

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jul 2026

Comparison of the effects of aroma Inhalation and essential oil massage of lavender and sweet orange on quality of life, anxiety and pain in women with breast cancer

Protocol summary

Study aim

Comparison of the effects of aroma Inhalation and essential oil massage of lavender and sweet orange on quality of life, anxiety and pain in women with breast cancer

Design

This study is an experimental study of clinical trial with control group and is single blind. Simple randomized, the sample size is 50 patients; one group is essential oil inhalation and the other group is aromatic massage.

Settings and conduct

There is one intervention group of combined inhalation of lavender and sweet orange essential oil and the other group of intervention intervention combines both aromas. Each intervention is performed every day for 15 minutes for two weeks. Location of study in the oncology ward of the hospital, in a private room at the end of the ward, while obtaining permission from the relevant authorities. The control group was selected from patients who did not want to participate in the study and receive only routine care. Study is single blind and the samples do not know how to assign it to the intervention groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: according to the Spielberger questionnaire test, they had mild, moderate and severe anxiety; willing to participate in the study; Having a medical record for confirmation of a diagnosis of breast cancer by a specialist; Exclusion criteria: History of respiratory, diabetes, liver and kidney diseases; Drug addiction.

Intervention groups

One group inhaled the scent of essential oil and the other group the intervention of the scent massage

Main outcome variables

To improve the quality of life; To reduce pain; To reduce anxiety in patients

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150302021298N3**

Registration date: **2020-08-21, 1399/05/31**

Registration timing: **prospective**

Last update: **2020-08-21, 1399/05/31**

Update count: **0**

Registration date

2020-08-21, 1399/05/31

Registrant information

Name

Sanaz Bostani

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 3230 5410

Email address

sanaz.bostani@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-08-23, 1399/06/02

Expected recruitment end date

2020-09-23, 1399/07/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effects of aroma Inhalation and essential oil massage of lavender and sweet orange on quality of life, anxiety and pain in women with breast cancer

Public title

Comparison of the effect of Inhalation and essential oil massage of lavender and sweet orange on quality of life, anxiety and pain

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

According to the Spielberger questionnaire test, they had mild, moderate and severe anxiety Breast cancer confirmed by oncologist Healthy sense of smelling

Exclusion criteria:

Amputation of one or both legs Drug addiction History of respiratory, diabetes, heart, liver and kidney diseases

Age

From **30 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Single blind: only participants are unaware of the allocation of study groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Hormozgan University of Medical Sciences

Street address

Iran, Hormozgan, Bandar Abbas, at the beginning of

Imam Hossein Boulevard, in front of Kargaran Sports Club, next to Nabout Town - School of Nursing and Midwifery

City

BandarAbbas

Province

Hormozgan

Postal code

076-3317723

Approval date

2020-01-20, 1398/10/30

Ethics committee reference number

IR.HUMS.REC.1399.152

Health conditions studied

1

Description of health condition studied

Pain, anxiety and quality of life

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Anxiety score in Spielberger's questionnaire

Timepoint

Before and two weeks after the start of the intervention

Method of measurement

Spielberger trait anxiety inventory

2

Description

Pain

Timepoint

Before and two weeks after the intervention

Method of measurement

The brief pain inventory

3

Description

Quality of life

Timepoint

Before and two weeks after the intervention

Method of measurement

Based on standard quality of life questionnaires

Secondary outcomes

empty

Intervention groups

1

Description

The first intervention group: includes the use of aroma

by inhalation. How to do it: Pour two drops of lavender essential oil with sweet orange (Production of Mehrgol Broadcasting company) in a ratio of 1: 1 on a 2-by-2 gas dropper; The patient was then asked to breathe normally for 20-20 minutes. This will be done every day for 2 weeks.

Category

Rehabilitation

2

Description

Intervention group 2: Using aroma as a massage, inhale two drops of lavender essential oil with sweet orange (Production of Mehrgol Broadcasting company) in a ratio of 1: 1 and the next group mix lavender essential oil with sweet orange in a ratio of 1: 1, which has been diluted by 3% using sweet almond oil. 5 cc is used to massage the toes, soles of the feet to the ankles.

Category

Rehabilitation

3

Description

Control group: People who do not want to participate in the study will be selected; This group receives only routine care.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Mohammadi Hospital and Persian Gulf Bandar Abbas and Omid Cancer Center

Full name of responsible person

Sanaz Bostani

Street address

Iran, Hormozgan, Bandar Abbas, at the beginning of Imam Hossein Boulevard, in front of Kargaran Sports Club, next to Nabout Town - School of Nursing and Midwifery

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sanaz.bostani@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bandare-abbas University of Medical Sciences

Full name of responsible person

Sanaz Bostani

Street address

Iran, Hormozgan, Bandar Abbas, at the beginning of Imam Hossein Boulevard, in front of Kargaran Sports Club, next to Nabout Town - School of Nursing and Midwifery

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Bandare-abbas 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

Bandare-abbas University of Medical Sciences

Full name of responsible person

Sanaz Bostani

Position

Totur

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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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

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

No - There is not a plan to make this available

Data Dictionary

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