

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 2026

evaluation the effect of citrus aurantium on severity of primary dysmenorrhea in two models of skin massage and inhalation aromatherapy

Protocol summary

Reduce the severity of menstrual pain

Study aim

Evaluation the effect of citrus aurantium on severity of primary dysmenorrhea in two models of skin massage and inhalation aromatherapy

Design

This study is a four-group experimental clinical trial with two control groups and two intervention groups. In each group, 35 people are randomly selected and no blinding is performed. severity of pain will be assessed before and after the intervention in the first and second cycles.

Settings and conduct

The data collection place is the dormitories of Zanjan University of Medical Sciences. In confirmation of having dysmenorrhea, individuals will be randomly assigned in two intervention groups (citrus aurantium essential oil) and two control groups (almond oil).

Participants/Inclusion and exclusion criteria

Satisfaction to participate in the study, regular menstrual cycle with a duration of 3-7 days and interval of 21-35 days, menarche before the age of 18, primary dysmenorrhea with a score of 5 or more in VAS in two consecutive cycles, age 18-25 years, single, Iranian, lack of mental or physical illness, absence of gynecological disease, having a normal sense of smell exclusion criteria: Unwillingness to continue attending the study, very severe dysmenorrhea, incidence of dysmenorrhea after the age of 20, allergy to citrus aurantium essential oil, diagnosis of physical or mental illness during the study, abnormal bleeding during the study

Intervention groups

In the intervention group, people will receive abdominal massage and inhalation of citrus aurantium, and in the control group, people will receive abdominal massage and inhalation of sweet almond oil. Both types of intervention will be performed in the first two days of the menstrual cycle for two consecutive cycles.

Main outcome variables

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120414009463N62**

Registration date: **2021-02-18, 1399/11/30**

Registration timing: **registered_while_recruiting**

Last update: **2021-02-18, 1399/11/30**

Update count: **0**

Registration date

2021-02-18, 1399/11/30

Registrant information

Name

Zahra Behboodi Moghadam

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6692 7171

Email address

behboodi@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-02-14, 1399/11/26

Expected recruitment end date

2021-06-23, 1400/04/02

Actual recruitment start date

empty

Actual recruitment end date

empty	two groups of inhalation aromatherapy of citrus aurantium essential oil and sweet almond oil. The number B is written on the bottles of almond oil and the number A is written on the bottle containing of citrus aurantium essential oil.
Trial completion date	Blinding (investigator's opinion)
empty	Not blinded
Scientific title	Blinding description
evaluation the effect of citrus aurantium on severity of primary dysmenorrhea in two models of skin massage and inhalation aromatherapy	Placebo
Public title	Used
evaluation the effect of citrus aurantium on severity of primary dysmenorrhea in two models of skin massage and inhalation aromatherapy	Assignment
Purpose	Parallel
Treatment	Other design features
Inclusion/Exclusion criteria	Secondary Ids
Inclusion criteria:	empty
satisfaction to participate in the study having a regular menstrual cycle with a duration of 3-7 days and interval of 21-35 days menarche before the age of 18 primary dysmenorrhea with a score of 5 or more in the visual Analogue scale During two consecutive cycles age 18-25 years single Iranian lack of mental or physical illness absence of gynecological disease (myoma, endometriosis, ovarian cyst, pelvic inflammatory disease, etc.) having a normal sense of smell	Ethics committees
Exclusion criteria:	1
Unwillingness to continue attending the study very severe dysmenorrhea incidence of dysmenorrhea after the age of 20 allergy to citrus aurantium essential oil diagnosis of physical or mental illness during the study abnormal bleeding during the study	Ethics committee
Age	Name of ethics committee
From 18 years old to 25 years old	Ethics committee of tehran university of medical science
Gender	Street address
Female	Keshavarz Boulevard, corner of Quds Street, central building
Phase	City
N/A	tehran
Groups that have been masked	Province
No information	Tehran
Sample size	Postal code
Target sample size: 140	1417653761
Randomization (investigator's opinion)	Approval date
Randomized	2021-01-02, 1399/10/13
Randomization description	Ethics committee reference number
Sampling will be done with the consecutive presence of the researcher in the dormitories of Zanjan University of Medical Sciences in two stages. At first two dormitories of Zanjan University of Medical Sciences will be divided into two groups of massage therapy and inhalation aromatherapy with using of lottery card . Then in the first stage, people who have dysmenorrhea and met inclusion criteria and want to participate in the study will be determined, and then They will be randomly assigned to the intervention and control group within each dormitory. Randomization will be done by using the website Randomization with www.graphpad.com. Initially, inside each dormitory, people who met inclusion criteria were given the number one to 70, and with using web-based randomization will placed in two groups of massage therapy with citrus aurantium essential oil and massage with sweet almond oil, and in the another dormitory in	IR.TUMS.FNM.REC.1399.201
	Health conditions studied
	1
	Description of health condition studied
	Primary dysmenorrhea
	ICD-10 code
	N94.4
	ICD-10 code description
	Primary dysmenorrhea
	Primary outcomes
	1
	Description
	Percentage of people whose menstrual pain intensity has decreased after abdominal massage of citrus aurantium oil or inhalation of citrus aurantium essential oil.
	Timepoint
	Before the intervention, after the intervention in the first cycle and after the intervention in the second cycle in

