

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

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7851817783

Phone

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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

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Email

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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

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

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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

Nursery

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Person responsible for updating data

Contact

Name of organization / entity
Sirjan school of Medical Sciences
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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

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