Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The Effect of Reflexology on Anxiety Symptoms, Pain Intensity and Sleep Quality in Breast Cancer Patients Undergoing Chemotherapy: A Parallel Randomized Clinical Trial

Protocol summary

Study aim

Determining the effect of reflexology on anxiety symptoms, pain intensity, and sleep quality in breast cancer patients undergoing chemotherapy

Design

The present study is a parallel randomized clinical trial. Sixty breast cancer patients undergoing chemotherapy will be included in the study based on the inclusion and exclusion criteria and will be randomly assigned to intervention and control groups using quadruple blocks.

Settings and conduct

The study will take place at Loghman-e Hakim Hospital and Imam Hossein Hospital. In the intervention group, reflexology will be administered once a week for three weeks, with each session lasting half an hour. The control group will receive the usual care at the medical center. Data will be collected before the intervention and two weeks afterward.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Definitive breast cancer diagnosis by a specialist physician, age above 18 years, and speaking Persian. Exclusion criteria: Received reflexology in the past, receiving radiation therapy as the first complementary treatment or concurrently, having any bleeding, seizures, or fever, having varicose veins and any foot disease, including open wounds or fractures, having any psychiatric disorder or dementia, male gender.

Intervention groups

In the intervention group, reflexology will be performed once a week for three weeks, with each session lasting half an hour and taking place after each chemotherapy session. The patient will be prepared, and their feet will be lubricated with sweet almond oil. The researcher will then conduct a relaxing massage on both feet 3-4 times for 10 minutes each, followed by a 20-minute session focusing on the treatment points on the soles of both feet. The control group will only receive the usual care provided by the treatment center.

Main outcome variables

Anxiety symptoms, pain intensity and sleep quality

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231114060057N2**
Registration date: **2024-10-17, 1403/07/26**
Registration timing: **prospective**

Last update: **2024-10-17, 1403/07/26**
Update count: **0**

Registration date

2024-10-17, 1403/07/26

Registrant information

Name

Saeed Ghasempour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 23 3239 5054

Email address

saeed.ghasempoor@shmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-11-21, 1403/09/01

Expected recruitment end date

2025-05-22, 1404/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Reflexology on Anxiety Symptoms, Pain Intensity and Sleep Quality in Breast Cancer Patients Undergoing Chemotherapy: A Parallel Randomized Clinical Trial

Public title

The Effect of Reflexology on Anxiety Symptoms, Pain Intensity and Sleep Quality in Breast Cancer Patients Undergoing Chemotherapy: A Parallel Randomized Clinical Trial

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Definitive breast cancer diagnosis by a specialist physician Age above 18 years Speaking Persian

Exclusion criteria:

Received reflexology in the past Receiving radiation therapy as the first complementary treatment or concurrently Having any bleeding, seizures, or fever Having varicose veins and any foot disease, including open wounds or fractures Having any psychiatric disorder or dementia Male gender

Age

From **18 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

Patients will be included in the study based on the inclusion and exclusion criteria through purposive sampling. They will then be randomly assigned to two groups: Group A (intervention) and Group B (control) based on quadruple blocks. The sequence of random allocation will be determined by SPSS software. With a sample size of 60 people, 15 quadruple blocks will be considered. Participants will be randomly assigned to their respective groups based on the order of entry into the study and the quadruple blocks.

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 Shahroud University of Medical Sciences

Street address

University of Medical Sciences and Health Services, Hafte Tir Square, Shahroud, Iran.

City

Shahroud

Province

Semnan

Postal code

3614773943

Approval date

2024-04-15, 1403/01/27

Ethics committee reference number

IR.SHMU.REC.1403.016

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

Anxiety symptoms

Timepoint

Before the intervention and two weeks after the intervention

Method of measurement

Generalized Anxiety Disorder Questionnaire

2

Description

Pain intensity

Timepoint

Before the intervention and two weeks after the intervention

Method of measurement

Numerical Rating Scale

3

Description

Sleep quality

Timepoint

Before the intervention and two weeks after the intervention

Method of measurement

Pittsburgh Sleep Quality Index

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the intervention group, reflexology will be performed once a week for three weeks, with each session lasting half an hour and taking place after each chemotherapy session. The patient will be prepared, and their feet will be lubricated with sweet almond oil. The researcher will then conduct a relaxing massage on both feet 3-4 times for 10 minutes each, followed by a 20-minute session focusing on the treatment points on the soles of both feet.

Category

N/A

2

Description

Control group: The control group will only receive the usual care provided by the treatment center.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Loghman-e Hakim Hospital

Full name of responsible person

Haniyeh Ghanbarinasab

Street address

Iran, Tehran, Lashgar Intersection, Makhsous St, Loghman-e Hakim Hospital.

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2

Recruitment center

Name of recruitment center

Imam Hossein Hospital

Full name of responsible person

Haniyeh Ghanbarinasab

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Shahroud 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
Shahroud University of Medical Sciences
Full name of responsible person
Saeed Ghasempour
Position
Reseacher
Latest degree
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Other areas of specialty/work
Nursery
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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
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
The demographic and clinical characteristics of the participants, as well as all information related to their anxiety symptoms, pain intensity, and sleep quality, can be shared while maintaining confidentiality and not using the names of the participants.
When the data will become available and for how long
After publishing the article
To whom data/document is available
Project partners
Under which criteria data/document could be used
For people doing similar research work.
From where data/document is obtainable
The person in charge of the project should be contacted via email: abbasi_msn@yahoo.com
What processes are involved for a request to access data/document
Data will be provided to people through email.
Comments