethics committee reference number

IR.SUMS.REHAB.REC.1399.037

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

Premenstrual Syndrome (PMS)

ICD-10 code

N94.3

ICD-10 code description

Premenstrual tension syndrome

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

Mean scores of mood – behavioral and physical symptoms of premenstrual syndrome by using premenstrual symptoms screening tool (PSST)

Timepoint

At first study and 8 weeks after beginning of elastic exercises with fennel extract and vitamin D (pre and post-intervention)

Method of measurement

Premenstrual symptoms screening tool

Secondary outcomes

empty

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

Control group: Control group hasn't any intervention.

Category

Treatment - Other

2

Description

Intervention group 2: Elastic exercise is performed 3 sessions (45 minute) a week for 8 weeks.

Category

Treatment - Other

3

Description

Intervention group 3: Fennel extract (2% Fennelin Oral Drop (15.5 mg/ml anethole), Barij Essence Pharmaceutical company) is used 2 times a day (30 drops every 12 hours) for 8 weeks.

Category

Treatment - Drugs

4

Description

Intervention group 4: Calcium-vitamin D supplementation (Calcium-vitamin D pills (containing 500 mg calcium carbonate plus 200 IU Vitamin D3 or cholecalciferol), Iran Darou Pharmaceutical Company) is used twice a day (1000 mg every 12 hours) for 8 weeks.

Category

Treatment - Drugs

5

Description

Intervention group 5: Elastic exercise and Fennel extract are used (similar to post-interventions) for 8 weeks.

Category

Treatment - Drugs

6

Description

Intervention group 6: Elastic exercise and calcium-vitamin D supplementation are used (similar to post-interventions) for 8 weeks.

Category

Treatment - Drugs

7

Description

Intervention group 7: Elastic exercise, Fennel extract and calcium-vitamin D supplementation are used (similar to post-interventions) for 8 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

High School in the City of Shiraz Female (Rah Sadat industrial school)

Full name of responsible person

Schoolmaster

Street address

Next to the 13th Alley, in front of registry office, Edalat Blvd.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

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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

Shiraz University of Medical Sciences

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

Islamic Azad University

Full name of responsible person

Forouzan Esmailzadeh

Position

assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Animal Breeding

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available