Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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)

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+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

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Arak University of Medical Sciences, Basij Square, Sardasht

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Mohammad Arjomandzadegan

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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

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

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Person responsible for scientific inquiries

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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