

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

14 Jul 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

###### Country

Iran (Islamic Republic of)

###### Phone

+98 718219532

###### Email address

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

Premenstrual Syndrome

#### 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**

Ms of Midwifery

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**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Marzieh Akbarzadeh

**Position**

Ms of Midwifery

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**Postal code**

713451978

**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*