Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jul 2026

Comparison of the effects of lavender and citrus aurantium inhalation on the severity of primary dysmenorrhea in female students: A randomized controlled trial

Protocol summary

Study aim
Comparison of the effect of lavender and citrus aurantium inhalation on the severity of primary dysmenorrhea in female students

Design
A parallel randomized controlled clinical trial with 3 groups (two intervention groups and one control group) and 44 people in each group. Random allocation software is used for randomization.

Settings and conduct
The research environment is the dormitories of Gilan University of Medical Sciences in Rasht city. The research is conducted during four menstrual cycles (first 2 cycles of pain measurement and 2 cycles of intervention). During two intervention cycles, two test groups will receive aroma therapy with spring orange and lavender and the control group will receive inhalation of cotton dipped in distilled water. The intervention is performed on the first and second day of menstruation and the pain intensity is checked on the third day.

Participants/Inclusion and exclusion criteria
Inclusion: willingness and informed consent to participate in the research, having a regular menstrual cycle with a duration of 2-6 days and an interval of 21-35 days between periods, onset of menstruation before the age of 15, primary dysmenorrhea with a score of 5 or more in the Visual Analogue Scale of pain during two consecutive cycles, age 18-25 years, being single, being Iranian, lack of known mental or physical illness, absence of gynecological disease (myoma, etc.), having a normal sense of smell, no history of allergies. Non-entry: not wanting to participate in the study, having an allergy to citrus aurantium, having an allergy to lavender

Intervention groups
People in the intervention groups will receive inhalation of citrus aurantium and lavender scent and the control group will receive inhalation with distilled water.

Main outcome variables
The severity of primary dysmenorrhea in female students is investigated as the main outcome.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210220050418N2**
Registration date: **2023-10-11, 1402/07/19**
Registration timing: **prospective**

Last update: **2023-10-11, 1402/07/19**
Update count: **0**

Registration date
2023-10-11, 1402/07/19

Registrant information

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-11-22, 1402/09/01

Expected recruitment end date
2024-04-20, 1403/02/01

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effects of lavender and citrus aurantium inhalation on the severity of primary dysmenorrhea in female students: A randomized controlled trial

Public title
Comparison of the effects of lavender and citrus aurantium inhalation on the severity of primary dysmenorrhea
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
willingness and informed consent to participate in the research having a regular menstrual cycle with a duration of 2-6 days and an interval of 21-35 days between periods onset of menstruation before the age of 15 primary dysmenorrhea with a score of 5 or more in the Visual Analogue Scale of pain during two consecutive cycles age 18-25 years being single being Iranian lack of known mental or physical illness (according to the statements of the research participant) absence of gynecological disease (myoma, endometriosis, ovarian cyst , pelvic inflammatory disease, etc.) (according to the statements of the research participant) having a normal sense of smell no history of allergies
Exclusion criteria:
not wanting to participating in the study having an allergy to citrus aurantium having an allergy to lavender
Age
From **18 years** old to **25 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **44**
Randomization (investigator's opinion)
Randomized
Randomization description
Random allocation software is used for randomization. In addition to simple randomization, these random sequence generation softwares are capable of generating random sequences using the blocking method. For concealment, we use random allocation concealment, which refers to the method used to perform a random sequence on the participants in the study, so that the allocated group is not known before the allocation of the individual. By using opaque envelopes sealed with a random sequence (Sequentially numbered, sealed, opaque envelopes), in this method, each of the generated random sequences is recorded on a card, and the cards inside the letter envelopes are placed in order. In order to maintain a random sequence, the outer surface of the envelopes is numbered in the same order. Finally, the lid of the letter envelopes is glued and placed in a box. At the time of registration of the participants, based on the order in which the eligible participants entered the study, one of the envelopes will be opened and the assigned group of that participant will be revealed.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features
The current research is a clinical trial of 3 groups (2 intervention groups and one control group). In this study, sampling will be done with the consecutive presence of the researcher in the dormitories of Guilan University of Medical Sciences in Rasht city during two stages. In the first stage, qualified people will be selected by Convenience sampling method, then the restricted randomization method of block randomization will be used and the design of permutation blocks with 6 samples in each block will be used. With this method, patients will be divided into three treatment groups by inhaling lavender essential oil, citrus aurantium and distilled water (as placebo or control).

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of Guilan university of medical sciences
Street address
in front of 17 Shahrivar Hospital, Shahid Siyadati St., Namjo St., ,
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Rasht
Province
Guilan
Postal code
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Approval date
2023-02-15, 1401/11/26
Ethics committee reference number
IR.GUMS.REC.1401.566

Health conditions studied

1

Description of health condition studied
primary dysmenorrhea in female students
ICD-10 code

N94.4

ICD-10 code description

Primary dysmenorrhoea

Primary outcomes

1

Description

Measurable primary outcome: dysmenorrhea pain intensity, measured by the Visual Analogue Scale.

Timepoint

Dysmenorrhea pain intensity is measured in 4 cycles, two menstrual cycles before the start of the intervention, and two menstrual cycles after the entry of the study subjects for the intervention.

