Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effect of 12 sessions of lymphatic message and Pilates training on lymph edema volume, anxiety, stress and depression, of life, and pain of 30-60 year-old breast cancer survivors

Protocol summary

Study aim

The effect of 12 sessions of lymphatic massage and pilates exercise on the volume of lymphedema, anxiety, stress and depression, quality of life and pain in breast cancer survivors 30-60 years old

Design

A clinical trial with two intervention groups and a control group, with parallel groups, one-blind, randomized, on 75 patients, simple method was used for randomization.

Settings and conduct

This study will be conducted with the voluntary participation of people with breast cancer in the lymph edema clinic of the rehabilitation faculty. The sampling is done in the form of convenient sampling. The samples are randomly divided into three groups. The first group is treated with lymph massage plus Pilates exercises, the second group is treated with Pilates exercises, and the control group is also treated with routine care. None of the patients know about the groupings and the type of intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: female patients with breast cancer, having stage 2 and 3 breast cancer, and age range between 30 and 60 years. Exclusion criteria: bilateral mastectomy, advanced breast cancer and exercise prohibition.

Intervention groups

Pilates and lymph massage group: In this group, Pilates exercises and lymphatic drainage surface massage are performed according to the rVodde technique for 45 minutes per session, 5 sessions per week for 12 sessions. Pilates group: The patients in this group do Pilates exercises for 60 minutes in each session, three sessions every week for 4 weeks. Control group: routine care is taught.

Main outcome variables

Pain, quality of life, depression, stress, anxiety, lymphedema volume and arm range of motion

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190202042581N6**
Registration date: **2024-10-23, 1403/08/02**
Registration timing: **registered_while_recruiting**

Last update: **2024-10-23, 1403/08/02**
Update count: **0**

Registration date

2024-10-23, 1403/08/02

Registrant information

Name
Mohammad Reza Asadi
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 81 3423 0949
Email address
m.asadi@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-09-22, 1403/07/01

Expected recruitment end date

2024-12-21, 1403/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Effect of 12 sessions of lymphatic message and Pilates training on lymph edema volume, anxiety, stress and depression, of life, and pain of 30-60 year-old breast cancer survivors

Public title
Effect of 12 sessions of lymphatic message and Pilates training on lymph edema volume, anxiety, stress and depression, of life, and pain of 30-60 year-old breast cancer survivors

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Having stage 2 and 3 breast cancer Adjuvant treatment with hormone therapy
Exclusion criteria:
Bilateral mastectomy advanced cancer

Age
From **30 years** old to **60 years** old

Gender
Female

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **75**

Randomization (investigator's opinion)
Randomized

Randomization description
Participants are placed in one of the three study groups by a simple randomization method with the help of a lottery. The researcher gives a special code or number to each participant. Then he writes down the number of each of them on a small piece of paper or cardboard; Then he pours them into a bag or container and stirs them. Then he takes out the beads one by one, writes down their number, and continues until he chooses a number equal to the sample size. Opaque envelopes are also used to conceal randomization allocation.

Blinding (investigator's opinion)
Single blinded

Blinding description
None of the participants will know about the type of intervention.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Hamedan University of Medical Sciences
Street address
Hamedan University of Medical Sciences, Fahmideh Blvd
City
Hamedan
Province
Hamadan
Postal code
6517838736

Approval date
2024-10-05, 1403/07/14

Ethics committee reference number
IR.UMSHA.REC.1403.448

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
Pain severity

Timepoint
First session (before intervention), and 16 day (after intervention)

Method of measurement
Visual Analogue Scale

2

Description
lymphedema volume

Timepoint
First session (before intervention), and 16 day (after intervention)

Method of measurement
Tape measure

3

Description
arm range of motion

Timepoint
First session (before intervention), and 16 day (after intervention)

Method of measurement
Goniometer

4

Description
Perceived stress
Timepoint
First session (before intervention), and 16 day (after intervention)
Method of measurement
perceived stress scale (PSS) questionnaire

Secondary outcomes

1

Description
Depression and anxiety
Timepoint
First session (before intervention), and 16 day (after intervention)
Method of measurement
HADS questionnaire

2

Description
Quality of life
Timepoint
First session (before intervention), and 16 day (after intervention)
Method of measurement
Quality of life questionnaire

Intervention groups

1

Description
Intervention group: Pilates exercises and lymphatic massage are performed daily for 5 days a week and up to 12 sessions.
Category
Rehabilitation

2

Description
Intervention group: Pilates exercises are performed daily for 5 days a week and up to 12 sessions.
Category
Rehabilitation

3

Description
Control group: Routine care is taught to the patient.
Category
Lifestyle

Recruitment centers

1

Recruitment center
Name of recruitment center
Lymphedema Clinic
Full name of responsible person
Solmaz Rahbar
Street address
Hamedan University of Medical Sciences, Fahmideh Blvd
City
Hamedan
Province
Hamadan
Postal code
6517838736
Phone
+98 81 3838 1633
Email
s.rahbar@umsha.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Reza Shokoohi
Street address
Fahmideh Blvd
City
Hamedan
Province
Hamadan
Postal code
6517838736
Phone
+98 81 3838 0717
Email
Shokoohi@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Hamedan 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
Hamedan University of Medical Sciences

Full name of responsible person
Solmaz Rahbar

Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Physiotherapy

Street address
Rehabilitation School, Hamedan university of Medical sciences, Fahmideh Blvd

City
Hamadan

Province
Hamadan

Postal code
۶۵۱۷۸۳۸۷۳۶

Phone
+98 81 3838 1633

Email
s.rahbar@umsha.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Hamedan University of Medical Sciences

Full name of responsible person
Solmaz Rahbar

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Assistant professor

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۶۵۱۷۸۳۸۷۳۶

Phone
+98 81 3838 1633

Email
s.rahbar@umsha.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Hamedan University of Medical Sciences

Full name of responsible person
Mohammad Reza Asadi

Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Physiotherapy

Street address
Hamedan univercity of medical sciences, Famideh Blvd,

City
Hamedan

Province
Hamadan

Postal code
۶۵۱۷۸۳۸۷۳۶

Phone
+98 81 3423 0949

Fax

Email
m.asadi@umsha.ac.ir

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
Not applicable

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