Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 Jul 2026

The effect of conventional physical therapy with and without breathing pattern correction exercises on pain, range of motion, size, volume of the swollen limb, respiratory parameters and quality of life in patients with breast cancer related lymphedema (BCRL)

Protocol summary

Study aim
Investigating the effect of conventional physical therapy with and without breathing pattern correction exercises on pain, range of motion, size, volume of the swollen limb, respiratory parameters and quality of life in patients with breast cancer related lymphedema (BCRL)

Design
A clinical trial with a control group, with parallel groups, double-blind, randomized on 40 patients. Software will be used for block randomization.

Settings and conduct
Women with first-degree lymphedema after breast cancer treatment, who refer to the oncologist of Golestan Hospital in Ahvaz, will be included in the study if they are eligible and will be randomly assigned to the intervention and control groups using the random block method. This study will be performed in a double-blind manner and the blinding includes a physiotherapist who performs the pre- and post-treatment evaluation in addition to the person who analyzes the data.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age 80-32 years, First-degree unilateral lymphedema, Patients with breast cancer who had axillary lymph node surgery, The difference in the measured points between two organs should be between 2 and 8 cm at least in one point of the organ. Exclusion criteria: History of chronic respiratory disease, Receive other treatments at the same time

Intervention groups
Control group: usual treatment of lymphedema and intervention group: usual treatment along with respiratory pattern correction. The duration of the treatment will be 4 weeks (3 sessions per week, once a day). The duration of each session is 40 minutes. Common treatments include lymphatic massage, exercise, skin care, and compression sleeves. In the intervention group, breathing exercises are added.

Main outcome variables
pain, upper limb circumference size, Respiratory indicators

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20221009056124N1**
Registration date: **2023-01-30, 1401/11/10**
Registration timing: **registered_while_recruiting**

Last update: **2023-01-30, 1401/11/10**
Update count: **0**

Registration date
2023-01-30, 1401/11/10

Registrant information

Name
Arefe Fattah

Name of organization / entity

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Iran (Islamic Republic of)

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+98 56 3249 7077

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-11-12, 1401/08/21

Expected recruitment end date

2023-12-11, 1402/09/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of conventional physical therapy with and without breathing pattern correction exercises on pain, range of motion, size, volume of the swollen limb, respiratory parameters and quality of life in patients with breast cancer related lymphedema (BCRL)

Public title

The effect of adding respiratory physiotherapy to common physiotherapy on patients with lymphedema

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with breast cancer who had axillary lymph node surgery with and without radiotherapy or taxane chemotherapy or unilateral mastectomy First-degree unilateral lymphedema according to the lymphology assembly Age 32 to 80 years Body mass index less than 30 The difference in the measured points between two organs should be between 2 and 8 cm at least in one point of the organ

Exclusion criteria:

Infection in the operated area Lymphatic vessel inflammation or deep vein occlusion History of chronic respiratory disease Receiving other treatments at the same time as the study treatment

Age

From **32 years** old to **80 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Subjects are randomly divided into two groups using block randomization in individual units. Randomization is done using Random Allocation software (version 1.1, Isfahan University of Medical Sciences, Iran) by a statistician who has no role in the study. A random order of two words A (intervention) and B (control) will be made in blocks with random numbers of 4 and 6. Then another person puts them in a sealed envelope. Before starting the intervention, one of the envelopes will be opened and thus the person will be placed in one of the two groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

This is a double-blind clinical trial in which patients are evaluated by another physiotherapist who is unaware of assigning individuals to groups. Data analysis is done by a person who is unaware of assigning individuals to groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Jundi Shapur Ahvaz University of Medical Sciences

Street address

Ground Floor, Research and Technology Vice-Chancellor of Jundishapur University of Medical Sciences and Healthcare Services, University City, Golestan highway Ahvaz, 061-33333477

City

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Province

Khouzestan

Postal code

61357-15794

Approval date

2022-07-16, 1401/04/25

Ethics committee reference number

IR.AJUMS.REC.1401.160

Health conditions studied

1

Description of health condition studied

Upper limb lymphedema after breast cancer

ICD-10 code

I97.2

ICD-10 code description

Postmastectomy lymphedema syndrome

Primary outcomes

1

Description

pain

Timepoint

Before, immediately and one month after the treatment

Method of measurement

Visual Analog Scale

2

Description
Circumference size of upper limb
Timepoint
Before, immediately and one month after the treatment
Method of measurement
meter