Method of measurement

After defining the groups, each of them is asked to record their pain intensity using the Visual Analogue Scale in the first and second cycles of the intervention. If the pain score is 5 or more than 5 in the first cycle before the intervention, the pain intensity of the people will be measured in the second cycle as well. If they have 5 or more points in two consecutive cycles, people will be included in the study. The pain intensity of people in the second cycle will be evaluated as the pain intensity before the intervention. The intervention of this research was carried out in the third and fourth menstrual cycle of the research units and the effect of inhaled drugs will be investigated. People are asked to record and inform the type, dosage and exact time of use if they take any painkillers at the time of study. In order to ensure that the intervention is performed after the maximum effect of the painkiller and to prevent its effect from interfering with the desired intervention, it is necessary to accurately record the time of use of each painkiller so that the aromatherapy intervention can be performed after the effectiveness of the painkiller is lost. In the third and fourth menstrual cycles of the study subjects, on the first and second days of the cycle, the intervention will be performed and on the third day, the pain intensity of the subjects will be recorded in the presence of the researcher (the subjects will be asked to inform the researcher of the time of menstruation and record their symptoms in the questionnaire). In this study, distilled water will be used as a placebo. Bottles containing distilled water and citrus aurantium and lavender essential oil have the same volume, shape and size and the letters A, B and C will be recorded on them, letter A corresponds to citrus aurantium, letter B lavender and letter C distilled water (as a control). To ensure that the units are not allergic to lavender and citrus aurantium, a skin test will be performed for all patients. In this way, a drop of 100% lavender essential oil (a product of Barij Essential Oil Company) will be poured on the inner surface of the patient's wrist and a bandage will be placed on it to prevent breathing, and after two minutes of skin contact, the location of the oil will be observed on the wrist. and if there are no signs of sensitivity (redness, hives, itching), the person will enter the study. In case of any allergy, the person will be referred to a specialist doctor. In order to equalize the two studied groups, distilled water will be tested in the placebo group as well. People in the intervention groups will receive the inhalation of citrus aurantium and lavender scent and the control group will receive inhalation with distilled water. citrus aurantium and lavender essential oils with a concentration of 25 µl/l are prepared in standard form and with the same quality in all bottles by Barij Essential Oil Company. In the inhalation aromatherapy group, 10 drops of essential oil of spring orange or lavender, or 10 drops of distilled water are dripped into a cotton and the person is asked for 30 minutes (according to the studies done, the process of absorbing the essential oil and reaching the level metabolites of lavender and citrus aurantium in the blood to an acceptable level (therapeutic effect level) takes an average of 30 minutes, the duration of aromatherapy in this study will be considered 30 minutes), at a distance of 20 cm from her nose and smell it. All three inhalation aromatherapy and control groups are asked to repeat the intervention the next day at the same time and record their pain intensity in the presence of the researcher on the third day of menstruation. The researcher's contact number will be provided to the participants to answer any questions and problems, so that they can contact the researcher if needed.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: After identifying the individuals, each of them is asked to record their pain intensity using the Visual Analogue Scale in the first and second cycles of the intervention. If the pain score is 5 or more than 5 in the first cycle before the intervention, the pain intensity of the people in the second cycle will also be measured by the researcher. If they have 5 or more points in two consecutive cycles, people will be included in the study. The pain intensity of people in the second cycle will be evaluated as the pain intensity before the intervention. The intervention of this research was carried out in the third and fourth menstrual cycle of the research units and the effect of inhaled drugs will be investigated. The people of the first intervention group will receive the scent of citrus aurantium, the people of the second intervention group will receive the scent of lavender, and the control group will receive the inhalation of distilled water. Citrus aurantium and lavender essential oils with a concentration of 25 µl/l are prepared in standard form and with the same quality in all bottles by Barij Essential Oil Company. In the inhalation aromatherapy group, 10 drops of essential oil of citrus aurantium or lavender, or 10 drops of distilled water are dripped into a cotton and the person is asked for 30 minutes (according to the studies done, the process of absorbing the essential oil and reaching the level Metabolites of lavender and citrus aurantium in the blood to an acceptable level

(therapeutic effect level) takes an average of 30 minutes, the duration of aromatherapy in this study will be considered 30 minutes), at a distance of 20 cm from her nose and smell it. All three inhalation aromatherapy and control groups are asked to repeat the intervention the next day at the same time and record their pain intensity in the presence of the researcher on the third day of menstruation. The researcher's contact number will be provided to the participants to answer any questions and problems, so that they can contact the researcher if needed.

Category
Rehabilitation

2

Description
Intervention group: The second intervention group will receive lavender scent with a concentration of 25 µl/l, similar to the first group.

Category
Rehabilitation

3

Description
Control group: In this study, the control group will include students who have the conditions to enter the study, who will receive the same inhalation intervention as the test group with distilled water.

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Alzahra education, remedial & research center

Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

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Full name of responsible person
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Web page address
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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
Rasht 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
Rasht University of Medical Sciences

Full name of responsible person
Zahra Bostani Khalesi

Position
Associate Professor

Latest degree
Ph.D.

Other areas of specialty/work
Midwifery

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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
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Basic and general data
When the data will become available and for how long
One year
To whom data/document is available
Faculty members of Shahid Beheshti School of Nursing and Midwifery, Rasht
Under which criteria data/document could be used
In order to check the correctness of the data and having a written and approved request from the research assistant of Shahid Beheshti College of Nursing and Midwifery in Rasht
From where data/document is obtainable
Shahid Beheshti College of Nursing and Midwifery in Rasht, as well as a written request from the plan administrator
What processes are involved for a request to access data/document
A written request from the plan administrator
Comments