

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 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

Monireh Babashahi

Name of organization / entity

Islamic Azad University of Najafabad

Country

Iran (Islamic Republic of)

Phone

+98 913 107 5944

Email address

babashahi_m@pnu.iaun.ac.ir

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 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

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 addressMedical-Surgical group, Nursing-Midwifery School,
Isfahan Najafabad Islamic Azad University**City**

Isfahan

Fax**Email**babashahi_m@yahoo.com ;
babashahi_m@pnu.iaun.ac.ir**Web page address****Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Alireza sarkaki

Street addressVice chancellor for research, Ahvaz Jundishapur
University of Medical Sciences, Golestan St.**City**

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

Ahvaz 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**Contact****Name of organization / entity**

Islamic Azad University of najafabad

Full name of responsible person

Monireh Babashahi

Position

MA-instructor

Other areas of specialty/work**Street address**Medical-Surgical group, Nursing-Midwifery School,
Islamic Azad University of Najafabad, Najafabad**City**

Isfahan

Postal code

8186633731

Phone

+98 913 107 5944

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Sadighe Fayazi

Position

MA-instructor

Other areas of specialty/work**Street address**Medical-Surgical group, Nursing-Midwifery School,
Ahvaz Jundishapur University of Medical Sciences,
shahrak Daneshgahi**City**

Ahvaz

Postal code

61355-45

Phone

+98 916 113 6441

Fax**Email**

sadighe_fa@yahoo.com

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

Islamic Azad University of Najafabad

Full name of responsible person

Monireh Babashahi

Position

MA-instructor

Other areas of specialty/work**Street address**Medical-Surgical group, Nursing-Midwifery School,
Islamic Azad University of Najafabad, Najafabad**City**

Isfahan

Postal code

8186633731

Phone

+98 913 107 5944

Fax**Email**babashahi_m@yahoo.com ;
babashahi_m@pnu.iaun.ac.ir**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