Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparing the effect of floating feet in warm water and foot reflexology on fatigue and sleep quality in patients under radiotherapy

Protocol summary

Study aim
Comparing the effect of floating feet in warm water and foot reflexology on fatigue and sleep quality in patients under radiotherapy

Design
This study has two intervention groups. Simulation is performed by ssps software. The sample size in each group was 30 patients.The plan is a parallel And it's kind of a currency trial.

Settings and conduct
This study is performed on patients undergoing radiotherapy at Reza Sanatorium

Participants/Inclusion and exclusion criteria
1. To perform radiotherapy, refer to the center of Imam Reza Mashhad 2. Age is between 18 and 60 years old 3. Be alert 4. Stage cancer is zero, one, two or three, and non-metastatic 5. There is no peripheral vascular disease, ulcers, infection or cancer and foot radiotherapy and peripheral sensory loss 6. Do not use hypnotic and sedative drugs 7. The phone number has been provided to the researcher for follow up 8. At the same time, chemotherapy and other therapies, including hormone therapy,Target therapy, are not used 9. In response to the Smith's Fatigue Questionnaire, earns a score of 30 and above 10. In response to the Pittsburgh Sleep Quality Questionnaire, earns a score of 5 and above

Intervention groups
Intervention group1: In the group of floating legs in warm water, patients from the seventh day after starting radiotherapy every night for 2 weeks float their legs 10 cm above the wrist in water (41 to 42 ° C) for 20 minutes Inside the plastic container with a size of 40 × 27 × 45 Intervention group2: The intervention is performed within 2 weeks of the seventh day after radiotherapy is initiated every night for 10 minutes per foot. Reflexology intervention outcomes include preparation, warm-up and massage and stimulation techniques performed at the point of the solar plexus and the pituitary gland and pineal gland located on the soles of the toe

Main outcome variables
The amount of fatigue, Sleep Quality Score

General information

Reason for update
Termination of clinical trial

Acronym

IRCT registration information
IRCT registration number: **IRCT20190625044009N1**
Registration date: **2019-08-26, 1398/06/04**
Registration timing: **prospective**

Last update: **2024-04-09, 1403/01/21**
Update count: **2**

Registration date
2019-08-26, 1398/06/04

Registrant information

Name
Mahla Rajabzadeh

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 51 3601 6795

Email address
rajabzadehm951@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-08-11, 1398/05/20

Expected recruitment end date
2019-10-12, 1398/07/20

Actual recruitment start date
2019-08-31, 1398/06/09

Actual recruitment end date

2019-12-19, 1398/09/28

Trial completion date

2019-12-29, 1398/10/08

Scientific title

Comparing the effect of floating feet in warm water and foot reflexology on fatigue and sleep quality in patients under radiotherapy

Public title

Comparing the effect of floating feet in warm water and foot reflexology on fatigue and sleep quality in patients under radiotherapy

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

To perform radiotherapy, refer to the center of Imam Reza Mashhad Age is between 18 and 60 years old Is alert Stage cancer is zero, one, two or three, and non-metastatic.(Based on diagnostic tests, signs and clinical examinations and approval of an oncology specialist) There is no peripheral vascular disease, such as peripheral vascular thrombosis, burger disease, diabetes, ulcers, infection or cancer and foot radiotherapy and peripheral sensory loss Do not use hypnotic and sedative drugs There is no history of hospitalization for psychiatric causes (Stress, anxiety, Depression) The phone number has been provided to the researcher for follow up At the same time, chemotherapy and other therapies, including hormone therapy,Target therapy, heat therapy, and cold therapy are not used During the period of radiotherapy, Patient will stay at the Reza Health Center nursing home In response to the Smith's Fatigue Questionnaire, patient earns a score of 30 and above In response to the Pittsburgh Sleep Quality Questionnaire, patient earns a score of 5 and above

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: **60**

Actual sample size reached: **62**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization type: Simple This method uses computer randomization methods and divides people into two groups randomly by sequences generated by spss software. The method of concealing Allocation Concealment is done by the statistics consultant.

