Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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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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
Ir.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
premenstural syndrome screening
Timepoint
before and after mensturation
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

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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