

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

The Effect of Hand and Foot Reflexology on Fatigue Induced by Radiotherapy in Patients with Cancer

Protocol summary

Study aim

Determining the effect of hand and foot reflexology therapy on radiotherapy fatigue in cancer patients

Design

A clinical trial, without blinding, with three parallel groups (2 intervention groups and one control group), 90 outpatients

Settings and conduct

This is a single-blind clinical trial study in which the participant does not know which intervention or control group he or she belongs to. The research environment of this study is the radiotherapy department of Imam Hossein Educational and Medical Center affiliated to Shahid Beheshti University of Medical Sciences.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Willing to participate in the study; The subjects should be able to read and complete the questionnaire; Men and women 18 years and older; Cancer patients who have been prescribed radiotherapy; No mental disorders under treatment, according to the patient; No history of taking psychiatric drugs; No diabetes; Absence of hand or foot disease and problems such as vascular disorders and amputation; Not using complementary medicine in the last few weeks

Intervention groups

Two intervention groups: In the first intervention group, patients receive hand reflexology massage therapy and the second group receive foot reflexology massage therapy. Control group: In the control group, which is the third group, patients receive routine care and reflexology massage is not performed on them.

Main outcome variables

fatigue

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210623051684N1**

Registration date: **2022-02-17, 1400/11/28**

Registration timing: **registered_while_recruiting**

Last update: **2022-02-17, 1400/11/28**

Update count: **0**

Registration date

2022-02-17, 1400/11/28

Registrant information

Name

Fozieh Zoghi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6119 2534

Email address

fozieh.zoghi@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-26, 1400/11/06

Expected recruitment end date

2022-05-20, 1401/02/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Hand and Foot Reflexology on Fatigue Induced by Radiotherapy in Patients with Cancer

Public title

The Effect of Hand and Foot Reflexology on Fatigue

Induced by Radiotherapy in Patients with Cancer

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
 Have a desire to participate in the study. The subjects should be able to read and complete the questionnaire. Men and women 18 years and older Cancer patients who have been prescribed radiotherapy
Exclusion criteria:
 Have mental disorders according to the patient who is being treated. History of using psychiatric drugs Have diabetes Hand or foot diseases and problems such as vascular disorders and amputation Using complementary medicine in the last few weeks

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
 In this research, goal-based sampling and random allocation methods are used. After selecting 90 patients who met the appropriate criteria for inclusion in the study. Each patient receives a number and then, using a table of random numbers, it is determined which of the three groups (2 intervention groups and one control group) should be included in the study samples, respectively. They are included in the study groups in the order of enrollment and according to the table. A table of random numbers with a number of 30 random blocks is used. Thus, from this table, 3 consecutive blocks (Tables 1 to 3) are randomly selected. Each block contains 30 random numbers from 0 to 29. Look at each of the numbers from left to right. Random numbers 0 to 9 in group 1, numbers 9 to 19 in group 2, and numbers 20 to 29 in group 3. Placed. Based on this random table, it was determined in which group each patient should be included in the order of enrollment.

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 Shahid Beheshti University of Medical Sciences

Street address

Valiasr St., Amir Bahador Bridge, Moqarrabi St., No. 40

City

Tehran

Province

Tehran

Postal code

1334994431

Approval date

2020-10-24, 1399/08/03

Ethics committee reference number

IR.SBMU.PHARMACY.REC.1399.291

Health conditions studied

1

Description of health condition studied

Cancer

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

fatigue

Timepoint

The beginning of the study and the week after the intervention

Method of measurement

Fatigue Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The first group to receive reflexology massage therapy

Category

Other

2

Description

Intervention group: The second group who receive foot reflexology massage

Category

Other

3

Description

Control group: The third group receives only routine care and no reflexology massage

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hossein Hospital

Full name of responsible person

Fozieh Zoghi

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Valiasr St., Amir Bahador Bridge, Moqarrabi St., No. 40

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Afshin Zarghi

Street address

Valiasr St., Amir Bahador Bridge, Moqarrabi St., No. 40

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Fozieh Zoghi

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Fozieh Zoghi

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**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Fozieh Zoghi

Position

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Latest degree

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Other areas of specialty/work

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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

Part of the data, such as information about the main outcome, can be shared

When the data will become available and for how long

Start access 6 months after printing results

To whom data/document is available

Researchers working in academic and scientific institutions and people who are medical staff

Under which criteria data/document could be used

For further research by researchers and the use of medical staff to improve the quality of life of patients

From where data/document is obtainable

fozieh.zoghi@yahoo.com

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

It may take about a week

Comments