

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

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Name of organization / entity

Shiraz University of Medical Sciences

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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

Position

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Web page address

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