Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the Effect of Melissa Officinalis Capsules and Health Care Educational Program on the Severity of the Symptoms of Premenstrual Syndrome in High School Girl Students in Shiraz

Protocol summary

Summary

This is a randomized clinical controlled trial. Goal of study: to evaluate the effect of Melissa officinalis capsules and health care educational program on the severity of the symptoms of premenstrual syndrome of 200 girl students selected from 5 high schools of Shiraz. After obtaining informed consent, the students, who meet inclusion criteria, are randomly assigned to four groups (two experimental groups and two control groups). The first experimental group receives herbal capsules and the second experimental group attends health care educational program.Since the researcher supervise the performance of the participants of the control group, they are not allowed to take other medications during the intervention period. The participants in the first experimental group receive the medication for a 3-month period (they take 2 capsules daily for 3 months) and those in the second experimental group attend an educational program consisted of six two-hour educational sessions. Data are collected using General Health Questionnaire, awareness and insight and Premenstrual Syndrome Screening Questionnaire. The questionnaires are completed by the participants of experimental groups before, immediately after and every month after the intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014060717998N1**
Registration date: **2014-08-16, 1393/05/25**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-08-16, 1393/05/25

Registrant information

Name
Mansoreh Dehghani

Name of organization / entity
Shiraz University of Medical Sciences

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Iran (Islamic Republic of)

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+98 718219532

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dehghani-ma@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences, Vice Chancellor for Research Affairs

Expected recruitment start date

2004-01-21, 1382/11/01

Expected recruitment end date

2014-08-06, 1393/05/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effect of Melissa Officinalis Capsules and Health Care Educational Program on the Severity of the Symptoms of Premenstrual Syndrome in High School Girl Students in Shiraz

Public title

The Effect of Melissa Officinalis Capsules and Health Care Educational Program on the Severity of the Symptoms of

Premenstrual Syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: willingness to participate in the study, obtaining informed consent from the parents of the students, not being in any stressful situation at the time of enrollment or during the study, presence in the educational sessions, not consuming vitamin supplements at the time of enrollment, not consuming hormonal medications such as contraceptives for at least 2 months before or during the study, a menstrual period of 3 to 7 days, lack of any underlying diseases such as thyroid diseases, diabetes mellitus and psychiatric disease. Exclusion criteria: the children’s willingness to leave the study, the request of the parents for exclusion of their children from the study, occurrence of a stressful event for the students or their parents during the study, absence of more than 2 sessions in group interactions and not compensating for missed sessions by participating in the sessions of other groups, consuming any medications during the study, any changes in the menstrual period (less than 3 days and more than 7 days), any changes in menstrual cycle length (less than 24 days and more than 35 days) and having stress during the study or in the last 3 months (such as death of the relatives, marriage or undergoing any surgical procedure).

Age

From **76 years** old to **72 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **800**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Used

Assignment

Parallel

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

Central building of Shiraz University of Medical Sciences Shiraz, Zand Blvd.

City

Shiraz

Postal code

7193613119

Approval date

2013-12-16, 1392/09/25

Ethics committee reference number

CT-92-335154

Health conditions studied

1

Description of health condition studied

Premensstural Syndrom

ICD-10 code

N94.3

ICD-10 code description

Premenstrual tension syndrome

Primary outcomes

1

Description

Mental and emotional symptoms of premenstrual syndrome

Timepoint

In the second step before the intervention and at the end of each month after the intervention (for 3 months)

Method of measurement

Premenstrual Syndrome Screening Questionnaire

2

Description

Physical symptoms of premenstrual syndrome

Timepoint

In the second step before the intervention and at the end of each month after the intervention (for 3 months

Method of measurement

Premenstrual Syndrome Screening Questionnaire

Secondary outcomes

1

Description

Individual's general health especially mental health

Timepoint

Before the intervention

Method of measurement

General Health Questionnaire (G.H.Q)

Intervention groups

1

Description
In the control group who receive placebo: The participants take a dosage of 1200 mg per day taken as 2 capsules of 600 mg from the first day of the menstrual cycle for 3 cycles. Researcher calls the research unit at least 3 to 4 times and talks to them call them for guidance. Capsules are given to the students monthly. The participants complete the questionnaires at the end of each month.
Category
Placebo

2

Description
In the experimental group who attend health care educational program: The participants attend an educational program consisted of six two-hour educational sessions. The students complete the awareness and insight questionnaire once at the beginning of the program and once at the end of the 6th session.
Category
Prevention

3

Description
In the control group of the educational program: The participants only complete the awareness and insight questionnaire.
Category
N/A

4

Description
In the experimental group who receive Melissa officinalis capsules: The participants take a dosage of 1200 mg per day mg taken as 2 capsules of 600 mg from the first day of the menstrual cycle for 3 cycles. Researcher calls the research unit at least 3 to 4 times and talks to them call them for guidance. Capsules are given to the students monthly. The participants complete the questionnaires at the end of each month.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Narjas High school
Full name of responsible person
Ms. Mesforosh
Street address
Somayeh st., Gas square, Shiraz
City
Shiraz

2

Recruitment center
Name of recruitment center
Tohid High school
Full name of responsible person
Ms. Ahmadi
Street address
Bahar intersection, Shiraz
City
Shiraz

3

Recruitment center
Name of recruitment center
Erfan High school
Full name of responsible person
Ms.Moghadam
Street address
Parbast bridge, Shiraz
City
Shiraz

4

Recruitment center
Name of recruitment center
Fateme-Al-Zahra High school
Full name of responsible person
Ms. Laila Balaghi
Street address
Darion
City
Shiraz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr.Gholamreza Hatam
Street address
Central building of Shiraz University of Medical Sciences Shiraz, Zand Blvd.
City
Shiraz
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
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
Shiraz University of Medical Sciences
Full name of responsible person
Marzieh Akbarzadeh
Position
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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