3

Description
Vital Capacity of breathing(VC) (Volumetric lung function test)
Timepoint
Before, immediately and one month after the treatment
Method of measurement
Spirometer

4

Description
Forced Vital Capacity of breathing(FVC) (Volumetric lung function test)
Timepoint
Before, immediately and one month after the treatment
Method of measurement
Spirometer

5

Description
breathing Forced Expiratory Volume in First second(FEV1) (Volumetric lung function test)
Timepoint
Before, immediately and one month after the treatment
Method of measurement
Spirometer

6

Description
End-expiratory carbon dioxide concentration(End Tidal CO2) (biochemical lung function test)
Timepoint
Before, immediately and one month after the treatment
Method of measurement
capnograph

7

Description
Arterial oxygen concentration(PaO2) (biochemical lung function test)
Timepoint
Before, immediately and one month after the treatment
Method of measurement
capnograph

8

Description
Respiratory rate (biochemical lung function test)
Timepoint
Before, immediately and one month after the treatment
Method of measurement
capnograph

9

Description
Arterial carbon dioxide pressure(PaCO2) (biochemical lung function test)
Timepoint
Before, immediately and one month after the treatment
Method of measurement
capnograph

Secondary outcomes

1

Description
Range Of Motion(ROM)
Timepoint
Before the intervention, immediately and one month after the end of the intervention
Method of measurement
Goniometer

2

Description
Quality Of Life(QOL)
Timepoint
Before the intervention, immediately and one month after the end of the intervention
Method of measurement
lymphedema life impact scale Questionnaire (LLIS)

Intervention groups

1

Description
Control group: The Complete Decongestive Therapy of lymphedema is given to the patient which includes: Manual lymphatic Drainage , exercises (stretching and proprioceptive neuromuscular facilitation that repeats in 3 sets of 10 times), skin care and garment (compression sleeve). 12 treatment sessions (4 treatment weeks with a frequency of 3 times a week) and in each session 30 minutes of lymphatic massage and 10 minutes of exercise are performed.
Category
Rehabilitation

2

Description
Intervention group: The Common treatment of lymphedema is given to the patient along with the correction of the breathing pattern. 12 treatment sessions (4 weeks of treatment with a frequency of 3 times a week) and each session includes 30 minutes of lymphatic massage and 10 minutes of exercise. The

treatment for correcting the breathing pattern includes: breathing exercises (3 diaphragmatic breathing exercises, chest mobilization and butterfly breathing technique) in all sessions 10 times and the person will be taught how to do it at home. In patients who suffer from surgery (chest surgery), the movement of the ribs is limited, the rhythm of breathing is affected, and accessory muscles replace the main muscles. For this reason, one of the essential treatments is diaphragmatic breathing training, exercise to facilitate chest movement and improve breathing pattern. These exercises do not require equipment, they are taught by the therapist, and the patient will perform them at home in addition to the treatment session.

Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Research Center of Rehabilitation Faculty of Jundishapur University of Medical Sciences, Ahvaz

Full name of responsible person
Arefe Fattah

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Rehabilitation Faculty Research Center, Jundishapur University of Medical Sciences, Golestan Blvd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Ahvaz University of Medical Sciences

Full name of responsible person
Dr Mehrnoosh Zaker Kish

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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
Ahvaz 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
Ahvaz University of Medical Sciences

Full name of responsible person
Arefe Fattah

Position
PHD Candidate

Latest degree
Master

Other areas of specialty/work
Physiotherapy

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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
Yes - There is 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
Information on outcomes to be assessed is available after publication of the results.

When the data will become available and for how long
Access will begin 6 months after publication of the results

To whom data/document is available
Researchers working in academic and scientific institutions

Under which criteria data/document could be used
After publication the results, the data will be used to find a better way to treat lymphedema

From where data/document is obtainable
Arefe Fattah, Fattaha69@gmail.com

What processes are involved for a request to access data/document
When the requester needs the data, she sends an email to Arefe Fattah and receives it if possible.

Comments