Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 Presure

Timepoint

Pre intervention and 25 min after intervention

Method of measurement

Mercury blood pressure devices (Richter)

2

Description

Palse

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
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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