Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The Effect of Aromatherapy with Lemon Balm Essence on Perceived Stress and Anxiety in Infertile Women Undergoing IVF Treatment

Protocol summary

Study aim
Determining The Effect of Inhalation Aromatherapy with Lemon Balm Essential Oil on Perceived Stress and Anxiety in Infertile Women Undergoing In Vitro Fertilization Treatment.

Design
This study is a clinical trial type with control and intervention groups, in parallel and without blinding, randomized, phase 1 on 88 patients. www.sealedenvelope.com was used for randomization.

Settings and conduct
The study site is Milad Infertility Center in Imam Reza Hospital in Mashhad. The research population includes all infertile women undergoing IVF treatment. Blinding was not done in this study.

Participants/Inclusion and exclusion criteria
Inclusion criteria included: having a history of infertility, undergoing in vitro fertilization treatment, having no history of mental health problems, having no smell problems, not using sedatives, opiates, and benzodiazepines, not being allergic to lemon balm, not having any physical illnesses, not having experienced any adverse events in the past 6 months, and using a type of ovulation stimulation treatment with gonadotropins. Exclusion criteria: unwillingness to continue cooperation, allergy to lemon balm, failure to perform inhalation aromatherapy for two consecutive days, withdrawal from infertility treatment, occurrence of adverse events, change in health status that requires other treatments.

Intervention groups
In the aromatherapy intervention group, with the start of the in vitro fertilization hormone therapy cycle, 5-7 drops of lemon balm essential oil were dripped twice a day on a face mask for 2 weeks, and each time the mask was worn for 20-30 minutes while resting and in Calm conditions will be applied to the face and inhaled. In the control group, people will be given a placebo (almond oil). Questionnaires will be completed by both groups before the intervention and after the intervention.

Main outcome variables
Perceived Stress, Anxiety

General information

Reason for update
Changes in some parts

Acronym

IRCT registration information
IRCT registration number: **IRCT20240514061798N1**
Registration date: **2024-06-03, 1403/03/14**
Registration timing: **prospective**

Last update: **2025-02-27, 1403/12/09**
Update count: **3**

Registration date
2024-06-03, 1403/03/14

Registrant information

Name
Narges Abdollahi Senu

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-06-21, 1403/04/01

Expected recruitment end date
2024-09-20, 1403/06/30

Actual recruitment start date
2024-07-15, 1403/04/25

Actual recruitment end date
2024-09-20, 1403/06/30
Trial completion date
2024-10-05, 1403/07/14

Scientific title
The Effect of Aromatherapy with Lemon Balm Essence on Perceived Stress and Anxiety in Infertile Women Undergoing IVF Treatment

Public title
The Effect of Aromatherapy on Perceived Stress and Anxietyin Infertile Women
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Having a History of Infertility Treated by In Vitro Fertilization (IVF) No History of Psychological Problems No Smell Problem Not Using Sedatives, Narcotics and Benzodiazepines Using a Type of Ovulation Stimulation Therapy with Gonadotropins No physical illnesses No experience of any unfortunate events in the past 6 months
Exclusion criteria:
Unwillingness to continue collaborating in research Allergy to Lemon Balm Failure to perform inhalation aromatherapy for two consecutive days (four sessions) Refusing to continue infertility treatment Unfortunate events A change in health status that requires other treatments.
Age
From **18 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **88**
Actual sample size reached: **86**
Randomization (investigator's opinion)
Randomized
Randomization description
The Selection of Available Research Units will be Based on Inclusion criteria and Exclusion criteria. In order to Assign People to Intervention and Control groups, Permutation Block Method with Blocks of size 4 will be Used. For this Purpose, the Site www.sealedenvelope.com is Used. The Said Site will List The Number of 22 Blocks Randomly. This Method Continues Until all People are Assigned to Two Groups.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features
Lemon balm plant is purchased from trusted centers of the Faculty of Iranian and Complementary Medicine. The plant was approved by a botanist at the Medicinal Plants Research Institute of Ferdowsi University and its herbarium code was announced. Then, using the traditional method in the laboratory of the Faculty of Iranian and Complementary Medicine, 160 grams of lemon balm plant was soaked in 1600 cc of sweet almond oil for 4 to 5 days, then filtered. To ensure that the oil was saturated with essential oil, 100 grams of fresh plant was soaked in the resulting oil for a second time for 4 to 5 days. Finally, it was filtered and standardized in the "Testa" quality control laboratory using gas chromatography(GC). The placebo was just odorless sweet almond oil.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Faculty of Nursing and Midwifery - Mashhad University of Medical Sciences
Street address
Educational Complex of Shahid Dr. Kharazmi, University Campus, East Gate of Ferdowsi University of Mashhad, Azadi Square.
City
Mashhad
Province
Razavi Khorasan
Postal code
9137913199
Approval date
2024-05-14, 1403/02/25
Ethics committee reference number
IR.MUMS.NURSE.REC.1403.015

