Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 Esmaielzadeh

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.
City
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
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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
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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 Esmaielzadeh

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