Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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)
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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 cardiovasculardisease, (4) Absence of bone

fractures, skin lesions, ordisorders (5) Absence of mental disorders (6) Absence ofdiabetes mellitus (7) Aaving 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 othermethods 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
Nursery

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Person responsible for updating data

Contact

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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