

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jun 2026

### Comparison of the effect of aromatherapy with essence of Rosa Damascena and Bitter Orange (Citrus aurantium ) Blossom on symptoms of premenstrual syndrome in students of Shiraz University, 2015

#### Protocol summary

##### Summary

This study is a RCT in which compare the effect of aromatherapy with essence of Rosa Damascena and Bitter Orange (Citrus aurantium ) Blossom on symptoms of premenstrual syndrome in students of Shiraz University of Medical Sciences, in 2015. Study will be done on 99 students that randomly divided into three groups of 33 students. After screening and determination of students that have premenstrual syndrome in the intervention groups inhalation of rose essence and Bitter Orange blossom essence and in the control group inhalation of almond oil will be done. Subjects of three groups receive bottles ( 5 ml for a month) of Rose,Bitter Orange Blossom or Almond oil. Aromatherapy done a week before menstruation for 5 days ( 5 minute × 2 daily) for two consecutive cycles, each subject is instructed to decant the 10 drops of essence onto an eye pad, sit in a stable and comfortable place, position the pad 30 cm away from nose, and inhale the fragrance for 5 minutes with normal breathing. Then in menstrual period students complete the PSST questionnaire and will survey the effect of intervention on PMS.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016031113940N3**  
Registration date: **2016-03-15, 1394/12/25**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2016-03-15, 1394/12/25

##### Registrant information

##### Name

Marzieh Akbarzadeh

##### Name of organization / entity

Shiraz University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 1647 4254

##### Email address

akbarzadm@sums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Shiraz University of Medical Sciences

##### Expected recruitment start date

2016-01-21, 1394/11/01

##### Expected recruitment end date

2016-03-20, 1395/01/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of the effect of aromatherapy with essence of Rosa Damascena and Bitter Orange (Citrus aurantium ) Blossom on symptoms of premenstrual syndrome in students of Shiraz University, 2015

##### Public title

Comparison of the effect of aromatherapy with essence of Rose and Bitter Orange Blossom on premenstrual syndrome

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: 1-Willingness for participation; 2-Not using supplement; 3-Not using hormonal pills from 2 months before intervention; 4-Length of menstrual cycle between 24-35 days; 5-Not having disease like DM and psychologic disease; 6-Filling informed testimonial, GHQ and PSST questionnaire. Exclusion criteria: 1- Willingness for leaving the study; 2-Occurence of accident for participant in the phase of study;3-Length of menstrual cycle lower than 24 days or more than 35 days;4-Length of menstrual period lower than 3 days or more than 7 days;5- Stress event in recent 3 years like surgery or marriage;6-Using any medication in the time of study; 6- Allergy to essences.

**Age**

No age limit

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

No information

**Sample size**

Target sample size: 99

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Double blinded

**Blinding description****Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

Shiraz University of Medical Sciences

**Street address**

Zand Blvd

**City**

Shiraz

**Postal code****Approval date**

2015-11-22, 1394/09/01

**Ethics committee reference number**

lr.sums.rec.1394.163

**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**

premenstrual syndrome screening

**Timepoint**

before and after menstruation

**Method of measurement**

PSST Questionnaire

**Secondary outcomes****1****Description**

Psychologic health

**Timepoint**

before intervention

**Method of measurement**

GHQ

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

Intervention group: Aromatherapy will be done a week before menstruation for 5 days ( 5 minute × 2 daily) for two consecutive cycles, each subject is instructed to decant the 10 drops of essence onto an eye pad, sit in a stable and comfortable place, position the pad 30 cm away from nose, and inhale the fragrance for 5 minutes with normal breathing. Dose of Rose essence is 4% and Bitter orange essence is 0.5%. Control group:Like intervention group but by almond oil.

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Shiraz University of Medical Sciences dormitories

**Full name of responsible person****Street address****City**

Shiraz

**Sponsors / Funding sources**

## 1

### Sponsor

**Name of organization / entity**

Shiraz University of Medical sciences

**Full name of responsible person**

Vice chancellor of research of university

**Street address**

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**

Naval Heydari

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MSc. of Nursing/Instructor

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### Person responsible for scientific inquiries

**Contact**

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### Person responsible for updating data

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**Other areas of specialty/work**

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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*