Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Investigating the effect of aromatherapy with peppermint essential oil on the average score of fatigue and anxiety of cancer patients undergoing chemotherapy

Protocol summary

Study aim
Determining the effect of aromatherapy with peppermint essential oil on the average score of fatigue and anxiety of cancer patients undergoing chemotherapy

Design
Clinical trial with intervention group, control group, double-blind, randomized, on 64 patients.

Settings and conduct
People suffering from cancer undergoing chemotherapy who visit Shahid Jalil Yasouj Hospital during the study and eligible patients are randomly divided into 32 blocks including 2 patients and each of the 2 patients in the random block receives aromatherapy or placebo.Blinding is double-blind, and the doctor, patient, person responsible for data collection, and those who evaluate the outcome are unaware, and only the supervisor of the project knows.

Participants/Inclusion and exclusion criteria
Inclusion criteria: written consent to participate in the research, suffering from cancer as diagnosed by a specialist, 2 weeks have passed since the start of chemotherapy, the ability to read and write and see, having a healthy sense of smell based on the client's statement. Inclusion criteria: having a mental disorder, having a history of migraine, asthma and allergies, using anti-anxiety medication

Intervention groups
intervention group: This group was subjected to aromatherapy with peppermint essential oil prepared by Zardband Company in Tehran, so that intervention was performed on them for 4 sessions for 20 minutes during 4 days. control group: Distilled water was used for this group so that the intervention was carried out on them for 4 sessions for 20 minutes during 4 days.

Main outcome variables
Anxiety, fatigue

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20221017056207N1**
Registration date: **2024-01-04, 1402/10/14**
Registration timing: **prospective**

Last update: **2024-01-04, 1402/10/14**
Update count: **0**

Registration date
2024-01-04, 1402/10/14

Registrant information

Name
Akbar aminiparvar

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-01-14, 1402/10/24

Expected recruitment end date
2024-02-13, 1402/11/24

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the effect of aromatherapy with peppermint essential oil on the average score of fatigue and anxiety of cancer patients undergoing chemotherapy

Public title
Effect of peppermint on fatigue and anxiety of patients undergoing chemotherapy

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Having cancer diagnosed by a specialist 2 weeks have passed since the start of chemotherapy Being visually healthy and literate Having a healthy sense of smell based on the client's statement Informed consent to participate in research
Exclusion criteria:
Having mental disorders Having a history of migraines, asthma and allergies Use of anti-anxiety medication

Age
No age limit

Gender
Both

Phase
2

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **64**

Randomization (investigator's opinion)
Randomized

Randomization description
They are selected as study samples by random sampling from the list of patients available on the website. For this purpose, the table of random numbers and the two-group block random allocation method are used. In this method, 64 eligible patients are randomly divided into 32 blocks including 2 patients. Then, each of the 2 patients will receive aromatherapy or placebo in a random block, so that 32 patients will be assigned to each group.

Blinding (investigator's opinion)
Double blinded

Blinding description
The packaging of herbal medicine and placebo is prepared with a label with code A or B. Other specifications on the labels are the same. The doctor, nurse, patient, responsible for data collection and those who evaluate the outcome are unaware of the drug and placebo group. Only the supervisor of the project and the expert responsible for packing the dropper know the contents of the packages or code A or B. Patients are aware that they are either in the herbal medicine group or in the placebo group, but they do not know the type of group they are in.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Yasouj University of Medical Sciences
Street address
Motahari Blvd., Yasouj
City
Yasuj
Province
Kohgilouyeh-va-Boyrahmad
Postal code
7591741417

Approval date
2022-10-12, 1401/07/20

Ethics committee reference number
IR.YUMS.REC.1401.95

Health conditions studied

1

Description of health condition studied
neoplasms

ICD-10 code
C80.9

ICD-10 code description
Malignant neoplasm, primary site unspecified

Primary outcomes

1

Description
Anxiety

Timepoint
Before the intervention and after the intervention

Method of measurement
Spielberger Manifest Anxiety Questionnaire

2

Description
Fatigue

Timepoint
Before the intervention and after the intervention

Method of measurement
Fatigue Questionnaire (cancer patients)

Secondary outcomes

empty

Intervention groups

1

Description
32 people are selected as intervention group. For 4 days, 5 drops of peppermint essential oil (provided by Zardband, Tehran) will be sprinkled with a dropper on a non-absorbable napkin for 20 minutes a day and will be placed at a distance of 20 cm from the subject's nose for 20 minutes. After 4 days, the level of their fatigue and anxiety will be checked using two Spielberger anxiety questionnaires and cancer fatigue scale.

Category
Rehabilitation

2

Description
Control group: 32 people will be selected as the control group. For 4 days and every day for 20 minutes, 5 drops of distilled water will be sprinkled on a non-absorbable tissue with a dropper and placed at a distance of 20 cm from the subject's nose for 20 minutes. After 4 days, the level of their fatigue and anxiety will be checked using Spielberger anxiety questionnaire and cancer fatigue scale.

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Jalil Yasouj Hospital

Full name of responsible person
Amin Nazer Mozafari

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Shahid Jalil Hospital، Qorani Blvd، Yasuj

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Yasouj University of Medical Sciences

Full name of responsible person
Dr. Seyedamin Hosseini Mutlaq

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Vice President of Research and Technology, Headquarters of Yasouj University of Medical Sciences, Shahid Motahari Boulevard

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Grant name
Yasouj University of Medical Sciences

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Yasouj 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
Yasouj University of Medical Sciences

Full name of responsible person
Akbar aminiparvar

Position
Master's student in internal surgery

Latest degree
Bachelor

Other areas of specialty/work
Nursery

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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

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

Informed Consent Form

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

Clinical Study Report

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

Analytic Code

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

Data Dictionary

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