Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

A comparison between the effects of application versus non-application of foot reflexology massage on stress and neuropathic pain induced by chemotherapy in women with breast cancer and genital organs

Protocol summary

Summary

This clinical trial investigates the effect of foot reflexology massage on stress and neuropathic pain induced by chemotherapy in women with breast and genital tract cancer. The study is performed in one center and without blindness. Major inclusion criteria include female patients aged 18 to 60 years; definitive diagnosis of breast cancer; and having a pain score of 12 or more in Leeds Assessment of Neuropathic Symptoms and Signs Pain Scale. Major exclusion criteria include metastatic conditions for bone marrow, lung, liver and kidneys; and lack of patient collaboration until the end of the intervention. Participants will be selected from the Iranmehr Health Center, affiliated with Birjand University of Medical Sciences via convenience sampling method. They will be randomly assigned into intervention (n=30) and control (n=30) groups. Prior to the intervention, demographic characteristics form, Perceived Stress Scale (Cohen et al., 1983), and the Leeds Assessment of Neuropathic Symptoms and Signs Pain Scale will be completed by both groups. The intervention group will receive foot reflexology massage for two weeks, but the control group will not receive any intervention. Two weeks after the end of intervention, the groups will complete the two scales for a second round. The scores obtained in the two administrations of the scales by the groups will be compared whereby the effect of foot reflexology massage on stress and neuropathic pain will be determined.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017090517756N28**
Registration date: **2017-09-19, 1396/06/28**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2017-09-19, 1396/06/28

Registrant information

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Name of organization / entity
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Recruitment status

Recruitment complete

Funding source

Vice-chancellery for Research of Birjand University of Medical Sciences

Expected recruitment start date

2017-05-05, 1396/02/15

Expected recruitment end date

2018-02-04, 1396/11/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparison between the effects of application versus non-application of foot reflexology massage on stress and neuropathic pain induced by chemotherapy in women with breast cancer and genital organs

Public title
The effect of foot reflexology massage on stress and neuropathic pain induced by chemotherapy
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria: Definitive diagnosis of breast cancer; malignancy based on pathological studies, clinical findings, and physician diagnosis; women treated with Taxon; age between 18 and 60 years; neuropathic pain induced by chemotherapy with a score of 12 or more according to the Leeds Assessment of Neuropathic Symptoms and Signs Pain Scale; reading and writing literacy and the ability to speak for the patient or caregiver; having healthy limbs in the legs, especially the sole of the legs or lack of sensory and motor disorders; no drug abuse; non-use of psychotropic drugs; no history of mental illness; informed consent for participation; and the use of prophylaxis drugs for neuropathic pains such as gabapentin and pre-cabalin. Exclusion criteria: Metastasis for bone marrow, lung, liver and kidneys; patient's lack of cooperation until the end of the intervention; and the presence of stressors such as the death of first-degree relatives, divorce, and severe changes in lifestyle over the past 6 months.
Age
From **18 years** old to **60 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
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 Birjand University of Medical Sciences
Street address
Vice-chancellery for Research, Birjand University of Medical Sciences, Ghaffari St.,
City
Birjand,
Postal code
Approval date
2017-05-01, 1396/02/11
Ethics committee reference number
ir.bums.REC.1396.96

Health conditions studied

1

Description of health condition studied
breast cancer
ICD-10 code
D05
ICD-10 code description
Carcinoma in situ of breast

2

Description of health condition studied
Genital tract cancer
ICD-10 code
C57.9
ICD-10 code description
Female genital organ, unspecified

Primary outcomes

1

Description
Perceived stress
Timepoint
before intervention and 2 weeks after intervention is completed
Method of measurement
Cohen et al.’s Perceived Stress Scale

2

Description
Neuropathic pain severity
Timepoint
before intervention and 2 weeks after intervention is completed
Method of measurement
The Leeds Assessment of Neuropathic Symptoms and Signs Pain Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention Group (Foot reflexology message): Prior to the intervention, demographic characteristics form,

Perceived Stress Scale (Cohen et al., 1983), and the Leeds Assessment of Neuropathic Symptoms and Signs Pain Scale will be completed by the group. The intervention group will receive foot reflexology massage for two weeks. Two weeks after the end of intervention, the group will complete the two scales for a second round.

Category

Other

2

Description

Control Group (No intervention): Prior to the intervention, demographic characteristics form, Perceived Stress Scale (Cohen et al., 1983), and the Leeds Assessment of Neuropathic Symptoms and Signs Pain Scale will be completed by the group. The control group will not receive any intervention. Two weeks after the end of intervention, the group will complete the two scales for a second round.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Iranmehr Chemotherapy Center

Full name of responsible person

Dr Ahmadreza Sebzari

Street address

Ghafari Street,

City

Birjand,

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellery for Research, Birjand University of Medical Sciences

Full name of responsible person

Dr Tooba Kazemi

Street address

Vice chancellery for Research, Birjand University of Medical Sciences, Ayatollah Ghafari Street,

City

Birjand,

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice-chancellery for Research, Birjand University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

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Position

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Person responsible for scientific inquiries

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Instructor

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty