Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 Motahhari 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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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

City

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
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Shiraz, Zand Avenue, Namazi Square, Shahid Motahari Clinic, 5th Floor
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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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