Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The Comparative study on the Effect of Aromatherapy with Lavender and damask rose on Obvious Anxiety Level of the endoscopy Candidate Patients

Protocol summary

Study aim
The Effect of Aromatherapy with Lavender and damask rose on Obvious Anxiety Level of the endoscopy Candidate Patients

Design
clinical trial with a control group,with factorial groups, single-blind, randomized

Settings and conduct
The researcher refers to the research environment, With informed consent, eligible patients enter the study. Demographic questionnaire and anxiety are completed. Then, depending on which patient is located(lottery), intervention is performed. One hour before endoscopy, in the group, 2drops of 10% lavender oil are placed on a cotton ball and attached to the patient's collar with a pin and the patient is asked To breathe normally for 30 minutes. In the group2, the same intervention is performed with 2drops of oil of damask rose. In the control group, the same intervention was performed with two drops of odorless soy oil(placebo). Then again, the situational anxiety questionnaire is completed for all three groups after the intervention. All actions are done by a researcher. The study is single-blind, and patients are not informed of any of the study groups and their differences.

Participants/Inclusion and exclusion criteria
Inclusion criteria: age >=18, full awareness, interested in participating in the study, able to understand and speak Persian, endoscopy for the first time, and lack of Psychological and anxiety disease, mental retardation, blindness and deafness, history of allergies to plants, migraine and chronic headache, olfactory disorder, anxiety and narcotic drugs, and history of severe psychological stress recently. Exclusion criteria: emergency endoscopy, acute pain at the time of completing the questionnaire.

Intervention groups
Group1 aromatherapy with lavender Group2 aromatherapy with damask rose Control group aromatherapy with two drops of odorless soy oil(placebo)

Main outcome variables
Anxiety score Control; Use of non-pharmacological methods

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180303038934N1**
Registration date: **2018-10-13, 1397/07/21**
Registration timing: **registered_while_recruiting**

Last update: **2018-10-13, 1397/07/21**
Update count: **0**

Registration date
2018-10-13, 1397/07/21

Registrant information

Name
Arezoo Monfared

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 13 3355 5058

Email address
a.monfared@gums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-04-21, 1397/02/01

Expected recruitment end date

2018-12-22, 1397/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Comparative study on the Effect of Aromatherapy with Lavender and damask rose on Obvious Anxiety Level of the endoscopy Candidate Patients

Public title

The Comparative study on the Effect of Aromatherapy with Lavender and damask rose on Obvious Anxiety Level of the endoscopy Candidate Patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Be alert (relative to location, time, and surrounding) Gastrointestinal endoscopy for the first time. Not mental illness and anxiety, mental retardation, blindness and deafness. any disorder have not sense of smell. Do not use anti-anxiety and opioid drugs There is no history of severe psychological stress during endoscopy (such as relatives death).

Exclusion criteria:

Acute pain when completing the questionnaire.

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **105**

Randomization (investigator's opinion)

Randomized

Randomization description

Samples will be drawn by lottery and will be randomly assigned to the studied groups. After reviewing the eligible patients, they will be satisfied. A draw box in which there are three paper with numbers 1, 2 and 3 in it is provided to the patient to randomly remove a number. That number represents the group in which it is placed. If the number of samples of each group is completed, that number will be withdrawn from the lottery container. This will continue to the required number of samples for all three groups.

Blinding (investigator's opinion)

Single blinded

Blinding description

All actions, including the completion of questionnaires and the use of essential oils, are done by a researcher and the study is single blind, and the patients in all three groups are not informed of any of the groups studied and their differences. But the researcher is aware of the difference in groups and essential oils due to the categorization of the patients in the three groups and the implementation of the intervention.

Placebo

Used

Assignment

Parallel

Other design features

-

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Guilan University of Medical Sciences

Street address

In Front of the 17 Shahrivar Hospital .,Seiadati Ave., Namjo Ave., Rasht City

City

Rasht

Province

Guilan

Postal code

39841-41469

Approval date

2018-01-27, 1396/11/07

Ethics committee reference number

IR.GUMS.REC :1395.462

Health conditions studied

1

Description of health condition studied

Upper gastrointestinal endoscopy

ICD-10 code

K25

ICD-10 code description

Gastric ulcer

2

Description of health condition studied

anxiety

ICD-10 code

F41

ICD-10 code description

Other anxiety disorders

Primary outcomes

1

Description

Spielberger state anxiety score; score of 21-39 indicates

mild anxiety, 40-59 average anxiety and 60-80severe anxiety

Timepoint

The beginning of the study (before the intervention) and the end of the intervention, the questionnaire will be completed

Method of measurement

Spielberger state anxiety Inventory

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group1: One hour before endoscopy, two drops of 10% lavender essential oil (the product of Barij Essen Company) are placed on a cotton ball and attached to the patient's collar with a pin. The patient is asked to wait for 30 minutes Take a normal breath.

Category

Treatment - Drugs

2

Description

Intervention group 2: One hour before the patient goes to endoscopy, two drops of Damask Rose essential oil with a concentration of 10% (the product of Barij Essen Company) are placed on a cotton ball and attached to the patient's collar by the pin. They are asked to breathe normally for 30 minutes.

Category

Treatment - Drugs

3

Description

Control group: One hour before the patient goes to endoscopy, two drops of odorless soy oil (placebo) with a concentration of 10% (the product of Barij Essen Company) are placed on a cotton ball and attached to the patient's collar by the pin. They are asked to breathe normally for 30 minutes.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi Educational and Therapeutic Center of Rasht

Full name of responsible person

Maryam Mirzaee

Street address

Razi Educational and Therapeutic Center., Sardar Jangal St., Rasht

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Guilan

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Email

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Web page address

http://www.gums.ac.ir/razi/444/%D8%B5%D9%81%D8%AD%D9%87-%D8%A7%D8%B5%D9%84%DB%8C.aspx

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Dr Shadman Nemati

Street address

In Front of 17 Shahrivar Hospital., Siadati Ave., Namjo Ave., Rasht

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Web page address

http://www.gums.ac.ir/research/303/%D8%B5%D9%81%D8%AD%D9%87-%D8%A7%D8%B5%D9%84%DB%8C.aspx

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
Maryam Mirzaee

Position
faculty member

Latest degree
Master

Other areas of specialty/work
Nursery

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Student Ave., Shahid Beheshti Blu., Rasht

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Person responsible for scientific inquiries

Contact

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Position
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Latest degree
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Nursery

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Person responsible for updating data

Contact

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Other areas of specialty/work
Nursery

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Postal code
1873- 41635

Phone
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Email
a.monfared88@gmail.com

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
Not applicable

Title and more details about the data/document
Based on the goals in the design, the amount of anxiety is reported before and after the aromatherapy and some of the individual information listed in the Variables section

When the data will become available and for how long
Starting from the second half of 2019

To whom data/document is available
Researchers, Guilan University of Medical Sciences, samples of study, University and Hospital Researchers

Under which criteria data/document could be used
Data after analysis, is available to others through publication in scientific journals

From where data/document is obtainable
maryam mirzaee and Arezoo monfared Email : msnurse_mirzaee@yahoo.com Address: Student Ave., Shahid Beheshti Blu., Rasht, Iran Postal code: 41635-1873 Tel: +98 13 3355 5056 Tel: +98 911 766 3251

What processes are involved for a request to access data/document
Usually, information will be available through the publication of the paper. But if the person asks for more and more information, can submit application by email and phone and in person. Then information will be provided according to the size and type of data that will be considered.

Comments