Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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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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
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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Person responsible for scientific inquiries

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Other areas of specialty/work
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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