Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Jun 2026

Comparison of the effect of aromatherapy with aromatic geranium and crocus sativius essential oil on premenstrual syndrome in female employees of Gonabad University of Medical Sciences.

Protocol summary

Study aim
Comparison of the effect of aromatherapy with aromatic geranium and crocus sativius essential oil on premenstrual syndrome in female employees of Gonabad University of Medical Sciences.

Design
Clinical trial of three groups with a control group, parallelized, single-blind, randomized, in two phases before and after the study, with a sample size of 99 people who will be randomly divided into three groups of 3.

Settings and conduct
Setting and samples: female employees of Gonabad University of Medical Sciences. Intervention groups will be treated with 0.5% herbal essences (saffron and aromatic geranium). Aromatherapy will be performed by people one week before menstruation (for 5 days) twice a day for 5 minutes each time in 2 consecutive menstrual cycles, in such a way that the participants and cotton soaked with 10 drops of geranium essential oil twice a day A 30 cm distance from the nose will be connected to the clothes of the samples and they will inhale the scent for 5 minutes with normal breathing. In the control group, a placebo (odorless sweet almond oil) will be used. After two months, the intensity of PMS is compared with the average intensity before the intervention.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Willingness to participate in research, Limited age from 18 to 45 years, Having a history of regular menstruation, The length of menstrual days should be between 24 and 35 days. Exit criteria: Having a physical illness or taking medication; suffering from mental illness; use of antidepressants in the last few months; Taking hormonal drugs and vitamins.

Intervention groups
Intervention group 1: using 5% essential oil of the saffron plant. Intervention group 2: using 5% essential oil of the aromatic geranium plant. Intervention group 3: placebo.

Main outcome variables
Severity of premenstrual syndrome symptoms

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190622043968N4**
Registration date: **2023-09-09, 1402/06/18**
Registration timing: **registered_while_recruiting**

Last update: **2023-09-09, 1402/06/18**
Update count: **0**

Registration date
2023-09-09, 1402/06/18

Registrant information

Name
Maryam Moradi
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 51 5652 5792
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-07-23, 1402/05/01

Expected recruitment end date
2023-10-23, 1402/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of aromatherapy with aromatic geranium and crocus sativius essential oil on premenstrual syndrome in female employees of Gonabad University of Medical Sciences.

Public title

Comparison of the effect of aromatherapy with aromatic geranium and crocus sativius essential oil on premenstrual syndrome

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Willingness to participate in research Limited age from 18 to 45 years old Having a history of regular periods The length of menstrual days should be between 24 and 35 days.

Exclusion criteria:

Having a physical illness or taking medication Mental illness Taking antidepressants in the last few months Taking hormonal drugs and vitamins.

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

2

Groups that have been masked

- Participant

Sample size

Target sample size: **99**

Randomization (investigator's opinion)

Randomized

Randomization description

Gonabad University of Medical Sciences has several organizational units (headquarters, hospital, health centers and university campus). that each of these units will be considered as one floor and in the following the initial list of women employees will be the unit. Then people will be randomly selected according to the number of working women in that unit. And then they will be placed in 3 groups (scented geranium, crocus sativius, and control) by random allocation using permutation blocks with blocks of 3. 6 possible modes for blocks are as follows: ABC, BAC, CAB, ACB, BCA, CBA. Each block will be assigned a number between 1 and 6, and based on the block corresponding to the selected number, people will be assigned to the control group (A), Shadani Moatar (B) and crocus sativius (C). This will continue until the sample size (99 blocks) is completed. The symbol of randomization is a table of random numbers.

Blinding (investigator's opinion)

Single blinded

Blinding description

In the current study, the research units will not know about the type of medicine they will take, and people will be asked not to talk about the type of intervention. To blind the samples, essential oils will be presented in containers with the same color and shape.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Gonabad University of Medical Sciences

Street address

Gonabad university of medical scinces, next to the Asian Road, Gonabad city, Razavi Khorasan, Iran

City

Gonabad

Province

Razavi Khorasan

Postal code

9691793718

Approval date

2023-02-21, 1401/12/02

Ethics committee reference number

IR.GMU.REC.1402.013

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

Severity of premenstrual syndrome symptoms

Timepoint

Before the intervention and 1 and 2 months after it

Method of measurement

Premenstrual symptoms screening questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Aromatherapy with 0.5% saffron essential oil produced by Barij Essential Oil Company. Aromatherapy one week before menstruation (for 5 days) twice a day for 5 minutes each time in 2 consecutive menstrual cycles.
Category
Prevention

2

Description
Intervention group: Aromatherapy will be done with 0.5% aromatic geranium essential oil produced by Barij Essential Oil Company. Aromatherapy one week before menstruation (for 5 days) twice a day for 5 minutes each time in 2 consecutive menstrual cycles.
Category
Prevention

3

Description
Control group: Use of sweet almond oil without odor
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Gonabad University of Medical Sciences
Full name of responsible person
Maryam Moradi
Street address
Gonabad university of medical scinces, next to the Asian Road, Gonabad city, Razavi Khorasan, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Gonabad University of Medical Sciences
Full name of responsible person
Dr.Leila Sadegh Moghadam
Street address
Research Center for Social Determinants of Health, Gonabad University of Medical Sciences, Gonabad university of medical scinces, next to the Asian Road, Gonabad city, Razavi Khorasan, Iran
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Gonabad University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Gonabad University of Medical Sciences
Full name of responsible person
Maryam Moradi
Position
Instructor
Latest degree
Master
Other areas of specialty/work
Geriatrics
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable