

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

Evaluation of the effect of rose essential oil and its comparison with the effect of lemongrass tea on reducing stress and depression in gynecology assistants

Protocol summary

Study aim

Comparing the level of anxiety and stress of gynecology assistants in two groups of inhaling rose essential oil and drinking lemongrass tea.

Design

Clinical trial, with parallel groups and crossover, unblinded, randomized, phase 3 on 40 subjects. Block randomization was used for randomization.

Settings and conduct

Obstetrics and Gynecology Assistants of Mahdiah Hospital in Tehran will participate in this project and will be randomly divided into two groups by random block method. The study will be cross-over. This study is not blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Obstetrics and Gynecology assistants
Exclusion criteria: Major anxiety disorder, hypothyroidism

Intervention groups

group 1: is exposed to inhaling rose essential oil (Ide Daru Pars Company) for one minute a day for two weeks.
group 2: consumes lemon balm tea (Golkooh company) in the morning and in the evening for two weeks. After two-week break, the intervention groups will receive type of treatment that they did not receive in the first phase.

Main outcome variables

Depression

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220821055767N1**
Registration date: **2023-09-24, 1402/07/02**
Registration timing: **retrospective**

Last update: **2023-09-24, 1402/07/02**

Update count: **0**

Registration date

2023-09-24, 1402/07/02

Registrant information

Name

Somaye Fatali

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 5506 2628

Email address

somayeh_fathali@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-21, 1401/11/01

Expected recruitment end date

2023-03-21, 1402/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of rose essential oil and its comparison with the effect of lemongrass tea on reducing stress and depression in gynecology assistants

Public title

Comparing the effects of rose and lemongrass in reducing stress and depression

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

gynecology assistants

Exclusion criteria:

Hypothyroidism Major anxiety disorder

Age

No age limit

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **40**

More than 1 sample in each individual

Number of samples in each individual: **2**

Each person will consume one time of rose essential oil and one time of lemongrass tea while observing the washing period.

Randomization (investigator's opinion)

Randomized

Randomization description

The classification of the samples to the treatment groups will be done in a block randomization. The randomization unit is considered individual. RAS statistical software (Random Allocation Software), the block randomization tool will also be used to determine the sequence of blocks. The size of the blocks is 4. The sealed envelope will be used for allocation concealment. In the RAS software, we enter the size of the blocks along with the number of groups and the total sample size. Then, the software will provide us random blocks among all possible permutations of the same block size. The people who enter the study are assigned to two groups A and B based on these selection blocks. When all subjects are included in the study, we randomly assign indices B and A to one of the treatment groups.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee at the Shahid Beheshti University of Medical Sciences

Street address

Research and Technology Vice-Chancellor, 5th Floor, Sanad Building, Shahid Beheshti University, next to

the Taleghani Hospital, Shahid Abbas Arabi St. (Parvaneh), Yemen St., Shahid Chamran Highway

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2022-07-24, 1401/05/02

Ethics committee reference number

IR.SBMU.RETECH.REC.1401.228

Health conditions studied

1

Description of health condition studied

depression

ICD-10 code

F06.32

ICD-10 code description

Mood disorder due to known physiological condition with major depressive-like episode

Primary outcomes

1

Description

depression

Timepoint

Before starting the intervention and 2 weeks later, after completing the intervention

Method of measurement

Beck depression Inventory

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: For two weeks, a person inhales 5 drops of Rose essential oil (Produced by Ide Daru Pars Company. Each 100 ml of product contains 2 ml of natural rose essence.) for one minute once a day. Then two weeks rest is given. In the next stage, people drink 1.5 grams of Golkooh lemon balm tea twice a day for two weeks.

Category

Treatment - Drugs

2

Description

Intervention group 2: For two weeks, twice a day, 1.5 grams of lemon balm (tea bags from Golkooh Company) are brewed for 5 minutes and consumed. Then two

weeks rest is given. In the next stage, for two weeks, a person inhales 5 drops of Rose essential oil (Produced by Ide Daru Pars Company. Each 100 ml of product contains 2 ml of natural rose essence.) for one minute once a day.

Category

Treatment - Drugs

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

Mahdieh Hospital

Full name of responsible person

Atefeh Moridi

Street address

Mahdieh Hospital, Shishehgar Khaneh St., Fadayian
Islam Blvd., Shush Square

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1185817311

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mahdieh_hospital@sbmu.ac.ir

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

Street address

7th Floor, Bldg No.2 SBUMS, Next to Ayatollah
Taleghani Hospital, Arabi Ave, Daneshjoo Blvd,
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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Somayeh Fatali

Position

physician

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Somaye Fatali

Position

Physician

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

Somaye Fatali

Position

Physician

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

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Fax**Email**

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The questionnaires that the participants complete can be presented at the end of the study.

When the data will become available and for how long

After the completion of the project and 3 months after the publication of the results

To whom data/document is available

This information will be accessible to health researchers.

Under which criteria data/document could be used

The data can be reviewed to help conduct further studies or to summarize existing studies in this field.

From where data/document is obtainable

Office of vice-president for research at the Mahdiah Hospital

What processes are involved for a request to access data/document

First step, a written request must be made to the vice-president for research at hospital. If approved, the documents will be provided to the requester.

Comments