

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jul 2026

The effects of reflexology on fatigue severity of patients with cancer

Protocol summary

Study aim

The Effects of Reflexology on Fatigue Severity of Patients with Cancer

Design

randomized clinical trial with control group

Settings and conduct

educational hospitals Ilam province randomized clinical trial with control group

Participants/Inclusion and exclusion criteria

patient with definitive breast cancer diagnosis

Intervention groups

To prepare patients' legs before performing reflexology, the patients will carry out movements such as bending the legs up and down, stretching the calves and ankles, turning the ankles inward and outward, and flexing the feet. General reflexology will perform using a worm-like movement of the thumb and index finger on reflexive areas. Specialized reflexology will then perform by pressing the major reflexive points of the soles (solar plexus, pituitary gland, spinal cord, vertebral column, pelvis, and limbs) with the thumb and index finger. The toes and other reflexive areas of the soles, as well as the back of the feet will also massage. Pressing the thumb on the solar plexus will signal the end of the intervention. Control group will receive routine care and the prescribed medication by the oncologist.

Main outcome variables

fatigue

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190225042831N1**

Registration date: **2019-03-19, 1397/12/28**

Registration timing: **prospective**

Last update: **2019-03-19, 1397/12/28**

Update count: **0**

Registration date

2019-03-19, 1397/12/28

Registrant information

Name

behrouz soltani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 83 4843 5077

Email address

b_soltani@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-20, 1397/10/30

Expected recruitment end date

2019-07-21, 1398/04/30

Actual recruitment start date

2019-03-24, 1398/01/04

Actual recruitment end date

2019-07-16, 1398/04/25

Trial completion date

2019-08-11, 1398/05/20

Scientific title

The effects of reflexology on fatigue severity of patients with cancer

Public title

The effects of reflexology on fatigue of patients with cancer

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

(1) Definitive breastcancer diagnosis (2) Absence of metastasis according to oncologist' diagnosis (3) Absence of cardiovascular disease, (4) Absence of bone

fractures, skin lesions, or disorders (5) Absence of mental disorders (6) Absence of diabetes mellitus (7) Having cancer for at least one year (8) Residing in Ilam, Iran .

Exclusion criteria:

(1) Non-cooperation of patients during the intervention
(2) Absence for more than three sessions (3) Using other methods of complementary or alternative medicine
(4) Suffering from any crises affecting the patients' fatigue severity

Age

From **18 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Actual sample size reached: **57**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method: Simple randomization
Randomization unit: Individual
Randomization tool: Admission on Saturday, Monday, and Wednesday= intervention group
Admission on Sunday, Tuesday, and Thursday= control group

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kermanshah University of Medical Sciences

Street address

Shahid Beheshti Blvd, Kermanshah

City

Kermanshah

Province

Kermanshah

Postal code

67149-45878

Approval date

2019-01-09, 1397/10/19

Ethics committee reference number

IR.KUMS.REC.1397.830

Health conditions studied

1

Description of health condition studied

Breast cancer

ICD-10 code

C50

ICD-10 code description

Malignant neoplasm of breast

Primary outcomes

1

Description

Fatigue related to cancer

Timepoint

Pretest-post test

Method of measurement

Fatigue severity scale (FSS)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Experimental group will receive reflexology twice a week for 4 consecutive weeks while each session last for 20 minutes. To prepare patients' legs before performing reflexology, the patients will carry out movements such as bending the legs up and down, stretching the calves and ankles, turning the ankles inward and outward, and flexing the feet. General reflexology will perform using a worm-like movement of the thumb and index finger on reflexive areas. Specialized reflexology will then perform by pressing the major reflexive points of the soles (solar plexus, pituitary gland, spinal cord, vertebral column, pelvis, and limbs) with the thumb and index finger. The toes and other reflexive areas of the soles, as well as the back of the feet will also massage. Pressing the thumb on the solar plexus signal the end of the intervention.

Category

Rehabilitation

2

Description

Control group: Control group will receive routine care and the prescribed medication by the oncologist.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Mostafa Khomeini Hospital

Full name of responsible person

Milad Borji

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Keshvari square, Ilam

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Vice Chancellor for Research and Technology

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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

Kermanshah 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**

Kermanshah University of Medical Sciences

Full name of responsible person

Milad Borji

Position

Faculty

Latest degree

Master

Other areas of specialty/work

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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

Publish after data analysis

When the data will become available and for how long

0

To whom data/document is available

0

Under which criteria data/document could be used

0

From where data/document is obtainable

0

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

0

Comments