

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effect of Aromatherapy with Citrus aurantium Essential Oil On Anxiety during Magnetic Resonance Imaging in Spinal disorder Imam Khomeini Hospital Saghez,2018

Protocol summary

Study aim

Effect of Flavor Scent on Anxiety During Imaging of Magnetic Fields in Patients with Spinal disorder Referring to Imam Khomeini Hospital in Saqez City in 1396

Design

This study is a clinical trial " after only design intervention" with random allocation in two groups of control and intervention that will be performed on 60 patients who are referred to Imam Khomeini Hospital in Saqez for magnetic field imaging. In this study, Two groups of intervention and control are performed on a weekly basis, one week per week. Choosing which first group is to be drawn in random order. After that, the sampling will be carried out in a simple random manner. For this purpose The sampling frame contains the names of all patients who have been switched to the single-shot imaging schedule Dan is magnetic. After the numbering of the patients' names, a random number table is used for sampling. The patients' anxiety level was measured by the Spiel questionnaire and patients with a mild to moderate anxiety level were enrolled in the study.

Settings and conduct

Intervention in this study is an essential oil essential oil that is purchased from a prestigious university unit. After determining the concentration by weight measurement, this essential oil is 10 mg of essential oil in 100 ml of the product. Before intervention, anxiety scales MRI-AQ is not evaluated by any group. In the intervention group, three drops of essential oil are sprayed onto cotton swabs and patients are asked to smell it for 5 minutes at a distance of 10 cm and then after entering the Magnetic field imaging room A gas dipped into three drops of orange spring essential oil by the researcher A collaborator will be attached to the patient's collar with a plastic clamp and immediately after the magnetic field is evaluated, the MRI-AQ anxiety score is evaluated. In the control group, they receive only the usual care of the

treatment center. This process completes the necessary samples for further research. Finds. Heart rate and blood pressure and nausea, vomiting and headache are controlled by the aromatherapy.

Participants/Inclusion and exclusion criteria

Patients aged 65-18 years old, lack of specific illness (allergy, olfactory disorder, anxiety disorder), lack of psychotropic drugs, lack of respiratory problems, non-performing magnetic resonance imaging, outpatients, patients with spinal disorders (neck and waist)) And spinal column abnormalities (skeletal, kyphosis, lordosis), mild to moderate anxiety in both control and intervention groups. Entry into study Any medical or surgical problem requiring urgent medical intervention during the study, nausea and vomiting, and sensation of subtle scent, discontent after each inhalation, discontinuation of the research unit and reluctance to continue participating in the study for any reason, having severe anxiety , General anxiety disorder, compulsive obsessive-compulsive disorder, closed-air fear and social fear Exclusion criteria

Intervention groups

A group of 10% Orange Spring scents for 10 minutes before scanning magnetic field imaging and scanning. The control group only receives standard care from the health center

Main outcome variables

Anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180117038414N1**

Registration date: **2018-02-13, 1396/11/24**

Registration timing: **prospective**

Last update: **2018-05-20, 1397/02/30**

Update count: **1**

Registration date

2018-02-13, 1396/11/24

Registrant information**Name**

Nishtman Ahani

Name of organization / entity**Country**

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source**Expected recruitment start date**

2018-02-20, 1396/12/01

Expected recruitment end date

2018-05-22, 1397/03/01

Actual recruitment start date

2018-02-20, 1396/12/01

Actual recruitment end date

2018-05-22, 1397/03/01

Trial completion date

empty

Scientific title

Effect of Aromatherapy with Citrus aurantium Essential Oil On Anxiety during Magnetic Resonance Imaging in Spinal disorder Imam Khomeini Hospital Saghez,2018

Public title

Effect of Aromatherapy with Citrus aurantium Essential Oil On Anxiety during Magnetic Resonance Imaging in Spinal disorder

Purpose

Health service research

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients aged 65-18 years old, lack of specific illness (allergy, olfactory disorder, anxiety disorder), lack of psychotropic drugs, lack of respiratory problems, non-performing magnetic resonance imaging, outpatients, patients with spinal disorders (neck and waist)) And pituitary abnormalities (scoliosis, kyphosis, lordosis), mild to moderate anxiety in both control and intervention groups.

Exclusion criteria:

Any medical problem or required surgical interventions in medicine during the execution of the study, nausea and vomiting, and sensitivity to aromas of sour orange, dissatisfaction after each inhalation, dropped out of the study and an unwillingness to continue participation in the study for any reason, having severe anxiety , Generalized anxiety disorder, compulsive obsession, fear of closed space and social fear

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: **60**

Actual sample size reached: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomized and randomized drawings

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Other

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Kurdistan University of Medical Sciences

Street address

Kurdistan University of Medical Sciences, after Qods Hospital, Sanandaj

City

Sanandaj

Province

Kurdistan

Postal code

13446-66177

Approval date

2018-01-31, 1396/11/11

Ethics committee reference number

IR.MUK.REC.1396.329

Health conditions studied**1****Description of health condition studied**

Anxiety during magnetic field imaging

ICD-10 code

F41.1

ICD-10 code description

Generalized anxiety disorder

Primary outcomes**1****Description**

Anxiety during magnetic field imaging

Timepoint

During magnetic field scan

Method of measurement

MRI-AQ

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Aromatic notes of spring flavor

Category

Treatment - Other

2**Description**

Control group: Standard care center

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Imam Khomeini Hospital

Full name of responsible person

Ahani Nishtaman

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Nursing Avenue, Imam Khomeini Hospital

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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Full name of responsible person

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Grant name

Kurdistan University of Medical Sciences

Grant code / Reference number

305

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

Yes

Title of funding source

Sanandaj 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**

Sanandaj University of Medical Sciences

Full name of responsible person

Ahani Nishtaman

Position

Senior Care Nursing Student

Latest degree

Master

Other areas of specialty/work

Nursery

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inquiries

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Full name of responsible person

Salehi Kamal

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Latest degree

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Senior Care Nursing Student

Latest degree

Bachelor

Other areas of specialty/work

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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

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

No - There is not 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

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

Data Dictionary

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