

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

Comparison of the effect of aromatherapy with aromatic geranium and crocus sativus 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 sativus 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)

Phone

+98 51 5652 5792

Email address

moradi.mf69@gmail.com

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 sativus 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 sativus 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 sativus, 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 sativus (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 sciences, 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

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

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moradi.mf69@gmail.com

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

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Fax**Email**

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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