

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 May 2026

### The Effect of Yoga on Lymphedema Volume and Quality of Life in women with breast cancer

#### Protocol summary

volume of lymphedema and the quality of life of patients

#### Study aim

Determining the effect of yoga on the volume of edema and the quality of life of women with upper limb lymphedema caused by breast cancer

#### Design

randomised, two arm parallel group design of 110 patients with unblinded outcome assessment, The method of randomization into two groups will be done with permutation block (of four).

#### Settings and conduct

Sampling will be done in Afzalipur Hospital, Kerman, according to the inclusion and exclusion criteria of the study. The participants will be included in the study using available sampling, then they will be placed in two intervention groups with the method of yoga exercise and the control group using permutation blocks (quadruple). The intervention group will do online yoga using Instagram software for eight weeks and two one-hour sessions per week under the guidance of the instructor. Patients in the control group will receive only the routine follow-ups.

#### Participants/Inclusion and exclusion criteria

Inclusion criteria; Lymphedema of the upper limb diagnosed by a doctor Adult age above 18 years to 65 years The time interval of at least one month since the last surgical treatment and the time interval since the onset of lymphedema is a maximum of two years  
Absence of physical and sports activities during the last six months  
Absence of underlying and cognitive disease  
Exclusion criteria: patients with breast cancer referred to the oncology department; Patients with cancer recurrence and underlying and cognitive diseases

#### Intervention groups

The intervention group will do online yoga using Instagram software for eight weeks and two one-hour sessions per week under the guidance of the instructor. Patients in the control group will only receive routine follow-ups in the ward.

#### Main outcome variables

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220817055734N1**

Registration date: **2022-09-29, 1401/07/07**

Registration timing: **registered\_while\_recruiting**

Last update: **2022-09-29, 1401/07/07**

Update count: **0**

##### Registration date

2022-09-29, 1401/07/07

##### Registrant information

##### Name

samira beigmoradi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 34 4242 1155

##### Email address

samirabeig2018@sbmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-09-23, 1401/07/01

##### Expected recruitment end date

2022-12-21, 1401/09/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

The Effect of Yoga on Lymphedema Volume and Quality of Life in women with breast cancer

### Public title

Investigating the effect of yoga on the volume of hand edema and the quality of life of women with breast cancer

### Purpose

Supportive

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Lymphedema of the upper limb diagnosed by a doctor  
Adult age above 18 years to 65 years  
The time interval of at least one month since the last surgical treatment and the time interval since the onset of lymphedema is a maximum of two years  
Absence of physical and sports activities during the last six months  
Absence of underlying and cognitive disease

#### Exclusion criteria:

Recurrence of the disease  
Another cancer  
Failure to participate in more than three sessions of yoga exercises

### Age

From **18 years** old to **65 years** old

### Gender

Female

### Phase

N/A

### Groups that have been masked

*No information*

### Sample size

Target sample size: **110**

### Randomization (investigator's opinion)

Randomized

### Randomization description

Participants will be included in the study using available sampling, Then, by randomly assigning the samples, they are divided into intervention and control groups. The method of randomization into two groups will be done with permutation block (of four). In this way, considering that we have 112 samples, we will have 28 blocks of 4. In total, we have 4 blocks out of 6, that is ABBB, BBAA, ABAB, BABA, ABBA and BAAB, A will be the intervention group and B will be the control group. To randomly select blocks 1 to 6, this can be done using Excel or R software until the 28th block is selected, With this method, an equal number of people will be placed in two groups completely randomly.

### 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 sirjan school of Medical Sciences

##### Street address

ebne sina ave.

##### City

sirjan

##### Province

Kerman

##### Postal code

7851817783

#### Approval date

2022-08-28, 1401/06/06

#### Ethics committee reference number

IR.SIRUMS.REC.1401.005

## 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

The volume of lymphedema of the upper limb using a volumetric tank

#### Timepoint

Measurement of upper limb lymphedema volume at the beginning of the study and at the end of the eighth week (after the study was completed)

#### Method of measurement

Measuring the volume of edema with the method of water displacement, which is the gold standard method, uses a volume meter tank.

## Secondary outcomes

### 1

#### Description

Quality of life using a lymphedema Life Impact Scale questionnaire

#### Timepoint

Measurement of quality of life at the beginning of the study and at the end of the eighth week (after the study was completed)

#### Method of measurement

The questionnaire of lymphedema Life Impact Scale (LLIS) consists of 18 questions that measure the impact

of lymphedema on different dimensions of life.

## Intervention groups

### 1

#### Description

Intervention group: Yoga exercise, eight weeks, two one-hour sessions every week online under the guidance of an experienced trainer in this field

#### Category

Rehabilitation

### 2

#### Description

Control group: The control group will receive only the routine follow-ups performed in the ward

#### Category

N/A

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

afzalipour hospital

##### Full name of responsible person

samira beigmoradi

##### Street address

emam highway

##### City

kerman

##### Province

Kerman

##### Postal code

7851817783

##### Phone

+98 34 3222 2250

##### Email

samira.beigmoradi4002@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Sirjan school of Medical Sciences

##### Full name of responsible person

Dr mahmoudreza masoudi

##### Street address

ebne sina ave.

##### City

sirjan

##### Province

Kerman

##### Postal code

7851817783

##### Phone

+98 34 4223 2052

#### Email

samira.beigmoradi4002@gmail.com

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Sirjan school of Medical Sciences

#### Proportion provided by this source

90

#### 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

دانشکده علوم پزشکی سیرجان

##### Full name of responsible person

samira beigmoradi

##### Position

instructor

##### Latest degree

Master

##### Other areas of specialty/work

Nursery

##### Street address

ebne sina ave

##### City

sirjan

##### Province

Kerman

##### Postal code

7851817783

##### Phone

+98 34 4223 2052

##### Email

samira.beigmoradi4002@gmail.com

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Sirjan school of Medical Sciences

##### Full name of responsible person

samira beigmoradi

##### Position

instructor

##### Latest degree

Master

##### Other areas of specialty/work

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**City**  
sirjan  
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Kerman  
**Postal code**  
7851817783  
**Phone**  
+98 34 4223 2052  
**Email**  
samira.beigmoradi4002@gmail.com

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Sirjan school of Medical Sciences  
**Full name of responsible person**  
samira beigmoradi  
**Position**  
instructor  
**Latest degree**  
Master  
**Other areas of specialty/work**  
Nursery  
**Street address**  
ebne sina ave  
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sirjan  
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**Postal code**  
7851817783  
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+98 34 4223 2052

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samira.beigmoradi4002@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

Yes - There is a plan to make this available

### Data Dictionary

Yes - There is a plan to make this available

### Title and more details about the data/document

All data can be shared after de-identifying people.

### When the data will become available and for how long

4 months after publishing the results

### To whom data/document is available

sirjan school of medical science

### Under which criteria data/document could be used

Using data to conduct other studies

### From where data/document is obtainable

sirjan school of medical science, samira beigmoradi

### What processes are involved for a request to access data/document

Email should be sent first and after coordination, the data will be provided to the applicant by visiting in person

### Comments