the control and intervention groups.

Method of measurement

visual analogue scale tool

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Participants in the study who met the inclusion criteria in the In massage group, massage will be done in the first two days of the menstrual cycle daily for 30 minutes with 2cc of citrus aurantium essential oil for two consecutive cycles and In the aromatherapy group, in the first two days of the menstrual cycle for two consecutive cycles, 10 drops of citrus aurantium essential oil are sprayed on the piece of cotton and inhaled at a distance of 20 cm from the nose for 30 minutes.

Category

Treatment - Drugs

2

Description

Control group: Participants in the study who met the inclusion criteria in the In massage group, massage will be done in the first two days of the menstrual cycle daily for 30 minutes with 2cc of sweet almond oil for two consecutive cycles and In the aromatherapy group, in the first two days of the menstrual cycle for two consecutive cycles, 10 drops of sweet almond oil are sprayed on the piece of cotton and inhaled at a distance of 20 cm from the nose for 30 minutes.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dormitories of Zanjan University of Medical Sciences

Full name of responsible person

Zahra Behboodi Moghadam

Street address

Tehran, Enghelab Square, 16 Azar St., Tehran
University of Medical Sciences

City

Tehran

Province

Tehran

Postal code

1417614411

Phone

+98 21 6105 4227

Email

z.bayat1995sb@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

mohammad ali sahraeian

Street address

Tehran, Enghelab Square, 16 Azar St., Tehran
University of Medical Sciences

City

Tehran

Province

Tehran

Postal code

1419733171

Phone

+98 21 6105 4227

Email

Behboodi@tums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

معاونت پژوهشی دانشگاه علوم پزشکی تهران

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

Tehran University of Medical Sciences

Full name of responsible person

Zahra Behboodi Moghadam

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

Street address

School of Nursing and Midwifery - Tehran University of
Medical Sciences - Nosrat Sharghi - Tohid Square -
Tehran - Iran

City

Tehran

Province
Tehran
Postal code
1419733171
Phone
+98 21 6105 4227
Email
Behboodi@tums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Zahra Behboodi Moghadam
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
Reproductive Health
Street address
School of Nursing and Midwifery - Tehran University of Medical Sciences - Nosrat Sharghi - Tohid Square - Tehran - Iran
City
Tehran
Province
Tehran
Postal code
1419733171
Phone
+98 21 6105 4227
Email
Behboodi@tums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Zahra Behboodi Moghadam
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
Reproductive Health
Street address
School of Nursing and Midwifery - Tehran University of Medical Sciences - Nosrat Sharghi - Tohid Square - Tehran - Iran
City
Tehran
Province
Tehran
Postal code
1419733171
Phone
+98 21 6105 4227
Email
Behboodi@tums.ac.ir

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
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available