

# 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 56 3249 7077

##### Email address

fattaha69@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-11-12, 1401/08/21

##### Expected recruitment end date

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| <p>2023-12-11, 1402/09/20</p> <p><b>Actual recruitment start date</b><br/>empty</p> <p><b>Actual recruitment end date</b><br/>empty</p> <p><b>Trial completion date</b><br/>empty</p> <p><b>Scientific title</b><br/>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)</p> <p><b>Public title</b><br/>The effect of adding respiratory physiotherapy to common physiotherapy on patients with lymphedema</p> <p><b>Purpose</b><br/>Treatment</p> <p><b>Inclusion/Exclusion criteria</b><br/> <b>Inclusion criteria:</b><br/> 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<br/> <b>Exclusion criteria:</b><br/> 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</p> <p><b>Age</b><br/>From <b>32 years</b> old to <b>80 years</b> old</p> <p><b>Gender</b><br/>Female</p> <p><b>Phase</b><br/>N/A</p> <p><b>Groups that have been masked</b></p> <ul style="list-style-type: none"> <li>• Outcome assessor</li> <li>• Data analyser</li> </ul> <p><b>Sample size</b><br/>Target sample size: <b>40</b></p> <p><b>Randomization (investigator's opinion)</b><br/>Randomized</p> <p><b>Randomization description</b><br/>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.</p> <p><b>Blinding (investigator's opinion)</b></p> | <p>Double blinded</p> <p><b>Blinding description</b><br/>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.</p> <p><b>Placebo</b><br/>Not used</p> <p><b>Assignment</b><br/>Parallel</p> <p><b>Other design features</b></p> <p><b>Secondary Ids</b><br/>empty</p> <p><b>Ethics committees</b></p> <p><b>1</b></p> <p><b>Ethics committee</b><br/> <b>Name of ethics committee</b><br/>Ethics Committee of Jundi Shapur Ahvaz University of Medical Sciences<br/> <b>Street address</b><br/>Ground Floor, Research and Technology Vice-Chancellor of Jundishapur University of Medical Sciences and Healthcare Services, University City, Golestan highway Ahvaz, 061-33333477<br/> <b>City</b><br/>Ahvaz<br/> <b>Province</b><br/>Khouzestan<br/> <b>Postal code</b><br/>61357-15794</p> <p><b>Approval date</b><br/>2022-07-16, 1401/04/25</p> <p><b>Ethics committee reference number</b><br/>IR.AJUMS.REC.1401.160</p> |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | <p><b>Health conditions studied</b></p> <p><b>1</b></p> <p><b>Description of health condition studied</b><br/>Upper limb lymphedema after breast cancer</p> <p><b>ICD-10 code</b><br/>I97.2</p> <p><b>ICD-10 code description</b><br/>Postmastectomy lymphedema syndrome</p> <p><b>Primary outcomes</b></p> <p><b>1</b></p> <p><b>Description</b><br/>pain</p> <p><b>Timepoint</b><br/>Before, immediately and one month after the treatment</p> <p><b>Method of measurement</b><br/>Visual Analog Scale</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |

## 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

##### Street address

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

##### City

ahvaz

##### Province

Khouzestan

##### Postal code

6166754871

##### Phone

+98 61 3373 8537

##### Email

Fattaha69@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Ahvaz University of Medical Sciences

##### Full name of responsible person

Dr Mehrnoosh Zaker Kish

##### Street address

Ground floor, Research and Technology Vice-Chancellor of Jundishapur University of Medical Sciences, University City, Ahvaz, Iran

##### City

Ahvaz

##### Province

Khouzestan

##### Postal code

6135733133

##### Phone

+98 61 3336 2414

#### Email

itc@ajums.ac.ir

#### 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

##### Street address

No.15, 16, Emam Khomeini Ave, Qaen Town

##### City

Qaen

##### Province

South Khorasan

##### Postal code

9761873180

##### Phone

+98 56 3252 2217

##### Email

fattaha69@gmail.com

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Ahvaz University of Medical Sciences

##### Full name of responsible person

Arefe Fattah

##### Position

PHD Candidate

##### Latest degree

Master

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**Phone**

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**Email**

fattaha69@gmail.com

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Arefe Fattah

**Position**

Phd candidate

**Latest degree**

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9761873180

**Phone**

+98 56 3249 7077

**Fax**

**Email**

Fattaha69@gmail.com

## 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**