Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 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
Street address
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 updating data

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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