

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 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

Country

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

Kohgiluyeh-va-Boyerahmad

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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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,
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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