

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

The effect of aromatherapy with essential oil of lavender on anxiety of patients undergoing hand and upper extremity reconstructive surgery

Protocol summary

Summary

The aim of this study is to investigate the effects of aromatherapy on level of anxiety in patients undergoing hand and upper extremity reconstructive surgery. This randomized clinical trial; single-center; placebo-controlled randomized controlled trial will be conducted on 100 patients in 15 Khordad therapeutic and educational center in Tehran. This study is single blind, as the participants are not aware of the type of the intervention. Participants randomly assigned to two intervention and control groups by the toss of a coin. Inclusion criteria: having age more than 18 years; earn a higher score of 20 after responding to a questionnaire STAI; ability to read and write; lack of mental illness. Exclusion criteria: acute pain at the time of completing the questionnaire; tranquilizers and drugs psychiatric drugs; allergic rhinitis and asthma; history of migraine and headache; lack of participation and the willingness of patients to withdraw from the study. The participants in the inhalation aromatherapy group inhaled tree drops of lavender essential oil who was dropped on a piece of cotton pad and those in the control group inhaled tree drops of distilled water as placebo for 20 min. Main outcomes included anxiety, blood pressure, Pulse rate and respiratory rate. The level of anxiety was evaluated by Spielberg's State Anxiety questionnaire before and after intervention and the vital signs were documented as well. The scores will be calculate and compared together.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016060826136N1**

Registration date: **2016-08-22, 1395/06/01**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-08-22, 1395/06/01

Registrant information

Name

Elaheh Rouhi Rahim Begloo

Name of organization / entity

15 Khordad Hospital

Country

Iran (Islamic Republic of)

Phone

+98 21 8894 3434

Email address

e-ruhi@alumnus.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2016-06-21, 1395/04/01

Expected recruitment end date

2016-09-22, 1395/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of aromatherapy with essential oil of lavender on anxiety of patients undergoing hand and upper extremity reconstructive surgery

Public title

The effect of aromatherapy with essential oil of lavender on anxiety

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: having age more than 18 years; earn a higher score of 20 after responding to a questionnaire STAI (minimum score of 20 and higher than 20 can show the impact of the intervention); the ability to understand and speak Persian; ability to read and write; the absence of olfactory dysfunction; lack of mental illness. Exclusion criteria: acute pain at the time of completing the questionnaire; the use of benzodiazepines; tranquilizers and drugs psychiatric drugs; a history of eczema and allergies to plants, allergic rhinitis and asthma; history of migraine and headache; drug addiction (alcohol and cigarettes); lack of participation and the willingness of patients to withdraw from the study.

Age

From **18 years** old to **80 years** old

Gender

Male

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of
Medical Sciences

Street address

Near the Hospital Ayatollah Taleqani, Shahid Arabi
Street, Yemen Street, Chamran Higway, Tehran, Iran

City

Tehran

Postal code

Approval date

2016-07-03, 1395/04/13

Ethics committee reference number

IR.SBMU.REC.1395.12

Health conditions studied

1

Description of health condition studied

Anxiety

ICD-10 code

F41.1

ICD-10 code description

Generalized anxiety disorder

Primary outcomes

1

Description

Anxiety Intensity

Timepoint

Preintervention and 25 min after intervention

Method of measurement

Spielberger State Anxiety Inventory

Secondary outcomes

1

Description

Blood Pressure

Timepoint

Pre intervention and 25 min after intervention

Method of measurement

Mercury blood pressure devices (Richter)

2

Description

Pulse

Timepoint

Pre intervention and 25 min after intervention

Method of measurement

According to minutes using the pulse oximetry finger

3

Description

Breathing

Timepoint

Pre intervention and 25 min after intervention

Method of measurement

According to minutes using the standard digital clock

Intervention groups

1

Description

20 minute inhalation with 3 drop lavandula oil in
inhalation aromatherapy group.

Category

Prevention

2

Description

20 minute inhalation with 3 drop water injection in placebo group.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

15 Khordad Hospital

Full name of responsible person

Elaheh Rouhi Rahim Begloo

Street address

Sout Azodi Street, Karimkhan Avenue, Tehran, Iran.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr Afshin Zarghi

Street address

Near the Hospital Ayatollah Taleqani, Shahid Arabi Street, Yemen Street, Chamran Higway, Tehran, Iran

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research Shahid Beheshti University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

15 Khordad Hospital

Full name of responsible person

Elaheh Rouhi Rahim Begloo

Position

MSc in Nursing

Other areas of specialty/work

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Web page address

Person responsible for updating data

Contact

Name of organization / entity

15 Khordad Hospital

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty