Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 Mahdieh 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 enveloper 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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Tehran

Province
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1185817311

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Email
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, Tehran, Iran.

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mpd@sbmu.ac.ir

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

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Person responsible for updating data

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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 Mahdieh 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