Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of foot reflexology on anxiety of women with breast cancer

Protocol summary

Study aim
Provide a simple executive solution to reduce the anxiety of patients with breast cancer.

Design
In this study, 66 patients with breast cancer who were admitted to the Ayatollah Khansari Hospital in Arak were selected. Participants are randomly divided into intervention and control groups and each participant is assigned a code.

Settings and conduct
The present study will be conducted at Ayatollah Khansari Hospital in Arak, and on women with breast cancer. The samples will not know how to place the samples in the intervention and control group.

Participants/Inclusion and exclusion criteria
Inclusion criteria: women with breast cancer; no history of participation in anxiety management training classes; no history of participation in massage classes. Exclusion criteria: unwillingness continued participation in the study; participant's death; immigration.

Intervention groups
After receiving permission from the patient and considering which patient is in the group, foot reflexology massage will be done for the intervention group and there will be no specific treatment for the control group.

Main outcome variables
Reducing anxiety in women with breast cancer.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20161210031328N6**
Registration date: **2018-01-24, 1396/11/04**
Registration timing: **registered_while_recruiting**

Last update: **2018-01-24, 1396/11/04**
Update count: **0**

Registration date
2018-01-24, 1396/11/04

Registrant information

Name
Mahbobeh Sajadi
Name of organization / entity
Arak University of Medical Sciences
Country
Iran (Islamic Republic of)
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+98 86 3402 0115
Email address
m.sajadi@arakmu.ac.ir

Recruitment status
Recruitment complete

Funding source
66 patients with breast cancer were entered into the study according to inclusion and exclusion criteria and randomly divided into two intervention and control groups using blocking method.

Expected recruitment start date
2017-12-01, 1396/09/10

Expected recruitment end date
2018-03-20, 1396/12/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of foot reflexology on anxiety of women with breast cancer

Public title
The effect of foot reflexology on anxiety of women with breast cancer

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

women with breast cancer 20-60 years old no history of participation in anxiety management training classes no history of participation in massage classes willingness to participate in the study

Exclusion criteria:

unwillingness continued participation in the study absences from more than one session of training sessions immigration participant's death

Age

From **19 years** old to **59 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **66**

Randomization (investigator's opinion)

Randomized

Randomization description

Samples were divided into two intervention and control groups using randomized block assignment method and using the random numbers table.

Blinding (investigator's opinion)

Double blinded

Blinding description

Samples and researcher will not know how to allocate to the intervention and control group.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Arak University of Medical Sciences

Street address

Arak University of Medical Sciences, Alam al hoda St, Rail road St

City

Arak

Province

Markazi

Postal code

38481-7-6941

Approval date

2017-09-11, 1396/06/20

Ethics committee reference number

IR.ARAKMU.REC.1396.139

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 related to breast cancer

Timepoint

Before the intervention at the morning and after the intervention at the evening.

Method of measurement

Using the Spielberger Anxiety questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Massage of the anxiety point in the foot for 15 minutes before the intervention in the morning and after the intervention at the evening.

Category

Other

2

Description

Control group: No action is taken on control group samples

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Khansari hospital

Full name of responsible person

Reza Aghabozorgi

Street address

The end of the university street

City

Arak
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Markazi
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3819693345
Phone
+98 86 3367 5000
Email
head_khansari@arakmu.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research of Arak University of Medical Sciences
Full name of responsible person
Dr Ali Arash Anoshirvani, Vice Chancellor for Research of Arak University of Medical Sciences
Street address
Vice Chancellor for research, Piambar Azam University complex, sardasht region
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3819693345
Phone
+98 86 3417 3639
Email
Rsearch@arakmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for Research of Arak 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
Arak University of Medical Science
Full name of responsible person
Mohadeseh Rezaei
Position
BSc Student of Nursing
Latest degree
A Level or less
Other areas of specialty/work
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Person responsible for updating data

Contact
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Web page address

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
Not applicable
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
Part of the data, such as information on the main outcome and the demographic information, can be shared after unidentifiable of people.
When the data will become available and for how long
The beginning of the access period is 2 years after the results are published.
To whom data/document is available
Researchers working in academic and scientific institutions.
Under which criteria data/document could be used
In order to utilize scientific purposes and mention the source used.
From where data/document is obtainable
Dr Mahboubeh Sajjadi, Ph.D. of Nursing, Faculty of Nursing and Midwifery, Arak University of Medical Sciences, Arak, Iran. E-mail address: sajadimahbobeh@yahoo.com
What processes are involved for a request to access data/document
After receiving the email from the requester, the information will be sent within 2 to 3 business days.
Comments