Health conditions studied

1

Description of health condition studied
Infertile Women
ICD-10 code
N97
ICD-10 code description
Female infertility

Primary outcomes

1

Description
Perceived Stress
Timepoint
Measuring The Level of Perceived Stress will be Measured Initially Before the Start of The Intervention

(The Start of The Hormone Therapy Cycle) and after The Completion of The Intervention (The End of The Hormone Therapy Cycle).

Method of measurement

Fertility Problem Inventory (FPI)

2

Description

Anxiety

Timepoint

Measuring The Level of Anxiety will be Measured Initially Before the Start of The Intervention (The Start of The Hormone Therapy Cycle) and after The Completion of The Intervention (The End of The Hormone Therapy Cycle). Also, The People Participating in The Intervention Group will be given a Self-Report Form for Measuring The Level of Anxiety with a Visual Analogue Scale of Ten Parts, which they will Complete every Night before going to Bed During The Intervention Period Since they Started Using Lemon Balm Essential Oil.

Method of measurement

Anxiety Trait-State Inventory (STAI), Visual Analogue Scale.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The Lemon Balm Plant is Purchased from Trusted Centers of the Faculty of Iranian and Complementary Medicine. The Plant will be Confirmed and its Herbarium Code will be Announced by a Botanist at Ferdowsi University Medicinal Plant Research Center. Then it is Kept in a Traditional way in The Laboratory of the Faculty of Iranian and Complementary Medicine, in the base of Sweet Almond Oil, for 4-5 Days, then It becomes Smooth. To Ensure that the Oil is Saturated with Essential Oil, the Fresh Plant is Soaked in The Resulting Oil for the Second Time for 4-5 Days. Finally, it will be Smoothed and Standardized by Gas Chromatography Method. Participating in this Group will use Lemon Balm Essential Oil for Aromatherapy. In this way, at the beginning of the IVF Hormone Treatment Cycle, 5-7 drops are Dripped on a Face Mask Twice a Day for 2 Weeks, and The Mask is Applied to the Face for 20-30 Minutes each time while Resting and in Calm Conditions. and Inhale it.

Category

Treatment - Drugs

2

Description

Control group: Participants in This Group will be given a Placebo to Perform Aromatherapy. In this way, at the beginning of the IVF Hormone Treatment Cycle, 5-7 drops are Dripped on a Face Mask Twice a Day for 2 Weeks, and The Mask is Applied to the Face for 20-30 Minutes each time while Resting and in Calm Conditions. and Inhale it. The Placebo will be Sweet Almond Oil only, which is Odorless.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Milad Infertility Center in Mashhad

Full name of responsible person

Narges Abdollahi Senu

Street address

Infertility Department of Milad Building, Opposite Central Laboratory, Imam Reza Educational Research and Treatment Center, Imam Reza Hospital Square, Ibn Sina Ave.

City

Mashhad

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Razavi Khorasan

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۹۱۳۷۹۱۳۳۱۶

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

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Research and Technology Vice-Chancellor of Mashhad University of Medical Sciences, Second Floor, Qureshi Building, Front of 16 University Ave., University Ave.

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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

Mashhad 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
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Full name of responsible person
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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
Yes - There is a plan to make this available
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
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
All the data obtained from this research will be shared after the completion of the work.
When the data will become available and for how long
Access to the data will be possible 3 months after the results are published.
To whom data/document is available
These data will be used for researchers working in

academic and scientific institutions, as well as for infertile women treated with assisted reproductive techniques.

Under which criteria data/document could be used

The data obtained from this research can be used in other scientific studies.

From where data/document is obtainable

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

The applicant should send an email to the responsible author and register his request. After checking the accuracy of the information of the mentioned person, the required content will be provided to him with the reference of the source.

Comments