

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of Yoga exercise on quality of life and arm volume in women with post mastectomy Lymphedema

Protocol summary

Study aim

The aim of this study is determining the effect of yoga exercises on quality of life and arm volume in women with post mastectomy lymphedema

Design

This is a double-blind, randomized controlled trial that will be conducted with a pilot basis on 40 eligible patients admitted to the Motahari clinic in Shiraz.

Settings and conduct

This study examines the effect of yoga on patients with secondary lymph edema following mastectomy surgery at the lymph edema clinic of Motahari infirmary , Shiraz. During the research, participants and main investigators will be unaware of the initial allocation of individuals to the intervention and control groups. Therefore, the trial will be done in double-blinded design.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Having tendency to participate in the research; having the ability to communicate verbally for cooperation; Women with secondary upper limb lymph edema followed by mastectomy confirmed by the clinician; Possibility to use DVD at home; Ability to move independently without the need for auxiliary equipment; At least one year interval from mastectomy surgery to entering the research. Exclusion criteria: Unwillingness to cooperate; Establishing any condition that can lead to exacerbation of illness or hospitalization; The history of congestive heart failure or chronic obstructive pulmonary disease; Patients under chemotherapy or radiotherapy; Having pacemaker; Pregnancy.

Intervention groups

An 8-week yoga practice, based on specific protocol, in addition to the usual care is considered for the intervention group, and observation group will receive standardize routine care of clinic.

Main outcome variables

Changes in quality of life assessed by questionnaire ,
Changes in arm volume assessed by water displacement volume meter [Time Frame: baseline, 4 weeks, and 8

weeks after the yoga intervention]

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170925036390N1**

Registration date: **2017-12-03, 1396/09/12**

Registration timing: **prospective**

Last update: **2017-12-03, 1396/09/12**

Update count: **0**

Registration date

2017-12-03, 1396/09/12

Registrant information

Name

nazanin barshan tashnizi

Name of organization / entity

shiraz university of medical sciences

Country

Iran (Islamic Republic of)

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stud2281502694@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

This study founding source is Deputy of Research and Technology of Shiraz University of Medical Sciences which is governmental .

Expected recruitment start date

2017-12-16, 1396/09/25

Expected recruitment end date

2018-02-19, 1396/11/30

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of Yoga exercise on quality of life and arm volume in women with post mastectomy Lymphedema

Public title
The effect of Yoga on women with post mastectomy Lymphedema

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
 Having tendency to participate in the research Having the ability to communicate verbally for cooperation Women with secondary upper limb Lymphedema followed by mastectomy confirmed by the clinician Possibility to use DVD at home Ability to move independently without the need for auxiliary equipment At least one year interval from mastectomy surgery to entering the research
Exclusion criteria:
 Unwillingness to cooperate Establishing any condition that can lead to exacerbation of illness or hospitalization The history of congestive heart failure or chronic obstructive pulmonary disease Patients under chemotherapy or radiotherapy Having pacemaker Pregnancy

Age
From **18 years** old to **85 years** old

Gender
Female

Phase
N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
Samples will select according to study inclusion criteria and based on the target. Then they are randomly assigned to two groups using a random number table by block randomization method. First, researcher assistant writes all of the permutations A (representing the intervention group) and B (representing the control group), which consists of 6 different modes. Then, to allocate individuals with random number table, the finger moves randomly from a random point table to the row or column. If the number is between one and six, the permutation of that number is noted. For example, if the number 6 arrives, we will record ABAB permutations, and thus eligible patients will be in the control group and in

the intervention group (yoga practice group)

Blinding (investigator's opinion)
Double blinded

Blinding description
This study will be performed in Double blind method so that the first researcher assistant contributes to the initial selection of patients, the completion of the questionnaire and random allocation, so the participants, investigator and even the care providers are unaware of the study groups. In this way, at the times of arm volume control and completing the questionnaire, the participants will not have any information about the allocation of the groups. Data will be imported and analyzed by a non-informed data analyzer, and ultimately the results of the final analysis will be communicated to the researchers.

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shiraz University of Medical Sciences

Street address

Shiraz, Zand Avenue, Central Building of the University of Medical Sciences

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shiraz

Province

Fars

Postal code

713451978

Approval date

2017-09-23, 1396/07/01

Ethics committee reference number

IR.SUMS.REC.1396.108

Health conditions studied

1

Description of health condition studied

Postmastectomy lymphoedema syndrome

ICD-10 code

I97.2

ICD-10 code description

Postmastectomy lymphoedema syndrome

Primary outcomes

1

Description

Quality of Life

Timepoint

at baseline, 4 weeks, and 8 weeks after the intervention

Method of measurement

a specific quality of life assessment questionnaire for cancer patients

2

Description

arm volume

Timepoint

at baseline, 4 weeks, and 8 weeks after the intervention

Method of measurement

water displacement volumeter

Secondary outcomes

empty

Intervention groups

1

Description

The intervention of this study is yoga exercise for 8 weeks(3 sessions in each week). Two sessions of the weekly schedule will held in one hour at clinic training hall and under the supervision of the trained person and one session of it at home by pat

Category

Rehabilitation

2

Description

The observation group will receive standardize routine care of lymphedema clinic and will evaluate at three time steps.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Shiraz , Mottahari infirmary, Lymphedema clinic

Full name of responsible person

Dr.Zeinab Zakeri

Street address

Shiraz, Zand Avenue, Namazi Square, Shahid Motahari Clinic, 5th Floor

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Sponsors / Funding sources

1

Sponsor

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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

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Nazanin Barshan Tashnizi

Position

MSc student in Medical_Surgical Nursing

Latest degree

Bachelor

Other areas of specialty/work

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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

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

Data Dictionary

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