Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison the effect of Massage Aromatherapy and Inhalation Aromatherapy on the level of anxiety in preoperative patients

Protocol summary

Summary

Background: Surgery can cause high levels of anxiety in patients. Preoperative anxiety can increase postoperative pain and need for postoperative analgesia, delay wound healing and increase stay in hospital. Nurses often look for ways to help control anxiety following surgery and disease. Aromatherapy is currently recognized as a complementary therapy and tool holistic nursing care in many countries that may help patients and lower their anxiety. Objective of this study is comparison the effect of Massage Aromatherapy and Inhalation Aromatherapy on the level of anxiety in preoperative patients. Methods: This research is a randomized clinical trial on 144 preoperative patients who admitted to Golestan and Imam Khomeini hospitals in Ahwaz, Iran. Patients is going to divide to four groups; first group take inhalation aromatherapy, second group take inhalation placebo, third group take massage aromatherapy and forth group take massage with almond oil. The level of anxiety will be evaluated by Spillberger questionnaire before and after intervention and vital signs will be documented.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201107227090N1**
Registration date: **2011-08-21, 1390/05/30**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2011-08-21, 1390/05/30

Registrant information

Name

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Name of organization / entity

Islamic Azad University of Najafabad

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Recruitment status

Recruitment complete

Funding source

Ahwaz Jundishapur University of Medical Sciences

Expected recruitment start date

2008-05-27, 1387/03/07

Expected recruitment end date

2008-09-06, 1387/06/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of Massage Aromatherapy and Inhalation Aromatherapy on the level of anxiety in preoperative patients

Public title

Comparison the effect of Massage Aromatherapy and Inhalation Aromatherapy on the level of anxiety in preoperative patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: over 18 years old; getting more the 20 score from Spilburger questionnaire; hospitalizing at the night before surgery; ability to talk and understanding Persian language. Exclusion criteria: sever acute pain at

the time of filling out the questioner; taking benzodiazepine; anti coagulants; analgesics opioids; history of exema and allergy to plants, migraine; chronic headache; inflammation; wound or burn in back skin; bleeding disease; acute mental illness according to physician diagnose and olfactory disorder.

Age
From **18 years** old to **57 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **144**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ahwaz Jundishapur University of Medical Sciences

Street address
Golestan avenue

City
Ahwaz

Postal code
61355-45

Approval date
2008-05-27, 1387/03/07

Ethics committee reference number
8/20/1848/پ

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

Timepoint
before & after intervention

Method of measurement
Spillberger questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
20 minute inhalation of handkerchief with 2 drop lavandula in Inhalation Aromatherapy group.

Category
Other

2

Description
In group of massage with almond oil, after washing and drying hands, the patients back has been massaged by the 15cc of almond oil from the last cervical vertebral to the lumbar and from the left to right posterior axillary line for 20 minutes.

Category
Other

3

Description
In massage aromatherapy group after washing and dryintg hands the patients back has been massaged by the 15cc of almond oil from the last cervical vertebral to the lumbar and from the left to right posterior axillary line for 20 minutes.

Category
Other

4

Description
20 minute inhalation handkerchief with 2 drop water in placebo group .

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Golestan and Emam khomeini hospitals of Ahwaz

Full name of responsible person
Monireh Babashahi
Street address
Medical-Surgical group, Nursing-Midwifery School, Isfahan Najafabad Islamic Azad University
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahwaz Jundishapur University of Medical Sciences
Full name of responsible person
Alireza sarkaki
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Vice chancellor for research, Ahwaz Jundishapur University of Medical Sciences, Golestan St.
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Ahvaz
Grant name
u-87017
Grant code / Reference number
u-87017
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ahwaz Jundishapur 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

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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