

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

Compare the effect of aromatherapy with Citrus aurantium and music on the level of anxiety and physiological indexes in patients undergoing colonoscopy

Protocol summary

Study aim

Compare the effect of aromatherapy with Citrus aurantium(neroli oil) and music on the level of anxiety and physiological indexes in patients undergoing colonoscopy

Design

A randomized clinical trial study was conducted in three groups (control and two test groups), with parallel, randomized groups

Settings and conduct

The sample size will be 90 patients whom randomly assigned to three groups (two intervention groups and one control group).

Participants/Inclusion and exclusion criteria

Inclusion criteria: age of 18-65 years old; without history of mental illnesses, headacheas, migraines, asthma, heart disease, respiratory disease and olfactory dysfunction, allergy to the odor of plants specially plants of Citrus aurantium, the first experience of colonoscopy; willingness to participant in the study, ability to speak and comprehend Persian; being conscious, Do not take anti-anxiety drugs. Exclusion criteria: refuse to continue corporation in this study, cancellation of colonoscopy procedure on the scheduled day, outbreak of problems such as headaches that cause interruption of the intervention.

Intervention groups

There is no intervention for patients and they will receive routine nursing care. In the experimental group (1): At once, by using a dropper two drops of Citrus aurantium were poured on the 2 * 2 gases and attached to the collar of patients Then, asked them to inhald for 30 min. In the experimental group (2): Music is being played out using headphones for 30 min.

Main outcome variables

Anxiety Level and Physiological Indexes(Blood pressure, Heart rate, Respiration rate)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170124032147N5**

Registration date: **2018-07-25, 1397/05/03**

Registration timing: **retrospective**

Last update: **2018-07-25, 1397/05/03**

Update count: **0**

Registration date

2018-07-25, 1397/05/03

Registrant information

Name

Bahareh Ghafourzadeh Toomatari

Name of organization / entity

Tehran university of medical scienc, School of Nursing and Midwifery

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-12-22, 1396/10/01

Expected recruitment end date

2018-04-21, 1397/02/01

Actual recruitment start date

2018-01-10, 1396/10/20

Actual recruitment end date

2018-06-20, 1397/03/30

Trial completion date

empty

Scientific title

Compare the effect of aromatherapy with Citrus aurantium and music on the level of anxiety and physiological indexes in patients undergoing colonoscopy

Public title

Assessing the effect of aromatherapy with Citrus aurantium(neroli oil) and music on the level of anxiety and physiological indexes in patients undergoing colonoscopy

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Inclusion criteria: age of 18-65 years old; without history of mental illnesses, headacheas, migraines, asthma, heart disease, respiratory disease and olfactory dysfunction, allergy to the odor of plants specially plants of Citrus aurantium, the first experience of colonoscopy; willingness to participant in the study, ability to speak and comprehend Persian; being conscious, Do not take anti-anxiety drugs

Exclusion criteria:

Exclusion criteria: refuse to continue corporation in this study, cancellation of colonoscopy procedure on the scheduled day, outbreak of problems such as headaches that cause interruption of the intervention.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **120**

Actual sample size reached: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

The research samples were randomly assigned to the six-block questionnaire, which were performed by the software. Sixth permutations were determined using the three letters A for the control group, the letter B for the intervention group with music and the letter C for the intervention group with Citrus aurantium, and using the randomized method, six permutations in the triple groups were chosen

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical Committee of Tehran Faculty of Nursing and Midwifery and Rehabilitation

Street address

Tehran, Faculty of Nursing and Midwifery, Nosrat Sharghi, Tohid Square,

City

Tehran

Province

Tehran

Postal code

1419733171

Approval date

2017-06-20, 1396/03/30

Ethics committee reference number

IR.TUMS.FNM.REC.1396.2699

Health conditions studied

1

Description of health condition studied

colon disease

ICD-10 code

K52.9

ICD-10 code description

Noninfective gastroenteritis and colitis, unspecified

Primary outcomes

1

Description

Anxiety

Timepoint

in the morning of the day of colonoscopy prior to the intervention, immediately after the intervention, and immediately before colonoscopy

Method of measurement

Visual Analog Scale questionnaire

2

Description

Heart rate

Timepoint

in the morning of the day of colonoscopy prior to the intervention, immediately after the intervention, and immediately before colonoscopy(after theintervention)

Method of measurement

Radial puls count through touch

3

Description

Respiration rate

Timepoint

in the morning of the day of colonoscopy prior to the intervention, immediately after the intervention, and immediately before colonoscopy(after the intervention)

Method of measurement

Enumeration

Secondary outcomes

empty

Intervention groups

1

Description

First intervention group: The method of intervention were done as: On the morning of the procedure, before the intervention, the level of anxiety and physiological indices are measured. Then, 2 drops of essential oil are stained with 2 * 2 gases and attached to the collar of the patients and continue for half an hour, and then the level of anxiety and physiological indicators immediately after the end of aromatherapy and again immediately before colonoscopy and before Sedative infusion is measured.

Category

Other

2

Description

Second intervention group: The method of intervention were done as: On the morning of the procedure, before the intervention, the level of anxiety and physiological indices are measured. Then the indomitable music (called relaxing music by Dr. Arendestein called Relaxation in Dream) is broadcast to the patient for half an hour using the headphones, after the intervention, also immediately before the procedure, the level of anxiety and physiological parameters of the size is measured.

Category

Other

3

Description

Control group: In the control group, no interventions are performed on patients and they will receive routine nursing care.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Rohani Hospital

Full name of responsible person

Saeede Rostami Daronkola

Street address

Rohani Hospital, Keshavarz Boulevard, University Square, Babol

City

Babol

Province

Mazandaran

Postal code

4713965365

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+98 11 3231 6406

Email

rostamisaede@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Massoud Younesian

Street address

Beginning of Ghods Ave., Keshavarz Blvd

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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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Saeede Rostami Daronkola

Position

Master's degree in Internal Surgery Nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Latest degree

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Person responsible for updating data**Contact****Name of organization / entity**

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Latest degree

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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

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available