Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effects of foot reflexology on fatigue among cancer patients undergoing chemotherapy

Protocol summary

Study aim
The aim of this study will be assessing the effect of foot reflexology on chemo-induced fatigue in patients with colorectal cancer

Design
Study with random allocation, uncontrolled, non-phase trial

Settings and conduct
Reflexology Massage Therapy by Chevalier on Chemo Therapy Patients with Cavernous Cancer in Imam Hossein Hospital

Participants/Inclusion and exclusion criteria
Benchmark: Patients diagnosed with colorectal cancer; Patients with a history of mental illness; Patients who do not use sedative medications; Patients with no leg-related disease: Diabetic neuropathy, Deep vein thrombosis, Patients with no spinal cord injury. Age over 18; Have read and write literacy; Patients do not have experience in the use of medicine; Patients do not have a history of chemotherapy in the past Exit criteria: Patients with advanced and metastatic cancer

Intervention groups
The intervention group in this study is a patient with colorectal cancer whose fatigue criteria will be measured using the research tool. And receive reflective massage. Control group In this study, patients with colorectal cancer whose fatigue criteria are measured using the research tool. And they will not receive any massages.

Main outcome variables
Fatigue

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170703034874N2**
Registration date: **2018-01-27, 1396/11/07**
Registration timing: **retrospective**
Last update: **2018-01-27, 1396/11/07**
Update count: **0**

Registration date
2018-01-27, 1396/11/07

Registrant information

Name
Mohammad Moradi Akbari

Name of organization / entity
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Recruitment status
Recruitment complete

Funding source
Investigator

Expected recruitment start date
2017-07-23, 1396/05/01

Expected recruitment end date
2017-10-23, 1396/08/01

Actual recruitment start date
2017-10-07, 1396/07/15

Actual recruitment end date
2017-12-20, 1396/09/29

Trial completion date
empty

Scientific title
The effects of foot reflexology on fatigue among cancer patients undergoing chemotherapy

Public title
The effects of foot reflexology on fatigue among cancer patients undergoing chemotherapy

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Patients diagnosed with colon rectal cancer Patients do not have a history of mental illness Patients who do not use sedative medications Patients with no leg-related disease: Patients with deep vein thrombosis Patients with no spinal cord injury Age over 18 years Patients do not have a history of using complementary medicine Patients do not have a history of chemotherapy in the past Patients who are not diabetic neuropathy Have the ability to read and write

Exclusion criteria:

Patients with advanced and metastatic cancer

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Actual sample size reached: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

In this research, convenience sampling method and random allocation method were used. Researchers went to selected centers daily and using random numbers table, the study samples were allocated to groups A or B. This process continued until 30 samples per group and a total of 60 samples were obtained.

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

Shahid Beheshti University of Medical Sciences

Street address

Iran, Tehran Velenjak St. , Shahid Chamran Highway

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Province

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Postal code

1985717443

Approval date

2016-10-24, 1395/08/03

Ethics committee reference number

IR-SBMU.PHNM.1395.530

Health conditions studied

1

Description of health condition studied

Colorectal cancer

ICD-10 code

c18

ICD-10 code description

Malignant neoplasm of anus and anal canalc18Malignant neoplasm of colon, c19Malignant neoplasm of rectosigmoid junction, c20Malignant neoplasm of rectum, c21

Primary outcomes

1

Description

Fatigue

Timepoint

Before intervention, after intervention

Method of measurement

Florida inventory for fatigue symptom and Piper Fatigue Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

In the intervention group, foot reflexology massage will be performed in 4 courses of chemotherapy in patients with colorectal cancer and the fatigue will be measured before and after each massage. At the end of the work, these two groups will be compared, ie, intervention and control

Category

Treatment - Other

2

Description

Control group: routine care was performed and before and after each chemotherapy simultaneously with the massage, the fatigue was measured

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Emam Hosein Hospital
Full name of responsible person
Mohammad Moradi Akbari
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Sponsors / Funding sources

1

Sponsor

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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
Private

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Persons

Person responsible for general inquiries

Contact

Name of organization / entity
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available