

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of aromatherapy on anxiety and physiological indexes before endoscopy

Protocol summary

Study aim

Aromatherapy study on anxiety and physiological indexes

Design

343 patients undergoing endoscopy with an entry criteria are selected. Patients were randomly assigned to three control groups and two interventions using random numbers. To hide groups, a code is assigned to each group.

Settings and conduct

Amir Al-Momenin Hospital, Blind double-sided

Participants/Inclusion and exclusion criteria

Inclusion criteria 1. Age 18 years old 2. Have a healthy sense of smell 3.No history of smoking 4. Not a history of allergy and allergy to medicinal herbs 5. No history of asthma or respiratory diseases 6. Alertness and ability to speaking 7. Reading and writing literacy, ability to understand Persian language 8. No history of new crisis over the past six months 9. Do not history of previous surgery Non-compliance criteria: 1. Use of other complementary and alternative methods during the study 2. Use hypnotic and antipyretic drugs, antidepressants and anti-anxiety during the study

Intervention groups

In intervention group number 1: one hour before endoscopy, after completing the demographic and Spielberger questionnaires and determining the mood by qualified individuals, physiological parameters including systolic and diastolic blood pressure, heart rate and respiratory rate were recorded by the researcher. After completing the basic information, in the aromatherapy intervention group with lavender essential oil, cotton balls impregnated with 2 to 3 drops of lavender essential oil are placed at a distance of 15 to 20 cm from the nose of the patient, and the mean After 5 to 10 minutes, the patient will be inhaled. In the intervention group number 2: the essential oil of orange will be used in this way, but from 2 to 3 drops of orange essential oil on cotton balls will be used. In the control group, distilled water will be

used for aromatherapy.

Main outcome variables

anxiety, Physiological Indexes

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180103038211N6**

Registration date: **2019-01-27, 1397/11/07**

Registration timing: **prospective**

Last update: **2019-01-27, 1397/11/07**

Update count: **0**

Registration date

2019-01-27, 1397/11/07

Registrant information

Name

Fahime Davodabady

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 3226 7610

Email address

F_davodabady@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-02-20, 1397/12/01

Expected recruitment end date

2019-06-20, 1398/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effect of aromatherapy on anxiety and physiological indexes before endoscopy

Public title
The effect of aromatherapy on anxiety

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 All patients referring to the endoscopic unit Have a healthy sense of smell Be alert
Exclusion criteria:
 History of smoking History of allergy and allergy to medicinal herbs A history of asthma or respiratory illness The record of a new crisis, such as the death of a first-degree relative, a person or parent's divorce during the past six months History of endoscopy in the past

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **343**

Randomization (investigator's opinion)
Randomized

Randomization description
The Subjects with entry criteria were selected by simple sampling methods and then were assigned with using random numbers randomly to either an experimental or a control group.

Blinding (investigator's opinion)
Double blinded

Blinding description
Individuals with entry criteria are divided into two intervention and control groups according to the random numbers table. Before and after the intervention, the information is collected by the evaluator of the outcome that is unaware of the grouping of the groups. Data analysis is also done by someone who is unaware of the allocation of groups. Also, the participants in the study in both groups received similar interventions and were unaware of the allocation to the intervention and control groups. Essential oil storage containers are a shape and one color.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Arak University of Medical Sciences

Street address

Arak University of Medical Sciences, Basij Square, Sardasht

City

Arak

Province

Markazi

Postal code

6941-7-38481

Approval date

2019-01-20, 1397/10/30

Ethics committee reference number

IR.ARAKMU.REC

Health conditions studied

1

Description of health condition studied

Anxiety

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Level of anxiety

Timepoint

Measure one hour before endoscopy, 20 minutes after intervention

Method of measurement

Spielberger questionnaire

2

Description

blood pressure

Timepoint

Measure one hour before endoscopy, 20 minutes after intervention

Method of measurement

Mercury pressure gauge device

3

Description

Pulse

Timepoint

Measure one hour before endoscopy, 20 minutes after intervention
Method of measurement
Stopwatch

4

Description
Respiratory rate

Timepoint
Measure one hour before endoscopy, 20 minutes after intervention

Method of measurement
Stopwatch

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Aromatherapy will be done one hour before the endoscope. For aromatherapy, 2 to 3 drops of lavender essential oil are placed on a cotton ball and placed 15 to 20 cm from the nose for 5 to 10 minutes.

Category
Treatment - Other

2

Description
Intervention group: One hour before the endoscope, aromatherapy will be done. For aromatherapy, 2 to 3 drops of orange essential oil are placed on a cotton ball, placed 15 to 20 cm from the nose for 5 to 10 minutes.

Category
Treatment - Other

3

Description
Control group: Aromatherapy will be similar to the intervention groups, but water is used.

Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Amir Al-Momenin Hospital
Full name of responsible person
Fahimeh Davodabady
Street address
Arak University of Medical Sciences, Basij Square, Sardasht
City
Arak

Province
Markazi
Postal code
6941-7-38481
Phone
+98 86 3417 3505
Email
fahimedavodabady@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Mohammad Arjomandzadegan
Street address
Arak University of Medical Sciences, Basij Square, Sardasht
City
Arak
Province
Markazi
Postal code
6941-7-38481
Phone
+98 86 3417 3505
Email
arjomandzadegan@arakmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Arak 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
Arak University of Medical Sciences
Full name of responsible person
Fahimeh Davodabady
Position
Instructor
Latest degree
Master
Other areas of specialty/work

Nursery

Street address

Arak University of Medical Sciences, Basij Square,
Sardasht

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Email

fahimedavodabady@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

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Position

Instructor

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Email

Fahimedavodabady@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Arak University of Medical Sciences

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information

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