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 Mashhad University of Medical Sciences

Street address

Doktora four-way, Ebn Sina Street, Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913199

Approval date

2019-05-28, 1398/03/07

Ethics committee reference number

IR.MUMS.NURSE.REC.1398.022

Health conditions studied

1

Description of health condition studied

Caner

ICD-10 code

C80

ICD-10 code description

Malignant neoplasm without specification of site

Primary outcomes

1

Description

Fatigue

Timepoint

At the beginning of the study (before the intervention) and 7, 14 and 28 days after the intervention began

Method of measurement

Smith's Fatigue Questionnaire

2

Description

Sleep Quality

Timepoint

At the beginning of the study (before the intervention) and 7, 14 and 28 days after the intervention began

Method of measurement

Pittsburgh Sleep Quality Questionnaire

Secondary outcomes

1

Description
depression
Timepoint
At the beginning of the study (before the intervention) and on the 28th day of the radiotherapy course
Method of measurement
Depression- Anxiety- Stress Scale (DASS-21)

2

Description
Anxiety
Timepoint
At the beginning of the study (before the intervention) and on the 28th day of the radiotherapy course
Method of measurement
Depression- Anxiety- Stress Scale (DASS-21)

3

Description
Stress
Timepoint
At the beginning of the study (before the intervention) and on the 28th day of the radiotherapy course
Method of measurement
Depression- Anxiety- Stress Scale (DASS-21)

4

Description
Quality of Life
Timepoint
At the beginning of the study (before the intervention) and on the 28th day of the radiotherapy course
Method of measurement
Quality of Life Questionnaire of European Organization for Research and Treatment of Cancer

Intervention groups

1

Description
Intervention group1 : In the group of floating legs in warm water, patients from the seventh day after starting radiotherapy every night for two weeks an hour before normal sleep hours (between 9 to 10 pm) float their legs 10 cm above the wrist in water (41 to 42 ° C) for 20 minutes Inside the plastic container with a size of 40 × 27 × 45
Category
Rehabilitation

2

Description
Intervention group2:Intervention is performed for two weeks from the seventh day after starting radiotherapy every night for 10 minutes with olive oil for each foot massage. Reflexology intervention includes preparation, warm-up and stimulation and massage techniques which is done at the point of the solar plexus at the end of the first metatarsal bone of the foot to reduce fatigue, and at the pituitary gland and pineal gland at the toe to improve sleep quality. Massage duration for each foot is 10 minutes.(1 minute general foot massage and each area 3 minutes). The pressure is 4 to 5 kilogram, which the intervener calibrates by applying pressure on a digital scale to the amount of pressure on his hand. The patient should lie on the bed in a supine position so that the floor of both feet is at the end of the bed and is fully exposed and the intervener sits on a chair at the end of the bed so that the patient's foot is in front of her and in complete control.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza Radiotehrapy and Oncology Center
Full name of responsible person
Dr. Tabrizi's Warsaw
Street address
Rafsanjani 19, Seventh Azar Square, Ayatollah Hashemi Rafsanjani highway, Namayeshgah Blvd
City
Mashhad
Province
Razavi Khorasan
Postal code
9184166759
Phone
+98 51 3500 8520
Email
Info@rroc.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Mohsen Tafaghodi
Street address
Daneshgah Street
City
Mashhad
Province
Razavi Khorasan
Postal code
9138813944
Phone
+98 51 3841 2081
Email

vpreasearch@mums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Mahla Rajabzadeh

Position

Masters student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Unit 3, plate 100, Imamate 47, Imamate Blvd.

City

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Razavi Khorasan

Postal code

9188695612

Phone

+98 51 3601 6795

Email

rajabzadehm951@mums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mahla Rajabzadeh

Position

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Latest degree

Bachelor

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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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

Presentation of research findings in seminars, conferences and publishing articles extracted from research, in magazines at home and abroad for use by cancer patients as well as researchers who intend to conduct research on the subject.

When the data will become available and for how long

Start of access period 6 months after printing results

To whom data/document is available

Share the results of the research with other researchers for further research.

Under which criteria data/document could be used

The results obtained in this study can be used in the oncology wards of all hospitals and even in other wards, especially in chronic patients who require specific medications following the consequences of their long-term treatment and intensive care.

From where data/document is obtainable

Mashhad School of Nursing and Midwifery

What processes are involved for a request to access data/document

After the email is sent to the scientifically responsible person, the accountability process begins.

Comments