

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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
Name
Mojgan Moradi
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 21 7767 1376
Email address
moradi.m@tak.iums.ac.ir

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

City

Tehran

Province

Tehran

Postal code

161886374

Phone

+98 21 8214 1201

Email

Moradi.m@tak.iums.ac.ir

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,

City

Tehran

Province

Tehran

Postal code

۱۴۴۹۶۱۴۵۳۵

Phone

+98 21 86701

Email

admins@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

Street address

Iran University of Medical Sciences, Shahid Hemmat
Highway,

City

Tehran

Province

Tehran

Postal code

۱۴۴۹۶۱۴۵۳۵

Phone

+98 21 86701

Email

Moradi.m@tak.iums.ac.ir

Person responsible for scientific 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

Street address

School of Nursing & Midwifery, Rashid Yasemi st.,Valiasr St.,

City

Tehran

Province

Tehran

Postal code

۱۴۴۹۶۱۴۵۳۵

Phone

+98 21 7767 1376

Fax**Email**

Moradi.m@tak.iums.ac.ir

Person responsible for updating data**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

Street address

School of Nursing & Midwifery, Rashid Yasemi st.,Valiasr St.,

City

Tehran

Province

Tehran

Postal code

۱۴۴۹۶۱۴۵۳۵

Phone

+98 21 7767 1376

Fax**Email**

Moradi.m@tak.iums.ac.ir

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