Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The Effect of Aromatherapy By Inhalation And Massage On Radiotherapy-Induced Fatigue In Cancer Patients

Protocol summary

Study aim

1) Determination of Radiation Induced Fatigue in Cancer Patients in the Inhaled Aromatherapy Group Before Intervention 2) Determination of Radiation Induced Fatigue in Cancer Patients Inhaled Aromatherapy After Intervention 3) Determination of Radiation Induced Fatigue in Cancer Patients in the Massage Aromatherapy Group Before Intervention 4) Determination of Radiation Induced Fatigue in Cancer Patients in the Massage Aromatherapy Group After Intervention 5) Determination of Radiation Induced Fatigue in Cancer Patients in the Control Group Before the Study 6) Determination of Radiation Induced Fatigue in Cancer Patients in the Control Group After the Study 7) Determination of Radiation Induced Fatigue in Cancer Patients in Three Groups Before Intervention 8) Radiation Induced Fatigue in Cancer Patients in Three Groups After Intervention

Design

This Quasi-Experimental Clinical Trial With Control Group Was Conducted in Firoozgar Hospital in Tehran. 105 Cancer Patients Underwent Radiation Therapy According to the Conditions of Entry to the Study Using Simple Sampling Method Then By Throwing the Coins the Samples Will Be Randomized in 3 Groups as Inhaled Aromatherapy (35), Massage Aromatherapy (35) and Control Group (35) .

Settings and conduct

This Research Was Conducted at Firoozgar Hospital in Tehran.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Having 2 Weeks of Radiation Therapy History ؛ Ability to Communicate؛ Lack of Psychiatric Problems ؛ Accepting Intervention as Back Massage with oil or inhaling it ؛ Having a Healthy Sense of Smell ؛ Lack of Sore and Abnormal Swelling of the Extremities ؛Be able to Read and Write (Patient or His Companion)؛ No History of Migraine, Asthma and other Respiratory Diseases Exclusion Criteria: Hospitalization؛ Death؛ Absence of participating in an Intervention session

Intervention groups

After Sampling and Before Intervention, in Each of the Three Groups, Demographic Information and Fatigue Information Form Were First Completed Using Demographic Data Instrument and Multi-Dimensional MFI Fatigue Assay . Due to Fatigue and Inaccuracy in Answering the Questions, Patients Were Assisted to Complete the Questionnaires. At the first Session, After Completing the Questionnaires, the Inhaled Aromatherapy and the Massage Aromatherapy Had Begun in the Days When They Visited the center of Radiotherapy as Three Times a Day. The Control Group Received No Special Intervention.So, On the First Day, the Samples of the Intervention Group of the Inhaled Aromatherapy , After Receiving Radiation, 0/5 cc of Violets and Almond Aromatic Oils (Made in Tolu's Green Gold Company) by Pouring on Each Finger and Rubbed Inside Nasal Holes Inhaled it for 5 Minutes. For Massage Aromatherapy Samples, After Receiving Radiation, for 30 Minutes Massage Will Be Done, Throat Movements With 3-5 cc of Aromatic Violets and Almonds In the Back Shu Points Area on the Path of the Paravertebral Muscles in the Prone Position by Researcher and Assistant Will Be Intervented .

Main outcome variables

It Is Hoped that If the Results of the Research Will be Positive, the Results Could be given to the Radiation Management Staff of the Research Center to Reduce the Fatigue of These Patients by a Safe and Non-Invasive Strategy.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171203037735N1**
Registration date: **2018-02-14, 1396/11/25**
Registration timing: **prospective**

Last update: **2018-02-14, 1396/11/25**
Update count: **0**

Registration date
2018-02-14, 1396/11/25

Registrant information
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2018-03-01, 1396/12/10
Expected recruitment end date
2018-07-21, 1397/04/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The Effect of Aromatherapy By Inhalation And Massage On Radiotherapy-Induced Fatigue In Cancer Patients

Public title
The Effect Of Aromatherapy By Inhalation And Massage On Radiotherapy-Induced Fatigue
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Inclusion Criteria: Having 2 Weeks of Radiation Therapy History; Ability to Communicate; Lack of Psychiatric Problems; Accepting Intervention as Back Massage with oil or inhaling it; Having a Healthy Sense of Smell; Lack of Sore and Abnormal Swelling of the Extremities; Be Able to Read and Write (Patient or His Companion); No History of Migraine, Asthma and other Respiratory Diseases; Exclusion Criteria: Hospitalization; Death; Absence of participating in an Intervention Session
Exclusion criteria:
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **105**
Randomization (investigator's opinion)
Randomized
Randomization description
The Simple Sampling Method Is Being Used in This Study. Then, By Throwing the Coins the Samples Will Be Randomized. In Order to Prevent Leakage of the Information, the Control Group Was First Sampled, Then the Inhaling Aromatherapy Group and Finally, the Massage Aromatherapy Group will Be Selected.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Iran University of Medical Sciences
Street address
School of Nursing & Midwifery, Rashid Yasemi st.,
City
Tehran
Province
Tehran
Postal code
۱۴۴۹۶۱۴۵۳۵
Approval date
2017-05-28, 1396/03/07
Ethics committee reference number
IR.IUMS.FMD.REC 1396.9411686010

Health conditions studied

1

Description of health condition studied
Persons With Cancer Undergoing Radiotherapy
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Fatigue
Timepoint
The First Day And 6 Days After Starting Intervention.
Method of measurement
Multidimensional Fatigue Inventory Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention Group 1: Inhalation Aromatherapy After receiving radiation Was Done by Applying 0.5 cc Essential Oil of Violets and Almonds (Made in Tuba's Green Gold Company) Poured on Each Finger and Rubbed Inside Nasal Holes and Inhaled for 5 Minutes
Category
Treatment - Drugs

2

Description
Intervention group: In Aromatherapy Massage Group , After receiving radiation, Aromatherapy Massage for 30 Minutes Has Done by Thumb Rotational Movements by 3-5 cc of Essential Oil of Violets and Almonds in the Back Shu Points Area on the Path of the Paravertebral Muscles. The Researcher and Her Assistant Who Both Had Completed Massage Courses and Had a Relevant Degree and License for Massage Exercises Will Do the Massage Intervention
Category
Treatment - Drugs

3

Description
Control group: Control Group Did not Receive any Special Intervention
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Firuzgar Hospital
Full name of responsible person
Mojgan Moradi
Street address
Firoozgar Hospital., Vali Asr Square., Valadi Alley
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Province
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Email
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Deputy Director of Research and Technology University of Iran
Street address
Iran University of Medical Sciences, Shahid Hemmat Highway,
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adminsite@iums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran 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
Iran University of Medical Sciences
Full name of responsible person
Mojgan Moradi
Position
Master of Science of Nursing Student
Latest degree
Bachelor
Other areas of specialty/work
Nursery
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Total non-Identifiable Data, the Potential of the People Sharing
When the data will become available and for how long
Start Access 2018/5
To whom data/document is available
Professors and Students
Under which criteria data/document could be used
-
From where data/document is obtainable
Moradi.m@tak.iums.ac.ir
What processes are involved for a request to access data/document
Request Via E-mail and Respond by Email Within one Week To Do .
Comments